1 TITLE PAGE

Clinical Study Report: PXD101-CLN-19

Study Title:	**A Multicenter, Open-Label Trial of Belinostat in Patients with Relapsed or Refractory Peripheral T-Cell Lymphoma**
Study Number:	PXD101-**CLN-19**
Study Phase:	2
Study Design:	Open-label, non-randomized, multicenter
Product Name:	Belinostat
Indication:	Relapsed or refractory peripheral T-cell lymphoma (PTCL)
First Patient Dosed:	11-May-2009
Case Report Form Data Cut-off:	31-Aug-2012
Principal Investigator:	Owen O'Connor, MD, PhD (see Appendix 16.1.5)
Sponsor:	Spectrum Pharmaceuticals, Inc. 157 Technology Drive Irvine, CA 92618 949-788-6700
Responsible Medical Officer:	Shanta Chawla, MD
Final Date:	05-Nov-2013

This study was designed, conducted, recorded, and reported in compliance with the principles of Good Clinical Practice (GCP) guidelines. These guidelines are stated in U.S. Federal regulations as well as "Guidance for Good Clinical Practice," International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

CLINICAL STUDY REPORT APPROVAL SIGNATURE PAGE

Protocol Title: A Multicenter, Open-Label Trial of Belinostat in Patients with Relapsed or Refractory Peripheral T-Cell Lymphoma

Protocol Number: PXD101-**CLN-19**

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2 SYNOPSIS

NAME OF COMPANY Topotarget A/S and Spectrum Pharmaceuticals, Inc.	Individual Study Table Referring to Part of the Dossier: Volume: Page:	(FOR NATIONAL AUTHORITY USE ONLY)
NAME OF FINISHED PRODUCT Belinostat Injection 50 mg/mL		
NAME OF ACTIVE INGREDIENT Belinostat (PXD101)		

TITLE OF STUDY:
A Multicenter, Open-Label Trial of Belinostat in Patients with Relapsed or Refractory Peripheral T-Cell Lymphoma

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PUBLICATION (REFERENCE):

1. S. Horwitz,O. O'Connor, W. Jurczak, A.Van Hoof, G. Hess, Z. Gasztonyi et al. Belinostat in Relapsed or Refractory Peripheral T-Cell Lymphoma-Cell Lymphoma (R/R PTCL) Subtype Angioimmunoblastic Subtype Angioimmunoblastic T-cell lymphoma (AITL): Results from the Pivotal BELIEF TRIAL. 12th International Conference on Malignant Lymphoma. 2013.
2. O. O'Connor, T. Masszi, K. Savage, L. Pinter-Brown, F. Foss, L. Popplewell, et al. Belinostat-A Novel Pan-histone Deacetylase Inhibitor (HDACi) in Relapsed or Refractory Peripheral T-cell Lymphoma (R/R PTCL): Results from the BELIEF trial. ASCO 2013.
3. O. O'Connor, S. Horwitz, T. Masszi, L. Pinter-Brown, S. Chawla, A. Shustov. Belinostat in Relapsed or Refractory Peripheral T-Cell Lymphoma (R/R PTCL): Preliminary Safety Results from the BELIEF Trial. T-Cell Forum 2013.

STUDY PERIOD:		**PHASE OF DEVELOPMENT:**
First patient enrolled:	04-May-2009	Phase 2 (Pivotal)
Last Patient enrolled:	02- Aug-2011	

OBJECTIVES:

The primary objectives of the study were:

- To determine the efficacy of belinostat monotherapy treatment as measured by Objective Response Rate (ORR), in patients with recurrent or refractory peripheral T-cell lymphoma (PTCL).

The secondary objectives for the PTCL population were:

- To determine duration of response
- Time to Response (TTR)
- Time to Progression (TTP)
- Progression-free Survival (PFS)
- 1-year Progression-free Rate
- Overall Survival (OS)
- 1-year Survival Rate following belinostat monotherapy.
- To assess safety following belinostat monotherapy

Additional objectives were to assess:

- Population pharmacokinetics (PK)
- Medical Care Utilization

METHODOLOGY:

This was a single arm, open-label, multicenter, Phase 2 study designed to determine the safety and efficacy

of belinostat monotherapy at a dose of 1,000 mg/m^2/day in the treatment of patients with relapsed or refractory PTCL after failure of at least 1 line of prior systemic therapy.

The study used the optimal 2-stage Simon design. Under this design, ≥5 objective responses (defined as complete response [CR] or partial response [PR] based on Independent Review Committee [**IRC**]) among the initial 41 evaluable patients who had received at least 1 dose of belinostat were required or the study would have been discontinued for futility. An independent Data Monitoring Committee (**DMC**) was charged with monitoring the safety of the study and was empowered to make recommendations to the Sponsor including halting the study or proposing an amendment to the protocol. The planned enrollment was approximately 120 patients to ensure a minimum of 100 evaluable patients at the conclusion of accrual. A total of 129 PTCL patients with PTCL diagnosis based on local pathology were treated in the study.

A central pathology review group (**CPRG**) confirmed the diagnosis of eligible PTCL histopathological subtypes. The primary study endpoint was ORR, defined as a CR or PR based on the independent central radiology and oncology clinical review by the **IRC**. Tumor assessments according to the International Harmonization Project (IHP) revision of the International Working Group (IWG) criteria [Cheson et al, 2007] were made by radiologic imaging using computerized tomography (CT) scans.

Radiology and oncology response assessments to assess on-study efficacy were performed by the **IRC**. Assessments were performed at Baseline (Day -28 [Screening] to Cycle 1, Day 1 prior to belinostat treatment) and every 6 weeks for the first 12 months, then every 12 weeks until 2 years from the start of study treatment. Radiological assessments were discontinued at the time of tumor progression or initiation of new anticancer therapy, after which survival data was collected every 3 months until 2 years from the start of study treatment or until study closure.

Adverse event (AE) assessments, physical examination, Eastern Cooperative Oncology Group (ECOG) performance status, electrocardiogram (ECG), vital signs, blood chemistry, clinical hematology, coagulation parameters, and urinalysis were used to assess on-study safety.

ECGs were assessed on each treatment day. ECG readings were performed by a central laboratory for analysis purposes but ECG interpretation for clinical management of patients was conducted by the treating physician.

NUMBER OF PATIENTS (PLANNED AND ANALYZED):

The planned number of patients was 120. The actual number of patients enrolled was 129.

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION:

1. Male or female with age ≥18 years.
2. A histologically confirmed diagnosis of PTCL (based on histology and immunohistochemistry) by local pathology review, leading to the diagnosis of:
    - Anaplastic large-cell lymphoma (ALCL), anaplastic lymphoma kinase (ALK)-positive
    - ALCL, ALK-negative
    - Angioimmunoblastic T-cell lymphoma
    - Enteropathy-associated T-cell lymphoma
    - Extranodal natural killer (NK)/T-cell lymphoma, nasal type
    - Hepatosplenic T-cell lymphoma

- PTCL, not otherwise specified (NOS)
- Subcutaneous panniculitis-like T-cell lymphoma

3. Available pathology material for central review by the **CPRG**.
4. Relapsed or refractory disease after at least 1 prior systemic anti-lymphoma regimen.
5. At least 1 site of disease measurable in 2 dimensions by CT scans.
6. An absolute neutrophil count (ANC) $\geq 1.0 \times 10^9$/L, platelets $\geq 50 \times 10^9$/L.
7. ECOG performance status 0-2.
8.
9. Estimated life expectancy greater than 3 months.
10. Negative pregnancy test for women of childbearing potential.
11. Signed an Informed Consent form approved by the local Ethics Committee (EC) or Institutional Review Board (IRB).

Key Exclusion Criteria

1. Any use of anticancer therapies within 2 weeks prior to initiation of study treatment.
2. Relapse within 100 days of autologous or allogeneic bone marrow transplant.
3. Prior histone deacetylase (HDAC) inhibitor therapy.
4. Patients with a diagnosis of:
   - Precursor T-cell lymphoma or leukemia
   - Adult T-cell lymphoma/leukemia
   - T-cell prolymphocytic leukemia
   - T-cell large granular lymphocytic leukemia
   - Primary cutaneous type anaplastic large cell lymphoma
   - Mycosis fungoides/Sezary syndrome
5. Baseline prolongation of QT/corrected QT (QTc) interval, i.e., demonstration of a QTc interval >450 msec; long QT Syndrome; the required use of a concomitant medication that may cause Torsades de Pointes.

TEST PRODUCT, DOSE, AND MODE OF ADMINISTRATION; BATCH NUMBER:

Belinostat was administered at a dose of 1,000 mg/m^2 as a 30-minute IV infusion on Days 1-5 of a 21-day cycle.

The following belinostat batches were used: 07E24, 07H21, 09C06, 09J16, 10A28, 10C14, 11B04, 11H29.

DURATION OF TREATMENT:

All patients were to receive belinostat monotherapy unless a criterion for discontinuation occurred.

Patients were to be withdrawn from study drug treatment for the following reasons:

- Progressive Disease (PD)
- Unacceptable or recurrent toxicity despite optimal prophylaxis and appropriate dose modification
- Substantial non-compliance with the requirements of the study
- Positive pregnancy test
- Use of illicit drugs or other substances that may, in the opinion of the Investigator, have had a reasonable risk of contributing to toxicity or otherwise skewing results
- Development of an intercurrent illness or situation which, in the opinion of the Investigator, affected assessments of clinical status and study endpoints to a significant degree
- Interruption in study drug administration for >42 days since last study drug administration

The Investigator also could withdraw patients from study treatment, study-related procedures, or follow-up for the following reasons:

- In the Investigator's opinion, continuation would have been detrimental to the patient's well being
- The patient was lost to follow-up
- Patient withdrawal of consent

Patients who were withdrawn from study drug treatment were to continue study-related procedures and follow-up for toxicity, tumor assessments, and survival.

REFERENCE THERAPY, DOSE AND MODE OF ADMINISTRATION; BATCH NUMBER:

No other therapy.

CRITERIA FOR EVALUATION:

EFFICACY: Tumor response was assessed by IWG criteria for patients with PTCL. The primary efficacy endpoint was ORR that included patients with CRs and PRs. In addition, the secondary endpoints of TTR, Duration of Response (IWG and Statistical Analysis Plan [SAP]-defined criteria), TTP, PFS, and OS. Time-to-event endpoints (TTR, TTP, PFS, and OS) were calculated from the time of first administration of belinostat (Day 1) until the stated event or end of study. The stated event for TTP included disease progression, for PFS included disease progression and death, for OS included death from all causes. Patients receiving subsequent therapy before PD was documented were censored. The Duration of Response was calculated by the **IRC** using IWG criteria as well as IWG criteria plus death.

Response was assessed both locally, on the basis of clinical and radiological criteria by the treating Investigator, as well as independently by the **IRC.** The primary analysis was pre-defined to be based on the **IRC** assessment.

SAFETY:

Safety assessments included analysis of AEs, clinical laboratory results (including hematology, coagulation parameters, and serum chemistry), vital signs, performance status, physical examination, urine analysis and ECG results. The Medical Dictionary for Regulatory Activities (MedDRA, version 14) was used for assigning System Organ Classes (SOC) and Preferred Terms. The summary of AEs was provided by SOC, Preferred Term, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE)

grade, and seriousness criteria.

STATISTICAL METHODS:

Descriptive statistics (incidence and confidence intervals [CI]) were used to summarize the number of patients exhibiting an ORR in this study. The significance level (alpha) for the primary efficacy analysis was set at 0.05; therefore, ORR was reported with a 95% CI estimated using 2-sided Clopper-Pearson method.

Similarly, secondary analyses are presented with 95% CIs.

Duration of Response by IWG criteria was measured from the date the measurement criteria were first met for CR or PR (whichever status was recorded first) until the first subsequent date that relapse or progression was documented. Per the SAP-defined criteria, Duration of Response was expanded from the IWG criteria by also adding the first subsequent date that death was documented. All other secondary efficacy endpoints were calculated from the time of first administration of belinostat (Day 1) until the stated event or the end of study. Time-to-event parameters were estimated using the Kaplan-Meier method.

All reported symptoms and AEs were graded for intensity using the NCI-CTCAE (v3.0) coding system. AEs were mapped to SOC and Preferred Term using MedDRA. Any AEs that occurred on or after administration of belinostat were considered as treatment-emergent AEs (TEAEs).

All vital signs and laboratory measurements were summarized and presented by time. For laboratory measurements, a summary based on the maximum CTCAE grades for each patient and each laboratory parameter is presented.

A shift analysis of all graded laboratory parameters was also performed. This analysis accounted for any laboratory abnormalities present at Baseline, and presented as the maximum grade shift during treatment (i.e., if a patient had Grade 2 decreased hemoglobin at Baseline and the worst grade during treatment was Grade 4, the resulting shift was a 2-grade shift).

All ECG data was summarized by time. ECG analyses were performed by an independent ECG laboratory (eRT).

SUMMARY – CONCLUSIONS

EFFICACY RESULTS:

Of 129 patients enrolled with relapsed or refractory PTCL and treated with at least 1 dose of belinostat **(Full Analysis Dataset)**, 120 patients had a PTCL diagnosis confirmed by **CPRG** (**Efficacy Analysis Dataset**). **DMC** meetings were conducted at 2 time points in the study: an interim review of the data after the first cohort of 41 evaluable patients enrolled and results were available, and a final review at the end of enrollment. Upon completion of each of the reviews, the **DMC** recommended that the study continue. No changes to the protocol were recommended at either of the 2 **DMC** meetings.

IRC assessment of response by IWG criteria showed an ORR of 25.8% (31 patients), with 13 CRs and 18 PRs. Most patients (61.3% of responders) responded at the first scheduled tumor assessment within 30-45 days of the first dose, with a median TTR of 5.6 weeks. The ORR observed with belinostat was durable with a median Duration of Response by IWG criteria of 13.6 months. The median Duration of Response by expanded SAP-defined criteria and based on 31 responding patients was 8.4 months (95% CI, 4.5-29.4). Belinostat treated patients had a 63.5% probability of being in response at 6 months. The median PFS, based on response as assessed by the **IRC** and estimated by the Kaplan-Meier method, was 1.6 months (95% CI:

1.4-2.7) and the median TTP was 2.0 months (95% CI: 1.5-2.8). The median OS, estimated by the Kaplan-Meier method, was 7.9 months (95% CI: 6.1-13.9). Importantly, nearly 40% of the patients (n=46) were censored for OS because they were still alive at the time of the data cut-off date (31-Aug-2012).

The ORR in patients with Baseline platelet counts ≥100,000/μL was 28.0% based on **IRC** assessment with a median Duration of Response by IWG criteria of 13.6 months, median OS of 9.2 months, and median PFS of 1.8 months.

The ORR in the 20 patients with low Baseline platelet counts (<100,000/μL) was 15.0%, with 2 PRs and 1 patient with a CR; the median Duration of Response by IWG criteria in these patients was 4.1 months with a median OS of 4.3 months and median PFS of 1.3 months. The 3 responding patients with low Baseline platelet counts (<100,000/μL) had treatment durations of 66 days (PR), 125 days (PR), and 297 days (CR).

In addition, clinically meaningful ORRs were also observed in patients with angioimmunoblastic T-cell lymphoma (45.5%) and patients with bone marrow involvement at Baseline (22.9%). Patients who had failed to respond to their last prior systemic therapy for PTCL showed a response to belinostat with a response rate of 15.7%. Following belinostat treatment, 12 patients were able to go on to receive a stem cell transplant. While formal response assessments were not conducted after the start of any subsequent therapy, 10/12 (83.3%) of these patients remained alive as of 31-Aug-2012.

SAFETY RESULTS:

Overall in **CLN-19**, belinostat treatment at a dose of 1,000 mg/m^2, administered to 129 patients with relapsed or refractory PTCL over 30 minutes by IV infusion on Days 1-5 of a 21-day cycle, had an acceptable toxicity profile with no unexpected toxicities. The majority of patients (87.6%) were able to remain at this dose for the duration of treatment, and discontinuation of belinostat due to an AE occurred in only 19.4% of patients.

The overall incidence of TEAEs regardless of causality was high (96.9%), which is consistent with and not unexpected in a patient population with advanced, relapsed or refractory PTCL who had failed multiple therapies. Nausea (41.9%), fatigue (37.2%) and pyrexia (34.9%) were the most frequently occurring AEs, most of which were mild or moderate in severity. The Grade 3, 4 or 5 AEs regardless of causality reported most frequently were anemia (10.9%), thrombocytopenia (7.0%), dyspnea (6.2%), neutropenia (6.2%), and pneumonia (6.2%); the only Grade 5 AE among these was 1 case of pneumonia. Most patients (83.7%) experienced at least 1 AE considered related to belinostat. The most common AEs related to belinostat were nausea (38.0%), fatigue (28.7%), and vomiting (24.0%).

A total of 22 patients (17.1%) died while still on study or within 30 days of their last dose of belinostat, with 12 (54.5%) of the deaths being due to progressive disease. Ten (7.8%) patients experienced TEAEs that resulted in death. All of these deaths were considered not related to belinostat except for 1 patient with hepatic failure; this patient had a complicated medical history with multiple confounders, tolerated 9 cycles of belinostat without complication, and had elevated liver function tests at the time of Cycle 10 dosing that subsequently worsened with death due to toxic liver failure. The other 9 non-treatment-related deaths included multi-organ failure (3), cardiac failure (2), lung infection (1), gastrointestinal hemorrhage (1), euthanasia (1), and shock (1). Sixty-one (47.3%) patients experienced an SAE while on study or within 30 days after their last dose of belinostat. The most frequently reported non-hematologic SAEs were pneumonia (7.0%), pyrexia (5.4%), infection (3.1%), blood creatinine increased (2.3%) and multi-organ failure (2.3%). Hematologic SAEs occurred at a lower incidence than non-hematologic SAEs, the most common included anemia (2.3%) and thrombocytopenia (2.3%). All other SAEs were reported in 2 (1.6%) or fewer patients. Twenty-one percent of patients had SAEs considered related to belinostat treatment. The only treatment-related SAEs occurring in more than 2 patients were blood creatinine increased, pyrexia, and

thrombocytopenia each of which was reported in 2.3% of patients and anemia, infection, and pneumonia each of which was reported in 1.6% of patients.

Vital signs (heart rate, systolic and diastolic blood pressures) were within normal parameters at Baseline and following belinostat treatment. Central review of ECG data by eRT identified 2 patients with a Grade 3 QT prolongation. The conclusion of the expert report was that belinostat showed no effect on cardiac repolarization. The pharmacokinetic-pharmacodynamic analysis showed no correlation between belinostat concentration and change from Baseline in QT interval corrected using Fridericia's formula (QTcF). No clinically relevant changes in other ECG parameters were noted.

Decreased hematologic values were the most frequently recorded laboratory abnormalities on treatment, with decreased red blood cells (67.5% vs 93.6%), hemoglobin (66.7% vs 91.5%), and decreased lymphocyte (53.1% vs 83.6%) as the primary abnormalities compared to Baseline assessments. Increased serum chemistry abnormalities were also reported, the most frequent were increased glucose (86.7% vs. 35.2%) and decreased albumin (59.7% vs. 33.1%). Most patients had mild (n=72, 56.3%) to moderate (n=29, 22.7%) increased random glucose values during belinostat treatment. However, these data were based on non-fasting blood draws with no consistent timing relative to food intake across patients. Six patients were discontinued from belinostat due to laboratory abnormalities.

CONCLUSION:

Belinostat demonstrated clinically meaningful efficacy in heavily pretreated patients with relapsed or refractory PTCL. The achievement of an ORR of 25.8% exceeded the protocol predefined rate of interest (20%), and was comparable to that reported with the other agents approved for this patient population. In addition, belinostat given as monotherapy to a population of heavily pretreated patients with relapsed or refractory PTCL demonstrated an acceptable safety profile with manageable AEs. No safety concerns were identified and the benefit-risk balance was assessed as positive for patients with relapsed or refractory PTCL.

DATE OF THE REPORT: 05-Nov-2013

3 TABLE OF CONTENTS

List of Tables

List of Figures

4 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AE	Adverse Event
AITL	Angioimmunoblastic T-Cell Lymphoma
ALK	Anaplastic Lymphoma Kinase
ALT	Alanine Aminotransferase
ALCL	Anaplastic Large-Cell Lymphoma
ANC	Absolute Neutrophil Count
APTT	Activated Partial Thromboplastin Time
ASCO	American Society of Clinical Oncology
AST	Aspartate Aminotransferase
AUC	Area Under the Curve
BPM	Beats per Minute
BSA	Body Surface Area
BUN	Blood Urea Nitrogen
C	Cycle
CBC	Complete Blood Count
CFR	Code of Federal Regulations
CHOP	Cyclophosphamide, Doxorubicin, Vincristine, Prednisone
CI	Confidence Interval
CNS	Central Nervous System
CPRG	Central Pathology Review Group
CR	Complete Response
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
CSR	Clinical Study Report
CT	Computerized Tomography
CTC AE	Common Terminology Criteria for Adverse Events
CTCL	Cutaneous T-Cell Lymphoma
CV	Curriculum Vita
CYP450	Cytochrome P450
D	Day
DLT	Dose-Limiting Toxicity
DMC	Data Monitoring Committee
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EBER	EBV-encoded RNA

Abbreviation	Definition
eRT	eResearch Technologies, Inc.
FDA	Food and Drug Administration
EU	European Union
GCP	Good Clinical Practice
G-CSF	Granulocyte Colony-Stimulating Factor
GM-CSF	Granulocyte-Macrophage Colony Stimulating Factor
HDAC	Histone Deacetylase
HDACi	Histone Deacetylase Inhibitor
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ID	Identification
IHP	International Harmonization Project
IND	Investigational New Drug
INR	International Normalized Ratio
IQA	Image Quality Assessment
IRB/IEC	Institutional Review Board/ Ethics Committee
IRC	Independent Review Committee
IUD	Intrauterine Device
IWG	International Working Group
IV	Intravenous
LDH	Lactate dehydrogenase
MCV	Mean Corpuscular Volume
MedDRA	Medical Dictionary for Regulatory Activities
MTD	Maximum Tolerated Dose
NCI	National Cancer Institute
NE	Not Evaluable
NHL	Non-Hodgkin Lymphoma
NK	Natural Killer
NOS	Not Otherwise Specified
OECD	The Organisation for Economic Cooperation and Development
OR	Objective Response
ORR	Objective Response Rate
OS	Overall Survival
PD	Progressive Disease
PFS	Progression-free Survival

Abbreviation	Definition
PK	Pharmacokinetic
PR	Partial Response
PTCL	Peripheral T-Cell Lymphoma
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
QA	Quality Assurance
QC	Quality Control
QT/QTc	QT interval/corrected QT interval
QTcF	Corrected QT Interval Using Fridericia's Formula
RBC	Red Blood Cell
R-CHOP	Rituximab Cyclophosphamide Doxorubicin Hydrochloride Vincristine Sulfate Prednisone
ROW	Rest of World (excluding United States and Europe)
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Stable Disease
SDTM	Study Data Tabulation Model
SOC	System Organ Class
SPA	Special Protocol Agreement
SPD	Sum of Product of Diameters
TEAE	Treatment Emergent Adverse Event
tMF	Transformed Mycosis Fungoides
TTP	Time to Progression
TTR	Time to Response
ULN	Upper Limit of Normal Range
US	United States
WBC	White Blood Cells
WHO	World Health Organization

5 ETHICS

5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The conduct of this study was governed by the protocol designated PXD101-**CLN-19** (**CLN-19**). Prior to implementation, the protocol, protocol amendments, and patient consent documents were reviewed and approved by Institutional Review Boards (IRBs) for sites in the United States (US) and Canada, and Independent Ethics Committees (IECs) for all remaining sites.

A copy of each version of the protocol, including a summary of all amendments, is provided in Appendix 16.1.1. A list of the IRBs and/or IECs consulted for this study is in Appendix 16.1.3.

5.2 Ethical Conduct of the Study

Investigators agreed to conduct the study in accordance with national, state, and local laws intended to protect the rights and welfare of patients participating in medical research. These included the US Code of Federal Regulations (CFR, Title 21 CFR § 50, 54, 56, and 312), the Canadian Institutes of Health Research Act, the ethical principles that have their origins in the Declaration of Helsinki (48th World Medical Association General Assembly, Somerset West, Republic of South Africa, Oct 1996), and the International Conference on Harmonization (ICH) Good Clinical Practices (GCP) guidelines. Financial disclosures were obtained from all Investigators in accordance with Title 21 CFR Part 54. Where applicable, Ministries of Health reviewed and approved the protocol and amendments in their countries.

Agreement to adhere to the protocol was indicated by Investigators signing and returning the protocol signature page and providing a copy of their curriculum vita (CV) to the Sponsor. The Investigator signature pages and CVs are maintained in the Sponsor's Trial Master File.

Investigators were made aware that regulatory authorities and Sponsor representatives could inspect study documentation and patient records at any time.

Patient identities were kept confidential. As patients were registered for participation in the study, they were assigned a unique identifier consisting of a 3-digit site number and a 3-digit patient-specific numeric code (e.g., 101-001), which was used throughout the study in lieu of the patient's name.

5.3 Patient Information and Consent

Each Investigator was responsible for reviewing the informed consent form (ICF) provided by the Sponsor (included in Appendix 16.1.3) and a privacy authorization (US only). Sites used the template ICF and, if necessary, had it amended according to local law and translated into the local language. The Sponsor or its designee reviewed the privacy authorization

documents (US only) and updated ICFs that were used for this study prior to IRB, or IEC submission. A copy of the initial full ethics committee approval of the protocol and the approved ICF was sent to the Sponsor before the study initiation. All ICF updates and any written information provided to patients were approved by the appropriate IRB or IEC.

Before undertaking any study-related procedure, the Investigator or designee explained the nature and purpose of the study, participation and termination conditions, the costs, risks, and benefits to the patient. Written ICF and privacy authorizations were obtained from all patients prior to undertaking any study-specific procedure in accordance with GCP, the requirements of 21 CFR 50.20 through 50.27, Health Insurance Portability and Accountability Act (HIPAA) (US only), and current regulatory requirements. The informed consent statement was reviewed, signed, and dated by the patient and by the person administering informed consent. Some sites combined the ICF and privacy authorization into a single document. The signed original ICF and privacy authorization were kept in the patient's record and patients were provided a copy. Patients were also informed that their medical records would be examined by authorized representatives from the Sponsor and could be examined by authorized representatives from the health authorities.

At some sites, patients could be reimbursed for transportation, lodging, and parking expenses upon request. No other reimbursements, incentives, or stipends were provided to patients during the study.

A sample consent form is provided in Appendix 16.1.3.

6 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

6.1 Investigators

This multicenter study was activated[1] at 119 sites in 17 countries across the US, Canada, Europe, Russia, Israel, and South Africa. Twenty-three of the sites did not enroll patients and did not receive study drug (belinostat). A total of 96 investigational sites received study drug, and patients were enrolled at 62 sites.

To facilitate tracking, study sites were assigned unique 3 digit codes (see Section 9.4.3). The Principal Investigator for the study was Owen O'Connor, MD, PhD. A complete list of the Investigators, sites, site codes, and Investigator qualifications (CVs) are provided in Appendix 16.1.4.

6.2 Study Dates

The first patient was enrolled on 04-May-2009, and the last patient was enrolled on 02-Aug-2011. The database was locked on 01-Mar-2013 for data up to 31-Aug-2012; 7 patients remained on treatment with on-going data monitoring.

6.3 Study Administrative Structure

6.3.1 Sponsor Responsibilities

The **CLN-19** study was conducted under US Investigational New Drug (IND) application number 70,789. The study was initially sponsored by Topotarget A/S (Topotarget, Copenhagen, Denmark). The first study site was initiated by Topotarget in Dec 2008, and the first patient was enrolled in May 2009. Topotarget sponsored the study until March 2010, when Spectrum Pharmaceuticals Inc. (Spectrum, Irvine, CA, US) entered into a licensing and collaboration agreement with Topotarget for the development and commercialization of belinostat in patients with relapsed or refractory PTCL, and the IND was transferred to Spectrum. At the time Spectrum took over as Sponsor of the study, 18 patients had been entered into the trial. Key study personnel of the Sponsor or contracted by the Sponsor are listed in Appendix 16.1.4. The Sponsor provided the protocol, standardized case report forms (CRFs), and belinostat to the investigational sites, and was responsible for safety reporting in accordance with regulatory requirements.

Overall administration of the study was initially coordinated by Topotarget and as of March 2010 by Spectrum. The signatures attesting to the accuracy of this report by the responsible medical officer for Spectrum, and the Principal Investigator for the study, Owen O'Connor, MD, PhD, are provided on page 2 and in Appendix 16.1.5, respectively.

[1] Activated means site initiation visit was performed.

The Sponsor provided the investigational product (see Section 6.3.1) and also recruited and managed the contract research organizations (CROs) and independent contractors who monitored the study in their respective regions. The Sponsor's clinical research associates (CRAs) and contracted CRAs monitored investigational sites in North America, Europe and the rest of the world (ROW). Five independent CRAs were contracted to monitor the study: Isabelle Dugast (France) and Iris Mizrahi-Bentov (Israel), Leo Brommet (Belgium and The Netherlands), Sebastian Klingler (Canada), and Jennifer May (USA).

6.3.2 Contract Research Organizations (CROs)

The Sponsor (Topotarget/Spectrum) contracted the following CROs to manage the study in other countries:

1. Nuvisan Gmbh (Germany, Netherlands, Hungary, Croatia, Slovakia)
   1139 Budapest, POB 652
2. León Research (Spain)
   San Emilio 6, 28017 Madrid, Spain
3. PharmaTrials-Polska (Poland)
   Ul Rzymska 5, 03-976 Warszawa, Poland
4. AAI Pharma (EU, ROW, and US when the study was under the management of Topotarget)
   18-20 rue Pasteur
   94278 Le Kremlin-Bicêtre, France
5. Ad-Hoc Clinical (Belgium)
   Ter Waarde 33
   8900 Leeper, Belgium
6. Pharm- Olam International Srl (Italy)
   Via Alberto Giussano 9
   20145 Milano, Italy
7. Pharm- Olam International Srl (South Africa)
   Unit 1, Ground Floor 12
   Victoria Link, Route 21 Corporate Park
   Irene, South Africa X 22-0062
8. Wirral Clinical Consulting Ltd (United Kingdom [UK])
   76 Pipers Lane
   Lower Heswall, Wirral
   Cheshire UK CH60 9HN
9. Macnee Clinical Consulting Ltd (UK)
   Chapel Cottage, Newtown-Hullavington, Chippenham
   Wiltshire UK SN 14 6EQ
10. Clinitria Ltd (Slovakia)
    Mikulasska 29

811 01 Bratislava, Slovakia

Responsibilities delegated to the CROs included project management, Investigator qualification and recruitment, site coordination (under the direction of the Sponsor), data monitoring, resolution of queries, IRB, IEC and Ministries of Health submissions, and assistance with distribution of safety reports to sites and local regulatory authorities. The Sponsor reviewed study documentation for the sites recruited by the CROs prior to site activation and the monitoring reports over the course of the study.

6.3.3 Independent Data Monitoring Committee

The Sponsor coordinated an independent Data Monitoring Committee (DMC) that consisted of 3 members (see DMC Charter). Two members were medical hematologists/oncologists with experience in managing T-cell lymphoma, and the third member was a statistician (Table 1). None of the DMC members were directly involved with the conduct of the study. The DMC was charged with independently monitoring the safety of the study and was empowered to make recommendations to the Sponsor including halting the study or proposing an amendment to the protocol. The CVs of the DMC committee members are provided in Appendix 16.1.4.

The DMC met twice to review clinical data during the course of the study: the first meeting was on 25-Mar-2011 after the first 41 patients had received at least 1 dose of belinostat (efficacy and safety assessment), and the second meeting was on 18-Nov-2011 at the end of study enrollment (safety assessment). At the conclusion of both meetings, the DMC recommended that the study continue as planned. The DMC concluded that the observed adverse events (AEs) were generally mild and expected, as previously reported in the Investigators Brochure, and that the safety analyses revealed no concerns. In addition, the DMC recommended that patients remaining on-study be continued per the study protocol until disease progression (see DMC recommendation letters).

Table 1 Data Monitoring Committee

Member	Role	Location
Ulrik Lassen, MD	Chair/Oncologist	Copenhagen, Denmark
Thomas Relander, MD	Oncologist/hematologist	Lund, Sweden
Harald Anderson, PhD	Statistician	Lund, Sweden

Source: DMC Charter

6.3.4 Central Pathology Review

The diagnosis of eligible PTCL histopathological subtype was confirmed by a Central Pathology Review Group (**CPRG**). **CPRG** members individually and independently

reviewed the pathology material for all patients (see CPRG Charter). They were provided the pathology material (paraffin block/and or slides), local site pathology diagnosis, and other relevant Baseline information along with the information regarding the sample type.
Two reviewers in rotation assessed each sample and, in the event that their diagnoses did not concur, a third reviewer served as an adjudicator. The reviewers included:

1. Professor Elisabeth Ralfkiaer (Chair)
   Department of Pathology 5444 Righospitalet, University of Copenhagen
   Blegdamsvej 9, DK 2100, Copenhagen OE, Denmark
2. Professor Stefano A. Pileri
   Bologna University School of Medicine, St. Orsola Hospital
   Via Massarenti 9
   40138 Bologna, Italy
3. Elaine S. Jaffe, MD
   Head, Hematolopathology Section
   National Cancer Institute
   Laboratory of Pathology,
   Building 10, Room 2B42, MSC 1500
   Bethesda, MD 20892

   Elaine Jaffe resigned after analyzing samples from 3 patients, due to conflict of interest, and was replaced by Dennis Weisenburger, MD. Each of these 3 patient samples was assessed independently by another pathologist.
4. Professor Dennis Weisenburger, MD
   University of Nebraska Medical Center Pathology/Microbiology Department
   983135 Nebraska Medical Center
   Omaha, NE 68198-3135

The reviewers were provided with tissue and/or slides to confirm histopathology. The CVs of the reviewers are provided in Appendix 16.1.4.

6.3.5 Central Radiographic Review

Radiographic data were forwarded by the investigational sites directly to Bioclinica Inc (formerly CoreLab Partners, and RadPharm), the imaging laboratory, for centralized radiological review:

Bioclinica, Inc
100 Overlook Center
Princeton, NJ, 08540 US

Bioclinica provided an Independent Review Committee (**IRC**) that performed the efficacy evaluations, which included radiologic assessments of all the images provided by sites, and oncologic assessments of pre-defined clinical data provided by the Data Manager. Trained and approved radiology readers read patient scans according to a pre-defined 2-reader modified batch mode paradigm. Images were read according to a sequential locked read paradigm in which images were electronically presented to the assigned readers in chronological order starting with the Screening/Baseline time point to allow for the determination of progression and response through comparison with prior time points.

Oncology assessments were done based on the radiology assessment and on the pre-defined clinical data being sent to Bioclinica by the Sponsor.

Radiology and oncology response assessments performed by the **IRC** at Bioclinica were not subject to input from the Sponsor, its designees, or any site involved in this clinical trial. All readers were blinded to patient demographics, site assessment of response, site choice of index and non-index lesions and the identification of new lesions, the number of time points for a patient during the read (to eliminate progression bias), clinical history (other than that described in Sections 6.5.2 and 6.5.4 of the Bioclinica (Corelab) Charter, and the results from the other reader(s).

6.3.6 Central Laboratory

At each institution, the local laboratory was used for the hematology, chemistry, and pregnancy testing to assess study eligibility and safety.

The central laboratory used for pharmacokinetic (PK) analyses was Covance, Inc:

Covance, Inc.
8211 SciCor Drive, Suite B
Indianapolis, IN 46214

Covance Central Clinical Laboratories and Covance Bioanalytical Services were audited on 21 Mar 2011 and qualified in accordance with the Good Laboratory Practices as outlined in 21 Code of Federal Regulations Part 58 and OECD Principles of Good Laboratory Practices; and Principles of GCP as outlined in EU Directive 2001/20/EC and ICH GCP guidelines.

6.3.7 Electrocardiogram Analyses

Electrocardiogram machines were supplied to the site by the Sponsor through eResearch Technologies, Inc (eRT). Sites were trained and electrocardiograms (ECGs) were sent to eRT for analyses.

An independent analysis was conducted on all ECGs collected in the study by:

eResearch Technologies, Inc

1818 Market Street
Suite 1000
Philadelphia, PA 19103

6.3.8 Study Drug Supply

Belinostat was manufactured by:

Cenexi-Laboratoires Thissen

2-4 Rue de la Papyrée

B-1420 Braine-l'Alleud

Belgium

Belinostat was packaged, labeled, and shipped to investigational sites in the US by:

Almac Clinical Services
4204 Technology Drive
Durham, NC 27704

Belinostat was shipped to the Almac facility by the Sponsor and stored at a controlled room temperature (15-25°C [59-77°F]). Almac labeled each individual vial with a 2-part vial label and packaged in boxes containing 10 vials each. Drug product was kept in quarantine until the Almac Clinical Services Quality Unit approved its release. Shipments to sites were tracked and delivery was confirmed. Almac tracked the expiry dates at the sites and at Almac distribution warehouses and depots.

Belinostat was shipped to investigational sites in Canada, Europe, Israel and South Africa by:

KLIFO A/S
Symbion Science Park
Fruebjergevej 3
2100 Copenhagen, Denmark

Bulk vials were provided to KLIFO by the Sponsor. The European Union Qualified Person at KLIFO released the materials for stock. KLIFO designed and printed labels based on master labels provided by the Sponsor. All translations were provided by the Sponsor. Labels for vials and cartons were prepared and approved by the Sponsor. The EU Qualified Person performed the final release of the labeled and packaged drug product. Sites confirmed receipt of the study medication by returning the signed invoice by fax. All shipments took place under controlled and documented temperature at 2-8°C (36-46°F).

Drug accountability was monitored by representative CRAs from the Sponsor or its designees during clinical monitoring visits. All used and unused vials of belinostat were destroyed at the study sites or returned to the depot for destruction.

7 INTRODUCTION

Treatment of Peripheral T-cell Lymphomas

Peripheral T-cell lymphomas (PTCLs) are a heterogeneous group of clinically aggressive hematologic malignancies that represent approximately 10% of all non-Hodgkin's lymphomas (NHL) in Western populations, and are associated with a poorer outcome and survival compared to the B-cell lymphomas [1, 2]. The majority of patients with PTCL relapse after initial treatment with cytotoxic agents or alternative modalities such as immunomodulators, and 5-year survival is less than 32% [3, 4].

At the initiation of this protocol (2009), there were no therapies specifically approved for the treatment of PTCL. Primary treatment for most subtypes of PTCL was anthracycline-based chemotherapy regimens, predominantly the combination of cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), adopted from the management of B cell NHL. With the exception of anaplastic lymphoma kinase (ALK)-positive anaplastic large cell lymphoma (ALCL), PTCL subtypes respond poorly to these regimens. Few studies that specifically investigated optimal treatment options for patients with relapsed or refractory PTCL have been conducted. Subsequent to the initiation of **CLN-19**, 2 drugs received accelerated approval in the US for the treatment of relapsed or refractory PTCL based on nonrandomized Phase 2 studies: pralatrexate (Folotyn®; 2009) and romidepsin (Istodax®; 2011). Both of these agents, however, have limitations with regard to both safety and efficacy, and additional treatment options for these patients are needed.

Pralatrexate is a folate antagonist that had a 27% objective response rate (ORR) in the pivotal study that led to its accelerated approval. However, that study included many patients with PTCL subtypes known to have a better prognosis including 12 (11%) patients with transformed mycosis fungoides (tMF) and 17 (15%) patients with ALCL [1, 2, 3, 21]. Pralatrexate treatment is also frequently associated with myelosuppression and mucositis; 23% of patients had their target dose reductions due to mucositis and 23% of patients withdrew from the study due to AEs [21]. Because it causes bone marrow suppression, which may lead to thrombocytopenia (a common occurrence in PTCL), pralatrexate is generally not preferred for use in patients with compromised bone marrow function because of its mechanism of action as an antifolate and risk of worsening thrombocytopenia [26].

Romidepsin is a bicyclic histone deacetylase (HDAC) inhibitor that specifically inhibits Class 1 HDACs. It demonstrated a 25% ORR in a Phase 2 study population that also included many patients with better prognosis PTCL subtypes; 18% of enrolled patients were diagnosed with tMF or ALCL [22]. In the pivotal study for romidepsin in relapsed or refractory PTCL, fatigue and/or infection were reported in 55% of patients, and 19% of patients discontinued treatment due to AEs. In addition, romidepsin represents a class of

HDAC inhibitors known to have a risk of QTc prolongation as listed in the Warnings and Precautions section of its US Prescribing Information.

Therefore, there remains an important unmet medical need for patients with relapsed or refractory PTCL, who need additional new treatment options specifically effective for this disease. These patients typically have an extremely poor overall survival and frequently fail multiple treatments, requiring them to explore numerous sequential treatment options until drug resistance or death. [7] The approval of additional effective agents specifically designed to treat PTCL would also permit novel combinations of these agents with other experimental or approved anti-neoplastic T-cell agents, which potentially may have a greater impact on increasing the ORR and survival for these patients. To date, most treatment paradigms for PTCL have used therapeutic approaches previously studied for B-cell NHLs, which unfortunately have proven to be less efficacious when applied to T-cell neoplasms. [7, 8, 9]

Belinostat- *a pan-histone deacetylase inhibitor*

Belinostat is a hydroxamic acid-derived potent pan-inhibitor of HDAC enzymes that alters the acetylation levels of histone and non-histone proteins and, in turn, modulates the expression of various cellular genes and pathways. HDACs regulate numerous cellular processes involved in differentiation, proliferation, migration, and survival, and have been shown to play multiple roles in cancer pathogenesis. [5, 6] Through their pleiotropic effects, HDAC inhibitors may simultaneously target multiple signal transduction pathways crucial for tumor cell survival.

Preclinical studies support the exploration of belinostat in the treatment of T-cell lymphoma. [31] Belinostat also showed growth inhibitory activity *in vitro* against T-cell lymphoma cell lines including those representing ALCL and natural killer (NK)/T-cell lymphoma subtypes. Further support for the activity of HDAC inhibitors for the treatment of patients with PTCL comes from the recent FDA accelerated approval of romidepsin, a Class 1 HDAC inhibitor, for this indication. Belinostat is differentiated from romidepsin, in that it is a pan-inhibitor that inhibits multiple classes of the HDAC enzymes.

Based on Phase 1 studies (Studies **TT20** and **TT30**), the dose of belinostat monotherapy was determined to be 1,000 mg/m^2 intravenously (IV) over 30 minutes on Days 1-5 every 21 days. Clinical activity of belinostat was observed in a Phase 2 study [PXD101-**CLN-6 (CLN-6)**] of belinostat monotherapy in patients with recurrent or refractory cutaneous T-cell lymphoma (CTCL; N=29) or PTCL (N=24). Efficacy was analyzed separately with an ORR in the PTCL population of 25.0% that included 2 complete responses (CRs), and an ORR in the CTCL population of 13.8%.

Under the Special Protocol Assessment (SPA) process on 04 Sep 2008, the US Food and Drug Administration (FDA) agreed that the design and planned analyses of **CLN-19** were

adequate to address the objectives necessary to support a regulatory submission. The FDA granted Fast Track designation for the belinostat development program in relapsed or refractory PTCL on 28 May 2008 and Orphan Drug designation on 03 Sep 2009 to belinostat for the treatment of patients with PTCL.

8 STUDY OBJECTIVES

The primary objective of this study was to determine the ORR in patients with relapsed or refractory PTCL who were treated with belinostat monotherapy.

Secondary objectives of the study were to determine the following:

- Safety of belinostat monotherapy
- Time to Response
- Duration of Response
- Time to Progression (TTP)
- Progression-free Survival (PFS)
- 1-year Progression-free Rate
- 1-year Survival Rate
- Overall Survival (OS)

Additional objectives were to assess:

- Population PK
- Medical Care Utilization

9 INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan Description

CLN-19 was a Phase 2, single arm, open-label, multicenter study designed to determine the safety and efficacy of belinostat in the treatment of patients with relapsed or refractory PTCL. The planned enrollment was approximately 120 patients to ensure a minimum of 100 evaluable patients at the conclusion of accrual. A summary of all amendments to the protocol is provided in Table 8. All versions of the clinical study protocol (including summaries of all amendments to the protocol) are provided in Appendix 16.1.1. A sample CRF used for the study is provided in Appendix 16.1.2. The final statistical analysis plan (SAP) is provided in Appendix 16.1.9 and describes the planned analyses for the study. A 2-stage Simon design was employed for this study. [10] Under this design, at least 5 out of 41 evaluable patients had to experience a response (defined as CR or partial response [PR] based on the **IRC** assessment) or the study would have been discontinued for futility.

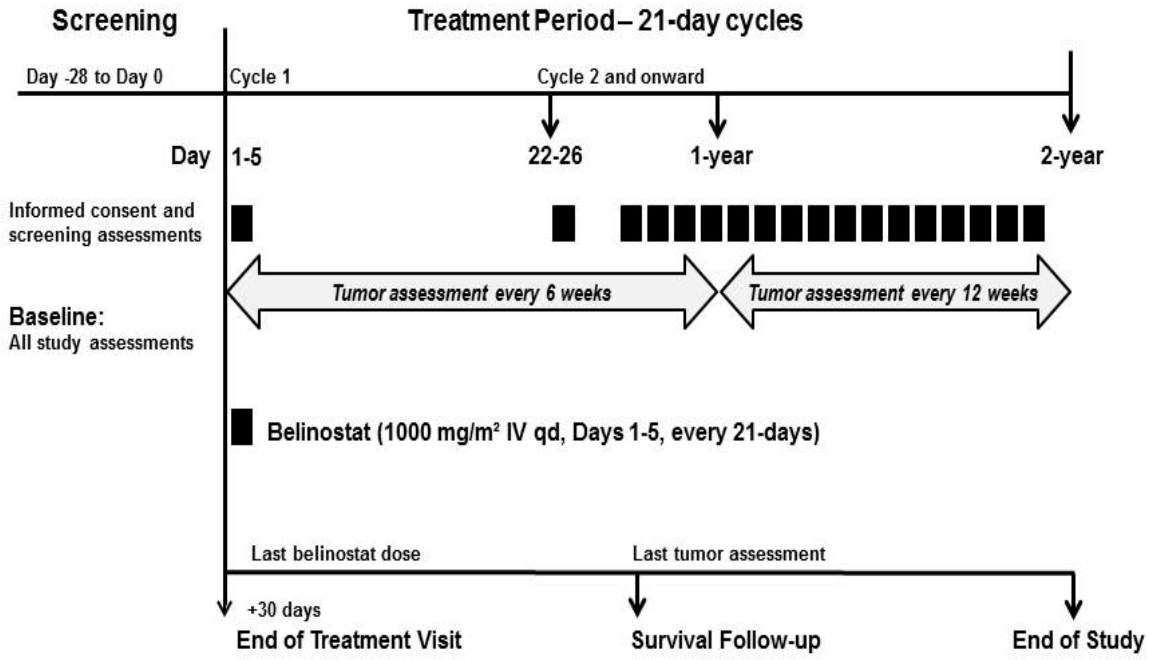
Patients received belinostat at a dose of 1,000 mg/m^2 as a 30 minute IV infusion on Days 1-5 of a 21-day cycle (see Section 9.4.1). The primary study endpoint was ORR, defined as a CR or PR based on the independent central radiology and oncology clinical review by the **IRC**. Tumor assessments according to the International Harmonization Project (IHP) revision of the International Working Group (IWG) criteria [11] were made by radiologic imaging using CT scans. Assessments were performed at Baseline (Day -28 [Screening] to Cycle 1, Day 1 prior to belinostat treatment) and every 6 weeks for the first 12 months, then every 12 weeks until 2 years from the start of study treatment. Radiological assessments were discontinued at the time of tumor progression or initiation of new anticancer therapy, after which survival data was collected every 3 months until 2 years from the start of study treatment or until study closure.

Safety was assessed at every study visit by evaluating changes in hematology and biochemistry parameters, and by monitoring the incidence, severity, and relationship of AEs to belinostat. AEs were graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), Version 3.0. Physical examinations were performed at Baseline and changes recorded on Day 1 of every cycle, and at the End of Study Treatment Visit.

After discontinuing protocol treatment, patients were to complete the End of Study Treatment Visit 30 days after the last dose of belinostat. A formal interim analysis of safety and efficacy was conducted by the DMC (see Section 6.3.3) after 41 evaluable patients had received at least 1 dose of belinostat. After accrual completion, a second DMC meeting occurred to review overall study safety.

Figure 1 provides a schematic of the study design indicating the timing of study assessments.

Figure 1: PXD101-CLN-19 Study Design



9.1.1 Schedule of Events

Table 2 presents the schedule of events for all study and follow-up visits.

Table 2: Schedule of Study Events

Study Procedures	Screening Period		Treatment Period											End of Treat-ment[14]	Follow Up
			Cycle 1						Cycle 2 and Onward						
Study Days	**Baseline Day -28 to 0**	**Baseline Day -14 to 0**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 11-15 [5]**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**		
BELINOSTAT TREATMENT	**-**	**-**	**X**	**X**	**X**	**X**	**X**	**-**	**X**	**X**	**X**	**X**	**X**	**-**	**-**
Informed Consent	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pathology material for **IRC** [16]	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Electrocardiogram (ECG) [1]	X	-	X	X	X	X	X	-	-	-	-	-	X	X	-
Pregnancy test (serum or urine)	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-
Medical history [2]	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-
Performance status (ECOG)	-	X	X	-	-	-	-	-	X	-	-	-	-	X	-
Physical examination [3]	-	X	X	-	-	-	-	-	X	-	-	-	-	X	-
Vital signs [4]	-	X	X	X	X	X	X	-	X	X	X	X	X	X	-
Hematology[5]	-	X	X	-	-	-	X	X	X	-	-	-	X	X	-
Blood chemistry[6]	-	X	X	-	-	-	X	X	X	-	-	-	X	X	-
Coagulation[7]	-	X	[X]	-	-	-	-	-	[X]	-	-	-	-	X	-
Urinalysis/dipstick[8]	-	X	-	-	-	-	-	-	-	-	-	-	-	X	-
Creatinine clearance[9]	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-
PK blood sampling[10]	-	-	X	-	-	X	-	-	-	-	-	-	-	-	-
Concomitant medications review	-	X	X	X	X	X	X	X	X	X	X	X	X	X	X[11]

Adverse event assessment	-	-	X	X	X	X	X	X	X	X	X	X	X	X	-
Tumor assessment[12]	X	-	-	-	-	-	-	-	Tumor assessments (see below)[12]					X[14]	X[12]
Survival information[13]	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X

Each treatment cycle was 21 days.

[X] indicates optional events.

1. Three 12-lead electrocardiograms were to be performed locally at Baseline. A 12-lead electrocardiogram was to be performed locally pre-dose and within 1 hour post-end of infusion on treatment Days 1 to 5 of Cycle 1 and on Day 5 of subsequent cycles.
2. Medical History at Baseline included the history of the neoplastic disease, its previous therapy and investigation, pre-existing diseases. Refer to Section 9.3.1 Inclusion Criteria for pathologic parameters for PTCL diagnosis. Previous pathologic analyses done at initial disease diagnosis were acceptable if tests performed fulfil the criteria in Section 9.3.1 Inclusion Criteria.
3. Included at Baseline: determination of height, weight, body surface area, description of external signs of the neoplastic disease, and co-morbidities; during trial: description of external signs of the neoplastic disease (cycle Day 1), and ECOG PS. Weight was also to be recorded at each cycle Day 1.
4. Heart rate, blood pressure, and temperature before and after (+/- 15 minutes) administration of belinostat.
5. Hematology: complete blood count (CBC) (including WBC (leucocytes), HGB (hemoglobin), MCV (mean corpuscular volume) with differential and platelets should be obtained at Baseline, Day 1 and 5 of each treatment cycle, at the End of Study Treatment Visit, and in addition once during Days 11-15 in Cycle 1. Special note for the Day 1 sampling of each cycle: blood samples were to be drawn the first day of each cycle (prior to treatment) if possible; however for logistical reasons it was also acceptable to draw samples for assessment up to 4 days prior to start of a cycle. In any case, the results of the laboratory assessments were to be evaluated and medically accepted by the responsible physician before start of a cycle.
6. Blood chemistry: comprehensive chemistry and electrolyte panel (including BUN, creatinine, AST, ALT, alkaline phosphatase, total bilirubin, uric acid, albumin, calcium, lactate dehydrogenase, sodium, potassium, chloride, phosphate, magnesium, and glucose) were to be obtained at Baseline, Days 1 and 5 of each treatment cycle, at the End of Study Treatment Visit, and in addition once during Days 11-15 in Cycle 1. Special note for the Day 1 sampling of each cycle: blood samples were to be drawn the first day of each cycle (prior to treatment) if possible; however for logistical reasons it was also acceptable to draw samples for assessment up to 4 days prior to start of a cycle. In any case, the results of the laboratory assessments were to be evaluated and medically accepted by the responsible physician before start of a cycle.
7. PT or INR and APTT at Baseline and at the End of Study Treatment Visit. PT or INR was to be done first day of each treatment cycle for patients on anticoagulation therapy, or when clinically indicated.
8. Urinalysis (dipstick) including albumin (protein), glucose, ketones and blood (microscopic analysis was to be performed if clinically indicated by symptoms or abnormal dipstick finding).
9. Creatinine clearance was to be calculated using the Cockroft-Gault formula (Section 15.5 Appendix E of the protocol, Appendix 16.1.1) and be repeated if serum creatinine increased $\geq$ 20 % from Baseline.
10. Three samples collected on Cycle 1 Day 1 and 2 samples collected on Cycle 1 Day 4 as described in Section 15.6 Appendix F of the protocol, Appendix 16.1.1.
11. In follow up period, concomitant medication review was limited to new anti-cancer treatment.

12. Tumor assessments according to IHP/IWG were to be made by appropriate radiologic imaging or other techniques. For radiographic assessment, CT of neck, chest, abdomen and pelvis was to be done at every assessment. Examination and documentation of the clinically measurable size and location of all palpable and skin tumor lesions were to be done, i.e., index and non-index lesions. Index and non-index lesions which were not followed by radiological methods were to be documented appropriately, e.g., by photographs that include a ruler.

    Tumor assessments were to be made at Baseline and by the same techniques every 6 weeks for the first 12 months, then every 12 weeks until 2 years from the start of study treatment. Tumor assessments stopped at the time of PD as evaluated by the Investigator, or upon initiation of new anticancer treatment. Tumor assessments were to be performed at the End of Study Treatment Visit if they had not been performed within the previous tumor assessment interval (i.e., previous 6 weeks for the first 12 months).

    Bone Marrow assessment was to be performed at Baseline within 28 days of protocol treatment start. If the Baseline bone marrow assessment was positive for lymphoma a bone marrow biopsy was mandatory to confirm a CR (i.e., after radiographic CR assessment).
13. Survival follow-up was to start after tumor assessments had been terminated, was to be carried out every 3 months until 2 years from the start of study treatment, or until study closure.
14. End of Study Treatment Visit activities were to occur for all patients. Tumor assessments were to be performed if not done within last scheduled time frame (i.e., last 6 weeks if patient discontinued during first 12 months of treatment). If patient discontinued treatment for reasons other than PD, tumor assessment was to continue as per footnote 12 above.
15. Pathology material had to be available at the site for each patient before enrolment so that it could be sent to the Sponsor (or designee) for central pathology review.

Abbreviations: ECG: electrocardiograms, ECOG: Eastern Cooperative Oncology Group, BUN: blood urea nitrogen, AST: aspartate aminotransferase, ALT: alanine aminotransferase, PT: prothrombin time, INR: international normalized ratio, APTT: activated partial thromboplastin time, IHP/IWG: Harmonization Project (IHP) revision of the International Working Group (IWG) criteria according to Cheson 2007, PD: progressive disease, CR: complete response

Source: Protocol, Appendix 16.1.1

9.2 Discussion of Study Design, Including the Choice of Control Groups

This study was a Phase 2, single arm, open-label, multicenter study designed to determine the safety and efficacy of belinostat in the treatment of patients with relapsed or refractory PTCL.

As described above (Section 9.1), a 2-stage Simon design was employed for this study. [10] This design was selected to minimize the risk of treating patients with an ineffective therapy, because it allowed for early termination of the study if the requisite pre-determined level of anti-tumor activity was not observed in the first stage of the study.

PTCL is a heterogeneous group of aggressive T-cell lymphoma histologic/pathologic subtypes. Primary treatment for most subtypes of PTCL is anthracycline-based regimens, predominantly CHOP. With the exception of ALK-positive ALCL, PTCL subtypes generally respond poorly to these treatment regimens. The use of radiotherapy, with or without chemotherapy, is preferred as front line treatment of extranodal NK/T-cell lymphoma. [32] The majority of patients with PTCL relapse after primary therapy and also after subsequent treatments.

Although a number of chemotherapy regimens are used for salvage therapy there is no clear standard of care. [2] At the initiation of **CLN-19**, there were no approved or standard therapies for relapsed or refractory PTCL, and therefore, no control group was included in this study. A placebo control was considered, but because of the aggressive nature of this disease, comparison with placebo was not considered to be appropriate.

Pralatrexate and romidepsin were subsequently approved for the treatment of relapsed or refractory PTCL patients under accelerated approval based on response rate, but have limitations in terms of both their safety and efficacy. To ensure consistency and an unbiased, objective assessment of the primary endpoint of ORR in this study, response was assessed by an independent committee, the **IRC**, as described in Section 6.3.5.

The single-arm study design of **CLN-19** can be used to accurately assess the response rate with belinostat using the above described independent review process, and response rate can be directly attributed to the antitumor activity of the treatment. [12]

9.3 Selection of Study Population

The target population for this study consisted of patients with relapsed or refractory PTCL. For inclusion in the **Efficay Analysis Dataset**, the diagnosis of an eligible PTCL histopathological subtype was confirmed centrally by the **CPRG** as described in Section 6.3.4.

9.3.1 Inclusion Criteria

Each patient had to meet the following criteria to be eligible for enrollment in the study:

1. A histologically confirmed diagnosis of PTCL based on pathology review at the local institution, using the most recent edition of the World Health Organization (WHO) Classification of Tumors of Haematopoietic and Lymphoid Tissues as guidance leading to the diagnosis of:

    - ALCL, ALK-positive
    - ALCL, ALK-negative
    - Angioimmunoblastic T-cell lymphoma
    - Enteropathy-associated T-cell lymphoma
    - Extranodal NK/T-cell lymphoma, nasal type
    - Hepatosplenic T-cell lymphoma
    - PTCL, not otherwise specified (NOS)
    - Subcutaneous panniculitis-like T-cell lymphoma

    The diagnosis of PTCL was based on identification in biopsy specimens of a PTCL disorder characterized by positivity in the malignant cell population of at least 3 T-cell markers: βF1, CD2, CD3, CD4, CD5, CD7, CD8, and negativity of at least 2 of the following B-cell markers CD19, CD20, CD79alpha and Pax-5. Further, CD56 was to be used for the diagnosis of the nasal type, while CD30, ALK-1 and Pax-5 (which should be negative) were required for the anaplastic type. CD10, CXCL13, PD-1 and CD 21 were needed for the diagnosis of angioimmunoblastic T-cell lymphoma along with EBV-encoded RNA (EBER) *in situ* hybridization. Determination of Mib-1/Ki-67 was to be performed; in cases where the local site pathologist could not provide Mib-1/Ki-67, the **CPRG** performed the test.

    Finally, additional markers useful in the context of anaplastic large cell lymphoma, extranodal NK/T-cell lymphoma and subcutaneous panniculitis-like T-cell lymphoma including TIA-1, granzyme B and Perforin were also assessed. However, it should be acknowledged that no marker has absolute lineage specificity for PTCL, and that immunophenotypic studies are, therefore, performed with panels of monoclonal antibodies.

    Due to difficulties in obtaining all markers at each study site, the following consensus was reached by the **CPRG** assessors in a teleconference on 10-Jan-2011. The pathologists agreed that the diagnosis of PTCL would be based on the histological and the immunohistochemistry patterns of the lymphoma biopsies. The pathology markers identified locally were used as an aid for the classification of cell types and diagnosis. It was <u>not</u> mandatory to have at least

2 negative B-cell markers and 3 positive T-cell markers as well as MIB/KI67 performed in order to determine the diagnosis of PTCL. The diagnosis was determined based on histology and immunohistochemistry.

Further, it was required that the pathology sample be considered adequate by the **CPRG**, meaning that there must have been enough well-preserved, formalin-fixed biopsy material for the central reviewing pathologist to be able to perform a morphological and immunohistochemical examinationto make an unequivocal diagnosis of PTCL. Final diagnoses containing caveats such as "suspicious of" or "presumably" were considered inadequate for a patient to be included in the trial.

2. Pathology material must have been available at the site for each patient before enrollment, so that it could be sent to the Sponsor (or designee) for central review by the **CPRG**.
3. Patients must have had relapsed or refractory disease after at least 1 prior systemic anti-lymphoma regimen. Systemic anti-lymphoma therapy was defined as chemotherapy or immunotherapy administered systemically.
4. Patients must have had at least 1 site of disease measurable in 2 dimensions by computed tomography (CT).
5. Age ≥18 years.
6. Laboratory status as follows:
    a. Absolute neutrophil count (ANC) $\geq 1.0 \times 10^9$/L, platelets $\geq 50 \times 10^9$/L.
    b. Total bilirubin ≤1.5 x upper normal limit (ULN), or ≤3 x ULN if documented hepatic involvement with lymphoma, or ≤5 x ULN if history of Gilbert's Disease.
    c. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤2.5 x ULN (≤5 x ULN limit if documented hepatic involvement with lymphoma).
    d. Serum potassium within normal range.
    e. Calculated creatinine clearance ≥45 mL/min/1.73 m^2 based on Cockcroft and Gault's method. [13]
    f. Prothrombin time (PT) or international normalized ratio (INR), and activated partial thromboplastin time (APTT) ≤1.5 x ULN unless patient was receiving anticoagulants. If patient was on anticoagulation therapy, levels were to be within therapeutic range.
7. Eastern Cooperative Oncology Group (ECOG) performance status 0-2.
8. Estimated life expectancy greater than 3 months.
9. Negative pregnancy test for women of childbearing potential.

10. Signed an Informed Consent form approved by the local EC, or IRB.

9.3.2 Exclusion Criteria

Patients who met any of the following criteria were excluded from the study:

1. Any use of anticancer therapies within 2 weeks prior to initiation of study treatment. In addition, patients should have recovered from prior treatment-related toxicities and meet laboratory and ECOG criteria for inclusion.
2. Any use of investigational therapies within 3 weeks prior to initiation of study treatment.
3. Major surgery within 2 weeks of study drug administration.
4. Relapse within 100 days of autologous or allogeneic bone marrow transplant.
5. Prior HDAC inhibitor therapy.
6. Patients with a diagnosis of:
    - Precursor T-cell lymphoma or leukemia
    - Adult T-cell lymphoma/leukemia (ATLL)
    - T-cell prolymphocytic leukemia
    - T-cell large granular lymphocytic leukemia
    - Primary cutaneous type anaplastic large cell lymphoma
    - Mycosis fungoides/Sezary syndrome
7. Co-existing active infection or any medical condition likely to interfere with trial procedures.
8. Significant cardiovascular disease (New York Heart Association Class III or IV cardiac disease), myocardial infarction within the past 6 months, unstable angina, unstable arrhythmia or a need for anti-arrhythmic therapy (use of frequency adjusting medication for atrial fibrillation was allowed, if stable medication for at least the last month prior to enrollment and medication not listed as causing Torsades de Pointes, or evidence of acute ischemia on ECG.
9. Baseline prolongation of QT/QTc interval, i.e., demonstration of a QTc interval >450 msec; long QT Syndrome; the required use of a concomitant medication that may cause Torsades de Pointes.
10. Clinically significant central nervous system (CNS) disorders with altered mental status or psychiatric disorders precluding understanding of the Informed Consent process and/or completion of the necessary studies.

11. Active concurrent malignancy (except adequately treated non-melanoma skin cancer or carcinoma in situ of the cervix). If there was a history of prior malignancy, the patient must have been disease free for ≥2 years (except carcinoma *in situ* of breast, prostate cancer, or superficial bladder cancer).
12. Symptomatic or untreated CNS metastases. Patients with previously treated CNS metastases, which were asymptomatic at Baseline, were permitted.
13. Pregnant or breast-feeding women.
14. Women of childbearing age and potential who were not willing to use effective contraception during the study and until 30 days after last dose of study drug. Male patients or male patients who had female partners of childbearing age and potential who were not willing to use effective contraception during the study and until 30 days after last dose of study drug. Highly effective methods of birth control were defined as those which result in a low failure rate (i.e., less than 1% per year) when used consistently and correctly such as implants, injectables, combined oral contraceptives, some intrauterine devices (IUDs), sexual abstinence or vasectomized partner.
15. Known infection with human immunodeficiency virus (HIV), hepatitis B or hepatitis C.
16. Patients that were not affiliated with social security (study sites in France only).

9.3.3 Removal of Patients from Therapy or Assessment

Patients, at their own request or at the request of their legally acceptable representative, could withdraw their consent from the study at any time and for any reason.

Patients were to be withdrawn from study drug treatment for the following reasons:

- Progressive disease
- Unacceptable or recurrent toxicity despite optimal prophylaxis and appropriate dose modification
- Substantial non-compliance with the requirements of the study
- Positive pregnancy test
- Use of illicit drugs or other substances that may, in the opinion of the Investigator, have had a reasonable risk of contributing to toxicity or otherwise skewing results

- Development of an intercurrent illness or situation which, in the opinion of the Investigator, affected assessments of clinical status and study endpoints to a significant degree
- Interruption in study drug administration for >42 days since last study drug administration

The Investigator also could withdraw patients from study treatment, study-related procedures, or follow-up for the following reasons:

- In the Investigator's opinion, continuation would have been detrimental to the patient's wellbeing
- The patient was lost to follow up

Patients who were withdrawn from study drug treatment were to continue study-related procedures and follow-up for toxicity, tumor assessments, and survival.

9.4 Treatments

9.4.1 Treatments Administered

Belinostat was administered to patients who met entry criteria at a dose of 1,000 mg/m^2 administered as a 30-minute IV infusion daily (with approximately 18 hours between infusions) for 5 consecutive days every 21 days on Days 1-5 of the 21-day treatment cycle. The individual dose was determined using body surface area (BSA) based on the actual weight of the patient as assessed at Baseline; the dose was recalculated if body weight changed from Baseline by more than 10% in subsequent cycles. Dose modification was allowed as described in Section 9.4.6.1.

9.4.2 Identity of Investigational Product(s), Packaging, Labeling, and Storage

The drug product, belinostat (50 mg/mL), is a yellow solution of pH 9.0 to 9.9, containing belinostat, arginine, and Water for Injection. The solution was supplied in single-use 10-mL clear glass vials with coated stoppers and aluminum crimp seals with “flip-off” caps. Each vial contained 10 mL of a solution of 500 mg belinostat at a concentration of 50 mg belinostat/mL. The country specific label contained the following information: concentration, lot number expiration date, and storage conditions. The belinostat drug product was stored refrigerated at 2-8°C (36-46°F).

For administration, the required volume from 1 or more vials was withdrawn from the glass vial and added to a 250 mL bag of either 0.9% Sodium Chloride Injection or 5% Dextrose Injection and mixed by gently inverting the bag several times. The resulting dilution could have then been stored at ambient room temperature (15-25 °C [59-77°F]) for up to 12 hours before infusion. The belinostat dilution was administered over

30 minutes using a health authority-approved administration set and a 0.22 µm in-line filter.

Appendix 16.1.6 provides a detailed list of patients and the belinostat lots received.

9.4.3 Drug Accountability

All empty and partially used vials were retained by the site during the study for verification by the CRA unless otherwise instructed by the Sponsor. Each time an IV dose was prepared, the following information was recorded in the dispensing log or/and CRF:

- Patient initials
- Patient number
- Number of vials used
- Lot number or an associated vial number
- Date and time study drug was prepared for dispensing
- Initials of the person preparing the study product
- Number of vials of study product that were remaining/unused.

Routine study drug reconciliation was performed by the CRA throughout the study to verify drug administered, and remaining drug supply. Copies of the disposition records were provided to the Sponsor at the conclusion of the study after completion of all study drug dosing, database lock, and analysis.

The Investigators agreed to not supply study drug to any person not enrolled in the study. Unused drug was to be destroyed on site or returned to the depot for destruction.

9.4.4 Method of Assigning Patients to Treatment Groups

There was 1 treatment group in this study and, therefore, no randomization of treatment assignment was necessary. Before enrolling a patient, the Investigator assured that the patient was eligible according to the Inclusion and Exclusion Criteria listed in Sections 9.3.1 and 9.3.2.

Once it had been determined that a patient met all inclusion and exclusion criteria, the site faxed enrollment forms to the Sponsor. Upon enrollment, the patient was assigned a unique patient ID number and was entered into the study. The ID number consisted of 6 digits; the first 3 digits were the site number used for all study activities, and the final 3 digits were a consecutive number assigned to each patient obtained from the site enrollment log starting with 001 (e.g., the patient number for the fourth patient screened

at site number 006 would be 006004). Confirmation of enrollment status, patient initials, and patient number was faxed back to the site. Upon receipt of the faxed confirmation at the site, the patient typically began treatment with belinostat.

9.4.5 Selection of Doses in the Study

The selection of the belinostat dose and schedule for this study was based on both safety and efficacy considerations. The belinostat dose of 1,000 mg/m^2 IV on Days 1-5 every 21 days was determined to be safe from Phase 1 studies in patients with solid and hematologic malignancies (Studies **TT20** and **TT30**).

Plasma PK analyses showed dose-dependent area under the curve (AUC) and maximum plasma concentrations (C_{max}), an elimination half-life of ~1 h, and no apparent significant drug accumulation over 5 consecutive days of belinostat treatment. [34] The dose limiting toxicity (DLT) observed at 600 mg/m^2 was fatigue (n=1). At 1,200 mg/m^2, the DLTs observed included supraventricular tachycardia subsequently developing into atrial fibrillation (n=1), fatigue (n=1), and diarrhea (n=1) (Study **TT20**). Further dose escalation was stopped in the Phase 1 study and 1,000 mg/m^2 was chosen and shown to be well tolerated without DLTs in 6 patients. Therefore, the maximum tolerated dose (MTD) was defined as 1,000 mg/m^2, which was the recommended dose for Phase 2 studies. No DLTs were observed in the second Phase 1 study (**TT30**).

Safety of this belinostat dose was further demonstrated in subsequent Phase 1/2 studies where approximately 220 patients were treated with IV belinostat at this dose and schedule prior to the initiation of **CLN-19**. Preliminary safety and efficacy of belinostat, specifically in the T-cell lymphoma population, had been demonstrated in the Phase 2 study **CLN-6**.

9.4.6 Selection and Timing of Dose for Each Patient

All patients received the same starting dose of belinostat (1,000 mg/m^2) as an IV infusion daily for 5 consecutive days on Days 1-5 every 21 days in a 21 day treatment cycle; there was to be a minimum of 18 hours between daily doses. The administration period was 30 minutes, however, if infusion site pain or other symptoms potentially attributable to the infusion occurred, the infusion time could be extended to 45 minutes.

The dose was based on each patient's BSA determined using their actual body weight at Baseline. The dose was to be recalculated at subsequent cycles if body weight changed by more than 10% compared to Baseline.

9.4.6.1 *Dose Modifications*

Dose reductions by 25% due to toxicity were allowed per protocol as described in Table 3 for hematologic toxicities and Table 4 for non-hematologic toxicities from the protocol

(Appendix 16.1.1). A maximum of 2 dose reductions were allowed. If toxicities were still observed after 2 dose reductions, study drug was to be discontinued.

Patients whose treatment was delayed because of toxicity were to be evaluated at weekly intervals (or less) until adequate recovery occurred. Toxicities must have improved to Baseline values or to NCI-CTCAE Grade ≤ 2 prior to retreatment. Patients who had not received any study drug for >42 days were to be discontinued from further study treatment.

Table 3: Dose Adjustments Based on Nadir Hematologic Values

Platelets (x 10^9/L) Nadir		ANC (x 10^9/L) Nadir	Daily Dose
≥25	and	≥0.5	No change
Any	and	<0.5	Decrease dose by 25%
<25	and	Any	Decrease dose by 25%

Abbreviation: ANC = absolute neutrophil count

Source: Protocol, Appendix 16.1.1

Table 4: Dose Adjustments Based on Non-Hematologic Toxicities

CTCAE Grade	Daily Dose
Any Grade 3 or 4 AE[a,b]	Decrease dose by 25%
Recurrence of Grade 3 or 4 AE after 2 dose reductions	Discontinue belinostat permanently

[a] For nausea, vomiting, and diarrhea, only if duration >7 days with supportive management.

[b]Discontinued belinostat permanently if there was a single occurrence of Grade 4 QTc prolongation. For consistency, QTcF was used.

Abbreviations: AE = adverse event, QTc = corrected interval between Q wave and T wave on the ECG trace, QTcF = Fridericia's formula for QTc interval correction

Source: Protocol, Appendix 16.1.1

9.4.7 Blinding

This was a single-arm, open label study that was not blinded. When this study was initiated, there were no approved agents for the treatment of patients with relapsed or refractory PTCL and no accepted standard of care; therefore no control arm was included. Because of the aggressive nature of this disease, comparison with placebo was not considered to be appropriate.

9.4.8 Prior and Concomitant Therapy

In addition to protocol treatment, palliative and supportive care was provided during this study, as clinically indicated, and in accordance with the standard practices of the study

site. All concomitant medications ongoing at the start of belinostat therapy through the End of Study Treatment Visit were recorded in the CRF. Additions, deletions, or changes of dosage of medications were also noted. Restrictions on medications were described in the exclusion criteria in Section 9.3.2 and Section 5, Protocol Appendix G and H (Versions 2-5).

Oral anticoagulants that are substrates of cytochrome P450 (CYP450) CYP2C8 and CYP2C9 enzymes were to be avoided during study treatment, unless deemed medically necessary by the treating physician. A list of such medications was provided in Section 15.7, Appendix G Versions 2-5 of the protocol (Appendix 16.1.1). If there was a medical necessity, it was recommended that the INR be monitored carefully at least once per week for the first month, then monthly if the INR was stable in the desired therapeutic range. Subcutaneous heparin was permitted.

In vitro, belinostat had been shown to induce a concentration-dependent inhibition of cytochrome P450 (CYP) enzymes CYP2C8 and CYP2C9. However, the clinical impact of such inhibition has not been fully elucidated, and, therefore, medications that were P450 substrates of these P450 enzymes were to be avoided during study treatment, unless deemed medically necessary by the treating physician. A list of such medications was provided in Section 15.7, Appendix G of the protocol (Appendix 16.1.1). In addition, belinostat had been shown *in vitro* to be a substrate of CYP3A4. Therefore, medications known to be moderate or strong inducers or inhibitors of CYP3A4 were also to be avoided during study treatment, unless deemed medically necessary by the treating physician. A list of these was also was provided in Section 15.8, Appendix H of Versions 2-5 of the protocol (Appendix 16.1.1).

Hematopoietic growth factors (e.g., granulocyte colony-stimulating factor [G-CSF], granulocyte-macrophage colony-stimulating factor [GM-CSF]), could be used according to institutional or other specific guideline (e.g., country, regional, or oncology organizations such as American Society of Clinical Oncology [ASCO], etc) to treat febrile neutropenia, but were not to be used as primary or secondary prophylaxis. Growth factors must have been discontinued at least 48 hours prior to initiation of the next cycle of belinostat therapy.

Concomitant medication for prophylaxis and/or treatment of nausea and vomiting were allowed. It was recommended that antiemetic administration follow the ASCO guidelines for antiemetics in oncology [14]; however local institutional standards or guidelines could be followed.

Loperamide treatment was recommended as standard therapy for diarrhea. Laxative drugs have the potential for exacerbation of diarrhea. However, laxative drugs might

have been needed during study treatment due to constipation associated with the study drug or concomitant treatment (e.g., antiemetics).

Low doses of steroids (equivalent to prednisone ≤20 mg/day) were permitted. Patients in need of higher doses of steroids than the equivalent of prednisone 20 mg/day to prevent, or treat, allergic conditions (for instance IV contrast allergies) could have received such doses when medically indicated.

Concomitant medications that could have caused Torsades de Pointes were not to be taken and a list was provided in Section 15.2 Appendix B of Versions 1- 5 of the protocol (Appendix 16.1.1).

9.4.9 Treatment Compliance

Patients received belinostat treatment at the investigational sites; therefore treatment compliance was assessed by monitors' review of the dose administration CRFs, as well as the AE CRFs, to ensure that treatment modification occurred when warranted.

Monitors confirmed receipt of all drug supplies at each site, and that lot numbers on the labels and the Investigational Drug Accountability Record matched.

9.5 Efficacy and Safety Variables

9.5.1 Efficacy and Safety Measurements Assessed

9.5.1.1 *Eligibility Evaluation*

Various assessments were performed during the Screening period to determine patient eligibility. Local pathological review and diagnosis were used to determine if a patient met the requirement of having an eligible PTCL subtype (see Section 9.3.1, Inclusion Criterion 1). To confirm the patients' diagnosis by central pathology review, disease histopathology was documented from the original diagnosis of PTCL, and/or a tumor biopsy in the relapsed setting. The pathology specimen/slides (stained or unstained) were shipped for central pathology review by the **CPRG** to confirm the histological type (see Section 6.3.4). Treatment with belinostat was initiated based on the local pathology report. However, if the **CPRG** determined that a patient did not have an eligible disease type, the patient was excluded from the evaluable patient population analyses (see Section 9.7.1.1).

Documentation of known measurable disease parameters was ascertained by CT of chest, neck, abdomen, and pelvis, and by other techniques documenting disease sites other than chest, neck, abdomen, and pelvis, if applicable. Protocol Amendment 5 (04-Jan-2010, Appendix 16.1.1) added a requirement for a Baseline bone marrow biopsy

assessment to be performed within 28 days of the first belinostat dose in subsequently enrolled patients as requested by FDA.

Hematology and serum chemistry, coagulation, and urinanalysis assessments were performed at Baseline (within 14 days prior to the projected start of belinostat administration) and are described in Section 9.5.1.4.2. In addition, a serum or urine pregnancy test for women of childbearing potential was to be performed within 14 days prior to Cycle 1, Dose 1.

9.5.1.2 *Medical History and Physical Examination*

A medical history and physical examination was completed within 14 days prior to projected start of belinostat administration, and the following data were recorded: date of birth, gender, race, height, weight, blood pressure, heart rate, temperature, prior history of disease, prior therapy and response to therapy, ECOG performance status, details of ongoing major medical problems, and medications taken prior to belinostat administration (which were listed by name, reason for use, dosage, route of administration, start and stop dates, or indication of continuation).

Physical examinations were repeated on Day 1 of each cycle and at the End of Study Treatment Visit. Data collected included weight (while on study only), ECOG performance status, new or discontinued medications.

9.5.1.3 *Efficacy Measurements*

Details of the efficacy variables are provided in Section 9.5.3. Efficacy was assessed by evaluation of response rate (CR, PR), Time to Response, Duration of Response, TTP, PFS, and OS. Response was assessed both locally, on the basis of clinical and radiological criteria by the treating Investigator, as well as independently by the **IRC** (see Section 6.3.5). **IRC** assessors were blinded to the response assessments determined by the treating Investigator and to the clinical data other than the prespecified dataset.

The primary efficacy endpoint analysis was pre-defined to be based on response as assessed by the **IRC**. As defined by IWG criteria, the Duration of Response was measured from the date that measurement criteria were first met for CR or PR (whichever status was recorded first) until the first subsequent date that relapse or progression was documented. [11] Duration of Response was also measured by SAP-defined criteria that expanded the IWG criteria by including death in addition to relapse or progression. For this, the Duration of Response was measured from the date that measurement criteria were first met for CR or PR (whichever status was recorded first) until the first subsequent date of relapse, progressive disease, or death was documented. Patients who neither progressed nor died at the time of the last tumor assessment were censored at that time point for both of the above measurements.

Time-to-event endpoints (TTP, PFS, and OS) were calculated from the time of first administration of belinostat (Day 1) until the stated event or end of study. Patients receiving subsequent therapy before PD was documented were censored.

The following procedures/tests were performed for evaluation of response:

- Radiographic imaging (using the same imaging technique as used at Baseline), which included CT of the chest, neck, abdomen, and pelvis and other necessary investigations (e.g., documentation of skin lesions was done by the Investigator using a ruler) to assess tumor status.
- If the Baseline bone marrow assessment was positive for lymphoma, a repeat bone marrow biopsy was mandatory if the patient had a CR after radiographic and clinical CR assessment.
- Evaluation of response was performed every 6 weeks for the first 12 months, then every 12 weeks until 2 years from the start of study treatment (Table 2). The allowable window for scheduled tumor assessments was ±7 days. These assessments were to be stopped at the time of PD or when the patient initiated new anti-cancer therapy. Local Investigator assessments were used to guide treatment decisions; while the independent central radiology and oncology review response assessment by the **IRC** was used for determination of the efficacy study endpoints.

Survival follow-up started after tumor assessments ended, and were carried out every 3 months until 2 years from the start of study treatment or until study closure.

9.5.1.4 *Safety Measurements*

9.5.1.4.1 Adverse Events

Symptoms, AEs, and intercurrent illnesses were monitored at every study visit. AEs were graded according to the NCI CTCAE Version 3.0.

9.5.1.4.2 Laboratory and Electrocardiogram Assessments

Laboratory assessments were performed at Baseline (within 14 days of first belinostat dose), during the treatment phase of the study, at the early termination visit (if applicable), and at the End of Study Treatment Visit. The data collected for each test included the performing laboratory code and normal reference ranges for analytes. The laboratory normal reference ranges are provided in Listing 16.2.8.1, Listing 16.2.8.2, and Listing 16.2.8.3. All results were converted to standard international (SI) units using standard definitions and conversion formula and flagged as low or high compared to

reference normal ranges. Laboratory values were classified as clinically significant based on the judgment of the Investigator.

Hematology assessment included a complete blood count (CBC) (including white blood cells [WBC; leucocytes], hemoglobin, red blood cells [RBC], mean corpuscular volume [MCV]) with differential count and platelets. These were measured at Baseline, prior to treatment on Days 1 and 5 of each cycle, once during Days 11-15 in Cycle 1 only, and at the End of Study Treatment Visit. The date and time of the sample, results, units, and any clinically significant or not clinically significant out of range results were recorded.

Blood chemistry assessment included a comprehensive chemistry and electrolyte panel (including blood urea nitrogen [BUN], creatinine, AST, ALT, alkaline phosphatase, total bilirubin, uric acid, albumin, calcium, lactate dehydrogenase [LDH], sodium, potassium, chloride, phosphate, magnesium, and glucose). These were measured at Baseline, prior to treatment on Days 1 and 5 of each cycle, once during Days 11-15 in Cycle 1 only, and at the End of Study Treatment Visit. The date and time, results, units, and any clinically significant or not clinically significant out of range results were recorded.

Creatinine clearance was determined at Baseline using the Cockroft-Gault formula [13] and was repeated if serum creatinine increased ≥20 % from Baseline.

A coagulation panel (PT or INR and APTT) was evaluated at Baseline and at the End of Study Treatment Visit. PT or INR was evaluated on the first day of each treatment cycle for patients on anticoagulation therapy, or when clinically indicated.

Urinalysis (dipstick) was performed at Baseline and at the End of Study Treatment Visit and included albumin (protein), glucose, ketones and blood (microscopic analysis was performed if clinically indicated by symptoms or abnormal dipstick finding). Further analysis by Urine Microscopy was performed if clinically indicated by symptoms or abnormal dipstick findings.

All patients were to have three 12-lead ECGs performed within 28 days prior to the projected start of belinostat administration. A 12-lead ECG was also to be performed at pre-dose and within 1 hour after the end of infusion on Day 1-5 of Cycle 1 and on Day 5 of all subsequent cycles. If clinically indicated at anytime during study, an ECG was repeated. An ECG was to be performed at the End of Study Treatment Visit. A brief summary of ECG assessments is provided in Section 12.5 and the detailed report from the central review by eRT is provided in the Electrocardiogram Cardiac Safety Evaluation.

9.5.1.5 *Post-Treatment Follow-Up*

All patients who received at least 1 dose of belinostat were to complete the End of Study Treatment Visit after discontinuation of study treatment. This visit included a physical

examination and assessment of the following: AEs; concomitant medications; ECOG performance status; hematology, chemistry, and coagulation panel laboratory assessments; urinalysis; ECG; and tumor assessments if not performed within the previous tumor assessment interval.

If a patient discontinued study treatment without having PD, further tumor assessments were to be made by the same techniques used at Baseline according to the schedule in Section 9.5.1.3. All patients who received at least 1 dose of belinostat were to be followed for safety for 30 days after the last dose of belinostat.

9.5.2 Appropriateness of Measurements

The primary efficacy endpoint of response was evaluated using the established IHP revision of the IWG criteria [11] based on clinical and radiologic criteria that are appropriate for patients with PTCL.

As pre-defined, response was assessed by central radiology review by the **IRC**, as described in Section 6.3.5, which was the basis for the primary analysis. In addition, the Investigator assessment of response was also collected and analyzed separately.

Secondary efficacy endpoints, namely time to response, Duration of Response, TTP, 1-year progression-free rate, PFS, 1-year survival rate, and OS were all measured using standard methods as described in Section 9.7.1.2. The combination of response rate and Duration of Response provided evidence of clinical anti-tumor activity and durability of the treatment effect, which are evidence of clinical efficacy.

The NCI CTCAE Version 3.0 is standard and appropriate for the clinical evaluation of safety in patients with cancer. Details of the analyses for assessment of safety are provided in Section.9.7.1.3.

9.5.3 Primary Efficacy Variable

The primary efficacy study variable was ORR as assessed by the **IRC**. The best overall response of an individual patient according to the IWG criteria was the best response recorded from the start of the treatment until PD or withdrawal from study, whichever came first.

9.5.4 Secondary Efficacy Variables

Secondary efficacy variables included:

- Time to Response
- Duration of Response
- TTP
- PFS

- 1-year progression-free rate
- 1-year survival rate
- OS
- Subgroup analyses by patient demographic characteristics for the primary and secondary endpoints

9.5.5 Safety Variables

The safety variables included the incidence and severity of AEs and serious AEs (SAEs), time to onset and duration of selected AEs, concomitant medication, laboratory parameters, premature withdrawals, physical examination, vital signs, ECOG performance status, total cumulative dose received versus planned dose, and incidence and timing of dose reductions and delays.

9.5.6 Other study variables

Other study variables included:

- Variables related to population PK
- Variables related to medical care utilization

9.5.7 Drug Concentration Measurements

PK samples were collected to evaluate exposure-response and exposure/safety relationships for measures of effectiveness and toxicity. These data were summarized in mathematical models that addressed variability, e.g., inter-individual variability caused by patient parameters such as renal function, gender, and age. Sampling in an individual patient was to occur on more than 1 occasion to estimate the components of intra-individual variability and to reduce the uncertainty in the population PK models. To enable the establishment of a predictive model that took variability from measurement errors and intra-individual variability between days into account, 3 samples were collected on Cycle 1, Day 1, and 2 samples on Cycle 1, Day 4. The blood sampling schedule was as outlined in Table 5.

Table 5: Pharmacokinetics Sampling Schedule

Cycle 1, Day	Timepoint	Blood Volume
1	End of infusion	4 mL
1	2 hours ± 15 minutes after end of infusion	4 mL
1	4-8 hours after end of infusion	4 mL
4	End of infusion	4 mL
4	2-12 hours after end of infusion	4 mL

Source: Protocol, Appendix 16.1.1

The planned analyses included correlations between exposures of belinostat and its major metabolites, and response variables, patient covariates and AEs, which are summarized in an independent Bioanalytical Report.

9.6 Data Quality Assurance

9.6.1 Study Administration and Conduct

The study was initially conducted under the sponsorship of Topotarget A/S and was later transferred to Spectrum. The overall study coordination and medical monitor role was managed by the Sponsor with certain sites monitored by CROs (see Section 6.3.1). Investigator meetings were held as follows to review the protocol, train site personnel, and assure consistency in study conduct:

- December 2009, US
- December 2009, Germany
- September 2010, Denmark
- November 2010, US

Individual site initiation visits were conducted at all sites. The Sponsor provided a standardized set of CRFs for the recording of clinical data. Documentation of medical history, medications, and narrative statements concerning the patient's progress during the study were maintained in the patient's chart.

The Investigators were required to permit authorized representatives of the Sponsor or its designee, and regulatory authorities to inspect facilities and records for this study. The Investigator was instructed to retain all study records until at least 2 years after the last approval of a marketing application in an ICH region and until there were no pending or contemplated marketing applications in an ICH region, or at least 2 years had elapsed since the formal discontinuation of the clinical development of the investigational product as per 21 CFR 312.62 and ICH GCP E6 4.9.5 and 5.5.12. It was the responsibility of the Sponsor to inform the Investigator when these documents no longer need to be retained. If the Investigator relocated, or for any reason desired to dispose of the records, the study records may have been transferred to another institution, another Investigator, or to the Sponsor upon written agreement between the Investigator and the Sponsor.

For all sites outside the US, the Investigators were required to comply with US FDA IND regulations and with those of the relevant national and local health authorities. Representatives of the Sponsor or its designee monitored the study to verify study data,

medical records, and CRFs in accordance with GCP and applicable regulations. Each Investigator signed a declaration, assuring the accuracy and content of the CRFs.

9.6.2 Global Communications

Project managers and medical monitors were available to study personnel by telephone, facsimile, and email. CRAs made on-site visits to investigational sites to assess regulatory compliance and to monitor data quality.

9.6.3 Compliance Audits

Independent GCP compliance audits were conducted of investigational sites, contractors, and study documentation and processes according to the Sponsor's standard operating procedures. Audit certificates are provided in Appendix 16.1.8.

Protocol deviations are described in Section 10.2.

9.6.4 Data Generation and Analysis

Overall data management for this study was performed using the Clintrial 4.5 system, based on an Oracle database by Topotarget A/S in Copenhagen, Denmark. Patients' clinical data were recorded by the site and were entered at Topotarget. Quality control (QC) techniques for data management included independent double data entry, electronic plausibility checks, data audits, and manual data review by data managers, clinicians and statisticians. Data in the database were reviewed by the Spectrum Biostatistics and Data Management Group and were converted into SDTM and Analysis datasets.

Data management and monitoring were performed according to the Sponsor's standards. CRFs were kept at the investigational site and were monitored by the Sponsor or its designee, who performed 100% source data verification.

Occasional exemptions granted by the Sponsor for protocol deviations were tracked in the Sponsor's project management database.

All patient data were reviewed by a medical monitor.

Coding of concomitant medications and AEs was conducted per WHO DRUG, Version 2012 and the Medical Dictionary for Regulatory Activities (MedDRA™), Version 14.0, respectively.

Tables and listings in this clinical study report may display rounded values; however, the computation results in all text/tables were based on full number precision stored in the clinical database.

The Bioclinica (CoreLab) Charter describes the Image Quality Assessment (IQA) conducted by Bioclinica to ensure that all imaging was performed according to the

technical guidelines of the protocol. The charter also describes the QC and quality assessment (QA) processes followed by Bioclinica, as well as their data management responsibilities.

9.6.5 Data Quality Assurance

The data from patient CRFs were entered into a validated database using double data entry. A database audit of 100% of data points in 10% of the patients was performed on the primary efficacy variables (tumor response), safety data (extent of exposure and AEs) and demographic variables. A total of 10 data entry errors were identified in a total of 68 treatment cycles in 13 patients. Errors were minor and did not include primary endpoint data; all errors were corrected in the database per the pre-defined process. Following the correction of these errors, the clinical database was locked on 01 March 2013.

Data analysis involved converting raw datasets to SDTM Datasets and to Analysis Datasets. Listings were produced using the raw CRF Datasets, while summary tables were produced using Analysis Datasets. There were 2 sets of QC performed. First, an independent programming QC was performed to ensure the transformations of raw data sources to SDTM Datasets and Analysis Datasets were accurate. Second, the listings were cross-checked against summary tables to verify their accuracy.

9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size

9.7.1 Statistical and Analytical Plans

CLN-19 was a Phase 2, single arm, open-label, multicenter, international study designed to evaluate the safety and efficacy of belinostat when administered to patients with relapsed or refractory PTCL. The SAP for this study is provided in Appendix 16.1.9.

The primary objective and primary endpoint of the study was to determine the efficacy of belinostat in patients with relapsed or refractory PTCL as measured by ORR, based on the central review of imaging and clinical data according to the IHP revision of the IWG criteria. [11]

As described in Sections 6.3.3 and 11.4.2.3, two analyses were conducted to provide data for the DMC to review; an interim review of the data after 41 patients enrolled and a final review at the end of enrollment. Upon completion of each of the interim reviews, the DMC recommended that the study continue. No changes to the protocol were recommended at either of the 2 DMC meetings.

9.7.1.1 *Analysis Datasets*

Two analysis population datasets were defined for this study: the **Full Analysis Dataset** and the **Efficacy Analysis Dataset**.

The **Full Analysis Dataset** included all patients who received at least 1 dose of belinostat; all safety analyses were performed on the **Full Analysis Dataset**.

The **Efficacy Analysis Dataset** consisted of all patients who received at least 1 dose of belinostat and had a confirmed PTCL diagnosis by central pathology review. Analyses of all efficacy endpoints were based on the **Efficacy Analysis Dataset**. Efficacy information on patients who were excluded from the **Efficacy Analysis Dataset** is presented in listings that include the collected efficacy parameter data.

9.7.1.2 *Efficacy Analyses*

9.7.1.2.1 Primary Efficacy Analysis

ORR, defined as the number of responders (CR + PR) divided by the number of patients who received at least 1 dose of belinostat and had a confirmed PTCL diagnosis by central pathology review (**Efficacy Analysis Dataset**), was estimated using response data assessed by the **IRC**. Descriptive statistics (n, percentage, and 95% confidence interval [CI]) were calculated to summarize the number of patients with CR, PR, stable disease (SD), and PD as the best overall response. The CI was based on the Clopper-Pearson methods ('exact' interval based on the binomial distribution). The number and percentage of patients without a response assessment (Not evaluable; NE) are also presented. In addition to the primary analysis discussed above, a secondary efficacy analysis was also performed based on the Investigators' assessments of tumor response.

Radiological assessments were discontinued at the time of tumor progression or initiation of a new anticancer therapy, after which survival was evaluated every 3 months until 2 years from the start of study treatment or until study closure.

9.7.1.2.2 Secondary Efficacy Analyses

The protocol objectives included the following secondary efficacy analyses:

- Time to Response
- Duration of Response
- TTP
- PFS
- One-year progression-free rate
- One-year survival rate

- OS

Secondary endpoint definitions are also described under Efficacy Measurements in Section 9.5.1.3.

Time-to-event endpoints were calculated from the time of first administration of belinostat (Cycle 1, Day 1) until the stated event or the end of study. These time-to-event parameters were estimated using Kaplan-Meier methods when events were censored. Table 6 outlines the start and end point for the time to event analyses, and the rules for censoring. Patients with no tumor assessments after Baseline were censored at the first day of treatment (Day 1). The scheduling for the planned tumor assessments are outlined in Table 7.

Table 6: Time-to Event Efficacy Analysis

Time to Event Endpoint	From Start Point	To Endpoint		Censoring
		Tumor Assessment	Other	
Time to Response	Cycle 1, Day 1	First CR or PR	-	-
Duration of Response *Per IWG Criteria**	CR or PR	PD	-	If PD not assessed /patient alive - Last tumor assessment - Last tumor assessment prior to new anti-lymphoma treatment - Cycle 1, Day 1
Per IWG Criteria Expanded to Include the Subsequent Date of Death (SAP-defined Criteria)	CR or PR	PD	Death	If PD not assessed /patient alive - Last tumor assessment - Last tumor assessment prior to new anti-lymphoma treatment - Cycle 1, Day 1
Time to Progression	Cycle 1, Day 1	PD	-	If PD not assessed - Last tumor assessment - Last tumor assessment prior to new anti-lymphoma treatment - -lymphoma treatment

Time to Event Endpoint	From Start Point	To Endpoint		Censoring
		Tumor Assessment	Other	
				- Cycle 1, Day 1
Progression-free Survival	Cycle 1, Day 1	PD	Death	If PD not assessed /patient alive - Last tumor assessment - Last tumor assessment prior to new anti-lymphoma treatment - Cycle 1, Day 1
Overall Survival	Cycle 1, Day 1	-	Death	Last known to be alive

* The analysis of Duration of Response per IWG criteria was added to permit benchmarking with other agents that use the standard IWG definition; the SAP-defined criteria for Duration of Response expanded on the IWG criteria by also including the subsequent date that death was documented.

Abbreviations: CR=complete response; IWG=International Working Group; PD=progressive disease; PR=partial response; SAP=Statistical Analysis Plan

Table 7: Scheduling of Tumor Assessments

Baseline	Treatment Period	Follow-up		
		Progression-free Survival (SD, PR, CR)		Overall Survival (PD)
		1st year	2nd year	
Yes	Every 6 weeks	Every 6 weeks	Yes	Every 6 weeks

Abbreviations: CR=complete response; PD=progressive disease; PR=partial response; SD=stable disease

Duration of Response

Per the IWG criteria, Duration of Response (Table 6) was measured from the date that measurement criteria were first met for CR or PR (whichever status was recorded first) until the date that relapse or progression was documented [11]; this analysis was included to permit benchmarking with other agents that use the standard IWG definition. Duration of response by SAP-defined criteria expanded on the IWG criteria adding the first subsequent date that death was documented.

For patients with an overall best response of CR or PR and an event to mark the end of response, descriptive statistics were presented for the Duration of Response in months. For patients in the **Efficacy Analysis Dataset** with an overall best response of CR or PR, Kaplan-Meier estimates of the 25th, 50th, and 75th percentiles for Duration of

Response, and their associated 95% CIs were presented. Patients who neither progressed nor relapsed at the time of the last tumor assessment were censored at that time point.

Time to Response

Time to response was calculated from the time of first administration of belinostat (Cycle 1, Day 1) until first response. Patients with no tumor assessment after Baseline were censored at the first day of treatment (Day 1).

For patients with an overall best response of CR or PR, descriptive statistics (median and range) are presented for the Time to Response in weeks. For patients in the **Efficacy Analysis Dataset** with an overall best response of CR or PR, Kaplan-Meier estimates of the 25^{th}, 50^{th}, and 75^{th} percentiles for Time to Response, and their associated 95% CIs were presented. Patients with a confirmed response were censored at the date of their last tumor measurement.

Time to Progression (TTP)

TTP was defined as the number of days from time of first administration of belinostat (Cycle 1, Day 1) to the date of PD based on tumor assessments made according to the IWG criteria as assessed by the **IRC**. For patients with PD, descriptive statistics were presented for TTP in months. Patients without PD were censored at the date of the last tumor assessment. Patients who commenced new anti-lymphoma therapy in the absence of radiologic PD were censored at the date of last tumor assessment prior to the initiation of new anti-lymphoma treatment. Patients with no tumor assessments after Baseline were censored at the first day of treatment (Day 1). If several response evaluations for a patient were PD, the first of these measurements was used in the analysis of TTP.

Progression-free Survival (PFS)

PFS was defined as the number of days from the time of first administration of belinostat (Cycle 1, Day 1) to the date of documented PD or death due to any cause. It was based on tumor assessments made according to the IWG criteria as assessed by the **IRC**.

Patients who neither progressed nor died were censored at the date of the last tumor assessment. Patients who commenced new anti-lymphoma therapy in the absence of radiologic PD were censored at the date of last tumor assessment prior to the initiation of new anti-lymphoma treatment. Patients with no tumor assessments after Baseline were censored at the first day of treatment (Day 1). If several response evaluations for a patient were PD, the first of these measurements was used in the analysis of PFS.

One-Year Progression-Free Survival Rate

The 1-year progression-free survival rate calculated the percentage of patients who did not have documented PD or death at the 1 year time point after their start of treatment (Cycle1, Day 1). Assessments of PD and censoring followed the same rules as for the determination of PFS as specified above.

Overall Survival (OS)

OS was calculated as the number of days from time of first administration of belinostat (Cycle 1, Day 1) to the date of death. Patients who were not reported as having died at the time of the analysis were censored using the date they were last known to be alive. OS follow-up was to be carried out every 3 months for 2 years from the start of study treatment or until study closure. The first analysis of OS was conducted at the time of the primary analysis of ORR (end of study).

One-Year Survival Rate

The 1-year survival rate calculated the percentage of patients who were living 1 year after their start of treatment. Patients who did not die within the first year following the start of treatment were censored at the date they were last known to be alive.

9.7.1.3 *Safety Analyses*

Safety parameters include the incidence of AEs and SAEs, time to onset and duration of selected AEs, concomitant medication laboratory parameters, premature withdrawals, vital signs, ECOG performance status, total cumulative dose received versus planned dose and incidence and timing of dose reductions and delays.

All AEs that occurred from the time the Informed Consent was obtained until 30 days after the last study drug administration were recorded in the CRF. AE severity was

graded by the Investigator according to the definitions set forth by the CTCAE (version 3). AEs were coded using MedDRA (version 14.0) and classified by MedDRA System Organ Class (SOC) and Preferred Term.

Only treatment emergent AEs (TEAEs) were included in the summary tables. TEAEs included those events that either began after initiation of study medication or increased in intensity or frequency after initiation of study medication. If it could not be determined whether an AE was treatment-emergent (based on start date or, if the start date is missing, the stop date), then the AE was conservatively considered treatment-emergent. Incidences of SAEs and AEs leading to dose reductions, dose delays, dose interruptions/missed doses, and to study drug termination were summarized overall and by relation to study drug. Time to onset and duration of frequent (>5% incidence) Grade 3 or 4 AEs were summarized overall and by relationship to study drug.

Patients who experienced more than 1 type of AE were counted once under each of the corresponding MedDRA Preferred Terms. Patients who experienced different episodes of the same AE were counted only once by the worst grade of the AE under the corresponding Preferred Term. Similarly, for determination of MedDRA SOC incidences, patients who experienced multiple AEs under the same SOC were counted only once for that SOC. AEs were classified by Investigators according to their relation to study drug (yes or no). Programmatically, an AE was conservatively assigned as treatment related if the relationship to study drug was missing.

For each laboratory parameter with NCI-CTCAE toxicity grading criteria, the number and percentage of patients with shifts from Baseline to the maximum post-Baseline toxicity grade (0, 1, 2, 3 or 4) were presented.

Changes in vital signs (systolic and diastolic blood pressure and temperature) from pre-infusion to post-infusion on Day 1 and Day 5 of each treatment cycle were summarized using descriptive statistics. Descriptive statistics were presented for ECOG scores at Cycle 1 (Baseline). ECG assessments were performed and analyzed by an independent reviewer. Descriptive statistics were to be presented for the maximum increase from Baseline.

9.7.2 Determination of Sample Size

Per the SPA, a 20% ORR was considered clinically meaningful for this study in patients with relapsed or refractory PTCL. The sample size for the **CLN-19** study was, therefore, determined based on a 2-stage optimal Simon design [10] with a hypothesized ORR of p_1=20% for belinostat and a minimal or "uninteresting" ORR of p_0=9% (Section 9.2 for Simon Design). If there were fewer than 5 objective responses in the first 41 evaluable patients (based on **IRC**), the trial would have been discontinued for futility. Otherwise,

the trial was to continue until there were at least 100 evaluable patients for the primary efficacy analysis. Assuming a 15% (±5%) attrition rate, it was assumed that approximately 120 patients would need to be enrolled. At least 14 objective responses in 100 evaluable patients were required to confirm the 20% target response rate with an alpha of 0.05 assuming a power of 90%. With a total sample size of n=100 treated patients, the half width of the 95% CI for ORR would be approximately 7.8% based on a normal approximation.

9.8 Changes in the Conduct of the Study or Planned Analyses

9.8.1 Changes in the Conduct of the Study

A copy of each version of the protocol, including a summary of all amendments, is provided in Appendix 16.1.1. The original study protocol was dated 25-Apr-2008. A summary of the primary changes made to the protocol during the course of the study is presented in Table 8. Administrative changes, section numbering, typographical error corrections, and abbreviation list changes, may have been made as a part of an amendment and may not be reflected in the table below. No patients were enrolled under protocol versions 1.0, 2.0, and 4.0.

Overall, 129 patients were enrolled in **CLN-19**. The first patient signed the informed consent form on 04-May-2009, and was enrolled under Protocol Version 3.0. Twenty-six patients were enrolled under Protocol Version 3.0. The protocol was later amended to include bone marrow biopsies at Baseline, which also added the requirement for bone marrow biopsies to confirm CR (Protocol Version 5.0, dated 04 Jan 2010). The remaining 103 patients were enrolled when Protocol Version 5.0 was effective.

Table 8: Summary of Changes to the Protocol

Amendment /Protocol Version (Date)	Primary Changes Made	Rationale	Number of Patients Enrolled
Version 1	-	-	0
Version 2 *Amendment 1* (23-Jul-2008)	• Planned number of patients increased from 90 to 120 • Added requirement for pathology material to be available prior to enrollment	Based on draft FDA meeting minutes dated July 2008, additional patients were recommended because decision made that **CLN-6** patients were not to be included as a combined analysis population.	0
Version 3 *Amendment 2* (09-Sep-2008)	• Added details on timing for collection of blood chemistry samples	Clarification	0
Version 4 *Amendment 3* (13-Nov-2009)	• Correlative studies will not be performed • Increased the number of Baseline ECGs from 1 to 3 • Added bone marrow biopsy at Baseline; mandatory to confirm CR • Added information on tumor lysis syndrome • Version 4 was submitted but never activated.	Added ECGs to ensure adequate Baseline assessment of QTc Bone marrow biopsy added to more accurately assess response Tumor lysis information added due to FDA request (SN 167)	26
Version 5 *Amendment 4* (23-Nov-2009)	• Version 5 included all changes from Version 4.	Amended due to FDA request to add bone marrow biopsy in Section 5.8.1	103
Version 6 *Amendment 5* (13-Mar-2013)	• Identified Spectrum as Sponsor • Change in Investigational Drug Product formulation from "Ready to Use" to "Lyophilized"		0

Abbreviations: CR=complete response; ECG=electrocardiogram; FDA=Food and Drug Administration; QTc=corrected QT interval

Source: Appendix 16.1.1 and Listing 16.2.1.1

9.8.2 Changes in the Planned Analyses

The original SAP was dated 11-Apr-2008. The SAP was amended twice during the course of the study, on 16-Jul-2008 and 11-Feb-2011, in order to align with amendments to the protocol. The analyses were conducted in accordance with the final SAP (Appendix 16.1.9) with the following exceptions.

- The Duration of Response, calculated per IWG criteria, was included in addition to the expanded SAP-defined criteria that added death (IWG+Death) to facilitate

comparison with other reported study results. Duration of Response per IWG criteria was measured from the date that measurement criteria were first met for CR or PR (whichever status was recorded first) until the first subsequent date that relapse or progression was documented. [11] Duration of Response using SAP-defined criteria was measured from the date that measurement criteria were first met for CR or PR (whichever status recorded first) until the first subsequent date that relapse, progression or death was documented. Patients who neither progressed nor relapsed at the time of the last tumor assessment were censored at that time point.

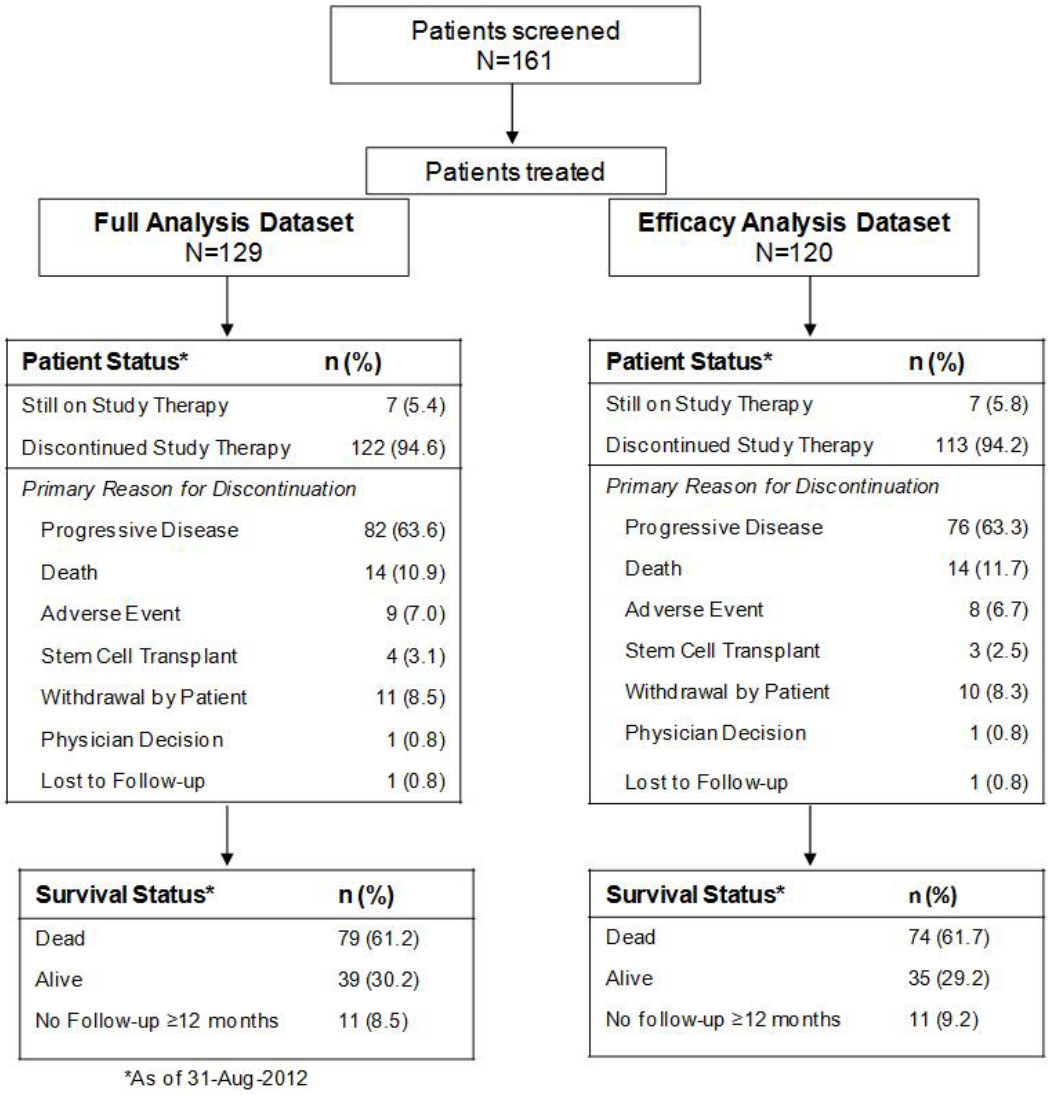
- Medical care utilization during treatment with belinostat monotherapy was not collected and this analysis was, therefore, not performed.
- ECOG performance change from Baseline was not reported. ECOG data at each time point was provided and the shift was assessed from Baseline to all post-Baseline timepoints.

10 STUDY PATIENTS

10.1 Disposition of Patients

A total of 161 patients were screened for this Phase 2 study and 129 patients were enrolled (**Full Analysis Dataset**) (Table 9). The **Efficacy Analysis Dataset** consisted of 120 patients (Figure 2) with confirmed diagnoses of PTCL by **CPRG**; the remaining 9 patients did not have confirmed **CPRG** diagnoses of PTCL. Most patients discontinued study treatment due to the development of PD (≈60%); 9 patients (7.0%) discontinued treatment due to AEs (see Section 12.3.2.1); 1 patient (Patient 220-001) was lost to follow-up; last contact date was in April 2010, approximately 3 months after discontinuation of study treatment (Listing 16.2.1.1).

Figure 2: Summary of Patient Selection, Disposition, and Survival Status



Source: Table 14.1.1.2, Listing 16.2.1.1

Table 9: Summary of Patient Populations and Pre-defined Datasets

Patient Population	n (%)
Full Analysis Dataset	**129**
Excluded Patients	0 (0)
Did not Receive Study Drug	0 (0)
Efficacy Analysis Dataset	**120**
Excluded Patients	9 (7.0)
Did not Receive Study Drug	0 (0)
Did not Have PTCL Diagnosis Confirmed by **CPRG**: Inadequate material to review No PTCL confirmed	9 (7.0) 7 (5.8) 2 (1.7)

Abbreviations: CPRG=Central Pathology Review Group; PCTL=Peripheral T-Cell Lymphoma

Source: Table 14.1.1.2, Listing 16.2.3.1.

Patients were enrolled between May 2009 and August 2011 (Listing 16.2.1.1) across 62 study sites: 18 sites in the US (37 patients), 3 sites in Canada (7 patients), 36 sites in Europe (78 patients), 3 sites in Israel (4 patients), and 2 sites in South Africa (3 patients) (Table 10). Thirty-four study sites received belinostat but did not enroll patients (Appendix 16.1.6). Accrual by region and site are summarized in Table 14.1.1.1 for the **Full Analysis Dataset** (all treated patients), and the **Efficacy Analysis Dataset** (all evaluable patients).

Table 10: Patient Enrollment by Geographic Area / Country

Geographic Area	Number of Sites n	Number of Patients	
		Full Analysis Dataset n (%)	Efficacy Analysis Dataset n (%)
United States	18	37 (28.7)	34 (28.3)
Canada	3	7 (5.4)	7 (5.8)
Europe	36	78 (60.5)	72 (60.0)
- Belgium	5	11 (8.5)	11 (9.2)
- Croatia	2	4 (3.1)	4 (3.3)
- Denmark	1	4 (3.1)	4 (3.3)
- France	3	4 (3.1)	3 (2.5)
- Germany	8	16 (12.4)	12 (10.0)
- Hungary	3	11 (8.5)	11 (9.2)
- Italy	1	3 (2.3)	3 (2.5)

Geographic Area	Number of Sites n	Number of Patients	
		Full Analysis Dataset n (%)	Efficacy Analysis Dataset n (%)
- Netherlands	5	10 (7.8)	9 (7.5)
- Poland	2	8 (6.2)	8 (6.7)
- Slovakia	1	2 (1.6)	2 (1.7)
- Spain	2	2 (1.6)	2 (1.7)
- United Kingdom	3	3 (2.3)	3 (2.5)
Israel	3	4 (3.1)	4 (3.3)
South Africa	2	3 (2.3)	3 (2.5)
Total	**62**	**129**	**120**

Note: Russia had 3 sites activated but due to logistical problems preventing the delivery of ECG machines the sites were closed before enrollment in the study.

Source: Table 14.1.1.1

Nine patients were considered not evaluable and were not included in the **Efficacy Analysis Dataset** either due to an inadequate sample for histological confirmation (n=7) or the finding of "No PTCL present" on their histopathological assessment by **CPRG** (n=2). These excluded patients are summarized in Listing 16.2.3.1. The 2 patients with "No PTCL present" were:

- Patient 162-002: with a primary cancer diagnosis of angioimmunoblastic t-cell lymphoma by the Investigator - had benign reactive lymphoid infiltrate of the skin according to **CPRG**.
- Patient 901-001: with a primary cancer diagnosis of peripheral T-cell lymphoma NOS by the Investigator - had benign lymph node with no lymphoma present according to **CPRG**.

The 7 patients with inadequate sample for histological confirmation by **CPRG** included: Patient 140-001, 144-001, Patient 147-001, Patient 147-002, Patient 221-001, Patient 914-002, and Patient 914-009.

The date of the database cut-off (no further CRF data entry) for study follow up and all analyses was 31-Aug-2012. As of the data cut-off date, 7 patients remained on therapy (Table 11) and were in follow-up.

Table 11: Patients on Therapy and in Follow-up at Cut-off Date of 31 Aug 2012

Patient Number	Age/Sex/Race	Primary Lymphoma Diagnosis (CPRG)	Number of Cycles at Data Cut-off
146-001	70/Female/White	Angioimmunoblastic T-Cell Lymphoma	25
220-002	70/Male/White	Peripheral T-Cell Lymphoma, NOS	22
516-004	40/Male/White	Anaplastic Large Cell Lymphoma, Alk-Negative	18
534-002	69/Female/White	Angioimmunoblastic T-Cell Lymphoma	29
534-006	54/Female/White	Angioimmunoblastic T-Cell Lymphoma	18
541-001	75/Female/White	Peripheral T-Cell Lymphoma, NOS	33
543-001	68/Female/White	Peripheral T-Cell Lymphoma, NOS	31

Abbreviations: NOS=not otherwise specified

Source: Listing 16.2.4.0, Listing 16.2.4.1, Listing 16.2.5.1

10.2 Protocol Deviations

Based on standard protocol guidelines relevant to this study, the following list of major protocol deviations was identified:

- Failure to obtain informed consent from patients prior to dosing
- Failure to meet inclusion/exclusion criteria
- Drug dispensing/dosing error, drug dose outside the protocol range
- Received prohibited medications during the study conduct

Table 12 summarizes the patients with Major Protocol Deviations.

10.2.1 Failure to Obtain Informed Consent Prior to Dosing

One patient (207-N/A) was not enrolled and had not signed an informed consent, was administered 4 vials of study medication (Site 207) in error by a new nurse hired for the holiday period. The site took corrective measures and submitted this violation to their Ethics Committee. Additionally, the site was retrained by the CRA. All subsequent patients enrolled at all sites signed Informed Consents prior to dosing.

10.2.2 Failure to Meet Inclusion/Exclusion Criteria

Listing 16.2.2.1 presents the eligibility deviations according to the Inclusion and Exclusion Criteria of the protocol (Section 9.3).

Based on the local pathology report, 13 patients did not meet the Inclusion Criterion #1 (histologically confirmed diagnosis of PTCL based on local pathology review) due to absence of T-cell and/or B-cell markers. However, based on central pathology review of these 13 patients, 12 of them were found by the **CPRG** to meet the entry requirements for PTCL and have all of the required markers listed in Inclusion Criterion #1; only 1 patient (140-001) did not have the assessment for MIB and Ki-67. The 12 patients with **CPRG** confirmed PTCL were, therefore, included in the efficacy analysis per the definition of the **Efficacy Analysis Dataset**.

In addition, 1 patient (600-003), who was reported as having a PR, who was continued in the study although they had developed withdrawal criteria during the study (2 new lesions; longest diameters <15mm). One patient (Patient 244-002) stopped CHOP on 22-Jul-2010 and started Chlorambucil on 22-Jul-2010 to 24-Sep-2010, stopped due to PD; belinostat was started (04 Oct 2010) prior to completion of a 2 week recovery period.

10.2.3 Drug Dispensing/Dosing Error, Drug Dose Outside the Protocol Range

Five patients (240-001, 534-006, 600-003, 752-002, and 900-001) received an incorrect dose (Listing 16.2.5.1 and Appendix 16.2.2). Patient 900-001 received 2050 mg of belinostat at Cycle 5 instead of 1,970 mg based on the Cycle 1 dose, although there was not a 10% change in the patient's weight from Cycle 1 (82.6 kg) to Cycle 5 (86 kg). Among the 5 patients who received an incorrect dose, 3 patients experienced Grade 3/4 AEs (1 case each of nasopharyngeal infection, worsening autoimmune hemolytic anemia, and pharyngitis), but the dose was not reduced by 25% as specified in the protocol. For the other 2 patients, 1 patient (752-002) received a 50-mg lower dose at Cycle 4 and 1 patient (Patient 900-001) received an 80-mg higher dose at Cycle 5.

10.2.4 Received Prohibited Medications during the Study Conduct

Three patients (Patients 126-002, 223-002, and 600-003) received prohibited concomitant medications (Listing 16.2.5.2). Upon review, 1 patient (126-002) received a short course of hydrocortisone as allowed per protocol to treat an infusion reaction. Patient 223-002 received 70 mg of prednisolone (equivalent to 70 mg prednisone) once a day for 2 short courses followed by 50 mg prednisolone (equivalent to 50 mg prednisone) daily for 1 course to treat anemia (Listing 16.2.5.2). Patient 600-003 received 4 mg of dexamethasone (equivalent to prednisone 25mg) twice a day for 3 days for Grade 3 mucosal pharyngitis. The patient received 8 mg of dexamethasone (equivalent to prednisone 50 mg) for 4 doses to treat mucosal pharyngitis (Listing 16.2.5.2).

Table 12: Patients with Protocol Deviations

Patient	Deviation	Criterion	Waiver	CPRG Confirmed PTCL	Response
120-001	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
	Treated after PD	Patient took study medication after date of confirmed disease progression			
140-002	Inclusion #1 [a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
140-003	Inclusion #1 [a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
	Treated after PD	Patient took 1 dose of study medication after date of confirmed disease progression			
144-001	Inclusion #1 [a]	Histologically confirmed diagnosis of PTCL based on local pathology review	No	Inadequate Sample	No
144-002	Inclusion #1 [a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
147-002	Inclusion #6	APTT was 65 sec at Baseline	No	Inadequate Sample	No
154-001	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
207-N/A	Inclusion #10	Patient not enrolled received study drug	N/A	N/A	N/A

Patient	Deviation	Criterion	Waiver	CPRG Confirmed PTCL	Response
222-001	Exclusion #4	Relapse within 100 days of autologous or allogeneic bone marrow transplant	Yes	Yes	No
223-002	Received Prohibited Medications during the Study Conduct	Received 70 mg of prednisolone(equiv alent to 70 mg prednisone) to treat anemia	N/A	Yes	No
223-004	Treated after PD	Patient took 2 doses of study medication after date of confirmed disease progression by the Investigator	No	Yes	No
240-001	Drug Dispensing/Dosing Error, Drug Dose Outside the Protocol Range	Patient had 2 SAEs; Grade 3 nasopharyngeal infection: Staphylococcus Aureus, related and Grade 3 Stomatatis: oral cavity: pharynx, related and received treatment without the 25% reduction required by protocol.	N/A	Yes	No
242-001	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
	Treated after PD	Patient took 7 doses of study medication after date of confirmed disease progression by the Investigator			
244-002	Exclusion #1 [a]	Anticancer therapy (CHOP; Chlorambucil) within 2 weeks prior to first study treatment, with recovery from prior treatment-related toxicities.	Yes	Yes	Not Evaluable

Patient	Deviation	Criterion	Waiver	CPRG Confirmed PTCL	Response
244-004	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	Not Evaluable
244-005	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
244-006	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
	Treated after PD	Patient took 5 doses of study medication after date of confirmed disease progression by the Investigator			
245-001	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
513-001	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
	Inclusion #6	Patient was enrolled with low serum potassium (3.3 mmol/L on Day -18 and 3.2 mmol/L on Day 1 prior to study drug) administration			
513-003	Treated after PD	Patient took 6 doses of study medication after date of confirmed disease progression by the Investigator	No	Yes	No

Patient	Deviation	Criterion	Waiver	CPRG Confirmed PTCL	Response
534-006	Drug Dispensing/Dosing Error, Drug Dose Outside the Protocol Range	Patient had Grade 4 anemia and received treatment without the 25% reduction required by protocol.	N/A	Yes	Yes
600-003	Drug Dispensing/Dosing Error, Drug Dose Outside the Protocol Range	Patient had Grade 3 pharyngitis and received treatment without the 25% reduction required by protocol.	N/A	Yes	Yes
	Received Prohibited Medications during the Study Conduct	Received 4 mg of dexamethasone (equivalent to prednisone 25mg) for Grade 3 mucosal pharyngitis			
752-002	Drug Dispensing/Dosing Error, Drug Dose Outside the Protocol Range	Received a 50-mg lower dose at Cycle 4	N/A	Yes	Yes
900-001	Drug Dispensing/Dosing Error, Drug Dose Outside the Protocol Range	Received 2,050 mg of belinostat at Cycle 5 instead of 1,970 mg based on the Cycle 1 dose, although there was not a 10% change in the patient's weight from Cycle 1 (82.6 kg) to Cycle 5 (86 kg). Received an 80-mg higher dose at Cycle 5	N/A	Yes	No

Patient	Deviation	Criterion	Waiver	CPRG Confirmed PTCL	Response
912-002	Inclusion #1[a]	Histologically confirmed diagnosis of PTCL based on local pathology review	Yes	Yes	No
	Treated after PD	Patient took 4 doses of study medication after date of confirmed disease progression by the Investigator			

Inclusion #1: Histologically confirmed diagnosis of PTCL based on local pathology review by WHO Classification of Tumors of Haematopoietic and Lymphoid Tissues with local or central determination of Mib-1/Ki-67Inclusion#6: ANC ≥1,000/uL; platelets ≥50,000/uL; bilirubin =<1.5 x ULN; AST & ALT ≤2.5 x ULN; normal serum potassium

Inclusion #10: Signed an Informed Consent form approved by the local EC, or IRB.

Exclusion #1: Anticancer therapy within 2 weeks prior to first study treatment, with recovery from prior treatment-related toxicities.

Exclusion #4: Relapse within 100 days of autologous or allogeneic bone marrow transplant

Patient did not have local or central determination of Mib-1/Ki-67 but were diagnosed by **CPRG**

Abbreviations: APTT=activated partial thromboplastin time; CHOP=cyclophosphamide, doxorubicin, vincristine, prednisone; PCTL=peripheral T-cell lymphoma; PD=progressive disease

Source: CRFs, Table 14.2.3.7, Listing 16.2.2.1, Listing 16.2.3.1, Listing 16.2.3.2, Listing 16.2.4.0, Listing 16.2.4.4, Listing 16.2.5.1, Listing 16.2.6.1, Listing 16.2.6.2, Appendix 16.2.2

10.2.5 Minor Protocol Deviations

During the monitoring of study sites, additional minor protocol deviations were collected by study monitors. Appendix 16.2.2 includes a listing of all patients with protocol deviations captured by monitors during the study.

11 EFFICACY EVALUATION

11.1 Datasets Analyzed

As described in Section 9.7.1.1, two analysis populations were pre-defined (Figure 2).

The **Full Analysis Dataset** (N=129) included all patients who received at least 1 dose of belinostat and was used for the safety analyses patients.

The **Efficacy Analysis Dataset** (N=120) consisted of all patients who received at least 1 dose of belinostat and had a confirmed diagnosis of PTCL by **CPRG**; all efficacy analyses were performed on the **Efficacy Analysis Dataset**.

11.2 Demographic and Other Baseline Characteristics

11.2.1 Demographics

Table 13 summarizes patient demographics for the **Full** and **Efficacy Analysis Datasets**. There were slightly more males (n=69, 53.5% **Full Analysis Dataset**; n=62, 51.7% **Efficacy Analysis Dataset**) than females (n=60, 46.5% **Full Analysis Dataset**; n=58, 48.3% **Efficacy Analysis Dataset**) treated in the study in both analysis datasets, consistent with the reported higher incidence of PTCL in males [15].

The median patient age was 63.0 years for the **Full Analysis Dataset** years and 64.0 years for the **Efficacy Analysis Dataset** (range for both 29-81 years). The majority of patients were White (n=111, 86.0% **Full Analysis Dataset**; n=105, 87.5% **Efficacy Analysis Dataset**). Demographics are provided by patient in Listing 16.2.4.1.

Table 13: Patient Demographics

Patient Population	Number of Patients (%)	
	Full Analysis Dataset (N=129)	Efficacy Analysis Dataset (N=120)
Gender		
Male	69 (53.5)	62 (51.7)
Female	60 (46.5)	58 (48.3)
Race		
White	111 (86.0)	105 (87.5)
Black	9 (7.0)	7 (5.8)
Asian	3 (2.3)	3 (2.5)
Latin	3 (2.3)	3 (2.5)
Other	3 (2.3)	2 (1.7)
***Age** (years)*		
< 65	67 (51.9)	61 (50.8)
≥ 65	62 (48.1)	59 (49.2)
Mean (std dev)	62.0 (11.1)	62.5 (10.4)
Median	63.0	64.0
Range	29 - 81	29 - 81
***Weight** (kg)*		
Mean	74.9	74.6
Std Dev	18.6	19.0
Min - Max	40.0.0-149.0	40.0-149.0
N Missing	0	0
***Height** (cm)*		

Mean	167.6	167.1
Std Dev	10.1	9.9
Min - Max	146.0-193.0	146.0-193.0
N Missing	6	6

Abbreviations: std dev = standard deviation

Source: Table 14.1.2.1, Table 14.1.2.7

11.2.2 Medical and Surgical History

Table 14.1.2.5 summarizes the number and percent of patients who reported medical/surgical history at Baseline by body system (**Full Analysis Dataset**). Medical histories are provided by patient in Listings 16.2.4.2 and 16.2.4.5.

All patients had a prior or ongoing medical problem in addition to or in relation to their PTCL. The body systems with the most common medical history reported included Cardiovascular (overall: n=87, 67.4%; ongoing at study entry: n=77, 59.7%), Gastrointestinal (overall: n=62, 48.1%; ongoing at study entry: n=41, 31.8%), Musculoskeletal (overall: n=59, 45.7%; ongoing at study entry: n=47, 36.4%), and Endocrine/Metabolic (overall: n=52, 40.3%; ongoing at study entry: n=42, 32.6%).

11.2.3 Baseline Performance Status

The ECOG performance status at study entry is summarized in Table 14. Approximately 78% of patients in both the **Full** and **Efficacy Analysis Datasets** entered the study with an ECOG performance status of 0-1. Listing 16.2.7.3 provides the ECOG performance status at study entry and at on-study assessments for each patient.

Table 14: Baseline ECOG Performance Status

Patient Population	Number of Patients (%)	
	Full Analysis Dataset (N=129)	Efficacy Analysis Dataset (N=120)
Performance Status		
ECOG 0	44 (34.1)	41 (34.2)
ECOG 1	57 (44.2)	52 (43.3)
ECOG 2	27 (20.9)	26 (21.7)
ECOG 3*	1 (0.8)	1 (0. 8)

Patient Population	Number of Patients (%)	
	Full Analysis Dataset (N=129)	Efficacy Analysis Dataset (N=120)

*Patient 915-002 had ECOG 1 at Screening but converted to ECOG 3 on Cycle 1, Day 1 prior to belinostat treatment

Abbreviation: ECOG = Eastern Cooperative Oncology Group

Source: Table 14.1.2.1

11.2.4 Additional Baseline Assessments

11.2.4.1 *Laboratory Assessments*

Assessment of Baseline platelet counts <100,000/ µL prior to study therapy is summarized Table 15 for the **Efficacy Analysis Dataset**. The enrollment criteria for this study allowed patients to be enrolled with platelet counts ≥50,000/µL and absolute neutrophil counts ≥1.0 × 10^9/L. Among the 120 evaluable patients enrolled with PTCL, 20 (15.8%) had Baseline platelet counts <100,000/µL at study entry; there were 24 patients with Baseline platelet counts <100,000/µL in the **Full Analysis Datatset** (N=129) (Table 14.1.2.9).

Table 15: Patients in the Efficacy Analysis Dataset with Baseline[a] Platelet Counts <100,000/ µL

Patient Number	Screening Platelet Counts Prior to Belinostat (x1,000/µL)	Cycle 1, Day 1 Platelets Prior to Belinostat (x1,000/µL)	Bone Marrow Involvement at Baseline[b]
100-004	83.0	94.0	Yes
121-001	104	69.0	Negative
141-001	125	78.0	Yes
144-002	60.0	50.0	Yes
146-002	98.0	70.0	Yes
161-001	106	53.0	Not Performed[c]
180-002	71.0	59.0	Not Performed [c]
180-003	145	80.0	Not Performed [c]
243-001	53.0	69.0	Yes
244-001	178	97.0	Not Performed [c]
513-003	88.0	87.0	Negative
516-006	70.0	71.0	Not Performed[d]

532-002	51.0	23. 0	Yes
534-006	154	79.0	Negative
600-003	89.0	78.0	Yes
801-001	123	96.0	Negative
907-005	95.0	83.0	Yes
907-006	48.0	76.0	Yes
914-008	67.0	69.0	Yes
934-001	97.0	94.0	Negative

[a] Screening or Cycle 1, Day 1 prior to belinostat treatment

[b] Listed as "Yes" if Baseline bone marrow assessment was performed.

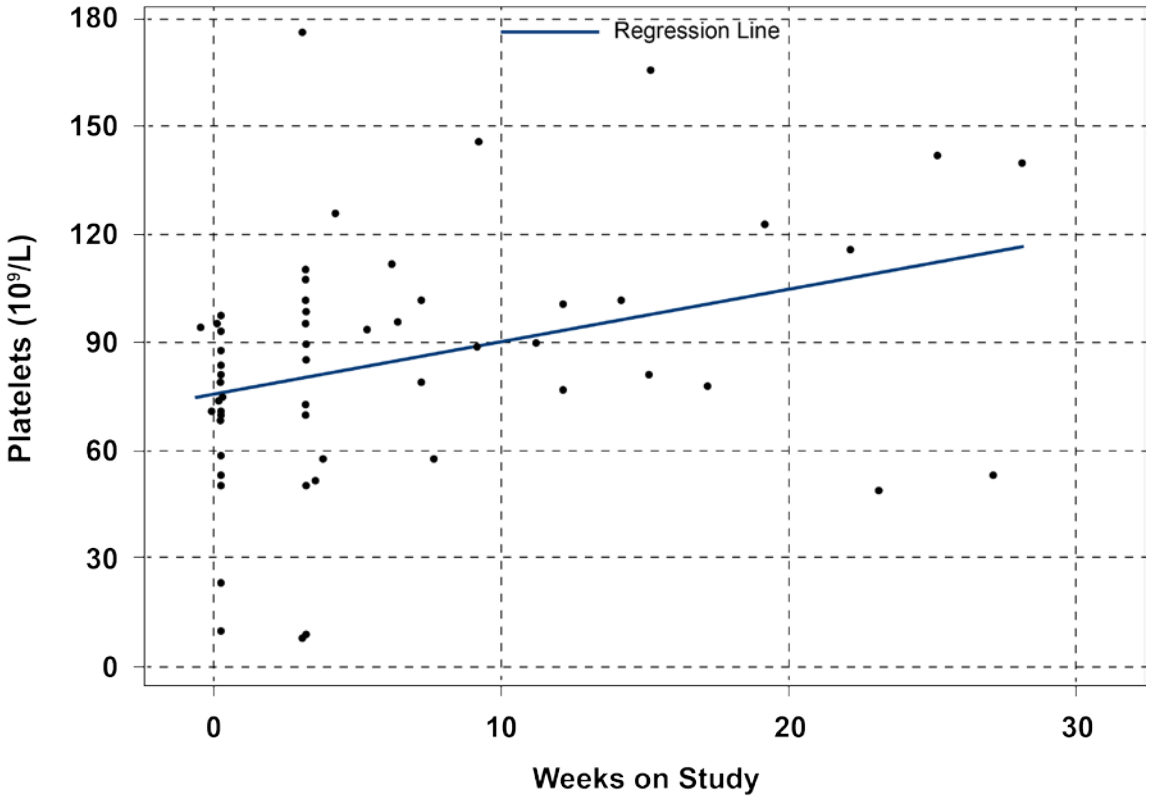
[c] Amendment 3

[d] Amendment 5

Source: CRF, Listing 16.2.4.0, Listing 16.2.6.7, Listing 16.2.8.1

Figure 3 shows the change in platelet counts over the course of the study in the subgroup of patients with Baseline platelet counts <100,000/µL. Overall, there was a trend toward increasing platelet counts in this subgroup over time (R-Square=0.1110, p-value for slope of time on X- axis=0.0087).

Figure 3: Platelet Values during the Study in the Subgroup of Patients with Baseline[a] Platelets of < 100,000/µL



[a] Screening or Cycle 1, Day 1 prior to belinostat treatment
Source: Listing 16.2.8.1

Listing 16.2.8.1 provides the individual hematology laboratory assessments for each patient in the **Full Analysis Dataset**, including 2 patients (Patient 144-001 and Patient 532-002) who met inclusion criteria for platelets at Screening (52,000/µL, 144-001; 51,000/µL,), but subsequently had Cycle 1, Day 1 platelet counts <50,000/µL. Both of these patients received only 2 cycles of treatment. Patient 144-001 withdrew from study, and Patient 532-022 died both due to progressive disease.

Table 14.1.2.6 summarizes the Baseline laboratory abnormalities for all patients based on the last sample taken prior to the first dose of belinostat (Table 16). CTC Grade 4 values at Baseline were reported for 7 (5.4%) patients with low lymphocyte counts, 2 (1.6%) patients with low platelets, 2 (1.6%) patients with high uric acid levels, and 1 (0.08%) patient with low hemoglobin.

Table 16: Grade 4 Laboratory Abnormalities at Baseline[a]

Patient	Study Day	Laboratory Test	Result	Unit	LLN	ULN	Grade
126-002	1	Urate	10.09	mg/dL	2.7	7.2	4
900-001	1	Urate	11	mg/dL	3.1	7	4
142-002	1	Lymphocytes	0.125	10/L	1	4	4
150-001	1	Lymphocytes	0.081	10/L	1	4	4
180-003	1	Lymphocytes	0.19	10/L	1	4.5	4
224-002	1	Lymphocytes	0.182	10/L	1	4	4
244-002	1	Lymphocytes	0.134	10/L	1	4	4
244-006	1	Lymphocytes	0.155	10/L	1	4	4
532-002	1	Lymphocytes	0.08	10/L	0.8	4	4
144-001	1	Platelets	10	10/L	150	350	4
532-002	1	Platelets	23	10/L	120	350	4
534-006	1	Hemoglobin	3.7	g/dL	12	15.5	4

[a] Screening or Cycle 1, Day 1 prior to belinostat treatment

Abbreviations: LLN=lower limit normal, ULN=upper limit normal

Source: Listing 16.2.8.1, Listing 16.2.8.3

11.2.5 Disease Characteristics

11.2.5.1 *Histopathology*

Patient histopathology is summarized for the central pathologic review by **CPRG** and for the local assessment by the study Investigators for the **Full** and **Efficacy Analysis Datasets** in Table 17 and Table 14.1.2.2; the primary criteria for patient diagnosis and analysis was pre-defined to be based on the **CPRG** assessment.

Histopathology assessed at the investigational site was recorded by the Investigator on the CRF. Investigator assessment of additional histopathology is presented by patient in Listing 16.2.4.3. Immunohistochemistry analysis by patient is provided in Listing 16.2.4.4. For the central pathology review, **CPRG** reviewers were provided with tissue and/or slides to confirm histopathology as described in Section 6.3.4. The **CPRG** pathology assessments are included in Listing 16.2.4.0 and patient case report forms (CRFs) are provided in Appendix 16.4.1.

Table 17: Histopathology per CPRG and Investigator Assessments

Patient Population	Full Analysis Dataset (N=129) n (%)	Efficacy Analysis Dataset (N=120) n (%)
Lymphoma Diagnosis by CPRG- Primary Analysis		
Peripheral T-cell Lymphoma, NOS	77 (59.7)	77 (64.2)
Angioimmunoblastic T-cell Lymphoma	22 (17.1)	22 (18.3)
Anaplastic Large Cell Lymphoma, ALK-negative	13 (10.1)	13 (10.8)
Anaplastic Large Cell Lymphoma, ALK-positive	2 (1.6)	2 (1.7)
Enteropathy-associated T-cell Lymphoma	2 (1.6)	2 (1.7)
Extranodal NK/T-cell Lymphoma, nasal type	2 (1.6)	2 (1.7)
Hepatosplenic T-cell Lymphoma	2 (1.6)	2 (1.7)
No Peripheral T-cell Lymphoma present[a]	2 (1. 6)	-
Inadequate Sample for Assessment	7 (5.4)	-
Lymphoma Diagnosis by Investigator		
Peripheral T-cell Lymphoma, NOS	75 (58.1)	71 (59.2)
Angioimmunoblastic T-cell Lymphoma	31 (24.0)	27 (22.5)
Anaplastic Large Cell Lymphoma, ALK-negative	15 (11.6)	15 (12.5)
Hepatosplenic T-cell Lymphoma	3 (2.3)	2 (1.7)
Anaplastic Large Cell Lymphoma, ALK-positive	2 (1.6)	2 (1.7)
Enteropathy-associated T-cell Lymphoma	2 (1.6)	2 (1.7)
Extranodal NK/T-cell Lymphoma, nasal type	1 (0.8)	1 (0.8)

[a] The comments per central pathology review for Patient 162-002 indicated that the provided pathology material represented benign reactive lymphoid infiltrate of the skin, and for Patient 901-001 it was noted that the pathology material represented a benign lymph node with no lymphoma present.

Abbreviations: NOS = not otherwise specified, anaplastic lymphoma kinase, NK = natural killer

Source: Table 14.1.2.2

The prevalence of the various histopathological subtypes in this study reflects the heterogeneity previously reported for patients with PTCL [15, 16]. The majority (n=77,

64.2%) of patients in the **Efficacy Analysis Dataset** had PTCL-NOS according to the **CPRG** assessment. Twenty-two patients (18.3%) had Angioimmunoblastic T-cell lymphoma. A total of 15 patients (12.5%) had ALCL, primary systemic type; 13 patients were ALK negative and 2 patients were ALK positive. ALCL patients with ALK negative disease have been shown to respond less favorably to treatment than the ALK positive subtype [17]. No other histological subtype was reported in >2 patients.

Per **CPRG** assessment, 9 treated patients (Listing 16.2.3.1) were determined to be unevaluable for efficacy due to inadequate specimens for **CPRG** assessment (n=7 patients: Patients 140-001, 144-001, 147-001, 147-002, 221-001, 914-002, and 914-009) or non-eligible PTCL histopathology (no PTCL present in the tissue sample analyzed) (n=2 patients: Patient 162-002 and 901-001); as described in Sections 9.7.1.1 and 10.1, these patients were excluded from the **Efficacy Analysis Dataset**.

Among the 120 patients included in the **Efficacy Analysis Dataset**, there was general concordance between the histopathology recorded by the Investigator and that as assessed by the **CPRG**. The primary differences were that the **CPRG** classified more patients as having PTCL-NOS compared with the Investigator assessments (64.2% vs. 59.2%) and that fewer patients were listed by **CPRG** as having Angioimmunoblastic T-cell lymphoma (18.3% vs. 22.5%). The primary criteria for patient diagnosis and analysis were pre-defined to be based on the central pathology review by the **CPRG**.

11.2.5.2 *Disease History*

The median time from initial diagnosis to study treatment was 12.2 months for the **Full Analysis Dataset** and 12.0 months for the **Efficacy Analysis Dataset** (range for both 2.6-266.4 months) (Table 14.1.2.2, by patient in Listing 16.2.4.3). The median number of months from the most recently confirmed PD assessment was 1 month (range 0.1-54.5 months) (Table 14.1.2.3). Most patients in the **Efficacy Analysis Dataset** (n=102, 85.0%) had Stage III or IV disease at study entry. (Table 14.1.2.2)

Bone marrow biopsies were not required at Baseline for patients enrolled prior to Protocol Version 5. As listed in Table 8, the assessment of possible bone marrow involvement by bone marrow biopsy was added per the FDA request in the protocol amendment that resulted in Protocol Version 5.0. Of the 13 (10.1%) patients without Baseline bone marrow biopsies in the **Efficacy Analysis Dataset**, all but 1 patient (516-006) was enrolled before biopsies were required in Protocol Version 5.0 (4 Jan 2010) (Table 18). Prior to enrollment, this patient had a bone marrow aspirate performed that indicated no cancer was present. Although the Investigator did not consider the bone marrow aspirate as a representative substitute for bone marrow biopsy, the patient refused the bone marrow assessment. Despite the negative aspirate result, the Investigator could not exclude the possibility of bone marrow involvement; therefore,

the patient was assessed as suspected of having bone marrow involvement at Baseline. The patient received 1 cycle of treatment (19-23 Jul 2011) (Listing 16.2.5.1), and did not have follow-up CT scans; the patient was subsequently discontinued from the study on 10-Aug-2011, and was considered not evaluable.

Table 18: Patients Enrolled With No Baseline Bone Marrow Biopsy

Protocol Version	Patient Number	PTCL Diagnosis
Version 3 (Baseline bone marrow biopsies were not required for patients enrolled under Protocol Version 3.0)	**161-001**	Angioimmunoblastic T-Cell Lymphoma
	180-001	Peripheral T-Cell Lymphoma, NOS
	180-002	Anaplastic Large Cell Lymphoma, Alk-Negative
	180-003	Angioimmunoblastic T-Cell Lymphoma
	206-001	Peripheral T-Cell Lymphoma, NOS
	221-001	Peripheral T-Cell Lymphoma, NOS
	224-001	Peripheral T-Cell Lymphoma,
	240-001	Extranodal NK/T-Cell Lymphoma, Nasal type
	240-002	Peripheral T-Cell Lymphoma, NOS
	244-001	Peripheral T-Cell Lymphoma, NOS
	752-001	Anaplastic Large Cell Lymphoma, Alk-Negative
	900-001	Peripheral T-Cell Lymphoma, NOS
Version 5	**516-006**	Peripheral T-Cell Lymphoma, NOS

Source: Listing 16.2.4.3, 16.2.6.7

Of the 13 patients in the **Efficacy Analysis Dataset** who did not have a Baseline bone marrow assessment, 1 patient with angioimmunoblastic T-cell lymphoma (AITL) (161-001) enrolled under protocol version 3.0 had a PR, which did not require a bone marrow assessment per Cheson criteria to assess a partial response. Of those patients enrolled in Protocol Version 5.0. who had bone marrow assessments at Baseline, 39 patients (30.2%) in the **Full Analysis Dataset** and 35 patients (29.2%) in the **Efficacy Analysis Dataset** had bone marrow involvement at Baseline (Table 14.1.2.2).

11.2.5.3 *Prior Therapy*

Patients were heavily pretreated prior to entering this study (Table 14.1.2.3 and Table 14.1.2.4). Prior therapy and response to those therapies are listed by patient in Listing 16.2.4.6.

The median number of prior systemic therapies was 2 (range 1-8) for the **Full** and **Efficacy Analysis Datasets**. Forty-eight patients (37.2%) in the **Full Analysis Dataset** and 44 patients (36.6%) in the **Efficacy Analysis Dataset** had received ≥ 3 prior therapies before entering this study. A total of 43.4% of patients in the **Full Analysis Dataset** and 44.2% in the **Efficacy Analysis Dataset** received prior CHOP chemotherapy. A total of 29 patients (22.5%) in the **Full Analysis Dataset** and 25 patients (20.8%) in the **Efficacy Analysis Dataset** had received a stem cell transplant prior to enrollment in this study.

Table 19 summarizes the most recent prior systemic therapies received and all prior therapies patients in the **Full** and **Efficacy Analysis Datasets** had received. Ten patients (8.3%) in **Efficacy Analysis Dataset** were treated with prior pralatrexate. Prior surgeries, radiation therapy, and transplant data are provided by patient in Listings 16.2.4.7, 16.2.4.8, and 16.2.4.9, respectively.

Table 19: Prior Systemic Therapy for Peripheral T-cell Lymphoma

Patient Population	Full Analysis Dataset (N=129) n (%)	Efficacy Analysis Dataset (N=120) n (%)
Last Systemic Regimen for PTCL		
Multi-agent Therapy		
CHOP or CHOP-like Regimens	56 (43.4)	53 (44.2)
Platinum-containing Regimens	17 (13.2)	16 (13.3)
Other multi-agent Regimens	35 (27.1)	33 (27.5)
Single-agent Therapy		
Pralatrexate	6 (4.7)	6 (5.0)
Corticosteroids	3 (2.3)	1 (0.8)
Other single-agent Regimens	12 (9.3)	11 (9.2)
All Systemic Regimens for PTCL		
Multi-agent Therapy		
CHOP or CHOP-like Regimens	125 (96.9)	116 (96.7)
Platinum-containing Regimens	42 (32.6)	38 (31.7)

Patient Population	Full Analysis Dataset (N=129) n (%)	Efficacy Analysis Dataset (N=120) n (%)
Other multi-agent Regimens	48 (37.2)	44 (36.7)
Single-agent Therapy		
Pralatrexate	11 (8.5)	10 (8.3)
Corticosteroids	6 (4.7)	4 (3.3)
Other single-agent Regimens	21 (16.3)	20 (16.7)

Abbreviations: PTCL = peripheral T-cell lymphoma, CHOP = cyclophosphamide, doxorubicin, vincristine, prednisone

Source: Table 14.1.2.4

11.3 Measurement of Treatment Compliance

All belinostat treatments were administered as an IV infusion in the hospital/clinic setting and were recorded on the Treatment Administration section of the CRF (presented by patient in Listing 16.2.5.1). As detailed in Section 12.1, toxicity was the majority reason for 27 (20.9%) patients missing a dose (Table 14.3.5.2).

Table 14.1.1.3 and Table 29 show the study drug completion rates by cycle for both treatment populations. Overall (N=129), 89/129 (69.0%) patients in the **Full Analysis Dataset** and 82/120 (68.3%) patients in the **Efficacy Analysis Dataset** received 5 full doses completing the treatment regimen with 122 (94.6%) patients in the **Full Analysis Dataset** and 114 (95.0%) patients in the **Efficacy Analysis Dataset** receiving at least 1 complete 5-day cycle of study drug.

11.4 Efficacy Results and Tabulations of Individual Patient Data

11.4.1 Analysis of Efficacy

The primary efficacy endpoint was ORR, and secondary efficacy endpoints included Time to Response, Duration of Response, TTP, PFS, 1-year progression-free survival rate, 1-year survival rate, and OS. To be evaluable for efficacy according to the pre-specified criteria of the protocol (Appendix 16.1.1) and the SAP (Appendix 16.1.9), a patient must have received at least 1 dose of belinostat and have had a confirmed diagnosis of PTCL by the **CPRG**. As described in Sections 10.1 and 11.2.5.1, 9 patients were excluded from the **Efficacy Analysis Dataset**; 2 patients due to incorrect histology and 7 patients due to insufficient material for confirmation by **CPRG**.

11.4.1.1 *Primary Endpoint – Objective Response Rate*

ORR was defined as the percentage of patients with a CR or a PR according to IWG criteria. Response was assessed on the basis of clinical and radiological criteria as described in Section 9.5.1.3. In addition to the primary analysis of response by central radiographic and clinical review by the **IRC**, the response assessment was also determined by the local Investigators. As pre-defined, the primary endpoint analysis for this study was based on the **IRC** assessment of response.

The data per **IRC** and per Investigator assessment are listed by patient in Listing 16.2.6.1 (response evaluation by visit per IRC). Additional response information is provided in Listings 16.2.6.2 (response evaluation by visit per Investigator), 16.2.6.3 (target lesion per IRC), 16.2.6.4 (target lesion per Investigator), 16.2.6.5 (new lesion details per **IRC**), 16.2.6.6 (new lesion details per Investigator), and 16.2.6.7 (bone marrow assessment).

11.4.1.1.1 Response as Assessed by Central Radiographic Review

The ORR in the **Efficacy Analysis Dataset**, based on independent review by the **IRC** (as described in Section 6.3.5) of imaging and clinical data using IWG criteria, was 25.8% (n=31) as presented in Table 20 and Table 14.2.3.1. There was a 77.5% concordance between the 2 independent readers; 27 (22.5%) patient responses required adjudication following the chartered pre-defined adjudication process (Table 14.2.3.1). Thirteen patients (10.8%) achieved a CR and 18 patients (15.0%) achieved a PR. Eighteen patients (15.0%) had SD. Importantly, 12 patients were able to proceed to a stem cell transplant after treatment with belinostat (Section 11.4.1.4).

Among the 7 patients who remained on belinostat treatment as of the database cut-off (31 Aug 2012), 5 patients (Patients 146-001, 220-002, 534-002, 534-006, 541-001) were classified as CRs, 1 patient (Patient 516-004) had a PR and 1 patient (Patient 543-001) had SD (Listing 16.2.6.1). Of the 13 patients who achieved a CR, 4 (Patients 244-003, 534-001, 901-006, 911-001) had PD and 1 patient died (**Patient 934-003**) at the time of data cut-off.

Table 20: Summary of Best Response per Central Radiologic Review by the IRC

Patient Population	Efficacy Analysis Dataset (N=120) n (%)
Objective Response Rate	
Objective Response Rate (CR+PR)	31 (25.8)
95% CI*	18.3 - 34.6
Complete Response	13 (10.8)
95% CI*	5.9 - 17.8
Best Tumor Response	
Complete Response	13 (10.8)
Partial Response	18 (15.0)
Stable Disease	18 (15.0)
Progressive Disease	47 (39.2)
Not Evaluable	24 (20)
Reason for Not-evaluable Assessments	
Clinical Progression Prior to First On-study Assessment	9 (7.5)
Death Prior to First on-study Assessment	7 (5.8)
Withdrawal by Patient Prior to First On-study Assessment	5 (4.2)
Lost to Follow-up Prior to First On-study Assessment	1 (0.8)
No Index Lesion Identified by **IRC** Radiologists	1 (0.8)
Other	1 (0.8)

*Clopper-Pearson 95% CI.

Abbreviations: CR = complete response, PR = partial response, CI = confidence interval, **IRC** = Independent Review Committee

Source: Table 14.2.3.1

Table 21 summarizes the reasons why the **IRC** assessed 24 (20%) of the 120 patients as not evaluable (Table 14.2.3.1; Listing 16.2.3.2). Imaging for response assessment was performed every 2 cycles (6 weeks), and 5 patients (4.2%) did not have a response assessment because they stopped treatment with belinostat prior to completion of Cycle 1 (Patients 100-001, 220-001, 224-001, 244-004, 752-001) (Listing 16.2.5.1). Nine patients (7.5%) developed PD based on clinical criteria prior to their first response assessment. Seven patients (5.8%) died prior to their first response assessment. One (0.8%) patient (Patient 516-006) was lost to follow-up prior to their first response

assessment and 1 (0.8%) patient (Patient 221-004) had no index lesions identified by **IRC**. Conservatively, these patients were considered non-responders, and they were, therefore, included in the denominator for all response rate calculations.

Table 21: Efficacy Analysis Dataset Patients not Evaluable for Response Assessment by IRC

Patient	Reason for "Not Evaluable" Response Assessment by IRC
100-001	Withdrawal by patient prior to first on-study assessment
142-001	Death prior to first on-study assessment
146-002	Death prior to first on-study assessment
147-001	No assessment after Baseline
147-002	Clinical progression prior to first on-study assessment
150-001	Clinical progression prior to first on-study assessment
165-001	Clinical progression prior to first on-study assessment
206-001	Death prior to first on-study assessment
220-001	Withdrawal by patient prior to first on-study assessment
221-004	No index lesion identified by the **IRC** radiologists
224-001	Withdrawal by patient prior to first on-study assessment
224-002	Clinical progression prior to first on-study assessment
244-002	No assessment after Baseline
244-004	Withdrawal by patient prior to first on-study assessment
244-005	Clinical progression prior to first on-study assessment
513-001	Death prior to first on-study assessment
516-001	Clinical progression prior to first on-study assessment
516-006	Lost to follow-up prior to first on-study assessment
752-001	Withdrawal by patient prior to first on-study assessment
801-001	Clinical progression prior to first on-study assessment
801-002	Death prior to first on-study assessment
803-001	Death prior to first on-study assessment
901-001	No index lesion identified by the **IRC** radiologists
907-002	Death prior to first on-study assessment
914-006	Clinical progression prior to first on-study assessment
914-008	Clinical progression prior to first on-study assessment
921-001	Clinical progression prior to first on-study assessment

Source: Listing16.2.3.2, Listing 16.2.6.1

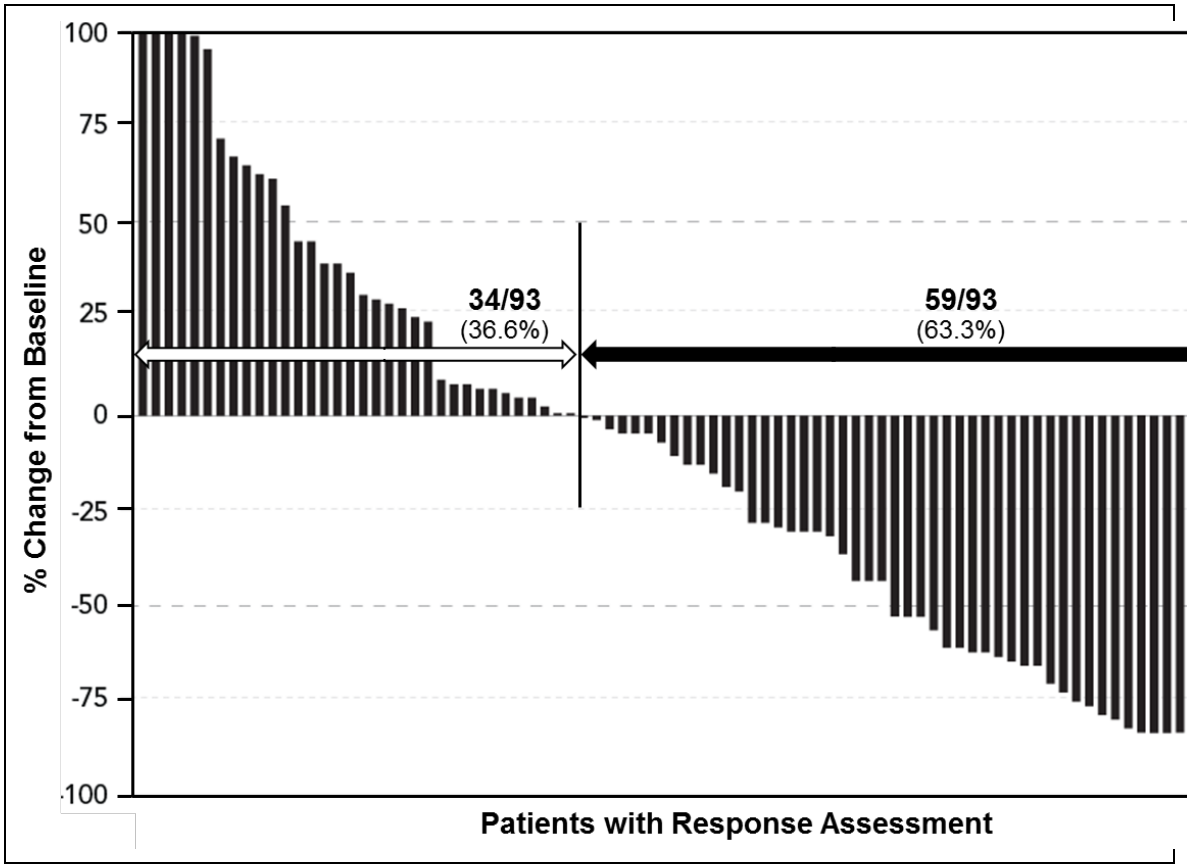
11.4.1.1.2 Individual Tumor Response

The waterfall plot in Figure 4 displays the maximum difference in the sum of the products of the greatest diameters (SPD) values as the percentage change from Baseline for 93 (77.5%) patients who had measurable disease at Baseline and post-treatment

assessment (Listing 16.2.6.1); 27 patients did not have both Baseline and post-treatment assessments to calculate the change in the SPD. As described in Table 20, 24 patients were not evaluable for response by the **IRC** using IWG criteria and 3 patients (141-001, 240-002, and 243-001) did not have the first radiology assessment. Patient 243-001 did not have a radiology assessment but had significant hepatomegaly of unknown etiology.

A decrease in tumor volume, as measured by the difference in the SPD between a patient's Baseline value and their maximum decrease on study, was observed in 59 patients (63.3% **Efficacy Analysis Dataset**). Twenty patients had a SPD decrease of ≥ 75%, 15 patients had a decrease between 50% and <75%, 11 patients had a decrease between 25% and < 50%, and 13 patients had a decrease of < 25%. Less than a third of patients (34; 36.6%) had an increase in their SPD compared with Baseline values.

Figure 4: Maximum Change from Baseline in the Sum of the Products of the Greatest Tumor Diameter



Source: Listing 16.2.6.9

11.4.1.1.3 Response as Assessed by the Investigators

The response rate according to IWG criteria based on the local assessment as reported by study Investigators in the 120 patient **Efficacy Analysis Dataset** was 22.5 % (n=27; 95% CI: 15.4-31.0 %) (Table 14.2.3.4). Eleven patients (9.2 %) achieved a CR and 16 patients (13.3 %) achieved a PR; 29 patients (24.2 %) had SD.

Table 14.2.3.6 presents the concordance of response assessments between the **IRC** and Investigator assessments. Overall, 6 patients were considered responders by **IRC** who were not assessed as such by the Investigators (Table 22). The primary difference in ORRs is the number of patients who were determined by **IRC** to have a CR (n=13 by **IRC**, n=9 by Investigators). The **IRC** also identified 2 additional patients as having a PR than did the study Investigators.

Table 22: Individual Patient Assessments for Responders by IRC and Investigators

Patients with a Response	Response Assessment	
	IRC Review	Local Investigator
146-001	CR	CR
207-001	CR	CR
220-002	CR	CR
221-003	CR	CR
244-003	CR	CR
534-001	CR	CR
534-002	CR	CR
534-006	CR	PR
541-001	CR	CR
901-006	CR	PR
911-001	CR	PR
931-003	CR	CR
934-003	CR	PR
100-002	PR	CR
142-005	PR	PD
154-001	PR	PR
161-001	PR	PD
245-001	PR	PR
516-004	PR	PD
532-003	PR	PR

Patients with a Response	Response Assessment	
	IRC Review	Local Investigator
533-001	PR	SD
534-003	PR	PR
534-004	PR	PR
534-005	PR	PR
600-003	PR	PR
752-002	PR	SD
800-001	PR	SD
915-001	PR	PR
919-001	PR	PR
938-001	PR	PR
543-001	PR	CR
532-004	SD	PR
908-003	SD	PR

Abbreviations: CR=complete response; PR=partial response; SD=stable disease
Source: Table 14.2.3.7, Listing 16.2.6.1, Listing 16.2.6.2

Nearly all patients (27/31; 87.1%) who were assessed as responders by the **IRC** per IWG criteria (n=31) were also considered responders by the Investigators' assessments (n=27) (Table 14.2.3.1, Table 14.2.3.4, and Table 14.2.3.6).

- 4 patients (Patients 534-006; 901-006; 911-001; 934-003) were assessed as CR by **IRC** but the Investigator assessed as PR
- 2 patients (Patients 100-002; 543-001) were assessed as PR by **IRC** but the Investigator assessed as CR
- 6 patients were assessed as PR by **IRC** but the Investigator assessed as not having a response and listed 3 patients (Patients 142-005; 161-001; 516-004) as PD and 3 patients (Patients 533-001; 752-002; 800-001) as SD
- 2 patients were assessed as SD by **IRC** but the Investigator assessed as PR (Patients 532-004; 908-003)

11.4.1.2 *Secondary Endpoints*

11.4.1.2.1 Time to Response (TTR)

Table 23 summarizes the TTR according to assessment by central radiographic review (**IRC**) and by the local Investigator. Most responding patients (n=19, 61% of responders) did so by the first response assessment (Table 25). The median TTR for the

Efficacy Analysis Dataset as assessed by **IRC** per IWG criteria was 5.6 weeks (range 4.3-50.4 weeks) (Table 14.2.3.2). For patients in the **Efficacy Analysis Dataset** with an overall best response of CR or PR, Kaplan-Meier estimates of the 25th and 75th percentiles for TTR were 5.4 months and 12.1 months, respectively.

Among the 28 responding patients with platelet counts ≥100,000/µL at Baseline (Screening or Cycle 1, Day 1), the median TTR per **IRC** was 5.6 (4.3-50.4) weeks (Table 14.2.3.9). Among the 3 responding patients with platelet counts <100,000/µL at Baseline, the median TTR per **IRC** was 6.4 (4.3-12.4) weeks (Table 14.2.3.9). The median TTR as assessed by the Investigator was 6.3 (4.1-44.1) weeks among 25 responding patients with ≥100,000/µL platelets at Baseline, and 13.1 (12.07-13.6) weeks among 2 responding patients with <100,000/µL platelets at Baseline (Table 14.2.3.10); all were scheduled radiologic assessments**.**

Table 23: Time to Response

Efficacy Analysis Dataset (N=120)	Number of Responders	Time to Response (weeks)	
Central Review			
All Responders	31/120	Median	5.6
		Min - Max	4.3-50.4
Baseline Platelets ≥100,000/µL	28/100	Median	5.6
		Min - Max	4.3-50.4
Baseline Platelets <100,000/µL	3/20	Median	6.4
		Min - Max	4.3-12.7
Local Investigator			
All Responders	27/120	Median	6.3
		Min - Max	4.1-44.1
Baseline Platelets ≥100,000/µL	25/100	Median	6.3
		Min - Max	4.1-44.1
Baseline Platelets <100,000/µL	2/20	Median	13.1
		Min - Max	12.7-13.6

Abbreviations: Max=maximum, Min=minimum

Source: Table 14.2.3.2 , Table 14.2.3.5, Table 14.2.3.9, Table 14.2.3.10

Table 24 provides details on the 7 of 31 patients who were assessed by **IRC** as having a CR, who had an earlier response assessed as a PR and that subsequently converted to a CR with further treatment:

- Patient 207-001 became a CR approximately 1 month after assessment as a PR, 129 days after starting belinostat.

- Patient 244-003 became a CR approximately 18 months after assessment as a PR, 555 days after starting belinostat.
- Patient 534-001 became a CR approximately 1.5 months after assessment as a PR, 80 days after starting belinostat.
- Patient 534-002 became a CR approximately 1.4 months after assessment as a PR, 80 days after starting belinostat.
- Patient 541-001 became a CR approximately 3.5 months after assessment as a PR, 439 days after starting belinostat.
- Patient 901-006 became a CR approximately 2.8 months after assessment as a PR, 121 days after starting belinostat.
- Patient 931-003 became a CR approximately 5.4 months after assessment as a PR, 235 days after starting belinostat.

The response data by visit per **IRC** are listed by patient in Listings 16.2.6.1, 16.2.6.3, and 16.2.6.5 for central radiographic review. The response data by visit by Investigator assessment are provided in Listings 16.2.6.2, 16.2.6.4, and 16.2.6.6.

Table 24: Summary of Patients Who Converted from PR to CR

Patient	Study Day of PR	Study Day of CR	Difference (days)
207-001	91	129	38
244-003	38	555	517
534-001	36	80	44
534-002	38	80	42
541-001	334	439	105
901-006	36	121	85
931-003	73	235	162

Abbreviations: CR=complete response; PR=partial response
Source: Listing 16.2.6.1

11.4.1.2.2 Duration of Response

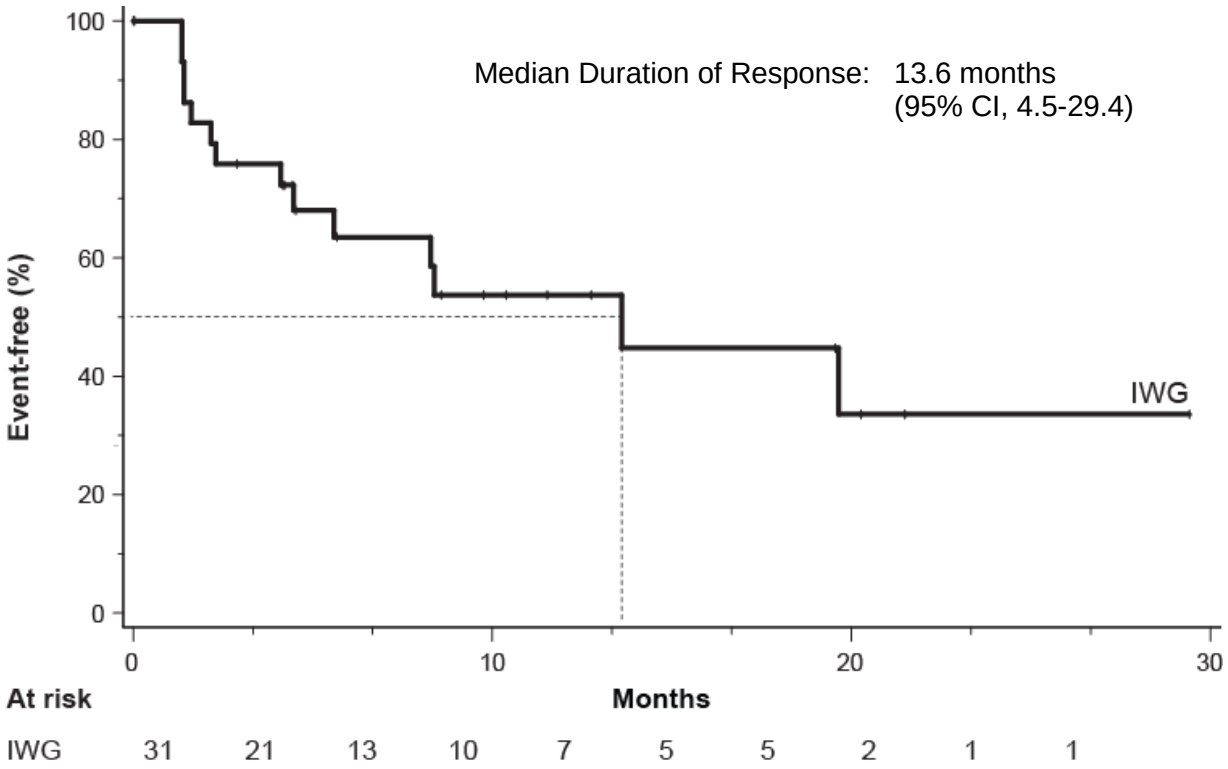
The calculation of Duration of Response is described in Section 9.7.1.2.2.

The Duration of Response as assessed by IWG criteria per the **IRC** and estimated by the Kaplan-Meier method is presented in Figure 5 and summarized in Table 14.2.3.2.

The median Duration of Response for the **Efficacy Analysis Dataset**, as assessed by **IRC** using IWG criteria and based on 31 responding patients, was 13.6 months (95% CI, 4.5-29.4). For patients with an overall best response of CR or PR in the **Efficacy Analysis Dataset**, the Kaplan-Meier estimate of the 25th percentile was 4.1 months and the 75th percentile was 29.4 months for Duration of Response by IWG criteria.

Among the 31 responding patients, the estimated probabilities of being in response by IWG criteria at 6 months, 1 year, and 2 years were 63.5%, 53.7%, and 35.8%, respectively.

Figure 5: Kaplan-Meier Estimate of the Duration of Response by IWG Criteria per IRC Assessment



Source: Table 14.2.3.2, Table 14.2.3.7

In the subgroup of patients with Baseline (Screening or Cycle 1, Day 1) platelets of ≥100,000/µL prior to belinostat therapy (n=100), the median Duration of Response among the 28 responding patients as assessed by the **IRC** using IWG criteria was 13.6 months (5.6-29.4) (Table 14.2.3.9). For these 28 patients, the estimated probabilities of being in response by IWG criteria at 6 months, 1 year, and 2 years were 67.0%, 55.8%, and 37.2%, respectively.

In the subgroup of patients with Baseline (Screening or Cycle 1, Day 1) platelets of <100,000/µL prior to therapy (n=20), the median Duration of Response among the 3 responding patients as assessed by the **IRC** using IWG criteria was 4.1 months (2.2-9.8) (Table 14.2.3.9). For these patients, the estimated probability of being in response by IWG criteria at 6 months was 33.3%.

The median Duration of Response for the **Efficacy Analysis Dataset** as assessed by local Investigators using IWG criteria , based on 27 responding patients, was

12.1 months (95% CI, 4.7-19.8) (Table 14.2.3.5). For patients in the **Efficacy Analysis Dataset** with an overall best response of CR or PR, the Kaplan-Meier estimate by Investigator assessment of the 25th percentile was 4.2 months and the75th percentile was 29.4 months for the Duration of Response by IWG criteria. The 6-month, 1-year, and 2-year Kaplan Meier estimates for the Duration of Response were 62.6%, 50.3 %, and 29.3 %, respectively.

Table 25 presents the individual Duration of Response and the basis of calculation for each responding patient based on response as assessed by the **IRC** using the IWG criteria. As mentioned previously, radiological assessments were discontinued at the time of tumor progression or initiation of new anticancer therapy, after which survival was evaluated every 3 months until 2 years from the start of study treatment or until study closure. The calculation of median Duration of Response the **IRC**, using response as assessed by IWG criteria, was based on 14 patients with PD event dates and censored end dates for the remaining 17 responding patients. Seven of the 17 other patients for whom Duration of Response was censored remained on treatment, and all 7 were continued to be followed for response as outlined in the protocol (until PD or initiation of subsequent therapy). The censoring status for all responding patients by each means of response assessment is provided in Table 14.2.3.7.

Table 25: Duration of Response Status per IRC Assessment by IWG Criteria

Patient Number	CPRG Diagnosis	Treatment				Response per IWG Criteria			
		Duration (Days)	Status	Best Response	Day of First Response	Response by Tumor Assessment	Status[a]	Day of Last Response	DoR (days)
100-002	PTCL, NOS	68	Withdrawn	PR	39	1	Progressed	81	43
142-005	PTCL, NOS	13	Withdrawn	PR	30	1	Death[b]	85	56
146-001	AITL	929	Ongoing	CR	33	1	Censored	927	895
154-001	PTCL, NOS	195	Withdrawn	PR	72	2	Death[c]	219	148
161-001	PTCL, NOS	52	Withdrawn	PR	30	1	Progressed	95	66
207-001	PTCL, NOS	450	Withdrawn	CR	91	2	Censored	441	351
220-002	PTCL, NOS	719	Ongoing	CR	38	1	Censored	715	678
221-003	PTCL, NOS	215	Withdrawn	CR	43	1	New therapy	215	173
244-003	Extra nodal, NK/T-cell Lymphoma, Nasal type	614	Withdrawn	CR	38	1	Progressed	635	598
245-001	PTCL, NOS	108	Withdrawn	PR	45	1	Progressed	85	41
516-004	ALCL, ALK (-)	425	Ongoing	PR	353	8	Censored	353	1
532-003	AITL	215	Withdrawn	PR	85	2	Progressed	127	43
533-001	AITL	131	Withdrawn	PR	85	2	New therapy	211	127
534-001	PTCL, NOS	166	Withdrawn	CR	36	1	Progressed	171	136
534-002	AITL	719	Ongoing	CR	38	1	New therapy	691	654
534-003	PTCL, NOS	600	Withdrawn	PR	37	1	Progressed	291	255
534-004	AITL	502	Withdrawn	PR	87	2	Progressed	500	414

534-005	PTCL, NOS	418	Withdrawn	PR	38	1	New therapy	425	388
534-006	AITL	369	Ongoing	CR	45	1	Censored	341	297
541-001	PTCL, NOS	691	Ongoing	CR	334	10	Censored	649	316
543-001	PTCL, NOS	768	Ongoing	PR	150	4	Censored	766	617
600-003	AITL	194	Withdrawn	PR	89	2	Progressed	213	125
752-002	PTCL, NOS	75	Withdrawn	PR	38	1	Progressed	107	70
800-001	PTCL, NOS	24	Withdrawn	PR	36	1	Censored	123	88
901-006	PTCL, NOS	194	Withdrawn	CR	36	1	Progressed	205	170
911-001	ALCL, ALK (-)	68	Withdrawn	CR	38	1	Progressed	78	41
915-001	AITL	411	Withdrawn	PR	171	4	Progressed	422	252
919-001	PTCL, NOS	229	Withdrawn	PR	39	1	New therapy	176	138
931-003	PTCL, NOS	299	Withdrawn	CR	73	2	New therapy	333	261
934-003	AITL	76	Withdrawn	CR	79	2	New therapy	213	135
938-001	AITL	75	Withdrawn	PR	38	1	Progressed	86	49

[a]Status column indicates whether a Duration of Response calculation was censored or had **IRC** documented PD. Censoring was done for patients who were still in response and were continuing follow-up for response duration follow-up at the time of the data cut-off.

[b]Primary cause of death was Progressive Disease 73 days after the last dose of belinostat.

[c]Primary cause of death was Hepatic Failure 25 days after the last dose of belinostat.

Abbreviations: AITL = Angioimmunoblastic T-cell lymphoma, ALCL = anaplastic large cell lymphoma, ALK = Anaplastic lymphoma kinase, CR = complete response, IWG = International Workshop Criteria, PD = progressive disease, PR = partial response, PTCL = Peripheral T-cell lymphoma, NK = Natural killer, NOS = not otherwise specified

Source: 14.2.3.7, Table 14.3.7.2; Listings 16.2.6.1, 16.2.7.4

The Duration of Response was also assessed by SAP-defined criteria, which expanded the IWG criteria by adding the subsequent date of death (IWG + Death) (Section 9.7.1.2.2); the results based on response as assessed by **IRC** and estimated by the Kaplan-Meier method, is summarized in Table 14.2.3.2. The median Duration of Response for the **Efficacy Analysis Dataset**, as assessed by **IRC** using SAP-defined criteria and based on 31 responding patients, was 8.4 months (95% CI, 4.5-29.4). For patients in the **Efficacy Analysis Dataset** with an overall best response of CR or PR, the Kaplan-Meier estimate of the 25th percentile was 2.3 months and the 75th percentile was 29.4 months for the Duration of Response by SAP-defined criteria.

Among the 31 responding patients, the estimated probabilities of being in response by SAP-defined criteria at 6 months, 1 year, and 2 years were 57.7%, 48.8%, and 32.6%, respectively.

In the subgroup of patients with Baseline (Screening or Cycle1, Day1) platelet counts <100,000/µL prior to therapy (n=20), the range of the Duration of Response by SAP-defined criteria among the 3 responding patients was 2.2-9.8 months (median of 4.1 months) (Table 14.2.3.9).

The median Duration of Response by SAP-defined criteria by local Investigator assessment, based on 27 responding patients, was 8.0 months (95% CI, 4.7-19.8) (Table 14.2.3.5). For patients in the **Efficacy Analysis Dataset** with an overall best response of CR or PR, the Kaplan-Meier estimate of the 25th percentile was 4.2 months and the 75th percentile was 29.4 months for the Duration of Response by SAP-defined criteria. The 6-month, 1-year, and 2-year Kaplan Meier estimates for the Duration of Response by the SAP-defined criteria were 59.3%, 47.6%, and 27.8%, respectively.

11.4.1.2.3 Time to Progression (TTP)

The calculation of TTP is described in Section 9.7.1.2.2. Table 14.2.4.1 summarizes the TTP data according to response assessment by **IRC**.

Seventy-two patients (60.0%) in the **Efficacy Analysis Dataset** had an event for the calculation of TTP. The median TTP, based on response as assessed by **IRC** and estimated by the Kaplan-Meier method, was 2.0 months (95% CI, 1.5 – 2.8). For patients in the **Efficacy Analysis Dataset**, the Kaplan-Meier estimate by **IRC** of the 25% quartile TTP was 1.3 months and the75% quartile to progression was 9.6 months. Median time for follow-up was 7.1 months. The Kaplan Meier estimates for remaining progression free at 6-month, 1-year, and 2-year were 30.3%, 24.2%, and 14.1%, respectively.

Eighty-nine patients (74.2%) in the **Efficacy Analysis Dataset** had an event for the calculation of TTP according to the response assessment by Investigator

(Table 14.2.4.3). The median TTP based on response assessed by Investigator, estimated by the Kaplan-Meier method, was 2.0 months (95% CI, 1.5 – 2.9). Median time for follow-up was 19.9 months.

11.4.1.2.4 Progression-Free Survival

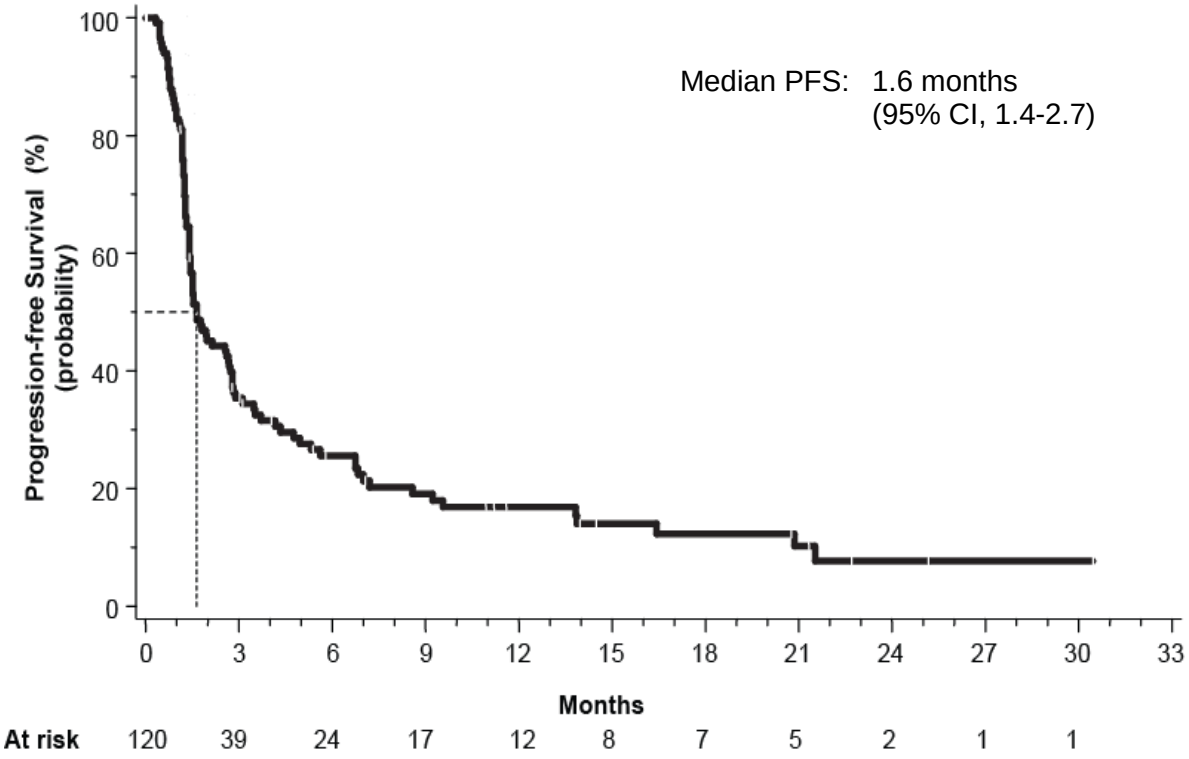
The PFS, based on response assessed by the **IRC** using IWG criteria and estimated by the Kaplan-Meier method, is presented in Figure 6; the calculation of PFS is described in Section 9.7.1.2.2. Table 14.2.4.2 and Table 14.2.4.3 summarize the PFS data according response assessment by **IRC** and local Investigator, respectively. Thirty-two (26.7%) patients of the efficacy analysis set were censored for PFS (based on response assessed by central review using IWG) as described in Section 9.7.1.2.2 and Table 6 (Listing 16.2.6.10). Eighty-eight patients (73.3%) in the **Efficacy Analysis Dataset** had an event for the calculation of PFS, based on response as assessed by the **IRC**. The median PFS estimated by the Kaplan-Meier method was 1.6 months (95% CI: 1.4-2.7), with a median follow-up period of 11.6 months. The probability of PFS at 6 months was 25.6%, 19.3% at 1 year, and 11.3% at 2 years.

The median PFS based on response as assessed by the Investigator, estimated by the Kaplan-Meier method and based in 102 patients (85%) with an event, was 1.8 months (95% CI: 1.5-2.7), with a median follow-up period of 23 months (Table 14.2.4.3). The probability of PFS at 6 months was 25.6%, 15.7% at 1 year, and 7.5% at 2 years.

For the 100 patients in the **Efficacy Analysis Dataset** with Baseline platelet values of ≥100,000/μL, the median PFS was assessed by the **IRC** as 1.8 (1.5-2.8) months based on a median follow-up period of 14.0 months (Table 27 and Table 14.2.4.7).

For the subgroup of 20 patients in the **Efficacy Analysis Dataset** with Baseline platelet counts of <100,000/μL prior to therapy, the median PFS as assessed by the **IRC** was 1.3 months (1.1-1.5) based on a median follow-up period of 11.2 months (Table 14.2.4.7).

Figure 6: Kaplan-Meier Estimate of Progression-Free Survival by IWG Criteria per IRC Review



Source: Listing 16.2.6.10, Table 14.2.4.2

11.4.1.2.5 One-Year Progression-Free Survival Rate

The calculation of the 1-year progression-free survival rate is described in Section 9.7.1.2.2. Table 14.2.4.2 summarizes the estimated 1-year progression-free rate data according to response assessment by the **IRC**, and Table 14.2.4.4 summarizes these data based on the Investigator assessment of response.

The probability of surviving and being progression free at 1 year, based on response as assessed by the **IRC**, was 19.3% (Table 14.2.4.2). The probability of surviving and being progression free at 1 year, based on response as assessed by the Investigators, was 15.7% (Table 14.2.4.4).

11.4.1.2.6 One-Year Survival Rate

The calculation of the 1-year survival rate is described in Section 9.7.1.2.2. Table 14.2.4.5 summarizes the estimated 1-year survival rate. Listings 16.2.1.1 and 16.2.6.8 provide the survival follow-up status by patient.

Seventy-four patients (61.7%) in the **Efficacy Analysis Dataset** had an event for the OS calculation. The probability of being alive at 1 year was 40.9%.

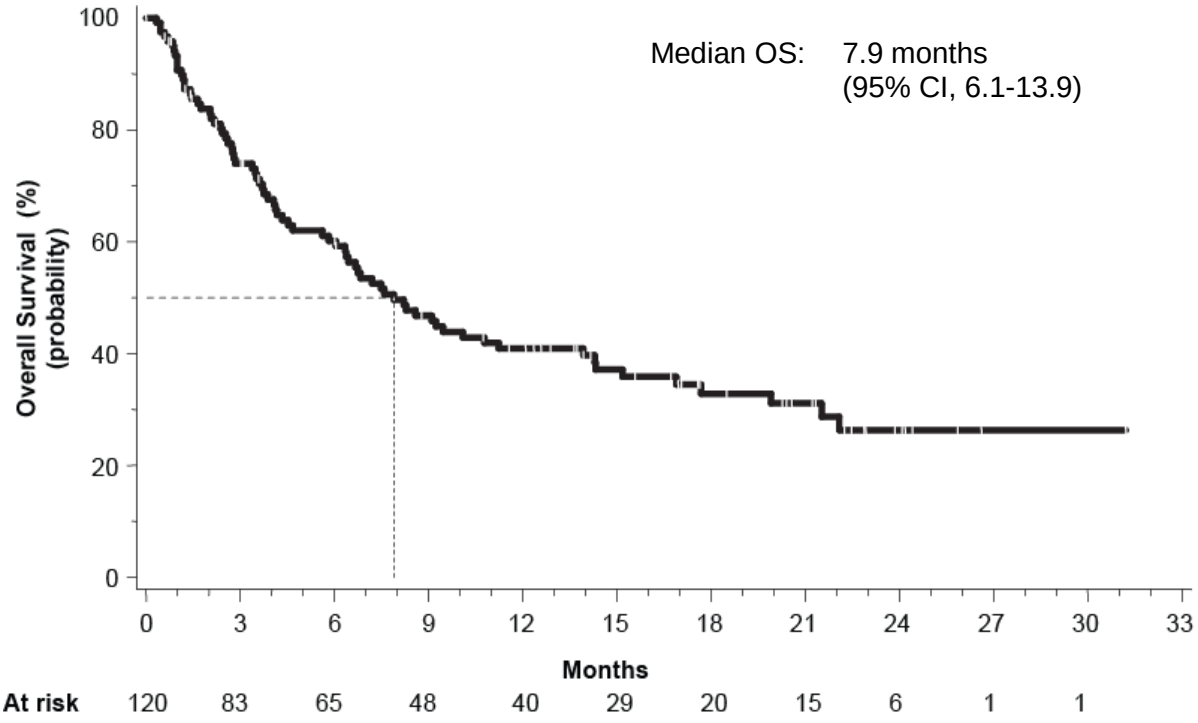
11.4.1.2.7 Overall Survival

OS, estimated by the Kaplan-Meier method, is presented in Figure 7. The median OS for the **Efficacy Analysis Dataset** was 7.9 months (95% CI: 6.1-13.9), with a median follow-up of 18.5 months. The calculation of OS is described in Section 9.7.1.2.2; Table 14.2.4.5 summarizes the OS data. Forty-six patients (38.3%) were censored for OS because they were still alive or lost to follow-up at the time of the data cut-off date (Listing 16.2.6.11). Seventy-four patients (61.7%) had died, most (n=53, 44.1%) due to progression of their PTCL (Listings 16.2.3.1 and 16.2.7.4).

Among the 100 patients with platelet counts ≥100,000/µL at Baseline, the median OS as assessed by the **IRC** was 9.2 (6.4-17.7) months based on a median follow-up period of 20.3 months (Table 14.2.4.8).

The median OS assessed by **IRC** for the 20 patients with Baseline platelet counts <100,000/µL was 4.3 (2.4-7.9) months based on a median follow-up period of 13.8 months (Table 14.2.4.8).

Figure 7: Kaplan-Meier Estimate of Overall Survival



Source: Listing 16.2.6.11, Table 14.2.4.5

11.4.1.3 *Subgroup Analyses- Response by Pre-treatment Characteristics*

Subgroup analyses were conducted to assess the activity of belinostat among certain important patient subsets including:

- ORR by Baseline platelet counts
- ORR by PTCL subtype
- ORR by bone marrow involvement at Baseline
- ORR by prior therapy
- ORR by age, gender, and ECOG status

Importantly, several subgroups demonstrated response rates that were even greater than that demonstrated in the overall **Efficacy Analysis Dataset** (25.8%). Table 26 displays the response outcome in the **Efficacy Analysis Dataset** by pre-treatment characteristics according to IWG criteria as assessed by central radiographic review by the **IRC**. Many of the other subgroups had wide confidence intervals due to the small number of patients in each subgroup.

Table 26: Overall Response Rate as Assessed by Central Radiology Review by the IRC by Pre-Treatment Characteristics

Patient Population	n (%)	CR + PR (%)	95 % CI
Gender			
Male	62 (51.7)	13 (21.0)	11.7 - 33.2
Female	58 (48.3)	18 (31.0)	19.5 - 44.5
Race			
White	105 (87.5)	26 (24.8)	16.9 – 34.1
Non-White	15 (12.5)	5 (33.3)	11.8 – 61.6
Age at Entry			
< 65 years	61 (50.8)	10 (16.4)	8.2 - 28.1
≥ 65 years	59 (49.2)	21 (35.6)	23.6 - 49.1
Performance Status			
ECOG 0	41 (34.2)	12 (29.3)	16.1 - 45.5
ECOG 1	52 (43.3)	8 (15.4)	6.9 - 28.1
ECOG 2	26 (21.7)	11 (42.3)	23.4 - 63.1
ECOG 3	1 (0.8)	0 (0)	0.0 - 97.5
CPRG Lymphoma Diagnosis			
Peripheral T-cell Lymphoma, NOS	77 (64.2)	18 (23.4)	14.5 - 34.4
Angioimmunoblastic T-cell Lymphoma	22 (18.3)	10 (45.5)	24.4 - 67.8
Anaplastic Large Cell Lymphoma, ALK-negative	13 (10.8)	2 (15.4)	1.9 - 45.4

Patient Population	n (%)	CR + PR (%)	95 % CI
Anaplastic Large Cell Lymphoma, ALK-positive	2 (1.7)	0 (0)	0.0 - 84.2
Enteropathy-associated T-cell Lymphoma	2 (1.7)	0 (0)	0.0 - 84.2
Extranodal NK/T-cell Lymphoma, nasal type	2 (1.7)	1 (50.0)	1.3 - 98.7
Hepatosplenic T-cell Lymphoma	2 (1.7)	0 (0)	0.0 - 84.2
Bone Marrow Involvement			
Yes	65 (54.2)	20 (30.8)	19.9 - 43.4
No	35 (29.2)	8 (22.9)	10.4 - 40.1
Indeterminate	8 (6.7)	2 (25.0)	3.2 - 65.1
Not Assessed	12 (10.0)	1 (8.3)	0.2 - 38.5
Prior Pralatrexate Therapy			
Yes	10 (8.3)	1 (10.0)	0.3 – 44.5
No	110 (91.7)	30 (27.3)	19.2 – 36.6
Response to Last Systemic Therapy			
Complete Response	29 (24.2)	14 (48.3)	29.4 – 67.5
Partial Response	21 (17.5)	6 (28.6)	11.3 – 52.2
Stable Disease	20 (16.7)	5 (25.0)	8.7 – 49.1
Progressive Disease	37 (30.8)	3 (8.1)	1.7 – 21.9
Not Evaluable	11 (9.2)	3 (27.3)	6.0 – 61.0
Unknown	2 (1.7)	0 (0.0)	0.0 – 84.2
Baseline Platelet Count			
≥100,000/µL	100 (83.3)	28 (28.0)	19.5 - 37.9
<100,000/µL	20 (16.7)	3 (15.0)	3.2 - 37.9

Abbreviations: CR = complete response, PR = partial response, CI = confidence interval, ECOG = Eastern Cooperative Oncology Group, NK = natural killer, NOS = not otherwise specified

Source: Table 14.2.3.3

Subset Analyses by Platelet Count

At Baseline, 100 patients in the **Efficacy Analysis Dataset** had platelet counts ≥100,000/µL and 20 patients had platelet counts <100, 000/µL. Among patients with a Baseline platelet count of ≥100,000/µL, the ORR was 28.0% (95% CI: 19.5-37.9; n=28). The median Duration of Response in these patients based on **IRC** was 13.6 months, median OS was 9.2 months, and median PFS was 1.8 months (Table 27).

Patients with relapsed or refractory PTCL and platelet counts <100,000/µL typically have poorer outcomes [27] and may not be eligible to participate in clinical trials or to be treated with currently approved agents for relapsed or refractory PTCL. **CLN-19**, however, enrolled patients with platelet counts <100,000/µL (≥50,000/µL). At Baseline, 20 patients in the **Efficacy Analysis Dataset** of **CLN-19** had platelet counts <100,000/µL. Importantly, 3 of these 20 patients responded to belinostat treatment with an ORR of 15.0% (95% CI 3.2-37.9), which included 1 patient who had a CR. The median Duration of Response in these patients was 4.1 months with a median OS of 4.3 months and median PFS of 1.3 months. These data are summarized in Table 27.

Table 27: Summary of IRC Assessment of Efficacy Endpoints by Baseline Platelet Count

Endpoint	All Patients (N=120)	Platelets ≥100,000/µL (N=100)	Platelets <100,000/µL (N=20)
ORR (**CPRG**), n (%)	31 (25.8)	28 (28.0)	3 (15.0)
Median DoR, months (95% CI)	13.6 (4.5-29.4)	13.6 (5.6-29.4)	4.1 (2.2-9.8)
Median PFS, months (95% CI)	1.6 (1.4-2.7)	1.8 (1.5-2.8)	1.3 (1.1-1.5)
Median OS, months (95% CI)	7.9 (6.1-13.9)	9.2 (6.4-17.7)	4.3 (2.4-7.9)
Median TTR, weeks (95% CI)	5.6 (4.3-50.4)	5.6 (4.3-50.4)	6.4 (4.3-12.7)

Abbreviations: CI=confidence interval; CPRG=Central Pathology Review Group; DoR=duration of response; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; TTR-time to response

Source: Table 14.2.3.1, Table 14.2.3.2, Table 14.2.3.3, Table 14.2.4.2, Table 14.2.4.5, Table 14.2.3.9, Table 14.2.4.7, and Table 14.2.4.8

Subset Analyses by PTCL Subtype:

The various PTCL subtypes have different response rates to various treatments. [3] AITL is known to be an aggressive PTCL subtype that has a poor prognosis with most treatment modalities. [7, 8, 9] The subgroup of patients in **CLN-19** with AITL (n=22; 18.3%) had an ORR of 45.5% (95% CI: 24.4-67.8%), and included 4 patients with CRs (Table 25; Table 26). ORRs reported in the literature for AITL patients with approved agents for PTCL range from 8%-30%. [21, 22] The ORR in the subgroup of patients with ALCL, ALK-negative (N=13; 10.8%), which also have a poor prognosis,[37] was 15.4% (95% CI: 1.9 - 45.4%), and included 1 patient with a CR (Table 26).

Subset Analysis by Baseline Bone Marrow Involvement:

Bone marrow involvement is commonly seen in patients with PTCL, and is estimated to occur in 30% of patients [26]; this patient subgroup is a more difficult to treat. [29] In **CLN-19**, the response rate among patients with bone marrow involvement at Baseline (n=65) was 30.8% (95% CI: 19.9-43.4; n=20) (Table 26).

Subset Analysis by Prior Therapy:

Patients who have failed to demonstrate a response to their prior treatment regimen have a poor prognosis and are less likely to respond to subsequent treatment. [36] Overall, patients enrolled in **CLN-19** were heavily pretreated prior study entry; the median number of prior systemic therapies was 2 (range 1-8) with 22 patients (18.3%) in the **Efficacy Analysis Dataset** having received ≥3 prior therapies.

Eight of the 70 patients who did not have a response reported for their most recent prior therapy did respond to treatment with belinostat with a response rate in this subgroup of 16% (Table 26) (Table 14.2.3.3). In addition, patients who had responded to their most recent prior systemic therapy also tended to respond to belinostat. Patients who had CR previously (n=29) had a 48.3% response rate (95% CI: 29.4-67.5) to belinostat and those with a PR to previous treatment (n=21) had a 28.6% response rate (95% CI: 11.3-52.2) to belinostat. Among the patients who had previously been treated with pralatrexate (n=10), the response rate with belinostat treatment was 10.0% (95% CI: 0.3- 44.5).

Subset Analysis by Age, Gender, ECOG Status:

Belinostat-treated patients with PTCL who were ≥ 65 years of age (n=59, 49.2%) had an ORR of 35.6% (95% CI: 23.6-49.1%) while those <65 years of age had an ORR of 16.4% (95% CI: 8.2-28.1%) (Table 26).

Forty-eight percent of the patients (n=58) enrolled in **CLN-19** were female. Belinostat-treated female patients had an ORR of 31.0% (95% CI: 19.5-44.5%) and the ORR in males was 21.0% (95% CI: 11.7-33.2%) (Table 26).

The highest response rate was reported in patients with an ECOG performance status of 2 (n=26, 21.7%) at Baseline, who had an ORR of 42.3% (95% CI: 23.4-63.1%) with belinostat (Table 26).

11.4.1.4 ***Subsequent Therapy***

Table 14.3.5.3 summarizes the therapies patients received after discontinuation in this study. A total of 77 patients (59.7%) went on to drug treatment with a subsequent therapy after discontinuing treatment with belinostat. The most common therapy was chemotherapy with gemcitabine (n=24, 18.6%). Importantly, 12 patients were able to

proceed on to stem cell transplant after treatment with belinostat, and their survival status is summarized in Table 28. Fourteen patients (10.9%) received pralatrexate as the next therapy and 5 patients (3.9%) received romidepsin.

Table 28: Survival Status of Belinostat-treated Patients who Subsequently Received a Stem Cell Transplant

Patient	Survival Status	Overall Survival (mo)
140-002	Alive	17.6
147-001	Alive	10.2
147-002	Alive	9.4
221-003	Alive	20.4
245-001	Dead	19.9
907-001	Alive	22.9
907-005	Alive	13.6
907-006	Alive	13.9
907-007	Alive	12.1
914-002	Dead	7.8
914-006	Alive	13.7
931-003	Alive	11.6

Source: Listing 16.2.6.12

11.4.2 Statistical/Analytical Issues

The primary analyses were briefly described in the protocol and additional details about statistical and analytical issues were contained in the SAP (Appendix 16.1.9).

11.4.2.1 *Adjustments for Covariates*

Not applicable.

11.4.2.2 *Handling of Dropouts or Missing Data*

Dropouts were not replaced. For the primary efficacy analysis of ORR, all patients with a missing response status or unevaluable response were conservatively classified as non-responders and were included in the denominator of the ORR (i.e., it was assumed that those patients did not achieve a CR or a PR).

For secondary survival endpoints (PFS and OS), surveillance methods were used periodically to gain further information on patients who were lost to follow-up, provided informed consent had not been withdrawn. These external data for survival follow-up were recorded on a CRF and were integrated into the clinical trial database for the affected patients. No other imputation of missing data was performed.

11.4.2.3 *Interim Analyses and Data Monitoring*

As described in Sections 6.3.3 and 9.1, the DMC met twice to review clinical data: 1) after the first 41 patients had received at least 1 dose of belinostat (25-Mar-2011, efficacy and safety assessment), and 2) at the end of study enrollment (18-Nov-2011, safety assessment). The DMC identified no safety issues and recommended continuation of the study after both meetings.

11.4.2.4 *Multicenter Studies*

There were 62 study sites that enrolled patients in this study. Since only a small number of patients were enrolled per site, data from all sites were pooled for analysis and no separate per site analysis was performed.

11.4.2.5 *Multiple Comparison/Multiplicity*

No adjustment for multiplicity was performed.

11.4.2.6 *Use of an "Efficacy Subset" of Patients.*

As described in Section 9.7.1.1, the analyses of efficacy endpoints were all based on the **Efficacy Analysis Dataset** to limit the impact of potential confounders on outcome assessment. The **Efficacy Analysis Dataset** consisted of all patients (n=120) who received at least 1 dose of belinostat and had a confirmed PTCL diagnosis on central pathology review by the **CPRG**.

11.4.2.7 *Active-Control Studies Intended to Show Equivalence*

Not applicable.

11.4.2.8 *Examination of Subgroups*

Efficacy analyses were conducted on patient subgroups based on gender, race, age, ECOG performance status, histological subtype of PTCL bone marrow involvement, prior pralatrexate treatment, response to last systemic therapy, and Baseline platelet counts as described in Section 11.4.1.3.

11.4.3 Tabulation of Individual Patient Response Data

By-patient listings of efficacy response data are included in Appendix 16.2.6. Tumor measurements, response assessments during the study, and best overall response with Duration of Response (if applicable) are presented in the following:

- Listing 16.2.6.1 Response Evaluation (**IRC**)
- Listing 16.2.6.2 Response Evaluation (Investigator Assessment)
- Listing 16.2.6.3 Target Lesions (**IRC**)

- Listing 16.2.6.4 Target Lesions (Investigator Assessment)
- Listing 16.2.6.5 Non-target and New Lesions (**IRC**)
- Listing 16.2.6.6 Non-target and New Lesions (Investigator Assessment)
- Listing 16.2.6.7 Bone Marrow Assessment
- Listing 16.2.6.8 Survival Follow-up

11.4.4 Drug Dose, Drug Concentration, and Relationships to Response

The target belinostat dose in this study was 1,000 mg/m^2 given on Days 1-5 every 21 days, and the majority of patients in the **Efficacy Analysis Dataset** (n = 112, 93%) remained at this dose for the Duration of Treatment (Section 12.1.2); 1 patient (532-002) started Cycle 1 at only 75% of the planned dose due to a low platelet count) (Listing 16.2.5.1). Of the 31 responding patients per **IRC**, 24 (20% overall, 77% of responders) patients stayed at the 1,000 mg/m^2 dose throughout the duration of their treatment, and 7 (13% overall, 5.8% of responders) had their dose reduced at some point during their treatment. Patient 142-005 had a dose reduction prior to being assessed as having a response. The remaining 6 patients (Patients 146-001, 533-001, 534-002, 541-001, 752-002, 911-001) who had a dose reduction, did so after achieving a response, and 3 of the 6 patients maintained a durable response while receiving the lower dose. Belinostat was administered within 30-45 minutes in 92% of the patients (Table 14.1.1.5). In the remaining 8% of patients, the infusion time exceeded 45 min; the majority in Cycle 1.

To fully characterize the population pharmacokinetics (PK) of belinostat and the metabolite belinostat glucuronide, data from 7 clinical studies (**CLN-19**, **TT20**, **CLN-15**, **CLN-20**, **301-G**, **CLN-4**, and **CLN-8**) were pooled; these results are briefly summarized here and are fully discussed in a separate report (Population Pharmacokinetics Report). A three-compartment (parent), one-compartment (metabolite) model with first order elimination adequately described the PK of belinostat and belinostat glucuronide. The population estimate for total clearance (CL) for belinostat was 69.7 L/hr, with an inter-individual variability (IIV) of 26.9%. Volume of distribution for the central compartment (V1) was 12.7 L. Population estimates of the inter-compartmental clearances, Q3 and Q4, were 17.4 and 1.94 L/hr, respectively. Peripheral volume of distributions for belinostat, V3 and V4, were 11.9 and 53.6 L, respectively. Since belinostat glucuronide was not administered alone and the true fraction of belinostat converted to belinostat glucuronide in humans (Fmet) is unknown, the volume of distribution of belinostat glucuronide (V2) was simplified and fixed to 1 L. Estimated Fmet ($Fmet_{est}$) was calculated as the ratio of the fraction of belinostat converted to belinostat glucuronide to the distribution volume of belinostat glucuronide

(Fmet/V2). The population estimate of $Fmet_{est}$ was 0.066 L^{-1} and clearance of belinostat glucuronide (CLM) was 0.461 L/hr. IIV on CLM was 32.6%.

Of the several covariates tested, the effect of height on clearance was the only significant covariate relationship identified. Inclusion of this covariate only resulted in a modest decrease (1.0%) in the IIV associated with CL, which likely has no clinical relevance. In general, the final model adequately fit the data.

Additionally, an exposure-efficacy analysis for **CLN-19** and exposure-safety analysis based on monotherapy studies was performed as a part of the Population Pharmacokinetic study. Different exposure metrics (C_{min}, C_{max}, AUC) were evaluated to identify any potential associations with efficacy and safety endpoints. The belinostat exposure-efficacy logistic regression analysis was performed based on the data from **CLN-19** patients with relapsed or refractory PTCL treated with belinostat 1,000 mg/m^2 on Day 1-5 in a 21-day cycle, a dose and schedule that was determined in earlier studies. In this analysis, relationship between different exposure metrics (AUC, C_{max} and C_{min}) and response endpoints (CR and PR) were analyzed. Analysis of data from 120 evaluable patients showed no relationship between belinostat exposure and response in this patient population; this is not unexpected given that only a single dose (1,000 mg/m^2) was included in this study. These results are summarized in a separate report (Population Pharmacokinetics Report).

To perform an exposure-safety analysis, data from the following studies: **CLN-19** (n=123), **TT20** (n=41), **CLN-20** (n=17) and **301-G** (n=6) were integrated. The **CLN-4**, **CLN-8** and **CLN-15** studies were not included in the exposure-safety analysis because each of these studies used belinostat in combination with other chemotherapeutic agents (5-FU, CaP or idarubicin, respectively). The exposure-safety analysis was performed using a regression analysis. AEs with >5% incidence were evaluated in this analysis, including anemia, dyspnea, neutropenia, fatigue, pneumonia, and thrombocytopenia. AUC, $C_{max,}$ and C_{min} were the exposure metrics used in this analysis.

Based on the exposure-safety analysis data from 187 patients treated with belinostat, the only AE that AUC was a predictor for was fatigue. No exposure relationship was found with regard to other exposure metrics and AEs (Population Pharmacokinetics Report).

In addition, the effect of belinostat exposure on cardiac safety was done as a part of integrated summary of cardiac safety. Data from all clinical studies where there was an interpretable QTc change from Baseline and where plasma concentrations were available were paired and analyzed to determine possible exposure-safety relationship. Analysis of data from a total of 308 patients showed there was no effect of belinostat exposure on cardiac repolarization (Integrated Cardiac Safety Report).

11.4.5 Drug-Drug and Drug-Disease Interactions

Patients received a variety of concomitant medications over the course of the study (Table 14.3.5.4). Although correlations between concomitant drugs and the relationship with study endpoints were not performed, concomitant medications were covariates in the population pharmacokinetics analysis and not correlation was observed. In addition, PTCL is a heterogeneous group of clinically aggressive, rare hematologic malignancies with various disease characteristics; therefore, due to small sample sizes of the various subtypes correlations between drug-disease interactions were not performed.

11.4.6 By-Patient Displays

By-patient listings provided as appendices are cited in each applicable section throughout Section 11. The response listings are described in Section 11.4.3. PK test results are provided in the Population PK Report.

11.4.7 Efficacy Conclusions

Belinostat treatment of heavily pretreated patients with relapsed or refractory PTCL produced a clinically meaningful ORR of 25.8% with 10.8% of patients achieving a CR and 15.0% of patients achieving a PR. The reported ORRs for pralatrexate (29%) and romidepsin (25%) were comparable [22]. Most belinostat-treated patients (61.3% of responders) responded at the first scheduled tumor assessment within 30-45 days of the first dose, with a median Time to Response of 5.6 weeks. The ORR observed with belinostat was durable with a median Duration of Response by IWG criteria of 13.6 months. Belinostat treated patients had a 63.5% probability of being in response at 6 months. The median PFS, based on response as assessed by the **IRC** and estimated by the Kaplan-Meier method, was 1.6 months (95% CI: 1.4-2.7) and the median TTP was 2.0 months (95% CI: 1.5-2.8). The median OS, estimated by the Kaplan-Meier method, was 7.9 months (95% CI: 6.1-13.9). Importantly, nearly 40% of the patients (n=46) were censored for OS because they were still alive at the time of the data cut-off date.

The ORR in patients with Baseline platelet counts ≥100,000/μL was 28.0% based on **IRC** assessment with a median Duration of Response of 13.6 months, median OS of 9.2 months, and median PFS of 1.8 months. Importantly, responses were also seen in PTCL patients with low Baseline platelet counts (<100,000/μL), who would not have been candidates for the other approved PTCL therapies, with an ORR of 15.0% that included 1 patient with a CR; the median Duration of Response in these patients was 4.1 months with a median OS of 4.3 months and median PFS of 1.3 months.

In addition, clinically meaningful ORRs were observed in patients with poor prognosis PTCL subtypes including AITL (45.5%) or those with bone marrow involvement at Baseline (22.9%). Even patients who had failed to respond to their last prior systemic

therapy had a response rate of 15.7% to belinostat. One patient, who had previously failed pralatrexate, had a response to belinostat treatment.

Attainment of a durable response is the desired goal of treatment for patients with relapsed or refractory PTCL, because it offers the opportunity for these patients to undergo a subsequent stem cell transplant; the only recognized and potentially curative approach for relapsed/refractory PTCL. With current PTCL treatment modalities, many of these patients never achieve remissions and, therefore, do not have the opportunity to optimize their outcome with a stem cell transplant. It is important, therefore, to note that 12 belinostat-treated patients with relapsed or refractory PTCL in this study were able to proceed to stem cell transplant. Following belinostat treatment, formal response assessments were not conducted after the start of any subsequent therapy, however; 10/12 (83.3%) of these patients remained alive as of 31-Aug-2012.

Based on data from **CLN-19**, belinostat demonstrated clinically meaningful efficacy for the treatment of patients with relapsed or refractory PTCL. The availability of an effective new drug approved for these patients with PTCL would provide an important additional treatment option, and belinostat could allow some of these patients to become candidates for potentially curative treatment with stem cell transplantation. The approval of belinostat could also facilitate subsequent studies of new combination therapies that may further optimize the outcomes for these patients, and permit the development of a new standard treatment paradigm specific for relapsed or refractory PTCL. This approach of combining single-agent drugs specific to and approved for T-cell diseases could mimic the success of R-CHOP, which importantly improved outcomes for patients with B-cell neoplasms. In addition as discussed below, the safety profile observed with belinostat monotherapy supports the clinical benefit of this agent and the feasibility of future studies with belinostat in combination with other active T-cell cytotoxic agents.

12 SAFETY EVALUATION

All safety analyses were performed on the **Full Analysis Dataset,** which included all 129 patients who received at least 1 dose of belinostat. The **Full Analysis Dataset** includes a subgroup of 24 patients with Baseline platelet counts <100,000/μL.

12.1 Extent of Exposure

An overall summary of the extent of belinostat exposure is provided in Table 29 for the **Full Analysis Dataset** and the subgroup of patients with Baseline platelet counts <100,000/μL.

Table 29: Summary of Extent of Exposure of Patients in the Full Analysis Dataset

Patient Population	Full Analysis Dataset (N=129)	Subgroup With Baseline Platelets <100,000/μL (N=24) n (%)
Total Duration of Treatment *(weeks)*		
Mean (std dev)	18.2 (25.56)	9.0 (11.44)
Median	7.0	6.0
Range	3 - 135	3 - 55
Number of Patients by Number of Completed Treatment Cycles Received *(%)*		
Cycle 1	122 (94.6)	22 (91.7)
Cycle 2	89 (69.0)	14 (58.3)
Cycle 3	60 (46.5)	4 (16.7)
Cycle 4	49 (38.0)	3 (12.5)
Cycle 5	37 (28.7)	3 (12.5)
Cycle 6	35 (27.1)	3 (12.5)
Cycle 7	28 (21.7)	2 (8.3)
Cycle 8	23 (17.8)	2 (8.3)
Cycle 9	20 (15.5)	1 (4.2)
Cycle 10	20 (15.5)	1 (4.2)
Cycle 11	17 (13.2)	1 (4.2)
Cycle 12	15 (11.6)	1 (4.2)
Cycle 13	14 (10.9)	1 (4.2)
Cycle 14	14 (10.9)	1 (4.2)
Cycle 15	13 (10.1)	1 (4.2)

Patient Population	Full Analysis Dataset (N=129)	Subgroup With Baseline Platelets <100,000/µL (N=24) n (%)
Cycle 16	13 (10.1)	1 (4.2)
Cycle 17	13 (10.1)	1 (4.2)
Cycle 18	12 (9.3) [b]	1 (4.2)[a]
Cycle 19	11 (8.5)	0 (0)
Cycle 20	9 (7.0)	0 (0)
Cycle 21	8 (6.2)	0 (0)
Cycle 22	7 (5.4) [a]	0 (0)
Cycle 23	6 (4.7)	0 (0)
Cycle 24	5 (3.9)	0 (0)
Cycle 25	5 (3.9) [a]	0 (0)
Cycle 26	4 (3.1)	0 (0)
Cycle 27	4 (3.1)	0 (0)
Cycle 28	4 (3.1)	0 (0)
Cycle 29	4 (3.1) [a]	0 (0)
Cycle 30	2 (1.6)	0 (0)
Cycle 31	2 (1.6) [a]	0 (0)
Cycle 32	1 (0.8)	0 (0)
Cycle 33	1 (0.8)[a]	0 (0)
Number of Patients Treated with Belinostat (%)		
≥ 3 months	46 (35.7)	3 (12.5)
≥ 6 months	23 (17.8)	2 (8.3)
≥ 12 months	13 (10.1)	1 (4.2)
Number of Treatment Cycles Administered		
Mean (std dev)	5.4 (6.91)	2.8 (3.62)
Median	2.0	2.0
Range	1 - 33	1 - 18
Number of Belinostat Doses Administered		
Mean (std dev)	26.6 (34.49)	13.8 (18.20)
Median	10.0	10.0
Range	1 - 165	3 - 90

Patient Population	Full Analysis Dataset (N=129)	Subgroup With Baseline Platelets <100,000/µL (N=24) n (%)
Total Cumulative Dose of Belinostat *(g/m²)*		
Mean (std dev)	26.0 (33.37)	13.5 (18.36)
Median	10.5	9.3
Range	1 - 164	3 - 91
Relative Dose Intensity *(%)*		
Mean (std dev)	91.82 (13.167)	89.45 (13.825)
Median	98.30	98.50
Range	19.9 - 105.2	54.9 - 102.6

[a] 1 patient in this group continued on treatment as of cut-off date.

[b] 2 patients in this group continued on treatment as of cut-off date.

Abbreviation: std dev = standard deviation

Source: Table 14.1.1.3, Table 14.1.1.4, Table 14.3.5.1, Table 14.3.5.6

12.1.1 Duration of Exposure

Table 14.3.5.1 summarizes the extent of exposure for all patients (**Full Analysis Dataset**) and Table 14.3.5.6 summarizes the extent of exposure in the subgroups by Baseline platelet count. Details of dosing are presented by patient in Listing 16.2.5.1.

The median Duration of Treatment was 7.0 weeks (range 3.0-135.0 weeks) for all treated patients. Seven patients remained on treatment at the time of data cut-off; therefore, the mean treatment duration will continue to increase until the last patient is off study. The median number of cycles administered to patients (based on cycles initiated) was 2 (range 1-33). Eighty-nine (69%) patients completed 2 belinostat treatment cycles. Twenty-three (17.8%) patients were treated with belinostat for ≥6 months (8.7 cycles), and 13 (10.1%) patients (Patients 146-001, 207-001, 220-002, 244-003, 516-004, 534-002, 534-003, 534-004, 534-005, 534-006, 541-001, 543-001, 915-001) were treated for ≥ 1 year. The median number of belinostat doses administered to patients was 10 (range 1-165) (Table 29). For the subgroup of 24 patients with Baseline platelets < 100,000/µL in the **Full Analysis Dataset**, 3 patients completed 6 cycles and 1 patient completed 18 cycles of treatment (Table 14.1.1.4).

12.1.2 Belinostat Dose

For all patients (**Full Analysis Dataset**), the median total cumulative belinostat dose administered per patient was 10,500 mg/m^2. The relative dose intensity was 98.3%

demonstrating that the vast majority of patients were able to tolerate and receive all intended treatment at the target dose (Table 29). The reasons for dose modification per the protocol are discussed in detail in Section 12.1.2.1 and are summarized in Table 14.3.5.2. The most frequent form of dose modification due to AEs was a cycle delay of ≥7 days; the reasons for these dose delays are summarized in Table 30. The target belinostat dose in this study was 1,000 mg/m^2 for 5 consecutive days repeated every 21 days, and the majority of patients (n=113, 87.6%) remained at this dose for the duration of treatment.

For the subgroup of patients with Baseline platelets <100,000/µL in the **Full Analysis Dataset**, the median total cumulative dose administered was 9,300 mg/m^2. The relative dose intensity was 98.5% demonstrating that the vast majority of patients in this subgroup were also able to tolerate and receive all intended treatment at the target dose despite their low platelet counts at the start of dosing (Table 29). Among patients with Baseline platelets <100,000/µL, 4 patients had a single dose reduction. Six patients had a cycle delay of ≥7 days as a dose modification due to AEs. The reasons for these dose delays are also summarized in Table 30 and Table 14.3.5.5.

12.1.2.1 *Reasons for Dose Modification*

Thirty-seven patients (28.7%) in the **Full Analysis Dataset** had a cycle delay of ≥7 days, and reasons for these cycle delays are summarized in Table 30. The most frequent reason for delay was due to holidays (n=5, 3.9%). Fever, rash, and upper respiratory infection caused a ≥7 day cycle delay in 2 patients (1.6%) each. Reasons for the cycle delays were unknown in 11 patients (8.5%). Twenty-seven (20.9%) patients missed 1 or more doses in a cycle, and 4 patients (3.1%) had a dose delay of ≥3 days within a cycle (Table 14.3.5.2). A total of 22 patients (17.1%) had infusion interruptions.

The protocol allowed for a maximum of 2 dose reductions. For 1 patient, the belinostat dose was reduced from 1,600 mg to 1,200 mg starting from Cycle 1, Day 1. The belinostat dose was reduced from 1,000 mg/m^2 to 750 mg/m^2 for 16 patients (12.4%), and further reduced[a] to 560 mg/m^2 for only 1 patient (0.8%). Table 31 summarizes the reasons for all dose reductions. Dose reduction due to a prolonged QTc was reported as the reason for dose reduction in 2 patients and an increase in transaminases were also reported in 2 patients; other AE terms reported were in 1 patient each.

For the subgroup of patients with Baseline platelet counts ≥50,000 to <100,000/µL in the **Full Analysis Dataset**, 6 patients (25.0%) had a cycle delay of ≥7 days, which are summarized in Table 30. A single dose reduction of 25% to 750 mg/m^2 was reported for 4 patients in this subgroup due to hypoglycemia, neutropenia, pancytopenia, and

[a] Cause of the second dose reduction was prolonged QTc

thrombocytopenia (Table 31). Among the subgroup of patients with Baseline platelets <100,000/µL, 5 (20.8%) patients missed 1 or more doses in a cycle (Table 14.3.5.5). A total of 3 (12.5%) patients had infusion interruptions due to extravasation, hypersensitivity, or nausea.

Table 30: Summary of Reasons for Cycle Delay of >7 Days in Full Analysis Dataset Patients

Patient Population	Full Analysis Dataset (N=129) n (%)	Subgroup of Patients with Baseline Platelets <100,000/µL (N=24) n (%)
Patients with Cycle Delay of 7+ Days	**37 (28.7)**	**6 (25.0)**
Causes for First Cycle Delay of 7+ Days		
Holiday	5 (3.9)	1 (4.2)
Fever	2 (1.6)	1 (4.2)
Rash	2 (1.6)	0 (0)
Upper Respiratory Infection	2 (1.6)	0 (0)
Alveolitis	1 (0.8)	0 (0)
Bronchitis	1 (0.8)	0 (0)
Bronchopneumonia	1 (0.8)	1 (4.2)
Congestive Heart Failure	1 (0.8)	0 (0)
Fatigue	1 (0.8)	0 (0)
Immune Hemolytic Anemia	1 (0.8)	0 (0)
Malaise	1 (0.8)	0 (0)
Pancytopenia	1 (0.8)	1 (4.2)
Patient Request	1 (0.8)	0 (0)
Pneumonia	1 (0.8)	0 (0)
Pulmonary embolus	1 (0.8)	0 (0)
Septic Shock	1 (0.8)	0 (0)
Thrombocytopenia	1 (0.8)	1 (4.2)
Vein access	1 (0.8)	0 (0)
Ventricular Extrasystoles	1 (0.8)	0 (0)
Unknown	11 (8.5)	1 (4.2)

Source: Table 14.3.5.2, Table 14.3.5.5

Table 31: Summary of Reasons for Dose Reduction

Patient Population	Full Analysis Dataset (N=129) n (%)	Subgroup of Patients with Baseline Platelets <100,000/µL (N=24) n (%)
Patients with 1 Dose Reduction of 25% to 750 mg/m^2	**16 (12.4)**	**4 (16.7)**
Causes for First Dose Reduction		
Prolonged QTc	2 (1.6)	0 (0)
Transaminases Increased	2 (1.6)	0 (0)
Bronchospasm	1 (0.8)	0 (0)
Dyspnea	1 (0.8)	0 (0)
Hyperbilirubinemia	1 (0.8)	0 (0)
Hypoglycemia	1 (0.8)	1 (4.2)
Hypokalemia	1 (0.8)	0 (0)
Immune Hemolytic Anemia	1 (0.8)	0 (0)
Nausea	1 (0.8)	0 (0)
Neutropenia	1 (0.8)	1 (4.2)
Pancytopenia	1 (0.8)	1(4.2)
Pulmonary Embolus	1 (0.8)	0 (0)
Rash	1 (0.8)	0 (0)
Thrombocytopenia	1 (0.8)	1 (4.2)
Patients with 2 dose reductions of 25% each to 560 mg/m^2	**1 (0.8)**	**0 (0)**
Causes for Second Dose Reduction		
Prolonged QTc	1 (0.8)	0 (0)

Abbreviation: QTc = corrected QT
Source: Table 14.3.5.2, Table 14.3.5.5

12.1.3 Concomitant Medications

Concomitant medications taken by patients while on belinostat treatment are summarized by the first and second level anatomical therapeutic chemical (ATC) code in Table 14.3.5.4 and the individual medications are listed by patient in Listing 16.2.5.2. Sites were instructed to record the generic names for concomitant medications, however, occasionally the trade names were recorded and these remain as the verbatim terms in Listing 16.2.5.2.

The most frequently used concomitant medications were consistent with those expected to treat AEs resulting from HDAC treatment and symptoms of the underlying disease and included antiemetics and antinauseants (n=101, 78.3%), analgesics (n=90, 69.8%), antacids and drugs for the treatment of peptic ulcers and flatulence (n=88, 68.2%), and corticosteroids (systemic use; n=83, 64.3%).

12.2 Adverse Events

12.2.1 Brief Summary of Adverse Events

AEs regardless of causality were collected for all patients from the time of first dose and through the 30-day follow-up period. An overall summary of the TEAEs observed in this study is presented in Table 32. A TEAE was defined as an event with an onset date and time on or after the first dosing start date and time, or on or after the first dosing start date if the onset time was missing.

A total of 125 of the 129 (96.9%) patients enrolled reported treatment-emergent AEs in this study. Overall, the incidence of Grade 3-4 AEs was 61.2% with 10/129 (7.8%) patients having AEs resulting in death. A total of 61 (47.3%) patients reported SAEs and 25 (19.4%) patients had an AE leading to withdrawal from the study.

Treatment-related AEs were reported in 83.7% of patients and 34.1% of patients had Grade 3-4 AEs. Only 1 (0.8%) patient had a treatment-related AE that was associated with death. Treatment-related SAEs were reported in 27 (20.9%) patients and 14 (10.9%) patients had a treatment-related AE leading to study withdrawal.

Table 32: Overall Summary of Safety

Adverse Event Category	Full Analysis Dataset (N=129) n (%[a])
Treatment Emergent Adverse Events (TEAEs)[b]	
TEAEs	125 (96.9)
Any Grade 3-4 TEAEs	79 (61.2)
All Deaths	22 (17.1)
TEAEs Resulting in Death	10 (7.8)
All Serious TEAEs	61 (47.3)
Serious TEAEs other than death	58 (45.0)
Any TEAEs Leading to Withdrawal	25 (19.4)
SAEs Leading to Withdrawal	14 (10.9)
Other TEAEs Leading to Withdrawal	11 (8.5)
Related TEAEs[c]	
All Treatment-related TEAEs	108 (83.7)
All Grade 3-4 Treatment-related TEAE	44 (34.1)
Treatment-related TEAEs Resulting in Death	1 (0.8)
All Serious Related TEAEs	27 (20.9)
Serious TEAEs other than death	27 (20.9)
All Related TEAEs Leading to Withdrawal	14 (10.9)
Related SAEs Leading to Withdrawal	9 (7.0)
Other Related TEAEs Leading to Withdrawal	5 (3.9)

[a] Percentages are based on the total numbers of patients in each AE category.

[b] Treatment emergent AEs are those AEs that occur or worsen on or after first study treatment up through 30 days post last study treatment, and/or any treatment-related adverse events, regardless of the onset date.

[c] Treatement-related TEAEs are those with 'Possible', 'Probable', 'Definite', or 'Related' relationship to study treatment(s) per the Investigators.

Abbreviations: SAE=serious adverse event; TEAE=treatment-emergent adverse event

Source: Tables 14.3.6.1, 14.3.7.1, 14.3.7.2, 14.3.7.9, 14.3.7.10, 14.3.7.4

12.2.2 Display of Adverse Events

Displays of treatment-emergent AEs are presented in the following tables:

- Overview of AEs in Table 14.3.6.1
- AEs by SOC, total and Grades 3-5 in Table 14.3.6.2 and Table 14.3.6.9
- AEs by Preferred Term, total and Grades 3-5 in Table 14.3.6.3 and Table 14.3.6.10

- AEs by SOC and Preferred Term, all grades in Table 14.3.6.4 and Table 14.3.6.11
- Treatment-related AEs by SOC, total and Grades 3-5 in Table 14.3.6.5
- Treatment-related AEs by preferred term, total and Grades 3-5 in Table 14.3.6.6
- Treatment-related AEs by SOC and Preferred Term, all grades in Table 14.3.6.7 and Table 14.3.6.12

12.2.3 Analysis of Adverse Events

AE verbatim terms were converted to MedDRA Preferred Term and summarized by worst severity (grade). The following sections provide summaries of all TEAEs regardless of causality, treatment-related AEs, and SAEs including deaths. In addition, a summary of TEAEs resulting in study treatment discontinuation is provided in Table 45.

12.2.3.1 *Adverse Events by MedDRA System Organ Class*

The incidence of TEAEs in each MedDRA SOC is presented in Table 33; incidence by SOC and Preferred Term is presented in Table 34.

The SOCs with the highest incidence of TEAEs (>40%) by All Grades (Table 14.3.6.2) included the General Disorders and Administration Site Conditions (n=103, 79.8%); Gastrointestinal Disorders (n=93, 72.1%); Infections and Infestations (n=64, 49.6%); Investigations (n =63, 48.8%); Blood and Lymphatic System Disorders (n=62, 48.1%); Metabolism and Nutrition Disorders (n=61, 47.3%), Respiratory, Thoracic, and Mediastinal Disorders (n=60, 46.5%); and Skin and Subcutaneous Tissue Disorders (n=56, 43.4%) SOCs.

The highest incidence of Grade 3-4 TEAEs (>10%) was in the Blood and Lymphatic System Disorders (n=33, 25.6%); Infections and Infestations (n=23, 17.8%); Investigations (n =22, 17.1%); Metabolism and Nutrition Disorders (n=17, 13.2%), General Disorders and Administration Site Conditions (n=16, 12.4%), Respiratory, Thoracic, and Mediastinal Disorders (n=16, 12.4%); and Vascular Disorders (n=13, 10.1%) SOCs; all other Grade 3-4 TEAEs were reported in less than 10% of patients (Table 14.3.6.2).

Grade 5 TEAEs were reported in more than a single patient only in the General Disorders and Administration Site Conditions (n=4, 3.1%); Infections and Infestations (n=2, 1.6%); and Cardiac Disorders (n=2, 1.6%) SOCs (Table 14.3.6.2).

Table 33: Adverse Events by MedDRA System Organ Class and Grade in Decreasing Frequency by All Grades (Full Analysis Dataset)

MedDRA System Organ Class (SOC)	Full Analysis Dataset (N=129)			
	All Grades n (%)	Grades 1-2 n (%)	Grades 3-4 n (%)	Grade 5 n (%)
All Adverse Events	**125 (96.9)**	**124 (96.1)**	**79 (61.2)**	**11 (8.5)**
General Disorders and Administration Site Conditions	103 (79.8)	83 (64.3)	16 (12.4)	4 (3.1)
Gastrointestinal Disorders	93 (72.1)	84 (65.1)	8 (6.2)	1 (0.8)
Infections and Infestations	64 (49.6)	39 (30.2)	23 (17.8)	2 (1.6)
Investigations	63 (48.8)	41 (31.8)	22 (17.1)	0 (0)
Blood and Lymphatic System Disorders	62 (48.1)	29 (22.5)	33 (25.6)	0 (0)
Metabolism and Nutrition Disorders	61 (47.3)	44 (34.1)	17 (13.2)	0 (0)
Respiratory, Thoracic and Mediastinal Disorders	60 (46.5)	44 (34.1)	16 (12.4)	0 (0)
Skin and Subcutaneous Tissue Disorders	56 (43.4)	47 (36.4)	9 (7.0)	0 (0)
Vascular Disorders	50 (38.8)	36 (27.9)	13 (10.1)	1 (0.8)
Musculoskeletal and Connective Tissue Disorders	45 (34.9)	36 (27.9	9 (7.0)	0 (0)
Nervous System Disorders	45 (34.9)	42 (32.6)	3 (2.3)	0 (0)
Psychiatric Disorders	29 (22.5)	25 (19.4)	4 (3.1)	0 (0)
Injury, Poisoning and Procedural Complications	16 (12.4)	14 (10.9)	2 (1.6)	0 (0)
Eye Disorders	15 (11.6)	13 (10.1)	2 (1.6)	0 (0)
Cardiac Disorders	13 (10.1)	9 (7.0)	2 (1.6)	2 (1.6)
Renal and Urinary Disorders	13 (10.1)	11 (8.5)	2 (1.6)	0 (0)
Neoplasms Benign, Malignant and Unspecified (includes cysts and polyps)	11 (8.5)	8 (6.2)	3 (2.3)	0 (0)
Hepatobiliary Disorders	8 (6.2)	5 (3.9)	2 (1.6)	1 (0.8)
Ear and Labyrinth Disorders	6 (4.7)	6 (4.7)	0 (0)	0 (0)
Immune System Disorders	3 (2.3)	2 (1.6)	1 (0.8)	0 (0)
Reproductive System and Breast Disorders	3 (2.3)	3 (2.3)	0 (0)	0 (0)
Surgical and Medical Procedures	1 (0.8)	1 (0.8)	0 (0)	0 (0)

Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities
Source: Tables 14.3.6.1, 14.3.6.2

Table 34: Adverse Event Incidence Occurring in ≥5% of Patients by MedDRA System Organ Class, Preferred Term and Grade in Decreasing Frequency by All Grades (Worst Grade per Patient) (Full Analysis Dataset)

MedDRA SOC and Preferred Term	Full Analysis Dataset (N=129)					
	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)
General Disorders and Administration Site Conditions						
Fatigue	48 (37.2)	22 (17.1)	19 (14.7)	7 (5.4)	0 (0)	0 (0)
Pyrexia	45 (34.9)	25 (19.4)	17 (13.2)	3 (2.3)	0 (0)	0 (0)
Edema Peripheral	26 (20.2)	20 (15.5)	6 (4.7)	0 (0)	0 (0)	0 (0)
Chills	21 (16.3)	15 (11.6)	5 (3.9)	1 (0.8)	0 (0)	0 (0)
Infusion Site Pain	18 (14.0)	9 (7.0)	9 (7.0)	0 (0)	0 (0)	0 (0)
Asthenia	12 (9.3)	3 (2.3)	5 (3.9)	3 (2.3)	1 (0.8)	0 (0)
Pain	12 (9.3)	8 (6.2)	2 (1.6)	1 (0.8)	1 (0.8)	0 (0)
Gastrointestinal Disorders						
Nausea	54 (41.9)	35 (27.1)	18 (14.0)	1 (0.8)	0 (0)	0 (0)
Vomiting	37 (28.7)	26 (20.2)	10 (7.8)	1 (0.8)	0 (0)	0 (0)
Constipation	30 (23.3)	23 (17.8)	6 (4.7)	1 (0.8)	0 (0)	0 (0)
Diarrhea	29 (22.5)	19 (14.7)	8 (6.2)	2 (1.6)	0 (0)	0 (0)
Abdominal Pain	14 (10.9)	4 (3.1)	9 (7.0)	1 (0.8)	0 (0)	0 (0)
Abdominal Pain Upper	7 (5.4)	3 (2.3)	3 (2.3)	1 (0.8)	0 (0)	0 (0)
Infections and Infestations						
Bronchitis	11 (8.5)	6 (4.7)	2 (1.6)	3 (2.3)	0 (0)	0 (0)
Pneumonia	10 (7.8)	0 (0)	2 (1.6)	7 (5.4)	0 (0)	1 (0.8)
Upper Respiratory Tract Infection	10 (7.8)	7 (5.4)	2 (1.6)	1 (0.8)	0 (0)	0 (0)
Nasopharyngitis	7 (5.4)	7 (5.4)	0 (0)	0 (0)	0 (0)	0 (0)
Sinusitis	7 (5.4)	3 (2.3)	3 (2.3)	1 (0.8)	0 (0)	0 (0)
Infection	6 (4.7)	1 (0.8)	1 (0.8)	3 (2.3)	1 (0.8)	0 (0)

MedDRA SOC and Preferred Term	Full Analysis Dataset (N=129)					
	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)
Investigations						
Blood Lactate Dehydrogenase Increased	20 (15.5)	14 (10.9)	4 (3.1)	1 (0.8)	1 (0.8)	0 (0)
Electrocardiogram QT Prolonged	14 (10.9)	5 (3.9)	4 (3.1)	5 (3.9)	0 (0)	0 (0)
Aspartate Aminotransferase Increased	9 (7.0)	4 (3.1)	1 (0.8)	4 (3.1)	0 (0)	0 (0)
Blood Creatinine Increased	9 (7.0)	2 (1.6)	7 (5.4)	0 (0)	0 (0)	0 (0)
Platelet Count Decreased	9 (7.0)	3 (2.3)	2 (1.6)	1 (0.8)	3 (2.3)	0 (0)
Alanine Aminotransferase Increased	8 (6.2)	3 (2.3)	1 (0.8)	4 (3.1)	0 (0)	0 (0)
Blood Alkaline Phosphatase Increased	7 (5.4)	4 (3.1)	2 (1.6)	1 (0.8)	0 (0)	0 (0)
Weight Decreased	7 (5.4)	4 (3.1)	3 (2.3)	0 (0)	0 (0)	0 (0)
Blood and Lymphatic System Disorders						
Anemia	41 (31.8)	7 (5.4)	20 (15.5)	8 (6.2)	6 (4.7)	0 (0)
Thrombocytopenia	21 (16.3)	7 (5.4)	5 (3.9)	0 (0)	9 (7.0)	0 (0)
Leukopenia	12 (9.3)	3 (2.3)	6 (4.7)	0 (0)	3 (2.3)	0 (0)
Neutropenia	12 (9.3)	2 (1.6)	2 (1.6)	5 (3.9)	3 (2.3)	0 (0)
Lymphopenia	11 (8.5)	1 (0.8)	4 (3.1)	5 (3.9)	1 (0.8)	0 (0)
Febrile Neutropenia	7 (5.4)	1 (0.8)	0 (0)	6 (4.7)	0 (0)	0 (0)
Metabolism and Nutrition Disorders						
Decreased appetite	19 (14.7)	13 (10.1)	3 (2.3)	3 (2.3)	0 (0)	0 (0)
Hypokalemia	16 (12.4)	7 (5.4)	4 (3.1)	5 (3.9)	0 (0)	0 (0)
Hyperglycemia	12 (9.3)	6 (4.7)	3 (2.3)	3 (2.3)	0 (0)	0 (0)
Hypoalbuminemia	10 (7.8)	6 (4.7)	2 (1.6)	2 (1.6)	0 (0)	0 (0)
Hyperuricemia	8 (6.2)	8 (6.2)	0 (0)	0 (0)	0 (0)	0 (0)
Hypomagnesemia	7 (5.4)	7 (5.4)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, Thoracic and Mediastinal Disorders						

MedDRA SOC and Preferred Term	Full Analysis Dataset (N=129)					
	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)
Dyspnea	28 (21.7)	12 (9.3)	8 (6.2)	8 (6.2)	0 (0)	0 (0)
Cough	24 (18.6)	17 (13.2)	7 (5.4)	0 (0)	0 (0)	0 (0)
Oropharyngeal Pain	8 (6.2)	6 (4.7)	2 (1.6)	0 (0)	0 (0)	0 (0)
Skin and Subcutaneous Tissue Disorders						
Rash	26 (20.2)	17 (13.2)	8 (6.2)	1 (0.8)	0 (0)	0 (0)
Pruritus	21 (16.3)	10 (7.8)	7 (5.4)	3 (2.3)	1 (0.8)	0 (0)
Night sweats	8 (6.2)	6 (4.7)	2 (1.6)	0 (0)	0 (0)	0 (0)
Hyperhidrosis	7 (5.4)	2 (1.6)	5 (3.9)	0 (0)	0 (0)	0 (0)
Vascular Disorders						
Hypotension	13 (10.1)	4 (3.1)	5 (3.9)	3 (2.3)	1 (0.8)	0 (0)
Phlebitis	13 (10.1)	2 (1.6)	10 (7.8)	1 (0.8)	0 (0)	0 (0)
Flushing	9 (7.0)	7 (5.4)	2 (1.6)	0 (0)	0 (0)	0 (0)
Hypertension	7 (5.4)	5 (3.9)	2 (1.6)	0 (0)	0 (0)	0 (0)
Musculoskeletal and Connective Tissue Disorders						
Pain In Extremity	11 (8.5)	4 (3.1)	6 (4.7)	1 (0.8)	0 (0)	0 (0)
Muscle Spasms	9 (7.0)	5 (3.9)	3 (2.3)	1 (0.8)	0 (0)	0 (0)
Back Pain	7 (5.4)	4 (3.1)	1 (0.8)	2 (1.6)	0 (0)	0 (0)
Arthralgia	6 (4.7)	3 (2.3)	2 (1.6)	1 (0.8)	0 (0)	0 (0)
Nervous System Disorders						
Headache	19 (14.7)	15 (11.6)	4 (3.1)	0 (0)	0 (0)	0 (0)
Dizziness	13 (10.1)	10 (7.8)	3 (2.3)	0 (0)	0 (0)	0 (0)
Neuropathy Peripheral	10 (7.8)	8 (6.2)	1 (0.8)	1 (0.8)	0 (0)	0 (0)
Psychiatric Disorders						
Insomnia	9 (7.0)	4 (3.1)	3 (2.3)	1 (0.8)	1 (0.8)	0 (0)
Anxiety	8 (6.2)	3 (2.3)	3 (2.3)	2 (1.6)	0 (0)	0 (0)
Depression	6 (4.7)	0 (0)	5 (3.9)	1 (0.8)	0 (0)	0 (0)

Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities
Source: Table 14.3.6.4

12.2.3.1.1 General Disorders and Administration Site Conditions

TEAEs were reported in the General Disorders and Administration Site Conditions SOC in 103 (79.8%) patients (Table 33). The AEs reported most often in this SOC were fatigue (n=48, 37.2%), pyrexia (n=45, 34.9%) and peripheral edema (n=26, 20.2%) (Table 34).

