

\*\*\*\*\* List of reported SAE's \*\*\*\*\*

-&gt; group == A:control

|             |  |
|-------------|--|
| ssoccd      | Soccode  |
| aeterm      | Event term                                       |
| affected    | Subjects affected number                         |
| exposed     | Subjects exposed number                          |
| occurrences | Occurrences all number                           |
| occurrel    | Occurrences causally related to treatment number |
| fatality    | Fatalities number                                |
| fatalrel    | Fatalities causally related to treatment number  |

|  | ssoccd                              | aeterm | affected | exposed | occurrences | occurrel | fatality | fatalrel |
|--|-------------------------------------|--------|----------|---------|-------------|----------|----------|----------|
| Blood and lymphatic system disorders                 | Coagulopathy                        |        | 1        | 186     | 1           | 1        | .        | .        |
| Blood and lymphatic system disorders                 | Febrile Neutropenia                 |        | 2        | 186     | 2           | 2        | .        | .        |
| Blood and lymphatic system disorders                 | Febrile neutropenia                 |        | 9        | 186     | 9           | 9        | .        | .        |
| Blood and lymphatic system disorders                 | Hemolytic anemia                    |        | 1        | 186     | 1           | .        | .        | .        |
| Blood and lymphatic system disorders                 | Leukopenia                          |        | 1        | 186     | 1           | 1        | .        | .        |
| Blood and lymphatic system disorders                 | Neutropenic fever                   |        | 6        | 186     | 6           | 5        | .        | .        |
| Blood and lymphatic system disorders                 | Subfebrile neutropenia              |        | 1        | 186     | 1           | 1        | .        | .        |
| Cardiac disorders                                    | Myocard infarction                  |        | 1        | 186     | 1           | .        | .        | .        |
| Cardiac disorders                                    | Pericarditis                        |        | 1        | 186     | 1           | .        | .        | .        |
| Cardiac disorders                                    | Tachycardia                         |        | 1        | 186     | 1           | .        | .        | .        |
| Gastrointestinal disorders                           | Abdominal perforation               |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Acute Pancreatitis                  |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Acute pancreatitis                  |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Colitis                             |        | 2        | 186     | 2           | 2        | .        | .        |
| Gastrointestinal disorders                           | Constipation                        |        | 3        | 186     | 3           | 1        | .        | .        |
| Gastrointestinal disorders                           | Diarrhea                            |        | 4        | 186     | 4           | 1        | .        | .        |
| Gastrointestinal disorders                           | Distal ileitis                      |        | 1        | 186     | 1           | .        | .        | .        |
| Gastrointestinal disorders                           | Enterocolitis                       |        | 1        | 186     | 1           | .        | .        | .        |
| Gastrointestinal disorders                           | Hematemesis                         |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Hemorrhagic gastritis               |        | 1        | 186     | 1           | .        | .        | .        |
| Gastrointestinal disorders                           | Nausea vomiting                     |        | 1        | 186     | 1           | .        | .        | .        |
| Gastrointestinal disorders                           | Nausea, throw up                    |        | 1        | 186     | 1           | .        | .        | .        |
| Gastrointestinal disorders                           | Obstruction Colon                   |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Oral Mucositis                      |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Oral mucositis                      |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Oral mucositis grade 3              |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Pancreatitis                        |        | 1        | 186     | 1           | 1        | .        | .        |
| Gastrointestinal disorders                           | Vomiting                            |        | 3        | 186     | 3           | 3        | .        | .        |
| General disorders and administration site conditions | Death                               |        | 1        | 186     | 1           | .        | 1        | .        |