The majority of AEs were Grade 1-2 (64.3%) followed by 12.4% Grade 3-4 and 3.1% Grade 5. There was 1 Grade 4 event of asthenia and 1 Grade 4 event of pain. Grade 5 AEs were reported in 4 (3.1%) patients in this SOC, including 3 patients with AEs of multi-organ failure and 1 of euthanasia (Section 12.3).

12.2.3.1.2 Gastrointestinal Disorders

TEAEs were reported in the Gastrointestinal Disorders SOC in 93 (72.1%) patients (Table 33). Nausea was the most common AE reported in this SOC (n=54, 41.9%); all occurrences were Grade 1 (n=35, 21.7%) or Grade 2 (n=18, 14.0%) except for 1 (0.8%) patient with a Grade 3 AE. The other AEs reported most often included vomiting (n=37, 28.7%), constipation (n=30, 23.3%), and diarrhea (n=29, 22.5%) (Table 34).

The majority of AEs in this SOC were Grade 1-2 (65.1%) followed by 6.2% Grade 3-4 and 0.8% Grade 5; there were no Grade 4 AEs. The 1 (0.8%) patient (Patient 244-002) with a Grade 5 AE in this SOC died of a gastrointestinal hemorrhage (Section 12.3).

12.2.3.1.3 Infections and Infestations

TEAEs were reported in the Infections and Infestations SOC in 64 (49.6%) patients (Table 33). The most frequent AEs in this SOC included bronchitis (11 patients, 8.5%), pneumonia (10 patients, 7.8 %), and upper respiratory tract infection (10 patients, 7.8 %) (Table 34).

The majority of AEs were Grade 1-2 (30.2%) followed by 17.8% Grade 3-4 and 1.6% Grade 5. There were 2 (1.6%) Grade 4 events of septic shock, 1 (0.8%) of endocarditis, and 1 (0.8%) of infection. Two (1.6%) patients with Grade 5 AEs were reported in this SOC, lung infection (Patient 221-004) and pneumonia (Patient 752-002) (Section 12.3).

12.2.3.1.4 Investigations

TEAEs were reported in the Investigations SOC in 63 (48.8%) patients (Table 33). The AEs reported most often in this SOC included increased LDH (n=20; 15.5%) and ECG QT prolonged (n=14; 10.9% by Investigator's assessment) (Table 34). Of the 5 patients reported by the Investigators to have had a Grade 3 prolonged QT, only 2 (1.6%) patients were confirmed on central ECG review by eRT (Section 12.3.1.3.3). The other terms reported most often in this SOC were increased AST, blood creatinine and decreased platelet count, which were each reported in 9 (7.0%) patients.

The majority of AEs were Grade 1-2 (31.8%) followed by 17.1% Grade 3-4. There were 3 (2.3%) patients with Grade 4 AEs of decreased platelet count, and 1 (0.8%) patient each with blood calcium increased, blood LDH increased, blood potassium decreased, ECOG performance worsening, gama-glutamyl transferase increased, neutrophil count decreased, and weight decreased. No Grade 5 AEs were reported in this SOC.

12.2.3.1.5 Blood and Lymphatic System Disorders

TEAEs were reported in the Blood and Lymphatic System Disorders SOC in 62 (48.1%) patients (Table 33). The AEs reported most often in this SOC were anemia (n=41; 31.8%) and thrombocytopenia (n=21; 16.3%) (Table 34). The other terms reported most often were leucopenia (n=12; 9.3%), neutropenia (n=12; 9.3%), lymphopenia (n=11; 8.5%), and febrile neutropenia (n=7; 5.4%).

The majority of AEs in this SOC were Grade 3-4 (25.6%) followed by 22.5% Grade 1-2. Grade 4 AEs included thrombocytopenia (n=9; 7.0%), anemia (n=6; 4.7%), leukopenia (n=3; 2.3%), neutropenia (n=3; 2.3%), lymphocytosis (n=1; 0.8%), lymphopenia (n=1; 0.8%), and pancytopenia (n=1; 0.8%). Of the 9 (7.0%) patients with Grade 4 thrombocytopenia, 5 (3.9%) patients (Patient 144-001, 243-001, 516-006, 600-003, 801-001) had Baseline platelet counts <100,000/µL. No Grade 5 AEs were reported in this SOC. The hematological AEs are discussed further by grade in Section 12.4.2.2.1.

12.2.3.1.6 Metabolism and Nutrition Disorders

TEAEs were reported in the Metabolism and Nutrition Disorders SOC in 61 (47.3%) patients (Table 33). Decreased appetite was the most common AE in this SOC (n=19, 14.7%) (Table 34). The other terms reported were hypokalemia (n=16, 12.4%), hyperglycemia (n=12, 9.3%), and hypoalbuminemia (n =10, 7.8%).

The majority of AEs in this SOC were Grade 1-2 (34.1%) followed by 13.2% Grade 3-4. There was 1 (0.8%) report each of Grade 4 hypercalcemia, hypoglycemia, and tumor lysis syndrome. No Grade 5 AEs were reported in this SOC.

12.2.3.1.7 Respiratory, Thoracic and Mediastinal Disorders

TEAEs were reported in the Respiratory, Thoracic and Mediastinal Disorders SOC in 60 (46.5%) patients (Table 33). Dyspnea was the most common AE in this SOC (n=28, 21.7%) (Table 34). The other terms reported most often were cough (n=24, 18.6%) and oropharyngeal pain (n=8, 6.2%).

The majority of AEs in this SOC were Grade 1-2 (34.1%) followed by 12.4% Grade 3-4. There were 2 (1.6%) reports of Grade 4 pulmonary embolism and 1 (0.8%) of Grade 4 respiratory failure. No Grade 5 AEs were reported in this SOC.

12.2.3.1.8 Skin and Subcutaneous Tissue Disorders

TEAEs were reported in the Skin and Subcutaneous Tissues Disorders SOC in 56 (43.4%) patients (Table 33). Rash was the most common AE in this SOC (n=26, 20.2%) (Table 34). The other terms reported most often were pruritus (n=21, 16.3%), night sweats (n=8, 6.2%), and hyperhidrosis (n=7, 5.4%).

The majority of AEs in this SOC were Grade 1-2 (36.4%) followed by 7.0% Grade 3-4. There was 1 (0.8%) report each of Grade 4 pain of skin and pruritus. No Grade 5 AEs were reported in this SOC.

12.2.3.1.9 Vascular Disorders

TEAEs were reported in the Vascular Disorders SOC in 50 (38.8%) patients (Table 33). Hypotension and phlebitis were each reported in 13 (10.1%) patients. The other most frequently reported AEs were flushing (n=9, 7.0%) and hypertension (n=7, 5.4%) (Table 34).

The majority of AEs in this SOC were Grade 1-2 (27.9%) followed by 10.1% Grade 3-4 and 0.8% Grade 5. There was 1 (0.8%) occurrence each of Grade 4 hypotension and hypovolemic shock. The 1 (0.8%) Grade 5 AE in this SOC was shock (Patient 803-001) (Section 12.3).

12.2.3.1.10 Musculoskeletal and Connective Tissue Disorders

TEAEs were reported in the Musculoskeletal and Connective Tissue Disorders SOC in 45 (34.9%) patients (Table 33). Pain in extremity (n=11, 8.5%) and muscle spasms (n=9, 7.0%) were the most often reported AEs (Table 34).

The majority of AEs in this SOC were Grade 1-2 (27.9%) followed by 7% Grade 3-4. There was 1 (0.8%) report of Grade 4 pathological fracture. No Grade 5 AEs were reported in this SOC.

12.2.3.1.11 Nervous System Disorders

TEAEs were reported in the Nervous System Disorders SOC in 45 (34.9%) patients (Table 33). Headache was the most often reported AE in this SOC (n=19, 14.7%) (Table 34). The other frequently reported AEs were dizziness (n=13, 10.1%) and peripheral neuropathy (n=10, 7.8%).

The majority of AEs were Grade 1-2 (32.6%) followed by 2.3% Grade 3-4. There were no Grade 4 or Grade 5 AEs reported in this SOC.

12.2.3.1.12 Psychiatric Disorders

TEAEs were reported in the Psychiatric Disorders SOC in 29 (22.5%) patients (Table 33). Insomnia was the most often reported AE in this SOC (n=9, 7.0%) (Table 34). The other frequently reported AEs were anxiety (n=8, 6.2%) and depression (n=6, 4.7%).

The majority of AEs in this SOC were Grade 1-2 (19.4%) followed by 3.1% Grade 3-4. There was 1 (0.8%) report of Grade 4 insomnia. No Grade 5 AEs were reported in this SOC.

12.2.3.1.13 Injury, Poisoning and Procedural Complications

TEAEs were reported in the Injury, Poisoning and Procedural Complications SOC in 16 (12.4%) patients (Table 33). Infusion related reaction was the most often reported AE in this SOC (n=5, 3.9%) (Table 14.3.6.4). The other frequently reported AEs, each reported in 2 (1.6%) patients, were excoriation and fall.

The majority of AEs in this SOC were Grade 1-2 (10.9%) followed by 1.6% Grade 3-4. There were no Grade 4 or Grade 5 AEs reported in this SOC.

12.2.3.1.14 Eye Disorders

TEAEs were reported in the Eye Disorders SOC in 15 (11.6%) patients (Table 33). Vision blurred occurred in 4 (3.1%) patients and dry eye was reported in 2 (1.6%) patients (Table 14.3.6.4). All other terms were reported in 1 patient each.

The majority of AEs in this SOC were Grade 1-2 (10.1%) followed by 1.6% Grade 3-4. There were no Grade 4 or Grade 5 AEs reported in this SOC.

12.2.3.1.15 Cardiac Disorders

TEAEs were reported in the Cardiac Disorders SOC in 13 (10.1%) patients (Table 33, Section 12.3.1.3.3). Atrial fibrillation was the most frequently reported AE in this SOC (n=3, 2.3%) (Table 14.3.6.4). The other frequently reported AEs, each reported in 2 (1.6%) patients, were cardiac failure, sinus tachycardia, and tachycardia.

The majority of AEs were Grade 1-2 (7.0%) followed by 1.6% Grade 3-4 and 1.6% Grade 5; there were no Grade 4 AEs. The 2 (1.6%) Grade 5 AEs in this SOC were cardiac failure events (Patients 142-001 and 513-003) (Section 12.3.1.1).

12.2.3.1.16 Renal and Urinary Disorders

TEAEs were reported in the Renal and Urinary Disorders SOC in 13 (10.1%) patients (Table 33). Pollakiuria and renal impairment were both reported in 3 (2.3%) patients, and dysuria and renal failure were each reported in 2 (1.6%) patients (Table 14.3.6.4).

The majority of AEs in this SOC were Grade 1-2 (8.5%) followed by 1.6% Grade 3-4. There were no Grade 4 or Grade 5 AEs reported in this SOC.

12.2.3.1.17 Neoplasms, Benign, Malignant and Unspecified (includes cysts and polyps)

TEAEs were reported in the Neoplasms, Benign, Malignant and Unspecified (includes cysts and polyps) SOC in 11 (8.5%) patients (Table 33). Tumor pain was reported in 3 (2.3%) patients and tumor associated fever was reported in 2 (1.6%) patients (Table 14.3.6.4).

The majority of AEs in this SOC were Grade 1-2 (6.2%) followed by 2.3% Grade 3-4. There was 1 (0.8%) report of Grade 4 lung squamous cell carcinoma. No Grade 5 AEs were reported in this SOC.

12.2.3.1.18 Hepatobiliary Disorders

AEs were reported in the Hepatobiliary Disorders SOC in 8 (6.2%) patients (Table 33). Hyperbilirubinemia was reported in 3 patients (2.3%); all other terms were reported in 1 (0.8%) patient each (Table 14.3.6.4).

The majority of AEs were Grade 1-2 (3.9%) followed by 1.6% Grade 3-4 and 0.8% Grade 5. There was 1 (0.8%) of Grade 5 AE in this SOC of hepatic failure in Patient 154-001 (Section 12.3).

12.2.3.2 *Common Adverse Events Regardless of Causality by MedDRA Preferred Term*

All TEAEs that were reported in ≥ 10% of patients are listed in Table 35 by decreasing frequency within each SOC. Table 14.3.6.4 summarizes all AEs by grade and MedDRA Preferred Term by worst grade toxicity by patient Table 14.3.6.3 lists AEs by Preferred Term by decreasing frequency (not within SOC), and Table 14.3.6.2 summarizes the SOCs of the AEs reported.

- All (96.9%) but 4 patients experienced at least 1 AE. The most common AEs regardless of causality were nausea (n=54, 41.9%), fatigue (n=48, 37.2%), pyrexia (n=45, 34.9%) and anemia (n=41, 31.8%), and most of these AEs were Grade 1 or 2 (Table 14.3.6.3) in severity. AEs that led to treatment discontinuation are discussed in Section 12.3.1.3.
- The most frequent Grade 3, 4 or 5 AEs, regardless of causality, were anemia (n=14, 10.9%), thrombocytopenia (n=9, 7. 0%), dyspnea (n=8, 6.2%), neutropenia (n=8, 6.2%) and pneumonia (n=8, 6.2%) (Table 14.3.6.3).

Table 35: Adverse Events Occurring in ≥10% of Patients by MedDRA Preferred Term and Grade in Decreasing Frequency by All Grades (Full Analysis Dataset)

MedDRA Preferred Term	Full Analysis Dataset (N=129)			
	All Grades n (%)	Grades 1-2 n (%)	Grades 3-4 n (%)	Grade 5 n (%)
All Adverse Events	**125 (96.9)**	**124 (96.1)**	**79 (61.2)**	**11 (8.5)**
Nausea	54 (41.9)	53 (41.1)	1 (0.8)	0 (0)
Fatigue	48 (37.2)	41 (31.8)	7 (5.4)	0 (0)
Pyrexia	45 (34.9)	42 (32.6)	3 (2.3)	0 (0)
Anemia	41 (31.8)	27 (20.9)	14 (10.9)	0 (0)
Vomiting	37 (28.7)	36 (27.9)	1 (0.8)	0 (0)
Constipation	30 (23.3)	29 (22.5)	1 (0.8)	0 (0)
Diarrhea	29 (22.5)	27 (20.9)	2 (1.6)	0 (0)
Dyspnea	28 (21.7)	20 (15.5)	8 (6.2)	0 (0)
Edema Peripheral	26 (20.2)	26 (20.2)	0 (0)	0 (0)
Rash	26 (20.2)	25 (19.4)	1 (0.8)	0 (0)
Cough	24 (18.6)	24 (18.6)	0 (0)	0 (0)
Chills	21 (16.3)	20 (15.5)	1 (0.8)	0 (0)
Pruritus	21 (16.3)	17 (13.2)	4 (3.1)	0 (0)
Thrombocytopenia	21 (16.3)	12 (9.3)	9 (7.0)	0 (0)
Blood Lactate Dehydrogenase Increased	20 (15.5)	18 (14.0)	2 (1.6)	0 (0)
Decreased Appetite	19 (14.7)	16 (12.4)	3 (2.3)	0 (0)
Headache	19 (14.7)	19 (14.7)	0 (0)	0 (0)
Infusion Site Pain	18 (14.0)	18 (14.0)	0 (0)	0 (0)
Hypokalemia	16 (12.4)	11 (8.5)	5 (3.9)	0 (0)
Abdominal Pain	14 (10.9)	13 (10.1)	1 (0.8)	0 (0)
Electrocardiogram QT Prolonged	14 (10.9)	9 (7.0)	5 (3.9)	0 (0)
Dizziness	13 (10.1)	13 (10.1)	0 (0)	0 (0)
Hypotension	13 (10.1)	9 (7.0)	4 (3.1)	0 (0)
Phlebitis	13 (10.1)	12 (9.3)	1 (0.8)	0 (0)

Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities

Source: Tables 14.3.6.1, 14.3.6.3

Among the subgroup of patients with Baseline platelets ≥100,000/µL (N=105), 30 (28.6%) had a TEAE of anemia (Table 14.3.6.11) including Grade 3 (n=7, 6.7%) AEs. Thrombocytopenia was reported in 12 patients (11.4%) including Grade 4 (n=2, 1.9%) AEs. The other Grade 3 hematological AEs reported were 5 (4.8%) patients with neutropenia, 5 (4.8%) patients with lymphopenia, 3 (2.9%) patients with febrile neutropenia, and 1 (1.0%) patient each with hemolytic anemia, leukocytosis, and splenomegaly. Other Grade 4 hematological AEs reported were in 1 (1.0%) patient each and included leucopenia and lymphocytosis. Additional details of hematological AEs are presented in Section 12.4.2.

Among the subgroup of patients with Baseline platelets <100,000/µL (N=24), 11 (45.8%) had a TEAE of anemia including Grade 3-4 (n=7, 29.2%) AEs (Table 14.3.6.10, Table 14.3.6.11). Thrombocytopenia was reported in 9 (37.5%) patients including Grade 3-4 (n=7, 29.2%) AEs. The other treatment-related hematological AEs reported were Grade 3 febrile neutropenia (n=3, 12.5%) and Grade 3-4 leucopenia (n=2, 8.3%), neutropenia (n=3, 12.5%), and pancytopenia (n=1, 4.2%). Additional details of hematological AEs are presented in Section 12.4.2.

12.2.3.3 *Treatment-Related Adverse Events by System Organ Class*

The incidence of treatment-related AEs in each MedDRA SOC is presented in Table 36; incidence by SOC and Preferred Term is presented in Table 37.

The SOCs with the highest incidence of treatment-related AEs (>25%) by All Grades (Table 14.3.6.5) included the Gastrointestinal Disorders (n=70, 54.3%); General Disorders and Administration Site Conditions (n=63, 48.8%); Blood and Lymphatic System Disorders (n=35, 27.1%); and Investigations (n=33, 25.6%) SOCs. Each of these SOCs is discussed in more detail below.

The highest incidence of Grade 3-4 treatment-related AEs (>5%) was in the Blood and Lymphatic System Disorders (n=19, 14.7%); Investigations (n=11, 8.5%); Infections and Infestations (n=9, 7.0%); and General Disorders and Administration Site Conditions (n=7, 5.4%) SOCs; all other Grade 3-4 treatment-related AEs were reported in less than 5% of patients.

A Grade 5 treatment-related AE was reported in only 1 (n=0.8%) patient in the Hepatobiliary Disorders SOC (Patient 154-001).

Table 36: Treatment-related Adverse Events by MedDRA System Organ Class and Grade in Decreasing Frequency by All Grades (Full Analysis Dataset)

MedDRA System Organ Class(SOC)	Full Analysis Dataset (N=129)			
	All Grades n (%)	Grades 1-2 n (%)	Grades 3-4 n (%)	Grade 5 n (%)
All Treatment-related AEs	**108 (83.7)**	**105 (81.4)**	**44 (34.1)**	**1 (0.8)**
Gastrointestinal Disorders	70 (55.3)	65 (50.4)	5 (3.9)	0 (0)
General Disorders and Administration Site Conditions	63 (48.8)	56 (43.4)	7 (5.4)	0 (0)
Blood and Lymphatic System Disorders	35 (27.1)	16 (12.4)	19 (14.7)	0 (0)
Investigations	33 (25.6)	22 (17.1)	11 (8.5)	0 (0)
Vascular Disorders	30 (23.3)	25 (19.4)	5 (3.9)	0 (0)
Nervous System Disorders	23 (17.8)	22 (17.1)	1 (0.8)	0 (0)
Skin and Subcutaneous Tissue Disorders	22 (17.1)	22 (17.1)	0 (0)	0 (0)
Infections and Infestations	19 (14.7)	10 (7.8)	9 (7.0)	0 (0)
Metabolism and Nutrition Disorders	18 (14.0)	12 (9.3)	6 (4.7)	0 (0)
Respiratory, Thoracic and Mediastinal Disorders	16 (12.4)	10 (7.8)	6 (4.7)	0 (0)
Musculoskeletal and Connective Tissue Disorders	12 (9.3)	10 (7.8)	2 (1.6)	0 (0)
Eye Disorders	6 (4.7)	6 (4.7)	0 (0)	0 (0)
Injury, Poisoning and Procedural Complications	6 (4.7)	6 (4.7)	0 (0)	0 (0)
Renal and Urinary Disorders	5 (3.9)	4 (3.1)	1 (0.8)	0 (0)
Cardiac Disorders	3 (2.3)	3 (2.3)	0 (0)	0 (0)
Psychiatric Disorders	3 (2.3)	2 (1.6)	1 (0.8)	0 (0)
Hepatobiliary Disorders	1 (0.8)	0 (0)	0 (0)	1 (0.8)
Immune System Disorders	1 (0.8)	1 (0.8)	0 (0)	0 (0)
Reproductive System and Breast Disorders	1 (0.8)	1 (0.8)	0 (0)	0 (0)

Source: Tables 14.3.6.1, 14.3.6.5

12.2.3.3.1 Gastrointestinal Disorders

Treatment-related TEAEs were reported in the Gastrointestinal Disorders SOC in 70 (54.3%) patients (Table 14.3.6.5). Nausea was the most common treatment-related AE reported in this SOC (n=49, 38.0%) (Table 14.3.6.6); all occurrences were Grade 1

(n=31, 24.0%) or Grade 2 (n=17, 13.2%) except for 1 (0.8%) patient with a Grade 3 AE (Table 14.3.6.7). The other treatment-related AEs reported most often were vomiting (n=31, 24.0%), and diarrhea (n=18, 14.0%).

The majority of treated-related AEs in this SOC were Grade 1-2 (50.4%) followed by 3.9% Grade 3-4 (Table 36). No Grade 4 or 5 treatment-related AEs were reported in this SOC (Table 14.3.6.7).

12.2.3.3.2 General Disorders and Administration Site Conditions

Treatment-related TEAEs were reported in the General Disorders and Administration Site Conditions SOC in 63 (48.8%) patients (Table 14.3.6.5). The treatment-related AEs (Table 14.3.6.6) reported most often in this SOC were fatigue (n=37, 28.7%), infusion site pain (n=16, 12.4%), and pyrexia (n=13, 10.1%).

The majority of treated-related AEs in this SOC were Grade 1-2 (43.4%) followed by 5.4% Grade 3-4 (Table 36). No Grade 4 or Grade 5 treatment-related AEs were reported in this SOC (Table 14.3.6.7).

12.2.3.3.3 Blood and Lymphatic System Disorders

Treatment-related TEAEs were reported in the Blood and Lymphatic System Disorders SOC in 35 (27.1%) patients (Table 14.3.6.5). Anemia was the most frequently reported treatment-related AE (Table 14.3.6.6) in this SOC (n=16, 12.4%). The other treatment-related AEs reported most often were thrombocytopenia (n=14, 10.9%), neutropenia (n=7, 5.4%), and leukopenia (n=7, 5.4%).

The majority of treated-related AEs in this SOC were Grade 1-2 (12.4%) followed by 14.7% Grade 3-4 (Table 36). Treatment-related Grade 4 AEs in this SOC included thrombocytopenia (n =6, 4.7%), leukopenia (n=3, 2.3%), anemia (n=2, 1.6%), neutropenia (n=2, 1.6%), and pancytopenia (n=1, 0.8%) (Table 14.3.6.7). No Grade 5 treatment-related AEs were reported in this SOC.

12.2.3.3.4 Investigations

Treatment-related TEAEs were reported in the Investigations SOC in 33 (25.6%) patients (Table 14.3.6.5). The treatment-related AE reported most often in this SOC was ECG QT prolonged (n=13; 10.1%); however, only 2 (1.6%) of 5 patients reported to have had a Grade 3 prolonged QT by the Investigators were confirmed on central ECG review by eRT (Section 12.3.1.3.3). Other treatment-related AEs reported most often in this SOC were increased ALT (n=5, 3.9%), increased AST (n=5, 3.9%), increased blood creatinine (n=5, 3.9%), weight decreased (n =4, 3.1%), and platelet count decreased (n=3, 2.3%).

The majority of treated-related AEs in this SOC were Grade 1-2 (17.1%) followed by 8.5% Grade 3-4 (Table 36). There were 3 (2.3%) patients with Grade 4 AEs; 1 (0.8%) patient each with gama-glutamyl transferase increased, neutrophil count decreased, and platelet count decreased (Table 14.3.6.7). No Grade 5 AEs occurred in this SOC.

12.2.3.3.5 Vascular Disorders

Treatment-related TEAEs were reported in the Vascular Disorders SOC in 30 (23.3%) patients (Table 14.3.6.5). Phlebitis was the most frequently reported treatment-related AE in this SOC (n=11, 8.5%) (Table14.3.6.6). The other most frequently reported treatment-related AEs were flushing (n=9, 7.0%) and hypotension (n=4, 3.1%).

The majority of treatment-related AEs in this SOC were Grade 1-2 (19.4%) followed by 3.9% Grade 3-4 (Table 36). There were no Grade 4 or Grade 5 treatment-related AEs reported in this SOC (Table 14.3.6.7).

12.2.3.3.6 Nervous System Disorders

Treatment-related TEAEs were reported in the Nervous System Disorders SOC in 23 (17.8%) patients (Table 14.3.6.5). Dizziness was the most often reported treatment-related AE (Table 14.3.6.6) in this SOC (n=8, 6.2%). The other frequently reported treatment-related AEs were headache (n=6, 4.7%) and dysgeusia (n=5, 3.9%).

The majority of treated-related AEs in this SOC were Grade 1-2 (17.1%) followed by 0.8% Grade 3-4 (Table 36). There were no Grade 4 or Grade 5 treatment-related AEs in this SOC (Table 14.3.6.7).

12.2.3.3.7 Skin and Subcutaneous Tissue Disorders

Treatment-related TEAEs were reported in the Skin and Subcutaneous Tissues Disorders SOC in 22 (17.1%) patients (Table 14.3.6.5). Rash was the most common treatment-related AE in this SOC (n=11, 8.5%). The other AEs reported most often in this SOC were pruritus (n=5, 3.9%), hyperhidrosis (n=3, 2.3%), and alopecia (n=2, 1.6%).

All of the AEs in this SOC were Grade 1-2 (17.1%). There were no Grade 3, Grade 4, or Grade 5 treatment-related AEs in this SOC (Table 36 and Table 14.3.6.7).

12.2.3.3.8 Infections and Infestations

Treatment-related TEAEs were reported in the Infections and Infestations SOC in 19 (14.7%) patients (Table 14.3.6.5). Cellulitis, pneumonia, and upper respiratory tract infection were the most commonly reported treatment-related AEs in this SOC, each was reported in 3 (2.3%) patients. Herpes simplex and infection were each reported in 2 (1.6%) patients.

The majority of treated-related AEs in this SOC were Grade 1-2 (7.8%) followed by Grade 3-4 (7.0%) (Table 36). There was 1 Grade 4 event of treatment-related septic shock reported in Patient 161-001 (Table 14.3.6.7). No Grade 5 treatment-related AEs were reported in this SOC.

12.2.3.3.9 Metabolism and Nutrition Disorders

Treatment-related TEAEs were reported in the Metabolism and Nutrition Disorders SOC in 18 (14.0%) patients (Table 14.3.6.5). Decreased appetite was the most common treatment-related AE in this SOC (n=9, 7.0%) (Table 14.3.6.6). The other terms reported most often were hypokalemia (n=5, 3.9%), hyperglycemia (n=2, 1.6%), and tumor lysis syndrome (n=2, 1.6%).

The majority of treatment-related AEs in this SOC were Grade 1-2 (9.3%) followed by 4.7% Grade 3-4 (Table 36). There was 1 (0.8%) report of treatment-related Grade 4 hypercalcemia (Table 14.3.6.7). No Grade 5 treatment-related AEs were reported in this SOC.

12.2.3.3.10 Respiratory, Thoracic and Mediastinal Disorders

Treatment-related TEAEs were reported in the Respiratory, Thoracic and Mediastinal Disorders SOC in 16 (12.4%) patients (Table 14.3.6.5). Dyspnea was the most common treatment-related AE in this SOC (n=8, 6.2%) (Table 14.3.6.6). The other terms reported most often were cough (n=3, 2.3%) and hiccups (n=2, 1.6%).

The majority of treatment-related AEs in this SOC were Grade 1-2 (7.8%) followed by 4.7% Grade 3-4 (Table 36). There were no Grade 4 or Grade 5 treatment-related AEs in this SOC (Table 14.3.6.7).

12.2.3.3.11 Musculoskeletal and Connective Tissue Disorders

Treatment-related TEAEs were reported in the Musculoskeletal and Connective Tissue Disorders SOC in 12 (9.3%) patients (Table 14.3.6.5). Pain in the extremity (n=4, 3.1%), myalgia (n=3, 2.3%) and bone pain (n=2, 1.6%) were the most often reported treatment-related AEs in this SOC (Table 14.3.6.6).

The majority of treated-related AEs in this SOC were Grade 1-2 (7.8%) followed by 1.6% Grade 3-4 (Table 36). There were no Grade 4 or Grade 5 treatment-related AEs in this SOC (Table 14.3.6.7).

12.2.3.3.12 Eye Disorders

Treatment-related TEAEs were reported in the Eye Disorders SOC in 6 (4.7%) patients (Table 14.3.6.5). The most frequently reported treatment-related AE in this SOC was blurred vision (n=4, 3.1%). All other terms were reported in single (0.8%) patients and

included dry eye, keratoconjunctivitis sicca, increased lacrimation, and toxic cataract (Table 14.3.6.6).

The majority of treatment-related AEs in this SOC were Grade 1-2 (4.7%) (Table 36). No Grade 3, Grade 4 or Grade 5 treatment-related AEs were reported in this SOC (Table 14.3.6.7).

12.2.3.3.13 Injury, Poisoning and Procedural Complications

Treatment-related TEAEs were reported in the Injury, Poisoning and Procedural Complications SOC in 6 (4.7%) patients (Table 14.3.6.5). Infusion-related reaction was the most frequent treatment-related AE reported in this SOC (n=5, 3.9%) (Table 14.3.6.6). The only other reported treatment-related AE was a tracheostomy malfunction that occurred in 1 (0.8%) patient.

The majority of treatment-related AEs in this SOC were Grade 1-2 (4.7%) (Table 36). There were no Grade 3, Grade 4 or Grade 5 AEs reported in this SOC (Table 14.3.6.7).

12.2.3.3.14 Renal and Urinary Disorders

Treatment-related TEAEs were reported in the Renal and Urinary Disorders SOC in 5 (3.9%) patients (Table 14.3.6.5). Pollakiuria was the most commonly reported treatment-related AE (n=2, 1.6%); all other treatment-related AES occurred in only single (0.8%) patients (Table 14.3.6.6).

The majority of treatment-related AEs in this SOC were Grade 1-2 (3.1%) followed by 0.8% Grade 3-4 (Table 36). There were no Grade 4 or Grade 5 treatment-related AEs reported in this SOC (Table 14.3.6.7).

12.2.3.3.15 Cardiac Disorders

Treatment-related TEAEs were reported in the Cardiac Disorders SOC in 3 (2.3%) patients (Table 14.3.6.5, Section 12.3.1.3.3). All treatment-related AEs in this SOC were reported in single (0.8%) patients and included atrial fibrillation, right bundle branch block, and ventricular extrasystoles (Table 14.3.6.6).

All treatment-related AEs in this SOC were Grade 1-2 (2.3%) (Table 36); there were no Grade 3, Grade 4 or Grade 5 treatment-related AEs reported in this SOC (Table 14.3.6.7).

12.2.3.3.16 Psychiatric Disorders

Treatment-related TEAEs were reported in the Psychiatric Disorders SOC in 3 (2.3%) patients (Table 14.3.6.5). All treatment-related AEs in this SOC were reported in single (0.8%) patients and included anxiety, confusional state, and insomnia (Table 14.3.6.6).

The majority of treated-related AEs in this SOC were Grade 1-2 (1.6%) followed by 0.8% Grade 3-4 (Table 36). There was 1 (0.8%) report of Grade 3 anxiety. No Grade 4 or Grade 5 treatment-related AEs were reported in this SOC (Table 14.3.6.7).

12.2.3.3.17 Hepatobiliary Disorders

Treatment-related TEAEs were reported in the Hepatobiliary Disorders SOC in 1 (0.8%) patient (Table 36). Two treatment-related AEs in this SOC occurred in a single (0.8%) patient and included hepatic cirrhosis (Grade 1) and hepatic failure (Grade 5) (Table 14.3.6.7); details of the patient with hepatic failure (Patient 154-001) are included in Section 12.3.2. No Grade 2, Grade 3 or Grade 4 treatment-related AEs were reported in this SOC (Table 14.3.6.7).

12.2.3.3.18 Immune System Disorders

One (0.8%) treatment-related TEAE of hypersensitivity was reported in the Immunne System Disorders SOC (Table 36); the event was Grade 1. No Grade 2, Grade 3 or Grade 4 treatment-related AEs were reported in this SOC (Table 14.3.6.7).

12.2.3.3.19 Reproductive System and Breast Disorders

One (0.8%) treatment-related TEAE of testicular pain was reported in the Reproductive System and Breast Disorders SOC (Table 36); the event was Grade 2. No Grade 1, Grade 3, Grade 4 or Grade 5 treatment-related AEs were reported in this SOC (Table 14.6.3.7).

12.2.3.4 *Common Treatment-related Adverse Events by MedDRA Preferred Term*

Adverse events considered by the Investigator to be related to belinostat are summarized in this section as treatment-related TEAEs. Table 14.3.6.6 summarizes all treatment-related AEs by Preferred Term and grade in decreasing frequency and treatment-related AEs reported in >5% of patients are listed in Table 37.

A total of 108 (83.7%) patients experienced AEs considered treatment-related.

- The most common treatment-related AEs were nausea (n=49, 38.0%), fatigue (n=37, 28.7%), vomiting (n=31, 24.0%) and diarrhea (n=18, 14.0%), and most of these AEs were Grade 1 or 2 (Table 14.3.6.6) in severity. AEs that led to treatment discontinuation are discussed in Section 12.3.1.3.
- The most frequent Grade 3, 4 or 5 treatment-related AEs were anemia (n=7, 5.4%), thrombocytopenia (n=6, 4.7%), neutropenia (n=6, 4.7%) and ECG QT prolonged (n=5, 3.9%) (Table 14.3.6.6); only 2 (1.6%) of the 5 patients reported to have had a Grade 3 prolonged QT by the Investigators were confirmed on central ECG review (Section 12.2.3.3.15).

Table 37: Treatment-related Adverse Events Occurring in >5% of Patients by MedDRA Preferred Term and Grade in Decreasing Frequency by All Grades (Full Analysis Dataset)

MedDRA Preferred Term	Full Analysis Dataset (N=129)			
	All Grades n (%)	Grades 1-2 n (%)	Grades 3-4 n (%)	Grade 5 n (%)
All Treatment-related AEs	**108 (83.7)**	**105 (81.4)**	**44 (34.1)**	**1 (0.8)**
Nausea	49 (38.0)	48 (37.2)	1 (0.8)	0 (0)
Fatigue	37 (28.7)	33 (25.6)	4 (3.1)	0 (0)
Vomiting	31 (24.0)	31 (24.0)	0 (0)	0 (0)
Diarrhea	18 (14.0)	17 (13.2)	1 (0.8)	0 (0)
Anemia	16 (12.4)	9 (7.0)	7 (5.4)	0 (0)
Infusion Site Pain	16 (12.4)	16 (12.4)	0 (0)	0 (0)
Thrombocytopenia	14 (10.9)	8 (6.2)	6 (4.7)	0 (0)
Electrocardiogram QT Prolonged	13 (10.1)	8 (6.2)	5 (3.9)[a]	0 (0)
Pyrexia	13 (10.1)	13 (10.1)	0 (0)	0 (0)
Phlebitis	11 (8.5)	10 (7.8)	1 (0.8)	0 (0)
Rash	11 (8.5)	11 (8.5)	0 (0)	0 (0)
Chills	9 (7.0)	9 (7.0)	0 (0)	0 (0)
Constipation	9 (7.0)	8 (6.2)	1 (0.8)	0 (0)
Decreased Appetite	9 (7.0)	7 (5.4)	2 (1.6)	0 (0)
Flushing	9 (7.0)	9 (7.0)	0 (0)	0 (0)
Dizziness	8 (6.2)	8 (6.2)	0 (0)	0 (0)
Dyspnea	8 (6.2)	6 (4.7)	2 (1.6)	0 (0)
Leukopenia	7 (5.4)	4 (3.1)	3 (2.3)	0 (0)
Neutropenia	7 (5.4)	1 (0.8)	6 (4.7)	0 (0)

[a] ERT central review of ECGs confirmed only 2 patients with Grade 3 Electrocardiogram QT Prolonged.
Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities
Source: Tables 14.3.6.1, 14.3.6.6

Among the subgroup of patients with Baseline platelets ≥100,000/µL (N=105), 12 (11.4%) had a treatment-related AE of anemia (Table 14.3.6.12) including Grade 1 (n=2, 1.9%), Grade2 (n=6, 5.7%) and Grade 3 (n=4, 3.8%) AEs. Thrombocytopenia was reported in 7 patients (6.7%) at severities of Grade 1 (n=4, 3.8%), Grade 2 (n=2, 1.9%) and Grade 4 (n=1, 1.0%). The other treatment-related Grade 3 hematological AEs reported were 4 (3.8%) patients with neutropenia, 3 (2.9%) patients with febrile

neutropenia, and 1 (1.0%) patient with hemolytic anemia. Additional details of hematological AEs are presented in Section 12.4.2.

Non-hematologic treatment-related Grade 3 AEs occurring in ≥1 patient among the subgroup of patients with Baseline platelets ≥100,000/µL (N=105) included fatigue (n=4, 3.8%), ALT increased (n=3, 2.9%), AST increased (n=3, 2.9%), ECG QT prolonged (n=3, 2.9%), decreased appetite (n=2, 1.9%), dyspnea (n=2, 1.95), infection (n=2, 1.9%), hypokalemia (n=2, 1.9%), pneumonia (n=2, 1.9%). No Grade 4 treatment-related AEs occurred in more than 1 (1.0%) patient. One Grade 5 treatment-related AE occurred in the subgroup of patients with Baseline platelets ≥100,000/µL; hepatic failure (n=1, 1.0%) (Table 14.3.6.12).

Among the subgroup of patients with Baseline platelets <100,000/µL (N=24), 4 (16.7%) had a treatment-related event of anemia (Table 14.3.6.12) including Grade 2 (n=1, 4.2%), Grade 3 (n=1, 4.2%), and Grade 4 (n=2, 8.3%) AEs. Thrombocytopenia was reported in 7 (29.2%) patients including Grade 2 (n=2, 8.3%) and Grade 4 (n=5, 20.8%) AEs. The other treatment-related hematological AEs reported were Grade 3 febrile neutropenia (n=1, 4.2%) and Grade 4 leucopenia (n=2, 8.3%), neutropenia (n=2, 8.3%), and pancytopenia (n=1, 4.2%). Additional details of hematological AEs are presented in Section 12.4.2.

Non-hematologic treatment-related Grade 3 or higher AEs occurring in ≥1 patient among the subgroup of patients with Baseline platelets <100,000/µL (N=24) included ECG QT prolonged (n=2, 8.3%). No Grade 4 treatment-related AEs occurred in more than 1 person and no Grade 5 treatment-related AEs occurred in the subgroup of patients with Baseline platelets <100,000/µL (Table 14.3.6.12).

12.2.4 Adverse Events by Intensity/Severity

The incidence of Grade 3-4 and Grade 5 TEAEs by Preferred Term reported in ≥2 patients is presented in Table 38. Overall 79 (61.2%) patients reported Grade 3-4 AEs, and 12 (9.3%) patients reported Grade 5 AEs.

The most common Grade 3-4 AEs included anemia (n=14, 10.9%), thrombocytopenia (n=9, 7.0%), dyspnea (n=8, 6.2%), neutropenia (n=8, 6.2%), fatigue (n=7, 5.4%), and pneumonia (n=7, 5.4%); the majority of these AEs were considered treatment related by the Investigators.

The most common Grade 5 AEs included multi-organ failure (n=3, 2.3%) and cardiac failure (n=2, 1.6%); all other Grade 5 AEs were reported in only single (0.8%) patients; all of these AEs were considered not related to study drug by the Investigators.

Table 38: Grade 3-4 and Grade 5 Adverse Events Occurring in ≥2 Patients by MedDRA Preferred Term (Full Analysis Dataset)

MedDRA Preferred Term	Patients n	Patients %	Relationship to Study Drug n	
Grade 3-4 TEAEs	**79**	**61.2**	**Related**	**Unrelated**
Anemia	14	10.9	7	7
Thrombocytopenia	9	7.0	6	3
Dyspnea	8	6.2	2	6
Neutropenia	8	6.2	6	2
Fatigue	7	5.4	4	3
Pneumonia	7	5.4	2	5
Lymphopenia	6	4.7	3	3
Febrile Neutropenia	6	4.7	4	2
Hypokalemia	5	3.9	2	3
Electrocardiogram QT Prolonged	5	3.9	5 [a]	0
Pruritus	4	3.1	0	4
Hypotension	4	3.1	1	3
Asthenia	4	3.1	1	3
Aspartate Aminotransferase Increased	4	3.1	3	1
Platelet Count Decreased	4	3.1	1	3
Alanine Aminotransferase Increased	4	3.1	3	1
Deep Vein Thrombosis	4	3.1	1	3
Infection	4	3.1	2	2
Pyrexia	3	2.3	0	3
Decreased Appetite	3	2.3	2	1
Hyperglycemia	3	2.3	0	3
Leukopenia	3	2.3	3	0
Bronchitis	3	2.3	1	2
International Normalized Ratio Increased	3	2.3	2	1
Pulmonary Embolism	3	2.3	1	2
Sepsis	3	2.3	1	2
Diarrhea	2	1.6	1	1
Blood Lactate Dehydrogenase Increased	2	1.6	0	2

Pain	2	1.6	1	1
Hypoalbuminaemia	2	1.6	0	2
Insomnia	2	1.6	0	2
Anxiety	2	1.6	1	1
Back pain	2	1.6	0	2
Pharyngitis	2	1.6	0	2
Staphylococcal Infection	2	1.6	0	2
Tumor Lysis Syndrome	2	1.6	1	1
Gamma-glutamyltransferase Increased	2	1.6	2	0
General Physical Health Deterioration	2	1.6	1	1
Hypercalcemia	2	1.6	1	1
Septic Shock	2	1.6	1	1
White Blood Cell Count Decreased	2	1.6	0	2
Hypoxia	2	1.6	0	2
Neck pain	2	1.6	0	2
Pancytopenia	2	1.6	1	1
Grade 5 TEAEs	**12**	**9.3**	**Related**	**Unrelated**
Multi-organ Failure	3	2.3	0	3
Cardiac Failure	2	1.6	0	2

[a] ERT central review of ECGs confirmed 2 patients with Grade 3 Electrocardiogram QT Prolonged.
Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities
Source: Table 14.3.6.1, Table 14.3.6.3, Table 14.3.6.6.

12.2.5 Listing of Adverse Events by Patient

All AEs are presented in detail by patient in Listing 16.2.7.1.

12.3 Deaths and Other Serious Adverse Events

12.3.1 Listing of Deaths and Other Serious Adverse Events

Listings of patients who died or experienced serious AEs during the study are provided in Appendix 16.2.7.

12.3.1.1 *Deaths*

The number of patients who terminated the study (ceasing survival follow-up) due to death is summarized in Figure 1. Of the 22 (17.1%) deaths reported within 30 days of the last dose of belinostat in this study, all were considered not related to study drug except for 1 death due to hepatic failure that was considered treatment-related.

Details on the patients who died while on treatment or within 30 days of their last dose of belinostat are summarized in, Table 39 and Table 14.3.7.2 (by patient list of deaths while on treatment or within 30 days of their last dose), a list of patient deaths reported during the study are listed in Table 40 and Listing 16.2.7.4 (comprehensive list of death dates). Summary narratives are included below and detailed narratives for these patients are provided in Section 14.3.3.

Table 39: Summary of Patient Deaths within 30 days of the Last Dose of Belinostat in Decreasing Frequency (Full Analysis Dataset)

Patient Population	Full Analysis Dataset (N=129) n (%)	Treatment-related
Causes of Death within 30 days of Last Dose	**22 (17.1)**	**1 (0.8)**
Disease Progression	12 (9.3)	-
Adverse Events	10 (7.8)	1 (0.8)
Multiple Organ Failure	3 (2.3)	-
Cardiac Failure	2 (1.6)	-
Lung Infection	1 (0.8)	-
Gastrointestinal Hemorrhage	1 (0.8)	-
Euthanasia	1 (0.8)	-
Hepatic Failure	1 (0.8)	1 (0.8)
Shock	1 (0.8)	-

Source: Table 14.3.7.1, Table 14.3.7.2

Table 40: Deaths Reported Within 30 days of the Last Dose of Belinostat by Days from Last Dose (Full Analysis Dataset)

Patient	Age/ Sex[a]	Investigator Term	MedDRA Preferred Term	Day of Death Relative to Last Dose	Treatment-related
Adverse Events					
CLN19-221-004	80 Male	Intercurrent Pulmonary Infection	Lung Infection	2	No
CLN19-244-002	77 Male	Gastro Intestinal Bleeding	Gastrointestinal Hemorrhage	5	No
CLN19-922-001	73 Female	Multi Factorial Shock	Shock	2	No
CLN19-146-002	76 Female	Multiple Organ Failure	Multi-Organ Failure	10	No
CLN19-513-001	56 Male	Multiple Organ Dysfunction	Multi-Organ Failure	10	No

Patient	Age/ Sex[a]	Investigator Term	MedDRA Preferred Term	Day of Death Relative to Last Dose	Treatment-related
CLN19-244-004	76 Male	Euthanasia	Euthanasia	14	No
CLN19-516-001	53 Female	Multiple Organ Failure	Multi-Organ Failure	22	No
CLN19-154-001	73 Male	Toxic Liver Failure	Hepatic Failure	25	Yes
CLN19-142-001	72 Female	Cardiac Decompensation	Cardiac Failure	26	No
CLN19-513-003	58 Male	Heart Failure	Cardiac Failure	29	No
Disease Progression					
CLN19-100-001	62 Male	Disease progression	N/A	10	No
CLN19-206-001	64 Male	Disease progression	N/A	10	No
CLN19-801-002	73 Female	Disease progression	N/A	11	No
CLN19-532-001	48 Female	Disease progression	N/A	13	No
CLN19-803-001	74 Male	Disease progression	N/A	17	No
CLN19-180-002	70 Male	Disease progression	N/A	19	No
CLN19-244-006	73 Female	Disease progression	N/A	21	No
CLN19-532-002	55 Male	Disease progression	N/A	21	No
CLN19-142-002	68 Male	Disease progression	N/A	23	No
CLN19-934-004	71 Male	Disease progression	N/A	23	No
CLN19-224-001	66 Male	Disease progression	N/A	24	No
CLN19-907-002	54 Male	Disease Progression	NA	26	No

Source: Table 14.3.7.2, Listings 16.2.4.1, 16.2.7.4

Twelve deaths (9.3%) were due to disease progression, all of which were not related to belinostat and occurred between 10-26 days post-dosing (Table 14.3.7.2, Listing 16.2.4.2, Listing 16.2.4.3, Listing 16.2.5.1, Listing 16.2.5.2, Listing 16.2.7.1, and Listing 16.2.7.4).

Summary narratives of the individual patients who died during the course of the study are included below and the detailed narratives are in Section 14.3.3.

The 12 patients who died with progressive disease, none of which was considered related to belinostat, included:

- Patient 100-001- a 62-year-old Caucasian male with ALCL ALK(+) treated with multiple concomitant medications, was administered belinostat (1,730 mg/day) only on Day 1 of Cycle 1. The patient expired due to progression of PTCL 10 days after the last dose of belinostat.
- Patient 206-001- a 64-year-old Caucasian male with PTCL, NOS and a previous history of hypertension, nephritic colic vesical tumor, and smoking treated with multiple concomitant medications, was administered 1 cycle of belinostat (Days 1-4: 1,880 mg/day; Day 5: 1,410 mg, which was followed by a Grade 3 bronchospasm. The patient expired due to progression of PTCL 10 days after the last dose of belinostat.
- Patient 532-001- a 48-year-old Caucasian female with AITL and a previous history of drug allergy, tachycardia, gastroesophageal reflux, chylothorax, and lympadenomegaly treated with multiple concomitant medications, was administered 3 cycles of belinostat (doses ranged from 1,620-1,730 mg/day) with 1 interruption due to Grade 1 vomiting. The patient developed choking and fever 7 days after his last dose of belinostat, was diagnosed with a chylothorax and underwent thoracentesis. She was withdrawn due to progression of PTCL and expired 13 days after the last dose of belinostat.
- Patient 801-002- a 73-year-old Caucasian female with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 05-Jun-2011 at a dose of 1,600 mg/day. The dose of belinostat was reduced to 1,170 mg/day for Cycle 2 due to an AE of hypokalemia. On 10-Jul-2011 (C2D14), the patient was admitted to the hospital with a suspected diagnosis of acute abdomen. Abdominal surgery was performed on 11-Jun-2011 (C2D15) and bowel perforation due to tumor invasion was found. The patient was diagnosed with Grade 5 disease progression and expired 2 hours after surgery 11 days after the last dose of belinostat. The immediate cause of death was multi-organ failure, with the underlying cause of disease progression.
- Patient 803-001- a 74-year-old Black male with PTCL, NOS and a previous history of hypertension, cholelithiasis, and calcified aortic valve CVA treated with multiple concomitant medications, was administered 1 cycle of belinostat (1,800 mg/day). Nine days post-last dose, he presented to the ER with severe weakness and abdominal distention and was found to have hypercalcemia and leukocytosis (WBC 209,000; lymphocytes 107,000). The patient subsequently developed multi-organ failure, was started on morphine and expired due to progression of PTCL 17 days after the last dose of belinostat.

- Patient 180-002- a 70-year-old Caucasian male with ALCL ALK(-) and a previous medical history of psoriasis treated with multiple concomitant medications, was administered 2 cycles of belinostat (1,900 mg/day) and expired due to progression of PTCL 19 days after the last dose of belinostat.
- Patient 244-006- a 73-year-old Caucasian female with PTCL, NOS and a previous history of diabetes, elevated LDH, hyperlipidemia, gastric polyps, breast cyst, Grade 2 leukopenia treated with multiple concomitant medications, was administered 3 cycles of belinostat (1,590 mg/day). The Cycle 3, Day 5 dose was interrupted due to Grade 4 thrombocytopenia. The patient was hospitalized 27 days after her last dose with nausea, weakness, and malaise, and was diagnosed with progressive disease; she died of progression of PTCL 21 days after the last dose of belinostat.
- Patient 532-002- a 55-year-old Caucasian male with PTCL, NOS and a previous history of hemolytic anemia associated with PTCL, low level of leukocytes, thrombocytopenia, and hepatosplenomegaly, was administered 2 cycles of belinostat at a reduced dose (1,200 mg/day) due to Grade 4 low platelet counts at Baseline. Belinostat treatment was delayed during Cycle 2 due to Grade 4 anemia, Grade 3 febrile neutropenia, and Grade 4 low platelets. The patient was diagnosed with disease progression and was withdrawn from the study 19 days after his last dose. He expired with cardiorespiratory insufficiency due to progression of PTCL 21 days after the last dose of belinostat.
- Patient 142-002- a 68-year-old Caucasian male with ALCL ALK (-) and a previous history of psoriasis, scrotal primary limpoma, anemia (Grade 1), lymphopenia (Grade 3), neutrophilia (Grade 1), and zencocytosis (Grade 1) treated with multiple concomitant medications, was administered 2 cycles of belinostat (2,000 mg/day). He was hospitalized with an increased creatinine (Grade 1) at the start of Cycle 2 and the Cycle 2, Day 4 and Day 5 doses were not administered due to Grade 2 increased creatinine. The patient remained hospitalized and was diagnosed with disease progression 12 days after his last dose, and was then withdrawn from study and started on a new therapy (dexamethasone). He expired due to progression of PTCL 23 days after the last dose of belinostat.
- Patient 934-004- a 71-year-old Caucasian male with PTCL, NOS and a previous history of asymptomatic atrial fibrillation, neutropenia, multiple liver and kidney cysts, numbness in foot secondary to chemotherapy, and plural effusion (right) treated with multiple concomitant medications, was administered 1 cycle of belinostat (1,990 mg/day), which was interrupted due to Grade 3 cellulitis of the

right forearm. He subsequently developed hypercalcemia, hyperkalemia, increased LDH and fever and was hospitalized for infection/sepsis. He had a complicated hospital course and was diagnosed with disease progression 12 days after his last dose of belinostat. The patient was withdrawn from the study and expired due to progression of PTCL 23 days after the last dose of belinostat.

- Patient 224-001- a 66-year-old Caucasian male with PTCL, NOS and a previous history of tumor fever, anemia, elevated LDH, low potassium, and low RBC count and on multiple concomitant medications, was administered 1 cycle of belinostat (1,900 mg/day). The patient withdrew consent 18 days after his last dose of belinostat and was discontinued from study. He expired due to progression of PTCL 24 days after the last dose of belinostat.
- Patient 907-002- a 54-year-old Latin male with PTCL, NOS and a previous history of colon polyp treated with multiple concomitant medications, was administered 1 cycle of belinostat (2,070 mg/day) and expired due to progression of PTCL 26 days after the last dose of belinostat.

Three patients died due to multiple organ failure (Table 14.3.7.2, Listing 16.2.7.4) and none of the cases were considered related to treatment with belinostat; these deaths occurred between 10 - 22 days after the last belinostat dose.

- Patient 146-002- a 76-year-old Caucasian female with PTCL, NOS with a previous history of arterial hypertension, hyperuricalmia, ovarian cyst, MRSA (nose), osteochondrosis, chronic bronchitis, and plural effusion treated with multiple concomitant medications, started Cycle 1 of belinostat at a dose of 1,640 mg/day. She was hospitalized with respiratory insufficiency, fever of unknown origin and was diagnosed with Grade 4 tumor lysis syndrome 9 days after her last dose. The patient subsequently developed heart and renal failure and died 10 days after the last dose of belinostat.
- Patient 513-001- a 56-year-old Caucasian female with ALCL ALK (-) and a previous history of angiolipoma (kidney and hepatic) treated with multiple concomitant medications, was administered 2 cycles of belinostat (1,560 mg/day). The Cycle 2, Day 5 dose was not administered due to a Grade 4 decreased platelet count. The patient received multiple platelet transfusions, but became unconscious 9 days after her last belinostat dose. The patient expired due to multiple organ system failure 10 days after the last dose of belinostat.
- Patient 516-001- a 53-year-old Caucasian female with PTCL, NOS and a previous history of arterial hypertension, cholecystectomy, splenectomy, hysterectomy, and mycositis post chemotherapy and treated with multiple concomitant medications,

was administered 1 cycle of belinostat (1,900 mg/day). The patient was hospitalized 5 days after her last dose with weakness, esophageal pain, bradypnea and hypotension, and was diagnosed with a gastrointestinal mycosis infection that was treated and she was discharged. She was hospitalized again 16 days after her last belinostat dose with fever and was diagnosed with progressive disease and was withdrawn from the study. She was then started on a new treatment (CHOP chemotherapy), subsequently developed cardiac arrest and multi-organ failure secondary to disease progression and died 10 days after the last dose of belinostat.

One patient died due to multifactorial shock (Table 14.3.7.2, Listing 16.2.7.4) that was considered not related to treatment with belinostat.

- Patient 922-001- a 73-year-old Black female with PTCL, NOS, with a previous history of atherosclerotic vascular disease, cardiomegaly, hypertension, chronic kidney disease, chemotherapy-induced anemia, and hyperlipidemia treated with multiple concomitant medications, received 5 cycles of belinostat (2,260 mg/day) with 2 dose delays due to multiple AEs (Cycle 3, Day1 and Cycle 4, Day1). The patient had a very complicated course with multiple hospitalizations for dehydration, acute renal failure, MRSA endocarditis, urosepsis, CHF, and hypotension requiring fluids, antibiotics, vasopressors, and an ICU stay. She was again admitted to the ICU 2 days after her last belinostat dose with hypotension and hypovolemia, received IV fluids, antibiotics and vasopressors, developed atrial fibrillation with a rapid ventricular response and cardiopulmonary arrest; she expired due to multifactorial shock 2 days after the last dose of belinostat.

Two patients died with cardiac failure, which was considered unrelated to belinostat treatment and was reported 26-29 days after the last dose of study drug.

- Patient 142-001- a 72-year-old Caucasian female with AITL and a previous history of hypotension, peripheral edema (ankle), hyperuricemia, tumor-related anemia, and tumor-related cough treated with multiple concomitant medications, was administered 1 cycle of belinostat (1,990 mg/day). The patient was hospitalized 9 days after her last dose with worsening ankle edema, dyspnea and diarrhea, and was diagnosed with Grade 4 cardiac decompensation. She expired due to cardiac decompensation and renal failure 26 days after the last dose of belinostat.
- Patient 513-003- a 58-year-old Caucasian male with PTCL, NOS and a previous history of Klebsiella Pneumonia, and pulmonary embolism treated with multiple concomitant medications, was administered 6 cycles of belinostat (Cycle 1-3: 2,150 mg/day; Cycle 4-7: 2,250 mg/day). The patient was withdrawn from the

study due to disease progression 10 days after Cycle 6, Day 5. He was subsequently hospitalized with weakness, fever, skin changes, thrombocytopenia, kidney and liver failure 27 days after his last belinostat dose, and expired due to Grade 5 acute heart failure 29 days after the last dose of belinostat.

Three patients died due to other AEs that were considered unrelated to belinostat treatment and included lung infection, gastrointestinal hemorrhage, and euthanasia that were reported 2–14 days after the last dose; all of these deaths were considered to be not related to belinostat by the Investigators.

- Patient 244-002- a 77-year-old Caucasian male with Enteropathy-associated T-Cell Lymphoma and a previous history of abdominal pain, antral ulceration, and prostate carcinoma treated with multiple concomitant medications, was administered 2 cycles of belinostat (Cycle 1: 1,600 mg/day; Cycle 2: 1,570 mg/day). The patient was hospitalized 2 days after his last belinostat dose with hematemesis and melena, and was diagnosed with a Grade 5 GI bleed. He died due to severe GI bleeding 5 days after his last dose of belinostat.
- Patient 244-004- a 76-year-old Caucasian male diagnosed with AITL with bone marrow involvement and ascites, previously treated with 7 cycles of CHOP, was administered 1 cycle of belinostat. The patient's ascites worsened during Cycle 1 and he withdrew consent 6 days after his last belinostat dose. He refused further treatments and opted for euthanasia, and died 14 days after the last dose of belinostat.
- Patient 221-004- an 80-year-old Caucasian male with ALCL ALK (-) with a history of hypertension, treated with multiple concomitant medications, started Cycle 1 of belinostat at a dose of 2,000 mg/day, which was reduced to 1,500 mg/day at the start of Cycle 3, due to a rash. Cycle 6 of belinostat was initiated as scheduled, despite worsening general condition and a swollen, painful lower limb. Lab assessments indicated that hemoglobin was 6.3 mmol/L and an echo was negative for thrombosis. The patient initiated Celebrex (celecoxib) treatment. On Cycle 6, Day 3, the patient experienced tachycardia, with a heart rate greater than 110 beats per minute (BPM). Chest X-ray was normal and hemoglobin was 6.3 mmol/L. The patient received a blood transfusion. During Cycle 6, the patient complained of periodic episodes of nausea, vomiting, diarrhea, and abdominal complaints. On Cycle 6, Day 5, the patient completed Cycle 6 and the lower limb pain resolved. The patient was admitted to the hospital due to worsened general condition. A chest X-ray suggested infiltration in the bilateral basal lung fields. The patient was treated with prednisolone, antibiotics, and intravenous fluids for Grade 3 intercurrent

pulmonary infection with secondary dehydration. The patient expired on Cycle 6, Day 6, 2 days after the last dose of belinostat.

One patient died with hepatic failure 25 days after their last dose of belinostat; this death was considered related to belinostat by the Investigator.

- Patient 154-001- a 73-year-old Caucasian male with PTCL, NOS and a previous history of hepatitis A, monoclonal gammopathy, peripheral neuropathy and nicotine abuse treated with multiple concomitant medications including allopurinol and Voltaren, was administered 10 cycles of belinostat (2,040 mg/day). The patient completed 9 cycles of treatment without complication, and then he developed hyperuricemia, which was treated with allopurinol, and otitis media that was treated with diclofenac. Liver enzymes were noted to be elevated on Cycle 10, Day 1 at the time of dosing, and the patient completed Cycle 10 of belinostat with stable/decreased liver function tests (LFTs). He was subsequently hospitalized 17 days after his last belinostat dose with fever and generalized worsening at that time his LFTs were noted to be markedly elevated. The patient left the hospital against medical advice, but was readmitted 21 days after his last belinostat dose at which time his LFTs had further elevated. The patient expired 25 days after the last dose of belinostat with an autopsy showing subtotal liver necrosis as the cause of death. The patient's underlying disease, complicated medical history and the use of Voltaren were confounding factors.

Listing 16.2.7.4 provides a comprehensive list of the death dates and the primary cause of death for all patients with a known death date including those who died beyond 30 days after their last dose of belinostat. As mentioned in Section 10.1, only 1 patient was lost to follow-up.

12.3.1.2 *Serious Adverse Events*

A by-patient listing of all patients who experienced an SAE while on belinostat treatment or within 30 days of their last dose is provided in Table 14.3.7.3. All SAEs regardless of causality are summarized by Preferred Term and decreasing frequency in Table 14.3.7.5. Belinostat-related SAEs are summarized by Preferred Term and decreasing frequency in Table 14.3.7.6.

Sixty-one (47.3%) patients experienced an SAE while on study or within 30 days after their last dose of belinostat (Table 14.3.6.1); the details of each event are summarized in the patient narratives in Section 14.3.3.

Table 41 summarizes the treatment emergent SAEs occurring in more than 1 patient by decreasing incidence.

The non-hematologic treatment emergent SAEs occurring in >2 patients were pneumonia (n=9, 7.0%), pyrexia (n=7, 5.4%), infection (n=4, 3.1%), blood creatinine increased (n=3, 2.3%), and multi-organ failure (n=3, 2.3%); all other SAEs were reported in 2 (1.6%) or fewer patients.

Treatment emergent hematological SAEs occurred at a lower incidence than non-hematologic SAEs (Table 14.3.7.3). The hematologic SAEs reported in >2 patients included anemia (n=3, 2.3%) and thrombocytopenia (n=3, 2.3%).

Table 41: Treatment Emergent Serious Adverse Events Reported in >1 Patient (Full Analysis Dataset)

MedDRA Preferred Term	Full Analysis Dataset (N=129) n (%)
All Treatment Emergent SAEs	**61 (47.3%)**
Pneumonia	9 (7.0)
Pyrexia	7 (5.4)
Infection	4 (3.1)
Anemia	3 (2.3)
Blood Creatinine Increased	3 (2.3)
Multi-organ Failure	3 (2.3)
Thrombocytopenia	3 (2.3)
Bronchitis	2 (1.6)
Cardiac Failure	2 (1.6)
Deep Vein Thrombosis	2 (1.6)
Fatigue	2 (1.6)
Febrile Neutropenia	2 (1.6)
Hypotension	2 (1.6)
Pulmonary Embolism	2 (1.6)
Sepsis	2 (1.6)
Tumor Lysis Syndrome	2 (1.6)

Source: Table 14.3.6.1 and Table 14.3.7.5

Table 42: Treatment Emergent Serious Adverse Events Reported in >1 Patient by Worst Grade and Patient (Full Analysis Dataset)

MedDRA Preferred Term	Patient	Outcome	Grade
Pneumonia	752-002	Fatal	5
	100-002	Resolved	3
	142-003	Resolved	3
	146-001	Resolved	3
	532-004	Resolved	3
	914-003	Resolved	3
	914-004	Resolved	3
	933-001	Resolved	3
	912-003	Resolved	2
Pyrexia	140-001	Resolved	2
	140-002	Resolved	2
	513-002	Resolved with Sequelae	2
	902-001	Resolved	2
	144-002	Resolved with Sequelae	1
	532-004	Resolved	1
	914-003	Resolved	1
Infection	240-002	Resolved	4
	100-004	Resolved	3
	914-003	Resolved	3
	934-003	Resolved	3
Anemia	144-001	Resolved with Sequelae	4
	801-001	Resolved	4
	161-001	Resolved	3
Blood Creatinine Increased	141-001	Resolved	2
	142-002	Resolved with Sequelae	2
	140-001	Resolved	1
Multi-organ Failure	146-002	Fatal	5
	513-001	Fatal	5
	516-001	Fatal	5

MedDRA Preferred Term	Patient	Outcome	Grade
Thrombocytopenia	144-001	Resolved with Sequelae	4
	161-001	Resolved	4
	516-006	Resolved with Sequelae	4
Bronchitis	144-002	Resolved	3
	534-002	Resolved	3
Cardiac Failure	142-001	Fatal	5
	513-003	Fatal	5
Deep Vein Thrombosis	146-001	Resolved with Sequelae	3
	534-002	Resolved	3
Fatigue	907-004	Resolved	3
	142-003	Resolved	2
Febrile Neutropenia	144-001	Resolved	3
	154-001	Resolved	3
Hypotension	934-003	Resolved	3
	243-001	Resolved	2
Pulmonary Embolism	100-002	Resolved	4
	908-003	Resolved	3
Tumor Lysis Syndrome	146-002	Resolved	4
	902-001	Resolved	2

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities
Source: Table 14.3.7.2, Table 14.3.7.3, Listing 16.2.7.1

Twenty-seven patients (20.9%) had SAEs considered related to belinostat treatment (Table 14.3.6.1). No Grade 5 treatment-related SAE was reported. SAEs that were reported in >1 patient are summarized in Table 43. The only SAEs reported in >2 patients included blood creatinine increase, pyrexia and thrombocytopenia, each of which were reported in 3 (2.3%) patients. Table 44 summarizes the treatment related SAEs that occurred in >1 patient by patient and by worst grade.

Table 43: Treatment-related Serious Adverse Events Reported in >1 Patient (Full Analysis Dataset)

MedDRA Preferred Term	Full Analysis Dataset (N=129) n (%)
All Treatment Related SAEs	**27 (20.9%)**
Blood Creatinine Increased	3 (2.3)
Pyrexia	3 (2.3)
Thrombocytopenia	3 (2.3)
Anemia	2 (1.6)
Infection	2 (1.6)
Pneumonia	2 (1.6)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities

Source: Tables 14.3.6.1, 14.3.7.6

Table 44: Treatment Related Serious Adverse Events Reported in >1 Patient by Worst Grade and Patient (Full Analysis Dataset)

MedDRA Preferred Term	Patient	Outcome	Grade
Blood Creatinine Increased	141-001	Resolved	2
	142-002	Resolved with Sequelae	2
	140-001	Resolved	1
Pyrexia	140-002	Resolved	2
	513-002	Resolved with Sequelae	2
	144-002	Resolved with Sequelae	1
Thrombocytopenia	144-001	Resolved with Sequelae	4
	161-001	Resolved	4
	516-006	Resolved with Sequelae	4
Anemia	144-001	Resolved with Sequelae	4
	161-001	Resolved	3
Infection	914-003	Resolved	3
	934-003	Resolved	3
Pneumonia	914-003	Resolved	3
	914-004	Resolved	3

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities

Source: Table 14.3.7.3

12.3.1.3 *Other Significant Adverse Events*

12.3.1.3.1 Adverse Events Leading to Treatment Discontinuation

Listings of patients who experienced AEs leading to discontinuation of study drug are provided in Appendix 16.2.7. Patient narratives in Section 14.3.3 discuss all AEs that were the primary reason for treatment withdrawal.

Overall, 25 (19.4%) patients had an AE leading to discontinuation of whom 14 (10.9%) had SAEs (Table 45). The only SAEs leading to treatment discontinuation that were reported in more than 1 patient included multiple organ failure and fatigue, each occurring in 2 (1.6%) patients (Table 14.3.7.10). The only other AEs leading to treatment discontinuation that were reported in more than 1 patient included anemia and febrile neutropenia, each of which were reported in 2 (1.6%) patients (Table 14.3.7.7).

A total of 14 patients who withdrew from treatment due to TEAEs were considered to have AEs related to belinostat treatment (Table 14.3.6.1). There were no related SAEs leading to treatment discontinuation that were reported in more than 1 patient (Table 14.3.7.10). The only related AEs leading to treatment discontinuation that were reported in more than 1 patient included anemia and febrile neutropenia, each of which was reported in 2 (1.6%) patients (Table 14.3.7.8).

Table 45: TEAEs Leading to Treatment Withdrawal by Decreasing Grade (Full Analysis Dataset)

MedDRA Preferred Term	Patient	Outcome	Grade
Withdrawal Due to SAE			
Cardiac Failure	142-001	Fatal	5
Hepatic Failure	154-001	Fatal	5
Liver function test abnormal		Resolved	3
Febrile neutropenia		Resolved	3
General physical health deterioration		Resolved	3
Thrombocytopenia*		Resolved	4
Leukopenia*		Resolved	4
Neutropenia*		Resolved	3
Opportunistic Infection*		Resolved	3
International Normalized Ratio Increased*		Resolved	3

MedDRA Preferred Term	Patient	Outcome	Grade
Prothrombin Time Shortened*		Resolved	3
Abdominal Pain*		Resolved	3
Hepatic Cirrhosis*		Resolved	1
Encephalopathy*		Resolved	1
Multi-organ failure	513-001	Fatal	5
Multi-organ failure	516-001	Fatal	5
Shock	922-001	Fatal	5
Pancytopenia	516-006	Unknown	4
Hypercalcaemia	803-001	Resolved with Sequelae	4
Anaemia	161-001	Resolved	3
Septic shock		Resolved	3
Fatigue	907-004	Resolved	3
Sepsis	934-003	Resolved	3
Hypotension		Resolved	3
Extremity necrosis	141-001	Resolved	3
Decreased appetite	142-003	Resolved	3
Pneumonia		Resolved	3
Fatigue		Resolved	2
Pyrexia	140-002	Resolved	2
Administration Site Infection*		Resolved	2
Blood creatinine increased	142-002	Resolved	2
Withdrawal Due to AE			
Neutrophil Count Decreased	532-002	Resolved	4
Hypoalbuminemia		Resolved	3
Lymphopenia		Resolved	4
Platelet Count Decreased	550-002	Not Resolved	4
ECOG Performance Status Worsened	600-003	Resolved	4
Lung Squamous Cell Carcinoma Stage Unspecified	912-003	Not Resolved	4
Subcutaneous Nodule	919-001	Resolved	3
Dyspnea	147-002	Resolved	3
Blood Lactate Dehydrogenase Increased		Resolved	3

MedDRA Preferred Term	Patient	Outcome	Grade
Electrocardiogram QT Prolonged		Resolved	3
Hyperhidrosis		Resolved	2
Febrile Neutropenia	934-001	Resolved	3
Pruritus	207-001	Not Resolved	2
Rash		Not Resolved	2
Anemia	533-001	Not Resolved	2
Epstein-Barr Virus Infection	140-001	Not Resolved	-
Neuropathy Peripheral	800-001		

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities

* *Non-serious TEAEs*

Source: Table 14.3.7.9 and Table 14.3.7.10

Table 46: Treatment-related Adverse Events Leading to Treatment Withdrawal (Full Analysis Dataset)

MedDRA Preferred Term	Full Analysis Dataset (N=129) n (%)
Anemia	2 (1.6)
Febrile Neutropenia	2 (1.6)
Abdominal Pain	1 (0.8)
Administration Site Infection	1 (0.8)
Blood Creatinine Increased	1 (0.8)
Decreased Appetite	1 (0.8)
Electrocardiogram QT Prolonged	1 (0.8)
Encephalopathy	1 (0.8)
Extremity Necrosis	1 (0.8)
Fatigue	1 (0.8)
General Physical Health Deterioration	1 (0.8)
Hepatic Cirrhosis	1 (0.8)
Hepatic Failure	1 (0.8)
Hypercalcemia	1 (0.8)
International Normalized Ratio Increased	1 (0.8)
Leukopenia	1 (0.8)
Liver Function Test Abnormal	1 (0.8)
Neuropathy Peripheral	1 (0.8)

MedDRA Preferred Term	Full Analysis Dataset (N=129) n (%)
Neutropenia	1 (0.8)
Opportunistic Infection	1 (0.8)
Pancytopenia	1 (0.8)
Prothrombin Time Shortened	1 (0.8)
Pruritus	1 (0.8)
Pyrexia	1 (0.8)
Rash	1 (0.8)
Sepsis	1 (0.8)
Thrombocytopenia	1 (0.8)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities
Source: Table 14.3.7.8

12.3.1.3.2 Adverse Events of Special Interest-Thrombocytopenia and Decreased Platelet Count

Patients with relapsed and refractory PTCL and platelet counts less than 100,000/µL often have poorer outcomes [27] and importantly may not be candidates for treatment with currently approved agents. **CLN-19** enrolled patients with lower platelet counts (≥50,000/µL).

At Baseline, 105 patients in the **Full Analysis Dataset** had platelet counts of ≥100,000/µL and 24 patients had platelet counts <100, 000/µL (Table 14.1.1.4). Two patients (144-001 and 532-002) were eligible for enrollment based on their initial platelet counts during Screening (52,000/µL and 51,000/µL, respectively) but subsequently had lower platelet counts pre-treatment on Cycle 1, Day 1 (Listing 16.2.8.1). Patient 144-001 had a platelet count of 10,000/µL on Cycle 1, Day1, before belinostat therapy. The patient completed Cycle 1 without any hematologic AEs. Prior to Cycle 2, the patient received several platelet transfusions and started Cycle 2 with a platelet count of 9,000/µL. On Cycle 2, Day 5, this patient's platelet count was 2,000/µL; study treatment was discontinued due to progressive disease after Cycle 2. Patient 532-002 started Cycle 1 at a 25% reduced dose. Between the Cycle 1 and 2, the patient received 3 platelet transfusions, which increased the platelet count to 94,000/µL before the Cycle 2. On Cycle 2, Day 5, the patient's platelet count decreased to 6,000/µL. Before Cycle 3, the patient was taken off study for progressive disease and expired 20 days after the last dose.

TEAEs related to decreased platelet counts in **CLN-19** in patients in the **Full Analysis Dataset** included Grade 4 thrombocytopenia (n=9, 7.0%) (Table 34); Grade 3 platelet

count decreased (n=1, 0.8%) and Grade 4 platelet count decreased (n=3, 2.3%) (Table 14.3.6.4). Table 47 provides a summary of the patients with Grade 3-4 thrombocytopenia or decreased platelet count by Baseline platelet count. Among the patients with Baseline platelet counts ≥100,000/µL who experienced a Grade 3 or Grade 4 TEAE, 3 (3.9%) patients had low platelets and 2 (1.9%) patients had thrombocytopenia. For patients with Baseline platelet counts <100,000/µL, 7 (29.2%) patients experienced Grade 3 or Grade 4 thrombocytopenia and 1 (4.2%) patient had Grade 3 or 4 decreased platelet counts (Table 14.3.6.10). Overall, 5 of these patients (154-001, 161-001, 600-003, 800-001, and 938-001) had a best overall response of PR and 1 patient had a best overall response of CR (534-006) (Table 14.2.3.7).

Table 47: Summary of Patients with Grade 3-4 Thrombocytopenia or Decreased Platelet Count (Full Analysis Dataset)

Patient	Preferred Term	Study Day	Grade
Baseline Platelet Counts ≥100,000/µL			
154-001	Thrombocytopenia	212	4
244-006	Thrombocytopenia	43	3
		45	3
		47	4
		58	3
		65	4
513-001	Platelet Count Decreased	25	4
550-002	Platelet Count Decreased	5	4
938-001	Platelet Count Decreased	82	3
Baseline Platelet Counts <100,000/µL			
144-001	Thrombocytopenia	-6	4
		6	4
		8	4
		43	4
144-002	Thrombocytopenia	23	3
		25	3
		29	4
161-001	Thrombocytopenia	2	3
		8	3
		29	3

		43	3
		67	3
		71	4
		78	3
		100	4
243-001	Thrombocytopenia	5	4
		26	4
516-006	Thrombocytopenia	5	3
		11	4
		22	4
532-002	Platelet Count Decreased	1	4
		11	3
		21	4
		42	4
600-003	Thrombocytopenia	36	3
		200	4
		219	4
801-001	Thrombocytopenia	26	4

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities
Source: Table 14.3.7.8, Table 14.3.6.10

12.3.1.3.3 Adverse Events of Special Interest- QT Prolongation

Cardiac Disorders

Table 48 summarizes treatment emergent and treatment-related AEs in the Cardiac Disorders and Investigations SOC. Overall, 13 (10.1%) AEs in the Cardiac Disorders SOC were treatment emergent and 3 (2.3%) were treatment-related as previously described in Sections 12.2.3.1.15 and 12.2.3.3.15, respectively. Treatment-related cardiac AEs included Grade 1 atrial fibrillation, Grade 1 bundle branch block right, and Grade 1 ventricular extrasystoles (Table 14.3.6.7). In addition, there were 14 (10.9%) treatment emergent investigations of electrocardiographs (ECGs) QT prolonged, of which 13 (10.1%) were considered to be treatment-related by the Investigators.. Treatment-related investigations also included 1 (0.8%) Grade 1 ECG ST segment depression. Among the treatment-related ECG QT prolonged investigations there were 4 (3.1%) Grade 1, 4 (3.1%) Grade 2, and 5 (3.9%) Grade 3 AEs of Electrocardiogram QT Prolonged reported by the Investigators; only 2 of the Grade 3 Electrocardiogram QT Prolonged cases were confirmed on central review by eRT.

Table 48: Cardiac Disorders and Investigations (Full Analysis Dataset)

Preferred Term	Full Analysis Dataset (N=129)					
	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)
Treatment Emergent Cardiac Disorders and Investigations						
Atrial fibrillation	3 (2.3)	2 (1.6)	1 (0.8)	0	0	0
Bundle branch block right	1 (0.8)	1 (0.8)	0	0	0	0
Cardiac failure	2 (1.6)	0	0	0	0	2 (1.6)
Cardiac failure congestive	1 (0.8)	0	0	1 (0.8)	0	0
Cor pulmonale	1 (0.8)	0	0	1 (0.8)	0	0
Coronary artery disease	1 (0.8)	1 (0.8)	0	0	0	0
Sinus bradycardia	1 (0.8)	1 (0.8)	0	0	0	0
Sinus tachycardia	2 (1.6)	0	1 (0.8)	1 (0.8)	0	0
Supraventricular tachycardia	1 (0.8)	0	0	1 (0.8)	0	0
Tachycardia	2 (1.6)	1 (0.8)	1 (0.8)	0	0	0
Ventricular extrasystoles	1 (0.8)	1 (0.8) [a]	0	0	0	0
Cardiac murmur	1 (0.8)	1 (0.8)	0	0	0	0
Electrocardiogram QT prolonged	14 (10.9)	5 (3.9)	4 (3.1)	5 (3.9)	0	0
Electrocardiogram ST segment depression	1 (0.8) [a]	1 (0.8)	0	0	0	0
Treatment-related Cardiac Disorders and Investigations						
Atrial fibrillation	1 (0.8)	1 (0.8)	0	0	0	0
Bundle branch block right	1 (0.8)	1 (0.8)	0	0	0	0
Ventricular extrasystoles	1 (0.8)	1 (0.8)	0	0	0	0
Electrocardiogram QT prolonged	13 (10.1)	4 (3.1)	4 (3.1)	5 (3.9)	0	0
Electrocardiogram ST segment depression	1 (0.8)	1 (0.8)	0	0	0	0

Source: Table 14.3.6.4, Table 14.3.6.7

Assessment of QTc Prolongation

As pre-defined in the protocol and described in Section 6.3.7, all ECGs collected in the study were independently analyzed by eRT. (Electrocardiogram Cardiac Safety Evaluation). All ECGs were performed on ECG machines provided by eRT and ECGs were sent to eRT for central analysis. Three 12-lead ECSs were performed at a Baseline Screening assessment to determine Baseline eligibility. A 12-lead ECG was performed locally pre-dose and within 1 hour post-end of infusion on treatment Days 1 to 5 of Cycle 1; on Day 5 of subsequent cycles and at the End of Treatment visit.

A summary of the Investigator and eRT (central) cardiac assessments of 5 patients (Patients 144-001, 147-002, 534-002, 911-001, and 912-001) is provided in Table 49 and Section 12.3.3. eRT only confirmed Grade 3 AEs in 2 (1.6%) patients (Patient 147-002 and Patient 911-001); there were no Grade 4 or Grade 5 QT prolongation AEs reported.

The eRT assessment of **CLN-19** ECGs suggested no effect of belinostat on cardiac repolarization. For the 128 patients who met the ECG analysis criteria, no signal of clinically relevant changes in heart rate, PR or QRS duration or nonspecific ST-T changes were identified. An average QTcF increase of 8.3 msec was noted after each infusion with some outliers. The PK-PD model revealed a positive intercept (the QTcF change from Baseline at 0 ng/mL belinostat was 13.56 msec [y-axis intercept]) with a flat relationship between change in QTcF and concentration (0.00001772) (i.e. flat slope), which suggested that the effect on QTcF was not related to belinostat plasma concentration. No clinically relevant changes in other ECG parameters were noted.

Table 49: Summary of Patients with Reported Grade 3 QTc Prolonged AEs by Investigators' and ERT Assessments

Patient ID	No. of Cycles	Concomitant Meds	Investigator Assessment	Outcome	eRT Assessment
144-001	2 cycles	No antiemetics	From C1D3 –D5, Grade 3 QTc prolongation.	C2 Dose reduced by 25% Off the study after C2	Grade 1
147-002	3 days of Cycle 1	Kevatril 3 mg	C1D3 – predose ECG normal and post dose ECGs x5 were abnormal and clinically significant Grade 3 AE, related	Discontinued from the study after D3	Confirmed Grade 3.
534-002	30 cycles	Dexamethasone	History of ischemic	Dose reduced	Grade 1

		12 mg daily; Ondanesterone 8 mg daily for 5 days of each cycle starting at C2D1	heart disease. Baseline ECG – Abnormal, NCS. C1-D5, post dose ECG –abnormal, CS, Grade 3 QTc prolongation reported as an AE	2X Discontinued due to progressive disease	
911-001	4 cycles	Zofran 24 mg and compazine 10 mg at each cycle from D1-D5	C2D5 Post dose ECG was reported as abnormal Grade 3 AE of QTcF	Discontinued due to progressive disease	Grade 1
912-001	1 cycle	No antiemetics	C1D1 ECG post dose was "abnormal, clinically significant." Belinostat dose was reduced. C1D2 was delayed due to biliary stricture requiring biliary stent. The C1D2 was resumed 12 days later and C1 QTcs was reported as Grade 3 and related.	Dose reduced x1 Discontinued due to progressive disease	Of all Grade 3 ECGS reported by Investigators, 1 was confirmed as Grade 3 QTc prolongation by eRT.

Abbreviations: ms=millisecond, C=cycle, D=day, ECG=electrocardiogram, QTcF=corrected QT interval
Source: CRFs, Listing 16.2.5.2, Listing 16.2.7.1, Listing 16.2.8.8, Electrocardiogram Cardiac Safety Evaluation

12.3.2 Narratives of Deaths, Other Serious Adverse Events and Certain Other Significant Adverse Events

Narratives for all patients who experienced treatment-emergent serious or other significant AEs during the study or death (within 30 days of the last dose of belinostat) and withdrawals from belinostat treatment due to an AE are presented in Section 14.3.3.

Each narrative describes all significant events that were reported to the Sponsor's Drug Safety Department and relevant data contained in data listings (based on the patients CRFs). The narratives in Section 14.3.3 are arranged in the following order of importance: deaths, SAEs, and AE treatment discontinuations. Narratives for patients who fell into 2 categories were not duplicated within each group but were prioritized by the primary category of the AE.

12.3.2.1 *Narratives of Deaths*

A total of 22 (17.1%) patients in **CLN-19** died within 30 days of the last dose of belinostat; of which 12 (9.3%) were due to progressive disease and the remaining 10 (7.8%) had AEs; the only AE associated with death that was considered related to treatment was hepatic failure in 1 patient (154-001) (Table 50).

Table 50: **Summary of Narratives for Patients Who Died 30 days of the Last Dose of Belinostat Due to a TEAE**

Patient	MedDRA Preferred Term	Treatment-related
Adverse Events		
142-001	Cardiac failure	No
146-002	Multi-organ failure	No
154-001	Hepatic failure	Yes
221-004	Lung infection	No
244-002	Gastrointestinal hemorrhage	No
244-004	Euthanasia	No
513-001	Multi-organ failure	No
513-003	Cardiac failure	No
516-001	Multi-organ failure	No
922-001	Shock	No
Disease Progression		
100-001	Disease progression	Unrelated
142-002	Disease progression	Unrelated
180-002	Disease progression	Unrelated
206-001	Disease progression	Unrelated
224-001	Disease progression	Unrelated
244-006	Disease progression	Unrelated
532-001	Disease progression	Unrelated
532-002	Disease progression	Unrelated
801-002	Disease progression	Unrelated
803-001	Disease progression	Unrelated
907-002	Disease progression	Unrelated
934-004	Disease progression	Unrelated

Source: Table 14.3.7.2

12.3.2.2 *Narratives for Patients Who Had Serious Adverse Events*

A total 61 (47.3%) patients in **CLN-19** had treatment emergent SAEs with 27 (20.9%) patients having SAEs that were considered related to treatment (Table 51).

Table 51: Summary of Narratives for Patients Who Had Had Treatment Emergent SAEs

Patient	MedDRA Preferred Term	Treatment-related
100-002	Pulmonary Embolism	No
	Pneumonia	No
100-004	Infection	No
126-002	Venous Thrombosis Limb	Yes
140-001	Blood Creatinine Increased	Yes
	Pyrexia	No
140-002	Pyrexia	Yes
	Pyrexia	Yes
141-001	Blood Creatinine Increased	Yes
	Extremity Necrosis	Yes
	Vasculitis	Yes
142-001	Renal Failure	No
	Cardiac Failure	No
142-002	Blood Creatinine Increased	Yes
142-003	Decreased Appetite	Yes
	Fatigue	Yes
	Pneumonia	No
142-005	Aspartate Aminotransferase Increased	Yes
	Alanine Aminotransferase Increased	Yes
	Gamma-glutamyltransferase Increased	Yes
144-001	Thrombocytopenia	Yes
	Anemia	Yes
	Febrile Neutropenia	No
144-002	Pyrexia	Yes
	Bronchitis	No
146-001	Alveolitis	Yes
	Constipation	Yes
	Pneumonia	No
	Deep Vein Thrombosis	Yes
	Multiple Fractures	No

Patient	MedDRA Preferred Term	Treatment-related
146-002	Multi-Organ Failure	No
	Tumor Lysis Syndrome	No
	Respiratory Failure	No
154-001	Hepatic Failure	Yes
	Liver Function Test Abnormal	Yes
	Febrile Neutropenia	Yes
	General Physical Health Deterioration	Yes
161-001	Asthenia	No
	Thrombocytopenia	Yes
	Septic Shock	Yes
	Anemia	Yes
	Septic Shock	No
	Thrombocytopenia	Yes
	Thrombocytopenia	Yes
207-001	Rash	Yes
	Actinic Keratosis	No
220-002	Hyperglycemia	No
221-004	Lung Infection	No
224-001	Anxiety	No
240-001	Upper Respiratory Tract Infection	Yes
240-002	Tumor Hemorrhage	No
	Infection	No
243-001	Hypotension	No
	Hypoglycemia	No
244-002	Malaise	No
	Gastrointestinal Haemorrhage	No
244-004	Euthanasia	No
244-006	Impaired Self-care	No
513-001	Platelet Count Decreased	Yes
	Multi-organ Failure	No
513-002	Pyrexia	Yes
513-003	Cardiac Failure	
516-001	Gastrointestinal Fungal Infection	No

Patient	MedDRA Preferred Term	Treatment-related
	Multi-organ Failure	No
516-004	Central Venous Catheterization	No
	Pulmonary Mass	Yes
516-006	Pancytopenia	Yes
	Thrombocytopenia	Yes
532-001	Chylothorax	No
532-004	Pyrexia	No
	Pneumonia	No
533-001	Hemolytic Anemia	Yes
	Hemolytic Anemia	Yes
534-001	Atrial Fibrillation	No
	Iliac Artery Thrombosis	No
534-002	Sepsis	No
	Deep Vein Thrombosis	No
	Bronchitis	No
	Bronchopneumonia	No
534-003	Toxic Cataract	Yes
534-005	Bronchitis Bacterial	Yes
534-006	Anemia Hemolytic Autoimmune	No
541-001	Thrombosis	No
600-003	Pharyngitis	No
752-002	Pneumonia	No
800-001	Hypoxia	Yes
801-001	Anemia	No
803-001	Hypercalcemia	Yes
902-001	Tumor Lysis Syndrome	No
	Tumor Associated Fever	No
	Pyrexia	No
	Pyrexia	No
907-001	Lower limb fracture	No
907-004	Fatigue	No
908-003	Pulmonary Embolism	Yes
912-001	Hyperbilirubinemia	No
912-003	Pneumonia	No

Patient	MedDRA Preferred Term	Treatment-related
914-003	Device Related Infection	No
	Infection	Yes
	Pneumonia	Yes
	Dyspnea	No
	Pyrexia	No
914-004	Pneumonia	Yes
915-002	Pain of Skin	No
	Pain	No
	Pathological Fracture	No
919-001	Peripheral Sensory Neuropathy	No
922-001	Endocarditis	No
	Urosepsis	No
931-003	Arthralgia	No
933-001	Pneumonia	No
934-003	Infection	Yes
	Sepsis	Yes
	Hypotension	No
936-001	Splenomegaly	No

Source: Table 14.3.7.3

12.3.2.3 *Narratives for Patients Who Discontinued Due to AEs*

A total of 25 (19.4%) patients in **CLN-19** discontinued treatment due to TEAEs, with 14 patients (10.9%) discontinuing due to AEs that were considered related to treatment.

Table 52: **Summary of Narratives for Patients Who Discontinued Due to AEs**

Patient	MedDRA Preferred Term	Treatment-related
140-001	Epstein-Barr Virus Infection	No
140-002	Administration Site Infection	Yes
	Pyrexia	Yes
141-001	Necrosis (Acral)	Yes
141-001	Cardiac Failure	No
142-002	Blood Creatinine Increased	Yes
142-003	Decreased Appetite	Yes

Patient	MedDRA Preferred Term	Treatment-related
	Fatigue	Yes
	Pneumonia	No
147-002	Dyspnea	No
	Blood Lactase Deydrogenase Increased	No
	Electrocardiogram QT prolonged	Yes
	Hyperhidrosis	No
154-001	Hepatic cirrhosis	Yes
	Neutropenia	Yes
	Thrombocytopenia	Yes
	Leukopenia	Yes
	Opportunistic Infection	Yes
	Encephalopathy	Yes
	International Normalized Ratio Increased	Yes
	Prothrombin Time Shortened	Yes
	Abdominal Pain	Yes
161-001	Anemia	Yes
	Septic Shock	Yes
207-001	Pruritus	Yes
	Rash	Yes
513-001	Multi-organ Failure	No
516-001	Multi-organ Failure	No
	Tumor Associated Fever	No
516-006	Pancytopenia	Yes
532-002	Hypoalbuminemia	No
	Neutrophil Count Decreased	No
	Lymphopenia	No
533-001	Anemia	Yes
550-002	Platelet Count Decreased	No
600-003	Eastern Cooperative Oncology Group Performance Status Worsened	No
800-001	Hypercalcemia	Yes
803-001	Hypercalcemia	Yes
907-004	Fatigue	No

Patient	MedDRA Preferred Term	Treatment-related
912-003	Lung Squamous Cell Carcinoma Stage Unspecified	No
919-001	Subcutaneous Nodule	No
922-001	Shock	No
934-001	Febrile Neutropenia	Yes
934-003	Sepsis	Yes
	Hypotension	No

Source: Table 14.3.7.9

12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

Of the 22 (17.1%) deaths reported within 30 days of the last dose of belinostat, all were considered not related to study drug except for 1 (0.8%) death due to hepatic failure that was considered treatment-related (Patient 154-001). After receiving 9 cycles of belinostat therapy, this patient died 25 days after the last belinostat dose due to hepatic failure. Details on all deaths are summarized in the narratives in Section 14.3.3; no safety signal was identified for belinostat.

12.4 Clinical Laboratory Evaluation

Laboratory evaluations were performed by local laboratories at Baseline (within 14 days prior to initiation of belinostat treatment), on study as described in Table 2, and at the End of Study Treatment Visit. Some patients also had unscheduled visits for laboratory testing. All test results were compared with each laboratory's normal range and to the applicable NCI CTCAE grades. Values that were outside of the reference range were flagged as being "high" or "low" (H or L).

Laboratory test value abnormalities were to be recorded on the AE page of the CRF as AEs, if deemed clinically relevant, i.e., there was an associated clinical condition for which the patient was given treatment or concomitant treatment was altered, the event was considered to be an SAE, study treatment was interrupted/delayed or the dose of study drugs were modified, or the patient was permanently discontinued from study treatment because of the abnormal test value. No specific safety signal was identified after review of the laboratory data.

12.4.1 Listing of Individual Laboratory Measurements by Patient and Each Abnormal Laboratory Value

Laboratory measurements are provided by patient in Listings 16.2.8.1 (hematology), 16.2.8.2 (coagulation), 16.2.8.3 (serum chemistry), 16.2.8.4 (urinalysis-dipstick), 16.2.8.5 (urine microscopy), and 16.2.8.6 (pregnancy assessment).

12.4.2 Evaluation of Key Laboratory Parameters

12.4.2.1 *Laboratory Values Over Time*

Decreased hematological values were the most frequently recorded treatment emergent laboratory abnormalities, with decreased hemoglobin (91.5%) and decreased lymphocyte count (83.6%) as the primary abnormalities (Table 14.3.8.1). Serum chemistry abnormalities were also reported; the most frequent were increased glucose (86.7%) and decreased albumin (59.7%). The most frequent Grade 3-4 laboratory abnormalities were decreased lymphocytes (47.7%) and thrombocytopenia (14.8%); no Grade 5 laboratory abnormalities were reported. The events that changed relative to normal laboratory ranges from Baseline for each laboratory parameter through the 30-day End of Study Treatment Visit are described in detail in Section 12.4.2.2. Clinically relevant changes are described in Section 12.4.2.3. The list of normal laboratory ranges is provided in Listing 16.2.8.1, Listing 16.2.8.2, and Listing 16.2.8.3.

12.4.2.1.1 Summary of Abnormal Hematology and Coagulation Parameters

The majority of patients in **CLN-19** had 1 or more abnormal hematology values during the study, with most being of Grade 1 or 2 severity. The incidence of all Grade 3 and Grade 4 hematology values was <8% except for Grade 4 low lymphocyte values (16.4%), Grade 3 low lymphocyte values (31.3%) and low leukocyte values (10.9%) (Table 53).

Table 53: Hematology and Coagulation Abnormalities Occurring in ≥10% of Patients

Laboratory Parameter	Patients With On-study Test	Number of Patients[a] (N=129)				
		Incidence of Abnormality[a]				
		Any Grade n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hemoglobin, low	129	118 (91.5)	51 (39.5)	52 (40.3)	10 (7.8)	5 (3.9)
Leukocytes, low	129	60 (46.5)	22 (17.1)	22 (17.1)	14 (10.9)	2 (1.6)
Lymphocytes, low	128	107 (83.6)	10 (7.8)	36 (28.1)	40 (31.3)	21 (16.4)
Neutrophils, low	128	46 (35.9)	13 (10.2)	17 (13.3)	10 (7.8)	6 (4.7)
Platelet, low	129	90 (69.8)	47 (36.4)	24 (18.6)	9 (7.0)	10 (7.8)
Activated PTT, high	91	34 (37.4)	23 (25.3)	7 (7.7)	4 (4.4)	0
Prothrombin INR, high	86	29 (33.7)	16 (18.6)	3 (3.5)	10 (11.6)	0
Prothrombin time, high	54	17 (31.5)	13 (24.1)	1 (1.9)	3 (5.6)	0

[a] Percentages are based on number of patients with on-study test

Abbreviations: INR=international normalized ratio; PTT=partial thromboplastin time

Source: Table 14.3.8.1

Fewer than 40% of patients had abnormal coagulation parameter values (aPTT, prothrombin INR, and prothrombin time). No patients had Grade 4 coagulation parameter values and the incidence of all Grade 3 values was <8% (Table 53).

12.4.2.1.2 Summary of Shifts in Hematology and Coagulation Parameters

Shifts in hematology parameter values in individual patients are summarized in Table 54. Overall, shifts of ≥2 grades occurred in ≥2 patients for all hematology parameters, with the majority of shifts to worse grades being observed for lymphocytes.

Shifts in coagulation parameter values in individual patients are also summarized in Table 54. Overall, shifts of ≥2 grades occurred in ≥2 patients for aPTT and prothrombin INR.

Table 54: Summary of Shifts in Hematology and Coagulation Values

Laboratory Parameter	Number of Patients (N=129)									
Baseline	Grade 0			Grade 1		Grade 2		Grade 3		Grade 4
Worst Grade	2	3	4	3	4	3	4	3	4	4

Laboratory Parameter	Number of Patients (N=129)									
Baseline	Grade 0			Grade 1		Grade 2		Grade 3		Grade 4
Worst Grade	2	3	4	3	4	3	4	3	4	4
Hematology										
Hemoglobin	7	1	0	4	1	3	2	2	1	1
Leukocytes	13	5	0	5	0	2	0	2	2	0
Lymphocytes	20	9	1	6	2	13	4	10	8	5
Neutrophils	14	8	3	0	0	2	2	0	1	0
Platelets	5	2	2	2	3	5	3	0	0	2
Coagulation										
Activated PTT	5	3	0	1	0	0	0	0	0	0
Prothrombin INR	1	3	0	5	0	1	0	1	0	0
Prothrombin time	0	1	0	1	0	1	0	0	0	0

Abbreviations: INR=international normalized ratio; PTT=partial thromboplastin time

Source: Table 14.3.8.2

Table 55 presents the biochemistry abnormalities occurring at Baseline in ≥10% of the patients. Table 56 presents the shifts in biochemistry parameter values in individual patients. Overall, shifts of ≥2 grades occurred in ≥2 patients for ALT, albumin, alkaline phosphatase, AST, bilirubin, calcium, creatinine, glucose, magnesium, phosphate, potassium, sodium, and urate, with the majority of shifts being from Grade 0 to 2 for low phosphate (18 patients), high glucose (14 patients), and low calcium (12 patients).

Table 55: Biochemistry Abnormalities Occurring in ≥10% of Patients

Laboratory Parameter	Patients With On-study Test	Number of Patients[a] (N=129)				
		Incidence of Abnormality				
		Any Grade n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine Aminotransferase, high	129	55 (42.6)	38 (29.5)	12 (9.3)	4 (3.1)	1 (0.8)
Albumin, low	124	74 (59.7)	37 (29.8)	35 (28.2)	2 (1.6)	0
Alkaline Phosphatase, high	128	56 (43.8)	39 (30.5)	15 (11.7)	2 (1.6)	0
Aspartate Aminotransferase, high	128	56 (43.8)	43 (33.6)	8 (6.3)	4 (3.1)	1 (0.8)
Bilirubin, high	129	38 (29.5)	27 (20.9)	4 (3.1)	6 (4.7)	1 (0.8)
Blood Urea Nitrogen, high	129	65 (50.4)	0	0	0	0
Creatinine, high	129	41 (31.8)	28 (21.7)	12 (9.3)	1 (0.8)	0
Magnesium, high	125	18 (14.4)	17 (13.6)	0	1 (0.8)	0
Magnesium, low	125	35 (28.0)	31 (24.8)	4 (3.2)	0	0
Potassium, high	129	20 (15.5)	12 (9.3)	5 (3.9)	2 (1.6)	1 (0.8)
Potassium, low	129	56 (43.4)	48 (37.2)	0	8 (6.2)	0
Urate, high	129	29 (22.5)	25 (19.4)	0	0	4 (3.1)
Calcium, high	128	13 (10.2)	10 (7.8)	0	2 (1.6)	1 (0.8)
Calcium. low	128	72 (56.3)	47 (36.7)	22 (17.2)	2 (1.6)	1 (0.8)
Glucose, high	128	111 (86.7)	72 (56.3)	29 (22.7)	9 (7.0)	1 (0.8)
Glucose, low	128	12 (9.4)	10 (7.8)	1 (0.8)	0	1 (0.8)
Lactate Dehydrogenase, high	128	107 (83.6)	0	0	0	0
Phosphate, low	122	34 (27.9)	2 (1.6)	21 (17.2)	10 (8.2)	1 (0.8)

[a] Percentages are based on number of patients with on-study test

Source: Table 14.3.8.1

Table 56: Summary of Shifts in Biochemistry Values

Laboratory Parameter	Number of Patients (N=129)									
Baseline	Grade 0			Grade 1		Grade 2		Grade 3		Grade 4
Worst Grade	2	3	4	3	4	3	4	3	4	4
Alanine Aminotransferase (High)	9	3	0	1	1	0	0	0	0	0
Albumin (Low)	9	0	0	1	0	1	0	0	0	0
Alkaline phosphatase (High)	5	0	0	0	0	1	0	1	0	0
Aspartate Aminotransferase (High)	2	2	0	0	1	2	0	0	0	0
Bilirubin (High)	4	4	1	0	0	1	0	1	0	0
Calcium (High)	0	1	1	0	0	0	0	1	0	0
Calcium (Low)	12	0	1	0	0	2	0	0	0	0
Creatinine (High)	7	0	0	0	0	1	0	0	0	0
Glucose (High)	14	3	0	3	0	3	1	0	0	0
Glucose (Low)	1	0	1	0	0	0	0	0	0	0
Magnesium (High)	0	1	0	0	0	0	0	0	0	0
Magnesium (Low)	1	0	0	0	0	0	0	0	0	0
Phosphate (Low)	18	7	1	0	0	1	0	2	0	0
Potassium (High)	3	2	1	0	0	0	0	0	0	0
Potassium (Low)	0	7	0	0	0	0	0	0	0	0
Sodium (Low)	0	5	0	3	1	0	0	1	0	0
Urate (High)	0	0	3	0	0	0	0	0	0	0

Source: Table 14.3.8.2

12.4.2.2 *Individual Patient Changes*

Table 14.1.2.6 summarizes the laboratory abnormalities that existed at Baseline, and Table 14.3.8.1 summarizes the worst NCI CTCAE grade on treatment for hematological parameters, coagulation parameters, and liver function parameters. Table 14.3.8.2 presents the Baseline and worst NCI CTCAE grade on-study laboratory shift values for hematological parameters, serum chemistry parameters, and coagulation parameters. The subsections below summarize the grade shifts for each parameter. Patients with Grade 4 values at Baseline were captured as protocol deviations.

12.4.2.2.1 Hematology

Hemoglobin

All patients had a hemoglobin assessment at Baseline (Table 14.3.8.2). Forty-three (33.3%) patients had normal hemoglobin values at Baseline and 25 (19.4%) patients had a worst on-study shift to Grade 1, 7 (5.4%) shifted to Grade 2, and 1 (0.8%) shifted to Grade 3. Sixty-one patients (47.3%) had Grade 1 hemoglobin values at Baseline and 30 (23.3%) patients worsened to Grade 2, 4 (3.1%) to Grade 3, and 1 (0.8%) to Grade 4. Twenty (15.5%) patients had Grade 2 hemoglobin values at Baseline, of whom 1 (0.8%) improved, 3 (2.3%) worsened to Grade 3, and 2 (1.6%) worsened to Grade 4. Four (3.1%) patients had Grade 3 hemoglobin at Baseline, 1 (0.8%) of whom improved and 1 (0.8%) worsened to Grade 4. One (0.8%) patient entered the study with Grade 4 hemoglobin, which did not change during the study.

Overall, 10 (7.8%) patients had Grade 3 post-Baseline hemoglobin values and 5 (3.9%) patients had Grade 4 post-Baseline hemoglobin values. Most patients (n=114, 88%) had mild (n=51, 39.5%) or moderate (n=52, 40.3%) anemia or normal (n=11, 8.5%) hemoglobin values during belinostat treatment.

Platelets

All patients had a platelet assessment at Baseline (Table 14.3.8.2). Eighty-three (64.3%) patients had normal platelets at Baseline and 36 (27.9%) patients had a worst on-study shift to Grade 1, 5 (3.9%) shifted to Grade 2, 2 (1.6%) shifted to Grade 3, and 2 (1.6%) shifted to Grade 4. Thirty-four (26.4%) patients had Grade 1 platelets at Baseline, 1 (0.8%) patient improved, 17 (13.2%) worsened to Grade 2, 2 (1.6%) to Grade 3, and 3 (2.3%) to Grade 4. Ten (7.8%) patients had Grade 2 platelets at Baseline, of whom 5 (3.9%) worsened to Grade 3 and 3 (2.3%) worsened to Grade 4. Two (1.6%) patients entered the study with Grade 4 platelets, which did not change during the study.

Overall, 9 (7.0%) patients had Grade 3 platelets and 10 (7.8%) patients had Grade 4. Most patients had mild (n=47, 36.4%) or moderate (n=24, 18.6%) decreased or normal (n=39, 30.2%) platelets during belinostat treatment.

White Blood Cells

All patients had a leukocyte assessment at Baseline (Table 14.3.8.2). One-hundred (77.5%) patients had normal leukocytes at Baseline and 17 (13.2%) patients had a worst on-study shift to Grade 1, 13 (10.1%) shifted to Grade 2, and 5 (3.9%) shifted to Grade 3. Eighteen (14.0%) patients had Grade 1 leukocytes at Baseline, 3 (2.3%) patients improved, 5 (3.9%) worsened to Grade 2, and 5 (3.9%) to Grade 3. Seven (5.4%) patients had Grade 2 leukocytes at Baseline, of whom 1 (0.8%) patient improved and 2 (1.6%) worsened to Grade 3. Four (3.1%) patients entered the study with Grade 3

leukocytes, 2 (1.6%) patients worsened to Grade 4. Overall, 14 (10.9%) patients had Grade 3 post-Baseline leukocytes and 2 (1.6%) patients had Grade 4. Most (88%) patients had normal (n=69, 53.5%), mild (n=22, 17.1%), or moderate (n=22, 17.1%) low leukocyte values during belinostat treatment.

A total of 127 patients had a neutrophil assessment at Baseline (Table 14.3.8.2). Most patients (n=113; 88.3%) had normal neutrophils at Baseline and 9 (7.0%) patients had a worst on-study shift to Grade 1, 14 (10.9%) shifted to Grade 2, 8 (6.3%) shifted to Grade 3, and 3 (2.3%) shifted to Grade 4. Five (3.9%) patients had Grade 1 neutrophils at Baseline, 2 (1.6%) patients improved and 1 (0.8%) worsened to Grade 2. Eight (6.3%) patients had Grade 2 neutrophils at Baseline, of whom 2 (1.6%) patients improved, 2 (1.6%) worsened to Grade 3, and 2 (1.6%) to Grade 4. One (1%) patient entered the study with Grade 3 neutrophils, which worsened to Grade 4.

Overall, 10 (7.88%) patients had Grade 3 post-Baseline neutrophils and 6 (4.7%) patients had Grade 4. Most patients (n=82, 64.1%) had normal neutrophils during belinostat treatment.

A total of 127 patients had a lymphocyte assessment at Baseline (Table 14.3.8.2). Fifty-nine (46.1%) patients had normal lymphocytes at Baseline and 8 (6.3%) patients had a worst on-study shift to Grade 1, 20 (15.6%) shifted to Grade 2, 9 (7.0%) shifted to Grade 3, and 1 (0.8%) shifted to Grade 4. Eighteen (14.1%) patients had Grade 1 lymphocytes at Baseline and 9 (7.0%) patients worsened to Grade 2, 6 (4.7%) to Grade 3, and 2 (1.6%) to Grade 4. Twenty-three (18.0%) patients had Grade 2 lymphocytes at Baseline, of whom 1 (0.8%) patient improved, 13 (10.2%) worsened to Grade 3, and 4 (3.1%) to Grade 4. Twenty (15.6%) patients entered the study with Grade 3 lymphocytes, 2 (1.2%) patients improved, and 8 (6.3%) worsened to Grade 4. Seven (5.5%) patients entered the study with Grade 4 lymphocytes, which improved in 2 (1.6%) patients.

Overall, 40 (31.3%) patients had Grade 3 post-Baseline lymphocytes and 21 (16.4%) patients had Grade 4. Approximately half of the patients had normal (n=21, 16.4%), mild (n=10, 7.8%), or moderate (n=36, 28.1%) low lymphocytes during belinostat treatment.

12.4.2.2.2 Serum Chemistry

Liver Function

All patients had a bilirubin assessment at Baseline (Table 14.3.8.2). Most patients (n=120; 93.0%) had normal bilirubin values at Baseline and 21 (16.3%) patients had a worst on-study shift to Grade 1, 4 (3.1%) shifted to Grade 2, 4 (3.1%) shifted to Grade 3, and only 1 (0.8%) shifted to Grade 4. Six (4.7%) patients had Grade 1 bilirubin values at

Baseline, which improved in 1 (0.8%) patient. Two (1.6%) patients had Grade 2 bilirubin at Baseline, 1 (0.8%) patient improved and 1 (0.8%) worsened to Grade 3. One (0.8%) patient had a Grade 3 bilirubin value at Baseline, which did not change. In total, 6 (4.7%) patients had Grade 3 post-Baseline bilirubin values and 1 (0.8%) patient had Grade 4. Most (n=91, 70.5%) patients had normal bilirubin values or mildly (n=27, 20.9%) elevated bilirubin values with belinostat treatment.

A total of 127 patients had an alkaline phosphatase assessment at Baseline (Table 14.3.8.2). Most patients (n=95; 74.2%) had normal alkaline phosphatase values at Baseline, 19 (14.8%) patients had a worst on-study shift to Grade 1 and 5 (3.9%) shifted to Grade 2. Twenty-three (18.0%) patients had Grade 1 alkaline phosphatase values at Baseline, 1 (0.8%) patient improved and 3 (2.3%) worsened to Grade 2. One (0.8%) patient entered the study with Grade 3 alkaline phosphatase, which did not change. A total of 2 (1.6%) patients had Grade 3 post-Baseline alkaline phosphatase values and no (0%) patients had a change to Grade 4. Most (n=99%) patients had normal (n=72, 56.3%), mild (n=39, 30.5%), or moderate (n=15, 11.7%) alkaline phosphatase elevation during belinostat treatment.

All patients had an ALT assessment and 128 patients had an AST assessment at Baseline (Table 14.3.8.2). Patients 142-005, 154-001, 223-004, and 914-003, who had an increase in ALT aminotransferases also had an increase in AST. ALT changes are discussed here; however, AST changes were very similar (Patients 142-001, 142-005, 154-001, 165-001, 223-004, 800-001, 901-001, 914-003, and 931-002) and can be found in Table 14.3.8.2. Most patients (n=110; 85.3%) had normal ALT values at Baseline and 28 (21.7%) patients had a worst on-study shift to Grade 1, 9 (7.0%) shifted to Grade 2, and 3 (2.3%) shifted to Grade 3. Nineteen (14.7%) patients had Grade 1 ALT values at Baseline, 4 (3.1%) patients improved, 3 (2.3%) worsened to Grade 2, 1 (0.8%) to Grade 3, and 1 (0.8%) to Grade 4. A total of 4 (3.1%) patients had Grade 3 post-Baseline ALT values and 1 (0.8%) patient had a change to Grade 4. Most (n=124, 96%) patients had normal (n=74; 57.4%), mild (n=38, 29.5%), or moderate (n=12, 9.3%) ALT elevation during belinostat treatment. Most (n=115; 90%) patients had normal (n=72, 56.3%), mild (n=43, 33.6%), or moderate (n=8, 6.3%) AST elevation during belinostat treatment.

A total of 120 patients had an albumin assessment at Baseline (Table 14.3.8.2). Eighty-one (65.3%) patients had normal albumin values at Baseline and 25 (20.2%) patients had a worst on-study shift to Grade 1 and 9 (7.3%) shifted to Grade 2. Twenty-five (20.2%) patients had Grade 1 albumin values at Baseline, 2 (1.6%) patients improved, 11 (8.9%) worsened to Grade 2, and 1(0.8%) to Grade 3. Thirteen (10.5%) patients had Grade 2 albumin levels at Baseline, 1 (0.8%) of whom worsened to Grade 3. One (0.8%) patient had Grade 3 albumin at Baseline, which improved. A total of 2 (1.6%) patients had

Grade 3 post-Baseline albumin values and no (0%) patients had a change to Grade 4. Most (n=118, 98%) patients had normal (n=50, 40.3%), mild (n=37, 29.8%), or moderate (n=35, 28.2%) low albumin values.

Kidney Function

All patients had a creatinine assessment at Baseline (Table 14.3.8.2). Most patients (n=119; 92.2%) had normal creatinine values at Baseline and 25 (19.4%) patients had a worst on-study shift to Grade 1 and 7 (5.4%) shifted to Grade 2. Nine (7.0%) patients had Grade 1 creatinine values at Baseline, 1 (0.8%) patient improved and 5 (3.9%) worsened to Grade 2. One (0.8%) patient had Grade 2 creatinine at Baseline and worsened to Grade3. No (0%) patients had a Grade 4 post-Baseline creatinine. Most (n=128; 99%) patients had normal (n=88; 68.2%), mild (n=28; 21.7%), or moderate (n=12; 9.3%) high creatinine values.

A total of 127 patients had a uric acid assessment at Baseline (Table 14.3.8.2). Most patients (n=110; 85.3%) had normal uric acid values at Baseline and 11 (8.5%) patients had a worst on-study shift to Grade 1 and 3 (2.3%) shifted to Grade 4. Fifteen (11.6%) patients had Grade 1 uric acid values at Baseline, 3 (2.3%) of whom improved. Two (1.6%) patients had Grade 4 uric acid at Baseline, both of whom improved. A total of 4 (3.1%) patients had Grade 4 post-Baseline uric acid values. Most (n=124, 98%) patients had normal (n=99, 77.5%) or mild (n=25, 19.4%) high urate values during belinostat treatment.

All patients had a sodium assessment at Baseline (Table 14.3.8.2). All (100%) patients had normal values for increased sodium at Baseline, 7 (5.4%) shifted to Grade 1. Most (n=117; 90.7%) patients had normal values for decreased sodium at Baseline, 44 (34.1%) patients worsened to Grade 1 and 5 (3.9%) to Grade 3. Eleven (8.5%) patients had Grade 1 decreased sodium at Baseline, 1 (0.8%) patient improved, 3 (2.3%) worsened to Grade 3 and 1 (0.8%) to Grade 4 post-Baseline. One (0.8%) patient had Grade 3 decreased sodium at Baseline, which did not change. Overall, 9 (7.0%) patients had Grade 3 post-Baseline decreased sodium and 1 (0.8%) had Grade 4. Patients had normal (n=122, 94.6%) or mild (n=7, 5.4%) increased sodium during belinostat treatment. Most (n=119, 92%) patients had normal (n=69; 53.5%) or mild (n=50, 38.8%) decreased sodium during belinostat treatment.

All patients had a potassium assessment at Baseline (Table 14.3.8.2). Most (n=127, 98.4%) patients had normal values for increased potassium at Baseline, 12 (9.3%) had a worst on-study shift to Grade 1, 3 (2.3%) shifted to Grade 2, 2 (1.6%) shifted to Grade 3, and 1 (0.8%) shifted to Grade 4. One (0.8%) patient had Grade 1 increased potassium at Baseline, which worsened to Grade 2. One (0.8%) patient had Grade 3 increased potassium at Baseline, which improved. Most (n=121; 93.8%) patients had normal

decreased potassium at Baseline, 44 (34.1%) patients worsened to Grade 1, and 7 (5.4%) to Grade 3. Seven (5.4%) patients had Grade 1 decreased potassium at Baseline, 2 (1.6%) patients improved, and 1 (0.8%) worsened to Grade 3. One (0.8%) patient had Grade 3 decreased potassium at Baseline, which improved. Overall, 8 (6.2%) patients had Grade 3 post-Baseline decreased potassium and no (0%) patients had Grade 4. Most (n=121, 94%) patients had normal (n=109, 84.5%) or mild (n=12, 9.3%) increased potassium values during belinostat treatment. Most (n=121; 94%) patients had normal (n=73, 56.6%) or mild (n=48, 37.2%) decreased potassium values during belinostat treatment.

A total of 125 patients had a magnesium assessment at Baseline (Table 14.3.8.2). Most (n=115, 92.0%) patients had normal values for increased magnesium at Baseline, 14 (11.2%) had a worst on-study shift to Grade 1, and 1 (0.8%) shifted to Grade 3. Two (1.6%) patients had Grade 1 increased magnesium at Baseline, which improved in 1 (0.8%) patient. One (0.8%) patient had Grade 3 increased magnesium at Baseline, which improved. Most (n=105, 84%) patients had normal values for decreased magnesium at Baseline, 22 (17.6%) patients worsened to Grade 1, and 1(0.8%) to Grade 2 post-Baseline. Nine (7.2%) patients had Grade 1 decreased magnesium at Baseline, of whom 3 (2.4%) patients improved. Four (3.2%) patients had Grade 2 decreased magnesium at Baseline, which improved in 1 (0.8%) patient. Overall, 1 (0.8%) patient had Grade 3 post-Baseline increased magnesium and no (0%) patients had Grade 3 or 4 decreased magnesium post-Baseline. Most (n= 117, 99%) patients had normal (n=107, 85.6%) or mild (n=17, 13.6%) increased magnesium values during belinostat treatment. Most patients had normal (n=90, 72.0%) or mild (n=31, 24.8%) decreased magnesium values during belinostat treatment.

Metabolic Function

A total of 122 patients had a phosphate assessment at Baseline (Table 14.3.8.2). Most patients (n=109, 89.3%) had normal values for decreased phosphate at Baseline, 2 (1.6%) had a worst on-study shift to Grade 1, 18 (14.8%) shifted to Grade 2, 7 (5.7%) shifted to Grade 3, and 1 (0.8%) shifted to Grade 4. Two (1.6%) patients had Grade 1 decreased phosphate at Baseline, 1 (0.8%) patient improved and 1 (0.8%) worsened to Grade 2 post-Baseline. Three (2.5%) patients had Grade 2 decreased phosphate at Baseline, which worsened post-Baseline to Grade 3 in 1 (0.8%) patient. Two (1.6%) patients had Grade 3 decreased phosphate at Baseline, which did not change. Overall, 10 (8.2%) patients had Grade 3 post-Baseline decreased phosphate and 1 (0.8%) had Grade 4. Most (n=105; 91%) patients had normal (n=88, 72.1%), mild (n=2, 1.6%), or moderate (n=21, 17.2%) decreased phosphate values during belinostat treatment.

A total of 128 patients had a calcium assessment at Baseline (Table 14.3.8.2). Most (n=125, 97.7%) patients had normal values for increased calcium at Baseline, 8 (6.3%) had a worst on-study shift to Grade 1, 1 (0.8%) shifted to Grade 3, and 1 (0.8%) shifted to Grade 4. Two (1.6%) patients had Grade 1 increased calcium at Baseline, which did not change post-Baseline, and 1 (0.8%) patient had Grade 3 at Baseline, which did not change. Most (n =104, 81.3%) patients had normal decreased calcium at Baseline, 35 (27.3%) patients worsened to Grade 1, 12 (9.4%) to Grade 2, and 1 (0.8%) to Grade 4 post-Baseline. Eighteen (14.1%) patients had Grade 1 decreased calcium at Baseline, of whom 9 (7.0%) worsened to Grade 2 during the study. Five (3.9%) patients had Grade 2 decreased calcium at Baseline, which improved in 2 (1.6%) patients, and worsened to Grade 3 in 1 (0.8%) patient. One (0.8%) patient had Grade 3 decreased calcium at Baseline, which improved. Overall, 2 (1.6%) patients had Grade 3 increased calcium and 1 (0.8%) patient had a Grade 4 increased calcium, and 2 (1.6%) patients had Grade 3 post-Baseline decreased calcium and 1 (0.8%) patient had Grade 4 decreased calcium. Most (n=125, 98%) patients had normal (n=115, 89.8%) or mild (n=10, 7.8%) increased calcium values during belinostat treatment. Most (n=125, 98%) patients had normal (n=56, 43.8%), mild (n=47, 36.7%), or moderate (n=22, 17.2%) decreased calcium values during belinostat treatment.

A total of 128 patients had a glucose assessment at Baseline (Table 14.3.8.2). Eighty-three (64.8%) patients had normal values for increased glucose at Baseline, 50 (39.1%) had a worst on-study shift to Grade 1, 14 (10.9%) shifted to Grade 2, and 3 (2.3%) shifted to Grade 3. Thirty-four (26.6%) patients had Grade 1 increased glucose at Baseline, which improved in 1 (0.8%) patient, worsened to Grade 2 in 11 (8.6%) and to Grade 3 in 3 (2.3%) patients over the course of the study. Eleven (8.6%) patients had Grade 2 increased glucose at Baseline, which improved in 3 (2.3%) patients, worsened to Grade 3 in 3 (2.3%) patients and Grade 4 in 1 (0.8%) patient post-Baseline. Most (n=127, 99.2%) patients had normal values for decreased glucose at Baseline, 9 (7.0%) patients worsened to Grade 1, 1 (0.8%) to Grade 2, and 1 (0.8%) to Grade 4 during the study. One (0.8%) patient had Grade 1 decreased glucose at Baseline, which did not change. Overall, 9 (7.0%) patients had Grade 3 post-Baseline increased glucose and 1 (0.8%) patient had Grade 4, and 1 (0.8%) patient had Grade 4 decreased glucose. Most patients had mild (n=72, 56.3%) to moderate (n=29, 22.7%) increased glucose values during belinostat treatment. Most patients had normal (n=116, 90.6%) decreased glucose values during belinostat treatment.

12.4.2.2.3 Coagulation

Fifty-four patients had Baseline and on-study prothrombin time data (Table 14.3.8.2). Forty-one (75.9%) patients had normal increased prothrombin time at Baseline, 10 (18.5%) patients shifted to Grade 1 and 1 (1.9%) shifted to Grade 3 post-Baseline.

Four (7.4%) patients had Grade 1 increased prothrombin time at Baseline, 1 (1.9%) patient improved and 1 (1.9%) worsened to Grade 3. Two (3.7%) patients had Grade 2 increased prothrombin time at Baseline, 1 (1.9%) of whom worsened to Grade 3 during the course of the study. Overall, 3 (5.6%) patients had Grade 3 post-Baseline increased prothrombin time and no (0%) patients had Grade 4. Of the patients with Baseline and on-study prothrombin time data, 37 (68.5%) patients had normal or mild (n=13, 24.1%) increased prothrombin time during belinostat treatment.

Eighty-six patients had Baseline and on-study INR data (Table 14.3.8.2). Sixty-nine (80.2%) patients had normal values for increased INR at Baseline, 11 (12.8%) patients shifted to Grade 1, 1 (1.2%) shifted to Grade 2, and 3 (3.5%) shifted to Grade 3 post-Baseline. Ten (11.6%) patients had Grade 1 increased INR at Baseline, 1 (1.2%) patient improved and 5 (5.8%) worsened to Grade 3. Two (2.3%) patients had Grade 2 increased INR at Baseline, 1 (1.2%) of whom worsened to Grade 3. Overall, 10 (11.6%) patients had Grade 3 post-Baseline increased INR and no (0%) patients had Grade 4. Of the patients with Baseline and on-study INR data, most patients had normal (n=57, 6.36%) or mild (n=16, 18.6%) increased INR values during belinostat treatment over the course of the study.

Ninety-one patients had Baseline and on-study APTT data (Table 14.3.8.2). Seventy-six (83.5%) patients had normal values for increased APTT at Baseline, 12 (13.2%) patients shifted to Grade 1, 5 (5.5%) shifted to Grade 2, and 3 (3.3%) shifted to Grade 3 post-Baseline. Twelve (13.2%) patients had Grade 1 increased APTT at Baseline, 1 (1.1%) worsened to Grade 2 and 1 (1.1%) worsened to Grade 3. One (1.1%) patient had Grade 2 increased APTT at Baseline, which improved over the course of the study. One (1%) patient had Grade 3 increased APTT at Baseline, which improved. Overall, 4 (4.4%) patients had Grade 3 post-Baseline increased APTT and no (0%) patients had Grade 4. Of the patients with Baseline and on-study APTT data, 57 (62.6%) had normal and 23 (25.3%) had mild increased APTT values during belinostat treatment.

12.4.2.3 *Individual Clinically Significant Abnormalities*

Five patients had laboratory abnormalities listed as at least 1 of the AEs responsible for discontinuation of study treatment, which are provided in Table 14.3.7.4. Details of these patients are provided in the narratives in Section 14.3.3. Patient 154-001 died of hepatic failure and also had neutropenia, leukopenia, thrombocytopenia, increased INR, and shortened prothrombin time and was considered as withdrawal from treatment due to AEs. The other MedDRA Preferred Terms for laboratory abnormalities listed among the other 4 patients (147-002, 532-002, 533-001, and 550-002) who withdrew from treatment due to AEs were blood lactate dehydrogenase increased, Hypoalbuminemia, neutrophil count decreased, lymphopenia, anemia, and platelet count decreased.

12.5 Vital Signs, Physical Findings and other Observations Related to Safety

Vital signs at Baseline are summarized in Table 14.1.2.7. End of Study measurements and change from Baseline are summarized in Table 14.3.8.3. Mean heart rate was within normal parameters at Baseline (82.2 BPM; Std Dev: 14.2) and at the End of Study (82.3 BPM; Std Dev: 15.5) with a mean change from Baseline of 0.1 BPM. The mean body temperatures at Baseline and End of Study were the same (36.5 ºC).

Mean systolic (124.7 mm Hg; Std Dev 15.7) blood pressure changed by -7.2 mm Hg (Std Dev 11.9) at the End of Study 117.9 mm Hg; Std Dev 19.9) and mean diastolic blood pressure decreased by -4.7 mm Hg from Baseline (75.4 mm Hg) to 70.8 mm Hg at the End of Study. Overall, vital signs were within normal parameters at Baseline and following belinostat treatment. The observed changes from Baseline were not clinically relevant.

Physical examination results are listed by patient in Listing 16.2.7.2.

No trends or safety signals were identified through review of the vital sign data.

12.6 Safety Conclusions

Overall in **CLN-19**, belinostat treatment at a dose of 1,000 mg/m^2, administered to 129 patients with relapsed or refractory PTCL over 30 minutes by IV infusion on Days 1-5 of a 21-day cycle, had an acceptable toxicity profile with no unexpected toxicities. The majority of patients (87%) were able to remain at this dose for the duration of treatment and dose reduction occurred only in 12.4% patients. The discontinuation of belinostat due to an AE occurred in only 19.4% of the total patients.

While the overall incidence of AEs regardless of causality was 96.9%, this high frequency of TEAEs is consistent and not unexpected in a patient population with advanced, relapsed or refractory PTCL who had failed multiple therapies. Nausea (41.9%), fatigue (37.2%) and pyrexia (34.9%) were the most frequently occurring AEs, most of which were mild or moderate in severity. The Grade 3, 4 or 5 AEs regardless of causality reported most frequently were anemia (10.9%), thrombocytopenia (7.0%), dyspnea (6.2%), neutropenia (6.2%), and pneumonia (6.2%), and the only Grade 5 AE among these was 1 case of pneumonia. Most patients (83.7%) experienced at least 1 AE considered related to belinostat. The most common AEs related to belinostat were nausea (38.0%), fatigue (28.7%), and vomiting (24.0%).

Twenty-two patients (17.1%) died while still on study or within 30 days of their last dose of Belinostat. Twelve deaths were attributed to disease progression and the remaining 10 (7.8%) patients experiencing treatment emergent AEs that resulted in death. All of these deaths were considered not related to belinostat except for 1 patient with hepatic failure; this patient had a complicated medical history with multiple

confounders, tolerated 9 cycles of belinostat without complication, and had elevated liver function tests at the start of Cycle 10 that subsequently worsened with death due to toxic liver failure. The other 9 non-treatment related deaths included multi-organ failure (3), cardiac failure (2), lung infection (1), gastrointestinal hemorrhage (1), euthanasia (1), and shock (1).

Forty-seven percent of patients experienced an SAE while on study or within 30 days after their last dose of belinostat. The most frequently reported non-hematologic SAEs were pneumonia (7.0%), pyrexia (5.4%), infection (3.1%), blood creatinine increased (2.3%) and multi-organ failure (2.3%). Hematologic SAEs occurred at a lower incidence than non-hematologic SAEs, the most common included anemia (2.3%) and thrombocytopenia (2.3%). All other SAEs were reported in 2 (1.6%) or fewer patients. Twenty-one percent of patients had a SAE considered related to belinostat treatment.

The only related SAEs occurring in more than 2 patients were blood creatinine increased, pyrexia, and thrombocytopenia, each of which were reported in 3 (2.3%) patients.

Vital signs (heart rate, systolic and diastolic blood pressures) were within normal parameters at Baseline and following belinostat treatment. In **CLN-19**, central review of ECG data by eRT identified 2 patients with a Grade 3 QT prolongation and the conclusion of the expert report was that belinostat showed no effect on cardiac repolarization. The PK-PD analysis showed no correlation between belinostat concentration and QTcF change from Baseline. No clinically relevant changes in other ECG parameters were noted.

Decreased hematologic values were the most frequently recorded laboratory abnormalities on treatment, with decreased red blood cells (93.6% vs. 67.5%), hemoglobin (91.5% vs. 66.7%), and decreased lymphocyte (83.6% vs. 53.1%) as the primary abnormalities compared to Baseline assessments. Increased serum chemistry abnormalities were also reported, the most frequent were increased glucose (86.7% vs. 35.2%) and decreased albumin (59.7% vs. 33.1%). Most patients had mild (n=72, 56.3%) to moderate (n=29, 22.7%) increased glucose values during belinostat treatment. However, these data were based on non-fasting blood draws with no control over food intake across patients. No analyses of fasting-glucose levels in patients treated with belinostat have been conducted. Due to the study design, no conclusive interpretation can be made regarding the impact of belinostat treatment on plasma glucose levels.

Six patients had laboratory abnormalities listed as at least 1 of the AEs responsible for discontinuation of study treatment.

In conclusion, this large, multicenter, Phase 2 study confirmed the acceptable safety profile of belinostat in a population of heavily pretreated patients with relapsed or refractory PTCL.

13 DISCUSSION AND OVERALL CONCLUSIONS

CLN-19 was a Phase 2, single arm, open-label, large, multicenter study of the safety and efficacy of belinostat conducted in patients with relapsed or refractory PTCL to assess the primary efficacy endpoint of response rate, utilizing the independent review by the **IRC**. A total of 129 patients were enrolled across 62 study sites in 17 countries. All PTCL histolopathologies were confirmed by central review by the **CPRG**. Baseline and demographic characteristics were reflective of the typical population of patients with relapsed or refractory PTCL. One hundred and twenty patients were evaluable for efficacy based on confirmation of PTCL histolopathology by **CPRG**. Patients received belinostat at a dose of 1,000 mg/m^2 as a 30 minute IV infusion on Days 1-5 of a 21-day cycle.

The enrolled patient population was heavily pre-treated with a range of 1-8 prior therapies and median of 2 before entering this study. Ninety-seven percent of patients had received CHOP/CHOP-like multiagent therapy and had progressed prior to enrolling in the **CLN-19** study. Nearly 25% of the patients previously received a prior stem cell transplant. Despite the extensive, aggressive prior treatments for PTCL, these patients had relapsed or did not respond to treatment and were in need of additional treatment options, and many were shown to respond to belinostat.

The primary efficacy endpoint of the study was ORR with response assessment per IWG criteria based on the review by the **IRC**. Patients treated with belinostat had an ORR (CR+PR) of 25.8% (95% CI: 18.3-34.6%) per **IRC,** exceeding the pre-defined 20% ORR that was considered clinically meaningful per the SAP and SPA in this patient population. Eighteen patients (15.0%) achieved a PR, and importantly, 13 patients (10.8%) achieved a CR. Most patients (n=19, 61.3% of responders) responded at the first scheduled tumor assessment, i.e., within 30-45 days of the first dose of belinostat, with a median Time to Response of 5.6 weeks. The response rate based on local response assessment as reported by study Investigators was 22.5% (95% CI: 15.4-31.0%).

Responses were clinically meaningful with a median Duration of Response, as defined by IWG criteria, of 13.6 months (95% CI: 4.5-29.4) for the 31 responding patients based on central response assessment by the **IRC**. Fifty-five percent of responders had a Duration of Response of at least 6 months, and importantly, 12 patients were able to proceed to a stem cell transplant after treatment with belinostat.

CLN-19 enrolled PTCL patients who were more difficult to treat, including patients with low platelet counts or more aggressive PTCL subtypes. Patients with Baseline platelets <100,000/μL due to bone marrow involvement or immune phenomena in the setting of T-cell disease or hypersplenism were enrolled, and shown to tolerate a high

dose intensity (98.5%) and benefit from belinostat therapy with a 15.0% ORR; this included 1 patient with a CR. Patients with thrombocytopenia to this degree would not have been eligible for enrollment in many other studies nor would they have met the labeled recommendations for full dose treatment with other FDA approved agents due to concerns regarding the potential for additional drug-induced bone marrow suppression exacerbating thrombocytopenia. For example, the pivotal trials leading to the accelerated approval of pralatrexate and romidepsin in relapsed and refractory PTCL, both limited the enrollment of patients with low platelet counts: romidepsin required platelet counts ≥75,000/uL if bone marrow involvement was documented or ≥100,000/µL if there was no bone marrow involvement; pralatrexate studies required all eligible patients to have platelet values >100,000/uL. [21,22] For pralatrexate, the USPI recommends platelet counts be ≥100,000/µL before administering the first dose, and both the pralatrexate and romidepsin labels recommend dose reductions for patients with low platelet counts.

For patients with platelet counts of ≥100,000/µL, the ORR was 28%. In addition, the response rate in patients with the AITL subtype, a more difficult to treat PTCL subtype, was shown to be high (45.5%) with belinostat compared with the reported ORRs of 8% with pralatrexate and 30% with romidepsin. [21,22] In comparing ORRs with other published data, it is also important to note that the pivotal trials for both the currently approved agents for PTCL, romidepsin and pralatrexate, permitted the enrollment of patients with tMF, [21, 22] a T-cell lymphoma subtype with a better prognosis than PTCLs. [30] In the pivotal pralatrexate trial, an ORR of 25% was reported in patients with tMF. Patients with tMF were not eligible to enroll in the **CLN-19** trial.

The **CLN-19** patient population included slightly more males (53.5%) than females (46.5%) in the **Full Analysis Dataset** and the **Efficacy Analysis Dataset** (51.7% male vs. 48.3% female). There was a slightly higher ORR observed in females (31%) than males (21%). [18, 35] Belinostat-treated patients with PTCL who were ≥65 years of age (n=59, 49.2%) had an ORR of 35.6% (95% CI: 23.6-49.1%) while those <65 years of age had an ORR of 16.4% (95% CI: 8.2-28.1%). Due to the broad CIs, these data should be interpreted conservatively.

In summary, belinostat treatment produced clinically meaningful ORRs in heavily pretreated patients with relapsed or refractory PTCL with an ORR of 25.8%. Importantly, 13 (10.8%) patients achieved a CR and 18 patients (15.0%) achieved a PR, and 11 (9.2%) patients were able to go on to stem cell transplantation. Most patients (n=19, 61.3% of responders) responded at the first scheduled tumor assessment within 30-45 days of first dose, with a median Time to Response of 5.6 weeks. The responses observed with belinostat were durable with a median Duration of Response of 13.6 months by **IRC**. Patients had a 63.5% probability of having a Duration of Response in excess of 6 months. The median PFS based on response as assessed by **IRC** and

estimated by the Kaplan-Meier method, was 1.6 months (95% CI: 1.4-2.7) and the median TTP was 2.0 months (95% CI: 1.5-2.8). The median OS, estimated by the Kaplan-Meier method, was 7.9 months (95% CI: 6.1-13.9). Almost 40% of the patients (n=46, 38.3%) were censored for OS because they were still alive at the time of the data cut-off date.

The majority of patients tolerated belinostat treatment, and experienced AEs expected for this disease and class of agent. The relative dose intensity was 98% for patients with greater than or less than 100,000/µL platelets indicating that the vast majority of patients received all intended treatment at the target dose. Treatment-related AEs were reported in 83.7% of patients and 34.1% of patients had Grade 3-4 AEs. Only 1 (0.8%) patient had a related-AE (hepatic failure) that was associated with death; this case was confounded by the patient's complicated medical history, and the use of multiple concomitant medications. Treatment-related SAEs were reported in 20.9% of patients and 7.0% of patients had a treatment-related SAE leading to study withdrawal.

The most common AEs in were nausea (41.9%), fatigue (37.2%), pyrexia (34.9%) and anemia (31.8%), and most of these were Grade 1 or 2 in severity. The most common treatment-related AEs were nausea (38.0%), fatigue (28.7%) and vomiting (24.0%). The most frequent Grade 3, 4 or 5 AEs, regardless of causality, included anemia (10.9%), thrombocytopenia (7. 0%), dyspnea (6.2%), neutropenia (6.2%) and pneumonia (6.2%). Central review of ECGs suggested that belinostat had no effect on cardiac repolarization in this study. The PK-PD analysis showed no correlation between belinostat concentration and QTcF change from Baseline. No clinically relevant changes in other ECG parameters were noted.

In summary, the **CLN-19** study demonstrated the clinical activity of belinostat treatment for patients with relapsed or refractory PTCL with the induction of durable tumor responses, delayed disease progression, and opportunities for continuation to potentially curative stem cell transplant. The toxicity profile of belinostat was shown to be acceptable for that of a cytotoxic therapy for heavily pre-treated patients with PTCL. In addition, belinostat was demonstrated to be tolerated and effective in aggressive PTCL subtypes and in patients with thrombocytopenia and platelet counts <100,000/µL, who are difficult to treat with other approved agents.

The approval of belinostat for the treatment of patients with relapsed or refractory PTCL would represent a major contribution to the treatment options available for these patients, and could help to address this unmet medical need. The population in the **CLN-19** study included many patients in the 3rd and later line of therapy with most patients having failed 2 lines of therapy. Currently, once the approved agents have been exhausted, the only remaining treatment options for these patients is the use of other

agents that have not been appropriately studied in this specific population. This often includes treatment with single agent or combination chemotherapy regimens that have been developed for other types of lymphoma, such as B-cell lymphoma or CTCL. Overall, **CLN-19** demonstrated that belinostat was well tolerated with manageable AEs, and induced durable tumor responses including CRs that provided the opportunity for potentially curative stem cell transplant; these data support the clinical activity of belinostat treatment in this population of patients with relapsed or refractory PTCL.

14 TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

14.1 Demographic Data Summary Tables

Table Number	Title
Table 14.1.1.1	Patient Enrollment by Investigational Center
Table 14.1.1.2	Patient Disposition
Table 14.1.1.3	Patient Disposition by Treatment Cycle
Table 14.1.1.4	Patient Disposition by Treatment Cycle by Baseline Platelet Group
Table 14.1.1.5	Overall Distribution of Infusion Time Regardless of Cycles and Days
Table 14.1.2.1	Demographics and Other Baseline Characteristics
Table 14.1.2.2	Pretreatment Disease Characteristics
Table 14.1.2.3	Prior Therapies for Peripheral T-cell Lymphoma
Table 14.1.2.4	Prior Systemic Regimens for Peripheral T-cell Lymphoma
Table 14.1.2.5	General Medical History
Table 14.1.2.6	Baseline Laboratory Abnormalities
Table 14.1.2.7	Pretreatment Vital Signs, Height and Weight
Table 14.1.2.8	Prior Medications (ATC Classification)
Table 14.1.2.9	Demographics and Other Baseline Characteristics by Baseline Platelet Group
Table 14.3.5.1	Extent of Exposure to Belinostat
Table 14.3.5.2	Treatment Adjustments and Modifications
Table 14.3.5.3	Subsequent Therapies for Peripheral T-cell Lymphoma
Table 14.3.5.4	Concomitant Medications (ATC Classification)
Table 14.3.5.5	Treatment Adjustments and Modifications Full Analysis Dataset by Baseline Platelet Group
Table 14.3.5.6	Extent of Exposure to Belinostat by Baseline Platelet Group (Full Analysis Dataset)

14.2 Efficacy Data Summary Tables

Table Number	Title
Table 14.2.3.1	Tumor Response, **IRC** Assessment
Table 14.2.3.2	Time to and Duration of Response, **IRC** Assessment
Table 14.2.3.3	Overall Response Rate, **IRC** Assessment, by Pre-treatment Characteristics
Table 14.2.3.4	Tumor Response, Investigator Assessment
Table 14.2.3.5	Time to and Duration of Response, Investigator Assessment
Table 14.2.3.6	Concordance of **IRC** and Investigator Best Overall Response
Table 14.2.3.7	Patient Listing of Duration of Response, **IRC** Assessment

Table 14.2.3.8	Duration of Treatment by **IRC** Response Cohort
Table 14.2.3.9	Time to and Duration of Response, **IRC** Assessment by Baseline Platelet Group
Table 14.2.3.10	Time to and Duration of Response, Investigator Assessment by Baseline Platelet Group
Table 14.2.3.11	Patient Listing of Duration of Response, **IRC** Assessment by Baseline Platelet Group
Table 14.2.4.1	Time to Progression, **IRC** Assessment
Table 14.2.4.2	Progression-free Survival, **IRC** Assessment
Table 14.2.4.3	Time to Progression, Investigator Assessment
Table 14.2.4.4	Progression-free Survival, Investigator Assessment
Table 14.2.4.5	Overall Survival
Table 14.2.4.7	Progression-free Survival, **IRC** Assessment by Baseline Platelet Group
Table 14.2.4.8	Overall Survival by Baseline Platelet Group

14.3 Safety Data Summary Tables

14.3.1 Displays of Adverse Events

Table Number	Title
Table 14.3.6.1	Overview of Treatment Emergent Adverse Events
Table 14.3.6.2	Treatment Emergent Adverse Events by MedDRA System Organ Class
Table 14.3.6.3	Treatment Emergent Adverse Events by MedDRA Preferred Term
Table 14.3.6.4	Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient
Table 14.3.6.5	Treatment Related Adverse Events by MedDRA System Organ Class
Table 14.3.6.6	Treatment Related Adverse Events by MedDRA Preferred Term
Table 14.3.6.7	Treatment Related Adverse Events by Worst Grade Toxicity per Patient
Table 14.3.6.8	Cross Reference of Treatment Emergent Adverse Events to Patients
Table 14.3.6.9	Treatment Emergent Adverse Events by MedDRA System Organ Class by Baseline Platelet Group
Table 14.3.6.10	Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group
Table 14.3.6.11	Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group
Table 14.3.6.12	Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Table Number	Title
Table 14.3.7.1	Deaths
Table 14.3.7.2	Patient Listing of Treatment Emergent Adverse Events Resulting in Death within 30 Days of Last Dose
Table 14.3.7.3	Patient Listing of All Treatment Emergent Serious Adverse Events
Table 14.3.7.4	Patient Listing of Other Treatment Emergent Adverse Events Leading to Discontinuation
Table 14.3.7.5	Treatment Emergent Serious Adverse Events
Table 14.3.7.6	Treatment Related Serious Adverse Events
Table 14.3.7.7	Treatment Emergent Adverse Events Leading to Withdrawal
Table 14.3.7.8	Treatment Related Adverse Events Leading to Withdrawal
Table 14.3.7.9	Listing of Patients with Any Adverse Events Leading to Discontinuation
Table 14.3.7.10	Listing of Patients with Serious Adverse Events Leading to Discontinuation

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

14.3.3.1 *Narratives of Deaths*

Narratives for patients who died during the study or within 30 days of the last belinostat dose are included below. Cross links to the individual narratives are available in Table 50.

14.3.3.1.1 100-001

Patient **100-001**, a 62-year-old Caucasian male with a diagnosis of anaplastic large cell lymphoma (ALK-positive; Stage IVA) with bone marrow involvement, started Cycle 1 of belinostat on 11-May-2009 at a dose of 1,730 mg. The patient withdrew consent prior to C1D2 infusion (12-May-2009) and died on 20-May-2009 (C1D10) due to disease progression. The patient had no relevant medical history and on prophylactic concomitant medications.

14.3.3.1.2 142-001

Patient **142-001**, a 72-year-old Caucasian female with an extensive medical history including hypotension, intermittent hyperuricemia, and oedema in both ankles on multiple concomitant medications, was treated with 1 cycle of belinostat at a dose of 1,990 mg. On 08-Oct-2009, prior to start of study treatment, the patient was hospitalized with Grade 4 hypercalcemia (blood calcium level 3.46 mmol/L). The event was considered resolved on 17-Oct-2009, with blood calcium levels 2.40 mmol/L, and Cycle 1 of belinostat was started on 19-Oct-2009.

On 31-Oct-2009 (C1D13), the patient presented to the ER with a 2-day history of progressive ankle edema, dyspnea, and diarrhea. Laboratory work revealed potassium 6.2 mmol/L, sodium 133 mmol/L, and calcium 2.17 mmol/L. The patient was hospitalized the same day with a diagnosis of Grade 4 cardiac decompensation. The potassium level returned to normal, however, creatinine and urea-nitrogen levels (not specified) elevated further. The patient did not respond to higher doses of furosemide and was subsequently treated with dialysis on 14-Nov-2009 (C1D27) and 16-Nov-2009 (C1D29). The patient was diagnosed with Grade 2 renal failure. On 16-Nov-2009 (C1D29), the patient experienced secondary anemia and received 2 transfusions of erythrocyte concentrate. On 17-Nov-2009 (C1D30), the patient expired due to cardiac decompensation.

The Investigator assessed all the events as unrelated to belinostat.

14.3.3.1.3 142-002

Patient **142-002**, a 68-year-old Caucasian male with a complicated medical history on multiple concomitant medications, was treated with 2 cycles of belinostat at a dose of 2,000 mg. The patient received Cycle 1 of belinostat from 07-Dec to 11-Dec-2009 and was hospitalized for Cycle 2 treatment on 04-Jan-2010 (C2D1). Laboratory work on the same day revealed Grade 1 increase in creatinine levels to 1.69 mg/dL (Baseline: 1.04 mg/dL on 07-Dec-2009; reference range 0.7–1.4) and increase in blood urea levels to 48 mg/dL (Baseline: 20mg/dL on 17-Dec-2009; reference range 8-25). The patient received 3 doses of belinostat during Cycle 2 and, on 06-Jan-2010 (C2D3), the creatinine levels increased to Grade 2 (values unspecified). Study treatment was temporarily discontinued and hospitalization prolonged due to Grade 2 increased creatinine. Cycle 2 treatment days 4 and 5 were not given due to the event. The patient was treated with furosemide and laboratory work on 08-Jan-2010 (C2D5), revealed creatinine level 3.18 mg/dL and blood urea level 62 mg/dL. On 16-Jan-2010 (C2D13), the creatinine level returned to Grade 1 (values unspecified) and the event was considered resolved with sequelae (Grade 1 increased creatinine). Laboratory values on 18-Jan-2010 (C2D15), revealed creatinine level of 1.9 mg/dL and blood urea level of 38 mg/dL.

The patient remained hospitalized for observation. On 18-Jan-2010 (C2D15), tumor assessment #1 scans were performed and revealed disease progression in lymph nodes at the aorta bifurcation, the kidney hilus, and among other sites. The patient was diagnosed with disease progression, was permanently withdrawn from study, and started new treatment with dexamethasone on 20-Jan-2010 (C2D17). The patient remained hospitalized until his death on 27-Jan-2010 (C2D24) due to disease progression.

The Investigator assessed the event of increased creatinine as related to the study drug, probably associated with a low fluid intake in combination with belinostat, and disease progression as unrelated to belinostat

14.3.3.1.4 146-002

Patient **146-002**, a 76-year-old Caucasian female with a medical history including arterial hypertension, pleural effusion and MRSA infection on multiple concomitant medications, received 1 cycle of belinostat from 27-Jan to 31-Jan-2011 at a dose of 1,640 mg. On 07-Feb-2011 (C1D12), the patient developed increasing respiratory insufficiency (Grade 4) of unknown origin and was hospitalized the same day, with a differential diagnosis of fever of undetermined origin (FUO) and tumor lysis provided. Admission labs revealed lactate dehydrogenase (LDH) 761U/L, calcium 1.82mmol/L, sodium 128 mmol/L, potassium 3.2 mmol/L, gamma-glutamyltransferase 164 U/L, lymphocyte count 63%, monocyte count 1%, and platelet count 42 T/uL. A CT scan showed increased pleural effusion and subcutaneous emphysema, as compared to a CT scan performed 02-Feb-2011. While in the ICU, the patient required non-invasive ventilation. On 08-Feb-2011 (C1D13), the patient was diagnosed with Grade 4 tumor lysis. Follow-up laboratory work, performed on 09-Feb-2011, revealed creatinine 0.94 mg/dL, glucose 186 mg/dL, LDH 1237 U/L and WBC 17.20 T/uL. The patient deteriorated and expired on 09-Feb-2011 (C1D14) 10 days after the last dose of belinostat due to Grade 5 multi-organ failure (heart and renal systems), attributed to tumor lysis.

The Investigator assessed the events as unrelated to study drug.

14.3.3.1.5 154-001

Patient **154-001**, a 73-year-old Caucasian male with a complicated medical history including monoclonal gammopathy, nicotine abuse and peripheral neuropathy of feet on multiple concomitant medications, was treated with 10 cycles of belinostat at a dose of 2030 mg. The patient tolerated 9 cycles of belinostat without complication. On 01-Sep-2011 (C10D16), the patient presented to the hospital with fever (38.1°C) and worsened general condition, since 20-Aug-2011, and was hospitalized the same day. Admission laboratory results revealed bilirubin 5.1mg/dL, GGT 522u/L, GPT (ALAT) 1271u/L, GOT (ASAT) 1536u/L and LDH 715u/L. On 02-Sep-2011 (C10D17), CRP was 8.2 mg/dL. The patient was diagnosed with Grade 3 neutropenic fever, Grade 3 increase of liver blood findings and Grade 3 worsened general condition. Treatment with antibiotics was initiated and on the same date, 02-Sep-2011, the patient left the hospital against medical advice. Treatment with belinostat was permanently discontinued.

On 05-Sep-2011 (C10D20), the patient was re-admitted to the hospital with a diagnosis of Grade 5 toxic liver failure. Laboratory work, performed on 06-Sep-2011, revealed bilirubin11.7 mg/dL, GGT 318 mg/dL, GPT 2185 mg/dL, GOT 2514 mg/dL and CRP 6.1 mg/dL. A biopsy (date unspecified) was suggestive of toxic liver failure. On 13-Sep-2011 (C10D28), the patient expired 25 days after the last dose of belinostat and an autopsy confirmed the cause of death as subtotal liver necrosis.
The Investigator assessed the events as serious (hospitalization and fatal) and related to belinostat.

14.3.3.1.6 180-002

Patient **180-002** was a 70-year-old Caucasian male with a medical history of anaplastic large cell lymphoma (ALK-negative; Stage IVA) and receiving multiple concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. The patient started Cycle 1 of belinostat on 09-Nov-2009 at a dose of 1,900 mg. The patient completed Cycle 2 of belinostat on 04-Dec-2009 and the patient died on 22-Dec-2009 (C2D23) due to disease progression, 19 days after the last dose of belinostat.

14.3.3.1.7 206-001

Patient **206-001** was a 64-year-old Caucasian male an extensive medical history including peripheral T-cell lymphoma, NOS, (Stage IIIB) and receiving multiple concomitant medications. Bone marrow assessment was not performed at Baseline because a bone marrow involvement was not clinically suspected. The patient received Cycle 1 of belinostat from 08-Feb to 12-Feb-2010. The initial dose of 1,880 mg was reduced on Day 5 to 1,710 mg due to an adverse event of bronchospasm. The patient died on 21-Feb-2010 (C1D14) due to progressive disease, 10 days after the last dose of belinostat.

14.3.3.1.8 221-004

Patient **221-004**, an 80-year-old Caucasian male with no relevant medical history and on multiple concomitant medications, started Cycle 1 of belinostat at a dose of 2,000 mg. The dose was reduced to 1,500 mg beginning in Cycle 3, due an adverse event (rash). On 21-Nov-2011, the patient initiated Cycle 6 of belinostat as scheduled, despite worsening general condition and a swollen, painful lower limb. Lab work performed as an outpatient the same day revealed hemoglobin 6.3 mmol/L and an echo was negative for thrombosis. The patient was started on Celebrex (celecoxib). On 23-Nov-2011 (C6D3), the patient experienced tachycardia, with a heart rate greater than 110 BPM. Chest X-ray was normal and lab work revealed hemoglobin 6.3 mmol/L. The patient received a blood transfusion. During Cycle 6, the patient complained of periodic

episodes of nausea, vomiting, diarrhea, and abdominal complaints. On 25-Nov-2011 (C6D5), the patient completed Cycle 6 and the lower limb pain resolved. The patient's general condition, however, worsened and the patient was admitted to the hospital. A chest X-ray suggested infiltration in the bilateral basal lung fields. The patient was treated with prednisone, antibiotics and intravenous fluids for Grade 3 intercurrent pulmonary infection with secondary dehydration. The patient expired on 26-Nov-2011 (C6D6), 2 days after the last dose of belinostat.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.1.9 224-001

Patient **224-001** was a 66-year-old Caucasian male with a relevant medical history of anxiety and receiving multiple concomitant medications. Bone marrow assessment was not performed at Baseline because a bone marrow involvement was not clinically suspected. The patient was treated with 1 cycle of belinostat from 15-Feb to 19-Feb-2010 at a dose of 1900 mg. On 26-Feb-2010 (C1D12), the patient was hospitalized with complaints of dyspnea and diagnosed with Grade 3 anxiety. Treatment included lorazepam. On 27-Feb-2010 (C1D13), the event was considered resolved and the patient was discharged to home. On 08-Mar-2010 (C1D22), the patient withdrew consent and was discontinued from the study. The patient expired due to progressive disease on 14-Mar-2010 (C1D28), 24 days after the last dose of belinostat.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.1.10 244-002

Patient **244-002**, a 77 year-old Caucasian male with an extensive medical history including antral ulceration on multiple concomitant medications, started Cycle 1 of belinostat on 04-Oct-2010 at a dose of 1,600mg. C1D3 was delayed due to a logistic error (belinostat was diluted in 500 mL of 0.9% sodium). On 20-Oct-2010 (C1D17), the patient was hospitalized due to weakness and abdominal pain and diagnosed with Grade 3 general malaise. Treatment with Dolantin (pethidine), Solu-Medrol (methylprednisolone) and Actrapid (insulin) was started, the patient responded and, on 25-Oct-2010 (C2D1), the event was considered resolved. No action was taken with regard to belinostat and the patient continued hospitalization to start Cycle 2.

Cycle 2 of belinostat was started on 25-Oct-2010 at a reduced dose of 1,570mg (due to change in BSA). C2D3 treatment was again delayed, due to a logistic error, and the cycle was completed on 29-Oct-2010. On 31-Oct-2010 (C2D7), the patient was hospitalized due to hematemesis and melena. Gastroscopy showed an active bleeding gastric ulcer and the patient was diagnosed with Grade 5 gastrointestinal bleeding.

Laboratory tests revealed low hemoglobin, hematocrit and RBC. The patient was stabilized after treatment with Pantomed (pantoprazole), packed cells, and adrenaline. On 01-Nov-2010 (C2D8), the patient experienced severe abdominal cramps, hematemesis and melena. The patient was transferred to the intensive care unit and treated with Exacyl (tranexamic acid), Litican (alizapride), packed cells, somatostatin, and Gelofusin (fluid gelatin). The patient died 5 days after the last dose of belinostat of severe gastrointestinal bleeding on 02-Nov-2010 (C2D9).

The Investigator assessed both events as unrelated to belinostat.

14.3.3.1.11 244-004

Patient **244-004**, a 76-year-old Caucasian male with no relevant medical history and on multiple concomitant medications, began Cycle 1 of belinostat on 29-Nov-2010 at a dose of 1,780mg. The principle Investigator stated that the patient did not show improvement and opted to change the treatment to combination chemotherapy. On 09-Dec-2010 (C4D11), the patient withdrew consent from the study. On 16-Dec-2010 (C4D18), the patient declined combination chemotherapy and opted for euthanasia 14 days after the last dose of belinostat.

The Investigator classified the event as unrelated to the study drug.

14.3.3.1.12 244-006

Patient **244-006**, a 73-year-old Caucasian female with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 21-Mar-2011 at a dose of 1,590mg. On 24-Mar-2011, prior to C1D4 belinostat infusion, the patient was admitted to the hospital due to Grade 2 unable to self-care. The patient reported falling several times at home, but the neurological assessment revealed no abnormalities. The event resolved and the patient was discharged home on 25-Mar-2011 (C1D5). No action was taken with regard to belinostat and the patient remained in the study.

The second cycle of belinostat was completed on 15-Apr-2011. On 11-May-2011 (C3D10), the patient was admitted to the hospital complaining of nausea and weakness due to general malaise. The patient was diagnosed with Grade 2 progressive disease and no further therapy was initiated. Treatment with Perfusalgan (acetaminophen), Solu-Cortef (hydrocortisone), Diamorphine (heroin) and midazolam was given, and the patient was discharged to the palliative care unit. The patient expired on 25-May-2011 (C3D24). Neither an autopsy report or death certificate was provided.

The Investigator assessed both events as unrelated to belinostat.

14.3.3.1.13 513-001

Patient **513-001**, a 56-year-old female with no relevant medical history or concomitant medications, was treated with 2 cycles of belinostat at a dose of 1,560mg. The patient started Cycle 2 on 03-Jan-2011, with a platelet count of $121x10^9$/L (150-300). The patient completed 4 days of treatment. On 06-Jan-2011 (C2D4), the patient experienced Grade 4 platelet count decreased ($16x10^9$/L) and the belinostat was temporarily discontinued. On 07-Jan-2011 (C2D5), the platelet count further decreased to $8x10^9$/L and a bone marrow biopsy revealed marrow free from anaplastic lymphoma. The patient received a platelet transfusion and was started on Cyclonamine. The patient received additional platelet transfusions on 12-Jan-2011 (C2D10) and 13-Jan-2011 (C2D11), and the platelet count increased to $46x10^9$/L. On the evening of 14-Jan-2011 (C2D12), the patient lost consciousness. A physical examination revealed pulmonary edema and the patient was treated with furosemide. The patient died 10 days after the last dose of belinostat due to multiple organ dysfunction syndrome on 15-Jan-2011 (C2D13).

The Investigator assessed platelet count decreased as related to the study drug and multiple organ dysfunction syndrome as unrelated.

14.3.3.1.14 513-003

Patient **513-003**, a 58-year-old Caucasian male with a medical history of Klebsiella pneumonia and pulmonary embolism on multiple concomitant medications, was treated with 3 cycles of belinostat at a dose of 2,150mg and subsequently increased to 2,250mg in Cycle 4. On 31-Oct-2011 (C6D15), the patient was withdrawn from the study due to disease progression. On 17-Nov-2011 (C6D32), the patient was admitted to the hospital with general weakness, fever, skin changes, thrombocytopenia, kidney failure, and liver failure. The patient was treated with Solu-Medrol and IV Milurit. On 18-Nov-2011 (C6D33), the patient expired 29 days after the last dose of belinostat due to Grade 5 sudden heart failure. The cause of death was confirmed by autopsy as secondary to PTCL progression to the heart muscle and other internal organs.

The Investigator assessed the event as unrelated to the study drug.

14.3.3.1.15 516-001

Patient **516-001**, a 53 year-old Caucasian female with a relevant medical history of mycositis on multiple concomitant medications, started Cycle 1 of belinostat on 26-Apr-2011 at a dose of 1,900mg. On 06-May-2011 (C1D11), the patient was hospitalized with symptoms of generalized weakness, esophageal pain, low respiration rate and blood pressure of 90/60mmHg. The patient was diagnosed with Grade 3 mycosis infection of gastrointestinal tract and treated with 0.9% NaCl IV solution, 5% glucose IV solution, Abelcet (amphotericin B), and paracetamol. On the third day of hospitalization, the

patient experienced chills and was treated with hydrocortisone and clemastine. On 13-May-2011 (C1D18), the event resolved with sequelae and the patient was discharged.

On 17-May-2011 (C1D22), the patient was hospitalized due to fever, diagnosed with disease progression after diagnostic testing and subsequently withdrawn from study. The patient was treated with fluids, antibiotics, and an intravenous course of CHOP. On the morning of 21-May-2011(C1D26), the patient's condition deteriorated with dyspnea, O2 saturation of 65% on oxygen therapy, and an episodic drop in blood pressure, revealing symptoms of multi-organ failure. Around noon the same day, the patient died of Grade 5 multi-organ failure, 10 days after the last dose of belinostat. The immediate cause of death was cardiac arrest, with an underlying cause of multi-organ failure caused by disease progression.

The Investigator assessed both events as unrelated to belinostat.

14.3.3.1.16 532-001

Patient **532-001**, a 48-year-old Caucasian female with an extensive medical history and on multiple concomitant medications, was treated with 3 cycles of belinostat at a dose of 1710mg. On 07-Sep-2010 (C2D12), the patient was admitted to the hospital complaining of choking and fever. A chest X-ray confirmed the diagnosis of Grade 2 chylothorax. The patient underwent thoracocentesis the same day, showed improvement and was discharged in stable condition on 20-Sep-2010 (C2D25).

The patient received the last dose of belinostat on 25-Sep-2010 (C3D5) and was withdrawn from study due to disease progression.

The Investigator classified the event as unrelated to belinostat.

14.3.3.1.17 532-002

Patient **532-002**, a 55-year-old Caucasian male with relevant medical history of hemolytic anemia, low level leucocytes, hepatosplenomegaly and thrombocytopenia on multiple concomitant medications, was treated with 2 cycles of belinostat at a dose of 1,200mg. On 05-Jan-2011 (C2D14), the first tumor assessment showed pulmonary disease progression. The patient was treated with transfusions (blood and thrombocytes), antibiotics and antimycotic prophylaxis, with no improvement.

The patient was withdrawn from study on 14-Jan-2011 (C2D23) due to disease progression and expired on 16-Jan-2011 (C2D25).

The Investigator assessed the event as unrelated to belinostat.

14.3.3.1.18 801-002

Patient **801-002**, a 73-year-old Caucasian female with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 05-Jun-2011 at a dose of 1600mg. The dose of belinostat was reduced to 1170 for Cycle 2 due to adverse event hypokalemia. On 10-Jul-2011, C2D14, the patient was admitted to the hospital with a suspected diagnosis of acute abdomen. Abdominal surgery was performed on 11-Jun-2011 (C2D15) and bowel perforation due to tumor invasion was found. The patient was diagnosed with Grade 5 disease progression and expired 2 hours after surgery. The immediate cause of death was multi-organ failure, with the underlying cause of disease progression.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.1.19 803-001

Patient **803-001**, a 74-year-old African-American male with medical history of hypertension, cholelythiasis, calcified aortic valve, CVA and mild right hemiparesis on multiple concomitant medications, completed Cycle 1 of belinostat on 01-Apr-2011 at a dose of 1800mg. On 10-Apr-2011 (C1D14), the patient presented to the emergency room with severe weakness and abdominal distention. Blood chemistry revealed Grade 4 hypercalcemia (16.8mg/dL), WBC count 209,000 and absolute lymphocyte count 107,000. The patient was treated with intravenous fluids, diuretics, steroids, calcitonin and Aredia (pamidronate disodium). The hypercalcemia resolved slowly, with some improvement in the patient's state. Subsequently, the patient deteriorated and developed MULTI-ORGAN FAILURE on 17-Apr-2011 (C1D21), manifesting with acute renal failure (creatinine 3.2mg/dL) and ascites. The patient was started on IV morphine and expired the same day.

The Investigator classified both events as related to the study drug.

14.3.3.1.20 907-002

Patient **907-002**, a 54-year-old Latino/Hispanic male with a diagnosis of peripheral T-cell lymphoma, NOS, (Stage IIIB) with no bone marrow involvement, received Cycle 1 of belinostat from 27-Jul to 31-Jul-2010 at a dose of 2070mg. The patient had an extensive medical history and on multiple concomitant medications. On 25-Aug-2010 (C1D30), the patient died due to progressive disease.

14.3.3.1.21 922-001

Patient **922-001**, a 73-year-old African-American female with an extensive medical history on multiple concomitant medications, was treated with 4 cycles of belinostat at a

dose of 2,260mg. On 27-Jul-2011 (C2D10), patient presented to the hospital with complaints of fever, weakness and malaise, and was admitted the same day. Upon hospitalization, the patient was found be dehydrated, in acute renal failure, with possible sepsis from a Port-A-Cath line infection and hypotension (86/53mmHg). The patient was treated with IV fluids, broad-spectrum antibiotics and medications to manage glucose level. The patient's blood culture was positive for methicillin-resistant staphylococcus aureus and a transesophageal echocardiogram revealed a 2cm thrombus on the mitral valve. The patient was diagnosed with Grade 4 methicillin resistant staphylococcus aureus infective endocarditis (mitral valve). On 25-Aug-2011 (C2D39), the patient was transferred to ICU at a nearby hospital with hypovolemia, low hematocrit, and altered mental status. The admission CT scan was negative for retroperitoneal and gastrointestinal bleed. The patient was infused with 2 units of packed red blood cells on 20-Aug-2011 (C2D34) and 25-Aug-2011 (C2D39). Due to elevated INR and bleeding at the PICC line, the patient received 2 units of fresh frozen plasma on 26-Aug-2011 (C2D40). In addition, a superior vena cava filter was placed the same day. The patient's hemoglobin and hematology parameters stabilized and, on 27-Aug-2011 (C2D41), the event was considered resolved. The patient was transferred to a rehabilitation facility to continue chemotherapy. On 29-Aug-2011, Cycle 3 was started, with no change in the dose.

On 07-Sep-2011 (C3D10), the patient was admitted to the hospital with tachycardia, hypotension, dehydration, altered mental status, and diagnosed with Grade 3 urosepsis. The patient was pan-cultured, and blood culture and urinalysis were positive for yeast, Klebsiella, and Enterobacter. Treatment with fluconazole and Levaquin (levofloxacin) was started and the patient was transferred to ICU. Brief pressor therapy with IV resuscitation was required, but the patient stabilized hemodynamically overnight, and was maintained on IV fluids and antibiotics for the remainder of the hospital stay. Secondary to urosepsis, patient was treated for CHF, acute renal failure, and depression. The patient responded to treatment and, on 15-Sep-2011 (C3D18), was discharged to a rehabilitation facility. Study treatment was temporarily interrupted.

On 20-Sep-2011 (C4D2) the patient was transferred from the rehabilitation facility to the hospital, with unmeasurable blood pressure and pulse, and admitted to ICU with an initial diagnosis of hypotension and hypovolemia. Treatment with broad-spectrum antibiotics, parenteral vasopressors and IV fluids was started. The patient deteriorated and developed atrial fibrillation with a rapid ventricular response. The patient was treated with antiarrhythmics, and cardioversion was required. The patient developed cardiopulmonary arrest and expired due to multifactorial shock 2 days after the last dose of Belinostat.

The Investigator assessed all the events as unrelated to belinostat.

14.3.3.1.22 934-004

Patient **934-004**, a 71-year-old Caucasian male with an extensive medical history on multiple concomitant medications started Cycle 1 of belinostat on 25-Jul-2011 at a dose of 1,990mg. On 29-Jul-2011, prior to C1D5 treatment, the patient complained of redness and swelling in the right arm. Ancef and Keflex were started for possible cellulitis of the right arm and the patient received day 5 infusion. On 02-Aug-2011 (C1D9), the patient presented to the emergency room with worsening of swelling and tenderness in the right arm, and was sent home on oral doxycycline. On 05-Aug-2011 (C1D12), the patient presented to the clinic for supportive care due to abnormal blood work, including hypercalcemia (calcium 2.79mmol/L), albumin 35g/L, mild hyperkalemia, elevated LDH 546U/L, temperature 37.9°C, and was hospitalized the same day for infection NOS/borderline sepsis. His temperature upon admission was 38.5°C and blood, urine and sputum cultures were collected. The patient's hospital stay was complicated by atrial fibrillation (HR 130-140/min), mild hypotension (systolic BP between 80-90mmHg), and hypoxia. The patient was treated with intravenous fluids, Lasix, prednisone, pamidronate, zoledronic acid, ceftazidime, metoprolol, digoxin, amiodarone, and calcitonin. The patient developed acute renal failure with hyperkalemia (potassium 5.5mmol/L) and digoxin was discontinued. The patient was diagnosed with progressive disease on 09-Aug-2011 (C1D16), withdrawn from the study and expired on 20-Aug-2011 (C1D27).

The Investigator assessed the event as unlikely unrelated to belinostat.

14.3.3.2 *Narratives of SAEs*

Narratives for patients who experienced SAEs during the study are included below. Cross links to the individual narratives are available in Table 51.

14.3.3.2.1 100-002

Patient **100-002**, a 70-year-old Caucasian male with a relevant medical history of atrium septal defect closure, sinus node syndrome and a pacemaker on multiple concomitant medications, began treatment with belinostat at a dose of 1,880 mg on 24-Aug-2009. On 01-Oct-2009 (C2D18), the patient was hospitalized due to Grade 4 lung embolia bilateral, confirmed by CT-scan. The patient's Baseline coagulation factors (13-Aug-2009) were INR 1.1 (reference range <1.2) and APTT 25 sec (reference range 23-35). Both values increased on 02-Oct-2009 (C2D19) to INR 1.9 sec and APTT 41 sec. The patient was treated with anti-coagulants and antibiotics. The event was considered resolved on 04-Oct-2009 (C2D21). The patient's coagulation factors were re-evaluated on 05-Oct-2009, revealing APTT of 68 sec with an INR of 2.1 and, on 26-Oct-2009

(C4D1), an APTT of 41 sec and INR of 1.4. No action was taken with regard to belinostat and the patient remained in the study.

On 07-Nov-2009 (C4D13), the patient was admitted to the hospital due to fever of 38.9 ºC. An X-ray of the thorax showed new infiltrate in the right lung. Lab results revealed C-reactive protein (CRP) 106 mg/L (reference range <10). The patient was diagnosed with Grade 3 pneumonia and treated with antibiotics, oxygen support, and intravenous hydration. The event was considered resolved on 23-Nov-2009 (C4D29).

On 28-Dec-2009 (C4D64), the patient expired due to disease progression.

The Investigator assessed these events as unrelated to belinostat.

14.3.3.2.2 100-004

Patient **100-004**, a 56-year-old Caucasian male with no relevant medical history and on multiple concomitant medications, started Cycle 1 of belinostat on 19-Oct-2009 at a dose of 1,770mg. C1D1 lab results revealed a low neutrophil count, with elevated CRP and lymphocytes. On 27-Oct-2009 (C1D9), the patient was hospitalized due to fever (38ºC). During hospitalization, the patient's WBC and CRP were checked and reported as elevated. The patient was diagnosed with Grade 3 infection, although no infectious source was identified. The patient was treated with antibiotics. On 28-Oct-2009 (C1D10), the event was considered resolved and the patient was discharged to home from the hospital (afebrile, 36.4ºC). The patient received the final dose of belinostat on 23-Oct-2009 (C1D5) at a dose of 1,770 mg and was withdrawn from the study due to disease progression.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.2.3 126-002

Patient **126-002**, a 59-year-old Caucasian male with a medical history of moderate left ventricular systolic impairment on multiple concomitant medications, began treatment with belinostat on 15-Aug-2011 at a dose of 2,200mg. The patient received Cycle 2 of belinostat treatment from 05-Sep-2011 to 09-Sep-2011. Due to an event of chemically-induced phlebitis (non-serious) during Cycle 1 treatment, a Lifecath Midline was inserted on 05-Sep-2011 (C2D1), prior to belinostat infusion. The catheter was removed on 16-Sep-2011(C2D12) due to signs of infection. Treatment included antibiotics. The patient was scheduled for a CT scan for tumor assessment, per protocol, on 20-Sep-2011 (C2D16). During this visit, the patient presented with swelling of the right forearm and fever of 38.4°C. An ultrasound revealed Grade 3 thrombosed right basilic vein and the patient was hospitalized the same day (20-Sep-2011). Treatment with an antithrombotic and intravenous antibiotic was started, the inflammatory markers improved and the

event was considered resolved with sequelae. The patient was discharged to home on 23-Sep-2011 (C2D19). No action was taken with regard to belinostat and Cycle 3 started, per schedule, on 26-Sep-2011 (C3D1).

The Investigator assessed this event as related to the study drug.

14.3.3.2.4 140-001

Patient **140-001**, a 71-year-old Caucasian male with an extensive medical history including autologous stem cell transplant, increased creatinine and renal cyst on multiple concomitant medications, started Cycle 1 of belinostat on 31-May-2010 at a dose of 2,000mg. On 04-Jun-2010 (C1D5), the patient was hospitalized with Grade 1 increased creatinine. Prior to hospitalization, the patient's creatinine and LDH were normal. During hospitalization, the patient had increased LDH and decreased creatinine clearance. The patient was treated with Sterofundin (electrolyte solution) and, on 18-Jun-2010 (C1D19), the event was considered resolved and the patient was discharged from the hospital. No action was taken with regard to belinostat and the patient remained in the study.

Cycle 2 was started on 21-Jun-2010. On 23-Jun-2010 (C2D3), the patient was hospitalized with Grade 2 fever (39.8ºC), without sign of infection. Prior to the hospitalization, the patient was experiencing a slight increase in temperature. The patient did not receive belinostat for the remaining days of Cycle 2 and was treated with antibiotics. On 02-Jul-2010 (C2D12), the event was considered resolved. The patient received the final dose of belinostat on 23-Jul-2010 (C3D5) and was withdrawn from study on 28-Jul-2010 (C3D10), due to an adverse event of EBV reactivation.

The Investigator assessed the event of increased creatinine as related to belinostat and the event of fever as unrelated to belinostat.

14.3.3.2.5 140-002

Patient **140-002**, a 66-year-old Caucasian female with no relevant medical history and on multiple concomitant medications, started Cycle 1 of belinostat on 14-Mar-2011 at a dose of 1,740mg. The dose was reduced to 1,720mg at Cycle 5 due to weight loss. On 25-Jul-2011 (C6D1), following belinostat infusion, the patient experienced fever. The patient improved after taking paracetamol. On 26-Jul-2011 (C6D2), the patient presented with weakness and shivers, and was hospitalized the same day. Laboratory work performed upon hospital admission revealed CRP 39.7mg/L and a staphylococcus aureus infection. The patient was diagnosed with Grade 1 fever of unknown origin and treated with antibiotics. The patient showed improvement and completed Cycle 6 treatment. On 01-Aug-2011 (C6D8), the patient was discharged from the hospital.

On 16-Aug-2011 (C7D2), following belinostat infusion, the patient experienced fever (>39°C) and was hospitalized on 17-Aug-2011 (C7D3) with the diagnosis of Grade 2 fever of unknown origin. On 19-Aug-2011 (C7D5), follow-up laboratory work revealed WBC $8.68x10^3$/µl and neutrophils 46%. Blood culture (17-Aug-2011) from the port was positive for staphylococcus aureus. The patient was treated with paracetamol and the fever returned to Grade 1 the same day. On 22-Aug-2011 (C7D8), follow-up lab work revealed WBC $11.20x10^3$/µl. The patient was withdrawn from the study due to the staphylococcus aureus infection and belinostat C7D3, 4, and 5 were not administered. On 23-Aug-2011 (C7D9), the event was considered resolved and the patient was discharged from the hospital.

The Investigator assessed both events as related to the study drug.

14.3.3.2.6 141-001

Patient **141-001**, a 69-year-old Caucasian male with a relevant medical history of arteriosclerosis, uricemia, edema of face and legs related to skin lymphoma on multiple concomitant medications, was treated with belinostat for 4 days of Cycle 1 at a dose of 2,000mg. On 26-Jul-2010 (C1D1), creatinine level was 145µmol/L (reference range 50-90 µmol/L) and blood urea level 8.7mmol/L (reference range 2.9-8.9mmol/L). On 30-Jul-2010 (C1D5), the patient was hospitalized due to Grade 2 creatinine elevation, with creatinine level 238µmol/L, blood urea level 9.9mmol/L, and no signs of tumor lysis. Day 5 belinostat treatment was not given. The study drug was permanently discontinued due to the event and the patient was withdrawn from the study on 30-Jul-2010 (C1D5). On 04-Aug-2010 (C1D10), the creatinine levels increased to 324µmol/L and blood urea levels to 15.3mmol/L. Treatment included intravenous fluids and Lasix (furosemide).

On 04-Aug-2010 (C1D10), during hospitalization, the patient developed small lesions on the finger tips, toes, nose, and auricles, resembling skin necrosis. Duplex ultrasound, echocardiogram, and laboratory work including ANA, ANCA, RF, C3 and C4 tests revealed no abnormality. The patient was diagnosed with Grade 3 acral necrosis. A skin biopsy was performed on 06-Aug-2010 (C1D12) and the patient was diagnosed with Grade 3 vasculitis, which was the possible cause of acral necrosis. Treatment included pain medications, steroids, and anti-coagulants. The patient was discharged on 24-Aug-2010 (C1D30), after significant improvement of the skin necrosis and normalization of serum creatinine. The event creatinine elevation resolved on 24-Aug-2010 (C1D30) and the event of vasculitis resolved on 08-Sep-2010 (C1D44). The event of acral necrosis continued as serious (medically significant) after hospital discharge and was considered resolved with sequelae (scars) on 28-Jan-2011 (C1D187).

The Investigator assessed all the events as possibly related to belinostat.

14.3.3.2.7 142-003

Patient **142-003**, an 81-year-old Caucasian male with an extensive medical history including arterial hypertension and atrial fibrillation on multiple concomitant medications, was treated with 1 cycle of belinostat from 08-Sep to 12-Sep-2010 at a dose of 1,830mg. On 21-Sep-2010 (C1D14), the patient was hospitalized with a diagnosis of Grade 2 fatigue and inappetence/anorexia, associated with weight loss. While in the hospital, the patient developed shortness of breath and the chest X-ray revealed increasing proliferation in the left lower lobe. On 29-Sep-2010 (C1D22), the patient was diagnosed with Grade 3 pneumonia. The patient was treated with parenteral nutrition, oxygen, and antibiotics, but showed no improvement. On 04-Oct-2010 (C1D27), a CT scan revealed significant pulmonary and mediastinal lymphoma progression (Progression of PTCL). The patient was discharged to hospice on 12-Oct-2010 (C1D35) and expired due to disease progression on 14-Oct-2010 (C1D37).

The Investigator assessed the events of fatigue and inappetence as possibly related to belinostat. The events of pneumonia and progression of PTCL were assessed as unrelated.

14.3.3.2.8 142-005

Patient **142-005**, a 63-year-old Caucasian female with an extensive medical history and on multiple concomitant medications, was hospitalized on 23-May-2011 for Cycle 1 of belinostat treatment (scheduled to begin on 24-May-2011) and experienced Grade 2 fever (39.2°C) the same day. The patient was treated with antibiotics, antivirals, pain medications, and diuretics. On 26-May-2011, the existing port, which was attributed as the cause for fever, was replaced by a new port. The event was considered resolved on 28-May-2011 and Cycle 1 of belinostat was started on 30-May-2011 (C1D1).

The patient had elevated levels of alanine aminotransferase (ALT), aspartate aminotransferase (AST) and gamma-glutamyl transferase (GGT) before initiation of the treatment. Baseline levels on 19-May-2011 were reported as ALT 37U/L, AST 79U/L and alkaline phosphatase 176U/L. Prior to C1D1 infusion on 30-May-2011, the lab values were reported as ALT 45U/L, AST 104U/L and GGT 393U/L. The patient received 1,510mg of belinostat on treatment days 1 and 2. On 02-Jun-2012 (C1D4), laboratory results revealed Grade 3 increased AST (358U/L) and Grade 2 INCREASED ALT (182U/L), and belinostat was temporarily withheld. On 03-Jun-2011 (C1D5), Grade 4 increased gamma GT (751U/L) was noted. On 05-Jun-2011 (C1D7), the ALT levels decreased to Grade 2 (149U/L), and the AST levels decreased to Grade 2 (93U/L) on 06-Jun-2011 (C1D8). A CT scan of the liver was performed on 07-Jun-2011 (C1D9) and revealed no evidence of metastasis. A decision was made to continue treatment with belinostat and C1D3-5 doses were given on 09-Jun (C1D11) to 11-Jun-2011

(C1D13), at a reduced dose of 1,117mg (due to the event of GGT increased). The events of increased ALT and AST were considered resolved at Grade 1 levels. As the gamma-GT levels continued to be elevated at Grade 4, the event was considered as resolved with sequelae. The patient was discharged on 14-Jun-2011 (C1D16) in stable condition. On 21-Jun-2011 (C1D23), the gamma-GT levels returned to Grade 3 (Baseline).

On 28-Jun-2011 (C1D30), the patient was discontinued from the study due to disease progression. The patient expired due to disease progression on 22-Aug-2011 (C1D85).

The Investigator assessed the event of fever as unrelated to the study drug. The events of increased GGT, increased ALT and increased AST were assessed as related to the study drug.

14.3.3.2.9 144-001

Patient **144-001**, a 58-year-old Caucasian female with no relevant medical history and on multiple concomitant medications, was treated with 1 cycle of belinostat from 20-Sep to 24-Sep-2010 at a dose of 1,650mg. On 08-Sep-2010, Baseline labs revealed platelet count $52x10^9$/L, hemoglobin 9.1g/dL and RBC $3.2x10^{12}$/L. Prior to the administration of belinostat, the patient received platelet transfusions on 16-Sep, 17-Sep and 19-Sep-2010. On 20-Sep-2010 (C1D1), pre-dosing laboratory work revealed platelet count 10 $x10^9$/L. On 24-Sep-2010 (C1D5), pre-dosing laboratory work revealed platelet count $6x10^9$/L. The patient was hospitalized the following day with a diagnosis of Grade 4 thrombopenia. Despite a platelet transfusion on 25-Sep-2010 (C1D6), the patient did not show significant improvement in platelet count and elected to be discharged. On 27-Sep-2010 (C1D8), the patient was discharged, against medical advice, after being advised of the risks of thrombopenia. The event was considered resolved with sequelae.

On 08-Oct-2010 (C1D19), the patient was admitted to the hospital with hemoglobin 54g/dL and thrombocyte count 8g/L. Additional admission laboratory work revealed leukocytes 1.38g/L. The patient was diagnosed with Grade 4 anemia and received transfusion of packed red cells. The patient continued to be hospitalized and started Cycle 2 of belinostat on 11-Oct-2010 (C2D1) at a reduced dose of 1225mg. The same day, the patient's temperature was 39.5°C and a diagnosis of Grade 3 fever in neutropenia was made. Treatment was started and subsequent temperature readings fluctuated between 36.4ºC to 38.6ºC. Cycle 2 of belinostat continued on schedule for days 2 through 5. On 19-Oct-2010 (C2D9), follow-up laboratory work showed hemoglobin 99g/L, thrombocyte count 6g/L, and leukocyte count 1.8g/L. On 20-Oct-2010 (C2D10), the patient was discharged in stable condition with hemoglobin 86g/L, thrombocyte count 12g/L and leukocyte count of 2.31g/L. The event of anemia was considered resolved with sequelae and fever in neutropenia resolved.

The patient was withdrawn from the study on 01-Nov-2010 (C2D22), due to disease progression. The patient expired on 26-Aug-2011(C2D320) due to urosepsis and ESBL (extended-spectrum beta lactamases).

The Investigator assessed all the events as related to the study drug.

14.3.3.2.10 144-002

Patient **144-002**, a 72-year-old Caucasian female with no medical history relevant to the events and on multiple concomitant medications, started Cycle 1 of belinostat on 06-Dec-2010 at a dose of 1,690mg. On 07-Dec-2010 (C1D2), the patient developed a fever (38.5 °C) and was admitted to the hospital on 11-Dec-2010 (C1D6) with a diagnosis of Grade 1 fever (37.8 °C). The patient was treated with antibiotics and, on 13-Dec-2010 (C1D8), was discharged in stable condition, but continued to have intermittent fever post-discharge. On 20-Dec-2010 (C1D15), the patient was re-hospitalized. Admission labs revealed leukocytes 6.5x 0^9/L and C-reactive protein (CRP) 3.98mg/dL. On 21-Dec-2010 (C1D16), a CT scan of thorax and neck was performed, but revealed no source of infection. Follow-up laboratory work, performed on 22-Dec-2010 (C1D17), revealed leukocyte count 12.2x10^9/L and a further increase in CRP to 7.02mg/dL. The patient was clinically diagnosed with Grade 3 bronchitis and treated with antibiotics. The patient continued to have fever until 24-Dec-2010 (C1D19). The leukocyte count returned to normal (4.7x10^9/L) on 27-Dec-2010 (C1D22) and the event was considered resolved on 28-Dec-2010 (C1D23). The patient received C2D1 of belinostat on 30-Dec-2010.

On 14-Jan-2011 (C2D16), the patient was discontinued from the study due to disease progression.

The Investigator classified the event of fever as related to the study drug and the event of bronchitis as unrelated to the study drug.

14.3.3.2.11 146-001

Patient **146-001**, a 70-year-old Caucasian female with no relevant medical history and on multiple concomitant medications, started Cycle 1 of belinostat on 25-Jan-2010 at a dose of 1,730mg. On 11-Feb-2010 (C1D18), the patient visited the emergency room due to fever and was hospitalized the same day. Admission labs revealed increased CRP 3.45. On 16-Feb-2010 (C1D23), a CT scan of the thorax showed Grade 3 alveolitis, and antibiotic and steroid treatment was started. On 18-Feb-2010 (C1D25), the event was considered resolved and Cycle 2 of belinostat was delayed for 1 week.

On 02-Mar-2010 (C2D9), the patient was hospitalized complaining of dorsal back pain. Following diagnostic tests, the patient was diagnosed with Grade 3 obstipation. The

dorsal pain was treated with ibuprofen and the patient underwent manual extraction of stool. The patient was discharged and the event considered resolved on 29-Mar-2010 (C2D36).

On 03-May-2010, the patient received C4D1 of belinostat. On 04-May-2010 (C4D2), the patient experienced fever and was hospitalized. A CT scan revealed bilateral atypical pneumonia and the patient was diagnosed with Grade 3 pneumonia. Blood cultures, performed at admission, were positive for Staphylococcus. The patient was treated with multiple antibiotics and, on 17-May-2010 (C4D15), the event was considered resolved. The patient resumed belinostat infusions on 18-May-2012. C4D2 was delayed by 14 days and the dose was decreased.

On 28-Jun-2010 (C5D22), the patient presented to the hospital with swelling, erythema, and increased temperature of left leg. Duplex sonography of the left leg showed thrombosis of the deep veins in all 4 sectors (4 levels) and the patient was diagnosed with 4- level-thrombosis of deep veins, left side (Grade 3). Treatment with low-molecular-weight heparin was started and, on 02-Jul-2010 (C6D1), the event was considered resolved with sequelae. Cycle 6 of belinostat was delayed.

On 17-Jan-2012 (C20D9), the patient was admitted to the hospital due to Grade 3 fracture arm and leg sustained following a fall on a frozen street. Surgery was performed for left femur and radius fractures on 18-Jan-2012, with no complications. The patient was discharged from the hospital in stable condition on 30-Jan-2012 (C20D22), with a follow-up radiology consult in 6 weeks. No action was taken with study medication and the event was considered resolved with sequelae.

The patient ended the study after 28 cycles of belinostat on 10-Dec-2012.

The Investigator reported the events of obstipation, Alveolitis, and DVT as related to study drug and the events of pneumonia and fracture arm and leg as unrelated.

14.3.3.2.12 161-001

Patient **161-001** was a 67-year-old Caucasian male with no medical history and no concomitant medications relevant to the events. Bone marrow involvement was clinically suspected, but a bone marrow assessment was not completed prior to starting study treatment. The patient started Cycle 1 of belinostat on 12-Oct-2009 at a dose of 1,800mg. On 17-Oct-2009 (C1D6), the patient experienced Grade 3 asthenia. The patient was hospitalized and it was determined that asthenia was caused by anemia. Prior to and during hospitalization, the patient experienced low hemoglobin and RBCs. The patient received no treatment and, on 18-Nov-2009 (C1D38), the event was considered resolved. The patient was discharged and no action was taken with regard to belinostat.

Cycle 2 of belinostat was started on 02-Nov-2009. On 23-Nov-2009 (C2D22), the patient was hospitalized due to Grade 3 thrombocytopenia. Prior to and during hospitalization, the patient experienced low platelet counts. On 24-Nov-2009 (C2D23), the event was considered resolved following 2 blood transfusions. No action was taken with regard to belinostat.

Cycle 3 of belinostat was started on 30-Nov-2009. On 03-Dec-2009 (C3D4), the patient experienced Grade 4 septic shock, with febrile neutropenia and dehydration. A bacterial infection was suspected and the patient received antibiotics. Blood cultures were negative and, on 09-Dec-2009 (C3D10), the event was resolved. The patient remained in the study, but did not receive Cycle 3 belinostat infusions for Days 4 and 5.

On 17-Dec-2009 (C3D18), the patient was hospitalized due to Grade 3 septic shock, with hypotension, Grade 3 thrombocytopenia and Grade 3 anemia. Prior to and during hospitalization, the patient experienced low platelet, hemoglobin and RBC counts. Blood cultures were positive for Enterobacter cloacae bacterium. The patient received treatment with antibiotics and folate. Anemia was considered resolved on 19-Dec-2009 (C3D20). Thrombocytopenia increased in severity to Grade 4 on 21-Dec-2009 (C3D22) and, following 2 platelet transfusions, the event was considered resolved on 28-Dec-2009 (C3D29). Septic shock resolved on 08-Jan-2010 (C3D40) and the patient was withdrawn from the study, due to the event, 36 days after the last dose of belinostat.

The Investigator assessed asthenia as unrelated to belinostat. The remaining events were assessed as related to belinostat.

14.3.3.2.13 207-001

Patient **207-001**, a 71-year-old Caucasian female with no relevant history and on multiple concomitant medications, started Cycle 1 of belinostat at a dose of 1,640mg on 19-Jun-2010. The dose was reduced to 1,620mg in Cycle 4 due to BSA change, and further reduced to 1560mg in Cycle 5.

On 16-Aug-2010 (C2D28), the patient was admitted to the hospital for C3D1of study treatment, with a 1 week history of Grade 2 cutaneo rash in the axillary and groin regions that started on 07-Aug-2010 (C2D19). The lesions were biopsied and the belinostat was temporarily withheld. The biopsy results were consistent with hypersensitivity reaction and the patient was treated with topical corticosteroids and antihistamines. The patient responded well to treatment and completed Cycle 3 of belinostat, without complications, from 30-Aug-2010 to 03-Sep-2010. The patient was discharged to home on 03-Sep-2010 (C3D5) in stable condition and the event resolved on 02-Dec-2010 (C6D22).

On 25-Aug-2011 (C17D21), a physical exam revealed a nasal lesion suggestive of carcinoma. Excision of the lesion was performed, as an outpatient, on 26-Sep-2011 (C19D10), and pathology confirmed a diagnosis of cutaneous lesion on the nose (actinic keratosis).

The patient was withdrawn from the study on 14-Oct-2011 (C19D28) due to worsening allergy problems.

The Investigator assessed cutaneous rash as related to study drug. Cutaneous lesion on the nose (actinic keratosis) was initially assessed as related to study drug, but subsequently downgraded to unrelated.

14.3.3.2.14 220-002

Patient **220-002**, a 70-year-old Caucasian male with no relevant medical history and on multiple concomitant medications, started Cycle 1 of belinostat on 06-Sep-2010 at a dose of 2050mg. The subsequent cycles were administered at a reduced dose of 2,000mg, due to weight reduction. On 29-Sep-2010 (C2D3), the patient was hospitalized due to dry mouth and thirst. Admission laboratory work revealed a blood glucose level of 27mmol/L. The patient was diagnosed with Grade 3 hyperglycemia and treated with metformin and NovoRapid. On 01-Oct-2010 (C2D5), the patient was discharged home in stable condition after completion of Cycle 2, administered on schedule.

On 18-Nov-2012 (C24D7), the patient was hospitalized with thoracic pain and a fever of 41°C. Imaging of the thorax region revealed a right lower lobe consolidation, consistent with right-sided pneumonia, and the patient was diagnosed with Grade 3 pneumonia. The patient was treated with 5 liters of oxygen via nasal cannula, antibiotics, and discharged home on 22-Nov-2012 (C24D11). No action was taken with regard to belinostat. The patient completed 28 cycles of belinostat.

The Investigator classified the events as unrelated to belinostat.

14.3.3.2.15 240-001

Patient **240-001**, a 61-year-old Caucasian female with a relevant medical history of sphenoid meningioma on multiple concomitant medications, was treated with 4 cycles of belinostat at varying doses (due to changes in BSA). Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. On 10-Aug-2009 (C2D21), the patient was hospitalized with a diagnosis of Grade 3 asopharyngeal infection. Admission labs revealed CRP 3.06 mg/dL and a blood culture positive for staphylococcus aureus. The patient also experienced dysphagia and stomatitis. The patient was treated with IV fluids, antibiotics, and fluconazole. The event was considered resolved on 14-Aug-2009 (C2D25) and the patient was discharged to

home in stable condition. Cycle 3 treatment was delayed 2 weeks, due to the event, and was administered from 24-Aug to 28-Aug-2009. The patient was withdrawn from the study on 08-Oct-2009 (C4D18) due to disease progression, 14 days after the last dose of belinostat.

The Investigator assessed the event as related to study drug.

14.3.3.2.16 240-002

Patient **240-002**, an 80-year-old Caucasian male, with no medical history relevant to the event and on multiple concomitant medications, started Cycle 1 of belinostat on 17-Aug-2009 at a dose of 1,620mg. . Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. On 31-Aug-2009 (C1D15), the patient was hospitalized with a diagnosis of Grade 3 hemorrhage from the tumor site and a left amygdalectomy was performed. The event was considered resolved the same day.

On 07-Sep-2009, Cycle 2 of belinostat was started at a reduced dose of 1,590mg (due to change in BSA). On 08-Sep-2009 (C2D2), the patient experienced fever (39 °C), chills, altered consciousness and false deglutition secondary to the sequelae of lymphoma in the throat. Laboratory work performed the same day, revealed elevated leukocyte count 13.42/µL, neutrophil count 11.246/µL and C-reactive protein 2.02 mg/dl. No source of infection was identified, however, the patient experienced clinical symptoms of infection at the site of recent surgery. The patient was diagnosed with Grade 4 infection and treated with Tazocin (piperacillin/tazobactam), Dolantin (pethidine), Amulsin (olanzapine), and paracetamol. On 08-Sep-2009 (C2D2), the event was considered resolved and the patient completed Cycle 2 on 11-Sep-2009.

On 29-Sep-2009 (C2D23), 19 days after the last dose of belinostat, the patient was withdrawn from the study due to lack of clinical benefit.

The Investigator assessed both events as unrelated to study drug.

14.3.3.2.17 243-001

Patient **243-001**, a 52 year-old Caucasian male with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 28-Sep-2009 at a dose of 2,080mg. On 07-Oct-2009 (C1D10), the patient was hospitalized with Grade 2 hypotension (75/60 mmHg). The patient's blood pressure rapidly recovered with hydration (500 mL of fluid) to 110/70 mmHg later the same day. The event was considered resolved on 08-Oct-2009 (C1D11) and no action was taken with regard to belinostat.

Cycle 2 of belinostat was started on 19-Oct-2009 (C2D1). Prior to infusion, the patient's glucose was low (26 mg/dL). Following C2D1 infusion, the patient was hospitalized with Grade 4 hypoglycemia. The patient had pre-existing type 2 diabetes and was being treated with Glurenorm (gliquidone). The patient received food and was started on intravenous glucose 10% perfusion and Glurenorm was discontinued. On 20-Oct-2009 (C2D2), belinostat infusion was withheld and the event was considered resolved on 21-Oct-2009 (C2D3). C2D3 was given at a reduced dose of 1,560mg. The patient received the final dose of belinostat on 22-Oct-2009 (C2D4) and was withdrawn from the study due to thrombocytopenia and disease progression. The patient expired on 15-Dec-2009 (C2D58).

The Investigator assessed the event of hypotension as related to belinostat and the event of hypoglycemia as unrelated to belinostat.

14.3.3.2.18 245-001

Patient **245-001**, a 71-year-old African-American female with an extensive medical history and on multiple concomitant medications, was treated with 2 cycles of belinostat at a dose of 1,940mg, and subsequently increased to 1,960mg for 4 cycles. On 03-Oct-2010, the patient was hospitalized in preparation for Cycle 1 and a catheter inserted for belinostat infusion. The patient developed a hematoma at the catheter site and was diagnosed with Grade 3 hematoma after placement of port-a-cath. The patient's condition was complicated by Grade 3 low sodium (119mEq/L). Conservative treatment was given and the patient was discharged to home on 10-Oct-2010. Cycle 1 of belinostat was started on 13-Oct-2010.

The patient was withdrawn from study on 14-Feb-2011 (C6D22), due to disease progression.

The Investigator assessed both events as unrelated to belinostat.

14.3.3.2.19 513-001

Patient **513-003**, a 58-year-old Caucasian male with a medical history of Klebsiella pneumonia and pulmonary embolism on multiple concomitant medications, was treated with 3 cycles of belinostat at a dose of 2,150mg and subsequently increased to 2,250mg in Cycle 4. On 31-Oct-2011 (C6D15), the patient was withdrawn from the study due to disease progression. On 17-Nov-2011 (C6D32), the patient was admitted to the hospital with general weakness, fever, skin changes, thrombocytopenia, kidney failure and liver failure. The patient was treated with Solu-Medrol and IV Milurit. On 18-Nov-2011 (C6D33), the patient expired due to Grade 5 sudden heart failure. The cause of death was confirmed by autopsy as secondary to PTCL progression to the heart muscle and other internal organs.

The Investigator assessed the event as unrelated to the study drug.

14.3.3.2.20 513-002

Patient **513-002**, a 61-year-old Caucasian male with a medical history of multiple episodes of fever on multiple concomitant medications, started Cycle 1 of belinostat on 14-Mar-2011 at a dose of 2150mg. The patient was hospitalized in preparation for belinostat Cycle 2 on 04-Apr-2011. Following treatment, on 08-Apr-2011 (C2D4), the patient experienced fever, followed by events of periodic abdominal pain, nausea and vomiting. Blood cultures were taken at that time and the patient received the final dose of belinostat on 09-Apr-2011. On 10-Apr-2011 (C2D6), the patient's hospitalization was prolonged due to Grade 2 fever, with no source of infection (blood culture negative). Prior to this hospitalization, the patient's white blood cell and neutrophil counts were normal. Blood and urine cultures were negative, and the patient was treated with paracetamol, Pyralgina (metamizole) and Heviran (acyclovir). On 14-Apr-2011 (C2D10), fever resolved with sequelae (persistent fever under control) and the patient was discharged to home. The patient was withdrawn from the study on 28-Apr-2011 (C2D24), due to disease progression.

The Investigator assessed the event as related to belinostat.

14.3.3.2.21 516-004

Patient **516-004**, a 40-year-old Caucasian male with no reported medical history or concomitant medications, received a total of 26 cycles of belinostat at a dose of 1900mg. The patient received Cycle 8 of belinostat treatment from 06-Dec-2011 to 10-Dec-2011. Cycle 9 was delayed due to inaccessibility of the veins. The patient was hospitalized on 12-Jan-2012 (C8D38) for insertion of venous port. The procedure was performed on 13-Jan-2012 (C8D39), with the port was placed in the subclavian area. No complications were reported during the procedure. On 14-Jan-2012 (C8D40), the patient was discharged to home. Cycle 9 of belinostat treatment was delayed by 3 weeks and was administered from 17-Jan to 21-Jan-2012, with no change in the dose.

On 20-Feb-2012 (C10D14), tumor assessment (TA) #5 scans were performed per protocol and the patient was diagnosed with bilateral lung masses. The patient was asymptomatic. TA #6 scans (29-Mar-2012) and TA #7 (07-May-2012) revealed an increase in the size and intensity of the lung masses, with suspicion of fungal masses, such as invasive bronchopulmonary aspergillosis. A biopsy performed on 16-May-2012 was inconclusive. TA #8 scans, performed on 14-Jun-2012 (C15D3), revealed reduced intensity and density of the masses. The patient remained asymptomatic, but was hospitalized on 18-Jun-2012 (C15D7) for further workup of the Grade 2 lung masses. A

bronchoscopy was performed on 20-Jun-2012 (C15D9) and samples were taken for mycology and bacteriology. A left-sided thoracoscopy was performed the same day, with resection of segment VI of the left lung. The pathology report from the thoracoscopy samples revealed purulent lung inflammation, and was positive for Staphylococcus aureus (MRSA) and Neisseria species. The event resolved with sequelae (Grade 2 purulent pneumonia) and the patient was discharged to home on 22-Jun-2012 (C15D11) in stable condition.

The Investigator assessed the event of insertion of venous port as unrelated to belinostat and lung masses as related to belinostat.

14.3.3.2.22 516-006

Patient **516-006**, a 60-year-old Caucasian male with no medical history relevant to the events and on no relevant concomitant medications, was treated with 1 cycle of belinostat at a dose of 1,700mg. Bone marrow involvement was clinically suspected at Baseline; however an assessment was not performed. On 08-Aug-2011 (C1D21), the patient had protocol-specified laboratory work conducted prior to initiating Cycle 2. On 09-Aug-2011 (C1D22), the results revealed Grade 4 thrombocytopenia, with WBC 2.29/µL, RBC 2,150,000/µL, hematocrit 21.4% and platelet count 8,000/µL. The patient was sent to the hematology clinic for blood and platelet transfusions. On 10-Aug-2011 (C1D23), the patient was discharged home in stable condition. Laboratory results at the time of discharge revealed WBC 2.8, RBC 2.99, hemoglobin 8.9g/dL and platelet count 21/µL. The event was considered resolved with sequelae and belinostat was temporarily discontinued. The patient was considered lost to follow-up on 10-Aug-2011.

On 02-Sep-2011 (C1D46), the sponsor was informed by the site that the patient had been admitted to a hospital with a diagnosis of Grade 4 pancytopenia (date unspecified). Multiple attempts were made by the site to contact the family, but were unsuccessful. On 07-Dec-2011, a certified letter was sent to the family and the site was informed that the patient expired on 09-Oct-2011 (C1D83), 79 days after the last dose of belinostat. No further information regarding the event or the patient's death was available.

The Investigator assessed the events of thrombocytopenia and pancytopenia as related to study drug.

14.3.3.2.23 532-004

Patient **532-004**, a 55-year-old Caucasian female with no relevant medical history on multiple concomitant medications, started Cycle 1 of belinostat at a dose of 1500mg on 16-Mar-2011. The patient experienced fever of 38-39°C on 20-Mar-2011 (C1D5) and

was hospitalized for Grade 1 fever the same day. The patient's ANC was reported as 2.41g/L (2.04-7.5), ruling out febrile neutropenia. A chest X-ray, performed on 21-Mar-2011 (C1D6), was negative and infection as a cause for fever was ruled out. The Investigator attributed the cause of fever as lymphoma. On 24-Mar-2011(C1D9), the patient was discharged in stable condition.

The patient was hospitalized to receive Cycle 6 of belinostat on 27-Jun-2011. On 29-Jun-2011 (C6D3), the patient experience a high temperature (39.2°C) and belinostat was temporarily interrupted. A chest X-ray performed the same day revealed Grade 3 pneumonia, prolonging hospitalization. The patient was treated with antibiotics and cough medicine. The event was considered resolved on 04-Jul-2011 (C6D8), and the patient received the 3 remaining days of Cycle 6 from 04-Jul to 06-Jul-2011. The patient discharged on 06-Jul-2011(C6D10).

The patient withdrew consent and was discontinued from the study on 05-Sep-2011 (C7D43).

The Investigator assessed the events as unrelated to belinostat.

14.3.3.2.24 533-001

Patient **533-001**, a 62-year-old Caucasian female with no relevant medical history on multiple concomitant medications, was treated with 6 cycles of belinostat at a dose of 1650mg. The patient had Baseline hemoglobin of 105g/L, platelets 12910^9/L and lactate dehydrogenase (LDH) 774U/L. On 06-Jun-2011 (C4D1), blood work revealed platelets 83Giga/L and LDH 759U/L. On 15-Jun-2011 (C4D10), the patient presented to the hospital complaining of extreme weakness and was hospitalized the same day. Lab work upon admission revealed severe anemia (hemoglobin 44g/L), with elevated levels of LDH 1177U/L, serum bilirubin total 62µmol/L and serum bilirubin direct 19.9µmol/L. A positive Coombs test confirmed hemolysis and the patient was diagnosed with Grade 3 immune hemolytic anemia. Between 15-Jun-2011 (C4D10) and 01-Jul-2011 (C4D26), the patient was transfused with 10 units of red blood cells and started on steroids. On 04-Jul-2011 (C4D29), the patient's hemoglobin improved to 90g/L and LDH returned to normal level. The event was considered resolved and the patient was discharged the same day. Cycle 5 of belinostat was delayed until 11-Jul-2011 and the dose was reduced to 1240mg.

On 19-Aug-2011 (C6D19), the patient was hospitalized with a diagnosis of Grade 3 immune hemolytic anemia. Admission lab work revealed hemoglobin 29g/L, hematocrit 9% and reticulocyte 100%. Elevated levels of serum bilirubin total 24.1µmol/L and serum bilirubin direct 6.9µmol/L were also noted. The patient was treated with steroids and transfused with 6 units of red blood cells. On 30-Aug-2011 (C6D30), the event was

considered resolved and the patient was discharged from the hospital. The patient was withdrawn from the study on 12-Sep-2011 (C6D43) due to an adverse event (anemia).

The Investigator assessed both events as related to the study drug.

14.3.3.2.25 534-001

Patient **534-001**, a 62-year-old Caucasian male with an extensive medical history on amlodipine, betaxolol and pentoxifylline started Cycle 1 of belinostat on 22-Feb-2010 at a dose of 2140mg. On 24-Feb-2010 (C1D3), a routine ECG revealed an asymptomatic, normal frequency Grade 1 atrial fibrillation (asymptomatic, with spontaneous resolution without medical intervention). The event was assessed as medically significant and resolved in one hour, confirmed by follow-up ECG.

On 11-Jun-2010 (C6D5), the patient was hospitalized with a diagnosis of Grade 3 iliac artery thrombosis. A thrombectomy and peripheral percutaneous transluminal angioplasty were performed and the patient was discharged in stable condition on 22-Jun-2010 (C6D16). The patient received their last dose of belinostat at 2000mg on 06-Aug-2010 (C8D5) and was withdrawn from the study at the patient's request.

The Investigator assessed both the events as unrelated to belinostat.

14.3.3.2.26 534-002

Patient **534-002**, a 69-year-old Caucasian female with relevant medical history of autoimmune pneumonitis with pulmonary fibrosis and chronic bronchitis on multiple concomitant medications, started Cycle 1 of belinostat at a dose of 1,800mg on 30-Aug-2010 and received a total of 30 cycles. The patient underwent 2 dose reductions due to prolonged QTc (Cycle 2 reduced to 1,350mg and, from Cycle 3, reduced to 1,000mg).

On 31-Mar-2011 (C10D11), following administration of IV contrast media, the patient developed wheezing, shortness of breath, decreased O_2 saturation (84%) and fever. The patient was admitted to the hospital the same day with a possible diagnosis of Grade 3 sepsis. Laboratory results (date unspecified) during hospitalization revealed CRP 127mg/l, procalcitonin 36.18ng/ml and WBC 32.6g/l, confirming the diagnosis of sepsis. Blood cultures were negative as of 05-Apr-2011 (C10D16). The patient was treated with antibiotics, steroids, fluid support and heparin anticoagulation. On 08-Apr-2011 (C10D19), the event was considered resolved and the patient was discharged to home in improved condition. Cycle 11 was delayed due to the event.

On 04-May-2011 (C11D17), laboratory results revealed INR within therapeutic range, but an increase in D-dimer level (2.90mg/mL). On 05-May-2011 (C11D18), the patient was hospitalized with complaints of pain and swelling of the right lower extremity. Doppler ultrasound of the lower extremities confirmed the diagnosis of Grade 3 thrombosis (of right lower extremity deep veins) and a CT scan of the chest ruled out pulmonary embolism. The patient was started on anticoagulant therapy. On 11-May-2011 (C11D24), the event was considered resolved and the patient was discharged. Cycle 12 was delayed due to the event.

On 13-Jul-2012 (C27D26), the patient was hospitalized with complaints of cough and dyspnea. Physical examination revealed slight hyperemia of the pharyngeal structures and tonsils, emphysematous chest, rough cellular breathing sounds with extensive whistling and throbbing, and bronchitis on both sides. Admission laboratory work revealed markedly elevated CRP levels (134mg/l) and a chest X-ray was negative for pneumonia. The patient was diagnosed with Grade 3 chronic bronchitis acute exacerbation and responded well to treatment with IV hydration and antibiotics. On 20-Jul-2012 (C28D05), the event was considered resolved and the patient was discharged to home.

On 09-Aug-2012, (C28D25), the patient was hospitalized with complaints of fever (38^{o}C), cough, expectoration, cold and dyspnoea. The physical exam revealed emphysematous thorax, significantly rough basic breathing and extendedly whistling bronchitis-like rhonchi bilaterally. An admission chest X-ray revealed infant palm-sized light transparency decrease corresponding to small-extent incipient bronchopneumonia and the patient was diagnosed with Grade 3 bronchopneumonia. The patient was started on antibiotics and, on 17-Aug-2012 (C29D05), a follow-up chest X-ray revealed pneumonia in regression. The patient was discharged to home in improved condition.

On 05-Sep-2012 (C29D24), the patient was hospitalized at a local hospital with complaints of weakness and a subfebrile status. The patient was diagnosed with Grade 2 dehydration and was treated with intravenous fluids. The patient also experienced tachycardia (non-serious) during hospitalization, which was treated by increasing the dose of ongoing bisoprolol. On 10-Sep-2012 (C30D1), the event was considered resolved and the patient was discharged to another hospital for a pre-arranged appointment.

On 01-Oct-2012 (C30D22), the patient was hospitalized with complaints of dyspnea at rest, weakness, chest pain and abdominal pain. The physical examination revealed emphysematous chest, expressly harsh basal respiration, bilateral basal fibrotic murmurs

and a decubitus ulcer on the left shoulder. The patient was dehydrated and was treated with intravenous antibiotics and hydration. While in the hospital, the patient experienced fever and laboratory results revealed gram negative rods. The patient was started on meropenem and amikacin. On 04-Oct-2012 (C30D25), the patient was diagnosed with disease progression and withdrawn from study. The patient expired the same day.

The Investigator assessed all the events as unrelated to belinostat.

14.3.3.2.27 534-003

Patient **534-003**, a 54-year-old Caucasian male with relevant history of hypertension on multiple concomitant medications, started Cycle 1 of belinostat on 13-Sep-2010 at a dose of 2350mg. On 15-Nov-2011 (C21D2), the patient was diagnosed with bilateral drug induced cataracts (the patient completed Cycle 21 on schedule). On 04-Apr-2012 (C27D17), the patient was hospitalized for planned surgery for drug induced cataract of the right eye, performed on 05-Apr-2012 (C27D18). The patient was discharged from the hospital on 06-Apr-2012 (C27D19) and no action was taken with study drug.
The patient was discontinued from the study on 21-May-2012 (C29D22) due to disease progression and expired on 07-Mar-2013 (C29D312).

The Investigator classified the event as possibly related to the study drug.

14.3.3.2.28 534-005

Patient **534-005**, a 72-year old Caucasian female with an extensive medical history on multiple concomitant medications, started Cycle 1 of Belinostat on 16-May-2011 at a dose of 1700mg and completed 19 cycles of treatment. On 20-Apr-2012 (C16D12), the patient was hospitalized with complaints of productive cough, runny nose, difficulty swallowing, weakness and fatigue. Upon examination, there was purulent nasal discharge and the pharynx was inflamed with massive whitish-yellow purulent discharge on the posterior pharyngeal wall. The chest was emphysematous with rough breathing sounds. After the otorhinolaryngology consultation, the patient was started on parenteral antibiotic and antifungal medications. Admission lab results revealed elevated WBCs 13.54g/L, ANC 10.49g/L and CRP 110mg/L. The radiology examination revealed air-containing accessory cavities and throat discharge cultures were positive for Staphylococcus aureus. The patient was diagnosed with Grade 2 purulent bronchitis and antifungal therapy was discontinued. After 6 days of parenteral antibiotic therapy, there was symptomatic improvement and the patient was started on oral medications. The lab work on 23-Apr-2012 (C16D15) revealed significant improvement in WBC 7.50g/L and ANC 5.37g/L. On 25-Apr-2012 (C16D17), the CRP was 15mg/L. The patient was discharged to home on 26-Apr-2012 (C16D18) in stable condition and the event was considered resolved. No action was taken with regard to belinostat.

The patient's was withdrawn from study due to disease progression and the end of study visit was conducted on 30-Jul-2012 (C19D29).

The Investigator assessed this event as possibly related to the study drug.

14.3.3.2.29 534-006

Patient **534-006**, a 54-year-old Caucasian female with an extensive medical history, including autoimmune hemolytic anemia, on Hyzaar (hydrochlorothiazide and losartan) was treated with 30 cycles of belinostat at a dose of 1930mg. On 22-Aug-2011, the patient was admitted to the hospital, per standard of care, for C1D1 belinostat infusion. The lab work upon admission revealed hemoglobin 37g/l, hematocrit 0.11L/L, RBCs 1.10T/L, platelets 78g/L, lactate dehydrogenase 821U/L, total bilirubin 51.6µmol/L, RDW-CV 24.2%, MCV 100.9fL and a positive Coombs test. The patient was diagnosed with Grade 3 worsening autoimmune hemolytic anemia on 29-Aug-2011 (C1D8), prolonging hospitalization. The patient received a transfusion and was treated with methylprednisolone. For patient safety and observation, the patient remained hospitalized until 05-Sep-2011(C1D15), when she was discharged in stable condition.

The Investigator assessed the event as unrelated to the study drug.

14.3.3.2.30 541-001

Patient **541-001**, a 75-year-old Caucasian female with relevant medical history of hypertension and cerebral infarction on multiple concomitant medications including corticosteroids, was treated with a total of 34 cycles of belinostat, 18 cycles at a dose of 1700mg and 16 cycles at a dose of 1850mg. The patient received Cycle 2 of belinostat treatment from 25-Oct to 29-Oct-2010. On 28-Oct-2010 (C2D4), a Hickman catheter was placed in the left subclavian vein. On 04-Nov-2010 (C2D11), the patient was hospitalized with complaints of left arm swelling. Doppler ultrasound confirmed the diagnosis of Grade 3 THROMBOSIS. The catheter was removed and the patient was treated with nadroparin calcium. The event resolved on 09-Nov-2010 (C2D16) and hospitalization was continued for administration of Cycle 3 of belinostat treatment.

The patient received Cycle 34 of belinostat treatment from 10-Sep-2012 to 13-Sep-2012. On 12-Sep-2012 (C34D3), the patient experienced dyspnea and thoracic pain, which resolved spontaneously after 20 minutes. A ventilation/perfusion scan and a D-dimer test (3.3mcg/ml, reference range <0.5) were performed and, on 14-Sep-2012 (C34D5), the patient was diagnosed with Grade 4 pulmonary embolism. The patient was treated with low molecular weight heparin and warfarin. Cycle 4 day 5 belinostat was not administered. The event resolved with sequelae (pulmonary embolism) and the patient

was discharged in fair condition on 18-Sep-2012 (C34D9). Belinostat was permanently discontinued.

The Investigator assessed both events as unrelated to the study drug.

14.3.3.2.31 600-003

Patient **600-003**, a 59-year-old Caucasian male with a history of autologous stem cell transplant on Pantoloc (pantoprazole), started Cycle 1 of belinostat on 08-Nov-2010 at a dose of 1578mg. The second cycle was started on 29-Nov-2010. The patient was hospitalized on 02-Dec-2010 (C2D4) for Grade 3 pharyngitis. The patient's oropharynx was swollen and red, with white plaques and infiltrates. The patient was unable to swallow due to pain. A throat culture was subsequently performed and reported as negative. The patient received treatment with antibiotics. On 13-Dec-2010 (C2D15), the event resolved and the patient was discharged. No action was taken with regard to belinostat.

The patient received a total of 8 cycles of belinostat, with the last dose infused on 20-May-2011(C8D5). A follow-up CT scan performed on 08-Jun-2011 (C8D24), revealed stable disease, with some of the lymph nodes reduced in size. Infiltrates in the lungs, present on 1 side only in a previous scan, were seen bilaterally. On 14-Jun-2011 (C8D30), the patient was hospitalized to due rapidly progressing severe fatigue, with decreasing hemoglobin 75g/L, platelet 7x10^9/L and neutrophil counts 0.4x10^9/L, and required transfusions every 3 days. During hospitalization, a bronchoscopy of lung lesions was performed on 17-Jun-2011(C8D33) and pathology was negative for malignant cells. A repeat CT performed on 23-Jun-2011 (C8D39) revealed a probable infection etiology, with further deterioration, and increased ground glass opacities, especially in the upper lobe bilaterally. On 27-Jun-2011 (C8D43), the patient was withdrawn from the study due to disease progression. A bone marrow aspiration/biopsy, performed 29-Jun-2011(C8D45), revealed interstitial infiltration of the bone marrow by isolated and small clusters of atypical T-cells, most consistent with involvement by the patient's known T-cell lymphoma. On 05-Jul-2011, (C8D51), the patient died of multi-organ failure due to progressive disease.

The Investigator assessed the events as unrelated to belinostat.

14.3.3.2.32 752-002

Patient **752-002**, a 66-year-old mixed /colored male with no reported medical history and no reported concomitant medications, completed 3 cycles of belinostat at a dose of 1,600mg. Although bone marrow involvement was not suspected at baseline, assessment

was performed on 17-Feb-2011 and showed lymphoma present. The patient completed Cycle 4 of belinostat on 13-May-2011 at a reduced dose of 1,450mg (dose reduction due to change in body surface area). The patient was hospitalized on 04-Jun-2011 (C4D27) with shortness of breath, tachypnea, hypotension, and tachycardia. The admitting diagnosis was infection. Heparin was started as thromboembolic prophylaxis on 06-Jun-2011 (C4D29). The patient deteriorated the same day and was transferred to the ICU. On 09-Jun-2011 (C4D32), the patient was intubated and mechanically ventilated until the following day. A CT scan, conducted on 14-Jun-2011 (C4D37), was compared to a previous scan performed on 16-May-2011 (C4D08) and revealed no change in the mediastinal and supraclavicular adenopathy. A marked increase in bilateral pleural effusions and ascites was noted, as well as bibasilar consolidation. The para- and pre-aortic adenopathy and splenic size remained unchanged. The previously seen splenic infarct was no longer visible; however 2 vague non-enhancing lesions were seen in the lower pole of the spleen. An ascites tap revealed a borderline finding favoring exudate rather than transudate. On 18-Jun-2011 (C4D41), the patient's condition deteriorated due to Grade 4 pneumonia and, on 20-Jun-2011 (C4D43), the patient was withdrawn from the study. The patient expired on 21-Jun-2011 (C4D44), due to respiratory failure secondary to pneumonia.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.2.33 800-001

Patient **800-001**, a 65-year-old Caucasian female with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 02-Jan-2011 at a dose of 1620mg. On 05-Jan-2011 (C1D4), 45-minutes following her infusion, the patient experienced Grade 3 hypoxia and rigors. Oxygen saturation was 87% on room air, with normal blood pressure, no fever, and the physical examination was described as unremarkable. The patient was treated with nasal O_2, with gradual relief, and was asymptomatic shortly thereafter. The event was considered medically significant and resolved the same day. Belinostat was not administered on day 5. On 25-Jan-2011 (C2D3), the patient received the last belinostat infusion at a reduced dose of 1337mg, due to phlebitis, and was withdrawn from the study for the same reason.

The Investigator assessed both events as related to belinostat.

14.3.3.2.34 801-001

Patient **801-001**, a 35-year-old Caucasian female with an extensive medical history, including anemia, on Losec, acyclovir and Lyrica, was treated with 1 cycle of belinostat at a dose of 1520mg. On 21-Mar-2011 (C1D13), the patient was admitted to the hospital

for treatment of Grade 4 anemia. The patient was treated with hydrocortisone and ceftazidime. Three units of packed red blood cells were administered the following day. The patient was discharged in stable condition on 22-Mar-2011 (C1D14).

On 03-Apr-2011 (C1D26), the patient arrived at the hospital to begin Cycle 2 treatment complaining of weakness and dyspnea. An abdominal ultrasound revealed an increase in the size of liver masses, new pancreatic lesions and ascites. The patient was admitted with a diagnosis of general deterioration due to disease progression the same day. Treatment with belinostat was permanently discontinued. On 20-Apr-2011 (C1D43), the patient expired due to disease progression.

The Investigator assessed both the events as unrelated to belinostat.

14.3.3.2.35 902-001

Patient **902-001**, a 71-year-old Latin female with an extensive medical history, including fever, on multiple concomitant medications, started Cycle 1 of belinostat on 06-Dec-2010 at a dose of 1560mg. The evening following C1D1 infusion, the patient experienced chills and fever. She was advised to go to the ER and, on 07-Dec-2010 (C1D2), the patient was admitted to the hospital. The temperature upon admission was 101.9ºF and laboratory results revealed WBC 16.4x10^9/L (4.0-10.0). Prior to the hospitalization, the patient's labs revealed normal uric acid, potassium, phosphate, calcium, BUN and creatinine clearance levels, with high WBC. The patient was diagnosed with Grade 2 tumor lysis syndrome and was treated with vancomycin. On 10-Dec-2010 (C1D5), the event resolved and the patient was discharged to home in stable condition after completing Cycle 1. No action was taken with regard to belinostat.

Cycle 2 of belinostat started on 27-Dec-2010. On 28-Dec-2010 (C2D2), after belinostat administration, the patient experienced Grade 2 ever associated with tumor of 104ºF, was brought to the ER and subsequently admitted the same day. Peripheral blood cultures obtained upon admission were positive for coagulase-negative staphylococcus. Urine culture and central (port) blood culture were negative. Treatment with vancomycin was started. The patient's blood cultures on 29-Dec-2010 (C2D3) and 30-Dec-2010 (C2D4) were negative (no growth after 5 days of incubation). On 01-Jan-2011 (C2D6), the patient's fever spiked to 103.1ºF and treatment with a single dose of vancomycin was given. The patient remained afebrile for more than 48 hours off antibiotics and, on 02-Jan-2011(C2D7), the event resolved and the patient was discharged to home in stable condition. The patient completed Cycle 2.

On 14-Jan-2011 (C2D19), the patient presented to the hospital with Grade 1 fever of 102ºF and chills, and was admitted the same day. Blood and urine cultures were negative and the patient was treated with vancomycin for past history of coagulase negative staph infection. On 16-Jan-2011 (C2D21), the event resolved and the patient was discharged in stable condition. No action was taken with regard to belinostat.

On 18-Jan-2011 (C2D23), the patient arrived for Cycle 3, with Grade 2 fever of 101.5ºF, and was admitted to the hospital the same day. A PET scan revealed progressive disease and the patient was withdrawn from the study on 18-Jan-2011 (C2D23). The patient was treated with vancomycin, and triglyceride and ferritin levels were obtained to rule out the presence of hemophagocytic lymphohistiocytosis. Triglycerides were within normal limits and ferritin only mildly elevated, ruling out the diagnosis. No bone marrow biopsy was performed. After 48 hours, blood and urine cultures revealed no growth and the patient remained afebrile. On 20-Jan-2011(C2D25), the event resolved and the patient was discharged to home.

The Investigator assessed the events as unrelated to belinostat.

14.3.3.2.36 907-001

Patient **907-001**, a 60-year-old Caucasian female with an extensive medical history and on multiple concomitant medications, received 2 cycles of belinostat at a dose of 1720mg, which was increased to 1730mg for Cycles 3 and 4. On 05-Jul-2010 (C3D15), the patient experienced a fall and presented to the emergency department. An X-ray of the left ankle revealed mildly displaced distal fibular and tibial fracture and a left tibial rod was surgically placed the same day. Following the procedure, the patient developed left lower extremity swelling and a noticeable drop in hematocrit of 4 points and hemoglobin of 2 points. Compartmental syndrome was entertained by the orthopedic surgery service and blood thinners, including unfractionated or low-molecular weight heparin, were discontinued for 24-48 hours. The left lower extremity swelling slowly subsided, and the hematocrit and hemoglobin values stabilized at 24% and 8.3 respectively. On 08-Jul-2010 (C3D18), the event resolved and the patient was discharged to home with no change to study drug.

On 26-Jul-2010 (C4D15), the patient was withdrawn from study due to disease progression.

The Investigator assessed the event as unrelated to the study drug.

14.3.3.2.37 907-004

Patient **907-004**, a 28-year-old African-American male with an extensive medical history and on multiple concomitant medications, completed Cycle 1 of belinostat on 31-Dec-2010 at a dose of 2120mg. On 24-Dec-2010 (C1D-4), prior to initiation of Cycle 1, the patient was admitted to the hospital for Grade 3 angina. The evaluation upon admission revealed summation gallop and elevated troponin levels of 2.5 (Baseline results on 23-Dec-2010 (C1D-5): 1.04). A transthoracic echocardiogram revealed atrial septal aneurysm and a possibility of thrombus associated with the patient's central venous catheter in the right atrium. The patient experienced no chest pain during hospitalization, but was febrile and anemic. Blood cultures from the Hickman catheter were positive for coagulase negative Staphylococcus aureus and a peripheral blood culture was negative. The patient was treated with antibiotics. The event was considered resolved and the patient was discharged on 25-Dec-2010 (C1D-3).

After completion of Cycle 1, the patient experienced decreased appetite and extreme fatigue. On 07-Jan-2011 (C1D8), the patient presented to the hospital with complaints of Grade 3 fatigue and fever. He was hospitalized the same day and admission evaluation revealed orthostatic hypotension. Blood cultures were negative. On 09-Jan-2011 (C1D10), the patient was withdrawn from the study due to disease progression. The SAE was considered resolved on 19-Jan-2011 (C1D20) and the patient was discharged to hospice, where he expired on 09-Apr-2011 (C1D100) due to disease progression.

The Investigator assessed both events as unrelated to study drug.

14.3.3.2.38 908-003

Patient **908-003**, a 53-year-old Caucasian female, with an extensive medical history and on multiple concomitant medications, was treated with a total of 4 cycles of belinostat at a dose of 1915mg. On 12-Sep-2011 (C3D1), the patient was diagnosed with right leg deep vein thrombosis (non-serious) and started on Lovenox. Cycle 3 of study treatment was administered from 12-Sep-2011 to 16-Sep-2011. On 30-Sep-2011 (C3D19), the patient presented to the emergency room with complaints of chest pain, shortness of breath and pain under her left breast for the past 2 days, and was admitted to the hospital the same day. Upon admission, the chest X-ray revealed left pleural effusion and the CT scan, without contrast (contrast could not be administered due to creatinine level of 1.6mg/dL), revealed infiltrates on left side, suspicious of infarct versus atypical pneumonia. A ventilation/perfusion scan revealed intermediate probability of pulmonary embolus. The patient was diagnosed with Grade 3 pulmonary embolus and anticoagulation treatment was started. On 03-Oct-2011 (C3D22), a Greenfield filter was

placed in the infra-renal inferior vena cava (IVC) at the level of L2-L3. On 04-Oct-2011 (C3D23), a repeat chest X-ray revealed possible pulmonary edema. The patient's O2 saturation was 85-88% on 2 liters O2 via nasal cannula, which improved to 88-92% on 4 liters. The patient was started on Proventil nebulizer treatment and, subsequently, the O2 saturation improved to 95% on 2 liters O2 via nasal cannula. On 06-Oct-2011 (C3D25), the event was considered resolved and the patient was discharged home on O2. Cycle 4 of study treatment was delayed and started on 17-Oct-2011 at a reduced dose of 1436mg.
The Investigator assessed the event as related to study drug.

14.3.3.2.39 911-001

Patient 911-001, a 67-year old Caucasian female with diagnosis of anaplastic large cell lymphoma (ALK-negative) Stage IVA, had bone marrow involvement at study entry. The patient, with no significant medical history on supplements only, started on C1D1 of belinostat on 23-Aug-2010 at a dose of 1770mg and completed 4 cycles. On 15-Nov-2010 (C4D21), the patient was withdrawn from the study due to progressive disease.

14.3.3.2.40 912-001

Patient **912-001**, a 55-year-old Asian male with medical history of dyslipidemia and gout on multiple concomitant medications started Cycle 1 of belinostat on 05-Apr-2010 at a dose of 1690mg and tolerated the first infusion well. That same evening (C1D1), the patient presented to the emergency room with anemia and fever, and was admitted. Lab work revealed elevated bilirubin (3.4mg/dl and 5.0mg/dl) and an abdominal sonogram showed biliary ductal dilatation. A magnetic resonance cholangiopancreatography (MRCP) revealed obstruction of the bile duct due to lymphoma. The patient was diagnosed with Grade 3 hyperbilirubinaemia and started on prophylactic ciprofloxacin and metronidazole, with a biliary stent placement. On 16-Apr-2010 (C1D12), the bilirubin level dropped to 2.7mg/dl and the event was considered resolved. Cycle 1, day 2-5 belinostat infusions were delayed and administered at a reduced dose of 1270mg. On 20-Apr-2010 (C1D16), the patient received the last dose of belinostat and was withdrawn from the study on 10-May-2010 (C1D36) due to disease progression.

The Investigator assessed the event as unrelated to study drug.

14.3.3.2.41 912-003

Patient **912-003**, a 66-year-old Caucasian male with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 31-Jan-2011 at a dose of 1960mg. On 06-Apr-2011 (C3D24) the patient was diagnosed with squamous cell

carcinoma of the left lower lobe (lung cancer) and was withdrawn from the study due to the secondary malignancy.

On 08-Apr-2011 (C3D26), the patient presented to the emergency room with a fever of 39.2ºC and a 2 to 3 day complaint of sleepiness, confusion and decreased intake. The urine (aerobic) culture was positive for vancomycin-resistant enterococcus. On 09-Apr-2011 (C3D27), the patient was admitted to the hospital with fever and dehydration. Laboratory tests revealed blood and nasopharyngeal cultures were negative, and the viral respiratory and fluorescent antibody (FA) stain was negative for respiratory syncytial virus (RSV), influenza types A and B, parainfluenza and adenovirus. The aerobic culture and gram stain sputum showed upper respiratory flora contamination and a chest X-ray revealed air space opacity in the left lung, likely pneumonia. The patient was diagnosed with Grade 3 post-obstructive pneumonia and treated with antibiotics. Due to hypoxia shortly after admission, supplemental oxygen was initiated requiring 100% non-rebreather mask, gradually weaning to 4 liters nasal cannula. On 18-Apr-2011 (C3D36), the event resolved and the patient was discharged to home in stable condition.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.2.42 914-003

Patient **914-003**, a 44-year-old Caucasian female with no medical history relevant to the events on multiple concomitant medications, started Cycle 1 of belinostat on 27-Sep-2010 at a dose of 2100mg. On 29-Sep-2010 (C1D3), a blood culture drawn from the MediPort site was positive for gram positive cocci. On 30-Sep-2010 (C1D4), the patient was hospitalized with a diagnosis of Grade 3 nfection at MediPort site. The C1D5 belinostat dose was withheld and the patient began treatment with Vancomycin. On 04-Oct-2010 (C1D8), the event was considered resolved and the patient was discharged in stable condition.

On 11-Oct-2010 (C1D15) the patient presented to the clinic for a follow-up visit, as per protocol, with complaints of fever over the previous weekend. A blood culture from the MediPort site revealed Grade 3 infection (gram negative rods), and the patient was readmitted to the hospital on 12-Oct-2010 (C1D16) for gram negative septicemia secondary to cholelythiasis and cholecystitis (reported as non-serious). The patient responded to ERCP with stenting and antibiotic therapy. The patient received Cycle 2 of belinostat from 21-Oct-2010 to 25-Oct-2010, at the same dose. On 25-Oct-2012 (C2D5) the event was considered resolved and the patient was discharged in stable condition.

On 03-Nov-2010 (C2D14), the patient was admitted to the hospital with complaints of fever, productive cough and rash. A chest X-ray revealed lung infiltrates in the right middle lobe. The patient was diagnosed with Grade 3 pneumonia and treated with IV antibiotics. On 6-Nov-2010 (C2D17), the event was considered resolved and the patient was discharged in stable condition.

The patient was withdrawn from the study on 15-Nov-2010 (C2D26) due to disease progression.

The Investigator assessed the event of MediPort infection as unrelated and the events of pneumonia and infection as related to belinostat.

14.3.3.2.43 914-004

Patient 914-004, a 58-year-old Caucasian female with a previous history of tuberculosis and receiving multiple concomitant medications started Cycle 1 of belinostat on 10-Jan-2011 at a dose of 1,400mg. On 24-Jan-2011 (C1D15), the patient presented to the clinic with low grade fever and cough over the past two days and was hospitalized the same day. A CT scan upon admission revealed progression of disease and Grade 3 right lower lobe pneumonia. The patient was treated with Zosyn and discharged in stable condition on 27-Jan-2011(C1D18). The event was considered resolved. The Investigator considered the event of pneumonia as related to belinostat. The patient was withdrawn from the study and expired on 18-Sep-2011 (C1D252), 248 days after last belinostat, due to disease progression.

14.3.3.2.44 915-002

Patient **915-002**, a 57-year old Caucasian female with no medical history relevant to the events on multiple concomitant medications, started Cycle 1 of Belinostat on 07-Jun-2010 at a dose of 1780mg. The dose was increased to 1880mg at Cycle 7 due to weight gain. On 28-Jun-2010 (C2D1), the patient was hospitalized with complaints of Grade 4 pain-skin, increasing in severity over the past week and causing sleeplessness. The pain was localized to the skin area and treated with IV Dilaudid. On 02-Jul-2008 (C2D5), the event was considered resolved and, following the completion of Cycle 2, the patient was discharged in stable condition.

On 04-Oct-2010 (C6D15), the patient was admitted to the hospital for increasing Grade 4 PAIN due to skin nodules. Treatment with PCA pump, IV Dilaudid and Neurontin was initiated. No action was taken with regard to belinostat. On 09-Oct-2010 (C6D20), the event was considered resolved and the patient was discharged in stable condition.

On 01-Nov-2010 (C8D1), an X-ray revealed a destructive lytic lesion in the right femur. On 04-Nov-2010 (C8D4), the patient was admitted to the hospital due to increasing pain in the right femur, diagnosed as Grade 4 right femur pathologic fracture, and underwent a right femoral internal fixation via intramedullary nail placement. On 12-Nov-2010 (C8D12), the event was considered resolved and patient was discharged. The patient did not receive C8D5 belinostat infusion.

The patient was withdrawn from the study due to disease progression on 22-Nov-2010 (C8D22).

The Investigator assessed all the events as unrelated to belinostat.

14.3.3.2.45 919-001

Patient **919-001**, a 65-year old Caucasian female with extensive medical history on multiple concomitant medications, started Cycle 1 of Belinostat on 25-Oct-2010 at a dose of 1,470mg. Beginning 08-Nov-2010 (C1D15), the patient complained of intermittent Grade 1 leg pain. Grade 2 foot numbness began 01-Dec-2010 (C2D17), with onset of neuropathy of the lower extremities on 07-Jan-2011 (C4D5). The patient complained of neuropathy of the hands and feet beginning 24-Jan-2011 (C5D1). MRIs were recommended twice for neurology evaluation and treatment with gabapentin ordered, but the patient refused. Cycle 9 was initially scheduled to begin 18-Apr-2011, but, due to patient complaints of significant fatigue and dizziness, treatment was held. On 02-May-2011, despite complaints of lower extremity neuropathy, Cycle 9 of belinostat was initiated at a dose of 1,580mg and Day 1 infusion was completed without incident. The patient arrived for Day 2 infusion complaining of worsening bilateral lower extremity pain and difficulty walking. Day 2 treatment was held due to Grade 3 neuropathy-sensory and the patient was referred to a neurologist. The consult neurologist's clinical impression was peripheral neuropathy secondary to chemotherapy and Lyrica was prescribed. Cycle 9 days 2 through 5 infusions were not administered. Treatment with belinostat resumed on 06-Jun-2011 (C10D1) and the event was considered resolved with sequelae the same day.

The patient was withdrawn from study on 06-Sep-2011 (C10D93) due to progressive disease.

The Investigator assessed the event as serious (medically significant) and unrelated.

14.3.3.2.46 931-003

Patient **931-003**, a 59-year-old Caucasian female with an extensive medical history on multiple concomitant medications, was treated with 2 cycles of belinostat at a dose of 1,300mg, increased to 1310mg for cycles 3 to 13. On 11-Dec-2011 (C7D7), the patient reported being admitted to the hospital for being unable to walk due to Grade 3 left knee pain. Morphine brought no relief, and the patient was admitted for further evaluation and pain management. Physical exam revealed the left knee and hip appeared clinically normal. Initial X-rays of the left hip and left knee were negative, as well as an arterial and venous duplex scan. The patient refused MRI of the hip, knee, and lumbosacral spine. The patient was discharged to home on 13-Dec-2011 (C7D9). Follow-up with primary care physician and oncologist was recommended. No action was taken with regard to belinostat and the event was considered resolved.
The Investigator assessed the event as serious (hospitalization) and unrelated to study drug.

14.3.3.2.47 933-001

Patient **933-001**, a 57-year-old African-American male with no medical history relevant to the events on multiple concomitant medications received belinostat at a dose of 2,160 mg. On 22-Oct-2010 (C5D5), the patient was admitted to the hospital, complaining of shortness of breath, and diagnosed with Grade 3 pneumonia. Treatment with antibiotics was started and the patient was discharged on 08-Nov-2010 (C5D22) in stable condition.

The site became aware of the patient's unexpected death on 12-Jan-2011(C5D87), after contacting the patient's wife to schedule an imaging procedure. Repeated attempts to gather additional information were unsuccessful.

The Investigator assessed both the events as unrelated to study drug.

14.3.3.2.48 934-003

Patient **934-003**, a 73-year-old Asian female with extensive medical history on no reported concomitant medications, was treated with a total of 4 cycles of belinostat at a dose of 1,500mg. The patient received 4 days Cycle 2 from 04-Apr to 07-Apr-2011. C2D5 was not given due to an adverse event of atrial fibrillation (non-serious). On 19-Apr-2011 (C2D16), the patient presented to the emergency department with history of fever (101°F) and sore throat. The patient was subsequently hospitalized for Grade 3 infection. Treatment with piperacillin/tazobactam (the history of penicillin allergy was not communicated) was started and the patient experienced an anaphylactic reaction to

piperacillin, in the form of pulmonary edema and hypotension. The hypotension was treated with pressors. The infection was subsequently treated with broad spectrum antibiotics. The patient was evaluated for pulmonary embolus, due to complaints of dyspnea and low oxygen saturation (90%) at admission, but the results were negative. Treatment with moxifloxacin for possible pneumonia was started and all cultures were negative. The patient responded to the treatment, the event resolved and the patient was discharged on 26-Apr-2011 (C2D23). Cycle 3 of belinostat was delayed due to this event and was administered from 02-May to 06-May-2011, with no change in the dose.

The patient received Cycle 4 of belinostat from 24-May to 28-May-2011. On 31-May-2011 (C4D8), the patient presented to the emergency department (ED) with complaints of fever, nausea, and vomiting. Evaluation in the ED revealed a temperature of 39°C and mean arterial pressure (MAP) of 50mmHg. After consultation with the Intensive Care Unit (ICU), the patient was treated with 8L of crystalloid, with no improvement in MAP. The patient was started on Levophed (norepinephrine bitartrate) and, on 01-Jun-2011 (C4D5), was admitted to the ICU with a diagnosis of Grade 3 sepsis. The blood and urine cultures were negative, and no definitive source of sepsis was identified. Laboratory results revealed WBC 15.5 and neutrophils 13.9. Antibiotic treatment was started. The patient responded well to the treatment and, later the same day, was transferred to the medical ward. On 03-Jun-2011 (C4D11), the antibiotics were switched to oral ciprofloxacin and Flagyl (metronidazole). The event resolved and the patient was discharged to home on 07-Jun-2011 (C4D15). Treatment with belinostat was permanently discontinued due to this event.

On 13-Jun-2011 (C4D21), the patient complained of fatigue, with a home blood pressure reading of 80/60mmHg. On 14-Jun-2011 (C4D22), the patient was hospitalized for Grade 3 hypotension (80/5 mmHg). The patient was given a bolus of normal saline, started on antibiotics and blood pressure improved to 110/60mmHg. The event was considered resolved on 15-Jun-2011 (C4D23). The patient experienced a brief episode of atrial fibrillation, hyponatremia, and diarrhea during hospitalization; all events were assessed as non-serious. Cultures, including C. difficile toxin, were negative. The patient was discharged to home on 18-Jun-2011 (C4D26). The Investigator attributed the event of hypotension to either the intravenous contrast administered during tumor assessment scan conducted on 31-May-2011 (C4D08) or residual reaction to belinostat.
The Investigator assessed all the events as related to belinostat.

14.3.3.2.49 936-001

Patient **936-001**, a 52-year-old Caucasian male with an extensive medical history on multiple concomitant medications, was treated with 8 cycles of belinostat at a dose of

2,260mg. The patient was withdrawn from study on 13-Dec-2011 (C8D09) due to eligibility for a stem cell transplant.

On 29-Dec-2011 (C8D25), the patient was admitted to the hospital for a planned splenectomy, due to symptomatic splenomegaly. The surgery was performed and, at the same time, the patient's pre-existing portacath was replaced by the Smart-port injector needed for interval CT scans. The procedures were uneventful and the patient was discharged to home on 01-Jan-2012 (C8D28) in a stable condition.
The Investigator assessed this event as unrelated to the study drug.

14.3.3.3 *Narratives of AEs Leading to Discontinuation*

Narratives for patients who experienced AEs during the study that resulted in study discontinuation are included below. Cross links to the individual narratives are available in Table 52.

14.3.3.3.1 801-002

Patient **801-002**, a 73-year-old Caucasian female with an extensive medical history on multiple concomitant medications, started Cycle 1 of belinostat on 05-Jun-2011 at a dose of 1,600mg. The dose of belinostat was reduced to 1,170 for Cycle 2, due to adverse event hypokalemia. On 10-Jul-2011 (C2D14), the patient was admitted to the hospital with a suspected diagnosis of acute abdomen. Abdominal surgery was performed on 11-Jun-2011 (C2D15) and bowel perforation, due to tumor invasion, was found. The patient was diagnosed with Grade 5 disease progression and expired 2 hours after surgery. The immediate cause of death was multi-organ failure, with the underlying cause of disease progression.

The Investigator assessed the event as unrelated to belinostat.

14.3.3.3.2 550-002

Patient **550-002**, a 62-year old Caucasian male with diagnosis of relapsed/refractory PTCL had bone marrow involvement with lymphoma and the platelet count of 140,000 at study entry. The patient also had an extensive medical history and was on multiple concomitant medications. The patient was started on C1D1 of belinostat on 17-May-2010 at a dose of 19,40mg. On C1D5 (21-May-2010), platelet count was 71,000 and the patient finished Cycle 1. A repeat platelet count on 01-Jun-2010 (C1D16) was 42,000 and the platelet counts continued to drop with the final platelet count on 08-Jul-2010 (C1D53) of 12,000. The patient was withdrawn from the study on 08-Jul-2010 (C1D53) due to Grade 4 low platelet count.

14.3.3.3.3 934-001

Patient **934-001**, a 61-year old Caucasian male with a diagnosis of relapsed/refractory PTCL had absolute neutrophil count of 2.5 at study entry. The patient also had an extensive medical history, including bone marrow transplant, and was on multiple concomitant medications. The patient was started on C1D1 of belinostat on 14-Feb-2011 at a dose of 2,000mg and completed 5 days of Cycle 1. The follow-up absolute neutrophil count on 25-Feb-2011 (C1D12), was 1.8. On 07-Mar-2011 (C1D22), the patient experienced Grade 3 febrile neutropenia. The CT scan on 08-Mar-2011 (C1D23) showed progressive disease and the patient was withdrawn from study.

14.3.3.3.4 147-002

Patient 147-002, a 46-year-old Caucasian female with a diagnosis of angioimmunoblastic T-cell lymphoma had bone marrow involvement with lymphoma and LDH of 24.96 at study entry. The patient had an extensive past medical history and was on numerous concomitant medications. The patient was started on C1D1 of belinostat on 23-Jul-2011 at a dose of 1,850mg. The patient completed 3 days (C1D3) of belinostat treatment on 25-Jul-2011. The same day, the patient experienced dyspnea, sweating, Grade 3 prolonged QTc interval, and LDH increase to 43.23. Following the C1D3 infusion, the patient was withdrawn from study due to disease progression.

14.3.3.3.5 180-001

Patient 180-001 was a 51-year-old Caucasian male with no reported medical history and on multiple concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. Belinostat treatment started at a dose of 1,700mg on 12-Oct-2009. The patient was withdrawn from the study on 27-Nov-2009 (C3D5) due to disease progression. The patient expired on 27-May-2010 (C3D186) due to progression of PTCL, 182 days after the last dose of belinostat.

14.3.3.3.6 180-003

Patient 180-003 was a 70 year old White Caucasian male with a medical history of angioimmunoblastic T-cell lymphoma and receiving several concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. Belinostat treatment started at a dose of 1,900 mg on 01-Mar-2010. On 22-Apr-2010 (C2D25), the patient was diagnosed with disease progression and withdrawn from the study. On 20-Oct-2010 (C2D206), the patient died due to disease progression, 181 number of days since last dose of belinostat.

14.3.3.3.7 221-001

Patient 221-001 was a 31-year-old Black male with a medical history of hepatitis B and PTCL unspecified and on multiple concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. Belinostat treatment started at a dose of 1,800 mg on 05-Oct-2009. On 11-Nov-2009 (C2D17), the patient was withdrawn from the study due to progressive disease and started new anti-cancer therapy. On 05-Apr-2010, the patient died due to progression of PTCL, 158 days after the last dose of belinostat.

14.3.3.3.8 244-001

Patient 244-001 was a 63-year-old Caucasian male, with an extensive medical history including PTCL unspecified and on multiple concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. Belinostat treatment started at a dose of 1,500 mg on 29-Mar-2010. On 10-May-2010 (C2D22), the patient was withdrawn from the study due to progressive disease and started new anti-cancer therapy. On 13-Jul-2010 (C2D86), the patient died due to progression of PTCL, 82 days after the last dose of belinostat.

14.3.3.3.9 752-001

Patient **752-001** was a 54-year-old Caucasian female with a medical history of hypertension, arthritis and anaplastic large cell lymphoma (ALK-negative; Stage IIA), and on multiple concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. The patient was treated with one cycle of belinostat from 15-Mar-2010 through 19-Mar-2010, at a dose of 2,400mg. On 05-Apr-2010 (C1D22), the patient withdrew consent for treatment, 18 days after the last dose of belinostat.

14.3.3.3.10 900-001

Patient 900-001 was a 74-year-old Caucasian male with an extensive medical history and on multiple concomitant medications. Bone marrow assessment was not performed at Baseline because bone marrow involvement was not clinically suspected. Belinostat treatment was started at a dose of 1970mg on 13-Jul-2009 (C1D1), increased to 2050mg in Cycle 3 (increase in BSA). The patient was withdrawn from the study on 07-Jan-2010 (C7D32) due to disease progression. The patient expired on 09-Sep-2010 (C7D277) due to cirrhosis and renal failure, 273 days after the last dose of belinostat.

14.3.4 Abnormal Laboratory Value Listing (each patient).

Table Number	Title
Table 14.3.8.4	Abnormal Laboratory Value Listing

Listings of hematology (Listing 16.2.8.1), coagulation (Listing 16.2.8.2), clinical chemistry (Listing 16.2.8.3), and urinalysis (Listing 16.2.8.4 and 16.2.8.5) parameters by patient are available in Appendix 16.2.8.

14.3.5 Laboratory Data Tables

Table Number	Title
Table 14.3.8.1	Treatment Emergent Clinical Laboratory Evaluation
Table 14.3.8.2	Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

14.3.6 Vital Signs Data Tables

Table Number	Title
Table 14.3.8.3	Summary of Vital Signs

Table Output Programming Codes

15 REFERENCE LIST

1. The Non-Hodgkin's Lymphoma Classification Project (1997): A clinical evaluation of the International Lymphoma Study Group classification of non-Hodgkin's lymphoma. Blood 89(11), 3909-3918.
2. Savage KJ. (2007): Peripheral T-cell lymphomas. Blood Rev 21(4), 201-16.
3. Vose J, Armitage J, Weisenburger D. International T-cell Lymphoma Project. International peripheral T-cell and natural killer/T-cell lymphoma study: pathology findings and clinical outcomes. J Clin Oncol 26(25):4124-4130.
4. Weisenburger DD, Savage KJ, Harris NL, et al. Peripheral T-cell lymphoma, not otherwise specified: a report of 340 cases from the International Peripheral T-cell Lymphoma Project. Blood. 2011;117(12):3402-3408.
5. Kristeleit R, Fong P, Aherne GW, de Bono J (2005): Histone deacetylase inhibitors: emerging anticancer therapeutic agents? Clin Lung Cancer 7(1), S19-30.
6. Minucci S, Pelicci PG (2006): Histone deacetylase inhibitors and the promise of epigenetic (and more) treatments for cancer. Nat Rev Cancer 6(1), 38-51.
7. O'Leary HM, Savage KJ: Novel therapies in peripheral T-cell lymphomas. Curr Oncol Rep 10:404-411, 2008.
8. Horwitz SM: Management of peripheral T-cell non-Hodgkin's lymphoma. Curr Opin Oncol 19:438-443, 2007.
9. Chen AI, Advani RH: Beyond the guidelines in the treatment of peripheral T-cell lymphoma: New drug development. J Natl Compr Canc Netw 6:428-435, 2008.
10. Simon R. (1989): Optimal two-stage designs for phase II clinical trials. Control Clin Trials 10(1), 1-10.
11. Cheson BD, Pfistner B, Juweid ME, Gascoyne RD, Specht L, Horning SJ, et al. (2007): Revised response criteria for malignant lymphoma. J Clin Oncol 25(5), 579-586.
12. Pazdur R. (2008): Endpoints for assessing drug activity in clinical trials. Oncologist 13(suppl 2), 19-21.
13. Cockcroft DW, Gault MH (1976): Prediction of creatinine clearance from serum creatinine. Nephron 16(1), 31-41.

14. Kris MG, Hesketh PJ, Somerfield MR, Feyer P, Clark-Snow R, Koeller JM, et al. (2006): American Society of Clinical Oncology guideline for antiemetics in oncology: update 2006. J Clin Oncol 24(18), 2932-2947. Includes Erratum in J Clin Oncol. 2006 Nov 20;24(33):5341-2.

15. Rodriguez-Abreu D, Filho VB, and Zucca E (2008): Peripheral T-cell lymphomas, unspecified (or not otherwise specified): a review. Hematol Oncol 26(1), 8-20.

16. Evens AM and Gartenhaus RB (2004): Treatment of T-cell non-Hodgkin's lymphoma. Curr Treat Options Oncol 5(4), 289-303.

17. Savage KJ, Harris NL, Vose JM, Ullrich F, Jaffe ES, Connors JM et al (2008) ALK-negative anaplastic large cell lymphoma is clinically and immunophenotypically different from both ALK-positive ALCL and peripheral T-cell lymphoma, not otherwise specified: Report from the International Peripheral T-cell Lymphoma Project. Blood 111(12):5496-5504.

18. Federico M, Rudiger T, Bellei, M, Nathwani BN, Luminari S, Coiffier B, et al. (2013) Clinicopathologic characteristics of angioimmunoblastic T-cell lymphoma: analysis of the International Peripheral T-Cell Lymphoma Projects. J Clin Oncol 31(2), 240-246.

19. Pautier P, Devidas A, Delmer A, et al. (1999) Angioimmunoblastic-like T-cell non Hodgkin's lymphoma: Outcome after chemotherapy in 33 patients and review of the literature. Leuk Lymphoma 32: 545-552.

20. Siegert W, Nerl C, Agthe A, et al (1995) Angioimmunoblastic lymphadenopathy (AILD)-type T-cell lymphoma: Prognostic impact of clinical observations and laboratory findings at presentation—The Kiel Lymphoma Study Group. Ann Oncol 6:659-664.

21. O'Connor OA, Pro B, Pinter-Brown L, Bartlett N, Popplewell L, Coiffier B, et al. (2011) Pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma: Results from the pivotal PROPEL study. J Clin Oncol 29(9): 1182-1189.

22. Coiffier B, Pro B, Prince HM, Foss F, Sokol L, Greenwood M., et al. (2012) Results from a pivotal, open-label, phase II study of romidepsin in relapsed or refractory peripheral T-cell lymphoma after prior systemic therapy. J Clin Oncol 30(6): 631-636.

23. Piekarz RL, Frye R, Prince HM, Kirschbaum MH, Zain J, Allen SL, et al. (2011) Phase 2 trial of romidepsin in patients with peripheral T-cell lymphoma. Blood 117(22): 5827-5834.

24. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Hodgkin's Lymphomas, v1.2013. National Compresensive Cancer Network; 2013. Accessed: 02 May 13. http://www.nccn.org/professionals/physician_gls/PDF/nhl.pdf

25. Folotyn® United States Prescribing Information, Allos Therapeutics Westminster, CO; May 2012.

26. Conlan MG, Bast M, Armitage JO, Weisenburger DD. (1990) Bone marrow involvement by non-Hodgkin's lymphoma: The clinical significance and morphologic discordance between the lymph node and bone marrow. Nebraska Lymphoma Study Group. J Clin Oncol. 8(7):1163-72.

27. Cairo MS, Dose Reductions and Delays: Limitations of myelosuppressive chemotherapy. Oncology 2000;14(9, suppl 8):21-31

28. Campo E, Gaulard P, Zucca E, Jaffe ES, Harris NL, Diebold J, et al (1998): Report of the European task force on lymphomas: workshop on peripheral T-cell lymphomas. Ann Oncol 9(8), 835-843.

29. Mounier N, Gisselbrecht C, Brière J, Haioun C, Feugier P, Offner F, et al. (2004) Prognostic factors in patients with aggressive non-hodgkin'slLymphoma treated by front-line autotransplantation after complete remission: a cohort study by the groupe d'Etude des lymphomas de l'adulte. J Clin Onclol 22(14):2826-2834.

30. Willemze R, Jaffe ES, Burg G, Cerroni L, Berti E, Swerdlow SH, Ralfkiaer E et al. WHO-EORTC classification for cutaneous lymphomas. Blood. 2005;105(10):3768-3785.

31. Gimsing P, Hansen M, Knudsen LM, Knoblauch P, Christensen IJ, Ooi CE, Buhl-Jensen P. A phase I clinical trial of the histone deacetylase inhibitor belinostat in patients with advanced hematological neoplasia. Eur J Haematol. 2008;81(3):170-176.

32. Savage KJ. Aggressive peripheral T-cell lymphomas (specified and unspecified types). Hematology Am Soc Hematol Educ Program. 2005:267-277.

33. Greer JP. Therapy of Peripheral T/NK Neoplasms. Hematology Am Soc Hematol Educ Progrm 2006:331-337.

34. Steele NL, Plumb JA, Vidal L, Tjørnelund J, Knoblauch P, Rasmussen A, et al. A phase 1 pharmacokinetic and pharmacodynamic study of the histone deacetylase inhibitor belinostat in patients with advanced solid tumors.Clin Cancer Res. 2008 Feb 1;14(3):804-810.

35. Jaffe, E. H., NL; Stein, H; Campo, E; Pileri, SA ;Swerdlow, S (2008). Introduction and overview of the classification of the lymphoid neoplasms. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissue (IARC WHO Classification of Tumours); Blue Book Series. S. C. Swerdlow, E; Harris, NL; Jaffe, ES; Pileri, SA; Stein, H; Thiele, J; Vardiman, JW.

36. Mak V, Hamm J, Chhanabhai M, Shenkier T, Klasa R, Sehn LH, Villa D, Gascoyne RD, Connors JM, Savage KJ. Survival of patients with peripheral T-cell lymphoma after first relapse or progression: spectrum of disease and rare long-term survivors. J Clin Oncol. 2013 Jun 1;31(16):1970-6.

37. Savage KJ, Harris NL, Vose JM et al. ALK- anaplastic large-cell lymphoma is clinically and immunophenotypically different from both ALK+ ALCL and peripheral T-cell lymphoma, not otherwise specified: report from the International Peripheral T-Cell. Lymphoma Project. *Blood* 2008;111:5496-504.

38. Istodax® United States Prescribing Information, Celgene Corporation, Summit, NJ, 2013.

16 LIST OF APPENDICES

16.1 Study Information

16.1.1 **Protocol and protocol amendments**

16.1.2 **Sample case report form**

16.1.3 **List of IECs or IRBs**

16.1.4 **List of Investigators and Other Important Participants**

List of Investigators – Part A

List of Investigators – Part B and Part C

16.1.5 **Signatures of Principal or Coordinating Investigator(s)**

16.1.6 **List of Patients Receiving Test Drug(s)/ Investigational Product(s) ,where more than one batch was used**

16.1.7 **Randomization codes (not appicable)**

16.1.8 **Audit certificates**

16.1.9 **Documentation of statistical methods**

16.1.10 **Documentation of inter-laboratory standardization methods and quality assurance procedures if used (not applicable)**

16.1.11 **Publications based on the study**

16.1.12 **Important publications referenced in the report**

16.2 Patient Data Listings

16.2.1 **Discontinued Patients**

Listing Number	Title
16.2.1.1	End of Treatment and Survival Follow-up Status

16.2.2 **Protocol Deviations**

Listing Number	Title
16.2.2.1	Protocol Deviations
16.2.2.3	Comments

16.2.3 Patients Excluded from the Efficacy Analysis

Listing Number	Title
16.2.3.1	Patients Not Evaluable by Central Pathology Review
16.2.3.2	IRS Response Not Evaluable Reason

16.2.4 Demographic Data

Listing Number	Title
16.2.4.0	Central Pathology Review Group Assessment (Part 1 of 2)
16.2.4.1	Patient Demographics
16.2.4.2	General Medical History
16.2.4.3	Disease Status
16.2.4.4	Pathology Evaluation
16.2.4.5	Prior Cancer History
16.2.4.6	Prior Antineoplastic Treatment
16.2.4.7	Prior Cancer Surgery
16.2.4.8	Prior Radiation Therapy
16.2.4.9	Prior Transplant History

16.2.5 Compliance and/or Drug Concentration Data

Listing Number	Title
16.2.5.1	Belinostat Administration
16.2.5.2	Concomitant Medications
16.2.5.3	Non-Drug Therapies
16.2.5.4	Subsequent Anti-Cancer Therapies

16.2.6 Individual Efficacy Response Data

Listing Number	Title
16.2.6.1	Response Evaluation (Independent Review Committee)
16.2.6.2	Response Evaluation (Investigator Assessment)
16.2.6.3	Target Lesions (Independent Review Committee)
16.2.6.4	Target Lesions (Investigator Assessment)
16.2.6.5	Non-Target and New Lesions (Independent Review Committee)
16.2.6.6	Non-Target and New Lesions (Investigator Assessment)
16.2.6.7	Bone Marrow Assessment
16.2.6.8	Survival Follow-Up
16.2.6.9	Maximum Change from Baseline in the Sum of the Products of the
16.2.6.10	Source Listing to Progression Free Survival Kaplan-Meier Plot
16.2.6.11	Source Listing to Overall Survival Kaplan-Meier Plot
16.2.6.12	Survival Status of Belinostat-treated Patients who Subsequently Received

16.2.7 Adverse Event Listings (each patient)

Listing Number	Title
16.2.7.1	Adverse Events
16.2.7.2	Physical Examinations
16.2.7.3	ECOG Performance Status
16.2.7.4	Deaths
16.2.7.5	All Serious Adverse Events for Patients With Reported Death at the End

16.2.8 Listing of Individual Laboratory Measurements by Patient, when Required by Regulatory Authorities

Listing Number	Title
16.2.8.1	Laboratory Measurements (Hematology)
16.2.8.2	Laboratory Measurements (Coagulation)
16.2.8.3	Laboratory Measurements (Serum Chemistry)
16.2.8.4	Laboratory Measurements (Urine Dipstick)
16.2.8.5	Laboratory Measurements (Urine Microscopy)
16.2.8.6	Pregnancy Test
16.2.8.7	Vital Signs
16.2.8.8	Electrocardiogram

16.3 Case Report Forms

16.3.1 CRFs for deaths, other SAEs and AE withdrawals

16.3.2 Other CRFs submitted

16.4 Individual patient data listings (Archival Listings)

16.4.1 Central Pathology Review Group Forms

Bioanalytical Report

Cardiac Safety Report

Bioclinica (Core Lab) Charter

CPRG Charter

DMC Charter

DMC Recommendations

Table 14.1.1.1: Patient Enrolment by Investigational Center

		Patient Population	Number of Patients (%)	
Country	**Center**	**Investigator**	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Belgium	240	Andre Bosly	2 (1.6)	2 (1.7)
	242	Fritz Offner	1 (0.8)	1 (0.8)
	243	Eric Van Den Neste	1 (0.8)	1 (0.8)
	244	Achiel Van Hoof	6 (4.7)	6 (5.0)
	245	Pierre Zachee	1 (0.8)	1 (0.8)
	Total		11 (8.5)	11 (9.2)
Canada	600	Sarit Assouline	2 (1.6)	2 (1.7)
	934	Kerry Savage	4 (3.1)	4 (3.3)
	947	Jean-Francois Larouche	1 (0.8)	1 (0.8)
	Total		7 (5.4)	7 (5.8)
Croatia	541	Igor Aurer	2 (1.6)	2 (1.7)
	543	Antica Duletic Nacinovic	2 (1.6)	2 (1.7)
	Total		4 (3.1)	4 (3.3)
Denmark	100	Peter Brown	4 (3.1)	4 (3.3)
	Total		4 (3.1)	4 (3.3)
France	161	Elisabeth Perez	1 (0.8)	1 (0.8)
	162	Nicolas Mounier	2 (1.6)	1 (0.8)
	165	Luciano Costa	1 (0.8)	1 (0.8)
	Total		4 (3.1)	3 (2.5)
Germany	140	Gerald Wulf	3 (2.3)	2 (1.7)
	141	Andreas Viardot	1 (0.8)	1 (0.8)
	142	Georg Hess	4 (3.1)	4 (3.3)
	144	Andreas Neubauer	2 (1.6)	1 (0.8)
	146	Peter Reimer	2 (1.6)	2 (1.7)
	147	Haifa Kathrin Al-Ali	2 (1.6)	-
	150	Maike Nickelsen	1 (0.8)	1 (0.8)
	154	Ulrich Keller	1 (0.8)	1 (0.8)
	Total		16 (12.4)	12 (10.0)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.1: Patient Enrolment by Investigational Center

		Patient Population	Number of Patients (%)	
Country	**Center**	**Investigator**	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Hungary	532	Zoltan Gasztonyl	4 (3.1)	4 (3.3)
	533	Zita Borbenyi	1 (0.8)	1 (0.8)
	534	Tamas Masszi	6 (4.7)	6 (5.0)
	Total		11 (8.5)	11 (9.2)
Israel	800	Ofer Shpilberg	1 (0.8)	1 (0.8)
	801	Dina Ben-Yehuda	2 (1.6)	2 (1.7)
	803	Itai Levi	1 (0.8)	1 (0.8)
	Total		4 (3.1)	4 (3.3)
Italy	180	Pier Luigi Zinzani	3 (2.3)	3 (2.5)
	Total		3 (2.3)	3 (2.5)
Netherlands	220	Hanneke Kluin-Nelemans	2 (1.6)	2 (1.7)
	221	Otto Visser	3 (2.3)	2 (1.7)
	222	Leo Verdonck	1 (0.8)	1 (0.8)
	223	Elly Lugtenburg	2 (1.6)	2 (1.7)
	224	Jeanette Doorduijn	2 (1.6)	2 (1.7)
	Total		10 (7.8)	9 (7.5)
Poland	513	Jan Walewski	4 (3.1)	4 (3.3)
	516	Wojciech Jurczak	4 (3.1)	4 (3.3)
	Total		8 (6.2)	8 (6.7)
Slovakia	550	Andrej Vranovsky	2 (1.6)	2 (1.7)
	Total		2 (1.6)	2 (1.7)
South Africa	751	Richard Khanyile	1 (0.8)	1 (0.8)
	752	Gerhard Sissolak	2 (1.6)	2 (1.7)
	Total		3 (2.3)	3 (2.5)
Spain	206	Eva Domingo	1 (0.8)	1 (0.8)
	207	Sonia Gonzalez	1 (0.8)	1 (0.8)
	Total		2 (1.6)	2 (1.7)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.1: Patient Enrolment by Investigational Center

		Patient Population	Number of Patients (%)	
Country	**Center**	**Investigator**	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
United Kingdom	120	Claire Dearden	1 (0.8)	1 (0.8)
	121	John Radford	1 (0.8)	1 (0.8)
	126	Anne Lennard	1 (0.8)	1 (0.8)
	Total		3 (2.3)	3 (2.5)
United States	900	Owen O'Connor	1 (0.8)	1 (0.8)
	901	Maria Delioukina	3 (2.3)	2 (1.7)
	902	Francine Foss	1 (0.8)	1 (0.8)
	906	Madeleine Duvic	1 (0.8)	1 (0.8)
	907	Andrei Shustov	7 (5.4)	7 (5.8)
	908	Owen O'Connor	1 (0.8)	1 (0.8)
	911	Nalini Janakiraman	1 (0.8)	1 (0.8)
	912	Amanda Cashen	3 (2.3)	3 (2.5)
	913	Beata Holkova	1 (0.8)	1 (0.8)
	914	Steven Horwitz	6 (4.7)	4 (3.3)
	915	Michele Frank	2 (1.6)	2 (1.7)
	919	Charles Farber	1 (0.8)	1 (0.8)
	921	Anne Beaven	1 (0.8)	1 (0.8)
	922	Ralph Boccia	1 (0.8)	1 (0.8)
	931	Lauren Pinter-Brown	3 (2.3)	3 (2.5)
	933	David Dennis	1 (0.8)	1 (0.8)
	936	Anand Jillella	1 (0.8)	1 (0.8)
	938	Leonard Klein	2 (1.6)	2 (1.7)
	Total		37 (28.7)	34 (28.3)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.2: Patient Disposition

	Number of Patients (%)	
Patient Population	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Entered study therapy	129	120
Still on study therapy	7 (5.4)	7 (5.8)
Discontinued study therapy	122 (94.6)	113 (94.2)
Primary reason for discontinuation		
Progressive Disease	82 (63.6)	76 (63.3)
Death	14 (10.9)	14 (11.7)
Adverse Event	9 (7.0)	8 (6.7)
Stem Cell Transplant	4 (3.1)	3 (2.5)
Withdrawal by Patient	11 (8.5)	10 (8.3)
Physician Decision	1 (0.8)	1 (0.8)
Lost to follow-up	1 (0.8)	1 (0.8)
Patient status at the cut-off date		
Alive	39 (30.2)	35 (29.2)
Dead	79 (61.2)	74 (61.7)
No follow-up for >12 mon	11 (8.5)	11 (9.2)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 1	129 (100.0)	120 (100.0)
Received 1 full dose	1 (0.8)	1 (0.8)
Received 2 full doses	0	0
Received 3 full doses	1 (0.8)	0
Received 4 full doses	5 (3.9)	5 (4.2)
Received 5 full doses	122 (94.6)	114 (95.0)
Discontinued during this cycle	33 (25.6)	32 (26.7)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 2	96 (74.4)	88 (73.3)
Received 1 full dose	0	0
Received 2 full doses	1 (0.8)	0
Received 3 full doses	3 (2.3)	3 (2.5)
Received 4 full doses	3 (2.3)	3 (2.5)
Received 5 full doses	89 (69.0)	82 (68.3)
Discontinued during this cycle	33 (25.6)	28 (23.3)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 3	63 (48.8)	60 (50.0)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	1 (0.8)	1 (0.8)
Received 4 full doses	2 (1.6)	2 (1.7)
Received 5 full doses	60 (46.5)	57 (47.5)
Discontinued during this cycle	12 (9.3)	10 (8.3)
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

	Number of Patients (%)	
Patient Population	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Patients entering Cycle 4	51 (39.5)	50 (41.7)
Received 1 full dose	1 (0.8)	1 (0.8)
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (0.8)	1 (0.8)
Received 5 full doses	49 (38.0)	48 (40.0)
Discontinued during this cycle	13 (10.1)	13 (10.8)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 5	38 (29.5)	37 (30.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (0.8)	1 (0.8)
Received 5 full doses	37 (28.7)	36 (30.0)
Discontinued during this cycle	3 (2.3)	3 (2.5)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 6	35 (27.1)	34 (28.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	35 (27.1)	34 (28.3)
Discontinued during this cycle	6 (4.7)	5 (4.2)
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 7	29 (22.5)	29 (24.2)
Received 1 full dose	0	0
Received 2 full doses	1 (0.8)	1 (0.8)
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	28 (21.7)	28 (23.3)
Discontinued during this cycle	3 (2.3)	3 (2.5)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 8	26 (20.2)	26 (21.7)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	3 (2.3)	3 (2.5)
Received 5 full doses	23 (17.8)	23 (19.2)
Discontinued during this cycle	5 (3.9)	5 (4.2)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 9	21 (16.3)	21 (17.5)
Received 1 full dose	1 (0.8)	1 (0.8)
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	20 (15.5)	20 (16.7)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 10	21 (16.3)	21 (17.5)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (0.8)	1 (0.8)
Received 5 full doses	20 (15.5)	20 (16.7)
Discontinued during this cycle	3 (2.3)	3 (2.5)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 11	18 (14.0)	18 (15.0)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (0.8)	1 (0.8)
Received 5 full doses	17 (13.2)	17 (14.2)
Discontinued during this cycle	2 (1.6)	2 (1.7)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 12	16 (12.4)	16 (13.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (0.8)	1 (0.8)
Received 5 full doses	15 (11.6)	15 (12.5)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 13	15 (11.6)	15 (12.5)
Received 1 full dose	0	0
Received 2 full doses	1 (0.8)	1 (0.8)
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	14 (10.9)	14 (11.7)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 14	14 (10.9)	14 (11.7)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	14 (10.9)	14 (11.7)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 15	13 (10.1)	13 (10.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	13 (10.1)	13 (10.8)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 16	13 (10.1)	13 (10.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	13 (10.1)	13 (10.8)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 17	13 (10.1)	13 (10.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	13 (10.1)	13 (10.8)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 18	13 (10.1)	13 (10.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	1 (0.8)	1 (0.8)
Received 4 full doses	0	0
Received 5 full doses	12 (9.3)	12 (10.0)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	2 (1.6)	2 (1.7)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

	Number of Patients (%)	
	Full Analysis Set	Efficacy Analysis Set*
Patient Population	**N=129**	**N=120**
Patients entering Cycle 19	11 (8.5)	11 (9.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	11 (8.5)	11 (9.2)
Discontinued during this cycle	2 (1.6)	2 (1.7)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 20	9 (7.0)	9 (7.5)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	9 (7.0)	9 (7.5)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 21	8 (6.2)	8 (6.7)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	8 (6.2)	8 (6.7)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

	Number of Patients (%)	
Patient Population	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Patients entering Cycle 22	7 (5.4)	7 (5.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	7 (5.4)	7 (5.8)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (0.8)	1 (0.8)
Patients entering Cycle 23	6 (4.7)	6 (5.0)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	6 (4.7)	6 (5.0)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 24	5 (3.9)	5 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	5 (3.9)	5 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 25	5 (3.9)	5 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	5 (3.9)	5 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (0.8)	1 (0.8)
Patients entering Cycle 26	4 (3.1)	4 (3.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.1)	4 (3.3)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 27	4 (3.1)	4 (3.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.1)	4 (3.3)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 28	4 (3.1)	4 (3.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.1)	4 (3.3)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 29	4 (3.1)	4 (3.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.1)	4 (3.3)
Discontinued during this cycle	1 (0.8)	1 (0.8)
Continuing on this cycle at the cut-off date	1 (0.8)	1 (0.8)
Patients entering Cycle 30	2 (1.6)	2 (1.7)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	2 (1.6)	2 (1.7)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.1.3: Patient Disposition by Treatment Cycle

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Patients entering Cycle 31	2 (1.6)	2 (1.7)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	2 (1.6)	2 (1.7)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (0.8)	1 (0.8)
Patients entering Cycle 32	1 (0.8)	1 (0.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	1 (0.8)	1 (0.8)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 33	1 (0.8)	1 (0.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	1 (0.8)	1 (0.8)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (0.8)	1 (0.8)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

**Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set**

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 1	105 (100.0)	24 (100.0)
Received 1 full dose	1 (1.0)	0
Received 2 full doses	0	0
Received 3 full doses	0	1 (4.2)
Received 4 full doses	4 (3.8)	1 (4.2)
Received 5 full doses	100 (95.2)	22 (91.7)
Discontinued during this cycle	25 (23.8)	8 (33.3)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 2	80 (76.2)	16 (66.7)
Received 1 full dose	0	0
Received 2 full doses	0	1 (4.2)
Received 3 full doses	2 (1.9)	1 (4.2)
Received 4 full doses	3 (2.9)	0
Received 5 full doses	75 (71.4)	14 (58.3)
Discontinued during this cycle	22 (21.0)	11 (45.8)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 3	58 (55.2)	5 (20.8)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	1 (4.2)
Received 4 full doses	2 (1.9)	0
Received 5 full doses	56 (53.3)	4 (16.7)
Discontinued during this cycle	10 (9.5)	2 (8.3)
Continuing on this cycle at the cut-off date	0	0

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 4	48 (45.7)	3 (12.5)
Received 1 full dose	1 (1.0)	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (1.0)	0
Received 5 full doses	46 (43.8)	3 (12.5)
Discontinued during this cycle	13 (12.4)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 5	35 (33.3)	3 (12.5)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (1.0)	0
Received 5 full doses	34 (32.4)	3 (12.5)
Discontinued during this cycle	3 (2.9)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 6	32 (30.5)	3 (12.5)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	32 (30.5)	3 (12.5)
Discontinued during this cycle	5 (4.8)	1 (4.2)
Continuing on this cycle at the cut-off date	0	0

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 7	27 (25.7)	2 (8.3)
Received 1 full dose	0	0
Received 2 full doses	1 (1.0)	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	26 (24.8)	2 (8.3)
Discontinued during this cycle	3 (2.9)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 8	24 (22.9)	2 (8.3)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	3 (2.9)	0
Received 5 full doses	21 (20.0)	2 (8.3)
Discontinued during this cycle	4 (3.8)	1 (4.2)
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 9	20 (19.0)	1 (4.2)
Received 1 full dose	1 (1.0)	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	19 (18.1)	1 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

**Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set**

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 10	20 (19.0)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (1.0)	0
Received 5 full doses	19 (18.1)	1 (4.2)
Discontinued during this cycle	3 (2.9)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 11	17 (16.2)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (1.0)	0
Received 5 full doses	16 (15.2)	1 (4.2)
Discontinued during this cycle	2 (1.9)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 12	15 (14.3)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	1 (1.0)	0
Received 5 full doses	14 (13.3)	1 (4.2)
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	0	0

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 13	14 (13.3)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	1 (1.0)	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	13 (12.4)	1 (4.2)
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 14	13 (12.4)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	13 (12.4)	1 (4.2)
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 15	12 (11.4)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	12 (11.4)	1 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 16	12 (11.4)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	12 (11.4)	1 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 17	12 (11.4)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	12 (11.4)	1 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 18	12 (11.4)	1 (4.2)
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	1 (1.0)	0
Received 4 full doses	0	0
Received 5 full doses	11 (10.5)	1 (4.2)
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (1.0)	1 (4.2)

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

	Number of Patients (%)	
	Platelet >= 100,000/ul	Platelet < 100,000/ul
Patient Population	**N=105**	**N=24**
Patients entering Cycle 19	11 (10.5)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	11 (10.5)	0
Discontinued during this cycle	2 (1.9)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 20	9 (8.6)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	9 (8.6)	0
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 21	8 (7.6)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	8 (7.6)	0
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	0	0

**Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set**

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients entering Cycle 22	7 (6.7)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	7 (6.7)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (1.0)	0
Patients entering Cycle 23	6 (5.7)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	6 (5.7)	0
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 24	5 (4.8)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	5 (4.8)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

	Number of Patients (%)	
	Platelet >= 100,000/ul	Platelet < 100,000/ul
Patient Population	**N=105**	**N=24**
Patients entering Cycle 25	5 (4.8)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	5 (4.8)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (1.0)	0
Patients entering Cycle 26	4 (3.8)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.8)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 27	4 (3.8)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.8)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

**Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set**

	Number of Patients (%)	
	Platelet >= 100,000/ul	Platelet < 100,000/ul
Patient Population	**N=105**	**N=24**
Patients entering Cycle 28	4 (3.8)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.8)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 29	4 (3.8)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	4 (3.8)	0
Discontinued during this cycle	1 (1.0)	0
Continuing on this cycle at the cut-off date	1 (1.0)	0
Patients entering Cycle 30	2 (1.9)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	2 (1.9)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0

Table 14.1.1.4: Patient Disposition by Treatment Cycle
by Baseline Platelet Group
Full Analysis Set

	Number of Patients (%)	
	Platelet >= 100,000/ul	Platelet < 100,000/ul
Patient Population	**N=105**	**N=24**
Patients entering Cycle 31	2 (1.9)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	2 (1.9)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (1.0)	0
Patients entering Cycle 32	1 (1.0)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	1 (1.0)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	0	0
Patients entering Cycle 33	1 (1.0)	0
Received 1 full dose	0	0
Received 2 full doses	0	0
Received 3 full doses	0	0
Received 4 full doses	0	0
Received 5 full doses	1 (1.0)	0
Discontinued during this cycle	0	0
Continuing on this cycle at the cut-off date	1 (1.0)	0

Table 14.1.1.5 (Part 1): Overall distribution of infusion time regardless of cycles and days

The FREQ Procedure

DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
30 min or less	1756	52.06	1756	52.06
30-45 min	1350	40.02	3106	92.08
45 min or more	267	7.92	3373	100.00

Frequency Missing = 107

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 1	**Day 1**	**30 min or less**	58	1.72	58	1.72
Cycle 1	**Day 1**	**30-45 min**	60	1.78	118	3.50
Cycle 1	**Day 1**	**45 min or more**	11	0.33	129	3.82
Cycle 1	**Day 2**	**30 min or less**	64	1.90	193	5.72
Cycle 1	**Day 2**	**30-45 min**	46	1.36	239	7.09
Cycle 1	**Day 2**	**45 min or more**	16	0.47	255	7.56
Cycle 1	**Day 3**	**30 min or less**	53	1.57	308	9.13
Cycle 1	**Day 3**	**30-45 min**	54	1.60	362	10.73
Cycle 1	**Day 3**	**45 min or more**	18	0.53	380	11.27
Cycle 1	**Day 4**	**30 min or less**	50	1.48	430	12.75
Cycle 1	**Day 4**	**30-45 min**	58	1.72	488	14.47
Cycle 1	**Day 4**	**45 min or more**	14	0.42	502	14.88
Cycle 1	**Day 5**	**30 min or less**	50	1.48	552	16.37
Cycle 1	**Day 5**	**30-45 min**	55	1.63	607	18.00
Cycle 1	**Day 5**	**45 min or more**	14	0.42	621	18.41
Cycle 10	**Day 1**	**30 min or less**	9	0.27	630	18.68
Cycle 10	**Day 1**	**30-45 min**	9	0.27	639	18.94
Cycle 10	**Day 1**	**45 min or more**	3	0.09	642	19.03
Cycle 10	**Day 2**	**30 min or less**	8	0.24	650	19.27
Cycle 10	**Day 2**	**30-45 min**	13	0.39	663	19.66
Cycle 10	**Day 3**	**30 min or less**	13	0.39	676	20.04
Cycle 10	**Day 3**	**30-45 min**	7	0.21	683	20.25
Cycle 10	**Day 3**	**45 min or more**	1	0.03	684	20.28
Cycle 10	**Day 4**	**30 min or less**	11	0.33	695	20.60
Cycle 10	**Day 4**	**30-45 min**	8	0.24	703	20.84
Cycle 10	**Day 4**	**45 min or more**	2	0.06	705	20.90
Cycle 10	**Day 5**	**30 min or less**	9	0.27	714	21.17
Cycle 10	**Day 5**	**30-45 min**	11	0.33	725	21.49
Cycle 11	**Day 1**	**30 min or less**	9	0.27	734	21.76
Cycle 11	**Day 1**	**30-45 min**	8	0.24	742	22.00
Cycle 11	**Day 1**	**45 min or more**	1	0.03	743	22.03
Cycle 11	**Day 2**	**30 min or less**	7	0.21	750	22.24
Cycle 11	**Day 2**	**30-45 min**	10	0.30	760	22.53
Cycle 11	**Day 3**	**30 min or less**	11	0.33	771	22.86
Cycle 11	**Day 3**	**30-45 min**	5	0.15	776	23.01

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 11	**Day 3**	**45 min or more**	1	0.03	777	23.04
Cycle 11	**Day 4**	**30 min or less**	8	0.24	785	23.27
Cycle 11	**Day 4**	**30-45 min**	8	0.24	793	23.51
Cycle 11	**Day 4**	**45 min or more**	2	0.06	795	23.57
Cycle 11	**Day 5**	**30 min or less**	10	0.30	805	23.87
Cycle 11	**Day 5**	**30-45 min**	7	0.21	812	24.07
Cycle 11	**Day 5**	**45 min or more**	1	0.03	813	24.10
Cycle 12	**Day 1**	**30 min or less**	4	0.12	817	24.22
Cycle 12	**Day 1**	**30-45 min**	11	0.33	828	24.55
Cycle 12	**Day 1**	**45 min or more**	1	0.03	829	24.58
Cycle 12	**Day 2**	**30 min or less**	3	0.09	832	24.67
Cycle 12	**Day 2**	**30-45 min**	8	0.24	840	24.90
Cycle 12	**Day 2**	**45 min or more**	4	0.12	844	25.02
Cycle 12	**Day 3**	**30 min or less**	6	0.18	850	25.20
Cycle 12	**Day 3**	**30-45 min**	9	0.27	859	25.47
Cycle 12	**Day 3**	**45 min or more**	1	0.03	860	25.50
Cycle 12	**Day 4**	**30 min or less**	8	0.24	868	25.73
Cycle 12	**Day 4**	**30-45 min**	6	0.18	874	25.91
Cycle 12	**Day 4**	**45 min or more**	2	0.06	876	25.97
Cycle 12	**Day 5**	**30 min or less**	8	0.24	884	26.21
Cycle 12	**Day 5**	**30-45 min**	6	0.18	890	26.39
Cycle 12	**Day 5**	**45 min or more**	1	0.03	891	26.42
Cycle 13	**Day 1**	**30 min or less**	4	0.12	895	26.53
Cycle 13	**Day 1**	**30-45 min**	8	0.24	903	26.77
Cycle 13	**Day 1**	**45 min or more**	3	0.09	906	26.86
Cycle 13	**Day 2**	**30 min or less**	8	0.24	914	27.10
Cycle 13	**Day 2**	**30-45 min**	6	0.18	920	27.28
Cycle 13	**Day 2**	**45 min or more**	1	0.03	921	27.31
Cycle 13	**Day 3**	**30 min or less**	8	0.24	929	27.54
Cycle 13	**Day 3**	**30-45 min**	5	0.15	934	27.69
Cycle 13	**Day 3**	**45 min or more**	1	0.03	935	27.72
Cycle 13	**Day 4**	**30 min or less**	3	0.09	938	27.81
Cycle 13	**Day 4**	**30-45 min**	10	0.30	948	28.11
Cycle 13	**Day 4**	**45 min or more**	1	0.03	949	28.14
Cycle 13	**Day 5**	**30 min or less**	5	0.15	954	28.28

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 13	**Day 5**	**30-45 min**	8	0.24	962	28.52
Cycle 13	**Day 5**	**45 min or more**	1	0.03	963	28.55
Cycle 14	**Day 1**	**30 min or less**	8	0.24	971	28.79
Cycle 14	**Day 1**	**30-45 min**	5	0.15	976	28.94
Cycle 14	**Day 1**	**45 min or more**	1	0.03	977	28.97
Cycle 14	**Day 2**	**30 min or less**	7	0.21	984	29.17
Cycle 14	**Day 2**	**30-45 min**	6	0.18	990	29.35
Cycle 14	**Day 2**	**45 min or more**	1	0.03	991	29.38
Cycle 14	**Day 3**	**30 min or less**	9	0.27	1000	29.65
Cycle 14	**Day 3**	**30-45 min**	5	0.15	1005	29.80
Cycle 14	**Day 4**	**30 min or less**	7	0.21	1012	30.00
Cycle 14	**Day 4**	**30-45 min**	6	0.18	1018	30.18
Cycle 14	**Day 5**	**30 min or less**	8	0.24	1026	30.42
Cycle 14	**Day 5**	**30-45 min**	6	0.18	1032	30.60
Cycle 15	**Day 1**	**30 min or less**	5	0.15	1037	30.74
Cycle 15	**Day 1**	**30-45 min**	7	0.21	1044	30.95
Cycle 15	**Day 1**	**45 min or more**	1	0.03	1045	30.98
Cycle 15	**Day 2**	**30 min or less**	6	0.18	1051	31.16
Cycle 15	**Day 2**	**30-45 min**	7	0.21	1058	31.37
Cycle 15	**Day 3**	**30 min or less**	6	0.18	1064	31.54
Cycle 15	**Day 3**	**30-45 min**	7	0.21	1071	31.75
Cycle 15	**Day 4**	**30 min or less**	4	0.12	1075	31.87
Cycle 15	**Day 4**	**30-45 min**	8	0.24	1083	32.11
Cycle 15	**Day 4**	**45 min or more**	1	0.03	1084	32.14
Cycle 15	**Day 5**	**30 min or less**	6	0.18	1090	32.32
Cycle 15	**Day 5**	**30-45 min**	7	0.21	1097	32.52
Cycle 16	**Day 1**	**30 min or less**	8	0.24	1105	32.76
Cycle 16	**Day 1**	**30-45 min**	2	0.06	1107	32.82
Cycle 16	**Day 1**	**45 min or more**	3	0.09	1110	32.91
Cycle 16	**Day 2**	**30 min or less**	5	0.15	1115	33.06
Cycle 16	**Day 2**	**30-45 min**	7	0.21	1122	33.26
Cycle 16	**Day 2**	**45 min or more**	1	0.03	1123	33.29
Cycle 16	**Day 3**	**30 min or less**	7	0.21	1130	33.50
Cycle 16	**Day 3**	**30-45 min**	5	0.15	1135	33.65
Cycle 16	**Day 3**	**45 min or more**	1	0.03	1136	33.68

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 16	**Day 4**	**30 min or less**	5	0.15	1141	33.83
Cycle 16	**Day 4**	**30-45 min**	7	0.21	1148	34.03
Cycle 16	**Day 4**	**45 min or more**	1	0.03	1149	34.06
Cycle 16	**Day 5**	**30 min or less**	6	0.18	1155	34.24
Cycle 16	**Day 5**	**30-45 min**	6	0.18	1161	34.42
Cycle 16	**Day 5**	**45 min or more**	1	0.03	1162	34.45
Cycle 17	**Day 1**	**30 min or less**	7	0.21	1169	34.66
Cycle 17	**Day 1**	**30-45 min**	5	0.15	1174	34.81
Cycle 17	**Day 1**	**45 min or more**	1	0.03	1175	34.84
Cycle 17	**Day 2**	**30 min or less**	9	0.27	1184	35.10
Cycle 17	**Day 2**	**30-45 min**	4	0.12	1188	35.22
Cycle 17	**Day 3**	**30 min or less**	6	0.18	1194	35.40
Cycle 17	**Day 3**	**30-45 min**	7	0.21	1201	35.61
Cycle 17	**Day 4**	**30 min or less**	7	0.21	1208	35.81
Cycle 17	**Day 4**	**30-45 min**	5	0.15	1213	35.96
Cycle 17	**Day 5**	**30 min or less**	7	0.21	1220	36.17
Cycle 17	**Day 5**	**30-45 min**	6	0.18	1226	36.35
Cycle 18	**Day 1**	**30 min or less**	7	0.21	1233	36.55
Cycle 18	**Day 1**	**30-45 min**	5	0.15	1238	36.70
Cycle 18	**Day 1**	**45 min or more**	1	0.03	1239	36.73
Cycle 18	**Day 2**	**30 min or less**	5	0.15	1244	36.88
Cycle 18	**Day 2**	**30-45 min**	8	0.24	1252	37.12
Cycle 18	**Day 3**	**30 min or less**	9	0.27	1261	37.39
Cycle 18	**Day 3**	**30-45 min**	3	0.09	1264	37.47
Cycle 18	**Day 3**	**45 min or more**	1	0.03	1265	37.50
Cycle 18	**Day 4**	**30 min or less**	8	0.24	1273	37.74
Cycle 18	**Day 4**	**30-45 min**	2	0.06	1275	37.80
Cycle 18	**Day 4**	**45 min or more**	2	0.06	1277	37.86
Cycle 18	**Day 5**	**30 min or less**	5	0.15	1282	38.01
Cycle 18	**Day 5**	**30-45 min**	7	0.21	1289	38.22
Cycle 19	**Day 1**	**30 min or less**	6	0.18	1295	38.39
Cycle 19	**Day 1**	**30-45 min**	4	0.12	1299	38.51
Cycle 19	**Day 1**	**45 min or more**	1	0.03	1300	38.54
Cycle 19	**Day 2**	**30 min or less**	6	0.18	1306	38.72
Cycle 19	**Day 2**	**30-45 min**	5	0.15	1311	38.87

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 19	**Day 3**	**30 min or less**	7	0.21	1318	39.08
Cycle 19	**Day 3**	**30-45 min**	4	0.12	1322	39.19
Cycle 19	**Day 4**	**30 min or less**	4	0.12	1326	39.31
Cycle 19	**Day 4**	**30-45 min**	7	0.21	1333	39.52
Cycle 19	**Day 5**	**30 min or less**	7	0.21	1340	39.73
Cycle 19	**Day 5**	**30-45 min**	4	0.12	1344	39.85
Cycle 2	**Day 1**	**30 min or less**	34	1.01	1378	40.85
Cycle 2	**Day 1**	**30-45 min**	43	1.27	1421	42.13
Cycle 2	**Day 1**	**45 min or more**	15	0.44	1436	42.57
Cycle 2	**Day 2**	**30 min or less**	36	1.07	1472	43.64
Cycle 2	**Day 2**	**30-45 min**	40	1.19	1512	44.83
Cycle 2	**Day 2**	**45 min or more**	11	0.33	1523	45.15
Cycle 2	**Day 3**	**30 min or less**	39	1.16	1562	46.31
Cycle 2	**Day 3**	**30-45 min**	41	1.22	1603	47.52
Cycle 2	**Day 3**	**45 min or more**	10	0.30	1613	47.82
Cycle 2	**Day 4**	**30 min or less**	43	1.27	1656	49.10
Cycle 2	**Day 4**	**30-45 min**	37	1.10	1693	50.19
Cycle 2	**Day 4**	**45 min or more**	8	0.24	1701	50.43
Cycle 2	**Day 5**	**30 min or less**	43	1.27	1744	51.70
Cycle 2	**Day 5**	**30-45 min**	34	1.01	1778	52.71
Cycle 2	**Day 5**	**45 min or more**	7	0.21	1785	52.92
Cycle 20	**Day 1**	**30 min or less**	6	0.18	1791	53.10
Cycle 20	**Day 1**	**30-45 min**	3	0.09	1794	53.19
Cycle 20	**Day 2**	**30 min or less**	3	0.09	1797	53.28
Cycle 20	**Day 2**	**30-45 min**	5	0.15	1802	53.42
Cycle 20	**Day 2**	**45 min or more**	1	0.03	1803	53.45
Cycle 20	**Day 3**	**30 min or less**	7	0.21	1810	53.66
Cycle 20	**Day 3**	**30-45 min**	2	0.06	1812	53.72
Cycle 20	**Day 4**	**30 min or less**	5	0.15	1817	53.87
Cycle 20	**Day 4**	**30-45 min**	4	0.12	1821	53.99
Cycle 20	**Day 5**	**30 min or less**	6	0.18	1827	54.17
Cycle 20	**Day 5**	**30-45 min**	3	0.09	1830	54.25
Cycle 21	**Day 1**	**30 min or less**	5	0.15	1835	54.40
Cycle 21	**Day 1**	**30-45 min**	2	0.06	1837	54.46
Cycle 21	**Day 1**	**45 min or more**	1	0.03	1838	54.49

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 21	**Day 2**	**30 min or less**	5	0.15	1843	54.64
Cycle 21	**Day 2**	**30-45 min**	2	0.06	1845	54.70
Cycle 21	**Day 2**	**45 min or more**	1	0.03	1846	54.73
Cycle 21	**Day 3**	**30 min or less**	6	0.18	1852	54.91
Cycle 21	**Day 3**	**30-45 min**	1	0.03	1853	54.94
Cycle 21	**Day 4**	**30 min or less**	5	0.15	1858	55.08
Cycle 21	**Day 4**	**30-45 min**	2	0.06	1860	55.14
Cycle 21	**Day 4**	**45 min or more**	1	0.03	1861	55.17
Cycle 21	**Day 5**	**30 min or less**	5	0.15	1866	55.32
Cycle 21	**Day 5**	**30-45 min**	3	0.09	1869	55.41
Cycle 22	**Day 1**	**30 min or less**	6	0.18	1875	55.59
Cycle 22	**Day 1**	**30-45 min**	1	0.03	1876	55.62
Cycle 22	**Day 2**	**30 min or less**	6	0.18	1882	55.80
Cycle 22	**Day 2**	**45 min or more**	1	0.03	1883	55.83
Cycle 22	**Day 3**	**30 min or less**	6	0.18	1889	56.00
Cycle 22	**Day 3**	**45 min or more**	1	0.03	1890	56.03
Cycle 22	**Day 4**	**30 min or less**	5	0.15	1895	56.18
Cycle 22	**Day 4**	**30-45 min**	1	0.03	1896	56.21
Cycle 22	**Day 4**	**45 min or more**	1	0.03	1897	56.24
Cycle 22	**Day 5**	**30 min or less**	5	0.15	1902	56.39
Cycle 22	**Day 5**	**30-45 min**	1	0.03	1903	56.42
Cycle 22	**Day 5**	**45 min or more**	1	0.03	1904	56.45
Cycle 23	**Day 1**	**30 min or less**	3	0.09	1907	56.54
Cycle 23	**Day 1**	**30-45 min**	3	0.09	1910	56.63
Cycle 23	**Day 2**	**30 min or less**	4	0.12	1914	56.74
Cycle 23	**Day 2**	**30-45 min**	2	0.06	1916	56.80
Cycle 23	**Day 3**	**30 min or less**	5	0.15	1921	56.95
Cycle 23	**Day 3**	**30-45 min**	1	0.03	1922	56.98
Cycle 23	**Day 4**	**30 min or less**	4	0.12	1926	57.10
Cycle 23	**Day 4**	**30-45 min**	2	0.06	1928	57.16
Cycle 23	**Day 5**	**30 min or less**	5	0.15	1933	57.31
Cycle 23	**Day 5**	**30-45 min**	1	0.03	1934	57.34
Cycle 24	**Day 1**	**30 min or less**	3	0.09	1937	57.43
Cycle 24	**Day 1**	**30-45 min**	2	0.06	1939	57.49
Cycle 24	**Day 2**	**30 min or less**	5	0.15	1944	57.63

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 24	**Day 3**	**30 min or less**	3	0.09	1947	57.72
Cycle 24	**Day 3**	**30-45 min**	2	0.06	1949	57.78
Cycle 24	**Day 4**	**30 min or less**	4	0.12	1953	57.90
Cycle 24	**Day 4**	**30-45 min**	1	0.03	1954	57.93
Cycle 24	**Day 5**	**30 min or less**	4	0.12	1958	58.05
Cycle 24	**Day 5**	**30-45 min**	1	0.03	1959	58.08
Cycle 25	**Day 1**	**30 min or less**	5	0.15	1964	58.23
Cycle 25	**Day 2**	**30 min or less**	4	0.12	1968	58.35
Cycle 25	**Day 2**	**30-45 min**	1	0.03	1969	58.38
Cycle 25	**Day 3**	**30 min or less**	5	0.15	1974	58.52
Cycle 25	**Day 4**	**30 min or less**	5	0.15	1979	58.67
Cycle 25	**Day 5**	**30 min or less**	4	0.12	1983	58.79
Cycle 25	**Day 5**	**30-45 min**	1	0.03	1984	58.82
Cycle 26	**Day 1**	**30 min or less**	4	0.12	1988	58.94
Cycle 26	**Day 2**	**30 min or less**	4	0.12	1992	59.06
Cycle 26	**Day 3**	**30 min or less**	3	0.09	1995	59.15
Cycle 26	**Day 3**	**30-45 min**	1	0.03	1996	59.18
Cycle 26	**Day 4**	**30 min or less**	3	0.09	1999	59.26
Cycle 26	**Day 4**	**30-45 min**	1	0.03	2000	59.29
Cycle 26	**Day 5**	**30 min or less**	3	0.09	2003	59.38
Cycle 26	**Day 5**	**30-45 min**	1	0.03	2004	59.41
Cycle 27	**Day 1**	**30 min or less**	4	0.12	2008	59.53
Cycle 27	**Day 2**	**30 min or less**	4	0.12	2012	59.65
Cycle 27	**Day 3**	**30 min or less**	3	0.09	2015	59.74
Cycle 27	**Day 3**	**30-45 min**	1	0.03	2016	59.77
Cycle 27	**Day 4**	**30 min or less**	4	0.12	2020	59.89
Cycle 27	**Day 5**	**30 min or less**	3	0.09	2023	59.98
Cycle 27	**Day 5**	**30-45 min**	1	0.03	2024	60.01
Cycle 28	**Day 1**	**30 min or less**	4	0.12	2028	60.12
Cycle 28	**Day 2**	**30 min or less**	3	0.09	2031	60.21
Cycle 28	**Day 2**	**30-45 min**	1	0.03	2032	60.24
Cycle 28	**Day 3**	**30 min or less**	4	0.12	2036	60.36
Cycle 28	**Day 4**	**30 min or less**	4	0.12	2040	60.48
Cycle 28	**Day 5**	**30 min or less**	3	0.09	2043	60.57
Cycle 28	**Day 5**	**30-45 min**	1	0.03	2044	60.60

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 29	**Day 1**	**30 min or less**	4	0.12	2048	60.72
Cycle 29	**Day 2**	**30 min or less**	4	0.12	2052	60.84
Cycle 29	**Day 3**	**30 min or less**	4	0.12	2056	60.95
Cycle 29	**Day 4**	**30 min or less**	3	0.09	2059	61.04
Cycle 29	**Day 4**	**30-45 min**	1	0.03	2060	61.07
Cycle 29	**Day 5**	**30 min or less**	4	0.12	2064	61.19
Cycle 3	**Day 1**	**30 min or less**	32	0.95	2096	62.14
Cycle 3	**Day 1**	**30-45 min**	28	0.83	2124	62.97
Cycle 3	**Day 1**	**45 min or more**	3	0.09	2127	63.06
Cycle 3	**Day 2**	**30 min or less**	32	0.95	2159	64.01
Cycle 3	**Day 2**	**30-45 min**	27	0.80	2186	64.81
Cycle 3	**Day 2**	**45 min or more**	2	0.06	2188	64.87
Cycle 3	**Day 3**	**30 min or less**	39	1.16	2227	66.02
Cycle 3	**Day 3**	**30-45 min**	20	0.59	2247	66.62
Cycle 3	**Day 3**	**45 min or more**	4	0.12	2251	66.74
Cycle 3	**Day 4**	**30 min or less**	36	1.07	2287	67.80
Cycle 3	**Day 4**	**30-45 min**	21	0.62	2308	68.43
Cycle 3	**Day 4**	**45 min or more**	4	0.12	2312	68.54
Cycle 3	**Day 5**	**30 min or less**	34	1.01	2346	69.55
Cycle 3	**Day 5**	**30-45 min**	23	0.68	2369	70.23
Cycle 3	**Day 5**	**45 min or more**	3	0.09	2372	70.32
Cycle 30	**Day 1**	**30 min or less**	2	0.06	2374	70.38
Cycle 30	**Day 2**	**30 min or less**	2	0.06	2376	70.44
Cycle 30	**Day 3**	**30 min or less**	1	0.03	2377	70.47
Cycle 30	**Day 3**	**30-45 min**	1	0.03	2378	70.50
Cycle 30	**Day 4**	**30 min or less**	2	0.06	2380	70.56
Cycle 30	**Day 5**	**30 min or less**	1	0.03	2381	70.59
Cycle 30	**Day 5**	**30-45 min**	1	0.03	2382	70.62
Cycle 31	**Day 1**	**30 min or less**	2	0.06	2384	70.68
Cycle 31	**Day 2**	**30 min or less**	2	0.06	2386	70.74
Cycle 31	**Day 3**	**30 min or less**	1	0.03	2387	70.77
Cycle 31	**Day 3**	**30-45 min**	1	0.03	2388	70.80
Cycle 31	**Day 4**	**30 min or less**	2	0.06	2390	70.86
Cycle 31	**Day 5**	**30 min or less**	1	0.03	2391	70.89
Cycle 31	**Day 5**	**30-45 min**	1	0.03	2392	70.92

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 32	**Day 1**	**30 min or less**	1	0.03	2393	70.95
Cycle 32	**Day 2**	**30 min or less**	1	0.03	2394	70.98
Cycle 32	**Day 3**	**30 min or less**	1	0.03	2395	71.01
Cycle 32	**Day 4**	**30 min or less**	1	0.03	2396	71.03
Cycle 32	**Day 5**	**30 min or less**	1	0.03	2397	71.06
Cycle 33	**Day 1**	**30 min or less**	1	0.03	2398	71.09
Cycle 33	**Day 2**	**30 min or less**	1	0.03	2399	71.12
Cycle 33	**Day 3**	**30 min or less**	1	0.03	2400	71.15
Cycle 33	**Day 4**	**30 min or less**	1	0.03	2401	71.18
Cycle 33	**Day 5**	**30 min or less**	1	0.03	2402	71.21
Cycle 4	**Day 1**	**30 min or less**	22	0.65	2424	71.86
Cycle 4	**Day 1**	**30-45 min**	24	0.71	2448	72.58
Cycle 4	**Day 1**	**45 min or more**	4	0.12	2452	72.69
Cycle 4	**Day 2**	**30 min or less**	27	0.80	2479	73.50
Cycle 4	**Day 2**	**30-45 min**	18	0.53	2497	74.03
Cycle 4	**Day 2**	**45 min or more**	4	0.12	2501	74.15
Cycle 4	**Day 3**	**30 min or less**	25	0.74	2526	74.89
Cycle 4	**Day 3**	**30-45 min**	20	0.59	2546	75.48
Cycle 4	**Day 3**	**45 min or more**	5	0.15	2551	75.63
Cycle 4	**Day 4**	**30 min or less**	26	0.77	2577	76.40
Cycle 4	**Day 4**	**30-45 min**	19	0.56	2596	76.96
Cycle 4	**Day 4**	**45 min or more**	5	0.15	2601	77.11
Cycle 4	**Day 5**	**30 min or less**	26	0.77	2627	77.88
Cycle 4	**Day 5**	**30-45 min**	17	0.50	2644	78.39
Cycle 4	**Day 5**	**45 min or more**	5	0.15	2649	78.54
Cycle 5	**Day 1**	**30 min or less**	20	0.59	2669	79.13
Cycle 5	**Day 1**	**30-45 min**	12	0.36	2681	79.48
Cycle 5	**Day 1**	**45 min or more**	5	0.15	2686	79.63
Cycle 5	**Day 2**	**30 min or less**	18	0.53	2704	80.17
Cycle 5	**Day 2**	**30-45 min**	15	0.44	2719	80.61
Cycle 5	**Day 2**	**45 min or more**	4	0.12	2723	80.73
Cycle 5	**Day 3**	**30 min or less**	23	0.68	2746	81.41
Cycle 5	**Day 3**	**30-45 min**	9	0.27	2755	81.68
Cycle 5	**Day 3**	**45 min or more**	5	0.15	2760	81.83
Cycle 5	**Day 4**	**30 min or less**	25	0.74	2785	82.57

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 5	**Day 4**	**30-45 min**	9	0.27	2794	82.83
Cycle 5	**Day 4**	**45 min or more**	3	0.09	2797	82.92
Cycle 5	**Day 5**	**30 min or less**	23	0.68	2820	83.61
Cycle 5	**Day 5**	**30-45 min**	11	0.33	2831	83.93
Cycle 5	**Day 5**	**45 min or more**	2	0.06	2833	83.99
Cycle 6	**Day 1**	**30 min or less**	23	0.68	2856	84.67
Cycle 6	**Day 1**	**30-45 min**	10	0.30	2866	84.97
Cycle 6	**Day 1**	**45 min or more**	1	0.03	2867	85.00
Cycle 6	**Day 2**	**30 min or less**	18	0.53	2885	85.53
Cycle 6	**Day 2**	**30-45 min**	13	0.39	2898	85.92
Cycle 6	**Day 2**	**45 min or more**	3	0.09	2901	86.01
Cycle 6	**Day 3**	**30 min or less**	22	0.65	2923	86.66
Cycle 6	**Day 3**	**30-45 min**	12	0.36	2935	87.01
Cycle 6	**Day 3**	**45 min or more**	1	0.03	2936	87.04
Cycle 6	**Day 4**	**30 min or less**	17	0.50	2953	87.55
Cycle 6	**Day 4**	**30-45 min**	16	0.47	2969	88.02
Cycle 6	**Day 4**	**45 min or more**	1	0.03	2970	88.05
Cycle 6	**Day 5**	**30 min or less**	22	0.65	2992	88.70
Cycle 6	**Day 5**	**30-45 min**	8	0.24	3000	88.94
Cycle 6	**Day 5**	**45 min or more**	5	0.15	3005	89.09
Cycle 7	**Day 1**	**30 min or less**	16	0.47	3021	89.56
Cycle 7	**Day 1**	**30-45 min**	11	0.33	3032	89.89
Cycle 7	**Day 1**	**45 min or more**	2	0.06	3034	89.95
Cycle 7	**Day 2**	**30 min or less**	14	0.42	3048	90.36
Cycle 7	**Day 2**	**30-45 min**	14	0.42	3062	90.78
Cycle 7	**Day 2**	**45 min or more**	1	0.03	3063	90.81
Cycle 7	**Day 3**	**30 min or less**	12	0.36	3075	91.17
Cycle 7	**Day 3**	**30-45 min**	15	0.44	3090	91.61
Cycle 7	**Day 3**	**45 min or more**	1	0.03	3091	91.64
Cycle 7	**Day 4**	**30 min or less**	18	0.53	3109	92.17
Cycle 7	**Day 4**	**30-45 min**	9	0.27	3118	92.44
Cycle 7	**Day 5**	**30 min or less**	13	0.39	3131	92.83
Cycle 7	**Day 5**	**30-45 min**	12	0.36	3143	93.18
Cycle 7	**Day 5**	**45 min or more**	3	0.09	3146	93.27
Cycle 8	**Day 1**	**30 min or less**	10	0.30	3156	93.57

Table 14.1.1.5 (Part 2): Distribution of infusion time by Cycle and Day

The FREQ Procedure

VISIT	EXTPT	DUR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Cycle 8	**Day 1**	**30-45 min**	12	0.36	3168	93.92
Cycle 8	**Day 1**	**45 min or more**	4	0.12	3172	94.04
Cycle 8	**Day 2**	**30 min or less**	14	0.42	3186	94.46
Cycle 8	**Day 2**	**30-45 min**	10	0.30	3196	94.75
Cycle 8	**Day 2**	**45 min or more**	2	0.06	3198	94.81
Cycle 8	**Day 3**	**30 min or less**	12	0.36	3210	95.17
Cycle 8	**Day 3**	**30-45 min**	11	0.33	3221	95.49
Cycle 8	**Day 3**	**45 min or more**	2	0.06	3223	95.55
Cycle 8	**Day 4**	**30 min or less**	13	0.39	3236	95.94
Cycle 8	**Day 4**	**30-45 min**	11	0.33	3247	96.26
Cycle 8	**Day 4**	**45 min or more**	2	0.06	3249	96.32
Cycle 8	**Day 5**	**30 min or less**	12	0.36	3261	96.68
Cycle 8	**Day 5**	**30-45 min**	11	0.33	3272	97.01
Cycle 8	**Day 5**	**45 min or more**	1	0.03	3273	97.04
Cycle 9	**Day 1**	**30 min or less**	14	0.42	3287	97.45
Cycle 9	**Day 1**	**30-45 min**	7	0.21	3294	97.66
Cycle 9	**Day 2**	**30 min or less**	11	0.33	3305	97.98
Cycle 9	**Day 2**	**30-45 min**	9	0.27	3314	98.25
Cycle 9	**Day 3**	**30 min or less**	10	0.30	3324	98.55
Cycle 9	**Day 3**	**30-45 min**	9	0.27	3333	98.81
Cycle 9	**Day 3**	**45 min or more**	1	0.03	3334	98.84
Cycle 9	**Day 4**	**30 min or less**	8	0.24	3342	99.08
Cycle 9	**Day 4**	**30-45 min**	9	0.27	3351	99.35
Cycle 9	**Day 4**	**45 min or more**	2	0.06	3353	99.41
Cycle 9	**Day 5**	**30 min or less**	8	0.24	3361	99.64
Cycle 9	**Day 5**	**30-45 min**	11	0.33	3372	99.97
Cycle 9	**Day 5**	**45 min or more**	1	0.03	3373	100.00

Frequency Missing = 107

Table 14.1.2.1: Demographics and Other Baseline Characteristics

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Gender		
Male	69 (53.5)	62 (51.7)
Female	60 (46.5)	58 (48.3)
Race		
White	111 (86.0)	105 (87.5)
Black	9 (7.0)	7 (5.8)
Asian	3 (2.3)	3 (2.5)
Latin	3 (2.3)	3 (2.5)
Other	3 (2.3)	2 (1.7)
Age (years)		
< 65	67 (51.9)	61 (50.8)
>=65	62 (48.1)	59 (49.2)
Mean (SD)	62.0 (11.05)	62.5 (10.40)
Median	63.0	64.0
Range	29 - 81	29 - 81
Performance status		
ECOG 0	44 (34.1)	41 (34.2)
ECOG 1	57 (44.2)	52 (43.3)
ECOG 2	27 (20.9)	26 (21.7)
ECOG 3	1 (0.8)	1 (0.8)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.2: Pretreatment Disease Characteristics

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Primary lymphoma diagnosis (central pathology)		
Peripheral T-cell lymphoma, NOS	77 (59.7)	77 (64.2)
Angioimmunoblastic T-cell lymphoma	22 (17.1)	22 (18.3)
Anaplastic large cell lymphoma, ALK-negative	13 (10.1)	13 (10.8)
Anaplastic large cell lymphoma, ALK-positive	2 (1.6)	2 (1.7)
Enteropathy-associated T-cell lymphoma	2 (1.6)	2 (1.7)
Extranodal NK/T-cell lymphoma, nasal type	2 (1.6)	2 (1.7)
Hepatosplenic T-cell lymphoma	2 (1.6)	2 (1.7)
No peripheral T-cell lymphoma present	2 (1.6)	-
Inadequate sample for assessment	7 (5.4)	-
Primary lymphoma diagnosis (Investigator)		
Peripheral T-cell lymphoma, NOS	75 (58.1)	71 (59.2)
Angioimmunoblastic T-cell lymphoma	31 (24.0)	27 (22.5)
Anaplastic large cell lymphoma, ALK-negative	15 (11.6)	15 (12.5)
Hepatosplenic T-cell lymphoma	3 (2.3)	2 (1.7)
Anaplastic large cell lymphoma, ALK-positive	2 (1.6)	2 (1.7)
Enteropathy-associated T-cell lymphoma	2 (1.6)	2 (1.7)
Extranodal NK/T-cell lymphoma, nasal type	1 (0.8)	1 (0.8)
Months from first lymphoma diagnosis to study entry		
N	129	120
Mean (SD)	26.5 (39.45)	27.1 (40.73)
Median	12.2	12.0
Range	2.6 - 266.4	2.6 - 266.4
Bone marrow involvement		
No	68 (52.7)	65 (54.2)
Yes	39 (30.2)	35 (29.2)
Indeterminate	9 (7.0)	8 (6.7)
Not assessed	13 (10.1)	12 (10.0)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.2: Pretreatment Disease Characteristics

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Ann Arbor staging at study entry		
Stage IA	6 (4.7)	5 (4.2)
Stage IIA	8 (6.2)	7 (5.8)
Stage IIB	4 (3.1)	4 (3.3)
Stage IIIA	26 (20.2)	23 (19.2)
Stage IIIB	19 (14.7)	19 (15.8)
Stage IVA	38 (29.5)	35 (29.2)
Stage IVB	26 (20.2)	25 (20.8)
Unknown	2 (1.6)	2 (1.7)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.3: Prior Therapies for Peripheral T-cell Lymphoma

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Prior therapy received		
Radiation therapy	28 (21.7)	28 (23.3)
Systemic therapy	129 (100.0)	120 (100.0)
Stem cell transplant	29 (22.5)	25 (20.8)
Autologous	27 (20.9)	23 (19.2)
Allogeneic	2 (1. 6)	2 (1. 7)
Number of prior PTCL therapies		
1	43 (33.3)	40 (33.3)
2	38 (29.5)	36 (30.0)
3	24 (18.6)	22 (18.3)
4	14 (10.9)	13 (10.8)
5	7 (5. 4)	7 (5. 8)
8	3 (2. 3)	2 (1. 7)
Mean (SD)	2.4 (1.47)	2.3 (1.41)
Median	2.0	2.0
Range	1 - 8	1 - 8
Complete or partial response to any prior systemic therapy	95 (73.6)	87 (72.5)
Response to the most recent systemic therapy		
Complete Response	32 (24.8)	29 (24.2)
Partial Response	22 (17.1)	21 (17.5)
Stable Disease	22 (17.1)	20 (16.7)
Progressive Disease	39 (30.2)	37 (30.8)
Not Evaluable	11 (8.5)	11 (9.2)
Unknown	3 (2. 3)	2 (1. 7)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.3: Prior Therapies for Peripheral T-cell Lymphoma

Patient Population	Number of Patients (%) Full Analysis Set N=129	Efficacy Analysis Set* N=120
Months from last disease progression to study entry		
N (%)	125 (96.9)	116 (96.7)
Mean (SD)	2.6 (6.12)	2.6 (6.34)
Median	1.0	1.0
Range	0.1 - 54.5	0.1 - 54.5

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.4: Prior Systemic Regimens for Peripheral T-cell Lymphoma

	Number of Patients (%)	
Patient Population	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
The last systemic regimen for PTCL		
Multi-agent therapy		
CHOP or CHOP-like regimens	56 (43.4)	53 (44.2)
Platinum-containing regimens	17 (13.2)	16 (13.3)
Other multi-agent regimens	35 (27.1)	33 (27.5)
Single agent therapy		
Pralatrexate	6 (4.7)	6 (5.0)
Corticosteroids	3 (2.3)	1 (0.8)
Other single-agent regimens	12 (9.3)	11 (9.2)
All systemic regimens for PTCL		
Multi-agent therapy		
CHOP or CHOP-like regimens	125 (96.9)	116 (96.7)
Platinum-containing regimens	42 (32.6)	38 (31.7)
Other multi-agent regimens	48 (37.2)	44 (36.7)
Single agent therapy		
Pralatrexate	11 (8.5)	10 (8.3)
Corticosteroids	6 (4.7)	4 (3.3)
Other single-agent regimens	21 (16.3)	20 (16.7)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.5: General Medical History

Patient Population: Full Analysis Set	Number of Patients (%)	
Site or System with Medical History (Other than PTCL)	All History N=129	Ongoing at Entry N=129
Cardiovascular	87 (67.4)	77 (59.7)
Gastrointestinal	62 (48.1)	41 (31.8)
Musculoskeletal	59 (45.7)	47 (36.4)
Endocrine/Metabolic	52 (40.3)	42 (32.6)
Genitourinary	51 (39.5)	26 (20.2)
Dermatologic	45 (34.9)	36 (27.9)
Head, Eyes, Ears, Nose, Throat	43 (33.3)	28 (21.7)
Neurological	41 (31.8)	32 (24.8)
Respiratory	40 (31.0)	25 (19.4)
Hematopoietic/Lymphatic	33 (25.6)	27 (20.9)
Psychological	26 (20.2)	25 (19.4)
Allergic Conditions Drug Related	25 (19.4)	25 (19.4)
Hepatobiliary	25 (19.4)	18 (14.0)
Constitutional	15 (11.6)	10 (7.8)
Allergic Conditions Environmental	11 (8.5)	9 (7.0)
Immunologic	4 (3.1)	3 (2.3)
Substance Use	1 (0.8)	-

Table 14.1.2.6: Baseline Laboratory Abnormalities

PAGE=1

Full Analysis Set N=129 Laboratory Test	Patients with On-study Test	Incidence of Abnormality	Number of Patients Worst CTCAE Grade On Treatment Grade 1	Grade 2	Grade 3	Grade 4
Hematology						
Hemoglobin, low	129	86 (66.7)	61 (47.3)	20 (15.5)	4 (3.1)	1 (0.8)
Erythrocytes, low	123	83 (67.5)	-	-	-	-
MCV, high	129	21 (16.3)	-	-	-	-
MCV, low	129	9 (7.0)	-	-	-	-
Leukocytes, low	129	29 (22.5)	18 (14.0)	7 (5.4)	4 (3.1)	-
Neutrophils, low	128	14 (10.9)	5 (3.9)	8 (6.3)	1 (0.8)	-
Lymphocytes, low	128	68 (53.1)	18 (14.1)	23 (18.0)	20 (15.6)	7 (5.5)
Coagulation						
Prothrombin Time, high	68	10 (14.7)	8 (11.8)	2 (2.9)	-	-
INR, high	120	18 (15.0)	14 (11.7)	2 (1.7)	2 (1.7)	-
APTT, high	124	19 (15.3)	17 (13.7)	1 (0.8)	1 (0.8)	-
Liver function						
Bilirubin, high	129	9 (7.0)	6 (4.7)	2 (1.6)	1 (0.8)	-
Alkaline Phosphatase, high	128	33 (25.8)	23 (18.0)	9 (7.0)	1 (0.8)	-
ALT, high	129	19 (14.7)	19 (14.7)	-	-	-
AST, high	129	25 (19.4)	22 (17.1)	3 (2.3)	-	-
Albumin, low	124	41 (33.1)	25 (20.2)	14 (11.3)	2 (1.6)	-
Renal function						
Creatinine, high	129	10 (7.8)	9 (7.0)	1 (0.8)	-	-
BUN, high	127	20 (15.7)	-	-	-	-
Urate (uric acid), high	127	17 (13.4)	15 (11.8)	-	-	2 (1.6)
Sodium, high	129	0 (0.0)	-	-	-	-
Sodium, low	129	12 (9.3)	11 (8.5)	-	1 (0.8)	-
Potassium, high	129	2 (1.6)	1 (0.8)	-	1 (0.8)	-
Potassium, low	129	8 (6.2)	7 (5.4)	-	1 (0.8)	-
Chloride, high	123	4 (3.3)	-	-	-	-
Chloride, low	123	8 (6.5)	-	-	-	-
Magnesium, high	122	4 (3.3)	3 (2.5)	-	1 (0.8)	-

Baseline samples were the last sample on or before the day of first dose of study treatment.

Table 14.1.2.6: Baseline Laboratory Abnormalities

PAGE=1

Full Analysis Set N=129	Patients with	Incidence of	Number of Patients Worst CTCAE Grade On Treatment			
Laboratory Test	**On-study Test**	**Abnormality**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Magnesium, low	122	14 (11.5)	10 (8.2)	4 (3.3)	-	-
Metabolic function						
LDH, high	128	72 (56.3)	-	-	-	-
Phosphate, low	119	8 (6.7)	2 (1.7)	4 (3.4)	2 (1.7)	-
Calcium, high	129	3 (2.3)	2 (1.6)	-	1 (0.8)	-
Calcium, low	129	25 (19.4)	18 (14.0)	6 (4.7)	1 (0.8)	-
Glucose, high	128	45 (35.2)	34 (26.6)	11 (8.6)	-	-
Glucose, low	128	1 (0.8)	1 (0.8)	-	-	-

Baseline samples were the last sample on or before the day of first dose of study treatment.

Table 14.1.2.7: Pretreatment Vital Signs, Height and Weight

PAGE=1

Patient Population	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Systolic Blood Pressure (mmHg)		
Number (%)	129 (100.0)	120 (100.0)
Mean (SD)	123.0 (17.32)	123.7 (17.54)
Median	120.0	120.0
Range	89 - 170	89 - 170
Diastolic Blood Pressure (mmHg)		
Number (%)	129 (100.0)	120 (100.0)
Mean (SD)	73.4 (10.44)	73.6 (10.35)
Median	72.0	72.5
Range	53 - 98	53 - 98
Heart Rate (beats/min)		
Number (%)	129 (100.0)	120 (100.0)
Mean (SD)	83.2 (15.09)	83.4 (15.30)
Median	82.0	82.5
Range	50 - 137	50 - 137
Temperature (°C)		
Number (%)	129 (100.0)	120 (100.0)
Mean (SD)	36.5 (0.60)	36.5 (0.60)
Median	36.5	36.5
Range	34.6 - 40.1	34.6 - 40.1

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.7: Pretreatment Vital Signs, Height and Weight

PAGE=2

Patient Population	**Full Analysis Set N=129**	**Efficacy Analysis Set* N=120**
Height (cm)		
Number (%)	123 (95.3)	114 (95.0)
Mean (SD)	167.6 (10.08)	167.1 (9.90)
Median	166.5	166.0
Range	146 - 193	146 - 193
Weight (kg)		
Number (%)	129 (100.0)	120 (100.0)
Mean (SD)	74.9 (18.64)	74.6 (18.95)
Median	73.0	72.5
Range	40 - 149	40 - 149

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.1.2.8: Prior Medications (ATC Classification)

ATC Classification, Level 1 **ATC Classification, Level 2**	**Number of Patients (%)** **Full Analysis Set** **N=129**
A - ALIMENTARY TRACT AND METABOLISM	79 (61.2)
A01 - STOMATOLOGICAL PREPARATIONS	2 (1.6)
A02 - ANTACIDS, DRUGS FOR TREATM.OF PEPT.ULC.AND FLATUL.	49 (38.0)
A03 - ANTISPAS. AND ANTICHOLINERGIC AGENTS AND PROPULSIV	10 (7.8)
A04 - ANTIEMETICS AND ANTINAUSEANTS	8 (6.2)
A06 - LAXATIVES	20 (15.5)
A07 - ANTIDIARR.,INTEST. ANTIINFL./ANTIINFECT. AGENTS	3 (2.3)
A10 - DRUGS USED IN DIABETES	7 (5.4)
A11 - VITAMINS	22 (17.1)
A12 - MINERAL SUPPLEMENTS	17 (13.2)
B - BLOOD AND BLOOD FORMING ORGANS	50 (38.8)
B01 - ANTITHROMBOTIC AGENTS	39 (30.2)
B02 - ANTIHEMORRHAGICS	2 (1.6)
B03 - ANTIANEMIC PREPARATIONS	7 (5.4)
B05 - BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	9 (7.0)
C - CARDIOVASCULAR SYSTEM	60 (46.5)
C01 - CARDIAC THERAPY	6 (4.7)
C03 - DIURETICS	19 (14.7)
C04 - PERIPHERAL VASODILATORS	3 (2.3)
C07 - BETA BLOCKING AGENTS	25 (19.4)
C08 - CALCIUM CHANNEL BLOCKERS	14 (10.9)
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	23 (17.8)
C10 - SERUM LIPID REDUCING AGENTS	16 (12.4)
D - DERMATOLOGICALS	11 (8.5)
D02 - EMOLLIENTS AND PROTECTIVES	4 (3.1)
D03 - PREPARATIONS FOR TREATMENT OF WOUNDS & ULCERS	1 (0.8)
D04 - ANTIPRURITICS,INCL ANTIHIST,ANESTHET,ETC.	2 (1.6)
D06 - ANTIBIOTICS AND CHEMOTHER. FOR DERMATOLOGICAL USE	2 (1.6)
D07 - CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	4 (3.1)
D08 - ANTISEPTICS AND DISINFECTANTS	1 (0.8)
D10 - ANTI-ACNE PREPARATIONS	1 (0.8)

Table 14.1.2.8: Prior Medications (ATC Classification)

ATC Classification, Level 1 ATC Classification, Level 2	Number of Patients (%) Full Analysis Set N=129
G - GENITO URINARY SYSTEM AND SEX HORMONES	1 (0.8)
G04 - UROLOGICALS	1 (0.8)
H - SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	38 (29.5)
H02 - CORTICOSTEROIDS FOR SYSTEMIC USE	29 (22.5)
H03 - THYROID THERAPY	14 (10.9)
H05 - CALCIUM HOMEOSTASIS	3 (2.3)
J - ANTIINFECTIVES FOR SYSTEMIC USE	44 (34.1)
J01 - ANTIBACTERIALS FOR SYSTEMIC USE	26 (20.2)
J02 - ANTIMYCOTICS FOR SYSTEMIC USE	11 (8.5)
J04 - ANTIMYCOBACTERIALS	3 (2.3)
J05 - ANTIVIRALS FOR SYSTEMIC USE	19 (14.7)
J06 - IMMUNE SERA AND IMMUNOGLOBULINS	1 (0.8)
J07 - VACCINES	1 (0.8)
L - ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	3 (2.3)
L02 - ENDOCRINE THERAPY	2 (1.6)
L04 - IMMUNOSUPPRESSIVE AGENTS	1 (0.8)
M - MUSCULO-SKELETAL SYSTEM	30 (23.3)
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	8 (6.2)
M03 - MUSCLE RELAXANTS	1 (0.8)
M04 - ANTIGOUT PREPARATIONS	21 (16.3)
M05 - DRUGS FOR TREATMENT OF BONE DISEASES	3 (2.3)
N - NERVOUS SYSTEM	56 (43.4)
N01 - ANESTHETICS	1 (0.8)
N02 - ANALGESICS	35 (27.1)
N03 - ANTIEPILEPTICS	5 (3.9)
N04 - ANTI-PARKINSON DRUGS	1 (0.8)
N05 - PSYCHOLEPTICS	35 (27.1)
N06 - PSYCHOANALEPTICS	9 (7.0)
R - RESPIRATORY SYSTEM	18 (14.0)
R03 - ANTI-ASTHMATICS	4 (3.1)

Table 14.1.2.8: Prior Medications (ATC Classification)

ATC Classification, Level 1 **ATC Classification, Level 2**	**Number of Patients (%)** **Full Analysis Set** **N=129**
R05 - COUGH AND COLD PREPARATIONS	3 (2.3)
R06 - ANTIHISTAMINES FOR SYSTEMIC USE	13 (10.1)
S - SENSORY ORGANS	3 (2.3)
S01 - OPHTHALMOLOGICALS	3 (2.3)
V - VARIOUS	11 (8.5)
V03 - ALL OTHER THERAPEUTIC PRODUCTS	3 (2.3)
V06 - GENERAL NUTRIENTS	2 (1.6)
V07 - ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (0.8)
V90 - UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	8 (6.2)

Table 14.1.2.9: Demographics and Other Baseline Characteristics
by Baseline Platelet Group
Full Analysis Set

	Number of Patients (%)	
	Platelet >= 100,000/ul	Platelet < 100,000/ul
Patient Population	**N=105**	**N=24**
Gender		
Male	55 (52.4)	14 (58.3)
Female	50 (47.6)	10 (41.7)
Race		
White	88 (83.8)	23 (95.8)
Black	9 (8.6)	0 (0.0)
Asian	3 (2.9)	0 (0.0)
Latin	3 (2.9)	0 (0.0)
Other	2 (1.9)	1 (4.2)
Age (years)		
< 65	52 (49.5)	15 (62.5)
>=65	53 (50.5)	9 (37.5)
Mean (SD)	62.3 (11.37)	60.5 (9.61)
Median	65.0	59.5
Range	29 - 81	35 - 76
Performance status		
ECOG 0	36 (34.3)	8 (33.3)
ECOG 1	48 (45.7)	9 (37.5)
ECOG 2	20 (19.0)	7 (29.2)
ECOG 3	1 (1.0)	0 (0.0)

Table 14.2.3.1: Tumor Response, IRC Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Best tumor response (IRC)	
CR - Complete Response	13 (10.8)
PR - Partial Response	18 (15.0)
SD - Stable Disease	18 (15.0)
PD - Progressive Disease	47 (39.2)
NE - Not Evaluable	24 (20.0)
Objective response rate (IRC)	
Complete response (CR)	13 (10.8)
95% confidence interval (%)	5.9 - 17.8
Partial response (PR)	18 (15.0)
95% confidence interval (%)	9.1 - 22.7
Overall response (CR+PR)	31 (25.8)
95% confidence interval (%)	18.3 - 34.6
Reason for not evaluable assessments	
Clinical progression prior to first on-study assessment	9 (7.5)
Death prior to first on-study assessment	7 (5.8)
Withdrawal by patient prior to first on-study assessment	5 (4.2)
Lost to follow-up prior to first on-study assessment	1 (0.8)
No index lesion identified by the IRC radiologists	1 (0.8)
Other	1 (0.8)
Number of adjudications between Reader 1 and Reader 2	27 (22.5)
Adjudicated CRs/PRs where only one reader scored a CR/PR	6 / 31 (19.4)

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.3.2: Time to and Duration of Response, IRC Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* with CR/PR N= 31
Time to response (IRC)	
Median (wk)	5.6
Quartiles (1st, 3rd)	5.4 - 12.1
Range (min, max)	4.3 - 50.4
Duration of response (IRC) - IWG criteria**	
Median follow-up (mo)	10.4
Number of events (%)	14 (45.2)
Median duration of response (mo)	13.6
Quartiles (1st, 3rd)	4.1 - 29.4
95% confidence interval	4.5 - 29.4
Probability of being in response (%)	
At 6 months	63.5
At 1 year	53.7
At 2 years	35.8
Duration of response (IRC) - IWG + Death***	
Median follow-up (mo)	11.5
Number of events (%)	16 (51.6)
Median duration of response (mo)	8.4
Quartiles (1st, 3rd)	2.3 - 29.4
95% confidence interval	4.5 - 29.4
Probability of being in response (%)	
At 6 months	57.7
At 1 year	48.8
At 2 years	32.6

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**
**** Time from the first infusion to the date of PD. Otherwise censored at the last disease assessment**
***** Time from the 1st infusion to the date of PD or death, censored at the last disease assessment prior to a new therapy.**

Table 14.2.3.3: Overall Response Rate, IRC Assessment, by Pre-treatment Characteristics

Efficacy Analysis Set*	n (%)	CR+PR (%)	95% Confidence Interval
All Patients	120	31 (25.8)	18.3 - 34.6
Gender			
Male	62 (51.7)	13 (21.0)	11.7 - 33.2
Female	58 (48.3)	18 (31.0)	19.5 - 44.5
Race			
White	105 (87.5)	26 (24.8)	16.9 - 34.1
Non-white	15 (12.5)	5 (33.3)	11.8 - 61.6
Age at Entry			
< 65 Years	61 (50.8)	10 (16.4)	8.2 - 28.1
>=65 Years	59 (49.2)	21 (35.6)	23.6 - 49.1
Performance Status			
ECOG 0	41 (34.2)	12 (29.3)	16.1 - 45.5
ECOG 1	52 (43.3)	8 (15.4)	6.9 - 28.1
ECOG 2	26 (21.7)	11 (42.3)	23.4 - 63.1
ECOG 3	1 (0.8)	0 (0)	0.0 - 97.5
CPRG lymphoma diagnosis			
Peripheral T-cell lymphoma, NOS	77 (64.2)	18 (23.4)	14.5 - 34.4
Angioimmunoblastic T-cell lymphoma	22 (18.3)	10 (45.5)	24.4 - 67.8
Anaplastic large cell lymphoma, ALK-negative	13 (10.8)	2 (15.4)	1.9 - 45.4
Anaplastic large cell lymphoma, ALK-positive	2 (1.7)	0 (0)	0.0 - 84.2
Enteropathy-associated T-cell lymphoma	2 (1.7)	0 (0)	0.0 - 84.2
Extranodal NK/T-cell lymphoma, nasal type	2 (1.7)	1 (50.0)	1.3 - 98.7
Hepatosplenic T-cell lymphoma	2 (1.7)	0 (0)	0.0 - 84.2
Bone Marrow Involvement			
No	65 (54.2)	20 (30.8)	19.9 - 43.4
Yes	35 (29.2)	8 (22.9)	10.4 - 40.1
Indeterminate	8 (6.7)	2 (25.0)	3.2 - 65.1
Not assessed	12 (10.0)	1 (8.3)	0.2 - 38.5

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG))**

Table 14.2.3.3: Overall Response Rate, IRC Assessment, by Pre-treatment Characteristics

Efficacy Analysis Set*	n (%)	CR+PR (%)	95% Confidence Interval
Prior pralatrexate therapy			
Yes	10 (8.3)	1 (10.0)	0.3 - 44.5
No	110 (91.7)	30 (27.3)	19.2 - 36.6
Response to the most recent systemic therapy			
Complete Response	29 (24.2)	14 (48.3)	29.4 - 67.5
Partial Response	21 (17.5)	6 (28.6)	11.3 - 52.2
Stable Disease	20 (16.7)	5 (25.0)	8.7 - 49.1
Progressive Disease	37 (30.8)	3 (8.1)	1.7 - 21.9
Not Evaluable	11 (9.2)	3 (27.3)	6.0 - 61.0
Unknown	2 (1.7)	0 (0)	0.0 - 84.2
Baseline platelet count			
>=100,000 ul	100 (83.3)	28 (28.0)	19.5 - 37.9
< 100,000 ul	20 (16.7)	3 (15.0)	3.2 - 37.9

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG))**

Table 14.2.3.4: Tumor Response, Investigator Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Best tumor response (investigator)	
CR - Complete Response	11 (9.2)
PR - Partial Response	16 (13.3)
SD - Stable Disease	29 (24.2)
PD - Progressive Disease	53 (44.2)
NE - Not Evaluable	11 (9.2)
Objective response rate (investigator)	
Complete response (CR)	11 (9.2)
95% confidence interval (%)	4.7 - 15.8
Overall response (CR+PR)	27 (22.5)
95% confidence interval (%)	15.4 - 31.0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.3.5: Time to and Duration of Response, Investigator Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* with CR/PR N= 27
Time to response (Investigator)	
Median (wk)	6.3
Quartiles (1st, 3rd)	5.4 - 11.1
Range (min, max)	4.1 - 44.1
Duration of response (Investigator) - IWG criteria**	
Median follow-up (mo)	21.8
Number of events (%)	17 (63.0)
Median duration of response (mo)	12.1
Quartiles (1st, 3rd)	4.2 - 29.4
95% confidence interval	4.7 - 19.8
Probability of being in response (%)	
At 6 months	62.6
At 1 year	50.3
At 2 years	29.3
Duration of response (Investigator) - IWG + Death***	
Median follow-up (mo)	21.8
Number of events (%)	18 (66.7)
Median duration of response (mo)	8.0
Quartiles (1st, 3rd)	4.2 - 29.4
95% confidence interval	4.7 - 19.8
Probability of being in response (%)	
At 6 months	59.3
At 1 year	47.6
At 2 years	27.8

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**
**** Time from the first infusion to the date of PD. Otherwise censored at the last disease assessment**
***** Time from the 1st infusion to the date of PD or death, censored at the last disease assessment prior to a new therapy.**
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Table 14.2.3.6: Concordance of IRC and Investigator Best Overall Response

Patient Population		Number of patients Efficacy Analysis Set* N=120 Investigator Best Tumor Response				
IRC Best Tumor Response	n	CR	PR	SD	PD	NE
All Response Categories	120	11	16	29	53	11
CR - Complete Response	13	9	4	-	-	-
PR - Partial Response	18	2	10	5	1	-
SD - Stable Disease	18	-	2	13	3	-
PD - Progressive Disease	47	-	-	10	36	1
NE - Not Evaluable	24	-	-	1	13	10

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.3.7: Patient Listing of Duration of Response, IRC Assessment

Patient	Day of Last Dose	Status of Treatment	Best Overall Response	Day of Onset of Response	Day of Last Response	Duration (Days)	Status
100-002	68	Withdrawn	PR	39	81	43	Progression
142-005	13	Withdrawn	PR	30	85	56	Death
146-001	929	Ongoing	CR	33	927	895	Censored
154-001	195	Withdrawn	PR	72	219	148	Death
161-001	52	Withdrawn	PR	30	95	66	Progression
207-001	450	Withdrawn	CR	91	441	351	Censored
220-002	719	Ongoing	CR	38	715	678	Censored
221-003	215	Withdrawn	CR	43	215	173	New therapy
244-003	614	Withdrawn	CR	38	635	598	Progression
245-001	108	Withdrawn	PR	45	85	41	Progression
516-004	425	Ongoing	PR	353	353	1	Censored
532-003	215	Withdrawn	PR	85	127	43	Progression
533-001	131	Withdrawn	PR	85	211	127	New therapy
534-001	166	Withdrawn	CR	36	171	136	Progression
534-002	719	Ongoing	CR	38	691	654	New therapy
534-003	600	Withdrawn	PR	37	291	255	Progression
534-004	502	Withdrawn	PR	87	500	414	Progression
534-005	418	Withdrawn	PR	38	425	388	New therapy

Table 14.2.3.7: Patient Listing of Duration of Response, IRC Assessment

Patient	Day of Last Dose	Status of Treatment	Best Overall Response	Day of Onset of Response	Day of Last Response	Duration (Days)	Status
534-006	369	Ongoing	CR	45	341	297	Censored
541-001	691	Ongoing	CR	334	649	316	Censored
543-001	768	Ongoing	PR	150	766	617	Censored
600-003	194	Withdrawn	PR	89	213	125	Progression
752-002	75	Withdrawn	PR	38	107	70	Progression
800-001	24	Withdrawn	PR	36	123	88	Censored
901-006	194	Withdrawn	CR	36	205	170	Progression
911-001	68	Withdrawn	CR	38	78	41	Progression
915-001	411	Withdrawn	PR	171	422	252	Progression
919-001	229	Withdrawn	PR	39	176	138	New therapy
931-003	299	Withdrawn	CR	73	333	261	New therapy
934-003	76	Withdrawn	CR	79	213	135	New therapy
938-001	75	Withdrawn	PR	38	86	49	Progression

Table 14.2.3.8: Duration of Treatment by IRC Response Cohort

IRC Best Tumor Response	N	Efficacy Analysis Set* N=120 Median	Minimum	Maximum
Number of treatment cycles				
CR - Complete Response	13	18.0	4	33
PR - Partial Response	18	9.0	1	31
SD - Stable Disease	18	4.5	2	12
PD - Progressive Disease	47	2.0	1	13
NE - Not Evaluable	24	1.0	1	6
Duration of treatment (wk)				
CR - Complete Response	13	55.0	12	135
PR - Partial Response	18	30.1	3	112
SD - Stable Disease	18	15.5	6	36
PD - Progressive Disease	47	6.0	3	40
NE - Not Evaluable	24	3.0	3	21

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.3.9: Time to and Duration of Response, IRC Assessment by Baseline Platelet Group

Patient Population	Efficacy Analysis Set* with CR/PR (%) Platelet >= 100,000uL N=28	Platelet < 100,000uL N=3
Time to response (IRC)		
Median (wk)	5.6	6.4
Quartiles (1st, 3rd)	5.4 - 12.1	4.3 - 12.7
Range (min, max)	4.3 - 50.4	4.3 - 12.7
Duration of response (IRC) - IWG criteria**		
Median follow-up (mo)	11.5	9.8
Number of events (%)	12 (42.9)	2 (66.7)
Median duration of response (mo)	13.6	4.1
Quartiles (1st, 3rd)	4.5 - 29.4	2.2 - 9.8
95% confidence interval	5.6 - 29.4	2.2 - 9.8
Probability of being in response (%)		
At 6 months	67.0	33.3
At 1 year	55.8	33.3
At 2 years	37.2	33.3
Duration of response (IRC) - IWG + Death***		
Median follow-up (mo)	11.5	9.8
Number of events (%)	14 (50.0)	2 (66.7)
Median duration of response (mo)	13.6	4.1
Quartiles (1st, 3rd)	2.3 - 29.4	2.2 - 9.8
95% confidence interval	4.5 - 29.4	2.2 - 9.8
Probability of being in response (%)		
At 6 months	60.4	33.3
At 1 year	50.4	33.3
At 2 years	33.6	33.3

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**
**** Time from the first infusion to the date of PD. Otherwise censored at the last disease assessment**
***** Time from the 1st infusion to the date of PD or death, censored at the last disease assessment prior to a new therapy.**

Table 14.2.3.10: Time to and Duration of Response, Investigator Assessment by Baseline Platelet Group

	Efficacy Analysis Set* with CR/PR	
	Platelet >= 100,000uL	Platelet < 100,000uL
Patient Population	**N=25**	**N=2**
Time to response (Investigator)		
Median (wk)	6.3	13.1
Quartiles (1st, 3rd)	5.4 - 10.3	12.7 - 13.6
Range (min, max)	4.1 - 44.1	12.7 - 13.6
Duration of response (Investigator) - IWG criteria**		
Median follow-up (mo)	21.8	9.1
Number of events (%)	16 (16.0)	1 (5.0)
Median duration of response (mo)	12.1	
Quartiles (1st, 3rd)	4.2 - 29.4	4.7 - 9.1
95% confidence interval	5.0 - 19.8	NA
Probability of being in response (%)		
At 6 months	63.5	50.0
At 1 year	50.2	50.0
At 2 years	29.3	50.0
Duration of response (Investigator) - IWG + Death***		
Median follow-up (mo)	21.8	9.1
Number of events (%)	17 (17.0)	1 (5.0)
Median duration of response (mo)	8.0	
Quartiles (1st, 3rd)	4.2 - 29.4	4.7 - 9.1
95% confidence interval	4.9 - 19.8	NA
Probability of being in response (%)		
At 6 months	60.0	50.0
At 1 year	47.4	50.0
At 2 years	27.6	50.0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**
**** Time from the first infusion to the date of PD. Otherwise censored at the last disease assessment**
***** Time from the 1st infusion to the date of PD or death, censored at the last disease assessment prior to a new therapy.**
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Table 14.2.3.11: Patient Listing of Duration of Response, IRC Assessment by Baseline Platelet Group

Baseline Platelet Group	Patient	Day of Last Dose	Status of Treatment	Best Overall Response	Day of Onset of Response	Day of Last Response	Duration (Days)	Status
Platelet >= 100,000/ul	100-002	68	Withdrawn	PR	39	81	43	Progression
	142-005	13	Withdrawn	PR	30	85	56	Death
	146-001	929	Ongoing	CR	33	927	895	Censored
	154-001	195	Withdrawn	PR	72	219	148	Death
	207-001	450	Withdrawn	CR	91	441	351	Censored
	220-002	719	Ongoing	CR	38	715	678	Censored
	221-003	215	Withdrawn	CR	43	215	173	New therapy
	244-003	614	Withdrawn	CR	38	635	598	Progression
	245-001	108	Withdrawn	PR	45	85	41	Progression
	516-004	425	Ongoing	PR	353	353	1	Censored
	532-003	215	Withdrawn	PR	85	127	43	Progression
	533-001	131	Withdrawn	PR	85	211	127	New therapy
	534-001	166	Withdrawn	CR	36	171	136	Progression
	534-002	719	Ongoing	CR	38	691	654	New therapy
	534-003	600	Withdrawn	PR	37	291	255	Progression
	534-004	502	Withdrawn	PR	87	500	414	Progression
	534-005	418	Withdrawn	PR	38	425	388	New therapy

Table 14.2.3.11: Patient Listing of Duration of Response, IRC Assessment by Baseline Platelet Group

Baseline Platelet Group	Patient	Day of Last Dose	Status of Treatment	Best Overall Response	Day of Onset of Response	Day of Last Response	Duration (Days)	Status
Platelet >= 100,000/ul	541-001	691	Ongoing	CR	334	649	316	Censored
	543-001	768	Ongoing	PR	150	766	617	Censored
	752-002	75	Withdrawn	PR	38	107	70	Progression
	800-001	24	Withdrawn	PR	36	123	88	Censored
	901-006	194	Withdrawn	CR	36	205	170	Progression
	911-001	68	Withdrawn	CR	38	78	41	Progression
	915-001	411	Withdrawn	PR	171	422	252	Progression
	919-001	229	Withdrawn	PR	39	176	138	New therapy
	931-003	299	Withdrawn	CR	73	333	261	New therapy
	934-003	76	Withdrawn	CR	79	213	135	New therapy
	938-001	75	Withdrawn	PR	38	86	49	Progression
Platelet < 100,000/ul	161-001	52	Withdrawn	PR	30	95	66	Progression
	534-006	369	Ongoing	CR	45	341	297	Censored
	600-003	194	Withdrawn	PR	89	213	125	Progression

Table 14.2.4.1: Time to Progression, IRC Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Time to progression (IRC)	
Median follow-up (mo)	7.1
Number of events (%)	72 (60.0)
25% quartile time to progression (mo)	1.3
95% confidence interval	1.2 - 1.4
Median time to progression (mo)	2.0
95% confidence interval	1.5 - 2.8
75% quartile time to progression (mo)	9.6
95% confidence interval	4.8 - 20.9
Probability of being progression free (%)	
At 6 months	30.3
At 1 year	24.2
At 2 years	14.1

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.4.2: Progression-free Survival, IRC Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Progression-free survival (IRC)	
Median follow-up (mo)	11.6
Number of events (%)	88 (73.3)
Median progression-free survival time (mo)	1.6
95% confidence interval	1.4 - 2.7
Probability of progression-free survival (%)	
At 6 months	25.6
At 1 year	19.3
At 2 years	11.3

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.4.3: Time to Progression, Investigator Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Time to progression (Investigator)	
Median follow-up (mo)	19.9
Number of events (%)	89 (74.2)
Median time to progression (mo)	2.0
95% confidence interval	1.5 - 2.9
Probability of being progression free (%)	
At 6 months	30.0
At 1 year	19.3
At 2 years	9.2

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.4.4: Progression-free Survival, Investigator Assessment

Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Progression-free survival (investigator)	
Median follow-up (mo)	23.0
Number of events (%)	102 (85.0)
Median progression-free survival time (mo)	1.8
95% confidence interval	1.5 - 2.7
Probability of progression-free survival (%)	
At 6 months	25.6
At 1 year	15.7
At 2 years	7.5

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.4.5: Overall Survival

	Patient Population	Number of patients (%) Efficacy Analysis Set* N=120
Overall survival		
Median follow-up (mo)		18.5
Number of deaths (%)		74 (61.7)
Median overall survival time (mo)		7.9
95% confidence interval		6.1 - 13.9
Probability of overall survival (%)		
At 6 months		60.1
At 1 year		40.9
At 2 years		26.3

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.4.7: Progression-free Survival, IRC Assessment by Baseline Platelet Group

Patient Population	Efficacy Analysis Set* (%) Platelet >= 100,000uL N=100	Platelet < 100,000uL N=20
Progression-free survival (IRC)		
Median follow-up (mo)	14.0	11.2
Number of events (%)	71 (71.0)	17 (85.0)
Median progression-free survival time (mo)	1.8	1.3
95% confidence interval	1.5 - 2.8	1.1 - 1.5
Probability of progression-free survival (%)		
At 6 months	28.3	11.5
At 1 year	22.1	5.7
At 2 years	12.9	5.7

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.2.4.8: Overall Survival
by Baseline Platelet Group

	Efficacy Analysis Set* (%)	
	Platelet >= 100,000uL	**Platelet < 100,000uL**
Patient Population	**N=100**	**N=20**
Overall survival		
Median follow-up (mo)	20.3	13.8
Number of deaths (%)	57 (57.0)	17 (85.0)
Median overall survival time (mo)	9.2	4.3
95% confidence interval	6.4 - 17.7	2.4 - 7.9
Probability of overall survival (%)		
At 6 months	63.5	45.0
At 1 year	45.7	20.0
At 2 years	30.3	0.0

*** Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group (CPRG)**

Table 14.3.5.1: Extent of Exposure to Belinostat

Patient Population	**Full Analysis Set N=129**
Total duration of treatment (wk)	
N	129
Mean (SD)	18.2 (25.56)
Median	7.0
Range	3 - 135
Number of treatment cycles administered	
N	129
Mean (SD)	5.4 (6.91)
Median	2.0
Range	1 - 33
Number of belinostat doses administered	
N	129
Mean (SD)	26.6 (34.49)
Median	10.0
Range	1 - 165
Total cumulative dose of belinostat (g/m2)	
N	129
Mean (SD)	26.0 (33.37)
Median	10.5
Range	1 - 164
Relative dose intensity (%)	
N	129
Mean (SD)	91.82 (13.167)
Median	98.30
Range	19.9 - 105.2

Table 14.3.5.2: Treatment Adjustments and Modifications

Patient Population	Full Analysis Set N=129
Patients with one dose reduction of 25% to 750 mg/m2	16 (12.4)
Cause of the first dose reduction	
Prolonged QTc	2 (1.6)
Transaminases increased	2 (1.6)
Bronchospasm	1 (0.8)
Dyspnea	1 (0.8)
Hyperbilirubinemia	1 (0.8)
Hypoglycemia	1 (0.8)
Hypokalemia	1 (0.8)
Immune hemolytic anemia	1 (0.8)
Nausea	1 (0.8)
Neutropenia	1 (0.8)
Pancytopenia	1 (0.8)
Pulmonary embolus	1 (0.8)
Rash	1 (0.8)
Thrombocytopenia	1 (0.8)
Patients with two dose reductions of 25% each to 560 mg/m2	1 (0.8)
Cause of the second dose reduction	
Prolonged QTc	1 (0.8)
Patients with infusion interruption	22 (17.1)
Cause of the first infusion interruption	
Extravasation	3 (2.3)
Poor venous access	3 (2.3)
Vomiting	3 (2.3)
Hypersensitivity	2 (1.6)
Injection site pain	2 (1.6)
Injection site phlebitis	2 (1.6)
Nausea	2 (1.6)
By error, no adverse event	1 (0.8)
Chest discomfort	1 (0.8)
Fatigue	1 (0.8)
Phlebitis	1 (0.8)
Prolonged QTc	1 (0.8)

Table 14.3.5.2: Treatment Adjustments and Modifications

Patient Population	Full Analysis Set N=129
Patients with a missed dose within a cycle	27 (20.9)
Cause of the first missed dose within a cycle	
Holiday	3 (2.3)
Disease progression	2 (1.6)
Injection site infection	2 (1.6)
Patient request	2 (1.6)
Prolonged QTc	2 (1.6)
Suspected abnormal ECG	2 (1.6)
Thrombocytopenia	2 (1.6)
Atrial fibrillation	1 (0.8)
Creatinine increased	1 (0.8)
Death	1 (0.8)
Extravasation	1 (0.8)
Fever	1 (0.8)
Hypoglycemia	1 (0.8)
Hypoxia	1 (0.8)
Nausea	1 (0.8)
Pneumonia	1 (0.8)
Septic shock	1 (0.8)
Tumour lysis syndrome	1 (0.8)
Upper respiratory infection	1 (0.8)
Patients with dose delay of 3+ days within a cycle	4 (3.1)
Cause of the first dose delay of 3+ days within a cycle	
Pneumonia	2 (1.6)
Hyperbilirubinemia	1 (0.8)
Transaminases increased	1 (0.8)

Table 14.3.5.2: Treatment Adjustments and Modifications

Patient Population	Full Analysis Set N=129
Patients with cycle delay of 7+ days	37 (28.7)
Cause of the first cycle delay of 7+ days	
Holiday	5 (3.9)
Fever	2 (1.6)
Rash	2 (1.6)
Upper respiratory infection	2 (1.6)
Alveolitis	1 (0.8)
Bronchitis	1 (0.8)
Bronchopneumonia	1 (0.8)
Congestive heart failure	1 (0.8)
Fatigue	1 (0.8)
Immune hemolytic anemia	1 (0.8)
Malaise	1 (0.8)
Pancytopenia	1 (0.8)
Patient request	1 (0.8)
Pneumonia	1 (0.8)
Pulmonary embolus	1 (0.8)
Septic shock	1 (0.8)
Thrombocytopenia	1 (0.8)
Vein access	1 (0.8)
Ventricular extrasystoles	1 (0.8)
Unknown	11 (8.5)

Table 14.3.5.3: Subsequent Therapies for Peripheral T-cell Lymphoma

Patient Population	Full Analysis Set N=129
Radiation Therapy	13 (10.1)
Stem Cell Transplant	12 (9.3)
Drug Therapy	77 (59.7)
Gemcitabine	24 (18.6)
Etoposide	16 (12.4)
Cyclophosphamide	15 (11.6)
Pralatrexate	14 (10.9)
Ifosfamide	10 (7.8)
Methylprednisolone	10 (7.8)
Fludarabine	9 (7.0)
Cytarabine	8 (6.2)
Prednisolone	8 (6.2)
Alemtuzumab	7 (5.4)
Cisplatin	7 (5.4)
Oxaliplatin	7 (5.4)
Dexamethasone	6 (4.7)
Doxorubicin	6 (4.7)
Vincristine	6 (4.7)
Vinorelbine	6 (4.7)
Carboplatin	5 (3.9)
Mesna	5 (3.9)
Romidepsin	5 (3.9)
Chlorambucil	4 (3.1)
Prednisone	4 (3.1)
Brentuximab	3 (2.3)
Bendamustine	2 (1.6)
Carmustine	2 (1.6)
Lenalidomide	2 (1.6)
Lomustine	2 (1.6)
Melphalan	2 (1.6)
Methotrexate	2 (1.6)
Anastrozole	1 (0.8)
Asparaginase	1 (0.8)
Bexarotene	1 (0.8)

Table 14.3.5.3: Subsequent Therapies for Peripheral T-cell Lymphoma

Patient Population	Full Analysis Set N=129
Bleomycin	1 (0.8)
Bortezomib	1 (0.8)
Busulfan	1 (0.8)
Ciclosporin	1 (0.8)
Cladribine	1 (0.8)
Ixazomib	1 (0.8)
Pentostatin	1 (0.8)
Rituximab	1 (0.8)
Thiotepa	1 (0.8)
Vorinostat	1 (0.8)

Table 14.3.5.4: Concomitant Medications (ATC Classification)

ATC Classification, Level 1 ATC Classification, Level 2	Number of Patients (%) Full Analysis Set N=129
A - ALIMENTARY TRACT AND METABOLISM	124 (96.1)
A01 - STOMATOLOGICAL PREPARATIONS	12 (9.3)
A02 - ANTACIDS, DRUGS FOR TREATM.OF PEPT.ULC.AND FLATUL.	88 (68.2)
A03 - ANTISPAS. AND ANTICHOLINERGIC AGENTS AND PROPULSIV	40 (31.0)
A04 - ANTIEMETICS AND ANTINAUSEANTS	101 (78.3)
A05 - BILE AND LIVER THERAPY	2 (1.6)
A06 - LAXATIVES	39 (30.2)
A07 - ANTIDIARR.,INTEST. ANTIINFL./ANTIINFECT. AGENTS	20 (15.5)
A10 - DRUGS USED IN DIABETES	14 (10.9)
A11 - VITAMINS	31 (24.0)
A12 - MINERAL SUPPLEMENTS	47 (36.4)
B - BLOOD AND BLOOD FORMING ORGANS	93 (72.1)
B01 - ANTITHROMBOTIC AGENTS	63 (48.8)
B02 - ANTIHEMORRHAGICS	12 (9.3)
B03 - ANTIANEMIC PREPARATIONS	23 (17.8)
B05 - BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	59 (45.7)
C - CARDIOVASCULAR SYSTEM	84 (65.1)
C01 - CARDIAC THERAPY	17 (13.2)
C02 - ANTIHYPERTENSIVES	3 (2.3)
C03 - DIURETICS	47 (36.4)
C04 - PERIPHERAL VASODILATORS	3 (2.3)
C05 - VASOPROTECTIVES	4 (3.1)
C07 - BETA BLOCKING AGENTS	31 (24.0)
C08 - CALCIUM CHANNEL BLOCKERS	18 (14.0)
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	27 (20.9)
C10 - SERUM LIPID REDUCING AGENTS	19 (14.7)
D - DERMATOLOGICALS	31 (24.0)
D01 - ANTIFUNGALS FOR DERMATOLOGICAL USE	4 (3.1)
D02 - EMOLLIENTS AND PROTECTIVES	6 (4.7)
D03 - PREPARATIONS FOR TREATMENT OF WOUNDS & ULCERS	1 (0.8)
D04 - ANTIPRURITICS,INCL ANTIHIST,ANESTHET,ETC.	6 (4.7)
D06 - ANTIBIOTICS AND CHEMOTHER. FOR DERMATOLOGICAL USE	4 (3.1)

Table 14.3.5.4: Concomitant Medications (ATC Classification)

ATC Classification, Level 1 **ATC Classification, Level 2**	**Number of Patients (%)** **Full Analysis Set** **N=129**
D07 - CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	21 (16.3)
D08 - ANTISEPTICS AND DISINFECTANTS	3 (2.3)
D10 - ANTI-ACNE PREPARATIONS	2 (1.6)
G - GENITO URINARY SYSTEM AND SEX HORMONES	4 (3.1)
G02 - OTHER GYNECOLOGICALS	1 (0.8)
G04 - UROLOGICALS	3 (2.3)
H - SYSTEMIC HORMONAL PREP,EXCL SEX HORM. AND INSULINS	89 (69.0)
H01 - PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	1 (0.8)
H02 - CORTICOSTEROIDS FOR SYSTEMIC USE	83 (64.3)
H03 - THYROID THERAPY	15 (11.6)
H05 - CALCIUM HOMEOSTASIS	3 (2.3)
J - ANTIINFECTIVES FOR SYSTEMIC USE	96 (74.4)
J01 - ANTIBACTERIALS FOR SYSTEMIC USE	85 (65.9)
J02 - ANTIMYCOTICS FOR SYSTEMIC USE	35 (27.1)
J04 - ANTIMYCOBACTERIALS	4 (3.1)
J05 - ANTIVIRALS FOR SYSTEMIC USE	39 (30.2)
J06 - IMMUNE SERA AND IMMUNOGLOBULINS	1 (0.8)
J07 - VACCINES	5 (3.9)
L - ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	19 (14.7)
L01 - ANTINEOPLASTIC AGENTS	1 (0.8)
L02 - ENDOCRINE THERAPY	4 (3.1)
L03 - IMMUNOSTIMULANTS	13 (10.1)
L04 - IMMUNOSUPPRESSIVE AGENTS	1 (0.8)
M - MUSCULO-SKELETAL SYSTEM	72 (55.8)
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	32 (24.8)
M02 - TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	2 (1.6)
M03 - MUSCLE RELAXANTS	4 (3.1)
M04 - ANTIGOUT PREPARATIONS	46 (35.7)
M05 - DRUGS FOR TREATMENT OF BONE DISEASES	7 (5.4)
M09 - OTHER DRUGS FOR DISORD. OF THE MUSCULO-SKELET.SYST	1 (0.8)

Table 14.3.5.4: Concomitant Medications (ATC Classification)

ATC Classification, Level 1 ATC Classification, Level 2	Number of Patients (%) Full Analysis Set N=129
N - NERVOUS SYSTEM	99 (76.7)
N01 - ANESTHETICS	8 (6.2)
N02 - ANALGESICS	90 (69.8)
N03 - ANTIEPILEPTICS	9 (7.0)
N04 - ANTI-PARKINSON DRUGS	1 (0.8)
N05 - PSYCHOLEPTICS	63 (48.8)
N06 - PSYCHOANALEPTICS	19 (14.7)
N07 - OTHER NERVOUS SYSTEM DRUGS	1 (0.8)
R - RESPIRATORY SYSTEM	59 (45.7)
R01 - NASAL PREPARATIONS	6 (4.7)
R02 - THROAT PREPARATIONS	4 (3.1)
R03 - ANTI-ASTHMATICS	15 (11.6)
R05 - COUGH AND COLD PREPARATIONS	20 (15.5)
R06 - ANTIHISTAMINES FOR SYSTEMIC USE	46 (35.7)
S - SENSORY ORGANS	14 (10.9)
S01 - OPHTHALMOLOGICALS	14 (10.9)
S02 - OTOLOGICALS	1 (0.8)
V - VARIOUS	40 (31.0)
V03 - ALL OTHER THERAPEUTIC PRODUCTS	18 (14.0)
V04 - DIAGNOSTIC AGENTS	1 (0.8)
V06 - GENERAL NUTRIENTS	3 (2.3)
V07 - ALL OTHER NON-THERAPEUTIC PRODUCTS	4 (3.1)
V08 - CONTRAST MEDIA	3 (2.3)
V90 - UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	23 (17.8)

Table 14.3.5.5: Treatment Adjustments and Modifications
Full Analysis Set, by Baseline Platelet Group

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients with one dose reduction of 25% to 750 mg/m2	12 (11.4)	4 (16.7)
Cause of the first dose reduction		
Prolonged QTc	2 (1.9)	0 (0.0)
Transaminases increased	2 (1.9)	0 (0.0)
Bronchospasm	1 (1.0)	0 (0.0)
Dyspnea	1 (1.0)	0 (0.0)
Hyperbilirubinemia	1 (1.0)	0 (0.0)
Hypoglycemia	0 (0.0)	1 (4.2)
Hypokalemia	1 (1.0)	0 (0.0)
Immune hemolytic anemia	1 (1.0)	0 (0.0)
Nausea	1 (1.0)	0 (0.0)
Neutropenia	0 (0.0)	1 (4.2)
Pancytopenia	0 (0.0)	1 (4.2)
Pulmonary embolus	1 (1.0)	0 (0.0)
Rash	1 (1.0)	0 (0.0)
Thrombocytopenia	0 (0.0)	1 (4.2)
Patients with two dose reductions of 25% each to 560 mg/m2	1 (1.0)	0 (0.0)
Cause of the second dose reduction		
Prolonged QTc	1 (1.0)	0 (0.0)
Patients with infusion interruption	19 (18.1)	3 (12.5)
Cause of the first infusion interruption		
Extravasation	2 (1.9)	1 (4.2)
Poor venous access	3 (2.9)	0 (0.0)
Vomiting	3 (2.9)	0 (0.0)
Hypersensitivity	1 (1.0)	1 (4.2)
Injection site pain	2 (1.9)	0 (0.0)
Injection site phlebitis	2 (1.9)	0 (0.0)
Nausea	1 (1.0)	1 (4.2)
By error, no adverse event	1 (1.0)	0 (0.0)
Chest discomfort	1 (1.0)	0 (0.0)
Fatigue	1 (1.0)	0 (0.0)
Phlebitis	1 (1.0)	0 (0.0)
Prolonged QTc	1 (1.0)	0 (0.0)

Table 14.3.5.5: Treatment Adjustments and Modifications
Full Analysis Set, by Baseline Platelet Group

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients with a missed dose within a cycle	22 (21.0)	5 (20.8)
Cause of the first missed dose within a cycle		
Holiday	3 (2.9)	0 (0.0)
Disease progression	2 (1.9)	0 (0.0)
Injection site infection	2 (1.9)	0 (0.0)
Patient request	2 (1.9)	0 (0.0)
Prolonged QTc	1 (1.0)	1 (4.2)
Suspected abnormal ECG	2 (1.9)	0 (0.0)
Thrombocytopenia	2 (1.9)	0 (0.0)
Atrial fibrillation	1 (1.0)	0 (0.0)
Creatinine increased	1 (1.0)	0 (0.0)
Death	1 (1.0)	0 (0.0)
Extravasation	0 (0.0)	1 (4.2)
Fever	0 (0.0)	1 (4.2)
Hypoglycemia	0 (0.0)	1 (4.2)
Hypoxia	1 (1.0)	0 (0.0)
Nausea	1 (1.0)	0 (0.0)
Pneumonia	1 (1.0)	0 (0.0)
Septic shock	0 (0.0)	1 (4.2)
Tumour lysis syndrome	1 (1.0)	0 (0.0)
Upper respiratory infection	1 (1.0)	0 (0.0)
Patients with dose delay of 3+ days within a cycle	4 (3.8)	0 (0.0)
Cause of the first dose delay of 3+ days within a cycle		
Pneumonia	2 (1.9)	0 (0.0)
Hyperbilirubinemia	1 (1.0)	0 (0.0)
Transaminases increased	1 (1.0)	0 (0.0)

Table 14.3.5.5: Treatment Adjustments and Modifications
Full Analysis Set, by Baseline Platelet Group

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Patients with cycle delay of 7+ days	31 (29.5)	6 (25.0)
Cause of the first cycle delay of 7+ days		
Holiday	4 (3.8)	1 (4.2)
Fever	1 (1.0)	1 (4.2)
Rash	2 (1.9)	0 (0.0)
Upper respiratory infection	2 (1.9)	0 (0.0)
Alveolitis	1 (1.0)	0 (0.0)
Bronchitis	1 (1.0)	0 (0.0)
Bronchopneumonia	0 (0.0)	1 (4.2)
Congestive heart failure	1 (1.0)	0 (0.0)
Fatigue	1 (1.0)	0 (0.0)
Immune hemolytic anemia	1 (1.0)	0 (0.0)
Malaise	1 (1.0)	0 (0.0)
Pancytopenia	0 (0.0)	1 (4.2)
Patient request	1 (1.0)	0 (0.0)
Pneumonia	1 (1.0)	0 (0.0)
Pulmonary embolus	1 (1.0)	0 (0.0)
Septic shock	1 (1.0)	0 (0.0)
Thrombocytopenia	0 (0.0)	1 (4.2)
Vein access	1 (1.0)	0 (0.0)
Ventricular extrasystoles	1 (1.0)	0 (0.0)
Unknown	10 (9.5)	1 (4.2)

Table 14.3.5.6: Extent of Exposure to Belinostat
by Baseline Platelet Group
Full Analysis Set

Patient Population	Number of Patients (%) Platelet >= 100,000/ul N=105	Platelet < 100,000/ul N=24
Total duration of treatment (wk)		
N	105	24
Mean (SD)	20.2 (27.42)	9.0 (11.44)
Median	9.0	6.0
Range	3 - 135	3 - 55
Number of treatment cycles administered		
N	105	24
Mean (SD)	6.0 (7.34)	2.8 (3.62)
Median	3.0	2.0
Range	1 - 33	1 - 18
Number of belinostat doses administered		
N	105	24
Mean (SD)	29.6 (36.66)	13.8 (18.20)
Median	15.0	10.0
Range	1 - 165	3 - 90
Total cumulative dose of belinostat (g/m2)		
N	105	24
Mean (SD)	28.9 (35.38)	13.5 (18.36)
Median	15.0	9.3
Range	1 - 164	3 - 91
Relative dose intensity (%)		
N	105	24
Mean (SD)	92.36 (13.021)	89.45 (13.825)
Median	97.70	98.50
Range	19.9 - 105.2	54.9 - 102.6

Table 14.3.6.1: Overview of Treatment Emergent Adverse Events

Patient Population	Full Analysis Set N=129	
	n	%
Patients with any treatment emergent AE	125	96.9
Patients with any Grade 1-2 treatment emergent AE	124	96.1
Patients with any Grade 3-4 treatment emergent AE	79	6 1.2
Patients with any Grade 3 treatment emergent AE	75	5 8.1
Patients with any Grade 4 treatment emergent AE	28	2 1.7
Patients with any Grade 5 treatment emergent AE	11	8 .5
Patients with any treatment emergent AE resulting in death within 30 days of last dose	10	7 .8
Patients with any serious AE	61	4 7.3
Patients with serious AE other than death	58	4 5.0
Patients with any AE leading to discontinuation	25	1 9.4
Patients with any serious AE leading to discontinuation	14	1 0.9
Patients with non-serious AE leading to discontinuation	11	8 .5
Patients with any treatment related AE	108	83.7
Patients with any Grade 1-2 treatment related AE	105	81.4
Patients with any Grade 3-4 treatment related AE	44	3 4.1
Patients with any Grade 3 treatment related AE	40	3 1.0
Patients with any Grade 4 treatment related AE	11	8 .5
Patients with any Grade 5 treatment related AE	1	0. 8

Table 14.3.6.1: Overview of Treatment Emergent Adverse Events

Patient Population	Full Analysis Set N=129	
	n	%
Patients with any treatment related AE resulting in death	1	0. 8
Patients with any serious treatment related AE	27	2 0.9
Patients with serious treatment related AE other than death	27	2 0.9
Patients with any treatment related AE leading to discontiuation	14	1 0.9
Patients with serious treatment related AE leading to discontiuation	9	7. 0
Patients with non-serious treatment related AE leading to discontiuation	5	3. 9

Table 14.3.6.2: Treatment Emergent Adverse Events by MedDRA System Organ Class

Full Analysis Set N=129 MedDRA System Organ Class	All Grades n %	Grades 1-2 n %	Grades 3-4 n %	Grade 5 n %
General disorders and administration site conditions	103 79.8	83 64.3	16 12.4	4 3.1
Gastrointestinal disorders	93 72.1	84 65.1	8 6.2	1 0.8
Infections and infestations	64 49.6	39 30.2	23 17.8	2 1.6
Investigations	63 48.8	41 31.8	22 17.1	-
Blood and lymphatic system disorders	62 48.1	29 22.5	33 25.6	-
Metabolism and nutrition disorders	61 47.3	44 34.1	17 13.2	-
Respiratory, thoracic and mediastinal disorders	60 46.5	44 34.1	16 12.4	-
Skin and subcutaneous tissue disorders	56 43.4	47 36.4	9 7.0	-
Vascular disorders	50 38.8	36 27.9	13 10.1	1 0.8
Musculoskeletal and connective tissue disorders	45 34.9	36 27.9	9 7.0	-
Nervous system disorders	45 34.9	42 32.6	3 2.3	-
Psychiatric disorders	29 22.5	25 19.4	4 3.1	-
Injury, poisoning and procedural complications	16 12.4	14 10.9	2 1.6	-
Eye disorders	15 11.6	13 10.1	2 1.6	-
Cardiac disorders	13 10.1	9 7.0	2 1.6	2 1.6
Renal and urinary disorders	13 10.1	11 8.5	2 1.6	-
Neoplasms benign, malignant and unspecified (incl cysts and poly	11 8.5	8 6.2	3 2.3	-
Hepatobiliary disorders	8 6.2	5 3.9	2 1.6	1 0.8

Table 14.3.6.2: Treatment Emergent Adverse Events by MedDRA System Organ Class

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA System Organ Class	n	%	n	%	n	%	n	%
Ear and labyrinth disorders	6	4.7	6	4.7	-		-	
Immune system disorders	3	2.3	2	1.6	1	0.8	-	
Reproductive system and breast disorders	3	2.3	3	2.3	-		-	
Surgical and medical procedures	1	0.8	1	0.8	-		-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Nausea	54	41.9	53	41.1	1	0.8	-	
Fatigue	48	37.2	41	31.8	7	5.4	-	
Pyrexia	45	34.9	42	32.6	3	2.3	-	
Anaemia	41	31.8	27	20.9	14	10.9	-	
Vomiting	37	28.7	36	27.9	1	0.8	-	
Constipation	30	23.3	29	22.5	1	0.8	-	
Diarrhoea	29	22.5	27	20.9	2	1.6	-	
Dyspnoea	28	21.7	20	15.5	8	6.2	-	
Oedema peripheral	26	20.2	26	20.2	-		-	
Rash	26	20.2	25	19.4	1	0.8	-	
Cough	24	18.6	24	18.6	-		-	
Chills	21	16.3	20	15.5	1	0.8	-	
Pruritus	21	16.3	17	13.2	4	3.1	-	
Thrombocytopenia	21	16.3	12	9.3	9	7.0	-	
Blood lactate dehydrogenase increased	20	15.5	18	14.0	2	1.6	-	
Decreased appetite	19	14.7	16	12.4	3	2.3	-	
Headache	19	14.7	19	14.7	-		-	
Infusion site pain	18	14.0	18	14.0	-		-	
Hypokalaemia	16	12.4	11	8.5	5	3.9	-	
Abdominal pain	14	10.9	13	10.1	1	0.8	-	
Electrocardiogram QT prolonged	14	10.9	9	7.0	5	3.9	-	
Dizziness	13	10.1	13	10.1	-		-	
Hypotension	13	10.1	9	7.0	4	3.1	-	
Phlebitis	13	10.1	12	9.3	1	0.8	-	
Asthenia	12	9.3	8	6.2	4	3.1	-	
Hyperglycaemia	12	9.3	9	7.0	3	2.3	-	
Leukopenia	12	9.3	9	7.0	3	2.3	-	
Neutropenia	12	9.3	4	3.1	8	6.2	-	
Pain	12	9.3	10	7.8	2	1.6	-	
Bronchitis	11	8.5	8	6.2	3	2.3	-	
Lymphopenia	11	8.5	5	3.9	6	4.7	-	
Pain in extremity	11	8.5	10	7.8	1	0.8	-	
Hypoalbuminaemia	10	7.8	8	6.2	2	1.6	-	
Neuropathy peripheral	10	7.8	9	7.0	1	0.8	-	
Pneumonia	10	7.8	2	1.6	7	5.4	1	0.8
Upper respiratory tract infection	10	7.8	9	7.0	1	0.8	-	
Aspartate aminotransferase increased	9	7.0	5	3.9	4	3.1	-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Blood creatinine increased	9	7.0	9	7.0		-		-
Flushing	9	7.0	9	7.0		-		-
Insomnia	9	7.0	7	5.4	2	1.6		-
Muscle spasms	9	7.0	8	6.2	1	0.8		-
Platelet count decreased	9	7.0	5	3.9	4	3.1		-
Alanine aminotransferase increased	8	6.2	4	3.1	4	3.1		-
Anxiety	8	6.2	6	4.7	2	1.6		-
Hyperuricaemia	8	6.2	8	6.2		-		-
Night sweats	8	6.2	8	6.2		-		-
Oropharyngeal pain	8	6.2	8	6.2		-		-
Abdominal pain upper	7	5.4	6	4.7	1	0.8		-
Back pain	7	5.4	5	3.9	2	1.6		-
Blood alkaline phosphatase increased	7	5.4	6	4.7	1	0.8		-
Febrile neutropenia	7	5.4	1	0.8	6	4.7		-
Hyperhidrosis	7	5.4	7	5.4		-		-
Hypertension	7	5.4	7	5.4		-		-
Hypomagnesaemia	7	5.4	7	5.4		-		-
Nasopharyngitis	7	5.4	7	5.4		-		-
Sinusitis	7	5.4	6	4.7	1	0.8		-
Weight decreased	7	5.4	7	5.4		-		-
Arthralgia	6	4.7	5	3.9	1	0.8		-
Deep vein thrombosis	6	4.7	2	1.6	4	3.1		-
Depression	6	4.7	5	3.9	1	0.8		-
Infection	6	4.7	2	1.6	4	3.1		-
Chest pain	5	3.9	4	3.1	1	0.8		-
Device related infection	5	3.9	4	3.1	1	0.8		-
Dysgeusia	5	3.9	5	3.9		-		-
Dyspepsia	5	3.9	5	3.9		-		-
Hiccups	5	3.9	5	3.9		-		-
Hypocalcaemia	5	3.9	5	3.9		-		-
Infusion related reaction	5	3.9	5	3.9		-		-
International normalised ratio increased	5	3.9	2	1.6	3	2.3		-
Myalgia	5	3.9	5	3.9		-		-
Nasal congestion	5	3.9	5	3.9		-		-
Oedema	5	3.9	4	3.1	1	0.8		-
Oral candidiasis	5	3.9	5	3.9		-		-
Stomatitis	5	3.9	4	3.1	1	0.8		-

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Urinary tract infection	5	3.9	5	3.9	-		-	
Activated partial thromboplastin time prolonged	4	3.1	3	2.3	1	0.8	-	
Blood bilirubin increased	4	3.1	3	2.3	1	0.8	-	
Dry mouth	4	3.1	3	2.3	1	0.8	-	
Erythema	4	3.1	4	3.1	-		-	
Gastrooesophageal reflux disease	4	3.1	4	3.1	-		-	
Hyperkalaemia	4	3.1	4	3.1	-		-	
Malaise	4	3.1	3	2.3	1	0.8	-	
Mucosal inflammation	4	3.1	4	3.1	-		-	
Musculoskeletal pain	4	3.1	4	3.1	-		-	
Pharyngitis	4	3.1	2	1.6	2	1.6	-	
Staphylococcal infection	4	3.1	2	1.6	2	1.6	-	
Tumour lysis syndrome	4	3.1	2	1.6	2	1.6	-	
Vision blurred	4	3.1	4	3.1	-		-	
Abdominal distension	3	2.3	3	2.3	-		-	
Ascites	3	2.3	2	1.6	1	0.8	-	
Atrial fibrillation	3	2.3	3	2.3	-		-	
Blood potassium decreased	3	2.3	2	1.6	1	0.8	-	
Blood urea increased	3	2.3	3	2.3	-		-	
Bone pain	3	2.3	2	1.6	1	0.8	-	
Cellulitis	3	2.3	2	1.6	1	0.8	-	
Confusional state	3	2.3	3	2.3	-		-	
Dehydration	3	2.3	3	2.3	-		-	
Depressed mood	3	2.3	3	2.3	-		-	
Diabetes mellitus	3	2.3	2	1.6	1	0.8	-	
Extravasation	3	2.3	3	2.3	-		-	
Face oedema	3	2.3	3	2.3	-		-	
Gamma-glutamyltransferase increased	3	2.3	1	0.8	2	1.6	-	
General physical health deterioration	3	2.3	1	0.8	2	1.6	-	
Glomerular filtration rate decreased	3	2.3	3	2.3	-		-	
Herpes simplex	3	2.3	3	2.3	-		-	
Hyperbilirubinaemia	3	2.3	2	1.6	1	0.8	-	
Hypercalcaemia	3	2.3	1	0.8	2	1.6	-	
Hyponatraemia	3	2.3	3	2.3	-		-	
Leukocytosis	3	2.3	2	1.6	1	0.8	-	
Lymphadenopathy	3	2.3	3	2.3	-		-	
Multi-organ failure	3	2.3	-		-		3	2.3

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Pathological fracture	3	2.3	2	1.6	1	0.8	-	
Peripheral sensory neuropathy	3	2.3	2	1.6	1	0.8	-	
Pollakiuria	3	2.3	3	2.3	-		-	
Pulmonary embolism	3	2.3	-		3	2.3	-	
Rash papular	3	2.3	3	2.3	-		-	
Renal impairment	3	2.3	2	1.6	1	0.8	-	
Rhinorrhoea	3	2.3	3	2.3	-		-	
Sepsis	3	2.3	-		3	2.3	-	
Septic shock	3	2.3	1	0.8	2	1.6	-	
Sleep disorder	3	2.3	3	2.3	-		-	
Tumour pain	3	2.3	3	2.3	-		-	
Vein pain	3	2.3	3	2.3	-		-	
White blood cell count decreased	3	2.3	1	0.8	2	1.6	-	
Abdominal discomfort	2	1.6	2	1.6	-		-	
Administration site infection	2	1.6	2	1.6	-		-	
Ageusia	2	1.6	2	1.6	-		-	
Alopecia	2	1.6	2	1.6	-		-	
Atelectasis	2	1.6	2	1.6	-		-	
Blood albumin decreased	2	1.6	2	1.6	-		-	
Blood calcium increased	2	1.6	1	0.8	1	0.8	-	
Blood creatinine	2	1.6	2	1.6	-		-	
Blood glucose increased	2	1.6	2	1.6	-		-	
Blood uric acid increased	2	1.6	2	1.6	-		-	
Body temperature increased	2	1.6	2	1.6	-		-	
Bronchitis chronic	2	1.6	2	1.6	-		-	
Bronchopneumonia	2	1.6	1	0.8	1	0.8	-	
C-reactive protein increased	2	1.6	2	1.6	-		-	
Candidiasis	2	1.6	2	1.6	-		-	
Cardiac failure	2	1.6	-		-		2	1.6
Cytomegalovirus infection	2	1.6	1	0.8	1	0.8	-	
Dry eye	2	1.6	2	1.6	-		-	
Dry skin	2	1.6	2	1.6	-		-	
Dysphagia	2	1.6	2	1.6	-		-	
Dysuria	2	1.6	2	1.6	-		-	
Eastern Cooperative Oncology Group performance status worsened	2	1.6	1	0.8	1	0.8	-	
Eczema	2	1.6	2	1.6	-		-	
Excoriation	2	1.6	2	1.6	-		-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Fall	2	1.6	2	1.6	-		-	
Generalised oedema	2	1.6	2	1.6	-		-	
Groin pain	2	1.6	2	1.6	-		-	
Haematemesis	2	1.6	1	0.8	1	0.8	-	
Haemoglobin decreased	2	1.6	1	0.8	1	0.8	-	
Herpes zoster	2	1.6	1	0.8	1	0.8	-	
Hot flush	2	1.6	2	1.6	-		-	
Hyperlipidaemia	2	1.6	2	1.6	-		-	
Hypersensitivity	2	1.6	2	1.6	-		-	
Hypoaesthesia	2	1.6	2	1.6	-		-	
Hypoxia	2	1.6	-		2	1.6	-	
Infusion site reaction	2	1.6	2	1.6	-		-	
Injection site pain	2	1.6	2	1.6	-		-	
Joint swelling	2	1.6	2	1.6	-		-	
Lung infection	2	1.6	1	0.8	-		1	0.8
Mean cell volume increased	2	1.6	2	1.6	-		-	
Melaena	2	1.6	1	0.8	1	0.8	-	
Muscular weakness	2	1.6	2	1.6	-		-	
Musculoskeletal chest pain	2	1.6	2	1.6	-		-	
Neck pain	2	1.6	-		2	1.6	-	
Neutrophil count decreased	2	1.6	1	0.8	1	0.8	-	
Oral herpes	2	1.6	2	1.6	-		-	
Pain of skin	2	1.6	1	0.8	1	0.8	-	
Pancytopenia	2	1.6	-		2	1.6	-	
Paraesthesia	2	1.6	2	1.6	-		-	
Paraesthesia oral	2	1.6	2	1.6	-		-	
Pleural effusion	2	1.6	2	1.6	-		-	
Prothrombin time prolonged	2	1.6	2	1.6	-		-	
Rash pruritic	2	1.6	2	1.6	-		-	
Renal failure	2	1.6	2	1.6	-		-	
Restlessness	2	1.6	2	1.6	-		-	
Sinus tachycardia	2	1.6	1	0.8	1	0.8	-	
Spinal osteoarthritis	2	1.6	2	1.6	-		-	
Splenomegaly	2	1.6	1	0.8	1	0.8	-	
Tachycardia	2	1.6	2	1.6	-		-	
Thrombophlebitis	2	1.6	2	1.6	-		-	
Thrombosis	2	1.6	1	0.8	1	0.8	-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Tonsillitis	2	1.6	2	1.6		-		-
Tremor	2	1.6	2	1.6		-		-
Tumour associated fever	2	1.6	2	1.6		-		-
Vasculitis	2	1.6	1	0.8	1	0.8		-
Abdominal pain lower	1	0.8	1	0.8		-		-
Acne	1	0.8	1	0.8		-		-
Actinic keratosis	1	0.8		-	1	0.8		-
Acute respiratory distress syndrome	1	0.8		-	1	0.8		-
Aggression	1	0.8	1	0.8		-		-
Allergic transfusion reaction	1	0.8	1	0.8		-		-
Alveolitis	1	0.8		-	1	0.8		-
Amnesia	1	0.8	1	0.8		-		-
Anaemia haemolytic autoimmune	1	0.8		-	1	0.8		-
Anal candidiasis	1	0.8	1	0.8		-		-
Anal fissure	1	0.8	1	0.8		-		-
Anal pruritus	1	0.8	1	0.8		-		-
Anaphylactic reaction	1	0.8		-	1	0.8		-
Aortic aneurysm	1	0.8	1	0.8		-		-
Aphasia	1	0.8		-	1	0.8		-
Arteriosclerosis	1	0.8	1	0.8		-		-
Arthritis	1	0.8	1	0.8		-		-
Axillary pain	1	0.8	1	0.8		-		-
Azotaemia	1	0.8	1	0.8		-		-
Bacterial infection	1	0.8	1	0.8		-		-
Basophilia	1	0.8	1	0.8		-		-
Bile duct stenosis	1	0.8		-	1	0.8		-
Blood bilirubin unconjugated increased	1	0.8	1	0.8		-		-
Blood magnesium decreased	1	0.8	1	0.8		-		-
Blood phosphorus decreased	1	0.8		-	1	0.8		-
Blood phosphorus increased	1	0.8	1	0.8		-		-
Blood potassium increased	1	0.8	1	0.8		-		-
Blood pressure increased	1	0.8	1	0.8		-		-
Blood thyroid stimulating hormone decreased	1	0.8	1	0.8		-		-
Body tinea	1	0.8	1	0.8		-		-
Bowel movement irregularity	1	0.8	1	0.8		-		-
Breast pain	1	0.8	1	0.8		-		-
Bronchitis bacterial	1	0.8	1	0.8		-		-

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Bronchospasm	1	0.8		-	1	0.8		-
Bundle branch block right	1	0.8	1	0.8		-		-
Cardiac failure congestive	1	0.8		-	1	0.8		-
Cardiac murmur	1	0.8	1	0.8		-		-
Cataract	1	0.8	1	0.8		-		-
Central venous catheterisation	1	0.8	1	0.8		-		-
Cerebral ischaemia	1	0.8	1	0.8		-		-
Cheilitis	1	0.8	1	0.8		-		-
Chest discomfort	1	0.8	1	0.8		-		-
Cholangitis	1	0.8		-	1	0.8		-
Cholecystitis	1	0.8		-	1	0.8		-
Cholecystitis acute	1	0.8		-	1	0.8		-
Cholelithiasis	1	0.8	1	0.8		-		-
Chylothorax	1	0.8	1	0.8		-		-
Clostridial infection	1	0.8	1	0.8		-		-
Complications of transplanted liver	1	0.8	1	0.8		-		-
Conjunctivitis	1	0.8	1	0.8		-		-
Convulsion	1	0.8	1	0.8		-		-
Cor pulmonale	1	0.8		-	1	0.8		-
Coronary artery disease	1	0.8	1	0.8		-		-
Crystal arthropathy	1	0.8	1	0.8		-		-
Cystitis	1	0.8	1	0.8		-		-
Deafness unilateral	1	0.8	1	0.8		-		-
Decubitus ulcer	1	0.8		-	1	0.8		-
Defaecation urgency	1	0.8	1	0.8		-		-
Dermatitis contact	1	0.8	1	0.8		-		-
Device occlusion	1	0.8	1	0.8		-		-
Dysphonia	1	0.8	1	0.8		-		-
Ear discomfort	1	0.8	1	0.8		-		-
Ear infection	1	0.8	1	0.8		-		-
Electrocardiogram ST segment depression	1	0.8	1	0.8		-		-
Encephalopathy	1	0.8	1	0.8		-		-
Endocarditis	1	0.8		-	1	0.8		-
Eosinophilia	1	0.8	1	0.8		-		-
Epigastric discomfort	1	0.8	1	0.8		-		-
Epstein-Barr virus infection	1	0.8	1	0.8		-		-
Eructation	1	0.8	1	0.8		-		-

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Escherichia infection	1	0.8	1	0.8	-		-	
Essential hypertension	1	0.8	1	0.8	-		-	
Euthanasia	1	0.8	-		-		1	0.8
Extrapyramidal disorder	1	0.8	1	0.8	-		-	
Extremity necrosis	1	0.8	-		1	0.8	-	
Eye discharge	1	0.8	1	0.8	-		-	
Eye infection	1	0.8	1	0.8	-		-	
Eye infection bacterial	1	0.8	1	0.8	-		-	
Eye pain	1	0.8	1	0.8	-		-	
Eyelid oedema	1	0.8	1	0.8	-		-	
Eyelid ptosis	1	0.8	1	0.8	-		-	
Feeling of body temperature change	1	0.8	1	0.8	-		-	
Flank pain	1	0.8	1	0.8	-		-	
Flatulence	1	0.8	1	0.8	-		-	
Fluid retention	1	0.8	1	0.8	-		-	
Fungaemia	1	0.8	-		1	0.8	-	
Fungal infection	1	0.8	1	0.8	-		-	
Gamma-glutamyltransferase	1	0.8	-		1	0.8	-	
Gastric ulcer	1	0.8	-		1	0.8	-	
Gastritis	1	0.8	1	0.8	-		-	
Gastroenteritis	1	0.8	1	0.8	-		-	
Gastroenteritis viral	1	0.8	1	0.8	-		-	
Gastrointestinal fungal infection	1	0.8	-		1	0.8	-	
Gastrointestinal haemorrhage	1	0.8	-		-		1	0.8
Gastrointestinal obstruction	1	0.8	-		1	0.8	-	
Genital herpes	1	0.8	1	0.8	-		-	
Gingival ulceration	1	0.8	1	0.8	-		-	
Glaucoma	1	0.8	-		1	0.8	-	
Glucose urine present	1	0.8	-		1	0.8	-	
Gout	1	0.8	1	0.8	-		-	
Haematocrit decreased	1	0.8	-		1	0.8	-	
Haemolytic anaemia	1	0.8	-		1	0.8	-	
Haemoptysis	1	0.8	1	0.8	-		-	
Hepatic cirrhosis	1	0.8	1	0.8	-		-	
Hepatic enzyme increased	1	0.8	1	0.8	-		-	
Hepatic failure	1	0.8	-		-		1	0.8
Hepatomegaly	1	0.8	1	0.8	-		-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Hepatosplenomegaly	1	0.8	1	0.8	-		-	
Hypermagnesaemia	1	0.8	1	0.8	-		-	
Hypoacusis	1	0.8	1	0.8	-		-	
Hypoglycaemia	1	0.8	-		1	0.8	-	
Hypophosphataemia	1	0.8	1	0.8	-		-	
Hypotonia	1	0.8	1	0.8	-		-	
Hypovolaemic shock	1	0.8	-		1	0.8	-	
Iliac artery thrombosis	1	0.8	-		1	0.8	-	
Impaired self-care	1	0.8	1	0.8	-		-	
Infusion site cellulitis	1	0.8	1	0.8	-		-	
Infusion site coldness	1	0.8	1	0.8	-		-	
Infusion site extravasation	1	0.8	1	0.8	-		-	
Infusion site inflammation	1	0.8	1	0.8	-		-	
Infusion site thrombosis	1	0.8	1	0.8	-		-	
Injection site induration	1	0.8	1	0.8	-		-	
Injection site inflammation	1	0.8	1	0.8	-		-	
Injection site phlebitis	1	0.8	1	0.8	-		-	
Injection site pruritus	1	0.8	1	0.8	-		-	
Injection site reaction	1	0.8	1	0.8	-		-	
International normalised ratio decreased	1	0.8	1	0.8	-		-	
Keratoacanthoma	1	0.8	1	0.8	-		-	
Keratoconjunctivitis sicca	1	0.8	1	0.8	-		-	
Lacrimation increased	1	0.8	1	0.8	-		-	
Lethargy	1	0.8	1	0.8	-		-	
Lip ulceration	1	0.8	1	0.8	-		-	
Listless	1	0.8	1	0.8	-		-	
Liver function test abnormal	1	0.8	-		1	0.8	-	
Local swelling	1	0.8	1	0.8	-		-	
Lower limb fracture	1	0.8	-		1	0.8	-	
Lung infiltration	1	0.8	1	0.8	-		-	
Lung neoplasm	1	0.8	1	0.8	-		-	
Lung squamous cell carcinoma stage unspecified	1	0.8	-		1	0.8	-	
Lymphocytosis	1	0.8	-		1	0.8	-	
Micturition urgency	1	0.8	1	0.8	-		-	
Monocyte count decreased	1	0.8	1	0.8	-		-	
Mood altered	1	0.8	1	0.8	-		-	
Multiple fractures	1	0.8	-		1	0.8	-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Mycosis fungoides	1	0.8		-	1	0.8		-
Nasal discomfort	1	0.8	1	0.8		-		-
Nasal dryness	1	0.8	1	0.8		-		-
Neoplasm skin	1	0.8	1	0.8		-		-
Obstructive airways disorder	1	0.8	1	0.8		-		-
Odynophagia	1	0.8	1	0.8		-		-
Oesophagitis	1	0.8		-	1	0.8		-
Oliguria	1	0.8	1	0.8		-		-
Opportunistic infection	1	0.8		-	1	0.8		-
Oral fungal infection	1	0.8	1	0.8		-		-
Oropharyngeal discomfort	1	0.8	1	0.8		-		-
Otitis media	1	0.8	1	0.8		-		-
Otorrhoea	1	0.8	1	0.8		-		-
Oxygen saturation decreased	1	0.8	1	0.8		-		-
PCO2 decreased	1	0.8	1	0.8		-		-
Palmar erythema	1	0.8	1	0.8		-		-
Palmar-plantar erythrodysaesthesia syndrome	1	0.8	1	0.8		-		-
Pancreatitis	1	0.8	1	0.8		-		-
Periorbital oedema	1	0.8	1	0.8		-		-
Periostitis	1	0.8	1	0.8		-		-
Peripheral motor neuropathy	1	0.8	1	0.8		-		-
Pharyngeal ulceration	1	0.8	1	0.8		-		-
Pharyngitis bacterial	1	0.8	1	0.8		-		-
Phlebitis superficial	1	0.8	1	0.8		-		-
Pneumonia viral	1	0.8		-	1	0.8		-
Polyneuropathy	1	0.8	1	0.8		-		-
Poor quality sleep	1	0.8	1	0.8		-		-
Procedural pain	1	0.8	1	0.8		-		-
Proctalgia	1	0.8	1	0.8		-		-
Productive cough	1	0.8	1	0.8		-		-
Prostatomegaly	1	0.8	1	0.8		-		-
Protein total decreased	1	0.8	1	0.8		-		-
Prothrombin time shortened	1	0.8		-	1	0.8		-
Pruritus generalised	1	0.8	1	0.8		-		-
Pulmonary mass	1	0.8	1	0.8		-		-
Pulmonary oedema	1	0.8	1	0.8		-		-
Rales	1	0.8	1	0.8		-		-

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Rash macular	1	0.8	1	0.8	-		-	
Rash maculo-papular	1	0.8	1	0.8	-		-	
Red blood cell count decreased	1	0.8	1	0.8	-		-	
Renal failure acute	1	0.8	-		1	0.8	-	
Respiratory alkalosis	1	0.8	-		1	0.8	-	
Respiratory distress	1	0.8	-		1	0.8	-	
Respiratory failure	1	0.8	-		1	0.8	-	
Respiratory syncytial virus infection	1	0.8	1	0.8	-		-	
Respiratory tract infection	1	0.8	1	0.8	-		-	
Restless legs syndrome	1	0.8	1	0.8	-		-	
Retinal vein thrombosis	1	0.8	-		1	0.8	-	
Rhinitis	1	0.8	1	0.8	-		-	
Salivary hypersecretion	1	0.8	1	0.8	-		-	
Shock	1	0.8	-		-		1	0.8
Sinus bradycardia	1	0.8	1	0.8	-		-	
Sinus polyp	1	0.8	1	0.8	-		-	
Skin burning sensation	1	0.8	1	0.8	-		-	
Skin cancer	1	0.8	1	0.8	-		-	
Skin candida	1	0.8	1	0.8	-		-	
Skin exfoliation	1	0.8	1	0.8	-		-	
Skin ulcer	1	0.8	1	0.8	-		-	
Somnolence	1	0.8	1	0.8	-		-	
Spinal fracture	1	0.8	1	0.8	-		-	
Staphylococcal sepsis	1	0.8	1	0.8	-		-	
Staphylococcal skin infection	1	0.8	1	0.8	-		-	
Subcutaneous nodule	1	0.8	-		1	0.8	-	
Supraventricular tachycardia	1	0.8	-		1	0.8	-	
Syncope	1	0.8	1	0.8	-		-	
Tachypnoea	1	0.8	1	0.8	-		-	
Testicular pain	1	0.8	1	0.8	-		-	
Thrombocytosis	1	0.8	1	0.8	-		-	
Thrombophlebitis superficial	1	0.8	1	0.8	-		-	
Thrombosed varicose vein	1	0.8	-		1	0.8	-	
Thrombosis in device	1	0.8	1	0.8	-		-	
Tongue haematoma	1	0.8	1	0.8	-		-	
Tooth fracture	1	0.8	1	0.8	-		-	
Toothache	1	0.8	1	0.8	-		-	

Table 14.3.6.3: Treatment Emergent Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Toxic cataract	1	0.8	1	0.8	-		-	
Tracheostomy malfunction	1	0.8	1	0.8	-		-	
Tumour haemorrhage	1	0.8	-		1	0.8	-	
Tympanic membrane disorder	1	0.8	1	0.8	-		-	
Urinary tract infection bacterial	1	0.8	1	0.8	-		-	
Urinary tract infection staphylococcal	1	0.8	1	0.8	-		-	
Urosepsis	1	0.8	-		1	0.8	-	
Urticaria	1	0.8	1	0.8	-		-	
Venous thrombosis limb	1	0.8	-		1	0.8	-	
Ventricular extrasystoles	1	0.8	1	0.8	-		-	
Vertigo	1	0.8	1	0.8	-		-	
Visual impairment	1	0.8	1	0.8	-		-	
Vitreous haemorrhage	1	0.8	1	0.8	-		-	
Weight increased	1	0.8	1	0.8	-		-	
Wheezing	1	0.8	1	0.8	-		-	
White blood cell count increased	1	0.8	1	0.8	-		-	

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Blood and lymphatic system disorders						
Anaemia	41 (31.8)	7 (5. 4)	20 (15.5)	8 (6. 2)	6 (4. 7)	-
Anaemia haemolytic autoimmune	1 (0. 8)	-	-	1 (0. 8)	-	-
Basophilia	1 (0. 8)	1 (0. 8)	-	-	-	-
Eosinophilia	1 (0. 8)	1 (0. 8)	-	-	-	-
Febrile neutropenia	7 (5. 4)	1 (0. 8)	-	6 (4. 7)	-	-
Haemolytic anaemia	1 (0. 8)	-	-	1 (0. 8)	-	-
Leukocytosis	3 (2. 3)	2 (1. 6)	-	1 (0. 8)	-	-
Leukopenia	12 (9.3)	3 (2. 3)	6 (4. 7)	-	3 (2. 3)	-
Lymphadenopathy	3 (2. 3)	3 (2. 3)	-	-	-	-
Lymphocytosis	1 (0. 8)	-	-	-	1 (0. 8)	-
Lymphopenia	11 (8.5)	1 (0. 8)	4 (3. 1)	5 (3. 9)	1 (0. 8)	-
Neutropenia	12 (9.3)	2 (1. 6)	2 (1. 6)	5 (3. 9)	3 (2. 3)	-
Pancytopenia	2 (1. 6)	-	-	1 (0. 8)	1 (0. 8)	-
Splenomegaly	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Thrombocytopenia	21 (16.3)	7 (5. 4)	5 (3. 9)	-	9 (7. 0)	-
Thrombocytosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Cardiac disorders						
Atrial fibrillation	3 (2. 3)	2 (1. 6)	1 (0. 8)	-	-	-
Bundle branch block right	1 (0. 8)	1 (0. 8)	-	-	-	-
Cardiac failure	2 (1. 6)	-	-	-	-	2 (1. 6)
Cardiac failure congestive	1 (0. 8)	-	-	1 (0. 8)	-	-
Cor pulmonale	1 (0. 8)	-	-	1 (0. 8)	-	-
Coronary artery disease	1 (0. 8)	1 (0. 8)	-	-	-	-
Sinus bradycardia	1 (0. 8)	1 (0. 8)	-	-	-	-
Sinus tachycardia	2 (1. 6)	-	1 (0. 8)	1 (0. 8)	-	-
Supraventricular tachycardia	1 (0. 8)	-	-	1 (0. 8)	-	-
Tachycardia	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Ventricular extrasystoles	1 (0. 8)	1 (0. 8)	-	-	-	-
Ear and labyrinth disorders						
Deafness unilateral	1 (0. 8)	1 (0. 8)	-	-	-	-
Ear discomfort	1 (0. 8)	1 (0. 8)	-	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Hypoacusis	1 (0. 8)	1 (0. 8)	-	-	-	-
Otorrhoea	1 (0. 8)	1 (0. 8)	-	-	-	-
Tympanic membrane disorder	1 (0. 8)	1 (0. 8)	-	-	-	-
Vertigo	1 (0. 8)	1 (0. 8)	-	-	-	-
Eye disorders						
Cataract	1 (0. 8)	1 (0. 8)	-	-	-	-
Conjunctivitis	1 (0. 8)	-	1 (0. 8)	-	-	-
Dry eye	2 (1. 6)	2 (1. 6)	-	-	-	-
Eye discharge	1 (0. 8)	1 (0. 8)	-	-	-	-
Eye pain	1 (0. 8)	1 (0. 8)	-	-	-	-
Eyelid oedema	1 (0. 8)	1 (0. 8)	-	-	-	-
Eyelid ptosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Glaucoma	1 (0. 8)	-	-	1 (0. 8)	-	-
Keratoconjunctivitis sicca	1 (0. 8)	1 (0. 8)	-	-	-	-
Lacrimation increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Periorbital oedema	1 (0. 8)	1 (0. 8)	-	-	-	-
Retinal vein thrombosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Toxic cataract	1 (0. 8)	1 (0. 8)	-	-	-	-
Vision blurred	4 (3. 1)	4 (3. 1)	-	-	-	-
Visual impairment	1 (0. 8)	1 (0. 8)	-	-	-	-
Vitreous haemorrhage	1 (0. 8)	-	1 (0. 8)	-	-	-
Gastrointestinal disorders						
Abdominal discomfort	2 (1. 6)	2 (1. 6)	-	-	-	-
Abdominal distension	3 (2. 3)	3 (2. 3)	-	-	-	-
Abdominal pain	14 (10.9)	4 (3. 1)	9 (7. 0)	1 (0. 8)	-	-
Abdominal pain lower	1 (0. 8)	1 (0. 8)	-	-	-	-
Abdominal pain upper	7 (5. 4)	3 (2. 3)	3 (2. 3)	1 (0. 8)	-	-
Anal fissure	1 (0. 8)	1 (0. 8)	-	-	-	-
Anal pruritus	1 (0. 8)	-	1 (0. 8)	-	-	-
Ascites	3 (2. 3)	-	2 (1. 6)	1 (0. 8)	-	-
Bowel movement irregularity	1 (0. 8)	1 (0. 8)	-	-	-	-
Cheilitis	1 (0. 8)	1 (0. 8)	-	-	-	-
Constipation	30 (23.3)	23 (17.8)	6 (4. 7)	1 (0. 8)	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Defaecation urgency	1 (0. 8)	1 (0. 8)	-	-	-	-
Diarrhoea	29 (22.5)	19 (14.7)	8 (6. 2)	2 (1. 6)	-	-
Dry mouth	4 (3. 1)	3 (2. 3)	-	1 (0. 8)	-	-
Dyspepsia	5 (3. 9)	4 (3. 1)	1 (0. 8)	-	-	-
Dysphagia	2 (1. 6)	-	2 (1. 6)	-	-	-
Epigastric discomfort	1 (0. 8)	-	1 (0. 8)	-	-	-
Eructation	1 (0. 8)	1 (0. 8)	-	-	-	-
Flatulence	1 (0. 8)	1 (0. 8)	-	-	-	-
Gastric ulcer	1 (0. 8)	-	-	1 (0. 8)	-	-
Gastritis	1 (0. 8)	-	1 (0. 8)	-	-	-
Gastrointestinal haemorrhage	1 (0. 8)	-	-	-	-	1 (0. 8)
Gastrointestinal obstruction	1 (0. 8)	-	-	1 (0. 8)	-	-
Gastrooesophageal reflux disease	4 (3. 1)	3 (2. 3)	1 (0. 8)	-	-	-
Gingival ulceration	1 (0. 8)	1 (0. 8)	-	-	-	-
Haematemesis	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Lip ulceration	1 (0. 8)	-	1 (0. 8)	-	-	-
Melaena	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Nausea	54 (41.9)	35 (27.1)	18 (14.0)	1 (0. 8)	-	-
Odynophagia	1 (0. 8)	-	1 (0. 8)	-	-	-
Oesophagitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Pancreatitis	1 (0. 8)	-	1 (0. 8)	-	-	-
Paraesthesia oral	2 (1. 6)	2 (1. 6)	-	-	-	-
Proctalgia	1 (0. 8)	1 (0. 8)	-	-	-	-
Salivary hypersecretion	1 (0. 8)	1 (0. 8)	-	-	-	-
Stomatitis	5 (3. 9)	2 (1. 6)	2 (1. 6)	1 (0. 8)	-	-
Tongue haematoma	1 (0. 8)	1 (0. 8)	-	-	-	-
Toothache	1 (0. 8)	-	1 (0. 8)	-	-	-
Vomiting	37 (28.7)	26 (20.2)	10 (7.8)	1 (0. 8)	-	-
General disorders and administration site conditions						
Asthenia	12 (9.3)	3 (2. 3)	5 (3. 9)	3 (2. 3)	1 (0. 8)	-
Axillary pain	1 (0. 8)	-	1 (0. 8)	-	-	-
Chest discomfort	1 (0. 8)	1 (0. 8)	-	-	-	-
Chest pain	5 (3. 9)	2 (1. 6)	2 (1. 6)	1 (0. 8)	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Chills	21 (16.3)	15 (11.6)	5 (3. 9)	1 (0. 8)	-	-
Device occlusion	1 (0. 8)	1 (0. 8)	-	-	-	-
Euthanasia	1 (0. 8)	-	-	-	-	1 (0. 8)
Extravasation	3 (2. 3)	2 (1. 6)	1 (0. 8)	-	-	-
Face oedema	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Fatigue	48 (37.2)	22 (17.1)	19 (14.7)	7 (5. 4)	-	-
Feeling of body temperature change	1 (0. 8)	-	1 (0. 8)	-	-	-
General physical health deterioration	3 (2. 3)	-	1 (0. 8)	2 (1. 6)	-	-
Generalised oedema	2 (1. 6)	-	2 (1. 6)	-	-	-
Infusion site coldness	1 (0. 8)	1 (0. 8)	-	-	-	-
Infusion site extravasation	1 (0. 8)	-	1 (0. 8)	-	-	-
Infusion site inflammation	1 (0. 8)	-	1 (0. 8)	-	-	-
Infusion site pain	18 (14.0)	9 (7. 0)	9 (7. 0)	-	-	-
Infusion site reaction	2 (1. 6)	2 (1. 6)	-	-	-	-
Infusion site thrombosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Injection site induration	1 (0. 8)	-	1 (0. 8)	-	-	-
Injection site inflammation	1 (0. 8)	-	1 (0.8)	-	-	-
Injection site pain	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Injection site phlebitis	1 (0. 8)	1 (0. 8)	-	-	-	-
Injection site pruritus	1 (0. 8)	1 (0. 8)	-	-	-	-
Injection site reaction	1 (0. 8)	1 (0. 8)	-	-	-	-
Local swelling	1 (0. 8)	1 (0. 8)	-	-	-	-
Malaise	4 (3. 1)	-	3 (2. 3)	1 (0. 8)	-	-
Mucosal inflammation	4 (3. 1)	4 (3. 1)	-	-	-	-
Multi-organ failure	3 (2. 3)	-	-	-	-	3 (2. 3)
Oedema	5 (3. 9)	2 (1. 6)	2 (1. 6)	1 (0. 8)	-	-
Oedema peripheral	26 (20.2)	20 (15.5)	6 (4. 7)	-	-	-
Pain	12 (9.3)	8 (6. 2)	2 (1. 6)	1 (0. 8)	1 (0. 8)	-
Pyrexia	45 (34.9)	25 (19.4)	17 (13.2)	3 (2. 3)	-	-
Thrombosis in device	1 (0. 8)	1 (0. 8)	-	-	-	-
Hepatobiliary disorders						
Bile duct stenosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Cholangitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Cholecystitis	1 (0. 8)	-	-	1 (0. 8)	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Cholecystitis acute	1 (0. 8)	-	-	1 (0. 8)	-	-
Cholelithiasis	1 (0. 8)	1 (0.8)	-	-	-	-
Hepatic cirrhosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Hepatic failure	1 (0. 8)	-	-	-	-	1 (0. 8)
Hepatomegaly	1 (0. 8)	1 (0. 8)	-	-	-	-
Hepatosplenomegaly	1 (0. 8)	1 (0. 8)	-	-	-	-
Hyperbilirubinaemia	3 (2. 3)	2 (1. 6)	-	1 (0. 8)	-	-
Immune system disorders						
Anaphylactic reaction	1 (0. 8)	-	-	-	1 (0. 8)	-
Hypersensitivity	2 (1. 6)	2 (1. 6)	-	-	-	-
Infections and infestations						
Administration site infection	2 (1. 6)	-	2 (1. 6)	-	-	-
Anal candidiasis	1 (0. 8)	-	1 (0. 8)	-	-	-
Bacterial infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Body tinea	1 (0. 8)	1 (0. 8)	-	-	-	-
Bronchitis	11 (8.5)	6 (4. 7)	2 (1. 6)	3 (2. 3)	-	-
Bronchitis bacterial	1 (0. 8)	-	1 (0. 8)	-	-	-
Bronchopneumonia	2 (1. 6)	-	1 (0. 8)	1 (0. 8)	-	-
Candidiasis	2 (1. 6)	-	2 (1. 6)	-	-	-
Cellulitis	3 (2. 3)	-	2 (1. 6)	1 (0. 8)	-	-
Clostridial infection	1 (0. 8)	-	1 (0. 8)	-	-	-
Cystitis	1 (0. 8)	-	1 (0. 8)	-	-	-
Cytomegalovirus infection	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Device related infection	5 (3. 9)	-	4 (3. 1)	1 (0. 8)	-	-
Ear infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Endocarditis	1 (0. 8)	-	-	-	1 (0. 8)	-
Epstein-Barr virus infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Escherichia infection	1 (0. 8)	-	1 (0. 8)	-	-	-
Eye infection	1 (0. 8)	-	1 (0. 8)	-	-	-
Eye infection bacterial	1 (0. 8)	1 (0. 8)	-	-	-	-
Fungaemia	1 (0. 8)	-	-	1 (0. 8)	-	-
Fungal infection	1 (0. 8)	-	1 (0. 8)	-	-	-
Gastroenteritis	1 (0. 8)	1 (0. 8)	-	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Gastroenteritis viral	1 (0. 8)	-	1 (0. 8)	-	-	-
Gastrointestinal fungal infection	1 (0. 8)	-	-	1 (0. 8)	-	-
Genital herpes	1 (0. 8)	-	1 (0. 8)	-	-	-
Herpes simplex	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Herpes zoster	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Infection	6 (4. 7)	1 (0. 8)	1 (0. 8)	3 (2. 3)	1 (0. 8)	-
Infusion site cellulitis	1 (0. 8)	-	1 (0. 8)	-	-	-
Lung infection	2 (1. 6)	-	1 (0. 8)	-	-	1 (0. 8)
Nasopharyngitis	7 (5. 4)	7 (5. 4)	-	-	-	-
Opportunistic infection	1 (0. 8)	-	-	1 (0. 8)	-	-
Oral candidiasis	5 (3. 9)	2 (1. 6)	3 (2. 3)	-	-	-
Oral fungal infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Oral herpes	2 (1. 6)	-	2 (1. 6)	-	-	-
Otitis media	1 (0. 8)	-	1 (0. 8)	-	-	-
Pharyngitis	4 (3. 1)	2 (1. 6)	-	2 (1. 6)	-	-
Pharyngitis bacterial	1 (0. 8)	1 (0. 8)	-	-	-	-
Pneumonia	10 (7.8)	-	2 (1. 6)	7 (5. 4)	-	1 (0. 8)
Pneumonia viral	1 (0. 8)	-	-	1 (0. 8)	-	-
Respiratory syncytial virus infection	1 (0. 8)	-	1 (0. 8)	-	-	-
Respiratory tract infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Rhinitis	1 (0. 8)	-	1 (0. 8)	-	-	-
Sepsis	3 (2. 3)	-	-	3 (2. 3)	-	-
Septic shock	3 (2. 3)	-	1 (0. 8)	-	2 (1. 6)	-
Sinusitis	7 (5. 4)	3 (2. 3)	3 (2. 3)	1 (0. 8)	-	-
Skin candida	1 (0. 8)	-	1 (0. 8)	-	-	-
Staphylococcal infection	4 (3. 1)	1 (0. 8)	1 (0. 8)	2 (1. 6)	-	-
Staphylococcal sepsis	1 (0. 8)	-	1 (0. 8)	-	-	-
Staphylococcal skin infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Tonsillitis	2 (1. 6)	-	2 (1. 6)	-	-	-
Upper respiratory tract infection	10 (7.8)	7 (5. 4)	2 (1. 6)	1 (0. 8)	-	-
Urinary tract infection	5 (3. 9)	-	5 (3. 9)	-	-	-
Urinary tract infection bacterial	1 (0. 8)	-	1 (0. 8)	-	-	-
Urinary tract infection staphylococcal	1 (0. 8)	-	1 (0. 8)	-	-	-
Urosepsis	1 (0. 8)	-	-	1 (0. 8)	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Injury, poisoning and procedural complications						
Allergic transfusion reaction	1 (0. 8)	-	1 (0. 8)	-	-	-
Complications of transplanted liver	1 (0. 8)	1 (0. 8)	-	-	-	-
Excoriation	2 (1. 6)	2 (1. 6)	-	-	-	-
Fall	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Infusion related reaction	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Lower limb fracture	1 (0. 8)	-	-	1 (0. 8)	-	-
Multiple fractures	1 (0. 8)	-	-	1 (0. 8)	-	-
Procedural pain	1 (0. 8)	-	1 (0. 8)	-	-	-
Spinal fracture	1 (0. 8)	1 (0. 8)	-	-	-	-
Tooth fracture	1 (0. 8)	1 (0. 8)	-	-	-	-
Tracheostomy malfunction	1 (0. 8)	1 (0. 8)	-	-	-	-
Investigations						
Activated partial thromboplastin time prolonged	4 (3. 1)	3 (2. 3)	-	1 (0. 8)	-	-
Alanine aminotransferase increased	8 (6. 2)	3 (2. 3)	1 (0. 8)	4 (3. 1)	-	-
Aspartate aminotransferase increased	9 (7. 0)	4 (3. 1)	1 (0. 8)	4 (3. 1)	-	-
Blood albumin decreased	2 (1. 6)	2 (1. 6)	-	-	-	-
Blood alkaline phosphatase increased	7 (5. 4)	4 (3. 1)	2 (1. 6)	1 (0. 8)	-	-
Blood bilirubin increased	4 (3. 1)	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-
Blood bilirubin unconjugated increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood calcium increased	2 (1. 6)	-	1 (0. 8)	-	1 (0. 8)	-
Blood creatinine	2 (1. 6)	2 (1. 6)	-	-	-	-
Blood creatinine increased	9 (7. 0)	2 (1. 6)	7 (5. 4)	-	-	-
Blood glucose increased	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Blood lactate dehydrogenase increased	20 (15.5)	14 (10.9)	4 (3. 1)	1 (0. 8)	1 (0. 8)	-
Blood magnesium decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood phosphorus decreased	1 (0. 8)	-	-	1 (0. 8)	-	-
Blood phosphorus increased	1 (0. 8)	-	1 (0. 8)	-	-	-
Blood potassium decreased	3 (2. 3)	2 (1. 6)	-	-	1 (0. 8)	-
Blood potassium increased	1 (0. 8)	-	1 (0. 8)	-	-	-
Blood pressure increased	1 (0. 8)	-	1 (0. 8)	-	-	-
Blood thyroid stimulating hormone decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood urea increased	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Blood uric acid increased	2 (1. 6)	2 (1. 6)	-	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Body temperature increased	2 (1. 6)	2 (1. 6)	-	-	-	-
C-reactive protein increased	2 (1. 6)	2 (1. 6)	-	-	-	-
Cardiac murmur	1 (0. 8)	1 (0. 8)	-	-	-	-
Eastern Cooperative Oncology Group performance status worsened	2 (1. 6)	1 (0. 8)	-	-	1 (0. 8)	-
Electrocardiogram QT prolonged	14 (10.9)	5 (3. 9)	4 (3. 1)	5 (3. 9)	-	-
Electrocardiogram ST segment depression	1 (0. 8)	1 (0. 8)	-	-	-	-
Gamma-glutamyltransferase	1 (0. 8)	-	-	1 (0. 8)	-	-
Gamma-glutamyltransferase increased	3 (2. 3)	1 (0. 8)	-	1 (0. 8)	1 (0. 8)	-
Glomerular filtration rate decreased	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Glucose urine present	1 (0. 8)	-	-	1 (0. 8)	-	-
Haematocrit decreased	1 (0. 8)	-	-	1 (0. 8)	-	-
Haemoglobin decreased	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Hepatic enzyme increased	1 (0. 8)	-	1 (0. 8)	-	-	-
International normalised ratio decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
International normalised ratio increased	5 (3. 9)	2 (1. 6)	-	3 (2. 3)	-	-
Liver function test abnormal	1 (0. 8)	-	-	1 (0. 8)	-	-
Mean cell volume increased	2 (1. 6)	2 (1. 6)	-	-	-	-
Monocyte count decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
Neutrophil count decreased	2 (1. 6)	-	1 (0. 8)	-	1 (0. 8)	-
Oxygen saturation decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
PCO2 decreased	1 (0. 8)	-	1 (0. 8)	-	-	-
Platelet count decreased	9 (7. 0)	3 (2. 3)	2 (1. 6)	1 (0. 8)	3 (2. 3)	-
Protein total decreased	1 (0. 8)	-	1 (0. 8)	-	-	-
Prothrombin time prolonged	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Prothrombin time shortened	1 (0. 8)	-	-	1 (0. 8)	-	-
Red blood cell count decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
Weight decreased	7 (5. 4)	4 (3. 1)	3 (2. 3)	-	-	-
Weight increased	1 (0. 8)	1 (0. 8)	-	-	-	-
White blood cell count decreased	3 (2. 3)	-	1 (0. 8)	1 (0. 8)	1 (0. 8)	-
White blood cell count increased	1 (0. 8)	-	1 (0. 8)	-	-	-
Metabolism and nutrition disorders						
Decreased appetite	19 (14.7)	13 (10.1)	3 (2. 3)	3 (2. 3)	-	-
Dehydration	3 (2. 3)	-	3 (2. 3)	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Diabetes mellitus	3 (2. 3)	-	2 (1. 6)	1 (0. 8)	-	-
Fluid retention	1 (0. 8)	-	1 (0. 8)	-	-	-
Gout	1 (0. 8)	-	1 (0. 8)	-	-	-
Hypercalcaemia	3 (2. 3)	1 (0. 8)	-	1 (0. 8)	1 (0. 8)	-
Hyperglycaemia	12 (9.3)	6 (4. 7)	3 (2. 3)	3 (2. 3)	-	-
Hyperkalaemia	4 (3. 1)	4 (3. 1)	-	-	-	-
Hyperlipidaemia	2 (1. 6)	2 (1. 6)	-	-	-	-
Hypermagnesaemia	1 (0. 8)	1 (0. 8)	-	-	-	-
Hyperuricaemia	8 (6. 2)	8 (6. 2)	-	-	-	-
Hypoalbuminaemia	10 (7.8)	6 (4. 7)	2 (1. 6)	2 (1. 6)	-	-
Hypocalcaemia	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Hypoglycaemia	1 (0. 8)	-	-	-	1 (0. 8)	-
Hypokalaemia	16 (12.4)	7 (5. 4)	4 (3. 1)	5 (3. 9)	-	-
Hypomagnesaemia	7 (5. 4)	7 (5. 4)	-	-	-	-
Hyponatraemia	3 (2. 3)	3 (2. 3)	-	-	-	-
Hypophosphataemia	1 (0. 8)	-	1 (0. 8)	-	-	-
Tumour lysis syndrome	4 (3. 1)	-	2 (1. 6)	1 (0. 8)	1 (0. 8)	-
Musculoskeletal and connective tissue disorders						
Arthralgia	6 (4. 7)	3 (2. 3)	2 (1. 6)	1 (0. 8)	-	-
Arthritis	1 (0. 8)	1 (0. 8)	-	-	-	-
Back pain	7 (5. 4)	4 (3. 1)	1 (0. 8)	2 (1. 6)	-	-
Bone pain	3 (2. 3)	1 (0. 8)	1 (0. 8)	1 (0. 8)	-	-
Crystal arthropathy	1 (0. 8)	1 (0. 8)	-	-	-	-
Flank pain	1 (0. 8)	-	1 (0. 8)	-	-	-
Groin pain	2 (1. 6)	2 (1. 6)	-	-	-	-
Joint swelling	2 (1. 6)	2 (1. 6)	-	-	-	-
Muscle spasms	9 (7. 0)	5 (3. 9)	3 (2. 3)	1 (0. 8)	-	-
Muscular weakness	2 (1. 6)	2 (1. 6)	-	-	-	-
Musculoskeletal chest pain	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Musculoskeletal pain	4 (3. 1)	2 (1. 6)	2 (1. 6)	-	-	-
Myalgia	5 (3. 9)	4 (3. 1)	1 (0. 8)	-	-	-
Neck pain	2 (1. 6)	-	-	2 (1. 6)	-	-
Pain in extremity	11 (8.5)	4 (3. 1)	6 (4. 7)	1 (0. 8)	-	-
Pathological fracture	3 (2. 3)	1 (0. 8)	1 (0. 8)	-	1 (0. 8)	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Periostitis	1 (0. 8)	1 (0. 8)	-	-	-	-
Spinal osteoarthritis	2 (1. 6)	2 (1. 6)	-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Keratoacanthoma	1 (0. 8)	1 (0. 8)	-	-	-	-
Lung neoplasm	1 (0. 8)	1 (0. 8)	-	-	-	-
Lung squamous cell carcinoma stage unspecified	1 (0. 8)	-	-	-	1 (0. 8)	-
Mycosis fungoides	1 (0. 8)	-	-	1 (0. 8)	-	-
Neoplasm skin	1 (0. 8)	1 (0. 8)	-	-	-	-
Skin cancer	1 (0. 8)	-	1 (0. 8)	-	-	-
Tumour associated fever	2 (1. 6)	-	2 (1. 6)	-	-	-
Tumour haemorrhage	1 (0. 8)	-	-	1 (0. 8)	-	-
Tumour pain	3 (2. 3)	2 (1. 6)	1 (0. 8)	-	-	-
Nervous system disorders						
Ageusia	2 (1. 6)	2 (1. 6)	-	-	-	-
Amnesia	1 (0. 8)	1 (0. 8)	-	-	-	-
Aphasia	1 (0. 8)	-	-	1 (0. 8)	-	-
Cerebral ischaemia	1 (0. 8)	-	1 (0. 8)	-	-	-
Convulsion	1 (0. 8)	-	1 (0. 8)	-	-	-
Dizziness	13 (10.1)	10 (7.8)	3 (2. 3)	-	-	-
Dysgeusia	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Encephalopathy	1 (0. 8)	1 (0. 8)	-	-	-	-
Extrapyramidal disorder	1 (0. 8)	-	1 (0. 8)	-	-	-
Headache	19 (14.7)	15 (11.6)	4 (3. 1)	-	-	-
Hypoaesthesia	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Hypotonia	1 (0. 8)	1 (0. 8)	-	-	-	-
Lethargy	1 (0. 8)	1 (0. 8)	-	-	-	-
Neuropathy peripheral	10 (7.8)	8 (6. 2)	1 (0. 8)	1 (0. 8)	-	-
Paraesthesia	2 (1. 6)	2 (1. 6)	-	-	-	-
Peripheral motor neuropathy	1 (0. 8)	1 (0. 8)	-	-	-	-
Peripheral sensory neuropathy	3 (2. 3)	2 (1. 6)	-	1 (0. 8)	-	-
Polyneuropathy	1 (0. 8)	1 (0. 8)	-	-	-	-
Poor quality sleep	1 (0. 8)	-	1 (0. 8)	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Restless legs syndrome	1 (0. 8)	1 (0. 8)	-	-	-	-
Somnolence	1 (0. 8)	1 (0. 8)	-	-	-	-
Syncope	1 (0. 8)	1 (0. 8)	-	-	-	-
Tremor	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Psychiatric disorders						
Aggression	1 (0. 8)	-	1 (0. 8)	-	-	-
Anxiety	8 (6. 2)	3 (2. 3)	3 (2. 3)	2 (1. 6)	-	-
Confusional state	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Depressed mood	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Depression	6 (4. 7)	-	5 (3. 9)	1 (0. 8)	-	-
Impaired self-care	1 (0. 8)	-	1 (0. 8)	-	-	-
Insomnia	9 (7. 0)	4 (3. 1)	3 (2. 3)	1 (0. 8)	1 (0. 8)	-
Listless	1 (0. 8)	1 (0. 8)	-	-	-	-
Mood altered	1 (0. 8)	-	1 (0. 8)	-	-	-
Restlessness	2 (1. 6)	2 (1. 6)	-	-	-	-
Sleep disorder	3 (2. 3)	3 (2. 3)	-	-	-	-
Renal and urinary disorders						
Azotaemia	1 (0. 8)	1 (0. 8)	-	-	-	-
Dysuria	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Micturition urgency	1 (0. 8)	1 (0. 8)	-	-	-	-
Oliguria	1 (0. 8)	-	1 (0. 8)	-	-	-
Pollakiuria	3 (2. 3)	2 (1. 6)	1 (0. 8)	-	-	-
Renal failure	2 (1. 6)	-	2 (1. 6)	-	-	-
Renal failure acute	1 (0. 8)	-	-	1 (0. 8)	-	-
Renal impairment	3 (2. 3)	2 (1. 6)	-	1 (0. 8)	-	-
Reproductive system and breast disorders						
Breast pain	1 (0. 8)	-	1 (0. 8)	-	-	-
Prostatomegaly	1 (0. 8)	1 (0. 8)	-	-	-	-
Testicular pain	1 (0. 8)	-	1 (0. 8)	-	-	-
Respiratory, thoracic and mediastinal disorders						
Acute respiratory distress syndrome	1 (0. 8)	-	-	1 (0. 8)	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Alveolitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Atelectasis	2 (1. 6)	2 (1. 6)	-	-	-	-
Bronchitis chronic	2 (1. 6)	2 (1. 6)	-	-	-	-
Bronchospasm	1 (0. 8)	-	-	1 (0. 8)	-	-
Chylothorax	1 (0. 8)	-	1 (0. 8)	-	-	-
Cough	24 (18.6)	17 (13.2)	7 (5. 4)	-	-	-
Dysphonia	1 (0. 8)	1 (0. 8)	-	-	-	-
Dyspnoea	28 (21.7)	12 (9.3)	8 (6. 2)	8 (6. 2)	-	-
Haemoptysis	1 (0. 8)	1 (0. 8)	-	-	-	-
Hiccups	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Hypoxia	2 (1. 6)	-	-	2 (1. 6)	-	-
Lung infiltration	1 (0. 8)	1 (0. 8)	-	-	-	-
Nasal congestion	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Nasal discomfort	1 (0. 8)	1 (0. 8)	-	-	-	-
Nasal dryness	1 (0. 8)	1 (0. 8)	-	-	-	-
Obstructive airways disorder	1 (0. 8)	-	1 (0. 8)	-	-	-
Oropharyngeal discomfort	1 (0. 8)	1 (0. 8)	-	-	-	-
Oropharyngeal pain	8 (6. 2)	6 (4. 7)	2 (1. 6)	-	-	-
Pharyngeal ulceration	1 (0. 8)	1 (0. 8)	-	-	-	-
Pleural effusion	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Productive cough	1 (0. 8)	-	1 (0. 8)	-	-	-
Pulmonary embolism	3 (2. 3)	-	-	1 (0. 8)	2 (1. 6)	-
Pulmonary mass	1 (0. 8)	-	1 (0. 8)	-	-	-
Pulmonary oedema	1 (0. 8)	-	1 (0. 8)	-	-	-
Rales	1 (0. 8)	1 (0. 8)	-	-	-	-
Respiratory alkalosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Respiratory distress	1 (0. 8)	-	-	1 (0. 8)	-	-
Respiratory failure	1 (0. 8)	-	-	-	1 (0. 8)	-
Rhinorrhoea	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Sinus polyp	1 (0. 8)	1 (0. 8)	-	-	-	-
Tachypnoea	1 (0. 8)	-	1 (0. 8)	-	-	-
Wheezing	1 (0. 8)	1 (0. 8)	-	-	-	-
Skin and subcutaneous tissue disorders						
Acne	1 (0. 8)	1 (0. 8)	-	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Actinic keratosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Alopecia	2 (1. 6)	2 (1. 6)	-	-	-	-
Decubitus ulcer	1 (0. 8)	-	-	1 (0. 8)	-	-
Dermatitis contact	1 (0. 8)	1 (0. 8)	-	-	-	-
Dry skin	2 (1. 6)	2 (1. 6)	-	-	-	-
Eczema	2 (1. 6)	2 (1. 6)	-	-	-	-
Erythema	4 (3. 1)	2 (1. 6)	2 (1. 6)	-	-	-
Hyperhidrosis	7 (5. 4)	2 (1. 6)	5 (3. 9)	-	-	-
Night sweats	8 (6. 2)	6 (4. 7)	2 (1. 6)	-	-	-
Pain of skin	2 (1. 6)	-	1 (0. 8)	-	1 (0. 8)	-
Palmar erythema	1 (0. 8)	1 (0. 8)	-	-	-	-
Palmar-plantar erythrodysaesthesia syndrome	1 (0. 8)	1 (0. 8)	-	-	-	-
Pruritus	21 (16.3)	10 (7.8)	7 (5. 4)	3 (2. 3)	1 (0. 8)	-
Pruritus generalised	1 (0. 8)	1 (0. 8)	-	-	-	-
Rash	26 (20.2)	17 (13.2)	8 (6. 2)	1 (0. 8)	-	-
Rash macular	1 (0. 8)	1 (0. 8)	-	-	-	-
Rash maculo-papular	1 (0. 8)	-	1 (0. 8)	-	-	-
Rash papular	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Rash pruritic	2 (1. 6)	2 (1. 6)	-	-	-	-
Skin burning sensation	1 (0. 8)	1 (0. 8)	-	-	-	-
Skin exfoliation	1 (0. 8)	1 (0. 8)	-	-	-	-
Skin ulcer	1 (0. 8)	-	1 (0. 8)	-	-	-
Subcutaneous nodule	1 (0. 8)	-	-	1 (0. 8)	-	-
Urticaria	1 (0. 8)	1 (0. 8)	-	-	-	-
Surgical and medical procedures						
Central venous catheterisation	1 (0. 8)	1 (0. 8)	-	-	-	-
Vascular disorders						
Aortic aneurysm	1 (0. 8)	1 (0. 8)	-	-	-	-
Arteriosclerosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Deep vein thrombosis	6 (4. 7)	-	2 (1. 6)	4 (3. 1)	-	-
Essential hypertension	1 (0. 8)	-	1 (0. 8)	-	-	-
Extremity necrosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Flushing	9 (7. 0)	7 (5. 4)	2 (1. 6)	-	-	-

Table 14.3.6.4: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient					
	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Hot flush	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Hypertension	7 (5. 4)	5 (3. 9)	2 (1. 6)	-	-	-
Hypotension	13 (10.1)	4 (3. 1)	5 (3. 9)	3 (2. 3)	1 (0. 8)	-
Hypovolaemic shock	1 (0. 8)	-	-	-	1 (0. 8)	-
Iliac artery thrombosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Phlebitis	13 (10.1)	2 (1. 6)	10 (7.8)	1 (0. 8)	-	-
Phlebitis superficial	1 (0. 8)	1 (0. 8)	-	-	-	-
Shock	1 (0. 8)	-	-	-	-	1 (0. 8)
Thrombophlebitis	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Thrombophlebitis superficial	1 (0. 8)	1 (0. 8)	-	-	-	-
Thrombosed varicose vein	1 (0. 8)	-	-	1 (0. 8)	-	-
Thrombosis	2 (1. 6)	-	1 (0. 8)	1 (0. 8)	-	-
Vasculitis	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Vein pain	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Venous thrombosis limb	1 (0. 8)	-	-	1 (0. 8)	-	-

Table 14.3.6.5: Treatment Related Adverse Events by MedDRA System Organ Class

Full Analysis Set N=129 MedDRA System Organ Class	All Grades n %	Grades 1-2 n %	Grades 3-4 n %	Grade 5 n %
Gastrointestinal disorders	70 5 4.3	65 5 0.4	5 3. 9	-
General disorders and administration site conditions	63 4 8.8	56 4 3.4	7 5. 4	-
Blood and lymphatic system disorders	35 2 7.1	16 1 2.4	19 1 4.7	-
Investigations	33 2 5.6	22 1 7.1	11 8. 5	-
Vascular disorders	30 2 3.3	25 1 9.4	5 3. 9	-
Nervous system disorders	23 1 7.8	22 1 7.1	1 0. 8	-
Skin and subcutaneous tissue disorders	22 1 7.1	22 1 7.1	-	-
Infections and infestations	19 1 4.7	10 7. 8	9 7. 0	-
Metabolism and nutrition disorders	18 1 4.0	12 9. 3	6 4. 7	-
Respiratory, thoracic and mediastinal disorders	16 1 2.4	10 7. 8	6 4. 7	-
Musculoskeletal and connective tissue disorders	12 9. 3	10 7. 8	2 1. 6	-
Eye disorders	6 4. 7	6 4. 7	-	-
Injury, poisoning and procedural complications	6 4. 7	6 4. 7	-	-
Renal and urinary disorders	5 3. 9	4 3. 1	1 0. 8	-
Cardiac disorders	3 2. 3	3 2. 3	-	-
Psychiatric disorders	3 2. 3	2 1. 6	1 0. 8	-
Hepatobiliary disorders	1 0. 8	-	-	1 0. 8
Immune system disorders	1 0. 8	1 0. 8	-	-

Table 14.3.6.5: Treatment Related Adverse Events by MedDRA System Organ Class

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA System Organ Class	n	%	n	%	n	%	n	%
Reproductive system and breast disorders	1	0.8	1	0.8	-		-	

Table 14.3.6.6: Treatment Related Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Nausea	49	38.0	48	37.2	1	0.8	-	
Fatigue	37	28.7	33	25.6	4	3.1	-	
Vomiting	31	24.0	31	24.0	-		-	
Diarrhoea	18	14.0	17	13.2	1	0.8	-	
Anaemia	16	12.4	9	7.0	7	5.4	-	
Infusion site pain	16	12.4	16	12.4	-		-	
Thrombocytopenia	14	10.9	8	6.2	6	4.7	-	
Electrocardiogram QT prolonged	13	10.1	8	6.2	5	3.9	-	
Pyrexia	13	10.1	13	10.1	-		-	
Phlebitis	11	8.5	10	7.8	1	0.8	-	
Rash	11	8.5	11	8.5	-		-	
Chills	9	7.0	9	7.0	-		-	
Constipation	9	7.0	8	6.2	1	0.8	-	
Decreased appetite	9	7.0	7	5.4	2	1.6	-	
Flushing	9	7.0	9	7.0	-		-	
Dizziness	8	6.2	8	6.2	-		-	
Dyspnoea	8	6.2	6	4.7	2	1.6	-	
Leukopenia	7	5.4	4	3.1	3	2.3	-	
Neutropenia	7	5.4	1	0.8	6	4.7	-	
Headache	6	4.7	6	4.7	-		-	
Alanine aminotransferase increased	5	3.9	2	1.6	3	2.3	-	
Aspartate aminotransferase increased	5	3.9	2	1.6	3	2.3	-	
Blood creatinine increased	5	3.9	5	3.9	-		-	
Dysgeusia	5	3.9	5	3.9	-		-	
Hypokalaemia	5	3.9	3	2.3	2	1.6	-	
Infusion related reaction	5	3.9	5	3.9	-		-	
Pruritus	5	3.9	5	3.9	-		-	
Abdominal pain	4	3.1	3	2.3	1	0.8	-	
Asthenia	4	3.1	3	2.3	1	0.8	-	
Febrile neutropenia	4	3.1	-		4	3.1	-	
Hypotension	4	3.1	3	2.3	1	0.8	-	
Lymphopenia	4	3.1	1	0.8	3	2.3	-	
Pain	4	3.1	3	2.3	1	0.8	-	
Pain in extremity	4	3.1	3	2.3	1	0.8	-	
Vision blurred	4	3.1	4	3.1	-		-	
Weight decreased	4	3.1	4	3.1	-		-	
Abdominal pain upper	3	2.3	2	1.6	1	0.8	-	

Table 14.3.6.6: Treatment Related Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Cellulitis	3	2.3	2	1.6	1	0.8	-	
Cough	3	2.3	3	2.3	-		-	
Dyspepsia	3	2.3	3	2.3	-		-	
Hyperhidrosis	3	2.3	3	2.3	-		-	
Myalgia	3	2.3	3	2.3	-		-	
Oedema peripheral	3	2.3	3	2.3	-		-	
Platelet count decreased	3	2.3	2	1.6	1	0.8	-	
Pneumonia	3	2.3	1	0.8	2	1.6	-	
Stomatitis	3	2.3	2	1.6	1	0.8	-	
Upper respiratory tract infection	3	2.3	2	1.6	1	0.8	-	
Vein pain	3	2.3	3	2.3	-		-	
Alopecia	2	1.6	2	1.6	-		-	
Bone pain	2	1.6	1	0.8	1	0.8	-	
Deep vein thrombosis	2	1.6	1	0.8	1	0.8	-	
Dry mouth	2	1.6	2	1.6	-		-	
Extravasation	2	1.6	2	1.6	-		-	
Gamma-glutamyltransferase increased	2	1.6	-		2	1.6	-	
Herpes simplex	2	1.6	2	1.6	-		-	
Hiccups	2	1.6	2	1.6	-		-	
Hyperglycaemia	2	1.6	2	1.6	-		-	
Infection	2	1.6	-		2	1.6	-	
Infusion site reaction	2	1.6	2	1.6	-		-	
Injection site pain	2	1.6	2	1.6	-		-	
International normalised ratio increased	2	1.6	-		2	1.6	-	
Mucosal inflammation	2	1.6	2	1.6	-		-	
Neuropathy peripheral	2	1.6	1	0.8	1	0.8	-	
Neutrophil count decreased	2	1.6	1	0.8	1	0.8	-	
Pollakiuria	2	1.6	2	1.6	-		-	
Tumour lysis syndrome	2	1.6	1	0.8	1	0.8	-	
Abdominal discomfort	1	0.8	1	0.8	-		-	
Abdominal distension	1	0.8	1	0.8	-		-	
Administration site infection	1	0.8	1	0.8	-		-	
Ageusia	1	0.8	1	0.8	-		-	
Alveolitis	1	0.8	-		1	0.8	-	
Amnesia	1	0.8	1	0.8	-		-	
Anxiety	1	0.8	-		1	0.8	-	
Atrial fibrillation	1	0.8	1	0.8	-		-	

Table 14.3.6.6: Treatment Related Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Azotaemia	1	0.8	1	0.8	-		-	
Back pain	1	0.8	1	0.8	-		-	
Blood alkaline phosphatase increased	1	0.8	1	0.8	-		-	
Blood bilirubin increased	1	0.8	1	0.8	-		-	
Blood glucose increased	1	0.8	1	0.8	-		-	
Blood lactate dehydrogenase increased	1	0.8	1	0.8	-		-	
Blood potassium decreased	1	0.8	1	0.8	-		-	
Blood urea increased	1	0.8	1	0.8	-		-	
Bronchitis	1	0.8	-		1	0.8	-	
Bronchitis bacterial	1	0.8	1	0.8	-		-	
Bronchospasm	1	0.8	-		1	0.8	-	
Bundle branch block right	1	0.8	1	0.8	-		-	
C-reactive protein increased	1	0.8	1	0.8	-		-	
Chest pain	1	0.8	1	0.8	-		-	
Confusional state	1	0.8	1	0.8	-		-	
Defaecation urgency	1	0.8	1	0.8	-		-	
Dehydration	1	0.8	1	0.8	-		-	
Dry eye	1	0.8	1	0.8	-		-	
Dry skin	1	0.8	1	0.8	-		-	
Dysphagia	1	0.8	1	0.8	-		-	
Electrocardiogram ST segment depression	1	0.8	1	0.8	-		-	
Encephalopathy	1	0.8	1	0.8	-		-	
Epigastric discomfort	1	0.8	1	0.8	-		-	
Eructation	1	0.8	1	0.8	-		-	
Erythema	1	0.8	1	0.8	-		-	
Essential hypertension	1	0.8	1	0.8	-		-	
Extremity necrosis	1	0.8	-		1	0.8	-	
Face oedema	1	0.8	1	0.8	-		-	
Feeling of body temperature change	1	0.8	1	0.8	-		-	
Gastroenteritis viral	1	0.8	1	0.8	-		-	
General physical health deterioration	1	0.8	-		1	0.8	-	
Glomerular filtration rate decreased	1	0.8	1	0.8	-		-	
Haemolytic anaemia	1	0.8	-		1	0.8	-	
Hepatic cirrhosis	1	0.8	1	0.8	-		-	
Hepatic failure	1	0.8	-		-		1	0.8
Herpes zoster	1	0.8	-		1	0.8	-	
Hypercalcaemia	1	0.8	-		1	0.8	-	

Table 14.3.6.6: Treatment Related Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Hyperkalaemia	1	0.8	1	0.8	-		-	
Hypersensitivity	1	0.8	1	0.8	-		-	
Hyperuricaemia	1	0.8	1	0.8	-		-	
Hypoaesthesia	1	0.8	1	0.8	-		-	
Hypotonia	1	0.8	1	0.8	-		-	
Hypoxia	1	0.8	-		1	0.8	-	
Infusion site cellulitis	1	0.8	1	0.8	-		-	
Infusion site coldness	1	0.8	1	0.8	-		-	
Infusion site extravasation	1	0.8	1	0.8	-		-	
Infusion site inflammation	1	0.8	1	0.8	-		-	
Injection site induration	1	0.8	1	0.8	-		-	
Injection site inflammation	1	0.8	1	0.8	-		-	
Injection site phlebitis	1	0.8	1	0.8	-		-	
Injection site pruritus	1	0.8	1	0.8	-		-	
Insomnia	1	0.8	1	0.8	-		-	
Keratoconjunctivitis sicca	1	0.8	1	0.8	-		-	
Lacrimation increased	1	0.8	1	0.8	-		-	
Lethargy	1	0.8	1	0.8	-		-	
Liver function test abnormal	1	0.8	-		1	0.8	-	
Lymphadenopathy	1	0.8	1	0.8	-		-	
Malaise	1	0.8	1	0.8	-		-	
Mean cell volume increased	1	0.8	1	0.8	-		-	
Micturition urgency	1	0.8	1	0.8	-		-	
Muscle spasms	1	0.8	1	0.8	-		-	
Musculoskeletal pain	1	0.8	1	0.8	-		-	
Nasal congestion	1	0.8	1	0.8	-		-	
Night sweats	1	0.8	1	0.8	-		-	
Oedema	1	0.8	1	0.8	-		-	
Oesophagitis	1	0.8	-		1	0.8	-	
Opportunistic infection	1	0.8	-		1	0.8	-	
Oral candidiasis	1	0.8	1	0.8	-		-	
Oral fungal infection	1	0.8	1	0.8	-		-	
Oral herpes	1	0.8	1	0.8	-		-	
Palmar erythema	1	0.8	1	0.8	-		-	
Palmar-plantar erythrodysaesthesia syndrome	1	0.8	1	0.8	-		-	
Pancytopenia	1	0.8	-		1	0.8	-	
Paraesthesia	1	0.8	1	0.8	-		-	

Table 14.3.6.6: Treatment Related Adverse Events by MedDRA Preferred Term

Full Analysis Set N=129	All Grades		Grades 1-2		Grades 3-4		Grade 5	
MedDRA Preferred Term	n	%	n	%	n	%	n	%
Paraesthesia oral	1	0.8	1	0.8	-		-	
Pharyngeal ulceration	1	0.8	1	0.8	-		-	
Pharyngitis bacterial	1	0.8	1	0.8	-		-	
Pneumonia viral	1	0.8	-		1	0.8	-	
Prothrombin time shortened	1	0.8	-		1	0.8	-	
Pulmonary embolism	1	0.8	-		1	0.8	-	
Pulmonary mass	1	0.8	1	0.8	-		-	
Rash macular	1	0.8	1	0.8	-		-	
Rash papular	1	0.8	1	0.8	-		-	
Renal impairment	1	0.8	-		1	0.8	-	
Rhinorrhoea	1	0.8	1	0.8	-		-	
Salivary hypersecretion	1	0.8	1	0.8	-		-	
Sepsis	1	0.8	-		1	0.8	-	
Septic shock	1	0.8	-		1	0.8	-	
Skin candida	1	0.8	1	0.8	-		-	
Staphylococcal sepsis	1	0.8	1	0.8	-		-	
Testicular pain	1	0.8	1	0.8	-		-	
Thrombocytosis	1	0.8	1	0.8	-		-	
Thrombosed varicose vein	1	0.8	-		1	0.8	-	
Thrombosis in device	1	0.8	1	0.8	-		-	
Tonsillitis	1	0.8	1	0.8	-		-	
Toxic cataract	1	0.8	1	0.8	-		-	
Tracheostomy malfunction	1	0.8	1	0.8	-		-	
Urinary tract infection staphylococcal	1	0.8	1	0.8	-		-	
Urticaria	1	0.8	1	0.8	-		-	
Vasculitis	1	0.8	-		1	0.8	-	
Venous thrombosis limb	1	0.8	-		1	0.8	-	
Ventricular extrasystoles	1	0.8	1	0.8	-		-	
White blood cell count decreased	1	0.8	1	0.8	-		-	

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Blood and lymphatic system disorders						
Anaemia	16 (12.4)	2 (1. 6)	7 (5. 4)	5 (3. 9)	2 (1. 6)	-
Febrile neutropenia	4 (3. 1)	-	-	4 (3. 1)	-	-
Haemolytic anaemia	1 (0. 8)	-	-	1 (0. 8)	-	-
Leukopenia	7 (5. 4)	1 (0. 8)	3 (2. 3)	-	3 (2. 3)	-
Lymphadenopathy	1 (0. 8)	1 (0. 8)	-	-	-	-
Lymphopenia	4 (3. 1)	-	1 (0. 8)	3 (2. 3)	-	-
Neutropenia	7 (5. 4)	-	1 (0. 8)	4 (3. 1)	2 (1. 6)	-
Pancytopenia	1 (0. 8)	-	-	-	1 (0. 8)	-
Thrombocytopenia	14 (10.9)	4 (3. 1)	4 (3. 1)	-	6 (4. 7)	-
Thrombocytosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Cardiac disorders						
Atrial fibrillation	1 (0. 8)	1 (0. 8)	-	-	-	-
Bundle branch block right	1 (0. 8)	1 (0. 8)	-	-	-	-
Ventricular extrasystoles	1 (0. 8)	1 (0. 8)	-	-	-	-
Eye disorders						
Dry eye	1 (0. 8)	1 (0. 8)	-	-	-	-
Keratoconjunctivitis sicca	1 (0. 8)	1 (0. 8)	-	-	-	-
Lacrimation increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Toxic cataract	1 (0. 8)	1 (0. 8)	-	-	-	-
Vision blurred	4 (3. 1)	4 (3. 1)	-	-	-	-
Gastrointestinal disorders						
Abdominal discomfort	1 (0. 8)	1 (0. 8)	-	-	-	-
Abdominal distension	1 (0. 8)	1 (0. 8)	-	-	-	-
Abdominal pain	4 (3. 1)	-	3 (2. 3)	1 (0. 8)	-	-
Abdominal pain upper	3 (2. 3)	1 (0. 8)	1 (0. 8)	1 (0. 8)	-	-
Constipation	9 (7. 0)	7 (5. 4)	1 (0. 8)	1 (0. 8)	-	-
Defaecation urgency	1 (0. 8)	1 (0. 8)	-	-	-	-
Diarrhoea	18 (14.0)	12 (9.3)	5 (3. 9)	1 (0. 8)	-	-
Dry mouth	2 (1. 6)	2 (1. 6)	-	-	-	-
Dyspepsia	3 (2. 3)	3 (2. 3)	-	-	-	-

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Dysphagia	1 (0. 8)	1 (0. 8)	-	-	-	-
Epigastric discomfort	1 (0. 8)	-	1 (0. 8)	-	-	-
Eructation	1 (0. 8)	1 (0. 8)	-	-	-	-
Nausea	49 (38.0)	31 (24.0)	17 (13.2)	1 (0. 8)	-	-
Oesophagitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Paraesthesia oral	1 (0. 8)	1 (0. 8)	-	-	-	-
Salivary hypersecretion	1 (0. 8)	1 (0. 8)	-	-	-	-
Stomatitis	3 (2. 3)	1 (0. 8)	1 (0. 8)	1 (0. 8)	-	-
Vomiting	31 (24.0)	21 (16.3)	10 (7.8)	-	-	-
General disorders and administration site conditions						
Asthenia	4 (3. 1)	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-
Chest pain	1 (0. 8)	1 (0. 8)	-	-	-	-
Chills	9 (7. 0)	6 (4. 7)	3 (2. 3)	-	-	-
Extravasation	2 (1. 6)	2 (1. 6)	-	-	-	-
Face oedema	1 (0. 8)	-	1 (0. 8)	-	-	-
Fatigue	37 (28.7)	17 (13.2)	16 (12.4)	4 (3. 1)	-	-
Feeling of body temperature change	1 (0. 8)	-	1 (0. 8)	-	-	-
General physical health deterioration	1 (0. 8)	-	-	1 (0. 8)	-	-
Infusion site coldness	1 (0. 8)	1 (0. 8)	-	-	-	-
Infusion site extravasation	1 (0. 8)	-	1 (0. 8)	-	-	-
Infusion site inflammation	1 (0. 8)	-	1 (0. 8)	-	-	-
Infusion site pain	16 (12.4)	7 (5. 4)	9 (7. 0)	-	-	-
Infusion site reaction	2 (1. 6)	2 (1. 6)	-	-	-	-
Injection site induration	1 (0. 8)	-	1 (0. 8)	-	-	-
Injection site inflammation	1 (0. 8)	-	1 (0. 8)	-	-	-
Injection site pain	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Injection site phlebitis	1 (0. 8)	1 (0. 8)	-	-	-	-
Injection site pruritus	1 (0. 8)	1 (0. 8)	-	-	-	-
Malaise	1 (0. 8)	-	1 (0. 8)	-	-	-
Mucosal inflammation	2 (1. 6)	2 (1. 6)	-	-	-	-
Oedema	1 (0. 8)	-	1 (0. 8)	-	-	-
Oedema peripheral	3 (2. 3)	3 (2. 3)	-	-	-	-
Pain	4 (3. 1)	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Pyrexia	13 (10.1)	7 (5. 4)	6 (4. 7)	-	-	-
Thrombosis in device	1 (0. 8)	1 (0. 8)	-	-	-	-
Hepatobiliary disorders						
Hepatic cirrhosis	1 (0. 8)	1 (0. 8)	-	-	-	-
Hepatic failure	1 (0. 8)	-	-	-	-	1 (0. 8)
Immune system disorders						
Hypersensitivity	1 (0. 8)	1 (0. 8)	-	-	-	-
Infections and infestations						
Administration site infection	1 (0. 8)	-	1 (0. 8)	-	-	-
Bronchitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Bronchitis bacterial	1 (0. 8)	-	1 (0. 8)	-	-	-
Cellulitis	3 (2. 3)	-	2 (1. 6)	1 (0. 8)	-	-
Gastroenteritis viral	1 (0. 8)	-	1 (0. 8)	-	-	-
Herpes simplex	2 (1. 6)	-	2 (1. 6)	-	-	-
Herpes zoster	1 (0. 8)	-	-	1 (0. 8)	-	-
Infection	2 (1. 6)	-	-	2 (1. 6)	-	-
Infusion site cellulitis	1 (0. 8)	1 (0. 8)	-	-	-	-
Opportunistic infection	1 (0. 8)	-	-	1 (0. 8)	-	-
Oral candidiasis	1 (0. 8)	1 (0. 8)	-	-	-	-
Oral fungal infection	1 (0. 8)	1 (0. 8)	-	-	-	-
Oral herpes	1 (0. 8)	-	1 (0. 8)	-	-	-
Pharyngitis bacterial	1 (0. 8)	1 (0. 8)	-	-	-	-
Pneumonia	3 (2. 3)	-	1 (0. 8)	2 (1. 6)	-	-
Pneumonia viral	1 (0. 8)	-	-	1 (0. 8)	-	-
Sepsis	1 (0. 8)	-	-	1 (0. 8)	-	-
Septic shock	1 (0. 8)	-	-	-	1 (0. 8)	-
Skin candida	1 (0. 8)	-	1 (0. 8)	-	-	-
Staphylococcal sepsis	1 (0. 8)	-	1 (0. 8)	-	-	-
Tonsillitis	1 (0. 8)	-	1 (0. 8)	-	-	-
Upper respiratory tract infection	3 (2. 3)	2 (1. 6)	-	1 (0. 8)	-	-
Urinary tract infection staphylococcal	1 (0. 8)	-	1 (0. 8)	-	-	-

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Injury, poisoning and procedural complications						
Infusion related reaction	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Tracheostomy malfunction	1 (0. 8)	1 (0. 8)	-	-	-	-
Investigations						
Alanine aminotransferase increased	5 (3. 9)	1 (0. 8)	1 (0. 8)	3 (2. 3)	-	-
Aspartate aminotransferase increased	5 (3. 9)	1 (0. 8)	1 (0. 8)	3 (2. 3)	-	-
Blood alkaline phosphatase increased	1 (0. 8)	-	1 (0. 8)	-	-	-
Blood bilirubin increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood creatinine increased	5 (3. 9)	2 (1. 6)	3 (2. 3)	-	-	-
Blood glucose increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood lactate dehydrogenase increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood potassium decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
Blood urea increased	1 (0. 8)	1 (0. 8)	-	-	-	-
C-reactive protein increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Electrocardiogram QT prolonged	13 (10.1)	4 (3. 1)	4 (3. 1)	5 (3. 9)	-	-
Electrocardiogram ST segment depression	1 (0. 8)	1 (0. 8)	-	-	-	-
Gamma-glutamyltransferase increased	2 (1. 6)	-	-	1 (0. 8)	1 (0. 8)	-
Glomerular filtration rate decreased	1 (0. 8)	1 (0. 8)	-	-	-	-
International normalised ratio increased	2 (1. 6)	-	-	2 (1. 6)	-	-
Liver function test abnormal	1 (0. 8)	-	-	1 (0. 8)	-	-
Mean cell volume increased	1 (0. 8)	1 (0. 8)	-	-	-	-
Neutrophil count decreased	2 (1. 6)	-	1 (0. 8)	-	1 (0. 8)	-
Platelet count decreased	3 (2. 3)	2 (1. 6)	-	-	1 (0. 8)	-
Prothrombin time shortened	1 (0. 8)	-	-	1 (0. 8)	-	-
Weight decreased	4 (3. 1)	3 (2. 3)	1 (0. 8)	-	-	-
White blood cell count decreased	1 (0. 8)	-	1 (0. 8)	-	-	-
Metabolism and nutrition disorders						
Decreased appetite	9 (7. 0)	7 (5. 4)	-	2 (1. 6)	-	-
Dehydration	1 (0. 8)	-	1 (0. 8)	-	-	-
Hypercalcaemia	1 (0. 8)	-	-	-	1 (0. 8)	-
Hyperglycaemia	2 (1. 6)	2 (1. 6)	-	-	-	-
Hyperkalaemia	1 (0. 8)	1 (0. 8)	-	-	-	-
Hyperuricaemia	1 (0. 8)	1 (0. 8)	-	-	-	-

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Hypokalaemia	5 (3. 9)	2 (1. 6)	1 (0. 8)	2 (1. 6)	-	-
Tumour lysis syndrome	2 (1. 6)	-	1 (0. 8)	1 (0. 8)	-	-
Musculoskeletal and connective tissue disorders						
Back pain	1 (0. 8)	1 (0. 8)	-	-	-	-
Bone pain	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Muscle spasms	1 (0. 8)	1 (0. 8)	-	-	-	-
Musculoskeletal pain	1 (0. 8)	1 (0. 8)	-	-	-	-
Myalgia	3 (2. 3)	2 (1. 6)	1 (0. 8)	-	-	-
Pain in extremity	4 (3. 1)	3 (2. 3)	-	1 (0. 8)	-	-
Nervous system disorders						
Ageusia	1 (0. 8)	1 (0. 8)	-	-	-	-
Amnesia	1 (0. 8)	1 (0. 8)	-	-	-	-
Dizziness	8 (6. 2)	8 (6. 2)	-	-	-	-
Dysgeusia	5 (3. 9)	3 (2. 3)	2 (1. 6)	-	-	-
Encephalopathy	1 (0. 8)	1 (0. 8)	-	-	-	-
Headache	6 (4. 7)	5 (3. 9)	1 (0. 8)	-	-	-
Hypoaesthesia	1 (0. 8)	1 (0. 8)	-	-	-	-
Hypotonia	1 (0. 8)	1 (0. 8)	-	-	-	-
Lethargy	1 (0. 8)	1 (0. 8)	-	-	-	-
Neuropathy peripheral	2 (1. 6)	1 (0. 8)	-	1 (0. 8)	-	-
Paraesthesia	1 (0. 8)	1 (0. 8)	-	-	-	-
Psychiatric disorders						
Anxiety	1 (0. 8)	-	-	1 (0. 8)	-	-
Confusional state	1 (0. 8)	1 (0. 8)	-	-	-	-
Insomnia	1 (0. 8)	1 (0. 8)	-	-	-	-
Renal and urinary disorders						
Azotaemia	1 (0. 8)	1 (0. 8)	-	-	-	-
Micturition urgency	1 (0. 8)	1 (0. 8)	-	-	-	-
Pollakiuria	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-	-
Renal impairment	1 (0. 8)	-	-	1 (0. 8)	-	-

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129 MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Reproductive system and breast disorders						
Testicular pain	1 (0. 8)	-	1 (0. 8)	-	-	-
Respiratory, thoracic and mediastinal disorders						
Alveolitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Bronchospasm	1 (0. 8)	-	-	1 (0. 8)	-	-
Cough	3 (2. 3)	3 (2. 3)	-	-	-	-
Dyspnoea	8 (6. 2)	5 (3. 9)	1 (0. 8)	2 (1. 6)	-	-
Hiccups	2 (1. 6)	2 (1. 6)	-	-	-	-
Hypoxia	1 (0. 8)	-	-	1 (0. 8)	-	-
Nasal congestion	1 (0. 8)	-	1 (0. 8)	-	-	-
Pharyngeal ulceration	1 (0. 8)	1 (0. 8)	-	-	-	-
Pulmonary embolism	1 (0. 8)	-	-	1 (0. 8)	-	-
Pulmonary mass	1 (0. 8)	-	1 (0. 8)	-	-	-
Rhinorrhoea	1 (0. 8)	-	1 (0. 8)	-	-	-
Skin and subcutaneous tissue disorders						
Alopecia	2 (1. 6)	2 (1. 6)	-	-	-	-
Dry skin	1 (0. 8)	1 (0. 8)	-	-	-	-
Erythema	1 (0. 8)	-	1 (0. 8)	-	-	-
Hyperhidrosis	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Night sweats	1 (0. 8)	1 (0. 8)	-	-	-	-
Palmar erythema	1 (0. 8)	1 (0. 8)	-	-	-	-
Palmar-plantar erythrodysaesthesia syndrome	1 (0. 8)	1 (0. 8)	-	-	-	-
Pruritus	5 (3. 9)	4 (3. 1)	1 (0. 8)	-	-	-
Rash	11 (8.5)	7 (5. 4)	4 (3. 1)	-	-	-
Rash macular	1 (0. 8)	1 (0. 8)	-	-	-	-
Rash papular	1 (0. 8)	1 (0. 8)	-	-	-	-
Urticaria	1 (0. 8)	1 (0. 8)	-	-	-	-
Vascular disorders						
Deep vein thrombosis	2 (1. 6)	-	1 (0. 8)	1 (0. 8)	-	-
Essential hypertension	1 (0. 8)	-	1 (0. 8)	-	-	-
Extremity necrosis	1 (0. 8)	-	-	1 (0. 8)	-	-
Flushing	9 (7. 0)	7 (5. 4)	2 (1. 6)	-	-	-

Table 14.3.6.7: Treatment Related Adverse Events by Worst Grade Toxicity per Patient

Full Analysis Set N=129	Number of Patients (%) Worst Grade per Patient					
MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Hypotension	4 (3. 1)	2 (1. 6)	1 (0. 8)	1 (0. 8)	-	-
Phlebitis	11 (8.5)	2 (1. 6)	8 (6. 2)	1 (0. 8)	-	-
Thrombosed varicose vein	1 (0. 8)	-	-	1 (0. 8)	-	-
Vasculitis	1 (0. 8)	-	-	1 (0. 8)	-	-
Vein pain	3 (2. 3)	1 (0. 8)	2 (1. 6)	-	-	-
Venous thrombosis limb	1 (0. 8)	-	-	1 (0. 8)	-	-

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Abdominal discomfort	1	2	901-009 9 19-001
Abdominal distension	1	3	914-004 9 19-001 9 34-001
Abdominal pain	1	6	513-002 9 07-007 9 34-001 934 -003 9 36-001 9 47-001
	2	9	244-001 2 44-002 5 13-002 513 -004 8 03-001 9 07-003 9 14-003 93 1-003 93 6-001
	3	1	154-001
Abdominal pain lower	1	1	911-001
Abdominal pain upper	1	5	221-003 2 24-002 6 00-004 752 -002 9 14-003
	2	3	600-004 7 52-002 9 31-002
	3	1	800-001
Acne	1	1	914-004
Actinic keratosis	3	1	207-001
Activated partial thromboplastin time prolonged	1	4	142-002 5 32-001 5 34-005 931 -003
	3	1	142-002
Acute respiratory distress syndrome	3	1	922-001
Administration site infection	2	2	140-002 1 62-002
Ageusia	1	2	243-001 5 34-001
Aggression	1	1	240-002
	2	1	240-002
Alanine aminotransferase increased	1	6	142-003 1 42-005 1 46-001 223 -004 5 34-006 8 00-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Alanine aminotransferase increased	2	4	142-005 2 23-004 8 00-001 914 -003
	3	4	142-005 1 54-001 2 23-004 914 -003
Allergic transfusion reaction	2	1	144-001
Alopecia	1	2	751-001 9 14-006
Alveolitis	3	1	146-001
Amnesia	1	1	534-001
Anaemia	1	18	141-001 1 42-003 1 61-001 221 -004 2 44-006 5 32-001 5 32-003 532-004 533-001
			534-002 5 34-003 5 34-004 534 -005 5 34-006 8 01-002 9 01-001 915-002 931-003
	2	30	142-002 1 44-002 1 46-001 161 -001 1 62-002 2 07-001 2 24-002 242-001 244-001
			244-002 2 44-005 2 44-006 513 -001 5 16-006 5 32-001 5 32-002 532-004 533-001
			534-002 5 34-003 5 34-004 534 -005 5 34-006 6 00-003 8 01-001 801-002 907-001
			907-004 9 33-001 9 38-001
	3	13	142-005 1 44-001 1 61-001 207 -001 2 23-002 2 44-002 5 13-001 532-002 534-006
			550-002 6 00-003 8 01-001 938 -001
	4	6	144-001 5 16-006 5 32-002 534 -006 6 00-003 8 01-001
Anaemia haemolytic autoimmune	1	1	534-006
	3	1	534-006
Anal candidiasis	2	1	207-001
Anal fissure	1	1	100-002
Anal pruritus	2	1	207-001
Anaphylactic reaction	4	1	934-003
Anxiety	1	4	513-001 5 32-004 9 14-003 919 -001
	2	3	161-001 2 06-001 9 11-001
	3	2	224-001 5 13-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Aortic aneurysm	1	1	534-001
Aphasia	3	1	240-001
Arteriosclerosis	1	1	534-002
Arthralgia	1	4	244-003 9 15-001 9 22-001 931 -002
	2	2	244-003 9 34-002
	3	1	931-003
Arthritis	1	1	534-004
Ascites	1	1	161-001
	2	3	161-001 2 44-004 7 52-002
	3	1	161-001
Aspartate aminotransferase increased	1	7	142-001 1 42-005 1 65-001 223 -004 8 00-001 9 01-001 9 31-002
	2	3	142-005 2 23-004 8 00-001
	3	4	142-005 154-001 2 23-004 914 -003
Asthenia	1	3	534-002 5 41-001 9 07-001
	2	5	180-002 1 80-003 9 14-003 922 -001 9 34-003
	3	3	144-002 1 61-001 2 43-001
	4	1	206-001
Atelectasis	1	2	908-003 9 38-001
Atrial fibrillation	1	2	534-001 9 34-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Atrial fibrillation	2	1	938-002
Axillary pain	2	1	911-001
Azotaemia	1	1	900-001
Back pain	1	4	907-001 9 08-003 9 14-004 934 -001
	2	2	146-001 9 31-003
	3	2	146-001 2 45-001
Bacterial infection	1	1	533-001
Basophilia	1	1	803-001
Bile duct stenosis	3	1	912-001
Blood albumin decreased	1	2	142-003 9 31-002
Blood alkaline phosphatase increased	1	6	154-001 2 20-001 8 01-001 803 -001 9 31-003 9 38-001
	2	3	154-001 2 20-001 9 14-003
	3	1	914-003
Blood bilirubin increased	1	3	144-001 1 54-001 2 23-002
	2	1	223-002
	3	1	914-003
Blood bilirubin unconjugated increased	1	1	534-006
Blood calcium increased	2	2	224-002 5 32-002
	4	1	532-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Blood creatinine	1	2	144-002 9 38-001
Blood creatinine increased	1	5	140-001 1 41-001 1 42-002 146 -001 9 00-001
	2	7	141-001 1 42-001 1 42-002 146 -001 2 24-002 5 32-001 9 07-004
Blood glucose increased	1	1	534-003
	2	1	532-002
Blood lactate dehydrogenase increased	-	3	126-002 8 01-001 8 01-002
	1	11	220-001 2 21-001 2 21-004 223 -004 5 34-001 5 34-002 5 34-003 534-004 534-005 534-006 9 14-003
	2	4	222-001 2 23-002 2 44-005 532 -002
	3	1	147-002
	4	1	803-001
Blood magnesium decreased	1	1	912-003
Blood phosphorus decreased	3	1	912-003
Blood phosphorus increased	2	1	908-003
Blood potassium decreased	1	3	120-001 1 44-001 9 02-001
	3	1	144-001
	4	1	144-001
Blood potassium increased	2	1	907-004
Blood pressure increased	2	1	516-001
Blood thyroid stimulating hormone decreased	1	1	934-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Blood urea increased	1	1	141-001
	2	2	142-002 5 32-002
Blood uric acid increased	1	2	126-002 1 42-002
Body temperature increased	1	2	934-003 9 34-004
Body tinea	1	1	922-001
Bone pain	1	1	908-003
	2	1	931-003
	3	1	800-001
Bowel movement irregularity	1	1	141-001
Breast pain	2	1	908-003
Bronchitis	1	6	533-001 5 34-001 5 34-004 534 -006 9 07-003 9 31-003
	2	2	912-003 9 38-001
	3	3	144-002 5 16-004 5 34-002
Bronchitis bacterial	2	1	534-005
Bronchitis chronic	1	2	534-001 5 34-002
Bronchopneumonia	2	1	600-003
	3	1	534-002
Bronchospasm	3	1	206-001
Bundle branch block right	1	1	534-004