| General disorders and administration site conditions | Death NOS (not otherwise specified) |        | 1        | 186     | 1           | 1        | 1        | 1        |
| General disorders and administration site conditions | Extravasation                       |        | 1        | 186     | 1           | 1        | .        | .        |
| General disorders and administration site conditions | Fever                               |        | 9        | 186     | 10          | 3        | .        | .        |
| General disorders and administration site conditions | Fever (not neutropenic)             |        | 2        | 186     | 2           | 1        | .        | .        |
| General disorders and administration site conditions | Fever e.c.i.                        |        | 1        | 186     | 1           | 1        | .        | .        |
| General disorders and administration site conditions | Lung infection                      |        | 1        | 186     | 1           | 1        | .        | .        |
| General disorders and administration site conditions | Malaise                             |        | 3        | 186     | 3           | 3        | .        | .        |
| General disorders and administration site conditions | Mucositis                           |        | 5        | 186     | 6           | 5        | .        | .        |
| Hepatobiliary disorders                              | Cholecystitis (acalculouse)         |        | 1        | 186     | 1           | .        | .        | .        |
| Hepatobiliary disorders                              | Hepatic failure                     |        | 2        | 186     | 2           | 2        | 1        | 1        |
| Hepatobiliary disorders                              | Hepatic impairment                  |        | 1        | 186     | 1           | 1        | .        | .        |
| Hepatobiliary disorders                              | Hepatic veno-occlusive disease      |        | 1        | 186     | 1           | 1        | .        | .        |
| Hepatobiliary disorders                              | Hepatitis                           |        | 1        | 186     | 1           | 1        | .        | .        |
| Hepatobiliary disorders                              | Hepatotoxicity                      |        | 1        | 186     | 1           | 1        | .        | .        |
| Hepatobiliary disorders                              | Liver function disorder             |        | 1        | 186     | 1           | 1        | .        | .        |
| Immune system disorders                              | AGVHD                               |        | 1        | 186     | 1           | 1        | .        | .        |
| Immune system disorders                              | Acute GVHD                          |        | 1        | 186     | 1           | .        | 1        | .        |
| Immune system disorders                              | GVHD                                |        | 2        | 186     | 2           | 1        | .        | .        |
| Immune system disorders                              | Graft versus host disease           |        | 1        | 186     | 1           | 1        | .        | .        |
| Immune system disorders                              | GvHD                                |        | 2        | 186     | 2           | 1        | 1        | .        |
| Infections and infestations                          | (upper)respiratory infection        |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | Abdominal infection                 |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | Airway infection                    |        | 1        | 186     | 1           | .        | .        | .        |
| Infections and infestations                          | Bacteremia (Enterobacter cloacae)   |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | CVL infection (Hickman)             |        | 1        | 186     | 1           | .        | .        | .        |
| Infections and infestations                          | Catheter related infection          |        | 2        | 186     | 2           | .        | .        | .        |
| Infections and infestations                          | Catheter sepsis                     |        | 2        | 186     | 3           | .        | .        | .        |
| Infections and infestations                          | Cellulitis orbita sinistra          |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | Colitis, infectious                 |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | Dental infection                    |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | Device related infection            |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | E. Coli sepsis                      |        | 1        | 186     | 1           | 1        | .        | .        |
| Infections and infestations                          | Fungal infection                    |        | 1        | 186     | 1           | .        | .        | .        |