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
C-reactive protein increased	1	2	144-002 1 54-001
Candidiasis	2	2	100-002 9 12-003
Cardiac failure	5	2	142-001 5 13-003
Cardiac failure congestive	3	1	922-001
Cardiac murmur	1	1	223-004
Cataract	1	1	534-001
Cellulitis	2	2	126-002 1 40-003
	3	1	934-004
Central venous catheterisation	1	1	516-004
Cerebral ischaemia	2	1	532-004
Cheilitis	1	1	244-003
Chest discomfort	1	1	919-001
Chest pain	1	2	140-001 9 31-003
	2	2	144-002 9 38-002
	3	1	908-003
Chills	1	15	120-001 2 23-002 2 24-001 513 -004 5 41-001 7 51-001 8 00-001 90 1-001 90 7-002 908-003 9 12-003 9 34-001 934 -002 9 34-003 9 38-002
	2	5	140-002 1 41-001 2 40-002 513 -002 9 07-004
	3	1	516-001
Cholangitis	3	1	914-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Cholecystitis	3	1	914-003
Cholecystitis acute	3	1	914-003
Cholelithiasis	1	1	803-001
Chylothorax	2	1	532-001
Clostridial infection	2	1	912-003
Complications of transplanted liver	1	1	533-001
Confusional state	1	2	240-002 9 07-006
	2	2	240-002 9 07-004
Conjunctivitis	2	1	513-001
Constipation	1	25	100-002 1 20-001 1 40-001 142 -002 1 44-002 2 23-002 2 23-004 240-001 242-001
			243-001 5 16-003 8 00-001 901 -009 9 02-001 9 07-003 9 07-005 907-006 908-003
			911-001 9 14-002 9 14-008 934 -001 9 34-003 9 34-004 9 38-001
	2	6	142-002 2 06-001 2 40-002 513-002 7 52-002 9 08-003
	3	1	146-001
Convulsion	2	1	100-002
Cor pulmonale	3	1	922-001
Coronary artery disease	1	1	534-001
Cough	1	18	121-001 1 40-001 1 42-002 144 -002 2 07-001 2 20-002 2 23-002 240-001 751-001
			800-001 8 01-001 9 08-003 912 -003 9 14-003 9 14-004 9 14-009 934-003 934-004
	2	7	162-002 2 24-001 9 15-001 922 -001 9 34-004 9 38-001 9 38-002
Crystal arthropathy	1	1	600-003
Cystitis	2	1	244-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Cytomegalovirus infection	1	1	144-002
	3	1	513-002
Deafness unilateral	1	1	534-005
Decreased appetite	1	13	165-001 2 40-001 5 16-003 600 -003 9 07-001 9 07-004 9 08-003 914-003 914-004 934-001 9 34-003 9 34-004 938 -001
	2	4	206-001 2 44-004 2 44-006 922 -001
	3	3	100-001 1 42-003 2 06-001
Decubitus ulcer	1	1	513-001
	3	1	513-001
Deep vein thrombosis	1	1	534-002
	2	2	242-001 9 08-003
	3	4	100-002 1 46-001 5 34-002 922 -001
Defaecation urgency	1	1	907-003
Dehydration	2	3	165-001 2 21-004 9 34-004
Depressed mood	1	1	142-005
	2	2	242-001 9 15-002
Depression	2	5	142-001 1 44-001 5 13-002 801 -002 9 22-001
	3	1	206-001
Dermatitis contact	1	1	121-001
Device occlusion	1	1	907-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Device related infection	2	4	126-002 1 61-001 2 07-001 513 -001
	3	1	914-003
Diabetes mellitus	2	2	161-001 9 22-001
	3	1	220-002
Diarrhoea	1	23	100-002 1 20-001 1 40-001 140 -003 1 42-001 1 46-001 1 61-001 240-002 244-001
			244-005 5 34-002 8 01-002 901 -006 9 02-001 9 08-003 9 12-003 914-003 915-001
			919-001 9 21-001 9 34-003 936 -001 9 47-001
	2	9	146-001 1 46-002 2 42-001 244 -004 8 03-001 9 02-001 9 07-004 907-005 908-003
	3	2	146-001 1 61-001
Dizziness	1	13	120-001 1 41-001 1 46-001 207 -001 9 00-001 9 01-001 9 07-006 908-003 919-001
			934-004 9 38-001 9 38-002 947 -001
	2	3	207-001 9 19-001 9 38-002
Dry eye	-	1	933-001
	1	1	223-004
Dry mouth	1	3	120-001 2 43-001 9 22-001
	3	1	206-001
Dry skin	1	2	221-004 9 33-001
Dysgeusia	1	3	154-001 2 20-002 9 34-002
	2	2	516-004 8 00-001
Dyspepsia	1	4	751-001 9 08-003 9 21-001 947 -001
	2	1	221-004
Dysphagia	1	1	240-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Dysphagia	2	2	240-001 2 40-002
Dysphonia	1	1	922-001
Dyspnoea	1	15	100-004 1 61-001 2 23-002 224 -001 5 16-001 9 07-006 9 08-003 914-002 914-003 914-004 9 22-001 9 31-002 931 -003 9 33-001 9 38-002
	2	8	100-002 1 42-002 1 42-003 144 -002 2 06-001 2 43-001 2 44-002 915-001
	3	8	144-001 1 47-002 1 50-001 223 -002 9 08-003 9 12-003 9 14-003 934-004
Dysuria	1	1	901-006
	2	1	513-002
Ear discomfort	1	1	100-004
Ear infection	1	1	906-001
Eastern Cooperative Oncology Group performance status worsened	-	1	242-001
	4	1	600-003
Eczema	1	2	244-003 5 16-003
Electrocardiogram QT prolonged	1	8	140-001 1 54-001 5 16-001 532 -004 5 34-002 6 00-003 9 02-001 931-003
	2	6	140-001 1 44-001 1 54-001 513 -004 5 34-002 9 12-003
	3	5	144-001 1 47-002 5 34-002 911 -001 9 12-001
Electrocardiogram ST segment depression	1	1	150-001
Encephalopathy	1	1	154-001
Endocarditis	4	1	922-001
Eosinophilia	1	1	534-004

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Epigastric discomfort	1	1	207-001
	2	1	207-001
Epstein-Barr virus infection	-	1	140-001
Eructation	1	1	947-001
Erythema	-	1	242-001
	1	1	922-001
	2	2	207-001 2 44-005
Escherichia infection	2	1	207-001
Essential hypertension	2	1	934-003
Euthanasia	5	1	244-004
Excoriation	1	2	906-001 9 34-004
Extrapyramidal disorder	2	1	541-001
Extravasation	1	2	140-003 2 44-005
	2	1	223-004
Extremity necrosis	3	1	141-001
Eye discharge	1	1	126-002
Eye infection	2	1	126-002
Eye infection bacterial	1	1	922-001
Eye pain	1	1	908-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Eyelid oedema	1	1	906-001
Eyelid ptosis	1	1	906-001
Face oedema	1	1	244-003
	2	2	207-001 2 44-005
Fall	1	1	244-006
	2	1	919-001
Fatigue	1	35	100-003 1 20-001 1 40-002 140 -003 1 65-001 2 20-002 2 23-002 22 3-004 24 0-001
			600-003 7 51-001 9 00-001 901 -006 9 01-009 9 06-001 9 07-004 90 7-006 91 1-001
			914-002 9 14-003 9 14-004 914 -006 9 14-008 9 14-009 9 15-001 91 9-001 93 1-003
			933-001 9 34-001 9 34-002 934 -003 9 34-004 9 38-001 9 38-002 94 7-001
	2	24	100-002 1 20-001 1 40-002 142 -003 2 20-002 2 40-001 2 40-002 24 4-002 24 4-003
			244-005 5 13-001 5 13-002 600 -003 9 00-001 9 07-004 9 08-003 91 4-003 92 2-001
			934-001 9 34-002 9 34-003 934 -004 9 36-001 9 38-001
	3	7	100-001 1 46-001 2 20-002 240 -001 240-002 9 07-004 9 08-003
Febrile neutropenia	1	1	533-001
	3	6	100-002 1 44-001 1 54-001 513 -004 5 32-002 9 34-001
Feeling of body temperature change	1	1	207-001
	2	1	207-001
Flank pain	1	1	931-003
	2	1	931-003
Flatulence	1	1	938-002
Fluid retention	2	1	224-002
Flushing	1	7	120-001 9 07-007 9 21-001 934 -001 9 34-002 9 34-004 9 47-001
	2	2	207-001 2 20-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Fungaemia	3	1	922-001
Fungal infection	2	1	922-001
Gamma-glutamyltransferase	3	1	146-001
Gamma-glutamyltransferase increased	1	1	534-004
	3	1	154-001
	4	1	142-005
Gastric ulcer	3	1	244-002
Gastritis	1	1	752-002
	2	1	752-002
Gastroenteritis	1	1	534-002
Gastroenteritis viral	2	1	516-004
Gastrointestinal fungal infection	3	1	516-001
Gastrointestinal haemorrhage	5	1	244-002
Gastrointestinal obstruction	3	1	513-002
Gastrooesophageal reflux disease	1	3	240-001 5 32-001 9 47-001
	2	1	752-002
General physical health deterioration	2	1	244-006
	3	2	154-001 2 40-002
Generalised oedema	2	2	907-004 9 22-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Genital herpes	2	1	907-005
Gingival ulceration	1	1	223-004
Glaucoma	3	1	220-002
Glomerular filtration rate decreased	1	2	532-002 9 33-001
	2	2	532-001 5 32-002
Glucose urine present	3	1	934-003
Gout	2	1	126-002
Groin pain	1	2	121-001 1 62-001
Haematemesis	1	1	240-002
	3	1	244-002
Haematocrit decreased	3	1	922-001
Haemoglobin decreased	1	1	220-001
	2	1	240-002
	3	1	240-002
Haemolytic anaemia	3	1	533-001
Haemoptysis	1	1	914-003
Headache	1	15	100-002 1 20-001 1 21-001 142 -005 1 46-001 2 40-001 2 44-003 534-005 600-004 751-001 9 07-003 9 07-005 908 -003 9 14-002 9 34-003
	2	4	144-001 5 32-004 9 22-001 934 -004
Hepatic cirrhosis	1	1	154-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Hepatic enzyme increased	2	1	224-002
Hepatic failure	5	1	154-001
Hepatomegaly	1	1	532-001
Hepatosplenomegaly	1	1	532-002
Herpes simplex	1	1	223-002
	2	2	140-002 2 23-004
Herpes zoster	1	1	142-005
	3	1	146-001
Hiccups	1	3	900-001 9 08-003 9 47-001
	2	2	907-004 9 34-004
Hot flush	1	1	244-003
	2	1	919-001
Hyperbilirubinaemia	1	2	144-002 9 38-001
	3	1	912-001
Hypercalcaemia	1	1	934-004
	3	1	165-001
	4	1	803-001
Hyperglycaemia	1	8	220-002 5 16-004 5 34-001 534 -002 5 34-003 5 34-004 5 34-006 93 1-003
	2	5	146-001 1 62-002 2 20-002 244 -002 5 34-006

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Hyperglycaemia	3	3	220-002 2 44-002 9 13-001
Hyperhidrosis	1	3	516-003 5 41-001 6 00-003
	2	5	147-002 2 24-001 5 13-002 516 -003 9 34-001
Hyperkalaemia	1	4	534-005 5 34-006 9 01-001 908 -003
Hyperlipidaemia	1	2	534-001 9 34-003
Hypermagnesaemia	1	1	911-001
Hypersensitivity	1	2	901-006 9 07-005
Hypertension	1	5	532-003 5 34-001 5 34-006 541 -001 8 03-001
	2	2	142-002 2 07-001
Hyperuricaemia	1	8	146-001 5 32-001 5 33-001 534 -002 534-005 5 34-006 7 51-001 93 8-001
Hypoacusis	1	1	140-002
Hypoaesthesia	1	1	933-001
	2	1	919-001
Hypoalbuminaemia	1	7	220-001 5 32-001 5 43-001 543 -002 8 01-001 9 00-001 9 38-001
	2	3	206-001 2 20-001 5 32-002
	3	2	513-001 5 32-002
Hypocalcaemia	1	4	142-005 2 20-001 5 34-004 934 -003
	2	2	220-001 5 32-001
Hypoglycaemia	4	1	243-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Hypokalaemia	1	11	144-002 1 46-001 5 16-004 534 -003 5 34-006 8 01-002 9 12-003 913-001 931-003 933-001 9 34-003
	2	4	513-001 5 13-002 9 08-003 915 -002
	3	5	100-001 1 44-002 1 46-001 801 -002 9 12-003
Hypomagnesaemia	1	7	221-004 5 34-001 5 34-004 534 -005 9 13-001 9 34-002 9 34-003
Hyponatraemia	1	3	532-001 8 01-001 9 34-003
Hypophosphataemia	2	1	532-002
Hypotension	-	1	244-002
	1	5	207-001 6 00-003 7 51-001 900 -001 9 11-001
	2	7	243-001 2 44-002 7 51-001 907 -004 9 19-001 9 34-003 9 38-002
	3	4	161-001 9 07-004 9 34-003 934 -004
	4	1	907-004
Hypotonia	1	1	144-001
Hypovolaemic shock	4	1	532-001
Hypoxia	3	2	800-001 9 34-004
Iliac artery thrombosis	3	1	534-001
Impaired self-care	2	1	244-006
Infection	1	1	142-001
	2	1	220-002
	3	4	100-004 2 40-002 9 14-003 934 -003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Infection	4	1	240-002
Infusion related reaction	1	4	154-001 2 20-001 2 21-001 947 -001
	2	2	126-002 2 21-001
Infusion site cellulitis	1	1	120-001
	2	1	120-001
Infusion site coldness	1	1	243-001
Infusion site extravasation	2	1	912-002
Infusion site inflammation	2	1	516-003
Infusion site pain	1	11	120-001 2 21-003 2 22-001 243 -001 2 44-005 5 13-004 5 32-002 93 1-001 93 4-004 938-002 9 47-001
	2	9	221-003 5 13-001 5 13-002 532 -003 5 32-004 9 06-001 9 11-001 91 4-002 93 8-002
Infusion site reaction	1	2	516-003 7 51-001
Infusion site thrombosis	1	1	142-002
Injection site induration	2	1	933-001
Injection site inflammation	2	1	516-003
Injection site pain	1	1	120-001
	2	1	933-001
Injection site phlebitis	1	1	934-004
Injection site pruritus	1	1	243-001
Injection site reaction	1	1	921-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Insomnia	1	5	224-001 7 51-001 9 19-001 934 -004 9 47-001
	2	3	142-001 9 06-001 9 34-004
	3	1	142-002
	4	1	206-001
International normalised ratio decreased	1	1	144-002
International normalised ratio increased	1	2	532-001 5 34-005
	3	3	154-001 9 22-001 9 34-001
Joint swelling	1	2	140-001 9 11-001
Keratoacanthoma	-	1	146-001
Keratoconjunctivitis sicca	1	1	751-001
Lacrimation increased	1	1	934-004
Lethargy	1	1	121-001
Leukocytosis	1	2	534-001 5 34-002
	3	1	803-001
Leukopenia	1	5	141-001 1 42-003 1 42-005 207 -001 9 01-001
	2	6	142-005 2 07-001 2 44-006 516 -006 5 33-001 8 01-001
	3	1	161-001
	4	3	144-001 1 54-001 1 61-001
Lip ulceration	2	1	915-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Listless	1	1	146-001
Liver function test abnormal	3	1	154-001
Local swelling	1	1	914-002
Lower limb fracture	2	1	907-001
	3	1	907-001
Lung infection	2	1	220-002
	5	1	221-004
Lung infiltration	1	1	534-006
Lung neoplasm	1	1	532-004
Lung squamous cell carcinoma stage unspecified	4	1	912-003
Lymphadenopathy	1	3	534-003 5 34-004 9 14-004
Lymphocytosis	4	1	803-001
Lymphopenia	1	3	532-003 5 33-001 5 34-006
	2	8	142-001 2 07-001 5 16-004 532 -002 5 32-003 5 32-004 5 33-001 534-001
	3	5	142-001 1 42-003 5 16-004 533 -001 5 34-004
	4	1	532-002
Malaise	2	3	221-004 2 44-004 5 41-001
	3	1	244-002
Mean cell volume increased	1	2	534-003 5 34-006

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Melaena	1	1	240-002
	3	1	244-002
Micturition urgency	1	1	907-001
Monocyte count decreased	1	1	220-001
Mood altered	2	1	146-001
Mucosal inflammation	1	4	144-001 5 13-003 6 00-003 931 -002
Multi-organ failure	5	3	146-002 5 13-001 5 16-001
Multiple fractures	3	1	146-001
Muscle spasms	1	8	121-001 1 40-001 1 42-005 240 -001 2 43-001 2 44-003 5 16-003 90 7-001
	2	3	121-001 1 42-005 2 40-001
	3	1	100-002
Muscular weakness	1	2	244-006 9 38-002
Musculoskeletal chest pain	1	1	908-003
	2	1	934-004
Musculoskeletal pain	1	2	243-001 9 14-009
	2	2	220-002 9 07-002
Myalgia	1	4	244-003 7 51-001 9 14-003 914 -009
	2	1	915-001
Mycosis fungoides	3	1	907-004

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Nasal congestion	1	3	100-003 5 34-003 9 33-001
	2	2	207-001 9 15-001
Nasal discomfort	1	1	244-003
Nasal dryness	1	1	244-003
Nasopharyngitis	1	7	146-001 1 47-001 2 07-001 221 -003 2 23-004 2 44-001 5 34-003
Nausea	1	42	120-001 1 21-001 1 42-005 144 -002 1 54-001 1 61-001 1 62-001 206-001 220-002
			221-001 2 21-003 2 22-001 240 -001 2 43-001 2 44-001 5 16-003 516-004 532-001
			533-001 5 41-001 6 00-003 900 -001 9 01-006 9 06-001 9 07-002 907-006 907-007
			908-003 9 11-001 9 14-002 914 -006 9 15-002 9 19-001 9 21-001 922-001 931-002
			931-003 9 33-001 9 34-003 934 -004 9 38-001 9 38-002
	2	18	165-001 2 07-001 2 21-004 240 -001 2 42-001 2 44-002 2 45-001 513-002 516-004
			541-001 8 00-001 9 07-001 907 -003 9 07-005 90 8-003 9 31-003 934-002 934-004
	3	1	161-001
Neck pain	2	1	240-002
	3	2	165-001 2 40-002
Neoplasm skin	1	1	751-001
Neuropathy peripheral	-	1	800-001
	1	7	140-001 9 00-001 9 08-003 914 -003 9 14-009 9 31-003 9 34-004
	2	1	919-001
	3	1	141-001
Neutropenia	1	2	207-001 5 34-006
	2	4	161-001 1 80-002 5 13-004 516 -006
	3	7	154-001 1 61-001 2 40-002 513 -004 6 00-003 9 07-007 9 38-002
	4	3	161-001 1 62-002 6 00-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Neutrophil count decreased	1	2	532-002 5 32-004
	2	2	532-002 5 32-004
	3	1	532-002
	4	1	532-002
Night sweats	1	6	240-001 5 34-004 5 43-001 914 -003 9 14-004 9 34-004
	2	2	144-002 9 19-001
Obstructive airways disorder	2	1	240-002
Odynophagia	2	1	240-001
Oedema	1	2	207-001 5 34-006
	2	3	140-002 2 06-001 9 34-004
	3	1	206-001
Oedema peripheral	1	21	100-003 1 40-001 1 42-005 144 -002 1 46-001 1 54-001 2 21-004 516-003 532-001 532-002 5 34-002 5 34-003 534 -004 6 00-004 9 06-001 9 08-003 913-001 915-001 915-002 9 31-001 9 31-003
	2	6	100-002 1 42-001 1 42-002 154 -001 2 07-001 5 16-006
Oesophagitis	3	1	161-001
Oliguria	2	1	142-001
Opportunistic infection	3	1	154-001
Oral candidiasis	1	2	534-005 9 34-003
	2	3	206-001 9 15-001 9 34-004
Oral fungal infection	1	1	224-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Oral herpes	2	2	121-001 5 32-004
Oropharyngeal discomfort	1	1	207-001
Oropharyngeal pain	1	7	100-003 1 54-001 5 41-001 752 -002 9 34-003 9 34-004 9 38-001
	2	2	100-003 2 44-003
Otitis media	2	1	154-001
Otorrhoea	1	1	906-001
Oxygen saturation decreased	1	1	908-003
PCO2 decreased	2	1	907-004
Pain	-	1	921-001
	1	7	100-002 1 20-001 1 61-001 207 -001 5 41-001 9 14-002 9 38-002
	2	3	516-001 7 52-002 9 15-002
	3	1	141-001
	4	1	915-002
Pain in extremity	-	1	921-001
	1	7	120-001 2 21-004 9 07-003 908 -003 9 19-001 9 33-001 9 38-002
	2	6	221-004 9 07-001 9 08-003 919 -001 9 34-004 9 38-002
	3	1	224-002
Pain of skin	2	1	224-001
	4	1	915-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Palmar erythema	1	1	140-003
Palmar-plantar erythrodysaesthesia syndrome	1	1	914-006
Pancreatitis	2	1	912-001
Pancytopenia	3	1	922-001
	4	1	516-006
Paraesthesia	1	2	154-001 5 16-004
Paraesthesia oral	1	2	934-003 9 47-001
Pathological fracture	1	1	915-001
	2	1	222-001
	4	1	915-002
Periorbital oedema	1	1	922-001
Periostitis	1	1	534-003
Peripheral motor neuropathy	1	1	100-003
Peripheral sensory neuropathy	1	2	534-001 9 14-006
	3	1	919-001
Pharyngeal ulceration	1	1	934-001
Pharyngitis	1	2	154-001 5 34-004
	3	2	100-002 6 00-003
Pharyngitis bacterial	1	1	534-005

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Phlebitis	1	5	121-001 2 21-001 2 21-003 751 -001 9 14-009
	2	11	121-001 1 26-002 2 20-001 221 -001 2 21-003 2 23-004 2 42-001 513-002 516-004 800-001 9 12-002
	3	1	800-001
Phlebitis superficial	1	1	534-002
Platelet count decreased	1	6	141-001 2 20-001 2 23-004 532 -001 5 32-002 5 32-004
	2	3	141-001 5 32-001 5 32-002
	3	2	532-002 9 38-001
	4	3	513-001 5 32-002 5 50-002
Pleural effusion	1	1	938-001
	2	1	142-002
Pneumonia	2	2	516-004 9 12-003
	3	7	100-002 1 42-003 1 46-001 532 -004 9 14-003 9 14-004 9 33-001
	5	1	752-002
Pneumonia viral	3	1	934-003
Pollakiuria	1	2	907-006 9 33-001
	2	1	516-004
Polyneuropathy	1	1	140-002
Poor quality sleep	2	1	207-001
Procedural pain	2	1	242-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Proctalgia	1	1	221-003
Productive cough	2	1	220-002
Prostatomegaly	1	1	901-006
Protein total decreased	2	1	142-001
Prothrombin time prolonged	1	1	534-001
	2	1	142-002
Prothrombin time shortened	3	1	154-001
Pruritus	-	1	921-001
	1	12	161-001 1 80-003 2 06-001 244 -001 5 32-004 5 34-002 5 34-003 53 4-004 90 7-004 908-003 9 14-003 9 33-001
	2	9	120-001 1 80-003 2 07-001 244 -005 6 00-004 7 51-001 9 07-004 91 5-001 92 1-001
	3	3	120-001 2 43-001 9 14-008
	4	1	180-003
Pruritus generalised	1	1	922-001
Pulmonary embolism	3	1	908-003
	4	2	100-002 2 23-004
Pulmonary mass	1	1	516-004
	2	1	516-004
Pulmonary oedema	2	1	907-004
Pyrexia	-	1	938-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Pyrexia	1	38	100-001 1 20-001 1 40-001 140 -002 1 44-002 1 46-001 1 54-001 206-001 207-001 221-003 2 24-001 2 24-002 240 -001 2 42-001 5 13-002 5 13-003 513-004 516-003 532-002 5 32-004 5 34-004 543 -001 5 43-002 9 02-001 9 08-003 912-001 912-003 914-003 9 14-004 9 14-009 915 -001 9 15-002 9 31-003 9 33-001 934-001 934-002 938-001 9 38-002
	2	18	140-001 1 40-002 1 41-001 146 -001 1 54-001 2 06-001 2 07-001 224-001 240-001 240-002 2 44-001 5 13-002 513 -003 9 02-001 9 07-002 9 07-004 914-004 922-001
	3	3	144-001 1 44-002 2 40-002
Rales	1	1	154-001
Rash	1	19	100-002 1 20-001 1 40-001 144 -002 1 54-001 1 62-001 2 24-001 240-001 242-001 532-004 5 34-002 5 34-004 912 -003 9 14-008 9 15-002 9 31-002 933-001 934-002 936-001
	2	9	120-001 1 46-001 2 06-001 207 -001 2 21-004 5 16-003 5 34-002 907-004 914-006
	3	1	221-004
Rash macular	1	1	242-001
Rash maculo-papular	2	1	915-001
Rash papular	1	2	513-004 5 34-002
	2	2	513-004 9 07-004
Rash pruritic	1	2	908-003 9 34-004
Red blood cell count decreased	1	1	801-001
Renal failure	2	2	142-001 1 61-001
Renal failure acute	3	1	922-001
Renal impairment	1	3	534-002 5 34-003 5 34-005
	2	1	534-003
	3	1	534-003

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Respiratory alkalosis	3	1	922-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Respiratory distress	3	1	244-002
Respiratory failure	4	1	146-002
Respiratory syncytial virus infection	2	1	207-001
Respiratory tract infection	1	1	534-003
Restless legs syndrome	1	1	915-001
Restlessness	1	2	140-001 1 42-001
Retinal vein thrombosis	3	1	142-002
Rhinitis	2	1	244-003
Rhinorrhoea	1	2	240-001 2 44-003
	2	2	207-001 2 44-003
Salivary hypersecretion	1	1	516-004
Sepsis	3	3	534-002 9 22-001 9 34-003
Septic shock	2	1	752-002
	3	1	161-001
	4	2	161-001 2 40-002
Shock	5	1	922-001
Sinus bradycardia	1	1	908-003
Sinus polyp	1	1	534-005
Sinus tachycardia	1	1	532-002

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Sinus tachycardia	2	1	532-002
	3	1	100-002
Sinusitis	1	3	534-002 5 34-006 9 31-002
	2	3	240-001 2 43-001 2 44-001
	3	1	224-001
Skin burning sensation	1	1	906-001
Skin cancer	2	1	126-002
Skin candida	2	1	207-001
Skin exfoliation	1	1	154-001
Skin ulcer	2	1	220-002
Sleep disorder	1	3	120-001 1 40-002 1 42-005
Somnolence	1	1	516-004
Spinal fracture	1	1	906-001
Spinal osteoarthritis	1	2	534-002 5 34-004
Splenomegaly	1	1	532-001
	3	1	936-001
Staphylococcal infection	1	1	907-004
	2	1	207-001
	3	2	146-002 9 22-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Staphylococcal sepsis	2	1	140-002
Staphylococcal skin infection	1	1	906-001
Stomatitis	1	2	154-001 5 16-001
	2	3	240-001 2 40-002 5 16-004
	3	1	240-001
Subcutaneous nodule	3	1	919-001
Supraventricular tachycardia	3	1	922-001
Syncope	1	1	146-001
Tachycardia	1	1	534-003
	2	1	907-004
Tachypnoea	2	1	907-004
Testicular pain	2	1	141-001
Thrombocytopenia	1	13	142-002 1 61-001 2 06-001 533 -001 5 34-002 5 34-003 5 34-006 80 1-001 90 1-001 914-002 9 14-003 9 31-001 931 -002
	2	8	142-002 1 61-001 2 44-001 244 -006 5 33-001 5 34-003 5 34-006 80 1-001
	3	5	144-002 1 61-001 2 44-006 516 -006 6 00-003
	4	9	144-001 1 44-002 1 54-001 161 -001 2 43-001 2 44-006 5 16-006 60 0-003 80 1-001
Thrombocytosis	1	1	534-001
Thrombophlebitis	1	1	534-002
	2	1	534-005

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Thrombophlebitis superficial	1	1	534-003
Thrombosed varicose vein	3	1	126-002
Thrombosis	2	1	142-005
	3	1	541-001
Thrombosis in device	1	1	914-003
Tongue haematoma	1	1	154-001
Tonsillitis	2	2	242-001 7 51-001
Tooth fracture	1	1	534-003
Toothache	2	1	803-001
Toxic cataract	1	1	534-003
Tracheostomy malfunction	1	1	933-001
Tremor	1	1	154-001
	2	1	146-001
Tumour associated fever	2	2	516-001 9 02-001
Tumour haemorrhage	3	1	240-002
Tumour lysis syndrome	2	2	533-001 9 02-001
	3	1	224-001
	4	1	146-002
Tumour pain	1	3	240-001 7 51-001 9 22-001

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Tumour pain	2	1	240-001
Tympanic membrane disorder	1	1	154-001
Upper respiratory tract infection	1	7	223-004 5 16-004 5 32-001 532 -004 5 34-002 7 51-001 9 19-001
	2	3	240-001 2 40-002 9 15-001
	3	1	240-001
Urinary tract infection	1	1	146-001
	2	5	146-001 2 07-001 2 42-001 906 -001 9 12-003
Urinary tract infection bacterial	2	1	207-001
Urinary tract infection staphylococcal	2	1	140-002
Urosepsis	3	1	922-001
Urticaria	1	1	907-003
Vasculitis	1	1	534-002
	3	1	141-001
Vein pain	1	2	533-001 5 34-001
	2	2	243-001 5 33-001
Venous thrombosis limb	3	1	126-002
Ventricular extrasystoles	1	1	534-005
Vertigo	1	1	541-001
Vision blurred	1	4	141-001 7 51-001 8 00-001 934 -004

Table 14.3.6.8: Cross Reference of Treatment Emergent Adverse Events to Patients

MedDRA Preferred Term	Tox. Grade	No. Pts	ID Number of Patients with Adverse Event
Visual impairment	1	1	922-001
Vitreous haemorrhage	2	1	142-002
Vomiting	1	33	120-001 1 40-003 1 42-001 142 -005 1 46-001 1 62-002 2 06-001 207-001 221-001 221-003 2 21-004 2 24-001 243 -001 2 44-001 5 16-003 5 16-004 532-001 532-003 532-004 5 41-001 8 00-001 906 -001 9 07-001 9 07-002 9 07-003 908-003 911-001 914-003 9 14-006 9 31-003 934 -003 9 38-001 9 38-002
	2	10	162-002 1 65-001 2 07-001 221 -004 2 43-001 5 13-002 5 16-004 800-001 911-001 921-001
	3	1	907-004
Weight decreased	1	4	100-003 1 40-002 9 08-003 914 -004
	2	3	242-001 5 32-002 5 34-001
Weight increased	1	1	144-001
Wheezing	1	1	908-003
White blood cell count decreased	1	1	532-004
	2	1	532-004
	3	2	144-001 5 32-002
	4	1	532-002
White blood cell count increased	2	1	532-001

Table 14.3.6.9: Treatment Emergent Adverse Events by MedDRA System Organ Class by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	General disorders and administration site conditions	85	81.0	71	67.6	11	10.5	3	2.9
	Gastrointestinal disorders	79	75.2	71	67.6	7	6.7	1	1.0
	Investigations	53	50.5	36	34.3	17	16.2		-
	Infections and infestations	52	49.5	32	30.5	18	17.1	2	1.9
	Metabolism and nutrition disorders	51	48.6	38	36.2	13	12.4		-
	Blood and lymphatic system disorders	48	45.7	26	24.8	22	21.0		-
	Respiratory, thoracic and mediastinal disorders	46	43.8	33	31.4	13	12.4		-
	Skin and subcutaneous tissue disorders	45	42.9	39	37.1	6	5.7		-
	Vascular disorders	43	41.0	31	29.5	11	10.5	1	1.0
	Musculoskeletal and connective tissue disorders	40	38.1	31	29.5	9	8.6		-
	Nervous system disorders	38	36.2	36	34.3	2	1.9		-
	Psychiatric disorders	25	23.8	21	20.0	4	3.8		-
	Injury, poisoning and procedural complications	15	14.3	13	12.4	2	1.9		-
	Eye disorders	14	13.3	12	11.4	2	1.9		-
	Cardiac disorders	11	10.5	8	7.6	2	1.9	1	1.0
	Neoplasms benign, malignant and unspecified (incl cysts and poly	11	10.5	8	7.6	3	2.9		-

Table 14.3.6.9: Treatment Emergent Adverse Events by MedDRA System Organ Class by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class	All Grades n %	Grades 1-2 n %	Grades 3-4 n %	Grade 5 n %
Platelet >= 100,000/ul (N=105)	Renal and urinary disorders	11 1 0.5	9 8. 6	2 1. 9	-
	Hepatobiliary disorders	6 5. 7	3 2. 9	2 1. 9	1 1. 0
	Ear and labyrinth disorders	5 4. 8	5 4. 8	-	-
	Immune system disorders	2 1. 9	1 1. 0	1 1. 0	-
	Reproductive system and breast disorders	2 1. 9	2 1. 9	-	-
	Surgical and medical procedures	1 1. 0	1 1. 0	-	-
Platelet < 100,000/ul (N=24)	General disorders and administration site conditions	18 7 5.0	12 5 0.0	5 20. 8	1 4. 2
	Blood and lymphatic system disorders	14 5 8.3	3 12. 5	11 4 5.8	-
	Gastrointestinal disorders	14 5 8.3	13 5 4.2	1 4. 2	-
	Respiratory, thoracic and mediastinal disorders	14 5 8.3	11 4 5.8	3 12. 5	-
	Infections and infestations	12 5 0.0	7 29. 2	5 20. 8	-
	Skin and subcutaneous tissue disorders	11 4 5.8	8 33. 3	3 12. 5	-
	Investigations	10 4 1.7	5 20. 8	5 20. 8	-
	Metabolism and nutrition disorders	10 4 1.7	6 25. 0	4 16. 7	-
	Nervous system disorders	7 29. 2	6 25. 0	1 4. 2	-
	Vascular disorders	7 29. 2	5 20. 8	2 8. 3	-

Table 14.3.6.9: Treatment Emergent Adverse Events by MedDRA System Organ Class by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class	All Grades n	%	Grades 1-2 n	%	Grades 3-4 n	%	Grade 5 n	%
Platelet < 100,000/ul (N=24)	Musculoskeletal and connective tissue disorders	5	20. 8	5	20. 8	-		-	
	Psychiatric disorders	4	16. 7	4	16. 7	-		-	
	Cardiac disorders	2	8. 3	1	4. 2	-		1	4. 2
	Hepatobiliary disorders	2	8. 3	2	8. 3	-		-	
	Renal and urinary disorders	2	8. 3	2	8. 3	-		-	
	Ear and labyrinth disorders	1	4. 2	1	4. 2	-		-	
	Eye disorders	1	4. 2	1	4. 2	-		-	
	Immune system disorders	1	4. 2	1	4. 2	-		-	
	Injury, poisoning and procedural complications	1	4. 2	1	4. 2	-		-	
	Reproductive system and breast disorders	1	4. 2	1	4. 2	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Nausea	46	43.8	46	43.8		-		-
	Fatigue	44	41.9	37	35.2	7	6.7		-
	Pyrexia	37	35.2	36	34.3	1	1.0		-
	Vomiting	34	32.4	33	31.4	1	1.0		-
	Anaemia	30	28.6	23	21.9	7	6.7		-
	Diarrhoea	24	22.9	23	21.9	1	1.0		-
	Constipation	23	21.9	22	21.0	1	1.0		-
	Rash	23	21.9	22	21.0	1	1.0		-
	Oedema peripheral	22	21.0	22	21.0		-		-
	Dyspnoea	21	20.0	15	14.3	6	5.7		-
	Chills	19	18.1	18	17.1	1	1.0		-
	Cough	19	18.1	19	18.1		-		-
	Decreased appetite	17	16.2	14	13.3	3	2.9		-
	Blood lactate dehydrogenase increased	16	15.2	15	14.3	1	1.0		-
	Headache	16	15.2	16	15.2		-		-
	Infusion site pain	16	15.2	16	15.2		-		-
	Pruritus	16	15.2	15	14.3	1	1.0		-
	Hypokalaemia	14	13.3	10	9.5	4	3.8		-
	Abdominal pain	12	11.4	11	10.5	1	1.0		-
	Phlebitis	12	11.4	11	10.5	1	1.0		-
	Thrombocytopenia	12	11.4	10	9.5	2	1.9		-
	Dizziness	11	10.5	11	10.5		-		-
	Pain in extremity	11	10.5	10	9.5	1	1.0		-
	Electrocardiogram QT prolonged	10	9.5	7	6.7	3	2.9		-
	Hyperglycaemia	10	9.5	7	6.7	3	2.9		-
	Hypotension	10	9.5	7	6.7	3	2.9		-
	Pain	10	9.5	9	8.6	1	1.0		-
	Pneumonia	10	9.5	2	1.9	7	6.7	1	1.0
	Upper respiratory tract infection	10	9.5	9	8.6	1	1.0		-
	Aspartate aminotransferase increased	9	8.6	5	4.8	4	3.8		-
	Bronchitis	9	8.6	7	6.7	2	1.9		-

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet >= 100,000/ul (N=105)	Insomnia	9	8.6	7	6.7	2	1.9	-	
	Lymphopenia	9	8.6	4	3.8	5	4.8	-	
	Flushing	8	7.6	8	7.6	-		-	
	Hypoalbuminaemia	8	7.6	7	6.7	1	1.0	-	
	Neuropathy peripheral	8	7.6	8	7.6	-		-	
	Oropharyngeal pain	8	7.6	8	7.6	-		-	
	Abdominal pain upper	7	6.7	6	5.7	1	1.0	-	
	Alanine aminotransferase increased	7	6.7	3	2.9	4	3.8	-	
	Anxiety	7	6.7	5	4.8	2	1.9	-	
	Asthenia	7	6.7	6	5.7	1	1.0	-	
	Blood creatinine increased	7	6.7	7	6.7	-		-	
	Hyperuricaemia	7	6.7	7	6.7	-		-	
	Hypomagnesaemia	7	6.7	7	6.7	-		-	
	Leukopenia	7	6.7	6	5.7	1	1.0	-	
	Night sweats	7	6.7	7	6.7	-		-	
	Platelet count decreased	7	6.7	4	3.8	3	2.9	-	
	Arthralgia	6	5.7	5	4.8	1	1.0	-	
	Back pain	6	5.7	4	3.8	2	1.9	-	
	Blood alkaline phosphatase increased	6	5.7	5	4.8	1	1.0	-	
	Deep vein thrombosis	6	5.7	2	1.9	4	3.8	-	
	Hypertension	6	5.7	6	5.7	-		-	
	Muscle spasms	6	5.7	5	4.8	1	1.0	-	
	Nasopharyngitis	6	5.7	6	5.7	-		-	
	Neutropenia	6	5.7	1	1.0	5	4.8	-	
	Weight decreased	6	5.7	6	5.7	-		-	
	Depression	5	4.8	4	3.8	1	1.0	-	
	Dysgeusia	5	4.8	5	4.8	-		-	
	Dyspepsia	5	4.8	5	4.8	-		-	
	Hiccups	5	4.8	5	4.8	-		-	
	Hypocalcaemia	5	4.8	5	4.8	-		-	
	Infection	5	4.8	2	1.9	3	2.9	-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Infusion related reaction	5	4.8	5	4.8	-		-	
	Myalgia	5	4.8	5	4.8	-		-	
	Nasal congestion	5	4.8	5	4.8	-		-	
	Oral candidiasis	5	4.8	5	4.8	-		-	
	Stomatitis	5	4.8	4	3.8	1	1.0	-	
	Urinary tract infection	5	4.8	5	4.8	-		-	
	Activated partial thromboplastin time prolonged	4	3.8	3	2.9	1	1.0	-	
	Device related infection	4	3.8	3	2.9	1	1.0	-	
	Erythema	4	3.8	4	3.8	-		-	
	Febrile neutropenia	4	3.8	1	1.0	3	2.9	-	
	Gastrooesophageal reflux disease	4	3.8	4	3.8	-		-	
	Hyperhidrosis	4	3.8	4	3.8	-		-	
	International normalised ratio increased	4	3.8	2	1.9	2	1.9	-	
	Malaise	4	3.8	3	2.9	1	1.0	-	
	Oedema	4	3.8	3	2.9	1	1.0	-	
	Sinusitis	4	3.8	3	2.9	1	1.0	-	
	Atrial fibrillation	3	2.9	3	2.9	-		-	
	Blood bilirubin increased	3	2.9	2	1.9	1	1.0	-	
	Bone pain	3	2.9	2	1.9	1	1.0	-	
	Cellulitis	3	2.9	2	1.9	1	1.0	-	
	Chest pain	3	2.9	2	1.9	1	1.0	-	
	Dehydration	3	2.9	3	2.9	-		-	
	Depressed mood	3	2.9	3	2.9	-		-	
	Dry mouth	3	2.9	2	1.9	1	1.0	-	
	Extravasation	3	2.9	3	2.9	-		-	
	Face oedema	3	2.9	3	2.9	-		-	
	Gamma-glutamyltransferase increased	3	2.9	1	1.0	2	1.9	-	
	General physical health deterioration	3	2.9	1	1.0	2	1.9	-	
	Herpes simplex	3	2.9	3	2.9	-		-	
	Hypercalcaemia	3	2.9	1	1.0	2	1.9	-	
	Hyperkalaemia	3	2.9	3	2.9	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Leukocytosis	3	2.9	2	1.9	1	1.0	-	
	Lymphadenopathy	3	2.9	3	2.9	-		-	
	Musculoskeletal pain	3	2.9	3	2.9	-		-	
	Pathological fracture	3	2.9	2	1.9	1	1.0	-	
	Peripheral sensory neuropathy	3	2.9	2	1.9	1	1.0	-	
	Pharyngitis	3	2.9	2	1.9	1	1.0	-	
	Pulmonary embolism	3	2.9	-		3	2.9	-	
	Rash papular	3	2.9	3	2.9	-		-	
	Renal impairment	3	2.9	2	1.9	1	1.0	-	
	Rhinorrhoea	3	2.9	3	2.9	-		-	
	Sepsis	3	2.9	-		3	2.9	-	
	Sleep disorder	3	2.9	3	2.9	-		-	
	Staphylococcal infection	3	2.9	2	1.9	1	1.0	-	
	Tumour lysis syndrome	3	2.9	2	1.9	1	1.0	-	
	Tumour pain	3	2.9	3	2.9	-		-	
	Vision blurred	3	2.9	3	2.9	-		-	
	Abdominal discomfort	2	1.9	2	1.9	-		-	
	Abdominal distension	2	1.9	2	1.9	-		-	
	Alopecia	2	1.9	2	1.9	-		-	
	Ascites	2	1.9	2	1.9	-		-	
	Atelectasis	2	1.9	2	1.9	-		-	
	Blood albumin decreased	2	1.9	2	1.9	-		-	
	Blood potassium decreased	2	1.9	2	1.9	-		-	
	Blood uric acid increased	2	1.9	2	1.9	-		-	
	Body temperature increased	2	1.9	2	1.9	-		-	
	Bronchitis chronic	2	1.9	2	1.9	-		-	
	Candidiasis	2	1.9	2	1.9	-		-	
	Confusional state	2	1.9	2	1.9	-		-	
	Diabetes mellitus	2	1.9	1	1.0	1	1.0	-	
	Dry eye	2	1.9	2	1.9	-		-	
	Dry skin	2	1.9	2	1.9	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Dysphagia	2	1.9	2	1.9	-		-	
	Dysuria	2	1.9	2	1.9	-		-	
	Eczema	2	1.9	2	1.9	-		-	
	Excoriation	2	1.9	2	1.9	-		-	
	Fall	2	1.9	2	1.9	-		-	
	Generalised oedema	2	1.9	2	1.9	-		-	
	Glomerular filtration rate decreased	2	1.9	2	1.9	-		-	
	Haematemesis	2	1.9	1	1.0	1	1.0	-	
	Haemoglobin decreased	2	1.9	1	1.0	1	1.0	-	
	Herpes zoster	2	1.9	1	1.0	1	1.0	-	
	Hot flush	2	1.9	2	1.9	-		-	
	Hyperbilirubinaemia	2	1.9	1	1.0	1	1.0	-	
	Hyperlipidaemia	2	1.9	2	1.9	-		-	
	Hypoaesthesia	2	1.9	2	1.9	-		-	
	Hyponatraemia	2	1.9	2	1.9	-		-	
	Hypoxia	2	1.9	-		2	1.9	-	
	Infusion site reaction	2	1.9	2	1.9	-		-	
	Injection site pain	2	1.9	2	1.9	-		-	
	Lung infection	2	1.9	1	1.0	-		1	1.0
	Melaena	2	1.9	1	1.0	1	1.0	-	
	Multi-organ failure	2	1.9	-		-		2	1.9
	Muscular weakness	2	1.9	2	1.9	-		-	
	Musculoskeletal chest pain	2	1.9	2	1.9	-		-	
	Neck pain	2	1.9	-		2	1.9	-	
	Pain of skin	2	1.9	1	1.0	1	1.0	-	
	Paraesthesia	2	1.9	2	1.9	-		-	
	Paraesthesia oral	2	1.9	2	1.9	-		-	
	Pleural effusion	2	1.9	2	1.9	-		-	
	Pollakiuria	2	1.9	2	1.9	-		-	
	Prothrombin time prolonged	2	1.9	2	1.9	-		-	
	Rash pruritic	2	1.9	2	1.9	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Septic shock	2	1.9	1	1.0	1	1.0	-	
	Spinal osteoarthritis	2	1.9	2	1.9	-		-	
	Splenomegaly	2	1.9	1	1.0	1	1.0	-	
	Tachycardia	2	1.9	2	1.9	-		-	
	Thrombophlebitis	2	1.9	2	1.9	-		-	
	Thrombosis	2	1.9	1	1.0	1	1.0	-	
	Tonsillitis	2	1.9	2	1.9	-		-	
	Tremor	2	1.9	2	1.9	-		-	
	Tumour associated fever	2	1.9	2	1.9	-		-	
	Vein pain	2	1.9	2	1.9	-		-	
	Abdominal pain lower	1	1.0	1	1.0	-		-	
	Acne	1	1.0	1	1.0	-		-	
	Actinic keratosis	1	1.0	-		1	1.0	-	
	Acute respiratory distress syndrome	1	1.0	-		1	1.0	-	
	Administration site infection	1	1.0	1	1.0	-		-	
	Ageusia	1	1.0	1	1.0	-		-	
	Aggression	1	1.0	1	1.0	-		-	
	Alveolitis	1	1.0	-		1	1.0	-	
	Amnesia	1	1.0	1	1.0	-		-	
	Anal candidiasis	1	1.0	1	1.0	-		-	
	Anal fissure	1	1.0	1	1.0	-		-	
	Anal pruritus	1	1.0	1	1.0	-		-	
	Anaphylactic reaction	1	1.0	-		1	1.0	-	
	Aortic aneurysm	1	1.0	1	1.0	-		-	
	Aphasia	1	1.0	-		1	1.0	-	
	Arteriosclerosis	1	1.0	1	1.0	-		-	
	Arthritis	1	1.0	1	1.0	-		-	
	Axillary pain	1	1.0	1	1.0	-		-	
	Azotaemia	1	1.0	1	1.0	-		-	
	Bacterial infection	1	1.0	1	1.0	-		-	
	Basophilia	1	1.0	1	1.0	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet >= 100,000/ul (N=105)	Bile duct stenosis	1	1.0	-		1	1.0	-	
	Blood calcium increased	1	1.0	1	1.0	-		-	
	Blood creatinine	1	1.0	1	1.0	-		-	
	Blood glucose increased	1	1.0	1	1.0	-		-	
	Blood magnesium decreased	1	1.0	1	1.0	-		-	
	Blood phosphorus decreased	1	1.0	-		1	1.0	-	
	Blood phosphorus increased	1	1.0	1	1.0	-		-	
	Blood potassium increased	1	1.0	1	1.0	-		-	
	Blood pressure increased	1	1.0	1	1.0	-		-	
	Blood thyroid stimulating hormone decreased	1	1.0	1	1.0	-		-	
	Blood urea increased	1	1.0	1	1.0	-		-	
	Body tinea	1	1.0	1	1.0	-		-	
	Breast pain	1	1.0	1	1.0	-		-	
	Bronchitis bacterial	1	1.0	1	1.0	-		-	
	Bronchopneumonia	1	1.0	-		1	1.0	-	
	Bronchospasm	1	1.0	-		1	1.0	-	
	Bundle branch block right	1	1.0	1	1.0	-		-	
	C-reactive protein increased	1	1.0	1	1.0	-		-	
	Cardiac failure	1	1.0	-		-		1	1.0
	Cardiac failure congestive	1	1.0	-		1	1.0	-	
	Cardiac murmur	1	1.0	1	1.0	-		-	
	Cataract	1	1.0	1	1.0	-		-	
	Central venous catheterisation	1	1.0	1	1.0	-		-	
	Cerebral ischaemia	1	1.0	1	1.0	-		-	
	Cheilitis	1	1.0	1	1.0	-		-	
	Chest discomfort	1	1.0	1	1.0	-		-	
	Cholangitis	1	1.0	-		1	1.0	-	
	Cholecystitis	1	1.0	-		1	1.0	-	
	Cholecystitis acute	1	1.0	-		1	1.0	-	
	Cholelithiasis	1	1.0	1	1.0	-		-	
	Chylothorax	1	1.0	1	1.0	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Clostridial infection	1	1.0	1	1.0	-		-	
	Complications of transplanted liver	1	1.0	1	1.0	-		-	
	Conjunctivitis	1	1.0	1	1.0	-		-	
	Convulsion	1	1.0	1	1.0	-		-	
	Cor pulmonale	1	1.0	-		1	1.0	-	
	Coronary artery disease	1	1.0	1	1.0	-		-	
	Cystitis	1	1.0	1	1.0	-		-	
	Cytomegalovirus infection	1	1.0	-		1	1.0	-	
	Deafness unilateral	1	1.0	1	1.0	-		-	
	Decubitus ulcer	1	1.0	-		1	1.0	-	
	Defaecation urgency	1	1.0	1	1.0	-		-	
	Device occlusion	1	1.0	1	1.0	-		-	
	Dysphonia	1	1.0	1	1.0	-		-	
	Ear infection	1	1.0	1	1.0	-		-	
	Eastern Cooperative Oncology Group performance status worsened	1	1.0	1	1.0	-		-	
	Electrocardiogram ST segment depression	1	1.0	1	1.0	-		-	
	Encephalopathy	1	1.0	1	1.0	-		-	
	Endocarditis	1	1.0	-		1	1.0	-	
	Eosinophilia	1	1.0	1	1.0	-		-	
	Epigastric discomfort	1	1.0	1	1.0	-		-	
	Eructation	1	1.0	1	1.0	-		-	
	Escherichia infection	1	1.0	1	1.0	-		-	
	Essential hypertension	1	1.0	1	1.0	-		-	
	Euthanasia	1	1.0	-		-		1	1.0
	Extrapyramidal disorder	1	1.0	1	1.0	-		-	
	Eye discharge	1	1.0	1	1.0	-		-	
	Eye infection	1	1.0	1	1.0	-		-	
	Eye infection bacterial	1	1.0	1	1.0	-		-	
	Eye pain	1	1.0	1	1.0	-		-	
	Eyelid oedema	1	1.0	1	1.0	-		-	
	Eyelid ptosis	1	1.0	1	1.0	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Feeling of body temperature change	1	1.0	1	1.0	-		-	
	Flank pain	1	1.0	1	1.0	-		-	
	Flatulence	1	1.0	1	1.0	-		-	
	Fluid retention	1	1.0	1	1.0	-		-	
	Fungaemia	1	1.0	-		1	1.0	-	
	Fungal infection	1	1.0	1	1.0	-		-	
	Gamma-glutamyltransferase	1	1.0	-		1	1.0	-	
	Gastric ulcer	1	1.0	-		1	1.0	-	
	Gastritis	1	1.0	1	1.0	-		-	
	Gastroenteritis	1	1.0	1	1.0	-		-	
	Gastroenteritis viral	1	1.0	1	1.0	-		-	
	Gastrointestinal fungal infection	1	1.0	-		1	1.0	-	
	Gastrointestinal haemorrhage	1	1.0	-		-		1	1.0
	Gastrointestinal obstruction	1	1.0	-		1	1.0	-	
	Gingival ulceration	1	1.0	1	1.0	-		-	
	Glaucoma	1	1.0	-		1	1.0	-	
	Glucose urine present	1	1.0	-		1	1.0	-	
	Gout	1	1.0	1	1.0	-		-	
	Groin pain	1	1.0	1	1.0	-		-	
	Haematocrit decreased	1	1.0	-		1	1.0	-	
	Haemolytic anaemia	1	1.0	-		1	1.0	-	
	Haemoptysis	1	1.0	1	1.0	-		-	
	Hepatic cirrhosis	1	1.0	1	1.0	-		-	
	Hepatic enzyme increased	1	1.0	1	1.0	-		-	
	Hepatic failure	1	1.0	-		-		1	1.0
	Hepatomegaly	1	1.0	1	1.0	-		-	
	Hypermagnesaemia	1	1.0	1	1.0	-		-	
	Hypersensitivity	1	1.0	1	1.0	-		-	
	Hypoacusis	1	1.0	1	1.0	-		-	
	Hypovolaemic shock	1	1.0	-		1	1.0	-	
	Iliac artery thrombosis	1	1.0	-		1	1.0	-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet >= 100,000/ul (N=105)	Impaired self-care	1	1.0	1	1.0	-		-	
	Infusion site cellulitis	1	1.0	1	1.0	-		-	
	Infusion site extravasation	1	1.0	1	1.0	-		-	
	Infusion site inflammation	1	1.0	1	1.0	-		-	
	Infusion site thrombosis	1	1.0	1	1.0	-		-	
	Injection site induration	1	1.0	1	1.0	-		-	
	Injection site inflammation	1	1.0	1	1.0	-		-	
	Injection site phlebitis	1	1.0	1	1.0	-		-	
	Injection site reaction	1	1.0	1	1.0	-		-	
	Joint swelling	1	1.0	1	1.0	-		-	
	Keratoacanthoma	1	1.0	1	1.0	-		-	
	Keratoconjunctivitis sicca	1	1.0	1	1.0	-		-	
	Lacrimation increased	1	1.0	1	1.0	-		-	
	Lip ulceration	1	1.0	1	1.0	-		-	
	Listless	1	1.0	1	1.0	-		-	
	Liver function test abnormal	1	1.0	-		1	1.0	-	
	Local swelling	1	1.0	1	1.0	-		-	
	Lower limb fracture	1	1.0	-		1	1.0	-	
	Lung neoplasm	1	1.0	1	1.0	-		-	
	Lung squamous cell carcinoma stage unspecified	1	1.0	-		1	1.0	-	
	Lymphocytosis	1	1.0	-		1	1.0	-	
	Mean cell volume increased	1	1.0	1	1.0	-		-	
	Micturition urgency	1	1.0	1	1.0	-		-	
	Monocyte count decreased	1	1.0	1	1.0	-		-	
	Mood altered	1	1.0	1	1.0	-		-	
	Mucosal inflammation	1	1.0	1	1.0	-		-	
	Multiple fractures	1	1.0	-		1	1.0	-	
	Mycosis fungoides	1	1.0	-		1	1.0	-	
	Nasal discomfort	1	1.0	1	1.0	-		-	
	Nasal dryness	1	1.0	1	1.0	-		-	
	Neoplasm skin	1	1.0	1	1.0	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Neutrophil count decreased	1	1.0	1	1.0	-		-	
	Obstructive airways disorder	1	1.0	1	1.0	-		-	
	Odynophagia	1	1.0	1	1.0	-		-	
	Oliguria	1	1.0	1	1.0	-		-	
	Opportunistic infection	1	1.0	-		1	1.0	-	
	Oral fungal infection	1	1.0	1	1.0	-		-	
	Oral herpes	1	1.0	1	1.0	-		-	
	Oropharyngeal discomfort	1	1.0	1	1.0	-		-	
	Otitis media	1	1.0	1	1.0	-		-	
	Otorrhoea	1	1.0	1	1.0	-		-	
	Oxygen saturation decreased	1	1.0	1	1.0	-		-	
	PCO2 decreased	1	1.0	1	1.0	-		-	
	Palmar erythema	1	1.0	1	1.0	-		-	
	Palmar-plantar erythrodysaesthesia syndrome	1	1.0	1	1.0	-		-	
	Pancreatitis	1	1.0	1	1.0	-		-	
	Pancytopenia	1	1.0	-		1	1.0	-	
	Periorbital oedema	1	1.0	1	1.0	-		-	
	Periostitis	1	1.0	1	1.0	-		-	
	Peripheral motor neuropathy	1	1.0	1	1.0	-		-	
	Pharyngitis bacterial	1	1.0	1	1.0	-		-	
	Phlebitis superficial	1	1.0	1	1.0	-		-	
	Pneumonia viral	1	1.0	-		1	1.0	-	
	Polyneuropathy	1	1.0	1	1.0	-		-	
	Poor quality sleep	1	1.0	1	1.0	-		-	
	Procedural pain	1	1.0	1	1.0	-		-	
	Proctalgia	1	1.0	1	1.0	-		-	
	Productive cough	1	1.0	1	1.0	-		-	
	Prostatomegaly	1	1.0	1	1.0	-		-	
	Protein total decreased	1	1.0	1	1.0	-		-	
	Prothrombin time shortened	1	1.0	-		1	1.0	-	
	Pruritus generalised	1	1.0	1	1.0	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Pulmonary mass	1	1.0	1	1.0	-		-	
	Pulmonary oedema	1	1.0	1	1.0	-		-	
	Rales	1	1.0	1	1.0	-		-	
	Rash macular	1	1.0	1	1.0	-		-	
	Rash maculo-papular	1	1.0	1	1.0	-		-	
	Renal failure	1	1.0	1	1.0	-		-	
	Renal failure acute	1	1.0	-		1	1.0	-	
	Respiratory alkalosis	1	1.0	-		1	1.0	-	
	Respiratory distress	1	1.0	-		1	1.0	-	
	Respiratory syncytial virus infection	1	1.0	1	1.0	-		-	
	Respiratory tract infection	1	1.0	1	1.0	-		-	
	Restless legs syndrome	1	1.0	1	1.0	-		-	
	Restlessness	1	1.0	1	1.0	-		-	
	Retinal vein thrombosis	1	1.0	-		1	1.0	-	
	Rhinitis	1	1.0	1	1.0	-		-	
	Salivary hypersecretion	1	1.0	1	1.0	-		-	
	Shock	1	1.0	-		-		1	1.0
	Sinus bradycardia	1	1.0	1	1.0	-		-	
	Sinus polyp	1	1.0	1	1.0	-		-	
	Sinus tachycardia	1	1.0	-		1	1.0	-	
	Skin burning sensation	1	1.0	1	1.0	-		-	
	Skin cancer	1	1.0	1	1.0	-		-	
	Skin candida	1	1.0	1	1.0	-		-	
	Skin exfoliation	1	1.0	1	1.0	-		-	
	Skin ulcer	1	1.0	1	1.0	-		-	
	Somnolence	1	1.0	1	1.0	-		-	
	Spinal fracture	1	1.0	1	1.0	-		-	
	Staphylococcal sepsis	1	1.0	1	1.0	-		-	
	Staphylococcal skin infection	1	1.0	1	1.0	-		-	
	Subcutaneous nodule	1	1.0	-		1	1.0	-	
	Supraventricular tachycardia	1	1.0	-		1	1.0	-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA Preferred Term	All Grades n	All Grades %	Grades 1-2 n	Grades 1-2 %	Grades 3-4 n	Grades 3-4 %	Grade 5 n	Grade 5 %
Platelet >= 100,000/ul (N=105)	Syncope	1	1.0	1	1.0	-		-	
	Tachypnoea	1	1.0	1	1.0	-		-	
	Thrombocytosis	1	1.0	1	1.0	-		-	
	Thrombophlebitis superficial	1	1.0	1	1.0	-		-	
	Thrombosed varicose vein	1	1.0	-		1	1.0	-	
	Thrombosis in device	1	1.0	1	1.0	-		-	
	Tongue haematoma	1	1.0	1	1.0	-		-	
	Tooth fracture	1	1.0	1	1.0	-		-	
	Toothache	1	1.0	1	1.0	-		-	
	Toxic cataract	1	1.0	1	1.0	-		-	
	Tracheostomy malfunction	1	1.0	1	1.0	-		-	
	Tumour haemorrhage	1	1.0	-		1	1.0	-	
	Tympanic membrane disorder	1	1.0	1	1.0	-		-	
	Urinary tract infection bacterial	1	1.0	1	1.0	-		-	
	Urinary tract infection staphylococcal	1	1.0	1	1.0	-		-	
	Urosepsis	1	1.0	-		1	1.0	-	
	Urticaria	1	1.0	1	1.0	-		-	
	Vasculitis	1	1.0	1	1.0	-		-	
	Venous thrombosis limb	1	1.0	-		1	1.0	-	
	Ventricular extrasystoles	1	1.0	1	1.0	-		-	
	Vertigo	1	1.0	1	1.0	-		-	
	Visual impairment	1	1.0	1	1.0	-		-	
	Vitreous haemorrhage	1	1.0	1	1.0	-		-	
	Wheezing	1	1.0	1	1.0	-		-	
	White blood cell count decreased	1	1.0	1	1.0	-		-	
	White blood cell count increased	1	1.0	1	1.0	-		-	
Platelet < 100,000/ul (N=24)	Anaemia	11	45.8	4	16.7	7	29.2	-	
	Thrombocytopenia	9	37.5	2	8.3	7	29.2	-	
	Nausea	8	33.3	7	29.2	1	4.2	-	
	Pyrexia	8	33.3	6	25.0	2	8.3	-	
	Constipation	7	29.2	7	29.2	-		-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet < 100,000/ul (N=24)	Dyspnoea	7	29. 2	5	20. 8	2	8. 3	-	
	Neutropenia	6	25. 0	3	12. 5	3	12. 5	-	
	Asthenia	5	20. 8	2	8. 3	3	12. 5	-	
	Cough	5	20. 8	5	20. 8	-		-	
	Diarrhoea	5	20. 8	4	16. 7	1	4. 2	-	
	Leukopenia	5	20. 8	3	12. 5	2	8. 3	-	
	Pruritus	5	20. 8	2	8. 3	3	12. 5	-	
	Blood lactate dehydrogenase increased	4	16. 7	3	12. 5	1	4. 2	-	
	Electrocardiogram QT prolonged	4	16. 7	2	8. 3	2	8. 3	-	
	Fatigue	4	16. 7	4	16. 7	-		-	
	Oedema peripheral	4	16. 7	4	16. 7	-		-	
	Febrile neutropenia	3	12. 5	-		3	12. 5	-	
	Headache	3	12. 5	3	12. 5	-		-	
	Hyperhidrosis	3	12. 5	3	12. 5	-		-	
	Hypotension	3	12. 5	2	8. 3	1	4. 2	-	
	Mucosal inflammation	3	12. 5	3	12. 5	-		-	
	Muscle spasms	3	12. 5	3	12. 5	-		-	
	Rash	3	12. 5	3	12. 5	-		-	
	Sinusitis	3	12. 5	3	12. 5	-		-	
	Vomiting	3	12. 5	3	12. 5	-		-	
	Abdominal pain	2	8. 3	2	8. 3	-		-	
	Blood creatinine increased	2	8. 3	2	8. 3	-		-	
	Blood urea increased	2	8. 3	2	8. 3	-		-	
	Bronchitis	2	8. 3	1	4. 2	1	4. 2	-	
	Chest pain	2	8. 3	2	8. 3	-		-	
	Chills	2	8. 3	2	8. 3	-		-	
	Decreased appetite	2	8. 3	2	8. 3	-		-	
	Dizziness	2	8. 3	2	8. 3	-		-	
	Hyperglycaemia	2	8. 3	2	8. 3	-		-	
	Hypoalbuminaemia	2	8. 3	1	4. 2	1	4. 2	-	
	Hypokalaemia	2	8. 3	1	4. 2	1	4. 2	-	

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet < 100,000/ul (N=24)	Infusion site pain	2	8. 3	2	8. 3		-		-
	Lymphopenia	2	8. 3	1	4. 2	1	4. 2		-
	Neuropathy peripheral	2	8. 3	1	4. 2	1	4. 2		-
	Pain	2	8. 3	1	4. 2	1	4. 2		-
	Platelet count decreased	2	8. 3	1	4. 2	1	4. 2		-
	White blood cell count decreased	2	8. 3		-	2	8. 3		-
	Abdominal distension	1	4. 2	1	4. 2		-		-
	Administration site infection	1	4. 2	1	4. 2		-		-
	Ageusia	1	4. 2	1	4. 2		-		-
	Alanine aminotransferase increased	1	4. 2	1	4. 2		-		-
	Allergic transfusion reaction	1	4. 2	1	4. 2		-		-
	Anaemia haemolytic autoimmune	1	4. 2		-	1	4. 2		-
	Anxiety	1	4. 2	1	4. 2		-		-
	Ascites	1	4. 2		-	1	4. 2		-
	Back pain	1	4. 2	1	4. 2		-		-
	Blood alkaline phosphatase increased	1	4. 2	1	4. 2		-		-
	Blood bilirubin increased	1	4. 2	1	4. 2		-		-
	Blood bilirubin unconjugated increased	1	4. 2	1	4. 2		-		-
	Blood calcium increased	1	4. 2		-	1	4. 2		-
	Blood creatinine	1	4. 2	1	4. 2		-		-
	Blood glucose increased	1	4. 2	1	4. 2		-		-
	Blood potassium decreased	1	4. 2		-	1	4. 2		-
	Bowel movement irregularity	1	4. 2	1	4. 2		-		-
	Bronchopneumonia	1	4. 2	1	4. 2		-		-
	C-reactive protein increased	1	4. 2	1	4. 2		-		-
	Cardiac failure	1	4. 2		-		-	1	4. 2
	Confusional state	1	4. 2	1	4. 2		-		-
	Crystal arthropathy	1	4. 2	1	4. 2		-		-
	Cytomegalovirus infection	1	4. 2	1	4. 2		-		-
	Depression	1	4. 2	1	4. 2		-		-
	Dermatitis contact	1	4. 2	1	4. 2		-		-

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet < 100,000/ul (N=24)	Device related infection	1	4. 2	1	4. 2	-		-	
	Diabetes mellitus	1	4. 2	1	4. 2	-		-	
	Dry mouth	1	4. 2	1	4. 2	-		-	
	Ear discomfort	1	4. 2	1	4. 2	-		-	
	Eastern Cooperative Oncology Group performance status worsened	1	4. 2	-		1	4. 2	-	
	Epstein-Barr virus infection	1	4. 2	1	4. 2	-		-	
	Extremity necrosis	1	4. 2	-		1	4. 2	-	
	Flushing	1	4. 2	1	4. 2	-		-	
	Genital herpes	1	4. 2	1	4. 2	-		-	
	Glomerular filtration rate decreased	1	4. 2	1	4. 2	-		-	
	Groin pain	1	4. 2	1	4. 2	-		-	
	Hepatosplenomegaly	1	4. 2	1	4. 2	-		-	
	Hyperbilirubinaemia	1	4. 2	1	4. 2	-		-	
	Hyperkalaemia	1	4. 2	1	4. 2	-		-	
	Hypersensitivity	1	4. 2	1	4. 2	-		-	
	Hypertension	1	4. 2	1	4. 2	-		-	
	Hyperuricaemia	1	4. 2	1	4. 2	-		-	
	Hypoglycaemia	1	4. 2	-		1	4. 2	-	
	Hyponatraemia	1	4. 2	1	4. 2	-		-	
	Hypophosphataemia	1	4. 2	1	4. 2	-		-	
	Hypotonia	1	4. 2	1	4. 2	-		-	
	Infection	1	4. 2	-		1	4. 2	-	
	Infusion site coldness	1	4. 2	1	4. 2	-		-	
	Injection site pruritus	1	4. 2	1	4. 2	-		-	
	International normalised ratio decreased	1	4. 2	1	4. 2	-		-	
	International normalised ratio increased	1	4. 2	-		1	4. 2	-	
	Joint swelling	1	4. 2	1	4. 2	-		-	
	Lethargy	1	4. 2	1	4. 2	-		-	
	Lung infiltration	1	4. 2	1	4. 2	-		-	
	Mean cell volume increased	1	4. 2	1	4. 2	-		-	
	Multi-organ failure	1	4. 2	-		-		1	4. 2

Table 14.3.6.10: Treatment Emergent Adverse Events by MedDRA Preferred Term by Baseline Platelet Group

Full Analysis Set

		All Grades		Grades 1-2		Grades 3-4		Grade 5	
Baseline Platelet Group	**MedDRA Preferred Term**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Platelet < 100,000/ul (N=24)	Musculoskeletal pain	1	4. 2	1	4. 2		-		-
	Nasopharyngitis	1	4. 2	1	4. 2		-		-
	Neutrophil count decreased	1	4. 2		-	1	4. 2		-
	Night sweats	1	4. 2	1	4. 2		-		-
	Oedema	1	4. 2	1	4. 2		-		-
	Oesophagitis	1	4. 2		-	1	4. 2		-
	Oral herpes	1	4. 2	1	4. 2		-		-
	Pancytopenia	1	4. 2		-	1	4. 2		-
	Pharyngeal ulceration	1	4. 2	1	4. 2		-		-
	Pharyngitis	1	4. 2		-	1	4. 2		-
	Phlebitis	1	4. 2	1	4. 2		-		-
	Pollakiuria	1	4. 2	1	4. 2		-		-
	Red blood cell count decreased	1	4. 2	1	4. 2		-		-
	Renal failure	1	4. 2	1	4. 2		-		-
	Respiratory failure	1	4. 2		-	1	4. 2		-
	Restlessness	1	4. 2	1	4. 2		-		-
	Septic shock	1	4. 2		-	1	4. 2		-
	Sinus tachycardia	1	4. 2	1	4. 2		-		-
	Staphylococcal infection	1	4. 2		-	1	4. 2		-
	Testicular pain	1	4. 2	1	4. 2		-		-
	Tumour lysis syndrome	1	4. 2		-	1	4. 2		-
	Vasculitis	1	4. 2		-	1	4. 2		-
	Vein pain	1	4. 2	1	4. 2		-		-
	Vision blurred	1	4. 2	1	4. 2		-		-
	Weight decreased	1	4. 2	1	4. 2		-		-
	Weight increased	1	4. 2	1	4. 2		-		-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Blood and lymphatic system disorders						
	Anaemia	30 (28.6)	6 (5. 7)	17 (16.2)	7 (6. 7)	-	-
	Basophilia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Eosinophilia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Febrile neutropenia	4 (3. 8)	1 (1. 0)	-	3 (2. 9)	-	-
	Haemolytic anaemia	1 (1. 0)	-	-	1 (1. 0)	-	-
	Leukocytosis	3 (2. 9)	2 (1. 9)	-	1 (1. 0)	-	-
	Leukopenia	7 (6. 7)	2 (1. 9)	4 (3. 8)	-	1 (1. 0)	-
	Lymphadenopathy	3 (2. 9)	3 (2. 9)	-	-	-	-
	Lymphocytosis	1 (1. 0)	-	-	-	1 (1. 0)	-
	Lymphopenia	9 (8. 6)	-	4 (3. 8)	5 (4. 8)	-	-
	Neutropenia	6 (5. 7)	1 (1. 0)	-	5 (4. 8)	-	-
	Pancytopenia	1 (1. 0)	-	-	1 (1. 0)	-	-
	Splenomegaly	2 (1. 9)	1 (1. 0)	-	1 (1. 0)	-	-
	Thrombocytopenia	12 (11.4)	7 (6. 7)	3 (2. 9)	-	2 (1. 9)	-
	Thrombocytosis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Cardiac disorders						
	Atrial fibrillation	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-	-
	Bundle branch block right	1 (1. 0)	1 (1. 0)	-	-	-	-
	Cardiac failure	1 (1. 0)	-	-	-	-	1 (1. 0)
	Cardiac failure congestive	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cor pulmonale	1 (1. 0)	-	-	1 (1. 0)	-	-
	Coronary artery disease	1 (1. 0)	1 (1. 0)	-	-	-	-
	Sinus bradycardia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Sinus tachycardia	1 (1. 0)	-	-	1 (1. 0)	-	-
	Supraventricular tachycardia	1 (1. 0)	-	-	1 (1. 0)	-	-
	Tachycardia	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Ventricular extrasystoles	1 (1.0)	1 (1.0)	-	-	-	-
	Ear and labyrinth disorders						
	Deafness unilateral	1 (1.0)	1 (1.0)	-	-	-	-
	Hypoacusis	1 (1.0)	1 (1.0)	-	-	-	-
	Otorrhoea	1 (1.0)	1 (1.0)	-	-	-	-
	Tympanic membrane disorder	1 (1.0)	1 (1.0)	-	-	-	-
	Vertigo	1 (1.0)	1 (1.0)	-	-	-	-
	Eye disorders						
	Cataract	1 (1.0)	1 (1.0)	-	-	-	-
	Conjunctivitis	1 (1.0)	-	1 (1.0)	-	-	-
	Dry eye	2 (1.9)	2 (1.9)	-	-	-	-
	Eye discharge	1 (1.0)	1 (1.0)	-	-	-	-
	Eye pain	1 (1.0)	1 (1.0)	-	-	-	-
	Eyelid oedema	1 (1.0)	1 (1.0)	-	-	-	-
	Eyelid ptosis	1 (1.0)	1 (1.0)	-	-	-	-
	Glaucoma	1 (1.0)	-	-	1 (1.0)	-	-
	Keratoconjunctivitis sicca	1 (1.0)	1 (1.0)	-	-	-	-
	Lacrimation increased	1 (1.0)	1 (1.0)	-	-	-	-
	Periorbital oedema	1 (1.0)	1 (1.0)	-	-	-	-
	Retinal vein thrombosis	1 (1.0)	-	-	1 (1.0)	-	-
	Toxic cataract	1 (1.0)	1 (1.0)	-	-	-	-
	Vision blurred	3 (2.9)	3 (2.9)	-	-	-	-
	Visual impairment	1 (1.0)	1 (1.0)	-	-	-	-
	Vitreous haemorrhage	1 (1.0)	-	1 (1.0)	-	-	-
	Gastrointestinal disorders						
	Abdominal discomfort	2 (1.9)	2 (1.9)	-	-	-	-
	Abdominal distension	2 (1.9)	2 (1.9)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Abdominal pain	12 (11.4)	3 (2. 9)	8 (7. 6)	1 (1. 0)	-	-
	Abdominal pain lower	1 (1. 0)	1 (1. 0)	-	-	-	-
	Abdominal pain upper	7 (6. 7)	3 (2. 9)	3 (2. 9)	1 (1. 0)	-	-
	Anal fissure	1 (1. 0)	1 (1. 0)	-	-	-	-
	Anal pruritus	1 (1. 0)	-	1 (1. 0)	-	-	-
	Ascites	2 (1. 9)	-	2 (1. 9)	-	-	-
	Cheilitis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Constipation	23 (21.9)	16 (15.2)	6 (5. 7)	1 (1. 0)	-	-
	Defaecation urgency	1 (1. 0)	1 (1. 0)	-	-	-	-
	Diarrhoea	24 (22.9)	17 (16.2)	6 (5. 7)	1 (1. 0)	-	-
	Dry mouth	3 (2. 9)	2 (1. 9)	-	1 (1. 0)	-	-
	Dyspepsia	5 (4. 8)	4 (3. 8)	1 (1. 0)	-	-	-
	Dysphagia	2 (1. 9)	-	2 (1. 9)	-	-	-
	Epigastric discomfort	1 (1. 0)	-	1 (1. 0)	-	-	-
	Eructation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Flatulence	1 (1. 0)	1 (1. 0)	-	-	-	-
	Gastric ulcer	1 (1. 0)	-	-	1 (1. 0)	-	-
	Gastritis	1 (1. 0)	-	1 (1. 0)	-	-	-
	Gastrointestinal haemorrhage	1 (1. 0)	-	-	-	-	1 (1. 0)
	Gastrointestinal obstruction	1 (1. 0)	-	-	1 (1. 0)	-	-
	Gastrooesophageal reflux disease	4 (3. 8)	3 (2. 9)	1 (1. 0)	-	-	-
	Gingival ulceration	1 (1. 0)	1 (1. 0)	-	-	-	-
	Haematemesis	2 (1. 9)	1 (1. 0)	-	1 (1. 0)	-	-
	Lip ulceration	1 (1. 0)	-	1 (1. 0)	-	-	-
	Melaena	2 (1. 9)	1 (1. 0)	-	1 (1. 0)	-	-
	Nausea	46 (43.8)	29 (27.6)	17 (16.2)	-	-	-
	Odynophagia	1 (1. 0)	-	1 (1. 0)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Pancreatitis	1 (1. 0)	-	1 (1. 0)	-	-	-
	Paraesthesia oral	2 (1. 9)	2 (1. 9)	-	-	-	-
	Proctalgia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Salivary hypersecretion	1 (1. 0)	1 (1. 0)	-	-	-	-
	Stomatitis	5 (4. 8)	2 (1. 9)	2 (1. 9)	1 (1. 0)	-	-
	Tongue haematoma	1 (1. 0)	1 (1. 0)	-	-	-	-
	Toothache	1 (1. 0)	-	1 (1. 0)	-	-	-
	Vomiting	34 (32.4)	25 (23.8)	8 (7. 6)	1 (1. 0)	-	-
	General disorders and administration site conditions						
	Asthenia	7 (6. 7)	3 (2. 9)	3 (2. 9)	-	1 (1. 0)	-
	Axillary pain	1 (1. 0)	-	1 (1. 0)	-	-	-
	Chest discomfort	1 (1. 0)	1 (1. 0)	-	-	-	-
	Chest pain	3 (2. 9)	1 (1. 0)	1 (1. 0)	1 (1. 0)	-	-
	Chills	19 (18.1)	14 (13.3)	4 (3. 8)	1 (1. 0)	-	-
	Device occlusion	1 (1. 0)	1 (1. 0)	-	-	-	-
	Euthanasia	1 (1. 0)	-	-	-	-	1 (1. 0)
	Extravasation	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-	-
	Face oedema	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-	-
	Fatigue	44 (41.9)	20 (19.0)	17 (16.2)	7 (6. 7)	-	-
	Feeling of body temperature change	1 (1. 0)	-	1 (1. 0)	-	-	-
	General physical health deterioration	3 (2. 9)	-	1 (1. 0)	2 (1. 9)	-	-
	Generalised oedema	2 (1. 9)	-	2 (1. 9)	-	-	-
	Infusion site extravasation	1 (1. 0)	-	1 (1. 0)	-	-	-
	Infusion site inflammation	1 (1. 0)	-	1 (1. 0)	-	-	-
	Infusion site pain	16 (15.2)	7 (6. 7)	9 (8. 6)	-	-	-
	Infusion site reaction	2 (1. 9)	2 (1. 9)	-	-	-	-
	Infusion site thrombosis	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Injection site induration	1 (1. 0)	-	1 (1. 0)	-	-	-
	Injection site inflammation	1 (1. 0)	-	1 (1. 0)	-	-	-
	Injection site pain	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Injection site phlebitis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Injection site reaction	1 (1. 0)	1 (1. 0)	-	-	-	-
	Local swelling	1 (1. 0)	1 (1. 0)	-	-	-	-
	Malaise	4 (3. 8)	-	3 (2. 9)	1 (1. 0)	-	-
	Mucosal inflammation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Multi-organ failure	2 (1. 9)	-	-	-	-	2 (1. 9)
	Oedema	4 (3. 8)	1 (1. 0)	2 (1. 9)	1 (1. 0)	-	-
	Oedema peripheral	22 (21.0)	17 (16.2)	5 (4. 8)	-	-	-
	Pain	10 (9.5)	7 (6. 7)	2 (1. 9)	-	1 (1. 0)	-
	Pyrexia	37 (35.2)	23 (21.9)	13 (12.4)	1 (1. 0)	-	-
	Thrombosis in device	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hepatobiliary disorders						
	Bile duct stenosis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cholangitis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cholecystitis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cholecystitis acute	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cholelithiasis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hepatic cirrhosis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hepatic failure	1 (1. 0)	-	-	-	-	1 (1. 0)
	Hepatomegaly	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hyperbilirubinaemia	2 (1. 9)	1 (1. 0)	-	1 (1. 0)	-	-
	Immune system disorders						
	Anaphylactic reaction	1 (1. 0)	-	-	-	1 (1. 0)	-
	Hypersensitivity	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Infections and infestations						
	Administration site infection	1 (1.0)	-	1 (1.0)	-	-	-
	Anal candidiasis	1 (1.0)	-	1 (1.0)	-	-	-
	Bacterial infection	1 (1.0)	1 (1.0)	-	-	-	-
	Body tinea	1 (1.0)	1 (1.0)	-	-	-	-
	Bronchitis	9 (8.6)	5 (4.8)	2 (1.9)	2 (1.9)	-	-
	Bronchitis bacterial	1 (1.0)	-	1 (1.0)	-	-	-
	Bronchopneumonia	1 (1.0)	-	-	1 (1.0)	-	-
	Candidiasis	2 (1.9)	-	2 (1.9)	-	-	-
	Cellulitis	3 (2.9)	-	2 (1.9)	1 (1.0)	-	-
	Clostridial infection	1 (1.0)	-	1 (1.0)	-	-	-
	Cystitis	1 (1.0)	-	1 (1.0)	-	-	-
	Cytomegalovirus infection	1 (1.0)	-	-	1 (1.0)	-	-
	Device related infection	4 (3.8)	-	3 (2.9)	1 (1.0)	-	-
	Ear infection	1 (1.0)	1 (1.0)	-	-	-	-
	Endocarditis	1 (1.0)	-	-	-	1 (1.0)	-
	Escherichia infection	1 (1.0)	-	1 (1.0)	-	-	-
	Eye infection	1 (1.0)	-	1 (1.0)	-	-	-
	Eye infection bacterial	1 (1.0)	1 (1.0)	-	-	-	-
	Fungaemia	1 (1.0)	-	-	1 (1.0)	-	-
	Fungal infection	1 (1.0)	-	1 (1.0)	-	-	-
	Gastroenteritis	1 (1.0)	1 (1.0)	-	-	-	-
	Gastroenteritis viral	1 (1.0)	-	1 (1.0)	-	-	-
	Gastrointestinal fungal infection	1 (1.0)	-	-	1 (1.0)	-	-
	Herpes simplex	3 (2.9)	1 (1.0)	2 (1.9)	-	-	-
	Herpes zoster	2 (1.9)	1 (1.0)	-	1 (1.0)	-	-
	Infection	5 (4.8)	1 (1.0)	1 (1.0)	2 (1.9)	1 (1.0)	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Infusion site cellulitis	1 (1.0)	-	1 (1.0)	-	-	-
	Lung infection	2 (1.9)	-	1 (1.0)	-	-	1 (1.0)
	Nasopharyngitis	6 (5.7)	6 (5.7)	-	-	-	-
	Opportunistic infection	1 (1.0)	-	-	1 (1.0)	-	-
	Oral candidiasis	5 (4.8)	2 (1.9)	3 (2.9)	-	-	-
	Oral fungal infection	1 (1.0)	1 (1.0)	-	-	-	-
	Oral herpes	1 (1.0)	-	1 (1.0)	-	-	-
	Otitis media	1 (1.0)	-	1 (1.0)	-	-	-
	Pharyngitis	3 (2.9)	2 (1.9)	-	1 (1.0)	-	-
	Pharyngitis bacterial	1 (1.0)	1 (1.0)	-	-	-	-
	Pneumonia	10 (9.5)	-	2 (1.9)	7 (6.7)	-	1 (1.0)
	Pneumonia viral	1 (1.0)	-	-	1 (1.0)	-	-
	Respiratory syncytial virus infection	1 (1.0)	-	1 (1.0)	-	-	-
	Respiratory tract infection	1 (1.0)	1 (1.0)	-	-	-	-
	Rhinitis	1 (1.0)	-	1 (1.0)	-	-	-
	Sepsis	3 (2.9)	-	-	3 (2.9)	-	-
	Septic shock	2 (1.9)	-	1 (1.0)	-	1 (1.0)	-
	Sinusitis	4 (3.8)	2 (1.9)	1 (1.0)	1 (1.0)	-	-
	Skin candida	1 (1.0)	-	1 (1.0)	-	-	-
	Staphylococcal infection	3 (2.9)	1 (1.0)	1 (1.0)	1 (1.0)	-	-
	Staphylococcal sepsis	1 (1.0)	-	1 (1.0)	-	-	-
	Staphylococcal skin infection	1 (1.0)	1 (1.0)	-	-	-	-
	Tonsillitis	2 (1.9)	-	2 (1.9)	-	-	-
	Upper respiratory tract infection	10 (9.5)	7 (6.7)	2 (1.9)	1 (1.0)	-	-
	Urinary tract infection	5 (4.8)	-	5 (4.8)	-	-	-
	Urinary tract infection bacterial	1 (1.0)	-	1 (1.0)	-	-	-
	Urinary tract infection staphylococcal	1 (1.0)	-	1 (1.0)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Urosepsis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Injury, poisoning and procedural complications						
	Complications of transplanted liver	1 (1. 0)	1 (1. 0)	-	-	-	-
	Excoriation	2 (1. 9)	2 (1. 9)	-	-	-	-
	Fall	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Infusion related reaction	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Lower limb fracture	1 (1. 0)	-	-	1 (1. 0)	-	-
	Multiple fractures	1 (1. 0)	-	-	1 (1. 0)	-	-
	Procedural pain	1 (1. 0)	-	1 (1. 0)	-	-	-
	Spinal fracture	1 (1. 0)	1 (1. 0)	-	-	-	-
	Tooth fracture	1 (1. 0)	1 (1. 0)	-	-	-	-
	Tracheostomy malfunction	1 (1. 0)	1 (1. 0)	-	-	-	-
	Investigations						
	Activated partial thromboplastin time prolonged	4 (3. 8)	3 (2. 9)	-	1 (1. 0)	-	-
	Alanine aminotransferase increased	7 (6. 7)	2 (1. 9)	1 (1. 0)	4 (3. 8)	-	-
	Aspartate aminotransferase increased	9 (8. 6)	4 (3. 8)	1 (1. 0)	4 (3. 8)	-	-
	Blood albumin decreased	2 (1. 9)	2 (1. 9)	-	-	-	-
	Blood alkaline phosphatase increased	6 (5. 7)	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-
	Blood bilirubin increased	3 (2. 9)	1 (1. 0)	1 (1. 0)	1 (1. 0)	-	-
	Blood calcium increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Blood creatinine	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood creatinine increased	7 (6. 7)	1 (1. 0)	6 (5. 7)	-	-	-
	Blood glucose increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood lactate dehydrogenase increased	16 (15.2)	12 (11.4)	3 (2. 9)	-	1 (1. 0)	-
	Blood magnesium decreased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood phosphorus decreased	1 (1. 0)	-	-	1 (1. 0)	-	-
	Blood phosphorus increased	1 (1. 0)	-	1 (1. 0)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Blood potassium decreased	2 (1. 9)	2 (1. 9)	-	-	-	-
	Blood potassium increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Blood pressure increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Blood thyroid stimulating hormone decreased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood urea increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Blood uric acid increased	2 (1. 9)	2 (1. 9)	-	-	-	-
	Body temperature increased	2 (1. 9)	2 (1. 9)	-	-	-	-
	C-reactive protein increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Cardiac murmur	1 (1. 0)	1 (1. 0)	-	-	-	-
	Eastern Cooperative Oncology Group performance status worsened	1 (1. 0)	1 (1. 0)	-	-	-	-
	Electrocardiogram QT prolonged	10 (9.5)	4 (3. 8)	3 (2. 9)	3 (2. 9)	-	-
	Electrocardiogram ST segment depression	1 (1. 0)	1 (1. 0)	-	-	-	-
	Gamma-glutamyltransferase	1 (1. 0)	-	-	1 (1. 0)	-	-
	Gamma-glutamyltransferase increased	3 (2. 9)	1 (1. 0)	-	1 (1. 0)	1 (1. 0)	-
	Glomerular filtration rate decreased	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Glucose urine present	1 (1. 0)	-	-	1 (1. 0)	-	-
	Haematocrit decreased	1 (1. 0)	-	-	1 (1. 0)	-	-
	Haemoglobin decreased	2 (1. 9)	1 (1. 0)	-	1 (1. 0)	-	-
	Hepatic enzyme increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	International normalised ratio increased	4 (3. 8)	2 (1. 9)	-	2 (1. 9)	-	-
	Liver function test abnormal	1 (1. 0)	-	-	1 (1. 0)	-	-
	Mean cell volume increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Monocyte count decreased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Neutrophil count decreased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Oxygen saturation decreased	1 (1. 0)	1 (1. 0)	-	-	-	-
	PCO2 decreased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Platelet count decreased	7 (6. 7)	3 (2. 9)	1 (1. 0)	1 (1. 0)	2 (1. 9)	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Protein total decreased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Prothrombin time prolonged	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Prothrombin time shortened	1 (1. 0)	-	-	1 (1. 0)	-	-
	Weight decreased	6 (5. 7)	4 (3. 8)	2 (1. 9)	-	-	-
	White blood cell count decreased	1 (1. 0)	-	1 (1. 0)	-	-	-
	White blood cell count increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Metabolism and nutrition disorders						
	Decreased appetite	17 (16.2)	11 (10.5)	3 (2. 9)	3 (2. 9)	-	-
	Dehydration	3 (2. 9)	-	3 (2. 9)	-	-	-
	Diabetes mellitus	2 (1. 9)	-	1 (1. 0)	1 (1. 0)	-	-
	Fluid retention	1 (1. 0)	-	1 (1. 0)	-	-	-
	Gout	1 (1. 0)	-	1 (1. 0)	-	-	-
	Hypercalcaemia	3 (2. 9)	1 (1. 0)	-	1 (1. 0)	1 (1. 0)	-
	Hyperglycaemia	10 (9.5)	6 (5. 7)	1 (1. 0)	3 (2. 9)	-	-
	Hyperkalaemia	3 (2. 9)	3 (2. 9)	-	-	-	-
	Hyperlipidaemia	2 (1. 9)	2 (1. 9)	-	-	-	-
	Hypermagnesaemia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hyperuricaemia	7 (6. 7)	7 (6. 7)	-	-	-	-
	Hypoalbuminaemia	8 (7. 6)	5 (4. 8)	2 (1. 9)	1 (1. 0)	-	-
	Hypocalcaemia	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Hypokalaemia	14 (13.3)	6 (5. 7)	4 (3. 8)	4 (3. 8)	-	-
	Hypomagnesaemia	7 (6. 7)	7 (6. 7)	-	-	-	-
	Hyponatraemia	2 (1. 9)	2 (1. 9)	-	-	-	-
	Tumour lysis syndrome	3 (2. 9)	-	2 (1. 9)	1 (1. 0)	-	-
	Musculoskeletal and connective tissue disorders						
	Arthralgia	6 (5. 7)	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-
	Arthritis	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Back pain	6 (5. 7)	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-
	Bone pain	3 (2. 9)	1 (1. 0)	1 (1. 0)	1 (1. 0)	-	-
	Flank pain	1 (1. 0)	-	1 (1. 0)	-	-	-
	Groin pain	1 (1. 0)	1 (1. 0)	-	-	-	-
	Joint swelling	1 (1. 0)	1 (1. 0)	-	-	-	-
	Muscle spasms	6 (5. 7)	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-
	Muscular weakness	2 (1. 9)	2 (1. 9)	-	-	-	-
	Musculoskeletal chest pain	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Musculoskeletal pain	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-	-
	Myalgia	5 (4. 8)	4 (3. 8)	1 (1. 0)	-	-	-
	Neck pain	2 (1. 9)	-	-	2 (1. 9)	-	-
	Pain in extremity	11 (10.5)	4 (3. 8)	6 (5. 7)	1 (1. 0)	-	-
	Pathological fracture	3 (2. 9)	1 (1. 0)	1 (1. 0)	-	1 (1. 0)	-
	Periostitis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Spinal osteoarthritis	2 (1. 9)	2 (1. 9)	-	-	-	-
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
	Keratoacanthoma	1 (1. 0)	1 (1. 0)	-	-	-	-
	Lung neoplasm	1 (1. 0)	1 (1. 0)	-	-	-	-
	Lung squamous cell carcinoma stage unspecified	1 (1. 0)	-	-	-	1 (1. 0)	-
	Mycosis fungoides	1 (1. 0)	-	-	1 (1. 0)	-	-
	Neoplasm skin	1 (1. 0)	1 (1. 0)	-	-	-	-
	Skin cancer	1 (1. 0)	-	1 (1. 0)	-	-	-
	Tumour associated fever	2 (1. 9)	-	2 (1. 9)	-	-	-
	Tumour haemorrhage	1 (1. 0)	-	-	1 (1. 0)	-	-
	Tumour pain	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-	-
	Nervous system disorders						
	Ageusia	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Amnesia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Aphasia	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cerebral ischaemia	1 (1. 0)	-	1 (1. 0)	-	-	-
	Convulsion	1 (1. 0)	-	1 (1. 0)	-	-	-
	Dizziness	11 (10.5)	8 (7. 6)	3 (2. 9)	-	-	-
	Dysgeusia	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Encephalopathy	1 (1. 0)	1 (1. 0)	-	-	-	-
	Extrapyramidal disorder	1 (1. 0)	-	1 (1. 0)	-	-	-
	Headache	16 (15.2)	13 (12.4)	3 (2. 9)	-	-	-
	Hypoaesthesia	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Neuropathy peripheral	8 (7. 6)	7 (6. 7)	1 (1. 0)	-	-	-
	Paraesthesia	2 (1. 9)	2 (1. 9)	-	-	-	-
	Peripheral motor neuropathy	1 (1. 0)	1 (1. 0)	-	-	-	-
	Peripheral sensory neuropathy	3 (2. 9)	2 (1. 9)	-	1 (1. 0)	-	-
	Polyneuropathy	1 (1. 0)	1 (1. 0)	-	-	-	-
	Poor quality sleep	1 (1. 0)	-	1 (1. 0)	-	-	-
	Restless legs syndrome	1 (1. 0)	1 (1. 0)	-	-	-	-
	Somnolence	1 (1. 0)	1 (1. 0)	-	-	-	-
	Syncope	1 (1. 0)	1 (1. 0)	-	-	-	-
	Tremor	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Psychiatric disorders						
	Aggression	1 (1. 0)	-	1 (1. 0)	-	-	-
	Anxiety	7 (6. 7)	3 (2. 9)	2 (1. 9)	2 (1. 9)	-	-
	Confusional state	2 (1. 9)	-	2 (1. 9)	-	-	-
	Depressed mood	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-	-
	Depression	5 (4. 8)	-	4 (3. 8)	1 (1. 0)	-	-
	Impaired self-care	1 (1. 0)	-	1 (1. 0)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Insomnia	9 (8. 6)	4 (3. 8)	3 (2. 9)	1 (1. 0)	1 (1. 0)	-
	Listless	1 (1. 0)	1 (1. 0)	-	-	-	-
	Mood altered	1 (1. 0)	-	1 (1. 0)	-	-	-
	Restlessness	1 (1. 0)	1 (1. 0)	-	-	-	-
	Sleep disorder	3 (2. 9)	3 (2. 9)	-	-	-	-
	Renal and urinary disorders						
	Azotaemia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Dysuria	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Micturition urgency	1 (1. 0)	1 (1. 0)	-	-	-	-
	Oliguria	1 (1. 0)	-	1 (1. 0)	-	-	-
	Pollakiuria	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Renal failure	1 (1. 0)	-	1 (1. 0)	-	-	-
	Renal failure acute	1 (1. 0)	-	-	1 (1. 0)	-	-
	Renal impairment	3 (2. 9)	2 (1. 9)	-	1 (1. 0)	-	-
	Reproductive system and breast disorders						
	Breast pain	1 (1. 0)	-	1 (1. 0)	-	-	-
	Prostatomegaly	1 (1. 0)	1 (1. 0)	-	-	-	-
	Respiratory, thoracic and mediastinal disorders						
	Acute respiratory distress syndrome	1 (1. 0)	-	-	1 (1. 0)	-	-
	Alveolitis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Atelectasis	2 (1. 9)	2 (1. 9)	-	-	-	-
	Bronchitis chronic	2 (1. 9)	2 (1. 9)	-	-	-	-
	Bronchospasm	1 (1. 0)	-	-	1 (1. 0)	-	-
	Chylothorax	1 (1. 0)	-	1 (1. 0)	-	-	-
	Cough	19 (18.1)	13 (12.4)	6 (5. 7)	-	-	-
	Dysphonia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Dyspnoea	21 (20.0)	9 (8. 6)	6 (5. 7)	6 (5. 7)	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Haemoptysis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hiccups	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Hypoxia	2 (1. 9)	-	-	2 (1. 9)	-	-
	Nasal congestion	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Nasal discomfort	1 (1. 0)	1 (1. 0)	-	-	-	-
	Nasal dryness	1 (1. 0)	1 (1. 0)	-	-	-	-
	Obstructive airways disorder	1 (1. 0)	-	1 (1. 0)	-	-	-
	Oropharyngeal discomfort	1 (1. 0)	1 (1. 0)	-	-	-	-
	Oropharyngeal pain	8 (7. 6)	6 (5. 7)	2 (1. 9)	-	-	-
	Pleural effusion	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Productive cough	1 (1. 0)	-	1 (1. 0)	-	-	-
	Pulmonary embolism	3 (2. 9)	-	-	1 (1. 0)	2 (1. 9)	-
	Pulmonary mass	1 (1. 0)	-	1 (1. 0)	-	-	-
	Pulmonary oedema	1 (1. 0)	-	1 (1. 0)	-	-	-
	Rales	1 (1. 0)	1 (1. 0)	-	-	-	-
	Respiratory alkalosis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Respiratory distress	1 (1. 0)	-	-	1 (1. 0)	-	-
	Rhinorrhoea	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-	-
	Sinus polyp	1 (1. 0)	1 (1. 0)	-	-	-	-
	Tachypnoea	1 (1. 0)	-	1 (1. 0)	-	-	-
	Wheezing	1 (1. 0)	1 (1. 0)	-	-	-	-
	Skin and subcutaneous tissue disorders						
	Acne	1 (1. 0)	1 (1. 0)	-	-	-	-
	Actinic keratosis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Alopecia	2 (1. 9)	2 (1. 9)	-	-	-	-
	Decubitus ulcer	1 (1. 0)	-	-	1 (1. 0)	-	-
	Dry skin	2 (1. 9)	2 (1. 9)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Eczema	2 (1. 9)	2 (1. 9)	-	-	-	-
	Erythema	4 (3. 8)	2 (1 .9)	2 (1. 9)	-	-	-
	Hyperhidrosis	4 (3. 8)	1 (1. 0)	3 (2. 9)	-	-	-
	Night sweats	7 (6. 7)	6 (5. 7)	1 (1. 0)	-	-	-
	Pain of skin	2 (1. 9)	-	1 (1. 0)	-	1 (1. 0)	-
	Palmar erythema	1 (1. 0)	1 (1. 0)	-	-	-	-
	Palmar-plantar erythrodysaesthesia syndrome	1 (1. 0)	1 (1. 0)	-	-	-	-
	Pruritus	16 (15.2)	8 (7. 6)	7 (6. 7)	1 (1. 0)	-	-
	Pruritus generalised	1 (1. 0)	1 (1. 0)	-	-	-	-
	Rash	23 (21.9)	14 (13.3)	8 (7. 6)	1 (1. 0)	-	-
	Rash macular	1 (1. 0)	1 (1. 0)	-	-	-	-
	Rash maculo-papular	1 (1. 0)	-	1 (1. 0)	-	-	-
	Rash papular	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-	-
	Rash pruritic	2 (1. 9)	2 (1. 9)	-	-	-	-
	Skin burning sensation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Skin exfoliation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Skin ulcer	1 (1. 0)	-	1 (1. 0)	-	-	-
	Subcutaneous nodule	1 (1. 0)	-	-	1 (1. 0)	-	-
	Urticaria	1 (1. 0)	1 (1. 0)	-	-	-	-
	Surgical and medical procedures						
	Central venous catheterisation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Vascular disorders						
	Aortic aneurysm	1 (1. 0)	1 (1. 0)	-	-	-	-
	Arteriosclerosis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Deep vein thrombosis	6 (5. 7)	-	2 (1. 9)	4 (3. 8)	-	-
	Essential hypertension	1 (1. 0)	-	1 (1. 0)	-	-	-
	Flushing	8 (7. 6)	6 (5. 7)	2 (1. 9)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Hot flush	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Hypertension	6 (5. 7)	4 (3. 8)	2 (1. 9)	-	-	-
	Hypotension	10 (9.5)	3 (2. 9)	4 (3. 8)	2 (1. 9)	1 (1. 0)	-
	Hypovolaemic shock	1 (1. 0)	-	-	-	1 (1. 0)	-
	Iliac artery thrombosis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Phlebitis	12 (11.4)	2 (1. 9)	9 (8. 6)	1 (1. 0)	-	-
	Phlebitis superficial	1 (1. 0)	1 (1. 0)	-	-	-	-
	Shock	1 (1. 0)	-	-	-	-	1 (1. 0)
	Thrombophlebitis	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Thrombophlebitis superficial	1 (1. 0)	1 (1. 0)	-	-	-	-
	Thrombosed varicose vein	1 (1. 0)	-	-	1 (1. 0)	-	-
	Thrombosis	2 (1. 9)	-	1 (1. 0)	1 (1. 0)	-	-
	Vasculitis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Vein pain	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Venous thrombosis limb	1 (1. 0)	-	-	1 (1. 0)	-	-
Platelet < 100,000/ul (N=24)	Blood and lymphatic system disorders						
	Anaemia	11 (45.8)	1 (4. 2)	3 (12.5)	1 (4. 2)	6 (25.0)	-
	Anaemia haemolytic autoimmune	1 (4. 2)	-	-	1 (4. 2)	-	-
	Febrile neutropenia	3 (12.5)	-	-	3 (12.5)	-	-
	Leukopenia	5 (20.8)	1 (4. 2)	2 (8. 3)	-	2 (8. 3)	-
	Lymphopenia	2 (8. 3)	1 (4. 2)	-	-	1 (4. 2)	-
	Neutropenia	6 (25.0)	1 (4. 2)	2 (8. 3)	-	3 (12.5)	-
	Pancytopenia	1 (4. 2)	-	-	-	1 (4. 2)	-
	Thrombocytopenia	9 (37.5)	-	2 (8. 3)	-	7 (29.2)	-
	Cardiac disorders						
	Cardiac failure	1 (4. 2)	-	-	-	-	1 (4. 2)
	Sinus tachycardia	1 (4. 2)	-	1 (4. 2)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet < 100,000/ul (N=24)	Ear and labyrinth disorders						
	Ear discomfort	1 (4. 2)	1 (4. 2)	-	-	-	-
	Eye disorders						
	Vision blurred	1 (4. 2)	1 (4. 2)	-	-	-	-
	Gastrointestinal disorders						
	Abdominal distension	1 (4. 2)	1 (4. 2)	-	-	-	-
	Abdominal pain	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-	-
	Ascites	1 (4. 2)	-	-	1 (4. 2)	-	-
	Bowel movement irregularity	1 (4. 2)	1 (4. 2)	-	-	-	-
	Constipation	7 (29.2)	7 (29.2)	-	-	-	-
	Diarrhoea	5 (20.8)	2 (8. 3)	2 (8. 3)	1 (4. 2)	-	-
	Dry mouth	1 (4. 2)	1 (4. 2)	-	-	-	-
	Nausea	8 (33.3)	6 (25.0)	1 (4. 2)	1 (4. 2)	-	-
	Oesophagitis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Vomiting	3 (12.5)	1 (4. 2)	2 (8. 3)	-	-	-
	General disorders and administration site conditions						
	Asthenia	5 (20.8)	-	2 (8. 3)	3 (12.5)	-	-
	Chest pain	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-	-
	Chills	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-	-
	Fatigue	4 (16.7)	2 (8. 3)	2 (8. 3)	-	-	-
	Infusion site coldness	1 (4. 2)	1 (4. 2)	-	-	-	-
	Infusion site pain	2 (8. 3)	2 (8. 3)	-	-	-	-
	Injection site pruritus	1 (4. 2)	1 (4. 2)	-	-	-	-
	Mucosal inflammation	3 (12.5)	3 (12.5)	-	-	-	-
	Multi-organ failure	1 (4. 2)	-	-	-	-	1 (4. 2)
	Oedema	1 (4. 2)	1 (4. 2)	-	-	-	-
	Oedema peripheral	4 (16.7)	3 (12.5)	1 (4. 2)	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet < 100,000/ul (N=24)	Pain	2 (8. 3)	1 (4. 2)	-	1 (4. 2)	-	-
	Pyrexia	8 (33.3)	2 (8. 3)	4 (16.7)	2 (8. 3)	-	-
	Hepatobiliary disorders						
	Hepatosplenomegaly	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hyperbilirubinaemia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Immune system disorders						
	Hypersensitivity	1 (4. 2)	1 (4. 2)	-	-	-	-
	Infections and infestations						
	Administration site infection	1 (4. 2)	-	1 (4. 2)	-	-	-
	Bronchitis	2 (8. 3)	1 (4. 2)	-	1 (4. 2)	-	-
	Bronchopneumonia	1 (4. 2)	-	1 (4. 2)	-	-	-
	Cytomegalovirus infection	1 (4. 2)	1 (4. 2)	-	-	-	-
	Device related infection	1 (4. 2)	-	1 (4. 2)	-	-	-
	Epstein-Barr virus infection	1 (4. 2)	1 (4. 2)	-	-	-	-
	Genital herpes	1 (4. 2)	-	1 (4. 2)	-	-	-
	Infection	1 (4. 2)	-	-	1 (4. 2)	-	-
	Nasopharyngitis	1 (4. 2)	1 (4. 2)	-	-	-	-
	Oral herpes	1 (4. 2)	-	1 (4. 2)	-	-	-
	Pharyngitis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Septic shock	1 (4. 2)	-	-	-	1 (4. 2)	-
	Sinusitis	3 (12.5)	1 (4. 2)	2 (8. 3)	-	-	-
	Staphylococcal infection	1 (4. 2)	-	-	1 (4. 2)	-	-
	Injury, poisoning and procedural complications						
	Allergic transfusion reaction	1 (4. 2)	-	1 (4. 2)	-	-	-
	Investigations						
	Alanine aminotransferase increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Blood alkaline phosphatase increased	1 (4. 2)	1 (4. 2)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet < 100,000/ul (N=24)	Blood bilirubin increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Blood bilirubin unconjugated increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Blood calcium increased	1 (4. 2)	-	-	-	1 (4. 2)	-
	Blood creatinine	1 (4. 2)	1 (4. 2)	-	-	-	-
	Blood creatinine increased	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-	-
	Blood glucose increased	1 (4. 2)	-	1 (4. 2)	-	-	-
	Blood lactate dehydrogenase increased	4 (16.7)	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-
	Blood potassium decreased	1 (4. 2)	-	-	-	1 (4. 2)	-
	Blood urea increased	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-	-
	C-reactive protein increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Eastern Cooperative Oncology Group performance status worsened	1 (4. 2)	-	-	-	1 (4. 2)	-
	Electrocardiogram QT prolonged	4 (16.7)	1 (4. 2)	1 (4. 2)	2 (8. 3)	-	-
	Glomerular filtration rate decreased	1 (4. 2)	-	1 (4. 2)	-	-	-
	International normalised ratio decreased	1 (4. 2)	1 (4. 2)	-	-	-	-
	International normalised ratio increased	1 (4. 2)	-	-	1 (4. 2)	-	-
	Mean cell volume increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Neutrophil count decreased	1 (4. 2)	-	-	-	1 (4. 2)	-
	Platelet count decreased	2 (8. 3)	-	1 (4. 2)	-	1 (4. 2)	-
	Red blood cell count decreased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Weight decreased	1 (4. 2)	-	1 (4. 2)	-	-	-
	Weight increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	White blood cell count decreased	2 (8. 3)	-	-	1 (4. 2)	1 (4. 2)	-
	Metabolism and nutrition disorders						
	Decreased appetite	2 (8. 3)	2 (8. 3)	-	-	-	-
	Diabetes mellitus	1 (4. 2)	-	1 (4. 2)	-	-	-
	Hyperglycaemia	2 (8. 3)	-	2 (8. 3)	-	-	-
	Hyperkalaemia	1 (4. 2)	1 (4. 2)	-	-	-	-

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet < 100,000/ul (N=24)	Hyperuricaemia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hypoalbuminaemia	2 (8. 3)	1 (4. 2)	-	1 (4. 2)	-	-
	Hypoglycaemia	1 (4. 2)	-	-	-	1 (4. 2)	-
	Hypokalaemia	2 (8. 3)	1 (4. 2)	-	1 (4. 2)	-	-
	Hyponatraemia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hypophosphataemia	1 (4. 2)	-	1 (4. 2)	-	-	-
	Tumour lysis syndrome	1 (4. 2)	-	-	-	1 (4. 2)	-
	Musculoskeletal and connective tissue disorders						
	Back pain	1 (4. 2)	1 (4. 2)	-	-	-	-
	Crystal arthropathy	1 (4. 2)	1 (4. 2)	-	-	-	-
	Groin pain	1 (4. 2)	1 (4. 2)	-	-	-	-
	Joint swelling	1 (4. 2)	1 (4. 2)	-	-	-	-
	Muscle spasms	3 (12.5)	2 (8. 3)	1 (4. 2)	-	-	-
	Musculoskeletal pain	1 (4. 2)	1 (4. 2)	-	-	-	-
	Nervous system disorders						
	Ageusia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Dizziness	2 (8. 3)	2 (8. 3)	-	-	-	-
	Headache	3 (12.5)	2 (8. 3)	1 (4. 2)	-	-	-
	Hypotonia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Lethargy	1 (4. 2)	1 (4. 2)	-	-	-	-
	Neuropathy peripheral	2 (8. 3)	1 (4. 2)	-	1 (4. 2)	-	-
	Psychiatric disorders						
	Anxiety	1 (4. 2)	-	1 (4. 2)	-	-	-
	Confusional state	1 (4. 2)	1 (4. 2)	-	-	-	-
	Depression	1 (4. 2)	-	1 (4. 2)	-	-	-
	Restlessness	1 (4. 2)	1 (4. 2)	-	-	-	-
	Renal and urinary disorders						

Table 14.3.6.11: Treatment Emergent Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet < 100,000/ul (N=24)	Pollakiuria	1 (4. 2)	1 (4. 2)	-	-	-	-
	Renal failure	1 (4. 2)	-	1 (4. 2)	-	-	-
	Reproductive system and breast disorders						
	Testicular pain	1 (4. 2)	-	1 (4. 2)	-	-	-
	Respiratory, thoracic and mediastinal disorders						
	Cough	5 (20.8)	4 (16.7)	1 (4. 2)	-	-	-
	Dyspnoea	7 (29.2)	3 (12.5)	2 (8. 3)	2 (8. 3)	-	-
	Lung infiltration	1 (4. 2)	1 (4. 2)	-	-	-	-
	Pharyngeal ulceration	1 (4. 2)	1 (4. 2)	-	-	-	-
	Respiratory failure	1 (4. 2)	-	-	-	1 (4. 2)	-
	Skin and subcutaneous tissue disorders						
	Dermatitis contact	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hyperhidrosis	3 (12.5)	1 (4. 2)	2 (8. 3)	-	-	-
	Night sweats	1 (4. 2)	-	1 (4. 2)	-	-	-
	Pruritus	5 (20.8)	2 (8. 3)	-	2 (8. 3)	1 (4. 2)	-
	Rash	3 (12.5)	3 (12.5)	-	-	-	-
	Vascular disorders						
	Extremity necrosis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Flushing	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hypertension	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hypotension	3 (12.5)	1 (4. 2)	1 (4. 2)	1 (4. 2)	-	-
	Phlebitis	1 (4. 2)	-	1 (4. 2)	-	-	-
	Vasculitis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Vein pain	1 (4. 2)	-	1 (4. 2)	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Blood and lymphatic system disorders						
	Anaemia	12 (11.4)	2 (1. 9)	6 (5. 7)	4 (3. 8)	-	-
	Febrile neutropenia	3 (2. 9)	-	-	3 (2. 9)	-	-
	Haemolytic anaemia	1 (1. 0)	-	-	1 (1. 0)	-	-
	Leukopenia	4 (3. 8)	1 (1. 0)	2 (1. 9)	-	1 (1. 0)	-
	Lymphadenopathy	1 (1. 0)	1 (1. 0)	-	-	-	-
	Lymphopenia	4 (3. 8)	-	1 (1. 0)	3 (2. 9)	-	-
	Neutropenia	4 (3. 8)	-	-	4 (3. 8)	-	-
	Thrombocytopenia	7 (6. 7)	4 (3. 8)	2 (1. 9)	-	1 (1. 0)	-
	Thrombocytosis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Cardiac disorders						
	Atrial fibrillation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Bundle branch block right	1 (1. 0)	1 (1. 0)	-	-	-	-
	Ventricular extrasystoles	1 (1. 0)	1 (1. 0)	-	-	-	-
	Eye disorders						
	Dry eye	1 (1. 0)	1 (1. 0)	-	-	-	-
	Keratoconjunctivitis sicca	1 (1. 0)	1 (1. 0)	-	-	-	-
	Lacrimation increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Toxic cataract	1 (1. 0)	1 (1. 0)	-	-	-	-
	Vision blurred	3 (2. 9)	3 (2. 9)	-	-	-	-
	Gastrointestinal disorders						
	Abdominal discomfort	1 (1. 0)	1 (1. 0)	-	-	-	-
	Abdominal distension	1 (1. 0)	1 (1. 0)	-	-	-	-
	Abdominal pain	4 (3. 8)	-	3 (2. 9)	1 (1. 0)	-	-
	Abdominal pain upper	3 (2. 9)	1 (1. 0)	1 (1. 0)	1 (1. 0)	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Constipation	7 (6. 7)	5 (4. 8)	1 (1. 0)	1 (1. 0)	-	-
	Defaecation urgency	1 (1. 0)	1 (1. 0)	-	-	-	-
	Diarrhoea	16 (15.2)	11 (10.5)	5 (4. 8)	-	-	-
	Dry mouth	1 (1. 0)	1 (1. 0)	-	-	-	-
	Dyspepsia	3 (2. 9)	3 (2. 9)	-	-	-	-
	Dysphagia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Epigastric discomfort	1 (1. 0)	-	1 (1. 0)	-	-	-
	Eructation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Nausea	42 (40.0)	25 (23.8)	17 (16.2)	-	-	-
	Paraesthesia oral	1 (1. 0)	1 (1. 0)	-	-	-	-
	Salivary hypersecretion	1 (1. 0)	1 (1. 0)	-	-	-	-
	Stomatitis	3 (2. 9)	1 (1. 0)	1 (1. 0)	1 (1. 0)	-	-
	Vomiting	28 (26.7)	20 (19.0)	8 (7. 6)	-	-	-
	General disorders and administration site conditions						
	Asthenia	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-	-
	Chest pain	1 (1. 0)	1 (1. 0)	-	-	-	-
	Chills	8 (7. 6)	6 (5. 7)	2 (1. 9)	-	-	-
	Extravasation	2 (1. 9)	2 (1. 9)	-	-	-	-
	Face oedema	1 (1. 0)	-	1 (1. 0)	-	-	-
	Fatigue	33 (31.4)	15 (14.3)	14 (13.3)	4 (3. 8)	-	-
	Feeling of body temperature change	1 (1. 0)	-	1 (1. 0)	-	-	-
	General physical health deterioration	1 (1. 0)	-	-	1 (1. 0)	-	-
	Infusion site extravasation	1 (1. 0)	-	1 (1. 0)	-	-	-
	Infusion site inflammation	1 (1. 0)	-	1 (1. 0)	-	-	-
	Infusion site pain	14 (13.3)	5 (4. 8)	9 (8. 6)	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Infusion site reaction	2 (1. 9)	2 (1. 9)	-	-	-	-
	Injection site induration	1 (1. 0)	-	1 (1. 0)	-	-	-
	Injection site inflammation	1 (1. 0)	-	1 (1. 0)	-	-	-
	Injection site pain	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Injection site phlebitis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Malaise	1 (1. 0)	-	1 (1. 0)	-	-	-
	Mucosal inflammation	1 (1. 0)	1 (1. 0)	-	-	-	-
	Oedema	1 (1. 0)	-	1 (1. 0)	-	-	-
	Oedema peripheral	2 (1. 9)	2 (1. 9)	-	-	-	-
	Pain	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-	-
	Pyrexia	10 (9.5)	6 (5. 7)	4 (3. 8)	-	-	-
	Thrombosis in device	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hepatobiliary disorders						
	Hepatic cirrhosis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hepatic failure	1 (1. 0)	-	-	-	-	1 (1. 0)
	Infections and infestations						
	Administration site infection	1 (1. 0)	-	1 (1. 0)	-	-	-
	Bronchitis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Bronchitis bacterial	1 (1. 0)	-	1 (1. 0)	-	-	-
	Cellulitis	3 (2. 9)	-	2 (1. 9)	1 (1. 0)	-	-
	Gastroenteritis viral	1 (1. 0)	-	1 (1. 0)	-	-	-
	Herpes simplex	2 (1. 9)	-	2 (1. 9)	-	-	-
	Herpes zoster	1 (1. 0)	-	-	1 (1. 0)	-	-
	Infection	2 (1. 9)	-	-	2 (1. 9)	-	-
	Infusion site cellulitis	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set

Baseline Platelet Group	MedDRA System Organ Class / MedDRA Preferred Term	Number of Patients (%) Worst Grade per Patient: Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Opportunistic infection	1 (1. 0)	-	-	1 (1. 0)	-	-
	Oral candidiasis	1 (1. 0)	1 (1. 0)	-	-	-	-
	Oral fungal infection	1 (1. 0)	1 (1. 0)	-	-	-	-
	Pharyngitis bacterial	1 (1. 0)	1 (1. 0)	-	-	-	-
	Pneumonia	3 (2. 9)	-	1 (1. 0)	2 (1. 9)	-	-
	Pneumonia viral	1 (1. 0)	-	-	1 (1. 0)	-	-
	Sepsis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Skin candida	1 (1. 0)	-	1 (1. 0)	-	-	-
	Staphylococcal sepsis	1 (1. 0)	-	1 (1. 0)	-	-	-
	Tonsillitis	1 (1. 0)	-	1 (1. 0)	-	-	-
	Upper respiratory tract infection	3 (2. 9)	2 (1. 9)	-	1 (1. 0)	-	-
	Urinary tract infection staphylococcal	1 (1. 0)	-	1 (1. 0)	-	-	-
	Injury, poisoning and procedural complications						
	Infusion related reaction	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Tracheostomy malfunction	1 (1. 0)	1 (1. 0)	-	-	-	-
	Investigations						
	Alanine aminotransferase increased	5 (4. 8)	1 (1. 0)	1 (1. 0)	3 (2. 9)	-	-
	Aspartate aminotransferase increased	5 (4. 8)	1 (1. 0)	1 (1. 0)	3 (2. 9)	-	-
	Blood alkaline phosphatase increased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Blood bilirubin increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood creatinine increased	3 (2. 9)	1 (1. 0)	2 (1. 9)	-	-	-
	Blood glucose increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood lactate dehydrogenase increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Blood potassium decreased	1 (1. 0)	1 (1. 0)	-	-	-	-
	C-reactive protein increased	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	**MedDRA System Organ Class MedDRA Preferred Term**	**Any Grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Platelet >= 100,000/ul (N=105)	Electrocardiogram QT prolonged	9 (8. 6)	3 (2. 9)	3 (2. 9)	3 (2. 9)	-	-
	Electrocardiogram ST segment depression	1 (1. 0)	1 (1. 0)	-	-	-	-
	Gamma-glutamyltransferase increased	2 (1. 9)	-	-	1 (1. 0)	1 (1. 0)	-
	Glomerular filtration rate decreased	1 (1. 0)	1 (1. 0)	-	-	-	-
	International normalised ratio increased	1 (1. 0)	-	-	1 (1. 0)	-	-
	Liver function test abnormal	1 (1. 0)	-	-	1 (1. 0)	-	-
	Mean cell volume increased	1 (1. 0)	1 (1. 0)	-	-	-	-
	Neutrophil count decreased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Platelet count decreased	3 (2. 9)	2 (1. 9)	-	-	1 (1. 0)	-
	Prothrombin time shortened	1 (1. 0)	-	-	1 (1. 0)	-	-
	Weight decreased	4 (3. 8)	3 (2. 9)	1 (1. 0)	-	-	-
	White blood cell count decreased	1 (1. 0)	-	1 (1. 0)	-	-	-
	Metabolism and nutrition disorders						
	Decreased appetite	8 (7. 6)	6 (5. 7)	-	2 (1. 9)	-	-
	Dehydration	1 (1. 0)	-	1 (1. 0)	-	-	-
	Hypercalcaemia	1 (1. 0)	-	-	-	1 (1. 0)	-
	Hyperglycaemia	2 (1. 9)	2 (1. 9)	-	-	-	-
	Hyperkalaemia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hyperuricaemia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Hypokalaemia	5 (4. 8)	2 (1. 9)	1 (1. 0)	2 (1. 9)	-	-
	Tumour lysis syndrome	2 (1. 9)	-	1 (1. 0)	1 (1. 0)	-	-
	Musculoskeletal and connective tissue disorders						
	Back pain	1 (1. 0)	1 (1. 0)	-	-	-	-
	Bone pain	2 (1. 9)	1 (1. 0)	-	1 (1. 0)	-	-
	Muscle spasms	1 (1. 0)	1 (1. 0)	-	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	**MedDRA System Organ Class MedDRA Preferred Term**	**Any Grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Platelet >= 100,000/ul (N=105)	Myalgia	3 (2. 9)	2 (1. 9)	1 (1. 0)	-	-	-
	Pain in extremity	4 (3. 8)	3 (2. 9)	-	1 (1. 0)	-	-
	Nervous system disorders						
	Amnesia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Dizziness	7 (6. 7)	7 (6. 7)	-	-	-	-
	Dysgeusia	5 (4. 8)	3 (2. 9)	2 (1. 9)	-	-	-
	Encephalopathy	1 (1. 0)	1 (1. 0)	-	-	-	-
	Headache	5 (4. 8)	5 (4. 8)	-	-	-	-
	Hypoaesthesia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Neuropathy peripheral	1 (1. 0)	1 (1. 0)	-	-	-	-
	Paraesthesia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Psychiatric disorders						
	Anxiety	1 (1. 0)	-	-	1 (1. 0)	-	-
	Insomnia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Renal and urinary disorders						
	Azotaemia	1 (1. 0)	1 (1. 0)	-	-	-	-
	Micturition urgency	1 (1. 0)	1 (1. 0)	-	-	-	-
	Pollakiuria	1 (1. 0)	-	1 (1. 0)	-	-	-
	Renal impairment	1 (1. 0)	-	-	1 (1. 0)	-	-
	Respiratory, thoracic and mediastinal disorders						
	Alveolitis	1 (1. 0)	-	-	1 (1. 0)	-	-
	Bronchospasm	1 (1. 0)	-	-	1 (1. 0)	-	-
	Cough	3 (2. 9)	3 (2. 9)	-	-	-	-
	Dyspnoea	7 (6. 7)	4 (3. 8)	1 (1. 0)	2 (1. 9)	-	-
	Hiccups	2 (1. 9)	2 (1. 9)	-	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	MedDRA System Organ Class MedDRA Preferred Term	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Platelet >= 100,000/ul (N=105)	Hypoxia	1 (1.0)	-	-	1 (1.0)	-	-
	Nasal congestion	1 (1.0)	-	1 (1.0)	-	-	-
	Pulmonary embolism	1 (1.0)	-	-	1 (1.0)	-	-
	Pulmonary mass	1 (1.0)	-	1 (1.0)	-	-	-
	Rhinorrhoea	1 (1.0)	-	1 (1.0)	-	-	-
	Skin and subcutaneous tissue disorders						
	Alopecia	2 (1.9)	2 (1.9)	-	-	-	-
	Dry skin	1 (1.0)	1 (1.0)	-	-	-	-
	Erythema	1 (1.0)	-	1 (1.0)	-	-	-
	Hyperhidrosis	3 (2.9)	1 (1.0)	2 (1.9)	-	-	-
	Night sweats	1 (1.0)	1 (1.0)	-	-	-	-
	Palmar erythema	1 (1.0)	1 (1.0)	-	-	-	-
	Palmar-plantar erythrodysaesthesia syndrome	1 (1.0)	1 (1.0)	-	-	-	-
	Pruritus	4 (3.8)	3 (2.9)	1 (1.0)	-	-	-
	Rash	8 (7.6)	4 (3.8)	4 (3.8)	-	-	-
	Rash macular	1 (1.0)	1 (1.0)	-	-	-	-
	Rash papular	1 (1.0)	1 (1.0)	-	-	-	-
	Urticaria	1 (1.0)	1 (1.0)	-	-	-	-
	Vascular disorders						
	Deep vein thrombosis	2 (1.9)	-	1 (1.0)	1 (1.0)	-	-
	Essential hypertension	1 (1.0)	-	1 (1.0)	-	-	-
	Flushing	8 (7.6)	6 (5.7)	2 (1.9)	-	-	-
	Hypotension	3 (2.9)	2 (1.9)	1 (1.0)	-	-	-
	Phlebitis	10 (9.5)	2 (1.9)	7 (6.7)	1 (1.0)	-	-
	Thrombosed varicose vein	1 (1.0)	-	-	1 (1.0)	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	**MedDRA System Organ Class MedDRA Preferred Term**	**Any Grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Platelet >= 100,000/ul (N=105)	Vein pain	2 (1. 9)	1 (1. 0)	1 (1. 0)	-	-	-
	Venous thrombosis limb	1 (1. 0)	-	-	1 (1. 0)	-	-
Platelet < 100,000/ul (N=24)	Blood and lymphatic system disorders						
	Anaemia	4 (16.7)	-	1 (4. 2)	1 (4. 2)	2 (8. 3)	-
	Febrile neutropenia	1 (4. 2)	-	-	1 (4. 2)	-	-
	Leukopenia	3 (12.5)	-	1 (4. 2)	-	2 (8. 3)	-
	Neutropenia	3 (12.5)	-	1 (4. 2)	-	2 (8. 3)	-
	Pancytopenia	1 (4. 2)	-	-	-	1 (4. 2)	-
	Thrombocytopenia	7 (29.2)	-	2 (8. 3)	-	5 (20.8)	-
	Eye disorders						
	Vision blurred	1 (4. 2)	1 (4. 2)	-	-	-	-
	Gastrointestinal disorders						
	Constipation	2 (8. 3)	2 (8. 3)	-	-	-	-
	Diarrhoea	2 (8. 3)	1 (4. 2)	-	1 (4. 2)	-	-
	Dry mouth	1 (4. 2)	1 (4. 2)	-	-	-	-
	Nausea	7 (29.2)	6 (25.0)	-	1 (4. 2)	-	-
	Oesophagitis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Vomiting	3 (12.5)	1 (4. 2)	2 (8. 3)	-	-	-
	General disorders and administration site conditions						
	Asthenia	1 (4. 2)	-	-	1 (4. 2)	-	-
	Chills	1 (4. 2)	-	1 (4. 2)	-	-	-
	Fatigue	4 (16.7)	2 (8. 3)	2 (8. 3)	-	-	-
	Infusion site coldness	1 (4. 2)	1 (4. 2)	-	-	-	-
	Infusion site pain	2 (8. 3)	2 (8. 3)	-	-	-	-
	Injection site pruritus	1 (4. 2)	1 (4. 2)	-	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	**MedDRA System Organ Class MedDRA Preferred Term**	**Any Grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Platelet < 100,000/ul (N=24)	Mucosal inflammation	1 (4. 2)	1 (4. 2)	-	-	-	-
	Oedema peripheral	1 (4. 2)	1 (4. 2)	-	-	-	-
	Pain	1 (4. 2)	-	-	1 (4. 2)	-	-
	Pyrexia	3 (12.5)	1 (4. 2)	2 (8. 3)	-	-	-
	Immune system disorders						
	Hypersensitivity	1 (4. 2)	1 (4. 2)	-	-	-	-
	Infections and infestations						
	Oral herpes	1 (4. 2)	-	1 (4. 2)	-	-	-
	Septic shock	1 (4. 2)	-	-	-	1 (4. 2)	-
	Investigations						
	Blood creatinine increased	2 (8. 3)	1 (4. 2)	1 (4. 2)	-	-	-
	Blood urea increased	1 (4. 2)	1 (4. 2)	-	-	-	-
	Electrocardiogram QT prolonged	4 (16.7)	1 (4. 2)	1 (4. 2)	2 (8. 3)	-	-
	International normalised ratio increased	1 (4. 2)	-	-	1 (4. 2)	-	-
	Neutrophil count decreased	1 (4. 2)	-	-	-	1 (4. 2)	-
	Metabolism and nutrition disorders						
	Decreased appetite	1 (4. 2)	1 (4. 2)	-	-	-	-
	Musculoskeletal and connective tissue disorders						
	Musculoskeletal pain	1 (4. 2)	1 (4. 2)	-	-	-	-
	Nervous system disorders						
	Ageusia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Dizziness	1 (4. 2)	1 (4. 2)	-	-	-	-
	Headache	1 (4. 2)	-	1 (4. 2)	-	-	-
	Hypotonia	1 (4. 2)	1 (4. 2)	-	-	-	-
	Lethargy	1 (4. 2)	1 (4. 2)	-	-	-	-

Table 14.3.6.12: Treatment Related Adverse Events by Worst Grade Toxicity per Patient by Baseline Platelet Group

Full Analysis Set		Number of Patients (%) Worst Grade per Patient					
Baseline Platelet Group	**MedDRA System Organ Class MedDRA Preferred Term**	**Any Grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Platelet < 100,000/ul (N=24)	Neuropathy peripheral	1 (4. 2)	-	-	1 (4. 2)	-	-
	Psychiatric disorders						
	Confusional state	1 (4. 2)	1 (4. 2)	-	-	-	-
	Renal and urinary disorders						
	Pollakiuria	1 (4. 2)	1 (4. 2)	-	-	-	-
	Reproductive system and breast disorders						
	Testicular pain	1 (4. 2)	-	1 (4. 2)	-	-	-
	Respiratory, thoracic and mediastinal disorders						
	Dyspnoea	1 (4. 2)	1 (4. 2)	-	-	-	-
	Pharyngeal ulceration	1 (4. 2)	1 (4. 2)	-	-	-	-
	Skin and subcutaneous tissue disorders						
	Pruritus	1 (4. 2)	1 (4. 2)	-	-	-	-
	Rash	3 (12.5)	3 (12.5)	-	-	-	-
	Vascular disorders						
	Extremity necrosis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Flushing	1 (4. 2)	1 (4. 2)	-	-	-	-
	Hypotension	1 (4. 2)	-	-	1 (4. 2)	-	-
	Phlebitis	1 (4. 2)	-	1 (4. 2)	-	-	-
	Vasculitis	1 (4. 2)	-	-	1 (4. 2)	-	-
	Vein pain	1 (4. 2)	-	1 (4. 2)	-	-	-

Table 14.3.7.1: Deaths

Patient Population	Full Analysis Set N=129
Patient deaths within 30 days of the LAST dose of belinostat	22 (17.1)
Progressive Disease	12 (9.3)
Adverse Events	10 (7.8)
Multi-Organ Failure	3 (2.3)
Cardiac Failure	2 (1.6)
Euthanasia	1 (0.8)
Gastrointestinal Haemorrhage	1 (0.8)
Hepatic Failure	1 (0.8)
Lung Infection	1 (0.8)
Shock	1 (0.8)

Table 14.3.7.2: Patient Listing of Treatment Emergent Adverse Events Resulting in Death within 30 Days of Last Dose

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
142-001	CARDIAC DECOMPENSATION	Cardiac failure	13	5		Discontinued	Fatal
146-002	MULTIPLE ORGAN FAILURE	Multi-organ failure	14	5		None	Fatal
154-001	TOXIC LIVER FAILURE	Hepatic failure	211	5	Y	Discontinued	Fatal
221-004	INTERCURRENT PULMONARY INFECTION	Lung infection	131	5		None	Fatal
244-002	GASTRO INTESTINAL BLEEDING	Gastrointestinal haemorrhage	28	5		None	Fatal
244-004	EUTHANASIA	Euthanasia	18	5		None	Fatal
513-001	MULTIPLE ORGAN DISFUNCTION SYNDROME	Multi-organ failure	34	5		Discontinued	Fatal
513-003	HEART FAILURE	Cardiac failure	138	5		None	Fatal
516-001	MULTIORGAN FAILURE	Multi-organ failure	22	5		Discontinued	Fatal
922-001	MULTI FACTORAL SHOCK	Shock	86	5		Discontinued	Fatal

Table 14.3.7.3: Patient Listing of All Treatment Emergent Serious Adverse Events

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
100-002	LUNGEMBOLIA	Pulmonary embolism	39	4		None	Resolved
	PNEUMONIA	Pneumonia	76	3		None	Resolved
100-004	INFECTION	Infection	9	3		None	Resolved
126-002	THROMBOSED RIGHT BASILIC VEIN	Venous thrombosis limb	37	3	Y	None	Resolved with Sequelae
140-001	INCREASED CREATININ	Blood creatinine increased	5	1	Y	None	Resolved
	FEVER	Pyrexia	23	2		Interrupted	Resolved
140-002	FEVER OF UNKNOWN ORIGIN	Pyrexia	134	1	Y	Dose delayed	Resolved
	FEVER FUO	Pyrexia	156	2	Y	Discontinued	Resolved
141-001	CREATININE ELEVATION	Blood creatinine increased	5	2	Y	None	Resolved
	NECROSIS (ACRAL)	Extremity necrosis	10	3	Y	Discontinued	Not Resolved
	VASCULITIS	Vasculitis	10	3	Y	None	Resolved
142-001	CARDIAC DECOMPENSATION	Cardiac failure	13	5		Discontinued	Fatal
	RENAL FAILURE	Renal failure	13	2		None	Resolved
142-002	CREATININ INCREASED	Blood creatinine increased	30	2	Y	Discontinued	Resolved with Sequelae
142-003	INAPPETENCE/ANOREXIA	Decreased appetite	7	3	Y	Discontinued	Resolved
	FATIGUE	Fatigue	9	2	Y	Discontinued	Resolved
	PNEUMONIA	Pneumonia	22	3		Discontinued	Resolved
142-005	AST INCREASED	Aspartate aminotransferase increased	3	3	Y	Delayed/Reduced	Resolved
	ALT INCREASE	Alanine aminotransferase increased	4	3	Y	Delayed/Reduced	Resolved
	G-GT INCREASED	Gamma-glutamyltransferase increased	5	4	Y	Delayed/Reduced	Resolved

All serious adverse events, other than those leading to death, per ICH E3.
V:\...\Spectrum\Belinostat\Programs\t-aelist.sas **DATE: 25OCT2013**

Table 14.3.7.3: Patient Listing of All Treatment Emergent Serious Adverse Events

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
144-001	THROMBOPENIA	Thrombocytopenia	6	4	Y	None	Resolved with Sequelae
	ANEMIA	Anaemia	19	4	Y	None	Resolved with Sequelae
	FEVER IN NEUTROPENIA	Febrile neutropenia	20	3		None	Resolved
144-002	FEVER	Pyrexia	6	1	Y	None	Resolved with Sequelae
	BRONCHITIS	Bronchitis	15	3		Dose delayed	Resolved
146-001	ALVEOLITIS	Alveolitis	23	3	Y	Dose delayed	Resolved
	CONSTIPATION	Constipation	36	3	Y	Dose delayed	Resolved
	PNEUMONIA	Pneumonia	100	3		Delayed/Reduced	Resolved
	4-LEVEL THROMBOSIS DEEP VEINS LEFT SEITE	Deep vein thrombosis	155	3	Y	Dose delayed	Resolved with Sequelae
	FRACTURE ARM AND LEG	Multiple fractures	723	3		None	Resolved with Sequelae
146-002	TUMOLYSIS	Tumour lysis syndrome	7	4		None	Resolved
	RESPIRATORY INSUFFICIENCY	Respiratory failure	12	4		None	Resolved
	MULTIPLE ORGAN FAILURE	Multi-organ failure	14	5		None	Fatal
154-001	INCREASE OF LIVER BLOOD FINDINGS	Liver function test abnormal	207	3	Y	Discontinued	Resolved
	NEUTROPENIC FEVER	Febrile neutropenia	207	3	Y	Discontinued	Resolved
	WORSENING GENERAL CONDITION	General physical health deterioration	207	3	Y	Discontinued	Resolved
	TOXIC LIVER FAILURE	Hepatic failure	211	5	Y	Discontinued	Fatal
161-001	ASTHENIA	Asthenia	6	3		None	Resolved
	THROMBOCYTOPENIA	Thrombocytopenia	43	3	Y	None	Resolved
	SEPTIC SHOCK	Septic shock	53	4	Y	Interrupted	Resolved
	ANEMIA	Anaemia	67	3	Y	Discontinued	Resolved
	SEPTIC SHOCK	Septic shock	67	3		Discontinued	Resolved
	THROMBOCYTOPENIA	Thrombocytopenia	67	3	Y	None	Resolved

All serious adverse events, other than those leading to death, per ICH E3.
V:\...\Spectrum\Belinostat\Programs\t-aelist.sas **DATE: 25OCT2013**

Table 14.3.7.3: Patient Listing of All Treatment Emergent Serious Adverse Events

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
161-001	THROMBOCYTOPENIA	Thrombocytopenia	71	4	Y	None	Resolved
207-001	CUTANOUS RASH	Rash	40	2	Y	Interrupted	Resolved
	CUTANEOUS LESION ON THE NOSE (ACTINIC KERATOSES), EPIDERMOID CARCINOMA CUTANEOUS LOW-GRADE TUMOR NOT RELATED TO LYMPHOMA	Actinic keratosis	423	3		None	Resolved
220-002	HYPERGLYCEMIA	Hyperglycaemia	24	3		None	Resolved
221-004	INTERCURRENT PULMONARY INFECTION	Lung infection	131	5		None	Fatal
224-001	ANXIETY	Anxiety	12	3		None	Resolved
240-001	NASOPHARYNGEAL INFECTION: STAPHYLOCOCCUS AUREUS	Upper respiratory tract infection	43	3	Y	Dose delayed	Resolved
240-002	HAEMORRHAGE FROM TUMOR SITE	Tumour haemorrhage	15	3		None	Resolved
	INFECTION	Infection	23	4		None	Resolved
243-001	HYPOTENSION	Hypotension	10	2		None	Resolved
	HYPOGLYCEMIA	Hypoglycaemia	22	4		Interrupted	Resolved
244-002	GENERAL MALAISE	Malaise	17	3		None	Resolved
	GASTRO INTESTINAL BLEEDING	Gastrointestinal haemorrhage	28	5		None	Fatal
244-004	EUTHANASIA	Euthanasia	18	5		None	Fatal
244-006	UNABLE TO SELFCARE	Impaired self-care	4	2		None	Resolved
513-001	PLATELET COUNT DECREASED	Platelet count decreased	25	4	Y	Interrupted	Resolved
	MULTIPLE ORGAN DISFUNCTION SYNDROME	Multi-organ failure	34	5		Discontinued	Fatal

All serious adverse events, other than those leading to death, per ICH E3.
V:\...\Spectrum\Belinostat\Programs\t-aelist.sas **DATE: 25OCT2013**

Table 14.3.7.3: Patient Listing of All Treatment Emergent Serious Adverse Events

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
513-002	FEVER	Pyrexia	28	2	Y	None	Resolved with Sequelae
513-003	HEART FAILURE	Cardiac failure	138	5		None	Fatal
516-001	MYCOSIS INFECTION OF GASTROINTESTINAL TRACT	Gastrointestinal fungal infection	11	3		None	Resolved with Sequelae
	MULTIORGAN FAILURE	Multi-organ failure	22	5		Discontinued	Fatal
516-004	HOSPITALIZATION FOR PUTTING ON VENOUS PORT	Central venous catheterisation	199	1		None	Resolved
	LUNG MASSES	Pulmonary mass	357	2	Y	None	Resolved with Sequelae
516-006	PANCYTOPENIA	Pancytopenia	5	4	Y	Discontinued	Unknown
	THROMBOCYTOPENIA	Thrombocytopenia	22	4	Y	Interrupted	Resolved with Sequelae
532-001	CHYLOTHORAX	Chylothorax	33	2		None	Resolved
532-004	FEVER	Pyrexia	5	1		None	Resolved
	PNEUMONIA	Pneumonia	106	3		Dose delayed	Resolved
533-001	IMMUNE HEMOLYTIC ANEMIA	Haemolytic anaemia	80	3	Y	Dose reduced	Resolved
	IMMUNE HEMOLYTIC ANEMIA	Haemolytic anaemia	145	3	Y	None	Resolved
534-001	PAROXYSMAL ATRIAL FIBRILLATION	Atrial fibrillation	3	1		None	Resolved
	THROMBOSIS OF LEFT ILIAC ARTERY	Iliac artery thrombosis	110	3		None	Resolved
534-002	SEPSIS	Sepsis	214	3		Dose delayed	Resolved
	THROMBOSIS (OF RIGHT LOWER EXTREMITY DEEP VEINS)	Deep vein thrombosis	249	3		Dose delayed	Resolved
	CHRONIC BRONCHITIS ACUTE EXACERBATION	Bronchitis	684	3		None	Resolved
	BRONCHOPNEUMONIA	Bronchopneumonia	711	3		None	Resolved

All serious adverse events, other than those leading to death, per ICH E3.

Table 14.3.7.3: Patient Listing of All Treatment Emergent Serious Adverse Events

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
534-003	DRUG-INDUCED CATARACT	Toxic cataract	430	1	Y	None	Not Resolved
534-005	PURULENT BRONCHITIS	Bronchitis bacterial	341	2	Y	None	Resolved
534-006	WORSENING OF AUTOIMMUNE HAEMOLYTIC ANAEMIAI	Anaemia haemolytic autoimmune	8	3		None	Resolved
541-001	THROMBOSIS	Thrombosis	32	3		None	Resolved
600-003	PHARYNGITIS	Pharyngitis	25	3		None	Resolved
752-002	PNEUMONIA	Pneumonia	97	5		Dose delayed	Fatal
800-001	HYPOXIA	Hypoxia	4	3	Y	Interrupted	Resolved
801-001	ANEMIA	Anaemia	13	4		None	Resolved
803-001	HYPERCALCEMIA	Hypercalcaemia	14	4	Y	Discontinued	Resolved with Sequelae
902-001	TUMOR LUSIS SYNDROME	Tumour lysis syndrome	2	2		None	Resolved
	FEVER ASSOCIATED WITH TUMOR	Tumour associated fever	23	2		None	Resolved
	FEVER	Pyrexia	40	1		None	Resolved
	FEVER	Pyrexia	44	2		None	Resolved
907-001	LEFT DISPLACED TIBRA + FIBULAR FX	Lower limb fracture	57	3		None	Resolved
907-004	FATIGUE	Fatigue	12	3		Discontinued	Resolved
908-003	PULMONARY EMBOLUS	Pulmonary embolism	61	3	Y	Delayed/Reduced	Resolved
912-001	HYPERBILIRUBINEMIA	Hyperbilirubinaemia	1	3		Delayed/Reduced	Resolved

All serious adverse events, other than those leading to death, per ICH E3.
V:\...\Spectrum\Belinostat\Programs\t-aelist.sas **DATE: 25OCT2013**

Table 14.3.7.3: Patient Listing of All Treatment Emergent Serious Adverse Events

	Serious Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
912-003	POST-OBSTRUCTIVE PNEUMONIA	Pneumonia	69	2		None	Resolved
914-003	MEDIPORT INFECTION	Device related infection	4	3		Interrupted	Resolved
	INFECTION	Infection	16	3	Y	None	Resolved
	PNEUMONIA	Pneumonia	38	3	Y	None	Resolved
	DYSPNEA	Dyspnoea	50	3		None	Resolved
	FEVER	Pyrexia	50	1		None	Resolved
914-004	PNEUMONIA	Pneumonia	15	3	Y	Interrupted	Resolved
915-002	PAIN-SKIN	Pain of skin	22	4		None	Resolved
	PAIN	Pain	120	4		None	Resolved
	RIGHT FEMUR PATHOLOGIC FRACTURE	Pathological fracture	151	4		None	Resolved
919-001	NEUROPATHY-SENSORY	Peripheral sensory neuropathy	190	3		Interrupted	Resolved with Sequelae
922-001	MRSA INFECTIVE ENDOCARDITIS	Endocarditis	31	4		Dose delayed	Resolved
	UROSEPSIS	Urosepsis	73	3		Dose delayed	Resolved
	MULTI FACTORAL SHOCK	Shock	86	5		Discontinued	Fatal
931-003	LEFT KNEE PAIN	Arthralgia	133	3		None	Resolved
933-001	PNEUMONIA	Pneumonia	89	3		Dose delayed	Resolved
934-003	INFECTION	Infection	37	3	Y	Dose delayed	Resolved
	SEPSIS	Sepsis	79	3	Y	Discontinued	Resolved
	HYPOTENSION	Hypotension	93	3		Discontinued	Resolved
936-001	SPLEENOMEGALY	Splenomegaly	172	3		None	Resolved

All serious adverse events, other than those leading to death, per ICH E3.
V:\...\Spectrum\Belinostat\Programs\t-aelist.sas **DATE: 25OCT2013**

Table 14.3.7.4: Patient Listing of Other Treatment Emergent Adverse Events Leading to Discontinuation

	Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
140-001	EBV REACTIVATION	Epstein-Barr virus infection	54			Discontinued	Not Resolved
147-002	DYSPNEA	Dyspnoea	3	3		Discontinued	Resolved
	LDH INCREASE	Blood lactate dehydrogenase increased	3	3		Discontinued	Resolved
	PROLONGED QTC INTERVAL CTC GR 3	Electrocardiogram QT prolonged	3	3	Y	Discontinued	Resolved
	SWEATING	Hyperhidrosis	3	2		Discontinued	Resolved
207-001	ITCHY SKIN	Pruritus	415	2	Y	Discontinued	Not Resolved
	RASH IN SUBMAMMARY AND INGUINAL FOLDS	Rash	423	2	Y	Discontinued	Not Resolved
532-002	HYPOALBUMINEMIA	Hypoalbuminaemia	59	3		Discontinued	Resolved
	LOW LEVEL OF NEUTROPHILES	Neutrophil count decreased	59	4		Discontinued	Resolved
	LYMPHOPENIA	Lymphopenia	59	4		Discontinued	Resolved
533-001	ANEMIA	Anaemia	156	2	Y	Discontinued	Not Resolved
550-002	LOW PLATELET COUNT	Platelet count decreased	5	4		Discontinued	Not Resolved
600-003	DETERIORATION IN PERFORMANCE STATUS REQUIRING HOSPITALIZATION	Eastern Cooperative Oncology Group performance status worsened	219	4		Discontinued	Resolved
800-001	NEUROPATHY	Neuropathy peripheral	1		Y	Discontinued	Not Resolved
912-003	SQUAMOUS CELL (LUNG) CANCER	Lung squamous cell carcinoma stage unspecified	66	4		Discontinued	Not Resolved
919-001	SUBCUTANEOUS LUMPS	Subcutaneous nodule	242	3		Discontinued	Resolved
934-001	FEBRILE NEUTROPENIA	Febrile neutropenia	22	3	Y	Discontinued	Resolved

Excludes patients that have both serious and non-serious AEs leading to discontiuation.
V:\...\Spectrum\Belinostat\Programs\t-aelist-nsae.sas
DATE: 16OCT2013

Table 14.3.7.5: Treatment Emergent Serious Adverse Events

Patient Population	**Full Analysis Set N=129**	
MedDRA Preferred Term	**n**	**%**
Pneumonia	9	7.0
Pyrexia	7	5.4
Infection	4	3.1
Anaemia	3	2.3
Blood creatinine increased	3	2.3
Multi-organ failure	3	2.3
Thrombocytopenia	3	2.3
Bronchitis	2	1.6
Cardiac failure	2	1.6
Deep vein thrombosis	2	1.6
Fatigue	2	1.6
Febrile neutropenia	2	1.6
Hypotension	2	1.6
Pulmonary embolism	2	1.6
Sepsis	2	1.6
Tumour lysis syndrome	2	1.6
Actinic keratosis	1	0.8
Alanine aminotransferase increased	1	0.8
Alveolitis	1	0.8
Anaemia haemolytic autoimmune	1	0.8
Anxiety	1	0.8
Arthralgia	1	0.8
Aspartate aminotransferase increased	1	0.8
Asthenia	1	0.8
Atrial fibrillation	1	0.8
Bronchitis bacterial	1	0.8
Bronchopneumonia	1	0.8
Central venous catheterisation	1	0.8
Chylothorax	1	0.8
Constipation	1	0.8
Decreased appetite	1	0.8
Device related infection	1	0.8
Dyspnoea	1	0.8
Endocarditis	1	0.8
Euthanasia	1	0.8
Extremity necrosis	1	0.8

Table 14.3.7.5: Treatment Emergent Serious Adverse Events

Patient Population	**Full Analysis Set N=129**	
MedDRA Preferred Term	**n**	**%**
Gamma-glutamyltransferase increased	1	0.8
Gastrointestinal fungal infection	1	0.8
Gastrointestinal haemorrhage	1	0.8
General physical health deterioration	1	0.8
Haemolytic anaemia	1	0.8
Hepatic failure	1	0.8
Hyperbilirubinaemia	1	0.8
Hypercalcaemia	1	0.8
Hyperglycaemia	1	0.8
Hypoglycaemia	1	0.8
Hypoxia	1	0.8
Iliac artery thrombosis	1	0.8
Impaired self-care	1	0.8
Liver function test abnormal	1	0.8
Lower limb fracture	1	0.8
Lung infection	1	0.8
Malaise	1	0.8
Multiple fractures	1	0.8
Pain	1	0.8
Pain of skin	1	0.8
Pancytopenia	1	0.8
Pathological fracture	1	0.8
Peripheral sensory neuropathy	1	0.8
Pharyngitis	1	0.8
Platelet count decreased	1	0.8
Pulmonary mass	1	0.8
Rash	1	0.8
Renal failure	1	0.8
Respiratory failure	1	0.8
Septic shock	1	0.8
Shock	1	0.8
Splenomegaly	1	0.8
Thrombosis	1	0.8
Toxic cataract	1	0.8
Tumour associated fever	1	0.8
Tumour haemorrhage	1	0.8

Table 14.3.7.5: Treatment Emergent Serious Adverse Events

Patient Population	Full Analysis Set N=129	
MedDRA Preferred Term	**n**	**%**
Upper respiratory tract infection	1	0.8
Urosepsis	1	0.8
Vasculitis	1	0.8
Venous thrombosis limb	1	0.8

Table 14.3.7.6: Treatment Related Serious Adverse Events

Patient Population	Full Analysis Set N=129	
MedDRA Preferred Term	**n**	**%**
Blood creatinine increased	3	2. 3
Pyrexia	3	2. 3
Thrombocytopenia	3	2. 3
Anaemia	2	1. 6
Infection	2	1. 6
Pneumonia	2	1. 6
Alanine aminotransferase increased	1	0. 8
Alveolitis	1	0. 8
Aspartate aminotransferase increased	1	0. 8
Bronchitis bacterial	1	0. 8
Constipation	1	0. 8
Decreased appetite	1	0. 8
Deep vein thrombosis	1	0. 8
Extremity necrosis	1	0. 8
Fatigue	1	0. 8
Febrile neutropenia	1	0. 8
Gamma-glutamyltransferase increased	1	0. 8
General physical health deterioration	1	0. 8
Haemolytic anaemia	1	0. 8
Hepatic failure	1	0. 8
Hypercalcaemia	1	0. 8
Hypoxia	1	0. 8
Liver function test abnormal	1	0. 8
Pancytopenia	1	0. 8
Platelet count decreased	1	0. 8
Pulmonary embolism	1	0. 8
Pulmonary mass	1	0. 8
Rash	1	0. 8
Sepsis	1	0. 8
Septic shock	1	0. 8
Toxic cataract	1	0. 8
Upper respiratory tract infection	1	0. 8
Vasculitis	1	0. 8
Venous thrombosis limb	1	0. 8

Table 14.3.7.7: Treatment Emergent Adverse Events Leading to Withdrawal

Patient Population	**Full Analysis Set N=129**	
MedDRA Preferred Term	**n**	**%**
Anaemia	2	1.6
Fatigue	2	1.6
Febrile neutropenia	2	1.6
Multi-organ failure	2	1.6
Abdominal pain	1	0.8
Administration site infection	1	0.8
Blood creatinine increased	1	0.8
Blood lactate dehydrogenase increased	1	0.8
Cardiac failure	1	0.8
Decreased appetite	1	0.8
Dyspnoea	1	0.8
Eastern Cooperative Oncology Group performance status worsened	1	0.8
Electrocardiogram QT prolonged	1	0.8
Encephalopathy	1	0.8
Epstein-Barr virus infection	1	0.8
Extremity necrosis	1	0.8
General physical health deterioration	1	0.8
Hepatic cirrhosis	1	0.8
Hepatic failure	1	0.8
Hypercalcaemia	1	0.8
Hyperhidrosis	1	0.8
Hypoalbuminaemia	1	0.8
Hypotension	1	0.8
International normalised ratio increased	1	0.8
Leukopenia	1	0.8
Liver function test abnormal	1	0.8
Lung squamous cell carcinoma stage unspecified	1	0.8
Lymphopenia	1	0.8
Neuropathy peripheral	1	0.8
Neutropenia	1	0.8
Neutrophil count decreased	1	0.8
Opportunistic infection	1	0.8
Pancytopenia	1	0.8
Platelet count decreased	1	0.8
Pneumonia	1	0.8
Prothrombin time shortened	1	0.8

Table 14.3.7.7: Treatment Emergent Adverse Events Leading to Withdrawal

Patient Population	Full Analysis Set N=129	
MedDRA Preferred Term	**n**	**%**
Pruritus	1	0.8
Pyrexia	1	0.8
Rash	1	0.8
Sepsis	1	0.8
Septic shock	1	0.8
Shock	1	0.8
Subcutaneous nodule	1	0.8
Thrombocytopenia	1	0.8
Tumour associated fever	1	0.8

Table 14.3.7.8: Treatment Related Adverse Events Leading to Withdrawal

Patient Population	**Full Analysis Set N=129**	
MedDRA Preferred Term	**n**	**%**
Anaemia	2	1.6
Febrile neutropenia	2	1.6
Abdominal pain	1	0.8
Administration site infection	1	0.8
Blood creatinine increased	1	0.8
Decreased appetite	1	0.8
Electrocardiogram QT prolonged	1	0.8
Encephalopathy	1	0.8
Extremity necrosis	1	0.8
Fatigue	1	0.8
General physical health deterioration	1	0.8
Hepatic cirrhosis	1	0.8
Hepatic failure	1	0.8
Hypercalcaemia	1	0.8
International normalised ratio increased	1	0.8
Leukopenia	1	0.8
Liver function test abnormal	1	0.8
Neuropathy peripheral	1	0.8
Neutropenia	1	0.8
Opportunistic infection	1	0.8
Pancytopenia	1	0.8
Prothrombin time shortened	1	0.8
Pruritus	1	0.8
Pyrexia	1	0.8
Rash	1	0.8
Sepsis	1	0.8
Thrombocytopenia	1	0.8

Table 14.3.7.9: Listing of Patients with Any Adverse Events Leading to Discontinuation

	Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
140-001	EBV REACTIVATION	Epstein-Barr virus infection	54			Discontinued	Not Resolved
140-002	FEVER FUO	Pyrexia	156	2	Y	Discontinued	Resolved
	STAPHYLOCOCCUS AUREUS (PORT DETECTION)	Administration site infection	157	2	Y	Discontinued	Resolved
141-001	NECROSIS (ACRAL)	Extremity necrosis	10	3	Y	Discontinued	Not Resolved
142-001	CARDIAC DECOMPENSATION	Cardiac failure	13	5		Discontinued	Fatal
142-002	CREATININ INCREASED	Blood creatinine increased	30	2	Y	Discontinued	Resolved with Sequelae
142-003	INAPPETENCE/ANOREXIA	Decreased appetite	7	3	Y	Discontinued	Resolved
	FATIGUE	Fatigue	9	2	Y	Discontinued	Resolved
	PNEUMONIA	Pneumonia	22	3		Discontinued	Resolved
147-002	DYSPNEA	Dyspnoea	3	3		Discontinued	Resolved
	LDH INCREASE	Blood lactate dehydrogenase increased	3	3		Discontinued	Resolved
	PROLONGED QTC INTERVAL CTC GR 3	Electrocardiogram QT prolonged	3	3	Y	Discontinued	Resolved
	SWEATING	Hyperhidrosis	3	2		Discontinued	Resolved
154-001	INCREASE OF LIVER BLOOD FINDINGS	Liver function test abnormal	207	3	Y	Discontinued	Resolved
	NEUTROPENIC FEVER	Febrile neutropenia	207	3	Y	Discontinued	Resolved
	WORSENING GENERAL CONDITION	General physical health deterioration	207	3	Y	Discontinued	Resolved
	LIVER CIRRHOSIS	Hepatic cirrhosis	211	1	Y	Discontinued	Resolved
	TOXIC LIVER FAILURE	Hepatic failure	211	5	Y	Discontinued	Fatal
	NEUTROPENIA	Neutropenia	212	3	Y	Discontinued	Resolved
	THROMBOPENIA	Thrombocytopenia	212	4	Y	Discontinued	Resolved
	LEUCOCYTOPENIA	Leukopenia	213	4	Y	Discontinued	Resolved
	OPPORTUNISTIC INFECTION (CANDIDA)	Opportunistic infection	213	3	Y	Discontinued	Resolved
	ENCEPHALOPATHIC	Encephalopathy	214	1	Y	Discontinued	Resolved
	INR INCREASE	International normalised ratio increased	214	3	Y	Discontinued	Resolved

Table 14.3.7.9: Listing of Patients with Any Adverse Events Leading to Discontinuation

	Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
154-001	DECREASE OF PROTHROMBIN TIME	Prothrombin time shortened	216	3	Y	Discontinued	Resolved
	PAIN ABDOMINAL	Abdominal pain	219	3	Y	Discontinued	Resolved
161-001	ANEMIA	Anaemia	67	3	Y	Discontinued	Resolved
	SEPTIC SHOCK	Septic shock	67	3		Discontinued	Resolved
207-001	ITCHY SKIN	Pruritus	415	2	Y	Discontinued	Not Resolved
	RASH IN SUBMAMMARY AND INGUINAL FOLDS	Rash	423	2	Y	Discontinued	Not Resolved
513-001	MULTIPLE ORGAN DISFUNCTION SYNDROME	Multi-organ failure	34	5		Discontinued	Fatal
516-001	FEVER DUE TO PROGRESSION	Tumour associated fever	22	2		Discontinued	Resolved
	MULTIORGAN FAILURE	Multi-organ failure	22	5		Discontinued	Fatal
516-006	PANCYTOPENIA	Pancytopenia	5	4	Y	Discontinued	Unknown
532-002	HYPOALBUMINEMIA	Hypoalbuminaemia	59	3		Discontinued	Resolved
	LOW LEVEL OF NEUTROPHILES	Neutrophil count decreased	59	4		Discontinued	Resolved
	LYMPHOPENIA	Lymphopenia	59	4		Discontinued	Resolved
533-001	ANEMIA	Anaemia	156	2	Y	Discontinued	Not Resolved
550-002	LOW PLATELET COUNT	Platelet count decreased	5	4		Discontinued	Not Resolved
600-003	DETERIORATION IN PERFORMANCE STATUS REQUIRING HOSPITALIZATION	Eastern Cooperative Oncology Group performance status worsened	219	4		Discontinued	Resolved
800-001	NEUROPATHY	Neuropathy peripheral	1		Y	Discontinued	Not Resolved
803-001	HYPERCALCEMIA	Hypercalcaemia	14	4	Y	Discontinued	Resolved with Sequelae
907-004	FATIGUE	Fatigue	12	3		Discontinued	Resolved

Table 14.3.7.9: Listing of Patients with Any Adverse Events Leading to Discontinuation

	Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
912-003	SQUAMOUS CELL (LUNG) CANCER	Lung squamous cell carcinoma stage unspecified	66	4		Discontinued	Not Resolved
919-001	SUBCUTANEOUS LUMPS	Subcutaneous nodule	242	3		Discontinued	Resolved
922-001	MULTI FACTORAL SHOCK	Shock	86	5		Discontinued	Fatal
934-001	FEBRILE NEUTROPENIA	Febrile neutropenia	22	3	Y	Discontinued	Resolved
934-003	SEPSIS	Sepsis	79	3	Y	Discontinued	Resolved
	HYPOTENSION	Hypotension	93	3		Discontinued	Resolved

Table 14.3.7.10: Listing of Patients with Serious Adverse Events Leading to Discontinuation

	Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
140-002	FEVER FUO	Pyrexia	156	2	Y	Discontinued	Resolved
141-001	NECROSIS (ACRAL)	Extremity necrosis	10	3	Y	Discontinued	Not Resolved
142-001	CARDIAC DECOMPENSATION	Cardiac failure	13	5		Discontinued	Fatal
142-002	CREATININ INCREASED	Blood creatinine increased	30	2	Y	Discontinued	Resolved with Sequelae
142-003	INAPPETENCE/ANOREXIA	Decreased appetite	7	3	Y	Discontinued	Resolved
	FATIGUE	Fatigue	9	2	Y	Discontinued	Resolved
	PNEUMONIA	Pneumonia	22	3		Discontinued	Resolved
154-001	INCREASE OF LIVER BLOOD FINDINGS	Liver function test abnormal	207	3	Y	Discontinued	Resolved
	NEUTROPENIC FEVER	Febrile neutropenia	207	3	Y	Discontinued	Resolved
	WORSENING GENERAL CONDITION	General physical health deterioration	207	3	Y	Discontinued	Resolved
	TOXIC LIVER FAILURE	Hepatic failure	211	5	Y	Discontinued	Fatal
161-001	ANEMIA	Anaemia	67	3	Y	Discontinued	Resolved
	SEPTIC SHOCK	Septic shock	67	3		Discontinued	Resolved
513-001	MULTIPLE ORGAN DISFUNCTION SYNDROME	Multi-organ failure	34	5		Discontinued	Fatal
516-001	MULTIORGAN FAILURE	Multi-organ failure	22	5		Discontinued	Fatal
516-006	PANCYTOPENIA	Pancytopenia	5	4	Y	Discontinued	Unknown
803-001	HYPERCALCEMIA	Hypercalcaemia	14	4	Y	Discontinued	Resolved with Sequelae
907-004	FATIGUE	Fatigue	12	3		Discontinued	Resolved

Table 14.3.7.10: Listing of Patients with Serious Adverse Events Leading to Discontinuation

	Adverse Event						
Patient	**Investigator Term**	**MedDRA Preferred Term**	**Study Day**	**Tox Grd**	**Rel**	**Action Taken**	**Outcome**
922-001	MULTI FACTORAL SHOCK	Shock	86	5		Discontinued	Fatal
934-003	SEPSIS	Sepsis	79	3	Y	Discontinued	Resolved
	HYPOTENSION	Hypotension	93	3		Discontinued	Resolved

Table 14.3.8.1: Treatment Emergent Clinical Laboratory Evaluation

Full Analysis Set N=129			Number Of Patients (%) Worst CTCAE Grade on Treatment			
Laboratory Test	**Patients with On study Test**	**Incidence of Abnormality**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Hematology						
Hemoglobin, low	129 (100)	118 (91.5)	51 (39.5)	52 (40.3)	10 (7.8)	5 (3. 9)
Erythrocytes, low	125 (96.9)	117 (93.6)	-	-	-	-
MCV, low	128 (99.2)	12 (9.4)	-	-	-	-
MCV, high	128 (99.2)	30 (23.4)	-	-	-	-
Platelets, low	129 (100)	90 (69.8)	47 (36.4)	24 (18.6)	9 (7. 0)	10 (7.8)
Leukocytes, low	129 (100)	60 (46.5)	22 (17.1)	22 (17.1)	14 (10.9)	2 (1. 6)
Neutrophils, low	128 (99.2)	46 (35.9)	13 (10.2)	17 (13.3)	10 (7.8)	6 (4. 7)
Lymphocytes, low	128 (99.2)	107 (83.6)	10 (7.8)	36 (28.1)	40 (31.3)	21 (16.4)
Coagulation						
Prothrombin time, high	54 (41.9)	17 (31.5)	13 (24.1)	1 (1. 9)	3 (5. 6)	-
INR, high	86 (66.7)	29 (33.7)	16 (18.6)	3 (3. 5)	10 (11.6)	-
APTT, high	91 (70.5)	34 (37.4)	23 (25.3)	7 (7. 7)	4 (4. 4)	-
Liver function						
Bilirubin, high	129 (100)	38 (29.5)	27 (20.9)	4 (3. 1)	6 (4. 7)	1 (0. 8)
Alkaline phosphatase, high	128 (99.2)	56 (43.8)	39 (30.5)	15 (11.7)	2 (1. 6)	-
ALT, high	129 (100)	55 (42.6)	38 (29.5)	12 (9.3)	4 (3. 1)	1 (0. 8)
AST, high	128 (99.2)	56 (43.8)	43 (33.6)	8 (6. 3)	4 (3. 1)	1 (0. 8)
Albumin, low	124 (96.1)	74 (59.7)	37 (29.8)	35 (28.2)	2 (1. 6)	-

Treatment-emergent tests were from samples collected after study day 1 through 30 days post last dose of any study drug.

Table 14.3.8.1: Treatment Emergent Clinical Laboratory Evaluation

Full Analysis Set N=129			Number Of Patients (%) Worst CTCAE Grade on Treatment			
Laboratory Test	**Patients with On study Test**	**Incidence of Abnormality**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Renal function						
Creatinine, high	129 (100)	41 (31.8)	28 (21.7)	12 (9.3)	1 (0. 8)	-
BUN, high	129 (100)	65 (50.4)	-	-	-	-
Urate (uric acid), high	129 (100)	29 (22.5)	25 (19.4)	-	-	4 (3. 1)
Sodium, high	129 (100)	7 (5. 4)	7 (5. 4)	-	-	-
Sodium, low	129 (100)	60 (46.5)	50 (38.8)	-	9 (7. 0)	1 (0. 8)
Potassium, high	129 (100)	20 (15.5)	12 (9.3)	5 (3. 9)	2 (1. 6)	1 (0. 8)
Potassium, low	129 (100)	56 (43.4)	48 (37.2)	-	8 (6. 2)	-
Chloride, high	125 (96.9)	34 (27.2)	-	-	-	-
Chloride, low	125 (96.9)	29 (23.2)	-	-	-	-
Magnesium, high	125 (96.9)	18 (14.4)	17 (13.6)	-	1 (0. 8)	-
Magnesium, low	125 (96.9)	35 (28.0)	31 (24.8)	4 (3. 2)	-	-
Metabolic function						
LDH, high	128 (99.2)	107 (83.6)	-	-	-	-
Phosphate, low	122 (94.6)	34 (27.9)	2 (1. 6)	21 (17.2)	10 (8.2)	1 (0. 8)
Calcium, high	128 (99.2)	13 (10.2)	10 (7.8)	-	2 (1. 6)	1 (0. 8)
Calcium, low	128 (99.2)	72 (56.3)	47 (36.7)	22 (17.2)	2 (1. 6)	1 (0. 8)
Glucose, high	128 (99.2)	111 (86.7)	72 (56.3)	29 (22.7)	9 (7. 0)	1 (0. 8)
Glucose, low	128 (99.2)	12 (9.4)	10 (7.8)	1 (0. 8)	-	1 (0. 8)

Treatment-emergent tests were from samples collected after study day 1 through 30 days post last dose of any study drug.

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Hemoglobin, low	129	Grade 0	10 (7.8%)	25 (19.4%)	7 (5.4%)	1 (0.8%)	-	43 (33.3%)
		Grade 1	-	26 (20.2%)	30 (23.3%)	4 (3.1%)	1 (0.8%)	61 (47.3%)
		Grade 2	1 (0.8%)	-	14 (10.9%)	3 (2.3%)	2 (1.6%)	20 (15.5%)
		Grade 3	-	-	1 (0.8%)	2 (1.6%)	1 (0.8%)	4 (3.1%)
		Grade 4	-	-	-	-	1 (0.8%)	1 (0.8%)
		Unknown	-	-	-	-	-	-
		Total	11 (8.5%)	51 (39.5%)	52 (40.3%)	10 (7.8%)	5 (3.9%)	129 (100.0%)
Platelet count, low	129	Grade 0	38 (29.5%)	36 (27.9%)	5 (3.9%)	2 (1.6%)	2 (1.6%)	83 (64.3%)
		Grade 1	1 (0.8%)	11 (8.5%)	17 (13.2%)	2 (1.6%)	3 (2.3%)	34 (26.4%)
		Grade 2	-	-	2 (1.6%)	5 (3.9%)	3 (2.3%)	10 (7.8%)
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	2 (1.6%)	2 (1.6%)
		Unknown	-	-	-	-	-	-
		Total	39 (30.2%)	47 (36.4%)	24 (18.6%)	9 (7.0%)	10 (7.8%)	129 (100.0%)
Leukocyte count, low	129	Grade 0	65 (50.4%)	17 (13.2%)	13 (10.1%)	5 (3.9%)	-	100 (77.5%)
		Grade 1	3 (2.3%)	5 (3.9%)	5 (3.9%)	5 (3.9%)	-	18 (14.0%)
		Grade 2	1 (0.8%)	-	4 (3.1%)	2 (1.6%)	-	7 (5.4%)
		Grade 3	-	-	-	2 (1.6%)	2 (1.6%)	4 (3.1%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	69 (53.5%)	22 (17.1%)	22 (17.1%)	14 (10.9%)	2 (1.6%)	129 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
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Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Neutrophil count, low	128	Grade 0	79 (61.7%)	9 (7.0%)	14 (10.9%)	8 (6.3%)	3 (2.3%)	113 (88.3%)
		Grade 1	2 (1.6%)	2 (1.6%)	1 (0.8%)	-	-	5 (3.9%)
		Grade 2	-	2 (1.6%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	8 (6.3%)
		Grade 3	-	-	-	-	1 (0.8%)	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	1 (0.8%)	-	-	-	-	1 (0.8%)
		Total	82 (64.1%)	13 (10.2%)	17 (13.3%)	10 (7.8%)	6 (4.7%)	128 (100.0%)
Lymphocyte count, low	128	Grade 0	21 (16.4%)	8 (6.3%)	20 (15.6%)	9 (7.0%)	1 (0.8%)	59 (46.1%)
		Grade 1	-	1 (0.8%)	9 (7.0%)	6 (4.7%)	2 (1.6%)	18 (14.1%)
		Grade 2	-	1 (0.8%)	5 (3.9%)	13 (10.2%)	4 (3.1%)	23 (18.0%)
		Grade 3	-	-	2 (1.6%)	10 (7.8%)	8 (6.3%)	20 (15.6%)
		Grade 4	-	-	-	2 (1.6%)	5 (3.9%)	7 (5.5%)
		Unknown	-	-	-	-	1 (0.8%)	1 (0.8%)
		Total	21 (16.4%)	10 (7.8%)	36 (28.1%)	40 (31.3%)	21 (16.4%)	128 (100.0%)
Prothrombin time, high	54	Grade 0	30 (55.6%)	10 (18.5%)	-	1 (1.9%)	-	41 (75.9%)
		Grade 1	1 (1.9%)	2 (3.7%)	-	1 (1.9%)	-	4 (7.4%)
		Grade 2	-	-	1 (1.9%)	1 (1.9%)	-	2 (3.7%)
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	6 (11.1%)	1 (1.9%)	-	-	-	7 (13.0%)
		Total	37 (68.5%)	13 (24.1%)	1 (1.9%)	3 (5.6%)	-	54 (100.0%)

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Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
INR, high	86	Grade 0	54 (62.8%)	11 (12.8%)	1 (1.2%)	3 (3.5%)	-	69 (80.2%)
		Grade 1	1 (1.2%)	4 (4.7%)	-	5 (5.8%)	-	10 (11.6%)
		Grade 2	-	-	1 (1.2%)	1 (1.2%)	-	2 (2.3%)
		Grade 3	-	1 (1.2%)	-	1 (1.2%)	-	2 (2.3%)
		Grade 4	-	-	-	-	-	-
		Unknown	2 (2.3%)	-	1 (1.2%)	-	-	3 (3.5%)
		Total	57 (66.3%)	16 (18.6%)	3 (3.5%)	10 (11.6%)	-	86 (100.0%)
APTT, high	91	Grade 0	56 (61.5%)	12 (13.2%)	5 (5.5%)	3 (3.3%)	-	76 (83.5%)
		Grade 1	-	10 (11.0%)	1 (1.1%)	1 (1.1%)	-	12 (13.2%)
		Grade 2	-	1 (1.1%)	-	-	-	1 (1.1%)
		Grade 3	1 (1.1%)	-	-	-	-	1 (1.1%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	1 (1.1%)	-	-	1 (1.1%)
		Total	57 (62.6%)	23 (25.3%)	7 (7.7%)	4 (4.4%)	-	91 (100.0%)
Bilirubin, high	129	Grade 0	90 (69.8%)	21 (16.3%)	4 (3.1%)	4 (3.1%)	1 (0.8%)	120 (93.0%)
		Grade 1	1 (0.8%)	5 (3.9%)	-	-	-	6 (4.7%)
		Grade 2	-	1 (0.8%)	-	1 (0.8%)	-	2 (1.6%)
		Grade 3	-	-	-	1 (0.8%)	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	91 (70.5%)	27 (20.9%)	4 (3.1%)	6 (4.7%)	1 (0.8%)	129 (100.0%)

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DATE: 10OCT2013

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Alkaline phosphatase, high	128	Grade 0	71 (55.5%)	19 (14.8%)	5 (3.9%)	-	-	95 (74.2%)
		Grade 1	1 (0.8%)	19 (14.8%)	3 (2.3%)	-	-	23 (18.0%)
		Grade 2	-	-	7 (5.5%)	1 (0.8%)	-	8 (6.3%)
		Grade 3	-	-	-	1 (0.8%)	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	1 (0.8%)	-	-	-	1 (0.8%)
		Total	72 (56.3%)	39 (30.5%)	15 (11.7%)	2 (1.6%)	-	128 (100.0%)
Alanine transaminase, high	129	Grade 0	70 (54.3%)	28 (21.7%)	9 (7.0%)	3 (2.3%)	-	110 (85.3%)
		Grade 1	4 (3.1%)	10 (7.8%)	3 (2.3%)	1 (0.8%)	1 (0.8%)	19 (14.7%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	74 (57.4%)	38 (29.5%)	12 (9.3%)	4 (3.1%)	1 (0.8%)	129 (100.0%)
Aspartate transaminase, high	128	Grade 0	70 (54.7%)	29 (22.7%)	2 (1.6%)	2 (1.6%)	-	103 (80.5%)
		Grade 1	2 (1.6%)	13 (10.2%)	6 (4.7%)	-	1 (0.8%)	22 (17.2%)
		Grade 2	-	1 (0.8%)	-	2 (1.6%)	-	3 (2.3%)
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	72 (56.3%)	43 (33.6%)	8 (6.3%)	4 (3.1%)	1 (0.8%)	128 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
On-study samples were those collected after study day 1 through 30 days post last dose of any study treatment.
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DATE: 10OCT2013

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Albumin, low	124	Grade 0	47 (37.9%)	25 (20.2%)	9 (7.3%)	-	-	81 (65.3%)
		Grade 1	2 (1.6%)	11 (8.9%)	11 (8.9%)	1 (0.8%)	-	25 (20.2%)
		Grade 2	-	-	12 (9.7%)	1 (0.8%)	-	13 (10.5%)
		Grade 3	-	-	1 (0.8%)	-	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	1 (0.8%)	1 (0.8%)	2 (1.6%)	-	-	4 (3.2%)
		Total	50 (40.3%)	37 (29.8%)	35 (28.2%)	2 (1.6%)	-	124 (100.0%)
Creatinine, high	129	Grade 0	87 (67.4%)	25 (19.4%)	7 (5.4%)	-	-	119 (92.2%)
		Grade 1	1 (0.8%)	3 (2.3%)	5 (3.9%)	-	-	9 (7.0%)
		Grade 2	-	-	-	1 (0.8%)	-	1 (0.8%)
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	88 (68.2%)	28 (21.7%)	12 (9.3%)	1 (0.8%)	-	129 (100.0%)
Urate (uric acid), high	129	Grade 0	96 (74.4%)	11 (8.5%)	-	-	3 (2.3%)	110 (85.3%)
		Grade 1	3 (2.3%)	12 (9.3%)	-	-	-	15 (11.6%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	-	-	-	-
		Grade 4	-	2 (1.6%)	-	-	-	2 (1.6%)
		Unknown	1 (0.8%)	-	-	-	1 (0.8%)	2 (1.6%)
		Total	100 (77.5%)	25 (19.4%)	-	-	4 (3.1%)	129 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
On-study samples were those collected after study day 1 through 30 days post last dose of any study treatment.
V:\...\Spectrum\Belinostat\Programs\t-labshift.sas
DATE: 10OCT2013

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Sodium, high	129	Grade 0	122 (94.6%)	7 (5.4%)	-	-	-	129 (100.0%)
		Grade 1	-	-	-	-	-	-
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	122 (94.6%)	7 (5.4%)	-	-	-	129 (100.0%)
Sodium, low	129	Grade 0	68 (52.7%)	44 (34.1%)	-	5 (3.9%)	-	117 (90.7%)
		Grade 1	1 (0.8%)	6 (4.7%)	-	3 (2.3%)	1 (0.8%)	11 (8.5%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	-	1 (0.8%)	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	69 (53.5%)	50 (38.8%)	-	9 (7.0%)	1 (0.8%)	129 (100.0%)
Potassium, high	129	Grade 0	109 (84.5%)	12 (9.3%)	3 (2.3%)	2 (1.6%)	1 (0.8%)	127 (98.4%)
		Grade 1	-	-	1 (0.8%)	-	-	1 (0.8%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	1 (0.8%)	-	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	109 (84.5%)	12 (9.3%)	5 (3.9%)	2 (1.6%)	1 (0.8%)	129 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
On-study samples were those collected after study day 1 through 30 days post last dose of any study treatment.
V:\...\Spectrum\Belinostat\Programs\t-labshift.sas
DATE: 10OCT2013

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Potassium, low	129	Grade 0	70 (54.3%)	44 (34.1%)	-	7 (5.4%)	-	121 (93.8%)
		Grade 1	2 (1.6%)	4 (3.1%)	-	1 (0.8%)	-	7 (5.4%)
		Grade 2	-	-	-	-	-	-
		Grade 3	1 (0.8%)	-	-	-	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	73 (56.6%)	48 (37.2%)	-	8 (6.2%)	-	129 (100.0%)
Magnesium, high	125	Grade 0	100 (80.0%)	14 (11.2%)	-	1 (0.8%)	-	115 (92.0%)
		Grade 1	1 (0.8%)	1 (0.8%)	-	-	-	2 (1.6%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	1 (0.8%)	-	-	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	6 (4.8%)	1 (0.8%)	-	-	-	7 (5.6%)
		Total	107 (85.6%)	17 (13.6%)	-	1 (0.8%)	-	125 (100.0%)
Magnesium, low	125	Grade 0	82 (65.6%)	22 (17.6%)	1 (0.8%)	-	-	105 (84.0%)
		Grade 1	3 (2.4%)	6 (4.8%)	-	-	-	9 (7.2%)
		Grade 2	-	1 (0.8%)	3 (2.4%)	-	-	4 (3.2%)
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	5 (4.0%)	2 (1.6%)	-	-	-	7 (5.6%)
		Total	90 (72.0%)	31 (24.8%)	4 (3.2%)	-	-	125 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
On-study samples were those collected after study day 1 through 30 days post last dose of any study treatment.
V:\...\Spectrum\Belinostat\Programs\t-labshift.sas **DATE: 10OCT2013**

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Phosphate, low	122	Grade 0	81 (66.4%)	2 (1.6%)	18 (14.8%)	7 (5.7%)	1 (0.8%)	109 (89.3%)
		Grade 1	1 (0.8%)	-	1 (0.8%)	-	-	2 (1.6%)
		Grade 2	-	-	2 (1.6%)	1 (0.8%)	-	3 (2.5%)
		Grade 3	-	-	-	2 (1.6%)	-	2 (1.6%)
		Grade 4	-	-	-	-	-	-
		Unknown	6 (4.9%)	-	-	-	-	6 (4.9%)
		Total	88 (72.1%)	2 (1.6%)	21 (17.2%)	10 (8.2%)	1 (0.8%)	122 (100.0%)
Calcium, high	128	Grade 0	115 (89.8%)	8 (6.3%)	-	1 (0.8%)	1 (0.8%)	125 (97.7%)
		Grade 1	-	2 (1.6%)	-	-	-	2 (1.6%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	-	1 (0.8%)	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	115 (89.8%)	10 (7.8%)	-	2 (1.6%)	1 (0.8%)	128 (100.0%)
Calcium, low	128	Grade 0	56 (43.8%)	35 (27.3%)	12 (9.4%)	-	1 (0.8%)	104 (81.3%)
		Grade 1	-	9 (7.0%)	9 (7.0%)	-	-	18 (14.1%)
		Grade 2	-	2 (1.6%)	1 (0.8%)	2 (1.6%)	-	5 (3.9%)
		Grade 3	-	1 (0.8%)	-	-	-	1 (0.8%)
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	56 (43.8%)	47 (36.7%)	22 (17.2%)	2 (1.6%)	1 (0.8%)	128 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
On-study samples were those collected after study day 1 through 30 days post last dose of any study treatment.
V:\...\Spectrum\Belinostat\Programs\t-labshift.sas **DATE: 10OCT2013**

Table 14.3.8.2: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study

Full Analysis Set			Number of Patients N=129 Worst On-study Toxicity Grade					
Laboratory Abnormality	**Number of Pts**	**Baseline Grade**	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
Glucose, high	128	Grade 0	16 (12.5%)	50 (39.1%)	14 (10.9%)	3 (2.3%)	-	83 (64.8%)
		Grade 1	1 (0.8%)	19 (14.8%)	11 (8.6%)	3 (2.3%)	-	34 (26.6%)
		Grade 2	-	3 (2.3%)	4 (3.1%)	3 (2.3%)	1 (0.8%)	11 (8.6%)
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	17 (13.3%)	72 (56.3%)	29 (22.7%)	9 (7.0%)	1 (0.8%)	128 (100.0%)
Glucose, low	128	Grade 0	116 (90.6%)	9 (7.0%)	1 (0.8%)	-	1 (0.8%)	127 (99.2%)
		Grade 1	-	1 (0.8%)	-	-	-	1 (0.8%)
		Grade 2	-	-	-	-	-	-
		Grade 3	-	-	-	-	-	-
		Grade 4	-	-	-	-	-	-
		Unknown	-	-	-	-	-	-
		Total	116 (90.6%)	10 (7.8%)	1 (0.8%)	-	1 (0.8%)	128 (100.0%)

Baseline samples were the last sample on or before the day of first dose of study treatment.
On-study samples were those collected after study day 1 through 30 days post last dose of any study treatment.
V:\...\Spectrum\Belinostat\Programs\t-labshift.sas **DATE: 10OCT2013**

Table 14.3.8.3: Summary of Vital Signs
Systolic Blood Pressure

The MEANS Procedure

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
PRE_TRIAL	Baseline	129	124.7209302	15.7485003	88.0000000	180.0000000
END_OF_TRIAL	Last Timepoint	126	117.9285714	16.1934202	81.0000000	152.0000000
CHANGE	Change from Baseline	126	-7.2142857	19.9192800	-89.0000000	54.0000000

Last Timepoint is last assessment in a patient on the study
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DATE: 10OCT2013

Table 14.3.8.3: Summary of Vital Signs
Diastolic Blood Pressure

The MEANS Procedure

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
PRE_TRIAL	Baseline	129	75.4108527	9.6035576	51.0000000	100.0000000
END_OF_TRIAL	Last Timepoint	126	70.8333333	11.2433091	40.0000000	91.0000000
CHANGE	Change from Baseline	126	-4.7142857	11.9631816	-35.0000000	26.0000000

Table 14.3.8.3: Summary of Vital Signs
Heart Rate

The MEANS Procedure

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
PRE_TRIAL	Baseline	129	82.2248062	14.1924497	51.0000000	138.0000000
END_OF_TRIAL	Last Timepoint	125	82.2640000	15.5206127	54.0000000	133.0000000
CHANGE	Change from Baseline	125	0.0960000	17.5868463	-43.0000000	60.0000000

Table 14.3.8.3: Summary of Vital Signs
Temperature

The MEANS Procedure

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
PRE_TRIAL	Baseline	129	36.5441860	0.6378561	34.0000000	39.2000000
END_OF_TRIAL	Last Timepoint	121	36.5595041	0.6148955	34.9000000	38.6000000
CHANGE	Change from Baseline	121	0.0157025	0.6834969	-1.9000000	1.9000000

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-001	Pre-trial	2009-05-06T06:00	Hemoglobin	9.51	g/dL	L	12.9	17.7
			Erythrocytes	3.15	10^12/L	L	4.1	6.1
			Leukocytes	45	10^9/L	H	3	9
			Neutrophils	38	10^9/L	H	1.8	7.4
			Prothrombin Intl. Normalized Ratio	1.4	ratio	H	0.8	1.2
			Potassium	2.7	mmol/L	L	3.2	4.7
			Calcium	7.66	mg/dL	L	10	11.5
			Phosphate	1.3	mg/dL	L	2.5	4.6
			Albumin	2.04	g/dL	L	3.4	4.5
			Alkaline Phosphatase	324	U/L	H	35	105
			Lactate Dehydrogenase	306	U/L	H	105	205
			Urate	1.18	mg/dL	L	3.4	7.6
	Cycle 1	2009-05-11T06:00	Hemoglobin	9.99	g/dL	L	12.9	17.7
			Leukocytes	68	10^9/L	H	3	9
			Neutrophils	62	10^9/L	H	1.8	7.4
			Monocytes	2.17	10^9/L	H	0	1.1
			Potassium	3.1	mmol/L	L	3.2	4.7
			Phosphate	1.52	mg/dL	L	2.5	4.6
			Magnesium	2.46	mg/dL	H	1.6	2.3
			Albumin	1.91	g/dL	L	3.4	4.5
			Alanine Aminotransferase	168	U/L	H	10	70
			Alkaline Phosphatase	421	U/L	H	35	105
			Lactate Dehydrogenase	526	U/L	H	105	205

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-001	End Trial	2009-05-12T06:00	Hemoglobin	9.02	g/dL	L	12.9	17.7
			Leukocytes	54	10^9/L	H	3	9
			Potassium	3	mmol/L	L	3.2	4.7
			Phosphate	1.27	mg/dL	L	2.5	4.6
			Alanine Aminotransferase	180	U/L	H	10	70
			Alkaline Phosphatase	418	U/L	H	35	105
			Lactate Dehydrogenase	445	U/L	H	105	205
			Blood Urea Nitrogen	24.37	mg/dL	H	7	21
			Urate	2.19	mg/dL	L	3.4	7.6
100-002	Pre-trial	2009-08-21T13:05	Hemoglobin	11.12	g/dL	L	13.1	16.6
			Erythrocytes	3.41	10^12/L	L	4.25	5.71
			Leukocytes	14.9	10^9/L	H	3.5	8.8
			Neutrophils	13.5	10^9/L	H	1.8	7.4
			Sodium	134	mmol/L	L	137	144
			Potassium	5.1	mmol/L	H	3.2	4.6
			Magnesium	2.33	mg/dL	H	1.7	2.3
			Creatinine	1.131	mg/dL	H	0.68	1.13
			Albumin	3.2	g/dL	L	3.4	4.5
			Aspartate Aminotransferase	48	U/L	H	15	45
			Alkaline Phosphatase	302	U/L	H	35	105
			Lactate Dehydrogenase	258	U/L	H	105	205
			Blood Urea Nitrogen	33.33	mg/dL	H	9.8	22.7
			Urate	3.19	mg/dL	L	3.9	8.1
			Glucose	129.7	mg/dL	H	76	113

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-002	Cycle 1	2009-08-24T08:18	Hemoglobin	11.28	g/dL	L	13.1	16.6
			Erythrocytes	3.49	10^12/L	L	4.25	5.71
			Leukocytes	19.4	10^9/L	H	3.5	8.8
			Neutrophils	14.6	10^9/L	H	1.8	7.4
			Calcium	8.58	mg/dL	L	8.6	10.1
			Magnesium	2.38	mg/dL	H	1.7	2.3
			Albumin	3.3	g/dL	L	3.4	4.5
			Aspartate Aminotransferase	52	U/L	H	15	45
			Alkaline Phosphatase	283	U/L	H	35	105
			Lactate Dehydrogenase	273	U/L	H	105	205
			Blood Urea Nitrogen	25.77	mg/dL	H	9.8	22.7
			Urate	3.19	mg/dL	L	3.9	8.1
		2009-08-28T08:15	Hemoglobin	9.83	g/dL	L	13.1	16.6
			Erythrocytes	3.13	10^12/L	L	4.25	5.71
			Leukocytes	15.8	10^9/L	H	3.5	8.8
			Neutrophils	14.4	10^9/L	H	1.8	7.4
			Lymphocytes	0.63	10^9/L	L	0.8	4.8
			Calcium	7.7	mg/dL	L	8.6	10.1
			Magnesium	2.38	mg/dL	H	1.7	2.3
			Albumin	2.7	g/dL	L	3.4	4.5
			Alkaline Phosphatase	283	U/L	H	35	105
			Lactate Dehydrogenase	273	U/L	H	105	205
			Urate	2.52	mg/dL	L	3.9	8.1
			Glucose	120.7	mg/dL	H	76	113

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-002	Cycle 1	2009-09-03T06:13	Hemoglobin	12.25	g/dL	L	13.1	16.6
			Erythrocytes	3.96	10^12/L	L	4.25	5.71
			Sodium	135	mmol/L	L	137	144
			Calcium	8.22	mg/dL	L	8.6	10.1
			Magnesium	2.31	mg/dL	H	1.7	2.3
			Albumin	3.1	g/dL	L	3.4	4.5
			Alanine Aminotransferase	86	U/L	H	10	70
			Aspartate Aminotransferase	66	U/L	H	15	45
			Alkaline Phosphatase	240	U/L	H	35	105
			Lactate Dehydrogenase	308	U/L	H	105	205
			Blood Urea Nitrogen	26.33	mg/dL	H	9.8	22.7
			Urate	2.19	mg/dL	L	3.9	8.1
			Glucose	61.3	mg/dL	L	76	113
	Cycle 2	2009-09-14T08:20	Hemoglobin	10.63	g/dL	L	13.1	16.6
			Erythrocytes	3.51	10^12/L	L	4.25	5.71
			Activated Partial Thromboplastin Time	44	sec	H	23	35
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.8	1.2
			Sodium	134	mmol/L	L	137	144
			Calcium	7.9	mg/dL	L	8.6	10.1
			Chloride	96	mmol/L	L	98	106
			Phosphate	2.32	mg/dL	L	2.6	4.6
			Albumin	2.7	g/dL	L	3.4	4.5
			Alanine Aminotransferase	151	U/L	H	10	70
			Aspartate Aminotransferase	69	U/L	H	15	45
			Alkaline Phosphatase	302	U/L	H	35	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-002	Cycle 2	2009-09-14T08:20	Lactate Dehydrogenase	257	U/L	H	105	205
			Urate	2.35	mg/dL	L	3.9	8.1
			Glucose	70.3	mg/dL	L	76	113
		2009-09-18T06:00	Hemoglobin	9.35	g/dL	L	13.1	16.6
			Erythrocytes	3.34	10^12/L	L	4.25	5.71
			Platelets	140	10^9/L	L	145	390
			Leukocytes	2.3	10^9/L	L	3.5	8.8
			Neutrophils	0.9	10^9/L	L	1.8	7.4
			Calcium	8.02	mg/dL	L	8.6	10.1
			Chloride	97	mmol/L	L	98	106
			Magnesium	2.38	mg/dL	H	1.7	2.3
			Albumin	2.8	g/dL	L	3.4	4.5
			Alanine Aminotransferase	94	U/L	H	10	70
			Aspartate Aminotransferase	60	U/L	H	15	45
			Alkaline Phosphatase	243	U/L	H	35	105
			Lactate Dehydrogenase	474	U/L	H	105	205
			Urate	2.35	mg/dL	L	3.9	8.1
			Glucose	154.9	mg/dL	H	76	113
	Cycle 3	2009-10-05T05:43	Hemoglobin	9.67	g/dL	L	13.1	16.6
			Erythrocytes	3.1	10^12/L	L	4.25	5.71
			Activated Partial Thromboplastin Time	68	sec	H	23	35
			Prothrombin Intl. Normalized Ratio	2.1	ratio	H	0.8	1.2
			Calcium	7.98	mg/dL	L	8.6	10.1
			Phosphate	2.57	mg/dL	L	2.6	4.6
			Creatinine	0.679	mg/dL	L	0.68	1.13

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-002	Cycle 3	2009-10-05T05:43	Albumin	2.8	g/dL	L	3.4	4.5
			Alanine Aminotransferase	135	U/L	H	10	70
			Aspartate Aminotransferase	61	U/L	H	15	45
			Alkaline Phosphatase	187	U/L	H	35	105
			Lactate Dehydrogenase	253	U/L	H	105	205
			Urate	3.7	mg/dL	L	3.9	8.1
			Glucose	75.7	mg/dL	L	76	113
		2009-10-09T05:22	Hemoglobin	10.15	g/dL	L	13.1	16.6
			Erythrocytes	3.23	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Calcium	8.22	mg/dL	L	8.6	10.1
			Magnesium	2.65	mg/dL	H	1.7	2.3
			Albumin	3.3	g/dL	L	3.4	4.5
			Alanine Aminotransferase	201	U/L	H	10	70
			Aspartate Aminotransferase	83	U/L	H	15	45
			Alkaline Phosphatase	218	U/L	H	35	105
			Lactate Dehydrogenase	264	U/L	H	105	205
	Cycle 4	2009-10-26	Hemoglobin	11.92	g/dL	L	13.1	16.6
			Erythrocytes	3.7	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	101	fL	H	82	98
			Activated Partial Thromboplastin Time	41	sec	H	23	35
			Prothrombin Intl. Normalized Ratio	1.4	ratio	H	0.8	1.2
			Calcium	8.38	mg/dL	L	8.6	10.1
			Alanine Aminotransferase	91	U/L	H	10	70
			Aspartate Aminotransferase	63	U/L	H	15	45

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-002	Cycle 4	2009-10-26	Alkaline Phosphatase	153	U/L	H	35	105
			Lactate Dehydrogenase	281	U/L	H	115	255
			Glucose	236	mg/dL	H	76	113
		2009-10-30T09:00	Hemoglobin	10.15	g/dL	L	13.1	16.6
			Erythrocytes	3.17	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	101	fL	H	82	98
			Platelets	141	10^9/L	L	145	390
			Lymphocytes	0.77	10^9/L	L	0.8	4.8
			Calcium	8.38	mg/dL	L	8.6	10.1
			Albumin	3.2	g/dL	L	3.6	4.5
			Alkaline Phosphatase	148	U/L	H	35	105
			Lactate Dehydrogenase	338	U/L	H	115	255
			Glucose	122.5	mg/dL	H	76	113
	End Trial	2009-11-13T06:00	Hemoglobin	9.51	g/dL	L	13.1	16.6
		2009-11-16T05:15	Activated Partial Thromboplastin Time	44	sec	H	23	35
			Prothrombin Intl. Normalized Ratio	4.1	ratio	H	0.8	1.2
			Calcium	7.9	mg/dL	L	8.6	10.1
			Chloride	96	mmol/L	L	97	108
			Albumin	2.8	g/dL	L	3.6	4.5
			Alanine Aminotransferase	225	U/L	H	10	70
			Aspartate Aminotransferase	157	U/L	H	15	45
			Alkaline Phosphatase	226	U/L	H	35	105
			Lactate Dehydrogenase	337	U/L	H	115	255
			Bilirubin	0.234	mg/dL	L	0.29	1.46
			Blood Urea Nitrogen	31.09	mg/dL	H	9.8	22.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-003	Pre-trial	2009-10-02T10:06	Hemoglobin	10.8	g/dL	L	13.1	16.6
			Erythrocytes	3.08	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	100	fL	H	82	98
			Lymphocytes	0.76	10^9/L	L	0.8	4.8
			Chloride	92	mmol/L	L	98	106
			Magnesium	1.17	mg/dL	L	1.7	2.3
			Aspartate Aminotransferase	96	U/L	H	15	45
	Cycle 1	2009-10-12T07:48	Hemoglobin	10.96	g/dL	L	13.1	16.6
			Erythrocytes	3.06	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	102	fL	H	82	98
			Sodium	133	mmol/L	L	137	144
			Chloride	90	mmol/L	L	98	106
			Magnesium	1.02	mg/dL	L	1.7	2.3
			Aspartate Aminotransferase	87	U/L	H	15	45
		2009-10-16T08:09	Hemoglobin	10.96	g/dL	L	13.1	16.6
			Erythrocytes	3.04	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	104	fL	H	82	98
			Lymphocytes	0.77	10^9/L	L	0.8	4.8
			Sodium	134	mmol/L	L	137	144
			Potassium	3.3	mmol/L	L	3.5	4.6
			Chloride	93	mmol/L	L	97	108
			Magnesium	1.31	mg/dL	L	1.6	2.3
			Creatinine	1.21	mg/dL	H	0.7	1.13
			Glucose	135.1	mg/dL	H	76	113

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-003	Cycle 1	2009-10-22T09:57	Hemoglobin	9.83	g/dL	L	13.1	16.6
			Erythrocytes	2.85	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	100	fL	H	82	98
			Lymphocytes	0.69	10^9/L	L	0.8	4.8
			Sodium	135	mmol/L	L	137	144
			Chloride	93	mmol/L	L	97	108
			Magnesium	1.12	mg/dL	L	1.6	2.3
	Cycle 2	2009-11-02T10:06	Hemoglobin	10.63	g/dL	L	13.1	16.6
			Erythrocytes	3	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	104	fL	H	82	98
			Lymphocytes	0.69	10^9/L	L	0.8	4.8
			Calcium	8.58	mg/dL	L	8.6	10.1
			Chloride	89	mmol/L	L	97	108
			Magnesium	1	mg/dL	L	1.6	2.3
			Glucose	120.7	mg/dL	H	76	113
		2009-11-06T09:44	Hemoglobin	9.99	g/dL	L	13.1	16.6
			Erythrocytes	2.88	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	104	fL	H	82	98
			Lymphocytes	0.58	10^9/L	L	0.8	4.8
			Potassium	3	mmol/L	L	3.5	4.6
			Chloride	94	mmol/L	L	97	108
			Magnesium	1.14	mg/dL	L	1.6	2.3
			Creatinine	1.629	mg/dL	H	0.7	1.13
			Blood Urea Nitrogen	31.09	mg/dL	H	9.8	22.7
			Glucose	118.9	mg/dL	H	76	113

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-003	End Trial	2009-11-20T10:48	Hemoglobin	8.86	g/dL	L	13.1	16.6
			Erythrocytes	2.55	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	106	fL	H	82	98
			Lymphocytes	0.53	10^9/L	L	0.8	4.8
			Potassium	3	mmol/L	L	3.5	4.6
			Chloride	89	mmol/L	L	97	108
			Magnesium	1.12	mg/dL	L	1.6	2.3
			Blood Urea Nitrogen	31.09	mg/dL	H	9.8	22.7
100-004	Pre-trial	2009-10-14T13:30	Hemoglobin	10.8	g/dL	L	13.1	16.6
			Erythrocytes	3.24	10^12/L	L	4.25	5.71
			Platelets	83	10^9/L	L	145	390
			Aspartate Aminotransferase	49	U/L	H	15	45
			Glucose	147.7	mg/dL	H	76	113
	Cycle 1	2009-10-19	Hemoglobin	11.6	g/dL	L	13.1	16.6
			Erythrocytes	3.35	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	101	fL	H	82	98
			Platelets	94	10^9/L	L	145	390
			Leukocytes	15.7	10^9/L	H	3.5	8.8
			Lymphocytes	7.97	10^9/L	H	0.8	4.8
			Albumin	3.5	g/dL	L	3.6	4.5
			Aspartate Aminotransferase	47	U/L	H	15	45

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
100-004	Cycle 1	2009-10-23T09:00	Hemoglobin	10.8	g/dL	L	13.1	16.6
			Erythrocytes	3.12	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	102	fL	H	82	98
			Platelets	55	10^9/L	L	145	390
			Neutrophils	0.7	10^9/L	L	1.8	7.4
			Potassium	4.7	mmol/L	H	3.5	4.6
			Albumin	3.5	g/dL	L	3.6	4.5
			Aspartate Aminotransferase	57	U/L	H	15	45
			Urate	3.87	mg/dL	L	3.9	8.1
			Glucose	126.1	mg/dL	H	76	113
		2009-10-30T11:00	Hemoglobin	10.8	g/dL	L	12.9	17.7
			Erythrocytes	3.2	10^12/L	L	4.1	6.1
			Platelets	47	10^9/L	L	135	400
			Neutrophils	0.4	10^9/L	L	1.6	8.5
			Sodium	136	mmol/L	L	137	145
	End Trial	2009-11-09T11:19	Hemoglobin	11.28	g/dL	L	13.1	16.6
			Erythrocytes	3.17	10^12/L	L	4.25	5.71
			Ery. Mean Corpuscular Volume	105	fL	H	82	98
			Platelets	29	10^9/L	L	145	390
			Leukocytes	84.5	10^9/L	H	3.5	8.8
			Neutrophils	0.68	10^9/L	L	1.8	7.4
			Lymphocytes	65.5	10^9/L	H	0.8	4.8
			Potassium	4.8	mmol/L	H	3.5	4.6
			Alanine Aminotransferase	81	U/L	H	10	70
			Aspartate Aminotransferase	85	U/L	H	15	45
			Lactate Dehydrogenase	356	U/L	H	105	255

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
100-004	End Trial	2009-11-09T11:19	Glucose	122.5	mg/dL	H	76	113
120-001	Pre-trial	2011-03-30T10:41	Lactate Dehydrogenase	258	U/L	H	98	192
		2011-03-30T10:45	Hemoglobin	11.7	g/dL	L	12	15
			Eosinophils	0	10^9/L	L	0.02	0.5
			Basophils	0	10^9/L	L	0.02	0.1
	Cycle 1	2011-04-11T10:05	Hemoglobin	11.8	g/dL	L	12	15
			Erythrocytes	3.79	10^12/L	L	3.8	4.8
			Monocytes	1.14	10^9/L	H	0.2	1
			Basophils	0.23	10^9/L	H	0.02	0.1
		2011-04-11T10:23	Lactate Dehydrogenase	259	U/L	H	98	192
			Blood Urea Nitrogen	19.33	mg/dL	H	7	17.9
		2011-04-15T10:05	Chloride	108	mmol/L	H	97	107
			Phosphate	2.48	mg/dL	L	2.5	4.5
			Lactate Dehydrogenase	219	U/L	H	98	192
			Urate	2.35	mg/dL	L	2.5	5.9
			Glucose	124.3	mg/dL	H	70	108
		2011-04-15T10:23	Hemoglobin	11.2	g/dL	L	12	15
			Erythrocytes	3.63	10^12/L	L	3.8	4.8
			Basophils	0.16	10^9/L	H	0.02	0.1
		2011-04-21T11:56	Hemoglobin	10	g/dL	L	12	15
			Erythrocytes	3.21	10^12/L	L	3.8	4.8
			Lymphocytes	0.95	10^9/L	L	1	3
			Basophils	0	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
120-001	Cycle 1	2011-04-21T11:57	Lactate Dehydrogenase	322	U/L	H	98	192
			Urate	2.35	mg/dL	L	2.5	5.9
	Cycle 2	2011-05-03T10:38	Chloride	110	mmol/L	H	97	107
			Lactate Dehydrogenase	271	U/L	H	98	192
			Urate	2.35	mg/dL	L	2.5	5.9
			Glucose	122.5	mg/dL	H	70	108
		2011-05-03T10:42	Hemoglobin	10.6	g/dL	L	12	15
			Erythrocytes	3.45	10^12/L	L	3.8	4.8
			Basophils	0	10^9/L	L	0.02	0.1
		2011-05-09T10:55	Hemoglobin	11.3	g/dL	L	12	15
			Erythrocytes	3.54	10^12/L	L	3.8	4.8
			Lymphocytes	0.55	10^9/L	L	1	3
			Monocytes	0.11	10^9/L	L	0.2	1
			Basophils	0	10^9/L	L	0.02	0.1
		2011-05-09T11:10	Chloride	111	mmol/L	H	97	107
			Lactate Dehydrogenase	223	U/L	H	98	192
			Blood Urea Nitrogen	18.21	mg/dL	H	7	17.9
	Cycle 3	2011-05-23T09:51	Leukocytes	11	10^9/L	H	4	10
			Lymphocytes	3.85	10^9/L	H	1	3
			Basophils	0	10^9/L	L	0.02	0.1
		2011-05-23T10:02	Potassium	3.4	mmol/L	L	3.5	5
			Chloride	109	mmol/L	H	97	107
			Lactate Dehydrogenase	233	U/L	H	98	192
			Blood Urea Nitrogen	19.33	mg/dL	H	7	17.9
			Glucose	165.7	mg/dL	H	70	108

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
120-001	Cycle 3	2011-05-27T09:49	Chloride	109	mmol/L	H	97	107
			Lactate Dehydrogenase	222	U/L	H	98	192
		2011-05-27T09:54	Lymphocytes	3.35	10^9/L	H	1	3
			Basophils	0.28	10^9/L	H	0.02	0.1
	Cycle 4	2011-06-20T10:48	Basophils	0	10^9/L	L	0.02	0.1
			Prothrombin Time	9.9	sec	L	10	13
			Activated Partial Thromboplastin Time	17.3	sec	L	20	32
		2011-06-20T11:18	Chloride	108	mmol/L	H	97	107
			Lactate Dehydrogenase	292	U/L	H	98	192
		2011-06-24T10:31	Phosphate	2.38	mg/dL	L	2.5	4.5
			Lactate Dehydrogenase	323	U/L	H	98	192
			Urate	2.35	mg/dL	L	2.5	5.9
			Glucose	124.3	mg/dL	H	70	108
		2011-06-24T10:41	Hemoglobin	11.4	g/dL	L	12	15
			Erythrocytes	3.44	10^12/L	L	3.8	4.8
			Platelets	146	10^9/L	L	150	410
			Monocytes	1.06	10^9/L	H	0.2	1
	Cycle 5	2011-07-11T10:07	Erythrocytes	3.79	10^12/L	L	3.8	4.8
			Ery. Mean Corpuscular Volume	102	fL	H	83	101
			Leukocytes	14.9	10^9/L	H	4	10
			Neutrophils	8.64	10^9/L	H	2	7
			Lymphocytes	5.66	10^9/L	H	1	3
			Eosinophils	0	10^9/L	L	0.02	0.5
			Basophils	0	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
120-001	Cycle 5	2011-07-11T10:10	Lactate Dehydrogenase	286	U/L	H	98	192
			Blood Urea Nitrogen	18.49	mg/dL	H	7	17.9
			Glucose	126.1	mg/dL	H	70	108
		2011-07-11T13:44	Prothrombin Time	9.9	sec	L	10	13
			Activated Partial Thromboplastin Time	18.5	sec	L	20	32
		2011-07-15T10:28	Potassium	3.1	mmol/L	L	3.5	5
			Lactate Dehydrogenase	293	U/L	H	98	192
		2011-07-15T10:51	Hemoglobin	10.7	g/dL	L	12	15
			Erythrocytes	3.24	10^12/L	L	3.8	4.8
			Monocytes	1.01	10^9/L	H	0.2	1
	Unplanned	2011-07-20T12:13	Potassium	3.4	mmol/L	L	3.5	5
			Chloride	109	mmol/L	H	97	107
			Lactate Dehydrogenase	369	U/L	H	98	192
		2011-07-20T12:44	Hemoglobin	11.3	g/dL	L	12	15
			Erythrocytes	3.43	10^12/L	L	3.8	4.8
			Monocytes	1.48	10^9/L	H	0.2	1
			Basophils	0.15	10^9/L	H	0.02	0.1
	End Trial	2011-08-03T10:47	Lactate Dehydrogenase	265	U/L	H	98	192
			Blood Urea Nitrogen	21.57	mg/dL	H	7	17.9
		2011-08-03T10:50	Ery. Mean Corpuscular Volume	103	fL	H	83	101
			Leukocytes	13.2	10^9/L	H	4	10
			Lymphocytes	5.02	10^9/L	H	1	3
			Eosinophils	0	10^9/L	L	0.02	0.5
			Basophils	0	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
120-001	End Trial	2011-08-03T10:50	Activated Partial Thromboplastin Time	17.9	sec	L	20	32
121-001	Pre-trial	2011-07-26T12:45	Lactate Dehydrogenase	1345	U/L	H	200	550
			Urate	7.4	mg/dL	H	0	7.1
			Glucose	111.7	mg/dL	H	55	99
		2011-07-26T12:51	Platelets	104	10^9/L	L	150	400
			Leukocytes	3	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	2	7.5
			Lymphocytes	0.4	10^9/L	L	1.5	4
	Cycle 1	2011-08-01T10:06	Lactate Dehydrogenase	1510	U/L	H	200	550
			Glucose	117.1	mg/dL	H	55	99
		2011-08-01T10:20	Hemoglobin	12.1	g/dL	L	13	18
			Erythrocytes	4.26	10^12/L	L	4.5	6.5
			Platelets	69	10^9/L	L	150	400
			Leukocytes	2.5	10^9/L	L	4	11
			Neutrophils	1.4	10^9/L	L	2	7.5
			Lymphocytes	0.4	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
		2011-08-05T09:12	Hemoglobin	11.6	g/dL	L	13	18
			Erythrocytes	4.09	10^12/L	L	4.5	6.5
			Platelets	44	10^9/L	L	150	400
			Leukocytes	2.3	10^9/L	L	4	11
			Neutrophils	1.5	10^9/L	L	2	7.5
			Lymphocytes	0.2	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
121-001	Cycle 1	2011-08-05T09:13	Lactate Dehydrogenase	1337	U/L	H	200	550
			Glucose	113.5	mg/dL	H	55	99
		2011-08-15T09:39	Hemoglobin	11.7	g/dL	L	13	18
			Erythrocytes	3.83	10^12/L	L	4.5	6.5
			Platelets	75	10^9/L	L	150	400
			Leukocytes	2.6	10^9/L	L	4	11
			Neutrophils	1.6	10^9/L	L	2	7.5
			Lymphocytes	0.3	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
		2011-08-15T09:48	Lactate Dehydrogenase	1247	U/L	H	200	550
			Glucose	142.3	mg/dL	H	55	99
	Cycle 2	2011-08-22T09:38	Hemoglobin	11.1	g/dL	L	13	18
			Erythrocytes	3.8	10^12/L	L	4.5	6.5
			Platelets	85	10^9/L	L	150	400
			Leukocytes	2.6	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	2	7.5
			Lymphocytes	0.3	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
		2011-08-22T09:44	Lactate Dehydrogenase	1320	U/L	H	200	550
			Glucose	126.1	mg/dL	H	55	99
		2011-08-26T09:27	Hemoglobin	10.7	g/dL	L	13	18
			Erythrocytes	3.83	10^12/L	L	4.5	6.5
			Platelets	64	10^9/L	L	150	400
			Leukocytes	2.5	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	2	7.5
			Lymphocytes	0.3	10^9/L	L	1.5	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
121-001	Cycle 2	2011-08-26T09:27	Basophils	0	10^9/L	L	0.02	0.1
		2011-08-26T09:30	Alkaline Phosphatase	143	U/L	H	25	110
			Lactate Dehydrogenase	1317	U/L	H	200	550
			Glucose	108.1	mg/dL	H	55	99
	End Trial	2011-10-03T09:31	Hemoglobin	10.8	g/dL	L	13	18
			Erythrocytes	3.55	10^12/L	L	4.5	6.5
			Platelets	72	10^9/L	L	150	400
			Leukocytes	2.8	10^9/L	L	4	11
			Neutrophils	1.8	10^9/L	L	2	7.5
			Lymphocytes	0.3	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.7	ratio	H	0.8	1.25
			Calcium	8.18	mg/dL	L	8.4	10.6
			Lactate Dehydrogenase	1389	U/L	H	200	550
			Urate	7.73	mg/dL	H	0	7.1
			Glucose	100.9	mg/dL	H	55	99
126-002	Pre-trial	2011-08-02T11:24	Erythrocytes	5.56	10^12/L	H	4.5	5.5
			Ery. Mean Corpuscular Volume	82.7	fL	L	83	101
			Lymphocytes	0.97	10^9/L	L	1.5	4
			Eosinophils	2	10^9/L	H	0.04	0.4
			Creatinine	0.69	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	224	U/L	H	0	215
			Blood Urea Nitrogen	22.41	mg/dL	H	7	21.8
			Urate	7.73	mg/dL	H	2.7	7.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	Cycle 1	2011-08-15T10:10	Erythrocytes	5.62	10^12/L	H	4.5	5.5
			Ery. Mean Corpuscular Volume	81.9	fL	L	83	101
			Lymphocytes	0.79	10^9/L	L	1.5	4
			Eosinophils	1.74	10^9/L	H	0.04	0.4
		2011-08-15T10:27	Lactate Dehydrogenase	304	U/L	H	0	215
			Blood Urea Nitrogen	22.13	mg/dL	H	7	21.8
			Urate	10.09	mg/dL	H	2.7	7.2
		2011-08-19T11:48	Ery. Mean Corpuscular Volume	82.3	fL	L	83	101
			Neutrophils	7.06	10^9/L	H	2	7
			Lymphocytes	0.6	10^9/L	L	1.5	4
			Eosinophils	1.4	10^9/L	H	0.04	0.4
		2011-08-19T11:54	Creatinine	0.758	mg/dL	L	0.85	1.36
			Urate	7.73	mg/dL	H	2.7	7.2
		2011-08-26T11:40	Lymphocytes	0.81	10^9/L	L	1.5	4
			Eosinophils	1.22	10^9/L	H	0.04	0.4
			Lactate Dehydrogenase	228	U/L	H	0	215
			Urate	8.91	mg/dL	H	2.7	7.2
	Cycle 2	2011-09-05T13:38	Lymphocytes	1.08	10^9/L	L	1.5	4
			Eosinophils	1.7	10^9/L	H	0.04	0.4
			Creatinine	0.701	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	247	U/L	H	0	215
			Urate	8.24	mg/dL	H	2.7	7.2
		2011-09-09T11:46	Lymphocytes	0.67	10^9/L	L	1.5	4
			Eosinophils	1.95	10^9/L	H	0.04	0.4
			Lactate Dehydrogenase	242	U/L	H	0	215

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	Cycle 3	2011-09-26T12:00	Platelets	580	10^9/L	H	150	450
			Lymphocytes	0.87	10^9/L	L	1.5	4
			Eosinophils	0.87	10^9/L	H	0.04	0.4
			Creatinine	0.803	mg/dL	L	0.85	1.36
			Alanine Aminotransferase	75	U/L	H	0	44.99
			Aspartate Aminotransferase	41	U/L	H	0	39.99
			Lactate Dehydrogenase	261	U/L	H	0	215
		2011-09-30T11:30	Hemoglobin	11.4	g/dL	L	13	18
			Erythrocytes	4.35	10^12/L	L	4.5	5.5
			Lymphocytes	0.59	10^9/L	L	1.5	4
			Eosinophils	0.65	10^9/L	H	0.04	0.4
			Creatinine	0.848	mg/dL	L	0.85	1.36
			Albumin	3.3	g/dL	L	3.5	5
	Cycle 4	2011-10-17T11:34	Lymphocytes	0.97	10^9/L	L	1.5	4
			Eosinophils	1.39	10^9/L	H	0.04	0.4
			Prothrombin Time	9	sec	L	10	13
			Creatinine	0.758	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	236	U/L	H	0	215
		2011-10-21T11:31	Hemoglobin	12.7	g/dL	L	13	18
			Lymphocytes	0.52	10^9/L	L	1.5	4
			Eosinophils	1.35	10^9/L	H	0.04	0.4
			Creatinine	0.735	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	230	U/L	H	0	215
			Blood Urea Nitrogen	22.13	mg/dL	H	7	21.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	Cycle 5	2011-11-07T13:19	Lymphocytes	0.98	10^9/L	L	1.5	4
			Eosinophils	1.47	10^9/L	H	0.04	0.4
			Basophils	0.12	10^9/L	H	0	0.1
			Prothrombin Time	9	sec	L	10	13
			Creatinine	0.713	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	280	U/L	H	0	215
			Urate	8.57	mg/dL	H	2.7	7.2
		2011-11-11T12:35	Lymphocytes	0.69	10^9/L	L	1.5	4
			Eosinophils	1.78	10^9/L	H	0.04	0.4
			Creatinine	0.814	mg/dL	L	0.85	1.36
			Alanine Aminotransferase	51	U/L	H	0	44.99
			Lactate Dehydrogenase	322	U/L	H	0	215
	Cycle 6	2011-11-28T10:30	Lymphocytes	0.8	10^9/L	L	1.5	4
			Eosinophils	1.46	10^9/L	H	0.04	0.4
			Prothrombin Time	9	sec	L	10	13
			Lactate Dehydrogenase	279	U/L	H	0	215
			Urate	9.08	mg/dL	H	2.7	7.2
		2011-12-02T11:52	Lymphocytes	0.62	10^9/L	L	1.5	4
			Eosinophils	1.99	10^9/L	H	0.04	0.4
			Creatinine	0.803	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	285	U/L	H	0	215

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	Cycle 7	2011-12-19T11:26	Lymphocytes	1.05	10^9/L	L	1.5	4
			Eosinophils	1.04	10^9/L	H	0.04	0.4
			Activated Partial Thromboplastin Time	44	sec	H	25	37
			Potassium	5.5	mmol/L	H	3.5	5.3
			Creatinine	0.781	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	316	U/L	H	0	215
			Blood Urea Nitrogen	22.97	mg/dL	H	7	21.8
			Urate	9.75	mg/dL	H	2.7	7.2
		2011-12-23T11:20	Lymphocytes	0.68	10^9/L	L	1.5	4
			Eosinophils	1.65	10^9/L	H	0.04	0.4
			Creatinine	0.747	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	328	U/L	H	0	215
			Urate	8.07	mg/dL	H	2.7	7.2
	Cycle 8	2012-01-09T11:45	Lymphocytes	1.11	10^9/L	L	1.5	4
			Eosinophils	1.37	10^9/L	H	0.04	0.4
			Creatinine	0.758	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	306	U/L	H	0	215
			Urate	9.41	mg/dL	H	2.7	7.2
		2012-01-13T11:39	Lymphocytes	0.84	10^9/L	L	1.5	4
			Eosinophils	1.85	10^9/L	H	0.04	0.4
			Creatinine	0.781	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	344	U/L	H	0	215
			Urate	7.9	mg/dL	H	2.7	7.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	Cycle 9	2012-01-30T11:19	Lymphocytes	1.36	10^9/L	L	1.5	4
			Eosinophils	1.73	10^9/L	H	0.04	0.4
			Potassium	5.4	mmol/L	H	3.5	5.3
			Creatinine	0.814	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	349	U/L	H	0	215
			Urate	9.92	mg/dL	H	2.7	7.2
		2012-02-03T12:30	Lymphocytes	1.18	10^9/L	L	1.5	4
			Eosinophils	1.59	10^9/L	H	0.04	0.4
			Creatinine	0.769	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	383	U/L	H	0	215
			Blood Urea Nitrogen	23.25	mg/dL	H	7	21.8
			Urate	7.23	mg/dL	H	2.7	7.2
	Cycle 10	2012-02-20T10:40	Lymphocytes	1.17	10^9/L	L	1.5	4
			Eosinophils	1.22	10^9/L	H	0.04	0.4
			Creatinine	0.769	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	350	U/L	H	0	215
			Urate	9.41	mg/dL	H	3.4	7.2
		2012-02-24T11:25	Lymphocytes	0.8	10^9/L	L	1.5	4
			Eosinophils	1.28	10^9/L	H	0.04	0.4
			Creatinine	0.769	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	315	U/L	H	0	215
			Urate	7.9	mg/dL	H	3.4	7.2

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	Cycle 11	2012-03-12T11:05	Eosinophils	1.68	10^9/L	H	0.04	0.4
			Activated Partial Thromboplastin Time	61	sec	H	25	37
			Creatinine	0.667	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	331	U/L	H	0	215
			Urate	9.92	mg/dL	H	3.4	7.2
		2012-03-16T10:55	Lymphocytes	1.08	10^9/L	L	1.5	4
			Eosinophils	1.38	10^9/L	H	0.04	0.4
			Creatinine	0.814	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	309	U/L	H	0	215
			Urate	7.4	mg/dL	H	3.4	7.2
	Cycle 12	2012-04-02T11:10	Eosinophils	1.29	10^9/L	H	0.04	0.4
			Creatinine	0.656	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	346	U/L	H	0	215
			Urate	9.25	mg/dL	H	3.4	7.2
		2012-04-05T11:49	Hemoglobin	12.3	g/dL	L	13	18
			Erythrocytes	4.43	10^12/L	L	4.5	5.5
			Neutrophils	7.63	10^9/L	H	2	7
			Lymphocytes	1.35	10^9/L	L	1.5	4
			Eosinophils	1.06	10^9/L	H	0.04	0.4
			Calcium	8.42	mg/dL	L	8.5	10.4
			Creatinine	0.781	mg/dL	L	0.85	1.36
			Lactate Dehydrogenase	317	U/L	H	0	215
			Urate	7.73	mg/dL	H	3.4	7.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
126-002	End Trial	2012-04-23T14:20	Hemoglobin	12.8	g/dL	L	13	18
			Ery. Mean Corpuscular Volume	82.8	fL	L	83	101
			Eosinophils	1.07	10^9/L	H	0.04	0.4
			Prothrombin Time	9	sec	L	10	13
			Calcium	8.26	mg/dL	L	8.5	10.4
			Creatinine	0.645	mg/dL	L	0.85	1.36
			Albumin	3.2	g/dL	L	3.5	5
			Glucose	117.1	mg/dL	H	65	115
140-001	Pre-trial	2010-05-19T11:34	Sodium	135	mmol/L	L	136	145
			Calcium	8.74	mg/dL	L	8.8	10.6
			Bilirubin	1.5	mg/dL	H	0	1.2
			Urate	7.7	mg/dL	H	3.5	7.4
			Glucose	116	mg/dL	H	60	100
		2010-05-19T11:37	Hemoglobin	13	g/dL	L	13.5	17.5
			Erythrocytes	4.28	10^12/L	L	4.4	5.9
			Platelets	115	10^9/L	L	150	350
			Lymphocytes	0.309	10^9/L	L	1	4
			Monocytes	0.185	10^9/L	L	0.2	1
			Activated Partial Thromboplastin Time	24.8	sec	L	26	37
	Cycle 1	2010-05-31T08:52	Potassium	3.4	mmol/L	L	3.5	4.8
			Bilirubin	1.3	mg/dL	H	0	1.2
			Urate	8.2	mg/dL	H	3.5	7.4
			Glucose	102	mg/dL	H	60	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-001	Cycle 1	2010-05-31T08:54	Hemoglobin	12.08	g/dL	L	13.5	17.5
			Erythrocytes	4.12	10^12/L	L	4.4	5.9
			Platelets	94.7	10^9/L	L	150	350
			Leukocytes	2.68	10^9/L	L	4	11
			Neutrophils	1.688	10^9/L	L	2	7.5
			Lymphocytes	0.402	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	24.6	sec	L	26	37
		2010-06-04T07:00	Hemoglobin	12.7	g/dL	L	13.5	17.5
			Erythrocytes	4.13	10^12/L	L	4.4	5.9
			Platelets	83.3	10^9/L	L	150	350
			Leukocytes	2.51	10^9/L	L	4	11
			Neutrophils	1.574	10^9/L	L	2	7.5
			Lymphocytes	0.324	10^9/L	L	1	4
			Creatinine	1.42	mg/dL	H	0.72	1.18
			Lactate Dehydrogenase	259	U/L	H	0	232
			Bilirubin	1.3	mg/dL	H	0	1.2
			Glucose	132	mg/dL	H	60	100
		2010-06-14	Lactate Dehydrogenase	349	U/L	H	60	248
		2010-06-14T12:12	Hemoglobin	12.2	g/dL	L	13.5	17.5
			Erythrocytes	3.98	10^12/L	L	4.1	5.1
			Platelets	86	10^9/L	L	150	360
			Leukocytes	3.4	10^9/L	L	4	9
			Lymphocytes	0.639	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-001	Cycle 2	2010-06-21T13:11	Calcium	8.58	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	348	U/L	H	0	232
			Glucose	101	mg/dL	H	60	100
		2010-06-21T13:12	Hemoglobin	11.2	g/dL	L	13.5	17.5
			Erythrocytes	3.62	10^12/L	L	4.4	5.9
			Platelets	110	10^9/L	L	150	350
			Leukocytes	3.29	10^9/L	L	4	11
			Lymphocytes	0.266	10^9/L	L	1	4
		2010-06-25T10:40	Hemoglobin	10.9	g/dL	L	13.7	17.5
			Erythrocytes	3.54	10^12/L	L	4.63	6.08
			Platelets	70	10^9/L	L	139	335
			Leukocytes	2.8	10^9/L	L	3.6	10.5
			Calcium	8.7	mg/dL	L	8.8	10
			Creatinine	1.39	mg/dL	H	0.73	1.18
			Alanine Aminotransferase	140	U/L	H	0	54
			Aspartate Aminotransferase	49	U/L	H	5	34
			Alkaline Phosphatase	159	U/L	H	40	150
			Lactate Dehydrogenase	309	U/L	H	0	249
			Bilirubin	1.4	mg/dL	H	0.2	1.2
	Cycle 3	2010-07-19T13:13	Lactate Dehydrogenase	250	U/L	H	0	232
			Urate	8	mg/dL	H	3.5	7.4
		2010-07-19T13:16	Hemoglobin	13	g/dL	L	13.5	17.5
			Erythrocytes	3.93	10^12/L	L	4.4	5.9
			Platelets	102	10^9/L	L	150	350
			Lymphocytes	0.476	10^9/L	L	1	4
			Eosinophils	0.52	10^9/L	H	0	0.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-001	Cycle 3	2010-07-23T07:00	Hemoglobin	11.1	g/dL	L	13.5	17.5
			Erythrocytes	3.57	10^12/L	L	4.4	5.9
			Platelets	55.8	10^9/L	L	150	350
			Lymphocytes	0.271	10^9/L	L	1	4
			Eosinophils	0.759	10^9/L	H	0	0.5
			Calcium	8.26	mg/dL	L	8.8	10.6
			Phosphate	2.17	mg/dL	L	2.5	4.3
			Creatinine	1.27	mg/dL	H	0.72	1.18
			Alanine Aminotransferase	60	U/L	H	0	45
			Alkaline Phosphatase	137	U/L	H	40	129
			Lactate Dehydrogenase	246	U/L	H	0	232
			Glucose	111	mg/dL	H	60	100
	End Trial	2010-07-28T10:28	Hemoglobin	12.3	g/dL	L	13.5	17.5
			Erythrocytes	3.93	10^12/L	L	4.4	5.9
			Platelets	90.4	10^9/L	L	150	350
			Lymphocytes	0.836	10^9/L	L	1	4
			Eosinophils	0.596	10^9/L	H	0	0.5
			Activated Partial Thromboplastin Time	25.7	sec	L	26	37
		2010-07-28T11:04	Creatinine	1.21	mg/dL	H	0.72	1.18
			Lactate Dehydrogenase	275	U/L	H	0	232
140-002	Pre-trial	2011-03-02T10:43	Calcium	8.54	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	321	U/L	H	0	232
			Glucose	105	mg/dL	H	60	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-002	Pre-trial	2011-03-02T10:44	Lymphocytes	0.177	10^9/L	L	1	4
			Monocytes	1.062	10^9/L	H	0.2	1
			Activated Partial Thromboplastin Time	24	sec	L	26	37
	Cycle 1	2011-03-14T09:58	Creatinine	0.51	mg/dL	L	0.55	1.02
			Lactate Dehydrogenase	294	U/L	H	0	232
			Blood Urea Nitrogen	5	mg/dL	L	8	21
			Glucose	105	mg/dL	H	60	100
		2011-03-14T09:59	Erythrocytes	3.89	10^12/L	L	3.9	5.1
			Lymphocytes	0.238	10^9/L	L	1	4
			Eosinophils	0.792	10^9/L	H	0	0.5
		2011-03-17T07:00	Hemoglobin	10.5	g/dL	L	11.5	15.5
			Erythrocytes	3.54	10^12/L	L	3.9	5.1
			Lymphocytes	0.237	10^9/L	L	1	4
			Eosinophils	1.501	10^9/L	H	0	0.5
			Calcium	8.42	mg/dL	L	8.8	10.6
			Phosphate	4.46	mg/dL	H	2.5	4.3
			Lactate Dehydrogenase	291	U/L	H	0	232
			Blood Urea Nitrogen	6	mg/dL	L	8	21
			Glucose	122	mg/dL	H	60	100
		2011-03-28T11:18	Erythrocytes	3.85	10^12/L	L	3.9	5.1
			Platelets	376	10^9/L	H	150	350
			Lymphocytes	0.531	10^9/L	L	1	4
			Eosinophils	1.593	10^9/L	H	0	0.5
			Lactate Dehydrogenase	316	U/L	H	0	232
			Blood Urea Nitrogen	5	mg/dL	L	8	21

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-002	Cycle 1	2011-03-28T11:18	Glucose	114	mg/dL	H	60	100
	Cycle 2	2011-04-04T09:25	Platelets	368	10^9/L	H	150	350
			Lymphocytes	0.295	10^9/L	L	1	4
			Eosinophils	1.483	10^9/L	H	0	0.5
			Activated Partial Thromboplastin Time	25.6	sec	L	26	37
		2011-04-04T09:28	Lactate Dehydrogenase	259	U/L	H	0	232
			Glucose	102	mg/dL	H	60	100
		2011-04-08T09:03	Hemoglobin	11	g/dL	L	11.5	15.5
			Erythrocytes	3.63	10^12/L	L	3.9	5.1
			Lymphocytes	0.381	10^9/L	L	1	4
			Eosinophils	2.131	10^9/L	H	0	0.5
		2011-04-08T09:05	Phosphate	4.4	mg/dL	H	2.5	4.3
			Lactate Dehydrogenase	292	U/L	H	0	232
	Cycle 3	2011-05-02T09:31	Erythrocytes	3.89	10^12/L	L	3.9	5.1
			Lymphocytes	0.662	10^9/L	L	1	4
			Monocytes	1.075	10^9/L	H	0.2	1
			Eosinophils	0.992	10^9/L	H	0	0.5
			Activated Partial Thromboplastin Time	37.2	sec	H	26	37
		2011-05-02T09:34	Aspartate Aminotransferase	32	U/L	H	0	31
			Lactate Dehydrogenase	288	U/L	H	0	232
			Blood Urea Nitrogen	7	mg/dL	L	8	21
			Glucose	108	mg/dL	H	60	100
		2011-05-12T09:44	Eosinophils	1.477	10^9/L	H	0	0.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-002	Cycle 3	2011-05-12T09:47	Lactate Dehydrogenase	411	U/L	H	0	232
			Blood Urea Nitrogen	7	mg/dL	L	8	21
			Glucose	112	mg/dL	H	60	100
	Cycle 4	2011-05-23T07:00	Lymphocytes	0.528	10^9/L	L	1	4
			Eosinophils	1.122	10^9/L	H	0	0.5
			Activated Partial Thromboplastin Time	47.6	sec	H	26	37
			Aspartate Aminotransferase	34	U/L	H	0	31
			Lactate Dehydrogenase	309	U/L	H	0	232
			Glucose	114	mg/dL	H	60	100
		2011-05-27T09:59	Hemoglobin	11.1	g/dL	L	11.5	15.5
			Erythrocytes	3.67	10^12/L	L	3.9	5.1
			Lymphocytes	0.176	10^9/L	L	1	4
			Eosinophils	1.697	10^9/L	H	0	0.5
		2011-05-27T10:01	Phosphate	4.49	mg/dL	H	2.5	4.3
			Lactate Dehydrogenase	292	U/L	H	0	232
			Glucose	116	mg/dL	H	60	100
	Cycle 5	2011-06-20T09:07	Lymphocytes	0.418	10^9/L	L	1	4
			Eosinophils	1.114	10^9/L	H	0	0.5
			Activated Partial Thromboplastin Time	25.6	sec	L	26	37
		2011-06-20T09:08	Lactate Dehydrogenase	275	U/L	H	0	232
		2011-06-24T09:36	Lactate Dehydrogenase	289	U/L	H	0	232
		2011-06-24T09:38	Lymphocytes	0.436	10^9/L	L	1	4
			Eosinophils	1.62	10^9/L	H	0	0.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-002	Cycle 6	2011-07-25T07:00	Lymphocytes	0.451	10^9/L	L	1	4
			Eosinophils	1.263	10^9/L	H	0	0.5
		2011-07-25T10:26	Calcium	8.46	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	300	U/L	H	0	232
			Glucose	133	mg/dL	H	60	100
		2011-07-30T07:00	Lactate Dehydrogenase	319	U/L	H	0	232
	Cycle 7	2011-08-15T08:43	Lymphocytes	0.692	10^9/L	L	1	4
			Eosinophils	2.272	10^9/L	H	0	0.5
		2011-08-15T08:44	Calcium	8.46	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	332	U/L	H	0	232
			Glucose	123	mg/dL	H	60	100
		2011-08-19T07:00	Hemoglobin	11.4	g/dL	L	11.5	15.5
			Lymphocytes	0.521	10^9/L	L	1	4
			Eosinophils	3.385	10^9/L	H	0	0.5
			Calcium	8.78	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	346	U/L	H	0	232
			Blood Urea Nitrogen	6	mg/dL	L	8	21
			Glucose	107	mg/dL	H	60	100
	Unplanned	2011-07-26T12:27	Glucose	150	mg/dL	H	60	100
		2011-08-17T13:45	Hemoglobin	11.1	g/dL	L	11.5	15.5
			Erythrocytes	3.73	10^12/L	L	3.9	5.1
			Sodium	134	mmol/L	L	136	145
			Lactate Dehydrogenase	321	U/L	H	0	232

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
140-003	Pre-trial	2011-07-05T12:19	Lactate Dehydrogenase	264	U/L	H	0	232
			Glucose	124	mg/dL	H	60	100
		2011-07-05T12:21	Hemoglobin	12.6	g/dL	L	13.5	17.5
			Erythrocytes	3.73	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	99.3	fL	H	81	95
			Lymphocytes	0.785	10^9/L	L	1	4
	Cycle 1	2011-07-11T08:33	Hemoglobin	12.2	g/dL	L	13.5	17.5
			Erythrocytes	3.65	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	98.1	fL	H	81	95
			Lymphocytes	0.802	10^9/L	L	1	4
		2011-07-11T08:35	Calcium	8.58	mg/dL	L	8.8	10.6
			Glucose	101	mg/dL	H	60	100
		2011-07-15T11:00	Hemoglobin	12.1	g/dL	L	13.5	17.5
			Erythrocytes	3.55	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	98.2	fL	H	81	95
			Lymphocytes	0.71	10^9/L	L	1	4
		2011-07-15T12:46	Potassium	3.3	mmol/L	L	3.5	4.8
			Lactate Dehydrogenase	257	U/L	H	0	232
			Glucose	129	mg/dL	H	60	100
		2011-07-21T07:00	Calcium	8.7	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	252	U/L	H	0	232
		2011-07-21T12:30	Hemoglobin	12.5	g/dL	L	13.5	17.5
			Erythrocytes	3.79	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	99.2	fL	H	81	95
			Lymphocytes	0.941	10^9/L	L	1	4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-003	Cycle 2	2011-08-01T07:00	Hemoglobin	13	g/dL	L	13.5	17.5
			Erythrocytes	3.84	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	98.3	fL	H	81	95
			Lymphocytes	0.822	10^9/L	L	1	4
			Calcium	8.66	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	234	U/L	H	0	232
			Glucose	105	mg/dL	H	60	100
		2011-08-05T07:00	Hemoglobin	12.3	g/dL	L	13.5	17.5
			Erythrocytes	3.97	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	97	fL	H	81	95
			Lymphocytes	0.529	10^9/L	L	1	4
			Potassium	5.4	mmol/L	H	3.5	4.8
			Calcium	8.66	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	449	U/L	H	0	232
			Glucose	102	mg/dL	H	60	100
	Cycle 3	2011-08-22T07:00	Hemoglobin	12.8	g/dL	L	13.5	17.5
			Erythrocytes	3.97	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	97.3	fL	H	81	95
			Lymphocytes	0.896	10^9/L	L	1	4
			Calcium	8.74	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	312	U/L	H	0	232
		2011-08-26T09:09	Hemoglobin	12.9	g/dL	L	13.5	17.5
			Erythrocytes	3.96	10^12/L	L	4.4	5.9
			Ery. Mean Corpuscular Volume	97.8	fL	H	81	95
			Lymphocytes	0.866	10^9/L	L	1	4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
140-003	Cycle 3	2011-08-26T09:10	Lactate Dehydrogenase	349	U/L	H	0	232
			Glucose	103	mg/dL	H	60	100
141-001	Pre-trial	2010-07-16T08:15	Hemoglobin	12.6	g/dL	L	14	17.4
			Erythrocytes	4.4	10^12/L	L	4.5	5.9
			Platelets	125	10^9/L	L	150	450
			Leukocytes	27.4	10^9/L	H	4.4	11.3
			Lymphocytes	18.6	10^9/L	H	1.2	3.5
			Magnesium	1.77	mg/dL	L	1.8	2.6
			Creatinine	1.606	mg/dL	H	0.81	1.44
			Albumin	3.3	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	253	U/L	H	0	249.999
			Blood Urea Nitrogen	35.57	mg/dL	H	7.8	20.2
	Cycle 1	2010-07-26T10:10	Hemoglobin	12.1	g/dL	L	14	17.4
			Erythrocytes	4.3	10^12/L	L	4.5	5.9
			Platelets	78	10^9/L	L	150	450
			Lymphocytes	4.5	10^9/L	H	1.2	3.5
			Magnesium	1.77	mg/dL	L	1.8	2.4
			Creatinine	1.64	mg/dL	H	0.81	1.44
			Albumin	3	g/dL	L	3.5	5.3
			Blood Urea Nitrogen	24.37	mg/dL	H	7.8	20.2
		2010-07-30T08:05	Hemoglobin	10.3	g/dL	L	14	17.4
			Erythrocytes	3.5	10^12/L	L	4.5	5.9
			Platelets	51	10^9/L	L	150	450
			Leukocytes	3.6	10^9/L	L	4.4	11.3
			Lymphocytes	0.8	10^9/L	L	1.2	3.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
141-001	Cycle 1	2010-07-30T08:05	Sodium	134	mmol/L	L	135	145
			Potassium	3.1	mmol/L	L	3.4	4.6
			Chloride	94	mmol/L	L	95	105
			Creatinine	2.692	mg/dL	H	0.81	1.44
			Albumin	2.7	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	266	U/L	H	0	249.999
			Blood Urea Nitrogen	27.73	mg/dL	H	7.8	20.2
			Glucose	157	mg/dL	H	74	109
	Unplanned	2010-08-04T08:05	Hemoglobin	10.1	g/dL	L	14	17.4
			Erythrocytes	3.5	10^12/L	L	4.5	5.9
			Platelets	66	10^9/L	L	150	450
			Leukocytes	3	10^9/L	L	4.4	11.3
			Creatinine	3.665	mg/dL	H	0.81	1.44
			Blood Urea Nitrogen	42.86	mg/dL	H	7.8	20.2
		2010-08-05T08:05	Hemoglobin	10.7	g/dL	L	14	17.4
			Erythrocytes	3.8	10^12/L	L	4.5	5.9
			Platelets	82	10^9/L	L	150	450
			Leukocytes	3.5	10^9/L	L	4.4	11.3
			Activated Partial Thromboplastin Time	39	sec	H	26	36
			Creatinine	3.597	mg/dL	H	0.81	1.44
			Blood Urea Nitrogen	48.46	mg/dL	H	7.8	20.2
		2010-08-06T07:50	Potassium	3.3	mmol/L	L	3.4	4.6
			Creatinine	3.495	mg/dL	H	0.81	1.44
			Blood Urea Nitrogen	54.9	mg/dL	H	7.8	20.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
141-001	Unplanned	2010-08-06T08:05	Hemoglobin	11.3	g/dL	L	14	17.4
			Erythrocytes	3.9	10^12/L	L	4.5	5.9
			Platelets	88	10^9/L	L	150	450
		2010-08-07T07:50	Hemoglobin	10	g/dL	L	14	17.4
			Erythrocytes	3.5	10^12/L	L	4.5	5.9
			Platelets	85	10^9/L	L	150	450
			Creatinine	2.873	mg/dL	H	0.81	1.44
			Blood Urea Nitrogen	54.34	mg/dL	H	7.8	20.2
	End Trial	2010-07-30T08:05	Hemoglobin	10.3	g/dL	L	14	17.4
			Erythrocytes	3.5	10^12/L	L	4.5	5.9
			Platelets	51	10^9/L	L	150	450
			Leukocytes	3.6	10^9/L	L	4.4	11.3
			Lymphocytes	0.8	10^9/L	L	1.2	3.5
			Sodium	134	mmol/L	L	135	145
			Potassium	3.1	mmol/L	L	3.4	4.6
			Chloride	94	mmol/L	L	95	105
			Creatinine	2.692	mg/dL	H	0.81	1.44
			Albumin	2.7	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	266	U/L	H	0	249.999
			Blood Urea Nitrogen	27.73	mg/dL	H	7.8	20.2
			Glucose	157	mg/dL	H	74	109
142-001	Pre-trial	2009-10-13T17:36	Hemoglobin	8.8	g/dL	L	12	16
			Erythrocytes	2.96	10^12/L	L	3.7	4.8
			Lymphocytes	0.621	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-001	Pre-trial	2009-10-15T08:00	Sodium	147	mmol/L	H	136	145
			Calcium	10.86	mg/dL	H	8.9	10
			Chloride	116	mmol/L	H	98	107
			Creatinine	1.18	mg/dL	H	0.6	1.1
			Albumin	2.5	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	33	U/L	H	5	31
			Lactate Dehydrogenase	529	U/L	H	0	245
			Blood Urea Nitrogen	56	mg/dL	H	10	20
			Urate	6.6	mg/dL	H	2.6	6
			Glucose	106	mg/dL	H	70	100
		2009-10-15T10:00	Activated Partial Thromboplastin Time	25.9	sec	L	26	36
	Cycle 1	2009-10-19T09:00	Hemoglobin	9.3	g/dL	L	12	16
			Erythrocytes	3.11	10^12/L	L	3.7	4.8
			Leukocytes	12	10^9/L	H	3.5	10
			Neutrophils	10.584	10^9/L	H	2	7.5
			Lymphocytes	0.732	10^9/L	L	1	4
			Potassium	2.8	mmol/L	L	3.5	5.1
			Phosphate	2.4	mg/dL	L	2.5	4.7
			Magnesium	0.97	mg/dL	L	1.6	2.6
			Albumin	2.7	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	47	U/L	H	5	31
			Lactate Dehydrogenase	816	U/L	H	0	245
			Urate	6.3	mg/dL	H	2.6	6

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-001	Cycle 1	2009-10-23T09:10	Hemoglobin	10.3	g/dL	L	12	16
			Erythrocytes	3.67	10^12/L	L	3.7	4.8
			Leukocytes	11.1	10^9/L	H	3.5	10
			Neutrophils	10.068	10^9/L	H	2	7.5
			Lymphocytes	0.433	10^9/L	L	1	4
			Calcium	8.66	mg/dL	L	8.9	10
			Magnesium	1.48	mg/dL	L	1.6	2.6
			Creatinine	1.33	mg/dL	H	0.6	1.1
			Albumin	2.7	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	43	U/L	H	5	31
			Lactate Dehydrogenase	1016	U/L	H	0	245
			Blood Urea Nitrogen	28	mg/dL	H	10	20
			Urate	6.5	mg/dL	H	2.6	6
			Glucose	122	mg/dL	H	70	100
		2009-10-29T09:30	Hemoglobin	9.5	g/dL	L	12	16
			Erythrocytes	3.31	10^12/L	L	4	5.5
			Leukocytes	13.5	10^9/L	H	4	10
			Neutrophils	12.15	10^9/L	H	2	7.5
			Lymphocytes	0.675	10^9/L	L	1	4
			Sodium	133	mmol/L	L	136	145
			Calcium	8.74	mg/dL	L	8.9	10
			Phosphate	2.4	mg/dL	L	2.5	4.7
			Creatinine	1.81	mg/dL	H	0.6	1.1
			Albumin	2.7	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	49	U/L	H	5	31
			Lactate Dehydrogenase	1075	U/L	H	0	245

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-001	Cycle 1	2009-10-29T09:30	Blood Urea Nitrogen	30	mg/dL	H	10	20
			Urate	6.8	mg/dL	H	2.6	6
142-002	Pre-trial	2009-11-30T09:21	Hemoglobin	9.6	g/dL	L	13.5	17.5
			Erythrocytes	3.57	10^12/L	L	4	5.5
			Ery. Mean Corpuscular Volume	81	fL	L	83	100
			Platelets	301	10^9/L	H	150	300
			Leukocytes	16.3	10^9/L	H	4	10
			Neutrophils	15.648	10^9/L	H	2	7.5
			Lymphocytes	0.163	10^9/L	L	1	4
			Albumin	2.8	g/dL	L	3.4	4.8
			Alanine Aminotransferase	68	U/L	H	0	50
			Lactate Dehydrogenase	420	U/L	H	0	245
			Urate	7.6	mg/dL	H	3.4	7.2
	Cycle 1	2009-12-07T09:17	Hemoglobin	9.5	g/dL	L	13.5	17.5
			Erythrocytes	3.53	10^12/L	L	4	5.5
			Ery. Mean Corpuscular Volume	80.7	fL	L	83	100
			Leukocytes	12.5	10^9/L	H	4	10
			Neutrophils	11	10^9/L	H	2	7.5
			Lymphocytes	0.125	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	37.4	sec	H	26	36
			Calcium	8.34	mg/dL	L	8.9	10
			Albumin	2.4	g/dL	L	3.4	4.8
			Alkaline Phosphatase	152	U/L	H	40	129
			Lactate Dehydrogenase	443	U/L	H	0	245

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-002	Cycle 1	2009-12-10T08:55	Erythrocytes	3.79	10^12/L	L	4	5.5
			Leukocytes	12	10^9/L	H	4	10
			Neutrophils	11.04	10^9/L	H	2	7.5
			Lymphocytes	0.24	10^9/L	L	1	4
			Monocytes	0	10^9/L	L	0.2	1
			Eosinophils	0.72	10^9/L	H	0	0.5
		2009-12-11T08:55	Calcium	8.66	mg/dL	L	8.9	10
			Albumin	2.5	g/dL	L	3.4	4.8
			Alkaline Phosphatase	177	U/L	H	40	129
			Lactate Dehydrogenase	350	U/L	H	0	245
		2009-12-17T15:02	Albumin	2.7	g/dL	L	3.4	4.8
			Alkaline Phosphatase	135	U/L	H	40	129
			Lactate Dehydrogenase	347	U/L	H	0	245
			Glucose	102	mg/dL	H	70	100
		2009-12-17T15:09	Hemoglobin	10.7	g/dL	L	13.5	17.5
			Ery. Mean Corpuscular Volume	81.7	fL	L	83	100
			Platelets	343	10^9/L	H	150	300
			Leukocytes	11	10^9/L	H	4	10
			Neutrophils	10.23	10^9/L	H	2	7.5
			Lymphocytes	0.11	10^9/L	L	1	4
	Cycle 2	2010-01-04T11:30	Hemoglobin	8.8	g/dL	L	13.5	17.5
			Erythrocytes	3.5	10^12/L	L	4	5.5
			Ery. Mean Corpuscular Volume	78.9	fL	L	83	100
			Platelets	353	10^9/L	H	150	300
			Leukocytes	14.3	10^9/L	H	4	10
			Neutrophils	13.442	10^9/L	H	2	7.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-002	Cycle 2	2010-01-04T11:30	Lymphocytes	0.715	10^9/L	L	1	4
			Monocytes	0	10^9/L	L	0.2	1
			Activated Partial Thromboplastin Time	102.8	sec	H	26	36
			Calcium	8.38	mg/dL	L	8.9	10
			Creatinine	1.69	mg/dL	H	0.7	1.3
			Alkaline Phosphatase	163	U/L	H	40	129
			Lactate Dehydrogenase	471	U/L	H	0	245
			Blood Urea Nitrogen	48	mg/dL	H	8	26
			Urate	9	mg/dL	H	3.4	7.2
			Glucose	112	mg/dL	H	70	100
		2010-01-08T08:54	Hemoglobin	8.8	g/dL	L	13.5	17.5
			Erythrocytes	3.39	10^12/L	L	4	5.5
			Ery. Mean Corpuscular Volume	79.6	fL	L	83	100
			Platelets	82	10^9/L	L	150	300
			Leukocytes	12.2	10^9/L	H	4	10
			Neutrophils	11.956	10^9/L	H	2	7.5
			Lymphocytes	0	10^9/L	L	1	4
			Monocytes	0.122	10^9/L	L	0.2	1
			Phosphate	5.1	mg/dL	H	2.5	4.7
			Creatinine	3.18	mg/dL	H	0.7	1.3
			Albumin	2.3	g/dL	L	3.4	4.8
			Lactate Dehydrogenase	385	U/L	H	0	245
			Blood Urea Nitrogen	62	mg/dL	H	8	26
			Urate	9.7	mg/dL	H	3.4	7.2
			Glucose	147	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-002	Unplanned	2009-12-10T08:55	Hemoglobin	8.3	g/dL	L	13.5	17.5
			Ery. Mean Corpuscular Volume	81.3	fL	L	83	100
			Leukocytes	12	10^9/L	H	3.5	10
	End Trial	2010-01-18T09:35	Hemoglobin	8.1	g/dL	L	13.5	17.5
			Erythrocytes	3.09	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	79.9	fL	L	83	100
			Platelets	134	10^9/L	L	150	360
			Leukocytes	12.5	10^9/L	H	3.5	10
			Neutrophils	12.25	10^9/L	H	2	7.5
			Lymphocytes	0	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	46.9	sec	H	26	36
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.8	1.25
			Calcium	7.86	mg/dL	L	8.9	10
			Creatinine	1.9	mg/dL	H	0.7	1.3
			Albumin	2.5	g/dL	L	3.4	4.8
			Alkaline Phosphatase	163	U/L	H	40	129
			Lactate Dehydrogenase	639	U/L	H	0	245
			Blood Urea Nitrogen	38	mg/dL	H	8	26
			Urate	7.9	mg/dL	H	3.4	7.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-003	Pre-trial	2010-09-06T09:26	Leukocytes	11.1	10^9/L	H	4	10
			Neutrophils	8.658	10^9/L	H	2	7.5
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.9	1.3
			Sodium	133	mmol/L	L	136	145
			Chloride	96	mmol/L	L	98	107
			Glucose	162	mg/dL	H	70	100
	Cycle 1	2010-09-08T12:21	Sodium	134	mmol/L	L	136	145
			Glucose	101	mg/dL	H	70	100
		2010-09-08T12:31	Hemoglobin	13	g/dL	L	13.5	17.5
		2010-09-09T08:37	Activated Partial Thromboplastin Time	40.6	sec	H	26	36
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.9	1.3
			Albumin	2.7	g/dL	L	3.4	4.8
		2010-09-11T08:28	Hemoglobin	11.7	g/dL	L	13.5	17.5
			Erythrocytes	3.96	10^12/L	L	4.2	5.6
			Lymphocytes	0.765	10^9/L	L	1	4
			Calcium	8.58	mg/dL	L	8.7	10
			Albumin	3.1	g/dL	L	3.4	4.8
			Alanine Aminotransferase	70	U/L	H	0	50
			Glucose	119	mg/dL	H	70	100
		2010-09-21T11:12	Hemoglobin	12.5	g/dL	L	14	16
			Lymphocytes	0.44	10^9/L	L	1	4
			Monocytes	1.32	10^9/L	H	0.2	1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-003	Cycle 1	2010-09-21T11:27	Sodium	131	mmol/L	L	136	145
			Chloride	96	mmol/L	L	98	107
			Albumin	2.8	g/dL	L	3.4	4.8
			Alanine Aminotransferase	57	U/L	H	0	50
			Glucose	160	mg/dL	H	70	100
	End Trial	2010-10-06T10:01	Hemoglobin	11.8	g/dL	L	13.5	17.5
			Ery. Mean Corpuscular Volume	82.1	fL	L	83	100
			Leukocytes	11.6	10^9/L	H	3.5	10
			Neutrophils	9.176	10^9/L	H	2	7.5
			Lymphocytes	0.858	10^9/L	L	1	4
			Eosinophils	0.65	10^9/L	H	0	0.5
			Sodium	123	mmol/L	L	136	145
			Calcium	8.14	mg/dL	L	8.7	10
			Chloride	88	mmol/L	L	98	107
			Creatinine	0.68	mg/dL	L	0.7	1.3
			Albumin	2.4	g/dL	L	3.4	4.8
			Urate	2.7	mg/dL	L	3.4	7.2
			Glucose	114	mg/dL	H	70	100
142-005	Pre-trial	2011-05-19T14:40	Hemoglobin	8.7	g/dL	L	12	16
			Erythrocytes	2.97	10^12/L	L	3.7	4.8
			Platelets	118	10^9/L	L	150	360
			Leukocytes	2.81	10^9/L	L	3.5	10
			Neutrophils	1.995	10^9/L	L	2	7.5
			Lymphocytes	0.281	10^9/L	L	1	4
			Monocytes	0.084	10^9/L	L	0.2	1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-005	Pre-trial	2011-05-19T14:40	Sodium	122	mmol/L	L	136	145
			Calcium	8.46	mg/dL	L	8.7	10
			Chloride	94	mmol/L	L	98	107
			Albumin	2.6	g/dL	L	3.4	4.8
			Alanine Aminotransferase	37	U/L	H	0	35
			Aspartate Aminotransferase	79	U/L	H	5	31
			Alkaline Phosphatase	176	U/L	H	35	104
			Lactate Dehydrogenase	378	U/L	H	0	245
	Cycle 1	2011-05-30T09:00	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.37	10^12/L	L	3.7	4.8
			Platelets	122	10^9/L	L	150	360
			Leukocytes	2.1	10^9/L	L	3.5	10
		2011-05-30T09:23	Calcium	6.93	mg/dL	L	8.7	10
			Magnesium	1	mg/dL	L	1.6	2.6
			Creatinine	0.54	mg/dL	L	0.6	1.1
			Albumin	2	g/dL	L	3.4	4.8
			Alanine Aminotransferase	45	U/L	H	0	35
			Aspartate Aminotransferase	104	U/L	H	5	31
			Alkaline Phosphatase	280	U/L	H	35	104
			Lactate Dehydrogenase	352	U/L	H	0	245
			Blood Urea Nitrogen	4	mg/dL	L	10	20
			Urate	1.5	mg/dL	L	2.6	6

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-005	Cycle 1	2011-06-11T09:03	Hemoglobin	8.2	g/dL	L	12	16
			Erythrocytes	2.75	10^12/L	L	3.7	4.8
			Platelets	133	10^9/L	L	150	360
			Potassium	3	mmol/L	L	3.5	5.1
			Calcium	8.22	mg/dL	L	8.7	10
			Magnesium	1.05	mg/dL	L	1.6	2.6
			Creatinine	0.5	mg/dL	L	0.6	1.1
			Albumin	2.3	g/dL	L	3.4	4.8
			Alanine Aminotransferase	119	U/L	H	0	35
			Aspartate Aminotransferase	179	U/L	H	5	31
			Alkaline Phosphatase	348	U/L	H	35	104
			Lactate Dehydrogenase	266	U/L	H	0	245
			Urate	2.1	mg/dL	L	2.6	6
		2011-06-16T10:47	Erythrocytes	5	10^12/L	H	3.7	4.8
			Lymphocytes	0.711	10^9/L	L	1	4
			Sodium	130	mmol/L	L	136	145
			Calcium	10.9	mg/dL	H	8.7	10
			Chloride	93	mmol/L	L	98	107
			Phosphate	5	mg/dL	H	2.5	4.7
			Albumin	3.3	g/dL	L	3.4	4.8
			Alanine Aminotransferase	64	U/L	H	0	35
			Aspartate Aminotransferase	47	U/L	H	5	31
			Alkaline Phosphatase	391	U/L	H	35	104
			Lactate Dehydrogenase	319	U/L	H	0	245
			Glucose	129	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
142-005	End Trial	2011-06-28T10:40	Hemoglobin	11.7	g/dL	L	12	16
			Lymphocytes	0.742	10^9/L	L	1	4
			Sodium	129	mmol/L	L	136	145
			Magnesium	1.56	mg/dL	L	1.6	2.6
			Albumin	2.9	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	37	U/L	H	5	31
			Alkaline Phosphatase	209	U/L	H	35	104
			Lactate Dehydrogenase	325	U/L	H	0	245
			Glucose	113	mg/dL	H	70	100
144-001	Pre-trial	2010-09-08T14:43	Hemoglobin	9.1	g/dL	L	12	16
			Erythrocytes	3.2	10^12/L	L	4.1	5.4
			Platelets	52	10^9/L	L	150	350
			Leukocytes	3.93	10^9/L	L	4.3	10
			Neutrophils	1.454	10^9/L	L	2	7.5
			Eosinophils	0.59	10^9/L	H	0	0.5
		2010-09-13T09:06	Prothrombin Time	5.9	sec	L	11	13
			Activated Partial Thromboplastin Time	160	sec	H	26	36
			Prothrombin Intl. Normalized Ratio	1.4	ratio	H	0.85	1.15
		2010-09-14T13:02	Potassium	3.3	mmol/L	L	3.6	4.8
			Calcium	8.42	mg/dL	L	8.8	10.8
			Alkaline Phosphatase	540	U/L	H	38	126
			Lactate Dehydrogenase	269	U/L	H	0	247

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
144-001	Cycle 1	2010-09-20T11:43	Hemoglobin	7.1	g/dL	L	12	16
			Erythrocytes	2.5	10^12/L	L	4.1	5.4
			Platelets	10	10^9/L	L	150	350
			Leukocytes	1.78	10^9/L	L	4.3	10
			Neutrophils	0.623	10^9/L	L	2	7.5
			Monocytes	0.089	10^9/L	L	0.2	1
			Activated Partial Thromboplastin Time	65	sec	H	26	36
			Potassium	3.4	mmol/L	L	3.6	4.8
			Calcium	8.02	mg/dL	L	8.8	10.8
			Albumin	2.9	g/dL	L	3.5	4.8
			Alkaline Phosphatase	419	U/L	H	38	126
			Glucose	136	mg/dL	H	60	110
		2010-09-24T08:42	Hemoglobin	7.8	g/dL	L	12	16
			Erythrocytes	2.8	10^12/L	L	4.1	5.4
			Platelets	6	10^9/L	L	150	350
			Leukocytes	1.93	10^9/L	L	4.3	10
			Potassium	2.9	mmol/L	L	3.6	4.8
			Calcium	8.02	mg/dL	L	8.8	10.8
			Phosphate	2.48	mg/dL	L	2.5	5
			Albumin	2.8	g/dL	L	3.5	4.8
			Alkaline Phosphatase	332	U/L	H	38	126
			Urate	1.7	mg/dL	L	2.1	6.4
			Glucose	159	mg/dL	H	60	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
144-001	Cycle 2	2010-10-09T08:52	Activated Partial Thromboplastin Time	48	sec	H	26	36
		2010-10-11T08:24	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.5	10^12/L	L	4.1	5.4
			Platelets	9	10^9/L	L	150	350
			Leukocytes	1.22	10^9/L	L	4.3	10
			Neutrophils	0.183	10^9/L	L	2	7.5
			Lymphocytes	0.866	10^9/L	L	1	4
			Monocytes	0.073	10^9/L	L	0.2	1
			Calcium	8.42	mg/dL	L	8.8	10.8
			Alkaline Phosphatase	270	U/L	H	38	126
			Lactate Dehydrogenase	252	U/L	H	0	247
		2010-10-15T12:57	Hemoglobin	7	g/dL	L	12	16
			Erythrocytes	2.5	10^12/L	L	4.1	5.4
			Platelets	2	10^9/L	L	150	350
			Leukocytes	0.78	10^9/L	L	4.3	10
			Neutrophils	0.133	10^9/L	L	2	7.5
			Lymphocytes	0.562	10^9/L	L	1	4
			Monocytes	0.008	10^9/L	L	0.2	1
			Potassium	2.8	mmol/L	L	3.6	4.8
			Calcium	7.62	mg/dL	L	8.8	10.8
			Albumin	2.9	g/dL	L	3.5	4.8
			Alkaline Phosphatase	319	U/L	H	38	126
			Lactate Dehydrogenase	255	U/L	H	0	247
			Bilirubin	1.3	mg/dL	H	0.3	1.2
			Blood Urea Nitrogen	15	mg/dL	L	17	43

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
144-001	Cycle 2	2010-10-15T12:57	Glucose	118	mg/dL	H	60	110
	End Trial	2010-11-01T10:12	Hemoglobin	9.3	g/dL	L	12	16
			Erythrocytes	3.4	10^12/L	L	4.1	5.4
			Ery. Mean Corpuscular Volume	78	fL	L	80	96
			Platelets	9	10^9/L	L	150	350
			Leukocytes	1.62	10^9/L	L	4.3	10
			Calcium	8.42	mg/dL	L	8.8	10.8
			Alkaline Phosphatase	360	U/L	H	38	126
			Lactate Dehydrogenase	332	U/L	H	0	247
			Bilirubin	1.4	mg/dL	H	0.3	1.2
			Glucose	122	mg/dL	H	60	110
		2010-11-01T10:38	Activated Partial Thromboplastin Time	53	sec	H	26	36
144-002	Pre-trial	2010-12-02T12:05	Platelets	60	10^9/L	L	150	350
			Lymphocytes	0.535	10^9/L	L	1	4
			Monocytes	0.146	10^9/L	L	0.2	1
		2010-12-03T09:29	Lactate Dehydrogenase	346	U/L	H	0	247
	Cycle 1	2010-12-06T09:28	Hemoglobin	11.5	g/dL	L	12	16
			Platelets	50	10^9/L	L	150	350
			Lymphocytes	0.694	10^9/L	L	1	4
			Calcium	8.42	mg/dL	L	8.8	10.8
			Lactate Dehydrogenase	391	U/L	H	0	247

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
144-002	Cycle 1	2010-12-10T09:14	Hemoglobin	9.6	g/dL	L	12	16
			Erythrocytes	3.4	10^12/L	L	4.1	5.4
			Platelets	35	10^9/L	L	150	350
			Leukocytes	3.86	10^9/L	L	4.3	10
			Calcium	8.02	mg/dL	L	8.8	10.8
			Lactate Dehydrogenase	347	U/L	H	0	247
		2010-12-16T14:55	Hemoglobin	11.6	g/dL	L	12	18
			Erythrocytes	4.18	10^12/L	L	4.2	6.3
			Platelets	93	10^9/L	L	140	440
			Lymphocytes	0.944	10^9/L	L	1	4
			Alanine Aminotransferase	7	U/L	L	10	35
			Lactate Dehydrogenase	420	U/L	H	135	225
	Cycle 2	2010-12-29T09:54	Hemoglobin	9.9	g/dL	L	12	16
			Erythrocytes	3.5	10^12/L	L	4.1	5.4
			Platelets	52	10^9/L	L	150	350
			Lymphocytes	0.626	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.6	4.8
			Calcium	8.42	mg/dL	L	8.8	10.8
			Albumin	3.4	g/dL	L	3.5	4.8
			Lactate Dehydrogenase	349	U/L	H	0	247
			Bilirubin	1.3	mg/dL	H	0.3	1.2
		2011-01-03T08:28	Hemoglobin	8.2	g/dL	L	12	16
			Erythrocytes	3	10^12/L	L	4.1	5.4
			Platelets	23	10^9/L	L	150	350
			Lymphocytes	0.89	10^9/L	L	1	4
			Calcium	7.62	mg/dL	L	8.8	10.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
144-002	Cycle 2	2011-01-03T08:28	Creatinine	1.11	mg/dL	H	0.4	1
			Albumin	3.1	g/dL	L	3.5	4.8
			Lactate Dehydrogenase	387	U/L	H	0	247
			Blood Urea Nitrogen	13	mg/dL	L	17	43
	Unplanned	2010-12-20T09:40	Hemoglobin	10.8	g/dL	L	12	18
			Erythrocytes	3.86	10^12/L	L	4.2	6.3
			Platelets	61	10^9/L	L	140	440
			Lymphocytes	0.592	10^9/L	L	1	4
			Sodium	135	mmol/L	L	136	147
			Calcium	7.94	mg/dL	L	8.4	10.4
			Lactate Dehydrogenase	416	U/L	H	135	225
			Blood Urea Nitrogen	12	mg/dL	L	17	43
		2010-12-27T07:00	Hemoglobin	11	g/dL	L	12	18
			Erythrocytes	3.91	10^12/L	L	4.2	6.3
			Platelets	40	10^9/L	L	140	440
			Lymphocytes	0.794	10^9/L	L	1	4
			Potassium	2.9	mmol/L	L	3.3	5.5
			Lactate Dehydrogenase	360	U/L	H	135	225
	End Trial	2011-01-14T10:17	Hemoglobin	10.6	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4.1	5.4
			Platelets	24	10^9/L	L	150	350
			Lymphocytes	0.78	10^9/L	L	1	4
			Sodium	135	mmol/L	L	136	144
			Potassium	3.1	mmol/L	L	3.6	4.8
			Calcium	7.62	mg/dL	L	8.8	10.8
			Lactate Dehydrogenase	399	U/L	H	0	247

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
144-002	End Trial	2011-01-14T10:17	Glucose	115	mg/dL	H	60	110
		2011-01-14T11:02	Prothrombin Intl. Normalized Ratio	1.3	ratio	H	0.85	1.15
146-001	Pre-trial	2010-01-19T08:39	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.6	10^12/L	L	4	5.5
			Activated Partial Thromboplastin Time	23.6	sec	L	24	40
	Cycle 1	2010-01-25T08:00	Hemoglobin	11.5	g/dL	L	12	16
			Leukocytes	18.1	10^9/L	H	4	10
			Neutrophils	14.661	10^9/L	H	2	7.5
			Lymphocytes	0.905	10^9/L	L	1	4
			Monocytes	1.267	10^9/L	H	0.2	1
			Lactate Dehydrogenase	272	U/L	H	120	223
			Blood Urea Nitrogen	84	mg/dL	H	1	71
			Glucose	212	mg/dL	H	60	100
		2010-01-29T08:45	Hemoglobin	11.2	g/dL	L	12	16
			Erythrocytes	3.9	10^12/L	L	4	5.5
			Platelets	123	10^9/L	L	140	380
			Leukocytes	10.6	10^9/L	H	4	10
			Neutrophils	8.692	10^9/L	H	2	7.5
			Lymphocytes	0.53	10^9/L	L	1	4
			Phosphate	4.55	mg/dL	H	2.7	4.5
			Creatinine	1.07	mg/dL	H	0.1	0.9
			Lactate Dehydrogenase	237	U/L	H	120	223

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 1	2010-02-05T10:56	Hemoglobin	11.5	g/dL	L	12	16
			Lymphocytes	0.546	10^9/L	L	1	4
			Lactate Dehydrogenase	261	U/L	H	120	223
			Glucose	153	mg/dL	H	60	100
	Cycle 2	2010-02-22T08:38	Hemoglobin	10.6	g/dL	L	12	16
			Erythrocytes	3.6	10^12/L	L	4	5.5
			Lymphocytes	0.328	10^9/L	L	1	4
			Albumin	3.77	g/dL	L	3.8	5.2
			Glucose	161	mg/dL	H	60	100
		2010-02-26T08:45	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.3	10^12/L	L	4	5.5
			Platelets	134	10^9/L	L	140	380
			Lymphocytes	0.552	10^9/L	L	1	4
			Monocytes	0.138	10^9/L	L	0.2	1
			Creatinine	0.96	mg/dL	H	0.1	0.9
	Cycle 3	2010-04-09T09:11	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.5	10^12/L	L	4	5.5
			Lymphocytes	0.936	10^9/L	L	1	4
			Monocytes	1.014	10^9/L	H	0.2	1
			Albumin	3.23	g/dL	L	3.8	5.2
			Alanine Aminotransferase	37	U/L	H	1	34
			Lactate Dehydrogenase	225	U/L	H	120	223
			Urate	6.3	mg/dL	H	0.1	5.7

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 3	2010-04-13T09:19	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.6	10^12/L	L	4	5.5
			Platelets	113	10^9/L	L	140	380
			Lymphocytes	0.5	10^9/L	L	1	4
			Potassium	3.6	mmol/L	L	3.7	5.4
			Creatinine	1.12	mg/dL	H	0.1	0.9
			Albumin	3.09	g/dL	L	3.8	5.2
	Cycle 4	2010-05-03T10:30	Hemoglobin	10.5	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	4	5.5
			Platelets	101	10^9/L	L	140	380
			Leukocytes	3.5	10^9/L	L	4	10
			Lymphocytes	0.63	10^9/L	L	1	4
			Albumin	3.21	g/dL	L	3.8	5.2
			Lactate Dehydrogenase	315	U/L	H	120	223
		2010-05-20T09:05	Hemoglobin	9.6	g/dL	L	12	16
			Erythrocytes	3.4	10^12/L	L	4	5.5
			Platelets	83	10^9/L	L	140	380
			Lymphocytes	0.66	10^9/L	L	1	4
			Phosphate	4.58	mg/dL	H	2.7	4.5
			Creatinine	1.19	mg/dL	H	0.1	0.9
			Alanine Aminotransferase	44	U/L	H	1	34
			Alkaline Phosphatase	293	U/L	H	10	210
			Lactate Dehydrogenase	234	U/L	H	120	223

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 5	2010-06-07T09:24	Hemoglobin	10.4	g/dL	L	12	16
			Erythrocytes	3.9	10^12/L	L	4	5.5
			Platelets	116	10^9/L	L	140	380
			Lymphocytes	0.715	10^9/L	L	1	4
			Creatinine	0.97	mg/dL	H	0.1	0.9
			Albumin	2.95	g/dL	L	3.8	5.2
			Lactate Dehydrogenase	279	U/L	H	120	223
			Urate	6.2	mg/dL	H	0.1	5.7
		2010-06-14T09:05	Hemoglobin	8.8	g/dL	L	12	16
			Erythrocytes	3.2	10^12/L	L	4	5.5
			Platelets	65	10^9/L	L	140	380
			Potassium	3.4	mmol/L	L	3.7	5.4
			Creatinine	1.44	mg/dL	H	0.1	0.9
	Cycle 6	2010-07-02T15:05	Hemoglobin	10.6	g/dL	L	12	16
			Erythrocytes	3.9	10^12/L	L	4	5.5
			Platelets	119	10^9/L	L	140	380
			Leukocytes	3.8	10^9/L	L	4	10
			Calcium	7.98	mg/dL	L	8.4	10.2
			Creatinine	1.16	mg/dL	H	0.1	0.9
			Alanine Aminotransferase	91	U/L	H	1	34
			Lactate Dehydrogenase	254	U/L	H	120	223
			Urate	7	mg/dL	H	0.1	5.7
			Glucose	137	mg/dL	H	60	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 6	2010-07-06T11:29	Hemoglobin	10.5	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4	5.5
			Platelets	102	10^9/L	L	140	380
			Leukocytes	3.8	10^9/L	L	4	10
			Lymphocytes	0.722	10^9/L	L	1	4
			Monocytes	0.152	10^9/L	L	0.2	1
			Phosphate	5.54	mg/dL	H	2.7	4.5
			Magnesium	2.64	mg/dL	H	1.7	2.6
			Creatinine	1.42	mg/dL	H	0.1	0.9
			Albumin	2.71	g/dL	L	3.8	5.2
			Alanine Aminotransferase	141	U/L	H	1	34
			Aspartate Aminotransferase	49	U/L	H	1	31
			Alkaline Phosphatase	278	U/L	H	10	210
			Glucose	109	mg/dL	H	60	100
	Cycle 7	2010-08-16T10:01	Hemoglobin	11.3	g/dL	L	12	16
			Erythrocytes	3.6	10^12/L	L	4	5.5
			Lymphocytes	0.984	10^9/L	L	1	4
			Creatinine	1.27	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2
			Alanine Aminotransferase	35	U/L	H	1	34
			Blood Urea Nitrogen	73	mg/dL	H	1	71
			Urate	6.6	mg/dL	H	0.1	5.7
			Glucose	131	mg/dL	H	60	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 7	2010-08-20T09:08	Hemoglobin	11.6	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4	5.5
			Leukocytes	2.5	10^9/L	L	4	10
			Creatinine	1.64	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2
			Alanine Aminotransferase	46	U/L	H	1	34
	Cycle 8	2010-09-06T09:16	Leukocytes	3.9	10^9/L	L	4	10
			Creatinine	1.22	mg/dL	H	0.1	0.9
			Blood Urea Nitrogen	74	mg/dL	H	1	71
			Urate	5.8	mg/dL	H	0.1	5.7
			Glucose	125	mg/dL	H	60	100
		2010-09-10T09:18	Hemoglobin	11.5	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4	5.5
			Leukocytes	2.4	10^9/L	L	4	10
			Creatinine	1.47	mg/dL	H	0.1	0.9
			Alanine Aminotransferase	57	U/L	H	1	34
	Cycle 9	2010-10-04T09:18	Activated Partial Thromboplastin Time	48.8	sec	H	24	40
			Prothrombin Intl. Normalized Ratio	1.7	ratio	H	0.9	1.5
			Creatinine	1.21	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2
		2010-10-08T09:28	Hemoglobin	11.4	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	4	5.5
			Platelets	136	10^9/L	L	140	380
			Leukocytes	3.8	10^9/L	L	4	10
			Creatinine	1.37	mg/dL	H	0.1	0.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 10	2010-11-15T09:11	Lymphocytes	0.918	10^9/L	L	1	4
			Creatinine	1.33	mg/dL	H	0.1	0.9
			Glucose	117	mg/dL	H	60	100
		2010-11-19T09:02	Creatinine	1.5	mg/dL	H	0.1	0.9
			Lactate Dehydrogenase	226	U/L	H	120	223
			Bilirubin	1.03	mg/dL	H	0.1	1
	Cycle 11	2010-12-27T09:15	Prothrombin Intl. Normalized Ratio	2.2	ratio	H	0.9	1.5
			Creatinine	1.23	mg/dL	H	0.1	0.9
			Glucose	104	mg/dL	H	60	100
		2010-12-31T08:24	Hemoglobin	11.5	g/dL	L	12	16
			Erythrocytes	3.9	10^12/L	L	4	5.5
			Leukocytes	3.9	10^9/L	L	4	10
			Phosphate	4.65	mg/dL	H	2.7	4.5
			Creatinine	1.5	mg/dL	H	0.1	0.9
			Bilirubin	1.28	mg/dL	H	0.1	1
	Cycle 12	2011-02-07T08:58	Activated Partial Thromboplastin Time	40.3	sec	H	24	40
			Prothrombin Intl. Normalized Ratio	2.2	ratio	H	0.9	1.5
			Creatinine	1.13	mg/dL	H	0.1	0.9
			Glucose	43	mg/dL	L	60	100
		2011-02-11T08:50	Hemoglobin	11.8	g/dL	L	12	16
			Erythrocytes	3.9	10^12/L	L	4	5.5
			Leukocytes	3.9	10^9/L	L	4	10
			Lymphocytes	0.702	10^9/L	L	1	4
			Phosphate	4.74	mg/dL	H	2.7	4.5
			Creatinine	1.38	mg/dL	H	0.1	0.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 12	2011-02-11T08:50	Bilirubin	1.04	mg/dL	H	0.1	1
	Cycle 13	2011-03-21T08:56	Activated Partial Thromboplastin Time	44.5	sec	H	24	40
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.9	1.5
			Creatinine	1.22	mg/dL	H	0.1	0.9
			Glucose	112	mg/dL	H	60	100
		2011-03-25T08:46	Lymphocytes	0.72	10^9/L	L	1	4
			Creatinine	1.32	mg/dL	H	0.1	0.9
			Bilirubin	1.02	mg/dL	H	0.1	1
	Cycle 14	2011-05-02T08:58	Activated Partial Thromboplastin Time	49.7	sec	H	24	40
			Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.9	1.5
			Creatinine	1.11	mg/dL	H	0.1	0.9
		2011-05-06T14:24	Potassium	3.6	mmol/L	L	3.7	5.4
			Creatinine	1.43	mg/dL	H	0.1	0.9
			Bilirubin	1.1	mg/dL	H	0.1	1
	Cycle 15	2011-06-14T09:02	Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.9	1.5
			Glucose	106	mg/dL	H	60	100
		2011-06-18T09:06	Hemoglobin	11.8	g/dL	L	12	16
			Erythrocytes	3.9	10^12/L	L	4	5.5
			Monocytes	1.014	10^9/L	H	0.2	1
			Creatinine	1.06	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 16	2011-07-26T09:02	Prothrombin Intl. Normalized Ratio	3	ratio	H	0.9	1.5
			Creatinine	1.26	mg/dL	H	0.1	0.9
			Albumin	3.7	g/dL	L	3.8	5.2
			Glucose	109	mg/dL	H	60	100
		2011-07-30T08:39	Hemoglobin	11.8	g/dL	L	12	16
			Lymphocytes	0.943	10^9/L	L	1	4
			Creatinine	1.31	mg/dL	H	0.1	0.9
			Albumin	3.5	g/dL	L	3.8	5.2
			Bilirubin	1.25	mg/dL	H	0.1	1
	Cycle 17	2011-09-05T09:59	Potassium	3.6	mmol/L	L	3.7	5.4
			Creatinine	1.26	mg/dL	H	0.1	0.9
			Glucose	108	mg/dL	H	60	100
		2011-09-09T08:58	Lymphocytes	0.88	10^9/L	L	1	4
			Creatinine	1.51	mg/dL	H	0.1	0.9
			Bilirubin	1.03	mg/dL	H	0.1	1
	Cycle 18	2011-10-17T10:39	Potassium	3.4	mmol/L	L	3.7	5.4
			Creatinine	1.18	mg/dL	H	0.1	0.9
			Glucose	121	mg/dL	H	60	100
		2011-10-21T09:13	Hemoglobin	11.9	g/dL	L	12	16
			Lymphocytes	0.968	10^9/L	L	1	4
			Creatinine	1.4	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2
			Bilirubin	1.18	mg/dL	H	0.1	1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 19	2011-11-28T09:03	Prothrombin Intl. Normalized Ratio	0.8	ratio	L	0.9	1.5
			Creatinine	1.3	mg/dL	H	0.1	0.9
			Glucose	104	mg/dL	H	60	100
		2011-12-02T09:10	Hemoglobin	11.9	g/dL	L	12	16
			Lymphocytes	0.84	10^9/L	L	1	4
			Creatinine	1.5	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2
			Alanine Aminotransferase	47	U/L	H	1	34
			Aspartate Aminotransferase	43	U/L	H	1	31
			Bilirubin	1.18	mg/dL	H	0.1	1
	Cycle 20	2012-01-09T09:15	Lymphocytes	0.832	10^9/L	L	1	4
			Creatinine	1.32	mg/dL	H	0.1	0.9
			Albumin	3.7	g/dL	L	3.8	5.2
		2012-01-13T09:04	Phosphate	4.74	mg/dL	H	2.7	4.5
			Creatinine	1.63	mg/dL	H	0.1	0.9
			Bilirubin	1.45	mg/dL	H	0.1	1
			Glucose	119	mg/dL	H	60	100
	Cycle 21	2012-02-20T10:23	Hemoglobin	11.8	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4	5.5
			Lymphocytes	0.462	10^9/L	L	1	4
			Potassium	2.9	mmol/L	L	3.7	5.4
			Albumin	3.7	g/dL	L	3.8	5.2
			Alkaline Phosphatase	219	U/L	H	10	210
			Urate	7.4	mg/dL	H	0.1	5.7
			Glucose	108	mg/dL	H	60	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 21	2012-02-24T09:01	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.4	10^12/L	L	4	5.5
			Leukocytes	3.7	10^9/L	L	4	10
			Lymphocytes	0.629	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.7	5.4
			Calcium	8.38	mg/dL	L	8.4	10.2
			Albumin	3	g/dL	L	3.8	5.2
	Cycle 22	2012-04-02T09:27	Monocytes	1.005	10^9/L	H	0.2	1
			Albumin	3.7	g/dL	L	3.8	5.2
		2012-04-06T08:29	Hemoglobin	11	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4	5.5
			Lymphocytes	0.96	10^9/L	L	1	4
			Potassium	3.4	mmol/L	L	3.7	5.4
			Albumin	3.4	g/dL	L	3.8	5.2
	Cycle 23	2012-05-14T10:11	Activated Partial Thromboplastin Time	57.6	sec	H	24	40
			Magnesium	1.46	mg/dL	L	1.7	2.6
			Creatinine	0.99	mg/dL	H	0.1	0.9
			Albumin	3.7	g/dL	L	3.8	5.2
		2012-05-18T09:15	Hemoglobin	10.6	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4	5.5
			Lymphocytes	0.936	10^9/L	L	1	4
			Monocytes	1.152	10^9/L	H	0.2	1
			Potassium	3.3	mmol/L	L	3.7	5.4
			Phosphate	4.61	mg/dL	H	2.7	4.5
			Creatinine	1.18	mg/dL	H	0.1	0.9

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-001	Cycle 23	2012-05-18T09:15	Albumin	3	g/dL	L	3.8	5.2
	Cycle 24	2012-06-25T09:12	Hemoglobin	11.3	g/dL	L	12	16
			Lymphocytes	0.945	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	68.1	sec	H	24	40
			Creatinine	1	mg/dL	H	0.1	0.9
			Albumin	3.6	g/dL	L	3.8	5.2
			Glucose	111	mg/dL	H	60	100
		2012-06-29T08:47	Hemoglobin	9.9	g/dL	L	12	16
			Erythrocytes	3.5	10^12/L	L	4	5.5
			Potassium	3.6	mmol/L	L	3.7	5.4
			Creatinine	1.01	mg/dL	H	0.1	0.9
	Cycle 25	2012-08-06T11:26	Lymphocytes	0.672	10^9/L	L	1	4
			Creatinine	1.09	mg/dL	H	0.1	0.9
			Albumin	3.5	g/dL	L	3.8	5.2
		2012-08-10T08:54	Creatinine	1.12	mg/dL	H	0.1	0.9
	Unplanned	2010-02-12T11:38	Hemoglobin	9.2	g/dL	L	12	16
			Erythrocytes	3.2	10^12/L	L	4	5.5
			Lymphocytes	0.78	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	49.4	sec	H	24	40
			Calcium	8.34	mg/dL	L	8.4	10.2
			Lactate Dehydrogenase	240	U/L	H	120	223
			Glucose	148	mg/dL	H	60	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-002	Pre-trial	2011-01-24T12:32	Hemoglobin	11.4	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	4	5.5
			Platelets	98	10^9/L	L	140	380
			Leukocytes	61	10^9/L	H	4	10
			Neutrophils	17.69	10^9/L	H	2	7.5
			Lymphocytes	25.01	10^9/L	H	1	4
			Monocytes	1.83	10^9/L	H	0.2	1
			Sodium	124	mmol/L	L	132	146
			Calcium	8.26	mg/dL	L	8.4	10.2
			Magnesium	1.63	mg/dL	L	1.7	2.6
			Albumin	3.1	g/dL	L	3.8	5.2
			Aspartate Aminotransferase	37	U/L	H	1	31
			Lactate Dehydrogenase	661	U/L	H	120	223
			Urate	5.8	mg/dL	H	0.1	5.7
			Glucose	126	mg/dL	H	60	100
	Cycle 1	2011-01-27T09:01	Hemoglobin	11.7	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	4	5.5
			Platelets	70	10^9/L	L	140	380
			Leukocytes	100.7	10^9/L	H	4	10
			Neutrophils	14.098	10^9/L	H	2	7.5
			Lymphocytes	18.126	10^9/L	H	1	4
			Monocytes	2.014	10^9/L	H	0.2	1
			Sodium	126	mmol/L	L	132	146
			Chloride	85	mmol/L	L	94	110
			Albumin	2.8	g/dL	L	3.8	5.2
			Aspartate Aminotransferase	46	U/L	H	1	31

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-002	Cycle 1	2011-01-27T09:01	Lactate Dehydrogenase	814	U/L	H	120	223
			Urate	7.5	mg/dL	H	0.1	5.7
			Glucose	122	mg/dL	H	60	100
		2011-01-31T09:04	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3	10^12/L	L	4	5.5
			Platelets	39	10^9/L	L	140	380
			Leukocytes	51.7	10^9/L	H	4	10
			Neutrophils	9.823	10^9/L	H	2	7.5
			Monocytes	1.034	10^9/L	H	0.2	1
			Sodium	127	mmol/L	L	132	146
			Potassium	3.6	mmol/L	L	3.7	5.4
			Calcium	7.54	mg/dL	L	8.4	10.2
			Albumin	2.9	g/dL	L	3.8	5.2
			Aspartate Aminotransferase	35	U/L	H	1	31
			Lactate Dehydrogenase	657	U/L	H	120	223
			Urate	7.2	mg/dL	H	0.1	5.7
			Glucose	115	mg/dL	H	60	100
	End Trial	2011-02-08T07:46	Hemoglobin	11.4	g/dL	L	12	16
			Erythrocytes	3.5	10^12/L	L	4	5.5
			Platelets	46	10^9/L	L	140	380
			Leukocytes	22.5	10^9/L	H	4	10
			Neutrophils	13.725	10^9/L	H	2	7.5
			Lymphocytes	7.65	10^9/L	H	1	4
			Monocytes	0	10^9/L	L	0.2	1
			Activated Partial Thromboplastin Time	49.6	sec	H	24	40

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
146-002	End Trial	2011-02-08T07:46	Calcium	7.74	mg/dL	L	8.4	10.2
			Phosphate	4.77	mg/dL	H	2.7	4.5
			Creatinine	0.94	mg/dL	H	0.1	0.9
			Albumin	2	g/dL	L	3.8	5.2
			Lactate Dehydrogenase	808	U/L	H	120	223
			Glucose	247	mg/dL	H	60	100
147-001	Pre-trial	2011-06-22T08:10	Hemoglobin	11.5	g/dL	L	13.8	19.5
			Ery. Mean Corpuscular Volume	75.9	fL	L	80	94
			Leukocytes	16	10^9/L	H	3.8	10.8
			Lymphocytes	6.9	10^9/L	H	1.3	2.9
			Monocytes	5.1	10^9/L	H	0.3	0.8
			Eosinophils	0.4	10^9/L	H	0	0.2
			Basophils	0.9	10^9/L	H	0	0.1
			Creatinine	0.52	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	398.4	U/L	H	40.2	129
			Lactate Dehydrogenase	368.4	U/L	H	135	225
	Cycle 1	2011-06-27T09:30	Hemoglobin	10.7	g/dL	L	13.8	19.5
			Erythrocytes	4.57	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	75	fL	L	80	94
			Leukocytes	19.7	10^9/L	H	3.8	10.8
			Neutrophils	6.3	10^9/L	H	2.2	4.8
			Lymphocytes	7.5	10^9/L	H	1.3	2.9
			Monocytes	3.9	10^9/L	H	0.3	0.8
			Eosinophils	1.38	10^9/L	H	0	0.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
147-001	Cycle 1	2011-06-27T09:30	Activated Partial Thromboplastin Time	49.9	sec	H	25	37
			Creatinine	0.577	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	390	U/L	H	40.2	129
			Lactate Dehydrogenase	301.8	U/L	H	135	225
			Blood Urea Nitrogen	10.36	mg/dL	L	10.6	22.4
		2011-07-01T09:45	Hemoglobin	10.1	g/dL	L	13.8	19.5
			Erythrocytes	4.27	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	74.8	fL	L	80	94
			Leukocytes	19.2	10^9/L	H	3.8	10.8
			Neutrophils	8.4	10^9/L	H	2.2	4.8
			Lymphocytes	7.68	10^9/L	H	1.3	2.9
			Monocytes	1.73	10^9/L	H	0.3	0.8
			Potassium	3.3	mmol/L	L	3.6	4.8
			Creatinine	0.566	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	320.4	U/L	H	40.2	129
			Lactate Dehydrogenase	257.4	U/L	H	135	225
			Bilirubin	1.234	mg/dL	H	0.12	1.2
			Blood Urea Nitrogen	9.8	mg/dL	L	10.6	22.4
			Urate	2.59	mg/dL	L	3.4	7
		2011-07-08T08:10	Hemoglobin	11.3	g/dL	L	13.8	19.5
			Ery. Mean Corpuscular Volume	74.5	fL	L	80	94
			Leukocytes	20.2	10^9/L	H	3.8	10.8
			Neutrophils	7.1	10^9/L	H	2.2	4.8
			Lymphocytes	6.1	10^9/L	H	1.3	2.9
			Monocytes	4.4	10^9/L	H	0.3	0.8

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
147-001	Cycle 1	2011-07-08T08:10	Eosinophils	0.81	10^9/L	H	0	0.2
		2011-07-08T09:30	Creatinine	0.6	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	363	U/L	H	40.2	129
			Lactate Dehydrogenase	291.6	U/L	H	135	225
			Bilirubin	1.289	mg/dL	H	0.12	1.2
			Blood Urea Nitrogen	10.08	mg/dL	L	10.6	22.4
	Cycle 2	2011-07-18T08:30	Hemoglobin	10.6	g/dL	L	13.8	19.5
			Erythrocytes	4.6	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	73.8	fL	L	80	94
			Leukocytes	16.4	10^9/L	H	3.8	10.8
			Neutrophils	2	10^9/L	L	2.2	4.8
			Lymphocytes	8.8	10^9/L	H	1.3	2.9
			Monocytes	2.7	10^9/L	H	0.3	0.8
			Eosinophils	2.3	10^9/L	H	0	0.2
			Basophils	0.6	10^9/L	H	0	0.1
			Activated Partial Thromboplastin Time	39.2	sec	H	25	37
			Creatinine	0.554	mg/dL	L	0.67	1.18
			Aspartate Aminotransferase	51.6	U/L	H	10.2	51
			Alkaline Phosphatase	384.6	U/L	H	40.2	129
			Lactate Dehydrogenase	273	U/L	H	135	225
			Bilirubin	1.316	mg/dL	H	0.12	1.2
			Blood Urea Nitrogen	8.96	mg/dL	L	10.6	22.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
147-001	Cycle 2	2011-07-22T08:15	Hemoglobin	10.6	g/dL	L	13.8	19.5
			Erythrocytes	4.53	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	74.2	fL	L	80	94
			Leukocytes	20.2	10^9/L	H	3.8	10.8
			Neutrophils	8.3	10^9/L	H	2.2	4.8
			Lymphocytes	7.3	10^9/L	H	1.3	2.9
			Monocytes	3.4	10^9/L	H	0.3	0.8
			Basophils	1.2	10^9/L	H	0	0.1
			Creatinine	0.532	mg/dL	L	0.67	1.18
			Alanine Aminotransferase	56.4	U/L	H	10.2	51
			Alkaline Phosphatase	326.4	U/L	H	40.2	129
			Blood Urea Nitrogen	9.8	mg/dL	L	10.6	22.4
			Urate	2.93	mg/dL	L	3.4	7
	Cycle 3	2011-08-08T08:45	Hemoglobin	10.7	g/dL	L	13.8	19.5
			Ery. Mean Corpuscular Volume	73	fL	L	80	94
			Platelets	477	10^9/L	H	110	450
			Leukocytes	22.9	10^9/L	H	3.8	10.8
			Neutrophils	5.4	10^9/L	H	2.2	4.8
			Lymphocytes	10.2	10^9/L	H	1.3	2.9
			Monocytes	3.5	10^9/L	H	0.3	0.8
			Eosinophils	1.7	10^9/L	H	0	0.2
			Basophils	2.1	10^9/L	H	0	0.1
			Creatinine	0.622	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	401.4	U/L	H	40.2	129
			Lactate Dehydrogenase	255.6	U/L	H	135	225
			Blood Urea Nitrogen	8.68	mg/dL	L	10.6	22.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
147-001	Cycle 3	2011-08-12T08:45	Hemoglobin	11	g/dL	L	13.8	19.5
			Ery. Mean Corpuscular Volume	72.1	fL	L	80	94
			Leukocytes	20.5	10^9/L	H	3.8	10.8
			Neutrophils	9.43	10^9/L	H	2.2	4.8
			Lymphocytes	5.74	10^9/L	H	1.3	2.9
			Monocytes	2.67	10^9/L	H	0.3	0.8
			Creatinine	0.577	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	341.4	U/L	H	40.2	129
			Lactate Dehydrogenase	234	U/L	H	135	225
			Urate	2.87	mg/dL	L	3.4	7
	End Trial	2011-08-25T09:30	Hemoglobin	11.4	g/dL	L	13.8	19.5
			Ery. Mean Corpuscular Volume	71.5	fL	L	80	94
			Platelets	608	10^9/L	H	110	450
			Leukocytes	17.7	10^9/L	H	3.8	10.8
			Neutrophils	5.3	10^9/L	H	2.2	4.8
			Lymphocytes	7.1	10^9/L	H	1.3	2.9
			Monocytes	3.2	10^9/L	H	0.3	0.8
			Eosinophils	1	10^9/L	H	0	0.2
			Basophils	1.1	10^9/L	H	0	0.1
			Potassium	5	mmol/L	H	3.6	4.8
			Creatinine	0.622	mg/dL	L	0.67	1.18
			Alkaline Phosphatase	410.4	U/L	H	40.2	129
			Lactate Dehydrogenase	278.4	U/L	H	135	225
			Blood Urea Nitrogen	8.68	mg/dL	L	10.6	22.4
			Glucose	72.6	mg/dL	L	75	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
147-002	Pre-trial	2011-07-22	Hemoglobin	5.9	g/dL	L	11.9	17.2
			Erythrocytes	1.9	10^12/L	L	4.2	5.4
			Platelets	62	10^9/L	L	110	450
			Lymphocytes	0.9	10^9/L	L	1.3	2.9
		2011-07-22T12:00	Activated Partial Thromboplastin Time	64.7	sec	H	25	37
			Prothrombin Intl. Normalized Ratio	1.34	ratio	H	0.8	1.25
			Phosphate	2.45	mg/dL	L	2.6	4.5
			Aspartate Aminotransferase	51	U/L	H	10.2	36
			Lactate Dehydrogenase	1497.6	U/L	H	135	213
			Urate	6.25	mg/dL	H	2.4	5.7
	Cycle 1	2011-07-23T07:35	Hemoglobin	7.9	g/dL	L	11.9	17.2
			Erythrocytes	2.58	10^12/L	L	4.2	5.4
			Platelets	70	10^9/L	L	110	450
			Activated Partial Thromboplastin Time	24.9	sec	L	25	37
			Aspartate Aminotransferase	39	U/L	H	10.2	36
			Lactate Dehydrogenase	1590.6	U/L	H	135	213
			Urate	6.15	mg/dL	H	2.4	5.7
	End Trial	2011-07-25	Hemoglobin	7.2	g/dL	L	11.9	17.2
			Erythrocytes	2.27	10^12/L	L	4.2	5.4
			Platelets	40	10^9/L	L	110	450
			Neutrophils	5.7	10^9/L	H	2.2	4.8
			Lymphocytes	0.7	10^9/L	L	1.3	2.9
			Sodium	134.2	mmol/L	L	135	145
			Chloride	94.6	mmol/L	L	95	112

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
147-002	End Trial	2011-07-25	Alanine Aminotransferase	43.2	U/L	H	10.2	36
			Aspartate Aminotransferase	81	U/L	H	10.2	36
			Lactate Dehydrogenase	2593.8	U/L	H	135	213
			Glucose	118.2	mg/dL	H	75	115
		2011-07-26	Magnesium	2.53	mg/dL	H	1.8	2.4
		2011-07-26T07:30	Activated Partial Thromboplastin Time	22.6	sec	L	25	37
150-001	Pre-trial	2010-09-09T11:29	Hemoglobin	10.5	g/dL	L	12	16
			Erythrocytes	3.8	10^12/L	L	4.1	5.1
			Lymphocytes	0.274	10^9/L	L	1	4
			Monocytes	0	10^9/L	L	0.2	1
			Calcium	7.74	mg/dL	L	8.6	10.3
			Alkaline Phosphatase	345	U/L	H	35	105
			Lactate Dehydrogenase	433	U/L	H	0	250
			Blood Urea Nitrogen	26	mg/dL	H	7.939	20.081
	Cycle 1	2010-09-20T07:00	Hemoglobin	10.1	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	4.1	5.1
			Neutrophils	8.595	10^9/L	H	2	7.5
			Lymphocytes	0.081	10^9/L	L	1	4
			Monocytes	0.162	10^9/L	L	0.2	1
			Prothrombin Intl. Normalized Ratio	1.22	ratio	H	0.85	1.15
			Calcium	7.78	mg/dL	L	8.6	10.3
			Lactate Dehydrogenase	303	U/L	H	0	250
			Glucose	127	mg/dL	H	74	109

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
150-001	Cycle 1	2010-09-24T07:00	Hemoglobin	8.8	g/dL	L	12	16
			Erythrocytes	3.3	10^12/L	L	4.1	5.1
			Lymphocytes	0.4	10^9/L	L	1	2.9
			Potassium	3.16	mmol/L	L	3.4	5.1
			Calcium	7.7	mg/dL	L	8.6	10.3
			Lactate Dehydrogenase	333	U/L	H	0	250
			Blood Urea Nitrogen	46	mg/dL	H	7.939	20.081
			Glucose	125	mg/dL	H	74	109
		2010-10-01T07:00	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.6	10^12/L	L	4.1	5.1
			Platelets	116	10^9/L	L	140	360
			Lymphocytes	0.112	10^9/L	L	1	4
			Calcium	7.98	mg/dL	L	8.6	10.3
			Lactate Dehydrogenase	405	U/L	H	0	250
			Blood Urea Nitrogen	73	mg/dL	H	7.939	20.081
			Urate	7.27	mg/dL	H	2.3	6.1
154-001	Pre-trial	2011-01-24T10:30	Lactate Dehydrogenase	430	U/L	H	0	243
		2011-02-02T10:30	Potassium	5.1	mmol/L	H	3.5	5
			Aspartate Aminotransferase	66	U/L	H	10	50
			Alkaline Phosphatase	237	U/L	H	40	129
			Blood Urea Nitrogen	22	mg/dL	H	7	18

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Pre-trial	2011-02-02T10:31	Hemoglobin	13.6	g/dL	L	14	18
			Platelets	131	10^9/L	L	140	440
			Leukocytes	2.75	10^9/L	L	4.3	10.1
			Lymphocytes	0.42	10^9/L	L	0.9	5.2
	Cycle 1	2011-02-07T09:40	Hemoglobin	13.3	g/dL	L	14	18
			Platelets	122	10^9/L	L	140	440
			Leukocytes	2.65	10^9/L	L	4.3	10.1
			Lymphocytes	0.4	10^9/L	L	0.9	5.2
		2011-02-07T09:42	Alanine Aminotransferase	60	U/L	H	10	50
			Aspartate Aminotransferase	86	U/L	H	10	50
			Alkaline Phosphatase	252	U/L	H	40	129
			Lactate Dehydrogenase	379	U/L	H	0	243
			Blood Urea Nitrogen	23	mg/dL	H	7	18
		2011-02-11T08:44	Calcium	8.58	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	66	U/L	H	10	50
			Aspartate Aminotransferase	78	U/L	H	10	50
			Alkaline Phosphatase	261	U/L	H	40	129
			Lactate Dehydrogenase	369	U/L	H	0	243
			Bilirubin	1.3	mg/dL	H	0	1.19
			Blood Urea Nitrogen	21	mg/dL	H	7	18
		2011-02-11T09:04	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4.19	10^12/L	L	4.3	5.9
			Platelets	93	10^9/L	L	140	440
			Leukocytes	2.41	10^9/L	L	4.3	10.1
			Neutrophils	1.5	10^9/L	L	1.9	7
			Lymphocytes	0.53	10^9/L	L	0.9	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 1	2011-02-21T10:09	Sodium	134	mmol/L	L	135	145
			Alanine Aminotransferase	62	U/L	H	10	50
			Aspartate Aminotransferase	87	U/L	H	10	50
			Alkaline Phosphatase	263	U/L	H	40	129
			Lactate Dehydrogenase	412	U/L	H	0	243
			Blood Urea Nitrogen	20	mg/dL	H	7	18
		2011-02-21T10:12	Hemoglobin	12.8	g/dL	L	14	18
			Leukocytes	3.03	10^9/L	L	4.3	10.1
			Lymphocytes	0.7	10^9/L	L	0.9	5.2
	Cycle 2	2011-02-28T11:52	Alanine Aminotransferase	61	U/L	H	10	50
			Aspartate Aminotransferase	82	U/L	H	10	50
			Alkaline Phosphatase	293	U/L	H	40	129
			Lactate Dehydrogenase	403	U/L	H	0	243
			Blood Urea Nitrogen	23	mg/dL	H	7	18
		2011-02-28T12:14	Hemoglobin	13.2	g/dL	L	14	18
			Leukocytes	2.25	10^9/L	L	4.3	10.1
		2011-03-04T09:42	Potassium	5.2	mmol/L	H	3.5	5
			Calcium	8.46	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	63	U/L	H	10	50
			Aspartate Aminotransferase	71	U/L	H	10	50
			Alkaline Phosphatase	273	U/L	H	40	129
			Lactate Dehydrogenase	412	U/L	H	0	243
			Bilirubin	1.2	mg/dL	H	0	1.19
			Blood Urea Nitrogen	21	mg/dL	H	7	18

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 2	2011-03-04T09:47	Hemoglobin	12.6	g/dL	L	14	18
			Erythrocytes	4.28	10^12/L	L	4.3	5.9
			Platelets	127	10^9/L	L	140	440
			Leukocytes	2.45	10^9/L	L	4.3	10.1
			Neutrophils	1.64	10^9/L	L	1.9	7
			Lymphocytes	0.51	10^9/L	L	0.9	5.2
	Cycle 3	2011-03-21T12:18	Alanine Aminotransferase	78	U/L	H	10	50
			Aspartate Aminotransferase	113	U/L	H	10	50
			Alkaline Phosphatase	302	U/L	H	40	129
			Lactate Dehydrogenase	414	U/L	H	0	243
			Blood Urea Nitrogen	21	mg/dL	H	7	18
		2011-03-21T12:39	Hemoglobin	11.4	g/dL	L	14	18
			Erythrocytes	3.77	10^12/L	L	4.3	5.9
			Leukocytes	1.72	10^9/L	L	4.3	10.1
			Neutrophils	0.93	10^9/L	L	1.9	7
			Lymphocytes	0.62	10^9/L	L	0.9	5.2
			Monocytes	0.14	10^9/L	L	0.16	1
		2011-03-25T10:23	Calcium	8.42	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	81	U/L	H	10	50
			Aspartate Aminotransferase	92	U/L	H	10	50
			Alkaline Phosphatase	354	U/L	H	40	129
			Lactate Dehydrogenase	348	U/L	H	0	243
			Bilirubin	1.5	mg/dL	H	0	1.19
			Blood Urea Nitrogen	20	mg/dL	H	7	18
			Glucose	128	mg/dL	H	70	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 3	2011-03-25T10:47	Hemoglobin	11.5	g/dL	L	14	18
			Erythrocytes	3.82	10^12/L	L	4.3	5.9
			Platelets	126	10^9/L	L	140	440
			Leukocytes	1.7	10^9/L	L	4.3	10.1
			Neutrophils	1.14	10^9/L	L	1.9	7
			Lymphocytes	0.29	10^9/L	L	0.9	5.2
			Monocytes	0.11	10^9/L	L	0.16	1
	Cycle 4	2011-04-11T10:55	Hemoglobin	13.5	g/dL	L	14	18
			Leukocytes	1.81	10^9/L	L	4.3	10.1
			Neutrophils	1.16	10^9/L	L	1.9	7
			Lymphocytes	0.38	10^9/L	L	0.9	5.2
		2011-04-14T09:49	Calcium	8.58	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	143	U/L	H	10	50
			Aspartate Aminotransferase	167	U/L	H	10	50
			Alkaline Phosphatase	355	U/L	H	40	129
			Lactate Dehydrogenase	378	U/L	H	0	243
			Bilirubin	1.5	mg/dL	H	0	1.19
			Blood Urea Nitrogen	22	mg/dL	H	7	18
		2011-04-15T08:57	Alanine Aminotransferase	143	U/L	H	10	50
			Aspartate Aminotransferase	136	U/L	H	10	50
			Alkaline Phosphatase	356	U/L	H	40	129
			Lactate Dehydrogenase	338	U/L	H	0	243
			Bilirubin	1.5	mg/dL	H	0	1.19

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 4	2011-04-15T09:01	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4.16	10^12/L	L	4.3	5.9
			Platelets	133	10^9/L	L	140	440
			Leukocytes	2.25	10^9/L	L	4.3	10.1
			Neutrophils	1.42	10^9/L	L	1.9	7
			Lymphocytes	0.58	10^9/L	L	0.9	5.2
			Monocytes	0.11	10^9/L	L	0.16	1
	Cycle 5	2011-05-02T11:37	Hemoglobin	12.9	g/dL	L	14	18
			Erythrocytes	4.22	10^12/L	L	4.3	5.9
			Leukocytes	2.19	10^9/L	L	4.3	10.1
			Neutrophils	1.38	10^9/L	L	1.9	7
			Lymphocytes	0.48	10^9/L	L	0.9	5.2
			Monocytes	0.15	10^9/L	L	0.16	1
		2011-05-02T12:48	Alanine Aminotransferase	92	U/L	H	10	50
			Aspartate Aminotransferase	116	U/L	H	10	50
			Alkaline Phosphatase	269	U/L	H	40	129
			Lactate Dehydrogenase	423	U/L	H	0	243
			Bilirubin	1.3	mg/dL	H	0	1.19
			Blood Urea Nitrogen	20	mg/dL	H	7	18
	Cycle 6	2011-05-23T12:06	Alanine Aminotransferase	71	U/L	H	10	50
			Aspartate Aminotransferase	78	U/L	H	10	50
			Alkaline Phosphatase	207	U/L	H	40	129
			Lactate Dehydrogenase	330	U/L	H	0	243
			Blood Urea Nitrogen	25	mg/dL	H	7	18

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 6	2011-05-23T12:31	Hemoglobin	13	g/dL	L	14	18
			Erythrocytes	4.19	10^12/L	L	4.3	5.9
			Leukocytes	2.17	10^9/L	L	4.3	10.1
			Neutrophils	1.46	10^9/L	L	1.9	7
			Lymphocytes	0.35	10^9/L	L	0.9	5.2
		2011-05-27T10:12	Hemoglobin	12.2	g/dL	L	14	18
			Erythrocytes	3.91	10^12/L	L	4.3	5.9
			Platelets	105	10^9/L	L	140	440
			Leukocytes	2.21	10^9/L	L	4.3	10.1
	Cycle 7	2011-06-14T09:01	Aspartate Aminotransferase	51	U/L	H	10	50
			Alkaline Phosphatase	180	U/L	H	40	129
			Blood Urea Nitrogen	24	mg/dL	H	7	18
		2011-06-14T09:07	Hemoglobin	13.5	g/dL	L	14	18
			Erythrocytes	4.23	10^12/L	L	4.3	5.9
			Leukocytes	2.92	10^9/L	L	4.3	10.1
	Cycle 8	2011-07-04T09:04	Hemoglobin	13.6	g/dL	L	14	18
			Erythrocytes	4.2	10^12/L	L	4.3	5.9
			Leukocytes	3.13	10^9/L	L	4.3	10.1
		2011-07-08T08:46	Alanine Aminotransferase	67	U/L	H	10	50
			Aspartate Aminotransferase	51	U/L	H	10	50
			Alkaline Phosphatase	199	U/L	H	40	129
			Blood Urea Nitrogen	21	mg/dL	H	7	18

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 8	2011-07-08T08:56	Hemoglobin	13.3	g/dL	L	14	18
			Erythrocytes	4.07	10^12/L	L	4.3	5.9
			Platelets	95	10^9/L	L	140	440
			Leukocytes	2.84	10^9/L	L	4.3	10.1
			Neutrophils	1.82	10^9/L	L	1.9	7
			Lymphocytes	0.34	10^9/L	L	0.9	5.2
	Cycle 9	2011-07-25T09:40	Hemoglobin	12.7	g/dL	L	14	18
			Erythrocytes	4.04	10^12/L	L	4.3	5.9
			Leukocytes	2.74	10^9/L	L	4.3	10.1
		2011-07-25T09:42	Aspartate Aminotransferase	70	U/L	H	10	50
			Alkaline Phosphatase	263	U/L	H	40	129
			Lactate Dehydrogenase	386	U/L	H	0	243
	Cycle 10	2011-08-16T09:04	Alanine Aminotransferase	375	U/L	H	10	50
			Aspartate Aminotransferase	414	U/L	H	10	50
			Alkaline Phosphatase	309	U/L	H	40	129
			Lactate Dehydrogenase	528	U/L	H	0	243
			Bilirubin	1.8	mg/dL	H	0	1.19
			Blood Urea Nitrogen	22	mg/dL	H	7	18
		2011-08-16T10:01	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4	10^12/L	L	4.3	5.9
			Platelets	126	10^9/L	L	140	440
			Leukocytes	2.09	10^9/L	L	4.3	10.1
			Neutrophils	1.46	10^9/L	L	1.9	7
			Lymphocytes	0.27	10^9/L	L	0.9	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Cycle 10	2011-08-20T08:56	Alanine Aminotransferase	310	U/L	H	10	50
			Aspartate Aminotransferase	224	U/L	H	10	50
			Alkaline Phosphatase	391	U/L	H	40	129
			Lactate Dehydrogenase	346	U/L	H	0	243
			Bilirubin	1.9	mg/dL	H	0	1.19
			Blood Urea Nitrogen	27	mg/dL	H	7	18
		2011-08-20T09:32	Hemoglobin	11.3	g/dL	L	14	18
			Erythrocytes	3.69	10^12/L	L	4.3	5.9
			Platelets	98	10^9/L	L	140	440
			Leukocytes	1.94	10^9/L	L	4.3	10.1
			Neutrophils	1.36	10^9/L	L	1.9	7
			Lymphocytes	0.19	10^9/L	L	0.9	5.2
	Unplanned	2011-09-01T10:16	Hemoglobin	11.6	g/dL	L	14	18
			Erythrocytes	3.8	10^12/L	L	4.3	5.9
			Platelets	72	10^9/L	L	140	440
			Leukocytes	2.16	10^9/L	L	4.3	10.1
		2011-09-02T06:53	Alanine Aminotransferase	1378	U/L	H	10	50
			Aspartate Aminotransferase	1669	U/L	H	10	50
			Alkaline Phosphatase	327	U/L	H	40	129
			Bilirubin	6.8	mg/dL	H	0	1.19
		2011-09-02T09:59	Hemoglobin	12	g/dL	L	14	18
			Erythrocytes	3.87	10^12/L	L	4.3	5.9
			Platelets	75	10^9/L	L	140	440
			Leukocytes	2.07	10^9/L	L	4.3	10.1
			Neutrophils	1.49	10^9/L	L	1.9	7
			Lymphocytes	0.43	10^9/L	L	0.9	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
154-001	Unplanned	2011-09-02T09:59	Monocytes	0.1	10^9/L	L	0.16	1
161-001	Pre-trial	2009-10-02T07:45	Erythrocytes	4.3	10^12/L	L	4.5	6.5
			Platelets	106	10^9/L	L	150	400
			Lymphocytes	0.6	10^9/L	L	1	4
			Monocytes	1.2	10^9/L	H	0.2	1
			Eosinophils	2.1	10^9/L	H	0	0.8
			Activated Partial Thromboplastin Time	48	sec	H	24	36
			Prothrombin Intl. Normalized Ratio	1.68	ratio	H	0.8	1.25
			Creatinine	0.566	mg/dL	L	0.74	1.36
			Albumin	3.2	g/dL	L	3.5	5
			Lactate Dehydrogenase	1522	U/L	H	200	500
			Bilirubin	2.164	mg/dL	H	0.06	0.99
			Blood Urea Nitrogen	21.01	mg/dL	H	7	21
	Cycle 1	2009-10-12T07:45	Hemoglobin	11.7	g/dL	L	13	17
			Erythrocytes	3.6	10^12/L	L	4.5	6.5
			Platelets	53	10^9/L	L	150	400
			Leukocytes	1.8	10^9/L	L	4	10
			Neutrophils	1.1	10^9/L	L	1.5	7.5
			Lymphocytes	0.3	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	41	sec	H	24	36
			Prothrombin Intl. Normalized Ratio	1.63	ratio	H	0.8	1.25
			Calcium	8.38	mg/dL	L	9	10.6
			Phosphate	2.6	mg/dL	L	2.7	4.6

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
161-001	Cycle 1	2009-10-12T07:45	Creatinine	0.452	mg/dL	L	0.74	1.36
			Albumin	3.3	g/dL	L	3.5	5
			Lactate Dehydrogenase	759	U/L	H	200	500
			Bilirubin	1.52	mg/dL	H	0.06	0.99
			Blood Urea Nitrogen	22.13	mg/dL	H	7	21
			Glucose	198.2	mg/dL	H	70	104
		2009-10-16T09:45	Hemoglobin	9.5	g/dL	L	13	17
			Erythrocytes	2.9	10^12/L	L	4.5	6.5
			Platelets	52	10^9/L	L	150	400
			Leukocytes	3	10^9/L	L	4	10
			Lymphocytes	0.5	10^9/L	L	1	4
			Calcium	7.82	mg/dL	L	9	10.6
			Creatinine	0.701	mg/dL	L	0.74	1.36
			Albumin	3.1	g/dL	L	3.5	5
			Alkaline Phosphatase	157	U/L	H	40	129
			Lactate Dehydrogenase	544	U/L	H	200	500
			Bilirubin	1.17	mg/dL	H	0.06	0.99
			Blood Urea Nitrogen	29.69	mg/dL	H	7	21
			Glucose	187.4	mg/dL	H	70	104
		2009-10-23T07:30	Hemoglobin	9.1	g/dL	L	13	17
			Erythrocytes	2.8	10^12/L	L	4.5	6.5
			Platelets	60	10^9/L	L	150	400
			Leukocytes	2.3	10^9/L	L	4	10
			Neutrophils	1.4	10^9/L	L	1.5	7.5
			Lymphocytes	0.2	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
161-001	Cycle 1	2009-10-26	Sodium	135	mmol/L	L	136	146
			Calcium	8.38	mg/dL	L	9	10.6
			Phosphate	2.48	mg/dL	L	2.7	4.6
			Albumin	3.4	g/dL	L	3.5	5
			Alkaline Phosphatase	161	U/L	H	40	129
			Lactate Dehydrogenase	879	U/L	H	200	500
			Bilirubin	1.462	mg/dL	H	0.06	0.99
			Blood Urea Nitrogen	24.93	mg/dL	H	7	21
			Glucose	109.9	mg/dL	H	70	104
	Cycle 2	2009-11-02T07:00	Hemoglobin	10.4	g/dL	L	13	17
			Erythrocytes	3.2	10^12/L	L	4.5	6.5
			Platelets	73	10^9/L	L	150	400
			Lymphocytes	0.4	10^9/L	L	1	4
			Monocytes	1.2	10^9/L	H	0.2	1
			Calcium	8.46	mg/dL	L	9	10.6
			Creatinine	1.584	mg/dL	H	0.74	1.36
			Alkaline Phosphatase	168	U/L	H	40	129
			Lactate Dehydrogenase	751	U/L	H	200	500
			Blood Urea Nitrogen	55.74	mg/dL	H	7	21
			Glucose	272	mg/dL	H	70	104
		2009-11-02T11:30	Activated Partial Thromboplastin Time	44	sec	H	24	36
			Prothrombin Intl. Normalized Ratio	1.54	ratio	H	0.8	1.25

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
161-001	Cycle 2	2009-11-06T07:00	Hemoglobin	8.7	g/dL	L	13	17
			Erythrocytes	2.8	10^12/L	L	4.5	6.5
			Platelets	52	10^9/L	L	150	400
			Leukocytes	1.7	10^9/L	L	4	10
			Neutrophils	1.2	10^9/L	L	1.5	7.5
			Lymphocytes	0.1	10^9/L	L	1	4
			Sodium	133	mmol/L	L	136	146
			Calcium	7.37	mg/dL	L	9	10.6
			Creatinine	1.991	mg/dL	H	0.74	1.36
			Albumin	3.3	g/dL	L	3.5	5
			Aspartate Aminotransferase	6	U/L	L	8	45
			Blood Urea Nitrogen	63.87	mg/dL	H	7	21
			Glucose	279.2	mg/dL	H	70	104
	Cycle 3	2009-11-30T09:30	Hemoglobin	10.7	g/dL	L	13	17
			Erythrocytes	3.4	10^12/L	L	4.5	6.5
			Platelets	79	10^9/L	L	150	400
			Neutrophils	0.9	10^9/L	L	1.5	7.5
			Lymphocytes	0.3	10^9/L	L	1	4
			Eosinophils	2	10^9/L	H	0	0.8
			Activated Partial Thromboplastin Time	45	sec	H	24	36
			Prothrombin Intl. Normalized Ratio	1.52	ratio	H	0.8	1.25
			Sodium	133	mmol/L	L	136	146
			Potassium	5.8	mmol/L	H	3.5	5.1
			Calcium	8.06	mg/dL	L	9	10.6
			Chloride	107	mmol/L	H	98	106

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
161-001	Cycle 3	2009-11-30T09:30	Creatinine	1.787	mg/dL	H	0.74	1.36
			Albumin	3.4	g/dL	L	3.5	5
			Alkaline Phosphatase	149	U/L	H	40	129
			Lactate Dehydrogenase	741	U/L	H	200	500
			Blood Urea Nitrogen	43.42	mg/dL	H	7	21
			Glucose	117.1	mg/dL	H	70	104
	End Trial	2010-01-08T07:00	Hemoglobin	9.6	g/dL	L	13	17
			Erythrocytes	3.2	10^12/L	L	4.5	6.5
			Platelets	31	10^9/L	L	150	400
			Leukocytes	1.9	10^9/L	L	4	10
			Lymphocytes	0.1	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	44	sec	H	24	36
			Prothrombin Intl. Normalized Ratio	1.44	ratio	H	0.8	1.25
			Calcium	7.58	mg/dL	L	9	10.6
			Chloride	107	mmol/L	H	98	106
			Phosphate	1.95	mg/dL	L	2.7	4.6
			Albumin	3.1	g/dL	L	3.5	5
			Blood Urea Nitrogen	35.57	mg/dL	H	7	21
			Urate	2.98	mg/dL	L	3.4	7.1
162-001	Pre-trial	2009-11-30T06:00	Hemoglobin	14.82	g/dL	H	11.9	14.5
			Erythrocytes	2.75	10^12/L	L	4.1	5.3
			Ery. Mean Corpuscular Volume	98.5	fL	H	80	95
			Lymphocytes	0.3	10^9/L	L	1.4	4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
162-001	Cycle 1	2009-12-07T08:02	Hemoglobin	16.92	g/dL	H	11.9	14.5
			Erythrocytes	3.05	10^12/L	L	4.1	5.3
			Ery. Mean Corpuscular Volume	98.7	fL	H	80	95
			Lymphocytes	0.7	10^9/L	L	1.4	4
		2009-12-11T06:30	Hemoglobin	10.5	g/dL	L	13.8	16.1
			Erythrocytes	3.21	10^12/L	L	4.1	5.3
			Ery. Mean Corpuscular Volume	96	fL	H	80	95
			Lymphocytes	0.6	10^9/L	L	1.4	4
		2009-12-17	Hemoglobin	11.4	g/dL	L	11.5	16.5
			Erythrocytes	3.58	10^12/L	L	4	5
			Lymphocytes	0.431	10^9/L	L	1.5	4
	Cycle 2	2009-12-28	Hemoglobin	16.11	g/dL	H	11.9	14.5
			Erythrocytes	3.09	10^12/L	L	4.1	5.3
			Ery. Mean Corpuscular Volume	96.8	fL	H	80	95
			Lymphocytes	0.6	10^9/L	L	1.4	4
			Alanine Aminotransferase	7	U/L	L	10	31
		2010-01-07	Lymphocytes	1.023	10^9/L	L	1.5	4
			Monocytes	1.023	10^9/L	H	0	1
	End Trial	2010-01-18T08:30	Hemoglobin	18.37	g/dL	H	11.9	14.5
			Erythrocytes	3.67	10^12/L	L	4.1	5.3
			Ery. Mean Corpuscular Volume	95.1	fL	H	80	95
			Lymphocytes	0.3	10^9/L	L	1.4	4
			Monocytes	1.2	10^9/L	H	0.2	0.95
			Alanine Aminotransferase	8	U/L	L	10	31
			Glucose	116	mg/dL	H	70	104

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
162-002	Pre-trial	2009-12-15T18:00	Hemoglobin	10.6	g/dL	L	13.8	16.1
			Erythrocytes	3.4	10^12/L	L	4.3	5.7
			Ery. Mean Corpuscular Volume	96.2	fL	H	80	95
			Platelets	102	10^9/L	L	150	400
			Lymphocytes	0.9	10^9/L	L	1.4	4
			Eosinophils	0	10^9/L	L	0.1	0.7
			Lactate Dehydrogenase	678	U/L	H	200	480
			Bilirubin	0.175	mg/dL	L	0.18	1.29
			Blood Urea Nitrogen	25.21	mg/dL	H	7.8	22.4
			Glucose	243.7	mg/dL	H	70	104
	Cycle 1	2009-12-18T06:05	Hemoglobin	10.6	g/dL	L	13.8	16.1
			Erythrocytes	3.48	10^12/L	L	4.3	5.7
			Platelets	74	10^9/L	L	150	400
			Leukocytes	3.2	10^9/L	L	4	10
			Neutrophils	1.4	10^9/L	L	1.83	7.25
			Lymphocytes	1.1	10^9/L	L	1.4	4
			Prothrombin Time	10.92	sec	L	11	13
			Calcium	8.3	mg/dL	L	8.6	10.2
			Lactate Dehydrogenase	515	U/L	H	200	480
		2009-12-22T06:00	Hemoglobin	10.3	g/dL	L	13.8	16.1
			Erythrocytes	3.31	10^12/L	L	4.3	5.7
			Platelets	63	10^9/L	L	150	400
			Leukocytes	3.1	10^9/L	L	4	10
			Lymphocytes	0.7	10^9/L	L	1.4	4
			Eosinophils	0	10^9/L	L	0.1	0.7
			Calcium	8.14	mg/dL	L	8.6	10.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
162-002	Cycle 1	2009-12-22T06:00	Chloride	107	mmol/L	H	98	106
			Urate	2.29	mg/dL	L	3.4	7.1
			Glucose	146.1	mg/dL	H	70	104
		2010-01-06T06:00	Hemoglobin	11.6	g/dL	L	13.8	16.1
			Erythrocytes	3.73	10^12/L	L	4.3	5.7
			Platelets	76	10^9/L	L	150	400
			Leukocytes	1	10^9/L	L	4	10
			Neutrophils	0.1	10^9/L	L	1.83	7.25
			Lymphocytes	0.6	10^9/L	L	1.4	4
			Eosinophils	0	10^9/L	L	0.1	0.7
	Cycle 2	2010-01-12T06:00	Hemoglobin	10.1	g/dL	L	13.8	16.1
			Erythrocytes	3.34	10^12/L	L	4.3	5.7
			Platelets	58	10^9/L	L	150	400
			Leukocytes	2.6	10^9/L	L	4	10
			Neutrophils	1.3	10^9/L	L	1.83	7.25
			Lymphocytes	0.8	10^9/L	L	1.4	4
			Urate	2.3	mg/dL	L	3.4	7.1
		2010-01-15T06:00	Hemoglobin	10.1	g/dL	L	13.8	16.1
			Erythrocytes	3.3	10^12/L	L	4.3	5.7
			Platelets	65	10^9/L	L	150	400
			Leukocytes	3	10^9/L	L	4	10
			Lymphocytes	0.8	10^9/L	L	1.4	4
			Calcium	8.5	mg/dL	L	8.6	10.2
			Blood Urea Nitrogen	23.53	mg/dL	H	7.8	22.4
			Urate	2.19	mg/dL	L	3.4	7.1
			Glucose	227.7	mg/dL	H	70	104

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
162-002	End Trial	2010-02-03T06:00	Hemoglobin	9.2	g/dL	L	13.8	16.1
			Erythrocytes	3.08	10^12/L	L	4.3	5.7
			Platelets	112	10^9/L	L	150	400
			Lymphocytes	0.2	10^9/L	L	1.4	4
			Eosinophils	0	10^9/L	L	0.1	0.7
			Lactate Dehydrogenase	593	U/L	H	200	480
			Bilirubin	0.175	mg/dL	L	0.18	1.29
			Urate	2.59	mg/dL	L	3.4	7.1
			Glucose	195.1	mg/dL	H	70	104
165-001	Pre-trial	2011-05-12T09:43	Hemoglobin	11.1	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	4.2	5.4
			Leukocytes	12.93	10^9/L	H	4.8	10.8
			Neutrophils	9.051	10^9/L	H	2	7.5
			Phosphate	4.8	mg/dL	H	2.5	4.7
			Magnesium	1.4	mg/dL	L	1.6	2.3
			Aspartate Aminotransferase	60	U/L	H	8	34
			Lactate Dehydrogenase	3478	U/L	H	100	240
	Cycle 1	2011-05-16T09:45	Erythrocytes	3.94	10^12/L	L	4.2	5.4
			Leukocytes	33.84	10^9/L	H	4.8	10.8
			Neutrophils	26.734	10^9/L	H	2	7.5
			Monocytes	3.384	10^9/L	H	0.2	1
			Calcium	13.2	mg/dL	H	8.4	10.2
			Magnesium	1.3	mg/dL	L	1.6	2.3
			Creatinine	1.2	mg/dL	H	0.4	1
			Alanine Aminotransferase	58	U/L	H	7	35

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
165-001	Cycle 1	2011-05-16T09:45	Aspartate Aminotransferase	102	U/L	H	8	34
			Alkaline Phosphatase	153	U/L	H	25	100
			Lactate Dehydrogenase	5475	U/L	H	100	240
		2011-05-20T08:45	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.28	10^12/L	L	4.2	5.4
			Platelets	137	10^9/L	L	140	440
			Leukocytes	17.02	10^9/L	H	4.8	10.8
			Neutrophils	10.382	10^9/L	H	2	7.5
			Lymphocytes	4.595	10^9/L	H	1	4
			Monocytes	1.532	10^9/L	H	0.2	1
			Chloride	109	mmol/L	H	98	107
			Aspartate Aminotransferase	35	U/L	H	8	34
			Lactate Dehydrogenase	3368	U/L	H	100	240
			Glucose	118	mg/dL	H	70	100
		2011-05-26T09:30	Hemoglobin	10.6	g/dL	L	12	16
			Erythrocytes	3.53	10^12/L	L	4.2	5.4
			Leukocytes	43.15	10^9/L	H	4.8	10.8
			Neutrophils	20.712	10^9/L	H	2	7.5
			Monocytes	2.158	10^9/L	H	0.2	1
			Calcium	10.7	mg/dL	H	8.4	10.2
			Aspartate Aminotransferase	85	U/L	H	8	34
			Lactate Dehydrogenase	4004	U/L	H	100	240

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
165-001	End Trial	2011-06-01T09:50	Hemoglobin	11.4	g/dL	L	12	16
			Erythrocytes	3.75	10^12/L	L	4.2	5.4
			Leukocytes	25.52	10^9/L	H	4.8	10.8
			Neutrophils	17.098	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	20.7	sec	L	23.3	35.7
			Sodium	132	mmol/L	L	135	144
			Calcium	13.5	mg/dL	H	8.4	10.2
			Chloride	92	mmol/L	L	98	107
			Magnesium	1.3	mg/dL	L	1.6	2.3
			Aspartate Aminotransferase	50	U/L	H	8	34
			Lactate Dehydrogenase	4096	U/L	H	100	240
			Blood Urea Nitrogen	29	mg/dL	H	8	20
			Glucose	106	mg/dL	H	70	100
180-001	Pre-trial	2009-09-21T08:00	Activated Partial Thromboplastin Time	0.7	sec	L	23	36.5
		2009-09-29T08:00	Leukocytes	10.3	10^9/L	H	4	10
			Neutrophils	8.53	10^9/L	H	1.8	7
			Lymphocytes	0.9	10^9/L	L	1	4.5
			Alanine Aminotransferase	76	U/L	H	0	40.99
			Lactate Dehydrogenase	852	U/L	H	230	480
			Blood Urea Nitrogen	55	mg/dL	H	15	50
			Urate	2.5	mg/dL	L	3.4	7
			Glucose	181	mg/dL	H	60	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-001	Cycle 1	2009-10-12T08:00	Erythrocytes	4.06	10^12/L	L	4.2	5.9
			Leukocytes	11.3	10^9/L	H	4	10
			Neutrophils	8.98	10^9/L	H	1.8	7
			Monocytes	1.08	10^9/L	H	0.12	1
		2009-10-16T08:00	Erythrocytes	4.02	10^12/L	L	4.2	5.9
		2009-10-16T10:00	Alanine Aminotransferase	97	U/L	H	0	40.99
			Lactate Dehydrogenase	753	U/L	H	230	480
			Urate	1.9	mg/dL	L	3.4	7
		2009-10-23T08:00	Erythrocytes	4.14	10^12/L	L	4.2	5.9
		2009-10-23T10:00	Potassium	3.4	mmol/L	L	3.5	5.3
			Alanine Aminotransferase	53	U/L	H	0	40.99
			Lactate Dehydrogenase	639	U/L	H	230	480
			Urate	1.6	mg/dL	L	3.4	7
			Glucose	132	mg/dL	H	60	110
	Cycle 2	2009-11-02T10:00	Alanine Aminotransferase	68	U/L	H	0	40.99
			Lactate Dehydrogenase	643	U/L	H	230	480
			Urate	2.3	mg/dL	L	3.4	7
			Glucose	122	mg/dL	H	60	110
		2009-11-02T11:13	Erythrocytes	3.96	10^12/L	L	4.2	5.9
		2009-11-06T06:00	Alanine Aminotransferase	51	U/L	H	0	40.99
			Lactate Dehydrogenase	615	U/L	H	230	480
			Urate	2.5	mg/dL	L	3.4	7
		2009-11-06T11:50	Erythrocytes	4.18	10^12/L	L	4.2	5.9
			Lymphocytes	0.88	10^9/L	L	1	4.5

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-001	Cycle 3	2009-11-23T10:00	Lactate Dehydrogenase	797	U/L	H	230	480
			Urate	2.9	mg/dL	L	3.4	7
		2009-11-23T10:23	Erythrocytes	4.19	10^12/L	L	4.2	5.9
		2009-11-27T09:30	Erythrocytes	4.04	10^12/L	L	4.2	5.9
		2009-11-27T10:00	Urate	3	mg/dL	L	3.4	7
	End Trial	2009-11-27T09:30	Erythrocytes	4.04	10^12/L	L	4.2	5.9
		2009-11-27T10:00	Urate	3	mg/dL	L	3.4	7
180-002	Pre-trial	2009-11-05T11:07	Prothrombin Time	10.83	sec	L	11	13
			Activated Partial Thromboplastin Time	0.89	sec	L	23	36.5
			Alanine Aminotransferase	87	U/L	H	0	40.99
			Aspartate Aminotransferase	43	U/L	H	0	37.99
			Lactate Dehydrogenase	727	U/L	H	230	480
			Bilirubin	1.14	mg/dL	H	0.2	1.1
			Blood Urea Nitrogen	52	mg/dL	H	15	50
			Urate	3.2	mg/dL	L	3.4	7
			Glucose	116	mg/dL	H	60	110
		2009-11-05T11:27	Hemoglobin	12.4	g/dL	L	12.5	18
			Platelets	71	10^9/L	L	130	400
			Lymphocytes	0.23	10^9/L	L	1	4.5
			Eosinophils	0	10^9/L	L	0.004	0.3
			Basophils	0	10^9/L	L	0.004	0.15

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-002	Cycle 1	2009-11-09T08:00	Prothrombin Time	10.83	sec	L	11	13
			Activated Partial Thromboplastin Time	0.9	sec	L	23	36.5
			Alanine Aminotransferase	70	U/L	H	0	40.999
			Aspartate Aminotransferase	42	U/L	H	0	37.999
			Alkaline Phosphatase	284	U/L	H	98	280
			Lactate Dehydrogenase	968	U/L	H	230	480
			Bilirubin	1.32	mg/dL	H	0.2	1.1
			Blood Urea Nitrogen	53	mg/dL	H	15	50
			Urate	3	mg/dL	L	3.4	7
		2009-11-09T10:13	Platelets	59	10^9/L	L	130	400
			Leukocytes	3.3	10^9/L	L	4	10
			Lymphocytes	0.28	10^9/L	L	1	4.5
			Eosinophils	0	10^9/L	L	0.004	0.3
			Basophils	0	10^9/L	L	0.004	0.15
		2009-11-13T10:00	Alanine Aminotransferase	43	U/L	H	0	40.999
			Lactate Dehydrogenase	833	U/L	H	230	480
			Urate	2.9	mg/dL	L	3.4	7
			Glucose	189	mg/dL	H	60	110
		2009-11-13T10:44	Hemoglobin	10.5	g/dL	L	12.5	18
			Erythrocytes	3.57	10^12/L	L	4.2	5.9
			Platelets	44	10^9/L	L	130	400
			Leukocytes	3.3	10^9/L	L	4	10
			Lymphocytes	0.18	10^9/L	L	1	4.5
			Basophils	0	10^9/L	L	0.004	0.15

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-002	Cycle 1	2009-11-20T06:30	Hemoglobin	10.4	g/dL	L	13.5	17.5
			Erythrocytes	3.55	10^12/L	L	4.5	6
			Platelets	43	10^9/L	L	150	400
			Leukocytes	1.45	10^9/L	L	4	9
			Neutrophils	1.31	10^9/L	L	1.5	6.5
			Lymphocytes	0.05	10^9/L	L	1	3.5
			Monocytes	0.09	10^9/L	L	0.2	0.8
			Eosinophils	0	10^9/L	L	0.03	0.5
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	132	mmol/L	L	135	145
			Creatinine	0.51	mg/dL	L	0.6	1.3
			Alanine Aminotransferase	44	U/L	H	8	40
			Urate	2.1	mg/dL	L	3.4	7
			Glucose	281	mg/dL	H	70	109
	Cycle 2	2009-11-30T08:00	Sodium	134	mmol/L	L	135	146
			Alanine Aminotransferase	58	U/L	H	0	40.999
			Aspartate Aminotransferase	46	U/L	H	0	37.999
			Alkaline Phosphatase	312	U/L	H	98	280
			Lactate Dehydrogenase	1801	U/L	H	230	480
			Bilirubin	1.61	mg/dL	H	0.2	1.1
			Blood Urea Nitrogen	67	mg/dL	H	15	50
			Glucose	198	mg/dL	H	60	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-002	Cycle 2	2009-11-30T10:49	Hemoglobin	12	g/dL	L	12.5	18
			Erythrocytes	4.11	10^12/L	L	4.2	5.9
			Platelets	50	10^9/L	L	130	400
			Leukocytes	2.9	10^9/L	L	4	10
			Lymphocytes	0.05	10^9/L	L	1	4.5
			Eosinophils	0	10^9/L	L	0.004	0.3
			Basophils	0	10^9/L	L	0.004	0.15
		2009-12-04T09:29	Hemoglobin	10.7	g/dL	L	12.5	18
			Erythrocytes	3.63	10^12/L	L	4.2	5.9
			Platelets	57	10^9/L	L	130	400
			Leukocytes	2.5	10^9/L	L	4	10
		2009-12-04T10:00	Sodium	130	mmol/L	L	135	146
			Potassium	3.4	mmol/L	L	3.5	5.3
			Calcium	8.2	mg/dL	L	8.5	10.5
			Aspartate Aminotransferase	39	U/L	H	0	37.999
			Alkaline Phosphatase	287	U/L	H	98	280
			Lactate Dehydrogenase	1487	U/L	H	230	480
			Blood Urea Nitrogen	54	mg/dL	H	15	50
			Glucose	154	mg/dL	H	60	110
180-003	Pre-trial	2010-02-15T09:13	Hemoglobin	12.1	g/dL	L	12.5	18
			Erythrocytes	3.95	10^12/L	L	4.2	5.9

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-003	Pre-trial	2010-02-15T10:00	Prothrombin Time	10.83	sec	L	11	13
			Activated Partial Thromboplastin Time	0.73	sec	L	23	36.5
			Chloride	95	mmol/L	L	98	110
			Lactate Dehydrogenase	516	U/L	H	230	480
			Blood Urea Nitrogen	61	mg/dL	H	15	50
			Urate	3	mg/dL	L	3.4	7
	Cycle 1	2010-03-01T12:00	Potassium	3.3	mmol/L	L	3.5	5.3
			Calcium	7.5	mg/dL	L	8.5	10.5
			Urate	3.1	mg/dL	L	3.4	7
			Glucose	172	mg/dL	H	60	110
		2010-03-01T13:13	Hemoglobin	10.3	g/dL	L	12.5	18
			Erythrocytes	3.58	10^12/L	L	4.2	5.9
			Platelets	80	10^9/L	L	130	400
			Leukocytes	2.1	10^9/L	L	4	10
			Neutrophils	1.43	10^9/L	L	1.8	7
			Lymphocytes	0.19	10^9/L	L	1	4.5
		2010-03-05T09:55	Hemoglobin	10.7	g/dL	L	12.5	18
			Erythrocytes	3.53	10^12/L	L	4.2	5.9
			Platelets	70	10^9/L	L	130	400
			Leukocytes	2.6	10^9/L	L	4	10
			Neutrophils	1.59	10^9/L	L	1.8	7
			Lymphocytes	0.42	10^9/L	L	1	4.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-003	Cycle 1	2010-03-05T10:00	Albumin	2.82	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	547	U/L	H	230	480
			Urate	2.5	mg/dL	L	3.4	7
			Glucose	129	mg/dL	H	60	110
		2010-03-15	Hemoglobin	9.5	g/dL	L	13.5	17.5
			Erythrocytes	3.34	10^12/L	L	4.5	6
			Platelets	96	10^9/L	L	150	400
			Lymphocytes	0.74	10^9/L	L	1	3.5
			Calcium	8.4	mg/dL	L	8.5	10.5
			Albumin	3.2	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	590	U/L	H	230	480
			Glucose	119	mg/dL	H	60	110
	Cycle 2	2010-03-29T10:00	Blood Urea Nitrogen	52	mg/dL	H	15	50
		2010-03-29T10:24	Hemoglobin	10.8	g/dL	L	12.5	18
			Erythrocytes	3.56	10^12/L	L	4.2	5.9
			Platelets	126	10^9/L	L	130	400
			Lymphocytes	0.5	10^9/L	L	1	4.5
			Eosinophils	0.42	10^9/L	H	0.004	0.3
		2010-04-02T09:22	Hemoglobin	10.4	g/dL	L	12.5	18
			Erythrocytes	3.38	10^12/L	L	4.2	5.9
			Platelets	115	10^9/L	L	130	400
			Lymphocytes	0.51	10^9/L	L	1	4.5
			Basophils	0	10^9/L	L	0.004	0.15
		2010-04-02T10:00	Lactate Dehydrogenase	515	U/L	H	230	480
			Urate	3	mg/dL	L	3.4	7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
180-003	End Trial	2010-04-22T10:00	Lactate Dehydrogenase	550	U/L	H	230	480
			Blood Urea Nitrogen	52	mg/dL	H	15	50
		2010-04-22T10:16	Hemoglobin	11.1	g/dL	L	12.5	18
			Erythrocytes	3.47	10^12/L	L	4.2	5.9
			Platelets	106	10^9/L	L	130	400
			Leukocytes	2.8	10^9/L	L	4	10
			Lymphocytes	0.31	10^9/L	L	1	4.5
206-001	Pre-trial	2010-02-05	Hemoglobin	10.8	g/dL	L	12.6	16.6
			Erythrocytes	3.61	10^12/L	L	4.1	5.7
			Lymphocytes	0.6	10^9/L	L	1.1	3.4
			Eosinophils	0.06	10^9/L	L	0.07	0.5
			Prothrombin Time	10.62	sec	L	11	13
			Activated Partial Thromboplastin Time	36.3	sec	H	24	36
			Calcium	8.66	mg/dL	L	8.8	10.2
			Albumin	3	g/dL	L	3.3	5
			Lactate Dehydrogenase	366	U/L	H	0	204
	Cycle 1	2010-02-08	Hemoglobin	10.3	g/dL	L	12.6	16.6
			Erythrocytes	3.48	10^12/L	L	4.1	5.7
			Platelets	133	10^9/L	L	135	333
			Lymphocytes	0.8	10^9/L	L	1.1	3.4
			Eosinophils	0.06	10^9/L	L	0.07	0.5
			Calcium	8.7	mg/dL	L	8.8	10.2
			Albumin	3	g/dL	L	3.3	5
			Lactate Dehydrogenase	318	U/L	H	0	204

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
206-001	Cycle 1	2010-02-08	Glucose	133.3	mg/dL	H	74	124
		2010-02-12	Hemoglobin	9.6	g/dL	L	12.6	16.6
			Erythrocytes	3.2	10^12/L	L	4.1	5.7
			Platelets	130	10^9/L	L	135	333
			Lymphocytes	0.3	10^9/L	L	1.1	3.4
			Calcium	7.94	mg/dL	L	8.8	10.2
			Albumin	2.9	g/dL	L	3.3	5
			Lactate Dehydrogenase	282	U/L	H	0	204
			Blood Urea Nitrogen	28.01	mg/dL	H	10.1	24.1
			Glucose	162.1	mg/dL	H	74	124
	Unplanned	2010-02-17	Hemoglobin	9.5	g/dL	L	12.6	16.6
			Erythrocytes	3.12	10^12/L	L	4.1	5.7
			Platelets	120	10^9/L	L	135	333
			Lymphocytes	0.9	10^9/L	L	1.1	3.4
			Eosinophils	0.04	10^9/L	L	0.07	0.5
207-001	Pre-trial	2010-06-22	Hemoglobin	9.3	g/dL	L	12.2	16.1
			Erythrocytes	3.01	10^12/L	L	3.9	5.1
			Lymphocytes	0.467	10^9/L	L	1	4
		2010-06-28	Activated Partial Thromboplastin Time	23.3	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.96	ratio	L	1	1.2
			Calcium	8.3	mg/dL	L	8.7	10.6
			Alkaline Phosphatase	215	U/L	H	65	195
			Lactate Dehydrogenase	379	U/L	H	140	310
			Blood Urea Nitrogen	47	mg/dL	H	12	44

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Pre-trial	2010-08-22	Albumin	3.6	g/dL	L	4	5.2
	Cycle 1	2010-06-28	Activated Partial Thromboplastin Time	23.3	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.96	ratio	L	1	1.2
		2010-06-29	Hemoglobin	9.59	g/dL	L	12.2	16.1
			Erythrocytes	3.13	10^12/L	L	3.9	5.1
			Lymphocytes	0.757	10^9/L	L	1	4
			Eosinophils	0.683	10^9/L	H	0	0.5
			Calcium	8.6	mg/dL	L	8.7	10.6
			Albumin	3.3	g/dL	L	4	5.2
			Alkaline Phosphatase	222	U/L	H	65	195
			Glucose	108	mg/dL	H	74	105
		2010-07-04	Hemoglobin	9	g/dL	L	12.2	16.1
			Erythrocytes	3.06	10^12/L	L	3.9	5.1
			Lymphocytes	0.303	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.6	4.9
			Calcium	8.4	mg/dL	L	8.7	10.6
			Albumin	3.4	g/dL	L	4	5.2
		2010-07-12	Hemoglobin	9.3	g/dL	L	12.2	16.1
			Lactate Dehydrogenase	464	U/L	H	140	310
			Blood Urea Nitrogen	52	mg/dL	H	12	44

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 2	2010-07-20	Hemoglobin	8	g/dL	L	12.2	16.1
			Erythrocytes	2.52	10^12/L	L	3.9	5.1
			Leukocytes	3	10^9/L	L	4	10
			Neutrophils	1.77	10^9/L	L	2	7.5
			Lymphocytes	0.471	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	0.96	ratio	L	1	1.2
			Albumin	3.1	g/dL	L	4	5.2
		2010-07-23	Hemoglobin	8.4	g/dL	L	12.2	16.1
			Erythrocytes	2.68	10^12/L	L	3.9	5.1
			Leukocytes	3.6	10^9/L	L	4	10
			Lymphocytes	0.439	10^9/L	L	1	4
			Urate	1.4	mg/dL	L	2.4	6.2
		2010-07-24	Calcium	8.5	mg/dL	L	8.7	10.6
			Albumin	3.4	g/dL	L	4	5.2
			Blood Urea Nitrogen	11	mg/dL	L	12	44
			Glucose	165	mg/dL	H	74	105
	Cycle 3	2010-08-30	Hemoglobin	9.4	g/dL	L	12.2	16.1
			Erythrocytes	2.94	10^12/L	L	3.9	5.1
			Leukocytes	2.5	10^9/L	L	4	10
			Neutrophils	0.98	10^9/L	L	2	7.5
			Lymphocytes	0.825	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	0.96	ratio	L	1	1.2
			Calcium	8.5	mg/dL	L	8.7	10.6
			Magnesium	1.47	mg/dL	L	1.55	2.5
			Albumin	3.1	g/dL	L	4	5.2
			Glucose	108	mg/dL	H	74	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 3	2010-09-03	Hemoglobin	9.1	g/dL	L	12.2	16.1
			Erythrocytes	2.83	10^12/L	L	3.9	5.1
			Leukocytes	3.3	10^9/L	L	4	10
			Lymphocytes	0.571	10^9/L	L	1	4
			Albumin	3.4	g/dL	L	4	5.2
			Alkaline Phosphatase	223	U/L	H	65	195
			Glucose	116	mg/dL	H	74	105
	Cycle 4	2010-09-22	Hemoglobin	8.8	g/dL	L	12.2	16.1
			Erythrocytes	2.67	10^12/L	L	3.9	5.1
			Leukocytes	2.6	10^9/L	L	4	10
			Neutrophils	1.199	10^9/L	L	2	7.5
			Lymphocytes	0.853	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	0.83	ratio	L	1	1.2
			Albumin	3.3	g/dL	L	4	5.2
		2010-09-26	Hemoglobin	8.8	g/dL	L	12.2	16.1
			Erythrocytes	2.78	10^12/L	L	3.9	5.1
			Leukocytes	3.23	10^9/L	L	4	10
			Lymphocytes	0.562	10^9/L	L	1	4
			Calcium	8.6	mg/dL	L	8.7	10.6
			Albumin	3.4	g/dL	L	4	5.2
			Alkaline Phosphatase	200	U/L	H	65	195
			Glucose	120	mg/dL	H	74	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 5	2010-10-18	Hemoglobin	10.3	g/dL	L	12.2	16.1
			Erythrocytes	3.03	10^12/L	L	3.9	5.1
			Leukocytes	2.8	10^9/L	L	4	10
			Neutrophils	1.002	10^9/L	L	2	7.5
			Prothrombin Intl. Normalized Ratio	0.92	ratio	L	1	1.2
			Albumin	3.8	g/dL	L	4	5.2
		2010-10-22	Hemoglobin	10.1	g/dL	L	12.2	16.1
			Erythrocytes	2.88	10^12/L	L	3.9	5.1
			Lymphocytes	0.664	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.6	4.9
			Albumin	3.6	g/dL	L	4	5.2
			Alkaline Phosphatase	253	U/L	H	65	195
			Glucose	108	mg/dL	H	74	105
	Cycle 6	2010-11-08	Activated Partial Thromboplastin Time	23.7	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.96	ratio	L	1	1.2
		2010-11-11	Hemoglobin	9.2	g/dL	L	12.2	16.1
			Erythrocytes	2.61	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.9	fL	H	81	101
			Leukocytes	2.8	10^9/L	L	4	10
			Neutrophils	1.308	10^9/L	L	2	7.5
			Lymphocytes	0.874	10^9/L	L	1	4
			Albumin	3.3	g/dL	L	4	5.2
		2010-11-14	Albumin	3.5	g/dL	L	4	5.2
			Alkaline Phosphatase	224	U/L	H	65	195

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 6	2010-11-15	Hemoglobin	8.6	g/dL	L	12.2	16.1
			Erythrocytes	2.46	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.5	fL	H	81	101
			Platelets	124	10^9/L	L	138	381
			Leukocytes	3.8	10^9/L	L	4	10
			Lymphocytes	0.726	10^9/L	L	1	4
	Cycle 7	2010-12-02	Albumin	3.9	g/dL	L	4	5.2
			Alkaline Phosphatase	200	U/L	H	65	195
			Blood Urea Nitrogen	63	mg/dL	H	12	44
		2010-12-03	Hemoglobin	9.8	g/dL	L	12.2	16.1
			Erythrocytes	2.77	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	102.2	fL	H	81	101
			Leukocytes	2.9	10^9/L	L	4	10
			Neutrophils	1.343	10^9/L	L	2	7.5
			Lymphocytes	0.89	10^9/L	L	1	4
			Prothrombin Time	10.1	sec	L	10.3	15
			Activated Partial Thromboplastin Time	23.9	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.9	ratio	L	1	1.2
		2010-12-07	Hemoglobin	9.2	g/dL	L	12.2	16.1
			Erythrocytes	2.58	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	102.6	fL	H	81	101
			Platelets	123	10^9/L	L	138	381
			Leukocytes	3.4	10^9/L	L	4	10
			Neutrophils	1.941	10^9/L	L	2	7.5
			Lymphocytes	0.663	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 7	2010-12-07	Albumin	3.4	g/dL	L	4	5.2
			Alkaline Phosphatase	210	U/L	H	65	195
	Cycle 8	2011-01-03	Hemoglobin	9.2	g/dL	L	12.2	16.1
			Erythrocytes	2.67	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.1	fL	H	81	101
			Leukocytes	3.1	10^9/L	L	4	10
			Neutrophils	1.435	10^9/L	L	2	7.5
			Lymphocytes	0.781	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	20.6	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.95	ratio	L	1	1.2
			Albumin	3.6	g/dL	L	4	5.2
			Glucose	68	mg/dL	L	74	105
		2011-01-07	Hemoglobin	10.4	g/dL	L	12.2	16.1
			Erythrocytes	3.01	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.3	fL	H	81	101
			Lymphocytes	0.88	10^9/L	L	1	4
			Monocytes	0.075	10^9/L	L	0.2	1
			Chloride	101	mmol/L	L	102	115
			Alanine Aminotransferase	28	U/L	H	0	22
			Alkaline Phosphatase	246	U/L	H	65	195
			Glucose	130	mg/dL	H	74	105

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 9	2011-01-24	Hemoglobin	9.8	g/dL	L	12.2	16.1
			Erythrocytes	2.8	10^12/L	L	3.9	5.1
			Leukocytes	3.2	10^9/L	L	4	10
			Neutrophils	1.405	10^9/L	L	2	7.5
			Lymphocytes	0.966	10^9/L	L	1	4
			Prothrombin Time	10	sec	L	10.3	15
			Prothrombin Intl. Normalized Ratio	0.9	ratio	L	1	1.2
			Albumin	3.5	g/dL	L	4	5.2
		2011-01-28	Hemoglobin	9.6	g/dL	L	12.2	16.1
			Erythrocytes	2.8	10^12/L	L	3.9	5.1
			Leukocytes	3.9	10^9/L	L	4	10
			Albumin	3.7	g/dL	L	4	5.2
	Cycle 10	2011-02-14	Hemoglobin	9	g/dL	L	12.2	16.1
			Erythrocytes	2.61	10^12/L	L	3.9	5.1
			Leukocytes	2.7	10^9/L	L	4	10
			Neutrophils	1.258	10^9/L	L	2	7.5
			Lymphocytes	0.818	10^9/L	L	1	4
			Prothrombin Time	10.2	sec	L	10.3	15
			Prothrombin Intl. Normalized Ratio	0.91	ratio	L	1	1.2
			Calcium	8.6	mg/dL	L	8.7	10.6
			Albumin	3.3	g/dL	L	4	5.2
		2011-02-18	Hemoglobin	9.3	g/dL	L	12.2	16.1
			Erythrocytes	2.68	10^12/L	L	3.9	5.1
			Platelets	135	10^9/L	L	138	381
			Leukocytes	3.5	10^9/L	L	4	10
			Neutrophils	1.834	10^9/L	L	2	7.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 10	2011-02-18	Albumin	3.8	g/dL	L	4	5.2
			Alanine Aminotransferase	24	U/L	H	0	22
	Cycle 11	2011-03-14	Hemoglobin	9	g/dL	L	12.2	16.1
			Erythrocytes	2.69	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.9	fL	H	81	101
			Platelets	137	10^9/L	L	138	381
			Leukocytes	3.7	10^9/L	L	4	10
			Neutrophils	1.695	10^9/L	L	2	7.5
			Prothrombin Time	9.6	sec	L	10.3	15
			Activated Partial Thromboplastin Time	23.6	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.86	ratio	L	1	1.2
			Albumin	3.4	g/dL	L	4	5.2
			Blood Urea Nitrogen	58	mg/dL	H	12	44
		2011-03-18	Hemoglobin	8.8	g/dL	L	12.2	16.1
			Erythrocytes	2.61	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.6	fL	H	81	101
			Leukocytes	3.8	10^9/L	L	4	10
			Albumin	3.6	g/dL	L	4	5.2
			Glucose	110	mg/dL	H	74	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 12	2011-04-15	Hemoglobin	9.1	g/dL	L	12.2	16.1
			Erythrocytes	2.75	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.2	fL	H	81	101
			Lymphocytes	0.884	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	23.9	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.92	ratio	L	1	1.2
			Albumin	3.3	g/dL	L	4	5.2
		2011-04-19	Hemoglobin	8.5	g/dL	L	12.2	16.1
			Erythrocytes	2.55	10^12/L	L	3.9	5.1
			Platelets	132	10^9/L	L	138	381
			Albumin	3.6	g/dL	L	4	5.2
			Glucose	113	mg/dL	H	74	105
	Cycle 13	2011-05-06	Hemoglobin	8.7	g/dL	L	12.2	16.1
			Erythrocytes	2.62	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	102.1	fL	H	81	101
			Leukocytes	3.2	10^9/L	L	4	10
			Neutrophils	1.706	10^9/L	L	2	7.5
			Lymphocytes	0.803	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	0.92	ratio	L	1	1.2
			Albumin	3.4	g/dL	L	4	5.2
		2011-05-10	Hemoglobin	8.9	g/dL	L	12.2	16.1
			Erythrocytes	2.69	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.4	fL	H	81	101
			Albumin	3.7	g/dL	L	4	5.2

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 14	2011-05-27	Hemoglobin	8.4	g/dL	L	12.2	16.1
			Erythrocytes	2.52	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.1	fL	H	81	101
			Leukocytes	3.4	10^9/L	L	4	10
			Neutrophils	1.741	10^9/L	L	2	7.5
			Lymphocytes	0.887	10^9/L	L	1	4
			Prothrombin Time	9.7	sec	L	10.3	15
			Prothrombin Intl. Normalized Ratio	0.87	ratio	L	1	1.2
			Albumin	3.6	g/dL	L	4	5.2
		2011-05-31	Hemoglobin	9.8	g/dL	L	12.2	16.1
			Erythrocytes	2.96	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.4	fL	H	81	101
			Neutrophils	1.961	10^9/L	L	2	7.5
			Alanine Aminotransferase	38	U/L	H	0	22
			Lactate Dehydrogenase	567	U/L	H	140	310
	Cycle 15	2011-06-21	Hemoglobin	8	g/dL	L	12.2	16.1
			Erythrocytes	2.4	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.5	fL	H	81	101
			Platelets	124	10^9/L	L	138	381
			Leukocytes	2.4	10^9/L	L	4	10
			Neutrophils	0.826	10^9/L	L	2	7.5
			Lymphocytes	0.744	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	23.7	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.97	ratio	L	1	1.2
			Calcium	8.6	mg/dL	L	8.7	10.6

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 15	2011-06-21	Albumin	3.8	g/dL	L	4	5.2
		2011-06-25	Hemoglobin	8.4	g/dL	L	12.2	16.1
			Erythrocytes	2.66	10^12/L	L	3.9	5.1
			Leukocytes	3.03	10^9/L	L	4	10
			Neutrophils	1.63	10^9/L	L	2	7.5
			Lymphocytes	0.933	10^9/L	L	1	4
			Albumin	3.8	g/dL	L	4	5.2
			Alanine Aminotransferase	32	U/L	H	0	22
			Alkaline Phosphatase	213	U/L	H	65	195
			Glucose	111	mg/dL	H	74	105
	Cycle 16	2011-07-12	Hemoglobin	7.8	g/dL	L	12.2	16.1
			Erythrocytes	2.34	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.5	fL	H	81	101
			Leukocytes	2.8	10^9/L	L	4	10
			Neutrophils	1.456	10^9/L	L	2	7.5
			Lymphocytes	0.661	10^9/L	L	1	4
			Prothrombin Time	10	sec	L	10.3	15
			Activated Partial Thromboplastin Time	23.2	sec	L	24	38
			Prothrombin Intl. Normalized Ratio	0.9	ratio	L	1	1.2
			Calcium	8.5	mg/dL	L	8.7	10.6
			Albumin	3.5	g/dL	L	4	5.2
			Glucose	122	mg/dL	H	74	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 17	2011-08-05	Hemoglobin	9.4	g/dL	L	12.2	16.1
			Erythrocytes	2.94	10^12/L	L	3.9	5.1
			Leukocytes	3.4	10^9/L	L	4	10
			Neutrophils	1.598	10^9/L	L	2	7.5
			Lymphocytes	0.83	10^9/L	L	1	4
			Calcium	8.6	mg/dL	L	8.7	10.6
			Albumin	3.7	g/dL	L	4	5.2
		2011-08-09	Hemoglobin	10	g/dL	L	12.2	16.1
			Erythrocytes	3.09	10^12/L	L	3.9	5.1
			Lymphocytes	0.964	10^9/L	L	1	4
			Albumin	3.7	g/dL	L	4	5.2
			Alanine Aminotransferase	26	U/L	H	0	22
	Cycle 18	2011-08-26	Hemoglobin	9.7	g/dL	L	12.2	16.1
			Erythrocytes	3.01	10^12/L	L	3.9	5.1
			Leukocytes	3.4	10^9/L	L	4	10
			Neutrophils	1.724	10^9/L	L	2	7.5
			Lymphocytes	0.979	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	0.93	ratio	L	1	1.2
			Albumin	3.6	g/dL	L	4	5.2
		2011-08-30	Hemoglobin	8.1	g/dL	L	12.2	16.1
			Erythrocytes	2.48	10^12/L	L	3.9	5.1
			Leukocytes	3.4	10^9/L	L	4	10
			Neutrophils	1.89	10^9/L	L	2	7.5
			Lymphocytes	0.962	10^9/L	L	1	4
			Calcium	8.5	mg/dL	L	8.7	10.6
			Albumin	3.8	g/dL	L	4	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
207-001	Cycle 18	2011-08-30	Alanine Aminotransferase	33	U/L	H	0	22
	Cycle 19	2011-09-17	Hemoglobin	9	g/dL	L	12.2	16.1
			Erythrocytes	2.81	10^12/L	L	3.9	5.1
			Leukocytes	3.63	10^9/L	L	4	10
			Neutrophils	1.793	10^9/L	L	2	7.5
			Lymphocytes	0.969	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	0.95	ratio	L	1	1.2
			Albumin	3.3	g/dL	L	4	5.2
		2011-09-21	Hemoglobin	8.5	g/dL	L	12.2	16.1
			Erythrocytes	2.57	10^12/L	L	3.9	5.1
			Phosphate	2.4	mg/dL	L	2.7	5
			Albumin	3.9	g/dL	L	4	5.2
			Alanine Aminotransferase	25	U/L	H	0	22
			Lactate Dehydrogenase	346	U/L	H	140	310
	End Trial	2011-10-14	Hemoglobin	9.3	g/dL	L	12.2	16.1
			Erythrocytes	2.79	10^12/L	L	3.9	5.1
			Ery. Mean Corpuscular Volume	101.1	fL	H	81	101
			Leukocytes	3.4	10^9/L	L	4	10
			Neutrophils	1.142	10^9/L	L	2	7.5
			Prothrombin Time	10	sec	L	10.3	15
			Albumin	3.6	g/dL	L	4	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-001	Pre-trial	2009-12-24T13:00	Hemoglobin	12.57	g/dL	L	14	17.1
			Leukocytes	11.7	10^9/L	H	4	10
			Neutrophils	9.71	10^9/L	H	2	7.5
			Prothrombin Time	14.1	sec	H	9	12
			Sodium	132	mmol/L	L	135	145
			Calcium	7.94	mg/dL	L	8.8	10.4
			Albumin	2.6	g/dL	L	3.5	5
			Aspartate Aminotransferase	40	U/L	H	0	39.99
			Alkaline Phosphatase	505	U/L	H	0	119.99
			Lactate Dehydrogenase	1147	U/L	H	0	249.99
			Bilirubin	0.994	mg/dL	H	0	0.99
			Urate	3.19	mg/dL	L	3.4	7.6
	Cycle 1	2009-12-28T07:00	Hemoglobin	10.8	g/dL	L	14	17.1
			Leukocytes	10.4	10^9/L	H	4	10
			Neutrophils	7.88	10^9/L	H	2	7.5
			Sodium	133	mmol/L	L	135	145
			Calcium	7.54	mg/dL	L	8.8	10.4
			Albumin	2.6	g/dL	L	3.5	5
			Alkaline Phosphatase	351	U/L	H	0	119.99
			Lactate Dehydrogenase	672	U/L	H	0	249.99
		2010-01-01T07:00	Hemoglobin	10.63	g/dL	L	14	17.1
			Leukocytes	11.3	10^9/L	H	4	10
			Calcium	8.14	mg/dL	L	8.8	10.4
			Albumin	3.1	g/dL	L	3.5	5
			Alkaline Phosphatase	283	U/L	H	0	119.99
			Lactate Dehydrogenase	488	U/L	H	0	249.99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-001	Cycle 1	2010-01-01T07:00	Urate	2.69	mg/dL	L	3.4	7.6
		2010-01-11T07:00	Hemoglobin	10.15	g/dL	L	14	17.1
			Platelets	97	10^9/L	L	150	350
			Monocytes	0.183	10^9/L	L	0.3	0.9
			Sodium	123	mmol/L	L	135	145
			Calcium	6.97	mg/dL	L	8.8	10.4
			Phosphate	1.95	mg/dL	L	2.5	4.6
			Albumin	2.5	g/dL	L	3.5	5
			Alkaline Phosphatase	393	U/L	H	0	119.99
			Lactate Dehydrogenase	877	U/L	H	0	249.99
			Glucose	108.1	mg/dL	H	72	99
	End Trial	2010-01-11T07:00	Hemoglobin	10.15	g/dL	L	14	17.1
			Platelets	97	10^9/L	L	150	350
			Monocytes	0.183	10^9/L	L	0.3	0.9
			Sodium	123	mmol/L	L	135	145
			Calcium	6.97	mg/dL	L	8.8	10.4
			Phosphate	1.95	mg/dL	L	2.5	4.6
			Albumin	2.5	g/dL	L	3.5	5
			Alkaline Phosphatase	393	U/L	H	0	119.99
			Lactate Dehydrogenase	877	U/L	H	0	249.99
			Glucose	108.1	mg/dL	H	72	99
220-002	Pre-trial	2010-08-26T08:28	Monocytes	0.28	10^9/L	L	0.3	0.9
			Glucose	216.2	mg/dL	H	72	99

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 1	2010-09-06T10:11	Activated Partial Thromboplastin Time	39	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.9	ratio	H	0.8	1.3
			Phosphate	2.14	mg/dL	L	2.5	4.6
			Glucose	203.6	mg/dL	H	72	99
		2010-09-10T07:00	Hemoglobin	12.73	g/dL	L	14	17.1
			Erythrocytes	4.43	10^12/L	L	4.6	6.2
			Leukocytes	11.4	10^9/L	H	4	10
			Neutrophils	10.1	10^9/L	H	2	7.5
			Lymphocytes	0.78	10^9/L	L	0.8	3.2
			Alanine Aminotransferase	104	U/L	H	0	44.99
			Bilirubin	1.053	mg/dL	H	0	0.99
			Blood Urea Nitrogen	25.21	mg/dL	H	7	21
			Glucose	322.5	mg/dL	H	72	99
		2010-09-16T11:57	Platelets	127	10^9/L	L	150	350
			Leukocytes	14.7	10^9/L	H	4	10
			Neutrophils	12.02	10^9/L	H	2	7.5
			Monocytes	0.97	10^9/L	H	0.3	0.9
			Glucose	189.2	mg/dL	H	72	99
	Cycle 2	2010-09-27T12:20	Hemoglobin	13.7	g/dL	L	14	17.1
			Leukocytes	10.8	10^9/L	H	4	10
			Neutrophils	9.06	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	35	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.8	1.3
			Potassium	5.1	mmol/L	H	3.5	5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 2	2010-09-27T12:20	Blood Urea Nitrogen	23.81	mg/dL	H	7	21
			Glucose	380.1	mg/dL	H	72	99
		2010-10-01T09:45	Hemoglobin	12.25	g/dL	L	14	17.1
			Erythrocytes	4.22	10^12/L	L	4.6	6.2
			Lymphocytes	0.76	10^9/L	L	0.8	3.2
			Bilirubin	0.994	mg/dL	H	0	0.99
			Blood Urea Nitrogen	24.93	mg/dL	H	7	21
	Cycle 3	2010-10-18T11:05	Hemoglobin	11.76	g/dL	L	14	17.1
			Erythrocytes	4.19	10^12/L	L	4.6	6.2
			Neutrophils	8.58	10^9/L	H	2	7.5
			Monocytes	4.8	10^9/L	H	0.3	0.9
			Eosinophils	0.7	10^9/L	H	0	0.39
			Basophils	0.5	10^9/L	H	0	0.199
			Prothrombin Intl. Normalized Ratio	2.1	ratio	H	0.8	1.3
			Potassium	5.2	mmol/L	H	3.5	5
			Phosphate	2.42	mg/dL	L	2.5	4.6
			Magnesium	1.65	mg/dL	L	1.7	2.4
			Glucose	136.9	mg/dL	H	72	99
		2010-10-22T09:57	Hemoglobin	10.31	g/dL	L	14	17.1
			Erythrocytes	3.59	10^12/L	L	4.6	6.2
			Lymphocytes	0.64	10^9/L	L	0.8	3.2
			Monocytes	0.28	10^9/L	L	0.3	0.9
			Glucose	178.3	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 4	2010-11-08T10:59	Hemoglobin	12.25	g/dL	L	14	17.1
			Erythrocytes	4.39	10^12/L	L	4.6	6.2
			Prothrombin Intl. Normalized Ratio	2	ratio	H	0.8	1.3
			Glucose	140.5	mg/dL	H	72	99
		2010-11-12T10:01	Hemoglobin	10.96	g/dL	L	14	17.1
			Erythrocytes	3.86	10^12/L	L	4.6	6.2
			Lymphocytes	0.71	10^9/L	L	0.8	3.2
			Monocytes	0.24	10^9/L	L	0.3	0.9
			Chloride	109	mmol/L	H	97	107
			Bilirubin	1.111	mg/dL	H	0	0.99
			Blood Urea Nitrogen	21.29	mg/dL	H	7	21
			Glucose	156.7	mg/dL	H	72	99
	Cycle 5	2010-11-29T10:49	Hemoglobin	13.21	g/dL	L	14	17.1
			Erythrocytes	4.52	10^12/L	L	4.6	6.2
			Neutrophils	8.26	10^9/L	H	2	7.5
		2010-11-29T10:56	Prothrombin Intl. Normalized Ratio	2	ratio	H	0.8	1.3
			Glucose	126.1	mg/dL	H	72	99
	Cycle 6	2010-12-20T10:49	Hemoglobin	13.54	g/dL	L	14	17.1
			Neutrophils	8.05	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	36	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.8	1.3
			Potassium	5.1	mmol/L	H	3.5	5
			Glucose	163.9	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 6	2010-12-24T08:23	Hemoglobin	11.92	g/dL	L	14	17.1
			Erythrocytes	4.12	10^12/L	L	4.6	6.2
			Lymphocytes	0.65	10^9/L	L	0.8	3.2
			Monocytes	0.24	10^9/L	L	0.3	0.9
			Chloride	108	mmol/L	H	97	107
			Blood Urea Nitrogen	22.69	mg/dL	H	7	21
			Glucose	162.1	mg/dL	H	72	99
	Cycle 7	2011-01-10T10:31	Hemoglobin	13.21	g/dL	L	14	17.1
			Erythrocytes	4.53	10^12/L	L	4.6	6.2
			Glucose	126.1	mg/dL	H	72	99
		2011-01-14T10:28	Hemoglobin	11.76	g/dL	L	14	17.1
			Erythrocytes	4.1	10^12/L	L	4.6	6.2
			Platelets	140	10^9/L	L	150	350
			Leukocytes	11.1	10^9/L	H	4	10
			Neutrophils	10.21	10^9/L	H	2	7.5
			Lymphocytes	0.41	10^9/L	L	0.8	3.2
			Calcium	8.7	mg/dL	L	8.8	10.4
			Magnesium	1.68	mg/dL	L	1.7	2.4
			Alanine Aminotransferase	45	U/L	H	0	44.99
			Glucose	257.6	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 8	2011-01-31T11:07	Hemoglobin	13.37	g/dL	L	14	17.1
			Leukocytes	10.4	10^9/L	H	4	10
			Neutrophils	8.85	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	36	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.5	ratio	H	0.8	1.3
			Potassium	5.1	mmol/L	H	3.5	5
			Glucose	131.5	mg/dL	H	72	99
		2011-02-04T09:00	Hemoglobin	11.76	g/dL	L	14	17.1
			Erythrocytes	4.13	10^12/L	L	4.6	6.2
			Lymphocytes	0.52	10^9/L	L	0.8	3.2
			Monocytes	0.18	10^9/L	L	0.3	0.9
			Bilirubin	0.994	mg/dL	H	0	0.99
			Glucose	207.2	mg/dL	H	72	99
	Cycle 9	2011-02-21T10:47	Hemoglobin	13.54	g/dL	L	14	17.1
			Neutrophils	8.31	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	35	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.2	ratio	H	0.8	1.3
			Magnesium	1.63	mg/dL	L	1.7	2.4
			Glucose	122.5	mg/dL	H	72	99
		2011-02-25T08:42	Hemoglobin	11.76	g/dL	L	14	17.1
			Erythrocytes	4.2	10^12/L	L	4.6	6.2
			Platelets	133	10^9/L	L	150	350
			Lymphocytes	0.66	10^9/L	L	0.8	3.2
			Monocytes	0.26	10^9/L	L	0.3	0.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 9	2011-02-25T08:42	Calcium	8.66	mg/dL	L	8.8	10.4
			Bilirubin	1.053	mg/dL	H	0	0.99
			Blood Urea Nitrogen	21.29	mg/dL	H	7	21
			Glucose	232.4	mg/dL	H	72	99
	Cycle 10	2011-04-04T11:15	Hemoglobin	11.44	g/dL	L	14	17.1
			Erythrocytes	4.04	10^12/L	L	4.6	6.2
			Neutrophils	7.51	10^9/L	H	2	7.5
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.8	1.3
			Glucose	136.9	mg/dL	H	72	99
		2011-04-08T09:48	Hemoglobin	10.31	g/dL	L	14	17.1
			Erythrocytes	3.71	10^12/L	L	4.6	6.2
			Lymphocytes	0.53	10^9/L	L	0.8	3.2
			Albumin	3.4	g/dL	L	3.5	5
			Blood Urea Nitrogen	21.01	mg/dL	H	7	21
			Glucose	246.8	mg/dL	H	72	99
	Cycle 11	2011-05-16T10:46	Hemoglobin	13.05	g/dL	L	14	17.1
			Erythrocytes	4.59	10^12/L	L	4.6	6.2
			Neutrophils	7.59	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	36	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.5	ratio	H	0.8	1.3
			Alanine Aminotransferase	47	U/L	H	0	44.99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 11	2011-05-20T10:45	Hemoglobin	11.28	g/dL	L	14	17.1
			Erythrocytes	3.96	10^12/L	L	4.6	6.2
			Lymphocytes	0.64	10^9/L	L	0.8	3.2
			Glucose	189.2	mg/dL	H	72	99
	Cycle 12	2011-06-27T11:42	Prothrombin Intl. Normalized Ratio	1.6	ratio	H	0.8	1.3
			Blood Urea Nitrogen	22.41	mg/dL	H	7	21
		2011-07-01T08:38	Hemoglobin	11.76	g/dL	L	14	17.1
			Erythrocytes	4.21	10^12/L	L	4.6	6.2
			Platelets	136	10^9/L	L	150	350
			Lymphocytes	0.68	10^9/L	L	0.8	3.2
			Blood Urea Nitrogen	21.01	mg/dL	H	7	21
			Glucose	201.8	mg/dL	H	72	99
	Cycle 13	2011-08-08T11:24	Hemoglobin	13.37	g/dL	L	14	17.1
			Activated Partial Thromboplastin Time	36	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.5	ratio	H	0.8	1.3
			Phosphate	2.38	mg/dL	L	2.5	4.6
		2011-08-12T08:43	Hemoglobin	11.6	g/dL	L	14	17.1
			Erythrocytes	4.16	10^12/L	L	4.6	6.2
			Lymphocytes	0.64	10^9/L	L	0.8	3.2
			Monocytes	0.27	10^9/L	L	0.3	0.9
			Calcium	8.78	mg/dL	L	8.8	10.4
			Magnesium	1.65	mg/dL	L	1.7	2.4
			Glucose	187.4	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 14	2011-09-19T11:45	Hemoglobin	13.54	g/dL	L	14	17.1
			Activated Partial Thromboplastin Time	36	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.8	ratio	H	0.8	1.3
			Blood Urea Nitrogen	22.69	mg/dL	H	7	21
		2011-09-23T08:35	Hemoglobin	11.6	g/dL	L	14	17.1
			Erythrocytes	4.33	10^12/L	L	4.6	6.2
			Platelets	140	10^9/L	L	150	350
			Lymphocytes	0.63	10^9/L	L	0.8	3.2
			Monocytes	0.27	10^9/L	L	0.3	0.9
			Bilirubin	0.994	mg/dL	H	0	0.99
			Glucose	205.4	mg/dL	H	72	99
	Cycle 15	2011-10-31T11:41	Hemoglobin	13.37	g/dL	L	14	17.1
			Leukocytes	10.4	10^9/L	H	4	10
			Neutrophils	8.37	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	35	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.8	1.3
			Phosphate	2.07	mg/dL	L	2.5	4.6
		2011-11-04T09:00	Hemoglobin	12.09	g/dL	L	14	17.1
			Erythrocytes	4.26	10^12/L	L	4.6	6.2
			Monocytes	0.28	10^9/L	L	0.3	0.9
			Blood Urea Nitrogen	24.37	mg/dL	H	7	21
			Glucose	185.6	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 16	2011-12-12T13:28	Activated Partial Thromboplastin Time	36	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.8	1.3
			Glucose	192.8	mg/dL	H	72	99
		2011-12-16T08:28	Hemoglobin	12.41	g/dL	L	14	17.1
			Erythrocytes	4.47	10^12/L	L	4.6	6.2
			Platelets	139	10^9/L	L	150	350
			Lymphocytes	0.54	10^9/L	L	0.8	3.2
			Monocytes	0.29	10^9/L	L	0.3	0.9
			Blood Urea Nitrogen	23.53	mg/dL	H	7	21
			Glucose	191	mg/dL	H	72	99
	Cycle 17	2012-01-23T10:53	Hemoglobin	13.7	g/dL	L	14	17.1
			Activated Partial Thromboplastin Time	34	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.2	ratio	H	0.8	1.3
			Phosphate	2.32	mg/dL	L	2.5	4.6
			Alanine Aminotransferase	56	U/L	H	0	44.99
			Aspartate Aminotransferase	40	U/L	H	0	39.99
			Glucose	127.9	mg/dL	H	72	99
		2012-01-27T08:39	Hemoglobin	11.92	g/dL	L	14	17.1
			Erythrocytes	4.3	10^12/L	L	4.6	6.2
			Lymphocytes	0.69	10^9/L	L	0.8	3.2
			Calcium	8.7	mg/dL	L	8.8	10.4
			Blood Urea Nitrogen	24.37	mg/dL	H	7	21
			Glucose	172.9	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 18	2012-03-05T10:55	Hemoglobin	13.54	g/dL	L	14	17.1
			Neutrophils	7.77	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	35	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.3	ratio	H	0.8	1.3
			Phosphate	2.32	mg/dL	L	2.5	4.6
			Glucose	124.3	mg/dL	H	72	99
		2012-03-09T10:54	Hemoglobin	11.76	g/dL	L	14	17.1
			Erythrocytes	4.1	10^12/L	L	4.6	6.2
			Magnesium	1.68	mg/dL	L	1.7	2.4
	Cycle 19	2012-04-16T12:19	Hemoglobin	13.86	g/dL	L	14	17.1
			Activated Partial Thromboplastin Time	37	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.6	ratio	H	0.8	1.3
			Phosphate	2.35	mg/dL	L	2.5	4.6
		2012-04-20T09:15	Hemoglobin	12.09	g/dL	L	14	17.1
			Erythrocytes	4.31	10^12/L	L	4.6	6.2
			Lymphocytes	0.78	10^9/L	L	0.8	3.2
			Monocytes	0.29	10^9/L	L	0.3	0.9
			Calcium	8.78	mg/dL	L	8.8	10.4
			Glucose	176.5	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 20	2012-05-28T12:16	Hemoglobin	13.54	g/dL	L	14	17.1
			Chloride	109	mmol/L	H	97	107
			Phosphate	2.45	mg/dL	L	2.5	4.6
			Blood Urea Nitrogen	22.13	mg/dL	H	7	21
			Glucose	115.3	mg/dL	H	72	99
		2012-06-01T09:27	Hemoglobin	11.92	g/dL	L	14	17.1
			Erythrocytes	4.34	10^12/L	L	4.6	6.2
			Platelets	142	10^9/L	L	150	350
			Neutrophils	8.3	10^9/L	H	2	7.5
			Lymphocytes	0.45	10^9/L	L	0.8	3.2
			Monocytes	0.28	10^9/L	L	0.3	0.9
			Calcium	8.74	mg/dL	L	8.8	10.4
			Alanine Aminotransferase	76	U/L	H	0	44.99
			Glucose	230.6	mg/dL	H	72	99
	Cycle 21	2012-07-09T11:38	Neutrophils	7.75	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	37	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.8	1.2
			Potassium	5.1	mmol/L	H	3.5	5
			Phosphate	2.35	mg/dL	L	2.5	4.6
		2012-07-13T09:15	Hemoglobin	11.92	g/dL	L	14	17.1
			Erythrocytes	4.22	10^12/L	L	4.6	6.2
			Lymphocytes	0.68	10^9/L	L	0.8	3.2
			Glucose	172.9	mg/dL	H	72	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
220-002	Cycle 22	2012-08-20T10:51	Leukocytes	10.4	10^9/L	H	4	10
			Neutrophils	8.61	10^9/L	H	2	7.5
			Prothrombin Intl. Normalized Ratio	2.1	ratio	H	0.8	1.25
			Chloride	108	mmol/L	H	97	107
			Phosphate	2.26	mg/dL	L	2.5	4.6
			Glucose	102.7	mg/dL	H	72	99
		2012-08-24T09:00	Hemoglobin	11.6	g/dL	L	14	17.1
			Erythrocytes	4.15	10^12/L	L	4.6	6.2
			Platelets	136	10^9/L	L	150	350
			Lymphocytes	0.7	10^9/L	L	0.8	3.2
			Monocytes	0.22	10^9/L	L	0.3	0.9
			Calcium	8.78	mg/dL	L	8.8	10.4
			Magnesium	1.63	mg/dL	L	1.7	2.4
			Glucose	171.1	mg/dL	H	72	99
221-001	Pre-trial	2009-09-25T10:49	Lactate Dehydrogenase	258	U/L	H	0	249.99
	Cycle 1	2009-10-05T11:32	Platelets	143	10^9/L	L	150	400
			Leukocytes	3.8	10^9/L	L	4	10
		2009-10-09T12:11	Platelets	120	10^9/L	L	150	400
			Bilirubin	1.462	mg/dL	H	0	1.17
		2009-10-19T11:06	Leukocytes	3.7	10^9/L	L	4	10
			Lactate Dehydrogenase	291	U/L	H	0	249.99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-001	Cycle 2	2009-10-26T12:07	Hemoglobin	13.05	g/dL	L	13.7	17.7
			Platelets	137	10^9/L	L	150	400
			Lymphocytes	0.96	10^9/L	L	1	3.5
			Sodium	147	mmol/L	H	136	146
			Calcium	8.62	mg/dL	L	8.8	10.4
			Phosphate	2.48	mg/dL	L	2.5	4.3
		2009-10-30T14:02	Hemoglobin	11.92	g/dL	L	13.7	17.7
			Erythrocytes	4.2	10^12/L	L	4.5	5.5
			Platelets	89	10^9/L	L	150	400
			Calcium	8.74	mg/dL	L	8.8	10.4
			Lactate Dehydrogenase	391	U/L	H	0	249.99
	Unplanned	2009-10-12T13:47	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Platelets	146	10^9/L	L	150	400
			Lactate Dehydrogenase	253	U/L	H	0	249.99
		2009-11-04T08:47	Platelets	99	10^9/L	L	150	400
			Leukocytes	3.1	10^9/L	L	4	10
			Lymphocytes	0.66	10^9/L	L	1	3.5
			Lactate Dehydrogenase	555	U/L	H	0	249.99
			Blood Urea Nitrogen	21.85	mg/dL	H	8.4	21
	End Trial	2009-11-11T12:30	Platelets	109	10^9/L	L	150	400
			Leukocytes	3.7	10^9/L	L	4	10
			Lymphocytes	0.96	10^9/L	L	1	3.5
			Aspartate Aminotransferase	38	U/L	H	0	34.99
			Lactate Dehydrogenase	1245	U/L	H	0	249.99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-003	Pre-trial	2010-12-15T09:16	Neutrophils	7.59	10^9/L	H	1.5	7.5
			Monocytes	1.09	10^9/L	H	0.1	1
			Phosphate	2.07	mg/dL	L	2.5	4.3
			Creatinine	1.335	mg/dL	H	0.72	1.18
	Cycle 1	2010-12-20T10:09	Phosphate	2.2	mg/dL	L	2.5	4.3
		2010-12-20T10:56	Erythrocytes	4.2	10^12/L	L	4.5	5.5
		2010-12-24T10:56	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Erythrocytes	4.1	10^12/L	L	4.5	5.5
			Lymphocytes	0.96	10^9/L	L	1	3.5
		2011-01-03T16:28	Erythrocytes	4	10^12/L	L	4.5	5.5
	Cycle 2	2011-01-10T14:32	Erythrocytes	4.2	10^12/L	L	4.5	5.5
			Creatinine	1.222	mg/dL	H	0.72	1.18
		2011-01-14T11:52	Erythrocytes	4.3	10^12/L	L	4.5	5.5
			Lymphocytes	0.87	10^9/L	L	1	3.5
	Cycle 3	2011-01-31T11:44	Erythrocytes	4.2	10^12/L	L	4.5	5.5
			Calcium	8.74	mg/dL	L	8.8	10.4
		2011-02-04T10:58	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Erythrocytes	4	10^12/L	L	4.5	5.5
			Lymphocytes	0.83	10^9/L	L	1	3.5
			Creatinine	1.21	mg/dL	H	0.72	1.18
	Cycle 4	2011-02-21T11:38	Erythrocytes	4.4	10^12/L	L	4.5	5.5
			Phosphate	2.45	mg/dL	L	2.5	4.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-003	Cycle 4	2011-02-25T11:01	Erythrocytes	4.1	10^12/L	L	4.5	5.5
			Platelets	148	10^9/L	L	150	400
			Lymphocytes	0.8	10^9/L	L	1	3.5
			Creatinine	1.29	mg/dL	H	0.72	1.18
	Cycle 5	2011-03-14T11:31	Erythrocytes	4.2	10^12/L	L	4.5	5.5
			Calcium	8.7	mg/dL	L	8.8	10.4
			Chloride	109	mmol/L	H	98	108
		2011-03-18T11:27	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Erythrocytes	4	10^12/L	L	4.5	5.5
			Leukocytes	3.6	10^9/L	L	4	10
			Lymphocytes	0.69	10^9/L	L	1	3.5
			Creatinine	1.199	mg/dL	H	0.72	1.18
	Cycle 6	2011-04-04T10:59	Erythrocytes	4.1	10^12/L	L	4.5	5.5
			Phosphate	1.77	mg/dL	L	2.5	4.3
		2011-04-08T11:14	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Erythrocytes	4	10^12/L	L	4.5	5.5
			Lymphocytes	0.96	10^9/L	L	1	3.5
			Calcium	8.78	mg/dL	L	8.8	10.4
			Creatinine	1.199	mg/dL	H	0.72	1.18
	Cycle 7	2011-04-21T10:14	Leukocytes	10.8	10^9/L	H	4	10
			Neutrophils	8.5	10^9/L	H	1.5	7.5
			Phosphate	2.2	mg/dL	L	2.5	4.6
			Creatinine	1.414	mg/dL	H	0.68	1.24

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-003	Cycle 7	2011-04-29T10:53	Hemoglobin	13.37	g/dL	L	13.7	17.7
			Erythrocytes	3.8	10^12/L	L	4.5	5.5
			Lymphocytes	0.9	10^9/L	L	1	3.5
			Creatinine	1.29	mg/dL	H	0.72	1.18
	Cycle 8	2011-05-16T10:58	Erythrocytes	4	10^12/L	L	4.5	5.5
			Phosphate	1.7	mg/dL	L	2.5	4.3
		2011-05-20T11:23	Hemoglobin	13.21	g/dL	L	13.7	17.7
			Erythrocytes	4	10^12/L	L	4.5	5.5
			Lymphocytes	0.94	10^9/L	L	1	3.5
			Creatinine	1.21	mg/dL	H	0.72	1.18
	Cycle 9	2011-06-06T11:05	Erythrocytes	3.9	10^12/L	L	4.5	5.5
			Chloride	109	mmol/L	H	98	108
			Phosphate	1.42	mg/dL	L	2.5	4.3
		2011-06-10T11:21	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Erythrocytes	3.8	10^12/L	L	4.5	5.5
			Creatinine	1.29	mg/dL	H	0.72	1.18
	Cycle 10	2011-06-27T12:01	Erythrocytes	4.1	10^12/L	L	4.5	5.5
			Lymphocytes	0.9	10^9/L	L	1	3.5
			Phosphate	1.98	mg/dL	L	2.5	4.3
		2011-07-01T11:21	Hemoglobin	12.41	g/dL	L	13.7	17.7
			Erythrocytes	3.8	10^12/L	L	4.5	5.5
			Chloride	109	mmol/L	H	98	108
			Creatinine	1.324	mg/dL	H	0.72	1.18

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-003	Cycle 11	2011-07-18T10:35	Erythrocytes	4	10^12/L	L	4.5	5.5
			Chloride	109	mmol/L	H	98	108
			Phosphate	1.95	mg/dL	L	2.5	4.3
			Creatinine	1.188	mg/dL	H	0.72	1.18
		2011-07-22T10:33	Erythrocytes	3.9	10^12/L	L	4.5	5.5
			Lymphocytes	0.9	10^9/L	L	1	3.5
			Creatinine	1.278	mg/dL	H	0.72	1.18
	Unplanned	2011-03-16T10:46	Lymphocytes	0.65	10^9/L	L	1	3.5
	End Trial	2011-08-08T12:57	Hemoglobin	13.54	g/dL	L	13.7	17.7
			Creatinine	1.222	mg/dL	H	0.72	1.18
221-004	Pre-trial	2011-07-06T14:01	Hemoglobin	11.6	g/dL	L	13.7	17.7
			Erythrocytes	3.1	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	102	fL	H	80	100
			Magnesium	1.65	mg/dL	L	1.7	2.4
			Creatinine	1.276	mg/dL	H	0.72	1.18
			Albumin	3.2	g/dL	L	3.5	5.2
			Blood Urea Nitrogen	28.29	mg/dL	H	8.4	21
		2011-07-06T14:02	Activated Partial Thromboplastin Time	44	sec	H	25	40
	Cycle 1	2011-07-18T10:38	Activated Partial Thromboplastin Time	41	sec	H	25	40
		2011-07-18T10:40	Hemoglobin	11.44	g/dL	L	13.7	17.7
			Erythrocytes	3.1	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	103	fL	H	80	100
			Eosinophils	0.52	10^9/L	H	0	0.499

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-004	Cycle 1	2011-07-18T10:40	Albumin	3.3	g/dL	L	3.5	5.2
			Blood Urea Nitrogen	22.97	mg/dL	H	8.4	21
			Urate	8.91	mg/dL	H	3.4	7.6
		2011-07-22T11:46	Hemoglobin	11.92	g/dL	L	13.7	17.7
			Erythrocytes	3.2	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	103	fL	H	80	100
			Platelets	145	10^9/L	L	150	400
			Creatinine	1.233	mg/dL	H	0.72	1.18
			Blood Urea Nitrogen	28.57	mg/dL	H	8.4	21
		2011-08-01T14:41	Hemoglobin	11.44	g/dL	L	13.7	17.7
			Erythrocytes	3.1	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	104	fL	H	80	100
		2011-08-01T16:13	Sodium	135	mmol/L	L	136	146
			Creatinine	1.188	mg/dL	H	0.72	1.18
			Blood Urea Nitrogen	27.73	mg/dL	H	8.4	21
			Urate	8.71	mg/dL	H	3.4	7.6
	Cycle 2	2011-08-08T10:44	Hemoglobin	10.96	g/dL	L	13.7	17.7
			Erythrocytes	2.9	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	103	fL	H	80	100
			Magnesium	1.68	mg/dL	L	1.7	2.4
			Albumin	3.3	g/dL	L	3.5	5.2
			Blood Urea Nitrogen	26.33	mg/dL	H	8.4	21
			Urate	8.25	mg/dL	H	3.4	7.6
		2011-08-08T10:52	Activated Partial Thromboplastin Time	42	sec	H	25	40

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-004	Cycle 2	2011-08-12T11:06	Hemoglobin	10.47	g/dL	L	13.7	17.7
			Erythrocytes	2.8	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	103	fL	H	80	100
			Platelets	104	10^9/L	L	150	400
			Lymphocytes	0.94	10^9/L	L	1	3.5
			Magnesium	1.65	mg/dL	L	1.7	2.4
			Creatinine	1.267	mg/dL	H	0.72	1.18
			Albumin	3.2	g/dL	L	3.5	5.2
			Blood Urea Nitrogen	23.25	mg/dL	H	8.4	21
	Cycle 3	2011-09-19T10:40	Hemoglobin	11.28	g/dL	L	13.7	17.7
			Erythrocytes	3	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	103	fL	H	80	100
			Eosinophils	0.8	10^9/L	H	0	0.499
			Magnesium	1.68	mg/dL	L	1.7	2.4
			Albumin	3.4	g/dL	L	3.5	5.2
			Urate	8.57	mg/dL	H	3.4	7.6
		2011-09-19T10:46	Activated Partial Thromboplastin Time	42	sec	H	25	40
		2011-09-23T09:49	Hemoglobin	10.96	g/dL	L	13.7	17.7
			Platelets	140	10^9/L	L	150	400
			Creatinine	1.244	mg/dL	H	0.72	1.18

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-004	Cycle 4	2011-10-10T11:23	Hemoglobin	10.15	g/dL	L	13.7	17.7
			Erythrocytes	2.8	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	106	fL	H	80	100
			Calcium	8.7	mg/dL	L	8.8	10.4
			Phosphate	2.26	mg/dL	L	2.5	4.3
			Magnesium	1.58	mg/dL	L	1.7	2.4
			Albumin	2.6	g/dL	L	3.5	5.2
		2011-10-14T10:36	Hemoglobin	9.99	g/dL	L	13.7	17.7
			Erythrocytes	2.6	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	107	fL	H	80	100
			Lymphocytes	0.76	10^9/L	L	1	3.5
			Calcium	8.7	mg/dL	L	8.8	10.4
			Phosphate	2.42	mg/dL	L	2.5	4.3
			Magnesium	1.65	mg/dL	L	1.7	2.4
			Albumin	3	g/dL	L	3.5	5.2
			Blood Urea Nitrogen	21.57	mg/dL	H	8.4	21
	Cycle 5	2011-10-31T10:53	Hemoglobin	11.44	g/dL	L	13.7	17.7
			Erythrocytes	3	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	106	fL	H	80	100
			Lymphocytes	0.78	10^9/L	L	1	3.5
			Sodium	135	mmol/L	L	136	146
			Calcium	8.58	mg/dL	L	8.8	10.4
			Phosphate	2.26	mg/dL	L	2.5	4.3
			Magnesium	1.53	mg/dL	L	1.7	2.4
			Albumin	3.3	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	258	U/L	H	0	250

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-004	Cycle 5	2011-11-04T09:47	Hemoglobin	10.31	g/dL	L	13.7	17.7
			Erythrocytes	2.7	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	106	fL	H	80	100
			Platelets	144	10^9/L	L	150	400
			Lymphocytes	0.67	10^9/L	L	1	3.5
			Calcium	8.62	mg/dL	L	8.8	10.4
			Chloride	112	mmol/L	H	98	108
			Phosphate	2.45	mg/dL	L	2.5	4.3
			Magnesium	1.56	mg/dL	L	1.7	2.4
			Albumin	3	g/dL	L	3.5	5.2
	Cycle 6	2011-11-21T10:35	Hemoglobin	10.15	g/dL	L	13.7	17.7
			Erythrocytes	2.8	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	106	fL	H	80	100
			Lymphocytes	0.59	10^9/L	L	1	3.5
			Activated Partial Thromboplastin Time	42	sec	H	25	40
			Potassium	3.4	mmol/L	L	3.6	4.8
			Calcium	8.14	mg/dL	L	8.8	10.4
			Phosphate	1.39	mg/dL	L	2.5	4.3
			Magnesium	1.46	mg/dL	L	1.7	2.4
			Albumin	2.6	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	802	U/L	H	0	250
			Blood Urea Nitrogen	27.17	mg/dL	H	8.4	21

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
221-004	Cycle 6	2011-11-25T10:42	Hemoglobin	11.12	g/dL	L	13.7	17.7
			Platelets	113	10^9/L	L	150	400
			Lymphocytes	0.92	10^9/L	L	1	3.5
			Calcium	8.42	mg/dL	L	8.8	10.4
			Magnesium	1.6	mg/dL	L	1.7	2.4
			Creatinine	0.69	mg/dL	L	0.72	1.18
			Albumin	1.6	g/dL	L	3.5	5.2
			Alkaline Phosphatase	234	U/L	H	0	120
			Blood Urea Nitrogen	22.97	mg/dL	H	8.4	21
			Urate	1.41	mg/dL	L	3.4	7.6
			Glucose	174.7	mg/dL	H	65	141
	Unplanned	2011-10-18T15:14	Hemoglobin	11.44	g/dL	L	13.7	17.7
		2011-11-23T10:26	Hemoglobin	9.99	g/dL	L	13.7	17.7
			Erythrocytes	2.7	10^12/L	L	4.5	5.5
			Ery. Mean Corpuscular Volume	105	fL	H	80	100
			Potassium	3.5	mmol/L	L	3.6	4.8
			Phosphate	2.01	mg/dL	L	2.5	4.3
			Magnesium	1.63	mg/dL	L	1.7	2.4
			Albumin	2.7	g/dL	L	3.5	5.2
			Aspartate Aminotransferase	38	U/L	H	0	35
			Lactate Dehydrogenase	904	U/L	H	0	250
			Blood Urea Nitrogen	28.85	mg/dL	H	8.4	21
222-001	Pre-trial	2010-10-14T15:38	Eosinophils	3.2	10^9/L	H	0	0.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
222-001	Cycle 1	2010-10-18T10:30	Lymphocytes	0.8	10^9/L	L	1	4
			Eosinophils	2.4	10^9/L	H	0	0.4
		2010-10-22T09:57	Lymphocytes	0.7	10^9/L	L	1	4
			Eosinophils	2	10^9/L	H	0	0.4
			Alanine Aminotransferase	122	U/L	H	0	45
			Alkaline Phosphatase	160	U/L	H	0	120
		2010-10-28T09:25	Eosinophils	2.6	10^9/L	H	0	0.4
			Alkaline Phosphatase	133	U/L	H	0	120
	Cycle 2	2010-11-08T09:26	Eosinophils	2.5	10^9/L	H	0	0.4
			Alkaline Phosphatase	121	U/L	H	0	120
			Lactate Dehydrogenase	276	U/L	H	0	250
		2010-11-12T14:32	Eosinophils	3.1	10^9/L	H	0	0.4
			Phosphate	5.14	mg/dL	H	2.5	4.6
			Alanine Aminotransferase	72	U/L	H	0	45
			Aspartate Aminotransferase	42	U/L	H	0	40
			Alkaline Phosphatase	157	U/L	H	0	120
			Lactate Dehydrogenase	357	U/L	H	0	250
	End Trial	2010-11-25T11:27	Lymphocytes	0.7	10^9/L	L	1	4
			Eosinophils	1.7	10^9/L	H	0	0.4
			Alanine Aminotransferase	50	U/L	H	0	45
			Lactate Dehydrogenase	442	U/L	H	0	250

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-002	Pre-trial	2010-04-02T11:25	Hemoglobin	11.44	g/dL	L	13.9	16.9
			Leukocytes	12.4	10^9/L	H	3.5	10
			Neutrophils	1.488	10^9/L	L	2	7.5
			Lymphocytes	0.248	10^9/L	L	1	4
			Monocytes	1.116	10^9/L	H	0.2	1
			Eosinophils	0.62	10^9/L	H	0	0.5
			Alkaline Phosphatase	141	U/L	H	0	120
			Lactate Dehydrogenase	651	U/L	H	0	450
			Bilirubin	1.17	mg/dL	H	0	0.99
			Blood Urea Nitrogen	22.13	mg/dL	H	7	21
	Cycle 1	2010-04-12T08:45	Hemoglobin	8.06	g/dL	L	13.9	16.9
			Leukocytes	14.9	10^9/L	H	3.5	10
			Neutrophils	12.963	10^9/L	H	2	7.5
			Lymphocytes	0.596	10^9/L	L	1	4
			Monocytes	1.192	10^9/L	H	0.2	1
			Sodium	132	mmol/L	L	136	145
			Magnesium	1.68	mg/dL	L	1.7	2.6
			Albumin	3.1	g/dL	L	3.5	5
			Alkaline Phosphatase	184	U/L	H	0	120
			Lactate Dehydrogenase	805	U/L	H	0	450
		2010-04-16	Hemoglobin	6.61	g/dL	L	13.9	16.9
			Leukocytes	11.5	10^9/L	H	3.5	10
			Bilirubin	0.994	mg/dL	H	0	0.99
			Glucose	113.5	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-002	Cycle 1	2010-04-22T08:45	Hemoglobin	7.41	g/dL	L	13.9	16.9
			Leukocytes	14.8	10^9/L	H	3.5	10
			Neutrophils	12.876	10^9/L	H	2	7.5
			Lymphocytes	0.74	10^9/L	L	1	4
			Sodium	135	mmol/L	L	136	145
			Creatinine	1.324	mg/dL	H	0.74	1.3
			Alkaline Phosphatase	125	U/L	H	0	120
			Lactate Dehydrogenase	828	U/L	H	0	450
			Bilirubin	1.345	mg/dL	H	0	0.99
			Blood Urea Nitrogen	41.18	mg/dL	H	7	21
	Cycle 2	2010-05-03T08:30	Hemoglobin	8.38	g/dL	L	13.9	16.9
			Ery. Mean Corpuscular Volume	101	fL	H	80	100
			Leukocytes	17.9	10^9/L	H	3.5	10
			Neutrophils	17.005	10^9/L	H	2	7.5
			Lymphocytes	0.179	10^9/L	L	1	4
			Calcium	8.74	mg/dL	L	8.8	10.6
			Albumin	3.3	g/dL	L	3.5	5
			Lactate Dehydrogenase	517	U/L	H	0	450
			Blood Urea Nitrogen	31.93	mg/dL	H	7	21
			Glucose	120.7	mg/dL	H	72	110
		2010-05-07T09:00	Hemoglobin	8.06	g/dL	L	13.9	16.9
			Erythrocytes	2.29	10^12/L	L	4.4	5.6
			Platelets	113	10^9/L	L	150	370
			Leukocytes	10.3	10^9/L	H	3.5	10
			Neutrophils	9.455	10^9/L	H	2	7.5
			Lymphocytes	0.206	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-002	Cycle 2	2010-05-07T09:00	Sodium	135	mmol/L	L	136	145
			Calcium	8.58	mg/dL	L	8.8	10.6
			Albumin	3.2	g/dL	L	3.5	5
			Alanine Aminotransferase	51	U/L	H	0	40.99
			Alkaline Phosphatase	131	U/L	H	0	120
			Lactate Dehydrogenase	545	U/L	H	0	450
			Blood Urea Nitrogen	30.25	mg/dL	H	7	21
			Glucose	117.1	mg/dL	H	72	110
	End Trial	2010-05-28T09:00	Hemoglobin	8.54	g/dL	L	13.9	16.9
			Erythrocytes	2.38	10^12/L	L	4.4	5.6
			Platelets	131	10^9/L	L	150	370
			Leukocytes	13.5	10^9/L	H	3.5	10
			Neutrophils	11.3	10^9/L	H	2	7.5
			Sodium	130	mmol/L	L	136	145
			Chloride	95	mmol/L	L	97	107
			Phosphate	4.71	mg/dL	H	2.5	4.3
			Albumin	3.1	g/dL	L	3.5	5
			Lactate Dehydrogenase	477	U/L	H	0	450
			Blood Urea Nitrogen	37.25	mg/dL	H	7	21
			Urate	8.07	mg/dL	H	3.4	7.1
			Glucose	117.1	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Pre-trial	2010-09-27T08:55	Hemoglobin	13.21	g/dL	L	13.9	16.9
			Platelets	107	10^9/L	L	150	370
			Leukocytes	12.5	10^9/L	H	3.5	10
			Neutrophils	8.863	10^9/L	H	2	7.5
			Creatinine	1.38	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	44	U/L	H	0	40.99
			Aspartate Aminotransferase	37	U/L	H	0	36.99
			Bilirubin	1.053	mg/dL	H	0	0.99
			Urate	8.41	mg/dL	H	3.4	7.1
			Glucose	261.2	mg/dL	H	72	110
	Cycle 1	2010-10-04T08:30	Hemoglobin	13.54	g/dL	L	13.9	16.9
			Leukocytes	11.9	10^9/L	H	3.5	10
			Monocytes	1.166	10^9/L	H	0.2	1
			Creatinine	1.301	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	41	U/L	H	0	40.99
			Aspartate Aminotransferase	39	U/L	H	0	36.99
			Lactate Dehydrogenase	459	U/L	H	0	450
			Urate	8.24	mg/dL	H	3.4	7.1
			Glucose	145.9	mg/dL	H	72	110
		2010-10-08	Hemoglobin	13.05	g/dL	L	13.9	16.9
			Platelets	126	10^9/L	L	150	370
			Creatinine	1.301	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	54	U/L	H	0	40.99
			Urate	7.23	mg/dL	H	3.4	7.1
			Glucose	117.1	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 1	2010-10-15	Hemoglobin	13.37	g/dL	L	13.9	16.9
			Platelets	141	10^9/L	L	150	370
			Creatinine	1.346	mg/dL	H	0.74	1.3
			Aspartate Aminotransferase	37	U/L	H	0	36.99
			Urate	8.24	mg/dL	H	3.4	7.1
			Glucose	140.5	mg/dL	H	72	110
	Cycle 2	2010-10-25	Hemoglobin	13.54	g/dL	L	13.9	16.9
			Platelets	109	10^9/L	L	150	370
			Basophils	0.221	10^9/L	H	0	0.2
			Creatinine	1.301	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	51	U/L	H	0	40.99
			Urate	8.74	mg/dL	H	3.4	7.1
			Glucose	237.8	mg/dL	H	72	110
		2010-10-29	Hemoglobin	12.57	g/dL	L	13.9	16.9
			Platelets	81	10^9/L	L	150	370
			Alanine Aminotransferase	61	U/L	H	0	40.99
			Urate	7.73	mg/dL	H	3.4	7.1
	Cycle 3	2010-11-15T08:00	Platelets	126	10^9/L	L	150	370
			Basophils	0.29	10^9/L	H	0	0.2
			Creatinine	1.312	mg/dL	H	0.74	1.3
			Urate	8.74	mg/dL	H	3.4	7.1
		2010-11-19T09:46	Hemoglobin	12.25	g/dL	L	13.9	16.9
			Erythrocytes	4.2	10^12/L	L	4.4	5.6
			Platelets	78	10^9/L	L	150	370
			Calcium	8.7	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	75	U/L	H	0	40.99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 3	2010-11-19T09:46	Aspartate Aminotransferase	38	U/L	H	0	36.99
	Cycle 4	2010-12-06T08:00	Hemoglobin	12.89	g/dL	L	13.9	16.9
			Platelets	126	10^9/L	L	150	370
			Calcium	8.66	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	41	U/L	H	0	40.99
			Urate	7.9	mg/dL	H	3.4	7.1
			Glucose	171.1	mg/dL	H	72	110
		2010-12-10	Hemoglobin	13.21	g/dL	L	13.9	16.9
			Platelets	108	10^9/L	L	150	370
			Basophils	0.23	10^9/L	H	0	0.2
			Creatinine	1.312	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	49	U/L	H	0	40.99
			Aspartate Aminotransferase	39	U/L	H	0	36.99
			Urate	7.23	mg/dL	H	3.4	7.1
	Cycle 5	2010-12-27T08:00	Hemoglobin	13.86	g/dL	L	13.9	16.9
			Platelets	125	10^9/L	L	150	370
			Basophils	0.232	10^9/L	H	0	0.2
			Phosphate	2.26	mg/dL	L	2.5	4.3
			Creatinine	1.312	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	44	U/L	H	0	40.99
			Blood Urea Nitrogen	21.01	mg/dL	H	7	21
			Urate	8.07	mg/dL	H	3.4	7.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 5	2010-12-31	Hemoglobin	13.21	g/dL	L	13.9	16.9
			Erythrocytes	4.38	10^12/L	L	4.4	5.6
			Platelets	93	10^9/L	L	150	370
			Creatinine	1.357	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	63	U/L	H	0	40.99
			Blood Urea Nitrogen	22.69	mg/dL	H	7	21
			Urate	8.07	mg/dL	H	3.4	7.1
			Glucose	113.5	mg/dL	H	72	110
	Cycle 6	2011-01-17T09:00	Hemoglobin	13.21	g/dL	L	13.9	16.9
			Platelets	142	10^9/L	L	150	370
			Basophils	0.243	10^9/L	H	0	0.2
			Sodium	149	mmol/L	H	136	145
			Chloride	111	mmol/L	H	97	107
			Magnesium	1.68	mg/dL	L	1.7	2.6
			Alanine Aminotransferase	52	U/L	H	0	40.99
			Aspartate Aminotransferase	38	U/L	H	0	36.99
			Blood Urea Nitrogen	21.01	mg/dL	H	7	21
			Urate	7.57	mg/dL	H	3.4	7.1
			Glucose	154.9	mg/dL	H	72	110
		2011-01-21	Hemoglobin	13.37	g/dL	L	13.9	16.9
			Platelets	116	10^9/L	L	150	370
			Basophils	0.202	10^9/L	H	0	0.2
			Creatinine	1.403	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	83	U/L	H	0	40.99
			Aspartate Aminotransferase	39	U/L	H	0	36.99
			Urate	7.23	mg/dL	H	3.4	7.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 6	2011-01-21	Glucose	122.5	mg/dL	H	72	110
	Cycle 7	2011-02-07T08:25	Hemoglobin	13.54	g/dL	L	13.9	16.9
			Platelets	127	10^9/L	L	150	370
			Basophils	0.273	10^9/L	H	0	0.2
			Chloride	109	mmol/L	H	97	107
			Phosphate	2.32	mg/dL	L	2.5	4.3
			Alanine Aminotransferase	45	U/L	H	0	40.99
			Glucose	124.3	mg/dL	H	72	110
		2011-02-11	Hemoglobin	12.73	g/dL	L	13.9	16.9
			Erythrocytes	4.27	10^12/L	L	4.4	5.6
			Platelets	109	10^9/L	L	150	370
			Creatinine	1.324	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	60	U/L	H	0	40.99
			Glucose	131.5	mg/dL	H	72	110
	Cycle 8	2011-02-28T09:30	Hemoglobin	13.86	g/dL	L	13.9	16.9
			Platelets	118	10^9/L	L	150	370
			Activated Partial Thromboplastin Time	56	sec	H	28	39
			Chloride	108	mmol/L	H	97	107
			Creatinine	1.357	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	43	U/L	H	0	40.99
			Urate	8.24	mg/dL	H	3.4	7.1
			Glucose	163.9	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 8	2011-03-04	Hemoglobin	13.54	g/dL	L	13.9	16.9
			Erythrocytes	4.38	10^12/L	L	4.4	5.6
			Platelets	102	10^9/L	L	150	370
			Calcium	8.54	mg/dL	L	8.8	10.6
			Creatinine	1.391	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	60	U/L	H	0	40.99
			Aspartate Aminotransferase	39	U/L	H	0	36.99
			Glucose	149.5	mg/dL	H	72	110
	Cycle 9	2011-03-21T09:00	Hemoglobin	13.54	g/dL	L	13.9	16.9
			Platelets	111	10^9/L	L	150	370
			Basophils	0.27	10^9/L	H	0	0.2
			Chloride	108	mmol/L	H	97	107
			Creatinine	1.425	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	45	U/L	H	0	40.99
			Aspartate Aminotransferase	38	U/L	H	0	36.99
			Urate	8.91	mg/dL	H	3.4	7.1
			Glucose	135.1	mg/dL	H	72	110
		2011-03-25	Hemoglobin	13.21	g/dL	L	13.9	16.9
			Erythrocytes	4.33	10^12/L	L	4.4	5.6
			Platelets	93	10^9/L	L	150	370
			Calcium	8.62	mg/dL	L	8.8	10.6
			Chloride	109	mmol/L	H	97	107
			Creatinine	1.403	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	44	U/L	H	0	40.99
			Glucose	124.3	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 10	2011-04-11T09:00	Hemoglobin	13.7	g/dL	L	13.9	16.9
			Platelets	127	10^9/L	L	150	370
			Prothrombin Time	38.6	sec	H	10.9	13.3
			Activated Partial Thromboplastin Time	52	sec	H	28	39
			Prothrombin Intl. Normalized Ratio	3.2	ratio	H	0.8	1.3
			Calcium	8.66	mg/dL	L	8.8	10.6
			Phosphate	4.55	mg/dL	H	2.5	4.3
			Aspartate Aminotransferase	40	U/L	H	0	36.99
			Lactate Dehydrogenase	312	U/L	H	0	249
			Blood Urea Nitrogen	21.01	mg/dL	H	7	21
			Urate	7.73	mg/dL	H	3.4	7.1
		2011-04-15	Hemoglobin	13.7	g/dL	L	13.9	16.9
			Platelets	105	10^9/L	L	150	370
			Chloride	108	mmol/L	H	97	107
			Creatinine	1.414	mg/dL	H	0.74	1.3
			Blood Urea Nitrogen	21.85	mg/dL	H	7	21
			Urate	7.57	mg/dL	H	3.4	7.1
			Glucose	122.5	mg/dL	H	72	110
	Cycle 11	2011-05-02T08:30	Platelets	128	10^9/L	L	150	370
			Prothrombin Time	37.4	sec	H	10.9	13.3
			Activated Partial Thromboplastin Time	60	sec	H	28	39
			Prothrombin Intl. Normalized Ratio	3.1	ratio	H	0.8	1.3
			Calcium	8.74	mg/dL	L	8.8	10.6
			Chloride	110	mmol/L	H	97	107

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 11	2011-05-02T08:30	Creatinine	1.391	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	282	U/L	H	0	40.99
			Aspartate Aminotransferase	184	U/L	H	0	36.99
			Lactate Dehydrogenase	330	U/L	H	0	249
			Urate	7.73	mg/dL	H	3.4	7.1
			Glucose	124.3	mg/dL	H	72	110
		2011-05-06	Platelets	105	10^9/L	L	150	370
			Creatinine	1.505	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	95	U/L	H	0	40.99
			Aspartate Aminotransferase	46	U/L	H	0	36.99
			Blood Urea Nitrogen	22.97	mg/dL	H	7	21
			Urate	8.57	mg/dL	H	3.4	7.1
	Cycle 12	2011-05-23T08:30	Hemoglobin	13.7	g/dL	L	13.9	16.9
			Platelets	118	10^9/L	L	150	370
			Prothrombin Time	32.6	sec	H	10.9	13.3
			Activated Partial Thromboplastin Time	43	sec	H	28	39
			Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.8	1.3
			Chloride	109	mmol/L	H	97	107
			Phosphate	1.89	mg/dL	L	2.5	4.3
			Creatinine	1.369	mg/dL	H	0.74	1.3
			Lactate Dehydrogenase	270	U/L	H	0	249
			Urate	8.57	mg/dL	H	3.4	7.1
			Glucose	145.9	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	Cycle 12	2011-05-27	Hemoglobin	13.54	g/dL	L	13.9	16.9
			Platelets	103	10^9/L	L	150	370
			Chloride	109	mmol/L	H	97	107
			Creatinine	1.391	mg/dL	H	0.74	1.3
			Lactate Dehydrogenase	256	U/L	H	0	249
			Urate	7.73	mg/dL	H	3.4	7.1
			Glucose	115.3	mg/dL	H	72	110
	Cycle 13	2011-06-20T08:00	Prothrombin Time	35.3	sec	H	10.9	13.3
			Activated Partial Thromboplastin Time	43	sec	H	28	39
			Prothrombin Intl. Normalized Ratio	2.9	ratio	H	0.8	1.3
		2011-06-20T08:10	Hemoglobin	13.37	g/dL	L	13.9	16.9
			Platelets	104	10^9/L	L	150	370
			Chloride	109	mmol/L	H	97	107
			Phosphate	0.65	mg/dL	L	2.5	4.3
			Magnesium	1.65	mg/dL	L	1.7	2.6
			Creatinine	1.437	mg/dL	H	0.74	1.3
			Aspartate Aminotransferase	37	U/L	H	0	36.99
			Lactate Dehydrogenase	313	U/L	H	0	249
			Urate	7.57	mg/dL	H	3.4	7.1
			Glucose	160.3	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
223-004	End Trial	2011-07-01T09:00	Hemoglobin	13.86	g/dL	L	13.9	16.9
			Platelets	121	10^9/L	L	150	370
			Prothrombin Time	40	sec	H	10.9	13.3
			Activated Partial Thromboplastin Time	41	sec	H	28	39
			Prothrombin Intl. Normalized Ratio	3	ratio	H	0.9	1.1
			Magnesium	1.68	mg/dL	L	1.7	2.6
			Alanine Aminotransferase	116	U/L	H	0	40.99
			Aspartate Aminotransferase	51	U/L	H	0	36.99
			Lactate Dehydrogenase	300	U/L	H	0	246.99
			Urate	8.41	mg/dL	H	3.4	7.1
			Glucose	115.3	mg/dL	H	72	110
224-001	Pre-trial	2010-02-10T08:00	Hemoglobin	9.18	g/dL	L	13.9	16.9
			Platelets	128	10^9/L	L	150	370
			Activated Partial Thromboplastin Time	44	sec	H	28	39
			Potassium	3.4	mmol/L	L	3.5	5.1
			Calcium	8.14	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	557	U/L	H	0	450
	Cycle 1	2010-02-15T08:00	Hemoglobin	9.51	g/dL	L	13.9	16.9
			Platelets	147	10^9/L	L	150	370
			Calcium	7.86	mg/dL	L	8.8	10.6
			Alanine Aminotransferase	42	U/L	H	0	41
			Aspartate Aminotransferase	58	U/L	H	0	37
			Lactate Dehydrogenase	557	U/L	H	0	450

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
224-001	Cycle 1	2010-02-18T08:00	Hemoglobin	9.35	g/dL	L	13.9	16.9
			Erythrocytes	3.09	10^12/L	L	4.4	5.6
			Platelets	106	10^9/L	L	150	370
			Leukocytes	3.1	10^9/L	L	3.5	10
			Lymphocytes	0.093	10^9/L	L	1	4
			Calcium	8.14	mg/dL	L	8.8	10.6
			Chloride	109	mmol/L	H	97	107
			Albumin	3.2	g/dL	L	3.5	5
			Alanine Aminotransferase	64	U/L	H	0	41
			Aspartate Aminotransferase	85	U/L	H	0	37
			Lactate Dehydrogenase	590	U/L	H	0	450
			Urate	1.18	mg/dL	L	3.4	7.1
			Glucose	129.7	mg/dL	H	72	110
		2010-02-26T14:09	Hemoglobin	11.12	g/dL	L	13.9	16.9
			Lymphocytes	0.288	10^9/L	L	1	4
			Calcium	8.14	mg/dL	L	8.8	10.6
			Albumin	3.3	g/dL	L	3.5	5
			Aspartate Aminotransferase	40	U/L	H	0	37
			Lactate Dehydrogenase	613	U/L	H	0	450
			Bilirubin	1.053	mg/dL	H	0	0.99

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
224-002	Pre-trial	2011-06-07T10:09	Activated Partial Thromboplastin Time	25	sec	L	28	39
		2011-06-16T11:21	Hemoglobin	9.02	g/dL	L	13.9	16.9
			Lymphocytes	0.14	10^9/L	L	1	4
			Calcium	10.86	mg/dL	H	8.8	10.6
			Phosphate	2.26	mg/dL	L	2.5	4.3
			Creatinine	1.674	mg/dL	H	0.74	1.3
			Alanine Aminotransferase	71	U/L	H	0	41
			Aspartate Aminotransferase	135	U/L	H	0	37
			Alkaline Phosphatase	634	U/L	H	0	120
			Lactate Dehydrogenase	2176	U/L	H	0	450
			Blood Urea Nitrogen	28.01	mg/dL	H	7	21
	Cycle 1	2011-06-27T10:10	Hemoglobin	7.73	g/dL	L	13.9	16.9
			Erythrocytes	3.1	10^12/L	L	4.4	5.6
			Ery. Mean Corpuscular Volume	79	fL	L	80	100
			Leukocytes	3.2	10^9/L	L	3.5	10
			Lymphocytes	0.182	10^9/L	L	1	4
			Creatinine	1.38	mg/dL	H	0.74	1.3
			Albumin	3.3	g/dL	L	3.5	5
			Alanine Aminotransferase	75	U/L	H	0	41
			Aspartate Aminotransferase	157	U/L	H	0	37
			Alkaline Phosphatase	732	U/L	H	0	120
			Lactate Dehydrogenase	2737	U/L	H	0	450
			Blood Urea Nitrogen	33.05	mg/dL	H	7	21

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
224-002	Cycle 1	2011-07-01T09:43	Hemoglobin	8.54	g/dL	L	13.9	16.9
			Erythrocytes	3.38	10^12/L	L	4.4	5.6
			Ery. Mean Corpuscular Volume	79	fL	L	80	100
			Lymphocytes	0.21	10^9/L	L	1	4
			Creatinine	1.652	mg/dL	H	0.74	1.3
			Albumin	3.3	g/dL	L	3.5	5
			Alanine Aminotransferase	51	U/L	H	0	41
			Aspartate Aminotransferase	114	U/L	H	0	37
			Alkaline Phosphatase	533	U/L	H	0	120
			Lactate Dehydrogenase	2873	U/L	H	0	450
			Blood Urea Nitrogen	35.57	mg/dL	H	7	21
		2011-07-12T13:15	Hemoglobin	9.51	g/dL	L	13.9	16.9
			Erythrocytes	3.7	10^12/L	L	4.4	5.6
			Sodium	133	mmol/L	L	136	145
			Calcium	13.43	mg/dL	H	8.8	10.6
			Phosphate	4.68	mg/dL	H	2.5	4.3
			Creatinine	2.443	mg/dL	H	0.74	1.3
			Albumin	3.4	g/dL	L	3.5	5
			Alanine Aminotransferase	54	U/L	H	0	41
			Aspartate Aminotransferase	204	U/L	H	0	37
			Alkaline Phosphatase	717	U/L	H	0	120
			Lactate Dehydrogenase	3553	U/L	H	0	450
			Bilirubin	1.404	mg/dL	H	0	0.99
			Blood Urea Nitrogen	43.14	mg/dL	H	7	21
			Urate	11.6	mg/dL	H	3.4	7.1
			Glucose	115.3	mg/dL	H	72	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
224-002	End Trial	2011-07-14T08:00	Hemoglobin	8.7	g/dL	L	13.9	16.9
			Ery. Mean Corpuscular Volume	79	fL	L	80	100
			Sodium	132	mmol/L	L	136	145
			Calcium	11.74	mg/dL	H	8.8	10.6
			Magnesium	1.43	mg/dL	L	1.7	2.6
			Creatinine	1.957	mg/dL	H	0.74	1.3
			Albumin	2.9	g/dL	L	3.5	5
			Alanine Aminotransferase	55	U/L	H	0	41
			Aspartate Aminotransferase	208	U/L	H	0	37
			Alkaline Phosphatase	795	U/L	H	0	120
			Lactate Dehydrogenase	3245	U/L	H	0	450
			Bilirubin	1.988	mg/dL	H	0	0.99
			Blood Urea Nitrogen	35.85	mg/dL	H	7	21
			Urate	10.59	mg/dL	H	3.4	7.1
		2011-07-15T08:00	Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.1
240-001	Pre-trial	2009-06-26T08:14	Hemoglobin	10.1	g/dL	L	12	16
			Erythrocytes	3.48	10^12/L	L	3.5	5.3
			Platelets	135	10^9/L	L	150	400
			Leukocytes	3.79	10^9/L	L	4	10
			Neutrophils	1.668	10^9/L	L	2.1	6.3
		2009-06-29T10:09	Albumin	3.34	g/dL	L	3.7	5.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
240-001	Cycle 1	2009-06-29T10:09	Hemoglobin	9.6	g/dL	L	12	16
			Erythrocytes	3.34	10^12/L	L	3.5	5.3
			Platelets	131	10^9/L	L	150	400
			Leukocytes	3.02	10^9/L	L	4	10
			Neutrophils	1.489	10^9/L	L	2.1	6.3
			Albumin	3.34	g/dL	L	3.7	5.3
		2009-07-03T07:48	Hemoglobin	9.2	g/dL	L	12	16
			Erythrocytes	3.2	10^12/L	L	3.5	5.3
			Platelets	124	10^9/L	L	150	400
			Leukocytes	3.19	10^9/L	L	4	10
			Neutrophils	1.621	10^9/L	L	2.1	6.3
		2009-07-09T11:12	Hemoglobin	11	g/dL	L	12	16
			Platelets	148	10^9/L	L	150	400
			Neutrophils	1.768	10^9/L	L	2.1	6.3
	Cycle 2	2009-07-20T10:06	Hemoglobin	11.1	g/dL	L	12	16
			Platelets	130	10^9/L	L	150	400
			Leukocytes	2.88	10^9/L	L	4	10
			Neutrophils	1.233	10^9/L	L	2.1	6.3
		2009-07-24T12:39	Hemoglobin	10.5	g/dL	L	12	16
			Platelets	112	10^9/L	L	150	400
			Sodium	136	mmol/L	L	137	145
			Phosphate	4.7	mg/dL	H	2.5	4.5

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
240-001	Cycle 3	2009-08-24T10:28	Hemoglobin	11.7	g/dL	L	12	16
			Platelets	130	10^9/L	L	150	400
			Leukocytes	3.71	10^9/L	L	4	10
			Neutrophils	1.907	10^9/L	L	2.1	6.3
			Sodium	136	mmol/L	L	137	145
		2009-08-28T10:16	Hemoglobin	11.1	g/dL	L	12	16
			Platelets	128	10^9/L	L	150	400
	Cycle 4	2009-09-21T09:53	Hemoglobin	11.5	g/dL	L	12	16
			Platelets	126	10^9/L	L	150	400
			Leukocytes	3.5	10^9/L	L	4	10
			Neutrophils	1.547	10^9/L	L	2.1	6.3
			Sodium	136	mmol/L	L	137	145
		2009-09-25T11:52	Hemoglobin	11.4	g/dL	L	12	16
			Platelets	112	10^9/L	L	150	400
			Sodium	136	mmol/L	L	137	145
			Creatinine	1.1	mg/dL	H	0.52	1.04
			Alkaline Phosphatase	130	U/L	H	38	126
240-002	Pre-trial	2009-08-10T19:31	Hemoglobin	12.1	g/dL	L	14	18
			Erythrocytes	3.73	10^12/L	L	4.1	5.7
			Platelets	109	10^9/L	L	150	400
			Neutrophils	7.162	10^9/L	H	2.1	6.3
			Lymphocytes	0.464	10^9/L	L	1	3
			Sodium	131	mmol/L	L	137	145
			Creatinine	0.6	mg/dL	L	0.66	1.25
			Albumin	3.09	g/dL	L	3.7	5.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
240-002	Pre-trial	2009-08-10T19:31	Lactate Dehydrogenase	653	U/L	H	313	618
			Urate	1.2	mg/dL	L	4	8
			Glucose	118	mg/dL	H	70	110
	Cycle 1	2009-08-17T07:48	Hemoglobin	10.3	g/dL	L	14	18
			Erythrocytes	3.17	10^12/L	L	4.1	5.7
			Ery. Mean Corpuscular Volume	100.6	fL	H	80	99
			Leukocytes	13.42	10^9/L	H	4	10
			Neutrophils	11.246	10^9/L	H	2.1	6.3
			Lymphocytes	0.738	10^9/L	L	1	3
			Monocytes	1.396	10^9/L	H	0.24	0.91
			Sodium	132	mmol/L	L	137	145
			Albumin	2.783	g/dL	L	3.7	5.3
			Aspartate Aminotransferase	15	U/L	L	17	59
			Urate	1.5	mg/dL	L	4	8
		2009-08-21T07:59	Hemoglobin	8.5	g/dL	L	14	18
			Erythrocytes	2.61	10^12/L	L	4.1	5.7
			Ery. Mean Corpuscular Volume	101.9	fL	H	80	99
			Leukocytes	11.41	10^9/L	H	4	10
			Neutrophils	9.984	10^9/L	H	2.1	6.3
			Lymphocytes	0.445	10^9/L	L	1	3
			Monocytes	0.924	10^9/L	H	0.24	0.91
			Sodium	131	mmol/L	L	137	145
			Calcium	8	mg/dL	L	8.4	10.5
			Albumin	2.25	g/dL	L	3.7	5.3
			Alanine Aminotransferase	20	U/L	L	21	71
			Aspartate Aminotransferase	12	U/L	L	17	59

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
240-002	Cycle 1	2009-08-21T07:59	Urate	1.9	mg/dL	L	4	8
		2009-08-31T07:56	Hemoglobin	11.8	g/dL	L	14	18
			Erythrocytes	3.73	10^12/L	L	4.1	5.7
			Ery. Mean Corpuscular Volume	99.7	fL	H	80	99
			Leukocytes	10.57	10^9/L	H	4	10
			Neutrophils	9.048	10^9/L	H	2.1	6.3
			Lymphocytes	0.772	10^9/L	L	1	3
			Sodium	132	mmol/L	L	137	145
			Albumin	2.759	g/dL	L	3.7	5.3
			Alanine Aminotransferase	20	U/L	L	21	71
			Aspartate Aminotransferase	14	U/L	L	17	59
			Urate	2.3	mg/dL	L	4	8
	Cycle 2	2009-09-07T08:19	Hemoglobin	9.7	g/dL	L	14	18
			Erythrocytes	3.1	10^12/L	L	4.1	5.7
			Platelets	111	10^9/L	L	150	400
			Lymphocytes	0.889	10^9/L	L	1	3
			Sodium	132	mmol/L	L	137	145
			Creatinine	0.6	mg/dL	L	0.66	1.25
			Albumin	2.681	g/dL	L	3.7	5.3
			Blood Urea Nitrogen	52	mg/dL	H	15	50
			Urate	1.9	mg/dL	L	4	8
			Glucose	111	mg/dL	H	70	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
240-002	Cycle 2	2009-09-11T09:44	Hemoglobin	9.4	g/dL	L	14	18
			Erythrocytes	3.09	10^12/L	L	4.1	5.7
			Platelets	66	10^9/L	L	150	400
			Leukocytes	3.82	10^9/L	L	4	10
			Lymphocytes	0.359	10^9/L	L	1	3
			Sodium	136	mmol/L	L	137	145
			Calcium	7.7	mg/dL	L	8.4	10.5
			Albumin	2.24	g/dL	L	3.7	5.3
			Lactate Dehydrogenase	731	U/L	H	313	618
			Urate	1.3	mg/dL	L	4	8
			Glucose	127	mg/dL	H	70	110
	End Trial	2009-09-30T07:49	Hemoglobin	10.3	g/dL	L	14	18
			Erythrocytes	3.45	10^12/L	L	4.1	5.7
			Leukocytes	3.6	10^9/L	L	4	10
			Neutrophils	0.968	10^9/L	L	2.1	6.3
		2009-10-05T07:58	Prothrombin Time	29.6	sec	H	19	26
			Sodium	135	mmol/L	L	137	145
			Calcium	7.8	mg/dL	L	8.4	10.5
			Lactate Dehydrogenase	654	U/L	H	313	618
			Urate	2.6	mg/dL	L	4	8
			Glucose	114	mg/dL	H	70	110

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
242-001	Pre-trial	2010-12-16	Lymphocytes	0.64	10^9/L	L	1	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Potassium	4.9	mmol/L	H	3.6	4.8
			Creatinine	0.5	mg/dL	L	0.55	0.96
	Cycle 1	2010-12-20T08:30	Activated Partial Thromboplastin Time	43.2	sec	H	28.9	38.1
			Urate	2.2	mg/dL	L	2.4	5.7
		2010-12-24	Lymphocytes	0.444	10^9/L	L	1	4
			Monocytes	0.88	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.015	0.1
			Calcium	8.1	mg/dL	L	8.5	10.5
			Urate	1.6	mg/dL	L	2.4	5.7
			Glucose	148	mg/dL	H	82	115
		2010-12-30	Hemoglobin	11.5	g/dL	L	11.7	15.7
			Erythrocytes	3.78	10^12/L	L	3.79	5.23
			Lymphocytes	0.6	10^9/L	L	1	4
			Monocytes	1.7	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.015	0.1
			Calcium	8.4	mg/dL	L	8.5	10.5
			Glucose	79	mg/dL	L	82	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
242-001	Cycle 2	2011-01-10T09:30	Hemoglobin	9.7	g/dL	L	11.7	15.7
			Erythrocytes	3.26	10^12/L	L	3.79	5.23
			Monocytes	1.467	10^9/L	H	0.2	1
			Potassium	3.4	mmol/L	L	3.6	4.8
			Calcium	8.2	mg/dL	L	8.5	10.5
			Chloride	107	mmol/L	H	98	106
			Magnesium	1.64	mg/dL	L	1.7	2.55
			Creatinine	0.47	mg/dL	L	0.55	0.96
		2011-01-14T09:00	Hemoglobin	8.9	g/dL	L	11.7	15.7
			Erythrocytes	2.96	10^12/L	L	3.79	5.23
			Lymphocytes	0.333	10^9/L	L	1	4
			Basophils	0	10^9/L	L	0.015	0.1
			Potassium	3	mmol/L	L	3.6	4.8
			Calcium	7.7	mg/dL	L	8.5	10.5
			Chloride	107	mmol/L	H	98	106
			Albumin	3.1	g/dL	L	3.4	4.8
			Urate	2.2	mg/dL	L	2.4	5.7
			Glucose	151	mg/dL	H	82	115
	Cycle 3	2011-01-31T09:30	Hemoglobin	10.3	g/dL	L	11.7	15.7
			Erythrocytes	3.43	10^12/L	L	3.79	5.23
			Lymphocytes	0.546	10^9/L	L	1	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.015	0.1
			Magnesium	1.58	mg/dL	L	1.7	2.55
			Creatinine	0.51	mg/dL	L	0.55	0.96

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
242-001	Cycle 3	2011-02-04	Hemoglobin	9.1	g/dL	L	11.7	15.7
			Erythrocytes	3.04	10^12/L	L	3.79	5.23
			Lymphocytes	0.75	10^9/L	L	1	4
			Monocytes	0.99	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.015	0.1
			Potassium	3	mmol/L	L	3.6	4.8
			Calcium	7.7	mg/dL	L	8.5	10.5
			Magnesium	1.57	mg/dL	L	1.7	2.55
			Urate	2	mg/dL	L	2.4	5.7
	Cycle 4	2011-02-21T11:00	Hemoglobin	10.1	g/dL	L	11.7	15.7
			Erythrocytes	3.42	10^12/L	L	3.79	5.23
			Lymphocytes	0.58	10^9/L	L	1	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Calcium	8.4	mg/dL	L	8.5	10.5
			Creatinine	0.46	mg/dL	L	0.55	0.96
			Lactate Dehydrogenase	598	U/L	H	231	462
			Urate	2.2	mg/dL	L	2.4	5.7
		2011-02-25	Hemoglobin	10	g/dL	L	11.7	15.7
			Erythrocytes	3.45	10^12/L	L	3.79	5.23
			Platelets	132	10^9/L	L	149	409
			Leukocytes	3.88	10^9/L	L	4	10
			Lymphocytes	0.68	10^9/L	L	1	4
			Basophils	0	10^9/L	L	0.015	0.1
			Sodium	134	mmol/L	L	136	145
			Lactate Dehydrogenase	636	U/L	H	231	462
			Urate	1.3	mg/dL	L	2.4	5.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
242-001	Cycle 4	2011-02-25	Glucose	138	mg/dL	H	82	115
	End Trial	2011-03-21	Hemoglobin	9.9	g/dL	L	11.7	15.7
			Erythrocytes	3.62	10^12/L	L	3.79	5.23
			Platelets	122	10^9/L	L	149	409
			Lymphocytes	0.294	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	53.2	sec	H	28.9	38.1
			Prothrombin Intl. Normalized Ratio	1.28	ratio	H	0.9	1.1
			Sodium	134	mmol/L	L	136	145
			Calcium	8	mg/dL	L	8.5	10.5
			Phosphate	4.7	mg/dL	H	2.5	4.5
			Lactate Dehydrogenase	602	U/L	H	231	462
			Blood Urea Nitrogen	57	mg/dL	H	13	43
			Urate	1.6	mg/dL	L	2.4	5.7
			Glucose	184	mg/dL	H	82	115
243-001	Pre-trial	2009-09-21T11:16	Hemoglobin	9.4	g/dL	L	14	18
			Erythrocytes	2.77	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	105.8	fL	H	85	95
			Platelets	53	10^9/L	L	150	350
			Leukocytes	18.92	10^9/L	H	4	10
			Neutrophils	10.6	10^9/L	H	1.6	7
			Monocytes	3.7	10^9/L	H	0.2	1
			Eosinophils	0	10^9/L	L	0.08	0.6
			Basophils	0.4	10^9/L	H	0	0.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
243-001	Pre-trial	2009-09-21T13:46	Sodium	134	mmol/L	L	135	145
			Albumin	3	g/dL	L	3.4	5.2
			Alanine Aminotransferase	9	U/L	L	14	63
			Alkaline Phosphatase	148	U/L	H	28	94
			Lactate Dehydrogenase	97	U/L	L	98	192
			Bilirubin	2.9	mg/dL	H	0.3	1.2
			Glucose	111	mg/dL	H	70	100
	Cycle 1	2009-09-28T09:38	Hemoglobin	9.5	g/dL	L	14	18
			Erythrocytes	2.72	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	110.3	fL	H	85	95
			Platelets	69	10^9/L	L	150	350
			Leukocytes	20.67	10^9/L	H	4	10
			Neutrophils	12	10^9/L	H	1.6	7
			Monocytes	4.3	10^9/L	H	0.2	1
			Basophils	0.6	10^9/L	H	0	0.2
			Albumin	2.5	g/dL	L	3.4	5.2
			Alanine Aminotransferase	7	U/L	L	14	63
			Alkaline Phosphatase	113	U/L	H	28	94
			Bilirubin	2.9	mg/dL	H	0.3	1.2
		2009-10-02T10:58	Hemoglobin	10.6	g/dL	L	14	18
			Erythrocytes	2.94	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	110.9	fL	H	85	95
			Platelets	22	10^9/L	L	150	350
			Leukocytes	17.5	10^9/L	H	4	10
			Neutrophils	9.9	10^9/L	H	1.6	7
			Monocytes	4.3	10^9/L	H	0.2	1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
243-001	Cycle 1	2009-10-02T10:58	Sodium	134	mmol/L	L	135	145
			Potassium	5.02	mmol/L	H	3.5	5
			Magnesium	2.33	mg/dL	H	1.8	2.3
			Albumin	2.7	g/dL	L	3.4	5.2
			Alanine Aminotransferase	7	U/L	L	14	63
			Alkaline Phosphatase	128	U/L	H	28	94
			Bilirubin	2.9	mg/dL	H	0.3	1.2
			Glucose	128	mg/dL	H	70	100
		2009-10-08T06:46	Hemoglobin	9	g/dL	L	14	18
			Erythrocytes	2.56	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	111.3	fL	H	85	95
			Platelets	52	10^9/L	L	150	350
			Leukocytes	20.83	10^9/L	H	4	10
			Neutrophils	9.9	10^9/L	H	1.6	7
			Monocytes	5.5	10^9/L	H	0.2	1
			Eosinophils	0	10^9/L	L	0.08	0.6
			Albumin	2.4	g/dL	L	3.4	5.2
			Alanine Aminotransferase	7	U/L	L	14	63
			Bilirubin	3.3	mg/dL	H	0.3	1.2
			Glucose	61	mg/dL	L	70	100
	Cycle 2	2009-10-19T09:16	Sodium	132	mmol/L	L	135	145
			Calcium	8.14	mg/dL	L	8.6	10
			Alanine Aminotransferase	9	U/L	L	14	63
			Alkaline Phosphatase	100	U/L	H	28	94
			Bilirubin	5.7	mg/dL	H	0.3	1.2
			Blood Urea Nitrogen	69	mg/dL	H	15	50

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
243-001	Cycle 2	2009-10-19T09:16	Glucose	26	mg/dL	L	70	100
		2009-10-19T09:17	Hemoglobin	9.1	g/dL	L	14	18
			Erythrocytes	2.61	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	109.6	fL	H	85	95
			Platelets	95	10^9/L	L	150	350
			Leukocytes	23.72	10^9/L	H	4	10
			Neutrophils	11.7	10^9/L	H	1.6	7
			Monocytes	7	10^9/L	H	0.2	1
			Basophils	0.6	10^9/L	H	0	0.2
		2009-10-23T10:06	Hemoglobin	9.8	g/dL	L	14	18
			Erythrocytes	2.76	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	110.9	fL	H	85	95
			Platelets	9	10^9/L	L	150	350
			Leukocytes	19.72	10^9/L	H	4	10
			Neutrophils	10.4	10^9/L	H	1.6	7
			Monocytes	5.8	10^9/L	H	0.2	1
			Basophils	0.3	10^9/L	H	0	0.2
			Sodium	130	mmol/L	L	135	145
			Calcium	8.37	mg/dL	L	8.6	10
			Alanine Aminotransferase	9	U/L	L	14	63
			Alkaline Phosphatase	102	U/L	H	28	94
			Bilirubin	7	mg/dL	H	0.3	1.2
			Blood Urea Nitrogen	70	mg/dL	H	15	50
			Glucose	111	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
243-001	End Trial	2009-10-26T09:47	Hemoglobin	9	g/dL	L	14	18
			Erythrocytes	2.52	10^12/L	L	4	6
			Ery. Mean Corpuscular Volume	111.9	fL	H	85	95
			Platelets	24	10^9/L	L	150	350
			Leukocytes	24.72	10^9/L	H	4	10
			Neutrophils	14.7	10^9/L	H	1.6	7
			Monocytes	6.4	10^9/L	H	0.2	1
			Basophils	0.3	10^9/L	H	0	0.2
			Activated Partial Thromboplastin Time	38	sec	H	20	33
			Sodium	134	mmol/L	L	135	145
			Calcium	8.01	mg/dL	L	8.6	10
			Albumin	2	g/dL	L	3.4	5.2
			Alanine Aminotransferase	6	U/L	L	14	63
			Bilirubin	6.6	mg/dL	H	0.3	1.2
			Glucose	132	mg/dL	H	70	100
244-001	Pre-trial	2010-03-23T15:34	Hemoglobin	10.9	g/dL	L	11.5	16.5
			Erythrocytes	3.4	10^12/L	L	3.8	5.8
			Lymphocytes	0.66	10^9/L	L	0.8	4.4
			Magnesium	0.97	mg/dL	L	1.6	2.6
			Alkaline Phosphatase	123	U/L	H	35	104

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-001	Cycle 1	2010-03-29T10:37	Hemoglobin	10.1	g/dL	L	11.5	16.5
			Erythrocytes	3.07	10^12/L	L	3.8	5.8
			Platelets	97	10^9/L	L	140	440
			Lymphocytes	0.33	10^9/L	L	0.8	4.4
			Alkaline Phosphatase	106	U/L	H	35	104
		2010-04-07T14:10	Hemoglobin	9.4	g/dL	L	11.5	16.5
			Erythrocytes	2.91	10^12/L	L	3.8	5.8
			Platelets	106	10^9/L	L	140	440
			Lymphocytes	0.35	10^9/L	L	0.8	4.4
			Calcium	8.42	mg/dL	L	8.6	10.2
			Magnesium	1.22	mg/dL	L	1.6	2.6
			Alanine Aminotransferase	40	U/L	H	0	31
			Alkaline Phosphatase	129	U/L	H	35	104
			Lactate Dehydrogenase	567	U/L	H	240	480
			Glucose	206	mg/dL	H	70	115
	Cycle 2	2010-04-19T12:02	Hemoglobin	10.7	g/dL	L	11.5	16.5
			Erythrocytes	3.28	10^12/L	L	3.8	5.8
			Platelets	90	10^9/L	L	140	440
			Lymphocytes	0.3	10^9/L	L	0.8	4.4
			Calcium	8.22	mg/dL	L	8.6	10.2
			Magnesium	1.09	mg/dL	L	1.6	2.6
			Alanine Aminotransferase	36	U/L	H	0	31
			Aspartate Aminotransferase	41	U/L	H	0	31
			Alkaline Phosphatase	130	U/L	H	35	104
			Lactate Dehydrogenase	755	U/L	H	240	480

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-001	Cycle 2	2010-04-23T07:21	Hemoglobin	9.5	g/dL	L	11.5	16.5
			Erythrocytes	2.89	10^12/L	L	3.8	5.8
			Platelets	58	10^9/L	L	140	440
			Lymphocytes	0.14	10^9/L	L	0.8	4.4
			Calcium	8.22	mg/dL	L	8.6	10.2
			Magnesium	0.97	mg/dL	L	1.6	2.6
			Alkaline Phosphatase	124	U/L	H	35	104
			Lactate Dehydrogenase	560	U/L	H	240	480
	End Trial	2010-05-11T06:44	Hemoglobin	10	g/dL	L	11.5	16.5
			Erythrocytes	2.92	10^12/L	L	3.8	5.8
			Platelets	114	10^9/L	L	140	440
			Leukocytes	3.3	10^9/L	L	4	11
			Lymphocytes	0.23	10^9/L	L	0.8	4.4
			Potassium	2.92	mmol/L	L	3.3	5.4
			Calcium	7.82	mg/dL	L	8.6	10.2
			Chloride	89	mmol/L	L	94	110
			Magnesium	0.97	mg/dL	L	1.6	2.6
			Alkaline Phosphatase	109	U/L	H	35	104
			Lactate Dehydrogenase	599	U/L	H	240	480
			Glucose	137	mg/dL	H	70	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-002	Pre-trial	2010-10-01T06:01	Hemoglobin	11.8	g/dL	L	13	18
			Erythrocytes	3.92	10^12/L	L	4.5	6.5
			Lymphocytes	0.14	10^9/L	L	1	4
			Monocytes	0.07	10^9/L	L	0.2	1
			Creatinine	0.56	mg/dL	L	0.7	1.2
			Albumin	2.2	g/dL	L	3.4	4.8
			Glucose	204	mg/dL	H	70	115
	Cycle 1	2010-10-04T05:44	Hemoglobin	10.9	g/dL	L	13	18
			Erythrocytes	3.61	10^12/L	L	4.5	6.5
			Leukocytes	13.4	10^9/L	H	4	11
			Neutrophils	12.998	10^9/L	H	2	7.5
			Lymphocytes	0.134	10^9/L	L	1	4
			Calcium	7.62	mg/dL	L	8.6	10.2
			Phosphate	2.6	mg/dL	L	2.7	4.5
			Creatinine	0.51	mg/dL	L	0.7	1.2
			Lactate Dehydrogenase	510	U/L	H	240	480
			Glucose	209	mg/dL	H	70	115
		2010-10-08T06:15	Hemoglobin	10	g/dL	L	13	18
			Erythrocytes	3.27	10^12/L	L	4.5	6.5
			Platelets	133	10^9/L	L	140	440
			Neutrophils	8.93	10^9/L	H	2	7.5
			Lymphocytes	0.094	10^9/L	L	1	4
			Potassium	2.83	mmol/L	L	3.3	5.4
			Calcium	6.81	mg/dL	L	8.6	10.2
			Chloride	93	mmol/L	L	94	110
			Magnesium	1.46	mg/dL	L	1.6	2.6

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-002	Cycle 1	2010-10-08T06:15	Creatinine	0.69	mg/dL	L	0.7	1.2
			Glucose	225	mg/dL	H	70	115
		2010-10-14T15:05	Hemoglobin	10.1	g/dL	L	13	18
			Erythrocytes	3.37	10^12/L	L	4.5	6.5
			Platelets	128	10^9/L	L	140	440
			Lymphocytes	0.174	10^9/L	L	1	4
			Potassium	5.7	mmol/L	H	3.3	5.4
			Calcium	8.02	mg/dL	L	8.6	10.2
			Blood Urea Nitrogen	56	mg/dL	H	10	50
			Glucose	504	mg/dL	H	70	115
	Cycle 2	2010-10-25T06:45	Hemoglobin	7.5	g/dL	L	13	18
			Erythrocytes	2.48	10^12/L	L	4.5	6.5
			Leukocytes	2.8	10^9/L	L	4	11
			Lymphocytes	0.42	10^9/L	L	1	4
			Monocytes	0.14	10^9/L	L	0.2	1
			Calcium	7.21	mg/dL	L	8.6	10.2
			Creatinine	0.34	mg/dL	L	0.7	1.2
			Glucose	188	mg/dL	H	70	115
		2010-10-29T07:10	Hemoglobin	8.3	g/dL	L	13	18
			Erythrocytes	2.67	10^12/L	L	4.5	6.5
			Lymphocytes	0.329	10^9/L	L	1	4
			Monocytes	0.141	10^9/L	L	0.2	1
			Calcium	7.01	mg/dL	L	8.6	10.2
			Creatinine	0.59	mg/dL	L	0.7	1.2
			Glucose	245	mg/dL	H	70	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-003	Cycle 1	2010-11-19T06:21	Erythrocytes	3.76	10^12/L	L	3.8	5.8
			Potassium	3.13	mmol/L	L	3.3	5.4
			Calcium	7.82	mg/dL	L	8.6	10.2
			Glucose	398	mg/dL	H	70	115
		2010-11-26T10:58	Erythrocytes	3.74	10^12/L	L	3.8	5.8
			Calcium	8.42	mg/dL	L	8.6	10.2
	Cycle 2	2010-12-06T10:44	Glucose	116	mg/dL	H	70	115
		2010-12-10T15:16	Erythrocytes	3.68	10^12/L	L	3.8	5.8
			Platelets	121	10^9/L	L	140	440
			Leukocytes	15.1	10^9/L	H	4	11
			Neutrophils	12.533	10^9/L	H	2	7.5
			Potassium	3.03	mmol/L	L	3.3	5.4
			Glucose	121	mg/dL	H	70	115
	Cycle 3	2010-12-27T15:41	Erythrocytes	3.7	10^12/L	L	3.8	5.8
		2010-12-31T09:36	Erythrocytes	3.7	10^12/L	L	3.8	5.8
	Cycle 4	2011-01-17T09:08	Erythrocytes	3.67	10^12/L	L	3.8	5.8
	Cycle 5	2011-02-11T11:34	Neutrophils	8.343	10^9/L	H	2	7.5
			Chloride	93	mmol/L	L	94	110
			Phosphate	5.1	mg/dL	H	2.7	4.5
			Glucose	122	mg/dL	H	70	115
	Cycle 6	2011-03-04T08:55	Erythrocytes	3.72	10^12/L	L	3.8	5.8
	Cycle 7	2011-03-25T11:28	Erythrocytes	3.71	10^12/L	L	3.8	5.8
			Phosphate	4.6	mg/dL	H	2.7	4.5
	Cycle 8	2011-04-11T08:36	Erythrocytes	3.77	10^12/L	L	3.8	5.8
		2011-04-15T08:22	Erythrocytes	3.65	10^12/L	L	3.8	5.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-003	Cycle 9	2011-05-02T11:59	Erythrocytes	3.71	10^12/L	L	3.8	5.8
		2011-05-06T13:09	Erythrocytes	3.48	10^12/L	L	3.8	5.8
	Cycle 10	2011-05-23T10:09	Glucose	120	mg/dL	H	70	115
		2011-05-27T09:11	Erythrocytes	3.61	10^12/L	L	3.8	5.8
			Creatinine	0.97	mg/dL	H	0.5	0.9
	Cycle 11	2011-06-20T11:43	Erythrocytes	3.69	10^12/L	L	3.8	5.8
			Glucose	131	mg/dL	H	70	115
	Cycle 12	2011-07-25T14:17	Erythrocytes	3.74	10^12/L	L	3.8	5.8
		2011-07-29T11:14	Erythrocytes	3.74	10^12/L	L	3.8	5.8
			Chloride	93	mmol/L	L	94	110
	Cycle 13	2011-08-19T12:38	Erythrocytes	3.72	10^12/L	L	3.8	5.8
			Platelets	132	10^9/L	L	140	440
			Potassium	3.24	mmol/L	L	3.3	5.4
			Bilirubin	1.12	mg/dL	H	0.2	1.1
	Cycle 14	2011-09-12T15:35	Potassium	3.26	mmol/L	L	3.3	5.4
		2011-09-16T09:25	Erythrocytes	3.77	10^12/L	L	3.8	5.8
			Platelets	133	10^9/L	L	140	440
			Phosphate	4.6	mg/dL	H	2.7	4.5
			Creatinine	0.95	mg/dL	H	0.5	0.9
	Cycle 15	2011-10-07T11:55	Erythrocytes	3.65	10^12/L	L	3.8	5.8
			Platelets	131	10^9/L	L	140	440
			Creatinine	0.98	mg/dL	H	0.5	0.9
	Cycle 16	2011-10-24T09:16	Erythrocytes	3.66	10^12/L	L	3.8	5.8
			Creatinine	0.97	mg/dL	H	0.5	0.9

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-003	Cycle 16	2011-10-28T08:53	Erythrocytes	3.66	10^12/L	L	3.8	5.8
			Creatinine	1.08	mg/dL	H	0.5	0.9
			Glucose	119	mg/dL	H	70	115
	Cycle 17	2011-11-14T09:35	Glucose	117	mg/dL	H	70	115
	Cycle 18	2011-12-19T08:38	Erythrocytes	3.76	10^12/L	L	3.8	5.8
		2011-12-22T08:44	Erythrocytes	3.59	10^12/L	L	3.8	5.8
			Calcium	8.42	mg/dL	L	8.6	10.2
			Phosphate	4.6	mg/dL	H	2.7	4.5
			Creatinine	0.95	mg/dL	H	0.5	0.9
	Cycle 19	2012-01-30T10:17	Calcium	8.42	mg/dL	L	8.6	10.2
		2012-02-03T10:10	Erythrocytes	3.58	10^12/L	L	3.8	5.8
			Creatinine	0.97	mg/dL	H	0.5	0.9
	Cycle 20	2012-03-12T08:36	Erythrocytes	3.74	10^12/L	L	3.8	5.8
		2012-03-16T08:41	Erythrocytes	3.49	10^12/L	L	3.8	5.8
			Creatinine	0.98	mg/dL	H	0.5	0.9
			Glucose	61	mg/dL	L	70	115
	Cycle 21	2012-04-23T10:41	Calcium	8.22	mg/dL	L	8.6	10.2
		2012-04-27T09:26	Platelets	96	10^9/L	L	140	440
			Phosphate	4.7	mg/dL	H	2.7	4.5
			Creatinine	1.03	mg/dL	H	0.5	0.9
	Cycle 23	2012-07-16T09:18	Calcium	8.42	mg/dL	L	8.6	10.2
		2012-07-20T09:21	Lymphocytes	0.756	10^9/L	L	1	4
			Creatinine	1.03	mg/dL	H	0.5	0.9
			Bilirubin	1.13	mg/dL	H	0.2	1.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-003	End Trial	2012-08-21T08:56	Erythrocytes	3.63	10^12/L	L	3.8	5.8
			Lymphocytes	0.946	10^9/L	L	1	4
			Monocytes	1.204	10^9/L	H	0.2	1
			Calcium	8.22	mg/dL	L	8.6	10.2
			Chloride	93	mmol/L	L	94	110
244-004	Pre-trial	2010-11-25T07:16	Hemoglobin	11.4	g/dL	L	13	18
			Erythrocytes	3.73	10^12/L	L	4.5	6.5
			Albumin	3.3	g/dL	L	3.4	4.8
			Alkaline Phosphatase	248	U/L	H	40	129
			Lactate Dehydrogenase	547	U/L	H	240	480
			Glucose	156	mg/dL	H	70	115
	Cycle 1	2010-11-29T06:46	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	4.02	10^12/L	L	4.5	6.5
			Platelets	129	10^9/L	L	140	440
			Eosinophils	0.576	10^9/L	H	0	0.5
			Albumin	3.2	g/dL	L	3.4	4.8
			Alanine Aminotransferase	57	U/L	H	0	37
			Alkaline Phosphatase	262	U/L	H	40	129
		2010-12-03T06:22	Hemoglobin	10.7	g/dL	L	13	18
			Erythrocytes	3.45	10^12/L	L	4.5	6.5
			Platelets	74	10^9/L	L	140	440
			Calcium	8.02	mg/dL	L	8.6	10.2
			Albumin	2.7	g/dL	L	3.4	4.8
			Alkaline Phosphatase	245	U/L	H	40	129
			Glucose	145	mg/dL	H	70	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-004	Cycle 1	2010-12-08T14:37	Hemoglobin	12.7	g/dL	L	13	18
			Erythrocytes	4.11	10^12/L	L	4.5	6.5
			Platelets	110	10^9/L	L	140	440
			Lymphocytes	0.888	10^9/L	L	1	4
			Calcium	8.42	mg/dL	L	8.6	10.2
			Albumin	3.3	g/dL	L	3.4	4.8
			Alkaline Phosphatase	234	U/L	H	40	129
			Lactate Dehydrogenase	607	U/L	H	240	480
244-005	Pre-trial	2011-01-19T07:40	Erythrocytes	3.68	10^12/L	L	3.8	5.8
			Neutrophils	1.722	10^9/L	L	2	7.5
			Lymphocytes	5.74	10^9/L	H	1	4
			Sodium	148	mmol/L	H	132	146
			Chloride	111	mmol/L	H	94	110
			Creatinine	0.45	mg/dL	L	0.5	0.9
			Alanine Aminotransferase	52	U/L	H	0	31
			Lactate Dehydrogenase	514	U/L	H	240	480
	Cycle 1	2011-01-24T16:25	Hemoglobin	9.6	g/dL	L	11.5	16.5
			Erythrocytes	3.04	10^12/L	L	3.8	5.8
			Neutrophils	1.8	10^9/L	L	2	7.5
			Lymphocytes	7.2	10^9/L	H	1	4
			Creatinine	0.49	mg/dL	L	0.5	0.9
			Alanine Aminotransferase	54	U/L	H	0	31
			Aspartate Aminotransferase	44	U/L	H	0	31
			Lactate Dehydrogenase	950	U/L	H	240	480
			Bilirubin	0.16	mg/dL	L	0.3	1.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-005	Cycle 1	2011-01-28T06:30	Erythrocytes	3.7	10^12/L	L	3.8	5.8
			Leukocytes	18.2	10^9/L	H	4	11
			Lymphocytes	13.286	10^9/L	H	1	4
			Monocytes	1.274	10^9/L	H	0.2	1
			Sodium	147	mmol/L	H	132	146
			Potassium	3.1	mmol/L	L	3.3	5.4
			Creatinine	0.49	mg/dL	L	0.5	0.9
			Alanine Aminotransferase	62	U/L	H	0	31
			Aspartate Aminotransferase	40	U/L	H	0	31
			Lactate Dehydrogenase	733	U/L	H	240	480
		2011-02-04T10:10	Leukocytes	59.2	10^9/L	H	4	11
			Neutrophils	8.288	10^9/L	H	2	7.5
			Lymphocytes	47.952	10^9/L	H	1	4
			Monocytes	2.368	10^9/L	H	0.2	1
			Sodium	149	mmol/L	H	132	146
			Phosphate	2.5	mg/dL	L	2.7	4.5
			Alanine Aminotransferase	116	U/L	H	0	31
			Aspartate Aminotransferase	81	U/L	H	0	31
			Alkaline Phosphatase	133	U/L	H	35	104
			Lactate Dehydrogenase	1483	U/L	H	240	480
			Urate	6.1	mg/dL	H	0	5.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
244-006	Pre-trial	2011-03-14T11:49	Hemoglobin	10.1	g/dL	L	11.5	16.5
			Erythrocytes	2.85	10^12/L	L	3.8	5.8
			Leukocytes	2.7	10^9/L	L	4	11
			Lymphocytes	0.135	10^9/L	L	1	4
			Calcium	10.22	mg/dL	H	8.6	10.2
			Creatinine	0.47	mg/dL	L	0.5	0.9
			Lactate Dehydrogenase	872	U/L	H	240	480
	Cycle 1	2011-03-21T09:44	Hemoglobin	9.2	g/dL	L	11.5	16.5
			Erythrocytes	2.67	10^12/L	L	3.8	5.8
			Platelets	138	10^9/L	L	140	440
			Leukocytes	3.1	10^9/L	L	4	11
			Lymphocytes	0.155	10^9/L	L	1	4
			Activated Partial Thromboplastin Time	79	sec	H	22	38
			Prothrombin Intl. Normalized Ratio	1.33	ratio	H	0.8	1.25
			Creatinine	0.48	mg/dL	L	0.5	0.9
			Lactate Dehydrogenase	1028	U/L	H	240	480
			Glucose	150	mg/dL	H	70	115
		2011-03-25T08:20	Hemoglobin	10.7	g/dL	L	11.5	16.5
			Erythrocytes	3.18	10^12/L	L	3.8	5.8
			Platelets	64	10^9/L	L	140	440
			Leukocytes	2.3	10^9/L	L	4	11
			Lymphocytes	0.023	10^9/L	L	1	4
			Albumin	3.1	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	33	U/L	H	0	31
			Lactate Dehydrogenase	973	U/L	H	240	480

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-006	Cycle 1	2011-03-30T14:45	Hemoglobin	10.6	g/dL	L	11.5	16.5
			Erythrocytes	3.22	10^12/L	L	3.8	5.8
			Platelets	72	10^9/L	L	140	440
			Lymphocytes	0.12	10^9/L	L	1	4
			Lactate Dehydrogenase	1029	U/L	H	240	480
			Glucose	130	mg/dL	H	70	115
	Cycle 2	2011-04-11T12:24	Hemoglobin	9.3	g/dL	L	11.5	16.5
			Erythrocytes	2.88	10^12/L	L	3.8	5.8
			Platelets	80	10^9/L	L	140	440
			Leukocytes	3.2	10^9/L	L	4	11
			Lymphocytes	0.128	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	1.44	ratio	H	0.8	1.25
			Creatinine	0.49	mg/dL	L	0.5	0.9
			Lactate Dehydrogenase	987	U/L	H	240	480
			Glucose	119	mg/dL	H	70	115
		2011-04-14T06:33	Hemoglobin	9.4	g/dL	L	11.5	16.5
			Erythrocytes	2.85	10^12/L	L	3.8	5.8
			Platelets	56	10^9/L	L	140	440
			Leukocytes	2.5	10^9/L	L	4	11
			Lymphocytes	0.025	10^9/L	L	1	4
			Monocytes	0.125	10^9/L	L	0.2	1
			Albumin	3.2	g/dL	L	3.4	4.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-006	Cycle 3	2011-05-02T10:50	Hemoglobin	10.1	g/dL	L	11.5	16.5
			Erythrocytes	3.14	10^12/L	L	3.8	5.8
			Platelets	46	10^9/L	L	140	440
			Leukocytes	1.9	10^9/L	L	4	11
			Neutrophils	1.482	10^9/L	L	2	7.5
			Lymphocytes	0.133	10^9/L	L	1	4
			Prothrombin Intl. Normalized Ratio	1.39	ratio	H	0.8	1.25
			Albumin	3.3	g/dL	L	3.4	4.8
			Aspartate Aminotransferase	34	U/L	H	0	31
			Lactate Dehydrogenase	1108	U/L	H	240	480
		2011-05-06T05:51	Hemoglobin	11.3	g/dL	L	11.5	16.5
			Erythrocytes	3.52	10^12/L	L	3.8	5.8
			Platelets	24	10^9/L	L	140	440
			Leukocytes	1.6	10^9/L	L	4	11
			Neutrophils	1.408	10^9/L	L	2	7.5
			Lymphocytes	0.032	10^9/L	L	1	4
			Monocytes	0.144	10^9/L	L	0.2	1
			Potassium	3.06	mmol/L	L	3.3	5.4
			Chloride	111	mmol/L	H	94	110
			Creatinine	0.48	mg/dL	L	0.5	0.9
			Lactate Dehydrogenase	1105	U/L	H	240	480
	End Trial	2011-05-05T06:23	Prothrombin Intl. Normalized Ratio	1.76	ratio	H	0.8	1.25
		2011-05-06T05:51	Hemoglobin	11.3	g/dL	L	11.5	16.5
			Erythrocytes	3.52	10^12/L	L	3.8	5.8
			Platelets	24	10^9/L	L	140	440
			Leukocytes	1.6	10^9/L	L	4	11

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
244-006	End Trial	2011-05-06T05:51	Neutrophils	1.408	10^9/L	L	2	7.5
			Lymphocytes	0.032	10^9/L	L	1	4
			Monocytes	0.144	10^9/L	L	0.2	1
			Potassium	3.06	mmol/L	L	3.3	5.4
			Chloride	111	mmol/L	H	94	110
			Creatinine	0.48	mg/dL	L	0.5	0.9
			Lactate Dehydrogenase	1105	U/L	H	240	480
245-001	Pre-trial	2010-10-11T07:13	Hemoglobin	8.6	g/dL	L	11	14.4
			Erythrocytes	3.29	10^12/L	L	3.65	4.59
			Ery. Mean Corpuscular Volume	77.5	fL	L	82.4	97.3
		2010-10-11T07:14	Activated Partial Thromboplastin Time	41.8	sec	H	28	38.8
			Sodium	136	mmol/L	L	137	145
			Calcium	7.9	mg/dL	L	8.8	10.2
			Albumin	3.3	g/dL	L	3.5	5
			Alanine Aminotransferase	112	U/L	H	0	40.99
			Aspartate Aminotransferase	103	U/L	H	14	36
			Lactate Dehydrogenase	1555	U/L	H	313	618
	Cycle 1	2010-10-13T07:26	Hemoglobin	8.8	g/dL	L	11	14.4
			Erythrocytes	3.3	10^12/L	L	3.65	4.59
			Ery. Mean Corpuscular Volume	78.7	fL	L	82.4	97.3
			Lymphocytes	4.187	10^9/L	H	1	4
			Calcium	8.09	mg/dL	L	8.8	10.2
			Albumin	3.4	g/dL	L	3.5	5
			Alanine Aminotransferase	91	U/L	H	0	40.99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
245-001	Cycle 1	2010-10-13T07:26	Aspartate Aminotransferase	74	U/L	H	14	36
			Lactate Dehydrogenase	1244	U/L	H	313	618
		2010-10-17T07:17	Hemoglobin	8.9	g/dL	L	11	14.4
			Erythrocytes	3.4	10^12/L	L	3.65	4.59
			Ery. Mean Corpuscular Volume	79.7	fL	L	82.4	97.3
			Platelets	347	10^9/L	H	142	340
			Leukocytes	2.83	10^9/L	L	3.45	9.76
			Neutrophils	0.877	10^9/L	L	2	7.5
			Phosphate	5.3	mg/dL	H	2.5	4.5
			Magnesium	2.5	mg/dL	H	1.6	2.3
			Alanine Aminotransferase	46	U/L	H	0	40.99
			Lactate Dehydrogenase	783	U/L	H	313	618
		2010-10-25T09:09	Hemoglobin	10.3	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	82	fL	L	82.4	97.3
			Lactate Dehydrogenase	679	U/L	H	313	618
			Glucose	116	mg/dL	H	70	100
	Cycle 2	2010-11-02T09:48	Hemoglobin	10.7	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	81	fL	L	82.4	97.3
			Prothrombin Time	8.74	sec	L	11	13
			Activated Partial Thromboplastin Time	40.2	sec	H	28	38.8
			Phosphate	4.8	mg/dL	H	2.5	4.5
			Lactate Dehydrogenase	752	U/L	H	313	618

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
245-001	Cycle 2	2010-11-06T07:32	Hemoglobin	10.2	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	79.8	fL	L	82.4	97.3
			Leukocytes	2.58	10^9/L	L	3.45	9.76
			Neutrophils	1.109	10^9/L	L	2	7.5
			Calcium	8.73	mg/dL	L	8.8	10.2
			Phosphate	5.6	mg/dL	H	2.5	4.5
			Magnesium	2.4	mg/dL	H	1.6	2.3
			Blood Urea Nitrogen	14	mg/dL	L	15	36
	Cycle 3	2010-11-22T11:57	Ery. Mean Corpuscular Volume	79.8	fL	L	82.4	97.3
			Leukocytes	3.44	10^9/L	L	3.45	9.76
			Neutrophils	1.17	10^9/L	L	2	7.5
			Prothrombin Time	8.97	sec	L	11	13
			Lactate Dehydrogenase	671	U/L	H	313	618
		2010-11-26T09:58	Hemoglobin	10.4	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	78.9	fL	L	82.4	97.3
			Leukocytes	2.51	10^9/L	L	3.45	9.76
			Phosphate	5.9	mg/dL	H	2.5	4.5
			Creatinine	1.07	mg/dL	H	0.52	1.04
			Aspartate Aminotransferase	37	U/L	H	14	36
			Alkaline Phosphatase	37	U/L	L	38	126

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
245-001	Cycle 4	2010-12-13T09:27	Hemoglobin	10.9	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	79.4	fL	L	82.4	97.3
			Neutrophils	1.679	10^9/L	L	2	7.5
			Prothrombin Time	6.61	sec	L	11	13
			Activated Partial Thromboplastin Time	42	sec	H	28	38.8
			Prothrombin Intl. Normalized Ratio	1.41	ratio	H	0.8	1.25
			Alkaline Phosphatase	36	U/L	L	38	126
			Bilirubin	0.1	mg/dL	L	0.2	1.3
		2010-12-17T07:07	Hemoglobin	10.4	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	78.6	fL	L	82.4	97.3
			Leukocytes	1.99	10^9/L	L	3.45	9.76
			Neutrophils	0.86	10^9/L	L	2	7.5
			Lymphocytes	0.691	10^9/L	L	1	4
			Phosphate	5.6	mg/dL	H	2.5	4.5
			Creatinine	1.06	mg/dL	H	0.52	1.04
			Albumin	3.2	g/dL	L	3.5	5
			Bilirubin	0.1	mg/dL	L	0.2	1.3
	Cycle 5	2011-01-03T08:55	Hemoglobin	10.6	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	78.3	fL	L	82.4	97.3
			Leukocytes	3.01	10^9/L	L	3.45	9.76
			Neutrophils	1.92	10^9/L	L	2	7.5
			Lymphocytes	0.671	10^9/L	L	1	4
			Prothrombin Time	2.86	sec	L	11	13
			Activated Partial Thromboplastin Time	39.9	sec	H	28	38.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
245-001	Cycle 5	2011-01-03T08:55	Prothrombin Intl. Normalized Ratio	2	ratio	H	0.8	1.25
			Bilirubin	0.1	mg/dL	L	0.2	1.3
			Glucose	103	mg/dL	H	70	100
		2011-01-07T07:15	Hemoglobin	10.5	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	77.4	fL	L	82.4	97.3
			Leukocytes	2.03	10^9/L	L	3.45	9.76
			Neutrophils	0.889	10^9/L	L	2	7.5
			Lymphocytes	0.769	10^9/L	L	1	4
			Calcium	8.64	mg/dL	L	8.8	10.2
			Phosphate	5.7	mg/dL	H	2.5	4.5
			Creatinine	1.23	mg/dL	H	0.52	1.04
			Albumin	3.4	g/dL	L	3.5	5
	Cycle 6	2011-01-24T11:09	Hemoglobin	10.4	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	76.4	fL	L	82.4	97.3
			Leukocytes	3.35	10^9/L	L	3.45	9.76
			Lymphocytes	0.462	10^9/L	L	1	4
			Prothrombin Time	8.52	sec	L	11	13
			Activated Partial Thromboplastin Time	46.4	sec	H	28	38.8
			Sodium	134	mmol/L	L	137	145
			Lactate Dehydrogenase	741	U/L	H	313	618
			Bilirubin	0.1	mg/dL	L	0.2	1.3
			Glucose	104	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
245-001	Cycle 6	2011-01-28T07:07	Hemoglobin	10.2	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	76.5	fL	L	82.4	97.3
			Leukocytes	3.14	10^9/L	L	3.45	9.76
			Lymphocytes	0.609	10^9/L	L	1	4
			Sodium	135	mmol/L	L	137	145
			Calcium	8.2	mg/dL	L	8.8	10.2
			Albumin	3.24	g/dL	L	3.5	5
			Lactate Dehydrogenase	729	U/L	H	313	618
			Glucose	102	mg/dL	H	70	100
	End Trial	2011-02-14T10:24	Hemoglobin	10.4	g/dL	L	11	14.4
			Ery. Mean Corpuscular Volume	76.2	fL	L	82.4	97.3
			Leukocytes	3.19	10^9/L	L	3.45	9.76
			Neutrophils	1.78	10^9/L	L	2	7.5
			Lymphocytes	0.711	10^9/L	L	1	4
			Sodium	134	mmol/L	L	137	145
			Lactate Dehydrogenase	622	U/L	H	313	618
513-001	Pre-trial	2010-11-25T10:00	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.34	10^12/L	L	4.2	5.4
			Platelets	140	10^9/L	L	150	380
			Neutrophils	7.23	10^9/L	H	3	5.8
			Lymphocytes	0.81	10^9/L	L	1.5	3
			Monocytes	1.11	10^9/L	H	0.3	0.8
			Eosinophils	0	10^9/L	L	0.05	0.32
			Sodium	133	mmol/L	L	135	145
			Potassium	3.3	mmol/L	L	3.6	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-001	Pre-trial	2010-11-25T10:00	Calcium	8.3	mg/dL	L	8.4	10.4
			Albumin	2	g/dL	L	3.4	5
			Alanine Aminotransferase	52	U/L	H	15	50
			Aspartate Aminotransferase	51	U/L	H	15	37
			Alkaline Phosphatase	271	U/L	H	38	126
			Urate	2.2	mg/dL	L	2.5	6
			Glucose	122	mg/dL	H	70	110
	Cycle 1	2010-12-12T08:20	Hemoglobin	9.1	g/dL	L	12	16
			Erythrocytes	3.05	10^12/L	L	4.2	5.4
			Leukocytes	13.5	10^9/L	H	4	10
			Neutrophils	11.5	10^9/L	H	3	5.8
			Lymphocytes	1.4	10^9/L	L	1.5	3
		2010-12-13T11:15	Sodium	132.8	mmol/L	L	135	145
			Potassium	3.2	mmol/L	L	3.6	5.1
			Calcium	8.3	mg/dL	L	8.4	10.4
			Albumin	1.46	g/dL	L	3.4	5
			Aspartate Aminotransferase	38	U/L	H	15	37
			Alkaline Phosphatase	181	U/L	H	38	126
			Urate	1.9	mg/dL	L	2.5	6
		2010-12-16T07:25	Hemoglobin	8	g/dL	L	12	16
			Erythrocytes	2.72	10^12/L	L	4.2	5.4
			Platelets	148	10^9/L	L	150	380
			Leukocytes	15.07	10^9/L	H	4	10
			Neutrophils	13.33	10^9/L	H	3	5.8
			Lymphocytes	0.8	10^9/L	L	1.5	3
			Monocytes	0.92	10^9/L	H	0.3	0.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-001	Cycle 1	2010-12-16T07:25	Eosinophils	0.01	10^9/L	L	0.05	0.32
			Urate	0.9	mg/dL	L	2.5	6
		2010-12-27	Hemoglobin	8	g/dL	L	12	16
			Erythrocytes	2.76	10^12/L	L	4.2	5.4
			Leukocytes	14.89	10^9/L	H	4	10
			Neutrophils	12.08	10^9/L	H	3	5.8
			Monocytes	1.03	10^9/L	H	0.3	0.8
			Eosinophils	0.01	10^9/L	L	0.05	0.32
			Sodium	130.6	mmol/L	L	135	145
			Albumin	2.62	g/dL	L	3.4	5
			Alkaline Phosphatase	217	U/L	H	38	126
			Lactate Dehydrogenase	216	U/L	H	100	210
			Urate	1.9	mg/dL	L	2.5	6
			Glucose	126	mg/dL	H	70	110
	Cycle 2	2011-01-03T07:40	Hemoglobin	8.1	g/dL	L	12	16
			Erythrocytes	2.74	10^12/L	L	4.2	5.4
			Platelets	121	10^9/L	L	150	380
			Leukocytes	25.53	10^9/L	H	4	10
			Neutrophils	23.61	10^9/L	H	3	5.8
			Lymphocytes	0.91	10^9/L	L	1.5	3
			Monocytes	1	10^9/L	H	0.3	0.8
			Eosinophils	0	10^9/L	L	0.05	0.32
			Prothrombin Intl. Normalized Ratio	1.58	ratio	H	0.9	1.3
			Sodium	130	mmol/L	L	135	145
			Chloride	89	mmol/L	L	98	107
			Magnesium	1.6	mg/dL	L	1.7	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-001	Cycle 2	2011-01-03T07:40	Creatinine	1.31	mg/dL	H	0.6	1.3
			Albumin	2.06	g/dL	L	3.4	5
			Alanine Aminotransferase	12	U/L	L	15	50
			Alkaline Phosphatase	277	U/L	H	38	126
			Urate	2	mg/dL	L	2.5	6
		2011-01-07T07:40	Hemoglobin	9.1	g/dL	L	12	16
			Erythrocytes	3.01	10^12/L	L	4.2	5.4
			Platelets	8	10^9/L	L	150	380
			Leukocytes	16.19	10^9/L	H	4	10
			Neutrophils	15.31	10^9/L	H	3	5.8
			Lymphocytes	0.5	10^9/L	L	1.5	3
			Eosinophils	0	10^9/L	L	0.05	0.32
			Sodium	145.3	mmol/L	H	135	145
			Potassium	3.1	mmol/L	L	3.6	5.1
			Calcium	8.18	mg/dL	L	8.4	10.4
			Albumin	2.47	g/dL	L	3.4	5
			Alanine Aminotransferase	11	U/L	L	15	50
			Alkaline Phosphatase	160	U/L	H	38	126
			Lactate Dehydrogenase	250	U/L	H	100	210
			Urate	1.2	mg/dL	L	2.5	6
			Glucose	115	mg/dL	H	70	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-002	Pre-trial	2011-03-10T09:30	Hemoglobin	13.1	g/dL	L	14	18
			Erythrocytes	4.49	10^12/L	L	4.6	6.2
			Monocytes	1	10^9/L	H	0.3	0.8
			Prothrombin Intl. Normalized Ratio	0.87	ratio	L	0.9	1.3
			Alkaline Phosphatase	130	U/L	H	38	126
	Cycle 1	2011-03-14T09:45	Hemoglobin	12.9	g/dL	L	14	18
			Erythrocytes	4.47	10^12/L	L	4.6	6.2
			Monocytes	0.93	10^9/L	H	0.3	0.8
			Lactate Dehydrogenase	217	U/L	H	100	210
		2011-03-19T07:30	Hemoglobin	11.1	g/dL	L	14	18
			Erythrocytes	3.92	10^12/L	L	4.6	6.2
			Lymphocytes	1.49	10^9/L	L	1.5	3
		2011-03-29T09:25	Hemoglobin	11.6	g/dL	L	14	18
			Erythrocytes	4.13	10^12/L	L	4.6	6.2
			Leukocytes	10.14	10^9/L	H	4	10
			Neutrophils	7.83	10^9/L	H	3	5.8
			Lymphocytes	1.3	10^9/L	L	1.5	3
			Monocytes	0.82	10^9/L	H	0.3	0.8
			Alanine Aminotransferase	71	U/L	H	13	69
			Alkaline Phosphatase	143	U/L	H	38	126
			Lactate Dehydrogenase	227	U/L	H	100	210
	Cycle 2	2011-04-05T07:32	Hemoglobin	11	g/dL	L	14	18
			Erythrocytes	3.97	10^12/L	L	4.6	6.2
			Alkaline Phosphatase	136	U/L	H	38	126

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-002	Cycle 2	2011-04-09T07:00	Hemoglobin	9.4	g/dL	L	14	18
			Erythrocytes	3.31	10^12/L	L	4.6	6.2
			Neutrophils	5.81	10^9/L	H	3	5.8
			Lymphocytes	1.08	10^9/L	L	1.5	3
			Eosinophils	0.04	10^9/L	L	0.05	0.32
			Albumin	2.83	g/dL	L	3.4	5
			Urate	2.6	mg/dL	L	3.4	7.2
			Glucose	128	mg/dL	H	70	110
	End Trial	2011-04-28T10:08	Hemoglobin	11.7	g/dL	L	14	18
			Erythrocytes	4.15	10^12/L	L	4.6	6.2
			Leukocytes	17.73	10^9/L	H	4	10
			Neutrophils	13.56	10^9/L	H	3	5.8
			Monocytes	1.64	10^9/L	H	0.3	0.8
			Eosinophils	0.02	10^9/L	L	0.05	0.32
			Chloride	94	mmol/L	L	98	107
			Creatinine	1.49	mg/dL	H	0.6	1.3
			Albumin	3.13	g/dL	L	3.4	5
			Alanine Aminotransferase	138	U/L	H	13	69
			Alkaline Phosphatase	309	U/L	H	38	126
			Lactate Dehydrogenase	223	U/L	H	100	210
			Blood Urea Nitrogen	53.3	mg/dL	H	10	45

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-003	Pre-trial	2011-06-30	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4.33	10^12/L	L	4.6	6.2
			Platelets	88	10^9/L	L	148	400
			Neutrophils	1.6	10^9/L	L	3	5.8
			Eosinophils	0.56	10^9/L	H	0.05	0.32
			Prothrombin Time	10.96	sec	L	11	13
			Lactate Dehydrogenase	242	U/L	H	100	210
	Cycle 1	2011-07-04T08:58	Hemoglobin	12.2	g/dL	L	14	18
			Erythrocytes	4.28	10^12/L	L	4.6	6.2
			Platelets	87	10^9/L	L	148	400
			Leukocytes	3.97	10^9/L	L	4	10
			Neutrophils	1.09	10^9/L	L	3	5.8
			Eosinophils	0.69	10^9/L	H	0.05	0.32
			Lactate Dehydrogenase	217	U/L	H	100	210
			Glucose	113	mg/dL	H	70	110
		2011-07-08T07:46	Hemoglobin	11.7	g/dL	L	14	18
			Erythrocytes	4.09	10^12/L	L	4.6	6.2
			Platelets	65	10^9/L	L	148	400
			Neutrophils	2.54	10^9/L	L	3	5.8
			Lymphocytes	0.83	10^9/L	L	1.5	3
			Eosinophils	0.43	10^9/L	H	0.05	0.32
		2011-07-15T08:42	Hemoglobin	13.4	g/dL	L	14	18
			Platelets	70	10^9/L	L	148	400
			Neutrophils	0.96	10^9/L	L	3	5.8
			Eosinophils	1.1	10^9/L	H	0.05	0.32

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-003	Cycle 2	2011-07-25T10:10	Hemoglobin	13.9	g/dL	L	14	18
			Platelets	99	10^9/L	L	148	400
			Neutrophils	1.71	10^9/L	L	3	5.8
			Eosinophils	0.94	10^9/L	H	0.05	0.32
		2011-07-29T07:55	Hemoglobin	11.4	g/dL	L	14	18
			Erythrocytes	4.05	10^12/L	L	4.6	6.2
			Platelets	70	10^9/L	L	148	400
			Leukocytes	3.76	10^9/L	L	4	10
			Neutrophils	1.64	10^9/L	L	3	5.8
			Lymphocytes	0.94	10^9/L	L	1.5	3
			Eosinophils	0.76	10^9/L	H	0.05	0.32
	Cycle 3	2011-08-16T08:58	Hemoglobin	13.1	g/dL	L	14	18
			Erythrocytes	4.58	10^12/L	L	4.6	6.2
			Platelets	96	10^9/L	L	148	400
			Leukocytes	3.81	10^9/L	L	4	10
			Neutrophils	1.32	10^9/L	L	3	5.8
			Lymphocytes	1.36	10^9/L	L	1.5	3
			Eosinophils	0.77	10^9/L	H	0.05	0.32
			Prothrombin Time	10.84	sec	L	11	13
		2011-08-20T08:06	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4.3	10^12/L	L	4.6	6.2
			Platelets	85	10^9/L	L	148	400
			Neutrophils	2.22	10^9/L	L	3	5.8
			Lymphocytes	1.01	10^9/L	L	1.5	3
			Eosinophils	0.86	10^9/L	H	0.05	0.32

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-003	Cycle 4	2011-09-05T09:58	Hemoglobin	13.1	g/dL	L	14	18
			Platelets	89	10^9/L	L	148	400
			Neutrophils	1.64	10^9/L	L	3	5.8
			Eosinophils	0.65	10^9/L	H	0.05	0.32
		2011-09-09T08:02	Hemoglobin	12.5	g/dL	L	14	18
			Erythrocytes	4.45	10^12/L	L	4.6	6.2
			Platelets	82	10^9/L	L	148	400
			Neutrophils	2.57	10^9/L	L	3	5.8
			Lymphocytes	0.81	10^9/L	L	1.5	3
			Monocytes	0.29	10^9/L	L	0.3	0.8
			Eosinophils	0.52	10^9/L	H	0.05	0.32
			Potassium	3.3	mmol/L	L	3.6	5.1
			Glucose	127	mg/dL	H	70	110
	Cycle 5	2011-09-26T10:58	Hemoglobin	13.3	g/dL	L	14	18
			Platelets	77	10^9/L	L	148	400
			Neutrophils	1.81	10^9/L	L	3	5.8
			Eosinophils	0.76	10^9/L	H	0.05	0.32
		2011-09-30T07:43	Hemoglobin	12.7	g/dL	L	14	18
			Erythrocytes	4.55	10^12/L	L	4.6	6.2
			Platelets	64	10^9/L	L	148	400
			Neutrophils	2.33	10^9/L	L	3	5.8
			Lymphocytes	0.77	10^9/L	L	1.5	3
			Eosinophils	0.67	10^9/L	H	0.05	0.32

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-003	Cycle 6	2011-10-17T09:46	Hemoglobin	12.8	g/dL	L	14	18
			Erythrocytes	4.55	10^12/L	L	4.6	6.2
			Platelets	81	10^9/L	L	148	400
			Leukocytes	3.11	10^9/L	L	4	10
			Neutrophils	1.41	10^9/L	L	3	5.8
			Lymphocytes	1.09	10^9/L	L	1.5	3
			Lactate Dehydrogenase	247	U/L	H	100	210
		2011-10-21T09:26	Hemoglobin	11.9	g/dL	L	14	18
			Erythrocytes	4.16	10^12/L	L	4.6	6.2
			Platelets	59	10^9/L	L	148	400
			Leukocytes	2.72	10^9/L	L	4	10
			Neutrophils	1.93	10^9/L	L	3	5.8
			Lymphocytes	0.41	10^9/L	L	1.5	3
			Monocytes	0.26	10^9/L	L	0.3	0.8
			Calcium	8.34	mg/dL	L	8.4	10.4
			Lactate Dehydrogenase	266	U/L	H	100	210
	End Trial	2011-10-31T09:34	Hemoglobin	12.5	g/dL	L	14	18
			Erythrocytes	4.44	10^12/L	L	4.6	6.2
			Platelets	55	10^9/L	L	148	400
			Leukocytes	3.09	10^9/L	L	4	10
			Neutrophils	2.1	10^9/L	L	3	5.8
			Lymphocytes	0.65	10^9/L	L	1.5	3
			Monocytes	0.27	10^9/L	L	0.3	0.8
			Sodium	131.5	mmol/L	L	135	145
			Calcium	7.98	mg/dL	L	8.4	10.4
			Creatinine	1.91	mg/dL	H	0.6	1.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-003	End Trial	2011-10-31T09:34	Albumin	3.13	g/dL	L	3.4	5
			Alanine Aminotransferase	94	U/L	H	13	69
			Aspartate Aminotransferase	107	U/L	H	15	46
			Alkaline Phosphatase	317	U/L	H	38	126
			Lactate Dehydrogenase	755	U/L	H	100	210
			Bilirubin	1.24	mg/dL	H	0.2	1.2
			Blood Urea Nitrogen	45.1	mg/dL	H	10	45
			Urate	7.7	mg/dL	H	3.4	7.2
			Glucose	115	mg/dL	H	70	110
513-004	Pre-trial	2011-07-26T11:00	Eosinophils	0.47	10^9/L	H	0.05	0.32
			Prothrombin Time	14.4	sec	H	11	13
			Activated Partial Thromboplastin Time	21	sec	L	25	36
			Sodium	134.4	mmol/L	L	135	145
			Chloride	97	mmol/L	L	98	107
			Magnesium	2.43	mg/dL	H	1.7	2.4
			Alanine Aminotransferase	11	U/L	L	15	50
			Aspartate Aminotransferase	9	U/L	L	15	37
	Cycle 1	2011-08-01T09:22	Eosinophils	0.48	10^9/L	H	0.05	0.32
			Activated Partial Thromboplastin Time	20.3	sec	L	25	36
			Prothrombin Intl. Normalized Ratio	0.86	ratio	L	0.9	1.3
			Aspartate Aminotransferase	11	U/L	L	15	37

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-004	Cycle 1	2011-08-05T08:00	Lymphocytes	1.24	10^9/L	L	1.5	3
			Eosinophils	0.03	10^9/L	L	0.05	0.32
			Alanine Aminotransferase	264	U/L	H	15	50
			Aspartate Aminotransferase	70	U/L	H	15	37
			Alkaline Phosphatase	165	U/L	H	38	126
			Urate	2.2	mg/dL	L	2.5	6
		2011-08-11T09:56	Neutrophils	2.56	10^9/L	L	3	5.8
			Lymphocytes	1.25	10^9/L	L	1.5	3
			Alanine Aminotransferase	51	U/L	H	15	50
			Alkaline Phosphatase	166	U/L	H	38	126
			Lactate Dehydrogenase	229	U/L	H	100	210
	Cycle 2	2011-08-22T09:30	Leukocytes	2.71	10^9/L	L	4	10
			Neutrophils	0.54	10^9/L	L	3	5.8
			Lymphocytes	1.12	10^9/L	L	1.5	3
			Eosinophils	0.39	10^9/L	H	0.05	0.32
			Chloride	97	mmol/L	L	98	107
			Alkaline Phosphatase	180	U/L	H	38	126
			Lactate Dehydrogenase	227	U/L	H	100	210
		2011-08-26T08:30	Hemoglobin	11.8	g/dL	L	12	16
			Erythrocytes	4.09	10^12/L	L	4.2	5.4
			Leukocytes	2.48	10^9/L	L	4	10
			Neutrophils	1.07	10^9/L	L	3	5.8
			Lymphocytes	1.21	10^9/L	L	1.5	3
			Monocytes	0.18	10^9/L	L	0.3	0.8
			Eosinophils	0.01	10^9/L	L	0.05	0.32

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-004	Cycle 2	2011-08-26T08:35	Potassium	3.3	mmol/L	L	3.6	5.1
			Aspartate Aminotransferase	56	U/L	H	15	37
			Lactate Dehydrogenase	226	U/L	H	100	210
			Urate	2.4	mg/dL	L	2.5	6
			Glucose	124	mg/dL	H	70	110
	Cycle 3	2011-09-12T09:52	Leukocytes	10.05	10^9/L	H	4	10
			Neutrophils	6.75	10^9/L	H	3	5.8
			Monocytes	0.97	10^9/L	H	0.3	0.8
			Basophils	0.08	10^9/L	H	0	0.05
			Sodium	134.2	mmol/L	L	135	145
			Chloride	96	mmol/L	L	98	107
			Alanine Aminotransferase	84	U/L	H	15	50
			Alkaline Phosphatase	264	U/L	H	38	126
			Lactate Dehydrogenase	270	U/L	H	100	210
		2011-09-16T08:40	Leukocytes	11.37	10^9/L	H	4	10
			Neutrophils	9.19	10^9/L	H	3	5.8
			Eosinophils	0.04	10^9/L	L	0.05	0.32
			Sodium	134.1	mmol/L	L	135	145
			Albumin	3.34	g/dL	L	3.4	5
			Alanine Aminotransferase	131	U/L	H	15	50
			Alkaline Phosphatase	335	U/L	H	38	126
			Glucose	172	mg/dL	H	70	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
513-004	End Trial	2011-10-03T10:10	Hemoglobin	10.3	g/dL	L	12	16
			Erythrocytes	3.61	10^12/L	L	4.2	5.4
			Neutrophils	6.48	10^9/L	H	3	5.8
			Monocytes	0.96	10^9/L	H	0.3	0.8
			Calcium	8.26	mg/dL	L	8.4	10.4
			Magnesium	1.48	mg/dL	L	1.7	2.4
			Albumin	2.3	g/dL	L	3.4	5
			Alkaline Phosphatase	307	U/L	H	38	126
			Lactate Dehydrogenase	252	U/L	H	100	210
			Bilirubin	2.433	mg/dL	H	0.2	1.2
			Urate	2.2	mg/dL	L	2.5	6
516-001	Pre-trial	2011-04-14T09:00	Platelets	521	10^9/L	H	140	440
			Leukocytes	10.8	10^9/L	H	3.8	10
			Neutrophils	7.73	10^9/L	H	2.5	7
			Sodium	131	mmol/L	L	136	146
			Calcium	10.22	mg/dL	H	8.6	10.2
			Chloride	95	mmol/L	L	98	107
			Magnesium	1.48	mg/dL	L	1.6	2.6
			Aspartate Aminotransferase	55	U/L	H	5	34
			Lactate Dehydrogenase	662	U/L	H	125	243
			Urate	6.15	mg/dL	H	2.5	5.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-001	Cycle 1	2011-04-22T08:30	Sodium	134	mmol/L	L	136	146
			Calcium	10.62	mg/dL	H	8.6	10.2
			Chloride	95	mmol/L	L	98	107
			Aspartate Aminotransferase	39	U/L	H	5	34
			Lactate Dehydrogenase	443	U/L	H	125	243
			Blood Urea Nitrogen	23.25	mg/dL	H	9.8	20.2
		2011-04-30T08:55	Lymphocytes	0.74	10^9/L	L	1	3.5
			Sodium	133	mmol/L	L	136	146
			Potassium	3.3	mmol/L	L	3.5	5.5
			Calcium	10.34	mg/dL	H	8.6	10.2
			Chloride	96	mmol/L	L	98	107
			Aspartate Aminotransferase	52	U/L	H	5	34
			Lactate Dehydrogenase	697	U/L	H	125	243
			Urate	6.72	mg/dL	H	2.5	5.9
		2011-05-06T08:55	Sodium	123	mmol/L	L	136	146
			Chloride	88	mmol/L	L	98	107
			Phosphate	4.86	mg/dL	H	2.5	4.7
			Creatinine	1.807	mg/dL	H	0.57	1.11
			Albumin	3.1	g/dL	L	3.5	5.3
			Aspartate Aminotransferase	96	U/L	H	5	34
			Lactate Dehydrogenase	1161	U/L	H	125	243
			Blood Urea Nitrogen	46.22	mg/dL	H	9.8	20.2
			Urate	10.63	mg/dL	H	2.5	5.9
		2011-05-06T12:12	Lymphocytes	0.85	10^9/L	L	1	3.5
			Eosinophils	0.01	10^9/L	L	0.1	0.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-001	End Trial	2011-05-16	Lymphocytes	0.53	10^9/L	L	1	3.5
			Eosinophils	0	10^9/L	L	0.1	0.5
			Basophils	0.2	10^9/L	H	0	0.1
			Sodium	119	mmol/L	L	136	146
			Calcium	10.22	mg/dL	H	8.6	10.2
			Chloride	86	mmol/L	L	98	107
			Albumin	2.6	g/dL	L	3.5	5.3
			Aspartate Aminotransferase	89	U/L	H	5	34
			Lactate Dehydrogenase	1282	U/L	H	125	243
			Blood Urea Nitrogen	30.25	mg/dL	H	9.8	20.2
			Urate	7.74	mg/dL	H	2.5	5.9
			Glucose	133.1	mg/dL	H	70	104
516-003	Pre-trial	2011-05-12T15:20	Blood Urea Nitrogen	29.41	mg/dL	H	8.4	25.8
			Glucose	109.2	mg/dL	H	70	104
	Cycle 1	2011-05-16T15:20	Hemoglobin	13.9	g/dL	L	14	18
		2011-05-21T09:25	Hemoglobin	13.1	g/dL	L	14	18
			Platelets	131	10^9/L	L	140	440
			Albumin	3.2	g/dL	L	3.5	5.3
			Glucose	130.2	mg/dL	H	70	104
		2011-05-27T08:20	Hemoglobin	13	g/dL	L	14	18
			Platelets	108	10^9/L	L	140	440
			Blood Urea Nitrogen	26.89	mg/dL	H	8.4	25.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-003	Cycle 2	2011-06-06T09:00	Hemoglobin	13.5	g/dL	L	14	18
		2011-06-11T09:00	Hemoglobin	12.3	g/dL	L	14	18
			Platelets	120	10^9/L	L	140	440
			Lymphocytes	0.77	10^9/L	L	1	3.5
			Chloride	108	mmol/L	H	98	107
			Albumin	3.2	g/dL	L	3.5	5.3
			Aspartate Aminotransferase	45	U/L	H	5	34
			Alkaline Phosphatase	150	U/L	H	30	120
			Blood Urea Nitrogen	26.05	mg/dL	H	8.4	25.8
	Cycle 3	2011-06-27	Eosinophils	0.05	10^9/L	L	0.1	0.5
			Albumin	3.4	g/dL	L	3.5	5.3
			Blood Urea Nitrogen	28.29	mg/dL	H	8.4	25.8
		2011-07-02T08:50	Hemoglobin	13.5	g/dL	L	14	18
			Platelets	114	10^9/L	L	140	440
			Leukocytes	3	10^9/L	L	3.8	10
			Neutrophils	2.16	10^9/L	L	2.5	7
			Lymphocytes	0.49	10^9/L	L	1	3.5
			Phosphate	2.45	mg/dL	L	2.5	4.7
			Albumin	3.1	g/dL	L	3.5	5.3
			Glucose	120.9	mg/dL	H	70	104
	Cycle 4	2011-07-23T08:05	Albumin	3.3	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	348	U/L	H	125	243
			Glucose	112.1	mg/dL	H	70	104

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-003	Cycle 5	2011-08-08T08:05	Hemoglobin	13.5	g/dL	L	14	18
			Lymphocytes	0.96	10^9/L	L	1	3.5
			Eosinophils	0.07	10^9/L	L	0.1	0.5
		2011-08-13T06:45	Hemoglobin	13.8	g/dL	L	14	18
			Lymphocytes	0.82	10^9/L	L	1	3.5
			Lactate Dehydrogenase	277	U/L	H	125	243
	Cycle 6	2011-08-29T08:15	Lymphocytes	0.68	10^9/L	L	1	3.5
			Eosinophils	0.08	10^9/L	L	0.1	0.5
			Prothrombin Intl. Normalized Ratio	0.89	ratio	L	0.9	1.2
			Albumin	3.4	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	249	U/L	H	125	243
		2011-09-03T06:50	Hemoglobin	13.1	g/dL	L	14	18
			Platelets	134	10^9/L	L	140	440
			Lymphocytes	0.51	10^9/L	L	1	3.5
			Eosinophils	0.01	10^9/L	L	0.1	0.5
			Chloride	109	mmol/L	H	98	107
			Albumin	3.3	g/dL	L	3.5	5.3
			Lactate Dehydrogenase	252	U/L	H	125	243
			Blood Urea Nitrogen	28.01	mg/dL	H	8.4	25.8
			Glucose	106.5	mg/dL	H	70	104
516-004	Pre-trial	2011-06-21T09:15	Lymphocytes	0.95	10^9/L	L	1	3.5
			Eosinophils	0.51	10^9/L	H	0.1	0.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-004	Cycle 1	2011-06-27T08:30	Leukocytes	10.1	10^9/L	H	3.8	10
			Neutrophils	7.61	10^9/L	H	2.5	7
			Lactate Dehydrogenase	254	U/L	H	125	243
			Glucose	107.5	mg/dL	H	70	104
		2011-07-02T08:55	Platelets	127	10^9/L	L	140	440
			Lymphocytes	0.75	10^9/L	L	1	3.5
			Glucose	124.3	mg/dL	H	70	104
		2011-07-08T08:20	Eosinophils	0.52	10^9/L	H	0.1	0.5
			Lactate Dehydrogenase	251	U/L	H	125	243
	Cycle 2	2011-07-18T08:10	Neutrophils	7.62	10^9/L	H	2.5	7
			Lymphocytes	0.83	10^9/L	L	1	3.5
			Phosphate	2.48	mg/dL	L	2.5	4.7
			Lactate Dehydrogenase	297	U/L	H	125	243
		2011-07-23T08:35	Platelets	133	10^9/L	L	140	440
			Lymphocytes	0.67	10^9/L	L	1	3.5
			Potassium	3.4	mmol/L	L	3.5	5.5
			Lactate Dehydrogenase	246	U/L	H	125	243
			Glucose	128.3	mg/dL	H	70	104
	Cycle 3	2011-08-08T08:15	Lymphocytes	0.84	10^9/L	L	1	3.5
			Prothrombin Intl. Normalized Ratio	0.89	ratio	L	0.9	1.2
			Phosphate	2.2	mg/dL	L	2.5	4.7
			Lactate Dehydrogenase	278	U/L	H	125	243

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-004	Cycle 3	2011-08-13T06:40	Platelets	136	10^9/L	L	140	440
			Lymphocytes	0.97	10^9/L	L	1	3.5
			Phosphate	2.32	mg/dL	L	2.5	4.7
			Lactate Dehydrogenase	244	U/L	H	125	243
			Glucose	123.4	mg/dL	H	70	104
	Cycle 4	2011-08-29T08:30	Lymphocytes	0.77	10^9/L	L	1	3.5
			Lactate Dehydrogenase	250	U/L	H	125	243
		2011-09-03T06:40	Lymphocytes	0.57	10^9/L	L	1	3.5
			Lactate Dehydrogenase	244	U/L	H	125	243
			Glucose	136.9	mg/dL	H	70	104
	Cycle 5	2011-10-03T08:15	Lymphocytes	0.84	10^9/L	L	1	3.5
			Phosphate	2.23	mg/dL	L	2.5	4.7
			Lactate Dehydrogenase	359	U/L	H	125	243
		2011-10-08T09:05	Lymphocytes	0.79	10^9/L	L	1	3.5
			Phosphate	2.45	mg/dL	L	2.5	4.7
			Lactate Dehydrogenase	300	U/L	H	125	243
			Glucose	128.8	mg/dL	H	70	104
	Cycle 6	2011-10-24T09:30	Lymphocytes	0.99	10^9/L	L	1	3.5
			Lactate Dehydrogenase	352	U/L	H	125	243
		2011-10-29T07:30	Platelets	117	10^9/L	L	140	440
			Lymphocytes	0.75	10^9/L	L	1	3.5
			Lactate Dehydrogenase	360	U/L	H	125	243
			Glucose	125.7	mg/dL	H	70	104
	Cycle 7	2011-11-14T08:30	Lymphocytes	0.8	10^9/L	L	1	3.5
			Lactate Dehydrogenase	460	U/L	H	125	243

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-004	Cycle 7	2011-11-19T07:45	Platelets	116	10^9/L	L	140	440
			Lymphocytes	0.69	10^9/L	L	1	3.5
			Potassium	3.2	mmol/L	L	3.5	5.5
			Lactate Dehydrogenase	360	U/L	H	125	243
			Glucose	137.3	mg/dL	H	70	104
	Cycle 8	2011-12-05T11:00	Chloride	108	mmol/L	H	98	107
			Lactate Dehydrogenase	417	U/L	H	125	243
		2011-12-10T09:30	Platelets	122	10^9/L	L	140	440
			Lymphocytes	0.54	10^9/L	L	1	3.5
			Calcium	10.22	mg/dL	H	8.6	10.2
			Lactate Dehydrogenase	482	U/L	H	125	243
			Glucose	111.3	mg/dL	H	70	104
	Cycle 9	2012-01-16T10:30	Platelets	121	10^9/L	L	140	440
			Leukocytes	3.2	10^9/L	L	3.8	10
			Neutrophils	1.75	10^9/L	L	2.5	7
			Lymphocytes	0.84	10^9/L	L	1	3.5
			Phosphate	2.07	mg/dL	L	2.5	4.7
			Aspartate Aminotransferase	39	U/L	H	5	34
			Lactate Dehydrogenase	487	U/L	H	125	243
			Blood Urea Nitrogen	8.12	mg/dL	L	9	20.7
		2012-01-21T09:00	Hemoglobin	12.7	g/dL	L	14	18
			Erythrocytes	4	10^12/L	L	4.2	6
			Platelets	128	10^9/L	L	140	440
			Lymphocytes	0.3	10^9/L	L	1	3.5
			Potassium	3.3	mmol/L	L	3.5	5.5
			Phosphate	1.98	mg/dL	L	2.5	4.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-004	Cycle 9	2012-01-21T09:00	Lactate Dehydrogenase	369	U/L	H	125	243
			Glucose	136.6	mg/dL	H	70	104
	Cycle 10	2012-02-06T08:35	Lymphocytes	0.71	10^9/L	L	1	3.5
			Lactate Dehydrogenase	353	U/L	H	125	243
		2012-02-11T08:15	Hemoglobin	13.5	g/dL	L	14	18
			Platelets	134	10^9/L	L	140	440
			Lymphocytes	0.57	10^9/L	L	1	3.5
			Eosinophils	0.52	10^9/L	H	0.1	0.5
			Potassium	3.4	mmol/L	L	3.5	5.5
			Lactate Dehydrogenase	344	U/L	H	125	243
	Cycle 11	2012-02-27T09:40	Lymphocytes	0.72	10^9/L	L	1	3.5
			Lactate Dehydrogenase	318	U/L	H	125	243
		2012-03-03T08:00	Platelets	134	10^9/L	L	140	440
			Lymphocytes	0.82	10^9/L	L	1	3.5
			Eosinophils	0.51	10^9/L	H	0.1	0.5
			Potassium	3.3	mmol/L	L	3.5	5.5
			Lactate Dehydrogenase	316	U/L	H	125	243
	Cycle 12	2012-03-19T09:00	Lymphocytes	0.98	10^9/L	L	1	3.5
			Creatinine	0.718	mg/dL	L	0.72	1.25
			Lactate Dehydrogenase	339	U/L	H	125	243
		2012-03-24T08:00	Platelets	126	10^9/L	L	140	440
			Lymphocytes	0.53	10^9/L	L	1	3.5
			Eosinophils	0.6	10^9/L	H	0.1	0.5
			Lactate Dehydrogenase	303	U/L	H	125	243

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-004	Cycle 13	2012-04-10T09:10	Lymphocytes	0.74	10^9/L	L	1	3.5
			Lactate Dehydrogenase	353	U/L	H	125	243
		2012-04-14T08:15	Platelets	137	10^9/L	L	140	440
			Lymphocytes	0.7	10^9/L	L	1	3.5
			Eosinophils	0.51	10^9/L	H	0.1	0.5
			Lactate Dehydrogenase	300	U/L	H	125	243
	Cycle 14	2012-05-07T08:30	Lymphocytes	0.66	10^9/L	L	1	3.5
			Eosinophils	0.53	10^9/L	H	0.1	0.5
			Sodium	135	mmol/L	L	136	146
			Lactate Dehydrogenase	339	U/L	H	125	243
		2012-05-12T08:45	Platelets	122	10^9/L	L	140	440
			Lymphocytes	0.47	10^9/L	L	1	3.5
			Eosinophils	0.64	10^9/L	H	0.1	0.5
			Lactate Dehydrogenase	320	U/L	H	125	243
			Glucose	119.8	mg/dL	H	70	104
	Cycle 15	2012-06-11T10:00	Hemoglobin	13.7	g/dL	L	14	18
			Leukocytes	3.5	10^9/L	L	3.8	10
			Neutrophils	2.32	10^9/L	L	2.5	7
			Lymphocytes	0.59	10^9/L	L	1	3.5
			Lactate Dehydrogenase	485	U/L	H	125	243
			Glucose	105.6	mg/dL	H	70	104
		2012-06-16T08:15	Hemoglobin	13.5	g/dL	L	14	18
			Lymphocytes	0.25	10^9/L	L	1	3.5
			Lactate Dehydrogenase	403	U/L	H	125	243

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-004	Cycle 16	2012-07-02T10:00	Hemoglobin	13.9	g/dL	L	14	18
			Lymphocytes	0.71	10^9/L	L	1	3.5
			Lactate Dehydrogenase	410	U/L	H	125	243
		2012-07-07T08:00	Hemoglobin	13	g/dL	L	14	18
			Erythrocytes	4.09	10^12/L	L	4.2	6
			Platelets	136	10^9/L	L	140	440
			Lymphocytes	0.39	10^9/L	L	1	3.5
			Lactate Dehydrogenase	323	U/L	H	125	243
	Cycle 17	2012-07-23T09:30	Hemoglobin	13.5	g/dL	L	14	18
			Lymphocytes	0.63	10^9/L	L	1	3.5
		2012-07-24T09:30	Lactate Dehydrogenase	413	U/L	H	125	243
		2012-07-28T08:05	Hemoglobin	13.8	g/dL	L	14	18
			Platelets	132	10^9/L	L	140	440
			Lymphocytes	0.59	10^9/L	L	1	3.5
			Potassium	3.3	mmol/L	L	3.5	5.5
			Lactate Dehydrogenase	305	U/L	H	125	243
			Glucose	138.9	mg/dL	H	70	104
	Cycle 18	2012-08-20T11:00	Lymphocytes	0.62	10^9/L	L	1	3.5
			Lactate Dehydrogenase	442	U/L	H	125	243
		2012-08-25T08:15	Hemoglobin	13.6	g/dL	L	14	18
			Lymphocytes	0.32	10^9/L	L	1	3.5
			Lactate Dehydrogenase	426	U/L	H	125	243
			Glucose	116	mg/dL	H	70	104

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-006	Pre-trial	2011-07-11T17:45	Hemoglobin	9	g/dL	L	14	18
			Erythrocytes	3.3	10^12/L	L	4.2	6
			Platelets	70	10^9/L	L	140	440
			Leukocytes	3.3	10^9/L	L	3.8	10
			Neutrophils	2.21	10^9/L	L	2.5	7
			Lymphocytes	0.73	10^9/L	L	1	3.5
			Eosinophils	0.06	10^9/L	L	0.1	0.5
			Calcium	8.46	mg/dL	L	8.6	10.2
			Creatinine	0.691	mg/dL	L	0.72	1.25
			Albumin	3.3	g/dL	L	3.5	5.3
	Cycle 1	2011-07-18T08:15	Hemoglobin	8.9	g/dL	L	14	18
			Erythrocytes	3.1	10^12/L	L	4.2	6
			Platelets	71	10^9/L	L	140	440
			Lymphocytes	0.82	10^9/L	L	1	3.5
			Calcium	8.54	mg/dL	L	8.6	10.2
			Creatinine	0.707	mg/dL	L	0.72	1.25
			Albumin	3.1	g/dL	L	3.5	5.3
		2011-07-23T07:50	Hemoglobin	8.8	g/dL	L	14	18
			Erythrocytes	3.1	10^12/L	L	4.2	6
			Platelets	45	10^9/L	L	140	440
			Lymphocytes	0.78	10^9/L	L	1	3.5
			Sodium	134	mmol/L	L	136	146
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	8.34	mg/dL	L	8.6	10.2
			Albumin	3.2	g/dL	L	3.5	5.3
			Alkaline Phosphatase	145	U/L	H	30	120

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
516-006	Cycle 1	2011-07-29	Hemoglobin	6.3	g/dL	L	14	18
			Erythrocytes	2.2	10^12/L	L	4.2	6
			Platelets	17	10^9/L	L	140	440
			Leukocytes	2.8	10^9/L	L	3.8	10
			Neutrophils	1.56	10^9/L	L	2.5	7
			Lymphocytes	0.71	10^9/L	L	1	3.5
			Calcium	8.26	mg/dL	L	8.6	10.2
			Creatinine	0.652	mg/dL	L	0.72	1.25
			Albumin	3	g/dL	L	3.5	5.3
	Cycle 2	2011-08-08T09:10	Hemoglobin	7.3	g/dL	L	14	18
			Erythrocytes	2.5	10^12/L	L	4.2	6
			Platelets	8	10^9/L	L	140	440
			Leukocytes	2.2	10^9/L	L	3.8	10
			Neutrophils	1.35	10^9/L	L	2.5	7
			Lymphocytes	0.69	10^9/L	L	1	3.5
			Monocytes	0.16	10^9/L	L	0.2	1
			Eosinophils	0.02	10^9/L	L	0.1	0.5
			Calcium	8.54	mg/dL	L	8.6	10.2
			Creatinine	0.655	mg/dL	L	0.72	1.25
			Albumin	3.1	g/dL	L	3.5	5.3
			Urate	3.15	mg/dL	L	3.5	7.1

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-001	Pre-trial	2010-08-04T10:25	Hemoglobin	10.3	g/dL	L	12	16
			Erythrocytes	3.71	10^12/L	L	4	5.6
			Platelets	388	10^9/L	H	120	350
			Leukocytes	11.4	10^9/L	H	4	10
			Neutrophils	9.23	10^9/L	H	2.04	7.5
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Activated Partial Thromboplastin Time	31.7	sec	H	22.7	30.4
			Calcium	8.54	mg/dL	L	8.8	10.6
			Albumin	3.2	g/dL	L	3.5	5.2
			Alanine Aminotransferase	5	U/L	L	6	31
			Alkaline Phosphatase	280	U/L	H	98	279
			Lactate Dehydrogenase	569	U/L	H	240	480
			Bilirubin	1.053	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	3.92	mg/dL	L	7	21
	Cycle 1	2010-08-04T10:25	Hemoglobin	10.3	g/dL	L	12	16
			Erythrocytes	3.71	10^12/L	L	4	5.6
			Platelets	388	10^9/L	H	120	350
			Leukocytes	11.4	10^9/L	H	4	10
			Neutrophils	9.23	10^9/L	H	2.04	7.5
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Activated Partial Thromboplastin Time	31.7	sec	H	22.7	30.4
			Calcium	8.54	mg/dL	L	8.8	10.6
			Albumin	3.2	g/dL	L	3.5	5.2
			Alanine Aminotransferase	5	U/L	L	6	31

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-001	Cycle 1	2010-08-04T10:25	Alkaline Phosphatase	280	U/L	H	98	279
			Lactate Dehydrogenase	569	U/L	H	240	480
			Bilirubin	1.053	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	3.92	mg/dL	L	7	21
		2010-08-10T09:20	Hemoglobin	10.3	g/dL	L	12	16
			Erythrocytes	3.63	10^12/L	L	4	5.6
			Platelets	372	10^9/L	H	120	350
			Potassium	3.4	mmol/L	L	3.5	5.3
			Magnesium	1.85	mg/dL	L	1.9	2.5
			Alanine Aminotransferase	5	U/L	L	6	31
			Bilirubin	1.111	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	6.16	mg/dL	L	7	21
		2010-08-16T09:25	Hemoglobin	10.5	g/dL	L	12	16
			Erythrocytes	3.52	10^12/L	L	4	5.6
			Leukocytes	11.2	10^9/L	H	4	10
			Neutrophils	8.3	10^9/L	H	2.04	7.5
			Eosinophils	1.33	10^9/L	H	0.04	0.4
		2010-08-16T09:42	Calcium	8.78	mg/dL	L	8.8	10.6
			Magnesium	1.65	mg/dL	L	1.9	2.5
			Alanine Aminotransferase	5	U/L	L	6	31
			Lactate Dehydrogenase	509	U/L	H	240	480
			Blood Urea Nitrogen	6.16	mg/dL	L	7	21
			Urate	2.35	mg/dL	L	2.5	6

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-001	Cycle 2	2010-08-27T09:20	Platelets	353	10^9/L	H	120	350
			Leukocytes	21.8	10^9/L	H	4	10
			Neutrophils	18.12	10^9/L	H	2.04	7.5
			Lymphocytes	0.71	10^9/L	L	0.8	4
			Eosinophils	1.48	10^9/L	H	0.04	0.4
			Basophils	0.18	10^9/L	H	0	0.1
			Activated Partial Thromboplastin Time	33.7	sec	H	22.7	30.4
			Sodium	132	mmol/L	L	135	150
			Calcium	8.62	mg/dL	L	8.8	10.6
			Magnesium	1.85	mg/dL	L	1.9	2.5
			Creatinine	1.176	mg/dL	H	0.45	1
			Albumin	3.2	g/dL	L	3.5	5.2
			Alanine Aminotransferase	4	U/L	L	6	31
			Alkaline Phosphatase	346	U/L	H	98	279
			Lactate Dehydrogenase	830	U/L	H	240	480
		2010-08-31T08:45	Hemoglobin	9.93	g/dL	L	12	16
			Erythrocytes	3.37	10^12/L	L	4	5.6
			Eosinophils	0.41	10^9/L	H	0.04	0.4
			Calcium	7.98	mg/dL	L	8.8	10.6
			Phosphate	2.51	mg/dL	L	2.7	4.5
			Magnesium	1.73	mg/dL	L	1.9	2.5
			Albumin	3.2	g/dL	L	3.5	5.2
			Alkaline Phosphatase	315	U/L	H	98	279
			Lactate Dehydrogenase	642	U/L	H	240	480

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-001	Cycle 3	2010-09-21T07:50	Hemoglobin	11.2	g/dL	L	12	16
			Erythrocytes	3.79	10^12/L	L	4	5.6
			Platelets	106	10^9/L	L	120	350
			Leukocytes	14	10^9/L	H	4	10
			Neutrophils	12.47	10^9/L	H	2.04	7.5
			Lymphocytes	0.47	10^9/L	L	0.8	4
			Prothrombin Time	13.6	sec	H	7.4	9.4
			Activated Partial Thromboplastin Time	34.8	sec	H	22.7	30.4
			Prothrombin Intl. Normalized Ratio	1.45	ratio	H	0.85	1.15
			Sodium	129	mmol/L	L	135	150
			Calcium	7.58	mg/dL	L	8.8	10.6
			Phosphate	5.14	mg/dL	H	2.7	4.5
			Creatinine	2.545	mg/dL	H	0.45	1
			Albumin	2.7	g/dL	L	3.5	5.2
			Alanine Aminotransferase	5	U/L	L	6	31
			Lactate Dehydrogenase	2846	U/L	H	240	480
			Blood Urea Nitrogen	48.46	mg/dL	H	7	21
			Urate	12.29	mg/dL	H	2.5	6
		2010-09-25T11:00	Hemoglobin	9.52	g/dL	L	12	16
			Erythrocytes	3.19	10^12/L	L	4	5.6
			Platelets	61	10^9/L	L	120	350
			Leukocytes	20.2	10^9/L	H	4	10
			Neutrophils	17.2	10^9/L	H	2.04	7.5
			Lymphocytes	0.74	10^9/L	L	0.8	4
			Eosinophils	2.07	10^9/L	H	0.04	0.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-001	Cycle 3	2010-09-25T11:00	Sodium	133	mmol/L	L	135	150
			Calcium	7.86	mg/dL	L	8.8	10.6
			Magnesium	1.6	mg/dL	L	1.9	2.5
			Creatinine	1.923	mg/dL	H	0.45	1
			Albumin	2.1	g/dL	L	3.5	5.2
			Alkaline Phosphatase	490	U/L	H	98	279
			Lactate Dehydrogenase	1299	U/L	H	240	480
			Blood Urea Nitrogen	43.7	mg/dL	H	7	21
	End Trial	2010-10-01T09:30	Platelets	83	10^9/L	L	120	350
			Leukocytes	27.6	10^9/L	H	4	10
			Neutrophils	24.6	10^9/L	H	2.04	7.5
			Eosinophils	1.82	10^9/L	H	0.04	0.4
			Prothrombin Time	13.1	sec	H	7.4	9.4
			Prothrombin Intl. Normalized Ratio	1.4	ratio	H	0.85	1.15
		2010-10-01T15:00	Sodium	130	mmol/L	L	135	150
			Calcium	7.78	mg/dL	L	8.8	10.6
			Phosphate	4.92	mg/dL	H	2.7	4.5
			Magnesium	1.46	mg/dL	L	1.9	2.5
			Creatinine	1.923	mg/dL	H	0.45	1
			Albumin	2.3	g/dL	L	3.5	5.2
			Alkaline Phosphatase	372	U/L	H	98	279
			Blood Urea Nitrogen	34.73	mg/dL	H	7	21

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-002	Pre-trial	2010-11-11T12:25	Hemoglobin	9.7	g/dL	L	14	17
			Erythrocytes	3.05	10^12/L	L	4.4	5.8
			Platelets	51	10^9/L	L	120	350
			Leukocytes	3.1	10^9/L	L	4	10
			Lymphocytes	0.06	10^9/L	L	0.8	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
		2010-11-12T09:00	Activated Partial Thromboplastin Time	22.4	sec	L	22.7	30.4
			Phosphate	1.83	mg/dL	L	2.7	4.5
			Albumin	3.1	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	613	U/L	H	240	480
			Bilirubin	1.52	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	24.93	mg/dL	H	7	21
	Cycle 1	2010-11-16T08:05	Hemoglobin	7.9	g/dL	L	14	17
			Erythrocytes	2.44	10^12/L	L	4.4	5.8
			Platelets	23	10^9/L	L	120	350
			Leukocytes	1.5	10^9/L	L	4	10
			Neutrophils	1.28	10^9/L	L	2.04	7.5
			Lymphocytes	0.08	10^9/L	L	0.8	4
			Monocytes	0.07	10^9/L	L	0.08	1
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Albumin	2.8	g/dL	L	3.5	5.2
			Bilirubin	1.111	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	33.05	mg/dL	H	7	21
			Urate	7.01	mg/dL	H	3.4	7
			Glucose	120.7	mg/dL	H	70	106

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-002	Cycle 1	2010-11-20T08:20	Hemoglobin	8.13	g/dL	L	14	17
			Erythrocytes	2.54	10^12/L	L	4.4	5.8
			Platelets	16	10^9/L	L	120	350
			Leukocytes	1.4	10^9/L	L	4	10
			Neutrophils	0.46	10^9/L	L	2.04	7.5
			Lymphocytes	0.15	10^9/L	L	0.8	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.57	10^9/L	H	0	0.1
			Phosphate	2.26	mg/dL	L	2.7	4.5
			Creatinine	1.154	mg/dL	H	0.6	1.13
			Albumin	3.2	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	494	U/L	H	240	480
			Bilirubin	1.053	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	36.41	mg/dL	H	7	21
			Glucose	129.7	mg/dL	H	70	106
		2010-11-26T08:30	Hemoglobin	8.9	g/dL	L	14	17
			Erythrocytes	2.68	10^12/L	L	4.4	5.8
			Platelets	29	10^9/L	L	120	350
			Leukocytes	2	10^9/L	L	4	10
			Neutrophils	1.71	10^9/L	L	2.04	7.5
			Lymphocytes	0.12	10^9/L	L	0.8	4
		2010-11-26T08:45	Calcium	11.58	mg/dL	H	8.8	10.6
			Creatinine	1.38	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	509	U/L	H	240	480
			Bilirubin	1.462	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	40.34	mg/dL	H	7	21

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-002	Cycle 1	2010-11-26T08:45	Urate	7.35	mg/dL	H	3.4	7
			Glucose	178.3	mg/dL	H	70	106
	Cycle 2	2010-12-22T16:00	Hemoglobin	7.86	g/dL	L	14	17
			Erythrocytes	2.67	10^12/L	L	4.4	5.8
			Platelets	94	10^9/L	L	120	350
			Leukocytes	1.1	10^9/L	L	4	10
			Neutrophils	1.02	10^9/L	L	2.04	7.5
			Lymphocytes	0.09	10^9/L	L	0.8	4
			Monocytes	0.03	10^9/L	L	0.08	1
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Prothrombin Time	11.8	sec	H	7.4	9.4
			Prothrombin Intl. Normalized Ratio	1.27	ratio	H	0.85	1.15
			Calcium	14.83	mg/dL	H	8.8	10.6
			Chloride	95	mmol/L	L	98	107
			Creatinine	1.482	mg/dL	H	0.6	1.13
			Albumin	2.5	g/dL	L	3.5	5.2
			Alanine Aminotransferase	60	U/L	H	6	40
			Lactate Dehydrogenase	502	U/L	H	240	480
			Bilirubin	1.287	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	36.69	mg/dL	H	7	21
			Glucose	180.1	mg/dL	H	70	106
		2010-12-27T08:35	Hemoglobin	7.11	g/dL	L	14	17
			Erythrocytes	2.44	10^12/L	L	4.4	5.8
			Platelets	6	10^9/L	L	120	350
			Leukocytes	0.8	10^9/L	L	4	10
			Neutrophils	0.71	10^9/L	L	2.04	7.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-002	Cycle 2	2010-12-27T08:35	Lymphocytes	0.04	10^9/L	L	0.8	4
			Monocytes	0.05	10^9/L	L	0.08	1
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Calcium	12.34	mg/dL	H	8.8	10.6
			Magnesium	1.53	mg/dL	L	1.8	2.6
			Creatinine	1.595	mg/dL	H	0.6	1.13
			Albumin	2.1	g/dL	L	3.5	5.2
			Bilirubin	1.111	mg/dL	H	0.12	1.05
			Blood Urea Nitrogen	41.18	mg/dL	H	7	21
	Unplanned	2010-12-06T09:12	Hemoglobin	5.52	g/dL	L	14	17
			Erythrocytes	1.72	10^12/L	L	4.4	5.8
			Platelets	6.42	10^9/L	L	120	350
			Leukocytes	0.613	10^9/L	L	4	10
	End Trial	2011-01-13T13:15	Hemoglobin	7.2	g/dL	L	14	17
			Erythrocytes	2.54	10^12/L	L	4.4	5.8
			Platelets	54	10^9/L	L	120	350
			Leukocytes	0.3	10^9/L	L	4	10
			Neutrophils	0.19	10^9/L	L	2.04	7.5
			Lymphocytes	0.03	10^9/L	L	0.8	4
			Monocytes	0.04	10^9/L	L	0.08	1
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Prothrombin Time	11.7	sec	H	7.4	9.4
			Prothrombin Intl. Normalized Ratio	1.26	ratio	H	0.85	1.15
			Sodium	132	mmol/L	L	135	150
			Magnesium	1.75	mg/dL	L	1.8	2.6
			Albumin	1.8	g/dL	L	3.5	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-002	End Trial	2011-01-13T13:15	Blood Urea Nitrogen	40.9	mg/dL	H	7	21
			Glucose	163.9	mg/dL	H	70	106
532-003	Pre-trial	2010-11-15T10:30	Hemoglobin	11.7	g/dL	L	12	16
			Platelets	396	10^9/L	H	120	350
			Neutrophils	8.31	10^9/L	H	2.04	7.5
			Lymphocytes	0.65	10^9/L	L	0.8	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Alkaline Phosphatase	310	U/L	H	98	279
			Glucose	108.1	mg/dL	H	70	106
	Cycle 1	2010-11-22T08:55	Hemoglobin	11.5	g/dL	L	12	16
			Platelets	390	10^9/L	H	120	350
			Leukocytes	10.3	10^9/L	H	4	10
			Neutrophils	8.71	10^9/L	H	2.04	7.5
			Chloride	97	mmol/L	L	98	107
			Alanine Aminotransferase	5	U/L	L	6	31
			Alkaline Phosphatase	294	U/L	H	98	279
			Glucose	145.9	mg/dL	H	70	106
		2010-11-26T08:45	Hemoglobin	10.7	g/dL	L	12	16
			Erythrocytes	3.98	10^12/L	L	4	5.6
			Lymphocytes	0.65	10^9/L	L	0.8	4
			Phosphate	4.86	mg/dL	H	2.7	4.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-003	Cycle 1	2010-12-06T09:12	Platelets	367	10^9/L	H	120	350
			Leukocytes	10.9	10^9/L	H	4	10
			Neutrophils	9.32	10^9/L	H	2.04	7.5
			Chloride	96	mmol/L	L	98	107
	Cycle 2	2010-12-13T08:25	Platelets	357	10^9/L	H	120	350
			Neutrophils	8.37	10^9/L	H	2.04	7.5
			Lymphocytes	0.7	10^9/L	L	0.8	4
			Alkaline Phosphatase	281	U/L	H	98	279
			Glucose	106.3	mg/dL	H	70	106
		2010-12-17T08:15	Hemoglobin	11.4	g/dL	L	12	16
			Lymphocytes	0.58	10^9/L	L	0.8	4
			Phosphate	4.65	mg/dL	H	2.7	4.5
			Alkaline Phosphatase	306	U/L	H	98	279
			Glucose	106.3	mg/dL	H	70	106
	Cycle 3	2011-01-03T07:35	Hemoglobin	11.1	g/dL	L	12	16
			Phosphate	4.92	mg/dL	H	2.7	4.5
			Lactate Dehydrogenase	232	U/L	L	240	480
			Blood Urea Nitrogen	21.85	mg/dL	H	7	21
		2011-01-07T08:15	Hemoglobin	11.2	g/dL	L	12	16
			Lymphocytes	0.62	10^9/L	L	0.8	4
			Phosphate	5.17	mg/dL	H	2.7	4.5
			Alkaline Phosphatase	323	U/L	H	98	279

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-003	Cycle 4	2011-01-24T09:05	Hemoglobin	11.7	g/dL	L	12	16
		2011-01-28T08:40	Phosphate	4.99	mg/dL	H	2.7	4.5
			Magnesium	2.53	mg/dL	H	1.9	2.5
			Alkaline Phosphatase	328	U/L	H	98	279
			Glucose	113.5	mg/dL	H	70	106
	Cycle 5	2011-02-14T08:25	Lactate Dehydrogenase	222	U/L	L	240	480
		2011-02-18T09:50	Lymphocytes	0.65	10^9/L	L	0.8	4
			Alkaline Phosphatase	326	U/L	H	98	279
			Glucose	135.1	mg/dL	H	70	106
	Cycle 6	2011-03-07T09:35	Hemoglobin	11.5	g/dL	L	12	16
		2011-03-11T08:28	Hemoglobin	11.8	g/dL	L	12	16
			Lymphocytes	0.69	10^9/L	L	0.8	4
			Alkaline Phosphatase	344	U/L	H	98	279
			Glucose	115.3	mg/dL	H	70	106
	Cycle 7	2011-03-28T08:40	Hemoglobin	11.2	g/dL	L	12	16
			Erythrocytes	3.95	10^12/L	L	4	5.6
			Phosphate	4.96	mg/dL	H	2.7	4.5
			Alkaline Phosphatase	313	U/L	H	98	279
		2011-04-01T08:40	Hemoglobin	11.1	g/dL	L	12	16
			Lymphocytes	0.7	10^9/L	L	0.8	4
			Alkaline Phosphatase	381	U/L	H	98	279
	Cycle 8	2011-04-18T08:45	Hemoglobin	11.7	g/dL	L	12	16
		2011-04-18T08:46	Alkaline Phosphatase	303	U/L	H	98	279

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-003	Cycle 8	2011-04-22T08:40	Hemoglobin	11.5	g/dL	L	12	16
			Lymphocytes	0.67	10^9/L	L	0.8	4
			Chloride	109	mmol/L	H	98	107
			Alkaline Phosphatase	337	U/L	H	98	279
	Cycle 9	2011-05-09T07:45	Hemoglobin	11.5	g/dL	L	12	16
			Phosphate	4.52	mg/dL	H	2.7	4.5
		2011-05-13T08:05	Hemoglobin	11.7	g/dL	L	12	16
			Lymphocytes	0.6	10^9/L	L	0.8	4
			Alkaline Phosphatase	350	U/L	H	98	279
	Cycle 10	2011-05-30T08:35	Hemoglobin	11.8	g/dL	L	12	16
			Lymphocytes	0.76	10^9/L	L	0.8	4
		2011-06-03T08:25	Hemoglobin	10.8	g/dL	L	12	16
			Lymphocytes	0.43	10^9/L	L	0.8	4
			Phosphate	4.8	mg/dL	H	2.7	4.5
			Alkaline Phosphatase	304	U/L	H	98	279
	Cycle 11	2011-06-20T14:15	Hemoglobin	11.5	g/dL	L	12	16
		2011-06-24T09:05	Hemoglobin	11.2	g/dL	L	12	16
			Lymphocytes	0.43	10^9/L	L	0.8	4
			Phosphate	4.74	mg/dL	H	2.7	4.5
			Alkaline Phosphatase	285	U/L	H	98	279
	End Trial	2011-07-11T09:20	Platelets	353	10^9/L	H	120	350
			Neutrophils	8.17	10^9/L	H	2.04	7.5
			Blood Urea Nitrogen	21.29	mg/dL	H	7	21
			Glucose	165.7	mg/dL	H	70	106

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-004	Pre-trial	2011-03-08T08:35	Hemoglobin	11.8	g/dL	L	12	16
			Leukocytes	3.5	10^9/L	L	4	10
			Lymphocytes	0.62	10^9/L	L	0.8	4
			Prothrombin Intl. Normalized Ratio	0.84	ratio	L	0.85	1.15
	Cycle 1	2011-03-16T08:45	Leukocytes	3.3	10^9/L	L	4	10
			Lymphocytes	0.54	10^9/L	L	0.8	4
		2011-03-20T08:50	Hemoglobin	11.1	g/dL	L	12	16
			Ery. Mean Corpuscular Volume	79.7	fL	L	80	100
			Leukocytes	3.1	10^9/L	L	4	10
			Lymphocytes	0.46	10^9/L	L	0.8	4
			Calcium	8.22	mg/dL	L	8.8	10.6
			Chloride	109	mmol/L	H	98	107
			Phosphate	4.52	mg/dL	H	2.7	4.5
			Urate	2.2	mg/dL	L	2.5	6
		2011-03-28T09:23	Hemoglobin	11.3	g/dL	L	12	16
			Ery. Mean Corpuscular Volume	78.4	fL	L	80	100
			Leukocytes	3.8	10^9/L	L	4	10
			Neutrophils	1.46	10^9/L	L	2.04	7.5
			Lymphocytes	0.64	10^9/L	L	0.8	4
			Eosinophils	1.33	10^9/L	H	0.04	0.4
			Lactate Dehydrogenase	485	U/L	H	240	480

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-004	Cycle 2	2011-04-04T08:30	Hemoglobin	11.4	g/dL	L	12	16
			Ery. Mean Corpuscular Volume	79.2	fL	L	80	100
			Leukocytes	3.7	10^9/L	L	4	10
			Neutrophils	1.06	10^9/L	L	2.04	7.5
			Lymphocytes	0.58	10^9/L	L	0.8	4
			Eosinophils	1.71	10^9/L	H	0.04	0.4
			Blood Urea Nitrogen	6.16	mg/dL	L	7	21
		2011-04-08T09:15	Hemoglobin	11.3	g/dL	L	12	16
			Ery. Mean Corpuscular Volume	78.9	fL	L	80	100
			Leukocytes	2.8	10^9/L	L	4	10
			Neutrophils	1.36	10^9/L	L	2.04	7.5
			Lymphocytes	0.31	10^9/L	L	0.8	4
			Eosinophils	0.9	10^9/L	H	0.04	0.4
			Calcium	8.54	mg/dL	L	8.8	10.6
	Cycle 3	2011-04-26T09:45	Hemoglobin	11	g/dL	L	12	16
			Ery. Mean Corpuscular Volume	78.1	fL	L	80	100
			Leukocytes	2.1	10^9/L	L	4	10
			Neutrophils	1.27	10^9/L	L	2.04	7.5
			Lymphocytes	0.49	10^9/L	L	0.8	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Lactate Dehydrogenase	586	U/L	H	240	480
		2011-04-30T08:50	Hemoglobin	10.3	g/dL	L	12	16
			Erythrocytes	3.93	10^12/L	L	4	5.6
			Ery. Mean Corpuscular Volume	77.2	fL	L	80	100
			Leukocytes	2.3	10^9/L	L	4	10
			Neutrophils	1.68	10^9/L	L	2.04	7.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-004	Cycle 3	2011-04-30T08:50	Lymphocytes	0.26	10^9/L	L	0.8	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Calcium	8.34	mg/dL	L	8.8	10.6
			Lactate Dehydrogenase	525	U/L	H	240	480
	Cycle 4	2011-05-16T08:50	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.92	10^12/L	L	4	5.6
			Ery. Mean Corpuscular Volume	79.6	fL	L	80	100
			Platelets	115	10^9/L	L	120	350
			Leukocytes	1.5	10^9/L	L	4	10
			Neutrophils	1.05	10^9/L	L	2.04	7.5
			Lymphocytes	0.23	10^9/L	L	0.8	4
			Monocytes	0.07	10^9/L	L	0.08	1
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Calcium	8.42	mg/dL	L	8.8	10.6
			Aspartate Aminotransferase	34	U/L	H	6	31
			Lactate Dehydrogenase	666	U/L	H	240	480
		2011-05-20T08:50	Hemoglobin	9.5	g/dL	L	12	16
			Erythrocytes	3.55	10^12/L	L	4	5.6
			Ery. Mean Corpuscular Volume	77.9	fL	L	80	100
			Platelets	88	10^9/L	L	120	350
			Leukocytes	1.3	10^9/L	L	4	10
			Neutrophils	0.98	10^9/L	L	2.04	7.5
			Lymphocytes	0.11	10^9/L	L	0.8	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Calcium	8.22	mg/dL	L	8.8	10.6
			Albumin	3.4	g/dL	L	3.5	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-004	Cycle 4	2011-05-20T08:50	Aspartate Aminotransferase	32	U/L	H	6	31
			Lactate Dehydrogenase	664	U/L	H	240	480
			Glucose	111.7	mg/dL	H	70	106
	Cycle 5	2011-06-06T08:15	Hemoglobin	10.4	g/dL	L	12	16
			Erythrocytes	3.87	10^12/L	L	4	5.6
			Leukocytes	3.9	10^9/L	L	4	10
			Neutrophils	1.93	10^9/L	L	2.04	7.5
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Alanine Aminotransferase	54	U/L	H	6	31
			Aspartate Aminotransferase	61	U/L	H	6	31
			Lactate Dehydrogenase	685	U/L	H	240	480
		2011-06-10T07:40	Hemoglobin	11.1	g/dL	L	12	16
			Leukocytes	3.2	10^9/L	L	4	10
			Neutrophils	1.72	10^9/L	L	2.04	7.5
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Phosphate	5.3	mg/dL	H	2.7	4.5
			Alanine Aminotransferase	41	U/L	H	6	31
			Aspartate Aminotransferase	34	U/L	H	6	31
			Lactate Dehydrogenase	607	U/L	H	240	480
	Cycle 6	2011-06-27T09:00	Hemoglobin	10.4	g/dL	L	12	16
			Erythrocytes	3.82	10^12/L	L	4	5.6
			Leukocytes	3.1	10^9/L	L	4	10
			Neutrophils	2.01	10^9/L	L	2.04	7.5
			Lymphocytes	0.58	10^9/L	L	0.8	4
			Lactate Dehydrogenase	549	U/L	H	240	480

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
532-004	Cycle 6	2011-07-06T08:50	Hemoglobin	10.4	g/dL	L	12	16
			Erythrocytes	3.78	10^12/L	L	4	5.6
			Leukocytes	1.8	10^9/L	L	4	10
			Neutrophils	1.36	10^9/L	L	2.04	7.5
			Lymphocytes	0.14	10^9/L	L	0.8	4
			Lactate Dehydrogenase	574	U/L	H	240	480
	Cycle 7	2011-07-25T08:40	Hemoglobin	11.7	g/dL	L	12	16
			Leukocytes	2.8	10^9/L	L	4	10
			Lymphocytes	0.3	10^9/L	L	0.8	4
			Prothrombin Intl. Normalized Ratio	0.84	ratio	L	0.85	1.15
			Bilirubin	1.404	mg/dL	H	0.12	1.05
		2011-07-29T08:20	Hemoglobin	11.3	g/dL	L	12	16
			Platelets	106	10^9/L	L	120	350
			Leukocytes	3.1	10^9/L	L	4	10
			Lymphocytes	0.2	10^9/L	L	0.8	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
	Unplanned	2011-08-15T08:40	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.77	10^12/L	L	4	5.6
			Lymphocytes	0.62	10^9/L	L	0.8	4
			Calcium	8.54	mg/dL	L	8.8	10.6
	End Trial	2011-09-05T08:50	Hemoglobin	10.7	g/dL	L	12	16
			Leukocytes	2.5	10^9/L	L	4	10
			Neutrophils	1.47	10^9/L	L	2.04	7.5
			Lymphocytes	0.63	10^9/L	L	0.8	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Pre-trial	2011-03-23T08:35	Hemoglobin	10.5	g/dL	L	11.8	14.8
			Erythrocytes	3.63	10^12/L	L	3.88	4.99
			Platelets	129	10^9/L	L	150	358
			Lymphocytes	0.55	10^9/L	L	1	3.2
			Magnesium	1.48	mg/dL	L	1.7	2.6
			Creatinine	1.256	mg/dL	H	0.6	1.2
			Alkaline Phosphatase	109	U/L	H	0	103
			Lactate Dehydrogenase	774	U/L	H	0	529
			Urate	7.65	mg/dL	H	2.4	5.7
	Cycle 1	2011-03-28T08:30	Hemoglobin	8.9	g/dL	L	11.8	14.8
			Erythrocytes	3.12	10^12/L	L	3.88	4.99
			Platelets	128	10^9/L	L	150	358
			Leukocytes	3.5	10^9/L	L	3.9	11.1
			Lymphocytes	0.36	10^9/L	L	1	3.2
			Basophils	0.01	10^9/L	L	0.02	0.29
			Magnesium	1.39	mg/dL	L	1.7	2.6
			Creatinine	1.222	mg/dL	H	0.6	1.2
			Lactate Dehydrogenase	749	U/L	H	0	529
			Urate	8.39	mg/dL	H	2.4	5.7
		2011-04-01T09:00	Hemoglobin	9.2	g/dL	L	11.8	14.8
			Erythrocytes	3.14	10^12/L	L	3.88	4.99
			Platelets	94	10^9/L	L	150	358
			Leukocytes	3.77	10^9/L	L	3.9	11.1
			Lymphocytes	0.4	10^9/L	L	1	3.2
			Basophils	0.01	10^9/L	L	0.02	0.29
			Creatinine	1.55	mg/dL	H	0.6	1.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Cycle 1	2011-04-08T11:45	Hemoglobin	9.6	g/dL	L	11.8	14.8
			Erythrocytes	3.32	10^12/L	L	3.88	4.99
			Platelets	121	10^9/L	L	150	358
			Lymphocytes	0.85	10^9/L	L	1	3.2
			Basophils	0.01	10^9/L	L	0.02	0.29
			Magnesium	1.56	mg/dL	L	1.7	2.6
			Creatinine	1.584	mg/dL	H	0.6	1.2
			Alanine Aminotransferase	188	U/L	H	0	30
			Aspartate Aminotransferase	247	U/L	H	0	30
			Alkaline Phosphatase	371	U/L	H	0	103
			Lactate Dehydrogenase	1019	U/L	H	0	529
			Bilirubin	3.561	mg/dL	H	0	1.17
			Urate	5.99	mg/dL	H	2.4	5.7
	Cycle 2	2011-04-18T13:10	Hemoglobin	8.4	g/dL	L	11.8	14.8
			Erythrocytes	2.84	10^12/L	L	3.88	4.99
			Platelets	117	10^9/L	L	150	358
			Leukocytes	3.57	10^9/L	L	3.9	11.1
			Lymphocytes	0.72	10^9/L	L	1	3.2
			Chloride	107	mmol/L	H	98	106
			Magnesium	1.48	mg/dL	L	1.7	2.6
			Creatinine	1.301	mg/dL	H	0.6	1.2
			Alkaline Phosphatase	124	U/L	H	0	103
			Lactate Dehydrogenase	820	U/L	H	0	529
			Urate	8.54	mg/dL	H	2.4	5.7
			Glucose	151.3	mg/dL	H	59	101

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Cycle 2	2011-04-22T11:30	Hemoglobin	11.2	g/dL	L	11.8	14.8
			Erythrocytes	3.86	10^12/L	L	3.88	4.99
			Platelets	47	10^9/L	L	150	358
			Leukocytes	1.89	10^9/L	L	3.9	11.1
			Neutrophils	1.19	10^9/L	L	1.7	7.5
			Lymphocytes	0.39	10^9/L	L	1	3.2
			Monocytes	0.19	10^9/L	L	0.2	0.6
			Basophils	0.01	10^9/L	L	0.02	0.29
			Calcium	7.66	mg/dL	L	8.4	9.7
			Chloride	110	mmol/L	H	98	106
			Phosphate	2.32	mg/dL	L	2.7	4.5
			Magnesium	1.48	mg/dL	L	1.7	2.6
			Creatinine	1.301	mg/dL	H	0.6	1.2
			Albumin	2.9	g/dL	L	3.4	4.8
			Alanine Aminotransferase	38	U/L	H	0	30
			Aspartate Aminotransferase	35	U/L	H	0	30
			Alkaline Phosphatase	176	U/L	H	0	103
			Lactate Dehydrogenase	747	U/L	H	0	529
			Urate	6.54	mg/dL	H	2.4	5.7
	Cycle 3	2011-05-16T13:40	Hemoglobin	9.9	g/dL	L	11.8	14.8
			Erythrocytes	3.38	10^12/L	L	3.88	4.99
			Platelets	106	10^9/L	L	150	358
			Leukocytes	3.06	10^9/L	L	3.9	11.1
			Neutrophils	1.5	10^9/L	L	1.7	7.5
			Lymphocytes	0.4	10^9/L	L	1	3.2
			Eosinophils	0.63	10^9/L	H	0.03	0.6

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Cycle 3	2011-05-16T13:40	Basophils	0.01	10^9/L	L	0.02	0.29
			Chloride	107	mmol/L	H	98	106
			Magnesium	1.6	mg/dL	L	1.7	2.6
			Lactate Dehydrogenase	689	U/L	H	0	529
			Urate	7.48	mg/dL	H	2.4	5.7
			Glucose	102.7	mg/dL	H	59	101
		2011-05-20T08:50	Hemoglobin	8.8	g/dL	L	11.8	14.8
			Erythrocytes	3.02	10^12/L	L	3.88	4.99
			Platelets	79	10^9/L	L	150	358
			Leukocytes	2.22	10^9/L	L	3.9	11.1
			Neutrophils	1.54	10^9/L	L	1.7	7.5
			Lymphocytes	0.22	10^9/L	L	1	3.2
			Basophils	0.01	10^9/L	L	0.02	0.29
			Potassium	3.4	mmol/L	L	3.5	5.2
			Calcium	7.45	mg/dL	L	8.4	9.7
			Chloride	111	mmol/L	H	98	106
			Magnesium	1.48	mg/dL	L	1.7	2.6
			Lactate Dehydrogenase	679	U/L	H	0	529
			Urate	5.82	mg/dL	H	2.4	5.7
			Glucose	108.1	mg/dL	H	59	101
	Cycle 4	2011-06-06T15:00	Hemoglobin	6.1	g/dL	L	11.8	14.8
			Erythrocytes	2.02	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	98.5	fL	H	82	98
			Platelets	83	10^9/L	L	150	358
			Leukocytes	2.72	10^9/L	L	3.9	11.1
			Lymphocytes	0.41	10^9/L	L	1	3.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Cycle 4	2011-06-06T15:00	Calcium	8.1	mg/dL	L	8.4	9.7
			Chloride	107	mmol/L	H	98	106
			Lactate Dehydrogenase	759	U/L	H	0	529
			Urate	7.21	mg/dL	H	2.4	5.7
	Cycle 5	2011-07-11T11:10	Hemoglobin	7.9	g/dL	L	11.8	14.8
			Erythrocytes	2.4	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	102.9	fL	H	82	98
			Platelets	112	10^9/L	L	150	358
			Lymphocytes	0.24	10^9/L	L	1	3.2
			Monocytes	0.15	10^9/L	L	0.2	0.6
			Eosinophils	0.01	10^9/L	L	0.03	0.6
			Basophils	0.01	10^9/L	L	0.02	0.29
			Magnesium	1.51	mg/dL	L	1.7	2.6
			Lactate Dehydrogenase	548	U/L	H	0	529
		2011-07-15T08:30	Hemoglobin	8.5	g/dL	L	11.8	14.8
			Erythrocytes	2.56	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	102.7	fL	H	82	98
			Platelets	109	10^9/L	L	150	358
			Lymphocytes	0.3	10^9/L	L	1	3.2
			Eosinophils	0.02	10^9/L	L	0.03	0.6
			Basophils	0	10^9/L	L	0.02	0.29
			Potassium	3.3	mmol/L	L	3.5	5.2
			Creatinine	1.312	mg/dL	H	0.6	1.2
			Lactate Dehydrogenase	593	U/L	H	0	529

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Cycle 6	2011-08-01T10:00	Hemoglobin	7	g/dL	L	11.8	14.8
			Erythrocytes	2.02	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	107.4	fL	H	82	98
			Platelets	79	10^9/L	L	150	358
			Leukocytes	3.53	10^9/L	L	3.9	11.1
			Lymphocytes	0.16	10^9/L	L	1	3.2
			Monocytes	0.19	10^9/L	L	0.2	0.6
			Eosinophils	0	10^9/L	L	0.03	0.6
			Basophils	0	10^9/L	L	0.02	0.29
			Potassium	3.4	mmol/L	L	3.5	5.2
			Magnesium	1.31	mg/dL	L	1.7	2.6
			Lactate Dehydrogenase	569	U/L	H	0	529
			Blood Urea Nitrogen	35.57	mg/dL	H	8.1	31.1
			Urate	7.2	mg/dL	H	2.4	5.7
			Glucose	113.5	mg/dL	H	59	101
		2011-08-05T08:00	Hemoglobin	9	g/dL	L	11.8	14.8
			Erythrocytes	2.73	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	100.4	fL	H	82	98
			Platelets	48	10^9/L	L	150	358
			Leukocytes	1.7	10^9/L	L	3.9	11.1
			Neutrophils	1.33	10^9/L	L	1.7	7.5
			Lymphocytes	0.21	10^9/L	L	1	3.2
			Monocytes	0.15	10^9/L	L	0.2	0.6
			Eosinophils	0.01	10^9/L	L	0.03	0.6
			Basophils	0	10^9/L	L	0.02	0.29
			Calcium	8.22	mg/dL	L	8.4	9.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Cycle 6	2011-08-05T08:00	Magnesium	1.58	mg/dL	L	1.7	2.6
			Creatinine	1.244	mg/dL	H	0.6	1.2
			Lactate Dehydrogenase	605	U/L	H	0	529
			Bilirubin	1.602	mg/dL	H	0	1.17
	Unplanned	2011-06-09T08:25	Chloride	110	mmol/L	H	98	106
		2011-06-16T10:00	Hemoglobin	4.8	g/dL	L	11.8	14.8
			Erythrocytes	1.46	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	99.3	fL	H	82	98
			Platelets	19	10^9/L	L	150	358
			Leukocytes	2.31	10^9/L	L	3.9	11.1
			Neutrophils	1.54	10^9/L	L	1.7	7.5
			Lymphocytes	0.18	10^9/L	L	1	3.2
			Basophils	0	10^9/L	L	0.02	0.29
			Lactate Dehydrogenase	1177	U/L	H	0	529
			Bilirubin	3.626	mg/dL	H	0	1.17
		2011-07-04T08:00	Hemoglobin	9	g/dL	L	11.8	14.8
			Erythrocytes	2.76	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	100.7	fL	H	82	98
			Platelets	105	10^9/L	L	150	358
			Lymphocytes	0.5	10^9/L	L	1	3.2
			Basophils	0.01	10^9/L	L	0.02	0.29
			Creatinine	1.244	mg/dL	H	0.6	1.2
			Blood Urea Nitrogen	36.13	mg/dL	H	8.1	31.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	Unplanned	2011-08-19T09:30	Hemoglobin	2.9	g/dL	L	11.8	14.8
			Erythrocytes	0.82	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	109.8	fL	H	82	98
			Platelets	78	10^9/L	L	150	358
			Leukocytes	2.8	10^9/L	L	3.9	11.1
			Lymphocytes	0.78	10^9/L	L	1	3.2
			Eosinophils	0	10^9/L	L	0.03	0.6
			Basophils	0	10^9/L	L	0.02	0.29
			Potassium	3.4	mmol/L	L	3.5	5.2
			Creatinine	1.516	mg/dL	H	0.6	1.2
			Lactate Dehydrogenase	581	U/L	H	0	529
			Bilirubin	1.409	mg/dL	H	0	1.17
			Blood Urea Nitrogen	33.33	mg/dL	H	8.1	31.1
		2011-08-30T08:30	Hemoglobin	8.2	g/dL	L	11.8	14.8
			Erythrocytes	2.55	10^12/L	L	3.88	4.99
			Platelets	43	10^9/L	L	150	358
			Lymphocytes	0.5	10^9/L	L	1	3.2
			Eosinophils	0.01	10^9/L	L	0.03	0.6
			Basophils	0.01	10^9/L	L	0.02	0.29
			Potassium	3.1	mmol/L	L	3.5	5.2
			Phosphate	2.38	mg/dL	L	2.7	4.5
			Magnesium	1.48	mg/dL	L	1.7	2.6
			Alanine Aminotransferase	39	U/L	H	0	30
			Lactate Dehydrogenase	586	U/L	H	0	529
			Urate	5.78	mg/dL	H	2.4	5.7
			Glucose	104.5	mg/dL	H	59	101

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
533-001	End Trial	2011-09-12T12:00	Hemoglobin	7	g/dL	L	11.8	14.8
			Erythrocytes	2.07	10^12/L	L	3.88	4.99
			Ery. Mean Corpuscular Volume	104.8	fL	H	82	98
			Platelets	57	10^9/L	L	150	358
			Lymphocytes	0.31	10^9/L	L	1	3.2
			Eosinophils	0.01	10^9/L	L	0.03	0.6
			Basophils	0	10^9/L	L	0.02	0.29
			Activated Partial Thromboplastin Time	58.2	sec	H	28	42
			Phosphate	2.07	mg/dL	L	2.7	4.5
			Magnesium	1.09	mg/dL	L	1.7	2.6
			Creatinine	1.403	mg/dL	H	0.6	1.2
			Alanine Aminotransferase	31	U/L	H	0	30
			Lactate Dehydrogenase	712	U/L	H	0	529
			Blood Urea Nitrogen	39.22	mg/dL	H	8.1	31.1
			Urate	7.15	mg/dL	H	2.4	5.7
534-001	Pre-trial	2010-02-17T09:15	Ery. Mean Corpuscular Volume	97.3	fL	H	80	96
			Monocytes	0.9	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.15
			Magnesium	1.68	mg/dL	L	1.9	2.4
	Cycle 1	2010-02-22T09:12	Lymphocytes	1.27	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.39	ratio	H	0.9	1.15
			Magnesium	1.75	mg/dL	L	1.9	2.4
			Glucose	102.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-001	Cycle 1	2010-02-26T07:40	Ery. Mean Corpuscular Volume	96.7	fL	H	80	96
			Neutrophils	8.41	10^9/L	H	2	7.5
			Lymphocytes	0.77	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Glucose	172.9	mg/dL	H	63	99
		2010-03-04T10:56	Erythrocytes	4.15	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.9	fL	H	80	96
			Leukocytes	18.83	10^9/L	H	4	10
			Neutrophils	14.44	10^9/L	H	2	7.5
			Monocytes	2.46	10^9/L	H	0.2	0.8
			Eosinophils	0.41	10^9/L	H	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.74	mg/dL	L	9	11
	Cycle 2	2010-03-16T10:47	Hemoglobin	13	g/dL	L	13.6	17.7
			Erythrocytes	3.98	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	98.5	fL	H	80	96
			Platelets	509	10^9/L	H	150	400
			Leukocytes	10.13	10^9/L	H	4	10
			Prothrombin Intl. Normalized Ratio	1.27	ratio	H	0.9	1.15
		2010-03-20T09:14	Erythrocytes	4.25	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	98.8	fL	H	80	96
			Platelets	460	10^9/L	H	150	400
			Leukocytes	11.01	10^9/L	H	4	10
			Neutrophils	8.71	10^9/L	H	2	7.5
			Lymphocytes	1.43	10^9/L	L	1.5	4

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
534-001	Cycle 2	2010-03-20T09:14	Monocytes	0.86	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	4.8	mg/dL	H	2.7	4.5
			Glucose	124.3	mg/dL	H	63	99
	Cycle 3	2010-04-06T08:35	Erythrocytes	4.11	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	98.1	fL	H	80	96
			Leukocytes	12.25	10^9/L	H	4	10
			Neutrophils	8.8	10^9/L	H	2	7.5
			Prothrombin Intl. Normalized Ratio	1.27	ratio	H	0.9	1.15
			Chloride	106	mmol/L	H	95	105
			Magnesium	1.77	mg/dL	L	1.9	2.4
		2010-04-10T09:06	Hemoglobin	13.4	g/dL	L	13.6	17.7
			Erythrocytes	4.07	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	100.7	fL	H	80	96
			Leukocytes	10.64	10^9/L	H	4	10
			Neutrophils	8.8	10^9/L	H	2	7.5
			Lymphocytes	0.96	10^9/L	L	1.5	4
			Monocytes	0.87	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	4.55	mg/dL	H	2.7	4.5
			Glucose	118.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-001	Cycle 4	2010-04-26T11:22	Erythrocytes	4.08	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	101.7	fL	H	80	96
			Platelets	458	10^9/L	H	150	400
			Leukocytes	12.7	10^9/L	H	4	10
			Neutrophils	9.64	10^9/L	H	2	7.5
			Monocytes	0.92	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.28	ratio	H	0.9	1.15
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	579	U/L	H	153	463
		2010-04-30T06:58	Hemoglobin	13.1	g/dL	L	13.6	17.7
			Erythrocytes	4.06	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	97.1	fL	H	80	96
			Platelets	406	10^9/L	H	150	400
			Leukocytes	10.85	10^9/L	H	4	10
			Neutrophils	8.99	10^9/L	H	2	7.5
			Lymphocytes	1.07	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Phosphate	5.26	mg/dL	H	2.7	4.5
			Glucose	147.7	mg/dL	H	63	99
	Cycle 5	2010-05-17T10:10	Erythrocytes	4.16	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	102.6	fL	H	80	96
			Leukocytes	12.69	10^9/L	H	4	10
			Neutrophils	9.38	10^9/L	H	2	7.5
			Monocytes	0.81	10^9/L	H	0.2	0.8
			Eosinophils	0.43	10^9/L	H	0.04	0.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-001	Cycle 5	2010-05-17T10:10	Prothrombin Intl. Normalized Ratio	1.22	ratio	H	0.9	1.15
			Calcium	8.98	mg/dL	L	9	11
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Glucose	99.1	mg/dL	H	63	99
		2010-05-21T06:58	Erythrocytes	4	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	102.3	fL	H	80	96
			Leukocytes	11.69	10^9/L	H	4	10
			Neutrophils	9.47	10^9/L	H	2	7.5
			Lymphocytes	1.15	10^9/L	L	1.5	4
			Monocytes	1.07	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	5.45	mg/dL	H	2.7	4.5
			Glucose	126.1	mg/dL	H	63	99
	Cycle 6	2010-06-07T09:09	Erythrocytes	4.24	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	100.7	fL	H	80	96
			Platelets	407	10^9/L	H	150	400
			Leukocytes	14.17	10^9/L	H	4	10
			Neutrophils	10.07	10^9/L	H	2	7.5
			Monocytes	1.11	10^9/L	H	0.2	0.8
			Eosinophils	0.45	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.16	ratio	H	0.9	1.15
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	543	U/L	H	153	463
			Glucose	99.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-001	Cycle 6	2010-06-11T06:59	Hemoglobin	13.5	g/dL	L	13.6	17.7
			Erythrocytes	4.1	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	98.6	fL	H	80	96
			Leukocytes	11.74	10^9/L	H	4	10
			Neutrophils	9.81	10^9/L	H	2	7.5
			Lymphocytes	1	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.02	mg/dL	L	9	11
			Chloride	112	mmol/L	H	95	105
			Magnesium	1.75	mg/dL	L	1.9	2.4
			Albumin	3.5	g/dL	L	3.8	5
			Lactate Dehydrogenase	495	U/L	H	153	463
			Glucose	122.5	mg/dL	H	63	99
	Cycle 7	2010-07-05T09:59	Ery. Mean Corpuscular Volume	100	fL	H	80	96
			Leukocytes	11.64	10^9/L	H	4	10
			Neutrophils	7.51	10^9/L	H	2	7.5
			Monocytes	1.08	10^9/L	H	0.2	0.8
			Eosinophils	0.91	10^9/L	H	0.04	0.4
			Activated Partial Thromboplastin Time	46	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.86	ratio	H	0.9	1.15
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	522	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-001	Cycle 7	2010-07-09T07:09	Erythrocytes	4.31	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	101.2	fL	H	80	96
			Leukocytes	13.92	10^9/L	H	4	10
			Neutrophils	11.28	10^9/L	H	2	7.5
			Lymphocytes	1.19	10^9/L	L	1.5	4
			Monocytes	1.45	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	6.16	mg/dL	H	2.7	4.5
			Glucose	113.5	mg/dL	H	63	99
	Cycle 8	2010-08-02T09:55	Ery. Mean Corpuscular Volume	101.7	fL	H	80	96
			Leukocytes	17.09	10^9/L	H	4	10
			Neutrophils	13.37	10^9/L	H	2	7.5
			Monocytes	1.49	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	2.9	ratio	H	0.9	1.15
			Lactate Dehydrogenase	647	U/L	H	153	463
		2010-08-06T07:04	Erythrocytes	4.44	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.2	fL	H	80	96
			Leukocytes	16.51	10^9/L	H	4	10
			Neutrophils	14.33	10^9/L	H	2	7.5
			Lymphocytes	0.67	10^9/L	L	1.5	4
			Monocytes	1.31	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Sodium	131	mmol/L	L	135	145
			Lactate Dehydrogenase	469	U/L	H	153	463
			Glucose	178.3	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-001	End Trial	2010-09-03T11:21	Hemoglobin	12.3	g/dL	L	13.6	17.7
			Erythrocytes	3.94	10^12/L	L	4.5	6.5
			Platelets	428	10^9/L	H	150	400
			Leukocytes	15.37	10^9/L	H	4	10
			Neutrophils	12.47	10^9/L	H	2	7.5
			Lymphocytes	1.32	10^9/L	L	1.5	4
			Monocytes	0.96	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	47	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	High	ratio	L	0.9	1.15
			Sodium	131	mmol/L	L	135	145
			Chloride	94	mmol/L	L	95	105
			Magnesium	1.53	mg/dL	L	1.9	2.4
			Alkaline Phosphatase	980	U/L	H	95	364
			Lactate Dehydrogenase	604	U/L	H	153	463
			Glucose	99.1	mg/dL	H	63	99
534-002	Pre-trial	2010-08-16T09:00	Hemoglobin	11.2	g/dL	L	12	15.5
			Leukocytes	11.55	10^9/L	H	4	10
			Neutrophils	8.98	10^9/L	H	2	7.5
			Lymphocytes	1.09	10^9/L	L	1.5	4
			Eosinophils	0.47	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.37	ratio	H	0.9	1.15
			Calcium	11.1	mg/dL	H	9	11
			Lactate Dehydrogenase	726	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 1	2010-08-30T08:47	Leukocytes	18.85	10^9/L	H	4	10
			Neutrophils	16.04	10^9/L	H	2	7.5
			Monocytes	0.95	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.19	ratio	H	0.9	1.15
			Potassium	6.3	mmol/L	H	3.5	5.5
			Phosphate	4.61	mg/dL	H	2.7	4.5
			Lactate Dehydrogenase	1014	U/L	H	153	463
			Bilirubin	1.053	mg/dL	H	0.09	0.99
		2010-09-03T07:55	Leukocytes	10.45	10^9/L	H	4	10
			Neutrophils	7.99	10^9/L	H	2	7.5
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Magnesium	2.41	mg/dL	H	1.9	2.4
			Glucose	102.7	mg/dL	H	63	99
		2010-09-10T09:04	Leukocytes	15.85	10^9/L	H	4	10
			Neutrophils	12.5	10^9/L	H	2	7.5
			Monocytes	1.38	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Urate	6.72	mg/dL	H	2	6.4
	Cycle 2	2010-09-20T10:03	Neutrophils	7.87	10^9/L	H	2	7.5
			Lymphocytes	0.8	10^9/L	L	1.5	4
		2010-09-24T07:08	Lymphocytes	1.24	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Glucose	102.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 3	2010-10-11T11:22	Leukocytes	15.75	10^9/L	H	4	10
			Neutrophils	13.9	10^9/L	H	2	7.5
			Lymphocytes	1.29	10^9/L	L	1.5	4
			Glucose	100.9	mg/dL	H	63	99
		2010-10-15T06:52	Neutrophils	7.65	10^9/L	H	2	7.5
			Lymphocytes	1.38	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Alkaline Phosphatase	94	U/L	L	95	364
			Glucose	109.9	mg/dL	H	63	99
	Cycle 4	2010-11-02T12:09	Leukocytes	14.89	10^9/L	H	4	10
			Neutrophils	12.98	10^9/L	H	2	7.5
			Lymphocytes	0.83	10^9/L	L	1.5	4
		2010-11-06T08:41	Hemoglobin	11.8	g/dL	L	12	15.5
			Leukocytes	11.83	10^9/L	H	4	10
			Neutrophils	9.38	10^9/L	H	2	7.5
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	5.2	mg/dL	H	2.7	4.5
			Glucose	106.3	mg/dL	H	63	99
	Cycle 5	2010-11-22T09:28	Leukocytes	18.36	10^9/L	H	4	10
			Neutrophils	15.63	10^9/L	H	2	7.5
			Monocytes	0.96	10^9/L	H	0.2	0.8
			Urate	6.44	mg/dL	H	2	6.4

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 5	2010-11-26T08:00	Leukocytes	11.09	10^9/L	H	4	10
			Neutrophils	9.8	10^9/L	H	2	7.5
			Lymphocytes	0.86	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Glucose	122.5	mg/dL	H	63	99
	Cycle 6	2010-12-13T09:59	Hemoglobin	11.5	g/dL	L	12	15.5
			Erythrocytes	3.63	10^12/L	L	3.8	5.8
			Leukocytes	11.86	10^9/L	H	4	10
			Neutrophils	10.46	10^9/L	H	2	7.5
			Lymphocytes	0.64	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.15
			Glucose	138.7	mg/dL	H	63	99
		2010-12-17T09:01	Erythrocytes	3.78	10^12/L	L	3.8	5.8
			Leukocytes	15.26	10^9/L	H	4	10
			Neutrophils	12.23	10^9/L	H	2	7.5
			Monocytes	1.33	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Lactate Dehydrogenase	542	U/L	H	153	463
	Cycle 7	2011-01-10T12:08	Leukocytes	12.89	10^9/L	H	4	10
			Neutrophils	8	10^9/L	H	2	7.5
			Monocytes	1.29	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.22	ratio	H	0.9	1.15
			Lactate Dehydrogenase	494	U/L	H	153	463

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 7	2011-01-14T11:17	Hemoglobin	11.8	g/dL	L	12	15.5
			Erythrocytes	3.76	10^12/L	L	3.8	5.8
			Leukocytes	20.06	10^9/L	H	4	10
			Neutrophils	14.25	10^9/L	H	2	7.5
			Lymphocytes	4.28	10^9/L	H	1.5	4
			Monocytes	1.2	10^9/L	H	0.2	0.8
			Magnesium	2.5	mg/dL	H	1.9	2.4
			Glucose	99.1	mg/dL	H	63	99
	Cycle 8	2011-01-31T12:38	Hemoglobin	11.6	g/dL	L	12	15.5
			Leukocytes	14.38	10^9/L	H	4	10
			Neutrophils	8.75	10^9/L	H	2	7.5
			Eosinophils	0.43	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.32	ratio	H	0.9	1.15
			Calcium	8.86	mg/dL	L	9	11
			Albumin	3.7	g/dL	L	3.8	5
			Lactate Dehydrogenase	646	U/L	H	153	463
			Urate	6.56	mg/dL	H	2	6.4
			Glucose	106.3	mg/dL	H	63	99
		2011-02-04T08:15	Hemoglobin	11.2	g/dL	L	12	15.5
			Erythrocytes	3.65	10^12/L	L	3.8	5.8
			Leukocytes	14.23	10^9/L	H	4	10
			Neutrophils	10.13	10^9/L	H	2	7.5
			Chloride	106	mmol/L	H	95	105
			Albumin	3.3	g/dL	L	3.8	5
			Lactate Dehydrogenase	477	U/L	H	153	463
			Urate	7.25	mg/dL	H	2	6.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 8	2011-02-04T08:15	Glucose	118.9	mg/dL	H	63	99
	Cycle 9	2011-02-21T10:11	Leukocytes	17.81	10^9/L	H	4	10
			Neutrophils	14.07	10^9/L	H	2	7.5
			Monocytes	1.22	10^9/L	H	0.2	0.8
			Eosinophils	0.51	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.16	ratio	H	0.9	1.15
			Potassium	5.7	mmol/L	H	3.5	5.5
			Lactate Dehydrogenase	800	U/L	H	153	463
		2011-02-25T10:01	Leukocytes	20.75	10^9/L	H	4	10
			Neutrophils	13.1	10^9/L	H	2	7.5
			Lymphocytes	4.28	10^9/L	H	1.5	4
			Monocytes	1.5	10^9/L	H	0.2	0.8
			Eosinophils	1.57	10^9/L	H	0.04	0.4
			Phosphate	4.55	mg/dL	H	2.7	4.5
			Lactate Dehydrogenase	485	U/L	H	153	463
			Glucose	99.1	mg/dL	H	63	99
	Cycle 10	2011-03-21T09:45	Leukocytes	20.3	10^9/L	H	4	10
			Neutrophils	14.49	10^9/L	H	2	7.5
			Monocytes	1.8	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.23	ratio	H	0.9	1.15
			Lactate Dehydrogenase	692	U/L	H	153	463
			Urate	7.57	mg/dL	H	2	6.4
			Glucose	100.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 10	2011-03-25T07:19	Hemoglobin	11.2	g/dL	L	12	15.5
			Leukocytes	17.56	10^9/L	H	4	10
			Neutrophils	12.84	10^9/L	H	2	7.5
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Blood Urea Nitrogen	29.97	mg/dL	H	5	26.9
			Glucose	133.3	mg/dL	H	63	99
	Cycle 11	2011-04-18T10:07	Hemoglobin	11.8	g/dL	L	12	15.5
			Leukocytes	12.42	10^9/L	H	4	10
			Neutrophils	9.8	10^9/L	H	2	7.5
			Prothrombin Intl. Normalized Ratio	1.24	ratio	H	0.9	1.15
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Urate	7.18	mg/dL	H	2	6.4
			Glucose	129.7	mg/dL	H	63	99
		2011-04-22T06:52	Hemoglobin	11.1	g/dL	L	12	15.5
			Erythrocytes	3.74	10^12/L	L	3.8	5.8
			Monocytes	0.96	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Glucose	100.9	mg/dL	H	63	99
	Cycle 12	2011-05-12T09:58	Leukocytes	11.29	10^9/L	H	4	10
			Neutrophils	7.76	10^9/L	H	2	7.5
			Monocytes	1.32	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	93	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	4.74	ratio	H	0.9	1.15
			Creatinine	1.855	mg/dL	H	0.6	1.13

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 12	2011-05-12T09:58	Blood Urea Nitrogen	43.98	mg/dL	H	5	26.9
			Urate	10.57	mg/dL	H	2	6.4
		2011-05-16T07:06	Hemoglobin	11	g/dL	L	12	15.5
			Erythrocytes	3.73	10^12/L	L	3.8	5.8
			Leukocytes	13.16	10^9/L	H	4	10
			Neutrophils	9.83	10^9/L	H	2	7.5
			Monocytes	1.16	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	7.78	mg/dL	L	9	11
			Albumin	3.1	g/dL	L	3.8	5
			Blood Urea Nitrogen	27.17	mg/dL	H	5	26.9
			Urate	6.54	mg/dL	H	2	6.4
	Cycle 13	2011-06-06T07:31	Leukocytes	15.8	10^9/L	H	4	10
			Neutrophils	12.47	10^9/L	H	2	7.5
			Monocytes	0.9	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	2.52	ratio	H	0.9	1.15
			Lactate Dehydrogenase	490	U/L	H	153	463
			Blood Urea Nitrogen	34.73	mg/dL	H	5	26.9
			Urate	7.46	mg/dL	H	2	6.4
			Glucose	59.4	mg/dL	L	63	99
		2011-06-10T07:51	Hemoglobin	11.1	g/dL	L	12	15.5
			Leukocytes	14.51	10^9/L	H	4	10
			Neutrophils	12.37	10^9/L	H	2	7.5
			Lymphocytes	1.36	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Magnesium	2.58	mg/dL	H	1.9	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 13	2011-06-10T07:51	Albumin	3.7	g/dL	L	3.8	5
			Blood Urea Nitrogen	28.29	mg/dL	H	5	26.9
	Cycle 14	2011-07-04T09:52	Hemoglobin	11.4	g/dL	L	12	15.5
			Leukocytes	15.71	10^9/L	H	4	10
			Neutrophils	12.17	10^9/L	H	2	7.5
			Monocytes	0.84	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.3	ratio	H	0.9	1.15
			Phosphate	4.58	mg/dL	H	2.7	4.5
			Magnesium	2.41	mg/dL	H	1.9	2.4
			Lactate Dehydrogenase	542	U/L	H	153	463
			Urate	8.05	mg/dL	H	2	6.4
		2011-07-08T07:11	Hemoglobin	11.2	g/dL	L	12	15.5
			Leukocytes	16.31	10^9/L	H	4	10
			Neutrophils	11.89	10^9/L	H	2	7.5
			Monocytes	1.31	10^9/L	H	0.2	0.8
			Basophils	0.11	10^9/L	H	0.02	0.1
	Cycle 15	2011-08-01T09:23	Hemoglobin	11.4	g/dL	L	12	15.5
			Leukocytes	13.97	10^9/L	H	4	10
			Neutrophils	9.01	10^9/L	H	2	7.5
			Eosinophils	0.43	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.37	ratio	H	0.9	1.15
			Lactate Dehydrogenase	631	U/L	H	153	463
			Blood Urea Nitrogen	29.97	mg/dL	H	5	26.9
			Urate	7.33	mg/dL	H	2	6.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 15	2011-08-05T07:16	Hemoglobin	10.4	g/dL	L	12	15.5
			Erythrocytes	3.6	10^12/L	L	3.8	5.8
			Leukocytes	14.52	10^9/L	H	4	10
			Neutrophils	10.02	10^9/L	H	2	7.5
			Monocytes	0.85	10^9/L	H	0.2	0.8
			Magnesium	2.63	mg/dL	H	1.9	2.4
			Blood Urea Nitrogen	32.21	mg/dL	H	5	26.9
			Urate	7.16	mg/dL	H	2	6.4
			Glucose	100.9	mg/dL	H	63	99
	Cycle 16	2011-08-29T08:50	Hemoglobin	10.4	g/dL	L	12	15.5
			Erythrocytes	3.54	10^12/L	L	3.8	5.6
			Leukocytes	10.83	10^9/L	H	4	10
			Neutrophils	8.05	10^9/L	H	1.5	7
			Prothrombin Intl. Normalized Ratio	1.32	ratio	H	0.9	1.15
			Chloride	106	mmol/L	H	95	105
			Phosphate	4.58	mg/dL	H	2.7	4.5
			Creatinine	1.131	mg/dL	H	0.6	1.13
			Albumin	3.6	g/dL	L	3.8	5
			Urate	6.56	mg/dL	H	2	6.4
		2011-09-02T10:15	Hemoglobin	11.7	g/dL	L	12	15.5
			Erythrocytes	3.64	10^12/L	L	3.8	5.8
			Platelets	137	10^9/L	L	150	400
			Lymphocytes	0.61	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	4.86	mg/dL	H	2.7	4.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 16	2011-09-02T10:15	Magnesium	2.65	mg/dL	H	1.9	2.4
			Lactate Dehydrogenase	469	U/L	H	153	463
			Blood Urea Nitrogen	29.69	mg/dL	H	5	26.9
			Urate	7.31	mg/dL	H	2	6.4
			Glucose	61.3	mg/dL	L	63	99
	Cycle 17	2011-09-26T09:35	Leukocytes	17.7	10^9/L	H	4	10
			Neutrophils	12.86	10^9/L	H	2	7.5
			Monocytes	0.85	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.9	1.15
			Urate	7.57	mg/dL	H	2	6.4
			Glucose	111.7	mg/dL	H	63	99
		2011-09-30T06:56	Hemoglobin	11.8	g/dL	L	12	15.5
			Leukocytes	16.13	10^9/L	H	4	10
			Neutrophils	13.02	10^9/L	H	2	7.5
			Monocytes	0.88	10^9/L	H	0.2	0.8
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.42	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Albumin	3.6	g/dL	L	3.8	5
			Urate	6.79	mg/dL	H	2	6.4

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 18	2011-10-24T08:09	Leukocytes	13.81	10^9/L	H	4	10
			Neutrophils	11.44	10^9/L	H	2	7.5
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.15
			Urate	6.89	mg/dL	H	2	6.4
			Glucose	108.1	mg/dL	H	63	99
		2011-10-28T07:23	Leukocytes	13.66	10^9/L	H	4	10
			Neutrophils	11.44	10^9/L	H	2	7.5
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Phosphate	4.92	mg/dL	H	2.7	4.5
			Urate	6.71	mg/dL	H	2	6.4
			Glucose	113.5	mg/dL	H	63	99
	Cycle 19	2011-11-21T07:05	Leukocytes	17.44	10^9/L	H	4	10
			Neutrophils	12.57	10^9/L	H	2	7.5
			Monocytes	1.26	10^9/L	H	0.2	0.8
			Eosinophils	0.89	10^9/L	H	0.04	0.4
			Phosphate	5.2	mg/dL	H	2.7	4.5
			Magnesium	2.53	mg/dL	H	1.9	2.4
			Urate	7.06	mg/dL	H	2	6.4
		2011-11-25T08:01	Leukocytes	15.13	10^9/L	H	4	10
			Neutrophils	10.75	10^9/L	H	2	7.5
			Monocytes	1.09	10^9/L	H	0.2	0.8
			Chloride	106	mmol/L	H	95	105
			Phosphate	4.65	mg/dL	H	2.7	4.5
			Magnesium	2.5	mg/dL	H	1.9	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 20	2011-12-12T07:52	Hemoglobin	11.5	g/dL	L	12	15.5
			Leukocytes	13.96	10^9/L	H	4	10
			Neutrophils	11.29	10^9/L	H	2	7.5
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.33	ratio	H	0.9	1.15
			Chloride	107	mmol/L	H	95	105
			Urate	6.51	mg/dL	H	2	6.4
			Glucose	99.1	mg/dL	H	63	99
		2011-12-16T06:58	Leukocytes	13.31	10^9/L	H	4	10
			Neutrophils	9.64	10^9/L	H	2	7.5
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.78	mg/dL	L	9	11
			Phosphate	4.65	mg/dL	H	2.7	4.5
			Magnesium	2.46	mg/dL	H	1.9	2.4
			Blood Urea Nitrogen	28.01	mg/dL	H	5	26.9
			Urate	6.84	mg/dL	H	2	6.4
	Cycle 21	2012-01-09T10:30	Hemoglobin	11.3	g/dL	L	12	15.5
			Leukocytes	13.4	10^9/L	H	4	10
			Neutrophils	9.33	10^9/L	H	2	7.5
			Monocytes	0.92	10^9/L	H	0.2	0.8
			Eosinophils	0.51	10^9/L	H	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	77	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.62	ratio	H	0.9	1.15
			Chloride	108	mmol/L	H	95	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 21	2012-01-09T10:30	Albumin	3.7	g/dL	L	3.8	5
			Urate	6.41	mg/dL	H	2	6.4
		2012-01-13T07:08	Leukocytes	15.66	10^9/L	H	4	10
			Neutrophils	12.37	10^9/L	H	2	7.5
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Calcium	8.98	mg/dL	L	9	11
			Phosphate	5.05	mg/dL	H	2.7	4.5
			Magnesium	2.48	mg/dL	H	1.9	2.4
			Alanine Aminotransferase	68	U/L	H	8	55
			Urate	7.63	mg/dL	H	2	6.4
	Cycle 22	2012-02-06T08:22	Leukocytes	14.92	10^9/L	H	4	10
			Neutrophils	11.62	10^9/L	H	2	7.5
			Activated Partial Thromboplastin Time	70	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.14	ratio	H	0.9	1.15
			Urate	6.44	mg/dL	H	2	6.4
		2012-02-10T07:21	Hemoglobin	11.7	g/dL	L	12	15.5
			Leukocytes	17.04	10^9/L	H	4	10
			Neutrophils	13.34	10^9/L	H	2	7.5
			Monocytes	1.13	10^9/L	H	0.2	0.8
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.9	mg/dL	L	9	11
			Phosphate	5.39	mg/dL	H	2.7	4.5
			Magnesium	2.48	mg/dL	H	1.9	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 23	2012-03-05T07:48	Leukocytes	14.94	10^9/L	H	4	10
			Neutrophils	11.74	10^9/L	H	2	7.5
			Monocytes	1.11	10^9/L	H	0.2	0.8
			Eosinophils	0.52	10^9/L	H	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.49	ratio	H	0.9	1.15
			Chloride	106	mmol/L	H	95	105
			Magnesium	2.99	mg/dL	H	1.9	2.4
			Lactate Dehydrogenase	593	U/L	H	153	463
			Urate	6.81	mg/dL	H	2	6.4
		2012-03-09T07:35	Leukocytes	20.41	10^9/L	H	4	10
			Neutrophils	16.85	10^9/L	H	2	7.5
			Monocytes	1.14	10^9/L	H	0.2	0.8
			Sodium	134	mmol/L	L	135	145
	Cycle 24	2012-04-02T07:25	Hemoglobin	10.7	g/dL	L	12	15.5
			Erythrocytes	3.76	10^12/L	L	3.8	5.8
			Eosinophils	0.48	10^9/L	H	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	46	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	1.76	ratio	H	0.9	1.15
			Calcium	8.86	mg/dL	L	9	11
			Chloride	107	mmol/L	H	95	105
			Albumin	3.5	g/dL	L	3.8	5
			Urate	6.47	mg/dL	H	2	6.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 24	2012-04-06T05:50	Hemoglobin	10.9	g/dL	L	12	15.5
			Magnesium	2.46	mg/dL	H	1.9	2.4
			Albumin	3.7	g/dL	L	3.8	5
	Cycle 25	2012-04-23T08:26	Leukocytes	15.16	10^9/L	H	4	10
			Neutrophils	12.23	10^9/L	H	2	7.5
			Monocytes	1.03	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	2.22	ratio	H	0.9	1.15
			Lactate Dehydrogenase	645	U/L	H	153	463
		2012-04-27T06:15	Hemoglobin	11.4	g/dL	L	12	15.5
			Leukocytes	10.74	10^9/L	H	4	10
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.78	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Albumin	3.7	g/dL	L	3.8	5
	Cycle 26	2012-05-21T07:58	Leukocytes	12.34	10^9/L	H	4	10
			Neutrophils	9.54	10^9/L	H	2	7.5
			Eosinophils	0.42	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.84	ratio	H	0.9	1.15
			Creatinine	1.199	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	733	U/L	H	153	463
			Urate	8.37	mg/dL	H	2	6.4
			Glucose	113.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 26	2012-05-25T07:16	Hemoglobin	11.1	g/dL	L	12	15.5
			Leukocytes	11.6	10^9/L	H	4	10
			Neutrophils	8.76	10^9/L	H	2	7.5
			Monocytes	0.94	10^9/L	H	0.2	0.8
			Calcium	8.9	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Magnesium	2.58	mg/dL	H	1.9	2.4
			Urate	6.91	mg/dL	H	2	6.4
	Cycle 27	2012-06-18T08:29	Monocytes	0.93	10^9/L	H	0.2	0.8
			Eosinophils	0.46	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	2.51	ratio	H	0.9	1.15
			Creatinine	1.165	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	766	U/L	H	153	463
			Urate	8.29	mg/dL	H	2	6.4
			Glucose	111.7	mg/dL	H	63	99
		2012-06-22T06:41	Monocytes	1.08	10^9/L	H	0.2	0.8
			Chloride	109	mmol/L	H	95	105
			Magnesium	2.58	mg/dL	H	1.9	2.4
			Creatinine	1.188	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	510	U/L	H	153	463
			Blood Urea Nitrogen	36.69	mg/dL	H	5	26.9
			Urate	8.93	mg/dL	H	2	6.4
			Glucose	117.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 28	2012-07-16T07:10	Hemoglobin	10.2	g/dL	L	12	15.5
			Platelets	100	10^9/L	L	150	400
			Leukocytes	3.97	10^9/L	L	4	10
			Neutrophils	1.44	10^9/L	L	2	7.5
			Activated Partial Thromboplastin Time	46	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.43	ratio	H	0.9	1.15
			Calcium	8.1	mg/dL	L	9	11
			Magnesium	1.77	mg/dL	L	1.9	2.4
			Albumin	3.2	g/dL	L	3.8	5
			Lactate Dehydrogenase	621	U/L	H	153	463
			Urate	8.81	mg/dL	H	2	6.4
			Glucose	99.1	mg/dL	H	63	99
		2012-07-20T07:00	Hemoglobin	10.3	g/dL	L	12	15.5
			Platelets	97	10^9/L	L	150	400
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.06	mg/dL	L	9	11
			Chloride	111	mmol/L	H	95	105
			Magnesium	2.46	mg/dL	H	1.9	2.4
			Albumin	3.3	g/dL	L	3.8	5
			Blood Urea Nitrogen	34.17	mg/dL	H	5	26.9
			Urate	8.47	mg/dL	H	2	6.4
			Glucose	140.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Cycle 29	2012-08-13T06:59	Hemoglobin	9.7	g/dL	L	12	15.5
			Erythrocytes	3.3	10^12/L	L	3.8	5.8
			Platelets	89	10^9/L	L	150	400
			Leukocytes	2.83	10^9/L	L	4	10
			Neutrophils	1.25	10^9/L	L	2	7.5
			Lymphocytes	1.13	10^9/L	L	1.5	4
			Monocytes	0.15	10^9/L	L	0.2	0.8
			Activated Partial Thromboplastin Time	96	sec	H	28	40
			Calcium	7.9	mg/dL	L	9	11
			Phosphate	2.01	mg/dL	L	2.7	4.5
			Magnesium	1.68	mg/dL	L	1.9	2.4
			Albumin	2.9	g/dL	L	3.8	5
			Lactate Dehydrogenase	691	U/L	H	153	463
		2012-08-17T06:47	Hemoglobin	10.8	g/dL	L	12	15.5
			Platelets	83	10^9/L	L	150	400
			Neutrophils	1.96	10^9/L	L	2	7.5
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	7.54	mg/dL	L	9	11
			Chloride	111	mmol/L	H	95	105
			Magnesium	2.43	mg/dL	H	1.9	2.4
			Albumin	3	g/dL	L	3.8	5
			Lactate Dehydrogenase	508	U/L	H	153	463
			Glucose	142.3	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-002	Unplanned	2012-07-13T15:20	Platelets	98	10^9/L	L	150	400
			Monocytes	1.56	10^9/L	H	0.2	0.8
			Calcium	8.7	mg/dL	L	9	11
			Creatinine	1.516	mg/dL	H	0.6	1.13
			Albumin	3.6	g/dL	L	3.8	5
			Lactate Dehydrogenase	1109	U/L	H	153	463
			Blood Urea Nitrogen	34.17	mg/dL	H	5	26.9
			Urate	10.52	mg/dL	H	2	6.4
		2012-08-09T14:46	Hemoglobin	9	g/dL	L	12	15.5
			Erythrocytes	3.32	10^12/L	L	3.8	5.8
			Platelets	117	10^9/L	L	150	400
			Lymphocytes	1.16	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Creatinine	1.55	mg/dL	H	0.6	1.13
			Albumin	2.9	g/dL	L	3.8	5
			Lactate Dehydrogenase	956	U/L	H	153	463
			Urate	8.39	mg/dL	H	2	6.4
534-003	Pre-trial	2010-09-01T13:08	Hemoglobin	11.2	g/dL	L	13.6	17.7
			Erythrocytes	3.09	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.6	fL	H	80	96
			Platelets	134	10^9/L	L	150	400
			Lymphocytes	1.07	10^9/L	L	1.5	4
			Calcium	8.7	mg/dL	L	9	11
			Phosphate	2.69	mg/dL	L	2.7	4.5
			Creatinine	1.946	mg/dL	H	0.6	1.13

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Pre-trial	2010-09-01T13:08	Lactate Dehydrogenase	482	U/L	H	153	463
	Cycle 1	2010-09-13T11:52	Hemoglobin	11.2	g/dL	L	13.6	17.7
			Erythrocytes	3.02	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.3	fL	H	80	96
			Platelets	113	10^9/L	L	150	400
			Lymphocytes	1.24	10^9/L	L	1.5	4
			Eosinophils	0.54	10^9/L	H	0.04	0.4
			Creatinine	2.07	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	599	U/L	H	153	463
			Glucose	104.5	mg/dL	H	63	99
		2010-09-17T07:01	Hemoglobin	10.6	g/dL	L	13.6	17.7
			Erythrocytes	2.86	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.1	fL	H	80	96
			Platelets	94	10^9/L	L	150	400
			Lymphocytes	0.99	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.02	mg/dL	L	9	11
			Creatinine	2.477	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	40.62	mg/dL	H	5	26.9
			Glucose	160.3	mg/dL	H	63	99
		2010-09-24T13:07	Hemoglobin	11.2	g/dL	L	13.6	17.7
			Erythrocytes	3	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	111.3	fL	H	80	96
			Platelets	65	10^9/L	L	150	400
			Lymphocytes	0.96	10^9/L	L	1.5	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 1	2010-09-24T13:07	Basophils	0	10^9/L	L	0.02	0.1
			Calcium	7.86	mg/dL	L	9	11
			Phosphate	2.57	mg/dL	L	2.7	4.5
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Creatinine	2.138	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	28.85	mg/dL	H	5	26.9
			Glucose	124.3	mg/dL	H	63	99
	Cycle 2	2010-10-04T12:56	Hemoglobin	11.4	g/dL	L	13.6	17.7
			Erythrocytes	3.04	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.9	fL	H	80	96
			Platelets	94	10^9/L	L	150	400
			Leukocytes	3.97	10^9/L	L	4	10
			Lymphocytes	1.04	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.38	mg/dL	L	9	11
			Creatinine	2.195	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	28.57	mg/dL	H	5	26.9
			Glucose	115.3	mg/dL	H	63	99
		2010-10-08T10:49	Hemoglobin	10.4	g/dL	L	13.6	17.7
			Erythrocytes	2.82	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.8	fL	H	80	96
			Platelets	94	10^9/L	L	150	400
			Lymphocytes	1.16	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.34	mg/dL	L	9	11

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 2	2010-10-08T10:49	Creatinine	2.296	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	43.14	mg/dL	H	5	26.9
			Glucose	144.1	mg/dL	H	63	99
	Cycle 3	2010-10-25T12:10	Hemoglobin	10.7	g/dL	L	13.6	17.7
			Erythrocytes	2.9	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	110.3	fL	H	80	96
			Platelets	75	10^9/L	L	150	400
			Leukocytes	2.5	10^9/L	L	4	10
			Neutrophils	1.37	10^9/L	L	2	7.5
			Lymphocytes	0.78	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.22	mg/dL	L	9	11
			Creatinine	2.195	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	27.45	mg/dL	H	5	26.9
			Glucose	102.7	mg/dL	H	63	99
		2010-10-29T10:06	Hemoglobin	11.2	g/dL	L	13.6	17.7
			Erythrocytes	3.05	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.8	fL	H	80	96
			Platelets	82	10^9/L	L	150	400
			Lymphocytes	1.19	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.7	mg/dL	L	9	11
			Creatinine	2.376	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	518	U/L	H	153	463
			Blood Urea Nitrogen	38.94	mg/dL	H	5	26.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 3	2010-10-29T10:06	Glucose	124.3	mg/dL	H	63	99
	Cycle 4	2010-11-15T12:07	Hemoglobin	10.8	g/dL	L	13.6	17.7
			Erythrocytes	2.9	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	110.3	fL	H	80	96
			Platelets	104	10^9/L	L	150	400
			Lymphocytes	1.42	10^9/L	L	1.5	4
			Calcium	8.94	mg/dL	L	9	11
			Creatinine	2.081	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	505	U/L	H	153	463
		2010-11-19T11:46	Hemoglobin	10.6	g/dL	L	13.6	17.7
			Erythrocytes	2.9	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.3	fL	H	80	96
			Platelets	98	10^9/L	L	150	400
			Lymphocytes	1.16	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Creatinine	2.477	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	516	U/L	H	153	463
			Blood Urea Nitrogen	39.78	mg/dL	H	5	26.9
			Glucose	174.7	mg/dL	H	63	99
	Cycle 5	2010-12-06T11:24	Hemoglobin	10.2	g/dL	L	12	15.5
			Erythrocytes	2.81	10^12/L	L	3.8	5.6
			Ery. Mean Corpuscular Volume	111	fL	H	85	97
			Platelets	85	10^9/L	L	130	500
			Leukocytes	3.75	10^9/L	L	4	10
			Calcium	8.42	mg/dL	L	9	11

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 5	2010-12-06T11:24	Magnesium	1.75	mg/dL	L	1.9	2.4
			Creatinine	2.33	mg/dL	H	0.6	1.13
		2010-12-10T10:09	Hemoglobin	10.7	g/dL	L	13.6	17.7
			Erythrocytes	2.93	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	105.5	fL	H	80	96
			Platelets	101	10^9/L	L	150	400
			Lymphocytes	1	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.3	mmol/L	L	3.5	5.5
			Calcium	8.5	mg/dL	L	9	11
			Creatinine	2.624	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	536	U/L	H	153	463
			Blood Urea Nitrogen	41.46	mg/dL	H	5	26.9
			Glucose	154.9	mg/dL	H	63	99
	Cycle 6	2010-12-27T12:33	Hemoglobin	10.6	g/dL	L	13.6	17.7
			Erythrocytes	2.83	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	111.3	fL	H	80	96
			Platelets	81	10^9/L	L	150	400
			Lymphocytes	0.99	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.18	mg/dL	L	9	11
			Magnesium	1.8	mg/dL	L	1.9	2.4
			Creatinine	2.489	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	535	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 6	2010-12-31T09:33	Hemoglobin	11.2	g/dL	L	13.6	17.7
			Erythrocytes	3.03	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.3	fL	H	80	96
			Platelets	92	10^9/L	L	150	400
			Lymphocytes	1.25	10^9/L	L	1.5	4
			Monocytes	0.83	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.2	mmol/L	L	3.5	5.5
			Calcium	8.5	mg/dL	L	9	11
			Creatinine	2.579	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	583	U/L	H	153	463
			Blood Urea Nitrogen	40.62	mg/dL	H	5	26.9
			Glucose	237.8	mg/dL	H	63	99
	Cycle 7	2011-01-17T12:35	Hemoglobin	10.6	g/dL	L	13.6	17.7
			Erythrocytes	2.91	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	104.8	fL	H	80	96
			Platelets	73	10^9/L	L	150	400
			Leukocytes	3.62	10^9/L	L	4	10
			Lymphocytes	0.91	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	8.22	mg/dL	L	9	11
			Magnesium	1.82	mg/dL	L	1.9	2.4
			Creatinine	2.387	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	540	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 7	2011-01-17T12:35	Glucose	144.1	mg/dL	H	63	99
		2011-01-21T10:50	Hemoglobin	10.9	g/dL	L	13.6	17.7
			Erythrocytes	3.04	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	110.2	fL	H	80	96
			Platelets	86	10^9/L	L	150	400
			Lymphocytes	1.2	10^9/L	L	1.5	4
			Monocytes	0.85	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	7.78	mg/dL	L	9	11
			Creatinine	2.342	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	581	U/L	H	153	463
			Blood Urea Nitrogen	42.58	mg/dL	H	5	26.9
			Glucose	154.9	mg/dL	H	63	99
	Cycle 8	2011-02-07T10:26	Hemoglobin	10.3	g/dL	L	13.6	17.7
			Erythrocytes	2.85	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	114.4	fL	H	80	96
			Platelets	81	10^9/L	L	150	400
			Leukocytes	3.82	10^9/L	L	4	10
			Lymphocytes	0.99	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.34	mg/dL	L	9	11
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Creatinine	2.376	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	562	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 8	2011-02-11T10:21	Hemoglobin	10.9	g/dL	L	13.6	17.7
			Erythrocytes	3.01	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.3	fL	H	80	96
			Platelets	93	10^9/L	L	150	400
			Lymphocytes	1.27	10^9/L	L	1.5	4
			Monocytes	0.96	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.42	mg/dL	L	9	11
			Creatinine	2.726	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	596	U/L	H	153	463
			Blood Urea Nitrogen	42.86	mg/dL	H	5	26.9
	Cycle 9	2011-02-28T10:33	Hemoglobin	10.8	g/dL	L	13.6	17.7
			Erythrocytes	2.97	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.7	fL	H	80	96
			Platelets	82	10^9/L	L	150	400
			Leukocytes	3.62	10^9/L	L	4	10
			Lymphocytes	1	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.5	mg/dL	L	9	11
			Creatinine	2.036	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	570	U/L	H	153	463
			Blood Urea Nitrogen	29.13	mg/dL	H	5	26.9

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 9	2011-03-04T10:27	Hemoglobin	12.9	g/dL	L	13.6	17.7
			Erythrocytes	3.64	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.9	fL	H	80	96
			Platelets	109	10^9/L	L	150	400
			Lymphocytes	1.39	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.1	mmol/L	L	3.5	5.5
			Calcium	8.58	mg/dL	L	9	11
			Phosphate	5.48	mg/dL	H	2.7	4.5
			Magnesium	2.53	mg/dL	H	1.9	2.4
			Creatinine	2.692	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	602	U/L	H	153	463
			Blood Urea Nitrogen	54.34	mg/dL	H	5	26.9
			Glucose	100.9	mg/dL	H	63	99
	Cycle 10	2011-03-21T10:50	Hemoglobin	10.9	g/dL	L	13.6	17.7
			Erythrocytes	3.18	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	102.5	fL	H	80	96
			Platelets	99	10^9/L	L	150	400
			Lymphocytes	1.49	10^9/L	L	1.5	4
			Calcium	8.5	mg/dL	L	9	11
			Creatinine	2.251	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	532	U/L	H	153	463
			Blood Urea Nitrogen	31.37	mg/dL	H	5	26.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 10	2011-03-25T10:02	Hemoglobin	10.6	g/dL	L	13.6	17.7
			Erythrocytes	3.02	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.9	fL	H	80	96
			Platelets	85	10^9/L	L	150	400
			Lymphocytes	0.93	10^9/L	L	1.5	4
			Monocytes	0.84	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.2	mmol/L	L	3.5	5.5
			Calcium	8.46	mg/dL	L	9	11
			Creatinine	2.794	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	517	U/L	H	153	463
			Blood Urea Nitrogen	43.98	mg/dL	H	5	26.9
			Glucose	129.7	mg/dL	H	63	99
	Cycle 11	2011-04-11T10:20	Hemoglobin	9.6	g/dL	L	13.6	17.7
			Erythrocytes	2.71	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.7	fL	H	80	96
			Platelets	74	10^9/L	L	150	400
			Leukocytes	2.95	10^9/L	L	4	10
			Neutrophils	1.4	10^9/L	L	2	7.5
			Lymphocytes	1.22	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.54	mg/dL	L	9	11
			Creatinine	2.285	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	504	U/L	H	153	463
			Glucose	99.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 11	2011-04-15T07:12	Hemoglobin	10.1	g/dL	L	13.6	17.7
			Erythrocytes	2.83	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.9	fL	H	80	96
			Platelets	85	10^9/L	L	150	400
			Lymphocytes	0.98	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.66	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Creatinine	2.523	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	725	U/L	H	153	463
			Blood Urea Nitrogen	40.9	mg/dL	H	5	26.9
	Cycle 12	2011-05-02T10:37	Hemoglobin	10.3	g/dL	L	13.6	17.7
			Erythrocytes	2.85	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	111.6	fL	H	80	96
			Platelets	86	10^9/L	L	150	400
			Leukocytes	3.61	10^9/L	L	4	10
			Lymphocytes	1	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Creatinine	2.217	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	514	U/L	H	153	463
			Glucose	129.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 12	2011-05-06T10:24	Hemoglobin	10.5	g/dL	L	13.6	17.7
			Erythrocytes	2.86	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	111.2	fL	H	80	96
			Platelets	91	10^9/L	L	150	400
			Lymphocytes	1.12	10^9/L	L	1.5	4
			Monocytes	0.82	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.58	mg/dL	L	9	11
			Phosphate	5.23	mg/dL	H	2.7	4.5
			Magnesium	2.43	mg/dL	H	1.9	2.4
			Creatinine	2.76	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	607	U/L	H	153	463
			Blood Urea Nitrogen	50.98	mg/dL	H	5	26.9
	Cycle 13	2011-05-23T09:56	Hemoglobin	10.3	g/dL	L	13.6	17.7
			Erythrocytes	2.77	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	115.5	fL	H	80	96
			Platelets	86	10^9/L	L	150	400
			Lymphocytes	1.31	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.34	mg/dL	L	9	11
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Creatinine	2.183	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	529	U/L	H	153	463

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 13	2011-05-27T10:14	Hemoglobin	10.5	g/dL	L	13.6	17.7
			Erythrocytes	2.82	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	113.8	fL	H	80	96
			Platelets	93	10^9/L	L	150	400
			Lymphocytes	1.14	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.3	mmol/L	L	3.5	5.5
			Calcium	8.7	mg/dL	L	9	11
			Creatinine	2.704	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	37.82	mg/dL	H	5	26.9
			Glucose	131.5	mg/dL	H	63	99
	Cycle 14	2011-06-14T09:56	Hemoglobin	10.4	g/dL	L	13.6	17.7
			Erythrocytes	2.79	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	115.8	fL	H	80	96
			Platelets	92	10^9/L	L	150	400
			Leukocytes	3.99	10^9/L	L	4	10
			Lymphocytes	1.06	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.1	mmol/L	L	3.5	5.5
			Calcium	8.22	mg/dL	L	9	11
			Creatinine	2.081	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	598	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 14	2011-06-18T09:23	Hemoglobin	11.2	g/dL	L	13.6	17.7
			Erythrocytes	3.01	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	112.6	fL	H	80	96
			Platelets	107	10^9/L	L	150	400
			Lymphocytes	1.01	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	8.14	mg/dL	L	9	11
			Creatinine	3.541	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	720	U/L	H	153	463
			Blood Urea Nitrogen	49.58	mg/dL	H	5	26.9
			Glucose	169.3	mg/dL	H	63	99
	Cycle 15	2011-07-04T10:14	Hemoglobin	11.1	g/dL	L	13.6	17.7
			Erythrocytes	2.95	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	115.3	fL	H	80	96
			Platelets	81	10^9/L	L	150	400
			Lymphocytes	0.94	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	6.2	mmol/L	H	3.5	5.5
			Calcium	8.5	mg/dL	L	9	11
			Creatinine	2.07	mg/dL	H	0.6	1.13
			Aspartate Aminotransferase	71	U/L	H	6	54
			Lactate Dehydrogenase	1793	U/L	H	153	463
			Glucose	111.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 15	2011-07-08T10:15	Hemoglobin	10.3	g/dL	L	13.6	17.7
			Erythrocytes	2.68	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	113.4	fL	H	80	96
			Platelets	74	10^9/L	L	150	400
			Lymphocytes	0.79	10^9/L	L	1.5	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3	mmol/L	L	3.5	5.5
			Calcium	8.74	mg/dL	L	9	11
			Creatinine	2.545	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	512	U/L	H	153	463
			Blood Urea Nitrogen	39.5	mg/dL	H	5	26.9
			Glucose	120.7	mg/dL	H	63	99
	Cycle 16	2011-08-01T10:22	Hemoglobin	10.7	g/dL	L	13.6	17.7
			Erythrocytes	3.01	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.6	fL	H	80	96
			Platelets	121	10^9/L	L	150	400
			Leukocytes	3.83	10^9/L	L	4	10
			Neutrophils	1.85	10^9/L	L	2	7.5
			Lymphocytes	0.72	10^9/L	L	1.5	4
			Eosinophils	0.87	10^9/L	H	0.04	0.4
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	8.14	mg/dL	L	9	11
			Phosphate	2.51	mg/dL	L	2.7	4.5
			Magnesium	3.23	mg/dL	H	1.9	2.4
			Creatinine	2.296	mg/dL	H	0.6	1.13

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 16	2011-08-01T10:22	Lactate Dehydrogenase	577	U/L	H	153	463
			Glucose	117.1	mg/dL	H	63	99
		2011-08-05T07:38	Hemoglobin	10.7	g/dL	L	13.6	17.7
			Erythrocytes	3.08	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.2	fL	H	80	96
			Platelets	110	10^9/L	L	150	400
			Lymphocytes	0.93	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.06	mg/dL	L	9	11
			Creatinine	2.455	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	674	U/L	H	153	463
			Blood Urea Nitrogen	34.45	mg/dL	H	5	26.9
	Cycle 17	2011-08-22T10:10	Hemoglobin	10.5	g/dL	L	13.6	17.7
			Erythrocytes	2.91	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	108.6	fL	H	80	96
			Platelets	95	10^9/L	L	150	400
			Lymphocytes	0.94	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	7.86	mg/dL	L	9	11
			Phosphate	2.45	mg/dL	L	2.7	4.5
			Creatinine	2.262	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	581	U/L	H	153	463
			Glucose	149.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 17	2011-08-26T10:54	Hemoglobin	11	g/dL	L	13.6	17.7
			Erythrocytes	3.05	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.9	fL	H	80	96
			Platelets	97	10^9/L	L	150	400
			Lymphocytes	1.01	10^9/L	L	1.5	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.2	mmol/L	L	3.5	5.5
			Calcium	8.3	mg/dL	L	9	11
			Creatinine	2.681	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	598	U/L	H	153	463
			Blood Urea Nitrogen	36.41	mg/dL	H	5	26.9
			Glucose	144.1	mg/dL	H	63	99
	Cycle 18	2011-09-12T10:04	Hemoglobin	10.8	g/dL	L	13.6	17.7
			Erythrocytes	3.16	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	102.6	fL	H	80	96
			Platelets	115	10^9/L	L	150	400
			Leukocytes	3.41	10^9/L	L	4	10
			Lymphocytes	0.73	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Potassium	3.2	mmol/L	L	3.5	5.5
			Calcium	8.66	mg/dL	L	9	11
			Creatinine	2.489	mg/dL	H	0.6	1.13

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 18	2011-09-16T10:29	Hemoglobin	11.1	g/dL	L	13.6	17.7
			Erythrocytes	3.07	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	105.2	fL	H	80	96
			Platelets	102	10^9/L	L	150	400
			Lymphocytes	1.16	10^9/L	L	1.5	4
			Monocytes	0.81	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3	mmol/L	L	3.5	5.5
			Calcium	8.58	mg/dL	L	9	11
			Creatinine	2.704	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	583	U/L	H	153	463
			Blood Urea Nitrogen	39.5	mg/dL	H	5	26.9
			Glucose	100.9	mg/dL	H	63	99
	Cycle 19	2011-10-03T09:53	Hemoglobin	10.9	g/dL	L	13.6	17.7
			Erythrocytes	3.08	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.1	fL	H	80	96
			Platelets	110	10^9/L	L	150	400
			Lymphocytes	1.07	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Creatinine	2.206	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	571	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 19	2011-10-07T10:08	Hemoglobin	10.8	g/dL	L	13.6	17.7
			Erythrocytes	3.07	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	104.9	fL	H	80	96
			Platelets	111	10^9/L	L	150	400
			Lymphocytes	1.28	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.9	mg/dL	L	9	11
			Creatinine	2.387	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	499	U/L	H	153	463
			Blood Urea Nitrogen	34.73	mg/dL	H	5	26.9
			Glucose	127.9	mg/dL	H	63	99
	Cycle 20	2011-10-24T10:08	Hemoglobin	11.3	g/dL	L	13.6	17.7
			Erythrocytes	3.21	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.2	fL	H	80	96
			Platelets	109	10^9/L	L	150	400
			Lymphocytes	1.04	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3	mmol/L	L	3.5	5.5
			Calcium	8.7	mg/dL	L	9	11
			Creatinine	2.229	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	602	U/L	H	153	463
			Glucose	122.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 20	2011-10-28T10:20	Hemoglobin	11.5	g/dL	L	13.6	17.7
			Erythrocytes	3.25	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	104.9	fL	H	80	96
			Platelets	106	10^9/L	L	150	400
			Lymphocytes	0.99	10^9/L	L	1.5	4
			Monocytes	0.89	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.78	mg/dL	L	9	11
			Creatinine	2.557	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	563	U/L	H	153	463
			Blood Urea Nitrogen	36.97	mg/dL	H	5	26.9
			Glucose	115.3	mg/dL	H	63	99
	Cycle 21	2011-11-14T10:02	Hemoglobin	11	g/dL	L	13.6	17.7
			Erythrocytes	3.08	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	108.1	fL	H	80	96
			Platelets	124	10^9/L	L	150	400
			Lymphocytes	1.07	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.74	mg/dL	L	9	11
			Creatinine	2.692	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	580	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 21	2011-11-18T10:33	Hemoglobin	11.1	g/dL	L	13.6	17.7
			Erythrocytes	3.2	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	104.1	fL	H	80	96
			Platelets	134	10^9/L	L	150	400
			Lymphocytes	1.2	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.3	mmol/L	L	3.5	5.5
			Creatinine	3.563	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	722	U/L	H	153	463
			Blood Urea Nitrogen	42.86	mg/dL	H	5	26.9
			Glucose	120.7	mg/dL	H	63	99
	Cycle 22	2011-12-05T10:08	Hemoglobin	11.8	g/dL	L	13.6	17.7
			Erythrocytes	3.31	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.6	fL	H	80	96
			Platelets	134	10^9/L	L	150	400
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	27	sec	L	28	40
			Creatinine	2.466	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	579	U/L	H	153	463
		2011-12-09T10:23	Hemoglobin	12.3	g/dL	L	13.6	17.7
			Erythrocytes	3.45	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	105.2	fL	H	80	96
			Lymphocytes	1.01	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 22	2011-12-09T10:23	Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.2	mmol/L	L	3.5	5.5
			Calcium	8.86	mg/dL	L	9	11
			Creatinine	2.873	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	599	U/L	H	153	463
			Blood Urea Nitrogen	37.82	mg/dL	H	5	26.9
			Glucose	120.7	mg/dL	H	63	99
	Cycle 23	2011-12-26T08:04	Hemoglobin	12.6	g/dL	L	13.6	17.7
			Erythrocytes	3.52	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	108.2	fL	H	80	96
			Platelets	124	10^9/L	L	150	400
			Lymphocytes	1.46	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.6	ratio	H	0.9	1.15
			Creatinine	2.579	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	650	U/L	H	153	463
		2011-12-30T07:24	Hemoglobin	11.1	g/dL	L	13.6	17.7
			Erythrocytes	3.09	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.4	fL	H	80	96
			Platelets	109	10^9/L	L	150	400
			Lymphocytes	0.92	10^9/L	L	1.5	4
			Monocytes	0.82	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.66	mg/dL	L	9	11
			Creatinine	2.523	mg/dL	H	0.6	1.13

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 23	2011-12-30T07:24	Lactate Dehydrogenase	598	U/L	H	153	463
			Blood Urea Nitrogen	36.69	mg/dL	H	5	26.9
	Cycle 24	2012-01-16T07:39	Hemoglobin	11.5	g/dL	L	13.6	17.7
			Erythrocytes	3.31	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	104.1	fL	H	80	96
			Platelets	136	10^9/L	L	150	400
			Lymphocytes	0.89	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.87	ratio	H	0.9	1.15
			Calcium	8.9	mg/dL	L	9	11
			Phosphate	2.35	mg/dL	L	2.7	4.5
			Creatinine	2.195	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	708	U/L	H	153	463
		2012-01-20T07:40	Hemoglobin	11.5	g/dL	L	13.6	17.7
			Erythrocytes	3.24	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	105.2	fL	H	80	96
			Platelets	136	10^9/L	L	150	400
			Lymphocytes	0.87	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	8.5	mg/dL	L	9	11
			Creatinine	2.67	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	664	U/L	H	153	463
			Blood Urea Nitrogen	33.61	mg/dL	H	5	26.9
			Glucose	108.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 25	2012-02-06T07:31	Hemoglobin	11.6	g/dL	L	13.6	17.7
			Erythrocytes	3.33	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106	fL	H	80	96
			Platelets	137	10^9/L	L	150	400
			Leukocytes	3.63	10^9/L	L	4	10
			Lymphocytes	0.94	10^9/L	L	1.5	4
			Basophils	0.11	10^9/L	H	0.02	0.1
			Prothrombin Intl. Normalized Ratio	2.49	ratio	H	0.9	1.15
			Calcium	8.78	mg/dL	L	9	11
			Phosphate	2.54	mg/dL	L	2.7	4.5
			Creatinine	2.296	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	606	U/L	H	153	463
			Glucose	111.7	mg/dL	H	63	99
		2012-02-10T09:05	Hemoglobin	11.6	g/dL	L	13.6	17.7
			Erythrocytes	3.21	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.2	fL	H	80	96
			Platelets	120	10^9/L	L	150	400
			Lymphocytes	0.87	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.3	mg/dL	L	9	11
			Creatinine	2.489	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	609	U/L	H	153	463
			Blood Urea Nitrogen	34.17	mg/dL	H	5	26.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 26	2012-02-27T07:17	Hemoglobin	11.7	g/dL	L	13.6	17.7
			Erythrocytes	3.34	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	105.2	fL	H	80	96
			Platelets	140	10^9/L	L	150	400
			Leukocytes	2.73	10^9/L	L	4	10
			Neutrophils	1.34	10^9/L	L	2	7.5
			Lymphocytes	0.94	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	42	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	1.69	ratio	H	0.9	1.15
			Calcium	8.7	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Phosphate	2.2	mg/dL	L	2.7	4.5
			Creatinine	2.127	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	644	U/L	H	153	463
		2012-03-02T07:16	Hemoglobin	11.3	g/dL	L	13.6	17.7
			Erythrocytes	3.17	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.3	fL	H	80	96
			Platelets	123	10^9/L	L	150	400
			Lymphocytes	0.7	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.38	mg/dL	L	9	11
			Creatinine	2.41	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	561	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 26	2012-03-02T07:16	Blood Urea Nitrogen	33.61	mg/dL	H	5	26.9
	Cycle 27	2012-03-19T07:05	Hemoglobin	11.3	g/dL	L	13.6	17.7
			Erythrocytes	3.24	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	105	fL	H	80	96
			Platelets	142	10^9/L	L	150	400
			Leukocytes	3.23	10^9/L	L	4	10
			Neutrophils	1.96	10^9/L	L	2	7.5
			Lymphocytes	0.82	10^9/L	L	1.5	4
			Monocytes	0.18	10^9/L	L	0.2	0.8
			Activated Partial Thromboplastin Time	41	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.52	ratio	H	0.9	1.15
			Chloride	107	mmol/L	H	95	105
			Magnesium	1.82	mg/dL	L	1.9	2.4
			Creatinine	2.195	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	608	U/L	H	153	463
		2012-03-23T07:35	Hemoglobin	11.4	g/dL	L	13.6	17.7
			Erythrocytes	3.2	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	106.3	fL	H	80	96
			Platelets	131	10^9/L	L	150	400
			Lymphocytes	1.03	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.58	mg/dL	L	9	11
			Creatinine	2.466	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	652	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 27	2012-03-23T07:35	Blood Urea Nitrogen	36.41	mg/dL	H	5	26.9
			Glucose	111.7	mg/dL	H	63	99
	Cycle 28	2012-04-09T07:05	Erythrocytes	3.82	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	109.4	fL	H	80	96
			Lymphocytes	1.46	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.94	ratio	H	0.9	1.15
			Potassium	3.3	mmol/L	L	3.5	5.5
			Calcium	8.98	mg/dL	L	9	11
			Creatinine	2.771	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	549	U/L	H	153	463
			Glucose	124.3	mg/dL	H	63	99
		2012-04-13T06:35	Hemoglobin	12.2	g/dL	L	13.6	17.7
			Erythrocytes	3.4	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	108.8	fL	H	80	96
			Platelets	140	10^9/L	L	150	400
			Lymphocytes	0.91	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.74	mg/dL	L	9	11
			Creatinine	2.692	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	590	U/L	H	153	463
			Blood Urea Nitrogen	40.62	mg/dL	H	5	26.9
			Glucose	154.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Cycle 29	2012-04-30T09:30	Hemoglobin	11.3	g/dL	L	13.6	17.7
			Erythrocytes	3.11	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	110	fL	H	80	96
			Platelets	99	10^9/L	L	150	400
			Leukocytes	3.07	10^9/L	L	4	10
			Neutrophils	1.95	10^9/L	L	2	7.5
			Lymphocytes	0.63	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	42	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.37	ratio	H	0.9	1.15
			Calcium	8.82	mg/dL	L	9	11
			Creatinine	2.093	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	703	U/L	H	153	463
		2012-05-04T08:05	Hemoglobin	10.6	g/dL	L	13.6	17.7
			Erythrocytes	2.97	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.7	fL	H	80	96
			Platelets	109	10^9/L	L	150	400
			Lymphocytes	0.82	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.42	mg/dL	L	9	11
			Creatinine	2.466	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	585	U/L	H	153	463
			Blood Urea Nitrogen	35.85	mg/dL	H	5	26.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-003	Unplanned	2011-06-30T14:36	Calcium	8.9	mg/dL	L	9	11
			Creatinine	2.195	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	555	U/L	H	153	463
			Blood Urea Nitrogen	27.17	mg/dL	H	5	26.9
			Glucose	151.3	mg/dL	H	63	99
		2011-11-30T14:11	Calcium	8.62	mg/dL	L	9	11
			Creatinine	2.364	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	590	U/L	H	153	463
	End Trial	2012-05-21T10:02	Hemoglobin	10.9	g/dL	L	13.6	17.7
			Erythrocytes	3.05	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	107.2	fL	H	80	96
			Platelets	113	10^9/L	L	150	400
			Leukocytes	2.66	10^9/L	L	4	10
			Neutrophils	1.65	10^9/L	L	2	7.5
			Lymphocytes	0.5	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	42	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	1.8	ratio	H	0.9	1.15
			Calcium	8.26	mg/dL	L	9	11
			Chloride	107	mmol/L	H	95	105
			Phosphate	2.32	mg/dL	L	2.7	4.5
			Creatinine	2.115	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	603	U/L	H	153	463

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Pre-trial	2011-03-23T09:51	Hemoglobin	10.5	g/dL	L	13.6	17.7
			Erythrocytes	3.37	10^12/L	L	4.5	6.5
			Lymphocytes	0.71	10^9/L	L	1.5	4
			Monocytes	0.96	10^9/L	H	0.2	0.8
			Eosinophils	1.43	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.46	ratio	H	0.9	1.15
			Sodium	130	mmol/L	L	135	145
			Calcium	7.45	mg/dL	L	9	11
			Creatinine	1.165	mg/dL	H	0.6	1.13
			Albumin	3.6	g/dL	L	3.8	5
			Lactate Dehydrogenase	1053	U/L	H	153	463
			Glucose	109.9	mg/dL	H	63	99
	Cycle 1	2011-04-04T09:51	Hemoglobin	10.1	g/dL	L	13.6	17.7
			Erythrocytes	3.29	10^12/L	L	4.5	6.5
			Lymphocytes	0.96	10^9/L	L	1.5	4
			Eosinophils	0.49	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.3	ratio	H	0.9	1.15
			Calcium	8.7	mg/dL	L	9	11
			Glucose	115.3	mg/dL	H	63	99
		2011-04-08T09:56	Hemoglobin	9	g/dL	L	13.6	17.7
			Erythrocytes	2.94	10^12/L	L	4.5	6.5
			Lymphocytes	0.53	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.98	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 1	2011-04-08T09:56	Glucose	118.9	mg/dL	H	63	99
		2011-04-15T09:14	Hemoglobin	8.3	g/dL	L	13.6	17.7
			Erythrocytes	2.8	10^12/L	L	4.5	6.5
			Lymphocytes	0.44	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.22	mg/dL	L	9	11
			Magnesium	1.77	mg/dL	L	1.9	2.4
			Glucose	133.3	mg/dL	H	63	99
	Cycle 2	2011-04-26T08:45	Hemoglobin	8.2	g/dL	L	13.6	17.7
			Erythrocytes	2.62	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	98.1	fL	H	80	96
			Lymphocytes	0.71	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.25	ratio	H	0.9	1.15
			Calcium	8.18	mg/dL	L	9	11
			Phosphate	4.58	mg/dL	H	2.7	4.5
			Creatinine	1.131	mg/dL	H	0.6	1.13
			Lactate Dehydrogenase	492	U/L	H	153	463
			Glucose	115.3	mg/dL	H	63	99
		2011-04-30T08:12	Hemoglobin	9.6	g/dL	L	13.6	17.7
			Erythrocytes	3.02	10^12/L	L	4.5	6.5
			Lymphocytes	0.68	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.74	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Glucose	140.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 3	2011-05-16T09:55	Hemoglobin	12.2	g/dL	L	13.6	17.7
			Erythrocytes	3.69	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	102.7	fL	H	80	96
			Lymphocytes	0.71	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.3	ratio	H	0.9	1.15
			Potassium	5.7	mmol/L	H	3.5	5.5
			Calcium	8.54	mg/dL	L	9	11
			Magnesium	1.77	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	809	U/L	H	153	463
			Bilirubin	1.07	mg/dL	H	0.09	0.99
			Glucose	115.3	mg/dL	H	63	99
		2011-05-20T07:17	Hemoglobin	11.3	g/dL	L	13.6	17.7
			Erythrocytes	3.46	10^12/L	L	4.5	6.5
			Lymphocytes	0.7	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.74	mg/dL	L	9	11
			Phosphate	4.77	mg/dL	H	2.7	4.5
			Glucose	216.2	mg/dL	H	63	99
	Cycle 4	2011-06-06T09:24	Hemoglobin	11.6	g/dL	L	13.6	17.7
			Erythrocytes	3.47	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	103.5	fL	H	80	96
			Lymphocytes	0.58	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.25	ratio	H	0.9	1.15
			Chloride	108	mmol/L	H	95	105
			Magnesium	1.7	mg/dL	L	1.9	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 4	2011-06-06T09:24	Glucose	162.1	mg/dL	H	63	99
		2011-06-10T11:46	Hemoglobin	11.8	g/dL	L	13.6	17.7
			Erythrocytes	3.46	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	101.4	fL	H	80	96
			Lymphocytes	0.68	10^9/L	L	1.5	4
			Monocytes	0.81	10^9/L	H	0.2	0.8
			Basophils	0	10^9/L	L	0.02	0.1
			Glucose	127.9	mg/dL	H	63	99
	Cycle 5	2011-06-27T09:17	Hemoglobin	13.3	g/dL	L	13.6	17.7
			Erythrocytes	3.98	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	99.5	fL	H	80	96
			Lymphocytes	0.37	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.21	ratio	H	0.9	1.15
			Glucose	181.9	mg/dL	H	63	99
		2011-07-01T08:41	Hemoglobin	13.4	g/dL	L	13.6	17.7
			Erythrocytes	4	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	101.5	fL	H	80	96
			Lymphocytes	0.49	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Chloride	106	mmol/L	H	95	105
			Glucose	117.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 6	2011-07-18T10:54	Erythrocytes	4.06	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.5	fL	H	80	96
			Lymphocytes	0.38	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.26	ratio	H	0.9	1.15
			Calcium	8.94	mg/dL	L	9	11
			Magnesium	1.7	mg/dL	L	1.9	2.4
			Glucose	99.1	mg/dL	H	63	99
		2011-07-22T07:02	Erythrocytes	4.19	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	100	fL	H	80	96
			Lymphocytes	1.13	10^9/L	L	1.5	4
			Monocytes	1.01	10^9/L	H	0.2	0.8
			Eosinophils	0.57	10^9/L	H	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
	Cycle 7	2011-08-08T10:54	Erythrocytes	4.26	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	99.5	fL	H	80	96
			Platelets	137	10^9/L	L	150	400
			Lymphocytes	0.59	10^9/L	L	1.5	4
			Monocytes	0.85	10^9/L	H	0.2	0.8
			Eosinophils	0.5	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.17	ratio	H	0.9	1.15
			Calcium	8.9	mg/dL	L	9	11
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	527	U/L	H	153	463
			Glucose	194.6	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 7	2011-08-12T10:42	Hemoglobin	13.1	g/dL	L	13.6	17.7
			Erythrocytes	3.97	10^12/L	L	4.5	6.5
			Lymphocytes	0.37	10^9/L	L	1.5	4
			Monocytes	0.83	10^9/L	H	0.2	0.8
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.46	mg/dL	L	9	11
			Glucose	194.6	mg/dL	H	63	99
	Cycle 8	2011-08-29T08:30	Erythrocytes	4.13	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.4	fL	H	80	96
			Lymphocytes	0.65	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.22	ratio	H	0.9	1.15
			Calcium	8.74	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Lactate Dehydrogenase	532	U/L	H	153	463
			Glucose	118.9	mg/dL	H	63	99
	Cycle 9	2011-09-19T10:11	Erythrocytes	4.17	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.2	fL	H	80	96
			Lymphocytes	0.62	10^9/L	L	1.5	4
			Lactate Dehydrogenase	715	U/L	H	153	463
			Glucose	167.5	mg/dL	H	63	99
		2011-09-23T10:36	Hemoglobin	13.3	g/dL	L	13.6	17.7
			Erythrocytes	3.98	10^12/L	L	4.5	6.5
			Leukocytes	10.63	10^9/L	H	4	10
			Neutrophils	8.05	10^9/L	H	2	7.5
			Lymphocytes	1.3	10^9/L	L	1.5	4
			Monocytes	0.97	10^9/L	H	0.2	0.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 9	2011-09-23T10:36	Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.9	mg/dL	L	9	11
			Lactate Dehydrogenase	749	U/L	H	153	463
	Cycle 10	2011-10-17T07:29	Erythrocytes	4	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	97	fL	H	80	96
			Lymphocytes	0.45	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.24	ratio	H	0.9	1.15
			Calcium	8.98	mg/dL	L	9	11
			Magnesium	1.6	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	496	U/L	H	153	463
			Glucose	178.3	mg/dL	H	63	99
		2011-10-21T07:27	Erythrocytes	4.17	10^12/L	L	4.5	6.5
			Lymphocytes	0.95	10^9/L	L	1.5	4
			Monocytes	0.97	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Lactate Dehydrogenase	481	U/L	H	153	463
	Cycle 11	2011-11-14T07:11	Hemoglobin	12.6	g/dL	L	13.6	17.7
			Erythrocytes	3.84	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	97.7	fL	H	80	96
			Leukocytes	11	10^9/L	H	4	10
			Lymphocytes	0.9	10^9/L	L	1.5	4
			Monocytes	1.37	10^9/L	H	0.2	0.8
			Eosinophils	3.71	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.23	ratio	H	0.9	1.15
			Calcium	8.06	mg/dL	L	9	11
			Albumin	3.7	g/dL	L	3.8	5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 11	2011-11-14T07:11	Lactate Dehydrogenase	720	U/L	H	153	463
		2011-11-18T07:37	Hemoglobin	11.4	g/dL	L	13.6	17.7
			Erythrocytes	3.52	10^12/L	L	4.5	6.5
			Monocytes	0.88	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
	Cycle 12	2011-12-12T10:51	Hemoglobin	13.1	g/dL	L	13.6	17.7
			Erythrocytes	4.02	10^12/L	L	4.5	6.5
			Lymphocytes	0.82	10^9/L	L	1.5	4
			Eosinophils	1.13	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.25	ratio	H	0.9	1.15
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Glucose	126.1	mg/dL	H	63	99
		2011-12-16T07:56	Hemoglobin	13	g/dL	L	13.6	17.7
			Erythrocytes	4.01	10^12/L	L	4.5	6.5
			Leukocytes	10.45	10^9/L	H	4	10
			Neutrophils	8.84	10^9/L	H	2	7.5
			Lymphocytes	0.87	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Chloride	106	mmol/L	H	95	105
			Glucose	136.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 13	2012-01-09T07:16	Erythrocytes	4.25	10^12/L	L	4.5	6.5
			Lymphocytes	0.85	10^9/L	L	1.5	4
			Monocytes	0.81	10^9/L	H	0.2	0.8
			Eosinophils	0.68	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.32	ratio	H	0.9	1.15
			Calcium	8.62	mg/dL	L	9	11
			Magnesium	1.77	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	500	U/L	H	153	463
			Glucose	108.1	mg/dL	H	63	99
		2012-01-13T08:00	Hemoglobin	12.4	g/dL	L	13.6	17.7
			Erythrocytes	3.87	10^12/L	L	4.5	6.5
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.7	mg/dL	L	9	11
			Phosphate	2.48	mg/dL	L	2.7	4.5
			Glucose	207.2	mg/dL	H	63	99
	Cycle 14	2012-02-06T08:14	Erythrocytes	4.46	10^12/L	L	4.5	6.5
			Lymphocytes	0.73	10^9/L	L	1.5	4
			Monocytes	1.12	10^9/L	H	0.2	0.8
			Eosinophils	0.93	10^9/L	H	0.04	0.4
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.15
			Magnesium	1.82	mg/dL	L	1.9	2.4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 14	2012-02-10T08:05	Erythrocytes	4.17	10^12/L	L	4.5	6.5
			Leukocytes	10.44	10^9/L	H	4	10
			Neutrophils	8.3	10^9/L	H	2	7.5
			Lymphocytes	0.93	10^9/L	L	1.5	4
			Monocytes	1.2	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.66	mg/dL	L	9	11
			Chloride	107	mmol/L	H	95	105
	Cycle 15	2012-03-05T08:40	Erythrocytes	4.28	10^12/L	L	4.5	6.5
			Lymphocytes	0.83	10^9/L	L	1.5	4
			Monocytes	0.85	10^9/L	H	0.2	0.8
			Eosinophils	0.8	10^9/L	H	0.04	0.4
			Calcium	8.78	mg/dL	L	9	11
			Chloride	108	mmol/L	H	95	105
			Magnesium	1.82	mg/dL	L	1.9	2.4
		2012-03-09T07:40	Hemoglobin	13.2	g/dL	L	13.6	17.7
			Erythrocytes	4.13	10^12/L	L	4.5	6.5
			Lymphocytes	0.36	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Chloride	106	mmol/L	H	95	105
			Phosphate	2.69	mg/dL	L	2.7	4.5
			Glucose	156.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
534-004	Cycle 16	2012-04-02T07:20	Hemoglobin	13.3	g/dL	L	13.6	17.7
			Erythrocytes	4.14	10^12/L	L	4.5	6.5
			Lymphocytes	0.89	10^9/L	L	1.5	4
			Eosinophils	0.64	10^9/L	H	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	43	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	1.28	ratio	H	0.9	1.15
			Magnesium	1.75	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	473	U/L	H	153	463
			Glucose	133.3	mg/dL	H	63	99
		2012-04-06T06:50	Hemoglobin	12.7	g/dL	L	13.6	17.7
			Erythrocytes	3.95	10^12/L	L	4.5	6.5
			Lymphocytes	0.98	10^9/L	L	1.5	4
			Monocytes	0.99	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Chloride	106	mmol/L	H	95	105
	Cycle 17	2012-04-23T08:25	Erythrocytes	4.29	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.5	fL	H	80	96
			Lymphocytes	0.52	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	73	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.15

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 17	2012-04-23T08:25	Lactate Dehydrogenase	546	U/L	H	153	463
		2012-04-27T07:35	Hemoglobin	12	g/dL	L	13.6	17.7
			Erythrocytes	3.83	10^12/L	L	4.5	6.5
			Lymphocytes	0.47	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	8.9	mg/dL	L	9	11
			Chloride	107	mmol/L	H	95	105
			Blood Urea Nitrogen	28.29	mg/dL	H	5	26.9
			Glucose	127.9	mg/dL	H	63	99
	Cycle 18	2012-05-21T07:59	Hemoglobin	13.5	g/dL	L	13.6	17.7
			Erythrocytes	4.05	10^12/L	L	4.5	6.5
			Ery. Mean Corpuscular Volume	96.5	fL	H	80	96
			Lymphocytes	1.12	10^9/L	L	1.5	4
			Eosinophils	2.43	10^9/L	H	0.04	0.4
			Activated Partial Thromboplastin Time	44	sec	H	28	40
			Calcium	8.9	mg/dL	L	9	11
			Chloride	107	mmol/L	H	95	105
			Lactate Dehydrogenase	504	U/L	H	153	463
		2012-05-25T08:04	Hemoglobin	12.6	g/dL	L	13.6	17.7
			Erythrocytes	3.84	10^12/L	L	4.5	6.5
			Lymphocytes	1.08	10^9/L	L	1.5	4
			Monocytes	0.85	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 18	2012-05-25T08:04	Chloride	107	mmol/L	H	95	105
			Lactate Dehydrogenase	487	U/L	H	153	463
			Glucose	61.3	mg/dL	L	63	99
	Cycle 19	2012-06-18T07:23	Hemoglobin	13.3	g/dL	L	13.6	17.7
			Erythrocytes	4.1	10^12/L	L	4.5	6.5
			Lymphocytes	0.86	10^9/L	L	1.5	4
			Chloride	108	mmol/L	H	95	105
			Glucose	115.3	mg/dL	H	63	99
		2012-06-22T07:42	Hemoglobin	12.7	g/dL	L	13.6	17.7
			Erythrocytes	3.9	10^12/L	L	4.5	6.5
			Lymphocytes	0.96	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Chloride	106	mmol/L	H	95	105
			Glucose	111.7	mg/dL	H	63	99
	Cycle 20	2012-07-16T09:54	Lymphocytes	0.8	10^9/L	L	1.5	4
			Monocytes	0.94	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Lactate Dehydrogenase	546	U/L	H	153	463
			Glucose	122.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	Cycle 20	2012-07-20T07:51	Hemoglobin	12.5	g/dL	L	13.6	17.7
			Erythrocytes	3.9	10^12/L	L	4.5	6.5
			Lymphocytes	0.81	10^9/L	L	1.5	4
			Monocytes	0.91	10^9/L	H	0.2	0.8
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.5	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
			Lactate Dehydrogenase	470	U/L	H	153	463
			Glucose	111.7	mg/dL	H	63	99
	Cycle 21	2012-08-13T08:18	Hemoglobin	12.7	g/dL	L	13.6	17.7
			Erythrocytes	4.02	10^12/L	L	4.5	6.5
			Lymphocytes	0.43	10^9/L	L	1.5	4
			Monocytes	1.35	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.26	ratio	H	0.9	1.15
			Calcium	8.62	mg/dL	L	9	11
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	598	U/L	H	153	463
			Glucose	104.5	mg/dL	H	63	99
		2012-08-17T07:29	Hemoglobin	12	g/dL	L	13.6	17.7
			Erythrocytes	3.76	10^12/L	L	4.5	6.5
			Lymphocytes	0.44	10^9/L	L	1.5	4
			Monocytes	1.51	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Lactate Dehydrogenase	531	U/L	H	153	463
			Glucose	117.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-004	End Trial	2012-08-29T12:03	Hemoglobin	12.6	g/dL	L	13.6	17.7
			Erythrocytes	3.95	10^12/L	L	4.5	6.5
			Lymphocytes	0.45	10^9/L	L	1.5	4
			Monocytes	1.32	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	46	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	1.34	ratio	H	0.8	1.25
			Calcium	8.7	mg/dL	L	9	11
			Lactate Dehydrogenase	757	U/L	H	153	463
534-005	Pre-trial	2011-05-09T11:57	Leukocytes	10.14	10^9/L	H	4	10
			Neutrophils	7.87	10^9/L	H	2	7.5
			Lymphocytes	1.33	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	58	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.7	ratio	H	0.9	1.15
			Magnesium	1.68	mg/dL	L	1.9	2.4
			Urate	6.72	mg/dL	H	2	6.4
	Cycle 1	2011-05-16T07:01	Ery. Mean Corpuscular Volume	100.5	fL	H	80	96
			Lymphocytes	1.47	10^9/L	L	1.5	4
			Monocytes	1.06	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.9	1.15
			Calcium	8.06	mg/dL	L	9	11
			Magnesium	1.65	mg/dL	L	1.9	2.4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 1	2011-05-16T07:01	Urate	7.33	mg/dL	H	2	6.4
		2011-05-20T09:44	Ery. Mean Corpuscular Volume	97.2	fL	H	80	96
			Leukocytes	11.05	10^9/L	H	4	10
			Neutrophils	8.08	10^9/L	H	2	7.5
			Monocytes	1.41	10^9/L	H	0.2	0.8
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.78	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
		2011-05-30T12:09	Ery. Mean Corpuscular Volume	97.5	fL	H	80	96
			Neutrophils	7.56	10^9/L	H	2	7.5
			Lymphocytes	1.2	10^9/L	L	1.5	4
			Monocytes	0.88	10^9/L	H	0.2	0.8
			Magnesium	1.68	mg/dL	L	1.9	2.4
			Urate	6.67	mg/dL	H	2	6.4
	Cycle 2	2011-06-06T07:32	Ery. Mean Corpuscular Volume	99.1	fL	H	80	96
			Leukocytes	10.26	10^9/L	H	4	10
			Neutrophils	7.76	10^9/L	H	2	7.5
			Lymphocytes	1.29	10^9/L	L	1.5	4
			Monocytes	1.05	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	43	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	2.28	ratio	H	0.9	1.15
			Sodium	129	mmol/L	L	135	145
			Chloride	93	mmol/L	L	95	105
			Magnesium	1.7	mg/dL	L	1.9	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 2	2011-06-06T07:32	Urate	6.71	mg/dL	H	2	6.4
		2011-06-10T07:51	Chloride	107	mmol/L	H	95	105
	Cycle 3	2011-06-27T09:14	Hemoglobin	11	g/dL	L	12	15.5
			Erythrocytes	3.57	10^12/L	L	3.8	5.8
			Lymphocytes	0.65	10^9/L	L	1.5	4
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	969	U/L	H	153	463
			Urate	7.36	mg/dL	H	2	6.4
			Glucose	102.7	mg/dL	H	63	99
		2011-07-01T08:48	Erythrocytes	3.79	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	99.7	fL	H	80	96
			Lymphocytes	1.25	10^9/L	L	1.5	4
			Monocytes	0.84	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.5	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
	Cycle 4	2011-07-18T08:28	Ery. Mean Corpuscular Volume	101.8	fL	H	80	96
			Lymphocytes	1.42	10^9/L	L	1.5	4
			Monocytes	0.83	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	89	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	6.58	ratio	H	0.9	1.15
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	950	U/L	H	153	463
			Urate	6.56	mg/dL	H	2	6.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 4	2011-07-22T07:04	Ery. Mean Corpuscular Volume	100.8	fL	H	80	96
			Lymphocytes	1.19	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.7	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105
	Cycle 5	2011-08-08T09:49	Hemoglobin	11.2	g/dL	L	12	15.5
			Erythrocytes	3.55	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	100.8	fL	H	80	96
			Monocytes	0.98	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	84	sec	H	28	40
			Chloride	108	mmol/L	H	95	105
			Magnesium	1.8	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	623	U/L	H	153	463
		2011-08-12T06:57	Erythrocytes	3.71	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	96.8	fL	H	80	96
			Leukocytes	11.56	10^9/L	H	4	10
			Neutrophils	9.46	10^9/L	H	2	7.5
			Lymphocytes	1.49	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.5	mg/dL	L	9	11
			Blood Urea Nitrogen	27.17	mg/dL	H	5	26.9
			Glucose	118.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 6	2011-08-29T09:00	Hemoglobin	11.3	g/dL	L	12	15.5
			Erythrocytes	3.6	10^12/L	L	3.8	5.6
			Ery. Mean Corpuscular Volume	98.3	fL	H	85	97
			Activated Partial Thromboplastin Time	67	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	3.99	ratio	H	0.9	1.15
			Potassium	6.1	mmol/L	H	3.5	5.5
			Chloride	106	mmol/L	H	95	105
			Lactate Dehydrogenase	1035	U/L	H	153	463
			Urate	6.89	mg/dL	H	2	6.4
	Cycle 7	2011-09-19T09:12	Erythrocytes	3.67	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	99.2	fL	H	80	96
			Lymphocytes	1.2	10^9/L	L	1.5	4
			Monocytes	0.81	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.58	ratio	H	0.9	1.15
			Chloride	108	mmol/L	H	95	105
			Lactate Dehydrogenase	471	U/L	H	153	463
			Urate	7.53	mg/dL	H	2	6.4
		2011-09-23T06:57	Ery. Mean Corpuscular Volume	97.7	fL	H	80	96
			Lymphocytes	0.89	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	6.3	mmol/L	H	3.5	5.5
			Calcium	8.86	mg/dL	L	9	11
			Phosphate	5.11	mg/dL	H	2.7	4.5
			Lactate Dehydrogenase	846	U/L	H	153	463

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 7	2011-09-23T06:57	Glucose	126.1	mg/dL	H	63	99
	Cycle 8	2011-10-10T08:30	Erythrocytes	3.69	10^12/L	L	3.8	5.8
			Lactate Dehydrogenase	489	U/L	H	153	463
		2011-10-14T06:54	Hemoglobin	11.9	g/dL	L	12	15.5
			Erythrocytes	3.66	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	99.2	fL	H	80	96
			Lymphocytes	0.9	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Chloride	108	mmol/L	H	95	105
			Phosphate	4.61	mg/dL	H	2.7	4.5
	Cycle 9	2011-11-03T15:06	Erythrocytes	3.66	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	98.9	fL	H	80	96
			Lymphocytes	1.28	10^9/L	L	1.5	4
			Monocytes	0.84	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.54	ratio	H	0.9	1.15
			Magnesium	1.75	mg/dL	L	1.9	2.4
			Urate	6.57	mg/dL	H	2	6.4
		2011-11-07T07:48	Ery. Mean Corpuscular Volume	99.5	fL	H	80	96
			Leukocytes	12.47	10^9/L	H	4	10
			Neutrophils	8.8	10^9/L	H	2	7.5
			Monocytes	1.17	10^9/L	H	0.2	0.8
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Chloride	107	mmol/L	H	95	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 10	2011-11-21T07:30	Hemoglobin	11.7	g/dL	L	12	15.5
			Erythrocytes	3.6	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	99.7	fL	H	80	96
			Leukocytes	11.61	10^9/L	H	4	10
			Neutrophils	8.93	10^9/L	H	2	7.5
			Monocytes	0.95	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	49	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	3.6	ratio	H	0.9	1.15
			Chloride	107	mmol/L	H	95	105
			Magnesium	1.53	mg/dL	L	1.9	2.4
			Glucose	106.3	mg/dL	H	63	99
		2011-11-25T08:01	Hemoglobin	11.5	g/dL	L	12	15.5
			Erythrocytes	3.53	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	99.4	fL	H	80	96
			Leukocytes	10.32	10^9/L	H	4	10
			Neutrophils	8.24	10^9/L	H	2	7.5
			Lymphocytes	1.11	10^9/L	L	1.5	4
			Monocytes	0.95	10^9/L	H	0.2	0.8
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.7	mg/dL	L	9	11
			Chloride	106	mmol/L	H	95	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 11	2011-12-12T08:09	Ery. Mean Corpuscular Volume	98.8	fL	H	80	96
			Leukocytes	13.96	10^9/L	H	4	10
			Neutrophils	12.44	10^9/L	H	2	7.5
			Lymphocytes	0.93	10^9/L	L	1.5	4
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	96	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	High	ratio	L	0.9	1.15
			Magnesium	1.75	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	517	U/L	H	153	463
			Urate	6.51	mg/dL	H	2	6.4
		2011-12-16T06:58	Erythrocytes	3.77	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	98.1	fL	H	80	96
			Leukocytes	13.05	10^9/L	H	4	10
			Neutrophils	10.64	10^9/L	H	2	7.5
			Lymphocytes	1.49	10^9/L	L	1.5	4
			Monocytes	0.91	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.78	mg/dL	L	9	11

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
534-005	Cycle 12	2012-01-09T08:33	Erythrocytes	3.71	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	100.8	fL	H	80	96
			Lymphocytes	1.06	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.67	ratio	H	0.9	1.15
			Chloride	109	mmol/L	H	95	105
			Magnesium	1.46	mg/dL	L	1.9	2.4
			Urate	8.68	mg/dL	H	2	6.4
		2012-01-13T07:12	Hemoglobin	11.5	g/dL	L	12	15.5
			Erythrocytes	3.51	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	100.9	fL	H	80	96
			Leukocytes	13.09	10^9/L	H	4	10
			Neutrophils	10.55	10^9/L	H	2	7.5
			Monocytes	0.95	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Calcium	7.78	mg/dL	L	9	11
			Chloride	113	mmol/L	H	95	105
			Magnesium	1.65	mg/dL	L	1.9	2.4
			Albumin	3.4	g/dL	L	3.8	5
			Glucose	102.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 13	2012-02-06T08:20	Hemoglobin	11.1	g/dL	L	12	15.5
			Erythrocytes	3.45	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	98.3	fL	H	80	96
			Leukocytes	11.35	10^9/L	H	4	10
			Neutrophils	8.39	10^9/L	H	2	7.5
			Lymphocytes	1.44	10^9/L	L	1.5	4
			Monocytes	1.42	10^9/L	H	0.2	0.8
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.9	1.15
			Magnesium	1.63	mg/dL	L	1.9	2.4
			Albumin	3.7	g/dL	L	3.8	5
			Urate	6.96	mg/dL	H	2	6.4
		2012-02-10T07:21	Hemoglobin	11.2	g/dL	L	12	15.5
			Erythrocytes	3.51	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	96.3	fL	H	80	96
			Lymphocytes	1.1	10^9/L	L	1.5	4
			Monocytes	0.84	10^9/L	H	0.2	0.8
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.54	mg/dL	L	9	11
			Albumin	3.7	g/dL	L	3.8	5
	Cycle 14	2012-02-27T07:18	Hemoglobin	11.6	g/dL	L	12	15.5
			Erythrocytes	3.76	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	96.3	fL	H	80	96
			Lymphocytes	0.81	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	4.71	ratio	H	0.9	1.15
			Chloride	106	mmol/L	H	95	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 14	2012-02-27T07:18	Magnesium	1.56	mg/dL	L	1.9	2.4
			Urate	6.98	mg/dL	H	2	6.4
			Glucose	99.1	mg/dL	H	63	99
		2012-03-02T07:15	Hemoglobin	10	g/dL	L	12	15.5
			Erythrocytes	3.18	10^12/L	L	3.8	5.8
			Lymphocytes	0.9	10^9/L	L	1.5	4
			Monocytes	1.17	10^9/L	H	0.2	0.8
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.7	mg/dL	L	9	11
			Magnesium	1.87	mg/dL	L	1.9	2.4
	Cycle 15	2012-03-19T07:10	Hemoglobin	11.5	g/dL	L	12	15.5
			Platelets	475	10^9/L	H	150	400
			Lymphocytes	1.4	10^9/L	L	1.5	4
			Activated Partial Thromboplastin Time	45	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	3.16	ratio	H	0.9	1.15
			Calcium	8.82	mg/dL	L	9	11
			Magnesium	1.46	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	528	U/L	H	153	463
		2012-03-23T06:25	Hemoglobin	10.7	g/dL	L	12	15.5
			Erythrocytes	3.5	10^12/L	L	3.8	5.8
			Leukocytes	12.56	10^9/L	H	4	10
			Neutrophils	10.43	10^9/L	H	2	7.5
			Lymphocytes	1.2	10^9/L	L	1.5	4
			Monocytes	0.93	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 15	2012-03-23T06:25	Basophils	0	10^9/L	L	0.02	0.1
			Chloride	110	mmol/L	H	95	105
			Blood Urea Nitrogen	27.45	mg/dL	H	5	26.9
	Cycle 16	2012-04-09T07:50	Hemoglobin	11.3	g/dL	L	12	15.5
			Erythrocytes	3.68	10^12/L	L	3.8	5.8
			Leukocytes	12.85	10^9/L	H	4	10
			Neutrophils	10.38	10^9/L	H	2	7.5
			Lymphocytes	1.3	10^9/L	L	1.5	4
			Monocytes	1.07	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	49	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	3.13	ratio	H	0.9	1.15
			Chloride	106	mmol/L	H	95	105
			Magnesium	1.63	mg/dL	L	1.9	2.4
		2012-04-13T07:25	Hemoglobin	11.2	g/dL	L	12	15.5
			Erythrocytes	3.65	10^12/L	L	3.8	5.8
			Neutrophils	7.76	10^9/L	H	2	7.5
			Lymphocytes	1.16	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.7	mg/dL	L	9	11
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Blood Urea Nitrogen	28.01	mg/dL	H	5	26.9

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 17	2012-05-07T07:54	Lymphocytes	1.44	10^9/L	L	1.5	4
			Monocytes	1.59	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
			Prothrombin Intl. Normalized Ratio	2.1	ratio	H	0.9	1.15
			Chloride	107	mmol/L	H	95	105
			Magnesium	1.56	mg/dL	L	1.9	2.4
		2012-05-11T07:16	Leukocytes	13.41	10^9/L	H	4	10
			Neutrophils	10.34	10^9/L	H	2	7.5
			Monocytes	1.5	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.86	mg/dL	L	9	11
			Chloride	109	mmol/L	H	95	105
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Blood Urea Nitrogen	42.3	mg/dL	H	5	26.9
			Glucose	144.1	mg/dL	H	63	99
	Cycle 18	2012-06-04T07:11	Lymphocytes	1.04	10^9/L	L	1.5	4
			Activated Partial Thromboplastin Time	99	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	High	ratio	L	0.9	1.15
			Magnesium	1.65	mg/dL	L	1.9	2.4
			Creatinine	1.29	mg/dL	H	0.6	1.13
			Blood Urea Nitrogen	27.73	mg/dL	H	5	26.9
			Urate	8.15	mg/dL	H	2	6.4
			Glucose	102.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Cycle 18	2012-06-08T08:22	Hemoglobin	11.4	g/dL	L	12	15.5
			Erythrocytes	3.71	10^12/L	L	3.8	5.8
			Lymphocytes	1.35	10^9/L	L	1.5	4
			Monocytes	0.94	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Magnesium	1.56	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	474	U/L	H	153	463
			Blood Urea Nitrogen	29.13	mg/dL	H	5	26.9
	Cycle 19	2012-07-02T08:19	Hemoglobin	10.7	g/dL	L	12	15.5
			Erythrocytes	3.48	10^12/L	L	3.8	5.8
			Lymphocytes	1.18	10^9/L	L	1.5	4
			Prothrombin Intl. Normalized Ratio	1.85	ratio	H	0.9	1.15
			Magnesium	1.58	mg/dL	L	1.9	2.4
			Glucose	100.9	mg/dL	H	63	99
		2012-07-06T06:45	Hemoglobin	9.3	g/dL	L	12	15.5
			Erythrocytes	3.16	10^12/L	L	3.8	5.8
			Lymphocytes	1.01	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.42	mg/dL	L	9	11
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Albumin	3.6	g/dL	L	3.8	5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-005	Unplanned	2011-12-16T06:58	Prothrombin Intl. Normalized Ratio	1.32	ratio	H	0.9	1.15
		2012-04-23T08:21	Hemoglobin	9.7	g/dL	L	12	15.5
			Erythrocytes	3.19	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	97.8	fL	H	80	96
			Lymphocytes	1.22	10^9/L	L	1.5	4
			Monocytes	0.82	10^9/L	H	0.2	0.8
			Basophils	0.01	10^9/L	L	0.02	0.1
		2012-04-26T07:26	Lymphocytes	1.07	10^9/L	L	1.5	4
			Monocytes	0.88	10^9/L	H	0.2	0.8
	End Trial	2012-07-30T11:00	Ery. Mean Corpuscular Volume	96.3	fL	H	80	96
			Lymphocytes	0.97	10^9/L	L	1.5	4
			Monocytes	0.92	10^9/L	H	0.2	0.8
			Activated Partial Thromboplastin Time	49	sec	H	28	40
			Prothrombin Intl. Normalized Ratio	3.04	ratio	H	0.9	1.15
			Chloride	108	mmol/L	H	95	105
			Phosphate	4.86	mg/dL	H	2.7	4.5
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Creatinine	0.588	mg/dL	L	0.6	1.13
534-006	Pre-trial	2011-07-27T09:04	Calcium	8.94	mg/dL	L	9	11
			Lactate Dehydrogenase	556	U/L	H	153	463
			Bilirubin	1.24	mg/dL	H	0.09	0.99
			Urate	6.86	mg/dL	H	2	6.4
			Glucose	138.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Pre-trial	2011-07-27T10:40	Hemoglobin	10.4	g/dL	L	12	15.5
			Erythrocytes	3.45	10^12/L	L	3.8	5.8
			Lymphocytes	1.12	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	25	sec	L	28	40
	Cycle 1	2011-08-22T10:00	Hemoglobin	3.7	g/dL	L	12	15.5
			Erythrocytes	1.1	10^12/L	L	3.8	5.6
			Ery. Mean Corpuscular Volume	100.9	fL	H	85	97
			Platelets	79	10^9/L	L	130	500
			Leukocytes	3.83	10^9/L	L	4	10
			Lymphocytes	0.79	10^9/L	L	1	3.7
			Magnesium	3.09	mg/dL	H	1.9	2.4
			Lactate Dehydrogenase	821	U/L	H	153	463
			Bilirubin	3.018	mg/dL	H	0.09	0.99
			Urate	9.68	mg/dL	H	2	6.4
			Glucose	106.3	mg/dL	H	63	99
		2011-08-26T08:08	Hemoglobin	6.5	g/dL	L	12	15.5
			Erythrocytes	2.18	10^12/L	L	3.8	5.8
			Platelets	67	10^9/L	L	150	400
			Lymphocytes	0.62	10^9/L	L	1.5	4
			Monocytes	0.19	10^9/L	L	0.2	0.8
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.1	mg/dL	L	9	11
			Magnesium	2.46	mg/dL	H	1.9	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 1	2011-08-26T08:08	Lactate Dehydrogenase	610	U/L	H	153	463
			Bilirubin	3.029	mg/dL	H	0.09	0.99
			Glucose	187.4	mg/dL	H	63	99
		2011-09-02T08:06	Hemoglobin	10.1	g/dL	L	12	15.5
			Erythrocytes	3.33	10^12/L	L	3.8	5.8
			Platelets	129	10^9/L	L	150	400
			Lymphocytes	1.2	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Bilirubin	2.304	mg/dL	H	0.09	0.99
	Cycle 2	2011-09-12T10:00	Hemoglobin	9.4	g/dL	L	12	15.5
			Erythrocytes	2.92	10^12/L	L	3.8	5.8
			Platelets	108	10^9/L	L	150	400
			Lymphocytes	0.73	10^9/L	L	1.5	4
			Monocytes	0.03	10^9/L	L	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	25	sec	L	28	40
			Calcium	8.82	mg/dL	L	9	11
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	509	U/L	H	153	463
			Bilirubin	1.234	mg/dL	H	0.09	0.99
			Blood Urea Nitrogen	33.33	mg/dL	H	5	26.9
			Glucose	254	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 2	2011-09-16T06:51	Hemoglobin	9.2	g/dL	L	12	15.5
			Erythrocytes	2.81	10^12/L	L	3.8	5.8
			Platelets	79	10^9/L	L	150	400
			Lymphocytes	0.94	10^9/L	L	1.5	4
			Monocytes	0.17	10^9/L	L	0.2	0.8
			Basophils	0	10^9/L	L	0.02	0.1
			Calcium	8.78	mg/dL	L	9	11
			Bilirubin	1.713	mg/dL	H	0.09	0.99
			Glucose	126.1	mg/dL	H	63	99
	Cycle 3	2011-10-03T09:31	Hemoglobin	10.2	g/dL	L	12	15.5
			Erythrocytes	3.32	10^12/L	L	3.8	5.6
			Ery. Mean Corpuscular Volume	97.6	fL	H	85	97
			Platelets	112	10^9/L	L	130	500
			Leukocytes	3.79	10^9/L	L	4	10
			Lymphocytes	0.67	10^9/L	L	1	3.7
		2011-10-03T11:12	Activated Partial Thromboplastin Time	25	sec	L	28	40
			Magnesium	1.7	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	579	U/L	H	153	463
			Glucose	281	mg/dL	H	63	99
		2011-10-07T07:12	Hemoglobin	10.3	g/dL	L	12	15.5
			Erythrocytes	3.21	10^12/L	L	3.8	5.8
			Platelets	93	10^9/L	L	150	400
			Leukocytes	3.25	10^9/L	L	4	10
			Lymphocytes	0.98	10^9/L	L	1.5	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
534-006	Cycle 3	2011-10-07T07:12	Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.3	mmol/L	L	3.5	5.5
			Calcium	8.82	mg/dL	L	9	11
			Phosphate	4.86	mg/dL	H	2.7	4.5
			Bilirubin	1.082	mg/dL	H	0.09	0.99
			Glucose	106.3	mg/dL	H	63	99
	Cycle 4	2011-10-24T09:13	Hemoglobin	11.3	g/dL	L	12	15.5
			Erythrocytes	3.62	10^12/L	L	3.8	5.6
		2011-10-24T11:38	Activated Partial Thromboplastin Time	25	sec	L	28	40
			Lactate Dehydrogenase	548	U/L	H	153	463
			Glucose	115.3	mg/dL	H	63	99
		2011-10-28T07:15	Hemoglobin	10.7	g/dL	L	12	15.5
			Erythrocytes	3.37	10^12/L	L	3.8	5.8
			Platelets	102	10^9/L	L	150	400
			Lymphocytes	1.09	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Sodium	147	mmol/L	H	135	145
			Bilirubin	1.053	mg/dL	H	0.09	0.99
			Glucose	136.9	mg/dL	H	63	99
	Cycle 5	2011-11-14T08:12	Hemoglobin	11.2	g/dL	L	12	15.5
			Erythrocytes	3.5	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	98.3	fL	H	80	96
			Platelets	101	10^9/L	L	150	400
			Lymphocytes	0.87	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 5	2011-11-14T08:12	Activated Partial Thromboplastin Time	26	sec	L	28	40
			Lactate Dehydrogenase	629	U/L	H	153	463
			Urate	6.47	mg/dL	H	2	6.4
			Glucose	117.1	mg/dL	H	63	99
		2011-11-18T07:57	Hemoglobin	10.4	g/dL	L	12	15.5
			Erythrocytes	3.36	10^12/L	L	3.8	5.8
			Platelets	85	10^9/L	L	150	400
			Leukocytes	3.08	10^9/L	L	4	10
			Neutrophils	1.86	10^9/L	L	2	7.5
			Lymphocytes	0.06	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Magnesium	1.87	mg/dL	L	1.9	2.4
			Lactate Dehydrogenase	582	U/L	H	153	463
			Glucose	102.7	mg/dL	H	63	99
	Cycle 6	2011-12-05T09:23	Leukocytes	3.27	10^9/L	L	4	10
			Neutrophils	1.8	10^9/L	L	2	7.5
			Lymphocytes	1.22	10^9/L	L	1.5	4
			Monocytes	0.13	10^9/L	L	0.2	0.8
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Albumin	5.2	g/dL	H	3.8	5
			Glucose	102.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 6	2011-12-09T08:30	Hemoglobin	11.2	g/dL	L	12	15.5
			Erythrocytes	3.55	10^12/L	L	3.8	5.8
			Platelets	101	10^9/L	L	150	400
			Leukocytes	3.67	10^9/L	L	4	10
			Neutrophils	1.72	10^9/L	L	2	7.5
			Eosinophils	0.01	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.86	mg/dL	L	9	11
			Glucose	187.4	mg/dL	H	63	99
	Cycle 7	2012-01-02T08:30	Platelets	123	10^9/L	L	150	400
			Lymphocytes	1.35	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	27	sec	L	28	40
			Magnesium	2.63	mg/dL	H	1.9	2.4
			Albumin	5.2	g/dL	H	3.8	5
			Urate	7.53	mg/dL	H	2	6.4
			Glucose	117.1	mg/dL	H	63	99
		2012-01-06T08:14	Hemoglobin	11.3	g/dL	L	12	15.5
			Erythrocytes	3.71	10^12/L	L	3.8	5.8
			Platelets	103	10^9/L	L	150	400
			Leukocytes	3.28	10^9/L	L	4	10
			Neutrophils	1.84	10^9/L	L	2	7.5
			Lymphocytes	1.13	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 7	2012-01-06T08:14	Lactate Dehydrogenase	484	U/L	H	153	463
			Glucose	156.7	mg/dL	H	63	99
	Cycle 8	2012-01-23T07:34	Platelets	116	10^9/L	L	150	400
			Leukocytes	3.66	10^9/L	L	4	10
			Lymphocytes	1.32	10^9/L	L	1.5	4
			Monocytes	0.13	10^9/L	L	0.2	0.8
			Chloride	107	mmol/L	H	95	105
			Lactate Dehydrogenase	665	U/L	H	153	463
			Urate	7.18	mg/dL	H	2	6.4
			Glucose	117.1	mg/dL	H	63	99
		2012-01-27T07:41	Hemoglobin	11.5	g/dL	L	12	15.5
			Erythrocytes	3.77	10^12/L	L	3.8	5.8
			Platelets	108	10^9/L	L	150	400
			Lymphocytes	1.33	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Calcium	8.98	mg/dL	L	9	11
			Glucose	127.9	mg/dL	H	63	99
	Cycle 9	2012-02-13T08:33	Platelets	142	10^9/L	L	150	400
			Leukocytes	3.38	10^9/L	L	4	10
			Lymphocytes	0.86	10^9/L	L	1.5	4
			Monocytes	0.11	10^9/L	L	0.2	0.8
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Urate	6.88	mg/dL	H	2	6.4
			Glucose	109.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 9	2012-02-17T07:24	Hemoglobin	11	g/dL	L	12	15.5
			Erythrocytes	3.73	10^12/L	L	3.8	5.8
			Platelets	129	10^9/L	L	150	400
			Lymphocytes	0.87	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.2	mmol/L	L	3.5	5.5
			Albumin	5.3	g/dL	H	3.8	5
			Glucose	174.7	mg/dL	H	63	99
	Cycle 10	2012-03-05T08:47	Albumin	5.1	g/dL	H	3.8	5
			Urate	6.76	mg/dL	H	2	6.4
			Glucose	108.1	mg/dL	H	63	99
		2012-03-05T09:47	Platelets	140	10^9/L	L	150	400
			Lymphocytes	1.32	10^9/L	L	1.5	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
		2012-03-09T06:10	Hemoglobin	11.8	g/dL	L	12	15.5
			Platelets	137	10^9/L	L	150	400
			Lymphocytes	1.28	10^9/L	L	1.5	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Glucose	153.1	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 11	2012-03-26T08:30	Hemoglobin	11.5	g/dL	L	12	15.5
			Erythrocytes	3.79	10^12/L	L	3.8	5.8
			Platelets	122	10^9/L	L	150	400
			Lymphocytes	1.19	10^9/L	L	1.5	4
			Eosinophils	0.02	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Magnesium	1.73	mg/dL	L	1.9	2.4
			Urate	7.7	mg/dL	H	2	6.4
			Glucose	108.1	mg/dL	H	63	99
		2012-03-30T06:40	Hemoglobin	11.4	g/dL	L	12	15.5
			Erythrocytes	3.7	10^12/L	L	3.8	5.8
			Platelets	108	10^9/L	L	150	400
			Lymphocytes	1.37	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Phosphate	4.58	mg/dL	H	2.7	4.5
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Urate	6.61	mg/dL	H	2	6.4
			Glucose	127.9	mg/dL	H	63	99
	Cycle 12	2012-04-16T08:48	Activated Partial Thromboplastin Time	25	sec	L	28	40
			Magnesium	1.85	mg/dL	L	1.9	2.4
			Urate	6.59	mg/dL	H	2	6.4
			Glucose	127.9	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 12	2012-04-16T09:26	Hemoglobin	11.5	g/dL	L	12	15.5
			Leukocytes	3.77	10^9/L	L	4	10
		2012-04-20T08:20	Hemoglobin	11.1	g/dL	L	12	15.5
			Erythrocytes	3.61	10^12/L	L	3.8	5.8
			Platelets	110	10^9/L	L	150	400
			Lymphocytes	1.21	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Magnesium	1.82	mg/dL	L	1.9	2.4
			Glucose	106.3	mg/dL	H	63	99
	Cycle 13	2012-05-07T09:51	Lymphocytes	0.98	10^9/L	L	1.5	4
			Monocytes	0.13	10^9/L	L	0.2	0.8
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Albumin	5.9	g/dL	H	3.8	5
			Urate	7.31	mg/dL	H	2	6.4
			Glucose	142.3	mg/dL	H	63	99
		2012-05-11T08:18	Hemoglobin	11.6	g/dL	L	12	15.5
			Erythrocytes	3.74	10^12/L	L	3.8	5.8
			Platelets	123	10^9/L	L	150	400
			Lymphocytes	1.32	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Glucose	102.7	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 14	2012-05-28T09:28	Platelets	118	10^9/L	L	150	400
			Lymphocytes	1.41	10^9/L	L	1.5	4
			Activated Partial Thromboplastin Time	27	sec	L	28	40
			Urate	6.78	mg/dL	H	2	6.4
			Glucose	133.3	mg/dL	H	63	99
		2012-06-01T09:05	Hemoglobin	11.4	g/dL	L	12	15.5
			Erythrocytes	3.66	10^12/L	L	3.8	5.8
			Platelets	108	10^9/L	L	150	400
			Lymphocytes	1.32	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.4	mmol/L	L	3.5	5.5
			Glucose	118.9	mg/dL	H	63	99
	Cycle 15	2012-06-18T12:22	Platelets	130	10^9/L	L	150	400
			Lymphocytes	1.26	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	25	sec	L	28	40
			Chloride	107	mmol/L	H	95	105
			Urate	8.1	mg/dL	H	2	6.4
			Glucose	142.3	mg/dL	H	63	99
		2012-06-22T10:41	Hemoglobin	11.6	g/dL	L	12	15.5
			Platelets	112	10^9/L	L	150	400
			Lymphocytes	1.1	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 15	2012-06-22T10:41	Potassium	3	mmol/L	L	3.5	5.5
			Alanine Aminotransferase	71	U/L	H	8	55
			Bilirubin	1.018	mg/dL	H	0.09	0.99
			Urate	7.85	mg/dL	H	2	6.4
			Glucose	129.7	mg/dL	H	63	99
	Cycle 16	2012-07-09T11:17	Lymphocytes	1.22	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Potassium	3.3	mmol/L	L	3.5	5.5
			Albumin	5.2	g/dL	H	3.8	5
			Urate	8.12	mg/dL	H	2	6.4
			Glucose	115.3	mg/dL	H	63	99
		2012-07-13T08:30	Platelets	94	10^9/L	L	150	400
			Leukocytes	3.66	10^9/L	L	4	10
			Lymphocytes	0.72	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Potassium	3.1	mmol/L	L	3.5	5.5
			Albumin	5.1	g/dL	H	3.8	5
			Alanine Aminotransferase	77	U/L	H	8	55
			Bilirubin	1.094	mg/dL	H	0.09	0.99
			Urate	6.51	mg/dL	H	2	6.4
			Glucose	140.5	mg/dL	H	63	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
534-006	Cycle 17	2012-07-30T11:00	Hemoglobin	10.7	g/dL	L	12	15.5
			Erythrocytes	3.4	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	96.3	fL	H	80	96
			Platelets	117	10^9/L	L	150	400
			Leukocytes	3.71	10^9/L	L	4	10
			Neutrophils	1.85	10^9/L	L	2	7.5
			Lymphocytes	1.03	10^9/L	L	1.5	4
			Calcium	8.78	mg/dL	L	9	11
			Chloride	107	mmol/L	H	95	105
			Bilirubin	1.07	mg/dL	H	0.09	0.99
		2012-08-03T08:29	Platelets	145	10^9/L	L	150	400
			Lymphocytes	0.94	10^9/L	L	1.5	4
			Phosphate	5.05	mg/dL	H	2.7	4.5
			Albumin	5.1	g/dL	H	3.8	5
			Alanine Aminotransferase	142	U/L	H	8	55
			Urate	7.36	mg/dL	H	2	6.4
			Glucose	154.9	mg/dL	H	63	99
	Cycle 18	2012-08-20T11:06	Hemoglobin	11.9	g/dL	L	12	15.5
			Erythrocytes	3.78	10^12/L	L	3.8	5.8
			Platelets	117	10^9/L	L	150	400
			Lymphocytes	1.29	10^9/L	L	1.5	4
			Eosinophils	0.03	10^9/L	L	0.04	0.4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	26	sec	L	28	40
			Sodium	134	mmol/L	L	135	145

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
534-006	Cycle 18	2012-08-20T11:06	Potassium	3.4	mmol/L	L	3.5	5.5
			Magnesium	1.8	mg/dL	L	1.9	2.4
			Alanine Aminotransferase	69	U/L	H	8	55
			Urate	7.68	mg/dL	H	2	6.4
			Glucose	259.4	mg/dL	H	63	99
		2012-08-24T08:27	Hemoglobin	10.5	g/dL	L	12	15.5
			Erythrocytes	3.28	10^12/L	L	3.8	5.8
			Platelets	94	10^9/L	L	150	400
			Lymphocytes	0.99	10^9/L	L	1.5	4
			Basophils	0.01	10^9/L	L	0.02	0.1
			Alanine Aminotransferase	128	U/L	H	8	55
			Glucose	120.7	mg/dL	H	63	99
	Unplanned	2011-08-23T12:38	Hemoglobin	5.1	g/dL	L	12	15.5
			Erythrocytes	1.41	10^12/L	L	3.8	5.8
			Ery. Mean Corpuscular Volume	102.1	fL	H	80	96
			Platelets	78	10^9/L	L	150	400
			Lymphocytes	0.98	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
		2011-08-29T07:23	Hemoglobin	9.1	g/dL	L	12	15.5
			Erythrocytes	3.03	10^12/L	L	3.8	5.8
			Platelets	84	10^9/L	L	150	400
			Lymphocytes	1.07	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Pre-trial	2010-09-28T13:56	Erythrocytes	3.7	10^12/L	L	3.86	5.08
			Neutrophils	6.93	10^9/L	H	2.06	6.49
			Lymphocytes	0.54	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	21.3	sec	L	24	33
			Magnesium	2.97	mg/dL	H	1.6	2.6
			Albumin	3.37	g/dL	L	3.5	5.2
			Aspartate Aminotransferase	35	U/L	H	8	30
			Lactate Dehydrogenase	314	U/L	H	0	239.99
			Glucose	117.1	mg/dL	H	79	115
	Cycle 1	2010-10-04T10:50	Erythrocytes	3.85	10^12/L	L	3.86	5.08
			Lymphocytes	0.61	10^9/L	L	1.19	3.35
		2010-10-04T10:51	Albumin	3.33	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	367	U/L	H	0	239.99
			Glucose	66.7	mg/dL	L	79	115
		2010-10-08T09:18	Hemoglobin	9.8	g/dL	L	11.9	15.7
			Erythrocytes	3.32	10^12/L	L	3.86	5.08
			Platelets	134	10^9/L	L	150	424
			Neutrophils	7	10^9/L	H	2.06	6.49
			Lymphocytes	0.56	10^9/L	L	1.19	3.35
			Potassium	3.4	mmol/L	L	3.9	5.1
			Albumin	2.77	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	262	U/L	H	0	239.99
			Glucose	120.7	mg/dL	H	79	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 1	2010-10-18T20:19	Hemoglobin	11	g/dL	L	11.9	15.7
			Erythrocytes	3.61	10^12/L	L	3.86	5.08
			Leukocytes	11.59	10^9/L	H	3.4	9.7
			Neutrophils	9.89	10^9/L	H	2.06	6.49
			Lymphocytes	0.76	10^9/L	L	1.19	3.35
			Monocytes	0.85	10^9/L	H	0.12	0.84
			Potassium	3.7	mmol/L	L	3.9	5.1
			Creatinine	1.403	mg/dL	H	0.71	1.21
			Albumin	3.18	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	284	U/L	H	0	239.99
			Glucose	117.1	mg/dL	H	79	115
	Cycle 2	2010-10-25T10:33	Hemoglobin	10.3	g/dL	L	11.9	15.7
			Erythrocytes	3.14	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.6	fL	H	83	97.2
			Lymphocytes	0.51	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	22.7	sec	L	24	33
			Potassium	3.8	mmol/L	L	3.9	5.1
			Albumin	3.21	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	241	U/L	H	0	239.99
		2010-10-29T11:54	Potassium	3.2	mmol/L	L	3.9	5.1
			Calcium	8.46	mg/dL	L	8.6	10.1
			Albumin	2.65	g/dL	L	3.5	5.2
			Alanine Aminotransferase	9	U/L	L	10	36
			Lactate Dehydrogenase	281	U/L	H	0	239.99
			Bilirubin	1.228	mg/dL	H	0.18	1.17

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 2	2010-10-29T11:55	Hemoglobin	9.6	g/dL	L	11.9	15.7
			Erythrocytes	2.97	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.5	fL	H	83	97.2
			Platelets	119	10^9/L	L	150	424
			Lymphocytes	0.37	10^9/L	L	1.19	3.35
	Cycle 3	2010-11-14T08:21	Hemoglobin	10.8	g/dL	L	11.9	15.7
			Erythrocytes	3.32	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	103.9	fL	H	83	97.2
			Lymphocytes	0.65	10^9/L	L	1.19	3.35
			Chloride	109	mmol/L	H	97	108
			Albumin	3.19	g/dL	L	3.5	5.2
			Alkaline Phosphatase	47	U/L	L	64	153
		2010-11-19T11:04	Hemoglobin	11	g/dL	L	11.9	15.7
			Erythrocytes	3.21	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	104	fL	H	83	97.2
			Lymphocytes	0.32	10^9/L	L	1.19	3.35
			Calcium	8.54	mg/dL	L	8.6	10.1
			Chloride	110	mmol/L	H	97	108
			Albumin	3.37	g/dL	L	3.5	5.2
			Alkaline Phosphatase	59	U/L	L	64	153
	Cycle 4	2010-12-05T16:34	Hemoglobin	10.2	g/dL	L	11.9	15.7
			Erythrocytes	3.12	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	102.6	fL	H	83	97.2
			Lymphocytes	0.42	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Albumin	3.21	g/dL	L	3.5	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 4	2010-12-05T16:34	Alkaline Phosphatase	51	U/L	L	64	153
			Lactate Dehydrogenase	265	U/L	H	0	239.99
		2010-12-06T11:23	Prothrombin Intl. Normalized Ratio	1.32	ratio	H	0.8	1.25
		2010-12-10T08:59	Hemoglobin	11.8	g/dL	L	11.9	15.7
			Erythrocytes	3.39	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	105.1	fL	H	83	97.2
			Lymphocytes	0.5	10^9/L	L	1.19	3.35
			Lactate Dehydrogenase	261	U/L	H	0	239.99
	Cycle 5	2010-12-28T08:28	Hemoglobin	10.6	g/dL	L	11.9	15.7
			Erythrocytes	3.21	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	102.2	fL	H	83	97.2
			Lymphocytes	0.352	10^9/L	L	1	4
		2010-12-28T13:29	Prothrombin Time	4.6	sec	L	11	13
			Activated Partial Thromboplastin Time	150	sec	H	24	33
			Potassium	3.5	mmol/L	L	3.9	5.1
			Lactate Dehydrogenase	248	U/L	H	0	239.99
			Glucose	174.7	mg/dL	H	79	115
		2011-01-02T08:28	Hemoglobin	10.6	g/dL	L	11.9	15.7
			Erythrocytes	3.21	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	102.2	fL	H	83	97.2
			Lymphocytes	0.352	10^9/L	L	1	4
			Potassium	3.7	mmol/L	L	3.9	5.1
			Calcium	8.54	mg/dL	L	8.6	10.1
			Alkaline Phosphatase	59	U/L	L	64	153
			Glucose	122.5	mg/dL	H	79	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 6	2011-01-16T16:03	Hemoglobin	11.2	g/dL	L	11.9	15.7
			Erythrocytes	3.53	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	100.6	fL	H	83	97.2
			Lymphocytes	0.81	10^9/L	L	1.19	3.35
			Prothrombin Intl. Normalized Ratio	1.84	ratio	H	0.8	1.25
			Albumin	3.38	g/dL	L	3.5	5.2
			Glucose	61.3	mg/dL	L	79	115
		2011-01-20T09:50	Hemoglobin	10.4	g/dL	L	11.9	15.7
			Erythrocytes	3.09	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	101.8	fL	H	83	97.2
			Lymphocytes	0.52	10^9/L	L	1.19	3.35
			Potassium	3.8	mmol/L	L	3.9	5.1
			Chloride	109	mmol/L	H	97	108
			Albumin	3.18	g/dL	L	3.5	5.2
	Cycle 7	2011-02-06T18:03	Hemoglobin	9.8	g/dL	L	11.9	15.7
			Erythrocytes	3.06	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	100.7	fL	H	83	97.2
			Lymphocytes	0.771	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.9	5.1
			Albumin	3.4	g/dL	L	3.5	5.2
			Alkaline Phosphatase	53	U/L	L	64	153
		2011-02-10T11:55	Erythrocytes	3.63	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	104.8	fL	H	83	97.2
			Lymphocytes	0.511	10^9/L	L	1	4
			Albumin	3.4	g/dL	L	3.5	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 8	2011-02-28T11:01	Hemoglobin	10.8	g/dL	L	11.9	15.7
			Erythrocytes	3.12	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	103	fL	H	83	97.2
			Lymphocytes	0.26	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	38.1	sec	H	24	33
			Potassium	3.7	mmol/L	L	3.9	5.1
			Chloride	109	mmol/L	H	97	108
			Albumin	3.19	g/dL	L	3.5	5.2
			Alkaline Phosphatase	53	U/L	L	64	153
			Glucose	70.3	mg/dL	L	79	115
		2011-03-04T11:13	Erythrocytes	3.65	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	101.7	fL	H	83	97.2
			Lymphocytes	0.69	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Lactate Dehydrogenase	250	U/L	H	0	239.99
	Cycle 9	2011-03-20T11:34	Ery. Mean Corpuscular Volume	102.5	fL	H	83	97.2
			Lymphocytes	0.52	10^9/L	L	1.19	3.35
			Calcium	4.65	mg/dL	L	8.6	10.1
			Lactate Dehydrogenase	270	U/L	H	0	239.99
		2011-03-20T15:27	Activated Partial Thromboplastin Time	22.6	sec	L	24	33

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 9	2011-03-25T10:17	Hemoglobin	11.7	g/dL	L	11.9	15.7
			Erythrocytes	3.5	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	101.8	fL	H	83	97.2
			Lymphocytes	0.4	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
	Cycle 10	2011-04-10T13:39	Hemoglobin	11	g/dL	L	11.9	15.7
			Erythrocytes	3.43	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.7	fL	H	83	97.2
			Lymphocytes	0.78	10^9/L	L	1.19	3.35
			Potassium	3.8	mmol/L	L	3.9	5.1
			Alkaline Phosphatase	53	U/L	L	64	153
			Blood Urea Nitrogen	23.25	mg/dL	H	7.8	23.2
			Glucose	55.8	mg/dL	L	79	115
		2011-04-11T11:03	Activated Partial Thromboplastin Time	21.1	sec	L	24	33
		2011-04-15T10:16	Erythrocytes	3.62	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	103.2	fL	H	83	97.2
			Lymphocytes	0.4	10^9/L	L	1.19	3.35
			Potassium	3.6	mmol/L	L	3.9	5.1
			Alkaline Phosphatase	62	U/L	L	64	153

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 11	2011-05-01T11:41	Hemoglobin	10.8	g/dL	L	11.9	15.7
			Erythrocytes	3.32	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	100.6	fL	H	83	97.2
			Neutrophils	7.2	10^9/L	H	2.06	6.49
			Lymphocytes	0.44	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	23.3	sec	L	24	33
			Potassium	3.4	mmol/L	L	3.9	5.1
			Calcium	7.86	mg/dL	L	8.6	10.1
			Chloride	109	mmol/L	H	97	108
			Albumin	3.36	g/dL	L	3.5	5.2
			Alkaline Phosphatase	55	U/L	L	64	153
			Lactate Dehydrogenase	242	U/L	H	0	239.99
			Glucose	138.7	mg/dL	H	79	115
		2011-05-06T11:29	Erythrocytes	3.48	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	102.2	fL	H	83	97.2
			Platelets	148	10^9/L	L	150	424
			Lymphocytes	0.29	10^9/L	L	1.19	3.35
			Alkaline Phosphatase	60	U/L	L	64	153
			Lactate Dehydrogenase	291	U/L	H	0	239.99
			Glucose	129.7	mg/dL	H	79	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 12	2011-05-23T09:44	Erythrocytes	3.55	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	103.8	fL	H	83	97.2
			Lymphocytes	0.57	10^9/L	L	1.19	3.35
			Alkaline Phosphatase	55	U/L	L	64	153
			Glucose	72.1	mg/dL	L	79	115
		2011-05-27T07:31	Hemoglobin	10	g/dL	L	11.9	15.7
			Erythrocytes	3.13	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.4	fL	H	83	97.2
			Platelets	124	10^9/L	L	150	424
			Lymphocytes	0.349	10^9/L	L	1	4
			Potassium	3.3	mmol/L	L	3.9	5.1
			Calcium	8.22	mg/dL	L	8.6	10.1
			Alkaline Phosphatase	54	U/L	L	64	153
			Glucose	115.3	mg/dL	H	79	115
	Cycle 13	2011-06-13T09:37	Hemoglobin	10.9	g/dL	L	11.9	15.7
			Erythrocytes	3.39	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	100.3	fL	H	83	97.2
			Lymphocytes	0.54	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Alkaline Phosphatase	57	U/L	L	64	153
			Glucose	122.5	mg/dL	H	79	115
		2011-06-17T07:18	Hemoglobin	9.5	g/dL	L	11.9	15.7
			Erythrocytes	2.92	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.7	fL	H	83	97.2
			Platelets	131	10^9/L	L	150	424
			Lymphocytes	0.449	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 13	2011-06-17T07:18	Potassium	3.3	mmol/L	L	3.9	5.1
			Calcium	4.61	mg/dL	L	8.6	10.1
			Chloride	109	mmol/L	H	97	108
			Albumin	3.32	g/dL	L	3.5	5.2
			Alkaline Phosphatase	56	U/L	L	64	153
	Cycle 14	2011-07-04T10:57	Erythrocytes	3.6	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	104.2	fL	H	83	97.2
			Lymphocytes	0.52	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	23.1	sec	L	24	33
			Glucose	72.1	mg/dL	L	79	115
		2011-07-08T10:50	Erythrocytes	3.64	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	102.9	fL	H	83	97.2
			Lymphocytes	0.51	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
	Cycle 15	2011-07-25T10:52	Erythrocytes	3.5	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	103	fL	H	83	97.2
			Lymphocytes	0.63	10^9/L	L	1.19	3.35
			Prothrombin Time	13.2	sec	H	11	13
			Activated Partial Thromboplastin Time	23.5	sec	L	24	33
			Glucose	73.9	mg/dL	L	79	115

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 15	2011-07-29T20:29	Hemoglobin	11.1	g/dL	L	11.9	15.7
			Erythrocytes	3.45	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.4	fL	H	83	97.2
			Platelets	141	10^9/L	L	150	424
			Lymphocytes	0.611	10^9/L	L	1	4
			Potassium	3.2	mmol/L	L	3.9	5.1
			Alkaline Phosphatase	63	U/L	L	64	153
	Cycle 16	2011-08-14T13:35	Hemoglobin	9.8	g/dL	L	11.9	15.7
			Erythrocytes	3.08	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.7	fL	H	83	97.2
			Lymphocytes	0.519	10^9/L	L	1	4
			Potassium	3.7	mmol/L	L	3.9	5.1
			Chloride	110	mmol/L	H	97	108
			Alkaline Phosphatase	53	U/L	L	64	153
			Glucose	72.1	mg/dL	L	79	115
		2011-08-19T11:31	Hemoglobin	9.8	g/dL	L	11.9	15.7
			Erythrocytes	3.02	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.1	fL	H	83	97.2
			Platelets	144	10^9/L	L	150	424
			Lymphocytes	0.2	10^9/L	L	1.19	3.35
			Potassium	3.2	mmol/L	L	3.9	5.1
			Calcium	8.1	mg/dL	L	8.6	10.1
			Albumin	3.07	g/dL	L	3.5	5.2
			Alkaline Phosphatase	59	U/L	L	64	153
			Glucose	129.7	mg/dL	H	79	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 17	2011-09-04T15:54	Hemoglobin	10	g/dL	L	11.9	15.7
			Erythrocytes	3.16	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.1	fL	H	83	97.2
			Lymphocytes	0.609	10^9/L	L	1	4
			Prothrombin Time	9.7	sec	L	11	13
			Potassium	3.8	mmol/L	L	3.9	5.1
			Albumin	3.07	g/dL	L	3.5	5.2
			Alkaline Phosphatase	58	U/L	L	64	153
		2011-09-09T10:51	Hemoglobin	10.9	g/dL	L	11.9	15.7
			Erythrocytes	3.39	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.6	fL	H	83	97.2
			Lymphocytes	0.76	10^9/L	L	1.19	3.35
			Potassium	3.6	mmol/L	L	3.9	5.1
			Calcium	8.58	mg/dL	L	8.6	10.1
	Cycle 18	2011-09-26T13:47	Hemoglobin	10.7	g/dL	L	11.9	15.7
			Erythrocytes	3.4	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.2	fL	H	83	97.2
			Lymphocytes	0.359	10^9/L	L	1	4
			Prothrombin Time	10.5	sec	L	11	13
			Albumin	3.3	g/dL	L	3.5	5.2
			Glucose	124.3	mg/dL	H	79	115
		2011-09-30T09:47	Hemoglobin	11.4	g/dL	L	11.9	15.7
			Erythrocytes	3.52	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.8	fL	H	83	97.2
			Lymphocytes	0.632	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 19	2011-10-17T12:02	Hemoglobin	10.7	g/dL	L	11.9	15.7
			Erythrocytes	3.3	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.3	fL	H	83	97.2
			Leukocytes	3.1	10^9/L	L	3.4	9.7
			Lymphocytes	0.31	10^9/L	L	1	4
		2011-10-21T08:33	Hemoglobin	10.4	g/dL	L	11.9	15.7
			Erythrocytes	3.23	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.4	fL	H	83	97.2
			Lymphocytes	0.612	10^9/L	L	1	4
			Calcium	8.42	mg/dL	L	8.6	10.1
			Albumin	3.22	g/dL	L	3.5	5.2
	Cycle 20	2011-11-07T11:26	Hemoglobin	10.4	g/dL	L	11.9	15.7
			Erythrocytes	3.26	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.4	fL	H	83	97.2
			Leukocytes	2.7	10^9/L	L	3.4	9.7
			Neutrophils	1.998	10^9/L	L	2	7.5
			Lymphocytes	0.297	10^9/L	L	1	4
			Potassium	3.6	mmol/L	L	3.9	5.1
			Chloride	109	mmol/L	H	97	108
			Albumin	3.25	g/dL	L	3.5	5.2
			Glucose	151.3	mg/dL	H	79	115
		2011-11-11T10:06	Hemoglobin	11.2	g/dL	L	11.9	15.7
			Erythrocytes	3.52	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98	fL	H	83	97.2
			Lymphocytes	0.816	10^9/L	L	1	4
			Potassium	3.8	mmol/L	L	3.9	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 20	2011-11-11T10:06	Albumin	3.4	g/dL	L	3.5	5.2
	Cycle 21	2011-11-27T13:23	Hemoglobin	10.8	g/dL	L	11.9	15.7
			Erythrocytes	3.49	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.4	fL	H	83	97.2
			Lymphocytes	0.438	10^9/L	L	1	4
			Potassium	3.7	mmol/L	L	3.9	5.1
			Albumin	2.95	g/dL	L	3.5	5.2
		2011-12-02T08:34	Hemoglobin	10.9	g/dL	L	11.9	15.7
			Erythrocytes	3.51	10^12/L	L	3.86	5.08
			Lymphocytes	0.65	10^9/L	L	1.19	3.35
	Cycle 22	2011-12-18T11:42	Hemoglobin	7.9	g/dL	L	11.9	15.7
			Erythrocytes	2.57	10^12/L	L	3.86	5.08
			Platelets	122	10^9/L	L	150	424
			Leukocytes	2.55	10^9/L	L	3.4	9.7
			Neutrophils	1.928	10^9/L	L	2	7.5
			Lymphocytes	0.311	10^9/L	L	1	4
			Calcium	4.61	mg/dL	L	8.6	10.1
		2011-12-23T09:01	Hemoglobin	11.4	g/dL	L	11.9	15.7
			Erythrocytes	3.55	10^12/L	L	3.86	5.08
			Lymphocytes	0.868	10^9/L	L	1	4
		2011-12-23T10:51	Potassium	3.7	mmol/L	L	3.9	5.1
	Cycle 23	2012-01-08T13:24	Prothrombin Time	9.6	sec	L	11	13
			Activated Partial Thromboplastin Time	23.8	sec	L	24	33

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 23	2012-01-09T12:43	Hemoglobin	10.4	g/dL	L	11.9	15.7
			Erythrocytes	3.19	10^12/L	L	3.86	5.08
			Lymphocytes	0.47	10^9/L	L	1	4
			Albumin	3.03	g/dL	L	3.5	5.2
		2012-01-13T10:40	Hemoglobin	10.6	g/dL	L	11.9	15.7
			Erythrocytes	3.34	10^12/L	L	3.86	5.08
			Lymphocytes	0.427	10^9/L	L	1	4
			Potassium	3.8	mmol/L	L	3.9	5.1
			Chloride	110	mmol/L	H	97	108
			Albumin	3.42	g/dL	L	3.5	5.2
	Cycle 24	2012-01-30T09:06	Hemoglobin	10	g/dL	L	11.9	15.7
			Erythrocytes	3.15	10^12/L	L	3.86	5.08
			Lymphocytes	0.533	10^9/L	L	1	4
		2012-02-03T09:23	Hemoglobin	9.9	g/dL	L	11.9	15.7
			Erythrocytes	3.07	10^12/L	L	3.86	5.08
			Lymphocytes	0.42	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Albumin	3.13	g/dL	L	3.5	5.2
	Cycle 25	2012-02-20T07:42	Hemoglobin	10.7	g/dL	L	11.9	15.7
			Erythrocytes	3.3	10^12/L	L	3.86	5.08
			Lymphocytes	0.36	10^9/L	L	1.19	3.35
			Potassium	3.8	mmol/L	L	3.9	5.1
			Albumin	3.38	g/dL	L	3.5	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 25	2012-02-24T08:29	Hemoglobin	10	g/dL	L	11.9	15.7
			Erythrocytes	3.08	10^12/L	L	3.86	5.08
			Lymphocytes	0.74	10^9/L	L	1.19	3.35
			Potassium	3.5	mmol/L	L	3.9	5.1
			Calcium	8.22	mg/dL	L	8.6	10.1
	Cycle 26	2012-03-11T00:00	Prothrombin Time	10.5	sec	L	11	13
		2012-03-11T11:14	Calcium	8.14	mg/dL	L	8.6	10.1
			Chloride	109	mmol/L	H	97	108
		2012-03-12T10:22	Hemoglobin	10	g/dL	L	11.9	15.7
			Erythrocytes	3.22	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.5	fL	H	83	97.2
			Lymphocytes	0.63	10^9/L	L	1	4
		2012-03-16T07:02	Hemoglobin	10.7	g/dL	L	11.9	15.7
			Erythrocytes	3.29	10^12/L	L	3.86	5.08
			Lymphocytes	0.35	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Calcium	8.54	mg/dL	L	8.6	10.1
			Glucose	138.7	mg/dL	H	79	115
	Cycle 27	2012-04-02T09:32	Hemoglobin	11.1	g/dL	L	11.9	15.7
			Erythrocytes	3.43	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98	fL	H	83	97.2
			Lymphocytes	0.41	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	23.3	sec	L	24	33
			Calcium	8.5	mg/dL	L	8.6	10.1
			Albumin	3.26	g/dL	L	3.5	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 27	2012-04-02T09:32	Glucose	68.5	mg/dL	L	79	115
		2012-04-06T08:16	Hemoglobin	10.6	g/dL	L	11.9	15.7
			Erythrocytes	3.14	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.3	fL	H	83	97.2
			Lymphocytes	0.66	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
	Cycle 28	2012-04-23T12:48	Hemoglobin	11.5	g/dL	L	11.9	15.7
			Erythrocytes	3.55	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.2	fL	H	83	97.2
			Lymphocytes	0.59	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	22	sec	L	24	33
			Glucose	68.5	mg/dL	L	79	115
		2012-04-27T08:54	Hemoglobin	11.2	g/dL	L	11.9	15.7
			Erythrocytes	3.47	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.6	fL	H	83	97.2
			Lymphocytes	0.912	10^9/L	L	1	4
			Glucose	120.7	mg/dL	H	79	115
	Cycle 29	2012-05-15T08:00	Hemoglobin	10.7	g/dL	L	11.9	15.7
			Erythrocytes	3.34	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.6	fL	H	83	97.2
			Platelets	144	10^9/L	L	150	424
			Lymphocytes	0.4	10^9/L	L	1.19	3.35
			Basophils	0.07	10^9/L	H	0	0.06

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 29	2012-05-15T08:04	Potassium	3.6	mmol/L	L	3.9	5.1
			Calcium	8.3	mg/dL	L	8.6	10.1
			Albumin	3.25	g/dL	L	3.5	5.2
			Alkaline Phosphatase	58	U/L	L	64	153
		2012-05-19T07:46	Hemoglobin	10.2	g/dL	L	11.9	15.7
			Erythrocytes	3.24	10^12/L	L	3.86	5.08
			Platelets	145	10^9/L	L	150	424
			Lymphocytes	0.588	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.9	5.1
			Alkaline Phosphatase	51	U/L	L	64	153
			Glucose	142.3	mg/dL	H	79	115
	Cycle 30	2012-06-04T10:29	Hemoglobin	10.3	g/dL	L	11.9	15.7
			Erythrocytes	3.17	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	99.4	fL	H	83	97.2
			Lymphocytes	0.36	10^9/L	L	1.19	3.35
			Calcium	8.38	mg/dL	L	8.6	10.1
			Albumin	3.3	g/dL	L	3.5	5.2
			Alkaline Phosphatase	52	U/L	L	64	153
			Glucose	64.9	mg/dL	L	79	115
		2012-06-04T12:25	Activated Partial Thromboplastin Time	23.7	sec	L	24	33
		2012-06-08T08:16	Hemoglobin	10.8	g/dL	L	11.9	15.7
			Erythrocytes	3.25	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98	fL	H	83	97.2
			Lymphocytes	0.62	10^9/L	L	1.19	3.35
			Potassium	3.6	mmol/L	L	3.9	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 30	2012-06-08T08:16	Calcium	8.38	mg/dL	L	8.6	10.1
			Alkaline Phosphatase	55	U/L	L	64	153
	Cycle 31	2012-06-25T11:44	Hemoglobin	11	g/dL	L	11.9	15.7
			Erythrocytes	3.57	10^12/L	L	3.86	5.08
			Lymphocytes	0.737	10^9/L	L	1	4
			Potassium	3.5	mmol/L	L	3.9	5.1
			Alkaline Phosphatase	56	U/L	L	64	153
			Glucose	66.7	mg/dL	L	79	115
		2012-06-26T08:07	Erythrocytes	3.61	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98.2	fL	H	83	97.2
			Lymphocytes	0.768	10^9/L	L	1	4
		2012-06-28T10:09	Potassium	3.7	mmol/L	L	3.9	5.1
			Calcium	8.58	mg/dL	L	8.6	10.1
			Alkaline Phosphatase	50	U/L	L	64	153
			Glucose	118.9	mg/dL	H	79	115
	Cycle 32	2012-07-30T08:30	Hemoglobin	11.6	g/dL	L	11.9	15.7
			Erythrocytes	3.81	10^12/L	L	3.86	5.08
			Lymphocytes	0.961	10^9/L	L	1	4
			Potassium	3.7	mmol/L	L	3.9	5.1
			Phosphate	2.42	mg/dL	L	2.5	4.4
			Alkaline Phosphatase	61	U/L	L	64	153
		2012-08-03T09:18	Hemoglobin	10	g/dL	L	11.9	15.7
			Erythrocytes	3.05	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	97.6	fL	H	83	97.2
			Platelets	147	10^9/L	L	150	424
			Alkaline Phosphatase	49	U/L	L	64	153

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-001	Cycle 32	2012-08-03T09:18	Glucose	127.9	mg/dL	H	79	115
	Cycle 33	2012-08-20T08:18	Hemoglobin	10.9	g/dL	L	11.9	15.7
			Erythrocytes	3.42	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	98	fL	H	83	97.2
			Lymphocytes	0.62	10^9/L	L	1.19	3.35
			Activated Partial Thromboplastin Time	23.8	sec	L	24	33
		2012-08-20T09:18	Calcium	8.3	mg/dL	L	8.6	10.1
			Alkaline Phosphatase	59	U/L	L	64	153
			Glucose	75.7	mg/dL	L	79	115
		2012-08-24T09:02	Hemoglobin	11.7	g/dL	L	11.9	15.7
			Erythrocytes	3.62	10^12/L	L	3.86	5.08
			Lymphocytes	0.62	10^9/L	L	1.19	3.35
			Creatinine	1.244	mg/dL	H	0.71	1.21
			Albumin	3.23	g/dL	L	3.5	5.2
			Alkaline Phosphatase	56	U/L	L	64	153
			Glucose	154.9	mg/dL	H	79	115
541-002	Pre-trial	2010-11-25T15:14	Hemoglobin	9.8	g/dL	L	11.9	15.7
			Erythrocytes	3.78	10^12/L	L	3.86	5.08
			Ery. Mean Corpuscular Volume	80.7	fL	L	83	97.2
			Leukocytes	2.42	10^9/L	L	3.4	9.7
			Neutrophils	1.71	10^9/L	L	2.06	6.49
			Lymphocytes	0.45	10^9/L	L	1.19	3.35
			Eosinophils	0.51	10^9/L	H	0	0.43
			Basophils	0.09	10^9/L	H	0	0.06

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
541-002	Pre-trial	2010-11-26T07:34	Creatinine	0.69	mg/dL	L	0.71	1.21
			Lactate Dehydrogenase	255	U/L	H	0	239.99
	Cycle 1	2010-12-06T11:01	Hemoglobin	11.8	g/dL	L	11.9	15.7
			Ery. Mean Corpuscular Volume	82.6	fL	L	83	97.2
			Monocytes	0.93	10^9/L	H	0.12	0.84
		2010-12-06T11:39	Lactate Dehydrogenase	444	U/L	H	0	239.99
		2010-12-10T08:58	Hemoglobin	11.7	g/dL	L	11.9	15.7
			Lymphocytes	0.76	10^9/L	L	1.19	3.35
			Monocytes	0.9	10^9/L	H	0.12	0.84
			Basophils	0.07	10^9/L	H	0	0.06
			Albumin	5.27	g/dL	H	3.5	5.2
			Alkaline Phosphatase	185	U/L	H	64	153
			Lactate Dehydrogenase	402	U/L	H	0	239.99
			Glucose	160.3	mg/dL	H	79	115
		2010-12-16T12:56	Hemoglobin	11.8	g/dL	L	11.9	15.7
			Eosinophils	1.2	10^9/L	H	0	0.43
			Calcium	10.3	mg/dL	H	8.6	10.1
			Lactate Dehydrogenase	435	U/L	H	0	239.99
			Urate	2.27	mg/dL	L	2.3	5.7
	End Trial	2010-12-29T10:27	Hemoglobin	10.6	g/dL	L	11.9	15.7
			Lymphocytes	0.68	10^9/L	L	1.19	3.35
			Monocytes	0.86	10^9/L	H	0.12	0.84
			Eosinophils	0.63	10^9/L	H	0	0.43

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
541-002	End Trial	2010-12-30T10:49	Alkaline Phosphatase	169	U/L	H	64	153
			Lactate Dehydrogenase	555	U/L	H	0	239.99
			Urate	2.2	mg/dL	L	2.3	5.7
			Glucose	156.7	mg/dL	H	79	115
543-001	Pre-trial	2010-06-07T12:13	Hemoglobin	10	g/dL	L	13.8	17.5
			Erythrocytes	3.67	10^12/L	L	4.34	5.72
			Platelets	101	10^9/L	L	150	424
			Lymphocytes	1.18	10^9/L	L	1.19	3.35
			Creatinine	0.758	mg/dL	L	0.89	1.41
			Albumin	3.84	g/dL	L	3.96	4.84
			Alanine Aminotransferase	87	U/L	H	12	48
			Aspartate Aminotransferase	50	U/L	H	11	38
			Alkaline Phosphatase	296	U/L	H	60	142
		2010-06-08T08:31	Prothrombin Time	10.03	sec	L	11	13
	Cycle 1	2010-06-14T08:08	Hemoglobin	9.9	g/dL	L	13.8	17.5
			Erythrocytes	3.48	10^12/L	L	4.34	5.72
			Platelets	115	10^9/L	L	150	424
			Lymphocytes	0.84	10^9/L	L	1.19	3.35
			Eosinophils	0.46	10^9/L	H	0	0.43
			Prothrombin Time	9.83	sec	L	11	13
			Creatinine	0.747	mg/dL	L	0.89	1.41
			Albumin	3.56	g/dL	L	3.96	4.84
			Alkaline Phosphatase	236	U/L	H	60	142

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 1	2010-06-18T09:28	Hemoglobin	10.3	g/dL	L	13.8	17.5
			Erythrocytes	3.65	10^12/L	L	4.34	5.72
			Platelets	103	10^9/L	L	150	424
			Lymphocytes	0.52	10^9/L	L	1.19	3.35
			Sodium	134	mmol/L	L	137	146
			Potassium	3.8	mmol/L	L	3.9	5.1
			Phosphate	4.89	mg/dL	H	2.5	4.4
			Creatinine	0.871	mg/dL	L	0.89	1.41
			Alkaline Phosphatase	246	U/L	H	60	142
		2010-06-24T08:52	Hemoglobin	12.1	g/dL	L	13.8	17.5
			Erythrocytes	4.3	10^12/L	L	4.34	5.72
			Platelets	119	10^9/L	L	150	424
			Lymphocytes	0.8	10^9/L	L	1.19	3.35
			Eosinophils	0.49	10^9/L	H	0	0.43
			Calcium	10.14	mg/dL	H	8.6	10.1
			Phosphate	4.49	mg/dL	H	2.5	4.4
			Creatinine	0.837	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	77	U/L	H	12	48
			Aspartate Aminotransferase	66	U/L	H	11	38
			Alkaline Phosphatase	305	U/L	H	60	142
	Cycle 2	2010-06-30T07:50	Prothrombin Time	8.7	sec	L	11	13
		2010-06-30T14:27	Hemoglobin	11.3	g/dL	L	13.8	17.5
			Erythrocytes	3.9	10^12/L	L	4.34	5.72
			Platelets	98	10^9/L	L	150	424
			Lymphocytes	0.75	10^9/L	L	1.19	3.35
			Monocytes	1.29	10^9/L	H	0.12	0.84

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 2	2010-06-30T14:27	Sodium	131	mmol/L	L	137	146
			Chloride	96	mmol/L	L	97	108
			Creatinine	0.701	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	61	U/L	H	12	48
			Aspartate Aminotransferase	47	U/L	H	11	38
			Alkaline Phosphatase	292	U/L	H	60	142
		2010-07-05T08:17	Hemoglobin	10	g/dL	L	13.8	17.5
			Erythrocytes	3.58	10^12/L	L	4.34	5.72
			Platelets	89	10^9/L	L	150	424
			Leukocytes	3	10^9/L	L	3.4	9.7
			Neutrophils	1.92	10^9/L	L	2.06	6.49
			Lymphocytes	0.48	10^9/L	L	1.19	3.35
			Sodium	135	mmol/L	L	137	146
			Phosphate	4.74	mg/dL	H	2.5	4.4
			Creatinine	0.69	mg/dL	L	0.89	1.41
			Albumin	3.93	g/dL	L	3.96	4.84
			Alkaline Phosphatase	209	U/L	H	60	142
	Cycle 3	2010-07-21T08:48	Hemoglobin	11.4	g/dL	L	13.8	17.5
			Erythrocytes	4.07	10^12/L	L	4.34	5.72
			Platelets	113	10^9/L	L	150	424
			Lymphocytes	0.67	10^9/L	L	1.19	3.35
			Prothrombin Time	9.31	sec	L	11	13
			Activated Partial Thromboplastin Time	37	sec	H	23	33
			Sodium	136	mmol/L	L	137	146
			Creatinine	0.826	mg/dL	L	0.89	1.41

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 3	2010-07-21T08:48	Alanine Aminotransferase	53	U/L	H	12	48
			Aspartate Aminotransferase	39	U/L	H	11	38
			Alkaline Phosphatase	293	U/L	H	60	142
		2010-07-25T08:35	Hemoglobin	9.8	g/dL	L	13.8	17.5
			Erythrocytes	3.62	10^12/L	L	4.34	5.72
			Platelets	79	10^9/L	L	150	424
			Leukocytes	3.1	10^9/L	L	3.4	9.7
			Lymphocytes	0.41	10^9/L	L	1.19	3.35
			Phosphate	5.2	mg/dL	H	2.5	4.4
			Creatinine	0.679	mg/dL	L	0.89	1.41
			Albumin	3.73	g/dL	L	3.96	4.84
			Alkaline Phosphatase	195	U/L	H	60	142
	Cycle 4	2010-08-12T07:50	Prothrombin Time	8.7	sec	L	11	13
		2010-08-12T07:54	Hemoglobin	9.3	g/dL	L	13.8	17.5
			Erythrocytes	3.22	10^12/L	L	4.34	5.72
			Platelets	97	10^9/L	L	150	424
			Leukocytes	2.2	10^9/L	L	3.4	9.7
			Neutrophils	1.09	10^9/L	L	2.06	6.49
			Lymphocytes	0.64	10^9/L	L	1.19	3.35
			Creatinine	0.713	mg/dL	L	0.89	1.41
			Albumin	3.22	g/dL	L	3.96	4.84
			Alkaline Phosphatase	163	U/L	H	60	142
			Lactate Dehydrogenase	255	U/L	H	0	240

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 4	2010-08-16T09:07	Hemoglobin	9.3	g/dL	L	13.8	17.5
			Erythrocytes	3.19	10^12/L	L	4.34	5.72
			Platelets	80	10^9/L	L	150	424
			Leukocytes	2.4	10^9/L	L	3.4	9.7
			Lymphocytes	0.17	10^9/L	L	1.19	3.35
			Monocytes	0.02	10^9/L	L	0.12	0.84
			Creatinine	0.871	mg/dL	L	0.89	1.41
			Albumin	3.67	g/dL	L	3.96	4.84
	Cycle 5	2010-09-02T07:57	Hemoglobin	10.2	g/dL	L	13.8	17.5
			Erythrocytes	3.61	10^12/L	L	4.34	5.72
			Platelets	94	10^9/L	L	150	424
			Leukocytes	2.8	10^9/L	L	3.4	9.7
			Lymphocytes	0.56	10^9/L	L	1.19	3.35
			Monocytes	0.11	10^9/L	L	0.12	0.84
			Calcium	10.18	mg/dL	H	8.6	10.1
			Creatinine	0.803	mg/dL	L	0.89	1.41
			Alkaline Phosphatase	243	U/L	H	60	142
		2010-09-02T08:00	Prothrombin Time	9.01	sec	L	11	13
		2010-09-06T08:20	Hemoglobin	10	g/dL	L	13.8	17.5
			Erythrocytes	3.38	10^12/L	L	4.34	5.72
			Platelets	75	10^9/L	L	150	424
			Leukocytes	2.2	10^9/L	L	3.4	9.7
			Neutrophils	1.55	10^9/L	L	2.06	6.49
			Lymphocytes	0.26	10^9/L	L	1.19	3.35
			Creatinine	0.848	mg/dL	L	0.89	1.41
			Albumin	3.81	g/dL	L	3.96	4.84

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 5	2010-09-06T08:20	Alkaline Phosphatase	182	U/L	H	60	142
	Cycle 6	2010-09-23T09:12	Hemoglobin	11.8	g/dL	L	13.8	17.5
			Erythrocytes	4.04	10^12/L	L	4.34	5.72
			Platelets	113	10^9/L	L	150	424
			Leukocytes	3.3	10^9/L	L	3.4	9.7
			Lymphocytes	0.53	10^9/L	L	1.19	3.35
			Creatinine	0.713	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	134	U/L	H	12	48
			Aspartate Aminotransferase	79	U/L	H	11	38
			Alkaline Phosphatase	299	U/L	H	60	142
			Glucose	122.5	mg/dL	H	76	115
		2010-09-27T09:10	Hemoglobin	10.6	g/dL	L	13.8	17.5
			Erythrocytes	3.71	10^12/L	L	4.34	5.72
			Platelets	79	10^9/L	L	150	424
			Leukocytes	1.7	10^9/L	L	3.4	9.7
			Neutrophils	1.07	10^9/L	L	2.06	6.49
			Lymphocytes	0.35	10^9/L	L	1.19	3.35
			Creatinine	0.747	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	103	U/L	H	12	48
			Aspartate Aminotransferase	45	U/L	H	11	38
			Alkaline Phosphatase	253	U/L	H	60	142

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 7	2010-10-14T08:34	Hemoglobin	12	g/dL	L	13.8	17.5
			Erythrocytes	4.2	10^12/L	L	4.34	5.72
			Platelets	100	10^9/L	L	150	424
			Leukocytes	2.9	10^9/L	L	3.4	9.7
			Lymphocytes	0.32	10^9/L	L	1.19	3.35
			Alanine Aminotransferase	82	U/L	H	12	48
			Aspartate Aminotransferase	60	U/L	H	11	38
			Alkaline Phosphatase	194	U/L	H	60	142
			Glucose	115.3	mg/dL	H	76	115
		2010-10-18T08:12	Hemoglobin	11.3	g/dL	L	13.8	17.5
			Erythrocytes	3.99	10^12/L	L	4.34	5.72
			Platelets	68	10^9/L	L	150	424
			Leukocytes	2.4	10^9/L	L	3.4	9.7
			Neutrophils	1.73	10^9/L	L	2.06	6.49
			Lymphocytes	0.32	10^9/L	L	1.19	3.35
			Phosphate	4.89	mg/dL	H	2.5	4.4
			Creatinine	0.826	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	84	U/L	H	12	48
			Aspartate Aminotransferase	49	U/L	H	11	38
			Alkaline Phosphatase	173	U/L	H	60	142
			Glucose	117.1	mg/dL	H	76	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 8	2010-11-05T08:52	Hemoglobin	12.7	g/dL	L	13.8	17.5
			Erythrocytes	4.26	10^12/L	L	4.34	5.72
			Platelets	110	10^9/L	L	150	424
			Neutrophils	0.44	10^9/L	L	2.06	6.49
			Lymphocytes	0.7	10^9/L	L	1.19	3.35
			Creatinine	0.735	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	69	U/L	H	12	48
			Aspartate Aminotransferase	56	U/L	H	11	38
			Alkaline Phosphatase	212	U/L	H	60	142
			Glucose	144.1	mg/dL	H	76	115
		2010-11-09T07:39	Hemoglobin	11.6	g/dL	L	13.8	17.5
			Erythrocytes	3.9	10^12/L	L	4.34	5.72
			Platelets	82	10^9/L	L	150	424
			Lymphocytes	0.42	10^9/L	L	1.19	3.35
			Creatinine	0.826	mg/dL	L	0.89	1.41
			Albumin	3.76	g/dL	L	3.96	4.84
			Alanine Aminotransferase	52	U/L	H	12	48
	Cycle 9	2010-11-25T08:09	Hemoglobin	12.3	g/dL	L	13.8	17.5
			Erythrocytes	4.23	10^12/L	L	4.34	5.72
			Platelets	120	10^9/L	L	150	424
			Lymphocytes	0.69	10^9/L	L	1.19	3.35
			Creatinine	0.713	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	77	U/L	H	12	48
			Aspartate Aminotransferase	54	U/L	H	11	38
			Alkaline Phosphatase	168	U/L	H	60	142
			Glucose	129.7	mg/dL	H	76	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 9	2010-11-29T07:57	Hemoglobin	11.7	g/dL	L	13.8	17.5
			Erythrocytes	3.9	10^12/L	L	4.34	5.72
			Platelets	72	10^9/L	L	150	424
			Leukocytes	2.8	10^9/L	L	3.4	9.7
			Lymphocytes	0.37	10^9/L	L	1.19	3.35
			Creatinine	0.747	mg/dL	L	0.89	1.41
			Albumin	3.86	g/dL	L	3.96	4.84
			Alanine Aminotransferase	73	U/L	H	12	48
			Alkaline Phosphatase	151	U/L	H	60	142
			Glucose	144.1	mg/dL	H	76	115
	Cycle 10	2010-12-24T08:09	Hemoglobin	12.3	g/dL	L	13.8	17.5
			Erythrocytes	3.86	10^12/L	L	4.34	5.72
			Platelets	89	10^9/L	L	150	424
			Lymphocytes	0.618	10^9/L	L	1	4
			Creatinine	0.769	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	75	U/L	H	12	48
			Aspartate Aminotransferase	54	U/L	H	11	38
			Alkaline Phosphatase	180	U/L	H	60	142
			Lactate Dehydrogenase	246	U/L	H	0	240
			Glucose	140.5	mg/dL	H	76	115
		2010-12-28T14:24	Hemoglobin	11.5	g/dL	L	13.8	17.5
			Erythrocytes	3.78	10^12/L	L	4.34	5.72
			Platelets	72	10^9/L	L	150	424
			Lymphocytes	0.486	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 10	2010-12-28T15:03	Sodium	136	mmol/L	L	137	146
			Potassium	3.8	mmol/L	L	3.9	5.1
			Creatinine	0.543	mg/dL	L	0.89	1.41
			Albumin	3.86	g/dL	L	3.96	4.84
			Alanine Aminotransferase	59	U/L	H	12	48
			Alkaline Phosphatase	161	U/L	H	60	142
			Glucose	133.3	mg/dL	H	76	115
	Cycle 11	2011-01-14T08:10	Prothrombin Time	10.65	sec	L	11	13
		2011-01-14T08:19	Hemoglobin	12.3	g/dL	L	13.8	17.5
			Erythrocytes	3.73	10^12/L	L	4.34	5.72
			Platelets	79	10^9/L	L	150	424
			Lymphocytes	0.152	10^9/L	L	1	4
			Sodium	136	mmol/L	L	137	146
			Chloride	96	mmol/L	L	97	108
			Creatinine	0.645	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	54	U/L	H	12	48
			Aspartate Aminotransferase	55	U/L	H	11	38
			Alkaline Phosphatase	215	U/L	H	60	142
			Lactate Dehydrogenase	290	U/L	H	0	240
			Glucose	136.9	mg/dL	H	76	115
		2011-01-19T12:06	Hemoglobin	11.4	g/dL	L	13.8	17.5
			Erythrocytes	3.56	10^12/L	L	4.34	5.72
			Platelets	74	10^9/L	L	150	424
			Leukocytes	3.2	10^9/L	L	3.4	9.7
			Lymphocytes	0.346	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 11	2011-01-19T12:35	Potassium	3.7	mmol/L	L	3.9	5.1
			Creatinine	0.577	mg/dL	L	0.89	1.41
			Albumin	3.84	g/dL	L	3.96	4.84
			Alkaline Phosphatase	162	U/L	H	60	142
			Glucose	118.9	mg/dL	H	76	115
	Cycle 12	2011-02-04T12:00	Prothrombin Time	10.34	sec	L	11	13
		2011-02-04T12:05	Hemoglobin	12.8	g/dL	L	13.8	17.5
			Erythrocytes	4.05	10^12/L	L	4.34	5.72
			Platelets	115	10^9/L	L	150	424
			Lymphocytes	0.392	10^9/L	L	1	4
			Creatinine	0.588	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	120	U/L	H	12	48
			Aspartate Aminotransferase	96	U/L	H	11	38
			Alkaline Phosphatase	170	U/L	H	60	142
			Lactate Dehydrogenase	258	U/L	H	0	240
			Glucose	194.6	mg/dL	H	76	115
		2011-02-08T08:42	Hemoglobin	12.4	g/dL	L	13.8	17.5
			Erythrocytes	3.79	10^12/L	L	4.34	5.72
			Platelets	102	10^9/L	L	150	424
			Lymphocytes	0.408	10^9/L	L	1	4
			Potassium	3.4	mmol/L	L	3.9	5.1
			Magnesium	0.92	mg/dL	L	1.6	2.6
			Creatinine	0.667	mg/dL	L	0.89	1.41
			Albumin	3.92	g/dL	L	3.96	4.84
			Alanine Aminotransferase	108	U/L	H	12	48
			Aspartate Aminotransferase	68	U/L	H	11	38

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 12	2011-02-08T08:42	Alkaline Phosphatase	160	U/L	H	60	142
			Glucose	228.8	mg/dL	H	76	115
	Cycle 13	2011-02-25T10:50	Hemoglobin	12	g/dL	L	13.8	17.5
			Erythrocytes	3.8	10^12/L	L	4.34	5.72
			Platelets	115	10^9/L	L	150	424
			Lymphocytes	0.91	10^9/L	L	1.19	3.35
			Basophils	0.06	10^9/L	H	0	0.05
		2011-02-25T11:28	Calcium	8.38	mg/dL	L	8.6	10.1
			Creatinine	0.509	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	42	U/L	H	11	38
			Alkaline Phosphatase	165	U/L	H	60	142
			Glucose	120.7	mg/dL	H	76	115
		2011-03-01T10:55	Hemoglobin	11.6	g/dL	L	13.8	17.5
			Erythrocytes	3.62	10^12/L	L	4.34	5.72
			Platelets	91	10^9/L	L	150	424
			Lymphocytes	0.61	10^9/L	L	1.19	3.35
			Potassium	3.5	mmol/L	L	3.9	5.1
			Creatinine	0.52	mg/dL	L	0.89	1.41
			Albumin	3.77	g/dL	L	3.96	4.84
			Aspartate Aminotransferase	41	U/L	H	11	38
			Alkaline Phosphatase	144	U/L	H	60	142
			Glucose	183.8	mg/dL	H	76	115

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 14	2011-03-18T10:56	Hemoglobin	12	g/dL	L	13.8	17.5
			Erythrocytes	3.75	10^12/L	L	4.34	5.72
			Platelets	115	10^9/L	L	150	424
			Lymphocytes	0.67	10^9/L	L	1.19	3.35
			Calcium	8.54	mg/dL	L	8.6	10.1
			Creatinine	0.554	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	68	U/L	H	12	48
			Aspartate Aminotransferase	57	U/L	H	11	38
			Lactate Dehydrogenase	244	U/L	H	0	240
			Glucose	232.4	mg/dL	H	76	115
		2011-03-22T08:57	Hemoglobin	12.2	g/dL	L	13.8	17.5
			Erythrocytes	3.76	10^12/L	L	4.34	5.72
			Platelets	97	10^9/L	L	150	424
			Lymphocytes	0.55	10^9/L	L	1.19	3.35
		2011-03-22T10:05	Potassium	3.8	mmol/L	L	3.9	5.1
			Creatinine	0.498	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	64	U/L	H	12	48
			Aspartate Aminotransferase	51	U/L	H	11	38
			Alkaline Phosphatase	155	U/L	H	60	142
			Glucose	153.1	mg/dL	H	76	115
	Cycle 15	2011-04-15T08:40	Prothrombin Time	9.72	sec	L	11	13
		2011-04-15T08:49	Hemoglobin	13.1	g/dL	L	13.8	17.5
			Erythrocytes	4.15	10^12/L	L	4.34	5.72
			Platelets	92	10^9/L	L	150	424
			Lymphocytes	0.64	10^9/L	L	1.19	3.35
			Potassium	3.4	mmol/L	L	3.9	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 15	2011-04-15T08:49	Chloride	96	mmol/L	L	97	108
			Creatinine	0.69	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	54	U/L	H	11	38
			Alkaline Phosphatase	189	U/L	H	60	142
		2011-04-20T07:53	Hemoglobin	12.4	g/dL	L	13.8	17.5
			Erythrocytes	3.92	10^12/L	L	4.34	5.72
			Platelets	87	10^9/L	L	150	424
			Lymphocytes	0.52	10^9/L	L	1.19	3.35
			Creatinine	0.679	mg/dL	L	0.89	1.41
			Alkaline Phosphatase	165	U/L	H	60	142
			Glucose	144.1	mg/dL	H	76	115
	Cycle 16	2011-05-16T08:46	Hemoglobin	11.6	g/dL	L	13.8	17.5
			Erythrocytes	3.84	10^12/L	L	4.34	5.72
			Platelets	98	10^9/L	L	150	424
			Lymphocytes	0.47	10^9/L	L	1.19	3.35
			Prothrombin Time	9.42	sec	L	11	13
			Creatinine	0.633	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	41	U/L	H	11	38
			Lactate Dehydrogenase	326	U/L	H	0	240
			Glucose	135.1	mg/dL	H	76	115
		2011-05-20T08:50	Hemoglobin	10.2	g/dL	L	13.8	17.5
			Erythrocytes	3.36	10^12/L	L	4.34	5.72
			Platelets	69	10^9/L	L	150	424
			Leukocytes	1.7	10^9/L	L	3.4	9.7
			Neutrophils	1.3	10^9/L	L	2.06	6.49
			Lymphocytes	0.19	10^9/L	L	1.19	3.35

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 16	2011-05-20T08:50	Creatinine	0.633	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	43	U/L	H	11	38
			Glucose	142.3	mg/dL	H	76	115
	Cycle 17	2011-06-13T08:42	Hemoglobin	13.2	g/dL	L	13.8	17.5
			Platelets	125	10^9/L	L	150	424
			Leukocytes	2.5	10^9/L	L	3.4	9.7
			Neutrophils	1.65	10^9/L	L	2.06	6.49
			Lymphocytes	0.39	10^9/L	L	1.19	3.35
		2011-06-13T08:48	Creatinine	0.577	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	54	U/L	H	12	48
			Aspartate Aminotransferase	52	U/L	H	11	38
			Alkaline Phosphatase	235	U/L	H	60	142
			Lactate Dehydrogenase	265	U/L	H	0	240
			Glucose	120.7	mg/dL	H	76	115
		2011-06-13T08:50	Prothrombin Time	10.24	sec	L	11	13
		2011-06-17T08:37	Hemoglobin	11.8	g/dL	L	13.8	17.5
			Erythrocytes	4.18	10^12/L	L	4.34	5.72
			Platelets	84	10^9/L	L	150	424
			Leukocytes	2.7	10^9/L	L	3.4	9.7
			Lymphocytes	0.26	10^9/L	L	1.19	3.35
			Creatinine	0.577	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	49	U/L	H	12	48
			Alkaline Phosphatase	246	U/L	H	60	142
			Glucose	135.1	mg/dL	H	76	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 18	2011-07-11T08:37	Hemoglobin	13	g/dL	L	13.8	17.5
			Platelets	114	10^9/L	L	150	424
			Lymphocytes	0.58	10^9/L	L	1.19	3.35
			Creatinine	0.679	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	46	U/L	H	11	38
			Alkaline Phosphatase	193	U/L	H	60	142
			Glucose	129.7	mg/dL	H	76	115
		2011-07-11T08:40	Prothrombin Time	10.95	sec	L	11	13
		2011-07-15T08:55	Hemoglobin	12.5	g/dL	L	13.8	17.5
			Platelets	92	10^9/L	L	150	424
			Lymphocytes	0.78	10^9/L	L	1.19	3.35
		2011-07-15T09:42	Potassium	3.7	mmol/L	L	3.9	5.1
			Phosphate	4.43	mg/dL	H	2.5	4.4
			Creatinine	0.758	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	59	U/L	H	12	48
			Aspartate Aminotransferase	47	U/L	H	11	38
			Alkaline Phosphatase	196	U/L	H	60	142
			Glucose	165.7	mg/dL	H	76	115
	Cycle 19	2011-08-08T09:00	Prothrombin Time	10.75	sec	L	11	13
		2011-08-08T09:49	Hemoglobin	12.1	g/dL	L	13.8	17.5
			Erythrocytes	4.26	10^12/L	L	4.34	5.72
			Platelets	70	10^9/L	L	150	424
			Lymphocytes	0.37	10^9/L	L	1.19	3.35
			Creatinine	0.679	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	53	U/L	H	12	48
			Aspartate Aminotransferase	56	U/L	H	11	38

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 19	2011-08-08T09:49	Alkaline Phosphatase	164	U/L	H	60	142
			Glucose	118.9	mg/dL	H	76	115
		2011-08-12T10:41	Hemoglobin	11.2	g/dL	L	13.8	17.5
			Erythrocytes	3.98	10^12/L	L	4.34	5.72
			Platelets	61	10^9/L	L	150	424
			Leukocytes	3.2	10^9/L	L	3.4	9.7
			Creatinine	0.69	mg/dL	L	0.89	1.41
			Alkaline Phosphatase	150	U/L	H	60	142
			Glucose	144.1	mg/dL	H	76	115
	Cycle 20	2011-09-05T09:06	Hemoglobin	12	g/dL	L	13.8	17.5
			Erythrocytes	4.11	10^12/L	L	4.34	5.72
			Platelets	99	10^9/L	L	150	424
			Leukocytes	2.4	10^9/L	L	3.4	9.7
		2011-09-05T09:08	Prothrombin Time	10.24	sec	L	11	13
		2011-09-05T10:08	Creatinine	0.554	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	48	U/L	H	11	38
			Alkaline Phosphatase	213	U/L	H	60	142
			Lactate Dehydrogenase	245	U/L	H	0	240
			Glucose	120.7	mg/dL	H	76	115
		2011-09-09T08:36	Hemoglobin	12.7	g/dL	L	13.8	17.5
			Platelets	102	10^9/L	L	150	424
			Lymphocytes	0.28	10^9/L	L	1.19	3.35

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 20	2011-09-09T08:38	Chloride	95	mmol/L	L	97	108
			Phosphate	4.77	mg/dL	H	2.5	4.4
			Creatinine	0.735	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	54	U/L	H	12	48
			Aspartate Aminotransferase	41	U/L	H	11	38
			Alkaline Phosphatase	209	U/L	H	60	142
			Glucose	135.1	mg/dL	H	76	115
	Cycle 21	2011-10-03T09:03	Hemoglobin	12.3	g/dL	L	13.8	17.5
			Platelets	133	10^9/L	L	150	424
			Lymphocytes	0.5	10^9/L	L	1.19	3.35
			Creatinine	0.69	mg/dL	L	0.89	1.41
			Albumin	3.84	g/dL	L	3.96	4.84
			Aspartate Aminotransferase	53	U/L	H	11	38
			Alkaline Phosphatase	285	U/L	H	60	142
			Glucose	144.1	mg/dL	H	76	115
		2011-10-03T09:05	Prothrombin Time	8.7	sec	L	11	13
			Activated Partial Thromboplastin Time	34	sec	H	23	33
		2011-10-07T07:48	Hemoglobin	11.7	g/dL	L	13.8	17.5
			Erythrocytes	4.2	10^12/L	L	4.34	5.72
			Platelets	147	10^9/L	L	150	424
			Lymphocytes	0.34	10^9/L	L	1.19	3.35
			Calcium	8.46	mg/dL	L	8.6	10.1
			Creatinine	0.566	mg/dL	L	0.89	1.41
			Albumin	3.55	g/dL	L	3.96	4.84
			Alanine Aminotransferase	51	U/L	H	12	48

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 21	2011-10-07T07:48	Aspartate Aminotransferase	44	U/L	H	11	38
			Alkaline Phosphatase	305	U/L	H	60	142
			Glucose	122.5	mg/dL	H	76	115
	Cycle 22	2011-10-31T09:02	Hemoglobin	13.1	g/dL	L	13.8	17.5
			Platelets	112	10^9/L	L	150	424
			Lymphocytes	0.53	10^9/L	L	1.19	3.35
			Creatinine	0.611	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	95	U/L	H	12	48
			Aspartate Aminotransferase	56	U/L	H	11	38
			Alkaline Phosphatase	221	U/L	H	60	142
			Glucose	140.5	mg/dL	H	76	115
		2011-10-31T09:05	Prothrombin Time	10.54	sec	L	11	13
		2011-11-04T09:00	Hemoglobin	13.1	g/dL	L	13.8	17.5
			Platelets	91	10^9/L	L	150	424
			Lymphocytes	0.47	10^9/L	L	1.19	3.35
			Potassium	3.5	mmol/L	L	3.9	5.1
			Creatinine	0.633	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	94	U/L	H	12	48
			Aspartate Aminotransferase	48	U/L	H	11	38
			Alkaline Phosphatase	187	U/L	H	60	142
			Glucose	142.3	mg/dL	H	76	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 23	2011-11-28T08:41	Hemoglobin	12.8	g/dL	L	13.8	17.5
			Platelets	107	10^9/L	L	150	424
			Lymphocytes	0.8	10^9/L	L	1.19	3.35
			Calcium	8.34	mg/dL	L	8.6	10.1
			Creatinine	0.679	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	66	U/L	H	12	48
			Aspartate Aminotransferase	49	U/L	H	11	38
			Alkaline Phosphatase	170	U/L	H	60	142
			Glucose	133.3	mg/dL	H	76	115
		2011-12-02T08:56	Hemoglobin	11.8	g/dL	L	13.8	17.5
			Erythrocytes	4.17	10^12/L	L	4.34	5.72
			Platelets	83	10^9/L	L	150	424
			Lymphocytes	0.5	10^9/L	L	1.19	3.35
			Potassium	3.8	mmol/L	L	3.9	5.1
			Phosphate	4.43	mg/dL	H	2.5	4.4
			Creatinine	0.713	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	73	U/L	H	12	48
			Aspartate Aminotransferase	44	U/L	H	11	38
			Alkaline Phosphatase	159	U/L	H	60	142
	Cycle 24	2011-12-26T09:49	Hemoglobin	10.4	g/dL	L	13.8	17.5
			Erythrocytes	3.73	10^12/L	L	4.34	5.72
			Platelets	65	10^9/L	L	150	424
			Leukocytes	2.6	10^9/L	L	3.4	9.7
			Neutrophils	1.6	10^9/L	L	2.06	6.49
			Lymphocytes	0.7	10^9/L	L	1.19	3.35
			Potassium	3.1	mmol/L	L	3.9	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 24	2011-12-26T09:49	Creatinine	0.667	mg/dL	L	0.89	1.41
			Albumin	3.6	g/dL	L	3.96	4.84
			Alkaline Phosphatase	145	U/L	H	60	142
			Glucose	158.5	mg/dL	H	76	115
		2011-12-26T09:55	Prothrombin Time	8.5	sec	L	11	13
		2011-12-30T08:54	Hemoglobin	11.3	g/dL	L	13.8	17.5
			Erythrocytes	3.99	10^12/L	L	4.34	5.72
			Platelets	91	10^9/L	L	150	424
			Neutrophils	0.47	10^9/L	L	2.06	6.49
			Lymphocytes	0.51	10^9/L	L	1.19	3.35
			Sodium	136	mmol/L	L	137	146
			Potassium	3.2	mmol/L	L	3.9	5.1
			Calcium	8.38	mg/dL	L	8.6	10.1
			Creatinine	0.792	mg/dL	L	0.89	1.41
			Alkaline Phosphatase	170	U/L	H	60	142
			Glucose	147.7	mg/dL	H	76	115
	Cycle 25	2012-01-23T08:45	Prothrombin Time	10.44	sec	L	11	13
		2012-01-23T09:11	Hemoglobin	12.9	g/dL	L	13.8	17.5
			Platelets	91	10^9/L	L	150	424
			Lymphocytes	0.4	10^9/L	L	1.19	3.35
			Sodium	136	mmol/L	L	137	146
			Potassium	3.3	mmol/L	L	3.9	5.1
			Creatinine	0.645	mg/dL	L	0.89	1.41
			Albumin	3.82	g/dL	L	3.96	4.84
			Alanine Aminotransferase	60	U/L	H	12	48
			Aspartate Aminotransferase	54	U/L	H	11	38

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 25	2012-01-23T09:11	Alkaline Phosphatase	227	U/L	H	60	142
			Glucose	120.7	mg/dL	H	76	115
		2012-01-27T08:58	Hemoglobin	12.4	g/dL	L	13.8	17.5
			Erythrocytes	4.28	10^12/L	L	4.34	5.72
			Platelets	90	10^9/L	L	150	424
			Lymphocytes	0.7	10^9/L	L	1.19	3.35
			Potassium	3.4	mmol/L	L	3.9	5.1
			Phosphate	4.8	mg/dL	H	2.5	4.4
			Creatinine	0.758	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	56	U/L	H	12	48
			Aspartate Aminotransferase	46	U/L	H	11	38
			Alkaline Phosphatase	205	U/L	H	60	142
			Glucose	120.7	mg/dL	H	76	115
	Cycle 26	2012-02-20T08:46	Hemoglobin	13.1	g/dL	L	13.8	17.5
			Platelets	140	10^9/L	L	150	424
			Lymphocytes	0.8	10^9/L	L	1.19	3.35
			Potassium	3.8	mmol/L	L	3.9	5.1
			Creatinine	0.713	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	55	U/L	H	12	48
			Alkaline Phosphatase	192	U/L	H	60	142
			Glucose	115.3	mg/dL	H	76	115
		2012-02-24T09:08	Hemoglobin	11.5	g/dL	L	13.8	17.5
			Erythrocytes	4.04	10^12/L	L	4.34	5.72
			Platelets	88	10^9/L	L	150	424
			Lymphocytes	0.4	10^9/L	L	1.19	3.35
			Creatinine	0.6	mg/dL	L	0.89	1.41

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 26	2012-02-24T09:08	Albumin	3.79	g/dL	L	3.96	4.84
			Alkaline Phosphatase	159	U/L	H	60	142
			Glucose	140.5	mg/dL	H	76	115
	Cycle 27	2012-03-19T08:49	Hemoglobin	12.7	g/dL	L	13.8	17.5
			Platelets	121	10^9/L	L	150	424
			Lymphocytes	1.1	10^9/L	L	1.19	3.35
		2012-03-19T10:48	Potassium	3.1	mmol/L	L	3.9	5.1
			Creatinine	0.713	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	57	U/L	H	12	48
			Aspartate Aminotransferase	40	U/L	H	11	38
			Alkaline Phosphatase	144	U/L	H	60	142
			Glucose	178.3	mg/dL	H	76	115
		2012-03-23T09:11	Hemoglobin	12	g/dL	L	13.8	17.5
			Erythrocytes	4.18	10^12/L	L	4.34	5.72
			Platelets	123	10^9/L	L	150	424
			Neutrophils	0.11	10^9/L	L	2.06	6.49
			Lymphocytes	0.84	10^9/L	L	1.19	3.35
			Potassium	3.4	mmol/L	L	3.9	5.1
			Creatinine	0.667	mg/dL	L	0.89	1.41
			Albumin	3.85	g/dL	L	3.96	4.84
			Glucose	178.3	mg/dL	H	76	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 28	2012-04-16T08:42	Hemoglobin	13.5	g/dL	L	13.8	17.5
			Platelets	118	10^9/L	L	150	424
			Lymphocytes	0.9	10^9/L	L	1.19	3.35
			Potassium	3.5	mmol/L	L	3.9	5.1
			Creatinine	0.69	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	60	U/L	H	12	48
			Aspartate Aminotransferase	47	U/L	H	11	38
			Glucose	133.3	mg/dL	H	76	115
		2012-04-16T08:50	Prothrombin Time	9.62	sec	L	11	13
		2012-04-20T08:48	Hemoglobin	12.5	g/dL	L	13.8	17.5
			Erythrocytes	4.24	10^12/L	L	4.34	5.72
			Platelets	101	10^9/L	L	150	424
			Lymphocytes	0.6	10^9/L	L	1.19	3.35
			Potassium	3.5	mmol/L	L	3.9	5.1
			Creatinine	0.645	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	79	U/L	H	12	48
			Aspartate Aminotransferase	56	U/L	H	11	38
			Alkaline Phosphatase	155	U/L	H	60	142
			Glucose	129.7	mg/dL	H	76	115
	Cycle 29	2012-05-21T08:00	Prothrombin Time	10.24	sec	L	11	13
		2012-05-21T08:14	Hemoglobin	13.6	g/dL	L	13.8	17.5
			Platelets	127	10^9/L	L	150	424
			Lymphocytes	1.1	10^9/L	L	1.19	3.35
			Potassium	3.6	mmol/L	L	3.9	5.1
			Creatinine	0.701	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	53	U/L	H	12	48

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 29	2012-05-21T08:14	Aspartate Aminotransferase	41	U/L	H	11	38
			Glucose	136.9	mg/dL	H	76	115
		2012-05-25T08:16	Hemoglobin	12.4	g/dL	L	13.8	17.5
			Erythrocytes	4.1	10^12/L	L	4.34	5.72
			Platelets	95	10^9/L	L	150	424
			Lymphocytes	0.5	10^9/L	L	1.19	3.35
		2012-05-25T10:07	Potassium	3	mmol/L	L	3.9	5.1
			Calcium	8.46	mg/dL	L	8.6	10.1
			Creatinine	0.532	mg/dL	L	0.89	1.41
			Albumin	3.79	g/dL	L	3.96	4.84
			Alanine Aminotransferase	51	U/L	H	12	48
			Glucose	180.1	mg/dL	H	76	115
	Cycle 30	2012-06-18T08:37	Hemoglobin	12.6	g/dL	L	13.8	17.5
			Platelets	129	10^9/L	L	150	424
			Lymphocytes	0.9	10^9/L	L	1.19	3.35
			Potassium	3.2	mmol/L	L	3.9	5.1
			Creatinine	0.667	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	63	U/L	H	12	48
			Aspartate Aminotransferase	49	U/L	H	11	38
		2012-06-18T08:40	Prothrombin Time	10.44	sec	L	11	13
		2012-06-22T08:33	Potassium	3.4	mmol/L	L	3.9	5.1
			Creatinine	0.69	mg/dL	L	0.89	1.41
			Albumin	3.54	g/dL	L	3.96	4.84
			Alanine Aminotransferase	53	U/L	H	12	48
			Aspartate Aminotransferase	40	U/L	H	11	38

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-001	Cycle 30	2012-07-22T08:33	Hemoglobin	11.4	g/dL	L	13.8	17.5
			Erythrocytes	3.93	10^12/L	L	4.34	5.72
			Platelets	100	10^9/L	L	150	424
			Lymphocytes	0.8	10^9/L	L	1.19	3.35
	Cycle 31	2012-07-16T09:30	Prothrombin Time	10.95	sec	L	11	13
		2012-07-16T09:57	Hemoglobin	12.4	g/dL	L	13.8	17.5
			Erythrocytes	4.27	10^12/L	L	4.34	5.72
			Platelets	116	10^9/L	L	150	424
			Lymphocytes	0.7	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Creatinine	0.679	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	51	U/L	H	12	48
			Aspartate Aminotransferase	47	U/L	H	11	38
		2012-07-20T09:07	Hemoglobin	12.3	g/dL	L	13.8	17.5
			Erythrocytes	4.25	10^12/L	L	4.34	5.72
			Platelets	114	10^9/L	L	150	424
			Lymphocytes	0.8	10^9/L	L	1.19	3.35
			Potassium	3.4	mmol/L	L	3.9	5.1
			Chloride	95	mmol/L	L	97	108
			Creatinine	0.826	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	64	U/L	H	12	48
			Aspartate Aminotransferase	49	U/L	H	11	38
			Glucose	129.7	mg/dL	H	76	115

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-002	Pre-trial	2011-07-25T09:50	Prothrombin Time	8.6	sec	L	11	13
			Activated Partial Thromboplastin Time	37	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	1.97	ratio	H	0.8	1.25
		2011-07-25T09:52	Hemoglobin	13.6	g/dL	L	13.8	17.5
			Erythrocytes	4.27	10^12/L	L	4.34	5.72
			Platelets	141	10^9/L	L	150	424
			Lymphocytes	0.6	10^9/L	L	1.19	3.35
			Aspartate Aminotransferase	49	U/L	H	11	38
			Lactate Dehydrogenase	327	U/L	H	0	240
			Glucose	124.3	mg/dL	H	76	115
	Cycle 1	2011-08-01T08:47	Hemoglobin	12.6	g/dL	L	13.8	17.5
			Erythrocytes	4.01	10^12/L	L	4.34	5.72
			Platelets	120	10^9/L	L	150	424
			Leukocytes	2.8	10^9/L	L	3.4	9.7
			Neutrophils	1.91	10^9/L	L	2.06	6.49
			Lymphocytes	0.46	10^9/L	L	1.19	3.35
			Chloride	109	mmol/L	H	97	108
			Lactate Dehydrogenase	279	U/L	H	0	240
			Glucose	138.7	mg/dL	H	76	115
		2011-08-01T09:00	Prothrombin Time	4.2	sec	L	11	13
			Prothrombin Intl. Normalized Ratio	1.59	ratio	H	0.8	1.25

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-002	Cycle 1	2011-08-04T08:03	Hemoglobin	11.5	g/dL	L	13.8	17.5
			Erythrocytes	3.66	10^12/L	L	4.34	5.72
			Platelets	111	10^9/L	L	150	424
			Lymphocytes	0.65	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Creatinine	0.769	mg/dL	L	0.89	1.41
			Albumin	3.79	g/dL	L	3.96	4.84
			Alanine Aminotransferase	67	U/L	H	12	48
			Aspartate Aminotransferase	39	U/L	H	11	38
			Glucose	135.1	mg/dL	H	76	115
		2011-08-12T10:13	Hemoglobin	13.5	g/dL	L	13.8	17.5
			Platelets	101	10^9/L	L	150	424
			Lymphocytes	0.58	10^9/L	L	1.19	3.35
			Aspartate Aminotransferase	39	U/L	H	11	38
			Lactate Dehydrogenase	319	U/L	H	0	240
			Bilirubin	1.637	mg/dL	H	0.18	1.17
			Glucose	140.5	mg/dL	H	76	115
	Cycle 2	2011-08-22T09:22	Hemoglobin	12.3	g/dL	L	13.8	17.5
			Erythrocytes	4.09	10^12/L	L	4.34	5.72
			Leukocytes	2.8	10^9/L	L	3.4	9.7
			Lymphocytes	0.36	10^9/L	L	1.19	3.35
			Eosinophils	1.5	10^9/L	H	0	0.43
			Basophils	0.5	10^9/L	H	0	0.05
			Creatinine	0.826	mg/dL	L	0.89	1.41
			Aspartate Aminotransferase	61	U/L	H	11	38
			Lactate Dehydrogenase	530	U/L	H	0	240

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-002	Cycle 2	2011-08-22T09:22	Bilirubin	1.287	mg/dL	H	0.18	1.17
			Glucose	120.7	mg/dL	H	76	115
		2011-08-22T09:30	Prothrombin Time	2.76	sec	L	11	13
			Activated Partial Thromboplastin Time	38	sec	H	23	33
		2011-08-26T09:17	Hemoglobin	11.2	g/dL	L	13.8	17.5
			Erythrocytes	3.71	10^12/L	L	4.34	5.72
			Platelets	130	10^9/L	L	150	424
			Leukocytes	3.2	10^9/L	L	3.4	9.7
			Lymphocytes	0.2	10^9/L	L	1.19	3.35
			Potassium	3.7	mmol/L	L	3.9	5.1
			Alanine Aminotransferase	63	U/L	H	12	48
			Aspartate Aminotransferase	41	U/L	H	11	38
			Lactate Dehydrogenase	321	U/L	H	0	240
			Glucose	115.3	mg/dL	H	76	115
	Cycle 3	2011-09-12T08:36	Hemoglobin	13.4	g/dL	L	13.8	17.5
			Lymphocytes	0.32	10^9/L	L	1.19	3.35
			Alanine Aminotransferase	72	U/L	H	12	48
			Aspartate Aminotransferase	41	U/L	H	11	38
			Lactate Dehydrogenase	433	U/L	H	0	240
			Glucose	192.8	mg/dL	H	76	115
		2011-09-12T08:40	Prothrombin Time	1.74	sec	L	11	13
			Activated Partial Thromboplastin Time	44	sec	H	23	33
			Prothrombin Intl. Normalized Ratio	3.65	ratio	H	0.8	1.25

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-002	Cycle 3	2011-09-16T08:37	Hemoglobin	13.2	g/dL	L	13.8	17.5
			Platelets	79	10^9/L	L	150	424
			Lymphocytes	0.27	10^9/L	L	1.19	3.35
			Creatinine	0.803	mg/dL	L	0.89	1.41
			Alanine Aminotransferase	59	U/L	H	12	48
			Lactate Dehydrogenase	363	U/L	H	0	240
			Bilirubin	1.287	mg/dL	H	0.18	1.17
			Glucose	135.1	mg/dL	H	76	115
	End Trial	2011-09-27T10:54	Hemoglobin	11.3	g/dL	L	13.8	17.5
			Erythrocytes	3.74	10^12/L	L	4.34	5.72
			Platelets	71	10^9/L	L	150	424
			Leukocytes	1.6	10^9/L	L	3.4	9.7
			Neutrophils	1.22	10^9/L	L	2.06	6.49
			Lymphocytes	0.25	10^9/L	L	1.19	3.35
			Monocytes	0.05	10^9/L	L	0.12	0.84
			Sodium	134	mmol/L	L	137	146
			Potassium	3.6	mmol/L	L	3.9	5.1
			Calcium	8.58	mg/dL	L	8.6	10.1
			Albumin	3.56	g/dL	L	3.96	4.84
			Alanine Aminotransferase	106	U/L	H	12	48
			Aspartate Aminotransferase	85	U/L	H	11	38
			Lactate Dehydrogenase	703	U/L	H	0	240
			Bilirubin	8.246	mg/dL	H	0.18	1.17

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
543-002	End Trial	2011-09-29T09:15	Prothrombin Time	1.64	sec	L	11	13
			Prothrombin Intl. Normalized Ratio	3.87	ratio	H	0.8	1.25
550-001	Pre-trial	2009-12-02T13:58	Erythrocytes	3.29	10^12/L	L	3.7	5.7
			Ery. Mean Corpuscular Volume	121.3	fL	H	80	100
			Lymphocytes	0.73	10^9/L	L	0.8	5.4
			Monocytes	0.78	10^9/L	H	0.05	0.7
			Lactate Dehydrogenase	344	U/L	H	100	240
		2009-12-02T14:01	Prothrombin Time	13.12	sec	H	11	13
	Cycle 1	2009-12-18T10:17	Erythrocytes	3.41	10^12/L	L	3.7	5.7
			Ery. Mean Corpuscular Volume	112	fL	H	80	100
			Lymphocytes	0.63	10^9/L	L	0.8	5.4
			Lactate Dehydrogenase	317.4	U/L	H	100	240
		2009-12-28T09:08	Ery. Mean Corpuscular Volume	112	fL	H	80	100
			Lactate Dehydrogenase	319.8	U/L	H	100	240
	Cycle 2	2010-01-04T08:05	Prothrombin Time	13.12	sec	H	11	13
		2010-01-04T10:32	Erythrocytes	3.46	10^12/L	L	3.7	5.7
			Ery. Mean Corpuscular Volume	113	fL	H	80	100
			Leukocytes	11.02	10^9/L	H	3.5	10
			Neutrophils	8.6	10^9/L	H	1.825	8
		2010-01-08T07:30	Erythrocytes	3.17	10^12/L	L	3.7	5.7
			Ery. Mean Corpuscular Volume	118.6	fL	H	80	100
			Monocytes	1	10^9/L	H	0.05	0.7
			Magnesium	2.43	mg/dL	H	1.8	2.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
550-001	End Trial	2010-01-25T08:30	Erythrocytes	3.69	10^12/L	L	3.7	5.7
			Ery. Mean Corpuscular Volume	114.4	fL	H	80	100
			Eosinophils	0.03	10^9/L	L	0.045	0.4
		2010-01-25T08:50	Prothrombin Time	14.16	sec	H	11	13
550-002	Pre-trial	2010-05-12T08:20	Lactate Dehydrogenase	241.8	U/L	H	100.2	240
			Urate	8.47	mg/dL	H	3.1	7.7
			Glucose	134.6	mg/dL	H	74	106
		2010-05-12T08:21	Hemoglobin	12.1	g/dL	L	13.4	17.5
			Erythrocytes	3.09	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	120.7	fL	H	80	100
			Leukocytes	16.94	10^9/L	H	3.5	10
			Neutrophils	11.18	10^9/L	H	1.825	8
			Monocytes	2.54	10^9/L	H	0.05	0.7
	Cycle 1	2010-05-17T07:50	Hemoglobin	12.4	g/dL	L	13.4	17.5
			Erythrocytes	3.15	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	120	fL	H	80	100
			Leukocytes	16.69	10^9/L	H	3.5	10
			Neutrophils	9.03	10^9/L	H	1.825	8
			Monocytes	4.03	10^9/L	H	0.05	0.7
			Eosinophils	0.96	10^9/L	H	0.045	0.4
			Basophils	0.16	10^9/L	H	0	0.05
			Lactate Dehydrogenase	272.4	U/L	H	100.2	240
			Glucose	148.3	mg/dL	H	74	106

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
550-002	Cycle 1	2010-05-21T08:05	Hemoglobin	11.9	g/dL	L	13.4	17.5
			Erythrocytes	3.02	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	120.9	fL	H	80	100
			Platelets	71	10^9/L	L	140	300
			Leukocytes	17.26	10^9/L	H	3.5	10
			Neutrophils	10.43	10^9/L	H	1.825	8
			Monocytes	3.77	10^9/L	H	0.05	0.7
			Eosinophils	1.64	10^9/L	H	0.045	0.4
			Basophils	0.16	10^9/L	H	0	0.05
			Creatinine	1.312	mg/dL	H	0.57	1.24
			Lactate Dehydrogenase	271.2	U/L	H	100.2	240
			Urate	7.8	mg/dL	H	3.1	7.7
			Glucose	127.5	mg/dL	H	74	106
		2010-06-01T07:35	Hemoglobin	10	g/dL	L	13.4	17.5
			Erythrocytes	2.52	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	122.6	fL	H	80	100
			Platelets	42	10^9/L	L	140	300
			Leukocytes	14.2	10^9/L	H	3.5	10
			Lymphocytes	5.96	10^9/L	H	0.8	5.4
			Magnesium	1.53	mg/dL	L	1.8	2.4
			Glucose	127.4	mg/dL	H	74	106

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
550-002	Unplanned	2010-06-07T08:15	Hemoglobin	9.4	g/dL	L	13.4	17.5
			Erythrocytes	2.38	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	119	fL	H	80	100
			Platelets	30	10^9/L	L	140	300
			Leukocytes	11.29	10^9/L	H	3.5	10
			Monocytes	1.95	10^9/L	H	0.05	0.7
			Eosinophils	0.72	10^9/L	H	0.045	0.4
			Basophils	0.08	10^9/L	H	0	0.05
			Magnesium	1.7	mg/dL	L	1.8	2.4
			Glucose	141.2	mg/dL	H	74	106
		2010-06-14T07:50	Hemoglobin	7.6	g/dL	L	13.4	17.5
			Erythrocytes	1.94	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	120.6	fL	H	80	100
			Platelets	17	10^9/L	L	140	300
			Leukocytes	12.94	10^9/L	H	3.5	10
			Monocytes	2.76	10^9/L	H	0.05	0.7
			Eosinophils	0.89	10^9/L	H	0.045	0.4
			Prothrombin Time	10.68	sec	L	11	13
			Magnesium	1.7	mg/dL	L	1.8	2.4
			Glucose	155.3	mg/dL	H	74	106
		2010-06-21T08:50	Hemoglobin	6.9	g/dL	L	13.4	17.5
			Erythrocytes	1.8	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	118.9	fL	H	80	100
			Platelets	16	10^9/L	L	140	300
			Leukocytes	10.44	10^9/L	H	3.5	10
			Monocytes	1.53	10^9/L	H	0.05	0.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
550-002	Unplanned	2010-06-21T08:50	Eosinophils	0.45	10^9/L	H	0.045	0.4
			Prothrombin Time	10.1	sec	L	11	13
			Calcium	8.46	mg/dL	L	8.6	10.2
			Magnesium	1.56	mg/dL	L	1.8	2.4
			Glucose	157.1	mg/dL	H	74	106
		2010-06-28T07:55	Hemoglobin	6.1	g/dL	L	13.4	17.5
			Erythrocytes	1.59	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	113.8	fL	H	80	100
			Platelets	9	10^9/L	L	140	300
			Lymphocytes	5.56	10^9/L	H	0.8	5.4
			Monocytes	0.98	10^9/L	H	0.05	0.7
			Magnesium	1.75	mg/dL	L	1.8	2.4
			Lactate Dehydrogenase	261	U/L	H	100.2	240
			Bilirubin	1.023	mg/dL	H	0.01	1
			Glucose	151.3	mg/dL	H	74	106
	End Trial	2010-07-06T08:15	Hemoglobin	7.3	g/dL	L	13.4	17.5
			Erythrocytes	2.03	10^12/L	L	4.2	5.6
			Ery. Mean Corpuscular Volume	104.9	fL	H	80	100
			Platelets	12	10^9/L	L	140	300
			Lymphocytes	5.95	10^9/L	H	0.8	5.4
			Monocytes	1.13	10^9/L	H	0.05	0.7
			Magnesium	1.56	mg/dL	L	1.8	2.4
			Albumin	3.37	g/dL	L	3.5	5
			Blood Urea Nitrogen	24.65	mg/dL	H	4.8	23.2
			Glucose	172.9	mg/dL	H	74	106

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	Pre-trial	2010-10-28T13:32	Hemoglobin	8.7	g/dL	L	14	17.5
			Erythrocytes	2.69	10^12/L	L	4.5	5.9
			Platelets	89	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	12	U/L	L	15	55
			Lactate Dehydrogenase	231	U/L	H	110	220
			Blood Urea Nitrogen	36.13	mg/dL	H	9	23.8
	Cycle 1	2010-11-08T09:43	Hemoglobin	8.3	g/dL	L	14	17.5
			Erythrocytes	2.53	10^12/L	L	4.5	5.9
			Platelets	78	10^9/L	L	150	400
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
		2010-11-08T09:59	Aspartate Aminotransferase	13	U/L	L	15	55
			Blood Urea Nitrogen	33.05	mg/dL	H	9	23.8
		2010-11-12T09:57	Hemoglobin	9.6	g/dL	L	14	17.5
			Erythrocytes	2.99	10^12/L	L	4.5	5.9
			Platelets	74	10^9/L	L	150	400
			Leukocytes	3.9	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	11	U/L	L	15	55
			Blood Urea Nitrogen	40.9	mg/dL	H	9	23.8
		2010-11-19T10:12	Hemoglobin	9.6	g/dL	L	14	17.5
			Erythrocytes	3.04	10^12/L	L	4.5	5.9
			Platelets	61	10^9/L	L	150	400
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
			Magnesium	1.58	mg/dL	L	1.7	3
			Aspartate Aminotransferase	11	U/L	L	15	55

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	Cycle 1	2010-11-19T10:12	Blood Urea Nitrogen	38.38	mg/dL	H	9	23.8
	Cycle 2	2010-11-29T09:39	Hemoglobin	9.9	g/dL	L	14	17.5
			Erythrocytes	3.08	10^12/L	L	4.5	5.9
			Platelets	70	10^9/L	L	150	400
			Leukocytes	3.2	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
			Magnesium	1.58	mg/dL	L	1.7	3
			Aspartate Aminotransferase	14	U/L	L	15	55
			Blood Urea Nitrogen	35.01	mg/dL	H	9	23.8
		2010-12-03T09:40	Hemoglobin	9.3	g/dL	L	14	17.5
			Erythrocytes	2.9	10^12/L	L	4.5	5.9
			Platelets	61	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	1.8	7.5
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	12	U/L	L	15	55
			Blood Urea Nitrogen	28.29	mg/dL	H	9	23.8
			Glucose	153.1	mg/dL	H	70	141
	Cycle 3	2010-12-30T09:11	Hemoglobin	7.4	g/dL	L	14	17.5
			Erythrocytes	2.37	10^12/L	L	4.5	5.9
			Platelets	58	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	11
			Neutrophils	1.6	10^9/L	L	1.8	7.5
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
			Magnesium	1.63	mg/dL	L	1.7	3
			Aspartate Aminotransferase	14	U/L	L	15	55

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	Cycle 3	2010-12-30T09:11	Blood Urea Nitrogen	30.53	mg/dL	H	9	23.8
		2011-01-06T09:41	Hemoglobin	9.3	g/dL	L	14	17.5
			Erythrocytes	3.01	10^12/L	L	4.5	5.9
			Platelets	57	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4	11
			Neutrophils	1.4	10^9/L	L	1.8	7.5
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
			Calcium	10.66	mg/dL	H	8.5	10.5
			Lactate Dehydrogenase	222	U/L	H	110	220
			Blood Urea Nitrogen	30.53	mg/dL	H	9	23.8
	Cycle 4	2011-01-24T10:18	Hemoglobin	8.3	g/dL	L	14	17.5
			Erythrocytes	2.58	10^12/L	L	4.5	5.9
			Platelets	90	10^9/L	L	150	400
			Leukocytes	2.8	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	11	U/L	L	15	55
			Blood Urea Nitrogen	33.05	mg/dL	H	9	23.8
		2011-01-28T09:01	Hemoglobin	6.7	g/dL	L	14	17.5
			Erythrocytes	2.09	10^12/L	L	4.5	5.9
			Platelets	71	10^9/L	L	150	400
			Leukocytes	2.2	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	1.8	7.5
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
		2011-01-28T09:16	Aspartate Aminotransferase	14	U/L	L	15	55
			Blood Urea Nitrogen	24.93	mg/dL	H	9	23.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	Cycle 5	2011-02-14T07:54	Hemoglobin	9	g/dL	L	14	17.5
			Erythrocytes	2.88	10^12/L	L	4.5	5.9
			Platelets	102	10^9/L	L	150	400
			Leukocytes	3.3	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	12	U/L	L	15	55
			Blood Urea Nitrogen	35.01	mg/dL	H	9	23.8
		2011-02-18T09:31	Hemoglobin	7.7	g/dL	L	14	17.5
			Erythrocytes	2.39	10^12/L	L	4.5	5.9
			Platelets	92	10^9/L	L	150	400
			Leukocytes	2.8	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
		2011-02-18T09:48	Aspartate Aminotransferase	13	U/L	L	15	55
			Lactate Dehydrogenase	225	U/L	H	110	220
			Blood Urea Nitrogen	29.13	mg/dL	H	9	23.8
	Cycle 6	2011-03-07T11:46	Hemoglobin	9.5	g/dL	L	14	17.5
			Erythrocytes	3.17	10^12/L	L	4.5	5.9
			Platelets	78	10^9/L	L	150	400
			Leukocytes	3.5	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	12	U/L	L	15	55
			Blood Urea Nitrogen	33.33	mg/dL	H	9	23.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	Cycle 6	2011-03-10T11:00	Hemoglobin	8.7	g/dL	L	14	17.5
			Erythrocytes	2.83	10^12/L	L	4.5	5.9
			Platelets	68	10^9/L	L	150	400
			Leukocytes	2.6	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	1.8	7.5
			Lymphocytes	0.1	10^9/L	L	1.2	3.5
			Blood Urea Nitrogen	29.69	mg/dL	H	9	23.8
	Cycle 7	2011-04-18T11:04	Hemoglobin	9	g/dL	L	14	17.5
			Erythrocytes	2.95	10^12/L	L	4.5	5.9
			Platelets	49	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	11
			Neutrophils	1.6	10^9/L	L	1.8	7.5
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	14	U/L	L	15	55
			Blood Urea Nitrogen	39.22	mg/dL	H	9	23.8
		2011-04-22T10:29	Hemoglobin	9.4	g/dL	L	14	17.5
			Erythrocytes	3.12	10^12/L	L	4.5	5.9
			Platelets	46	10^9/L	L	150	400
			Leukocytes	2.3	10^9/L	L	4	11
			Neutrophils	1.5	10^9/L	L	1.8	7.5
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Aspartate Aminotransferase	10	U/L	L	15	55
			Bilirubin	1.053	mg/dL	H	0.18	0.99
			Blood Urea Nitrogen	37.54	mg/dL	H	9	23.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	Cycle 8	2011-05-16T10:32	Hemoglobin	7.5	g/dL	L	14	17.5
			Erythrocytes	2.5	10^12/L	L	4.5	5.9
			Platelets	53	10^9/L	L	150	400
			Leukocytes	2.5	10^9/L	L	4	11
			Neutrophils	1.7	10^9/L	L	1.8	7.5
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Sodium	133	mmol/L	L	134	144
			Bilirubin	1.053	mg/dL	H	0.18	0.99
			Blood Urea Nitrogen	32.77	mg/dL	H	9	23.8
		2011-05-20T10:09	Hemoglobin	7.5	g/dL	L	14	17.5
			Erythrocytes	2.49	10^12/L	L	4.5	5.9
			Platelets	38	10^9/L	L	150	400
			Leukocytes	1.7	10^9/L	L	4	11
			Neutrophils	1.4	10^9/L	L	1.8	7.5
			Lymphocytes	0.1	10^9/L	L	1.2	3.5
			Monocytes	0.1	10^9/L	L	0.2	0.8
		2011-05-20T11:08	Sodium	132	mmol/L	L	134	144
			Phosphate	1.92	mg/dL	L	2.5	4.5
			Magnesium	1.6	mg/dL	L	1.7	3
			Creatinine	1.414	mg/dL	H	0.62	1.36
			Bilirubin	1.345	mg/dL	H	0.18	0.99
			Blood Urea Nitrogen	38.38	mg/dL	H	9	23.8
			Glucose	144.1	mg/dL	H	70	141

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-003	End Trial	2011-06-24T06:45	Potassium	2.6	mmol/L	L	3.5	5.5
			Calcium	8.14	mg/dL	L	8.5	10.5
			Chloride	97	mmol/L	L	98	108
			Albumin	2.6	g/dL	L	3.5	5.1
			Alkaline Phosphatase	142	U/L	H	40	125
			Lactate Dehydrogenase	453	U/L	H	110	220
			Bilirubin	1.637	mg/dL	H	0.18	0.99
			Blood Urea Nitrogen	32.49	mg/dL	H	9	23.8
		2011-06-24T07:14	Hemoglobin	7.3	g/dL	L	14	17.5
			Erythrocytes	2.62	10^12/L	L	4.5	5.9
			Platelets	23	10^9/L	L	150	400
			Leukocytes	0.2	10^9/L	L	4	11
			Neutrophils	0.1	10^9/L	L	1.8	7.5
			Lymphocytes	0.1	10^9/L	L	1.2	3.5
			Monocytes	0	10^9/L	L	0.2	0.8
600-004	Pre-trial	2010-11-11T10:04	Erythrocytes	4.03	10^12/L	L	4.1	5.1
			Platelets	113	10^9/L	L	150	400
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
			Alanine Aminotransferase	42	U/L	H	5	40
			Lactate Dehydrogenase	274	U/L	H	110	220

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-004	Cycle 1	2010-11-15T09:45	Hemoglobin	11.6	g/dL	L	12	15.2
			Erythrocytes	3.94	10^12/L	L	4.1	5.1
			Platelets	109	10^9/L	L	150	400
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
			Alanine Aminotransferase	44	U/L	H	5	40
			Lactate Dehydrogenase	291	U/L	H	110	220
		2010-11-19T10:05	Hemoglobin	11.2	g/dL	L	12	15.2
			Erythrocytes	3.68	10^12/L	L	4.1	5.1
			Platelets	104	10^9/L	L	150	400
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
		2010-11-19T10:41	Phosphate	4.86	mg/dL	H	2.5	4.5
			Alanine Aminotransferase	42	U/L	H	5	40
			Lactate Dehydrogenase	291	U/L	H	110	220
			Glucose	145.9	mg/dL	H	70	141
		2010-11-26T11:12	Erythrocytes	4.04	10^12/L	L	4.1	5.1
			Platelets	125	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	1.2	3.5
		2010-11-26T11:31	Alanine Aminotransferase	41	U/L	H	5	40
			Lactate Dehydrogenase	379	U/L	H	110	220
	Cycle 2	2010-12-06T09:18	Hemoglobin	11.4	g/dL	L	12	15.2
			Erythrocytes	3.89	10^12/L	L	4.1	5.1
			Platelets	133	10^9/L	L	150	400
			Lymphocytes	0.7	10^9/L	L	1.2	3.5
			Lactate Dehydrogenase	370	U/L	H	110	220

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-004	Cycle 2	2010-12-10T10:08	Hemoglobin	11.5	g/dL	L	12	15.2
			Erythrocytes	3.82	10^12/L	L	4.1	5.1
			Platelets	136	10^9/L	L	150	400
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
			Lactate Dehydrogenase	327	U/L	H	110	220
			Glucose	181.9	mg/dL	H	70	141
	Cycle 3	2010-12-30T08:45	Platelets	136	10^9/L	L	150	400
			Lymphocytes	1.1	10^9/L	L	1.2	3.5
			Potassium	3.3	mmol/L	L	3.5	5.5
			Lactate Dehydrogenase	319	U/L	H	110	220
			Glucose	160.3	mg/dL	H	70	141
		2011-01-07T09:15	Hemoglobin	11.5	g/dL	L	12	15.2
			Erythrocytes	3.82	10^12/L	L	4.1	5.1
			Platelets	102	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	1.2	3.5
		2011-01-07T09:42	Lactate Dehydrogenase	297	U/L	H	110	220
			Glucose	149.5	mg/dL	H	70	141
	Cycle 4	2011-01-24T10:50	Hemoglobin	10.9	g/dL	L	12	15.2
			Erythrocytes	3.7	10^12/L	L	4.1	5.1
			Platelets	94	10^9/L	L	150	400
			Leukocytes	3	10^9/L	L	4	11
			Neutrophils	1.4	10^9/L	L	1.8	7.5
			Lymphocytes	0.6	10^9/L	L	1.2	3.5
			Activated Partial Thromboplastin Time	24.1	sec	L	27	35
			Lactate Dehydrogenase	456	U/L	H	110	220

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
600-004	Cycle 4	2011-01-28T09:24	Hemoglobin	10.3	g/dL	L	12	15.2
			Erythrocytes	3.55	10^12/L	L	4.1	5.1
			Platelets	96	10^9/L	L	150	400
			Leukocytes	3.4	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	1.2	3.5
			Eosinophils	0.6	10^9/L	H	0	0.5
			Lactate Dehydrogenase	378	U/L	H	110	220
			Glucose	147.7	mg/dL	H	70	141
	End Trial	2011-02-14T09:27	Hemoglobin	11.9	g/dL	L	12	15.2
			Erythrocytes	4.06	10^12/L	L	4.1	5.1
			Platelets	117	10^9/L	L	150	400
			Leukocytes	3.3	10^9/L	L	4	11
			Neutrophils	1.6	10^9/L	L	1.8	7.5
			Lymphocytes	0.5	10^9/L	L	1.2	3.5
			Eosinophils	0.8	10^9/L	H	0	0.5
			Activated Partial Thromboplastin Time	25	sec	L	27	35
			Lactate Dehydrogenase	381	U/L	H	110	220
751-001	Pre-trial	2011-01-27T12:00	Ery. Mean Corpuscular Volume	82.4	fL	L	83	101
			Aspartate Aminotransferase	34	U/L	H	0	32
			Lactate Dehydrogenase	375	U/L	H	135	214
			Urate	7.06	mg/dL	H	2.4	5.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
751-001	Cycle 1	2011-02-01T09:10	Ery. Mean Corpuscular Volume	80.1	fL	L	83	101
			Aspartate Aminotransferase	33	U/L	H	0	32
			Lactate Dehydrogenase	416	U/L	H	135	214
			Urate	8.07	mg/dL	H	2.4	5.7
		2011-02-07T09:40	Ery. Mean Corpuscular Volume	80.2	fL	L	83	101
			Leukocytes	10.84	10^9/L	H	4	10
			Neutrophils	8.35	10^9/L	H	2	7
			Lactate Dehydrogenase	220	U/L	H	135	214
			Urate	5.88	mg/dL	H	2.4	5.7
		2011-02-14T10:25	Lymphocytes	0.76	10^9/L	L	1	3
			Lactate Dehydrogenase	312	U/L	H	135	214
			Urate	6.39	mg/dL	H	2.4	5.7
	Cycle 2	2011-02-21T09:40	Ery. Mean Corpuscular Volume	81	fL	L	83	101
			Lactate Dehydrogenase	324	U/L	H	135	214
			Urate	6.89	mg/dL	H	2.4	5.7
		2011-02-25T08:25	Ery. Mean Corpuscular Volume	82.5	fL	L	83	101
			Lymphocytes	0.9	10^9/L	L	1	3
			Eosinophils	0.01	10^9/L	L	0.02	0.5
			Basophils	0.01	10^9/L	L	0.02	0.1
	Cycle 3	2011-03-22T10:08	Lactate Dehydrogenase	384	U/L	H	135	214
	Cycle 4	2011-04-11T08:15	Basophils	0	10^9/L	L	0.02	0.1
			Lactate Dehydrogenase	373	U/L	H	135	214

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
751-001	Cycle 4	2011-04-15T08:25	Lymphocytes	0.83	10^9/L	L	1	3
			Eosinophils	0	10^9/L	L	0.02	0.5
			Basophils	0.01	10^9/L	L	0.02	0.1
			Lactate Dehydrogenase	242	U/L	H	135	214
			Glucose	158.5	mg/dL	H	74	141
	Cycle 5	2011-05-03T09:05	Lactate Dehydrogenase	412	U/L	H	135	214
			Blood Urea Nitrogen	7.6	mg/dL	L	8	23
		2011-05-07T15:40	Platelets	435	10^9/L	H	150	400
			Lymphocytes	0.5	10^9/L	L	1	3
			Monocytes	0.14	10^9/L	L	0.2	1
			Basophils	0	10^9/L	L	0.02	0.1
			Magnesium	2.77	mg/dL	H	1.6	2.7
			Lactate Dehydrogenase	216	U/L	H	100	190
			Glucose	144.1	mg/dL	H	74	141
	End Trial	2011-05-30T08:25	Sodium	135	mmol/L	L	136	145
			Potassium	7.1	mmol/L	H	3.5	5.1
			Aspartate Aminotransferase	99	U/L	H	0	32
			Lactate Dehydrogenase	1310	U/L	H	135	214
752-001	Pre-trial	2010-03-08T13:30	Leukocytes	17.2	10^9/L	H	4	10
			Neutrophils	15.3	10^9/L	H	2	7
			Basophils	0	10^9/L	L	0.02	0.1
			Activated Partial Thromboplastin Time	21	sec	L	23.6	30.6
			Alanine Aminotransferase	78	U/L	H	0	55
			Lactate Dehydrogenase	274	U/L	H	125	243

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
752-001	Pre-trial	2010-03-08T13:30	Glucose	189.2	mg/dL	H	65	115
	Cycle 1	2010-03-15T09:45	Leukocytes	10.8	10^9/L	H	4	10
			Neutrophils	8.2	10^9/L	H	2	7
			Basophils	0	10^9/L	L	0.02	0.1
			Albumin	3.4	g/dL	L	3.5	5
			Glucose	120.7	mg/dL	H	65	115
		2010-03-19T08:30	Leukocytes	19.1	10^9/L	H	4	10
			Neutrophils	15.1	10^9/L	H	2	7
			Monocytes	1.5	10^9/L	H	0.2	1
			Chloride	97	mmol/L	L	98	107
			Magnesium	2.99	mg/dL	H	2.1	2.8
			Alanine Aminotransferase	145	U/L	H	0	55
			Aspartate Aminotransferase	51	U/L	H	5	34
			Lactate Dehydrogenase	393	U/L	H	125	243
			Urate	6.9	mg/dL	H	2.5	5.9
			Glucose	153.1	mg/dL	H	65	115
		2010-03-29T15:00	Leukocytes	13.2	10^9/L	H	4	10
			Neutrophils	9.7	10^9/L	H	2	7
			Monocytes	1.2	10^9/L	H	0.2	1
			Basophils	0	10^9/L	L	0.02	0.1
			Magnesium	2.02	mg/dL	L	2.1	2.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
752-002	Pre-trial	2011-02-15T13:10	Hemoglobin	12.3	g/dL	L	13	17
			Lymphocytes	0.5	10^9/L	L	1	3
			Eosinophils	0	10^9/L	L	0.02	0.5
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	135	mmol/L	L	136	145
			Magnesium	2.07	mg/dL	L	2.1	2.8
			Albumin	2.9	g/dL	L	3.5	5
			Alkaline Phosphatase	480	U/L	H	40	150
			Lactate Dehydrogenase	473	U/L	H	125	243
			Urate	7.57	mg/dL	H	2.5	5.9
	Cycle 1	2011-02-28T11:15	Basophils	0	10^9/L	L	0.02	0.1
			Sodium	134	mmol/L	L	136	145
			Albumin	2.8	g/dL	L	3.5	5
			Aspartate Aminotransferase	40	U/L	H	5	34
			Alkaline Phosphatase	642	U/L	H	40	150
			Lactate Dehydrogenase	537	U/L	H	125	243
			Urate	6.9	mg/dL	H	2.5	5.9
		2011-03-04T10:55	Hemoglobin	12.7	g/dL	L	13	17
			Leukocytes	12.2	10^9/L	H	4	10
			Neutrophils	10.5	10^9/L	H	2	7
			Lymphocytes	0.7	10^9/L	L	1	3
			Basophils	0	10^9/L	L	0.02	0.1
			Albumin	3.3	g/dL	L	3.5	5
			Alkaline Phosphatase	534	U/L	H	40	150
			Lactate Dehydrogenase	435	U/L	H	125	243
			Blood Urea Nitrogen	24.9	mg/dL	H	9.8	20.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
752-002	Cycle 1	2011-03-14T11:05	Platelets	91	10^9/L	L	150	400
			Potassium	5.5	mmol/L	H	3.5	5.1
			Aspartate Aminotransferase	40	U/L	H	5	34
			Alkaline Phosphatase	380	U/L	H	40	150
			Lactate Dehydrogenase	431	U/L	H	125	243
	Cycle 2	2011-03-28T09:00	Hemoglobin	12.4	g/dL	L	13	17
			Basophils	0	10^9/L	L	0.02	0.1
			Magnesium	1.97	mg/dL	L	2.1	2.8
			Albumin	2.9	g/dL	L	3.5	5
			Alkaline Phosphatase	640	U/L	H	40	150
			Lactate Dehydrogenase	523	U/L	H	125	243
			Blood Urea Nitrogen	7.2	mg/dL	L	9.8	20.1
			Glucose	59.4	mg/dL	L	65	115
		2011-04-01T08:45	Hemoglobin	11.5	g/dL	L	13	17
			Platelets	87	10^9/L	L	150	400
			Monocytes	1.82	10^9/L	H	0.2	1
			Basophils	0	10^9/L	L	0.02	0.1
		2011-04-01T10:00	Phosphate	2.35	mg/dL	L	2.5	4.7
			Alkaline Phosphatase	526	U/L	H	40	150
			Lactate Dehydrogenase	629	U/L	H	125	243
			Blood Urea Nitrogen	6.8	mg/dL	L	9.8	20.1
	Cycle 3	2011-04-14T16:15	Hemoglobin	11.5	g/dL	L	13	17
			Platelets	86	10^9/L	L	150	400
			Lymphocytes	0.8	10^9/L	L	1	3
			Basophils	0	10^9/L	L	0.02	0.1

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
752-002	Cycle 3	2011-04-14T17:46	Sodium	134	mmol/L	L	136	145
			Magnesium	1.87	mg/dL	L	2.1	2.8
			Albumin	3.3	g/dL	L	3.5	5
			Aspartate Aminotransferase	35	U/L	H	5	34
			Alkaline Phosphatase	422	U/L	H	40	150
			Lactate Dehydrogenase	367	U/L	H	125	243
	Cycle 4	2011-05-08T21:25	Hemoglobin	9.5	g/dL	L	13	17
			Lymphocytes	0.8	10^9/L	L	1	3
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	132	mmol/L	L	136	145
			Calcium	8.34	mg/dL	L	8.6	10
			Creatinine	1.267	mg/dL	H	0.72	1.18
			Albumin	2.5	g/dL	L	3.5	5
			Alkaline Phosphatase	455	U/L	H	40	150
			Lactate Dehydrogenase	585	U/L	H	125	243
			Bilirubin	1.801	mg/dL	H	0.2	1.2
			Blood Urea Nitrogen	29.7	mg/dL	H	9.8	20.1
			Urate	7.73	mg/dL	H	2.5	5.9
		2011-05-13T08:45	Hemoglobin	12.1	g/dL	L	13	17
			Platelets	102	10^9/L	L	150	400
			Lymphocytes	0.77	10^9/L	L	1	3
			Monocytes	0.11	10^9/L	L	0.2	1
			Calcium	8.5	mg/dL	L	8.6	10
			Chloride	115	mmol/L	H	98	107
			Albumin	3	g/dL	L	3.5	5
			Alkaline Phosphatase	406	U/L	H	40	150

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
752-002	Cycle 4	2011-05-13T08:45	Lactate Dehydrogenase	602	U/L	H	125	243
			Blood Urea Nitrogen	42.6	mg/dL	H	9.8	20.1
			Urate	7.4	mg/dL	H	2.5	5.9
			Glucose	117.1	mg/dL	H	65	115
800-001	Pre-trial	2010-12-19T08:30	Leukocytes	4.76	10^9/L	L	4.8	10.8
			Potassium	Hemolytic	mmol/L	L	3.5	5
			Creatinine	0.39	mg/dL	L	0.51	0.95
			Aspartate Aminotransferase	Hemolytic	U/L	L	0	31
			Lactate Dehydrogenase	Hemolytic	U/L	L	230	480
	Cycle 1	2011-01-02T08:35	Leukocytes	3.78	10^9/L	L	4.8	10.8
			Creatinine	0.33	mg/dL	L	0.51	0.95
			Glucose	101	mg/dL	H	70	100
		2011-01-06T07:05	Hemoglobin	11.8	g/dL	L	12	16
			Erythrocytes	4.08	10^12/L	L	4.2	5.4
			Lymphocytes	0.8	10^9/L	L	0.9	5.2
		2011-01-06T08:39	Creatinine	0.4	mg/dL	L	0.51	0.95
			Alanine Aminotransferase	60	U/L	H	0	35
			Aspartate Aminotransferase	39	U/L	H	0	31
		2011-01-18T15:22	Calcium	10.6	mg/dL	H	8.5	10.5
			Creatinine	0.3	mg/dL	L	0.51	0.95
	Cycle 2	2011-01-23T08:15	Creatinine	0.33	mg/dL	L	0.51	0.95
		2011-01-27T06:59	Erythrocytes	4.13	10^12/L	L	4.2	5.4
			Leukocytes	4.72	10^9/L	L	4.8	10.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
800-001	Cycle 2	2011-01-27T08:31	Creatinine	0.41	mg/dL	L	0.51	0.95
			Alanine Aminotransferase	163	U/L	H	0	35
			Aspartate Aminotransferase	92	U/L	H	0	31
	End Trial	2011-02-15T10:42	Creatinine	0.37	mg/dL	L	0.51	0.95
801-001	Pre-trial	2011-03-07T09:30	Hemoglobin	7.8	g/dL	L	12	16
			Erythrocytes	3.18	10^12/L	L	4.2	5.4
			Ery. Mean Corpuscular Volume	75.6	fL	L	77	91
			Platelets	123	10^9/L	L	140	400
			Leukocytes	2.9	10^9/L	L	4	10
			Lymphocytes	0.4	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Prothrombin Time	9.23	sec	L	11	13
			Sodium	130	mmol/L	L	135	145
			Albumin	3.2	g/dL	L	3.5	5
			Alkaline Phosphatase	246	U/L	H	40	130
			Lactate Dehydrogenase	529	U/L	H	240	480
			Glucose	115.3	mg/dL	H	72	108
	Cycle 1	2011-03-09T09:51	Hemoglobin	11	g/dL	L	12	16
			Platelets	96	10^9/L	L	140	400
			Leukocytes	3.4	10^9/L	L	4	10
			Lymphocytes	0.4	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	132	mmol/L	L	135	145

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
801-001	Cycle 1	2011-03-09T09:51	Albumin	3.1	g/dL	L	3.5	5
			Alkaline Phosphatase	257	U/L	H	40	130
			Glucose	117.1	mg/dL	H	72	108
		2011-03-13T10:30	Hemoglobin	8.5	g/dL	L	12	16
			Erythrocytes	3.31	10^12/L	L	4.2	5.4
			Ery. Mean Corpuscular Volume	76.8	fL	L	77	91
			Platelets	54	10^9/L	L	140	400
			Lymphocytes	0.5	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	131	mmol/L	L	135	145
			Calcium	8.18	mg/dL	L	8.6	10.2
			Albumin	2.6	g/dL	L	3.5	5
			Alkaline Phosphatase	415	U/L	H	40	130
			Lactate Dehydrogenase	497	U/L	H	240	480
			Bilirubin	1.111	mg/dL	H	0	0.99
			Glucose	140.5	mg/dL	H	72	108
		2011-03-21T11:20	Hemoglobin	6.1	g/dL	L	12	16
			Erythrocytes	2.67	10^12/L	L	4.2	5.4
			Ery. Mean Corpuscular Volume	22.8	fL	L	77	91
			Platelets	52	10^9/L	L	140	400
			Lymphocytes	0.5	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	132	mmol/L	L	135	145
			Alkaline Phosphatase	373	U/L	H	30	120
			Lactate Dehydrogenase	658	U/L	H	208	480

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
801-001	Cycle 1	2011-03-21T11:20	Glucose	111	mg/dL	H	74	106
	End Trial	2011-04-03T08:50	Hemoglobin	11.3	g/dL	L	12	16
			Platelets	7	10^9/L	L	140	400
			Neutrophils	7.6	10^9/L	H	2	7.5
			Lymphocytes	0.6	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Phosphate	2.17	mg/dL	L	2.5	4.3
			Albumin	2.3	g/dL	L	3.5	5
			Alkaline Phosphatase	228	U/L	H	40	130
			Lactate Dehydrogenase	1182	U/L	H	240	480
			Bilirubin	2.573	mg/dL	H	0	0.99
			Blood Urea Nitrogen	44.54	mg/dL	H	0	23.2
			Urate	7.75	mg/dL	H	2.5	6.4
			Glucose	127.9	mg/dL	H	72	108
		2011-04-03T11:09	Prothrombin Time	9.75	sec	L	11	13
801-002	Pre-trial	2011-05-31T12:22	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.45	10^12/L	L	4.2	5.4
			Ery. Mean Corpuscular Volume	93.6	fL	H	77	91
			Lymphocytes	0.6	10^9/L	L	1.5	4
			Monocytes	0.9	10^9/L	H	0.2	0.8
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
801-002	Pre-trial	2011-05-31T12:24	Sodium	132	mmol/L	L	135	145
			Potassium	3.2	mmol/L	L	3.5	5
			Aspartate Aminotransferase	44	U/L	H	0	35
			Lactate Dehydrogenase	618	U/L	H	240	480
	Cycle 1	2011-06-05T10:19	Hemoglobin	10.4	g/dL	L	12	16
			Erythrocytes	3.53	10^12/L	L	4.2	5.4
			Ery. Mean Corpuscular Volume	92.2	fL	H	77	91
			Lymphocytes	0.3	10^9/L	L	1.5	4
			Basophils	0	10^9/L	L	0.02	0.1
		2011-06-05T10:22	Sodium	133	mmol/L	L	135	145
			Aspartate Aminotransferase	52	U/L	H	0	35
			Lactate Dehydrogenase	797	U/L	H	240	480
		2011-06-10T10:42	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.4	10^12/L	L	4.2	5.4
			Platelets	120	10^9/L	L	140	400
			Lymphocytes	0.2	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
		2011-06-10T10:51	Glucose	126.1	mg/dL	H	72	108
		2011-06-19T09:31	Hemoglobin	11	g/dL	L	12	18
			Erythrocytes	3.92	10^12/L	L	4.2	6.1
			Lymphocytes	0.36	10^9/L	L	0.9	5.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
801-002	Cycle 2	2011-06-27T10:35	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.46	10^12/L	L	4.2	5.4
			Platelets	97	10^9/L	L	140	400
			Lymphocytes	0.2	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	129	mmol/L	L	135	145
			Calcium	7.9	mg/dL	L	8.6	10.2
			Chloride	94	mmol/L	L	95	105
			Phosphate	1.86	mg/dL	L	2.5	4.3
			Albumin	3	g/dL	L	3.5	5
			Aspartate Aminotransferase	48	U/L	H	0	35
			Lactate Dehydrogenase	1465	U/L	H	240	480
		2011-07-01T08:46	Hemoglobin	9.2	g/dL	L	12	16
			Erythrocytes	3.19	10^12/L	L	4.2	5.4
			Platelets	55	10^9/L	L	140	400
			Leukocytes	3.6	10^9/L	L	4	10
			Lymphocytes	0.1	10^9/L	L	1.5	4
			Eosinophils	0	10^9/L	L	0.04	0.4
			Basophils	0	10^9/L	L	0.02	0.1
			Sodium	132	mmol/L	L	135	145
			Calcium	8.38	mg/dL	L	8.6	10.2
			Albumin	3.2	g/dL	L	3.5	5
			Aspartate Aminotransferase	39	U/L	H	0	35
			Lactate Dehydrogenase	1648	U/L	H	240	480
			Glucose	113.5	mg/dL	H	72	108

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
801-002	Unplanned	2011-06-09T09:29	Sodium	133	mmol/L	L	135	145
			Potassium	2.7	mmol/L	L	3.5	5
			Aspartate Aminotransferase	49	U/L	H	0	35
			Alkaline Phosphatase	135	U/L	H	40	130
			Lactate Dehydrogenase	835	U/L	H	240	480
			Glucose	129.7	mg/dL	H	72	108
803-001	Pre-trial	2011-03-24T09:37	Chloride	107	mmol/L	H	98	106
			Aspartate Aminotransferase	47	U/L	H	0	35
			Alkaline Phosphatase	215	U/L	H	30	120
			Lactate Dehydrogenase	1736	U/L	H	230	480
		2011-03-24T09:39	Hemoglobin	10.7	g/dL	L	14	18
			Erythrocytes	4.11	10^12/L	L	4.7	6.1
			Platelets	445	10^9/L	H	130	400
			Leukocytes	116	10^9/L	H	4.8	10.8
			Neutrophils	25.58	10^9/L	H	1.9	8
			Lymphocytes	76.49	10^9/L	H	0.9	5.2
			Monocytes	1.73	10^9/L	H	0.16	1
			Basophils	3.65	10^9/L	H	0	0.2
		2011-03-24T10:22	Activated Partial Thromboplastin Time	24.6	sec	L	26	39

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
803-001	Cycle 1	2011-03-28T09:21	Hemoglobin	10.2	g/dL	L	14	18
			Erythrocytes	3.35	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	95.6	fL	H	80	94
			Leukocytes	83.71	10^9/L	H	4.8	10.8
			Neutrophils	16.35	10^9/L	H	1.9	8
			Lymphocytes	56.4	10^9/L	H	0.9	5.2
			Monocytes	1.28	10^9/L	H	0.16	1
			Basophils	3.35	10^9/L	H	0	0.2
		2011-03-28T09:30	Chloride	109	mmol/L	H	98	106
			Aspartate Aminotransferase	42	U/L	H	0	35
			Alkaline Phosphatase	159	U/L	H	30	120
			Lactate Dehydrogenase	1490	U/L	H	230	480
		2011-03-28T10:14	Activated Partial Thromboplastin Time	22.8	sec	L	26	39
		2011-04-01T12:20	Hemoglobin	9.5	g/dL	L	14	18
			Erythrocytes	2.97	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	95.3	fL	H	80	94
			Leukocytes	66.5	10^9/L	H	4.8	10.8
			Neutrophils	10.3	10^9/L	H	1.9	8
			Lymphocytes	39.2	10^9/L	H	0.9	5.2
			Monocytes	16.5	10^9/L	H	0.16	1
			Chloride	108	mmol/L	H	98	106
			Magnesium	1.3	mg/dL	L	1.6	2.6
			Alanine Aminotransferase	54	U/L	H	0	45
			Aspartate Aminotransferase	60	U/L	H	0	35
			Alkaline Phosphatase	173	U/L	H	30	120

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
803-001	Cycle 1	2011-04-01T12:20	Lactate Dehydrogenase	1921	U/L	H	230	480
			Glucose	103	mg/dL	H	70	100
		2011-04-07T08:29	Hemoglobin	10.2	g/dL	L	14	18
			Erythrocytes	3.13	10^12/L	L	4.7	6.1
			Ery. Mean Corpuscular Volume	98.6	fL	H	80	94
			Platelets	114	10^9/L	L	130	400
			Leukocytes	103.6	10^9/L	H	4.8	10.8
			Neutrophils	17.2	10^9/L	H	1.9	8
			Lymphocytes	75.6	10^9/L	H	0.9	5.2
			Monocytes	8.3	10^9/L	H	0.16	1
			Basophils	2.3	10^9/L	H	0	0.2
		2011-04-07T09:10	Sodium	134	mmol/L	L	135	145
			Calcium	11.1	mg/dL	H	8.5	10.5
			Chloride	108	mmol/L	H	98	106
			Magnesium	1.3	mg/dL	L	1.6	2.6
			Albumin	3.3	g/dL	L	3.5	5.2
			Alanine Aminotransferase	46	U/L	H	0	45
			Aspartate Aminotransferase	56	U/L	H	0	35
			Alkaline Phosphatase	182	U/L	H	30	120
			Lactate Dehydrogenase	1782	U/L	H	230	480
			Glucose	120	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Pre-trial	2009-07-09T15:15	Hemoglobin	12	g/dL	L	13.3	16.2
			Erythrocytes	4.03	10^12/L	L	4.3	5.6
			Platelets	131	10^9/L	L	150	415
			Leukocytes	3.5	10^9/L	L	3.54	9.06
			Lymphocytes	0.665	10^9/L	L	1	4
			Monocytes	0.105	10^9/L	L	0.2	1
			Chloride	98	mmol/L	L	102	109
			Creatinine	1.7	mg/dL	H	0.6	1.2
			Alkaline Phosphatase	102	U/L	H	33	96
			Lactate Dehydrogenase	280	U/L	H	115	221
			Blood Urea Nitrogen	26	mg/dL	H	7	20
			Urate	9.8	mg/dL	H	3.1	7
			Glucose	106	mg/dL	H	70	105
	Cycle 1	2009-07-13T09:30	Hemoglobin	11.8	g/dL	L	13.3	16.2
			Erythrocytes	3.89	10^12/L	L	4.3	5.6
			Platelets	112	10^9/L	L	150	415
			Leukocytes	3.2	10^9/L	L	3.54	9.06
			Lymphocytes	0.512	10^9/L	L	1	4
			Chloride	100	mmol/L	L	102	109
			Creatinine	1.7	mg/dL	H	0.6	1.2
			Lactate Dehydrogenase	225	U/L	H	115	221
			Blood Urea Nitrogen	33	mg/dL	H	7	20
			Urate	11	mg/dL	H	3.1	7
			Glucose	143	mg/dL	H	70	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 1	2009-07-17T09:10	Hemoglobin	10.8	g/dL	L	13.3	16.2
			Erythrocytes	3.59	10^12/L	L	4.3	5.6
			Platelets	82	10^9/L	L	150	415
			Leukocytes	2.5	10^9/L	L	3.54	9.06
			Neutrophils	1.85	10^9/L	L	2	7.5
			Lymphocytes	0.375	10^9/L	L	1	4
			Chloride	100	mmol/L	L	102	109
			Creatinine	1.9	mg/dL	H	0.6	1.2
			Albumin	4	g/dL	L	4.1	5.3
			Alanine Aminotransferase	52	U/L	H	7	41
			Alkaline Phosphatase	150	U/L	H	33	96
			Blood Urea Nitrogen	30	mg/dL	H	7	20
			Urate	9.1	mg/dL	H	3.1	7
			Glucose	141	mg/dL	H	70	105
		2009-07-27T08:56	Platelets	114	10^9/L	L	140	440
			Leukocytes	3.3	10^9/L	L	4	10.9
			Lymphocytes	0.627	10^9/L	L	1	4
			Creatinine	2.11	mg/dL	H	0.62	1.28
			Lactate Dehydrogenase	203	U/L	H	98	185
			Blood Urea Nitrogen	41	mg/dL	H	6	22
			Urate	9.4	mg/dL	H	2.4	8.2
			Glucose	243	mg/dL	H	79	113

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 2	2009-08-03T09:20	Hemoglobin	11.1	g/dL	L	13.3	16.2
			Erythrocytes	3.6	10^12/L	L	4.3	5.6
			Platelets	109	10^9/L	L	150	415
			Leukocytes	2.7	10^9/L	L	3.54	9.06
			Neutrophils	1.917	10^9/L	L	2	7.5
			Lymphocytes	0.486	10^9/L	L	1	4
			Monocytes	0.135	10^9/L	L	0.2	1
			Chloride	101	mmol/L	L	102	109
			Creatinine	1.9	mg/dL	H	0.6	1.2
			Albumin	4	g/dL	L	4.1	5.3
			Lactate Dehydrogenase	248	U/L	H	115	221
			Blood Urea Nitrogen	26	mg/dL	H	7	20
			Urate	8.3	mg/dL	H	3.1	7
			Glucose	125	mg/dL	H	70	105
		2009-08-07T09:20	Hemoglobin	10.5	g/dL	L	13.3	16.2
			Erythrocytes	3.39	10^12/L	L	4.3	5.6
			Platelets	81	10^9/L	L	150	415
			Leukocytes	2.4	10^9/L	L	3.54	9.06
			Neutrophils	1.704	10^9/L	L	2	7.5
			Lymphocytes	0.432	10^9/L	L	1	4
			Monocytes	0.192	10^9/L	L	0.2	1
			Chloride	101	mmol/L	L	102	109
			Creatinine	2.2	mg/dL	H	0.6	1.2
			Alkaline Phosphatase	142	U/L	H	33	96
			Lactate Dehydrogenase	244	U/L	H	115	221
			Blood Urea Nitrogen	34	mg/dL	H	7	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 2	2009-08-07T09:20	Urate	7.8	mg/dL	H	3.1	7
			Glucose	196	mg/dL	H	70	105
	Cycle 3	2009-08-24T10:36	Hemoglobin	10.7	g/dL	L	13.7	17.5
			Erythrocytes	3.59	10^12/L	L	4.63	6.08
			Platelets	91	10^9/L	L	150	400
			Leukocytes	2.9	10^9/L	L	4	10
			Neutrophils	1.784	10^9/L	L	2	7.5
			Lymphocytes	0.583	10^9/L	L	1	4
			Potassium	5.2	mmol/L	H	3.5	5
			Creatinine	1.6	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	665	U/L	H	313	618
			Blood Urea Nitrogen	25	mg/dL	H	7	20
			Glucose	193	mg/dL	H	65	105
		2009-08-28T10:10	Hemoglobin	10.3	g/dL	L	13.7	17.5
			Erythrocytes	3.42	10^12/L	L	4.63	6.08
			Platelets	64	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4	10
			Neutrophils	1.726	10^9/L	L	2	7.5
			Lymphocytes	0.334	10^9/L	L	1	4
			Creatinine	1.8	mg/dL	H	0.7	1.3
			Alkaline Phosphatase	130	U/L	H	38	126
			Blood Urea Nitrogen	33	mg/dL	H	7	20
			Glucose	183	mg/dL	H	65	105

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 4	2009-09-14T09:21	Hemoglobin	11.6	g/dL	L	13.7	17.5
			Erythrocytes	3.9	10^12/L	L	4.63	6.08
			Platelets	95	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	10
			Neutrophils	1.906	10^9/L	L	2	7.5
			Lymphocytes	0.432	10^9/L	L	1	4
			Creatinine	1.6	mg/dL	H	0.7	1.3
			Blood Urea Nitrogen	31	mg/dL	H	7	20
		2009-09-18T09:47	Hemoglobin	10.4	g/dL	L	13.7	17.5
			Erythrocytes	3.42	10^12/L	L	4.63	6.08
			Platelets	63	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4	10
			Neutrophils	1.666	10^9/L	L	2	7.5
			Lymphocytes	0.358	10^9/L	L	1	4
		2009-09-18T10:25	Creatinine	1.8	mg/dL	H	0.7	1.3
			Albumin	3.4	g/dL	L	3.5	5
			Blood Urea Nitrogen	32	mg/dL	H	7	20
			Glucose	172	mg/dL	H	65	105
	Cycle 5	2009-10-26T09:34	Hemoglobin	11.3	g/dL	L	13.7	17.5
			Erythrocytes	3.7	10^12/L	L	4.63	6.08
			Platelets	97	10^9/L	L	150	400
			Leukocytes	2.8	10^9/L	L	4	10
			Lymphocytes	0.384	10^9/L	L	1	4
			Creatinine	1.7	mg/dL	H	0.7	1.3
			Blood Urea Nitrogen	30	mg/dL	H	7	20
			Glucose	181	mg/dL	H	65	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 5	2009-10-30T09:11	Hemoglobin	10.8	g/dL	L	13.7	17.5
			Erythrocytes	3.52	10^12/L	L	4.63	6.08
			Platelets	69	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	10
			Neutrophils	1.936	10^9/L	L	2	7.5
			Lymphocytes	0.356	10^9/L	L	1	4
			Creatinine	1.8	mg/dL	H	0.7	1.3
			Blood Urea Nitrogen	33	mg/dL	H	7	20
			Glucose	189	mg/dL	H	65	105
	Cycle 6	2009-11-16T10:40	Hemoglobin	10.8	g/dL	L	13.7	17.5
			Erythrocytes	3.58	10^12/L	L	4.63	6.08
			Platelets	90	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	10
			Neutrophils	1.806	10^9/L	L	2	7.5
			Lymphocytes	0.446	10^9/L	L	1	4
		2009-11-16T14:19	Creatinine	1.5	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	737	U/L	H	313	618
			Blood Urea Nitrogen	30	mg/dL	H	7	20
		2009-11-20T10:10	Hemoglobin	9.6	g/dL	L	13.7	17.5
			Erythrocytes	3.33	10^12/L	L	4.63	6.08
			Platelets	61	10^9/L	L	150	400
			Leukocytes	2.1	10^9/L	L	4	10
			Neutrophils	1.577	10^9/L	L	2	7.5
			Lymphocytes	0.202	10^9/L	L	1	4
			Creatinine	1.8	mg/dL	H	0.7	1.3
			Alkaline Phosphatase	133	U/L	H	38	126

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 6	2009-11-20T10:10	Lactate Dehydrogenase	677	U/L	H	313	618
			Blood Urea Nitrogen	32	mg/dL	H	7	20
			Glucose	280	mg/dL	H	65	105
	Cycle 7	2009-12-07T11:41	Hemoglobin	10.1	g/dL	L	13.7	17.5
			Erythrocytes	3.47	10^12/L	L	4.63	6.08
			Platelets	81	10^9/L	L	150	400
			Leukocytes	2.2	10^9/L	L	4	10
			Neutrophils	1.582	10^9/L	L	2	7.5
			Lymphocytes	0.255	10^9/L	L	1	4
		2009-12-07T13:58	Sodium	134	mmol/L	L	135	145
			Creatinine	1.6	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	865	U/L	H	313	618
			Blood Urea Nitrogen	27	mg/dL	H	7	20
			Glucose	113	mg/dL	H	65	105
		2009-12-11T09:24	Hemoglobin	10	g/dL	L	13.7	17.5
			Erythrocytes	3.43	10^12/L	L	4.63	6.08
			Platelets	63	10^9/L	L	150	400
			Leukocytes	2	10^9/L	L	4	10
			Neutrophils	1.526	10^9/L	L	2	7.5
			Lymphocytes	0.182	10^9/L	L	1	4
			Monocytes	0.192	10^9/L	L	0.2	1
			Sodium	133	mmol/L	L	135	145
			Chloride	96	mmol/L	L	98	107
			Creatinine	2	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	702	U/L	H	313	618
			Blood Urea Nitrogen	35	mg/dL	H	7	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
900-001	Cycle 7	2009-12-11T09:24	Glucose	270	mg/dL	H	65	105
	Unplanned	2009-07-27T08:56	Urate	9.4	mg/dL	H	2.4	8.2
	End Trial	2010-01-04T08:57	Hemoglobin	10.5	g/dL	L	13.7	17.5
			Erythrocytes	3.71	10^12/L	L	4.63	6.08
			Platelets	118	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	10
			Neutrophils	1.69	10^9/L	L	2	7.5
			Lymphocytes	0.4	10^9/L	L	1	4
		2010-01-05T13:45	Sodium	134	mmol/L	L	135	145
			Chloride	96	mmol/L	L	98	107
			Creatinine	2.1	mg/dL	H	0.7	1.3
			Albumin	3.4	g/dL	L	3.5	5
			Lactate Dehydrogenase	803	U/L	H	313	618
			Blood Urea Nitrogen	34	mg/dL	H	7	20
			Urate	9.4	mg/dL	H	3.5	8.5
			Glucose	111	mg/dL	H	65	105
901-001	Pre-trial	2009-06-04T11:10	Hemoglobin	12.5	g/dL	L	13	18
			Erythrocytes	4.14	10^12/L	L	4.2	5.7
			Lactate Dehydrogenase	827	U/L	H	297	537
			Bilirubin	0.1	mg/dL	L	0.3	1.5
			Blood Urea Nitrogen	24	mg/dL	H	8	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
901-001	Cycle 1	2009-06-08T08:55	Potassium	5.4	mmol/L	H	3.5	5.2
			Alanine Aminotransferase	5	U/L	L	7	40
			Aspartate Aminotransferase	51	U/L	H	15	46
			Lactate Dehydrogenase	1142	U/L	H	297	537
			Blood Urea Nitrogen	21	mg/dL	H	8	20
			Glucose	164	mg/dL	H	70	140
		2009-06-12T09:45	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	4.1	10^12/L	L	4.2	5.7
			Lymphocytes	0.994	10^9/L	L	1	4
			Lactate Dehydrogenase	807	U/L	H	297	537
		2009-06-19T09:25	Hemoglobin	12.6	g/dL	L	13	18
			Lactate Dehydrogenase	909	U/L	H	297	537
			Blood Urea Nitrogen	21	mg/dL	H	8	20
	Cycle 2	2009-06-29T08:35	Lactate Dehydrogenase	731	U/L	H	297	537
		2009-07-03T09:26	Hemoglobin	12.9	g/dL	L	13	18
			Platelets	147	10^9/L	L	150	350
			Leukocytes	3.9	10^9/L	L	4	11
			Lymphocytes	0.917	10^9/L	L	1	4
			Lactate Dehydrogenase	845	U/L	H	297	537
	Cycle 3	2009-07-20T09:00	Hemoglobin	12.6	g/dL	L	13	18
			Erythrocytes	4.09	10^12/L	L	4.2	5.7
			Leukocytes	3.8	10^9/L	L	4	11
		2009-07-20T11:20	Lactate Dehydrogenase	726	U/L	H	297	537
			Bilirubin	0.2	mg/dL	L	0.3	1.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-001	Cycle 3	2009-07-24T09:51	Lymphocytes	0.952	10^9/L	L	1	4
			Potassium	5.3	mmol/L	H	3.5	5.2
			Alanine Aminotransferase	6	U/L	L	7	40
			Aspartate Aminotransferase	52	U/L	H	15	46
			Lactate Dehydrogenase	929	U/L	H	297	537
	Cycle 4	2009-08-10T08:45	Potassium	5.5	mmol/L	H	3.5	5.2
			Alanine Aminotransferase	6	U/L	L	7	40
			Aspartate Aminotransferase	63	U/L	H	15	46
			Lactate Dehydrogenase	1146	U/L	H	297	537
		2009-08-14T10:31	Lactate Dehydrogenase	688	U/L	H	297	537
			Bilirubin	0.1	mg/dL	L	0.3	1.5
	Cycle 5	2009-08-31T08:00	Lactate Dehydrogenase	821	U/L	H	297	537
			Glucose	155	mg/dL	H	70	140
		2009-09-04T08:58	Lymphocytes	0.823	10^9/L	L	1	4
			Potassium	5.8	mmol/L	H	3.5	5.2
			Alanine Aminotransferase	6	U/L	L	7	40
			Lactate Dehydrogenase	905	U/L	H	297	537
			Glucose	156	mg/dL	H	70	140
	Cycle 6	2009-09-21T08:00	Erythrocytes	4.18	10^12/L	L	4.2	5.7
			Potassium	5.7	mmol/L	H	3.5	5.2
			Alanine Aminotransferase	6	U/L	L	7	40
			Lactate Dehydrogenase	971	U/L	H	297	537

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-001	Cycle 6	2009-09-25T09:38	Erythrocytes	4.16	10^12/L	L	4.2	5.7
			Lactate Dehydrogenase	663	U/L	H	297	537
			Bilirubin	0.1	mg/dL	L	0.3	1.5
	End Trial	2009-10-12T10:30	Lactate Dehydrogenase	891	U/L	H	297	537
901-006	Pre-trial	2010-12-13T10:18	Erythrocytes	3.71	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101.5	fL	H	81	100
			Alanine Aminotransferase	80	U/L	H	7	56
			Aspartate Aminotransferase	71	U/L	H	15	46
			Lactate Dehydrogenase	663	U/L	H	313	618
	Cycle 1	2010-12-20T08:55	Erythrocytes	3.73	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101	fL	H	81	100
			Alanine Aminotransferase	82	U/L	H	7	56
			Aspartate Aminotransferase	69	U/L	H	15	46
		2010-12-24T09:15	Hemoglobin	12.2	g/dL	L	13	18
			Erythrocytes	3.51	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101	fL	H	81	100
			Lymphocytes	0.744	10^9/L	L	1	4
			Sodium	135	mmol/L	L	137	145
			Magnesium	2.4	mg/dL	H	1.6	2.3
			Alanine Aminotransferase	61	U/L	H	7	56
			Aspartate Aminotransferase	52	U/L	H	15	46
			Glucose	134	mg/dL	H	80	128
		2011-01-03T09:30	Erythrocytes	3.79	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101.8	fL	H	81	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-006	Cycle 2	2011-01-10T13:05	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.47	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101.1	fL	H	81	100
			Sodium	136	mmol/L	L	137	145
		2011-01-14T09:17	Erythrocytes	3.69	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	102	fL	H	81	100
			Lymphocytes	0.657	10^9/L	L	1	4
		2011-01-14T10:40	Phosphate	4.7	mg/dL	H	2.5	4.5
			Magnesium	2.4	mg/dL	H	1.6	2.3
	Cycle 3	2011-01-31T12:04	Erythrocytes	3.8	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101.1	fL	H	81	100
			Sodium	135	mmol/L	L	137	145
		2011-02-04T13:13	Erythrocytes	3.74	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101.3	fL	H	81	100
			Platelets	144	10^9/L	L	150	350
			Lymphocytes	0.755	10^9/L	L	1	4
			Phosphate	4.9	mg/dL	H	2.5	4.5
			Blood Urea Nitrogen	21	mg/dL	H	4	20
	Cycle 4	2011-02-21T09:55	Erythrocytes	3.97	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101.3	fL	H	81	100
		2011-02-25T13:00	Hemoglobin	12.3	g/dL	L	13	18
			Erythrocytes	3.45	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	101	fL	H	81	100
			Lymphocytes	0.764	10^9/L	L	1	4
			Phosphate	5.1	mg/dL	H	2.5	4.5
			Blood Urea Nitrogen	22	mg/dL	H	4	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-006	Cycle 5	2011-03-14T13:10	Hemoglobin	12.3	g/dL	L	13	18
			Erythrocytes	3.42	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	102.8	fL	H	81	100
			Lymphocytes	0.858	10^9/L	L	1	4
			Sodium	135	mmol/L	L	137	145
		2011-03-18T12:25	Hemoglobin	12.2	g/dL	L	13	18
			Erythrocytes	3.42	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	103	fL	H	81	100
			Platelets	125	10^9/L	L	150	350
			Lymphocytes	0.76	10^9/L	L	1	4
			Phosphate	5.5	mg/dL	H	2.5	4.5
			Blood Urea Nitrogen	22	mg/dL	H	4	20
	Cycle 6	2011-04-04T14:11	Hemoglobin	12	g/dL	L	13	18
			Erythrocytes	3.2	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	104.3	fL	H	81	100
			Blood Urea Nitrogen	23	mg/dL	H	4	20
		2011-04-08T14:10	Hemoglobin	11.8	g/dL	L	13	18
			Erythrocytes	3.18	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	104.9	fL	H	81	100
			Platelets	142	10^9/L	L	150	350
			Lymphocytes	0.869	10^9/L	L	1	4
			Sodium	135	mmol/L	L	137	145
			Phosphate	5.2	mg/dL	H	2.5	4.5
			Blood Urea Nitrogen	21	mg/dL	H	4	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-006	Cycle 7	2011-04-25T13:38	Hemoglobin	12.5	g/dL	L	13	18
			Erythrocytes	3.36	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	106.7	fL	H	81	100
			Glucose	151	mg/dL	H	80	128
		2011-04-29T14:15	Hemoglobin	11.6	g/dL	L	13	18
			Erythrocytes	3.1	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	107	fL	H	81	100
			Platelets	133	10^9/L	L	150	350
			Lymphocytes	0.832	10^9/L	L	1	4
			Sodium	136	mmol/L	L	137	145
			Phosphate	5.3	mg/dL	H	2.5	4.5
			Lactate Dehydrogenase	630	U/L	H	313	618
	Cycle 8	2011-05-16T13:27	Hemoglobin	12.9	g/dL	L	13	18
			Erythrocytes	3.34	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	105.6	fL	H	81	100
			Calcium	8.5	mg/dL	L	8.6	10.2
		2011-05-20T13:20	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.3	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	106.6	fL	H	81	100
			Platelets	122	10^9/L	L	150	350
			Lymphocytes	0.893	10^9/L	L	1	4
			Sodium	136	mmol/L	L	137	145
			Phosphate	5	mg/dL	H	2.5	4.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-006	Cycle 9	2011-06-06T13:45	Hemoglobin	12.3	g/dL	L	13	18
			Erythrocytes	3.19	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	106.6	fL	H	81	100
			Lymphocytes	0.952	10^9/L	L	1	4
			Calcium	8.5	mg/dL	L	8.6	10.2
		2011-06-10T13:15	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.31	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	105.5	fL	H	81	100
			Platelets	129	10^9/L	L	150	350
			Lymphocytes	0.846	10^9/L	L	1	4
			Sodium	136	mmol/L	L	137	145
			Phosphate	5.2	mg/dL	H	2.5	4.5
			Lactate Dehydrogenase	626	U/L	H	313	618
	Cycle 10	2011-06-27T13:23	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.37	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	105.6	fL	H	81	100
			Lactate Dehydrogenase	703	U/L	H	313	618
		2011-07-01T12:50	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.38	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	103.6	fL	H	81	100
			Platelets	121	10^9/L	L	150	350
			Lymphocytes	0.926	10^9/L	L	1	4
			Phosphate	4.7	mg/dL	H	2.5	4.5
			Lactate Dehydrogenase	643	U/L	H	313	618

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
901-006	End Trial	2011-07-18T11:40	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.37	10^12/L	L	4.2	5.7
			Ery. Mean Corpuscular Volume	104.4	fL	H	81	100
			Calcium	8.5	mg/dL	L	8.6	10.2
			Lactate Dehydrogenase	720	U/L	H	313	618
901-009	Pre-trial	2011-06-07T11:15	Hemoglobin	10.9	g/dL	L	11.5	15.5
			Erythrocytes	3.21	10^12/L	L	3.8	5.2
			Platelets	395	10^9/L	H	150	350
			Leukocytes	19.5	10^9/L	H	4	11
			Neutrophils	16.673	10^9/L	H	2	7.5
			Lymphocytes	0.878	10^9/L	L	1	4
			Monocytes	1.716	10^9/L	H	0.2	1
			Activated Partial Thromboplastin Time	20.6	sec	L	22.4	34.4
			Blood Urea Nitrogen	31	mg/dL	H	4	20
	Cycle 1	2011-06-13T10:10	Activated Partial Thromboplastin Time	22	sec	L	22.4	34.4
		2011-06-20T09:00	Hemoglobin	10.1	g/dL	L	11.5	15.5
			Erythrocytes	2.94	10^12/L	L	3.8	5.2
			Ery. Mean Corpuscular Volume	100.2	fL	H	81	100
			Alanine Aminotransferase	6	U/L	L	7	56
			Blood Urea Nitrogen	30	mg/dL	H	4	20
			Glucose	176	mg/dL	H	80	128

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-009	Cycle 1	2011-06-23T12:40	Hemoglobin	10.1	g/dL	L	11.5	15.5
			Erythrocytes	2.94	10^12/L	L	3.8	5.2
			Neutrophils	8.518	10^9/L	H	2	7.5
			Lymphocytes	0.978	10^9/L	L	1	4
			Sodium	136	mmol/L	L	137	145
			Creatinine	1.29	mg/dL	H	0.6	1
			Blood Urea Nitrogen	33	mg/dL	H	4	20
			Glucose	165	mg/dL	H	80	128
		2011-07-01T09:55	Hemoglobin	10.5	g/dL	L	11.5	15.5
			Erythrocytes	3.11	10^12/L	L	3.8	5.2
			Neutrophils	7.77	10^9/L	H	2	7.5
			Lymphocytes	0.63	10^9/L	L	1	4
			Monocytes	1.24	10^9/L	H	0.2	1
			Creatinine	1.04	mg/dL	H	0.6	1
			Blood Urea Nitrogen	33	mg/dL	H	4	20
	Cycle 2	2011-07-11T11:12	Hemoglobin	10.4	g/dL	L	11.5	15.5
			Erythrocytes	3.13	10^12/L	L	3.8	5.2
			Lymphocytes	0.695	10^9/L	L	1	4
			Creatinine	1.05	mg/dL	H	0.6	1
			Blood Urea Nitrogen	29	mg/dL	H	4	20
		2011-07-15T11:10	Hemoglobin	10.4	g/dL	L	11.5	15.5
			Erythrocytes	3.1	10^12/L	L	3.8	5.2
			Platelets	136	10^9/L	L	150	350
			Lymphocytes	0.719	10^9/L	L	1	4
			Creatinine	1.38	mg/dL	H	0.6	1
			Blood Urea Nitrogen	35	mg/dL	H	4	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-009	Cycle 3	2011-08-08T10:35	Erythrocytes	3.55	10^12/L	L	3.8	5.2
			Lymphocytes	0.585	10^9/L	L	1	4
			Creatinine	1.12	mg/dL	H	0.6	1
			Blood Urea Nitrogen	25	mg/dL	H	4	20
		2011-08-12T08:00	Erythrocytes	3.63	10^12/L	L	3.8	5.2
			Lymphocytes	0.605	10^9/L	L	1	4
			Creatinine	1.45	mg/dL	H	0.6	1
			Blood Urea Nitrogen	29	mg/dL	H	4	20
	Cycle 4	2011-08-29T10:58	Hemoglobin	10.5	g/dL	L	11.5	15.5
			Erythrocytes	3.2	10^12/L	L	3.8	5.2
			Lymphocytes	0.718	10^9/L	L	1	4
			Creatinine	1.09	mg/dL	H	0.6	1
			Blood Urea Nitrogen	33	mg/dL	H	4	20
		2011-09-02T09:20	Hemoglobin	10.7	g/dL	L	11.5	15.5
			Erythrocytes	3.25	10^12/L	L	3.8	5.2
			Lymphocytes	0.577	10^9/L	L	1	4
			Eosinophils	0.672	10^9/L	H	0	0.5
			Creatinine	1.38	mg/dL	H	0.6	1
			Blood Urea Nitrogen	38	mg/dL	H	4	20
			Glucose	139	mg/dL	H	80	128
	End Trial	2011-09-19T13:20	Hemoglobin	9.3	g/dL	L	11.5	15.5
			Erythrocytes	2.86	10^12/L	L	3.8	5.2
			Platelets	49	10^9/L	L	150	350
			Lymphocytes	0.542	10^9/L	L	1	4
			Monocytes	1.118	10^9/L	H	0.2	1
			Eosinophils	0.722	10^9/L	H	0	0.5

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
901-009	End Trial	2011-09-19T13:20	Sodium	129	mmol/L	L	137	145
			Chloride	97	mmol/L	L	98	107
			Creatinine	1.3	mg/dL	H	0.6	1
			Lactate Dehydrogenase	627	U/L	H	313	618
			Blood Urea Nitrogen	30	mg/dL	H	4	20
902-001	Pre-trial	2010-11-22T13:42	Hemoglobin	10.1	g/dL	L	12	16
			Erythrocytes	3.3	10^12/L	L	3.8	5.2
			Leukocytes	12.6	10^9/L	H	4	10
			Neutrophils	10.2	10^9/L	H	2	7.5
			Lymphocytes	0.8	10^9/L	L	1	4
			Albumin	3.4	g/dL	L	3.5	5
	Cycle 1	2010-12-06T09:08	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.1	10^12/L	L	3.8	5.2
			Ery. Mean Corpuscular Volume	95	fL	H	78	94
			Leukocytes	20.3	10^9/L	H	4	10
			Lymphocytes	0.8	10^9/L	L	1	4
			Eosinophils	14.82	10^9/L	H	0	5
			Potassium	3.4	mmol/L	L	3.5	5
			Albumin	3.3	g/dL	L	3.5	5
			Lactate Dehydrogenase	320	U/L	H	118	242
		2010-12-10T04:00	Hemoglobin	8.2	g/dL	L	12	16
			Erythrocytes	2.7	10^12/L	L	3.8	5.2
			Platelets	115	10^9/L	L	150	350
			Leukocytes	13	10^9/L	H	4	10
			Neutrophils	1.95	10^9/L	L	2	7.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
902-001	Cycle 1	2010-12-10T04:00	Eosinophils	9.62	10^9/L	H	0	0.5
			Potassium	3.4	mmol/L	L	3.5	5
			Calcium	8.1	mg/dL	L	8.8	10.2
			Albumin	2.8	g/dL	L	3.5	5
			Alanine Aminotransferase	36	U/L	H	0	34
			Aspartate Aminotransferase	40	U/L	H	0	34
			Glucose	109	mg/dL	H	70	100
		2010-12-16T09:37	Hemoglobin	11.6	g/dL	L	12	16
			Leukocytes	23.8	10^9/L	H	4	10
			Eosinophils	16.9	10^9/L	H	0	5
			Albumin	3.2	g/dL	L	3.5	5
			Lactate Dehydrogenase	349	U/L	H	118	242
			Blood Urea Nitrogen	6	mg/dL	L	7	20
	Cycle 2	2010-12-27T13:24	Hemoglobin	11.4	g/dL	L	12	16
			Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Platelets	146	10^9/L	L	150	350
			Leukocytes	26.3	10^9/L	H	4	10
			Monocytes	0	10^9/L	L	0.2	1
			Eosinophils	21.57	10^9/L	H	0	5
			Albumin	3.2	g/dL	L	3.5	5
			Alanine Aminotransferase	37	U/L	H	0	34
			Lactate Dehydrogenase	269	U/L	H	118	242

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
902-001	Cycle 2	2010-12-31T05:00	Hemoglobin	9.5	g/dL	L	12	16
			Erythrocytes	3.1	10^12/L	L	3.8	5.2
			Platelets	102	10^9/L	L	150	350
			Leukocytes	10.1	10^9/L	H	4	10
			Lymphocytes	0.9	10^9/L	L	1	4
			Eosinophils	5.96	10^9/L	H	0	5
			Potassium	3.3	mmol/L	L	3.5	5
			Calcium	8.5	mg/dL	L	8.8	10.2
			Albumin	2.9	g/dL	L	3.5	5
			Glucose	108	mg/dL	H	70	100
	End Trial	2011-01-18T11:18	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.4	10^12/L	L	3.8	5.2
			Platelets	77	10^9/L	L	150	350
			Leukocytes	3.6	10^9/L	L	4	10
			Neutrophils	1.8	10^9/L	L	2	7.5
			Lymphocytes	0.4	10^9/L	L	1	4
			Sodium	134	mmol/L	L	135	145
			Calcium	8.7	mg/dL	L	8.8	10.2
			Albumin	3	g/dL	L	3.5	5
			Glucose	116	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Pre-trial	2010-08-04T10:55	Hemoglobin	11.8	g/dL	L	14	18
			Erythrocytes	4.07	10^12/L	L	4.5	6
			Leukocytes	22.8	10^9/L	H	4	11
			Lymphocytes	7.98	10^9/L	H	1	4.8
			Eosinophils	7.98	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	212	U/L	H	38	126
			Lactate Dehydrogenase	878	U/L	H	313	618
			Blood Urea Nitrogen	25	mg/dL	H	8	20
	Cycle 1	2010-08-11T13:36	Hemoglobin	12.8	g/dL	L	14	18
			Erythrocytes	4.33	10^12/L	L	4.5	6
			Leukocytes	25.3	10^9/L	H	4	11
			Eosinophils	11.64	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	155	U/L	H	38	126
			Lactate Dehydrogenase	862	U/L	H	313	618
		2010-08-16T07:05	Hemoglobin	11.8	g/dL	L	14	18
			Erythrocytes	4.04	10^12/L	L	4.5	6
			Leukocytes	18.5	10^9/L	H	4	11
			Lymphocytes	5.36	10^9/L	H	1	4.8
			Monocytes	0.74	10^9/L	H	0.08	0.7
			Eosinophils	5.55	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	147	U/L	H	38	126
			Lactate Dehydrogenase	698	U/L	H	313	618
			Blood Urea Nitrogen	21	mg/dL	H	8	20

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Cycle 1	2010-08-23T09:26	Hemoglobin	12	g/dL	L	14	18
			Erythrocytes	4.42	10^12/L	L	4.5	6
			Leukocytes	22.3	10^9/L	H	4	11
			Lymphocytes	4.91	10^9/L	H	1	4.8
			Eosinophils	8.92	10^9/L	H	0.04	0.4
			Magnesium	1.7	mg/dL	L	1.8	2.9
			Alkaline Phosphatase	160	U/L	H	38	126
			Lactate Dehydrogenase	933	U/L	H	313	618
	Cycle 2	2010-08-30T09:27	Hemoglobin	13.1	g/dL	L	14	18
			Leukocytes	29.3	10^9/L	H	4	11
			Monocytes	0.88	10^9/L	H	0.08	0.7
			Eosinophils	11.43	10^9/L	H	0.04	0.4
			Magnesium	1.6	mg/dL	L	1.8	2.9
			Alkaline Phosphatase	189	U/L	H	38	126
			Lactate Dehydrogenase	1032	U/L	H	313	618
		2010-09-03T10:29	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4.27	10^12/L	L	4.5	6
			Leukocytes	33.7	10^9/L	H	4	11
			Lymphocytes	7.08	10^9/L	H	1	4.8
			Eosinophils	12.47	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	198	U/L	H	38	126
			Lactate Dehydrogenase	1148	U/L	H	313	618

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Cycle 3	2010-09-20T08:30	Hemoglobin	12	g/dL	L	14	18
			Erythrocytes	4.02	10^12/L	L	4.5	6
			Leukocytes	33.4	10^9/L	H	4	11
			Lymphocytes	10.35	10^9/L	H	1	4.8
			Eosinophils	10.69	10^9/L	H	0.04	0.4
			Chloride	109	mmol/L	H	98	108
			Magnesium	1.7	mg/dL	L	1.8	2.9
			Alkaline Phosphatase	129	U/L	H	38	126
			Lactate Dehydrogenase	1029	U/L	H	313	618
		2010-09-24T10:05	Hemoglobin	11.4	g/dL	L	14	18
			Erythrocytes	3.93	10^12/L	L	4.5	6
			Platelets	131	10^9/L	L	140	440
			Leukocytes	36.6	10^9/L	H	4	11
			Neutrophils	9.88	10^9/L	H	1.7	7.3
			Lymphocytes	6.59	10^9/L	H	1	4.8
			Eosinophils	9.15	10^9/L	H	0.04	0.4
			Magnesium	1.7	mg/dL	L	1.8	2.9
			Aspartate Aminotransferase	69	U/L	H	15	46
			Alkaline Phosphatase	169	U/L	H	38	126
			Lactate Dehydrogenase	1224	U/L	H	313	618
			Blood Urea Nitrogen	21	mg/dL	H	8	20

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Cycle 4	2010-10-11T14:30	Hemoglobin	11.4	g/dL	L	14	18
			Erythrocytes	3.95	10^12/L	L	4.5	6
			Leukocytes	22.8	10^9/L	H	4	11
			Monocytes	1.37	10^9/L	H	0.08	0.7
			Eosinophils	1.6	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	135	U/L	H	38	126
			Lactate Dehydrogenase	1195	U/L	H	313	618
		2010-10-15T16:53	Hemoglobin	11.2	g/dL	L	14	18
			Erythrocytes	3.84	10^12/L	L	4.5	6
			Leukocytes	23.8	10^9/L	H	4	11
			Lymphocytes	12.14	10^9/L	H	1	4.8
			Eosinophils	6.19	10^9/L	H	0.04	0.4
			Chloride	111	mmol/L	H	98	108
			Albumin	3.3	g/dL	L	3.5	4.7
			Alkaline Phosphatase	135	U/L	H	38	126
			Lactate Dehydrogenase	1011	U/L	H	313	618
	Cycle 5	2010-11-01T10:25	Hemoglobin	12.5	g/dL	L	14	18
			Erythrocytes	4.31	10^12/L	L	4.5	6
			Leukocytes	35	10^9/L	H	4	11
			Eosinophils	7	10^9/L	H	0.04	0.4
			Magnesium	1.7	mg/dL	L	1.8	2.9
			Alkaline Phosphatase	138	U/L	H	38	126
			Lactate Dehydrogenase	1217	U/L	H	313	618
			Glucose	127	mg/dL	H	70	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Cycle 5	2010-11-05T11:30	Hemoglobin	11.3	g/dL	L	14	18
			Erythrocytes	3.89	10^12/L	L	4.5	6
			Platelets	121	10^9/L	L	140	440
			Leukocytes	27.7	10^9/L	H	4	11
			Monocytes	1.38	10^9/L	H	0.08	0.7
			Eosinophils	4.43	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	151	U/L	H	38	126
			Lactate Dehydrogenase	1072	U/L	H	313	618
			Bilirubin	1.1	mg/dL	H	0	1
			Glucose	115	mg/dL	H	70	110
	Cycle 6	2010-11-26T11:40	Hemoglobin	11.4	g/dL	L	14	18
			Erythrocytes	3.96	10^12/L	L	4.5	6
			Leukocytes	33.1	10^9/L	H	4	11
			Monocytes	0	10^9/L	L	0.08	0.7
			Eosinophils	5.63	10^9/L	H	0.04	0.4
			Magnesium	1.7	mg/dL	L	1.8	2.9
			Alkaline Phosphatase	177	U/L	H	38	126
			Lactate Dehydrogenase	828	U/L	H	313	618
			Glucose	138	mg/dL	H	70	110
		2010-11-30T10:21	Hemoglobin	11.4	g/dL	L	14	18
			Erythrocytes	3.94	10^12/L	L	4.5	6
			Leukocytes	28.7	10^9/L	H	4	11
			Monocytes	0	10^9/L	L	0.08	0.7
			Eosinophils	5.74	10^9/L	H	0.04	0.4
			Chloride	110	mmol/L	H	98	108
			Alkaline Phosphatase	177	U/L	H	38	126

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Cycle 6	2010-11-30T10:21	Lactate Dehydrogenase	1051	U/L	H	313	618
			Bilirubin	1.1	mg/dL	H	0	1
	Cycle 7	2010-12-17T16:32	Hemoglobin	12.1	g/dL	L	14	18
			Erythrocytes	4.22	10^12/L	L	4.5	6
			Leukocytes	34.7	10^9/L	H	4	11
			Lymphocytes	6.59	10^9/L	H	1	4.8
			Eosinophils	13.19	10^9/L	H	0.04	0.4
			Basophils	0.35	10^9/L	H	0	0.1
			Alkaline Phosphatase	215	U/L	H	38	126
			Lactate Dehydrogenase	1018	U/L	H	313	618
			Glucose	117	mg/dL	H	70	110
		2010-12-21T10:16	Hemoglobin	10.7	g/dL	L	14	18
			Erythrocytes	3.78	10^12/L	L	4.5	6
			Leukocytes	28.2	10^9/L	H	4	11
			Lymphocytes	16.92	10^9/L	H	1	4.8
			Eosinophils	6.2	10^9/L	H	0.04	0.4
			Basophils	0.28	10^9/L	H	0	0.1
			Alkaline Phosphatase	187	U/L	H	38	126
			Lactate Dehydrogenase	1110	U/L	H	313	618
			Glucose	119	mg/dL	H	70	110
	Cycle 8	2011-01-10T15:25	Hemoglobin	11.3	g/dL	L	14	18
			Erythrocytes	4.04	10^12/L	L	4.5	6
			Leukocytes	35.4	10^9/L	H	4	11
			Lymphocytes	19.47	10^9/L	H	1	4.8
			Eosinophils	11.33	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	186	U/L	H	38	126

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
906-001	Cycle 8	2011-01-10T15:25	Lactate Dehydrogenase	1341	U/L	H	313	618
		2011-01-14T09:25	Hemoglobin	9.9	g/dL	L	14	18
			Erythrocytes	3.5	10^12/L	L	4.5	6
			Platelets	117	10^9/L	L	140	440
			Leukocytes	33.4	10^9/L	H	4	11
			Lymphocytes	18.7	10^9/L	H	1	4.8
			Monocytes	0	10^9/L	L	0.08	0.7
			Eosinophils	8.02	10^9/L	H	0.04	0.4
			Chloride	109	mmol/L	H	98	108
			Magnesium	1.7	mg/dL	L	1.8	2.9
			Albumin	3.3	g/dL	L	3.5	4.7
			Alkaline Phosphatase	194	U/L	H	38	126
			Lactate Dehydrogenase	1322	U/L	H	313	618
			Bilirubin	1.4	mg/dL	H	0	1
			Glucose	154	mg/dL	H	70	110
	End Trial	2011-01-26T12:40	Erythrocytes	4.11	10^12/L	L	4.5	6
			Leukocytes	29.5	10^9/L	H	4	11
			Monocytes	0.88	10^9/L	H	0.08	0.7
			Eosinophils	5.31	10^9/L	H	0.04	0.4
			Alkaline Phosphatase	166	U/L	H	38	126
			Lactate Dehydrogenase	1573	U/L	H	313	618

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-001	Pre-trial	2010-05-03T12:20	Sodium	147	mmol/L	H	136	145
			Chloride	110	mmol/L	H	98	108
			Lactate Dehydrogenase	287	U/L	H	80	190
			Urate	2.2	mg/dL	L	2.9	6.3
		2010-05-06T08:17	Hemoglobin	10.9	g/dL	L	11.5	15.5
			Leukocytes	3.29	10^9/L	L	4.3	10
			Lymphocytes	0.46	10^9/L	L	1	4.8
	Cycle 1	2010-05-10T09:08	Hemoglobin	10.5	g/dL	L	11.5	15.5
			Leukocytes	2.7	10^9/L	L	4.3	10
			Neutrophils	1.6	10^9/L	L	1.8	7
			Lymphocytes	0.51	10^9/L	L	1	4.8
			Lactate Dehydrogenase	250	U/L	H	80	190
			Urate	2.3	mg/dL	L	2.9	6.3
		2010-05-14T08:59	Hemoglobin	10.9	g/dL	L	11.5	15.5
			Leukocytes	2.86	10^9/L	L	4.3	10
			Lymphocytes	0.43	10^9/L	L	1	4.8
			Lactate Dehydrogenase	258	U/L	H	80	190
			Urate	2.1	mg/dL	L	2.9	6.3
			Glucose	126	mg/dL	H	62	125
		2010-05-27T09:32	Hemoglobin	11.3	g/dL	L	11.5	15.5
			Leukocytes	2.84	10^9/L	L	4.3	10
			Neutrophils	1.59	10^9/L	L	1.8	7
			Lymphocytes	0.71	10^9/L	L	1	4.8
			Lactate Dehydrogenase	227	U/L	H	80	190
			Urate	1.8	mg/dL	L	2.9	6.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-001	Cycle 2	2010-06-01T09:52	Hemoglobin	11.4	g/dL	L	11.5	15.5
			Leukocytes	2.84	10^9/L	L	4.3	10
			Neutrophils	1.59	10^9/L	L	1.8	7
			Lymphocytes	0.8	10^9/L	L	1	4.8
			Lactate Dehydrogenase	221	U/L	H	80	190
			Urate	1.9	mg/dL	L	2.9	6.3
		2010-06-05T09:44	Hemoglobin	11	g/dL	L	11.5	15.5
			Platelets	132	10^9/L	L	150	400
			Leukocytes	2.68	10^9/L	L	4.3	10
			Lymphocytes	0.56	10^9/L	L	1	4.8
			Potassium	3.3	mmol/L	L	3.7	5.2
			Albumin	3.4	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	194	U/L	H	80	190
			Urate	2.1	mg/dL	L	2.9	6.3
			Glucose	135	mg/dL	H	62	125
	Cycle 3	2010-06-21T09:25	Hemoglobin	11.2	g/dL	L	11.5	15.5
			Leukocytes	3.02	10^9/L	L	4.3	10
			Lymphocytes	0.67	10^9/L	L	1	4.8
			Lactate Dehydrogenase	227	U/L	H	80	190
			Urate	1.9	mg/dL	L	2.9	6.3
		2010-06-25T09:25	Leukocytes	2.89	10^9/L	L	4.3	10
			Lymphocytes	0.49	10^9/L	L	1	4.8
			Sodium	147	mmol/L	H	136	145
			Potassium	3.4	mmol/L	L	3.7	5.2
			Chloride	109	mmol/L	H	98	108
			Aspartate Aminotransferase	14	U/L	L	15	40

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-001	Cycle 3	2010-06-25T09:25	Lactate Dehydrogenase	200	U/L	H	80	190
			Urate	1.9	mg/dL	L	2.9	6.3
			Glucose	147	mg/dL	H	62	125
	Cycle 4	2010-07-12T11:40	Hemoglobin	8.4	g/dL	L	11.5	15.5
			Erythrocytes	3.02	10^12/L	L	3.8	5
			Leukocytes	3.12	10^9/L	L	4.3	10
			Lymphocytes	0.5	10^9/L	L	1	4.8
			Sodium	146	mmol/L	H	136	145
			Calcium	8.8	mg/dL	L	8.9	10.2
			Chloride	109	mmol/L	H	98	108
			Albumin	3.3	g/dL	L	3.5	5.2
			Aspartate Aminotransferase	12	U/L	L	15	40
			Lactate Dehydrogenase	202	U/L	H	80	190
			Urate	1.9	mg/dL	L	2.9	6.3
		2010-07-16T09:53	Hemoglobin	10.8	g/dL	L	11.5	15.5
			Leukocytes	3.27	10^9/L	L	4.3	10
			Lymphocytes	0.39	10^9/L	L	1	4.8
			Potassium	3.3	mmol/L	L	3.7	5.2
			Magnesium	2.5	mg/dL	H	1.8	2.4
			Aspartate Aminotransferase	11	U/L	L	15	40
			Lactate Dehydrogenase	219	U/L	H	80	190
			Urate	2	mg/dL	L	2.9	6.3

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-001	End Trial	2010-08-16T11:51	Hemoglobin	9.7	g/dL	L	11.5	15.5
			Erythrocytes	3.47	10^12/L	L	3.8	5
			Leukocytes	3.79	10^9/L	L	4.3	10
			Lymphocytes	0.76	10^9/L	L	1	4.8
			Prothrombin Time	40	sec	H	10.7	15.6
			Activated Partial Thromboplastin Time	1.4	sec	L	22	35
			Potassium	3.3	mmol/L	L	3.7	5.2
			Calcium	8.2	mg/dL	L	8.9	10.2
			Albumin	3.1	g/dL	L	3.5	5.2
			Aspartate Aminotransferase	11	U/L	L	15	40
			Urate	1.5	mg/dL	L	2.9	6.3
907-002	Pre-trial	2010-07-26T13:54	Hemoglobin	11	g/dL	L	13	18
			Erythrocytes	3.36	10^12/L	L	4.4	5.2
			Leukocytes	23.05	10^9/L	H	4.3	10
			Neutrophils	13.37	10^9/L	H	1.8	7
			Monocytes	1.15	10^9/L	H	0	0.8
			Eosinophils	5.76	10^9/L	H	0	0.5
			Basophils	0.23	10^9/L	H	0	0.2
			Albumin	3.1	g/dL	L	3.5	5.2
			Alanine Aminotransferase	65	U/L	H	10	48

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-002	Cycle 1	2010-07-27T08:25	Hemoglobin	10.8	g/dL	L	13	18
			Erythrocytes	3.34	10^12/L	L	4.4	5.2
			Leukocytes	17.66	10^9/L	H	4.3	10
			Neutrophils	11.65	10^9/L	H	1.8	7
			Eosinophils	3.71	10^9/L	H	0	0.5
			Calcium	8.8	mg/dL	L	8.9	10.2
			Albumin	2.8	g/dL	L	3.5	5.2
			Alanine Aminotransferase	49	U/L	H	10	48
		2010-07-31T09:35	Hemoglobin	9.4	g/dL	L	13	18
			Erythrocytes	2.94	10^12/L	L	4.4	5.2
			Leukocytes	23.28	10^9/L	H	4.3	10
			Neutrophils	14.43	10^9/L	H	1.8	7
			Eosinophils	6.52	10^9/L	H	0	0.5
			Sodium	133	mmol/L	L	136	145
			Calcium	8.6	mg/dL	L	8.9	10.2
			Albumin	2.5	g/dL	L	3.5	5.2
			Aspartate Aminotransferase	9	U/L	L	15	40
			Glucose	143	mg/dL	H	62	125
		2010-08-10T11:52	Hemoglobin	8.7	g/dL	L	13.5	17.7
			Erythrocytes	2.64	10^12/L	L	4.4	5.9
			Leukocytes	31.6	10^9/L	H	3.5	11
			Neutrophils	15.2	10^9/L	H	1.8	8
			Eosinophils	14.5	10^9/L	H	0	0.5
			Sodium	131	mmol/L	L	135	144
			Calcium	7.9	mg/dL	L	8.3	10.4
			Albumin	2.7	g/dL	L	3.2	4.9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-002	Cycle 1	2010-08-10T11:52	Alanine Aminotransferase	91	U/L	H	6	42
			Alkaline Phosphatase	231	U/L	H	32	110
			Glucose	116	mg/dL	H	60	99
907-003	Pre-trial	2010-08-27T07:36	Leukocytes	3.66	10^9/L	L	4.3	10
			Neutrophils	1.79	10^9/L	L	1.8	7
	Cycle 1	2010-08-30T12:10	Leukocytes	4.22	10^9/L	L	4.3	10
		2010-09-03T09:47	Hemoglobin	11.2	g/dL	L	11.5	15.5
			Erythrocytes	3.7	10^12/L	L	3.8	5
			Platelets	139	10^9/L	L	150	400
			Lymphocytes	0.46	10^9/L	L	1	4.8
			Chloride	109	mmol/L	H	98	108
		2010-09-16T10:25	Leukocytes	3.8	10^9/L	L	4	11
			Bilirubin	0.1	mg/dL	L	0.2	1.3
			Glucose	110	mg/dL	H	65	99
	Cycle 2	2010-09-20T09:29	Leukocytes	3.7	10^9/L	L	4.3	10
			Lymphocytes	0.96	10^9/L	L	1	4.8
		2010-09-24T09:23	Hemoglobin	11.3	g/dL	L	11.5	15.5
			Erythrocytes	3.68	10^12/L	L	3.8	5
			Leukocytes	3.49	10^9/L	L	4.3	10
			Lymphocytes	0.77	10^9/L	L	1	4.8
			Glucose	126	mg/dL	H	62	125
	Cycle 3	2010-10-11T16:31	Erythrocytes	3.79	10^12/L	L	3.8	5
			Calcium	8.8	mg/dL	L	8.9	10.2

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-003	Cycle 3	2010-10-15T10:23	Erythrocytes	3.79	10^12/L	L	3.8	5
			Leukocytes	3.84	10^9/L	L	4.3	10
			Lymphocytes	0.64	10^9/L	L	1	4.8
	End Trial	2010-11-01T12:42	Leukocytes	4.08	10^9/L	L	4.3	10
			Aspartate Aminotransferase	14	U/L	L	15	40
907-004	Pre-trial	2010-12-21T10:22	Hemoglobin	9.4	g/dL	L	13	18
			Erythrocytes	2.69	10^12/L	L	4.4	5.2
			Ery. Mean Corpuscular Volume	108	fL	H	81	98
			Leukocytes	15.45	10^9/L	H	4.3	10
			Monocytes	1.55	10^9/L	H	0	0.8
			Eosinophils	4.64	10^9/L	H	0	0.5
			Sodium	135	mmol/L	L	136	145
			Creatinine	1.4	mg/dL	H	0.2	1.1
			Albumin	3.2	g/dL	L	3.5	5.2
			Alkaline Phosphatase	131	U/L	H	35	109
			Lactate Dehydrogenase	559	U/L	H	80	190
			Glucose	130	mg/dL	H	62	125
		2010-12-25T00:30	Prothrombin Time	17.5	sec	H	10.7	15.6
			Activated Partial Thromboplastin Time	37	sec	H	22	35
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.8	1.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-004	Cycle 1	2010-12-27T09:58	Hemoglobin	10.8	g/dL	L	13	18
			Erythrocytes	3.22	10^12/L	L	4.4	5.2
			Ery. Mean Corpuscular Volume	101	fL	H	81	98
			Leukocytes	22.18	10^9/L	H	4.3	10
			Neutrophils	10.42	10^9/L	H	1.8	7
			Monocytes	1.55	10^9/L	H	0	0.8
			Eosinophils	5.55	10^9/L	H	0	0.5
			Basophils	0.22	10^9/L	H	0	0.2
			Magnesium	1.6	mg/dL	L	1.8	2.4
			Creatinine	1.5	mg/dL	H	0.2	1.1
			Albumin	3.1	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	611	U/L	H	80	190
		2010-12-31T11:15	Hemoglobin	10.3	g/dL	L	13	18
			Erythrocytes	3.1	10^12/L	L	4.4	5.2
			Ery. Mean Corpuscular Volume	101	fL	H	81	98
			Platelets	135	10^9/L	L	150	400
			Leukocytes	24.09	10^9/L	H	4.3	10
			Neutrophils	13.73	10^9/L	H	1.8	7
			Monocytes	1.93	10^9/L	H	0	0.8
			Eosinophils	3.85	10^9/L	H	0	0.5
			Phosphate	4.9	mg/dL	H	2.5	4.5
			Creatinine	1.7	mg/dL	H	0.2	1.1
			Albumin	2.9	g/dL	L	3.5	5.2
			Aspartate Aminotransferase	8	U/L	L	15	40
			Lactate Dehydrogenase	494	U/L	H	80	190
			Glucose	143	mg/dL	H	62	125

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-004	Cycle 1	2011-01-07T22:30	Hemoglobin	9.6	g/dL	L	13	18
			Erythrocytes	2.87	10^12/L	L	4.4	5.2
			Ery. Mean Corpuscular Volume	100	fL	H	81	98
			Platelets	135	10^9/L	L	150	400
			Leukocytes	27.14	10^9/L	H	4.3	10
			Neutrophils	13.22	10^9/L	H	1.8	7
			Lymphocytes	7.65	10^9/L	H	1	4.8
			Monocytes	2.31	10^9/L	H	0	0.8
			Eosinophils	3.94	10^9/L	H	0	0.5
			Sodium	135	mmol/L	L	136	145
			Potassium	5.4	mmol/L	H	3.7	5.2
			Creatinine	1.6	mg/dL	H	0.2	1.1
			Albumin	2	g/dL	L	3.5	5.2
			Blood Urea Nitrogen	25	mg/dL	H	8	21
			Glucose	129	mg/dL	H	62	125
907-005	Pre-trial	2011-04-08T08:05	Alanine Aminotransferase	83	U/L	H	6	40
			Aspartate Aminotransferase	95	U/L	H	15	40
		2011-04-14T12:25	Platelets	95	10^9/L	L	150	400
			Leukocytes	2.36	10^9/L	L	4.3	10
			Neutrophils	1.45	10^9/L	L	1.8	7
			Lymphocytes	0.38	10^9/L	L	1	4.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-005	Pre-trial	2011-04-18T07:57	Prothrombin Time	24.8	sec	H	10.7	15.6
			Activated Partial Thromboplastin Time	39	sec	H	22	35
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.8	1.3
	Cycle 1	2011-04-18T07:57	Platelets	83	10^9/L	L	150	400
			Leukocytes	1.75	10^9/L	L	4.3	10
			Neutrophils	1.17	10^9/L	L	1.8	7
			Lymphocytes	0.25	10^9/L	L	1	4.8
			Prothrombin Time	24.8	sec	H	10.7	15.6
			Activated Partial Thromboplastin Time	39	sec	H	22	35
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.8	1.3
			Alanine Aminotransferase	88	U/L	H	6	40
			Aspartate Aminotransferase	81	U/L	H	15	40
			Urate	6.9	mg/dL	H	2.9	6.3
		2011-04-22T12:16	Platelets	62	10^9/L	L	150	400
			Leukocytes	1.69	10^9/L	L	4.3	10
			Neutrophils	1.12	10^9/L	L	1.8	7
			Lymphocytes	0.2	10^9/L	L	1	4.8
			Chloride	109	mmol/L	H	98	108
			Alanine Aminotransferase	44	U/L	H	6	40
			Lactate Dehydrogenase	206	U/L	H	80	190

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-005	Cycle 1	2011-04-29T08:25	Platelets	94	10^9/L	L	140	444
			Leukocytes	2.32	10^9/L	L	3.5	11
			Neutrophils	1.65	10^9/L	L	1.8	8
			Lymphocytes	0.2	10^9/L	L	1	4.8
			Alanine Aminotransferase	99	U/L	H	6	42
			Aspartate Aminotransferase	106	U/L	H	11	39
			Bilirubin	1.6	mg/dL	H	0.2	1.2
			Glucose	106	mg/dL	H	60	99
	Cycle 2	2011-05-09T12:09	Platelets	102	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4.3	10
			Neutrophils	1.63	10^9/L	L	1.8	7
			Lymphocytes	0.41	10^9/L	L	1	4.8
			Prothrombin Time	28.2	sec	H	10.7	15.6
			Prothrombin Intl. Normalized Ratio	2.8	ratio	H	0.8	1.3
			Chloride	111	mmol/L	H	98	108
			Lactate Dehydrogenase	254	U/L	H	80	190
		2011-05-13T09:00	Platelets	72	10^9/L	L	150	400
			Leukocytes	2.46	10^9/L	L	4.3	10
			Lymphocytes	0.27	10^9/L	L	1	4.8
			Lactate Dehydrogenase	281	U/L	H	80	190
	End Trial	2011-06-04T08:35	Lactate Dehydrogenase	231	U/L	H	80	190
		2011-06-04T09:22	Prothrombin Time	28.1	sec	H	10.7	15.6
			Activated Partial Thromboplastin Time	61	sec	H	22	35
			Prothrombin Intl. Normalized Ratio	2.8	ratio	H	0.8	1.3

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-005	End Trial	2011-06-09T08:45	Platelets	119	10^9/L	L	150	400
			Leukocytes	3.43	10^9/L	L	4.3	10
			Lymphocytes	0.27	10^9/L	L	1	4.8
907-006	Pre-trial	2011-06-02T11:09	Albumin	3.4	g/dL	L	3.5	5.2
			Lactate Dehydrogenase	265	U/L	H	80	190
		2011-06-06T11:09	Hemoglobin	9	g/dL	L	11.5	15.5
			Erythrocytes	2.88	10^12/L	L	3.8	5
			Platelets	48	10^9/L	L	150	400
			Lymphocytes	0.86	10^9/L	L	1	4.8
			Monocytes	1.29	10^9/L	H	0	0.8
	Cycle 1	2011-06-07T10:17	Hemoglobin	9	g/dL	L	11.5	15.5
			Erythrocytes	2.87	10^12/L	L	3.8	5
			Platelets	76	10^9/L	L	150	400
			Lymphocytes	0.59	10^9/L	L	1	4.8
			Monocytes	1.18	10^9/L	H	0	0.8
			Albumin	3.2	g/dL	L	3.5	5.2
		2011-06-11T08:01	Hemoglobin	9.2	g/dL	L	11.5	15.5
			Erythrocytes	2.91	10^12/L	L	3.8	5
			Lymphocytes	0.96	10^9/L	L	1	4.8
			Monocytes	0.92	10^9/L	H	0	0.8
			Phosphate	4.6	mg/dL	H	2.5	4.5
			Albumin	3.4	g/dL	L	3.5	5.2
			Alanine Aminotransferase	106	U/L	H	6	40
			Aspartate Aminotransferase	46	U/L	H	15	40

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-006	Cycle 1	2011-06-20T13:38	Hemoglobin	9.7	g/dL	L	11.5	15.5
			Erythrocytes	2.94	10^12/L	L	3.8	5
	Cycle 2	2011-06-27T09:50	Hemoglobin	10	g/dL	L	11.5	15.5
			Erythrocytes	3.08	10^12/L	L	3.8	5
			Ery. Mean Corpuscular Volume	99	fL	H	81	98
			Lactate Dehydrogenase	191	U/L	H	80	190
	End Trial	2011-07-14T17:22	Hemoglobin	10.2	g/dL	L	11.5	15.5
			Erythrocytes	3.01	10^12/L	L	3.8	5
			Ery. Mean Corpuscular Volume	100	fL	H	81	98
			Eosinophils	0.53	10^9/L	H	0	0.5
			Sodium	135	mmol/L	L	136	145
		2011-08-05T15:15	Activated Partial Thromboplastin Time	36	sec	H	22	35
907-007	Pre-trial	2011-07-27T08:56	Hemoglobin	12.3	g/dL	L	13	18
			Erythrocytes	3.72	10^12/L	L	4.4	5.2
			Platelets	143	10^9/L	L	150	400
			Leukocytes	3.96	10^9/L	L	4.3	10
			Lymphocytes	0.51	10^9/L	L	1	4.8
			Monocytes	1.23	10^9/L	H	0	0.8
		2011-08-01T09:55	Magnesium	1.4	mg/dL	L	1.8	2.4
			Lactate Dehydrogenase	216	U/L	H	80	190
			Urate	7.3	mg/dL	H	3.4	7
		2011-08-05T11:34	Activated Partial Thromboplastin Time	38	sec	H	22	35

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-007	Cycle 1	2011-08-05T11:34	Hemoglobin	12.4	g/dL	L	13	18
			Erythrocytes	3.71	10^12/L	L	4.4	5.2
			Platelets	127	10^9/L	L	150	400
			Lymphocytes	0.68	10^9/L	L	1	4.8
			Activated Partial Thromboplastin Time	38	sec	H	22	35
		2011-08-09T08:55	Hemoglobin	12.9	g/dL	L	13	18
			Erythrocytes	3.73	10^12/L	L	4.4	5.2
			Platelets	116	10^9/L	L	150	400
			Leukocytes	1.92	10^9/L	L	4.3	10
			Neutrophils	0.77	10^9/L	L	1.8	7
			Lymphocytes	0.44	10^9/L	L	1	4.8
		2011-08-16T11:57	Hemoglobin	12.2	g/dL	L	13	18
			Erythrocytes	3.64	10^12/L	L	4.4	5.2
			Platelets	76	10^9/L	L	150	400
			Leukocytes	1.68	10^9/L	L	4.3	10
			Neutrophils	0.47	10^9/L	L	1.8	7
			Lymphocytes	0.65	10^9/L	L	1	4.8
	Cycle 2	2011-08-29T09:24	Urate	0	mg/dL	L	3.4	7
		2011-08-31T07:50	Hemoglobin	12.7	g/dL	L	13	18
			Erythrocytes	3.75	10^12/L	L	4.4	5.2
			Platelets	86	10^9/L	L	150	400
			Leukocytes	4.02	10^9/L	L	4.3	10
			Lymphocytes	0.84	10^9/L	L	1	4.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
907-007	Cycle 2	2011-09-04T09:15	Hemoglobin	12.8	g/dL	L	13	18
			Erythrocytes	3.78	10^12/L	L	4.4	5.2
			Platelets	69	10^9/L	L	150	400
			Leukocytes	1.47	10^9/L	L	4.3	10
			Neutrophils	0.44	10^9/L	L	1.8	7
			Lymphocytes	0.52	10^9/L	L	1	4.8
	End Trial	2011-09-15T13:32	Hemoglobin	11.9	g/dL	L	13	18
			Erythrocytes	3.49	10^12/L	L	4.4	5.2
			Platelets	108	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4.3	10
			Neutrophils	1.18	10^9/L	L	1.8	7
			Lymphocytes	0.86	10^9/L	L	1	4.8
908-003	Pre-trial	2011-07-25T16:42	Hemoglobin	11	g/dL	L	11.2	15.7
			Erythrocytes	3.74	10^12/L	L	3.93	5.22
			Creatinine	1.2	mg/dL	H	0.6	1
			Alanine Aminotransferase	9	U/L	L	11	50
	Cycle 1	2011-08-01T08:54	Erythrocytes	3.84	10^12/L	L	3.93	5.22
			Lymphocytes	0.9	10^9/L	L	1.2	3.7
		2011-08-01T11:52	Creatinine	1.3	mg/dL	H	0.6	1
			Alanine Aminotransferase	10	U/L	L	11	50
			Blood Urea Nitrogen	22	mg/dL	H	7	20

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
908-003	Cycle 1	2011-08-05T10:15	Erythrocytes	3.89	10^12/L	L	3.93	5.22
			Platelets	114	10^9/L	L	150	400
			Lymphocytes	0.8	10^9/L	L	1.2	3.7
			Creatinine	1.4	mg/dL	H	0.6	1
			Alanine Aminotransferase	8	U/L	L	11	50
		2011-08-15T08:48	Platelets	149	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4	10
			Lymphocytes	0.7	10^9/L	L	1.2	3.7
			Creatinine	1.3	mg/dL	H	0.6	1
			Blood Urea Nitrogen	25	mg/dL	H	7	20
	Cycle 2	2011-08-22T08:31	Platelets	127	10^9/L	L	150	400
			Leukocytes	3	10^9/L	L	4	10
			Lymphocytes	0.7	10^9/L	L	1.2	3.7
			Creatinine	1.3	mg/dL	H	0.6	1
		2011-08-26T10:14	Hemoglobin	10.4	g/dL	L	11.2	15.7
			Erythrocytes	3.63	10^12/L	L	3.93	5.22
			Platelets	78	10^9/L	L	150	400
			Leukocytes	2.2	10^9/L	L	4	10
			Neutrophils	1.5	10^9/L	L	1.6	6.1
			Lymphocytes	0.4	10^9/L	L	1.2	3.7
			Creatinine	1.4	mg/dL	H	0.6	1
			Glucose	120	mg/dL	H	65	110

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
908-003	Cycle 3	2011-09-12T09:05	Hemoglobin	10.8	g/dL	L	11.2	15.7
			Erythrocytes	3.76	10^12/L	L	3.93	5.22
			Platelets	123	10^9/L	L	150	400
			Leukocytes	2.8	10^9/L	L	4	10
			Lymphocytes	0.8	10^9/L	L	1.2	3.7
		2011-09-12T17:53	Sodium	136	mmol/L	L	137	145
			Magnesium	1.6	mg/dL	L	1.7	2.6
			Creatinine	1.4	mg/dL	H	0.6	1
			Albumin	3.2	g/dL	L	3.5	5
			Alanine Aminotransferase	10	U/L	L	11	50
			Aspartate Aminotransferase	13	U/L	L	14	36
		2011-09-16T09:43	Hemoglobin	10.8	g/dL	L	11.2	15.7
			Erythrocytes	3.76	10^12/L	L	3.93	5.22
			Platelets	136	10^9/L	L	150	400
			Leukocytes	2.1	10^9/L	L	4	10
			Neutrophils	1.2	10^9/L	L	1.6	6.1
			Lymphocytes	0.4	10^9/L	L	1.2	3.7
			Chloride	108	mmol/L	H	95	107
			Creatinine	1.3	mg/dL	H	0.6	1
			Albumin	3.2	g/dL	L	3.5	5
			Lactate Dehydrogenase	654	U/L	H	313	618
	Cycle 4	2011-10-17T08:38	Lymphocytes	0.6	10^9/L	L	1.2	3.7
		2011-10-17T10:31	Sodium	136	mmol/L	L	137	145
			Creatinine	1.68	mg/dL	H	0.6	1
			Albumin	3.4	g/dL	L	3.5	5
			Alanine Aminotransferase	10	U/L	L	11	50

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
908-003	Cycle 4	2011-10-17T10:31	Aspartate Aminotransferase	13	U/L	L	14	36
			Glucose	129	mg/dL	H	65	110
		2011-10-21T09:10	Platelets	132	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	1.2	3.7
			Creatinine	1.75	mg/dL	H	0.6	1
			Albumin	3.2	g/dL	L	3.5	5
			Alanine Aminotransferase	10	U/L	L	11	50
			Aspartate Aminotransferase	10	U/L	L	14	36
	Unplanned	2011-10-19T09:40	Potassium	3.2	mmol/L	L	3.5	5
			Creatinine	1.6	mg/dL	H	0.6	1
			Albumin	3	g/dL	L	3.5	5
			Alanine Aminotransferase	7	U/L	L	11	50
			Aspartate Aminotransferase	8	U/L	L	14	36
			Glucose	164	mg/dL	H	65	110
		2011-10-20T09:50	Platelets	124	10^9/L	L	150	400
			Lymphocytes	0.4	10^9/L	L	1.2	3.7
			Chloride	108	mmol/L	H	95	107
			Creatinine	1.69	mg/dL	H	0.6	1
			Albumin	3	g/dL	L	3.5	5
			Alanine Aminotransferase	6	U/L	L	11	50
			Aspartate Aminotransferase	11	U/L	L	14	36

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
908-003	End Trial	2011-11-07T08:36	Platelets	93	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4	10
			Neutrophils	1.4	10^9/L	L	1.6	6.1
			Lymphocytes	0.4	10^9/L	L	1.2	3.7
		2011-11-07T10:13	Activated Partial Thromboplastin Time	35.3	sec	H	26.1	33.9
			Magnesium	1.6	mg/dL	L	1.7	2.6
			Creatinine	1.51	mg/dL	H	0.6	1
			Albumin	3.4	g/dL	L	3.5	5
			Lactate Dehydrogenase	691	U/L	H	313	618
911-001	Pre-trial	2010-08-19T08:40	Blood Urea Nitrogen	6	mg/dL	L	10	25
	Cycle 1	2010-08-23T08:00	Leukocytes	10.7	10^9/L	H	3.8	10.6
			Neutrophils	8.3	10^9/L	H	1.8	7.7
			Blood Urea Nitrogen	9	mg/dL	L	10	25
		2010-08-27T08:40	Leukocytes	12.4	10^9/L	H	3.8	10.6
			Neutrophils	10.3	10^9/L	H	1.8	7.7
		2010-09-02T11:38	Monocytes	1.4	10^9/L	H	0	0.8
			Albumin	3.1	g/dL	L	3.2	4.6
	Cycle 2	2010-09-17T08:55	Monocytes	1	10^9/L	H	0	0.8
			Magnesium	2.4	mg/dL	H	1.8	2.3
	Cycle 3	2010-10-08T09:45	Monocytes	0.9	10^9/L	H	0	0.8
			Magnesium	2.4	mg/dL	H	1.8	2.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
911-001	Cycle 4	2010-10-25T08:50	Erythrocytes	4.05	10^12/L	L	4.15	5.55
		2010-10-29T08:45	Erythrocytes	4.01	10^12/L	L	4.15	5.55
			Neutrophils	8.4	10^9/L	H	1.8	7.7
	End Trial	2010-11-15T08:40	Hemoglobin	11.7	g/dL	L	12	15
			Erythrocytes	4.04	10^12/L	L	4.15	5.55
			Platelets	596	10^9/L	H	150	450
912-001	Pre-trial	2010-03-31T11:55	Hemoglobin	10.2	g/dL	L	13.8	17.2
			Erythrocytes	3.24	10^12/L	L	4.5	5.7
			Lymphocytes	0.3	10^9/L	L	1.2	3.3
		2010-03-31T11:57	Activated Partial Thromboplastin Time	43.4	sec	H	23	36
			Alanine Aminotransferase	79	U/L	H	7	53
			Aspartate Aminotransferase	66	U/L	H	10	47
			Lactate Dehydrogenase	348	U/L	H	100	250
	Cycle 1	2010-04-05T08:58	Hemoglobin	10.3	g/dL	L	13.8	17.2
			Erythrocytes	3.23	10^12/L	L	4.5	5.7
			Neutrophils	6.9	10^9/L	H	1.8	6.6
			Lymphocytes	0.2	10^9/L	L	1.2	3.3
		2010-04-20T08:03	Alanine Aminotransferase	64	U/L	H	7	53
			Aspartate Aminotransferase	49	U/L	H	10	47
			Bilirubin	1.8	mg/dL	H	0.3	1.1
			Glucose	153	mg/dL	H	65	140

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
912-001	Cycle 1	2010-04-20T08:07	Hemoglobin	7.4	g/dL	L	13.8	17.2
			Erythrocytes	2.23	10^12/L	L	4.5	5.7
			Leukocytes	12.8	10^9/L	H	3.8	9.8
			Neutrophils	11.2	10^9/L	H	1.8	6.6
			Lymphocytes	0.3	10^9/L	L	1.2	3.3
			Eosinophils	0.6	10^9/L	H	0	0.5
		2010-04-26T08:08	Hemoglobin	10	g/dL	L	14	17.5
			Erythrocytes	3.3	10^12/L	L	4.2	6.02
			Platelets	118	10^9/L	L	133	382
			Leukocytes	12.14	10^9/L	H	4.26	9.66
			Neutrophils	10.77	10^9/L	H	1.5	5.69
			Lymphocytes	0.29	10^9/L	L	1.12	3.06
			Monocytes	0.97	10^9/L	H	0.17	0.8
			Sodium	131	mmol/L	L	137	145
			Chloride	93	mmol/L	L	98	107
			Aspartate Aminotransferase	79	U/L	H	17	59
			Alkaline Phosphatase	241	U/L	H	38	123
			Lactate Dehydrogenase	3675	U/L	H	313	618
			Glucose	168	mg/dL	H	65	140
	Unplanned	2010-04-07T12:35	Bilirubin	12.6	mg/dL	H	0.3	1.1
	End Trial	2010-05-10T07:45	Sodium	134	mmol/L	L	135	145
			Alanine Aminotransferase	95	U/L	H	7	53
			Aspartate Aminotransferase	89	U/L	H	10	47
			Alkaline Phosphatase	833	U/L	H	110	320
			Lactate Dehydrogenase	2124	U/L	H	100	250
			Bilirubin	1.4	mg/dL	H	0.3	1.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
912-001	End Trial	2010-05-10T07:47	Hemoglobin	8.6	g/dL	L	13.8	17.2
			Erythrocytes	2.59	10^12/L	L	4.5	5.7
			Platelets	62	10^9/L	L	140	440
			Lymphocytes	0.5	10^9/L	L	1.2	3.3
912-002	Pre-trial	2010-11-22T09:11	Hemoglobin	9.8	g/dL	L	13.8	17.2
			Erythrocytes	3.69	10^12/L	L	4.5	5.7
			Leukocytes	12.6	10^9/L	H	3.8	9.8
			Monocytes	1.8	10^9/L	H	0.2	1
		2010-11-22T10:23	Albumin	2.4	g/dL	L	3	5
			Alanine Aminotransferase	104	U/L	H	7	53
			Aspartate Aminotransferase	87	U/L	H	10	47
			Alkaline Phosphatase	590	U/L	H	110	320
			Glucose	54	mg/dL	L	65	140
	Cycle 1	2010-11-29T10:33	Alanine Aminotransferase	60	U/L	H	7	53
		2010-11-29T10:36	Hemoglobin	10.8	g/dL	L	13.8	17.2
			Erythrocytes	3.83	10^12/L	L	4.5	5.7
			Monocytes	1.5	10^9/L	H	0.2	1
		2010-12-02T11:55	Glucose	149	mg/dL	H	65	140
		2010-12-02T12:17	Hemoglobin	10.2	g/dL	L	13.8	17.2
			Erythrocytes	3.75	10^12/L	L	4.5	5.7
			Monocytes	1.2	10^9/L	H	0.2	1
		2010-12-10T01:12	Hemoglobin	10.5	g/dL	L	13.8	17.2
			Erythrocytes	3.79	10^12/L	L	4.5	5.7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
912-002	End Trial	2010-12-20T08:57	Hemoglobin	10.4	g/dL	L	13.8	17.2
			Erythrocytes	3.8	10^12/L	L	4.5	5.7
			Neutrophils	1.9	10^9/L	L	2	7.5
			Lymphocytes	0.7	10^9/L	L	1	4
			Monocytes	2.2	10^9/L	H	0.2	1
			Lactate Dehydrogenase	294	U/L	H	100	250
912-003	Pre-trial	2011-01-19T09:40	Alkaline Phosphatase	98	U/L	L	110	320
			Bilirubin	1.3	mg/dL	H	0.3	1.1
		2011-01-19T09:41	Hemoglobin	12.6	g/dL	L	13.8	17.2
			Erythrocytes	3.79	10^12/L	L	4.5	5.7
			Platelets	97	10^9/L	L	140	440
			Lymphocytes	0.6	10^9/L	L	1.2	3.3
	Cycle 1	2011-01-31T08:48	Hemoglobin	12.9	g/dL	L	13.8	17.2
			Erythrocytes	3.85	10^12/L	L	4.5	5.7
			Platelets	101	10^9/L	L	140	440
			Leukocytes	9.9	10^9/L	H	3.8	9.8
			Neutrophils	8.3	10^9/L	H	2	7.5
			Lymphocytes	0.8	10^9/L	L	1.2	3.3
		2011-01-31T08:50	Alkaline Phosphatase	94	U/L	L	110	320
		2011-02-05T08:25	Hemoglobin	12.5	g/dL	L	13.8	17.2
			Erythrocytes	3.74	10^12/L	L	4.5	5.7
			Platelets	56	10^9/L	L	140	440
			Lymphocytes	0.49	10^9/L	L	1	4
			Monocytes	1.029	10^9/L	H	0.2	1
			Potassium	2.9	mmol/L	L	3.5	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
912-003	Cycle 1	2011-02-05T08:25	Alanine Aminotransferase	54	U/L	H	7	53
			Aspartate Aminotransferase	58	U/L	H	10	47
			Alkaline Phosphatase	85	U/L	L	110	320
			Lactate Dehydrogenase	331	U/L	H	100	250
			Bilirubin	1.3	mg/dL	H	0.3	1.1
		2011-02-14T10:52	Hemoglobin	10.7	g/dL	L	13.8	17.2
			Erythrocytes	3.33	10^12/L	L	4.5	5.7
			Leukocytes	10.7	10^9/L	H	3.8	9.8
			Neutrophils	8.56	10^9/L	H	2	7.5
			Lymphocytes	0.963	10^9/L	L	1	4
			Alkaline Phosphatase	79	U/L	L	110	320
	Cycle 2	2011-02-21T09:03	Alkaline Phosphatase	85	U/L	L	110	320
		2011-02-21T09:05	Hemoglobin	11.5	g/dL	L	13.8	17.2
			Erythrocytes	3.48	10^12/L	L	4.5	5.7
			Platelets	110	10^9/L	L	140	440
			Neutrophils	8	10^9/L	H	2	7.5
			Lymphocytes	0.8	10^9/L	L	1.2	3.3
		2011-02-25T07:45	Hemoglobin	11.2	g/dL	L	13.8	17.2
			Erythrocytes	3.39	10^12/L	L	4.5	5.7
			Platelets	107	10^9/L	L	140	440
			Lymphocytes	0.9	10^9/L	L	1.2	3.3
	Cycle 3	2011-03-14T11:40	Alkaline Phosphatase	79	U/L	L	110	320
		2011-03-14T11:49	Hemoglobin	11.4	g/dL	L	13.8	17.2
			Erythrocytes	3.42	10^12/L	L	4.5	5.7
			Platelets	99	10^9/L	L	140	440
			Lymphocytes	0.7	10^9/L	L	1.2	3.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
912-003	Cycle 3	2011-03-18T07:43	Hemoglobin	11.5	g/dL	L	13.8	17.2
			Erythrocytes	3.46	10^12/L	L	4.5	5.7
			Platelets	85	10^9/L	L	140	440
			Lymphocytes	0.6	10^9/L	L	1.2	3.3
		2011-03-18T07:48	Alkaline Phosphatase	82	U/L	L	110	320
	Unplanned	2011-02-07T12:09	Hemoglobin	11.9	g/dL	L	13.8	17.2
			Erythrocytes	3.68	10^12/L	L	4.5	5.7
			Platelets	53	10^9/L	L	140	440
			Leukocytes	10	10^9/L	H	3.8	9.8
		2011-02-07T12:10	Alkaline Phosphatase	79	U/L	L	110	320
			Lactate Dehydrogenase	336	U/L	H	100	250
			Bilirubin	1.4	mg/dL	H	0.3	1.1
	End Trial	2011-04-10T11:00	Prothrombin Time	17.1	sec	H	11	15
			Activated Partial Thromboplastin Time	37.1	sec	H	23	36
			Prothrombin Intl. Normalized Ratio	1.33	ratio	H	0.8	1.25
		2011-04-10T11:15	Hemoglobin	8.6	g/dL	L	13.8	17.2
			Erythrocytes	2.65	10^12/L	L	4.5	5.7
			Platelets	91	10^9/L	L	140	440
			Leukocytes	10.9	10^9/L	H	3.8	9.8
			Neutrophils	9.919	10^9/L	H	2	7.5
			Lymphocytes	0.109	10^9/L	L	1	4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
912-003	End Trial	2011-04-10T11:19	Potassium	3	mmol/L	L	3.5	5.1
			Phosphate	1.6	mg/dL	L	2.5	4.5
			Albumin	2.9	g/dL	L	3	5
			Alkaline Phosphatase	106	U/L	L	110	320
913-001	Pre-trial	2011-06-14T13:00	Hemoglobin	12.7	g/dL	L	13.3	17.2
			Erythrocytes	4.26	10^12/L	L	4.54	5.78
			Monocytes	0.9	10^9/L	H	0.2	0.7
		2011-06-14T17:00	Calcium	8.7	mg/dL	L	8.9	10.7
			Bilirubin	2.1	mg/dL	H	0	1.3
	Cycle 1	2011-06-20T12:45	Hemoglobin	12	g/dL	L	13.3	17.2
			Erythrocytes	4.07	10^12/L	L	4.54	5.78
			Potassium	3.4	mmol/L	L	3.6	5.1
			Magnesium	1.7	mg/dL	L	1.8	2.4
			Bilirubin	1.4	mg/dL	H	0	1.3
			Glucose	123	mg/dL	H	65	100
		2011-06-24T09:35	Hemoglobin	12.2	g/dL	L	13.3	17.2
			Erythrocytes	4.06	10^12/L	L	4.54	5.78
			Leukocytes	10.4	10^9/L	H	3.7	9.7
			Neutrophils	8.2	10^9/L	H	2	6.7
			Monocytes	1	10^9/L	H	0.2	0.7
			Potassium	3.3	mmol/L	L	3.6	5.1
			Magnesium	1.7	mg/dL	L	1.8	2.4
			Blood Urea Nitrogen	24	mg/dL	H	8	23
			Glucose	317	mg/dL	H	65	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
913-001	Cycle 1	2011-07-01T11:33	Hemoglobin	12.4	g/dL	L	13.3	17.2
			Erythrocytes	4.2	10^12/L	L	4.54	5.78
		2011-07-01T11:35	Bilirubin	1.4	mg/dL	H	0	1.3
			Glucose	115	mg/dL	H	65	100
	End Trial	2011-07-11T10:50	Hemoglobin	12.1	g/dL	L	13.3	17.2
			Erythrocytes	4.07	10^12/L	L	4.54	5.78
			Potassium	3.4	mmol/L	L	3.6	5.1
			Glucose	155	mg/dL	H	65	100
914-002	Pre-trial	2010-09-08T14:44	Creatinine	1.5	mg/dL	H	0.6	1.3
			Albumin	3.9	g/dL	L	4	5.2
			Alkaline Phosphatase	101	U/L	H	33	97
			Lactate Dehydrogenase	295	U/L	H	12	246
			Blood Urea Nitrogen	21	mg/dL	H	6	20
		2010-09-08T14:45	Hemoglobin	12.8	g/dL	L	13	17
			Leukocytes	3.8	10^9/L	L	4	11
	Cycle 1	2010-09-13T10:17	Hemoglobin	12.5	g/dL	L	13	17
		2010-09-13T10:30	Albumin	3.9	g/dL	L	4	5.2
			Lactate Dehydrogenase	303	U/L	H	12	246
			Glucose	122	mg/dL	H	70	99
		2010-09-17T15:05	Hemoglobin	12.3	g/dL	L	13	17
			Erythrocytes	4.13	10^12/L	L	4.2	5.6
			Leukocytes	3.8	10^9/L	L	4	11
			Lymphocytes	0.7	10^9/L	L	0.8	5.3
			Chloride	110	mmol/L	H	98	109
			Alkaline Phosphatase	99	U/L	H	33	97

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-002	Cycle 1	2010-09-17T15:05	Lactate Dehydrogenase	340	U/L	H	12	246
			Blood Urea Nitrogen	21	mg/dL	H	6	20
		2010-09-23T07:25	Aspartate Aminotransferase	38	U/L	H	10	37
			Lactate Dehydrogenase	335	U/L	H	12	246
		2010-09-23T07:26	Hemoglobin	12.7	g/dL	L	13	17
	Cycle 2	2010-10-04T09:07	Albumin	3.9	g/dL	L	4	5.2
			Lactate Dehydrogenase	326	U/L	H	12	246
			Glucose	103	mg/dL	H	70	99
		2010-10-04T09:08	Hemoglobin	12.7	g/dL	L	13	17
			Leukocytes	3.2	10^9/L	L	4	11
			Lymphocytes	0.7	10^9/L	L	0.8	5.3
		2010-10-08T13:48	Hemoglobin	12.5	g/dL	L	13	17
			Platelets	130	10^9/L	L	150	400
			Leukocytes	2.4	10^9/L	L	4	11
			Neutrophils	1.3	10^9/L	L	1.5	8.8
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
			Potassium	3.3	mmol/L	L	3.5	5.1
			Albumin	3.9	g/dL	L	4	5.2
			Lactate Dehydrogenase	346	U/L	H	12	246
	End Trial	2010-10-25T09:18	Hemoglobin	12.6	g/dL	L	13	17
			Platelets	105	10^9/L	L	150	400
			Leukocytes	2.5	10^9/L	L	4	11
			Neutrophils	1.1	10^9/L	L	1.5	8.8
			Alkaline Phosphatase	110	U/L	H	33	97
			Lactate Dehydrogenase	388	U/L	H	12	246

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-003	Pre-trial	2010-09-24T22:19	Ery. Mean Corpuscular Volume	80	fL	L	82	98
			Leukocytes	2.4	10^9/L	L	4	11
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
			Creatinine	0.4	mg/dL	L	0.6	1.3
			Alkaline Phosphatase	384	U/L	H	33	97
			Lactate Dehydrogenase	260	U/L	H	12	246
			Glucose	115	mg/dL	H	70	99
	Cycle 1	2010-09-27T09:07	Creatinine	0.5	mg/dL	L	0.6	1.3
			Alkaline Phosphatase	394	U/L	H	33	97
			Lactate Dehydrogenase	269	U/L	H	12	246
		2010-09-27T09:08	Ery. Mean Corpuscular Volume	80	fL	L	82	98
			Leukocytes	3.3	10^9/L	L	4	11
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
		2010-10-01T08:50	Hemoglobin	10.1	g/dL	L	11.5	16
			Ery. Mean Corpuscular Volume	80	fL	L	82	98
			Platelets	104	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
			Calcium	8	mg/dL	L	8.5	10.5
			Chloride	110	mmol/L	H	98	109
			Phosphate	2	mg/dL	L	2.5	4.2
			Albumin	3.3	g/dL	L	4	5.2
			Alanine Aminotransferase	104	U/L	H	5	37
			Alkaline Phosphatase	491	U/L	H	33	97
			Glucose	106	mg/dL	H	70	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-003	Cycle 1	2010-10-11T08:25	Ery. Mean Corpuscular Volume	80	fL	L	82	98
			Leukocytes	2.5	10^9/L	L	4	11
			Neutrophils	1.475	10^9/L	L	2	7.5
			Lymphocytes	0.7	10^9/L	L	0.8	5.3
		2010-10-11T08:32	Creatinine	0.5	mg/dL	L	0.6	1.3
			Alanine Aminotransferase	422	U/L	H	5	37
			Aspartate Aminotransferase	258	U/L	H	10	37
			Alkaline Phosphatase	793	U/L	H	33	97
			Lactate Dehydrogenase	388	U/L	H	12	246
			Bilirubin	4.2	mg/dL	H	0	1
	Cycle 2	2010-10-21T07:15	Calcium	7.5	mg/dL	L	8.5	10.5
			Lactate Dehydrogenase	271	U/L	H	12	246
		2010-10-21T07:16	Erythrocytes	2.83	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	23.6	fL	L	82	98
			Platelets	112	10^9/L	L	150	400
			Leukocytes	2.9	10^9/L	L	4	11
			Neutrophils	1.995	10^9/L	L	2	7.5
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
		2010-10-21T13:53	Hemoglobin	8.6	g/dL	L	11.5	16
			Prothrombin Time	13.7	sec	H	9	13.2
			Prothrombin Intl. Normalized Ratio	1.23	ratio	H	0.81	1.19
		2010-10-25T01:46	Hemoglobin	8.9	g/dL	L	11.5	16
			Erythrocytes	3.27	10^12/L	L	4	5.2
			Platelets	101	10^9/L	L	150	400
			Leukocytes	2.2	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	0.8	5.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-003	Cycle 2	2010-10-25T01:46	Calcium	7.3	mg/dL	L	8.5	10.5
			Albumin	2.9	g/dL	L	4	5.2
			Alkaline Phosphatase	326	U/L	H	33	97
			Lactate Dehydrogenase	305	U/L	H	12	246
			Bilirubin	1.4	mg/dL	H	0	1
	Unplanned	2010-11-01T12:31	Alanine Aminotransferase	45	U/L	H	5	37
			Aspartate Aminotransferase	52	U/L	H	10	37
			Bilirubin	1.4	mg/dL	H	0	1
	End Trial	2010-11-15T11:50	Hemoglobin	8.4	g/dL	L	11.5	16
			Erythrocytes	2.98	10^12/L	L	4	5.2
			Platelets	75	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
			Sodium	133	mmol/L	L	136	144
			Calcium	7.6	mg/dL	L	8.5	10.5
			Phosphate	1.4	mg/dL	L	2.5	4.2
			Creatinine	0.5	mg/dL	L	0.6	1.3
			Albumin	3.2	g/dL	L	4	5.2
			Alkaline Phosphatase	247	U/L	H	33	97
			Lactate Dehydrogenase	304	U/L	H	12	246
			Bilirubin	1.2	mg/dL	H	0	1
			Glucose	131	mg/dL	H	70	99
		2010-11-15T13:38	Prothrombin Time	15.8	sec	H	9	13.2
			Prothrombin Intl. Normalized Ratio	1.42	ratio	H	0.81	1.19

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-004	Pre-trial	2011-01-03T16:23	Erythrocytes	3.35	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	104	fL	H	82	98
			Lymphocytes	0.93	10^9/L	L	1	4
			Basophils	0.2	10^9/L	H	0	0.16
			Chloride	110	mmol/L	H	98	109
	Cycle 1	2011-01-10T07:33	Erythrocytes	3.49	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Lymphocytes	0.826	10^9/L	L	1	4
			Phosphate	4.4	mg/dL	H	2.5	4.2
		2011-01-14T15:50	Hemoglobin	10.5	g/dL	L	11.5	16
			Erythrocytes	3.27	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Lymphocytes	0.6	10^9/L	L	0.8	5.3
			Glucose	109	mg/dL	H	70	99
		2011-01-24T12:25	Hemoglobin	10.8	g/dL	L	11.5	16
			Erythrocytes	3.42	10^12/L	L	4	5.2
			Platelets	448	10^9/L	H	150	400
			Lymphocytes	0.6	10^9/L	L	0.8	5.3
			Potassium	5.4	mmol/L	H	3.5	5.1
	End Trial	2011-01-31T08:13	Erythrocytes	3.84	10^12/L	L	4	5.2
			Platelets	432	10^9/L	H	150	400
			Leukocytes	11.1	10^9/L	H	4	11
			Albumin	3.9	g/dL	L	4	5.2
			Alanine Aminotransferase	57	U/L	H	5	37
			Lactate Dehydrogenase	266	U/L	H	12	246
			Glucose	111	mg/dL	H	70	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-004	End Trial	2011-02-02T12:04	Prothrombin Time	14	sec	H	9	13.2
914-006	Pre-trial	2011-03-14T11:47	Phosphate	4.5	mg/dL	H	2.5	4.2
			Alkaline Phosphatase	165	U/L	H	45	129
		2011-03-14T11:48	Erythrocytes	3.61	10^12/L	L	4	5.2
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
	Cycle 1	2011-04-04T10:31	Erythrocytes	3.49	10^12/L	L	4	5.2
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
			Alkaline Phosphatase	256	U/L	H	45	129
		2011-04-08T10:49	Hemoglobin	10.9	g/dL	L	11.5	16
			Erythrocytes	3.21	10^12/L	L	4	5.2
			Leukocytes	3.5	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	0.8	5.3
		2011-04-08T10:50	Alanine Aminotransferase	75	U/L	H	5	37
			Alkaline Phosphatase	321	U/L	H	45	129
		2011-04-18T17:51	Hemoglobin	10.7	g/dL	L	11.5	16
			Erythrocytes	3.12	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
		2011-04-18T17:52	Calcium	8.4	mg/dL	L	8.5	10.5
			Creatinine	0.5	mg/dL	L	0.6	1.3
			Albumin	3.9	g/dL	L	4	5.2
			Alkaline Phosphatase	191	U/L	H	45	129
			Blood Urea Nitrogen	21	mg/dL	H	6	20
			Glucose	112	mg/dL	H	70	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-006	Cycle 2	2011-04-22T11:46	Hemoglobin	11	g/dL	L	11.5	16
			Erythrocytes	3.19	10^12/L	L	4	5.2
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
			Calcium	8.3	mg/dL	L	8.5	10.5
			Albumin	3.9	g/dL	L	4	5.2
			Alanine Aminotransferase	38	U/L	H	5	37
			Aspartate Aminotransferase	40	U/L	H	10	37
			Alkaline Phosphatase	289	U/L	H	45	129
			Glucose	109	mg/dL	H	70	99
		2011-04-29T10:00	Hemoglobin	11.4	g/dL	L	11.5	16
			Erythrocytes	3.34	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
			Alkaline Phosphatase	443	U/L	H	45	129
			Blood Urea Nitrogen	22	mg/dL	H	6	20
			Glucose	101	mg/dL	H	70	99
	End Trial	2011-05-09T13:13	Erythrocytes	3.37	10^12/L	L	4	5.2
			Ery. Mean Corpuscular Volume	101	fL	H	82	98
		2011-05-09T13:26	Alkaline Phosphatase	185	U/L	H	45	129
			Blood Urea Nitrogen	23	mg/dL	H	6	20
			Glucose	100	mg/dL	H	70	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-008	Pre-trial	2011-06-27T12:24	Hemoglobin	10.2	g/dL	L	11.5	16
			Erythrocytes	3.22	10^12/L	L	4	5.2
			Platelets	67	10^9/L	L	150	400
			Leukocytes	2.9	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
		2011-06-27T12:25	Lactate Dehydrogenase	293	U/L	H	12	246
			Glucose	103	mg/dL	H	70	99
	Cycle 1	2011-06-28T07:15	Hemoglobin	9.4	g/dL	L	11.5	16
			Erythrocytes	2.88	10^12/L	L	4	5.2
			Platelets	69	10^9/L	L	150	400
			Leukocytes	3	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	0.8	5.3
		2011-06-28T08:21	Lactate Dehydrogenase	343	U/L	H	12	246
			Glucose	105	mg/dL	H	70	99
		2011-07-02T08:16	Hemoglobin	8.9	g/dL	L	11.5	16
			Erythrocytes	2.73	10^12/L	L	4	5.2
			Platelets	49	10^9/L	L	150	400
			Leukocytes	2.3	10^9/L	L	4	11
			Neutrophils	1.4	10^9/L	L	1.5	8.8
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
			Albumin	3.8	g/dL	L	4	5.2
			Lactate Dehydrogenase	295	U/L	H	12	246
			Glucose	102	mg/dL	H	70	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-008	Cycle 1	2011-07-11T08:11	Hemoglobin	8.5	g/dL	L	11.5	16
			Erythrocytes	2.68	10^12/L	L	4	5.2
			Platelets	54	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	0.8	5.3
			Albumin	3.8	g/dL	L	4	5.2
			Lactate Dehydrogenase	313	U/L	H	12	246
			Glucose	105	mg/dL	H	70	99
	End Trial	2011-07-18T09:03	Albumin	3.9	g/dL	L	4	5.2
			Alanine Aminotransferase	66	U/L	H	5	37
			Blood Urea Nitrogen	23	mg/dL	H	6	20
		2011-07-18T09:04	Hemoglobin	8.6	g/dL	L	11.5	16
			Erythrocytes	2.73	10^12/L	L	4	5.2
			Platelets	85	10^9/L	L	150	400
			Leukocytes	2.7	10^9/L	L	4	11
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
914-009	Pre-trial	2011-07-21T10:54	Lymphocytes	0.3	10^9/L	L	0.8	5.3
			Alkaline Phosphatase	162	U/L	H	45	129
			Glucose	110	mg/dL	H	70	99
	Cycle 1	2011-07-25T08:03	Platelets	126	10^9/L	L	150	400
			Lymphocytes	0.2	10^9/L	L	0.8	5.3
		2011-07-25T08:04	Alkaline Phosphatase	153	U/L	H	45	129
			Blood Urea Nitrogen	22	mg/dL	H	6	20
			Glucose	128	mg/dL	H	70	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
914-009	Cycle 1	2011-07-29T08:09	Alanine Aminotransferase	49	U/L	H	5	37
			Alkaline Phosphatase	199	U/L	H	45	129
			Lactate Dehydrogenase	257	U/L	H	12	246
			Glucose	156	mg/dL	H	70	99
		2011-07-29T08:13	Platelets	89	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	0.8	5.3
		2011-08-05T11:35	Hemoglobin	12.6	g/dL	L	13	17
			Lymphocytes	0.4	10^9/L	L	0.8	5.3
			Alkaline Phosphatase	166	U/L	H	45	129
			Lactate Dehydrogenase	275	U/L	H	12	246
			Glucose	104	mg/dL	H	70	99
	Cycle 2	2011-08-15T12:29	Hemoglobin	11.8	g/dL	L	13	17
			Lymphocytes	0.5	10^9/L	L	0.8	5.3
		2011-08-15T12:45	Albumin	3.9	g/dL	L	4	5.2
			Alkaline Phosphatase	185	U/L	H	45	129
			Blood Urea Nitrogen	21	mg/dL	H	6	20
			Glucose	118	mg/dL	H	70	99
		2011-08-19T09:38	Hemoglobin	10.7	g/dL	L	13	17
			Erythrocytes	3.82	10^12/L	L	4.2	5.6
			Platelets	149	10^9/L	L	150	400
			Leukocytes	3.8	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	0.8	5.3

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
914-009	Cycle 2	2011-08-19T09:40	Albumin	3.9	g/dL	L	4	5.2
			Alanine Aminotransferase	49	U/L	H	5	37
			Alkaline Phosphatase	234	U/L	H	45	129
			Glucose	100	mg/dL	H	70	99
	End Trial	2011-09-07T14:33	Hemoglobin	11.5	g/dL	L	13	17
			Erythrocytes	4.11	10^12/L	L	4.2	5.6
			Platelets	141	10^9/L	L	150	400
			Lymphocytes	0.2	10^9/L	L	0.8	5.3
		2011-09-07T14:34	Albumin	3.9	g/dL	L	4	5.2
			Alkaline Phosphatase	208	U/L	H	45	129
			Lactate Dehydrogenase	254	U/L	H	12	246
			Glucose	102	mg/dL	H	70	99
915-001	Pre-trial	2010-02-26T13:40	Erythrocytes	3.69	10^12/L	L	3.8	5.2
			Neutrophils	8.1	10^9/L	H	2	7.3
			Lymphocytes	0.8	10^9/L	L	1	3.4
			Basophils	0.2	10^9/L	H	0	0.1
		2010-03-04T12:42	Sodium	134	mmol/L	L	135	145
	Cycle 1	2010-03-08T11:15	Calcium	8.1	mg/dL	L	8.5	10.5
		2010-03-08T11:30	Erythrocytes	3.74	10^12/L	L	3.8	5.2
			Monocytes	0.9	10^9/L	H	0	0.8
		2010-03-12T10:20	Alanine Aminotransferase	62	U/L	H	5	50
			Alkaline Phosphatase	124	U/L	H	31	98

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-001	Cycle 1	2010-03-12T10:30	Hemoglobin	11.4	g/dL	L	11.6	15.5
			Erythrocytes	3.47	10^12/L	L	3.8	5.2
		2010-03-19T12:25	Sodium	134	mmol/L	L	135	145
		2010-03-19T12:29	Hemoglobin	11.5	g/dL	L	11.6	15.5
			Erythrocytes	3.75	10^12/L	L	3.8	5.2
			Lymphocytes	0.8	10^9/L	L	1	3.4
	Cycle 2	2010-03-29T11:31	Hemoglobin	10.7	g/dL	L	11.6	15.5
			Erythrocytes	3.41	10^12/L	L	3.8	5.2
			Lymphocytes	0.5	10^9/L	L	1	3.4
	Cycle 3	2010-04-19T14:40	Erythrocytes	3.79	10^12/L	L	3.8	5.2
			Lymphocytes	0.6	10^9/L	L	1	3.4
			Sodium	134	mmol/L	L	135	145
			Calcium	8.3	mg/dL	L	8.5	10.5
		2010-04-23T10:50	Calcium	8.4	mg/dL	L	8.5	10.5
			Alanine Aminotransferase	113	U/L	H	5	50
			Alkaline Phosphatase	138	U/L	H	31	98
		2010-04-23T10:56	Hemoglobin	10.6	g/dL	L	11.6	15.5
			Erythrocytes	3.42	10^12/L	L	3.8	5.2
			Platelets	137	10^9/L	L	150	400
			Lymphocytes	0.6	10^9/L	L	1	3.4
	Cycle 4	2010-05-07T12:10	Calcium	8.3	mg/dL	L	8.5	10.5
		2010-05-07T12:22	Hemoglobin	11.2	g/dL	L	11.6	15.5
			Erythrocytes	3.61	10^12/L	L	3.8	5.2
			Lymphocytes	0.5	10^9/L	L	1	3.4
			Basophils	0.3	10^9/L	H	0	0.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-001	Cycle 4	2010-05-14T12:39	Hemoglobin	10.7	g/dL	L	11.6	15.5
			Erythrocytes	3.51	10^12/L	L	3.8	5.2
			Platelets	143	10^9/L	L	150	400
			Lymphocytes	0.8	10^9/L	L	1	3.4
		2010-05-14T12:40	Sodium	131	mmol/L	L	135	145
			Alkaline Phosphatase	128	U/L	H	31	98
	Cycle 5	2010-06-04T12:29	Hemoglobin	11.2	g/dL	L	11.6	15.5
			Erythrocytes	3.7	10^12/L	L	3.8	5.2
		2010-06-11T11:55	Alanine Aminotransferase	54	U/L	H	5	50
			Alkaline Phosphatase	169	U/L	H	31	98
		2010-06-11T12:10	Hemoglobin	10.8	g/dL	L	11.6	15.5
			Erythrocytes	3.49	10^12/L	L	3.8	5.2
			Lymphocytes	0.4	10^9/L	L	1	3.4
	Cycle 6	2010-06-25T11:48	Hemoglobin	11.2	g/dL	L	11.6	15.5
			Lymphocytes	0.5	10^9/L	L	1	3.4
		2010-06-25T12:02	Potassium	3.4	mmol/L	L	3.5	5.3
			Calcium	8.1	mg/dL	L	8.5	10.5
		2010-07-02T11:30	Hemoglobin	10.8	g/dL	L	11.6	15.5
			Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Lymphocytes	0.5	10^9/L	L	1	3.4
			Calcium	8.4	mg/dL	L	8.5	10.5
			Alanine Aminotransferase	67	U/L	H	5	50
			Alkaline Phosphatase	152	U/L	H	31	98
	Cycle 7	2010-07-16T12:05	Erythrocytes	3.79	10^12/L	L	3.8	5.2
			Lymphocytes	0.3	10^9/L	L	1	3.4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-001	Cycle 7	2010-07-23T12:12	Hemoglobin	10.7	g/dL	L	11.6	15.5
			Erythrocytes	3.4	10^12/L	L	3.8	5.2
			Lymphocytes	0.2	10^9/L	L	1	3.4
		2010-07-23T12:38	Alanine Aminotransferase	82	U/L	H	5	50
			Alkaline Phosphatase	157	U/L	H	31	98
	Cycle 8	2010-08-09T10:50	Lymphocytes	0.8	10^9/L	L	1	3.4
		2010-08-09T11:26	Calcium	8.4	mg/dL	L	8.5	10.5
			Lactate Dehydrogenase	278	U/L	H	110	221
		2010-08-13T12:30	Lactate Dehydrogenase	306	U/L	H	110	221
			Blood Urea Nitrogen	26	mg/dL	H	7	23
		2010-08-13T13:10	Lymphocytes	0.4	10^9/L	L	1	3.4
			Basophils	0.2	10^9/L	H	0	0.1
	Cycle 9	2010-08-27T09:23	Lymphocytes	0.3	10^9/L	L	1	3.4
		2010-08-27T09:59	Calcium	8.3	mg/dL	L	8.5	10.5
			Lactate Dehydrogenase	319	U/L	H	110	221
		2010-09-03T12:00	Alanine Aminotransferase	112	U/L	H	5	50
			Alkaline Phosphatase	119	U/L	H	31	98
		2010-09-03T12:19	Lymphocytes	0.3	10^9/L	L	1	3.4
	Cycle 10	2010-09-17T13:00	Neutrophils	7.7	10^9/L	H	2	7.3
			Lymphocytes	0.8	10^9/L	L	1	3.4
		2010-09-24T11:30	Neutrophils	7.4	10^9/L	H	2	7.3
			Lymphocytes	0.5	10^9/L	L	1	3.4
			Calcium	8.4	mg/dL	L	8.5	10.5
			Alanine Aminotransferase	104	U/L	H	5	50
			Aspartate Aminotransferase	51	U/L	H	5	40
			Alkaline Phosphatase	125	U/L	H	31	98

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-001	Cycle 11	2010-10-08T11:56	Lymphocytes	0.5	10^9/L	L	1	3.4
		2010-10-08T12:33	Lactate Dehydrogenase	249	U/L	H	110	221
		2010-10-15T12:45	Alanine Aminotransferase	66	U/L	H	5	50
			Lactate Dehydrogenase	239	U/L	H	110	221
		2010-10-15T12:58	Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Lymphocytes	0.4	10^9/L	L	1	3.4
	Cycle 12	2010-10-29T10:40	Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Lymphocytes	0.3	10^9/L	L	1	3.4
		2010-11-05T10:35	Erythrocytes	3.7	10^12/L	L	3.8	5.2
		2010-11-05T11:21	Potassium	3.4	mmol/L	L	3.5	5.3
	Cycle 13	2010-11-26T11:40	Potassium	3.3	mmol/L	L	3.5	5.3
		2010-11-29T12:30	Lymphocytes	0.5	10^9/L	L	1	3.4
		2010-12-03T10:10	Neutrophils	9.1	10^9/L	H	2	7.3
			Lymphocytes	0.4	10^9/L	L	1	3.4
			Monocytes	0.9	10^9/L	H	0	0.8
			Alanine Aminotransferase	66	U/L	H	5	50
			Blood Urea Nitrogen	27	mg/dL	H	7	23
	Cycle 14	2010-12-10T14:43	Neutrophils	7.8	10^9/L	H	2	7.3
			Lymphocytes	0.4	10^9/L	L	1	3.4
		2010-12-17T11:20	Neutrophils	7.9	10^9/L	H	2	7.3
			Lymphocytes	0.5	10^9/L	L	1	3.4
		2010-12-17T11:31	Alanine Aminotransferase	56	U/L	H	5	50
			Blood Urea Nitrogen	27	mg/dL	H	7	23

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-001	Cycle 15	2010-12-30T12:35	Lymphocytes	0.4	10^9/L	L	1	3.4
		2011-01-03T11:55	Potassium	3.4	mmol/L	L	3.5	5.3
			Calcium	8.4	mg/dL	L	8.5	10.5
			Lactate Dehydrogenase	222	U/L	H	110	221
		2011-01-07T10:20	Leukocytes	12.2	10^9/L	H	4	11
			Neutrophils	10.8	10^9/L	H	2	7.3
			Lymphocytes	0.4	10^9/L	L	1	3.4
			Blood Urea Nitrogen	24	mg/dL	H	7	23
	Cycle 16	2011-01-18T13:00	Neutrophils	9.4	10^9/L	H	2	7.3
			Lymphocytes	0.3	10^9/L	L	1	3.4
			Basophils	0.2	10^9/L	H	0	0.1
			Blood Urea Nitrogen	25	mg/dL	H	7	23
		2011-01-28T10:00	Erythrocytes	3.6	10^12/L	L	3.8	5.2
			Lymphocytes	0.3	10^9/L	L	1	3.4
			Blood Urea Nitrogen	24	mg/dL	H	7	23
	Cycle 17	2011-02-10T11:07	Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Lymphocytes	0.3	10^9/L	L	1	3.4
		2011-02-18T09:40	Erythrocytes	3.5	10^12/L	L	3.8	5.2
			Platelets	141	10^9/L	L	150	400
			Lymphocytes	0.1	10^9/L	L	1	3.4
			Calcium	8.4	mg/dL	L	8.5	10.5
			Alanine Aminotransferase	82	U/L	H	5	50
	Cycle 18	2011-03-04T10:23	Calcium	8.4	mg/dL	L	8.5	10.5
		2011-03-04T10:26	Lymphocytes	0.4	10^9/L	L	1	3.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-001	Cycle 19	2011-03-25T10:12	Lymphocytes	0.4	10^9/L	L	1	3.4
		2011-04-01T10:11	Erythrocytes	3.66	10^12/L	L	3.8	5.2
			Platelets	132	10^9/L	L	150	400
			Lymphocytes	0.1	10^9/L	L	1	3.4
		2011-04-01T11:03	Alanine Aminotransferase	111	U/L	H	5	50
			Alkaline Phosphatase	148	U/L	H	31	98
			Glucose	144	mg/dL	H	70	140
	Cycle 20	2011-04-15T11:45	Alkaline Phosphatase	118	U/L	H	31	98
			Lactate Dehydrogenase	261	U/L	H	110	221
		2011-04-15T12:02	Lymphocytes	0.5	10^9/L	L	1	3.4
		2011-04-22T10:45	Alanine Aminotransferase	54	U/L	H	5	50
			Alkaline Phosphatase	138	U/L	H	31	98
			Lactate Dehydrogenase	300	U/L	H	110	221
		2011-04-22T10:56	Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Lymphocytes	0.2	10^9/L	L	1	3.4
	End Trial	2011-05-13T11:55	Prothrombin Time	13.8	sec	H	9.4	11.6
			Activated Partial Thromboplastin Time	56	sec	H	24	35
			Alkaline Phosphatase	173	U/L	H	31	98
			Lactate Dehydrogenase	312	U/L	H	110	221
		2011-05-13T12:02	Lymphocytes	0.2	10^9/L	L	1	3.4

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-002	Pre-trial	2010-06-02T11:55	Hemoglobin	10.4	g/dL	L	11.6	15.5
			Erythrocytes	3.4	10^12/L	L	3.8	5.2
			Leukocytes	3.5	10^9/L	L	4	11
			Lymphocytes	0.5	10^9/L	L	1	3.4
		2010-06-07T09:20	Albumin	2.9	g/dL	L	3	4.6
			Blood Urea Nitrogen	5	mg/dL	L	7	23
	Cycle 1	2010-06-07T09:20	Hemoglobin	10.6	g/dL	L	11.6	15.5
			Erythrocytes	3.57	10^12/L	L	3.8	5.2
			Lymphocytes	0.5	10^9/L	L	1	3.4
			Albumin	2.9	g/dL	L	3	4.6
			Blood Urea Nitrogen	5	mg/dL	L	7	23
		2010-06-11T11:33	Potassium	3	mmol/L	L	3.5	5.3
		2010-06-11T11:42	Hemoglobin	10.5	g/dL	L	11.6	15.5
			Erythrocytes	3.5	10^12/L	L	3.8	5.2
			Leukocytes	15	10^9/L	H	4	11
			Neutrophils	14.1	10^9/L	H	2	7.3
			Lymphocytes	0.5	10^9/L	L	1	3.4
		2010-06-18T14:36	Lymphocytes	0.9	10^9/L	L	1	3.4
			Monocytes	0.9	10^9/L	H	0	0.8
			Basophils	0.3	10^9/L	H	0	0.1
			Chloride	97	mmol/L	L	98	109
			Blood Urea Nitrogen	5	mg/dL	L	7	23

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-002	Cycle 2	2010-06-28T11:00	Hemoglobin	11.5	g/dL	L	11.6	15.5
			Lymphocytes	0.4	10^9/L	L	1	3.4
			Basophils	0.2	10^9/L	H	0	0.1
			Sodium	133	mmol/L	L	135	145
			Chloride	97	mmol/L	L	98	109
			Alkaline Phosphatase	100	U/L	H	31	98
		2010-07-02T13:40	Hemoglobin	10.9	g/dL	L	11.6	15.5
			Erythrocytes	3.6	10^12/L	L	3.8	5.2
			Leukocytes	12.5	10^9/L	H	4	11
			Neutrophils	11.4	10^9/L	H	2	7.3
			Lymphocytes	0.4	10^9/L	L	1	3.4
			Sodium	134	mmol/L	L	135	145
			Potassium	2.6	mmol/L	L	3.5	5.3
			Creatinine	0.5	mg/dL	L	0.6	1.2
			Aspartate Aminotransferase	3	U/L	L	5	40
			Glucose	65	mg/dL	L	70	140
	Cycle 3	2010-07-19T14:00	Potassium	3.4	mmol/L	L	3.5	5.3
			Alkaline Phosphatase	107	U/L	H	31	98
		2010-07-19T14:13	Lymphocytes	0.6	10^9/L	L	1	3.4
		2010-07-23T14:23	Hemoglobin	11.4	g/dL	L	11.6	15.5
			Neutrophils	9.6	10^9/L	H	2	7.3
			Lymphocytes	0.6	10^9/L	L	1	3.4
		2010-07-23T14:27	Potassium	3.1	mmol/L	L	3.5	5.3
			Aspartate Aminotransferase	3	U/L	L	5	40

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-002	Cycle 4	2010-08-09T13:45	Albumin	2.9	g/dL	L	3	4.6
			Alkaline Phosphatase	132	U/L	H	31	98
		2010-08-09T14:00	Hemoglobin	11.2	g/dL	L	11.6	15.5
			Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Lymphocytes	0.7	10^9/L	L	1	3.4
		2010-08-13T13:45	Hemoglobin	10.9	g/dL	L	11.6	15.5
			Erythrocytes	3.7	10^12/L	L	3.8	5.2
			Leukocytes	11.1	10^9/L	H	4	11
			Neutrophils	9.3	10^9/L	H	2	7.3
			Lymphocytes	0.6	10^9/L	L	1	3.4
			Basophils	0.3	10^9/L	H	0	0.1
	Cycle 5	2010-08-30T13:45	Hemoglobin	10.1	g/dL	L	11.6	15.5
			Erythrocytes	3.4	10^12/L	L	3.8	5.2
			Lymphocytes	0.7	10^9/L	L	1	3.4
			Phosphate	5	mg/dL	H	2.5	4.8
			Alkaline Phosphatase	106	U/L	H	31	98
		2010-09-03T13:40	Hemoglobin	10.3	g/dL	L	11.6	15.5
			Erythrocytes	3.3	10^12/L	L	3.8	5.2
			Lymphocytes	0.7	10^9/L	L	1	3.4
			Potassium	3	mmol/L	L	3.5	5.3
			Calcium	8.4	mg/dL	L	8.5	10.5
			Aspartate Aminotransferase	3	U/L	L	5	40

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-002	Cycle 6	2010-09-20T13:50	Alkaline Phosphatase	114	U/L	H	31	98
		2010-09-20T14:05	Hemoglobin	11.4	g/dL	L	11.6	15.5
			Erythrocytes	3.6	10^12/L	L	3.8	5.2
			Lymphocytes	0.7	10^9/L	L	1	3.4
	Cycle 7	2010-10-11T13:44	Hemoglobin	11.4	g/dL	L	11.6	15.5
			Erythrocytes	3.5	10^12/L	L	3.8	5.2
			Lymphocytes	0.5	10^9/L	L	1	3.4
			Alanine Aminotransferase	4	U/L	L	5	50
		2010-10-15T13:20	Potassium	3.2	mmol/L	L	3.5	5.3
			Alkaline Phosphatase	119	U/L	H	31	98
		2010-10-15T13:30	Hemoglobin	11	g/dL	L	11.6	15.5
			Erythrocytes	3.5	10^12/L	L	3.8	5.2
			Neutrophils	8.2	10^9/L	H	2	7.3
			Lymphocytes	0.8	10^9/L	L	1	3.4
	Cycle 8	2010-11-01T13:43	Albumin	2.9	g/dL	L	3	4.6
			Aspartate Aminotransferase	3	U/L	L	5	40
			Alkaline Phosphatase	134	U/L	H	31	98
		2010-11-01T13:54	Hemoglobin	10.5	g/dL	L	11.6	15.5
			Erythrocytes	3.3	10^12/L	L	3.8	5.2
			Lymphocytes	0.7	10^9/L	L	1	3.4
		2010-11-05T09:50	Hemoglobin	10.3	g/dL	L	11.6	15.5
			Erythrocytes	3.3	10^12/L	L	3.8	5.2
			Leukocytes	14.5	10^9/L	H	4	11
			Neutrophils	12.6	10^9/L	H	2	7.3
			Lymphocytes	0.7	10^9/L	L	1	3.4
			Monocytes	1.1	10^9/L	H	0	0.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
915-002	Cycle 8	2010-11-05T09:50	Sodium	134	mmol/L	L	135	145
			Potassium	3.2	mmol/L	L	3.5	5.3
			Alkaline Phosphatase	187	U/L	H	31	98
	End Trial	2010-11-22T11:40	Hemoglobin	9.4	g/dL	L	11.6	15.5
			Erythrocytes	3.1	10^12/L	L	3.8	5.2
			Platelets	581	10^9/L	H	150	400
			Neutrophils	8.2	10^9/L	H	2	7.3
			Lymphocytes	0.6	10^9/L	L	1	3.4
		2010-11-22T11:43	Sodium	132	mmol/L	L	135	145
			Chloride	92	mmol/L	L	98	109
			Albumin	2.5	g/dL	L	3	4.6
			Alkaline Phosphatase	241	U/L	H	31	98
919-001	Pre-trial	2010-10-19T13:46	Hemoglobin	10.9	g/dL	L	11.7	14.5
			Erythrocytes	3.55	10^12/L	L	3.69	5.13
			Leukocytes	10.8	10^9/L	H	3.4	9.8
			Neutrophils	7.7	10^9/L	H	1.5	6.8
			Chloride	111	mmol/L	H	98	107
			Creatinine	0.52	mg/dL	L	0.57	1.11
			Albumin	2.6	g/dL	L	3.5	5
			Alkaline Phosphatase	321	U/L	H	40	150
			Lactate Dehydrogenase	245	U/L	H	125	243

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
919-001	Cycle 1	2010-10-25T10:17	Erythrocytes	3.66	10^12/L	L	3.69	5.13
			Ery. Mean Corpuscular Volume	100.2	fL	H	81.5	96.7
			Leukocytes	9.9	10^9/L	H	3.4	9.8
			Lymphocytes	3.6	10^9/L	H	1.2	3
			Calcium	8.2	mg/dL	L	8.4	10.2
			Chloride	108	mmol/L	H	98	107
			Creatinine	0.52	mg/dL	L	0.57	1.11
			Albumin	2.6	g/dL	L	3.5	5
			Alkaline Phosphatase	260	U/L	H	40	150
		2010-10-25T14:41	Prothrombin Time	18.1	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	1.5	ratio	H	0.9	1.1
		2010-10-29T10:26	Hemoglobin	11.2	g/dL	L	11.7	14.5
			Erythrocytes	3.56	10^12/L	L	3.69	5.13
			Ery. Mean Corpuscular Volume	98.6	fL	H	81.5	96.7
			Potassium	3.2	mmol/L	L	3.5	5.1
			Calcium	8	mg/dL	L	8.4	10.2
			Chloride	110	mmol/L	H	98	107
			Creatinine	0.51	mg/dL	L	0.57	1.11
			Albumin	2.4	g/dL	L	3.5	5
			Alkaline Phosphatase	215	U/L	H	40	150
			Urate	2.5	mg/dL	L	2.6	6
		2010-11-04T11:10	Erythrocytes	3.56	10^12/L	L	3.69	5.13
			Ery. Mean Corpuscular Volume	101.6	fL	H	81.5	96.7
			Leukocytes	10.9	10^9/L	H	3.4	9.8
			Neutrophils	7.1	10^9/L	H	1.5	6.8
			Monocytes	1.2	10^9/L	H	0.1	1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
919-001	Cycle 1	2010-11-08T10:20	Sodium	146	mmol/L	H	136	145
			Albumin	3.3	g/dL	L	3.5	5
			Alkaline Phosphatase	217	U/L	H	40	150
	Cycle 2	2010-11-15T09:41	Erythrocytes	3.59	10^12/L	L	3.69	5.13
			Ery. Mean Corpuscular Volume	100.4	fL	H	81.5	96.7
			Platelets	426	10^9/L	H	144	400
			Leukocytes	10.9	10^9/L	H	3.4	9.8
			Lymphocytes	3.3	10^9/L	H	1.2	3
			Monocytes	1.3	10^9/L	H	0.1	1
			Albumin	3.4	g/dL	L	3.5	5
			Alkaline Phosphatase	196	U/L	H	40	150
			Lactate Dehydrogenase	251	U/L	H	125	243
		2010-11-19T09:41	Prothrombin Time	21.1	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	1.8	ratio	H	0.9	1.1
		2010-11-19T09:57	Hemoglobin	11.1	g/dL	L	11.7	14.5
			Erythrocytes	3.36	10^12/L	L	3.69	5.13
			Ery. Mean Corpuscular Volume	99.4	fL	H	81.5	96.7
			Monocytes	1.3	10^9/L	H	0.1	1
			Albumin	3.3	g/dL	L	3.5	5
			Alkaline Phosphatase	250	U/L	H	40	150
			Lactate Dehydrogenase	256	U/L	H	125	243

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
919-001	Cycle 3	2010-12-06T10:34	Ery. Mean Corpuscular Volume	104	fL	H	81.5	96.7
			Lymphocytes	3.6	10^9/L	H	1.2	3
			Monocytes	1.5	10^9/L	H	0.1	1
			Calcium	10.3	mg/dL	H	8.4	10.2
			Magnesium	2.2	mg/dL	H	1.3	2.1
			Alkaline Phosphatase	184	U/L	H	40	150
			Lactate Dehydrogenase	260	U/L	H	125	243
		2010-12-06T10:57	Prothrombin Time	26.8	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	2.4	ratio	H	0.9	1.1
		2010-12-10T10:05	Ery. Mean Corpuscular Volume	103.3	fL	H	81.5	96.7
			Lymphocytes	3.4	10^9/L	H	1.2	3
			Monocytes	1.3	10^9/L	H	0.1	1
			Chloride	109	mmol/L	H	98	107
			Alanine Aminotransferase	84	U/L	H	0	55
			Alkaline Phosphatase	211	U/L	H	40	150
			Lactate Dehydrogenase	280	U/L	H	125	243
			Blood Urea Nitrogen	30	mg/dL	H	7	20.1
			Glucose	113	mg/dL	H	70	105
	Cycle 4	2011-01-03T10:12	Ery. Mean Corpuscular Volume	101.9	fL	H	81.5	96.7
			Leukocytes	10.9	10^9/L	H	3.4	9.8
			Lymphocytes	3.1	10^9/L	H	1.2	3
			Monocytes	2.1	10^9/L	H	0.1	1
			Eosinophils	0.7	10^9/L	H	0	0.4
			Prothrombin Time	15	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.1
			Alkaline Phosphatase	168	U/L	H	40	150

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
919-001	Cycle 4	2011-01-03T10:12	Lactate Dehydrogenase	255	U/L	H	125	243
			Blood Urea Nitrogen	26	mg/dL	H	7	20.1
		2011-01-07T10:48	Ery. Mean Corpuscular Volume	101.2	fL	H	81.5	96.7
			Monocytes	1.4	10^9/L	H	0.1	1
			Calcium	10.3	mg/dL	H	8.4	10.2
			Magnesium	2.2	mg/dL	H	1.3	2.1
			Alkaline Phosphatase	183	U/L	H	40	150
			Lactate Dehydrogenase	264	U/L	H	125	243
			Blood Urea Nitrogen	23	mg/dL	H	7	20.1
	Cycle 5	2011-01-24T10:20	Hemoglobin	15.3	g/dL	H	11.7	14.5
			Ery. Mean Corpuscular Volume	103.1	fL	H	81.5	96.7
			Platelets	403	10^9/L	H	144	400
			Monocytes	1.2	10^9/L	H	0.1	1
			Prothrombin Time	37.5	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	3.6	ratio	H	0.9	1.1
			Lactate Dehydrogenase	259	U/L	H	125	243
			Blood Urea Nitrogen	21	mg/dL	H	7	20.1
		2011-01-28T09:53	Hemoglobin	15	g/dL	H	11.7	14.5
			Ery. Mean Corpuscular Volume	100.3	fL	H	81.5	96.7
			Monocytes	1.2	10^9/L	H	0.1	1
			Lactate Dehydrogenase	270	U/L	H	125	243
			Glucose	129	mg/dL	H	70	105

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnorm-ality[a]	Normal Range Low	Normal Range High
919-001	Cycle 6	2011-02-14T10:45	Hemoglobin	14.6	g/dL	H	11.7	14.5
			Ery. Mean Corpuscular Volume	100	fL	H	81.5	96.7
			Lymphocytes	3.7	10^9/L	H	1.2	3
			Prothrombin Time	22	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	1.9	ratio	H	0.9	1.1
			Glucose	108	mg/dL	H	70	105
	Cycle 7	2011-03-07T10:27	Hemoglobin	14.7	g/dL	H	11.7	14.5
			Ery. Mean Corpuscular Volume	101.3	fL	H	81.5	96.7
			Platelets	429	10^9/L	H	144	400
			Monocytes	1.2	10^9/L	H	0.1	1
			Prothrombin Time	16.1	sec	H	10.6	12.8
			Prothrombin Intl. Normalized Ratio	1.3	ratio	H	0.9	1.1
			Alkaline Phosphatase	151	U/L	H	40	150
			Glucose	123	mg/dL	H	70	105
		2011-03-09T10:09	Ery. Mean Corpuscular Volume	100.5	fL	H	81.5	96.7
	Cycle 8	2011-03-28T11:32	Ery. Mean Corpuscular Volume	102	fL	H	81.5	96.7
			Lymphocytes	3.7	10^9/L	H	1.2	3
			Chloride	109	mmol/L	H	98	107
		2011-04-01T10:04	Ery. Mean Corpuscular Volume	102.8	fL	H	81.5	96.7
			Lymphocytes	3.8	10^9/L	H	1.2	3
	Cycle 9	2011-05-02T10:18	Ery. Mean Corpuscular Volume	102.8	fL	H	81.5	96.7
			Monocytes	1.3	10^9/L	H	0.1	1
			Blood Urea Nitrogen	22	mg/dL	H	7	20.1
			Glucose	109	mg/dL	H	70	105

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
919-001	Cycle 10	2011-06-06T10:39	Hemoglobin	15	g/dL	H	11.7	14.5
			Ery. Mean Corpuscular Volume	103.1	fL	H	81.5	96.7
			Lymphocytes	3.4	10^9/L	H	1.2	3
			Monocytes	1.3	10^9/L	H	0.1	1
			Glucose	147	mg/dL	H	70	105
	End Trial	2011-09-06T11:15	Hemoglobin	14.7	g/dL	H	11.7	14.5
			Ery. Mean Corpuscular Volume	100.1	fL	H	81.5	96.7
			Leukocytes	16.8	10^9/L	H	3.4	9.8
			Neutrophils	12.1	10^9/L	H	1.5	6.8
			Monocytes	1.6	10^9/L	H	0.1	1
			Calcium	10.4	mg/dL	H	8.4	10.2
			Magnesium	2.3	mg/dL	H	1.3	2.1
			Alanine Aminotransferase	89	U/L	H	0	55
			Glucose	157	mg/dL	H	70	105
921-001	Pre-trial	2011-06-21T08:53	Hemoglobin	10.4	g/dL	L	13.7	17.3
			Erythrocytes	3.42	10^12/L	L	4.37	5.74
			Platelets	113	10^9/L	L	150	450
			Lymphocytes	0.5	10^9/L	L	0.8	4.2
			Potassium	3.3	mmol/L	L	3.5	5
			Chloride	109	mmol/L	H	98	108

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
921-001	Cycle 1	2011-06-27T08:00	Hemoglobin	11.7	g/dL	L	13.7	17.3
			Erythrocytes	3.93	10^12/L	L	4.37	5.74
			Platelets	101	10^9/L	L	150	450
			Lymphocytes	0.7	10^9/L	L	0.8	4.2
			Prothrombin Time	17.3	sec	H	9.5	13.1
			Prothrombin Intl. Normalized Ratio	1.4	ratio	H	0.8	1.1
			Chloride	109	mmol/L	H	98	108
			Lactate Dehydrogenase	216	U/L	H	100	200
		2011-07-01T10:55	Hemoglobin	10.7	g/dL	L	13.7	17.3
			Erythrocytes	3.54	10^12/L	L	4.37	5.74
			Platelets	69	10^9/L	L	150	450
			Leukocytes	3	10^9/L	L	3.2	9.8
			Lymphocytes	0.5	10^9/L	L	0.8	4.2
			Lactate Dehydrogenase	208	U/L	H	100	200
		2011-07-07T07:34	Hemoglobin	11.5	g/dL	L	13.7	17.3
			Erythrocytes	3.81	10^12/L	L	4.37	5.74
			Platelets	81	10^9/L	L	150	450
			Lymphocytes	0.7	10^9/L	L	0.8	4.2
			Potassium	3.4	mmol/L	L	3.5	5
			Lactate Dehydrogenase	208	U/L	H	100	200
	End Trial	2011-07-14T10:50	Hemoglobin	12.2	g/dL	L	13.7	17.3
			Erythrocytes	4.06	10^12/L	L	4.37	5.74
			Platelets	134	10^9/L	L	150	450
			Lymphocytes	0.7	10^9/L	L	0.8	4.2
			Lactate Dehydrogenase	215	U/L	H	100	200
			Bilirubin	1.6	mg/dL	H	0.4	1.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
922-001	Pre-trial	2011-06-14T11:58	Hemoglobin	10.6	g/dL	L	11	18
			Erythrocytes	3.54	10^12/L	L	4	6
			Leukocytes	4.1	10^9/L	L	4.5	10.5
			Lactate Dehydrogenase	226.5	U/L	H	100	210
			Blood Urea Nitrogen	24	mg/dL	H	6	20
			Glucose	108.7	mg/dL	H	74	106
	Cycle 1	2011-06-27T10:10	Hemoglobin	10.4	g/dL	L	11	18
			Erythrocytes	3.51	10^12/L	L	4	6
			Leukocytes	4.2	10^9/L	L	4.5	10.5
			Lactate Dehydrogenase	276.1	U/L	H	100	210
		2011-07-01T10:45	Hemoglobin	10	g/dL	L	11	18
			Erythrocytes	3.34	10^12/L	L	4	6
			Monocytes	0.7	10^9/L	H	0.1	0.6
			Sodium	134.9	mmol/L	L	135	145
			Blood Urea Nitrogen	28.7	mg/dL	H	6	20
			Glucose	168.5	mg/dL	H	74	106
		2011-07-11T13:18	Hemoglobin	10.1	g/dL	L	11	18
			Erythrocytes	3.41	10^12/L	L	4	6
			Sodium	131.9	mmol/L	L	135	145
			Magnesium	1.4	mg/dL	L	1.6	2.6
			Creatinine	1.6	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	273.2	U/L	H	100	210
			Blood Urea Nitrogen	25.1	mg/dL	H	6	20
			Glucose	206.7	mg/dL	H	74	106

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
922-001	Cycle 2	2011-07-18T13:06	Hemoglobin	10.7	g/dL	L	11	18
			Erythrocytes	3.5	10^12/L	L	4	6
			Chloride	91.6	mmol/L	L	97	107
			Phosphate	4.7	mg/dL	H	2.6	4.5
			Magnesium	1.5	mg/dL	L	1.6	2.6
			Creatinine	2.1	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	349.3	U/L	H	100	210
			Blood Urea Nitrogen	26.6	mg/dL	H	6	20
			Glucose	138.4	mg/dL	H	74	106
		2011-07-22T11:23	Hemoglobin	10.3	g/dL	L	11	18
			Erythrocytes	3.5	10^12/L	L	4	6
			Lymphocytes	1.1	10^9/L	L	1.2	3.4
			Sodium	132.2	mmol/L	L	135	145
			Creatinine	1.5	mg/dL	H	0.7	1.3
			Lactate Dehydrogenase	270	U/L	H	100	210
			Blood Urea Nitrogen	43.5	mg/dL	H	6	20
			Glucose	139.2	mg/dL	H	74	106
	Cycle 3	2011-08-29T12:56	Hemoglobin	9.5	g/dL	L	11	18
			Erythrocytes	3.1	10^12/L	L	4	6
			Neutrophils	7.8	10^9/L	H	1.5	6.5
			Lymphocytes	1	10^9/L	L	1.2	3.4
			Prothrombin Time	12.6	sec	H	10.4	11.9
			Activated Partial Thromboplastin Time	33.2	sec	H	23.6	31.6
			Potassium	3.2	mmol/L	L	3.6	5
			Chloride	96.6	mmol/L	L	97	107

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
922-001	Cycle 3	2011-08-29T12:56	Lactate Dehydrogenase	340.5	U/L	H	100	210
			Bilirubin	1.3	mg/dL	H	0.3	1.2
			Glucose	122.6	mg/dL	H	74	106
		2011-09-02T12:46	Hemoglobin	9.7	g/dL	L	11	18
			Erythrocytes	3.22	10^12/L	L	4	6
			Neutrophils	7.1	10^9/L	H	1.5	6.5
			Phosphate	4.8	mg/dL	H	2.6	4.5
			Creatinine	1.8	mg/dL	H	0.6	1.3
			Alanine Aminotransferase	44.7	U/L	H	0	39.9
			Alkaline Phosphatase	122.6	U/L	H	39	120
			Lactate Dehydrogenase	451.7	U/L	H	94	250
			Blood Urea Nitrogen	49.5	mg/dL	H	7	25
			Urate	8.2	mg/dL	H	2.4	7
			Glucose	308	mg/dL	H	70	99
931-001	Pre-trial	2011-04-11T12:55	Platelets	141	10^9/L	L	143	398
			Lymphocytes	0.6	10^9/L	L	0.8	4.2
			Prothrombin Time	11.4	sec	H	9.2	11.1
			Lactate Dehydrogenase	544	U/L	H	91	223
			Bilirubin	1.2	mg/dL	H	0.2	1.1
			Glucose	111	mg/dL	H	65	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-001	Cycle 1	2011-04-25T09:10	Platelets	137	10^9/L	L	143	398
			Lymphocytes	0.6	10^9/L	L	0.8	4.2
			Basophils	0.3	10^9/L	H	0	0.1
			Prothrombin Time	21.7	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	36.61	sec	H	25	32.6
			Prothrombin Intl. Normalized Ratio	2.2	ratio	H	0.8	1.3
			Lactate Dehydrogenase	640	U/L	H	91	223
		2011-04-29T10:50	Magnesium	2.67	mg/dL	H	1.6	2.3
			Lactate Dehydrogenase	463	U/L	H	91	223
			Blood Urea Nitrogen	31	mg/dL	H	7	23
			Glucose	142	mg/dL	H	65	100
		2011-05-11T12:02	Lactate Dehydrogenase	483	U/L	H	91	223
	Cycle 2	2011-05-16T11:10	Platelets	136	10^9/L	L	143	398
			Lymphocytes	0.678	10^9/L	L	1	4
			Prothrombin Time	22.5	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	32.8	sec	H	25	32.6
			Prothrombin Intl. Normalized Ratio	2.2	ratio	H	0.8	1.3
			Lactate Dehydrogenase	452	U/L	H	91	223
			Glucose	112	mg/dL	H	65	100
		2011-05-20T11:25	Monocytes	1.032	10^9/L	H	0.2	1
			Lactate Dehydrogenase	320	U/L	H	91	223
			Bilirubin	1.4	mg/dL	H	0.2	1.1
			Blood Urea Nitrogen	26	mg/dL	H	7	23

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-001	Cycle 3	2011-06-06T11:20	Erythrocytes	4.18	10^12/L	L	4.21	5.61
			Platelets	140	10^9/L	L	143	398
			Lymphocytes	0.925	10^9/L	L	1	4
			Prothrombin Time	12.9	sec	H	9.2	11.1
			Lactate Dehydrogenase	350	U/L	H	91	223
		2011-06-10	Erythrocytes	4.2	10^12/L	L	4.21	5.61
			Lymphocytes	0.707	10^9/L	L	1	4
			Lactate Dehydrogenase	276	U/L	H	91	223
			Blood Urea Nitrogen	24	mg/dL	H	7	23
			Glucose	144	mg/dL	H	65	100
	Cycle 4	2011-06-27T11:45	Platelets	126	10^9/L	L	143	398
			Lymphocytes	0.576	10^9/L	L	1	4
			Magnesium	2.31	mg/dL	H	1.6	2.3
		2011-06-27T12:15	Prothrombin Time	20.3	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	32.7	sec	H	25	32.6
			Prothrombin Intl. Normalized Ratio	2	ratio	H	0.8	1.3
		2011-07-01T10:55	Erythrocytes	4.08	10^12/L	L	4.21	5.61
			Platelets	108	10^9/L	L	143	398
			Lymphocytes	0.764	10^9/L	L	1	4
			Blood Urea Nitrogen	26	mg/dL	H	7	23

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-001	End Trial	2011-07-18T10:50	Platelets	94	10^9/L	L	143	398
			Lymphocytes	0.464	10^9/L	L	1	4
			Prothrombin Time	17.2	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	34.5	sec	H	25	32.6
			Prothrombin Intl. Normalized Ratio	1.7	ratio	H	0.8	1.3
931-002	Pre-trial	2011-06-09T15:00	Erythrocytes	4.19	10^12/L	L	4.21	5.61
			Lymphocytes	0.7	10^9/L	L	0.8	4.2
			Prothrombin Time	11.2	sec	H	9.2	11.1
			Albumin	3.5	g/dL	L	3.7	5.1
			Alkaline Phosphatase	115	U/L	H	31	103
			Lactate Dehydrogenase	289	U/L	H	91	223
	Cycle 1	2011-06-20T10:30	Erythrocytes	4.14	10^12/L	L	4.21	5.61
			Prothrombin Time	11.2	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	41.5	sec	H	25	32.6
			Albumin	3.6	g/dL	L	3.7	5.1
			Alkaline Phosphatase	110	U/L	H	31	103
			Lactate Dehydrogenase	276	U/L	H	91	223
		2011-06-24T10:30	Hemoglobin	12.2	g/dL	L	12.3	16.3
			Erythrocytes	3.8	10^12/L	L	4.21	5.61
			Leukocytes	13.23	10^9/L	H	3.28	9.29
			Neutrophils	10.3	10^9/L	H	1.5	7

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-002	Cycle 1	2011-06-24T12:25	Calcium	8.4	mg/dL	L	8.7	10.5
			Albumin	3.5	g/dL	L	3.7	5.1
			Urate	3.9	mg/dL	L	4	9
	Cycle 2	2011-07-11T09:20	Hemoglobin	11.8	g/dL	L	12.3	16.3
			Erythrocytes	3.72	10^12/L	L	4.21	5.61
			Lymphocytes	0.7	10^9/L	L	0.8	4.2
			Calcium	8.2	mg/dL	L	8.7	10.5
			Albumin	3.2	g/dL	L	3.7	5.1
			Alkaline Phosphatase	108	U/L	H	31	103
			Lactate Dehydrogenase	234	U/L	H	91	223
			Urate	3.4	mg/dL	L	4	9
			Glucose	118	mg/dL	H	65	100
		2011-07-15T08:10	Erythrocytes	3.98	10^12/L	L	4.21	5.61
			Urate	3.3	mg/dL	L	4	9
	End Trial	2011-08-08T10:55	Erythrocytes	4.09	10^12/L	L	4.21	5.61
			Platelets	138	10^9/L	L	143	398
			Sodium	133	mmol/L	L	135	145
			Calcium	8	mg/dL	L	8.7	10.5
			Albumin	3	g/dL	L	3.7	5.1
			Aspartate Aminotransferase	41	U/L	H	7	36
			Alkaline Phosphatase	218	U/L	H	31	103
			Lactate Dehydrogenase	346	U/L	H	91	223
			Urate	2.9	mg/dL	L	4	9

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-003	Pre-trial	2011-07-26T16:00	Leukocytes	10.92	10^9/L	H	3.28	9.29
			Neutrophils	8.1	10^9/L	H	1.5	7
			Prothrombin Time	11.4	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	35.4	sec	H	25	32.6
			Alkaline Phosphatase	123	U/L	H	31	103
	Cycle 1	2011-08-01T10:15	Hemoglobin	11.1	g/dL	L	11.5	14.6
			Leukocytes	13.16	10^9/L	H	3.28	9.29
			Neutrophils	10.7	10^9/L	H	1.5	7
			Prothrombin Time	11.2	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	35.9	sec	H	25	32.6
			Sodium	133	mmol/L	L	135	145
			Alkaline Phosphatase	111	U/L	H	31	103
		2011-08-05T15:35	Hemoglobin	11.2	g/dL	L	11.5	14.6
			Leukocytes	10.71	10^9/L	H	3.28	9.29
			Neutrophils	8.2	10^9/L	H	1.5	7
			Alkaline Phosphatase	116	U/L	H	31	103
		2011-08-11	Hemoglobin	11.3	g/dL	L	11.6	15.5
			Leukocytes	12.9	10^9/L	H	4.1	12.1
		2011-08-11T16:45	Alkaline Phosphatase	129	U/L	H	31	103
	Cycle 2	2011-08-22T10:05	Hemoglobin	10.8	g/dL	L	11.5	14.6
			Activated Partial Thromboplastin Time	32.7	sec	H	25	32.6
			Alkaline Phosphatase	114	U/L	H	31	103

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-003	Cycle 2	2011-08-26T14:35	Leukocytes	9.88	10^9/L	H	3.28	9.29
			Neutrophils	7.5	10^9/L	H	1.5	7
			Alkaline Phosphatase	136	U/L	H	31	103
			Glucose	125	mg/dL	H	65	100
	Cycle 3	2011-09-12T10:20	Hemoglobin	10.9	g/dL	L	11.5	14.6
			Activated Partial Thromboplastin Time	33.5	sec	H	25	32.6
			Alkaline Phosphatase	113	U/L	H	31	103
			Glucose	106	mg/dL	H	65	100
		2011-09-16T15:25	Leukocytes	10.19	10^9/L	H	3.28	9.29
			Neutrophils	7.6	10^9/L	H	1.5	7
			Alkaline Phosphatase	143	U/L	H	31	103
	Cycle 4	2011-10-03T11:00	Hemoglobin	11	g/dL	L	11.5	14.6
			Prothrombin Time	11.5	sec	H	9.2	11.1
			Activated Partial Thromboplastin Time	37.9	sec	H	25	32.6
			Alkaline Phosphatase	144	U/L	H	31	103
		2011-10-07T14:22	Hemoglobin	11.3	g/dL	L	11.5	14.6
			Potassium	3.3	mmol/L	L	3.6	5.4
			Alkaline Phosphatase	140	U/L	H	31	103
	Cycle 5	2011-10-24T10:30	Hemoglobin	10.9	g/dL	L	11.5	14.6
			Creatinine	0.4	mg/dL	L	0.5	1.3
			Alkaline Phosphatase	140	U/L	H	31	103

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-003	Cycle 5	2011-10-28T14:30	Calcium	8.6	mg/dL	L	8.7	10.5
			Alkaline Phosphatase	157	U/L	H	31	103
			Glucose	121	mg/dL	H	65	100
	Cycle 6	2011-11-14T11:35	Hemoglobin	10.7	g/dL	L	11.5	14.6
			Erythrocytes	3.73	10^12/L	L	3.76	4.93
			Alkaline Phosphatase	153	U/L	H	31	103
		2011-11-18T15:20	Hemoglobin	11.3	g/dL	L	11.5	14.6
			Alkaline Phosphatase	160	U/L	H	31	103
			Glucose	110	mg/dL	H	65	100
	Cycle 7	2011-12-05T11:30	Hemoglobin	11.2	g/dL	L	11.5	14.6
			Phosphate	5	mg/dL	H	2.5	4.7
			Alkaline Phosphatase	166	U/L	H	31	103
			Glucose	139	mg/dL	H	65	100
		2011-12-09T15:08	Hemoglobin	11.2	g/dL	L	11.5	14.6
			Leukocytes	9.44	10^9/L	H	3.28	9.29
			Neutrophils	7.1	10^9/L	H	1.5	7
			Alkaline Phosphatase	180	U/L	H	31	103
			Glucose	109	mg/dL	H	65	100
	Cycle 8	2012-01-09T10:40	Hemoglobin	11.1	g/dL	L	11.5	14.6
			Phosphate	4.8	mg/dL	H	2.5	4.7
			Alkaline Phosphatase	161	U/L	H	31	103
			Glucose	106	mg/dL	H	65	100
		2012-01-13T10:50	Phosphate	4.8	mg/dL	H	2.5	4.7
			Alkaline Phosphatase	173	U/L	H	31	103
			Glucose	128	mg/dL	H	65	100

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-003	Cycle 9	2012-01-30T11:40	Hemoglobin	11.4	g/dL	L	11.5	14.6
			Phosphate	4.9	mg/dL	H	2.5	4.7
			Alkaline Phosphatase	170	U/L	H	31	103
			Glucose	124	mg/dL	H	65	100
		2012-02-03T11:52	Phosphate	5.1	mg/dL	H	2.5	4.7
			Alkaline Phosphatase	172	U/L	H	31	103
			Glucose	124	mg/dL	H	65	100
	Cycle 10	2012-02-21T12:00	Hemoglobin	11.3	g/dL	L	11.5	14.6
			Alkaline Phosphatase	169	U/L	H	31	103
			Glucose	108	mg/dL	H	65	100
	Cycle 11	2012-03-12T12:45	Hemoglobin	11.1	g/dL	L	11.2	15.7
			Phosphate	5.1	mg/dL	H	2.5	4.7
			Alanine Aminotransferase	40	U/L	H	7	35
			Alkaline Phosphatase	159	U/L	H	35	123
			Glucose	114	mg/dL	H	65	100
		2012-03-16T10:45	Hemoglobin	11.4	g/dL	L	11.5	14.6
			Alkaline Phosphatase	160	U/L	H	31	103
	Cycle 12	2012-04-09T10:40	Hemoglobin	11.1	g/dL	L	11.5	14.6
			Phosphate	4.9	mg/dL	H	2.5	4.7
			Alanine Aminotransferase	60	U/L	H	4	45
			Alkaline Phosphatase	156	U/L	H	31	103
			Glucose	101	mg/dL	H	65	100
		2012-04-13T11:55	Hemoglobin	11.4	g/dL	L	11.5	14.6
			Alanine Aminotransferase	61	U/L	H	4	45
			Alkaline Phosphatase	155	U/L	H	31	103

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
931-003	Cycle 13	2012-04-30T11:40	Calcium	8.6	mg/dL	L	8.7	10.5
			Phosphate	5	mg/dL	H	2.5	4.7
			Creatinine	0.5	mg/dL	L	0.7	1.3
			Alanine Aminotransferase	42	U/L	H	7	35
			Alkaline Phosphatase	135	U/L	H	35	123
		2012-05-04T11:45	Hemoglobin	10.7	g/dL	L	11.5	14.6
			Potassium	3.4	mmol/L	L	3.6	5.4
			Calcium	8.6	mg/dL	L	8.7	10.5
			Chloride	110	mmol/L	H	98	108
			Alkaline Phosphatase	140	U/L	H	31	103
			Glucose	121	mg/dL	H	65	100
	Cycle 14	2012-05-21T11:20	Hemoglobin	11.1	g/dL	L	11.5	14.6
			Alkaline Phosphatase	146	U/L	H	31	103
		2012-05-25T11:25	Hemoglobin	10.7	g/dL	L	11.5	14.6
			Alkaline Phosphatase	135	U/L	H	31	103
			Glucose	123	mg/dL	H	65	100
	End Trial	2012-06-11T15:45	Hemoglobin	10.7	g/dL	L	11.5	14.6
			Activated Partial Thromboplastin Time	35.7	sec	H	25	32.6
			Alkaline Phosphatase	144	U/L	H	31	103
			Glucose	126	mg/dL	H	65	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
933-001	Pre-trial	2010-07-15T16:19	Hemoglobin	10.7	g/dL	L	12.5	17
			Ery. Mean Corpuscular Volume	69	fL	L	80	98
			Lymphocytes	5	10^9/L	H	0.8	4.5
			Monocytes	1.2	10^9/L	H	0.1	1
			Phosphate	4.6	mg/dL	H	2.5	4.5
			Creatinine	1.41	mg/dL	H	0.76	1.27
	Cycle 1	2010-07-26T09:39	Hemoglobin	10.2	g/dL	L	12	18
			Ery. Mean Corpuscular Volume	69.2	fL	L	80	97
			Lymphocytes	0.404	10^9/L	L	1	4
			Creatinine	1.53	mg/dL	H	0.76	1.27
			Glucose	182	mg/dL	H	65	99
		2010-07-30T13:11	Hemoglobin	9.4	g/dL	L	12	18
			Ery. Mean Corpuscular Volume	67.5	fL	L	80	97
			Lymphocytes	0.42	10^9/L	L	1	4
			Potassium	3.4	mmol/L	L	3.5	5.5
			Creatinine	1.81	mg/dL	H	0.76	1.27
			Glucose	191	mg/dL	H	65	99
		2010-08-05T11:12	Hemoglobin	9.8	g/dL	L	12.5	17
			Ery. Mean Corpuscular Volume	70	fL	L	80	98
			Leukocytes	11	10^9/L	H	4	10.5
			Lymphocytes	4.7	10^9/L	H	0.8	4.5
			Monocytes	1.1	10^9/L	H	0.1	1
			Creatinine	1.62	mg/dL	H	0.76	1.27
			Glucose	185	mg/dL	H	65	99

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
933-001	Cycle 2	2010-08-16T13:46	Hemoglobin	10.2	g/dL	L	12.5	17
			Ery. Mean Corpuscular Volume	72	fL	L	80	98
			Leukocytes	11.3	10^9/L	H	4	10.5
			Monocytes	1.1	10^9/L	H	0.1	1
			Eosinophils	0.5	10^9/L	H	0	0.4
			Creatinine	1.47	mg/dL	H	0.76	1.27
			Glucose	153	mg/dL	H	65	99
		2010-08-20T11:07	Hemoglobin	9.2	g/dL	L	12	18
			Ery. Mean Corpuscular Volume	68.8	fL	L	80	97
			Leukocytes	11	10^9/L	H	4.1	10.9
			Lymphocytes	0.396	10^9/L	L	1	4
			Creatinine	1.78	mg/dL	H	0.76	1.27
			Glucose	155	mg/dL	H	65	99
	Cycle 3	2010-09-06T10:03	Hemoglobin	9.8	g/dL	L	12	18
			Ery. Mean Corpuscular Volume	67.4	fL	L	80	97
			Leukocytes	11.8	10^9/L	H	4.1	10.9
			Lymphocytes	0.637	10^9/L	L	1	4
			Calcium	8.3	mg/dL	L	8.5	10.6
			Creatinine	1.58	mg/dL	H	0.76	1.27
			Glucose	177	mg/dL	H	65	99
	Cycle 4	2010-09-27T11:20	Hemoglobin	9.9	g/dL	L	12.5	17
			Ery. Mean Corpuscular Volume	74	fL	L	80	98
			Leukocytes	13.9	10^9/L	H	4	10.5
			Lymphocytes	6.6	10^9/L	H	0.8	4.5
			Monocytes	1.3	10^9/L	H	0.1	1
			Eosinophils	0.7	10^9/L	H	0	0.4

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
933-001	Cycle 4	2010-09-27T11:20	Creatinine	1.5	mg/dL	H	0.76	1.27
		2010-10-01T09:50	Hemoglobin	9.3	g/dL	L	12.5	17
			Ery. Mean Corpuscular Volume	74	fL	L	80	98
			Leukocytes	14.6	10^9/L	H	4	10.5
			Lymphocytes	7.3	10^9/L	H	0.8	4.5
			Eosinophils	1.3	10^9/L	H	0	0.4
			Potassium	3.2	mmol/L	L	3.5	5.5
			Phosphate	4.6	mg/dL	H	2.5	4.5
			Creatinine	1.83	mg/dL	H	0.76	1.27
			Glucose	158	mg/dL	H	65	99
	Cycle 5	2010-10-18T09:48	Hemoglobin	10.2	g/dL	L	12	18
			Ery. Mean Corpuscular Volume	67.6	fL	L	80	97
			Leukocytes	16.3	10^9/L	H	4.1	10.9
934-001	Pre-trial	2011-02-02T07:51	Platelets	97	10^9/L	L	150	400
			Activated Partial Thromboplastin Time	41	sec	H	24	40
			Prothrombin Intl. Normalized Ratio	2.6	ratio	H	0.9	1.2
			Lactate Dehydrogenase	262	U/L	H	90	240
			Glucose	153.1	mg/dL	H	65	141
	Cycle 1	2011-02-10T11:08	Hemoglobin	13.2	g/dL	L	13.5	17
			Platelets	94	10^9/L	L	147	375
			Prothrombin Intl. Normalized Ratio	2.5	ratio	H	0.8	1.2
			Lactate Dehydrogenase	672	U/L	H	313	618

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-001	Cycle 1	2011-02-18T08:25	Hemoglobin	13	g/dL	L	13.5	17
			Platelets	100	10^9/L	L	150	400
			Lymphocytes	0.8	10^9/L	L	1.2	3.5
			Creatinine	1.346	mg/dL	H	0.68	1.3
			Alanine Aminotransferase	23	U/L	L	25	80
			Lactate Dehydrogenase	335	U/L	H	90	240
			Blood Urea Nitrogen	25.49	mg/dL	H	5.6	23
			Glucose	207.2	mg/dL	H	65	141
		2011-02-25T11:20	Hemoglobin	11.9	g/dL	L	13.5	17
			Erythrocytes	4.11	10^12/L	L	4.2	5.8
			Platelets	104	10^9/L	L	150	400
			Leukocytes	2.9	10^9/L	L	4	11
			Neutrophils	1.8	10^9/L	L	2	8
			Lymphocytes	0.6	10^9/L	L	1.2	3.5
			Phosphate	2.48	mg/dL	L	2.5	4.5
			Albumin	3.3	g/dL	L	3.4	5
			Lactate Dehydrogenase	317	U/L	H	90	240
			Glucose	162.1	mg/dL	H	65	141
	End Trial	2011-03-11T10:22	Hemoglobin	10.8	g/dL	L	13.5	17
			Erythrocytes	3.88	10^12/L	L	4.2	5.8
			Platelets	100	10^9/L	L	150	400
			Leukocytes	2.5	10^9/L	L	4	11
			Neutrophils	1.3	10^9/L	L	2	8
			Lymphocytes	0.8	10^9/L	L	1.2	3.5
			Prothrombin Intl. Normalized Ratio	1.7	ratio	H	0.9	1.2
			Phosphate	2.11	mg/dL	L	2.5	4.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-001	End Trial	2011-03-11T10:22	Albumin	3.2	g/dL	L	3.4	5
			Lactate Dehydrogenase	407	U/L	H	90	240
			Glucose	212.6	mg/dL	H	65	141
934-002	Pre-trial	2011-02-25T11:15	Platelets	119	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	1.2	3.5
			Lactate Dehydrogenase	353	U/L	H	90	240
	Cycle 1	2011-03-02T07:44	Platelets	146	10^9/L	L	150	400
			Lymphocytes	0.5	10^9/L	L	1.2	3.5
		2011-03-02T12:15	Magnesium	1.6	mg/dL	L	1.7	2.7
			Lactate Dehydrogenase	355	U/L	H	90	240
			Urate	6.04	mg/dL	H	2.6	6
			Glucose	167.5	mg/dL	H	65	141
		2011-03-11T13:00	Erythrocytes	3.69	10^12/L	L	3.8	5.2
			Platelets	100	10^9/L	L	150	400
			Leukocytes	3.9	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	1.2	3.5
			Magnesium	1.58	mg/dL	L	1.7	2.7
			Creatinine	1.097	mg/dL	H	0.45	1.07
			Lactate Dehydrogenase	349	U/L	H	90	240
			Glucose	154.9	mg/dL	H	65	141
		2011-03-18T10:22	Lymphocytes	0.3	10^9/L	L	1	4
			Aspartate Aminotransferase	43	U/L	H	0	36
			Lactate Dehydrogenase	378	U/L	H	0	220
			Urate	8.68	mg/dL	H	2.4	6.1

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-002	Cycle 2	2011-03-24T09:50	Hemoglobin	11.4	g/dL	L	11.5	15.5
			Erythrocytes	3.52	10^12/L	L	3.8	5.2
			Leukocytes	3.8	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Phosphate	2.23	mg/dL	L	2.5	4.5
			Magnesium	1.6	mg/dL	L	1.7	2.7
			Lactate Dehydrogenase	322	U/L	H	90	240
			Urate	6.62	mg/dL	H	2.6	6
			Glucose	212.6	mg/dL	H	65	141
		2011-04-01T09:40	Erythrocytes	3.69	10^12/L	L	3.8	5.2
			Platelets	99	10^9/L	L	150	400
			Leukocytes	2.9	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Potassium	3.3	mmol/L	L	3.5	5
			Magnesium	1.63	mg/dL	L	1.7	2.7
			Creatinine	1.12	mg/dL	H	0.45	1.07
			Lactate Dehydrogenase	317	U/L	H	90	240
			Glucose	176.5	mg/dL	H	65	141
	End Trial	2011-04-13T11:35	Erythrocytes	3.66	10^12/L	L	3.8	5.2
			Leukocytes	3.9	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	1.2	3.5
			Phosphate	2.07	mg/dL	L	2.5	4.5
			Magnesium	1.53	mg/dL	L	1.7	2.7
			Lactate Dehydrogenase	320	U/L	H	90	240
			Urate	7.13	mg/dL	H	2.6	6

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-003	Pre-trial	2011-03-07T08:10	Lymphocytes	1.1	10^9/L	L	1.2	3.5
			Alanine Aminotransferase	18	U/L	L	20	65
			Aspartate Aminotransferase	8	U/L	L	10	38
			Glucose	160.3	mg/dL	H	65	141
	Cycle 1	2011-03-11T07:57	Lymphocytes	0.7	10^9/L	L	1.2	3.5
			Glucose	163.9	mg/dL	H	65	141
		2011-03-18T07:42	Leukocytes	3.8	10^9/L	L	4	11
			Lymphocytes	0.7	10^9/L	L	1.2	3.5
			Sodium	134	mmol/L	L	135	145
			Alanine Aminotransferase	18	U/L	L	20	65
		2011-03-25T10:00	Lymphocytes	0.9	10^9/L	L	1.2	3.5
			Sodium	134	mmol/L	L	135	145
	Cycle 2	2011-03-30T14:10	Lymphocytes	1	10^9/L	L	1.2	3.5
			Sodium	134	mmol/L	L	135	145
			Aspartate Aminotransferase	9	U/L	L	10	38
		2011-04-08T12:40	Sodium	132	mmol/L	L	135	145
			Aspartate Aminotransferase	7	U/L	L	10	38
			Lactate Dehydrogenase	251	U/L	H	90	240
	Cycle 3	2011-05-02T07:27	Neutrophils	1.9	10^9/L	L	2	8
			Sodium	134	mmol/L	L	135	145
			Albumin	3	g/dL	L	3.4	5
			Lactate Dehydrogenase	353	U/L	H	90	240
			Glucose	257.6	mg/dL	H	65	141
		2011-05-06T13:10	Lactate Dehydrogenase	314	U/L	H	90	240
			Glucose	149.5	mg/dL	H	65	141

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-003	Cycle 4	2011-05-20T08:58	Aspartate Aminotransferase	6	U/L	L	10	38
		2011-05-27T12:42	Sodium	134	mmol/L	L	135	145
			Alanine Aminotransferase	17	U/L	L	20	65
			Aspartate Aminotransferase	6	U/L	L	10	38
			Lactate Dehydrogenase	242	U/L	H	90	240
	End Trial	2011-06-09T12:25	Lymphocytes	1	10^9/L	L	1.2	3.5
			Sodium	126	mmol/L	L	135	145
			Potassium	3.2	mmol/L	L	3.5	5
			Chloride	89	mmol/L	L	95	107
			Urate	2.39	mg/dL	L	2.6	6
			Glucose	183.8	mg/dL	H	65	141
934-004	Pre-trial	2011-07-20T07:37	Erythrocytes	4.19	10^12/L	L	4.2	5.8
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Neutrophils	1.4	10^9/L	L	2	8
			Lymphocytes	1	10^9/L	L	1.2	3.5
			Eosinophils	0.8	10^9/L	H	0	0.7
			Calcium	11.18	mg/dL	H	8.4	10.2
			Phosphate	2.45	mg/dL	L	2.5	4.5
			Alkaline Phosphatase	191	U/L	H	30	135
	Cycle 1	2011-07-25T07:57	Platelets	424	10^9/L	H	150	400
			Lymphocytes	1.1	10^9/L	L	1.2	3.5
			Monocytes	1.2	10^9/L	H	0.2	1
			Eosinophils	0.8	10^9/L	H	0	0.7
			Calcium	10.26	mg/dL	H	8.4	10.2
			Phosphate	1.7	mg/dL	L	2.5	4.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-004	Cycle 1	2011-07-25T07:57	Albumin	3.1	g/dL	L	3.4	5
			Alkaline Phosphatase	231	U/L	H	30	135
			Lactate Dehydrogenase	262	U/L	H	90	240
		2011-07-29T07:22	Hemoglobin	13.4	g/dL	L	13.5	17
			Erythrocytes	4.12	10^12/L	L	4.2	5.8
			Ery. Mean Corpuscular Volume	99	fL	H	82	98
			Leukocytes	13.7	10^9/L	H	4	11
			Neutrophils	9.9	10^9/L	H	2	8
			Monocytes	1.6	10^9/L	H	0.2	1
			Albumin	3.2	g/dL	L	3.4	5
			Alkaline Phosphatase	179	U/L	H	30	135
		2011-08-05T10:27	Platelets	474	10^9/L	H	150	400
			Leukocytes	11.5	10^9/L	H	4	10
			Lymphocytes	0.9	10^9/L	L	1	4
			Monocytes	2.9	10^9/L	H	0.1	0.8
			Eosinophils	1.3	10^9/L	H	0	0.5
			Potassium	5.5	mmol/L	H	3.5	5
			Calcium	10.78	mg/dL	H	8.4	10.2
			Alkaline Phosphatase	198	U/L	H	48	138
			Lactate Dehydrogenase	546	U/L	H	260	494
	End Trial	2011-08-10T08:12	Hemoglobin	12.6	g/dL	L	13.5	17
			Erythrocytes	3.81	10^12/L	L	4.2	5.8
			Platelets	505	10^9/L	H	150	400
			Leukocytes	16.8	10^9/L	H	4	11
			Neutrophils	13	10^9/L	H	2	8
			Lymphocytes	1	10^9/L	L	1.2	3.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
934-004	End Trial	2011-08-10T08:12	Monocytes	1.2	10^9/L	H	0.2	1
			Eosinophils	1.6	10^9/L	H	0	0.7
			Phosphate	1.95	mg/dL	L	2.5	4.5
			Albumin	2.2	g/dL	L	3.4	5
			Alkaline Phosphatase	140	U/L	H	30	135
			Lactate Dehydrogenase	305	U/L	H	90	240
			Blood Urea Nitrogen	24.93	mg/dL	H	5.6	23
936-001	Pre-trial	2011-06-17T09:50	Hemoglobin	12.1	g/dL	L	14	16
			Erythrocytes	3.49	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	34.8	fL	L	80	98
			Platelets	94	10^9/L	L	150	400
			Leukocytes	3.9	10^9/L	L	4.5	11
			Alkaline Phosphatase	189	U/L	H	45	129
			Lactate Dehydrogenase	397	U/L	H	120	246
			Glucose	104	mg/dL	H	70	100
	Cycle 1	2011-07-11T07:48	Hemoglobin	11.6	g/dL	L	14	16
			Erythrocytes	3.35	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.6	fL	H	80	98
			Platelets	103	10^9/L	L	150	400
			Leukocytes	3.8	10^9/L	L	4.5	11
			Alkaline Phosphatase	188	U/L	H	45	129
			Lactate Dehydrogenase	401	U/L	H	120	246
			Glucose	116	mg/dL	H	70	100

[a]Abnormality: L=Low, H=High

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 1	2011-07-15T07:45	Hemoglobin	11.4	g/dL	L	14	16
			Erythrocytes	3.28	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.8	fL	H	80	98
			Platelets	90	10^9/L	L	150	400
			Leukocytes	4.2	10^9/L	L	4.5	11
			Alanine Aminotransferase	85	U/L	H	10	49
			Aspartate Aminotransferase	39	U/L	H	11	34
			Alkaline Phosphatase	186	U/L	H	45	129
			Lactate Dehydrogenase	352	U/L	H	120	246
			Urate	3.1	mg/dL	L	3.5	7.2
			Glucose	112	mg/dL	H	70	100
		2011-07-21T07:50	Hemoglobin	11.4	g/dL	L	14	16
			Erythrocytes	3.19	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.5	fL	H	80	98
			Platelets	87	10^9/L	L	150	400
			Leukocytes	3.5	10^9/L	L	4.5	11
			Neutrophils	1.7	10^9/L	L	1.8	7.8
			Alkaline Phosphatase	182	U/L	H	45	129
			Lactate Dehydrogenase	365	U/L	H	120	246
			Glucose	103	mg/dL	H	70	100
	Cycle 2	2011-08-01T08:09	Hemoglobin	11	g/dL	L	14	16
			Erythrocytes	3.22	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.1	fL	H	80	98
			Platelets	75	10^9/L	L	150	400
			Leukocytes	3.7	10^9/L	L	4.5	11
			Aspartate Aminotransferase	35	U/L	H	11	34

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 2	2011-08-01T08:09	Alkaline Phosphatase	203	U/L	H	45	129
			Lactate Dehydrogenase	451	U/L	H	120	246
			Glucose	108	mg/dL	H	70	100
		2011-08-05T08:59	Hemoglobin	10.7	g/dL	L	14	16
			Erythrocytes	3.15	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	98.8	fL	H	80	98
			Platelets	72	10^9/L	L	150	400
			Leukocytes	4.3	10^9/L	L	4.5	11
			Alanine Aminotransferase	53	U/L	H	10	49
			Alkaline Phosphatase	207	U/L	H	45	129
			Lactate Dehydrogenase	381	U/L	H	120	246
			Glucose	119	mg/dL	H	70	100
	Cycle 3	2011-08-22T07:40	Hemoglobin	11.2	g/dL	L	14	16
			Erythrocytes	3.18	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.3	fL	H	80	98
			Platelets	79	10^9/L	L	150	400
			Leukocytes	3.4	10^9/L	L	4.5	11
			Neutrophils	1.7	10^9/L	L	1.8	7.8
			Alanine Aminotransferase	50	U/L	H	10	49
			Aspartate Aminotransferase	36	U/L	H	11	34
			Alkaline Phosphatase	229	U/L	H	45	129
			Lactate Dehydrogenase	483	U/L	H	120	246
			Bilirubin	0.2	mg/dL	L	0.3	1.2
			Glucose	131	mg/dL	H	70	100

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 3	2011-08-26T07:38	Hemoglobin	10.6	g/dL	L	14	16
			Erythrocytes	3.06	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	100.2	fL	H	80	98
			Platelets	74	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4.5	11
			Alanine Aminotransferase	58	U/L	H	10	49
			Alkaline Phosphatase	218	U/L	H	45	129
			Lactate Dehydrogenase	379	U/L	H	120	246
			Urate	3.3	mg/dL	L	3.5	7.2
			Glucose	121	mg/dL	H	70	100
	Cycle 4	2011-09-12T07:47	Hemoglobin	11.7	g/dL	L	14	16
			Erythrocytes	3.37	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	100	fL	H	80	98
			Platelets	87	10^9/L	L	150	400
			Leukocytes	4.2	10^9/L	L	4.5	11
			Alkaline Phosphatase	218	U/L	H	45	129
			Lactate Dehydrogenase	472	U/L	H	120	246
			Urate	3.4	mg/dL	L	3.5	7.2
			Glucose	112	mg/dL	H	70	100
		2011-09-12T08:22	Activated Partial Thromboplastin Time	24.8	sec	L	25	32.4
		2011-09-16T07:45	Hemoglobin	11	g/dL	L	14	16
			Erythrocytes	3.16	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.9	fL	H	80	98
			Platelets	72	10^9/L	L	150	400
			Alanine Aminotransferase	54	U/L	H	10	49

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 4	2011-09-16T07:45	Alkaline Phosphatase	202	U/L	H	45	129
			Lactate Dehydrogenase	389	U/L	H	120	246
			Urate	2.7	mg/dL	L	3.5	7.2
			Glucose	142	mg/dL	H	70	100
	Cycle 5	2011-10-03T07:45	Hemoglobin	11	g/dL	L	14	16
			Erythrocytes	3.13	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	101.1	fL	H	80	98
			Platelets	70	10^9/L	L	150	400
			Leukocytes	3.5	10^9/L	L	4.5	11
			Aspartate Aminotransferase	36	U/L	H	11	34
			Alkaline Phosphatase	220	U/L	H	45	129
			Lactate Dehydrogenase	481	U/L	H	120	246
			Urate	3	mg/dL	L	3.5	7.2
			Glucose	118	mg/dL	H	70	100
		2011-10-07T07:53	Alanine Aminotransferase	50	U/L	H	10	49
			Alkaline Phosphatase	200	U/L	H	45	129
			Lactate Dehydrogenase	377	U/L	H	120	246
			Urate	2.7	mg/dL	L	3.5	7.2
			Glucose	102	mg/dL	H	70	100
		2011-10-07T07:57	Hemoglobin	10.2	g/dL	L	14	16
			Erythrocytes	2.9	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	99.7	fL	H	80	98
			Platelets	66	10^9/L	L	150	400
			Leukocytes	3.8	10^9/L	L	4.5	11

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 6	2011-10-24T07:45	Hemoglobin	11	g/dL	L	14	16
			Erythrocytes	3.05	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	101.6	fL	H	80	98
			Platelets	76	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4.5	11
			Alkaline Phosphatase	195	U/L	H	45	129
			Lactate Dehydrogenase	451	U/L	H	120	246
			Urate	3.4	mg/dL	L	3.5	7.2
			Glucose	111	mg/dL	H	70	100
		2011-10-28T07:35	Hemoglobin	10.4	g/dL	L	14	16
			Erythrocytes	2.93	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	101	fL	H	80	98
			Platelets	72	10^9/L	L	150	400
			Leukocytes	4.2	10^9/L	L	4.5	11
			Alanine Aminotransferase	54	U/L	H	10	49
			Alkaline Phosphatase	191	U/L	H	45	129
			Lactate Dehydrogenase	356	U/L	H	120	246
			Bilirubin	0.2	mg/dL	L	0.3	1.2
			Urate	2.8	mg/dL	L	3.5	7.2
			Glucose	117	mg/dL	H	70	100
	Cycle 7	2011-11-14T07:50	Hemoglobin	10.5	g/dL	L	14	16
			Erythrocytes	2.9	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	101	fL	H	80	98
			Platelets	66	10^9/L	L	150	400
			Leukocytes	3.3	10^9/L	L	4.5	11
			Neutrophils	1.6	10^9/L	L	1.8	7.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 7	2011-11-14T07:50	Alkaline Phosphatase	215	U/L	H	45	129
			Lactate Dehydrogenase	497	U/L	H	120	246
			Glucose	109	mg/dL	H	70	100
		2011-11-18T07:45	Hemoglobin	9.5	g/dL	L	14	16
			Erythrocytes	2.68	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	100.7	fL	H	80	98
			Platelets	65	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4.5	11
			Alanine Aminotransferase	54	U/L	H	10	49
			Alkaline Phosphatase	210	U/L	H	45	129
			Lactate Dehydrogenase	380	U/L	H	120	246
			Bilirubin	0.2	mg/dL	L	0.3	1.2
			Urate	3.4	mg/dL	L	3.5	7.2
			Glucose	104	mg/dL	H	70	100
	Cycle 8	2011-12-05T07:49	Hemoglobin	10.1	g/dL	L	14	16
			Erythrocytes	2.79	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	101.7	fL	H	80	98
			Platelets	91	10^9/L	L	150	400
			Leukocytes	3.8	10^9/L	L	4.5	11
			Alkaline Phosphatase	182	U/L	H	45	129
			Lactate Dehydrogenase	417	U/L	H	120	246
			Urate	3.2	mg/dL	L	3.5	7.2

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
936-001	Cycle 8	2011-12-09T07:45	Hemoglobin	10	g/dL	L	14	16
			Erythrocytes	2.87	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	100.5	fL	H	80	98
			Platelets	79	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4.5	11
			Neutrophils	1.6	10^9/L	L	1.8	7.8
			Alkaline Phosphatase	176	U/L	H	45	129
			Lactate Dehydrogenase	369	U/L	H	120	246
			Urate	2.9	mg/dL	L	3.5	7.2
			Glucose	109	mg/dL	H	70	100
	End Trial	2011-12-13T07:53	Hemoglobin	9.7	g/dL	L	14	16
			Erythrocytes	2.76	10^12/L	L	4.5	6.4
			Ery. Mean Corpuscular Volume	101.6	fL	H	80	98
			Platelets	77	10^9/L	L	150	400
			Leukocytes	3.6	10^9/L	L	4.5	11
			Neutrophils	1.4	10^9/L	L	1.8	7.8
			Alkaline Phosphatase	168	U/L	H	45	129
			Lactate Dehydrogenase	343	U/L	H	120	246
			Urate	3.2	mg/dL	L	3.5	7.2
938-001	Pre-trial	2010-12-27T13:30	Hemoglobin	10.8	g/dL	L	12	16
			Erythrocytes	3.44	10^12/L	L	4.2	5.5
			Leukocytes	11.2	10^9/L	H	4	11
			Neutrophils	8.8	10^9/L	H	2	7.8

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-001	Pre-trial	2010-12-27T14:50	Sodium	134	mmol/L	L	135	146
			Creatinine	0.61	mg/dL	L	0.63	1.22
			Albumin	3.5	g/dL	L	3.6	5.1
			Alanine Aminotransferase	51	U/L	H	6	40
			Blood Urea Nitrogen	34	mg/dL	H	7	25
			Glucose	157	mg/dL	H	65	99
	Cycle 1	2011-01-03T09:38	Hemoglobin	10.9	g/dL	L	12	16
			Erythrocytes	3.61	10^12/L	L	4.2	5.5
			Leukocytes	14.2	10^9/L	H	4	11
			Neutrophils	12.5	10^9/L	H	2	7.8
		2011-01-03T10:40	Blood Urea Nitrogen	30	mg/dL	H	7	25
			Glucose	105	mg/dL	H	65	99
		2011-01-07T10:15	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.22	10^12/L	L	4.2	5.5
			Platelets	138	10^9/L	L	140	440
			Neutrophils	8.3	10^9/L	H	2	7.8
		2011-01-07T10:24	Phosphate	2.4	mg/dL	L	2.5	4.3
			Albumin	3.3	g/dL	L	3.6	5.1
			Glucose	134	mg/dL	H	65	99
		2011-01-13T10:08	Hemoglobin	9.6	g/dL	L	12	16
			Erythrocytes	3.11	10^12/L	L	4.2	5.5
		2011-01-13T10:16	Calcium	8.5	mg/dL	L	8.6	10.2
			Albumin	3.3	g/dL	L	3.6	5.1

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-001	Cycle 2	2011-01-21T10:06	Phosphate	4.4	mg/dL	H	2.5	4.3
			Albumin	3.1	g/dL	L	3.6	5.1
			Alkaline Phosphatase	274	U/L	H	33	130
			Lactate Dehydrogenase	101	U/L	L	120	250
			Blood Urea Nitrogen	36	mg/dL	H	7	25
			Glucose	105	mg/dL	H	65	99
		2011-01-21T11:17	Hemoglobin	9.1	g/dL	L	12	16
			Erythrocytes	2.91	10^12/L	L	4.2	5.5
			Platelets	131	10^9/L	L	140	440
			Neutrophils	8.4	10^9/L	H	2	7.8
		2011-01-28T09:54	Hemoglobin	9.2	g/dL	L	12	16
			Erythrocytes	3.05	10^12/L	L	4.2	5.5
		2011-01-28T10:30	Lactate Dehydrogenase	114	U/L	L	120	250
			Glucose	105	mg/dL	H	65	99
	Cycle 3	2011-02-11T10:34	Creatinine	0.57	mg/dL	L	0.63	1.22
		2011-02-11T11:28	Hemoglobin	10.8	g/dL	L	12	16
			Erythrocytes	3.41	10^12/L	L	4.2	5.5
			Ery. Mean Corpuscular Volume	99.8	fL	H	80	97
			Lymphocytes	0.7	10^9/L	L	0.8	4.1
		2011-02-18T10:00	Glucose	144	mg/dL	H	65	99
		2011-02-18T10:13	Hemoglobin	10.1	g/dL	L	12	16
			Erythrocytes	3.19	10^12/L	L	4.2	5.5
			Ery. Mean Corpuscular Volume	98.3	fL	H	80	97
			Lymphocytes	0.5	10^9/L	L	0.8	4.1

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-001	Cycle 4	2011-03-11T09:36	Hemoglobin	10	g/dL	L	12	16
			Erythrocytes	3.32	10^12/L	L	4.2	5.5
			Eosinophils	2.079	10^9/L	H	0	0.5
			Albumin	3.5	g/dL	L	3.6	5.1
			Glucose	112	mg/dL	H	65	99
		2011-03-18T10:44	Hemoglobin	9.3	g/dL	L	12	16
			Erythrocytes	3.04	10^12/L	L	4.2	5.5
			Ery. Mean Corpuscular Volume	99.3	fL	H	80	97
			Phosphate	4.8	mg/dL	H	2.5	4.3
			Albumin	3.3	g/dL	L	3.6	5.1
			Aspartate Aminotransferase	9	U/L	L	10	35
			Glucose	122	mg/dL	H	65	99
	Unplanned	2011-01-14T10:59	Hemoglobin	9.7	g/dL	L	12	16
			Erythrocytes	3.21	10^12/L	L	4.2	5.5
			Platelets	135	10^9/L	L	140	440
		2011-01-24T10:21	Hemoglobin	8.9	g/dL	L	12	16
			Erythrocytes	2.75	10^12/L	L	4.2	5.5
			Monocytes	1.023	10^9/L	H	0.2	1
			Eosinophils	0.651	10^9/L	H	0	0.5
		2011-02-03T09:58	Hemoglobin	9.5	g/dL	L	12	16
			Erythrocytes	2.9	10^12/L	L	4.2	5.5
			Ery. Mean Corpuscular Volume	97.6	fL	H	80	97
			Leukocytes	12.9	10^9/L	H	4	11
			Neutrophils	10.9	10^9/L	H	2	7.8
			Lactate Dehydrogenase	114	U/L	L	120	250
			Blood Urea Nitrogen	33	mg/dL	H	7	25

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-001	Unplanned	2011-02-24T09:38	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.33	10^12/L	L	4.2	5.5
			Lymphocytes	0.6	10^9/L	L	0.8	4.1
		2011-02-24T10:36	Blood Urea Nitrogen	26	mg/dL	H	7	25
			Glucose	112	mg/dL	H	65	99
		2011-03-04T09:58	Hemoglobin	10.2	g/dL	L	12	16
			Erythrocytes	3.42	10^12/L	L	4.2	5.5
			Monocytes	1.065	10^9/L	H	0.2	1
		2011-03-04T13:54	Glucose	111	mg/dL	H	65	99
		2011-04-13T14:38	Sodium	130	mmol/L	L	135	146
			Albumin	3.1	g/dL	L	3.6	5.1
			Aspartate Aminotransferase	9	U/L	L	10	35
			Lactate Dehydrogenase	102	U/L	L	120	250
			Bilirubin	1.3	mg/dL	H	0.2	1.2
			Blood Urea Nitrogen	31	mg/dL	H	7	25
	End Trial	2011-04-06T13:13	Hemoglobin	7.6	g/dL	L	12	16
			Erythrocytes	2.51	10^12/L	L	4.2	5.5
			Platelets	43	10^9/L	L	140	440
			Leukocytes	13.2	10^9/L	H	4	11
			Neutrophils	8.4	10^9/L	H	2	7.8
			Monocytes	1.716	10^9/L	H	0.2	1
			Eosinophils	2.112	10^9/L	H	0	0.5

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-001	End Trial	2011-04-06T14:55	Sodium	131	mmol/L	L	135	146
			Calcium	8	mg/dL	L	8.6	10.2
			Creatinine	1.7	mg/dL	H	0.63	1.22
			Albumin	2.9	g/dL	L	3.6	5.1
			Aspartate Aminotransferase	9	U/L	L	10	35
			Alkaline Phosphatase	174	U/L	H	33	130
			Bilirubin	1.5	mg/dL	H	0.2	1.2
			Blood Urea Nitrogen	34	mg/dL	H	7	25
			Urate	8.4	mg/dL	H	2.5	7
			Glucose	123	mg/dL	H	65	99
		2011-04-06T15:05	Prothrombin Time	11.7	sec	H	9	11.5
938-002	Pre-trial	2011-03-15T16:20	Activated Partial Thromboplastin Time	37	sec	H	22	34
			Albumin	3.2	g/dL	L	3.6	5.1
			Lactate Dehydrogenase	318	U/L	H	120	250
		2011-03-15T16:26	Hemoglobin	13.5	g/dL	L	14	18
			Leukocytes	3.8	10^9/L	L	4	11
			Lymphocytes	0.2	10^9/L	L	0.8	4.1
	Cycle 1	2011-03-21T09:48	Lymphocytes	0.7	10^9/L	L	0.8	4.1
		2011-03-21T14:10	Phosphate	4.8	mg/dL	H	2.5	4.5
			Albumin	3.2	g/dL	L	3.6	5.1
			Lactate Dehydrogenase	275	U/L	H	120	250
			Glucose	119	mg/dL	H	65	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-002	Cycle 1	2011-03-25T10:12	Hemoglobin	13	g/dL	L	14	18
			Lymphocytes	0.4	10^9/L	L	0.8	4.1
			Monocytes	0.11	10^9/L	L	0.2	1
		2011-03-25T10:30	Albumin	3.2	g/dL	L	3.6	5.1
			Lactate Dehydrogenase	258	U/L	H	120	250
			Glucose	160	mg/dL	H	65	99
		2011-03-31T14:38	Glucose	121	mg/dL	H	65	99
		2011-03-31T14:49	Hemoglobin	13.9	g/dL	L	14	18
	Cycle 2	2011-04-11T13:08	Hemoglobin	13.7	g/dL	L	14	18
		2011-04-11T13:50	Calcium	8.5	mg/dL	L	8.6	10.2
			Glucose	156	mg/dL	H	65	99
		2011-04-15T14:07	Hemoglobin	12.3	g/dL	L	14	18
			Erythrocytes	4.08	10^12/L	L	4.4	5.5
			Platelets	139	10^9/L	L	140	440
			Leukocytes	2.9	10^9/L	L	4	11
			Lymphocytes	0.3	10^9/L	L	0.8	4.1
			Monocytes	0.174	10^9/L	L	0.2	1
			Potassium	3.4	mmol/L	L	3.5	5.3
			Calcium	8.3	mg/dL	L	8.6	10.2
			Phosphate	4.9	mg/dL	H	2.5	4.5
			Albumin	3.5	g/dL	L	3.6	5.1
			Lactate Dehydrogenase	253	U/L	H	120	250
			Glucose	129	mg/dL	H	65	99

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-002	Cycle 3	2011-05-02T12:57	Glucose	106	mg/dL	H	65	99
		2011-05-02T13:07	Hemoglobin	12.9	g/dL	L	14	18
			Erythrocytes	4.35	10^12/L	L	4.4	5.5
			Leukocytes	1.7	10^9/L	L	4	11
			Neutrophils	1.1	10^9/L	L	2	7.8
			Lymphocytes	0.4	10^9/L	L	0.8	4.1
		2011-05-06T14:00	Phosphate	5.6	mg/dL	H	2.5	4.5
		2011-05-06T14:09	Hemoglobin	12.1	g/dL	L	14	18
			Erythrocytes	4.05	10^12/L	L	4.4	5.5
			Leukocytes	1.3	10^9/L	L	4	11
			Neutrophils	0.8	10^9/L	L	2	7.8
			Lymphocytes	0.3	10^9/L	L	0.8	4.1
			Monocytes	0.13	10^9/L	L	0.2	1
	Unplanned	2011-04-21T15:25	Hemoglobin	12.4	g/dL	L	14	18
			Erythrocytes	4.09	10^12/L	L	4.4	5.5
			Leukocytes	3	10^9/L	L	4	11
			Lymphocytes	0.5	10^9/L	L	0.8	4.1
		2011-04-21T16:05	Lactate Dehydrogenase	255	U/L	H	120	250
			Glucose	119	mg/dL	H	65	99
		2011-05-12T15:16	Hemoglobin	13	g/dL	L	14	18
			Erythrocytes	4.33	10^12/L	L	4.4	5.5
			Leukocytes	2.2	10^9/L	L	4	11
			Neutrophils	1.5	10^9/L	L	2	7.8
			Lymphocytes	0.4	10^9/L	L	0.8	4.1

[a] **Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
938-002	Unplanned	2011-05-23T14:02	Albumin	3.4	g/dL	L	3.6	5.1
			Glucose	147	mg/dL	H	65	99
		2011-05-23T14:13	Hemoglobin	13.9	g/dL	L	14	18
			Leukocytes	1.3	10^9/L	L	4	11
			Neutrophils	0.9	10^9/L	L	2	7.8
			Lymphocytes	0.3	10^9/L	L	0.8	4.1
			Monocytes	0.052	10^9/L	L	0.2	1
		2011-05-26T15:02	Hemoglobin	13.9	g/dL	L	14	18
			Lymphocytes	0.5	10^9/L	L	0.8	4.1
			Monocytes	1.083	10^9/L	H	0.2	1
	End Trial	2011-05-27T13:54	Hemoglobin	12.7	g/dL	L	14	18
			Erythrocytes	4.19	10^12/L	L	4.4	5.5
			Lymphocytes	0.3	10^9/L	L	0.8	4.1
		2011-05-27T15:00	Prothrombin Time	11.9	sec	H	9	11.5
			Activated Partial Thromboplastin Time	39	sec	H	22	34
			Prothrombin Intl. Normalized Ratio	1.2	ratio	H	0.9	1.1
		2011-05-27T15:06	Albumin	3.5	g/dL	L	3.6	5.1
			Lactate Dehydrogenase	423	U/L	H	120	250
			Blood Urea Nitrogen	27	mg/dL	H	7	25
			Glucose	190	mg/dL	H	65	99

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
947-001	Pre-trial	2011-07-21T12:00	Hemoglobin	13.3	g/dL	L	13.5	17.5
			Erythrocytes	3.98	10^12/L	L	4.5	5.9
			Platelets	146	10^9/L	L	150	400
			Alanine Aminotransferase	56	U/L	H	0	49
	Cycle 1	2011-07-29T10:30	Hemoglobin	13.1	g/dL	L	13.5	17.5
			Erythrocytes	3.93	10^12/L	L	4.5	5.9
			Platelets	136	10^9/L	L	150	400
			Alanine Aminotransferase	59	U/L	H	0	49
			Glucose	133.3	mg/dL	H	55	108
		2011-08-01T18:55	Activated Partial Thromboplastin Time	23.4	sec	L	24	31
		2011-08-05T13:05	Hemoglobin	12.7	g/dL	L	13.5	17.5
			Erythrocytes	3.9	10^12/L	L	4.5	5.9
			Platelets	127	10^9/L	L	150	400
			Potassium	3.4	mmol/L	L	3.5	5
			Glucose	140.5	mg/dL	H	55	108
		2011-08-11T08:10	Hemoglobin	12.6	g/dL	L	13.5	17.5
			Erythrocytes	3.74	10^12/L	L	4.5	5.9
			Platelets	122	10^9/L	L	150	400
			Magnesium	2.77	mg/dL	H	1.7	2.5
			Lactate Dehydrogenase	210	U/L	H	90	200
			Glucose	108.1	mg/dL	H	55	108

[a]**Abnormality: L=Low, H=High**

Table 14.3.8.4: Abnormal Laboratory Value Listing

Patient ID	Visit	Sample Date/time	Test Name	Result (SI)	Unit (SI)	Abnormality[a]	Normal Range Low	Normal Range High
947-001	Cycle 2	2011-08-22T12:00	Hemoglobin	12.9	g/dL	L	13.5	17.5
			Erythrocytes	3.91	10^12/L	L	4.5	5.9
			Platelets	141	10^9/L	L	150	400
			Activated Partial Thromboplastin Time	22.8	sec	L	24	31
			Glucose	120.7	mg/dL	H	55	108
		2011-08-26T13:15	Hemoglobin	12.8	g/dL	L	13.5	17.5
			Erythrocytes	3.79	10^12/L	L	4.5	5.9
			Platelets	122	10^9/L	L	150	400
			Magnesium	2.63	mg/dL	H	1.7	2.5
			Lactate Dehydrogenase	201	U/L	H	90	200
			Glucose	118.9	mg/dL	H	55	108
	End Trial	2011-09-12T11:40	Hemoglobin	13	g/dL	L	13.5	17.5
			Erythrocytes	3.82	10^12/L	L	4.5	5.9
		2011-09-19T07:30	Activated Partial Thromboplastin Time	23.6	sec	L	24	31

[a]Abnormality: L=Low, H=High

```
/*************************************************************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.08.2013
/*Program:    t_enroll.sas
/*Purpose:    Creates Table of Enrollment by Center
/*Modifications: Bob Hull 4/4/2013: Updated formatting for new mock.


/************************************************/

%let filename=t-enroll;
%let tabno=14.1.1.1;
%let outno=14-1-1-1;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


%macro enroll(pop);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where fasfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('allpat',put(_n_,3.));
run;

*get total number of patients for CPRG;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=adsl;
  by country siteid invnam;
run;

%macro grp(where,denom);

proc freq data=adsl;
where &where;
tables country / out=out&denom noprint;
run;

data out&denom.2;
set out&denom;
  length site $8 col&denom $15;
  site="Total";
```

```
  col&denom=put(count,3.)||" ("||put(count/&&&denom*100,4.1)||")";
  subord=999;
run;

proc freq data=adsl;
by country siteid;
where &where;
tables invnam / out=list&denom noprint;
run;

data list&denom.2;
set list&denom;
  length  col&denom $15;
  col&denom=put(count,3.)||" ("||put(count/&&&denom*100,4.1)||")";

run;

data &denom;
set out&denom.2 list&denom.2 (in=inl);
  if inl then site=siteid;
  drop siteid count percent;
run;
%mend;

%grp(%str(fasfl="Y"),allpat);
%grp(%str(ptclfl="Y"),n_cprg);

proc sort data=allpat;
  by country site invnam;
run;

proc sort data=n_cprg ;
  by country site invnam;
run;

data final;
merge allpat n_cprg;
  by country site invnam;
  length country2 $25;
  site2=site;
  if country='BEL' then do;country2='Belgium';page=1;end;
  if country='CAN' then do;country2='Canada';page=1;end;
  if country='HRV' then do;country2='Croatia';page=1;end;
  if country='DEU' then do;country2='Germany';page=1;end;
  if country='DNK' then do;country2='Denmark';page=1;end;
  if country='FRA' then do;country2='France';page=1;end;

  if country='HUN' then do;country2='Hungary';page=2;end;
  if country='ISR' then do;country2='Israel';page=2;end;
  if country='ITA' then do;country2='Italy';page=2;end;
  if country='NLD' then do;country2='Netherlands';page=2;end;
  if country='POL' then do;country2='Poland';page=2;end;
  if country='SVK' then do;country2='Slovakia';page=2;end;
  if country='ZAF' then do;country2='South Africa';page=2;end;
  if country='ESP' then do;country2='Spain';page=2;end;

  if country='GBR' then do;country2='United Kingdom';page=3;end;
  if country='USA' then do;country2='United States';page=3;end;
```

```
  if colallpat ='' then colallpat ='  -         ';
  if  coln_cprg='' then  coln_cprg='  -         ';

run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-enroll.rtf" style=vg_rtf;

title3 "Table &tabno: Patient Enrolment by Investigational Center";
footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";
%footsrce(line=2);


proc report data=final nowindows headskip split='@';
columns page country2 site2 ("Patient Population" site invnam) ("Number of Patients (%)"
colallpat coln_cprg);

  define page / order noprint order=internal;
  define country2 / order 'Country' style=[cellwidth=1.75 in asis=on] style(header)=[just=left] ;
  define site2 / order order=internal noprint;
  define site / display 'Center' style=[cellwidth=1 in asis=on] style(header)=[just=left];
  define invnam / display 'Investigator' style=[cellwidth=2.3 in asis=on] style(header)=
[just=left] ;
  define colallpat / display "Full Analysis Set@N=&allpat" style=[cellwidth=1.2 in asis=on ]
center;
  define coln_cprg / display "&ptclflname*@N=&n_cprg" style=[cellwidth=1.5 in asis=on] center;
break after page / page;
  compute before country2;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%enroll(fasfl);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       03.05.2013
/*Program:    t_disp.sas
/*Purpose:    Creates Patient Disposition
/*Modifications:


/************************************************/

%let filename=t-disp;
%let tno=14.1.1.2;
%let outno=14-1-1-2;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


proc format;
  value cat
    1="Entered study therapy"
    2="Still on study therapy"
    3="Discontinued study therapy"
    4="  Primary reason for discontinuation"
    5="Patient status at the cut-off date";
  value disreas
    1="Progressive Disease"
    2="Death"
    3="Adverse Event"
    4="Stem Cell Transplant"
    5="Withdrawal by Patient"
    6="Physician Decision"
    7="Lost to follow-up";
  value survstat
    1="Alive"
    2="Dead"
    3="No follow-up for >12 mon";
run;

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
```

```
  call symputx(pop,totcount);
run;

data cat;
  set demog0;
  cat=1;varn=0;
  output;
  cat=2;varn=0;
  if dsreas='' then output;
  cat=3;varn=0;
  if dsreas ne '' then do;
    output;
    cat=4;
    select (dsreas);
      when ("Progressive Disease")   varn=1;
      when ("Death")                 varn=2;
      when ("Adverse Event")         varn=3;
      when ("Stem Cell Transplant")  varn=4;
      when ("Withdrawal by Patient") varn=5;
      when ("Physician Decision")    varn=6;
      when ("Lost to Follow-up")     varn=7;
    end;
    output;
  end;
  cat=5;varn=0;
  varc=survstat;
  select(survstat);
    when ("Alive") varn=1;
    when ("Dead")  varn=2;
    when ("No follow-up for >12 mon") varn=3;
  end;
  output;
run;

proc sort;
  by pop cat;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn / out=freq0;
run;

data shell;
  length catdesc $75;
  set totfreq (keep=pop);
  do cat=1 to 5;
    varn=0;
    catdesc=put(cat,cat.);
    output;
    if cat=4 then do varn=1 to 7;
      catdesc="    "||strip(put(varn,disreas.));
      output;
    end;
    if cat=5 then do varn=1 to 3;
      catdesc="  "||strip(put(varn,survstat.));
      output;
    end;
```

```
  end;
run;

proc sort data=shell;
  by pop cat varn;
run;

data combo;
  length value $20;
  merge shell (in=x) freq0 (in=b);
  by pop cat varn;
  if cat=1 then value=strip(put(count,best.));
  else if not (cat>=4 and varn=0) then do;
    if count=. then count=0;
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
  end;
  keep pop cat catdesc varn value;
run;

proc sort data=combo;
  by cat varn catdesc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc;
  var value;
  id pop;
run;

data final;
  set trans;
  array _pop{*} fasfl ptclfl;
  do i=1 to dim(_pop);
    if _pop{i}='' and not (cat>=4 and varn=0) then _pop{i}="-";
  end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-disp.rtf" style=vg_rtf;

title3 "Table &tno: Patient Disposition";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  columns cat varn catdesc ('Number of Patients (%)' fasfl ptclfl);

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=2.75 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl  / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
```

```
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       05.08.2013
/*Program:    t_disp.sas
/*Purpose:    Creates Table 14.1.1.3: Patient Disposition by Treatment Cycle
/*Modifications:


/************************************************/

%let filename=t-dispbycycle;
%let tno=14.1.1.3;
%let outno=14-1-1-3;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

/*maximum number of cycles*/
proc means data=db.adex noprint;
  var visitnum;
  output out=max max=max;
run;

data _null_;
  set max;
  call symputx("max",max);
run;

%put &max;

data disp0;
  merge db.adex (keep=usubjid fasfl ptclfl visitnum visit exdose where=(exdose>0))
        db.adsl (keep=usubjid fasfl ptclfl cyclenum dsstdt);
  by usubjid;
run;
```

```
proc sort data=disp0 out=order9 (keep=usubjid fasfl ptclfl visitnum) nodupkey;
  by usubjid fasfl ptclfl visitnum;
  where visitnum=cyclenum and dsstdt=.;
run;

proc sort data=disp0 out=order7 (keep=usubjid fasfl ptclfl visitnum) nodupkey;
  by usubjid fasfl ptclfl visitnum;
  where visitnum=cyclenum and dsstdt ne .;
run;

proc freq data=disp0 noprint;
  by usubjid fasfl ptclfl;
  tables visitnum / out=dosefreq (drop=percent rename=(count=order));
run;

proc sort data=disp0 out=order0 (keep=usubjid fasfl ptclfl visitnum) nodupkey;
  by usubjid fasfl ptclfl visitnum;
run;

data disp1;
  set dosefreq order0 (in=in0) order7 (in=in7) order9 (in=in9);
  if in0 then order=0;
  if in7 then order=7;
  if in9 then order=9;
run;

data disp;
  set disp1;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc freq data=disp noprint;
  tables visitnum*order*pop / out=freq0 (drop=percent);
run;


data shell;
  length desc $100;
  set totfreq;
  do visitnum=1 to &max;
    order=0;
    desc="Patients entering Cycle "||strip(put(visitnum,best.));
    output;
    do order=1 to 5;
      if order=1 then desc="  Received 1 full dose";
      else desc="  Received "||strip(put(order,best.))||" full doses";
      output;
    end;
    do order=6,8;
      desc="";
      output;
    end;
    order=7;desc="  Discontinued during this cycle";
    output;
    order=9;desc="  Continuing on this cycle at the cut-off date";
```

```
    output;
  end;
run;

proc sort data=shell;
  by visitnum order pop;
run;

data combo;
  merge shell freq0;
  by visitnum order pop;
  if count=. then count=0;
  value=strip(put(count,3.))||" ("||strip(put(100*count/totcount,5.1))||")";
  if count=0 then value="0";
  if order in (6 8) then value="";
run;

proc transpose data=combo out=trans (drop=_name_);
  by visitnum order desc;
  var value;
  id pop;
run;

data final;
  set trans;
  page=ceil(visitnum/3);
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-dispbycycle.rtf" style=vg_rtf;

title3 "Table &tno: Patient Disposition by Treatment Cycle";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns visitnum order desc ('Number of Patients (%)' fasfl ptclfl);

  define visitnum / order order=internal noprint;
  define order    / order order=internal noprint;
  define desc     / order "Patient Population"
                       style=[cellwidth=2.75 in asis=on] left style(header)=[just=left asis=on];

  define fasfl    / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl   / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before visitnum;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       07.24.2013
/*Program:    t_PLTdispbycycle.sas
/*Purpose:    Creates Table 14.1.1.3: Patient Disposition by Treatment Cycle
/*Modifications:  REH - 9/25/2013, corrected output file name.
/************************************************/

%let filename=t-pltdispbycycle;
%let tno=14.1.1.4;
%let outno=14-1-1-4;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

/*BL PLT < 100,000/ul" (Y) and "BL PLT >= 100,000/ul (N)*/

data demog0;
  set db.adsl;
  where fasfl="Y";
  if platfl="" then platfl="N";
  pop=platfl;
run;

proc sort;
  by usubjid;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

/*maximum number of cycles*/
proc means data=db.adex noprint;
  var visitnum;
  output out=max max=max;
run;

data _null_;
  set max;
  call symputx("max",max);
run;

%put &max;

data disp0;
  merge db.adex (keep=usubjid fasfl platfl visitnum visit exdose where=(exdose>0 and fasfl="Y"))
        db.adsl (keep=usubjid fasfl platfl cyclenum dsstdt where=(fasfl="Y"))
        demog0 (in=x keep=usubjid pop);
  by usubjid;
run;
```

```
proc sort data=disp0 out=order9 (keep=usubjid pop visitnum) nodupkey;
  by usubjid pop visitnum;
  where visitnum=cyclenum and dsstdt=.;
run;

proc sort data=disp0 out=order7 (keep=usubjid pop visitnum) nodupkey;
  by usubjid pop visitnum;
  where visitnum=cyclenum and dsstdt ne .;
run;

proc freq data=disp0 noprint;
  by usubjid pop;
  tables visitnum / out=dosefreq (drop=percent rename=(count=order));
run;

proc sort data=disp0 out=order0 (keep=usubjid pop visitnum) nodupkey;
  by usubjid pop visitnum;
run;

data disp;
  set dosefreq order0 (in=in0) order7 (in=in7) order9 (in=in9);
  if in0 then order=0;
  if in7 then order=7;
  if in9 then order=9;
run;


proc freq data=disp noprint;
  tables visitnum*order*pop / out=freq0 (drop=percent);
run;

data shell;
  length desc $100;
  set totfreq;
  do visitnum=1 to &max;
    order=0;
    desc="Patients entering Cycle "||strip(put(visitnum,best.));
    output;
    do order=1 to 5;
      if order=1 then desc="  Received 1 full dose";
      else desc="  Received "||strip(put(order,best.))||" full doses";
      output;
    end;
    do order=6,8;
      desc="";
      output;
    end;
    order=7;desc="  Discontinued during this cycle";
    output;
    order=9;desc="  Continuing on this cycle at the cut-off date";
    output;
  end;
run;

proc sort data=shell;
  by visitnum order pop;
run;
```

```
data combo;
  merge shell freq0;
  by visitnum order pop;
  if count=. then count=0;
  value=strip(put(count,3.))||" ("||strip(put(100*count/totcount,5.1))||")";
  if count=0 then value="0";
  if order in (6 8) then value="";
run;

proc transpose data=combo out=trans (drop=_name_);
  by visitnum order desc;
  var value;
  id pop;
run;

data final;
  set trans;
  page=ceil(visitnum/3);
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTdispbycycle.rtf" style=vg_rtf;

title3 "Table &tno: Patient Disposition by Treatment Cycle";
title4 "by Baseline Platelet Group";
title5 "Full Analysis Set";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns visitnum order desc ('Number of Patients (%)' N Y);

  define visitnum / order order=internal noprint;
  define order    / order order=internal noprint;
  define desc     / order "Patient Population"
                       style=[cellwidth=2.75 in asis=on] left style(header)=[just=left asis=on];

  define n        / display "Platelet >= 100,000/ul@N=&n"     style=[cellwidth=1.2 in] center;
  define y        / display "Platelet < 100,000/ul@N=&y" style=[cellwidth=1.5 in] center;

  compute before visitnum;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Pamela Hsu
/*Date:       10/15/2013
/*Program:    t-infu-dur.sas
/*Purpose:    Creates Infusion Duration Table
/*Modifications:
/************************************************/

%let filename=t-infu-dur;
%let tno=14.1.1.5;
%let outno=14-1-1-5;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc sort data=sdtm.ex out=ex1;
    by usubjid visitnum visit extpt;
run;

*** note: two patients 220-002 had partial time in exstdtc (2012-03-09T10)and  ***;
***       221-003 had both exstdtc and exendtc as partial time (2011-05-18T11) ***;
***       make it to :00 minute                                                 ***;

data ex;
    set ex1;
    by usubjid visitnum visit extpt;
    length dur $15. ex_dur 8.;
    if length(exendtc)=13 then exendtc=compress(exendtc)||':00';
    if length(exstdtc)=13 then exstdtc=compress(exstdtc)||':00';
/*  if substr(exendtc,11,1)='T' and substr(exstdtc,11,1)='T' then ex_dur=input(substr
(exendtc,12,5),time5.)-input(substr(exstdtc,12,5),time5.);*/
    if length(exendtc)=16 and length(exstdtc)=16 then ex_dur=(input(substr(exendtc,12,5),time5.)-
input(substr(exstdtc,12,5),time5.))/60;
    if ex_dur ne . then do;
        if ex_dur le 30 then dur='30 min or less';
        else if ex_dur gt 30 and ex_dur le 45 then dur='30-45 min';
        else if ex_dur gt 45 then dur='45 min or more';
    end;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno.-infu-dur.rtf" style=vg_rtf;

%footsrce(line=1);

proc freq data=ex;
    tables dur;
    title3 "Table &tno (Part 1): Overall distribution of infusion time regardless of cycles and
days";
run;

proc freq data=ex;
    tables visit*extpt*dur/list;
    title3 "Table &tno (Part 2): Distribution of infusion time by Cycle and Day";
run;
```

```
ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       02.27.2013
/*Program:    t_demog.sas
/*Purpose:    Creates Demographics Table
/*Modifications:


/************************************************/

%let filename=t-demog;
%let tno=14.1.2.1;
%let outno=14-1-2-1;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data cat;
  length varc $100;
  set demog0;
  select (sex);
    when ("F") do;sexn=2;gender="Female";end;
    when ("M") do;sexn=1;gender="Male  ";end;
    otherwise;
  end;
  select (race);
    when ("White") racen=1;
    when ("Black") racen=2;
    when ("Asian") racen=3;
    when ("Latin") racen=4;
    when ("Other") racen=5;
    otherwise;
  end;
  select (agegrp);
    when ("< 65") agegrpn=1;
    when (">=65") agegrpn=2;
```

```
    otherwise;
  end;
  perfstatn=input(compress(perfstat,"ECOG"),best.)+1;

  /*gender*/
  cat=1;
  varc=gender;
  varn=sexn;
  if gender ne '' then output;

  /*race*/
  cat=2;
  varc=race;
  varn=racen;
  if race ne '' then output;

  /*age*/
  cat=3;
  varc=agegrp;
  varn=agegrpn;
  if agegrp ne '' then output;

  cat=4;
  varc=perfstat;
  varn=perfstatn;
  if perfstat ne '' then output;
run;

proc sort;
  by pop cat;
run;

proc means data=demog0 noprint;
  by pop;
  var age;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
run;

proc format;
  value cat
    1="Gender"
    2="Race"
    3="Age (years)"
    4="Performance status";
run;

data shell;
  length catdesc $30;
  set totfreq (keep=pop);
  do cat=1 to 4;
    catdesc=put(cat,cat.);
    varn=0;
    output;
```

```
    if cat=3 then do;
      varn=3;
      output;
    end;
  end;
run;

data combo;
  length value $20 catdesc $30;
  set shell (in=x) stats0 (in=a) freq0 (in=b);
  by pop;
  if x then output;
  else if a then do;
    cat=3;
    catdesc=put(cat,cat.);
    varn=4;varc="Mean (SD)";
    value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
    output;
    varn=5;varc="Median";
    value=strip(put(median,8.1));
    output;
    varn=6;varc="Range";
    value=strip(put(min,best.))||" - "||strip(put(max,best.));
    output;
  end;
  else do;
    catdesc=put(cat,cat.);
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
    output;
  end;
  keep pop cat catdesc varn varc value;
run;

proc sort data=combo;
  by cat varn catdesc varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc varc;
  var value;
  id pop;
run;

data final;
  set trans;
  if varn>0 then catdesc="   "||strip(varc);
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-demog.rtf" style=vg_rtf;

title3 "Table &tno: Demographics and Other Baseline Characteristics";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  columns cat varn catdesc ('Number of Patients (%)' fasfl ptclfl);
```

```
  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=1.5 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl  / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       02.27.2013
/*Program:    t_dischar.sas
/*Purpose:    Creates Pretreatment Disease Characteristics
/*Modifications:


/************************************************/

%let filename=t-dischar;
%let tno=14.1.2.2;
%let outno=14-1-2-2;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;


data cat;
  length varc $100;
  set demog0;

  select (cprgdiag);
    when ("Peripheral T-cell lymphoma, NOS")              cprimn=1;
    when ("Angioimmunoblastic T-cell lymphoma")           cprimn=2;
    when ("Anaplastic large cell lymphoma, ALK-negative") cprimn=3;
    when ("Anaplastic large cell lymphoma, ALK-positive") cprimn=4;
    when ("Enteropathy-associated T-cell lymphoma")       cprimn=5;
    when ("Extranodal NK/T-cell lymphoma, nasal type")    cprimn=6;
    when ("Hepatosplenic T-cell lymphoma")                cprimn=7;
    when ("No peripheral T-cell lymphoma present")        cprimn=8;
    when ("Inadequate sample for assessment")             cprimn=9;
  end;

  select (primary);
    when ("Peripheral T-cell lymphoma, NOS")              primn=1;
```

```
    when ("Angioimmunoblastic T-cell lymphoma")           primn=2;
    when ("Anaplastic large cell lymphoma, ALK-negative") primn=3;
    when ("Hepatosplenic T-cell lymphoma")                primn=4;
    when ("Anaplastic large cell lymphoma, ALK-positive") primn=5;
    when ("Enteropathy-associated T-cell lymphoma")       primn=6;
    when ("Extranodal NK/T-cell lymphoma, nasal type")    primn=7;
  end;

  select (dcstg);
    when ("Stage IA")   stagen=1;
    when ("Stage IIA")  stagen=2;
    when ("Stage IIB")  stagen=3;
    when ("Stage IIIA") stagen=4;
    when ("Stage IIIB") stagen=5;
    when ("Stage IVA")  stagen=6;
    when ("Stage IVB")  stagen=7;
    when ("Unknown")    stagen=8;
    otherwise;
  end;

  select (bminvolv);
    when ("No")            bmin=1;
    when ("Yes")           bmin=2;
    when ("Indeterminate") bmin=3;
    when ("Not assessed")  bmin=4;
    otherwise;
  end;

  /*Primary lymphoma diagnosis (Central Pathology)*/
  cat=1;
  varc=cprgdiag;
  varn=cprimn;
  if cprgdiag ne '' then output;

  /*Primary lymphoma diagnosis (Investigator)*/
  cat=2;
  varc=primary;
  varn=primn;
  if primary ne '' then output;

  /*Bone marrow involvement*/
  cat=4;
  varc=bminvolv;
  varn=bmin;
  if bminvolv ne '' then output;

  /*Ann Arbor staging at study entry*/
  cat=5;
  varc=dcstg;
  varn=stagen;
  if dcstg ne '' then output;


run;

proc sort;
  by pop cat;
run;
```

```
proc means data=demog0 noprint;
  by pop;
  var diagdur;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
run;

proc format;
  value cat
    1="Primary lymphoma diagnosis (central pathology)"
    2="Primary lymphoma diagnosis (Investigator)"
    3="Months from first lymphoma diagnosis to study entry"
    4="Bone marrow involvement"
    5="Ann Arbor staging at study entry";
run;

data shell;
  length catdesc $75;
  set totfreq (keep=pop);
  do cat=1 to 5;
    catdesc=put(cat,cat.);
    varn=0;
    output;
  end;
run;

data combo;
  length value $20 catdesc $75;
  set shell (in=x) stats0 (in=a) freq0 (in=b);
  by pop;
  if x then output;
  else if a then do;
    cat=3;
    catdesc=put(cat,cat.);
    varn=1;varc="N";
    value=strip(put(n,best.));
    output;
    varn=2;varc="Mean (SD)";
    value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
    output;
    varn=3;varc="Median";
    value=strip(put(median,8.1));
    output;
    varn=4;varc="Range";
    value=strip(put(min,best.))||" - "||strip(put(max,best.));
    output;
  end;
  else do;
    catdesc=put(cat,cat.);
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
    output;
  end;
  keep pop cat catdesc varn varc value;
```

```
run;

proc sort data=combo;
  by cat varn catdesc varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc varc;
  var value;
  id pop;
run;

data final;
  set trans;
  if varn>0 then catdesc="   "||strip(varc);
  page=ceil(cat/4);
  array _pop{*} fasfl ptclfl;
  do i=1 to dim(_pop);
    if _pop{i}='' and varn>0 then _pop{i}="-";
  end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-dischar.rtf" style=vg_rtf;

title3 "Table &tno: Pretreatment Disease Characteristics";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns cat varn catdesc ('Number of Patients (%)' fasfl ptclfl);

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=2.75 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl  / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       02.28.2013
/*Program:    t_priortx.sas
/*Purpose:    Prior Lymphoma Therapies
/*Modifications:
  5/6/2013  REH  Added "Response to the last systemic therapy"
  5/16/2013 REH  Added "Complete or partial response to any prior systemic therapy"
/************************************************/

%let filename=t-priortx;
%let tno=14.1.2.3;
%let outno=14-1-2-3;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data cat;
  length varc $100;
  set demog0;
  /*radiation*/
  cat=1;
  if prrt="Y" then do;
    varn=1;
    varc="  Radiation therapy";
    output;
  end;
  /*prior therapy received*/
  cat=2;
  /*systemic - per protocol, all subjects had failed prior systemic therapy*/
  varn=1;
  varc="  Systemic therapy";
  if prrgmnum>0 then output;
  /*cat=2;
  if prpuva="Y" then do;
    varn=1;
```

```
    varc="  Psoralen + UVA";
    output;
  end;*/

  /*stem cell transplant*/
  cat=4;
  if prsctp ne "" then do;
    varn=1;
    varc="  Stem cell transplant";
    output;
    varc="    "||strip(prsctp);
    select (prsctp);
      when ("Autologous") varn=2;
      when ("Allogeneic") varn=3;
    end;
    output;
  end;
  /*number of prior PTCL therapies*/
  cat=5;
  varn=prrgmnum;
  varc="    "||strip(put(prrgmnum,best.));
  output;
  /*CR/PR to any prior systemic therapy*/
  cat=5.5;
  varn=1;
  varc="Complete or partial response to any prior systemic therapy";
  if prrsp="Y" or prbstrsp in ("Partial Response" "Complete Response") then output;
  /*response to the last systemic therapy*/
  cat=6;
  select (prbstrsp);
    when ("Complete Response")   varn=1;
    when ("Partial Response")    varn=2;
    when ("Stable Disease")      varn=3;
    when ("Progressive Disease") varn=4;
    when ("Not Evaluable")       varn=5;
    when ("","Unknown")          varn=6;
  end;
  varc="    "||strip(prbstrsp);
  output;
run;

proc sort;
  by pop cat;
run;

proc means data=demog0 noprint;
  by pop;
  var prrgmnum;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;
proc means data=demog0 noprint;
  by pop;
  var prprgdur;
  output out=stats1 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

proc freq data=cat noprint;
  by pop cat;
```

```
  tables varn*varc/ out=freq0;
run;

proc format;
  value cat
    1="Prior therapy received"
    5="Number of prior PTCL therapies"
    6="Response to the most recent systemic therapy"
    7="Months from last disease progression to study entry";
run;

data shell;
  length catdesc $75;
  set totfreq (keep=pop);
  do cat=1,5,6,7;
    catdesc=put(cat,cat.);
    varn=0;
    output;
  end;
run;

data combo;
  length value $20 catdesc $75;
  set shell (in=x) stats0 (in=a1) stats1 (in=a2) freq0 (in=b);
  by pop;
  if x then output;
  else if a1 or a2 then do;
    if a1 then cat=5;
    else cat=7;
    catdesc=put(cat,cat.);
    varn=21;varc="  N (%)";
    value=strip(put(n,best.))||" ("||put(100*n/symgetn(pop),5.1)||")";
    output;
    varn=22;varc="  Mean (SD)";
    value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
    output;
    varn=23;varc="  Median";
    value=strip(put(median,8.1));
    output;
    varn=24;varc="  Range";
    value=strip(put(min,best.))||" - "||strip(put(max,best.));
    output;
  end;
  else do;
    *catdesc=put(cat,cat.);
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),5.1)||")";
    output;
  end;
  keep pop cat catdesc varn varc value;
run;

proc sort data=combo;
  by cat varn catdesc varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc varc;
  var value;
```

```
  id pop;
run;

data final;
  set trans;
  if varn>0 then catdesc=varc;
  array _pop{*} fasfl ptclfl;
  do i=1 to dim(_pop);
    if _pop{i}='' and varn>0 then _pop{i}="-";
  end;
  if not (cat=5 and varn=21);
  if cat=5 and varn>20 then cat=cat+.1;
  page=ceil(cat/6);
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-priortx.rtf" style=vg_rtf;

title3 "Table &tno: Prior Therapies for Peripheral T-cell Lymphoma";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns cat varn catdesc ('Number of Patients (%)' fasfl ptclfl);

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=3.05 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl  / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       04.03.2013
/*Program:    t_priorreg.sas
/*Purpose:    Prior Systemic Regimens for Peripheral T-cell Lymphoma
/*Modifications:


/************************************************/

%let filename=t-priorreg;
%let tno=14.1.2.4;
%let outno=14-1-2-4;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

proc sort data=db.adct out=reg0 (keep=usubjid fasfl ptclfl ctseq ctstdt ctendt ctrgm);
  by usubjid ctseq;
run;

data reg1;
  set reg0;
  by usubjid ctseq;

  select (ctrgm);
    when ("CHOP or CHOP-like regimens")   order=2;
    when ("Platinum-containing regimens") order=3;
    when ("Other multi-agent regimens")   order=4;
    when ("Pralatrexate")                 order=6;
    when ("Corticosteroids")              order=7;
    when ("Other single-agent regimens")  order=8;
    otherwise;
  end;

  cat=2;
```

```
  output;
  if last.usubjid then do;
   cat=1;
   output;
  end;
  keep usubjid fasfl ptclfl cat ctrgm order;
run;

data reg2;
  set reg1;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=reg2 out=reg nodupkey;
  by cat order ctrgm pop usubjid;
run;

proc freq data=reg noprint;
  tables cat*order*ctrgm*pop / out=freq0 (drop=percent);
  where order ne .;
run;

data shell;
  length pop $6 ctrgm $40;
  do pop="FASFL ","PTCLFL";
  cat=1;
  order=0;ctrgm="The last systemic regimen for PTCL";
  output;
  order=1;ctrgm="  Multi-agent therapy";
  output;
  order=5;ctrgm="  Single agent therapy";
  output;
  cat=2;
  order=0;ctrgm="All systemic regimens for PTCL";
  output;
  order=1;ctrgm="  Multi-agent therapy";
  output;
  order=5;ctrgm="  Single agent therapy";
  output;
  end;
run;

data combo;
  length value $20 ;
  set shell (in=x) freq0 (in=b);
  if b then do;
    ctrgm="    "||strip(ctrgm);
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
  end;
  keep pop cat ctrgm order value;
run;

proc sort data=combo;
  by cat order ctrgm;
run;
```

```
proc transpose data=combo out=trans (drop=_name_);
  by cat order ctrgm;
  var value;
  id pop;
run;

data final;
  set trans;
  array _pop{*} fasfl ptclfl;
  do i=1 to dim(_pop);
    if _pop{i}='' and order in (2 3 4 6 7 8) then _pop{i}="-";
  end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-priorreg.rtf" style=vg_rtf;

title3 "Table &tno: Prior Systemic Regimens for Peripheral T-cell Lymphoma";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  columns cat order ctrgm ('Number of Patients (%)' fasfl ptclfl);

  define cat     / order order=internal noprint;
  define order   / order order=internal noprint;
  define ctrgm   / order "Patient Population"
                       style=[cellwidth=2.75 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl  / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       04.03.2013
/*Program:    t_priorreg.sas
/*Purpose:    Prior Systemic Regimens for Peripheral T-cell Lymphoma
/*Modifications:


/************************************************/

%let filename=t-mh;
%let tno=14.1.2.5;
%let outno=14-1-2-5;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data admh0;
  set db.admh (where=(fasfl="Y"));
  pop="FASFL ";
  cat=1;
  output;
  cat=2;
  if mhongo="Y" then output;
run;

proc sort data=admh0 out=admh1 (keep=pop cat mhcat usubjid) nodupkey;
  by pop cat mhcat usubjid;
run;

proc freq data=admh1 noprint;
  tables pop*mhcat*cat / out=freq0 (drop=percent);
run;

data combo;
  merge freq0 freq0 (where=(xcat=1) rename=(cat=xcat count=sort));
  by pop mhcat;
  value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
```

```
  keep pop mhcat cat value sort;
run;

proc sort data=combo;
  by pop descending sort mhcat;
run;

proc transpose data=combo out=trans (drop=_name_);
  by pop descending sort mhcat;
  var value;
  id cat;
run;

data final;
  set trans;
  array _pop{*} _1 _2;
  do i=1 to dim(_pop);
    if _pop{i}='' then _pop{i}="-";
  end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-mh.rtf" style=vg_rtf;

title3 "Table &tno: General Medical History";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  columns sort mhcat ('Number of Patients (%)' _1 _2);

  define sort    / order descending noprint;
  define mhcat   / order "Patient Population: Full Analysis Set@Site or System with Medical
History (Other than PTCL)"
                       style=[cellwidth=3.0 in asis=on] left style(header)=[just=left asis=on];

  define _1   / display "All History@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define _2  / display "Ongoing at Entry@N=&fasfl" style=[cellwidth=1.5 in] center;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       04.04.2013
/*Program:    t_baselab.sas
/*Purpose:    Creates Table 14.1.2.6: Baseline Laboratory Abnormalities
/*Modifications:

Bob Hull 7/5/2013: Updated denominators to be based on available results, not overall population.
/************************************************/

%let filename=t-baselab;
%let tno=14.1.2.6;
%let outno=14-1-2-6;
%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data lb0;
  length lbcat $25 indic $6;
  set db.adlb (where=(lbblfl="Y"));
  select (lbtest);
    /*Hematology*/
    when ("Hemoglobin")                   do;order=1;lbcat="Hematology";end;/* low*/
    when ("Erythrocytes")                 do;order=2;lbcat="Hematology";end;/* low*/
    when ("Ery. Mean Corpuscular Volume") do;order=3;lbcat="Hematology";lbtest="MCV";end;/* high
& low*/
    when ("Platelet")                     do;order=4;lbcat="Hematology";lbtest="Platelets";end;/*
low*/
    when ("Leukocytes")                   do;order=5;lbcat="Hematology";end;/* low*/
    when ("Neutrophils")                  do;order=6;lbcat="Hematology";end;/* low*/
    when ("Lymphocytes")                  do;order=7;lbcat="Hematology";end;/* low*/
    /*Coagulation*/
    when ("Prothrombin Time")                       do;order=8;lbcat="Coagulation";end;/* high*/
    when ("Prothrombin Intl. Normalized Ratio")    do;order=
9;lbcat="Coagulation";lbtest="INR";end;/* high*/
    when ("Activated Partial Thromboplastin Time") do;order=
10;lbcat="Coagulation";lbtest="APTT";end;/* high*/
```

```
    /*Liver function*/
    when ("Bilirubin")                  do;order=11;lbcat="Liver function";end;/* high*/
    when ("Alkaline Phosphatase")       do;order=12;lbcat="Liver function";end;/*high*/
    when ("Alanine Aminotransferase")   do;order=13;lbcat="Liver function";lbtest="ALT";end;/*
high*/
    when ("Aspartate Aminotransferase") do;order=14;lbcat="Liver function";lbtest="AST";end;/*
high*/
    when ("Albumin")                    do;order=15;lbcat="Liver function";end;/* low*/
    /*Renal function*/
    when ("Creatinine")           do;order=16;lbcat="Renal function";end;/* high*/
    when ("Blood Urea Nitrogen")  do;order=17;lbcat="Renal function";lbtest="BUN";end;/* high*/
    when ("Urate")                do;order=18;lbcat="Renal function";lbtest="Urate (uric
acid)";end;/* high*/
    when ("Sodium")               do;order=19;lbcat="Renal function";end;/* high & low*/
    when ("Potassium")            do;order=20;lbcat="Renal function";end;/* high & low*/
    when ("Chloride")             do;order=21;lbcat="Renal function";end;/* high & low*/
    when ("Magnesium")            do;order=22;lbcat="Renal function";end;/* high & low*/
    /*Metabolic function*/
    when ("Lactate Dehydrogenase") do;order=23;lbcat="Metabolic function";lbtest="LDH";end;/*
high*/
    when ("Phosphate")             do;order=24;lbcat="Metabolic function";end;/* low*/
    when ("Calcium")               do;order=25;lbcat="Metabolic function";end; /*high & low*/
    when ("Glucose")               do;order=26;lbcat="Metabolic function";end; /*high & low*/
    otherwise;
  end;
  if order ne .;
  select (lbcat);
    when ("Hematology")         lbcatn=1;
    when ("Coagulation")        lbcatn=2;
    when ("Liver function")     lbcatn=3;
    when ("Renal function")     lbcatn=4;
    when ("Metabolic function") lbcatn=5;
  end;
  indic="Low";
  if order not in (8 9 10 11 12 13 14 16 17 18 23) then output;
  else do;
    indic="High";
    output;
  end;
  if order in (3 19 20 21 22 25 26) then do;
    indic="High";
    output;
  end;
run;

data lb1;
  length cat $8 desc $100;
  set lb0;
  desc=strip(lbtest)||", "||strip(lowcase(indic));
  /*patients with test*/
  cat="ANY";
  output;
  cat="ABNORM";
  /*abnorm*/
  if lbnrind=indic then do;
    output;
    /*tox grade*/
    cat="";
```

```
    cat="TOX"||strip(put(lbtoxgrn,best.));
    if lbtoxgrn>0 then output;
  end;
run;

proc sort data=lb1;
  by lbcatn lbcat order descending indic;
run;

proc freq data=lb1 noprint;
  by lbcatn lbcat order descending indic;
  tables desc*cat / out=freq0 (drop=percent);
run;

proc sort data=lb1 out=shell0 (keep=lbcatn lbcat) nodupkey;
  by lbcatn lbcat;
run;

data shell;
  set shell0;
  order=0;
run;

data freq1;
  set freq0;
  value=strip(put(count,best.));
run;

proc transpose data=freq1 out=trans (drop=_name_);
  by lbcatn lbcat order descending indic desc;
  var value;
  id cat;
run;

data final;
  set shell (in=a) trans;
  by lbcatn lbcat order;
  if a then desc=lbcat;
  else desc="  "||strip(desc);
  if order ne 0 and abnorm='' then abnorm="0";
  page=1;

  if substr(desc,1,1)='' and abnorm ne '' then abnorm=strip(abnorm)||" ("||strip(put(100*input
(abnorm,best.)/input(any,best.),5.1))||")";
  if substr(desc,1,1)='' and tox1 ne '' then tox1=strip(tox1)||" ("||strip(put(100*input
(tox1,best.)/input(any,best.),5.1))||")";
  if substr(desc,1,1)='' and tox2 ne '' then tox2=strip(tox2)||" ("||strip(put(100*input
(tox2,best.)/input(any,best.),5.1))||")";
  if substr(desc,1,1)='' and tox3 ne '' then tox3=strip(tox3)||" ("||strip(put(100*input
(tox3,best.)/input(any,best.),5.1))||")";
  if substr(desc,1,1)='' and tox4 ne '' then tox4=strip(tox4)||" ("||strip(put(100*input
(tox4,best.)/input(any,best.),5.1))||")";

  array _tx{*} tox1-tox4;
  do i=1 to dim(_tx);
    if order ne 0 and _tx{i}='' then _tx{i}="-";
  end;
```

```
run;



ods listing close;
ods rtf file="&_outpath\t-&outno.-baselab.rtf" style=vg_rtf;

title3 "Table &tno: Baseline Laboratory Abnormalities";
footnote1 j=l "Baseline samples were the last sample on or before the day of first dose of study
treatment.";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns lbcatn lbcat order indic ("Full Analysis Set   N=&fasfl" desc) ("Number of Patients"
("Patients with" any) ("Incidence of" abnorm) ("Worst CTCAE Grade On Treatment" tox1-tox4));

  define lbcatn   / order order=internal noprint;
  define lbcat    / order order=internal noprint;
  define order    / order order=internal noprint;
  define indic    / order order=internal noprint;*descending noprint;
  define desc     / order "Laboratory Test"
                       style=[cellwidth=2.2 in asis=on] left style(header)=[just=left asis=on];

  define any     / display "On-study Test"  style=[cellwidth=.9 in] center;
  define abnorm  / display "Abnormality"  style=[cellwidth=.9 in] center;
  define tox1    / display "Grade 1"  style=[cellwidth=.9 in] center;
  define tox2    / display "Grade 2"  style=[cellwidth=.9 in] center;
  define tox3    / display "Grade 3"  style=[cellwidth=.9 in] center;
  define tox4    / display "Grade 4"  style=[cellwidth=.9 in] center;

  compute before lbcatn;
    line put '';
  endcomp;

run;

ods rtf close;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       04.04.2013
/*Program:    t_basevs.sas
/*Purpose:    Creates Table 14.1.2.7: Pretreatment Vital Signs, Height and Weight
/*Modifications:


/************************************************/

%let filename=t-basevs;
%let tno=14.1.2.7;
%let outno=14-1-2-7;
%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data vs;
  length unit $12 param $60;
  set db.advs (where=(vsblfl="Y"));
  select (vstestcd);
    when ("SYSBP")  do;paramn=1;unit="(mmHg)";end;
    when ("DIABP")  do;paramn=2;unit="(mmHg)";end;
    when ("HR")     do;paramn=3;unit="(beats/min)";end;
    when ("TEMP")   do;paramn=4;unit="(°C)";end;
    when ("HEIGHT") do;paramn=5;unit="(cm)";end;
    when ("WEIGHT") do;paramn=6;unit="(kg)";end;
    otherwise;
  end;
  param=strip(vstest)||" "||strip(unit);
  if paramn ne .;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;
```

```
proc sort;
  by pop paramn param;
run;

proc means data=vs noprint;
  by pop paramn param;
  var vsstresn;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

data combo;
  length value $20 varc $60;
  set stats0 (in=a);
  by pop;
  sort=0;varc=param;value='';
  output;
  sort=1;varc="Number (%)";
  value=strip(put(n,best.))||" ("||put(100*n/symgetn(pop),5.1)||")";
  output;
  sort=2;varc="Mean (SD)";
  value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
  output;
  sort=3;varc="Median";
  value=strip(put(median,8.1));
  output;
  sort=4;varc="Range";
  value=strip(put(min,best.))||" - "||strip(put(max,best.));
  output;
  keep pop paramn param sort varc value;
run;

proc sort data=combo;
  by paramn sort varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by paramn sort varc;
  var value;
  id pop;
run;

data final;
 set trans;
 if sort ne 0 then varc="  "||strip(varc);
 page=ceil(paramn/4);
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-basevs.rtf" style=vg_rtf;

title3 "Table &tno: Pretreatment Vital Signs, Height and Weight";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns paramn sort varc fasfl ptclfl;
```

```
  define paramn   / order order=internal noprint;
  define sort     / order order=internal noprint;
  define varc     / order "Patient Population"
                        style=[cellwidth=1.85 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;
  define ptclfl  / display "&ptclflname*@N=&ptclfl" style=[cellwidth=1.5 in] center;

  compute before paramn;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       05.06.2013
/*Program:    t_cmatc.sas
/*Purpose:    Prior Medications (ATC Classification)
/*Modifications:


/************************************************/
%let tno=14.1.2.8;
%let outno=14-1-2-8;
%let filename=t-pmatc;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data cat;
  length l1 l2 $200;
  set db.adcm (where=(fasfl="Y" and cmstdy<=0));
  l1=substr(cmclascd,1,1)||" - "||strip(cmclas1);
  l2=substr(cmclascd,1,3)||" - "||strip(cmclas2);
  pop="FASFL";
run;

proc sort data=cat out=anyl1 (keep=pop usubjid l1) nodupkey;
  by pop usubjid l1;
run;

proc sort data=cat out=anyl2 (keep=pop usubjid l1 l2) nodupkey;
  by pop usubjid l1 l2;
run;

data combo;
  length desc $200;
  set anyl1 anyl2;
  if l2='' then desc=l1;
```

```
  else desc="  "||strip(l2);
run;

proc freq data=combo noprint;
  tables l1*l2*desc*pop / out=freq0 (drop=percent);
run;

data freq;
  set freq0;
  value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
run;

proc transpose data=freq out=final (drop=_name_);
  by l1 l2 desc;
  var value;
  id pop;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-pmatc.rtf" style=vg_rtf;

title3 "Table &tno: Prior Medications (ATC Classification)";
%footsrce(line=1);

proc report data=final nowindows headskip headline split='@' missing;
  columns l1 l2 desc fasfl;
  define l1      / order order=internal noprint;
  define l2      / order order=internal noprint;
  define desc    / order "ATC Classification, Level 1@  ATC Classification, Level 2"
                       style=[cellwidth=4.6 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Number of Patients (%)@Full Analysis Set@N=&fasfl"  style=[cellwidth=
1.35 in] center;

  compute before l1;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       07.24.2013
/*Program:    t_PLTdemog.sas
/*Purpose:    Creates Demographics Table
/*Modifications:


/************************************************/

%let filename=t-pltdemog;
%let tno=14.1.2.9;
%let outno=14-1-2-9;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

/*BL PLT < 100,000/ul" (Y) and "BL PLT >= 100,000/ul (N)*/

data demog0;
  set db.adsl;
  where fasfl="Y";
  if platfl="" then platfl="N";
  pop=platfl;
run;

proc sort;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data cat;
  length varc $100;
  set demog0;
  select (sex);
    when ("F") do;sexn=2;gender="Female";end;
    when ("M") do;sexn=1;gender="Male  ";end;
    otherwise;
  end;
  select (race);
    when ("White") racen=1;
    when ("Black") racen=2;
    when ("Asian") racen=3;
    when ("Latin") racen=4;
    when ("Other") racen=5;
    otherwise;
  end;
  select (agegrp);
    when ("< 65") agegrpn=1;
```

```
    when (">=65") agegrpn=2;
    otherwise;
  end;
  perfstatn=input(compress(perfstat,"ECOG"),best.)+1;

  /*gender*/
  cat=1;
  varc=gender;
  varn=sexn;
  if gender ne '' then output;

  /*race*/
  cat=2;
  varc=race;
  varn=racen;
  if race ne '' then output;

  /*age*/
  cat=3;
  varc=agegrp;
  varn=agegrpn;
  if agegrp ne '' then output;

  cat=4;
  varc=perfstat;
  varn=perfstatn;
  if perfstat ne '' then output;
run;

proc sort;
  by pop cat;
run;

proc means data=demog0 noprint;
  by pop;
  var age;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
run;

proc format;
  value cat
    1="Gender"
    2="Race"
    3="Age (years)"
    4="Performance status";
run;

data shell;
  length catdesc $30;
  set totfreq (keep=pop);
  do cat=1 to 4;
    catdesc=put(cat,cat.);
    varn=0;
```

```
    output;
    if cat=3 then do;
      varn=3;
      output;
    end;
  end;
run;

data combo;
  length value $20 catdesc $30;
  set shell (in=x) stats0 (in=a) freq0 (in=b);
  by pop;
  if x then output;
  else if a then do;
    cat=3;
    catdesc=put(cat,cat.);
    varn=4;varc="Mean (SD)";
    value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
    output;
    varn=5;varc="Median";
    value=strip(put(median,8.1));
    output;
    varn=6;varc="Range";
    value=strip(put(min,best.))||" - "||strip(put(max,best.));
    output;
  end;
  else do;
    catdesc=put(cat,cat.);
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
    output;
  end;
  keep pop cat catdesc varn varc value;
run;

proc sort data=combo;
  by cat varn catdesc varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc varc;
  var value;
  id pop;
run;

data final;
  set trans;
  if varn>0 then catdesc="   "||strip(varc);
  array _col{*} n y;
  do i=1 to dim (_col);
    if _col{i}='' and cat ne 3 and varn ne 0 then _col{i}=strip(put(0,best.))||" ("||put(0,4.1)
||")";
  end;
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTdemog.rtf" style=vg_rtf;

title3 "Table &tno: Demographics and Other Baseline Characteristics";
```

```
title4 "by Baseline Platelet Group";
title5 "Full Analysis Set";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  columns cat varn catdesc ('Number of Patients (%)' N Y);

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=1.5 in asis=on] left style(header)=[just=left asis=on];

  define n        / display "Platelet >= 100,000/ul@N=&n"     style=[cellwidth=1.2 in] center;
  define y        / display "Platelet < 100,000/ul@N=&y" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       07.27.2013
/*Program:    t_PLTtum_resp_iwg.sas
/*Purpose:    Tumor Response, Investigator IWG Assessment
/*Modifications:
   REH 7/27/13   Modified to run by Platelet subgroup.  Began with t_tum_resp_iwg
   Bob Hull 7/29/2013 Changed CI to show NA if it is not calculated with upper and lower limit.
/************************************************/

%let filename=t-plttum-resp-iwg;
%let tno=14.2.3.10;
%let outno=14-2-3-10;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro resp(group,plat,x);
%global n_1 n_2;
*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&PLAT";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=p2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&PLAT" /* and nrpltfl='Y'*/ and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set p2cnt nobs=last;
  if _n_=last then call symputx("n_&group",put(_n_,3.));
run;

*repeat to get two different sets of the data from different vars.;
%do abc=1 %to 2;
data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &abc=1 %then %do;
    cens=pfscnsr;
    if pfscnsr=0 and rspcd in ("CR" "PR") then event='Y';

    weekresp=rspdy/7;
    followup=dormo;
    dur_resp=dormo;
  %end;
```

```
  %if &abc=2 %then %do;
    cens=adorcnsr;
    if adorcnsr=0 and rspcd in ("CR" "PR") then event='Y';
    weekresp=adordy/7;
    followup=adormo;
    dur_resp=adormo;
  %end;

  if ptclfl="Y"  and platfl="&PLAT" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;

proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max q1=q1 q3=q3 std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  subord=2.5;
  descrip='   Quartiles (1st, 3rd)';
  result=put(q1,4.1)||" - "||put(q3,4.1);
  output;
  descrip='   Range (min, max)';
  result=put(min,4.1)||" - "||put(max,5.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
```

```
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
  *alternate upper limit when KM does not show it due to not enough data. ;
  if last.treat and treat='CPRG' then call symput('altupper',put(dur_resp,5.1));
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;

data dresp2;
set quart_dr nobs=last;
  by stratum;
  retain descrip result;
  length descrip $200 result $15;
  if first.stratum then result='';
  ord=6;
  subord=1.5;
  descrip='      Quartiles (1st, 3rd)';
  treat=strip(treat)||"C";
  if percent=75 then result=strip(put(max(upperlimit,&altupper),5.1));
```

```
  if percent=25 then result=put(estimate,5.1)||' - '||strip(result);
  if last.stratum;
run;

proc print data=quart_dr;
run;

data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median duration of response (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  if upperlimit ne . then result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  else result='NA';*put(lowerlimit,5.1)||" - NC";
  output;
run;

data dresp;
set dresp dresp2;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
```

```
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*********************************************
Best response, overall Response, Number of events section
*********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;

proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc/* bplatc*/ $15;
  subord=2;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=4;
run;


data headrows;
length descrip $200;
  subord=0;
  descrip="Time to response (Investigator)";
  ord=3;
  output;
  descrip="Duration of response (Investigator)";
  ord=4;
  output;
  descrip="   Probability of being in response (%)";
  ord=7;
  output;
run;

data final&abc;
set headrows wstat2 flwstat ev2 dresp2 prob3;
run;
%end;
```

```
data fin&group;
set final1 (in=in1) final2 (in=in2 where=(ord ne 3));
  if in2 then do;
   ord=ord+100;*group to appear second in the table.;
   if ord=104 and subord=0 then descrip=strip(descrip)||' - IWG criteria**';
  end;
  if ord=4 and subord=0 then descrip=strip(descrip)||' - IWG + Death***';

  if ord in (4 5 6 7) then ord=ord+1000;*move to end for latest mock change. ;
run;

proc sort data=fin&group;
  by ord subord descrip;
run;
%mend resp;



%resp(1,)
proc datasets nolist memtype=data lib=work;
  save fin1;
quit;
%resp(2,Y)

data final;
merge fin1 fin2 (rename=bcprgc=bcprgc2);
  by ord subord descrip;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTtum-resp-iwg.rtf" style=vg_rtf;

title3 "Table &tno: Time to and Duration of Response, Investigator Assessment";
title4 "by Baseline Platelet Group";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";
footnote2 j=l "** Time from the first infusion to the date of PD. Otherwise censored at the last
disease assessment";
footnote3 j=l "*** Time from the 1st infusion to the date of PD or death, censored at the last
disease assessment prior to a new therapy.";
footnote4 j=l "Note: NC = Not calculable.";
%footsrce(line=4);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ("Efficacy Analysis Set* with CR/PR" bcprgc bcprgc2);
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "Patient Population"  style=[cellwidth=4 in asis=on] left style(header)=
[just=left];
  define bcprgc / display "Platelet >= 100,000uL@N=&n_1" style=[cellwidth=1.9 in] center;
  define bcprgc2 / display "Platelet < 100,000uL@ N=&n_2" style=[cellwidth=1.9 in] center;

  compute before ord / style=[font_size=5pt];
    line put '';
```

```
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       07.24.2013
/*Program:    t_PLT_dor_irc.sas
/*Purpose:    Patient Listing of Duration of Response, IRC Assessment
/*Modifications: Bob Hull 7/5/2013: Changed XPFSSTAT to XDORSTAT.
   REH 7/24/13   Began with t_dor_irc and modified to run by Platelet subgroup
/************************************************/

%let filename=t-pltdor-irc;
%let tabno=14.2.3.11;
%let outno=14-2-3-11;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc format;
  value $_platfl
    "Y"="Platelet < 100,000/ul"
    other="Platelet >= 100,000/ul";
run;

/*BL PLT < 100,000/ul" (Y) and "BL PLT >= 100,000/ul (N)*/
data dor;
set db.adsl;
subject=compress(subjid,'-');
length treatstat $10;
where xrspdy ne .;
if dsreas ne '' then treatstat='Withdrawn';
else treatstat='Ongoing';

lastdose=trtendt-trtstdt+1;

platdesc=put(platfl,$_platfl.);
run;

proc sort;
  by platfl platdesc subjid;
run;

data final;
  set dor;
  by platfl platdesc subjid;
  page=ceil(_n_/17);
run;

options nobyline;

ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTdor-irc.rtf" style=vg_rtf;


title3 "Table &tabno: Patient Listing of Duration of Response, IRC Assessment";
title4 "by Baseline Platelet Group";

%footsrce(line=1);
```

```
proc report data=final nowindows headskip split='@' missing style(header column)=
[protectspecialchars=off];
  columns platfl platdesc subjid lastdose treatstat xrspcd xrspdy xpfsdy xdordy xdorstat;
  by page;
  define platfl  / order order=internal noprint;
  define platdesc / order order=internal "Baseline Platelet Group" style(column)=[cellwidth=1.5
in] style(header)=[just=left];
  define subjid / order "Patient" style(column)=[cellwidth=.65 in] center;
  define lastdose /  display "Day of@Last Dose" style(column)=[cellwidth=.85 in] center ;
  define treatstat / display "Status of@Treatment" style(column)=[cellwidth=.8 in] left;
  define xrspcd / display "Best Overall@Response" style(column)=[cellwidth=.9 in] center ;
  define xrspdy / display "Day of Onset@of Response" style(column)=[cellwidth=.85 in] center ;

  define xpfsdy / display "Day of Last@Response" style(column)=[cellwidth=0.9 in] center ;
  define xdordy / display "Duration@(Days)" style(column)=[cellwidth=.75 in] center ;
  define xdorstat / display "Status"  style(column)=[cellwidth=.75 in] center ;

  compute before subjid;
    line put '';
  endcomp;

run;


ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       5.16.2013
/*Program:    t_tum_resp1.sas
/*Purpose:    Tumor Response, IRC Assessment
/*Modifications:
   Bob Hull 7/5/2013: Added "Other" to list of reasons for new terms showing up not in list.
Strange patient id in reason not eval ??
/************************************************/

%let filename=t-tum-resp1;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro resp(title,tno1,tno2,outno1,outno2,label,x);


*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";* and nrpltfl='Y';*variable removed, this allows easy return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

*get denominator for all CR/PR patients;
proc sort data=db.adsl out=patcnt2 (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set patcnt2 nobs=last;
  if _n_=last then call symput('n_cprg2',put(_n_,3.));
run;

proc sort data=db.adsl out=p2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y"/* and nrpltfl='Y'*/ and &x.rspcd in ('CR' 'PR');
run;

data _null_;
```

```
set p2cnt nobs=last;
  if _n_=last then call symput('n_plat2',put(_n_,3.));
run;

data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &label=IRC %then %do;
    neval=xreasne;
    cens=xpfscnsr;
    if xpfscnsr=0 and xrspcd in ("CR" "PR") then event='Y';
    if xrspcd in ("CR" "PR") then ovresp='Y';
     else ovresp='Z';*needs to be after Y to get right CI later.;
     if xrspcd = 'CR' then crresp='Y';
     else crresp='Z';
    bestresp=xrsp;
     weekresp=xrspdy/7;
     followup=xdormo;
    dur_resp=xdormo;
     if xrspr1cd ne xrspr2cd then adj='YES';
    if xrspcd in ("CR" "PR") then crpr='YES';
     if xrspr1cd in ("CR" "PR") then r1=1;
     if xrspr2cd in ('CR' 'PR') then r2=1;
     if crpr='YES' and sum(r1,r2)=1 then onlyone='YES';
  %end;

  %if &label=investigator %then %do;
    neval=xreasne;
    cens=pfscnsr;
    if pfscnsr=0 and rspcd in ("CR" "PR") then event='Y';
    if rspcd in ("CR" "PR") then ovresp='Y';
     else ovresp='Z';*needs to be after Y to get right CI later.;
     if rspcd = 'CR' then crresp='Y';
     else crresp='Z';
    bestresp=rsp;
    weekresp=rspdy/7;
     followup=dormo;
    dur_resp=dormo;
  %end;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
     output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
     output;
  end;
  keep usubjid treat bestresp ovresp weekresp followup event dur_resp crresp cens neval adj crpr
onlyone ;
run;

proc sort data=efficacy;
  by treat;
run;
```

```
*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  descrip='   Range (wk)';
  result=put(min,4.1)||" - "||put(max,4.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
```

```
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;


data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median duration of response (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
```

```
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

**********************************************
Best response, overall Response, Number of events section
**********************************************;
proc freq data=efficacy;
  by treat;
  tables neval / out=nevcnt noprint;
  tables bestresp  / out=bestcnt noprint;
  tables ovresp  / out=ovcnt noprint;
  tables crresp  / out=crcnt noprint;
  tables event / out=evcnt noprint;
  tables crpr / out=crprcnt noprint;
  tables adj / out=adjcnt noprint;
  tables onlyone / out=oocnt noprint;
run;

proc sort data=nevcnt;
  by neval;
  where neval ne '';
run;

proc transpose data=nevcnt out=nevcnt2 prefix=b;
  by neval;
  var count;
  id treat;
run;

data nevcnt2;
set nevcnt2;
  length descrip $200 bcprgc bplatc $15;
  if neval=:"C" then subord=1;
  if neval=:"D" then subord=2;
  if neval=:"W" then subord=3;
  if neval=:"L" then subord=4;
  if neval=:"N" then subord=5;
  if subord=. then do;
    put 'NOTE: description is not in list from mock, moved to OTHER ' neval=;
    neval='Other';
    subord=6;
  end;
```

```
  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip="   "||neval;
  ord=2.5;
run;


%macro resprte(data,var,row,sord,s2);
proc freq data=efficacy noprint;
by treat;
  tables &var  / binomial exact ;
   output out=&var.ci binomial exact;
run;

data &var.ci2;
set &var.ci;
  length descrip $200 result $15;
  descrip='     95% confidence interval (%)';
  treat=strip(treat)||"C";
  result=put(xl_bin*100,4.1)||" - "||put(xu_bin*100,4.1);
  ord=2;
  subord=&s2;
run;

proc transpose data=&var.ci2 out=&var.ci3 prefix=b;
  by ord subord descrip;
  var result;
  id treat;
run;

proc sort data=&data;
  by &var;
  where &var='Y';
run;

proc transpose data=&data out=&data.2 prefix=b;
  by &var;
  var count;
  id treat;
run;

data &data.2;
set &data.2;
  length descrip $200 bcprgc bplatc $15;
  subord=&sord;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip="   &row";
  ord=2;
run;

%mend;

%resprte(ovcnt,ovresp,%str(Overall response (CR+PR)),4,5);
```

```
%resprte(crcnt,crresp,%str(Complete response (CR)),2,3);


proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg2*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat2*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=5;
run;

proc sort data=bestcnt;
  by bestresp;
run;

proc transpose data=bestcnt out=best2 prefix=b;
  by bestresp;
  var count;
  id treat;
run;

data best2;
set best2;
  length descrip $200 bcprgc bplatc $15;
  if substr(bestresp,1,2)='CR' then subord=1;
  if substr(bestresp,1,2)='PR' then subord=2;
  if substr(bestresp,1,2)='SD' then subord=3;
  if substr(bestresp,1,2)='PD' then subord=4;
  if substr(bestresp,1,2)='NE' then subord=5;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip='   '||bestresp;
  ord=1;
run;

proc transpose data=adjcnt out=adj2 prefix=b;
  by adj;
  where adj='YES';
  var count;
  id treat;
run;
```

```
data adj2;
set adj2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip='Number of adjudications between Reader 1 and Reader 2';
  ord=2.6;
run;

data _null_;
set crprcnt;
where crpr='YES';
  call symput('CRPR',strip(put(count,3.)));
run;

proc transpose data=oocnt out=oo2 prefix=b;
  by onlyone;
  where onlyone='YES';
  var count;
  id treat;
run;

data oo2;
set oo2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" / &crpr ("||strip(put(bcprg/&crpr*100,5.1))||")";
  bplatc=put(bplat,3.)||" / &crpr ("||strip(put(bplat/&crpr*100,5.1))||")";

  descrip='Adjudicated CRs/PRs where only one reader scored a CR/PR';
  ord=2.7;
run;

data headrows;
length descrip $200;
  ord=1;
  subord=0;
  descrip="Best tumor response (&label)";
  output;
  ord=2;
  descrip="Objective response rate (&label)";
  output;
  ord=2.5;
  descrip=" Reason for not evaluable assessments";
  output;
  descrip="Time to response (&label)";
  ord=3;
  output;
  descrip="Duration of response (&label)";
  ord=4;
  output;
  descrip="   Probability of being in response (%)";
  ord=7;
```

```
  output;
run;

data final;
set headrows best2 ovcnt2 ovrespci3 crcnt2 nevcnt2 crrespci3 wstat2 flwstat ev2 dresp2 prob3 adj2
oo2;
  *investigator assessment does not have reason not evaluable collected.;
  %if &label=investigator %then %do;
    if ord=2.5 then delete;
  %end;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno1.-tum-resp1&x..rtf" style=vg_rtf;

title3 "Table &tno1: Tumor Response, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord<3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "&ptclflname*@N=&n_cprg" style=[cellwidth=1.45 in] center;
 * define bplatc / display "Normal Platelets#@N=&n_plat" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close;
ods listing;

%mend;

%resp(IRC Assessment,14.2.3.1,14.2.3.2,14-2-3-1,14-2-3-2,IRC,x);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.25.2013
/*Program:    t_tum_resp.sas
/*Purpose:    Tumor Response, IRC Assessment and Investigator Assessment
/*Modifications:

   Bob Hull 4/4/2013: Updated formatting for new mock.
   Bob Hull 5/16/2013: Commented out 3.1 and 3.2 as these had larger revisions and will be moved
to their own program.
   Bob Hull 7/5/2013: Removed creation of 14.2.3.5, created in different program now after their
lates mock changes were significantly different.
/************************************************/

%let filename=t-tum-resp;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro resp(title,tno1,tno2,label,x,outno);


*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";* and nrpltfl='Y';*variable removed, this allows easy return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

*get denominator for all CR/PR patients;
proc sort data=db.adsl out=patcnt2 (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set patcnt2 nobs=last;
  if _n_=last then call symput('n_cprg2',put(_n_,3.));
run;

proc sort data=db.adsl out=p2cnt (keep=usubjid) nodupkey;
  by usubjid;
```

```
  where ptclfl="Y"/* and nrpltfl='Y'*/ and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set p2cnt nobs=last;
  if _n_=last then call symput('n_plat2',put(_n_,3.));
run;

data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &label=IRC %then %do;
    neval=xreasne;
    cens=xpfscnsr;
    if xpfscnsr=0 and xrspcd in ("CR" "PR") then event='Y';
    if xrspcd in ("CR" "PR") then ovresp='Y';
     else ovresp='Z';*needs to be after Y to get right CI later.;
     if xrspcd = 'CR' then crresp='Y';
     else crresp='Z';
    bestresp=xrsp;
     weekresp=xrspdy/7;
     followup=xdormo;
    dur_resp=xdormo;
  %end;

  %if &label=investigator %then %do;
    neval=xreasne;
    cens=pfscnsr;
    if pfscnsr=0 and rspcd in ("CR" "PR") then event='Y';
    if rspcd in ("CR" "PR") then ovresp='Y';
     else ovresp='Z';*needs to be after Y to get right CI later.;
     if rspcd = 'CR' then crresp='Y';
     else crresp='Z';
    bestresp=rsp;
    weekresp=rspdy/7;
     followup=dormo;
    dur_resp=dormo;
  %end;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
    output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat bestresp ovresp weekresp followup event dur_resp crresp cens neval;
run;


proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
```

```
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  descrip='   Range (wk)';
  result=put(min,4.1)||" - "||put(max,4.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
```

```
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;


data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median duration of response (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;
```

```
data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*********************************************
Best response, overall Response, Number of events section
*********************************************;
proc freq data=efficacy;
  by treat;
  tables neval / out=nevcnt noprint;
  tables bestresp  / out=bestcnt noprint;
  tables ovresp  / out=ovcnt noprint;
  tables crresp  / out=crcnt noprint;
  tables event / out=evcnt noprint;
run;

proc sort data=nevcnt;
  by neval;
  where neval ne '';
run;

proc transpose data=nevcnt out=nevcnt2 prefix=b;
  by neval;
  var count;
  id treat;
run;

data nevcnt2;
set nevcnt2;
  length descrip $200 bcprgc bplatc $15;
  if neval=:"C" then subord=1;
  if neval=:"D" then subord=2;
  if neval=:"W" then subord=3;
  if neval=:"L" then subord=4;
  if neval=:"N" then subord=5;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip="   "||neval;
  ord=2.5;
run;

%macro resprte(data,var,row,sord,s2);
```

```
proc freq data=efficacy noprint;
by treat;
  tables &var  / binomial exact ;
   output out=&var.ci binomial exact;
run;

data &var.ci2;
set &var.ci;
  length descrip $200 result $15;
  descrip='     95% confidence interval (%)';
  treat=strip(treat)||"C";
  result=put(xl_bin*100,4.1)||" - "||put(xu_bin*100,4.1);
  ord=2;
  subord=&s2;
run;

proc transpose data=&var.ci2 out=&var.ci3 prefix=b;
  by ord subord descrip;
  var result;
  id treat;
run;

proc sort data=&data;
  by &var;
  where &var='Y';
run;

proc transpose data=&data out=&data.2 prefix=b;
  by &var;
  var count;
  id treat;
run;

data &data.2;
set &data.2;
  length descrip $200 bcprgc bplatc $15;
  subord=&sord;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip="   &row";
  ord=2;
run;

%mend;

%resprte(ovcnt,ovresp,%str(Overall response (CR+PR)),4,5);
%resprte(crcnt,crresp,%str(Complete response (CR)),2,3);


proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
```

```
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg2*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat2*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=5;
run;

proc sort data=bestcnt;
  by bestresp;
run;

proc transpose data=bestcnt out=best2 prefix=b;
  by bestresp;
  var count;
  id treat;
run;

data best2;
set best2;
  length descrip $200 bcprgc bplatc $15;
  if substr(bestresp,1,2)='CR' then subord=1;
  if substr(bestresp,1,2)='PR' then subord=2;
  if substr(bestresp,1,2)='SD' then subord=3;
  if substr(bestresp,1,2)='PD' then subord=4;
  if substr(bestresp,1,2)='NE' then subord=5;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip='   '||bestresp;
  ord=1;
run;

data headrows;
length descrip $200;
  ord=1;
  subord=0;
  descrip="Best tumor response (&label)";
  output;
  ord=2;
  descrip="Objective response rate (&label)";
  output;
  ord=2.5;
  descrip=" Reason for not evaluable assessments";
  output;
  descrip="Time to response (&label)";
  ord=3;
  output;
  descrip="Duration of response (&label)";
```

```
  ord=4;
  output;
  descrip="   Probability of being in response (%)";
  ord=7;
  output;
run;

data final;
set headrows best2 ovcnt2 ovrespci3 crcnt2 nevcnt2 crrespci3 wstat2 flwstat ev2 dresp2 prob3;
  *investigator assessment does not have reason not evaluable collected.;
  %if &label=investigator %then %do;
    if ord=2.5 then delete;
  %end;
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-tum-resp&x..rtf" style=vg_rtf;

title3 "Table &tno1: Tumor Response, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord<=2.5;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "&ptclflname*@N=&n_cprg" style=[cellwidth=1.45 in] center;
 * define bplatc / display "Normal Platelets#@N=&n_plat" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

/* Original output was broken into two tables. Program was set up to do one output, so it was
decided to leave it as
   one program and split the output up to go to separate files. */

/*  Table was replaced with a very different version. Created in a separate program now... Bob
Hull 7/5/2013
ods listing close;
ods rtf file="&_outpath\t&tno2._tum_resp&x.dur &exedate..rtf" style=vg_rtf;

title3 "Table &tno2: Time to and Duration of Response, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";
```

```
%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "&ptclflname* with CR/PR@N=&n_cprg2" style=[cellwidth=1.9 in] center;
 * define bplatc / display "Normal Platelets#@N=&n_plat" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;*/

%mend;

*%resp(IRC Assessment,14.2.3.1,14.2.3.2,IRC,x);
%resp(Investigator Assessment,14.2.3.4,Removed,investigator,,14-2-3-4);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       5.16.2013
/*Program:    t_tum_resp2.sas
/*Purpose:    Tumor Response, IRC Assessment
/*Modifications:

Bob Hull 7/5/2013: Fixed max put statement to solve w.d in log.

/************************************************/

%let filename=t-tum-resp2;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro resp(title,tno2,outno2,label,x);


*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";* and nrpltfl='Y';*variable removed, this allows easy return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

*get denominator for all CR/PR patients;
proc sort data=db.adsl out=patcnt2 (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set patcnt2 nobs=last;
  if _n_=last then call symput('n_cprg2',put(_n_,3.));
run;

proc sort data=db.adsl out=p2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y"/* and nrpltfl='Y'*/ and &x.rspcd in ('CR' 'PR');
run;
```

```
data _null_;
set p2cnt nobs=last;
  if _n_=last then call symput('n_plat2',put(_n_,3.));
run;

*repeat to get two different sets of the data from different vars.;
%do abc=1 %to 2;
data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &abc=1 %then %do;
    cens=xpfscnsr;
    if xpfscnsr=0 and xrspcd in ("CR" "PR") then event='Y';

     weekresp=xrspdy/7;
     followup=xdormo;
    dur_resp=xdormo;
  %end;

  %if &abc=2 %then %do;
    cens=idorcnsr;
    if idorcnsr=0 and xrspcd in ("CR" "PR") then event='Y';
    weekresp=idordy/7;
    followup=idormo;
    dur_resp=idormo;
  %end;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
     output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
     output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;

proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max q1=q1 q3=q3 std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
```

```
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  subord=2.5;
  descrip='   Quartiles (1st, 3rd)';
  result=put(q1,4.1)||" - "||put(q3,4.1);
  output;
  descrip='   Range (min, max)';
  result=put(min,4.1)||" - "||put(max,5.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
  *alternate upper limit when KM does not show it due to not enough data. ;
  if last.treat and treat='CPRG' then call symput('altupper',put(dur_resp,5.1));
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
```

```
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;

data dresp2;
set quart_dr nobs=last;
  by stratum;
  retain descrip result;
  length descrip $200 result $15;
  if first.stratum then result='';
  ord=6;
  subord=1.5;
  descrip='      Quartiles (1st, 3rd)';
  treat=strip(treat)||"C";
  if percent=75 then result=strip(put(max(upperlimit,&altupper),5.1));
  if percent=25 then result=put(estimate,5.1)||' - '||strip(result);
  if last.stratum;
run;

data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median duration of response (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(max(upperlimit,&altupper),5.1));
  output;
run;

data dresp;
set dresp dresp2;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
```

```
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

***********************************************
Best response, overall Response, Number of events section
***********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;

proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=2;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg2*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat2*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=4;
```

```
run;


data headrows;
length descrip $200;
  subord=0;
  descrip="Time to response (&label)";
  ord=3;
  output;
  descrip="Duration of response (&label)";
  ord=4;
  output;
  descrip="   Probability of being in response (%)";
  ord=7;
  output;
run;

data final&abc;
set headrows wstat2 flwstat ev2 dresp2 prob3;
run;
%end;

data final;
set final1 (in=in1) final2 (in=in2 where=(ord ne 3));
  if in2 then do;
   ord=ord+100;*group to appear second in the table.;
   if ord=104 and subord=0 then descrip=strip(descrip)||' - IWG criteria**';
  end;
  if ord=4 and subord=0 then descrip=strip(descrip)||' - IWG + Death***';

  if ord in (4 5 6 7) then ord=ord+1000;*move to end for latest mock change. ;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno2.-tum-resp2&x.dur.rtf" style=vg_rtf;

title3 "Table &tno2: Time to and Duration of Response, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";
footnote2 j=l "** Time from the first infusion to the date of PD. Otherwise censored at the last
disease assessment";
footnote3 j=l "*** Time from the 1st infusion to the date of PD or death, censored at the last
disease assessment prior to a new therapy.";


%footsrce(line=4);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "Efficacy Analysis Set* with CR/PR@N=&n_cprg2" style=[cellwidth=1.9 in]
```

```
center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%resp(IRC Assessment,14.2.3.2,14-2-3-2,IRC,x);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.25.2013
/*Program:    t_orr_bybase.sas
/*Purpose:    Overall Response Rate, IRC Assessment, by Pre-treatment Characteristics
/*Modifications:
      Bob Hull 4/4/2013: Updated formatting for new mock.
      Rob Howard 5/8/13: Added: Race (White/Non-White),
                                Prior pralatrexate therapy
                                Response to last systemic therapy
/************************************************/

%let filename=t-orr-bybase;
%let tabno=14.2.3.3;
%let outno=14-2-3-3;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


%macro orr(title);


%macro denom(where,mcvar);
%global &mcvar;
*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" &where;
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput("&mcvar",put(_n_,3.));
run;
%mend;
%denom( ,n_cprg);
%denom( ,n_plat);
/*%str(and nrpltfl='Y')*/

data efficacy;
  length treat $5 race $10 prpdx $3;
set db.adsl;

  if sex='F' then sexn=2;
  if sex='M' then sexn=1;

  /*race - white, non-white - REH added 5/6/13*/
  if race="White" then racen=1;
  else do;
    race="Non-white";
    racen=2;
  end;

  if agegrp='< 65' then agegrpn=1;
  if agegrp='>=65' then agegrpn=2;
```

```
  if perfstat='ECOG 0' then perfstatn=1;
  else if perfstat='ECOG 1' then perfstatn=2;
  else if perfstat='ECOG 2' then perfstatn=3;
  else if perfstat='ECOG 3' then perfstatn=4;*blanking out, not on mock.;

  if bminvolv='No' then bminvolvn=1;
  else if bminvolv='Yes' then bminvolvn=2;
  else if bminvolv='Indeterminate' then bminvolvn=3;
  else if bminvolv='Not assessed' then bminvolvn=4;


  if cprgdiag='Anaplastic large cell lymphoma, ALK-negative' then cprgdiagn=3;
  else if cprgdiag='Angioimmunoblastic T-cell lymphoma' then cprgdiagn=2;
  else if cprgdiag='Peripheral T-cell lymphoma, NOS ' then cprgdiagn=1;
  else if cprgdiag='Anaplastic large cell lymphoma, ALK-positive' then cprgdiagn=4;
  else if cprgdiag='Enteropathy-associated T-cell lymphoma' then cprgdiagn=5;
  else if cprgdiag='Extranodal NK/T-cell lymphoma, nasal type' then cprgdiagn=6;
  else if cprgdiag='Hepatosplenic T-cell lymphoma' then cprgdiagn=7;
  else cprgdiag='';

  if .<platbl<100 then do;platelet='< 100,000 ul';plateletn=2;end;
  else if platbl>=100 then do;platelet='>=100,000 ul';plateletn=1;end;

  /*Response to last systemic therapy*/
  select (prbstrsp);
    when ("Complete Response")   prbstrspn=1;
    when ("Partial Response")    prbstrspn=2;
    when ("Stable Disease")      prbstrspn=3;
    when ("Progressive Disease") prbstrspn=4;
    when ("Not Evaluable")       prbstrspn=5;
    when ("","Unknown")          prbstrspn=6;
  end;

  /*prior pralatrexate therapy*/
  select (prpdx);
    when ("Y") do;prpdxn=1;prpdx="Yes";end;
    otherwise  do;prpdxn=2;prpdx="No";end;
  end;

  if xrspcd in ("CR" "PR") then ovresp='Y';
     else ovresp='Z';*needs to be after Y to get right CI later.;

  *rather than fix the whole program this is put in, but not true. The column is not included in
the proc report later on.
   If the PLAT group is added in at another time, then take out the commented out part and put it
in the proc report. It
   does make the code more flexible. Due to change from client mock removing column;
  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
    output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
    output;
  end;

  keep usubjid treat ovresp sexn sex race racen agegrp agegrpn perfstat perfstatn bminvolv
bminvolvn cprgdiag cprgdiagn platelet plateletn prbstrsp prbstrspn prpdx prpdxn;
```

```
run;

proc sort data=efficacy;
  by treat;
run;

*********************************************
Best response, overall Response, Number of events section
*********************************************;
proc freq data=efficacy;
  by treat;
  tables ovresp  / out=ovcnt noprint;
run;

proc freq data=efficacy noprint;
by treat;
  tables ovresp  / binomial exact ;
   output out=ovci binomial exact;
run;

data ovci2;
set ovci;
  length descrip $200 result $30;
  descrip='All Patients';
  treat=strip(treat)||"C";
  result=put(xl_bin*100,4.1)||" - "||put(xu_bin*100,4.1);
  ord=1;
  subord=1;
run;

proc transpose data=ovci2 out=ovci3 prefix=b;
  by ord subord descrip;
  var result;
  id treat;
run;

proc sort data=ovcnt;
  by ovresp;
  where ovresp='Y';
run;

proc transpose data=ovcnt out=ov2 prefix=b;
  by ovresp;
  var count;
  id treat;
run;


data ov2;
set ov2;
  length descrip $200 _bcprgc _bplatc $15;
  _bcprgc=strip(put(bcprg/&n_cprg*100,5.1));
  _bplatc=strip(put(bplat/&n_plat*100,5.1));
  descrip='All Patients';
run;

data ov3;
merge ov2 ovci3;
```

```
  length cprg1 plat1 bcpci bplci $15;
  by descrip;
  bcpci=bcprgc;
  bplci=bplatc;
  bcprgc=strip(bcprg)||' ('||strip(_bcprgc)||')';
  bplatc=strip(bplat)||' ('||strip(_bplatc)||')';
  cprg1="&n_cprg";
  plat1="&n_plat";
run;

*macro for subset categories. ;
%macro grp(order,var);

proc sort data=efficacy out=eff2;
  by treat &var;
  where &var ne '';
run;

*freq of responders within each category.;
proc freq data=eff2;
  by treat &var &var.n;
  tables ovresp  / out=&var.cnt noprint;
run;

*freq for simple percent of patients in each category;
proc freq data=eff2;
  by treat;
  tables &var  / out=&var.pcnt noprint;
run;

proc sort data=&var.pcnt;
  by &var;
run;

proc transpose data=&var.pcnt out=&var.pcnt2 prefix=j;
  by &var;
  id treat;
  var count;
run;

data &var.pcnt3;
set &var.pcnt2;
  length descrip $200 plat1 cprg1 $15;
  descrip='   '||&var;
  plat1=put(jplat,3.)||" ("||strip(put(jplat/&n_plat*100,5.1))||")";
  cprg1=put(jcprg,3.)||" ("||strip(put(jcprg/&n_cprg*100,5.1))||")";;
run;

proc freq data=eff2 noprint;
by treat &var &var.n;
   tables ovresp  / binomial exact ;
   output out=&var.ci binomial exact;
run;

data &var.ci2;
set &var.ci;
  length descrip $200 result $30;
  descrip='   '||&var;
```

```
  treat=strip(treat)||"C";
  if pl_bin ne . then result=put(xl_bin*100,4.1)||" - "||put(xu_bin*100,4.1);
  else  result="0.0 - "||put((xu_bin-xl_bin)*100,4.1);
  ord=&order;
  subord=&var.n;
run;

proc sort data=&var.ci2;
  by ord subord descrip;
run;

proc transpose data=&var.ci2 out=&var.ci3 prefix=b;
  by ord subord descrip;
  var result;
  id treat;
run;

proc sort data=&var.cnt;
  by &var;
  where ovresp='Y';
run;

proc transpose data=&var.cnt out=&var.2 prefix=b;
  by &var;
  var count;
  id treat;
run;


data &var.2;
set &var.2;
  length descrip $200 ;
  descrip='   '||&var;
run;

proc sort data=&var.2;
  by descrip;
run;

proc sort data=&var.ci3;
  by descrip;
run;

proc sort data=&var.pcnt3;
  by descrip;
run;

data &var.3;
merge &var.2 &var.ci3 &var.pcnt3;
  by descrip;
  length bcpci bplci $15;
  bcpci=bcprgc;
  bplci=bplatc;
  if bcprg ne . then bcprgc=put(bcprg,2.)||' ('||strip(put(bcprg/jcprg*100,5.1))||")";
  else bcprgc='0 (0)';
  bplatc=put(bplat,2.)||' ('||strip(put(bplat/jplat*100,5.1))||")";
run;
```

```
%mend;

%grp(2,sex);
%grp(2.5,race);
%grp(3,agegrp);
%grp(4,perfstat);
%grp(5,cprgdiag);
%grp(6,bminvolv);
%grp(6.25,prpdx);
%grp(6.5,prbstrsp);
%grp(7,platelet);


data headrows;
length descrip $200;
  ord=2;
  subord=0;
  descrip="Gender";
  output;
  ord=2.5;
  descrip="Race";
  output;
  descrip="Age at Entry";
  ord=3;
  output;
  descrip="Performance Status";
  ord=4;
  output;
  descrip='CPRG lymphoma diagnosis';
  ord=5;
  output;
  descrip="Bone Marrow Involvement";
  ord=6;
  output;
  ord=6.25;
  descrip="Prior pralatrexate therapy";
  output;
  ord=6.5;
  descrip="Response to the most recent systemic therapy";
  output;
  descrip='Baseline platelet count';
  ord=7;
  output;
run;

data final;
set headrows ov3 sex3 race3 agegrp3 perfstat3 cprgdiag3 bminvolv3 platelet3 prbstrsp3 prpdx3;
  if descrip='   M' then descrip='   Male';
  if descrip='   F' then descrip='   Female';

  if descrip='   < 65' then descrip='   < 65 Years';
  if descrip='   >=65' then descrip='   >=65 Years';
  page=1;
  if ord>6 then page=2;
run;

proc sort;
```

```
  by page ord subord;
run;

options nobyline;

ods listing close;
ods rtf file="&_outpath\t-&outno.-orr-bybase.rtf" style=vg_rtf;

title3 "Table &tabno: Overall Response Rate, IRC Assessment, by Pre-treatment Characteristics";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG))";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
  by page;
columns  ord subord  descrip   cprg1 bcprgc bcpci ;

  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "&ptclflname*"  style=[cellwidth=4 in asis=on] left style(header)=
[just=left] ;
  define cprg1 / display "n (%)" style=[cellwidth=.85 in] center;
  define bcprgc / display "CR+PR (%)" style=[cellwidth=1.45 in] center;
  define bcpci / display "95% Confidence Interval" style=[cellwidth=1.45 in] center;

  /*define plat1 / display "n (%)" style=[cellwidth=.85 in] center;
  define bplatc / display "ORR (95% C.I.)" style=[cellwidth=1.45 in] center;*/

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%orr(IRC Assessment);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       5.16.2013
/*Program:    t_tum_resp_iwg.sas
/*Purpose:    Tumor Response, Investigator IWG Assessment
/*Modifications:


/************************************************/

%let filename=t-tum-resp-iwg;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro resp(title,tno2,outno,label,x);


*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";* and nrpltfl='Y';*variable removed, this allows easy return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

*get denominator for all CR/PR patients;
proc sort data=db.adsl out=patcnt2 (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set patcnt2 nobs=last;
  if _n_=last then call symput('n_cprg2',put(_n_,3.));
run;

proc sort data=db.adsl out=p2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y"/* and nrpltfl='Y'*/ and &x.rspcd in ('CR' 'PR');
run;

data _null_;
```

```
set p2cnt nobs=last;
  if _n_=last then call symput('n_plat2',put(_n_,3.));
run;

*repeat to get two different sets of the data from different vars.;
%do abc=1 %to 2;
data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &abc=1 %then %do;
    cens=pfscnsr;
    if pfscnsr=0 and rspcd in ("CR" "PR") then event='Y';

     weekresp=rspdy/7;
     followup=dormo;
    dur_resp=dormo;
  %end;

  %if &abc=2 %then %do;
    cens=adorcnsr;
    if adorcnsr=0 and rspcd in ("CR" "PR") then event='Y';
    weekresp=adordy/7;
    followup=adormo;
    dur_resp=adormo;
  %end;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
     output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
     output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;

proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max q1=q1 q3=q3 std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
```

```
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  subord=2.5;
  descrip='   Quartiles (1st, 3rd)';
  result=put(q1,4.1)||" - "||put(q3,4.1);
  output;
  descrip='   Range (min, max)';
  result=put(min,4.1)||" - "||put(max,5.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
  *alternate upper limit when KM does not show it due to not enough data. ;
  if last.treat and treat='CPRG' then call symput('altupper',put(dur_resp,5.1));
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
```

```
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;

data dresp2;
set quart_dr nobs=last;
  by stratum;
  retain descrip result;
  length descrip $200 result $15;
  if first.stratum then result='';
  ord=6;
  subord=1.5;
  descrip='      Quartiles (1st, 3rd)';
  treat=strip(treat)||"C";
  if percent=75 then result=strip(put(max(upperlimit,&altupper),5.1));
  if percent=25 then result=put(estimate,5.1)||' - '||strip(result);
  if last.stratum;
run;

data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median duration of response (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

data dresp;
set dresp dresp2;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;
```

```
ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

***********************************************
Best response, overall Response, Number of events section
***********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;

proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=2;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg2*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat2*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=4;
run;
```

```
data headrows;
length descrip $200;
  subord=0;
  descrip="Time to response (&label)";
  ord=3;
  output;
  descrip="Duration of response (&label)";
  ord=4;
  output;
  descrip="   Probability of being in response (%)";
  ord=7;
  output;
run;

data final&abc;
set headrows wstat2 flwstat ev2 dresp2 prob3;
run;
%end;

data final;
set final1 (in=in1) final2 (in=in2 where=(ord ne 3));
  if in2 then do;
   ord=ord+100;*group to appear second in the table.;
   if ord=104 and subord=0 then descrip=strip(descrip)||' - IWG criteria**';
  end;
  if ord=4 and subord=0 then descrip=strip(descrip)||' - IWG + Death***';

  if ord in (4 5 6 7) then ord=ord+1000;*move to end for latest mock change. ;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno.-tum-resp-iwg.rtf" style=vg_rtf;

title3 "Table &tno2: Time to and Duration of Response, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";
footnote2 j=l "** Time from the first infusion to the date of PD. Otherwise censored at the last
disease assessment";
footnote3 j=l "*** Time from the 1st infusion to the date of PD or death, censored at the last
disease assessment prior to a new therapy.";


%footsrce(line=4);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "Efficacy Analysis Set* with CR/PR@N=&n_cprg2" style=[cellwidth=1.9 in]
center;
```

```
  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%resp(Investigator Assessment,14.2.3.5,14-2-3-5,Investigator);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       3/5/2013
/*Program:    t_concordance.sas
/*Purpose:    Concordance of IRC and Investigator Best Overall Response
/*Modifications:
     Bob Hull 4/4/2013: Updated formatting for new mock.
/************************************************/

%let filename=t-concordance;
%let tabno=14.2.3.6;
%let outno=14-2-3-6;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

%macro orr(title);


%macro denom(where,mcvar);
%global &mcvar;
*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" &where;
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput("&mcvar",put(_n_,3.));
run;
%mend;
%denom( ,n_cprg);
%denom( ,n_plat);
/*str(and nrpltfl='Y')*/
data efficacy;
set db.adsl;
  length treat $12;

  *concatenate on the INV response code for easy transpose later.;
  if ptclfl="Y"  then do;*and nrpltfl='Y';*this disables this portion, but lets program work
without more mods.;
    treat='PLAT'||rspcd;
    output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG'||rspcd;
    output;
  end;

  keep usubjid treat xrspcd xrsp rsp rspcd;
run;

data efficacy;
set efficacy;
  output;
  xrspcd='AP';
```

```
  xrsp='All Response Categories';
  output;
run;

proc sort data=efficacy;
  by xrspcd xrsp;
run;

proc freq data=efficacy;
  by xrspcd xrsp;
  tables treat  / out=concord noprint;
run;

proc transpose data=concord out=c2 prefix=b;
by xrspcd xrsp;
  var count;
  id treat;
run;

data final;
set c2;
  length c1-c5 p1-p5 $4;

  array ina (10) bcprgCR bcprgPR bcprgSD bcprgPD bcprgNE bplatCR bplatPR bplatSD bplatPD bplatNE;
  array out (10) c1-c5 p1-p5;

  descrip=xrsp;
  space='' ;

  if xrspcd='AP' then ord=0;
  if xrspcd='CR' then ord=1;
  if xrspcd='PR' then ord=2;
  if xrspcd='SD' then ord=3;
  if xrspcd='PD' then ord=4;
  if xrspcd='NE' then ord=5;

  do b=1 to 10;
    if ina(b) ne . then out(b)=put(ina(b),3.);
    else out(b)='-';
  end;
  n=sum(bcprgCR, bcprgPR, bcprgSD, bcprgPD, bcprgNE );
run;



ods listing close;
ods rtf file="&_outpath\t-&outno.-concordance.rtf" style=vg_rtf;

title3 "Table &tabno: Concordance of IRC and Investigator Best Overall Response";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord ('Patient Population@ @ ' (' ' descrip)) n ("Number of
```

```
patients@&ptclflname*@N=&n_cprg@ @" ('Investigator Best Tumor Response' c1 c2 c3 c4 c5))/* space
                    ("Normal Platelets#@N=&n_plat" ('Investigator Best Tumor Response' p1 p2 p3
p4 p5))*/;

  define ord / order order=internal noprint;
  define descrip / order "IRC Best Tumor Response"  style=[cellwidth=1.75 in asis=on] left ;
  define n  / display "n" style(column)=[cellwidth=.65 in] center;
  define c1 / display "CR" style(column)=[cellwidth=.65 in] center;
  define c2 / display "PR" style(column)=[cellwidth=.65 in] center;
  define c3 / display "SD" style(column)=[cellwidth=.65 in] center;
  define c4 / display "PD" style(column)=[cellwidth=.65 in] center;
  define c5 / display "NE" style(column)=[cellwidth=.65 in] center;/*
  define space / display '' style=[cellwidth=.35 in] center;
  define p1 / display "CR" style=[cellwidth=.65 in] center;
  define p2 / display "PR" style=[cellwidth=.65 in] center;
  define p3 / display "SD" style=[cellwidth=.65 in] center;
  define p4 / display "PD" style=[cellwidth=.65 in] center;
  define p5 / display "NE" style=[cellwidth=.65 in] center;*/

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%orr(IRC Assessment);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       04.15.2013
/*Program:    t_DOR_IRC.sas
/*Purpose:    Patient Listing of Duration of Response, IRC Assessment
/*Modifications: Bob Hull 7/5/2013: Changed XPFSSTAT to XDORSTAT.
/************************************************/

%let filename=t-dor-irc;
%let tabno=14.2.3.7;
%let outno=14-2-3-7;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data dor;
set db.adsl;
subject=compress(subjid,'-');
length treatstat $10;
where xrspdy ne .;
if dsreas ne '' then treatstat='Withdrawn';
else treatstat='Ongoing';

lastdose=trtendt-trtstdt+1;
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-DOR_IRC.rtf" style=vg_rtf;


title3 "Table &tabno: Patient Listing of Duration of Response, IRC Assessment";

%footsrce(line=1);

proc report data=dor nowindows headskip split='@' missing style(header column)=
[protectspecialchars=off];
columns subjid lastdose treatstat xrspcd xrspdy xpfsdy xdordy xdorstat;

  define subjid / order "Patient" style(column)=[cellwidth=.65 in] center;
  define lastdose /  display "Day of@Last Dose" style(column)=[cellwidth=.85 in] center ;
  define treatstat / display "Status of@Treatment" style(column)=[cellwidth=.8 in] left;
  define xrspcd / display "Best Overall@Response" style(column)=[cellwidth=.9 in] center ;
  define xrspdy / display "Day of Onset@of Response" style(column)=[cellwidth=.85 in] center ;

  define xpfsdy / display "Day of Last@Response" style(column)=[cellwidth=0.9 in] center ;
  define xdordy / display "Duration@(Days)" style(column)=[cellwidth=.75 in] center ;
  define xdorstat / display "Status"  style(column)=[cellwidth=.75 in] center ;

  compute before subjid;
    line put '';
  endcomp;

run;


ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       05.21.2013
/*Program:    t_durtx.sas
/*Purpose:    Duration of Treatment by IRC Response Cohort
/*Modifications:
/************************************************/

%let filename=t-durtx;
%let tno=14.2.3.8;
%let outno=14-2-3-8;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc format;
  invalue xrsp
    "CR - Complete Response"=1
    "PR - Partial Response"=2
    "SD - Stable Disease"=3
    "PD - Progressive Disease"=4
    "NE - Not Evaluable"=5;
run;

proc freq data=db.adsl noprint;
  tables ptclfl / out=totfreq;
  where ptclfl="Y";
run;

data _null_;
  set totfreq;
  call symputx("ptclfl",count);
run;

data durtx0;
  length desc $50;
  set db.adsl (where=(ptclfl="Y"));
  xrspn=input(xrsp,xrsp.);
  order=1;
  desc="Number of treatment cycles";
  var=cyclenum;
  output;
  order=2;
  desc="Duration of treatment (wk)";
  var=cycledur;
  output;
  keep usubjid xrspn xrsp order desc var;
run;

proc sort data=durtx0;
  by order desc xrspn xrsp;
run;

proc means data=durtx0 noprint;
  by order desc xrspn xrsp;
  output out=stats (drop=_type_ _freq_) n=nx median=medianx min=minx max=maxx;
run;
```

```
data durtx;
  length xdesc $50;
  set stats;
  by order desc xrspn xrsp;
  n=strip(put(nx,best.));
  median=strip(put(medianx,8.1));
  min=strip(put(minx,8.0));
  max=strip(put(maxx,8.0));
  xdesc="  "||strip(xrsp);
  output;
  if first.order then do;
    xdesc=desc;
    xrspn=0;
    n='';median='';min='';max='';
    output;
  end;
  keep order xdesc xrspn median min max n;
run;

proc sort;
  by order xrspn xdesc;
run;


options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-durtx.rtf" style=vg_rtf;

title3 "Table &tno: Duration of Treatment by IRC Response Cohort";
footnote1 j=l "&ptclflfoot";
%footsrce(line=2);

proc report data=durtx nowindows headskip split='@' missing;
  columns order xrspn xdesc n ("&ptclflname*@N=&ptclfl" median min max);
  define order    / order order=internal noprint;
  define xrspn    / order order=internal noprint;
  define xdesc    / display "IRC Best Tumor Response" style=[cellwidth=1.85 in asis=on] left
style(header)=[just=left asis=on];

  define n        / display "N" style=[cellwidth=.75 in] center;
  define median   / display "Median" style=[cellwidth=.75 in] center;
  define min      / display "Minimum" style=[cellwidth=.75 in] center;
  define max      / display "Maximum" style=[cellwidth=.75 in] center;

  compute before order;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/*************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       7.24.2013
/*Program:    t_PLTtum_resp.sas
/*Purpose:    Tumor Response, IRC Assessment by Platelet Count
/*Modifications:
   REH 7/24/13   Updated table number and program name
/*************************************************/

%let filename=t-plttum-resp;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro resp(title,tno2,outno,label,x,group,plat);

%global n_1 n_2;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&PLAT";* and nrpltfl='Y';*variable removed, this allows easy
return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

*get denominator for all CR/PR patients;
proc sort data=db.adsl out=patcnt2 (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&PLAT" and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set patcnt2 nobs=last;
  if _n_=last then call symputx("n_&group",put(_n_,3.));
run;

%put 'abcd ' &&n_&group ;

proc sort data=db.adsl out=p2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y"  and platfl="&PLAT"/* and nrpltfl='Y'*/ and &x.rspcd in ('CR' 'PR');
run;

data _null_;
set p2cnt nobs=last;
  if _n_=last then call symput('n_plat2',put(_n_,3.));
run;

*repeat to get two different sets of the data from different vars.;
%do abc=1 %to 2;
data efficacy;
set db.adsl;
```

```
  where platfl="&PLAT";
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &abc=1 %then %do;
    cens=xpfscnsr;
    if xpfscnsr=0 and xrspcd in ("CR" "PR") then event='Y';

     weekresp=xrspdy/7;
     followup=xdormo;
    dur_resp=xdormo;
  %end;

  %if &abc=2 %then %do;
    cens=idorcnsr;
    if idorcnsr=0 and xrspcd in ("CR" "PR") then event='Y';
    weekresp=idordy/7;
    followup=idormo;
    dur_resp=idormo;
  %end;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
     output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
     output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;

proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max q1=q1 q3=q3 std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  subord=2.5;
```

```
  descrip='   Quartiles (1st, 3rd)';
  result=put(q1,4.1)||" - "||put(q3,4.1);
  output;
  descrip='   Range (min, max)';
  result=put(min,4.1)||" - "||put(max,5.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
  *alternate upper limit when KM does not show it due to not enough data. ;
  if last.treat and treat='CPRG' then call symput('altupper',put(dur_resp,5.1));
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
```

```
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;

data dresp2;
set quart_dr nobs=last;
  by stratum;
  retain descrip result;
  length descrip $200 result $15;
  if first.stratum then result='';
  ord=6;
  subord=1.5;
  descrip='      Quartiles (1st, 3rd)';
  treat=strip(treat)||"C";
  if upperlimit=. then upperlimit=&altupper;
  if percent=75 then result=strip(put(upperlimit,5.1));
  if percent=25 then result=put(estimate,5.1)||' - '||strip(result);
  if last.stratum;
run;

data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median duration of response (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  if upperlimit=. then upperlimit=&altupper;
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

data dresp;
set dresp dresp2;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
```

```
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

***********************************************
Best response, overall Response, Number of events section
***********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;

proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=2;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&&n_&group*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat2*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=4;
run;


data headrows;
length descrip $200;
  subord=0;
```

```
  descrip="Time to response (&label)";
  ord=3;
  output;
  descrip="Duration of response (&label)";
  ord=4;
  output;
  descrip="   Probability of being in response (%)";
  ord=7;
  output;
run;

data final&abc;
set headrows wstat2 flwstat ev2 dresp2 prob3;
run;
%end;

data fin&group;
set final1 (in=in1) final2 (in=in2 where=(ord ne 3));
  if in2 then do;
   ord=ord+100;*group to appear second in the table.;
   if ord=104 and subord=0 then descrip=strip(descrip)||' - IWG criteria**';
  end;
  if ord=4 and subord=0 then descrip=strip(descrip)||' - IWG + Death***';

  if ord in (4 5 6 7) then ord=ord+1000;*move to end for latest mock change. ;
run;

proc sort data=fin&group;
  by ord subord descrip;
run;

*output is run once second group is run and data is put together for a single table.;
%if &group=2 %then %do;

data final;
merge fin1 fin2 (rename=bcprgc=bcprgc2);
  by ord subord descrip;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTtum-resp.rtf" style=vg_rtf;

title3 "Table &tno2: Time to and Duration of Response, &title";
title4 "by Baseline Platelet Group";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";
footnote2 j=l "** Time from the first infusion to the date of PD. Otherwise censored at the last
disease assessment";
footnote3 j=l "*** Time from the 1st infusion to the date of PD or death, censored at the last
disease assessment prior to a new therapy.";


%footsrce(line=4);


proc report data=final nowindows headskip split='@' missing;
```

```
columns  ord subord  descrip ('Efficacy Analysis Set* with CR/PR (%)' bcprgc bcprgc2);
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "Patient Population@   "  style=[cellwidth=4 in asis=on] left  style
(header)=[just=left];
  define bcprgc / display "Platelet >= 1OO,OOOuL@N=&n_1" style=[cellwidth=1.9 in] center;
  define bcprgc2 / display "Platelet < 1OO,OOOuL@ N=&n_2" style=[cellwidth=1.9 in] center;
  compute before ord / style=[font_size=6pt];
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%end;

%mend;

%resp(IRC Assessment,14.2.3.9,14-2-3-9,IRC,x,1,);
%resp(IRC Assessment,14.2.3.9,14-2-3-9,IRC,x,2,Y);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       04.02.2013
/*Program:    t_TTP.sas
/*Purpose:    Time to Progression, IRC Assessment
/*Modifications:  REH 7/24/2013 Updated to include 25% and 75% quartiles


/************************************************/

%let filename=t-ttp;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro ttp(title,tno1,outno,label,x);

*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &label=IRC %then %do;
    cens=xttpcnsr;
    if xpfscnsr=0 and xprgdt ne . then event='Y';
    followup=xttpmo;
    dur_resp=xttpmo;
  %end;

  if ptclfl="Y" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat followup event dur_resp cens ;
run;


*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;
```

```
data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;

/*Time to progression + confidence interval */
data dresp;
set quart_dr;
  length descrip $200 result $15;
  if percent=25 then do;
    ord=6.1;
    subord=1;
    descrip='   25% quartile time to progression (mo)';
    treat=strip(treat)||"C";
    result=put(estimate,5.1);
    output;
    subord=2;
    descrip='      95% confidence interval';
    result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
    output;
  end;
  if percent=50 then do;
    ord=6.2;
    subord=1;
    descrip='   Median time to progression (mo)';
    treat=strip(treat)||"C";
    result=put(estimate,5.1);
    output;
    subord=2;
```

```
    descrip='      95% confidence interval';
    result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
    output;
  end;
  if percent=75 then do;
    ord=6.3;
    subord=1;
    descrip='   75% quartile time to progression (mo)';
    treat=strip(treat)||"C";
    result=put(estimate,5.1);
    output;
    subord=2;
    descrip='      95% confidence interval';
    result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
    output;
  end;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*********************************************
Number of events section
*********************************************;
```

```
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;


proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=5;
run;

data headrows;
length descrip $200;
  subord=0;
  descrip="Time to progression (&label)";
  ord=4;
  output;
  descrip="   Probability of being progression free (%)";
  ord=7;
  output;
run;

data final;
set headrows ev2 prob3 flwstat dresp2;
run;

proc sort;
  by ord subord descrip;
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-ttp&x.dur.rtf" style=vg_rtf;

title3 "Table &tno1: Time to Progression, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);
```

```
proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "Efficacy Analysis Set*@N=&n_cprg" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%ttp(IRC Assessment,14.2.4.1,14-2-4-1,IRC,x);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_pfs.sas
/*Purpose:    Progression Free Survival, IRC Assessment and Investigator Assessment
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Bob Hull 5.16.2013: Changed table number for second macro call to 4.4;
/************************************************/


%let filename=t-pfs;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

options mprint;

%macro resp(title,tno1,outno,label,x);


*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";* and nrpltfl='Y';*variable removed, this allows easy return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &label=IRC %then %do;
    cens=xpfscnsr;
    if xpfscnsr=0 then event='Y';
    weekresp=xrspdy/7;
    followup=xpfsmo;
    dur_resp=xpfsmo;
  %end;

  %if &label=investigator %then %do;
```

```
    cens=pfscnsr;
    if pfscnsr=0 then event='Y';
    weekresp=rspdy/7;
     followup=pfsmo;
    dur_resp=pfsmo;
  %end;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
    output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;


proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  descrip='   Range (wk)';
  result=put(min,4.1)||" - "||put(max,4.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
```

```
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;


data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median progression-free survival time (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
```

```
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

**********************************************
Number of events section
**********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;



proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
```

```
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=5;
run;

data headrows;
length descrip $200;
  subord=0;
  descrip="Progression-free survival (&label)";
  ord=4;
  output;
  descrip="   Probability of progression-free survival (%)";
  ord=7;
  output;
run;

data final;
set headrows wstat2 flwstat dresp2 prob3 ev2;
  *investigator assessment does not have reason not evaluable collected.;
  if ord<=3 then delete;
run;


footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";


/* Original output was broken into two tables. Program was set up to do one output, so it was
decided to leave it as
   one program and split the output up to go to separate files. */
ods listing close;
ods rtf file="&_outpath\t-&outno.-pfs&x..rtf" style=vg_rtf;

title3 "Table &tno1: Progression-free Survival, &title";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
```

```
in asis=on] left ;
  define bcprgc / display "&ptclflname*@N=&n_cprg" style=[cellwidth=1.45 in] center;
 * define bplatc / display "Normal Platelets#@N=&n_plat" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%resp(IRC Assessment,14.2.4.2,14-2-4-2,IRC,x);
%resp(Investigator Assessment,14.2.4.4,14-2-4-4,investigator,);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       05.16.2013
/*Program:    t_TTP_inv.sas
/*Purpose:    Time to Progression, Investigator Assessment
/*Modifications:


/************************************************/

%let filename=t-ttp-inv;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro ttp(title,tno1,outno,label,x);

*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;


data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;

    cens=ttpcnsr;
    if pfscnsr=0 and prgdt ne . then event='Y';
    followup=ttpmo;
    dur_resp=ttpmo;


  if ptclfl="Y" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat followup event dur_resp cens ;
run;


*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;
```

```
data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;

/*Time to progression + confidence interval */
data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median time to progression (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
```

```
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

***********************************************
Number of events section
***********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;


proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
```

```
  descrip='   Number of events (%)';
  ord=5;
run;

data headrows;
length descrip $200;
  subord=0;
  descrip="Time to progression (&label)";
  ord=4;
  output;
  descrip="   Probability of being progression free (%)";
  ord=7;
  output;
run;

data final;
set headrows ev2 prob3 flwstat dresp2;
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-ttp-inv.rtf" style=vg_rtf;

title3 "Table &tno1: Time to Progression, Investigator Assessment";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  where ord>=3;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "Efficacy Analysis Set*@N=&n_cprg" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%ttp(Investigator Assessment,14.2.4.3,14-2-4-3,Investigator,);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_survival.sas
/*Purpose:    Survival, IRC Assessment and Investigator Assessment
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Bob Hull 5/16/2013: Updated table number for Take 9.2
Bob Hull 7/5/2013: Fixed format w.d in log.
/************************************************/


%let filename=t-survival;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro surv(tno1,outno);


*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y";* and nrpltfl='Y';*variable removed, this allows easy return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;


data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
    cens=survcnsr;
    if survcnsr=0 then event='Y';
    weekresp=survdy/7;
    followup=survmo;
    dur_resp=survmo;

  if ptclfl="Y" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
```

```
    output;
  end;
  if ptclfl="Y" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;


proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  descrip='   Range (wk)';
  result=put(min,4.1)||" - "||put(max,5.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
```

```
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;


data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median overall survival time (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;
```

```
proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

***********************************************
Number of events section
***********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;



proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;
```

```
  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip='   Number of deaths (%)';
  ord=5;
run;

data headrows;
length descrip $200;
  subord=0;
  descrip="Overall survival";
  ord=4;
  output;
  descrip="   Probability of overall survival (%)";
  ord=7;
  output;
run;

data final;
set headrows wstat2 flwstat dresp2 prob3 ev2;
  *investigator assessment does not have reason not evaluable collected.;
  if ord<=3 then delete;
run;


footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";


/* Original output was broken into two tables. Program was set up to do one output, so it was
decided to leave it as
   one program and split the output up to go to separate files. */
ods listing close;
ods rtf file="&_outpath\t-&outno.-survival.rtf" style=vg_rtf;

title3 "Table &tno1: Overall Survival";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Number of patients (%)' bcprgc );
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define bcprgc / display "&ptclflname*@N=&n_cprg" style=[cellwidth=1.45 in] center;
 * define bplatc / display "Normal Platelets#@N=&n_plat" style=[cellwidth=1.45 in] center;

  compute before ord;
    line put '';
  endcomp;

run;
```

```
ods rtf close ;
ods listing;

%mend;

%surv(14.2.4.5,14-2-4-5);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_pfs.sas
/*Purpose:    Progression Free Survival, IRC Assessment and Investigator Assessment
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Bob Hull 5.16.2013: Changed table number for second macro call to 4.4;
Rob Howard 7/24/2013: Began with t_pfs and modified to run by
/************************************************/


%let filename=t-pltpfs;
%let tno=14.2.4.7;
%let outno=14-2-4-7;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

data demog0;
  set db.adsl;
  where ptclfl="Y";
  if platfl="" then platfl="N";
  pop=platfl;
run;

proc sort;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

%macro dobyplat(platfl,group,label=IRC);

*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&platfl";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=pop2cnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&platfl";* and nrpltfl='Y';*variable removed, this allows easy
```

```
return if necessary.;
run;

data _null_;
set pop2cnt nobs=last;
  if _n_=last then call symput('n_plat',put(_n_,3.));
run;

data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
  %if &label=IRC %then %do;
    cens=xpfscnsr;
    if xpfscnsr=0 then event='Y';
    weekresp=xrspdy/7;
    followup=xpfsmo;
    dur_resp=xpfsmo;
  %end;

  %if &label=investigator %then %do;
    cens=pfscnsr;
    if pfscnsr=0 then event='Y';
    weekresp=rspdy/7;
    followup=pfsmo;
    dur_resp=pfsmo;
  %end;

  if ptclfl="Y" and platfl="&platfl" /*and nrpltfl='Y'*/ then do;
    treat='PLAT';
    output;
  end;
  if ptclfl="Y" and platfl="&platfl" then do;
    treat='CPRG';
    output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;


proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
```

```
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  descrip='   Range (wk)';
  result=put(min,4.1)||" - "||put(max,4.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;

data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
```

```
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;


data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median progression-free survival time (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;
```

```
proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*********************************************
Number of events section
*********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;



proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc bplatc $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
  bplatc=put(bplat,3.)||" ("||strip(put(bplat/&n_plat*100,5.1))||")";

  descrip='   Number of events (%)';
  ord=5;
run;

data headrows;
length descrip $200;
  subord=0;
  descrip="Progression-free survival (&label)";
  ord=4;
  output;
  descrip="   Probability of progression-free survival (%)";
  ord=7;
  output;
run;

data final&group;
set headrows wstat2 flwstat dresp2 prob3 ev2;
  *investigator assessment does not have reason not evaluable collected.;
  if ord<=3 then delete;
  keep ord subord descrip bcprgc;
run;

proc sort;
```

```
  by ord subord descrip;
run;

%mend dobyplat;

%dobyplat(,1)
%dobyplat(Y,2)


data final;
  merge final1 (rename=(bcprgc=platflN)) final2 (rename=(bcprgc=platflY));
  by ord subord descrip;
run;



footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";


/* Original output was broken into two tables. Program was set up to do one output, so it was
decided to leave it as
   one program and split the output up to go to separate files. */
ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTpfsx.rtf" style=vg_rtf;

title3 "Table &tno: Progression-free Survival, IRC Assessment";
title4 "by Baseline Platelet Group";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);


proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Efficacy Analysis Set* (%)'  platflN platflY);
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                          Patient Population@   "  style=[cellwidth=4
in asis=on] left ;
  define platflN / display "Platelet >= 100,000uL@N=&n" style=[cellwidth=1.9 in] center;
  define platflY / display "Platelet < 100,000uL@ N=&y" style=[cellwidth=1.9 in] center;

  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_survival.sas
/*Purpose:    Survival, IRC Assessment and Investigator Assessment
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Bob Hull 5/16/2013: Updated table number for Take 9.2
Bob Hull 7/5/2013: Fixed format w.d in log.
/************************************************/


%let filename=t-pltsurvival;
%let tno=14.2.4.8;
%let outno=14-2-4-8;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";
options mprint;

%macro surv(group,plat);


%global n_1 n_2;
*get total number of patients for both populations in headers;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&PLAT";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('n_cprg',put(_n_,3.));
run;

proc sort data=db.adsl out=patcnt2 (keep=usubjid) nodupkey;
  by usubjid;
  where ptclfl="Y" and platfl="&PLAT";
run;

data _null_;
set patcnt2 nobs=last;
  if _n_=last then call symputx("n_&group",put(_n_,3.));
run;

data efficacy;
set db.adsl;
  length treat $5;

  *vars for each table are set to standard name here based on table being used. ;
    cens=survcnsr;
    if survcnsr=0 then event='Y';
    weekresp=survdy/7;
    followup=survmo;
    dur_resp=survmo;
```

```
    if ptclfl="Y" and platfl="&PLAT" then do;
    treat='CPRG';
     output;
  end;
  keep usubjid treat weekresp followup event dur_resp cens ;
run;


proc sort data=efficacy;
  by treat;
run;

*stats for time to response in weeks;
proc means data=efficacy noprint;
  by treat;
  var weekresp;
  output out=weekstat n=n mean=mean median=median min=min max=max std=std;
run;

data wstat;
set weekstat;
  length descrip $200 result $15;
  treat=strip(treat)||"C";*allows transpose to give the character version of name since var is
char.;
  ord=3;
  subord=1;
  descrip='   Mean (SD)';
  result=put(mean,4.1)||" ("||strip(put(std,5.2))||")";
  output;
  subord=2;
  descrip='   Median (wk)';
  result=put(median,4.1);
  output;
  descrip='   Range (wk)';
  result=put(min,4.1)||" - "||put(max,5.1);
  subord=3;
  output;
run;

proc sort data=wstat;
  by descrip ord subord;
  where subord ne 1;*remove mean since it is not in mock.;
run;

proc transpose data=wstat out=wstat2 prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

*get KM median duration of response;
ods output quartiles=quart_dr;
proc lifetest data=efficacy outs=probresp;
  strata treat;
time dur_resp*cens(1);
run;
ods output close;
```

```
data probr2;
set probresp;
  by treat;
  retain _6mo _12mo _24mo;
  if first.treat then do;
    _6mo=.;
    _12mo=.;
    _24mo=.;
  end;
  if _censor_=0 and dur_resp<6 then _6mo=survival*100;
  if _censor_=0 and dur_resp<12 then _12mo=survival*100;
  if _censor_=0 and dur_resp<24 then _24mo=survival*100;
  if last.treat;
run;

data prob3;
set probr2;
  length descrip $200 bcprgc $15;
  where treat='CPRG';
  ord=7;
  subord=1;
  descrip='      At 6 months';
  bcprgc=put(_6mo,5.1);
  output;
  subord=2;
  descrip='      At 1 year';
  bcprgc=put(_12mo,5.1);
  output;
  subord=3;
  descrip='      At 2 years';
  bcprgc=put(_24mo,5.1);
  output;
run;


data dresp;
set quart_dr;
  length descrip $200 result $15;
  where percent=50;
  ord=6;
  subord=1;
  descrip='   Median overall survival time (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  output;

  subord=2;
  descrip='      95% confidence interval';
  result=put(lowerlimit,5.1)||" - "||strip(put(upperlimit,5.1));
  output;
run;

proc sort data=dresp;
  by descrip ord subord;
run;

proc transpose data=dresp out=dresp2 prefix=b;
  by descrip ord subord;
```

```
  var result;
  id treat;
run;

ods trace on ;
ods output quartiles=_quartiles;

proc lifetest data=efficacy ;
  strata treat;
time followup*cens(0);
run;
ods output close;
ods trace off;

data flw;
set _quartiles;
  where percent=50;
  length descrip $200 result $15;
  descrip='   Median follow-up (mo)';
  treat=strip(treat)||"C";
  result=put(estimate,5.1);
  ord=4;
  subord=1;
run;

proc transpose data=flw out=flwstat prefix=b;
  by descrip ord subord;
  var result;
  id treat;
run;

***********************************************
Number of events section
***********************************************;
proc freq data=efficacy;
  by treat;
  tables event / out=evcnt noprint;
run;



proc sort data=evcnt;
  by event;
  where event='Y';
run;

proc transpose data=evcnt out=ev2 prefix=b;
  by event;
  var count;
  id treat;
run;

data ev2;
set ev2;
  length descrip $200 bcprgc /*bplatc*/ $15;
  subord=1;

  bcprgc=put(bcprg,3.)||" ("||strip(put(bcprg/&n_cprg*100,5.1))||")";
```

```
  descrip='   Number of deaths (%)';
  ord=5;
run;

data headrows;
length descrip $200;
  subord=0;
  descrip="Overall survival";
  ord=4;
  output;
  descrip="   Probability of overall survival (%)";
  ord=7;
  output;
run;

data final&group;
set headrows wstat2 flwstat dresp2 prob3 ev2;
  *investigator assessment does not have reason not evaluable collected.;
  if ord<=3 then delete;
  keep ord subord descrip bcprgc;
run;

proc sort;
  by ord subord descrip;
run;


%mend surv;



%surv(1,)
proc datasets nolist memtype=data lib=work;
  save final1;
quit;
%surv(2,Y)

data final;
merge final1 final2 (rename=bcprgc=bcprgc2);
  by ord subord descrip;
run;


/* Original output was broken into two tables. Program was set up to do one output, so it was
decided to leave it as
   one program and split the output up to go to separate files. */
ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTsurvival.rtf" style=vg_rtf;

title3 "Table &tno: Overall Survival";
title4 "by Baseline Platelet Group";

footnote1 j=l "* Patients with confirmed diagnosis of PTCL by the Central Pathology Review Group
(CPRG)";

%footsrce(line=2);
```

```
proc report data=final nowindows headskip split='@' missing;
columns  ord subord  descrip ('Efficacy Analysis Set* (%)' bcprgc bcprgc2);
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "Patient Population@   "  style=[cellwidth=4 in asis=on] left style
(header)=[just=left];
  define bcprgc / display "Platelet >= 100,000uL@N=&n_1" style=[cellwidth=1.9 in] center;
  define bcprgc2 / display "Platelet < 100,000uL@ N=&n_2" style=[cellwidth=1.9 in] center;
  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       03.05.2013
/*Program:    t_demog.sas
/*Purpose:    Creates
/*Modifications:


/************************************************/

%let filename=t-exp;
%let tno=14.3.5.1;
%let outno=14-3-5-1;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

proc format;
  value cat
    1="Total duration of treatment (wk)"
    2="Number of treatment cycles administered"
    3="Number of belinostat doses administered"
    4="Total cumulative dose of belinostat (g/m2)"
    5="Relative dose intensity (%)"
    6="Patients with dose reduction of 25% (%)"
    7="Patients with cycle delay of 7+ days (%)"
    8="Total number of treatment cycles per patient (%)";
run;

/*data cat;
  length varc $100;
  set demog0;
  cat=6;
  if EXDOSDEC=1 then do;
    varn=1;
    varc="Only 1 dose reduction";
```

```
    output;
  end;
  else if EXDOSDEC=2 then do;
    varn=2;
    varc="2 dose reductions";
    output;
  end;
  cat=7;
  if EXDOSDEL=1 then do;
    varn=1;
    varc="Only 1 dose delay";
    output;
  end;
  else if EXDOSDEL>=2 then do;
    varn=2;
    varc="2 or more dose delays";
    output;
  end;
  cat=8;
  if CYCLENUM ne . then do;
    varn=CYCLENUM;
    varc=strip(put(varn,best.))||" cycles";
    if varn=1 then varc="1 cycle";
    output;
  end;
run;

proc sort;
  by pop cat;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
run;
*/

data cont;
  set demog0;
  cat=1;varn=cycledur;output;
  cat=2;varn=cyclenum;output;
  cat=3;varn=exdosnum;output;
  cat=4;varn=exdoscum/1000;output;
  cat=5;varn=exdosint;output;
run;

proc sort;
  by pop cat;
run;

proc means data=cont noprint;
  by pop cat;
  var varn;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

data shell;
  length catdesc $75;
```

```
  set totfreq (keep=pop);
  do cat=1 to 5;*8;
    catdesc=put(cat,cat.);
    varn=0;
    output;
  end;
run;

data combo;
  length value $20 varc $100;;
  set shell (in=x) stats0 (in=a)/* freq0 (in=b)*/;
  by pop cat;
  if x then output;
  else if a then do;
    varn=1;varc="N";
    value=strip(put(n,best.));
    output;
    varn=2;varc="Mean (SD)";
    if cat ne 5 then value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
    else value=strip(put(mean,8.2))||" ("||strip(put(std,8.3))||")";
    output;
    varn=3;varc="Median";
    if cat ne 5 then value=strip(put(median,8.1));
    else value=strip(put(median,8.2));
    output;
    varn=4;varc="Range";
    if cat=4 then value=strip(put(min,8.0))||" - "||strip(put(max,8.0));
    else value=strip(put(min,best.))||" - "||strip(put(max,best.));
    output;
  end;
  /*else do;
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
    output;
  end;*/
  keep pop cat catdesc varn varc value;
run;

proc sort data=combo;
  by cat varn catdesc varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc varc;
  var value;
  id pop;
run;

data final;
  set trans;
  if varn>0 then catdesc="   "||strip(varc);
  page=ceil(cat/5);
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-exp.rtf" style=vg_rtf;

title3 "Table &tno: Extent of Exposure to Belinostat";
```

```
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns cat varn catdesc fasfl;

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=2.5 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       04.03.2013
/*Program:    t_trtadj.sas
/*Purpose:    Creates
/*Modifications:


/************************************************/

%let filename=t-trtadj;
%let tno=14.3.5.2;
%let outno=14-3-5-2;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  /*pop="PTCLFL";
  if ptclfl="Y" then output;*/
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

proc format;
  value cat
    1="Cause of the first dose reduction"
    2="Cause of the second dose reduction"
    3="Cause of the first infusion interruption"
    4="Cause of the first missed dose within a cycle"
    5="Cause of the first dose delay of 3+ days within a cycle"
    6="Cause of the first cycle delay of 7+ days";
run;

data cat;
  length varc $100;
  set demog0;
  cat=1;
  if exreducn>=1 then do;
    varn=0;
    varc="Patients with one dose reduction of 25% to 750 mg/m2";
    output;
    varn=1;
```

```
    varc=exdosdec;
    output;
  end;
  cat=2;
  if exreducn=2 then do;
    varn=0;
    varc="Patients with two dose reductions of 25% each to 560 mg/m2";
    output;
    varn=1;
    varc=exdosdec;
    output;
  end;
  cat=3;
  if exinfint ne '' then do;
    varn=0;
    varc="Patients with infusion interruption";
    output;
    varn=1;
    varc=exinfint;
    output;
  end;
  cat=4;
  if exdosmis ne '' then do;
    varn=0;
    varc="Patients with a missed dose within a cycle";
    output;
    varn=1;
    varc=exdosmis;
    output;
  end;
  cat=5;

  if exdosdel ne '' then do;
    varn=0;
    varc="Patients with dose delay of 3+ days within a cycle";
    output;
    varn=1;
    varc=exdosdel;
    output;
  end;
  cat=6;
  if excycdel ne '' then do;
    varn=0;
    varc="Patients with cycle delay of 7+ days";
    output;
    varn=1;
    varc=excycdel;
    output;
  end;
run;

proc sort;
  by pop cat;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
```

```
run;

data shell;
  length varc $100;
  set totfreq (keep=pop);
  do cat=1 to 6;
    varc=put(cat,cat.);
    varn=0.5;
    output;
  end;
run;

data combo;
  length value $20 varc $100;;
  set shell (in=x) freq0 (in=b);
  by pop cat;
  if b then value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
  sort=count;
  if varc="Unknown" then sort=0;
  keep pop cat varn varc value sort;
run;

proc sort data=combo;
  by cat varn descending sort varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn descending sort varc;
  var value;
  id pop;
run;

data final;
  set trans;
  if varn=0.5 then varc="  "||strip(varc);
  else if varn>=1 then varc="    "||strip(varc);
  select (cat);
    when (1,2,3) page=1;
    when (4,5)   page=2;
    otherwise    page=3;
  end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-trtadj.rtf" style=vg_rtf;

title3 "Table &tno: Treatment Adjustments and Modifications";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns cat varn sort varc fasfl;

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define sort    / order descending noprint;
  define varc    / order "Patient Population"
```

```
                      style=[cellwidth=3.25 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       04.04.2013
/*Program:    t_subther.sas
/*Purpose:    Creates Table 14.3.5.3: Subsequent Therapies for Peripheral T-cell Lymphoma
/*Modifications:


/************************************************/

%let filename=t-subther;
%let tno=14.3.5.3;
%let outno=14-3-5-3;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  /*pop="PTCLFL";
  if ptclfl="Y" then output;*/
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data cat0;
  length desc $100;
  set db.adst (where=(fasfl="Y"));
  pop="FASFL ";
  if stcat="Radiation Therapy" then do;
    cat=1;order=1;
    desc=stcat;
    output;
  end;
  if stcat="Stem Cell Transplant" then do;
    cat=2;order=1;
    desc=stcat;
    output;
  end;
  if stcat="Systemic Therapy" then do;
    cat=3;order=1;
    desc="Drug Therapy";
    output;
    order=2;
```

```
    desc="  "||strip(stdecod);
    output;
  end;
  keep pop cat order desc usubjid;
run;

proc sort data=cat0 out=cat nodupkey;
  by pop cat order desc usubjid;
run;

proc freq data=cat noprint;
  tables pop*cat*order*desc / out=freq0;
run;

data freq;
  length value $20 ;
  set freq0;
  value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
  sort=count;
  keep pop cat order desc value sort;
run;

proc sort data=freq;
  by cat order descending sort desc;
run;

proc transpose data=freq out=final (drop=_name_);
  by cat order descending sort desc;
  var value;
  id pop;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-subther.rtf" style=vg_rtf;

title3 "Table &tno: Subsequent Therapies for Peripheral T-cell Lymphoma";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  columns cat order sort desc fasfl;

  define cat     / order order=internal noprint;
  define order   / order order=internal noprint;
  define sort    / order descending noprint;
  define desc    / order "Patient Population"
                       style=[cellwidth=3.25 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Full Analysis Set@N=&fasfl"     style=[cellwidth=1.2 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       03.11.2013
/*Program:    t_cmatc.sas
/*Purpose:    Concomitant Medications (ATC Classification)
/*Modifications:


/************************************************/
%let tno=14.3.5.4;
%let outno=14-3-5-4;
%let filename=t-cmatc;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl;
  pop="FASFL ";
  if fasfl="Y" then output;
  pop="PTCLFL";
  if ptclfl="Y" then output;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

data cat;
  length l1 l2 $200;
  set db.adcm (where=(fasfl="Y"));
  l1=substr(cmclascd,1,1)||" - "||strip(cmclas1);
  l2=substr(cmclascd,1,3)||" - "||strip(cmclas2);
  pop="FASFL";
run;

proc sort data=cat out=anyl1 (keep=pop usubjid l1) nodupkey;
  by pop usubjid l1;
run;

proc sort data=cat out=anyl2 (keep=pop usubjid l1 l2) nodupkey;
  by pop usubjid l1 l2;
run;

data combo;
  length desc $200;
  set anyl1 anyl2;
  if l2='' then desc=l1;
```

```
  else desc="  "||strip(l2);
run;

proc freq data=combo noprint;
  tables l1*l2*desc*pop / out=freq0 (drop=percent);
run;

data freq;
  set freq0;
  value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
run;

proc transpose data=freq out=final (drop=_name_);
  by l1 l2 desc;
  var value;
  id pop;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-cmatc.rtf" style=vg_rtf;

title3 "Table &tno: Concomitant Medications (ATC Classification)";
%footsrce(line=1);

proc report data=final nowindows headskip headline split='@' missing;
  columns l1 l2 desc fasfl;
  define l1      / order order=internal noprint;
  define l2      / order order=internal noprint;
  define desc    / order "ATC Classification, Level 1@  ATC Classification, Level 2"
                       style=[cellwidth=4.6 in asis=on] left style(header)=[just=left asis=on];

  define fasfl   / display "Number of Patients (%)@Full Analysis Set@N=&fasfl"  style=[cellwidth=
1.35 in] center;

  compute before l1;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       07.27.2013
/*Program:    t_PLTtrtadj.sas
/*Purpose:    Creates
/*Modifications:
   REH 7/27/13   Began with t_trtadj and modified to run by Platelet subgroup
/************************************************/

%let filename=t-plttrtadj;
%let tno=14.3.5.5;
%let outno=14-3-5-5;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc format;
  value $_platfl
    "Y"="Platelet < 100,000/ul"
    other="Platelet >= 100,000/ul";
run;

data demog0;
  set db.adsl (where=(fasfl="Y"));
  if platfl="" then platfl="N";
  platdesc=put(platfl,$_platfl.);
  pop=platfl;
  output;
  pop="Z";
  output;
  /*pop="PTCLFL";
  if ptclfl="Y" then output;*/
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

proc format;
  value cat
    1="Cause of the first dose reduction"
    2="Cause of the second dose reduction"
    3="Cause of the first infusion interruption"
    4="Cause of the first missed dose within a cycle"
    5="Cause of the first dose delay of 3+ days within a cycle"
    6="Cause of the first cycle delay of 7+ days";
run;
```

```
data cat;
  length varc $100;
  set demog0;
  cat=1;
  if exreducn>=1 then do;
    varn=0;
    varc="Patients with one dose reduction of 25% to 750 mg/m2";
    output;
    varn=1;
    varc=exdosdec;
    output;
  end;
  cat=2;
  if exreducn=2 then do;
    varn=0;
    varc="Patients with two dose reductions of 25% each to 560 mg/m2";
    output;
    varn=1;
    varc=exdosdec;
    output;
  end;
  cat=3;
  if exinfint ne '' then do;
    varn=0;
    varc="Patients with infusion interruption";
    output;
    varn=1;
    varc=exinfint;
    output;
  end;
  cat=4;
  if exdosmis ne '' then do;
    varn=0;
    varc="Patients with a missed dose within a cycle";
    output;
    varn=1;
    varc=exdosmis;
    output;
  end;
  cat=5;

  if exdosdel ne '' then do;
    varn=0;
    varc="Patients with dose delay of 3+ days within a cycle";
    output;
    varn=1;
    varc=exdosdel;
    output;
  end;
  cat=6;
  if excycdel ne '' then do;
    varn=0;
    varc="Patients with cycle delay of 7+ days";
    output;
    varn=1;
    varc=excycdel;
    output;
  end;
```

```
run;

proc sort;
  by pop cat;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
run;

data shell;
  length varc $100;
  set totfreq (keep=pop);
  do cat=1 to 6;
    varc=put(cat,cat.);
    varn=0.5;
    output;
  end;
run;

data combo;
  length value $20 varc $100;;
  set shell (in=x) freq0 (in=b);
  by pop cat;
  if b then value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
  sort=count;
  keep pop cat varn varc value sort;
run;

proc sort data=combo;
  by cat varn varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn varc;
  var value;
  id pop;
run;

data trans2;
  merge trans freq0 (where=(pop="Z") keep=cat varn varc count pop);
  by cat varn varc;
  sort=count;
  if varc="Unknown" then sort=0;
run;

proc sort data=trans2;
  by cat varn descending sort varc;
run;

data final;
  set trans2;
  array _col{*} n y;
  do i=1 to dim (_col);
    if _col{i}=''  and z ne '' then _col{i}=strip(put(0,best.))||" ("||put(0,4.1)||")";
  end;
  if varn=0.5 then varc="  "||strip(varc);
```

```
  else if varn>=1 then varc="    "||strip(varc);
  select (cat);
    when (1,2,3) page=1;
    when (4,5)   page=2;
    otherwise    page=3;
  end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTtrtadj.rtf" style=vg_rtf;

title3 "Table &tno: Treatment Adjustments and Modifications";
title4 "Full Analysis Set, by Baseline Platelet Group";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns cat varn sort varc ('Number of Patients (%)' N Y);

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define sort    / order descending noprint;
  define varc    / order "Patient Population"
                       style=[cellwidth=3.25 in asis=on] left style(header)=[just=left asis=on];

  define n        / display "Platelet >= 100,000/ul@N=&n"     style=[cellwidth=1.2 in] center;
  define y        / display "Platelet < 100,000/ul@N=&y" style=[cellwidth=1.5 in] center;

  compute before cat / style=[font_size=5pt];
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       08.12.2013
/*Program:    t_PLTexp.sas
/*Purpose:    Creates by-Platelet subgroup tables for t_exp (began with t_exp)
/*Modifications:

/************************************************/

%let filename=t-pltexp;
%let tno=14.3.5.6;
%let outno=14-3-5-6;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data demog0;
  set db.adsl (where=(fasfl="Y"));
  if platfl="" then platfl="N";
  pop=platfl;
run;

proc sort data=demog0;
  by pop;
run;

proc freq data=demog0 noprint;
  tables pop / out=totfreq (drop=percent rename=(count=totcount));
run;

data _null_;
  set totfreq;
  call symputx(pop,totcount);
run;

proc format;
  value cat
    1="Total duration of treatment (wk)"
    2="Number of treatment cycles administered"
    3="Number of belinostat doses administered"
    4="Total cumulative dose of belinostat (g/m2)"
    5="Relative dose intensity (%)"
    6="Patients with dose reduction of 25% (%)"
    7="Patients with cycle delay of 7+ days (%)"
    8="Total number of treatment cycles per patient (%)";
run;

/*data cat;
  length varc $100;
  set demog0;
  cat=6;
  if EXDOSDEC=1 then do;
    varn=1;
    varc="Only 1 dose reduction";
    output;
  end;
  else if EXDOSDEC=2 then do;
```

```
    varn=2;
    varc="2 dose reductions";
    output;
  end;
  cat=7;
  if EXDOSDEL=1 then do;
    varn=1;
    varc="Only 1 dose delay";
    output;
  end;
  else if EXDOSDEL>=2 then do;
    varn=2;
    varc="2 or more dose delays";
    output;
  end;
  cat=8;
  if CYCLENUM ne . then do;
    varn=CYCLENUM;
    varc=strip(put(varn,best.))||" cycles";
    if varn=1 then varc="1 cycle";
    output;
  end;
run;

proc sort;
  by pop cat;
run;

proc freq data=cat noprint;
  by pop cat;
  tables varn*varc/ out=freq0;
run;
*/

data cont;
  set demog0;
  cat=1;varn=cycledur;output;
  cat=2;varn=cyclenum;output;
  cat=3;varn=exdosnum;output;
  cat=4;varn=exdoscum/1000;output;
  cat=5;varn=exdosint;output;
run;

proc sort;
  by pop cat;
run;

proc means data=cont noprint;
  by pop cat;
  var varn;
  output out=stats0 n=n mean=mean std=std stderr=stderr median=median min=min max=max;
run;

data shell;
  length catdesc $75;
  set totfreq (keep=pop);
  do cat=1 to 5;*8;
    catdesc=put(cat,cat.);
```

```
    varn=0;
    output;
  end;
run;

data combo;
  length value $20 varc $100;;
  set shell (in=x) stats0 (in=a)/* freq0 (in=b)*/;
  by pop cat;
  if x then output;
  else if a then do;
    varn=1;varc="N";
    value=strip(put(n,best.));
    output;
    varn=2;varc="Mean (SD)";
    if cat ne 5 then value=strip(put(mean,8.1))||" ("||strip(put(std,8.2))||")";
    else value=strip(put(mean,8.2))||" ("||strip(put(std,8.3))||")";
    output;
    varn=3;varc="Median";
    if cat ne 5 then value=strip(put(median,8.1));
    else value=strip(put(median,8.2));
    output;
    varn=4;varc="Range";
    if cat=4 then value=strip(put(min,8.0))||" - "||strip(put(max,8.0));
    else value=strip(put(min,best.))||" - "||strip(put(max,best.));
    output;
  end;
  /*else do;
    value=strip(put(count,best.))||" ("||put(100*count/symgetn(pop),4.1)||")";
    output;
  end;*/
  keep pop cat catdesc varn varc value;
run;

proc sort data=combo;
  by cat varn catdesc varc;
run;

proc transpose data=combo out=trans (drop=_name_);
  by cat varn catdesc varc;
  var value;
  id pop;
run;

data final;
  set trans;
  if varn>0 then catdesc="   "||strip(varc);
  page=ceil(cat/5);
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTexp.rtf" style=vg_rtf;

title3 "Table &tno: Extent of Exposure to Belinostat";
title4 "by Baseline Platelet Group";
title5 "Full Analysis Set";
%footsrce(line=1);
```

```
proc report data=final nowindows headskip split='@' missing;
  by page;
  columns cat varn catdesc ('Number of Patients (%)' N Y);

  define cat     / order order=internal noprint;
  define varn    / order order=internal noprint;
  define catdesc / order "Patient Population"
                       style=[cellwidth=2.5 in asis=on] left style(header)=[just=left asis=on];

  define n        / display "Platelet >= 100,000/ul@N=&n"     style=[cellwidth=1.2 in] center;
  define y        / display "Platelet < 100,000/ul@N=&y" style=[cellwidth=1.5 in] center;

  compute before cat;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_ae_summary.sas
/*Purpose:    Creates Overall Summary AE Table
/*Comment:
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Rob Howard 5/8/13: Added "Patients with any treatment emergent AE resulting in death" and
                        "Patients with any treatment related AE resulting in death"
Pamela Hsu 10/18/13 added more category
Pamela Hsu 10/29/13 update the TEAE resulting in death to "within 30 days of last dose" in group
7
/************************************************/

%let filename=t-ae-summary;


%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


%macro aesum(tno,outno);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where fasfl="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;

%macro rows(label,clause,ord);
  if &clause then do;
    ord=&ord;
    descrip="&label";
    output;
  end;
%mend;

proc sql noprint;
    select distinct (quote(compress(usubjid))) into: ptid
    separated by ','
    from db.adae
    where AEDOSDIS='Y' and AESER='Y';

    select distinct (quote(compress(usubjid))) into: sptid
    separated by ','
    from db.adae
    where AERELFL='Y' and AEDOSDIS='Y' and AESER eq 'Y';
quit;

%put &ptid &sptid;
```

```
data adae;
set db.adae (where=(fasfl='Y'));
  length descrip $125;
  *output one record for each match to a descrip;
  %rows(Patients with any treatment emergent AE,%str(aetrtem="Y"),1);
  %rows(Patients with any Grade 1-2 treatment emergent AE,%str(aetrtem="Y" and aetoxgrn in (1
2)),2);
  %rows(Patients with any Grade 3-4 treatment emergent AE,%str(aetrtem="Y" and aetoxgrn in (3
4)),3);
  %rows(Patients with any Grade 3 treatment emergent AE,%str(aetrtem="Y" and aetoxgrn in (3)),4);
  %rows(Patients with any Grade 4 treatment emergent AE,%str(aetrtem="Y" and aetoxgrn in (4)),5);
  %rows(Patients with any Grade 5 treatment emergent AE,%str(aetrtem="Y" and aetoxgrn in (5)),6);
  %rows(Patients with any treatment emergent AE resulting in death within 30 days of last dose,%
str(aetrtem="Y" and aeout="Fatal" and (endosdy+ (aeendy - aestdy))<=30),7);
  %rows(Patients with any serious AE,%str(aetrtem="Y" and aeser='Y'),8);
  %rows(Patients with serious AE other than death,%str((aetrtem="Y" and (aeout ne 'Fatal' and
endosdy le 30 and aeser='Y') or (aeout='Fatal' and (endosdy+ (aeendy - aestdy)) gt 30))),9);
  %rows(Patients with any AE leading to discontinuation,%str(aetrtem="Y" and AEDOSDIS='Y'),10);
  %rows(Patients with any serious AE leading to discontinuation,%str(aetrtem="Y" and
AEDOSDIS='Y' and AESER='Y'),11);
  %rows(Patients with non-serious AE leading to discontinuation,%str(aetrtem="Y" and  aeser ne
'Y' and aeacn='Discontinued' and usubjid not in (&ptid)),12);
  %rows(Patients with any treatment related AE,%str(aerel='Related'),13);
  %rows(Patients with any Grade 1-2 treatment related AE,%str(aerel='Related' and aetoxgrn in (1
2)),14);
  %rows(Patients with any Grade 3-4 treatment related AE,%str(aerel='Related' and aetoxgrn in (3
4)),15);
  %rows(Patients with any Grade 3 treatment related AE,%str(aerel='Related' and aetoxgrn in
(3)),16);
  %rows(Patients with any Grade 4 treatment related AE,%str(aerel='Related' and aetoxgrn in
(4)),17);
  %rows(Patients with any Grade 5 treatment related AE,%str(aerel='Related' and aetoxgrn in
(5)),18);
  %rows(Patients with any treatment related AE resulting in death,%str(aerel='Related' and
aeout="Fatal"),19);
  %rows(Patients with any serious treatment related AE,%str(aerel='Related' and aeser='Y'),20);
  %rows(Patients with serious treatment related AE other than death,%str(aerel='Related' and
aeout ne 'Fatal' and aeser='Y'),21);
  %rows(Patients with any treatment related AE leading to discontiuation,%str(aerel='Related' and
aeout ne 'Fatal' and aeacn='Discontinued'),22);
  %rows(Patients with serious treatment related AE leading to discontiuation,%str
(aerel='Related' and aeout ne 'Fatal' and aeser eq 'Y' and aeacn='Discontinued'),23);
  %rows(Patients with non-serious treatment related AE leading to discontiuation,%str
(aerel='Related' and aeout ne 'Fatal' and aeser ne 'Y' and aeacn='Discontinued' and usubjid not
in (&sptid)),24);


run;


proc sort data=adae out=prep nodupkey;
  by usubjid descrip;
run;

proc freq data=prep;
  tables ord*descrip / out= counts noprint;
run;
```

```
data final;
set counts;
  length c1 $20;
  c1=strip(put(count,3.))||'   '||strip(put(count/&tot*100,5.1));
run;


ods listing close;
ods rtf file="&_outpath\t-&outno.-ae-summary.rtf" style=vg_rtf;

title3 "Table &tno: Overview of Treatment Emergent Adverse Events";

%footsrce(line=1);


proc report data=final nowindows headskip split='@';
columns  ord ("Patient Population" descrip) ("Full Analysis Set" c1) ;

  define ord / order order=internal noprint;
  define descrip / order " "  style=[cellwidth=4.6 in asis=on] left  style(header)=[just=left
asis=on];
  define c1 / display "N=&tot@n    %" style=[cellwidth=.9 in] center;

  compute after ord;
    line put '';
  endcomp;
run;

ods rtf close ;
ods listing;

%mend;


%aesum(14.3.6.1,14-3-6-1);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.24.2013
/*Program:    t_ae_pt.sas
/*Purpose:    Creates AE Tables using only PT
/*Comment: Copied from version that used SOC and overall AE row, that is why extra code is
floating around. Client changed from original mock.
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Rob Howard 5/8/13: Separated out Grade 5 AEs from Grades 3 and 4
Bob Hull 6/25/2013: Added Grade 1-2 to the table and took worst grade.
/************************************************/

%let filename=t-ae-ptg3-5;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


data _null_;
set db.adae;
if aeacn='Discontinued' and aetrtem='' then put 'WARNING: Adjust code for event leading to
discontinuation but not treat emerg.';
*all other cases use treatment emergent, so a percent if or other macro code could handle it.;
run;

%macro ae(pop,where,subset,label,title,tno,outno);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where &pop="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where &pop="Y" and aetrtem="Y" &where;
  if aetoxgrn=. then do;
    put 'NOTE: Missing Severity set to Grade 1 ' usubjid= aeterm= aedecod=;
    aetoxgrn=1;
  end;
  %if &subset=SOC or &subset=RelSOC %then %do;
    aedecod=aebodsys;
  %end;
  term="Patients with any &label";
  aebodsys='ABC';*To be removed later.;
run;

proc sort data=adae;
  by aebodsys aedecod;
```

```
run;

*this macro will use the overall data and by grade data separately, so the data is separated out.
;
data adae2;
set adae;
  if aetoxgrn ne .;
  aetoxgrn=0;
run;

*table just uses grade 3-5 for other column, remove low grades for those counts.;
/*REH - 5/8/2013 - separated Grade 5 from 3 and 4*/
data adae;
set adae;
  if 1<=aetoxgrn<=2 then do;
    aetoxgrn=1;
    output;
  end;
  if 3<=aetoxgrn<=4 then do;
    aetoxgrn=3;
    output;
  end;
  if aetoxgrn=5 then do;
    aetoxgrn=5;
    output;
  end;
run;

*get frequencies of per patient, grade irrelevant for all grade column, use ADAE if they want all
grades later. ;
proc sort data=adae2 out=tot2 nodupkey;
  by term usubjid aetoxgrn;
run;

proc freq data=tot2;
tables term*aetoxgrn / out=tot_cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=tot_cnt out=totcnt2 prefix=c;
  by term;
  var count;
  id aetoxgrn;
run;

%macro group(data,abv);
*get frequencies of worst grade per SOC;
proc sort data=&data out=soc&abv;
  by aebodsys usubjid aetoxgrn;
run;

data soc&abv.2;
set soc&abv;
  by aebodsys usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=soc&abv.2;
```

```
tables aebodsys*aetoxgrn / out=soc&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=soc&abv._cnt out=soc&abv.cnt2 prefix=c;
  by aebodsys;
  var count;
  id aetoxgrn;
run;

*get frequencies of worst grade per PT;
proc sort data=&data out=pt&abv;
  by aebodsys aedecod usubjid aetoxgrn;
run;

data pt&abv.2;
set pt&abv;
  by aebodsys aedecod usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=pt&abv.2;
tables aebodsys*aedecod*aetoxgrn / out=pt&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=pt&abv._cnt out=pt&abv.cnt2 prefix=c;
  by aebodsys aedecod;
  var count;
  id aetoxgrn;
run;
%mend;

%group(adae,a);
%group(adae2,b);

data counts1;
merge socacnt2 socbcnt2;
  by aebodsys;
run;

data counts2;
merge ptacnt2 ptbcnt2;
  by aebodsys aedecod;
run;

data final;
set /*counts1 (in=ins) totcnt2 (in=int)*/ counts2 (in=inp);
  length cv0-cv5 $15 descrip $200;

  array counts(*) c0-c5;
  array charvar(*) Cv0-cv5;
  do i=1 to 6;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||'   '||put(counts(i)/&tot*
100,5.1)||'';
    else charvar(i)='-';
  end;
/*
```

```
  if int then do;
    descrip=term;
    ord=1;
    aebodsys='1';*will be used for sorting, this makes it unique and come out on top;
  end;

  if ins then do;
    descrip=aebodsys;
    ord=2;
    cv0='';cv1='';cv2='';cv3='';cv4='';cv5='';
  end;*/

  if inp then do;
    ord=10000-c0;*gives descending;
    descrip=aedecod;
  end;

  drop c0-c5;
  drop _name_ _label_;
run;

*breaking ties here so that it can be used to break after each line.;
proc sort data=final;
  by ord descrip;
run;

data final;
set final;
  by ord descrip;
  ord2=_n_;
run;



ods listing close;
ods rtf file="&_outpath\t-&outno.-ae-ptg3-5&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";

%footsrce(line=1);

proc report data=final nowindows headskip split='@';
columns  ord2 descrip cv0 cv1 cv3 cv5;

  define ord2 / order order=internal noprint;
  define descrip / order "Full Analysis Set                              N=&tot@   &label"
       style=[cellwidth=4.6 in asis=on] left  style(header)=[just=left asis=on];

  define cv0 / display "All Grades@n    %" style=[cellwidth=.9 in] center;
  define cv1 / display "Grades 1-2@n    %" style=[cellwidth=.9 in] center;
  define cv3 / display "Grades 3-4@n    %" style=[cellwidth=.9 in] center;
  define cv5 / display "Grade 5@n    %" style=[cellwidth=.9 in] center;
  %if &subset=SOC or &subset=RelSOC %then %do;
    compute before ord2;
      line put '';
    endcomp;
  %end;
run;
```

```
ods rtf close ;
ods listing;

%mend;

%ae(fasfl, ,SOC,MedDRA System Organ Class,Treatment Emergent Adverse Events by MedDRA System
Organ Class,14.3.6.2,14-3-6-2);
%ae(fasfl, ,All,MedDRA Preferred Term,Treatment Emergent Adverse Events by MedDRA Preferred
Term,14.3.6.3,14-3-6-3);
%ae(fasfl,%str(and aerel='Related'),RelSOC,MedDRA System Organ Class,Treatment Related Adverse
Events by MedDRA System Organ Class,14.3.6.5,14-3-6-5);
%ae(fasfl,%str(and aerel='Related'),Rel,MedDRA Preferred Term,Treatment Related Adverse Events by
MedDRA Preferred Term,14.3.6.6,14-3-6-6);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.24.2013
/*Program:    t_ae.sas
/*Purpose:    Creates AE Tables
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Bob Hull 7/5/2013: Fixed uninit message.
/************************************************/

%let filename=t-ae;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data _null_;
set db.adae;
if aeacn='Discontinued' and aetrtem='' then put 'WARNING: Adjust code for event leading to
discontinuation but not treat emerg.';
*all other cases use treatment emergent, so a percent if or other macro code could handle it.;
run;

%macro ae(pop,where,subset,any,title,tno,outno);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where &pop="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where &pop="Y" and aetrtem="Y" &where;
  if aetoxgrn=. then do;
    put 'NOTE: Missing Severity set to Grade 1 ' usubjid= aeterm= aedecod=;
    aetoxgrn=1;
  end;
  term="Patients with any &any";
run;

proc sort data=adae;
  by aebodsys aedecod;
run;

*this macro will use the overall data and by grade data separately. ;
data adae2;
set adae;
  if aetoxgrn ne .;
  aetoxgrn=0;
run;
```

```
*get frequencies of worst grade per patient, getting overall only, use ADAE if they want all
grades later. ;
proc sort data=adae2 out=tot;
  by term usubjid aetoxgrn;
run;

data tot2;
set tot;
  by term usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=tot2;
tables term*aetoxgrn / out=tot_cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=tot_cnt out=totcnt2 prefix=c;
  by term;
  var count;
  id aetoxgrn;
run;

%macro group(data,abv);
*get frequencies of worst grade per SOC;
proc sort data=&data out=soc&abv;
  by aebodsys usubjid aetoxgrn;
run;

data soc&abv.2;
set soc&abv;
  by aebodsys usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=soc&abv.2;
tables aebodsys*aetoxgrn / out=soc&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=soc&abv._cnt out=soc&abv.cnt2 prefix=c;
  by aebodsys;
  var count;
  id aetoxgrn;
run;

*get frequencies of worst grade per PT;
proc sort data=&data out=pt&abv;
  by aebodsys aedecod usubjid aetoxgrn;
run;

data pt&abv.2;
set pt&abv;
  by aebodsys aedecod usubjid aetoxgrn;
  if last.usubjid;
run;
```

```
proc freq data=pt&abv.2;
tables aebodsys*aedecod*aetoxgrn / out=pt&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=pt&abv._cnt out=pt&abv.cnt2 prefix=c;
  by aebodsys aedecod;
  var count;
  id aetoxgrn;
run;
%mend;

%group(adae,a);
%group(adae2,b);

data counts1;
merge socacnt2 socbcnt2;
  by aebodsys;
run;

data counts2;
merge ptacnt2 ptbcnt2;
  by aebodsys aedecod;
run;


data final;
set counts1 (in=ins) /*totcnt2 (in=int)*/ counts2 (in=inp);
  length cv0-cv5 $15 descrip $200;

  array counts(*) c0-c5;
  array charvar(*) Cv0-cv5;
  do i=1 to 6;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||' ('||put(counts(i)/&tot*100,5.1)
||')';
    else charvar(i)='-';
  end;
/*
  if int then do;
    descrip=term;
    ord=1;
    aebodsys='1';*will be used for sorting, this makes it unique and come out on top;
  end;*/

  if ins then do;
    descrip=aebodsys;
    ord=2;
    cv0='';cv1='';cv2='';cv3='';cv4='';cv5='';
  end;

  if inp then do;
    ord=3;
    descrip='   '||aedecod;
  end;

  drop c0-c5;
  drop _name_ _label_;
run;
```

```
ods listing close;
ods rtf file="&_outpath\t-&outno.-ae&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";

%footsrce(line=1);


proc report data=final nowindows headskip split='@';
columns aebodsys ord ("Full Analysis Set                          N=&tot@ " descrip   )
             ('Number of Patients (%)@Worst Grade per Patient' cv0 cv1 cv2 cv3 cv4 cv5);

  define aebodsys / order order=internal noprint;
  define ord / order order=internal noprint;
  define descrip / order "MedDRA System Organ Class@     MedDRA Preferred Term"
                       style=[cellwidth=2.6 in asis=on] left
         style(header)=[just=left asis=on];

  define cv0 / display "Any Grade" style=[cellwidth=.9 in] center;
  define cv1 / display "Grade 1" style=[cellwidth=.9 in] center;
  define cv2 / display "Grade 2" style=[cellwidth=.9 in] center;
  define cv3 / display "Grade 3" style=[cellwidth=.9 in] center;
  define cv4 / display "Grade 4" style=[cellwidth=.9 in] center;
  define cv5 / display "Grade 5" style=[cellwidth=.9 in] center;

  compute before aebodsys;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%ae(fasfl, , ,treatment emergent AE,Treatment Emergent Adverse Events by Worst Grade Toxicity per
Patient,14.3.6.4,14-3-6-4);
%ae(fasfl,%str(and aerel='Related'),Rel,treatment related AE,Treatment Related Adverse Events by
Worst Grade Toxicity per Patient,14.3.6.7,14-3-6-7);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Rob Howard
/*Date:       05.16.2013
/*Program:    t_aecrossref.sas
/*Purpose:    Cross Reference of Treatment Emergent Adverse Events to Patients
/*Modifications: Updated length of PATLIST. Bob Hull 7/5/2013
/************************************************/

%let filename=t-aecrossref;
%let tno=14.3.6.8;
%let outno=14-3-6-8;
%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


proc sort data=db.adae out=unique (keep=subjid aedecod aetoxgrn) nodupkey;
  by aedecod aetoxgrn subjid;
  where aetrtem="Y";
run;

data cr;
  length patlist $600;
  set unique;
  by aedecod aetoxgrn subjid;
  retain patlist count;
  if first.aetoxgrn then do;
    patlist=subjid;
    count=1;
  end;
  else do;
    patlist=strip(patlist)||"  "||strip(subjid);
    count+1;
  end;
  if last.aetoxgrn;
  tox=strip(put(aetoxgrn,best.));
  if aetoxgrn=. then tox="-";
run;

data final;
  set cr;
  page=ceil(_n_/19);
run;


options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-aecrossref.rtf" style=vg_rtf;

title3 "Table &tno: Cross Reference of Treatment Emergent Adverse Events to Patients";
%footsrce(line=1);

proc report data=final nowindows headskip split='@' missing;
  by page;
  columns aedecod aetoxgrn tox count patlist;

  define aedecod  / order "MedDRA Preferred Term"
                       style=[cellwidth=3.5 in asis=on] left style(header)=[just=left asis=on];
```

```
  define aetoxgrn / order noprint;
  define tox      / display "Tox.@Grade" style=[cellwidth=.5 in] center;
  define count    / display "No.@Pts" style=[cellwidth=.5 in] center format=2.;
  define patlist  / display "ID Number of Patients with Adverse Event" style=[cellwidth=4.75 in
asis=on]  left style(header)=[just=left asis=on];

  compute before aedecod;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.24.2013
/*Program:    t_ae_pt.sas
/*Purpose:    Creates AE Tables using only PT
/*Comment: Copied from version that used SOC and overall AE row, that is why extra code is
floating around. Client changed from original mock.
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Rob Howard 5/8/13: Separated out Grade 5 AEs from Grades 3 and 4
Bob Hull 6/25/2013: Added Grade 1-2 to the table and took worst grade.
   REH 7/27/13   Began with t_ae_ptg3-5 and modified to run by Platelet subgroup
Bob Hull 7/29/2013 Fixed warnings in log for spanning headers.
/************************************************/

%let filename=t-pltae-ptg3-5;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc format;
  value $_platfl
    "Y"="Platelet < 100,000/ul"
    other="Platelet >= 100,000/ul";
run;

data _null_;
set db.adae;
if aeacn='Discontinued' and aetrtem='' then put 'WARNING: Adjust code for event leading to
discontinuation but not treat emerg.';
*all other cases use treatment emergent, so a percent if or other macro code could handle it.;
run;

data platpop;
  set db.adsl (where=(fasfl="Y"));
  if platfl="" then platfl="N";
  platdesc=put(platfl,$_platfl.);
run;

proc freq data=platpop noprint;
  tables fasfl           / out=totfreq;
  tables platfl*platdesc / out=platfreq (drop=percent);
run;

data _null_;
  set totfreq;
  call symputx("fasfl",count);
run;

data _null_;
  set platfreq;
  call symputx(platfl,count);
  call symputx(strip(platfl)||"desc",platdesc);
run;

%macro ae(pop,where,subset,label,title,tno,outno);
```

```
*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=platfl usubjid) nodupkey;
  by platfl usubjid;
  where &pop="Y";
run;

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where &pop="Y" and aetrtem="Y" &where;
  if aetoxgrn=. then do;
    put 'NOTE: Missing Severity set to Grade 1 ' usubjid= aeterm= aedecod=;
    aetoxgrn=1;
  end;
  %if &subset=SOC or &subset=RelSOC %then %do;
    aedecod=aebodsys;
  %end;
  term="Patients with any &label";
  aebodsys='ABC';*To be removed later.;
run;

proc sort data=adae;
  by platfl aebodsys aedecod;
run;

*this macro will use the overall data and by grade data separately, so the data is separated out.
;
data adae2;
set adae;
  if aetoxgrn ne .;
  aetoxgrn=0;
run;

*table just uses grade 3-5 for other column, remove low grades for those counts.;
/*REH - 5/8/2013 - separated Grade 5 from 3 and 4*/
data adae;
set adae;
  if 1<=aetoxgrn<=2 then do;
    aetoxgrn=1;
    output;
  end;
  if 3<=aetoxgrn<=4 then do;
    aetoxgrn=3;
    output;
  end;
  if aetoxgrn=5 then do;
    aetoxgrn=5;
    output;
  end;
run;

*get frequencies of per patient, grade irrelevant for all grade column, use ADAE if they want all
grades later. ;
proc sort data=adae2 out=tot2 nodupkey;
  by platfl term usubjid aetoxgrn;
run;
```

```
proc freq data=tot2;
  by platfl;
tables term*aetoxgrn / out=tot_cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=tot_cnt out=totcnt2 prefix=c;
  by platfl term;
  var count;
  id aetoxgrn;
run;

%macro group(data,abv);
*get frequencies of worst grade per SOC;
proc sort data=&data out=soc&abv;
  by platfl aebodsys usubjid aetoxgrn;
run;

data soc&abv.2;
set soc&abv;
  by platfl aebodsys usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=soc&abv.2;
  by platfl;
tables aebodsys*aetoxgrn / out=soc&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=soc&abv._cnt out=soc&abv.cnt2 prefix=c;
  by platfl aebodsys;
  var count;
  id aetoxgrn;
run;

*get frequencies of worst grade per PT;
proc sort data=&data out=pt&abv;
  by platfl aebodsys aedecod usubjid aetoxgrn;
run;

data pt&abv.2;
set pt&abv;
  by platfl aebodsys aedecod usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=pt&abv.2;
  by platfl;
tables aebodsys*aedecod*aetoxgrn / out=pt&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=pt&abv._cnt out=pt&abv.cnt2 prefix=c;
  by platfl aebodsys aedecod;
  var count;
  id aetoxgrn;
run;
```

```
%mend;

%group(adae,a);
%group(adae2,b);

data counts1;
merge socacnt2 socbcnt2;
  by platfl aebodsys;
run;

data counts2;
merge ptacnt2 ptbcnt2;
  by platfl aebodsys aedecod;
run;

data final;
set /*counts1 (in=ins) totcnt2 (in=int)*/ counts2 (in=inp);
  length cv0-cv5 $15 descrip $200;
  if platfl='' then platfl="N";
  platdesc=put(platfl,$_platfl.)||" (N="||symget(platfl)||")";

  array counts(*) c0-c5;
  array charvar(*) Cv0-cv5;
  do i=1 to 6;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||'   '||put(counts(i)/symgetn
(platfl)*100,5.1)||'';
    else charvar(i)='-';
  end;
/*
  if int then do;
    descrip=term;
    ord=1;
    aebodsys='1';*will be used for sorting, this makes it unique and come out on top;
  end;

  if ins then do;
    descrip=aebodsys;
    ord=2;
    cv0='';cv1='';cv2='';cv3='';cv4='';cv5='';
  end;*/

  if inp then do;
    ord=10000-c0;*gives descending;
    descrip=aedecod;
  end;

  drop c0-c5;
  drop _name_ _label_;
run;

*breaking ties here so that it can be used to break after each line.;
proc sort data=final;
  by platfl platdesc ord descrip;
run;

data final;
set final;
  by platfl platdesc ord descrip;
```

```
  ord2=_n_;
  page=ceil(_n_/16);
  %if &subset=All %then %do;
    page=ceil(_n_/31);
  %end;
run;

options nobyline;


ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTae-ptg3-5&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";
title4 "by Baseline Platelet Group";

%footsrce(line=1);

proc report data=final nowindows headskip split='@';
  by page;
columns platfl ("Full Analysis Set" platdesc)ord2 descrip cv0 cv1 cv3 cv5;
  define platfl   / order order=internal noprint;
  define platdesc / order order=internal "Baseline Platelet Group" style(column)=[cellwidth=1.7
in] style(header)=[just=left];
  define ord2 / order order=internal noprint;
  define descrip / order "&label"  style=[cellwidth=3.65 in asis=on] left  style(header)=
[just=left asis=on];

  define cv0 / display "All Grades@n    %" style(column)=[cellwidth=.9 in] center;
  define cv1 / display "Grades 1-2@n    %" style(column)=[cellwidth=.9 in] center;
  define cv3 / display "Grades 3-4@n    %" style(column)=[cellwidth=.9 in] center;
  define cv5 / display "Grade 5@n    %" style(column)=[cellwidth=.9 in] center;
  %if &subset=SOC or &subset=RelSOC %then %do;
    compute before ord2;
      line put '';
    endcomp;
  %end;
run;

ods rtf close ;
ods listing;

%mend;

%ae(fasfl, ,SOC,MedDRA System Organ Class,Treatment Emergent Adverse Events by MedDRA System
Organ Class,14.3.6.9,14-3-6-9);
%ae(fasfl, ,All,MedDRA Preferred Term,Treatment Emergent Adverse Events by MedDRA Preferred
Term,14.3.6.10,14-3-6-10);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       07.27.2013
/*Program:    t_PLTae.sas
/*Purpose:    Creates AE Tables
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Bob Hull 7/5/2013: Fixed uninit message.
   REH 7/27/13   Began with t_ae and modified to run by Platelet subgroup
/************************************************/

%let filename=t-pltae;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc format;
  value $_platfl
    "Y"="Platelet < 100,000/ul"
    other="Platelet >= 100,000/ul";
run;

data _null_;
set db.adae;
if aeacn='Discontinued' and aetrtem='' then put 'WARNING: Adjust code for event leading to
discontinuation but not treat emerg.';
*all other cases use treatment emergent, so a percent if or other macro code could handle it.;
run;

data platpop;
  set db.adsl (where=(fasfl="Y"));
  if platfl="" then platfl="N";
  platdesc=put(platfl,$_platfl.);
run;

proc freq data=platpop noprint;
  tables fasfl           / out=totfreq;
  tables platfl*platdesc / out=platfreq (drop=percent);
run;

data _null_;
  set totfreq;
  call symputx("fasfl",count);
run;

data _null_;
  set platfreq;
  call symputx(platfl,count);
  call symputx(strip(platfl)||"desc",platdesc);
run;


%macro ae(pop,where,subset,any,title,tno,outno);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=platfl usubjid) nodupkey;
```

```
  by platfl usubjid;
  where &pop="Y";
run;

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where &pop="Y" and aetrtem="Y" &where;
  if aetoxgrn=. then do;
    put 'NOTE: Missing Severity set to Grade 1 ' usubjid= aeterm= aedecod=;
    aetoxgrn=1;
  end;
  term="Patients with any &any";
run;

proc sort data=adae;
  by platfl aebodsys aedecod;
run;

*this macro will use the overall data and by grade data separately. ;
data adae2;
set adae;
  if aetoxgrn ne .;
  aetoxgrn=0;
run;

*get frequencies of worst grade per patient, getting overall only, use ADAE if they want all
grades later. ;
proc sort data=adae2 out=tot;
  by platfl term usubjid aetoxgrn;
run;

data tot2;
set tot;
  by platfl term usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=tot2;
  by platfl;
tables term*aetoxgrn / out=tot_cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=tot_cnt out=totcnt2 prefix=c;
  by platfl term;
  var count;
  id aetoxgrn;
run;

%macro group(data,abv);
*get frequencies of worst grade per SOC;
proc sort data=&data out=soc&abv;
  by platfl aebodsys usubjid aetoxgrn;
run;

data soc&abv.2;
set soc&abv;
```

```
  by platfl aebodsys usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=soc&abv.2;
  by platfl;
tables aebodsys*aetoxgrn / out=soc&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=soc&abv._cnt out=soc&abv.cnt2 prefix=c;
  by platfl aebodsys;
  var count;
  id aetoxgrn;
run;

*get frequencies of worst grade per PT;
proc sort data=&data out=pt&abv;
  by platfl aebodsys aedecod usubjid aetoxgrn;
run;

data pt&abv.2;
set pt&abv;
  by platfl aebodsys aedecod usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=pt&abv.2;
  by platfl;
tables aebodsys*aedecod*aetoxgrn / out=pt&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=pt&abv._cnt out=pt&abv.cnt2 prefix=c;
  by platfl aebodsys aedecod;
  var count;
  id aetoxgrn;
run;
%mend;

%group(adae,a);
%group(adae2,b);

data counts1;
merge socacnt2 socbcnt2;
  by platfl aebodsys;
run;

data counts2;
merge ptacnt2 ptbcnt2;
  by platfl aebodsys aedecod;
run;


data combo;
set counts1 (in=ins) /*totcnt2 (in=int)*/ counts2 (in=inp);
  length cv0-cv5 $15 descrip $200;
  if platfl='' then platfl="N";
```

```
  platdesc=put(platfl,$_platfl.)||" (N="||symget(platfl)||")";
  array counts(*) c0-c5;
  array charvar(*) Cv0-cv5;
  do i=1 to 6;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||' ('||put(counts(i)/symgetn
(platfl)*100,5.1)||')';
    else charvar(i)='-';
  end;
/*
  if int then do;
    descrip=term;
    ord=1;
    aebodsys='1';*will be used for sorting, this makes it unique and come out on top;
  end;*/

  if ins then do;
    descrip=aebodsys;
    ord=2;
    cv0='';cv1='';cv2='';cv3='';cv4='';cv5='';
  end;

  if inp then do;
    ord=3;
    descrip='   '||aedecod;
  end;

  drop c0-c5;
  drop _name_ _label_;
run;

proc sort;
  by platfl platdesc aebodsys ord descrip;
run;

data final;
  set combo;
  by platfl platdesc aebodsys ord descrip;
   page=ceil(_n_/27);
  %if &subset=Rel %then %do;
   page=ceil(_n_/25);
  %end;
run;

options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-PLTae&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";
title4 "by Baseline Platelet Group";

%footsrce(line=1);


proc report data=final nowindows headskip split='@';
  by page;
columns platfl ("Full Analysis Set" platdesc) aebodsys ord  descrip
             ('Number of Patients (%)@Worst Grade per Patient' cv0 cv1 cv2 cv3 cv4 cv5);
  define platfl   / order order=internal noprint;
```

```
  define platdesc / order order=internal "Baseline Platelet Group" style(column)=[cellwidth=1.7
in] style(header)=[just=left];
  define aebodsys / order order=internal noprint;
  define ord / order order=internal noprint;
  define descrip / order "MedDRA System Organ Class@     MedDRA Preferred Term"
                       style=[cellwidth=3.65 in asis=on] left
         style(header)=[just=left asis=on];

  define cv0 / display "Any Grade" style=[cellwidth=.75 in] center;
  define cv1 / display "Grade 1" style=[cellwidth=.75 in] center;
  define cv2 / display "Grade 2" style=[cellwidth=.75 in] center;
  define cv3 / display "Grade 3" style=[cellwidth=.75 in] center;
  define cv4 / display "Grade 4" style=[cellwidth=.75 in] center;
  define cv5 / display "Grade 5" style=[cellwidth=.75 in] center;

  compute before aebodsys;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%ae(fasfl, , ,treatment emergent AE,Treatment Emergent Adverse Events by Worst Grade Toxicity per
Patient,14.3.6.11,14-3-6-11);
%ae(fasfl,%str(and aerel='Related'),Rel,treatment related AE,Treatment Related Adverse Events by
Worst Grade Toxicity per Patient,14.3.6.12,14-3-6-12);
```

```
/*************************************************************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.24.2013
/*Program:    t_death.sas
/*Purpose:    Creates Table of Deaths
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
Pamela Hsu 10/29/2013: updated patient deaths within 30 days of the last dose and
                       updated the death reason by using AE preferred term for those
                       pat. died from AE and rest of them are due to disease progression
/************************************************/

%let filename=t-deaths;
%let tabno=14.3.7.1;
%let outno=14-3-7-1;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

%macro deaths(pop);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where &pop="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;

data grp1;
if _n_=.921 then output;*dummy code will not execute, get data with no obs.;
run;

%macro grp(label,where,order);

proc sort data=db.adsl out=adsl(keep=usubjid dthreas);
    by usubjid;
    where &pop="Y" &where;
run;

proc sort data=db.adae out=adae(keep=usubjid aedecod);
    by usubjid;
    where aeout='Fatal' and (endosdy+ (aeendy - aestdy))<=30;
run;

data all;
    length reason $50.;
    merge adsl(in=s) adae(in=e);
    by usubjid;
    if e then do;
        reason='Adverse Events';
        output;
    end;
```

```
    if e then reason=propcase(aedecod);
    if not e and s then reason='Progressive Disease';
    output;
run;

proc freq data=db.adsl;
where &pop="Y" &where;
tables studyid / out=out&order noprint;*freq of static variable will give count;
run;

data out&order.b;
set out&order;
  length descrip $150 col1 $15;
  descrip="&label";
  col1=put(count,3.)||" ("||put(count/&tot*100,4.1)||")";
  order=&order;
  subord=0;
run;

proc freq data=all;
tables reason / out=list&order noprint;
run;

proc sort data=list&order;
    by descending count;
run;

data list&order.b;
set list&order;
  length descrip $150 col1 $15;
  if reason not in ('Progressive Disease', 'Adverse Events') then descrip='    '||reason;
  else descrip='  '||reason;
  col1=put(count,3.)||" ("||put(count/&tot*100,4.1)||")";
  order=&order;
  if descrip='  Progressive Disease' then subord=1;
  else if descrip='  Adverse Events' then subord=2;
  else subord=_n_;
run;

data grp1;
set grp1 out&order.b list&order.b;
run;
%mend;

%grp(Patient deaths within 30 days of the LAST dose of belinostat,%str(and .<dthdt-trtendt+1<=
30),1);
/*%grp(Patient deaths within 60 days of the FIRST dose of belinostat,%str(and 0<dthdy<=60),2);*/
/*%grp(All deaths,and dthdy > .,3);*/


ods listing close;
ods rtf file="&_outpath\t-&outno.-deaths.rtf" style=vg_rtf;

title3 "Table &tabno: Deaths";

%footsrce(line=1);
```

```
proc report data=grp1 nowindows headskip split='@';
columns  order subord descrip col1;

  define order / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order "                              Patient Population@  "  style=[cellwidth=
3.5 in asis=on]
               left style(header)=[just=left asis=on];

  define col1 / display "Full Analysis Set@N=&tot" style=[cellwidth=.9 in] center;

  compute before order;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%deaths(fasfl);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_aelist.sas
/*Purpose:    Creates AE Listings
/*Modifications:
  Rob Howard   3/19/2013  Changed program name from l_ae to t_aelist
  Pamela Hsu  10/15/2013  Add two listings - All of AEs Leading to Discountiuation
                          and SAE Leading to Discountinuation
  Pamela Hsu  10/29/2013  update the TEAE resulting in death to "within 30 days of last dose" in
group 7
/************************************************/

%let filename=t-aelist;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

%macro lae(where,title,tno,outno,subset,label);

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where aetrtem="Y" &where;

run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-aelist&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";

%if &subset=death %then %do;
%footsrce(line=1);
%end;
%if &subset=Ser %then %do;
footnote1 j=l "All serious adverse events, other than those leading to death, per ICH E3.";
%footsrce(line=2);
%end;
%if &subset=withdraw %then %do;
footnote1 j=l "Excludes patients that have both serious and non-serious AEs leading to
discontiuation.";
%footsrce(line=2);
%end;

%macro bypage(rows);

proc sort data=adae;
  by subjid;
run;

data adae;
set adae nobs=last;
  by subjid;
  if aeout='Resolved with Sequelae' then extra=1;
  if first.subjid then addspace=1;
  extra2=ceil(length(aeterm)/40)-1;
```

```
  retain row;
  if _n_=1 then row=1;
  else row=sum(row,1);
  add=sum(addspace,max(extra,extra2));
  row=sum(row,add);
  if _n_=last then call symput('pgs',put(ceil(row/&rows),best.));
run;

%do b=1 %to &pgs;

proc report data=adae nowindows headskip split='@';
where (&rows*(&b-1))+1<=row<=&rows*&b;
columns subjid ("_____&label._____"  aeterm
aedecod) aestdy aetoxgrn aerelfl aeacn aeout;

  define subjid / order "Patient" style(column)=[cellwidth=.8 in] center;
  define aeterm / display  "Investigator Term" style(column)=[cellwidth=2.8 in asis=on] left
style(header)=[just=left asis=on];
  define aedecod / display  "MedDRA Preferred Term" style(column)=[cellwidth=2.6 in asis=on] left
style(header)=[just=left asis=on];

  define aestdy / display "Study@Day" style(column)=[cellwidth=.6 in] center;
  define aetoxgrn / display "Tox@Grd" style(column)=[cellwidth=.6 in] center;
  define aerelfl / display "Rel" style(column)=[cellwidth=.6 in] center;
  define aeacn / display "Action@Taken" style(column)=[cellwidth=1 in] left;
  define aeout / display "Outcome" style(column)=[cellwidth=.8 in] left;

  compute before subjid;
    line put '';
  endcomp;

run;

%end;

%mend;

%bypage(33);

ods rtf close ;
ods listing;

%mend;

%lae(%str(and aeout='Fatal' and (endosdy+ (aeendy - aestdy))<=30),Patient Listing of Treatment
Emergent Adverse Events Resulting in Death within 30 Days of Last Dose,14.3.7.2,14-3-7-
2,death,Serious Adverse Event);
%lae(%str(and aeser='Y'),Patient Listing of All Treatment Emergent Serious Adverse
Events,14.3.7.3,14-3-7-3,Ser,Serious Adverse Event);
*** move this to seperate program (t-aelist-nsae.sas) ***;
/*%lae(%str(and aetrtem="Y" and (aeout ne 'Fatal' and endosdy le 30 and aeser='Y') or
(aeout='Fatal' and (endosdy+ (aeendy - aestdy)) gt 30) ),Patient Listing of Other Treatment
Emergent Serious Adverse Events,14.3.7.3,14-3-7-3,Ser,Serious Adverse Event);*/
/*%lae(%str(and aeout ne 'Fatal' and aeser ne 'Y' and aeacn='Discontinued')*/
/*                ,Patient Listing of Other Treatment Emergent Adverse Events Leading to
Discontinuation,14.3.7.4,14-3-7-4,withdraw,Adverse Event);*/
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t_aelist.sas
/*Purpose:    Creates AE Listings
/*Modifications:
  Rob Howard   3/19/2013  Changed program name from l_ae to t_aelist
  Pamela Hsu  10/15/2013  modified - any non serious AEs Leading to Discountiuation
                          exclude the patients have SAEs leading to discountiuation
/************************************************/

%let filename=t-aelist-nsae;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

%macro lae(where,title,tno,outno,subset,label);

proc sql noprint;
     select distinct (quote(compress(usubjid))) into: ptid
     separated by ','
     from db.adae
    where aetrtem="Y" and fasfl='Y' and aeser eq 'Y' and aeacn='Discontinued';
quit;
%put &ptid;

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where aetrtem="Y" and usubjid not in (&ptid) &where;

run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-aelist&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";

%if &subset=withdraw %then %do;
footnote1 j=l "Excludes patients that have both serious and non-serious AEs leading to
discontiuation.";
%footsrce(line=2);
%end;

%macro bypage(rows);

proc sort data=adae;
  by subjid;
run;

data adae;
set adae nobs=last;
  by subjid;
  if aeout='Resolved with Sequelae' then extra=1;
  if first.subjid then addspace=1;
  extra2=ceil(length(aeterm)/40)-1;
  retain row;
```

```
  if _n_=1 then row=1;
  else row=sum(row,1);
  add=sum(addspace,max(extra,extra2));
  row=sum(row,add);
  if _n_=last then call symput('pgs',put(ceil(row/&rows),best.));
run;

%do b=1 %to &pgs;

proc report data=adae nowindows headskip split='@';
where (&rows*(&b-1))+1<=row<=&rows*&b;
columns subjid ("_____&label._____"  aeterm
aedecod) aestdy aetoxgrn aerelfl aeacn aeout;

  define subjid / order "Patient" style(column)=[cellwidth=.8 in] center;
  define aeterm / display  "Investigator Term" style(column)=[cellwidth=2.8 in asis=on] left
style(header)=[just=left asis=on];
  define aedecod / display  "MedDRA Preferred Term" style(column)=[cellwidth=2.6 in asis=on] left
style(header)=[just=left asis=on];

  define aestdy / display "Study@Day" style(column)=[cellwidth=.6 in] center;
  define aetoxgrn / display "Tox@Grd" style(column)=[cellwidth=.6 in] center;
  define aerelfl / display "Rel" style(column)=[cellwidth=.6 in] center;
  define aeacn / display "Action@Taken" style(column)=[cellwidth=1 in] left;
  define aeout / display "Outcome" style(column)=[cellwidth=.8 in] left;

  compute before subjid;
    line put '';
  endcomp;

run;

%end;

%mend;

%bypage(33);

ods rtf close ;
ods listing;

%mend;

%lae(%str(and aeout ne 'Fatal' and aeser ne 'Y' and aeacn='Discontinued')
                 ,Patient Listing of Other Treatment Emergent Adverse Events Leading to
Discontinuation,14.3.7.4,14-3-7-4,withdraw,Adverse Event);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.24.2013
/*Program:    t_ae_pt.sas
/*Purpose:    Creates AE Tables using only PT
/*Comment: Copied from version that used SOC and overall AE row, that is why extra code is
floating around. Client changed from original mock.
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.

/************************************************/

%let filename=t-ae-pt;


%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

data _null_;
set db.adae;
if aeacn='Discontinued' and aetrtem='' then put 'WARNING: Adjust code for event leading to
discontinuation but not treat emerg.';
*all other cases use treatment emergent, so a percent if or other macro code could handle it.;
run;

%macro ae(pop,where,subset,any,title,tno,outno);

*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where &pop="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;

data adae;
set db.adae;
  *analysis population, treatment emergent, then subset where clause;
  where &pop="Y" and aetrtem="Y" &where;
  if aetoxgrn=. then do;
    put 'NOTE: Missing Severity set to Grade 1 ' usubjid= aeterm= aedecod=;
    aetoxgrn=1;
  end;
  term="Patients with any &any";
  aebodsys='ABC';*To be removed later.;
run;

proc sort data=adae;
  by aebodsys aedecod;
run;

*this macro will use the overall data and by grade data separately. ;
data adae2;
```

```
set adae;
  if aetoxgrn ne .;
  aetoxgrn=0;
run;

*get frequencies of worst grade per patient, getting overall only, use ADAE if they want all
grades later. ;
proc sort data=adae2 out=tot;
  by term usubjid aetoxgrn;
run;

data tot2;
set tot;
  by term usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=tot2;
tables term*aetoxgrn / out=tot_cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=tot_cnt out=totcnt2 prefix=c;
  by term;
  var count;
  id aetoxgrn;
run;

%macro group(data,abv);
*get frequencies of worst grade per SOC;
proc sort data=&data out=soc&abv;
  by aebodsys usubjid aetoxgrn;
run;

data soc&abv.2;
set soc&abv;
  by aebodsys usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=soc&abv.2;
tables aebodsys*aetoxgrn / out=soc&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=soc&abv._cnt out=soc&abv.cnt2 prefix=c;
  by aebodsys;
  var count;
  id aetoxgrn;
run;

*get frequencies of worst grade per PT;
proc sort data=&data out=pt&abv;
  by aebodsys aedecod usubjid aetoxgrn;
run;

data pt&abv.2;
set pt&abv;
```

```
  by aebodsys aedecod usubjid aetoxgrn;
  if last.usubjid;
run;

proc freq data=pt&abv.2;
tables aebodsys*aedecod*aetoxgrn / out=pt&abv._cnt noprint;
run;

*transpose data and format for the table;
proc transpose data=pt&abv._cnt out=pt&abv.cnt2 prefix=c;
  by aebodsys aedecod;
  var count;
  id aetoxgrn;
run;
%mend;

%group(adae,a);
%group(adae2,b);

data counts1;
merge socacnt2 socbcnt2;
  by aebodsys;
run;

data counts2;
merge ptacnt2 ptbcnt2;
  by aebodsys aedecod;
run;

data final;
set /*counts1 (in=ins) totcnt2 (in=int)*/ counts2 (in=inp);
  length cv0-cv5 $15 descrip $200;

  array counts(*) c0-c5;
  array charvar(*) Cv0-cv5;
  do i=1 to 6;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||' '||put(counts(i)/&tot*100,5.1);
    else charvar(i)='-';
  end;
/*
  if int then do;
    descrip=term;
    ord=1;
    aebodsys='1';*will be used for sorting, this makes it unique and come out on top;
  end;

  if ins then do;
    descrip=aebodsys;
    ord=2;
    cv0='';cv1='';cv2='';cv3='';cv4='';cv5='';
  end;*/

  if inp then do;
    ord=10000-c0;*gives descending;
    descrip=aedecod;
  end;

  drop c0-c5;
```

```
  drop _name_ _label_;
run;


ods listing close;
ods rtf file="&_outpath\t-&outno.-ae-pt&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";

%footsrce(line=1);


proc report data=final nowindows headskip split='@';
columns  ord descrip
           cv0 ;

  define ord / order order=internal noprint;
  define descrip / order "                                Patient Population@    @MedDRA Preferred
Term"  style=[cellwidth=4.6 in asis=on] left
           style(header)=[just=left asis=on];

  define cv0 / display "Full Analysis Set@N=&tot@n    %" style=[cellwidth=.9 in] center;/*
  define cv1 / display "Grade 1" style=[cellwidth=.9 in] center;
  define cv2 / display "Grade 2" style=[cellwidth=.9 in] center;
  define cv3 / display "Grade 3" style=[cellwidth=.9 in] center;
  define cv4 / display "Grade 4" style=[cellwidth=.9 in] center;
  define cv5 / display "Grade 5" style=[cellwidth=.9 in] center;*/



run;

ods rtf close ;
ods listing;

%mend;


%ae(fasfl,%str(and aeser='Y'),Ser,treatment emergent SAE,Treatment Emergent Serious Adverse
Events,14.3.7.5,14-3-7-5);
%ae(fasfl,%str(and aeser='Y' and aerel='Related'),RelSer,treatment emergent Related SAE,Treatment
Related Serious Adverse Events,14.3.7.6,14-3-7-6);

%ae(fasfl,%str(and aeacn='Discontinued'),DC,leading to discontinuation of study therapy,Treatment
Emergent Adverse Events Leading to Withdrawal,14.3.7.7,14-3-7-7);
%ae(fasfl,%str(and aeacn='Discontinued' and aerel='Related'),RelDC,related adverse event leading
to discontinuation of study therapy,Treatment Related Adverse Events Leading to
Withdrawal,14.3.7.8,14-3-7-8);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       03.16.2013
/*Program:    t-aelist-all.sas
/*Purpose:    Creates AE Listings
/*Modifications:
  Rob Howard   3/19/2013  Changed program name from l_ae to t_aelist
  Pamela Hsu  10/15/2013  Add two listings - All of AEs Leading to Discountiuation
                          and SAE Leading to Discountinuation
/************************************************/

%let filename=t-aelist-all;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

%macro lae(where,title,tno,outno,subset,label);

data adae;
set db.adae;
  *analysis population, then subset where clause;
   where &where;

run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-aelist&subset..rtf" style=vg_rtf;

title3 "Table &tno: &title";

%footsrce(line=1);

%macro bypage(rows);

proc sort data=adae;
  by subjid;
run;

data adae;
set adae nobs=last;
  by subjid;
  if aeout='Resolved with Sequelae' then extra=1;
  if first.subjid then addspace=1;
  extra2=ceil(length(aeterm)/40)-1;
  retain row;
  if _n_=1 then row=1;
  else row=sum(row,1);
  add=sum(addspace,max(extra,extra2));
  row=sum(row,add);
  if _n_=last then call symput('pgs',put(ceil(row/&rows),best.));
run;

%do b=1 %to &pgs;

proc report data=adae nowindows headskip split='@';
where (&rows*(&b-1))+1<=row<=&rows*&b;
columns subjid ("_____&label._____"  aeterm
```

```
aedecod) aestdy aetoxgrn aerelfl aeacn aeout;

  define subjid / order "Patient" style(column)=[cellwidth=.8 in] center;
  define aeterm / display  "Investigator Term" style(column)=[cellwidth=2.8 in asis=on] left
style(header)=[just=left asis=on];
  define aedecod / display  "MedDRA Preferred Term" style(column)=[cellwidth=2.6 in asis=on] left
style(header)=[just=left asis=on];

  define aestdy / display "Study@Day" style(column)=[cellwidth=.6 in] center;
  define aetoxgrn / display "Tox@Grd" style(column)=[cellwidth=.6 in] center;
  define aerelfl / display "Rel" style(column)=[cellwidth=.6 in] center;
  define aeacn / display "Action@Taken" style(column)=[cellwidth=1 in] left;
  define aeout / display "Outcome" style(column)=[cellwidth=.8 in] left;

  compute before subjid;
    line put '';
  endcomp;

run;

%end;

%mend;

%bypage(33);

ods rtf close ;
ods listing;

%mend;

%lae(%str(fasfl='Y' and aeacn='Discontinued')
                 ,Listing of Patients with Any Adverse Events Leading to
Discontinuation,14.3.7.9,14-3-7-9,ae-discnt,Adverse Event);

%lae(%str(fasfl='Y' and aeser eq 'Y' and aeacn='Discontinued')
                 ,Listing of Patients with Serious Adverse Events Leading to
Discontinuation,14.3.7.10,14-3-7-10,sae-discnt,Adverse Event);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.24.2013
/*Program:    t_lab_event.sas
/*Purpose:    Treatment Emergent Clinical Laboratory Evaluation
/*Modifications:
        Bob Hull 4/4/2013: Updated formatting for new mock and added new tests.
        Bob Hull 7/5/2013: Fixed uninit message.
/************************************************/

%let filename=t-lab-event;
%let tabno=14.3.8.1;
%let outno=14-3-8-1;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


/*

proc freq data=db.adlb ;
tables lbtestcd*lbtoxgrn / list missing;
run;

*/

%macro shift(pop,title);

data lb;
set db.adlb;
  length descrip $200 lbcat2 $50;
  where &pop="Y";
  lbcat2=lbcat;*for those that do not need to be changed.;
  %macro tests(order,cat,code,name,highlow);

    ord=&order;
    if lbcat="&cat" and lbtestcd="&code" then do;
      highlow="&highlow";
      if ord in (12 13 14 15 16) then lbcat2='Liver function';
      if 17<= ord <= 27 then lbcat2='Renal function';
      if ord>27 then lbcat2='Metabolic function';
      descrip=put(ord,z2.)||"&name"||"$"||strip(lbcat2);
      if lbstresn>. then output;
    end;
  %mend;

  %tests(1,Hematology,HGB,%str(Hemoglobin, low),L);
  %tests(2,Hematology,RBC,%str(Erythrocytes, low),L);
  %tests(3,Hematology,MCV,%str(MCV, low),L);
  %tests(4,Hematology,MCV,%str(MCV, high),H);
  %tests(5,Hematology,PLAT,%str(Platelets, low),L);
  %tests(6,Hematology,WBC,%str(Leukocytes, low),L);
  %tests(7,Hematology,NEUT,%str(Neutrophils, low),L);
  %tests(8,Hematology,LYM,%str(Lymphocytes, low),L);

  %tests(9,Coagulation,PT,%str(Prothrombin time, high),H);
  %tests(10,Coagulation,INR,%str(INR, high),H);
```

```
  %tests(11,Coagulation,APTT,%str(APTT, high),H);

  %tests(12,Serum Chemistry,BILI,%str(Bilirubin, high),H);
  %tests(13,Serum Chemistry,ALP,%str(Alkaline phosphatase, high),H);
  %tests(14,Serum Chemistry,ALT,%str(ALT, high),H);
  %tests(15,Serum Chemistry,AST,%str(AST, high),H);
  %tests(16,Serum Chemistry,ALB,%str(Albumin, low),L);


  %tests(17,Serum Chemistry,CREAT,%str(Creatinine, high),H);
  %tests(18,Serum Chemistry,BUN,%str(BUN, high),H);
  %tests(19,Serum Chemistry,URATE,%str(Urate (uric acid), high),H);
  %tests(20,Serum Chemistry,SODIUM,%str(Sodium, high),H);
  %tests(21,Serum Chemistry,SODIUM,%str(Sodium, low),L);
  %tests(22,Serum Chemistry,K,%str(Potassium, high),H);
  %tests(23,Serum Chemistry,K,%str(Potassium, low),L);
  %tests(24,Serum Chemistry,CL,%str(Chloride, high),H);
  %tests(25,Serum Chemistry,CL,%str(Chloride, low),L);
  %tests(26,Serum Chemistry,MG,%str(Magnesium, high),H);
  %tests(27,Serum Chemistry,MG,%str(Magnesium, low),L);

  %tests(28,Serum Chemistry,LDH,%str(LDH, high),H);
  %tests(29,Serum Chemistry,PHOS,%str(Phosphate, low),L);
  %tests(30,Serum Chemistry,CA,%str(Calcium, high),H);
  %tests(31,Serum Chemistry,CA,%str(Calcium, low),L);
  %tests(32,Serum Chemistry,GLUC,%str(Glucose, high),H);
  %tests(33,Serum Chemistry,GLUC,%str(Glucose, low),L);

  *keep usubjid descrip highlow visit visitnum lbdy lbtrtem lbtoxgrn lbblfl ord lbtestcd lbnrind
lbstresn;
run;


*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where &pop="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;


data lb2;
set lb;
  where lbtrtem='Y';*get on-study labs only;
  *as of 2/23/2013 all of the Normal values with a grade are low grades.;
  if highlow='H' and lbnrind in ('Low' 'Normal') then lbtoxgrn=0;*these are low results and
should not count towards high;
  if highlow='L' and lbnrind='High' then lbtoxgrn=0;*high results set to 0 for low records. ;

  *tests added to output that do not have LBTOXGRN populated, only normal/abnormal shown. This
code will give them an abnormal
    value, but they will not show up in the tox grade columns;
  if highlow='H' and lbnrind='High' and lbtoxgrn=. then lbtoxgrn=9;
  if highlow='L' and lbnrind='Low' and lbtoxgrn=. then lbtoxgrn=9;
```

```
run;
/*
proc sort data=lb2 out=mcv nodupkey;
where descrip=:'32' and lbnrind='High';
by usubjid;
run;

proc sort data=lb2 out=nozar (keep=usubjid) nodupkey;
where descrip=:'32' and lbnrind='High' and lbmaxfl ='Y';
by usubjid;
run;

data find;
merge mcv (in=inm) nozar (in=inn);
  by usubjid;
  if not (inm and inn);
run;

proc print data=find;
run;

proc print data=lb2 width=min;
where usubjid='CLN19-907-005' and descrip=:"32";
run;

proc print data=mcv;
run;*/


*if they do not have a post-baseline record then they are removed from analysis. No where to put
them. ;
proc sort data=lb2 out=lb3;
  by usubjid descrip lbtoxgrn;
run;

*get the counts (denominator) for each test;
proc sort data=lb3 out=lbtot nodupkey;
  by usubjid descrip;
run;

proc freq data=lbtot;
  tables descrip / out=totcnts (rename=count=totcount) noprint;
run;

data shift;
set lb3;
  by usubjid descrip lbtoxgrn;
  *output worst grade for each test, and then again if they had any abnormality (set to 5);
  if last.descrip then do;
    output;
    if lbtoxgrn>0 then do;
       lbtoxgrn=5;
       output;
     end;
  end;
run;

proc sort data=shift;
```

```
  by descrip;
run;

*get the counts for each individual cell;
proc freq data=shift;
  tables descrip*lbtoxgrn / out=allcounts noprint;
run;

*transpose data and format for the table;
proc transpose data=allcounts out=allcnt2 prefix=c;
  by descrip;
  where lbtoxgrn ne .;
  var count;
  id lbtoxgrn;
run;

data final;
merge allcnt2 totcnts (in=int);
  by descrip ;
  length cv1-cv5 totc $15;

  subord=1;
  if totcount=&tot then totc=put(totcount,3.)||' ('||put(totcount/&tot*100,3.)||')';
  else totc=put(totcount,3.)||' ('||put(totcount/&tot*100,4.1)||')';

  array counts(*) c1-c5;
  array charvar(*) Cv1-cv5;
  do i=1 to 5;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||' ('||put(counts(i)/totcount*
100,5.1)||')';
    else charvar(i)='-';
  end;

  *pulling order/category out of descrip;
  ord=input(substr(descrip,1,2),best.);
  cat=scan(descrip,2,'$');
  descrip='   '||substr(scan(descrip,1,'$'),3);

  if ord<9 then catord=1;
  else if ord<12 then catord=2;
  else if ord<17 then catord=3;
  else if ord<28 then catord=4;
  else catord=5;

  *page grouping var;
 if catord>=4 then page=2;
 else page=1;

  if ord in (1 9 12 17 28) then do;
    output;
    subord=0;
    cv1='';cv2='';cv3='';cv4='';cv5='';totc='';
    descrip=cat;
    output;
  end;
  else output;
  drop c0-c5;
run;
```

```
ods listing close;
ods rtf file="&_outpath\t-&outno.-lab-event.rtf" style=vg_rtf;

title3 "Table &tabno: Treatment Emergent Clinical Laboratory Evaluation";

footnote1 j=l "Treatment-emergent tests were from samples collected after study day 1 through 30
days post last dose of any study drug.";
%footsrce(line=2);


proc report data=final nowindows headskip split='@';
columns page catord ord subord ("Full Analysis Set             " ("N=&tot" descrip )) ("Number Of
Patients (%)"  totc  cv5
                                                ('________Worst CTCAE Grade on
Treatment________' cv1 cv2 cv3 cv4));

  define page / order order=internal noprint;
  define catord / order order=internal noprint;
  define ord / order order=internal noprint;
  define subord / order order=internal noprint;
  define descrip / order 'Laboratory Test'  style(column)=[cellwidth=2 in asis=on] style(header)=
[just=left] left ;
  define totc / display "Patients with@On study Test"  style(column)=[cellwidth=.9 in] center;
  define cv5 / display "Incidence of@Abnormality" style(column)=[cellwidth=.9 in] center;
  define cv1 / display "Grade 1" style(column)=[cellwidth=.9 in] center;
  define cv2 / display "Grade 2" style(column)=[cellwidth=.9 in] center;
  define cv3 / display "Grade 3" style(column)=[cellwidth=.9 in] center;
  define cv4 / display "Grade 4" style(column)=[cellwidth=.9 in] center;

  break after page / page;

  compute before catord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%shift(fasfl,lab_event);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Bob Hull
/*Date:       02.23.2013
/*Program:    t_labshift.sas
/*Purpose:    Labshift Table
/*Modifications:

Bob Hull 4/4/2013: Updated formatting for new mock.
/************************************************/

%let filename=t-labshift;
%let tabno=14.3.8.2;
%let outno=14-3-8-2;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


/*    Toxicity grades and normal ranges do not usually match up, same is the case here. There are
57 results across various tests
      which are normal but have a tox grade. In looking through them they are all low grades now.
A variable would need to
      be added to the analysis dataset to indicate if these are high/low tox grades to remove
ambiguity. I will assume
      they are all low for now.

/*
proc print data=lb  width=min;
where  usubjid='CLN19-100-001' and descrip='Hemoglobin, decreased';
run;

proc print data=db.adlb  width=min;
where  usubjid='CLN19-100-001' and lbtestcd='HGB';
run;

proc print data=db.adlb width=min;
where lbtestcd='SODIUM' AND LBBLFL='Y' and lbtoxgrn>0;
RUN;*/

%macro shift(pop,title);

data lb;
set db.adlb;
  length descrip $200;
  where &pop="Y";

  %macro tests(order,cat,code,name,highlow);

    ord=&order;
    if lbcat="&cat" and lbtestcd="&code" then do;
      descrip=put(ord,z2.)||"&name";
      highlow="&highlow";
      if descrip ne '' and lbstresn>. then output;
    end;
  %mend;

  %tests(1,Hematology,HGB,%str(Hemoglobin, decreased),L);
```

```
  %tests(2,Hematology,PLAT,%str(Platelet count, decreased),L);
  %tests(3,Hematology,WBC,%str(Leukocyte count, decreased),L);
  %tests(4,Hematology,NEUT,%str(Neutrophil count, decreased),L);
  %tests(5,Hematology,LYM,%str(Lymphocyte count, decreased),L);
  %tests(6,Coagulation,PT,%str(Prothrombin time, increased),H);
  %tests(7,Coagulation,INR,%str(INR, increased),H);
  %tests(8,Coagulation,APTT,%str(APTT, increased),H);
  %tests(9,Serum Chemistry,BILI,%str(Bilirubin, increased),H);
  %tests(10,Serum Chemistry,ALP,%str(Alkaline phosphatase, increased),H);
  %tests(11,Serum Chemistry,ALT,%str(Alanine transaminase, increased),H);
  %tests(12,Serum Chemistry,AST,%str(Aspartate transaminase, increased),H);
  %tests(13,Serum Chemistry,ALB,%str(Albumin, decreased),L);
  %tests(14,Serum Chemistry,CREAT,%str(Creatinine, increased),H);
  %tests(15,Serum Chemistry,URATE,%str(Urate (uric acid), increased),H);
  %tests(16,Serum Chemistry,SODIUM,%str(Sodium, increased),H);
  %tests(17,Serum Chemistry,SODIUM,%str(Sodium, decreased),L);
  %tests(18,Serum Chemistry,K,%str(Potassium, increased),H);
  %tests(19,Serum Chemistry,K,%str(Potassium, decreased),L);
  %tests(20,Serum Chemistry,MG,%str(Magnesium, increased),H);
  %tests(21,Serum Chemistry,MG,%str(Magnesium, decreased),L);
  %tests(22,Serum Chemistry,PHOS,%str(Phosphate, decreased),L);
  %tests(23,Serum Chemistry,CA,%str(Calcium, increased),H);
  %tests(24,Serum Chemistry,CA,%str(Calcium, decreased),L);
  %tests(25,Serum Chemistry,GLUC,%str(Glucose, increased),H);
  %tests(26,Serum Chemistry,GLUC,%str(Glucose, decreased),L);


  keep usubjid descrip highlow visit visitnum lbdy lbtrtem lbtoxgrn lbblfl ord lbtestcd lbnrind
lbstresn;
run;

data lb;
set lb;
*this has to be done after all the output statements have completed.;
  *as of 2/23/2013 all of the Normal values with a grade are low grades.;
  if highlow='H' and lbnrind in ('Low' 'Normal') then lbtoxgrn=0;*these are low results and
should not count towards increased;
  if highlow='L' and lbnrind='High' then lbtoxgrn=0;*high results set to 0 for low records. ;
run;


*get total number of patients for header;
proc sort data=db.adsl out=patcnt (keep=usubjid) nodupkey;
  by usubjid;
  where &pop="Y";
run;

data _null_;
set patcnt nobs=last;
  if _n_=last then call symput('tot',put(_n_,3.));
run;



*merging on the baseline result to all records for that test;
proc sort data=lb out=baseline (keep=usubjid descrip lbtoxgrn rename=(lbtoxgrn=basetox));
  by usubjid descrip;
  where lbblfl='Y';
```

```
run;

proc sort data=lb;
  by usubjid descrip;
run;

data lb2;
merge lb (in=inl) baseline (in=inb);
  by usubjid descrip;
  if inl;* and inb;*no place for records that do not have a baseline result;
run;

data lb2;
set lb2;
  if basetox=. then basetox=6;
run;

*if they do not have a post-baseline record then they are removed from analysis. No where to put
them. ;
proc sort data=lb2 out=lb3;
  by usubjid descrip lbtoxgrn;
  where lbtrtem='Y';
run;

*get the counts for each test;
proc sort data=lb3 out=lbtot nodupkey;
  by usubjid descrip;
run;

proc freq data=lbtot;
  tables descrip / out=totcnts (rename=count=totcount) noprint;
run;

data totcnts;
set totcnts;
 *merge onto all rows for denominator.;
  do basetox=0 to 6;
    output;
  end;
run;

data shift;
set lb3;
  by usubjid descrip lbtoxgrn;
  tempbase=basetox;
  temptox=lbtoxgrn;
  *output once for regular, once for total basetox row, once for total grade column, and once for
total of both, excluding grade 0 in totals;
  if last.descrip then do;
    output;
    basetox=5;
    output;
    basetox=tempbase;
    lbtoxgrn=5;
    /*if temptox ne 0 then*/ output;
    basetox=5;
    lbtoxgrn=5;
   /* if temptox ne 0 then*/ output;
```

```
  end;
run;

proc sort data=shift;
  by descrip basetox;
run;

*get the counts for each individual cell;
proc freq data=shift;
  tables descrip*basetox*lbtoxgrn / out=allcounts noprint;
run;

*transpose data and format for the table;
proc transpose data=allcounts out=allcnt2 prefix=c;
  by descrip basetox;
  var count;
  id lbtoxgrn;
run;

*get a skeleton of data with all of the tests and baseline tox rows;
proc sort data=lb out=skel (keep=descrip) nodupkey;
  by descrip;
run;

data skel2;
set skel;
  do basetox=0 to 6;
    output;
  end;
run;

data final;
merge skel2 allcnt2 totcnts (in=int);
  by descrip basetox;
  length cv0-cv5 $13;
  array counts(*) c0-c5;
  array charvar(*) Cv0-cv5;
  do i=1 to 6;
    if counts(i) ne . then charvar(i)=strip(put(counts(i),3.))||' ('||strip(put(counts
(i)/totcount*100,5.1))||'%)';
    else charvar(i)='-';
  end;
  *if basetox=5 then cv0='-';*this row/column is not totaled since it is basetox=0 and labtox=0;
  bgrade='Grade '||strip(put(basetox,1.));
  if basetox=5 then bgrade='Total';
  if basetox=6 then bgrade='Unknown';

  subord=basetox;
  if subord=6 then subord=4.5;

  descrip=tranwrd(descrip,'decreased','low');
  descrip=tranwrd(descrip,'increased','high');

  *page grouping var;
  page=ceil(_n_/21);

  *pulling order out of descrip;
  ord=input(substr(descrip,1,2),best.);
```

```
  descrip=substr(descrip,3);
  drop c0-c5;
run;

ods listing close;
ods rtf file="&_outpath\t-&outno.-labshift.rtf" style=vg_rtf;

title3 "Table &tabno: Shift in Laboratory Values from Baseline Grade to Worst Grade On-study";

footnote1 j=l "Baseline samples were the last sample on or before the day of first dose of study
treatment.";
footnote2 j=l "On-study samples were those collected after study day 1 through 30 days post last
dose of any study treatment.";
%footsrce(line=3);


proc report data=final nowindows headskip split='@';
columns page ord ("Full Analysis Set@  @  " descrip) totcount subord bgrade ("Number of
Patients@N=&tot@Worst On-study Toxicity Grade" cv0 cv1 cv2 cv3 cv4 cv5);
  define page / order order=internal noprint;
  define ord / order order=internal noprint;
  define descrip / order "Laboratory Abnormality"  style(column)=[cellwidth=1.7 in] left style
(header)=[just=left];
  define totcount / order "Number@of Pts"  style(column)=[cellwidth=.7 in] center;
  define subord / order order=internal noprint;
  define bgrade / display "Baseline@Grade"  style(column)=[cellwidth=.7 in] left;
  define cv0 / display "Grade 0" style(column)=[cellwidth=.8 in] center;
  define cv1 / display "Grade 1" style(column)=[cellwidth=.8 in] center;
  define cv2 / display "Grade 2" style(column)=[cellwidth=.8 in] center;
  define cv3 / display "Grade 3" style(column)=[cellwidth=.8 in] center;
  define cv4 / display "Grade 4" style(column)=[cellwidth=.8 in] center;
  define cv5 / display "Total" style(column)=[cellwidth=.8 in] center;
  break after page / page;
  compute before ord;
    line put '';
  endcomp;

run;

ods rtf close ;
ods listing;

%mend;

%shift(fasfl,labshift);
```

```
/************************************************/
/*Client:     Spectrum
/*Protocol:   Belinostat PXD101-CLN-19
/*Programmer: Gajanan Bhat
/*Date:       07.24.2013
/*Program:    t_VS.sas
/*Purpose:    Creates VS summary
/*Modifications:


/************************************************/

%let filename=t-vs;
%let tno=14.3.8.3;
%let outno=14-3-8-3;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";


proc format;
  value cat
    1="Entered study therapy"
    2="Still on study therapy"
    3="Discontinued study therapy"
    4="  Primary reason for discontinuation"
    5="Patient status at the cut-off date";
  value disreas
    1="Progressive Disease"
    2="Death"
    3="Adverse Event"
    4="Stem Cell Transplant"
    5="Withdrawal by Patient"
    6="Physician Decision"
    7="Lost to follow-up";
  value survstat
    1="Alive"
    2="Dead"
    3="No follow-up for >12 mon";
run;

proc sort data=db.advs out=vs;
     by usubjid visit vstest;
     where vstestcd in('SYSBP','DIABP','HR','TEMP');
run;

data vs;
     set vs;
     by usubjid visit vstest;
     if last.vstest;
run;

proc sort data=vs out=vsend;
     by usubjid vstest vsdt;
run;

data vsprend;
     set vsend;
     by usubjid vstest vsdt;
```

```
    if last.vstest or visit in('Pre-trial');
run;

data vsprend;
    set vsprend;
    by usubjid vstest vsdt;
    length vis $20;
    if first.vstest then vis='Pre-trial';
    else if last.vstest then vis='End of Trial';
run;

proc sort data=vsprend;
    by usubjid vstest vis;
run;

proc transpose data=vsprend out=vs1;
    var vsstresn;
    by usubjid vstest;
    id vis;
run;

data vs1;
    set vs1;
    by usubjid vstest;
    if pre_trial ne . and end_of_trial ne . then change=end_of_trial - pre_trial;
    label end_of_trial='Last Timepoint' pre_trial='Baseline' change='Change from Baseline';
run;

proc sort data=vs1;
    by vstest;
run;

proc freq data=vs1;
tables vstest;
run;


options nobyline;
ods listing close;
ods rtf file="&_outpath\t-&outno.-VS.rtf" style=vg_rtf;

title3 "Table &tno: Summary of Vital Signs";
footnote1 j=l "Last Timepoint is last assessment in a patient on the study";
%footsrce(line=2);

title4 "Systolic Blood Pressure";

proc means data=vs1;
    var pre_trial end_of_trial change;
    by vstest;
    where vstest='Systolic Blood Pressure';
run;

title4 "Diastolic Blood Pressure";

proc means data=vs1;
    var pre_trial end_of_trial change;
    by vstest;
```

```
    where vstest='Diastolic Blood Pressure';
run;

title4 "Heart Rate";

proc means data=vs1;
    var pre_trial end_of_trial change;
    by vstest;
    where vstest='Heart Rate';
run;

title4 "Temperature";

proc means data=vs1;
    var pre_trial end_of_trial change;
    by vstest;
    where vstest='Temperature';
run;

ods rtf close ;
ods listing;
```

```
*******************************************************
*PROGRAM::       t_abnorm_lab
*PROJECT::       CLN19
*AUTHOR::        Pamela Hsu
*DATE::          09/20/2014
*MODIFICATIONS (Date - Author - Description):
*
*******************************************************;

%let filename=t-abnorm-lab;
%let tabno=14.3.8.4;
%let outno=14-3-8-4;

%include "M:\Clinical\Belinostat\Study\CLN-19\Programs\vg_init.sas";

proc sql noprint;
    create table lab as
    select a.* ,b.armn
    from sdtm.lb as a,db.adsl as b
    where a.usubjid=b.usubjid and b.saffl='Y';
quit;

data report;
    set lab;
    where LBNRIND in ('HIGH', 'LOW');
    pid=substr(usubjid,7);
    abn=substr(lbnrind,1,1);
proc sort;
    by usubjid;
run;

footnote1 j=l "^{super a}Abnormality: L=Low, H=High";
%footsrce(line=2);


%let uline = %qsysfunc(repeat(%str(_),12));


ods listing close;

title3 "Table &tabno: Abnormal Laboratory Value Listing";


ods rtf file="&_outpath\t-&outno.-abnormal-lab.rtf" style=vg_rtf;

proc report data=report nowd headline headskip split = '|' missing style=[cellpadding=1.5]
spanrows;
    column pid visitnum visit lbdtc lbtest lbstresc lbstresu abn ("Normal Range|&uline" lbstnrlo
lbstnrhi);

    define pid/'Patient|ID' center style(column)=[cellwidth=0.85in] order id;
    define visitnum/order noprint order=internal;
    define visit/left order 'Visit'  style(column)=[cellwidth=.85in] style(header)={just=left}id;
    define lbdtc/left order 'Sample|Date/time' style(column)=[cellwidth=1.4in] style(header)=
{just=c}id;
    define lbtest/ left 'Test Name' style(column)=[cellwidth=1.9in] style(header)={just=left}id;
    define lbstresc/ left 'Result|(SI)' style(column)=[cellwidth=0.65in] style(header)=
{just=left};
```

```
    define lbstresu/ left 'Unit|(SI)' style(column)=[cellwidth=0.6in] style(header)={just=left};
    define abn/ center 'Abnorm-|ality^{super a}' style(column)=[cellwidth=0.6in];
    define lbstnrlo/left 'Low' style(column)=[cellwidth=0.5in] style(header)={just=left};
    define lbstnrhi/left 'High' style(column)=[cellwidth=0.5in] style(header)={just=left};
    compute before pid;
        line ' ';
    endcomp;

run;


ods _ALL_ close;
ods listing;
```