|   |   |   |     |   |   |   |   |
|---|---|---|-----|---|---|---|---|
| Infections and infestations                     | Gastro enteritis  | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | HHV6 pneumonia  | 1 | 186 | 1 | 1 | 1 | 1 |
| Infections and infestations                     | Infection   | 2 | 186 | 2 | 2 | . | . |
| Infections and infestations                     | Infection (CVC) with normal ANC                         | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection - candida                                     | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection - catheter related                            | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection - wound (retrosternal)                        | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection catheter related (CVC)                        | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Infection e.c.i.  | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection gastrointestinal (norovirus)                  | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection gr 4 ANC                                      | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Infection normal ANC                                    | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Infection skin: erysipelas                              | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Infection with normal ANC-general: blood and pleural *  | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Infection-urinary tract                                 | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Neutropenic fever                                       | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Neutropenic sepsis                                      | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Opportunistic infection (oesophagus)                    | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | PJP infection   | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Pneumonia   | 4 | 186 | 5 | 4 | 1 | 1 |
| Infections and infestations                     | Pulmonal aspergillus infection                          | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Respiratory infection                                   | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Rota virus infection                                    | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Sepsis with pseudomonas aeruginosa                      | 1 | 186 | 1 | . | 1 | . |
| Infections and infestations                     | Septic shock  | 3 | 186 | 3 | 2 | 2 | 1 |
| Infections and infestations                     | Sinusitis   | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Spondylodiscitis  | 2 | 186 | 2 | 1 | . | . |
| Infections and infestations                     | Tonsillitis   | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Upper respiratory infection                             | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Urinary Tract Infection                                 | 1 | 186 | 1 | 1 | . | . |
| Infections and infestations                     | Urinary tract infection                                 | 1 | 186 | 1 | . | . | . |
| Infections and infestations                     | Urosepsis   | 1 | 186 | 1 | 1 | . | . |
| Injury, poisoning and procedural complications  | Allergic reaction on trombocyte transfusion             | 1 | 186 | 1 | . | . | . |
| Injury, poisoning and procedural complications  | Morfine-intoxication                                    | 1 | 186 | 1 | . | . | . |
| Injury, poisoning and procedural complications  | Osteoporotic vertebral collapse                         | 1 | 186 | 1 | 1 | . | . |
| Injury, poisoning and procedural complications  | Subdural hematoma bilateral                             | 1 | 186 | 1 | . | . | . |
| Investigations                                  | ASAT / ALAT elevation                                   | 1 | 186 | 1 | 1 | . | . |
| Investigations                                  | Blood bilirubin increased                               | 1 | 186 | 1 | 1 | . | . |
| Investigations                                  | GGT increased   | 1 | 186 | 1 | 1 | . | . |
| Investigations                                  | Increased liver enzymes                                 | 1 | 186 | 1 | 1 | . | . |
| Investigations                                  | Prolonged clotting times (PT/aPTT)                      | 1 | 186 | 1 | 1 | . | . |
| Metabolism and nutrition disorders              | Dehydration   | 1 | 186 | 1 | 1 | . | . |
| Metabolism and nutrition disorders              | Glucose intolerance                                     | 1 | 186 | 1 | 1 | . | . |
| Metabolism and nutrition disorders              | Hypertriglyceridemia                                    | 1 | 186 | 1 | 1 | . | . |
| Metabolism and nutrition disorders              | Hypoalbuminemia   | 1 | 186 | 1 | 1 | . | . |
| Metabolism and nutrition disorders              | Hyponatremia  | 1 | 186 | 1 | 1 | . | . |
| Musculoskeletal and connective tissue disorders | Loss of strenght in both legs                           | 1 | 186 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders | Muscle pain   | 1 | 186 | 1 | 1 | . | . |
| Musculoskeletal and connective tissue disorders | Second osteoporotic fracture                            | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | CVA   | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Cerebral thrombosis                                     | 1 | 186 | 1 | 1 | . | . |
| Nervous system disorder                         | Convulsive syncope                                      | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Critical illness neuropathy (motor-neuropathy)          | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Drug toxicity   | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Headache  | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Ischemia cerebrovascular                                | 1 | 186 | 1 | 1 | . | . |
| Nervous system disorder                         | Nervous system disorders transient cerebral dysfunction | 1 | 186 | 1 | 1 | . | . |
| Nervous system disorder                         | Neurological symptoms                                   | 1 | 186 | 1 | 1 | . | . |
| Nervous system disorder                         | Neuropathy (motor)                                      | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Seizure   | 1 | 186 | 1 | . | . | . |
| Nervous system disorder                         | Seizures  | 1 | 186 | 1 | 1 | . | . |
| Nervous system disorder                         | Sinus thrombosis  | 2 | 186 | 2 | 2 | . | . |
| Nervous system disorder                         | Vasovagal episode                                       | 1 | 186 | 1 | . | . | . |
| Psychiatric disorders                           | Confusion   | 2 | 186 | 2 | 1 | . | . |
| Psychiatric disorders                           | Delirium  | 1 | 186 | 1 | . | . | . |
| Psychiatric disorders                           | Mood alteration: depression                             | 1 | 186 | 1 | . | . | . |
| Psychiatric disorders                           | Psychosis   | 1 | 186 | 2 | . | . | . |
| Psychiatric disorders                           | Suicide   | 1 | 186 | 1 | . | 1 | . |
| Renal and urinary disorders                     | Acute Renal insufficiency                               | 1 | 186 | 1 | 1 | . | . |
| Renal and urinary disorders                     | Acute renal insufficiency                               | 1 | 186 | 1 | 1 | . | . |
| Renal and urinary disorders                     | Renal failure   | 1 | 186 | 1 | 1 | . | . |
| Renal and urinary disorders                     | Renal insufficiency                                     | 1 | 186 | 1 | . | . | . |
| Renal and urinary disorders                     | Urinary retention                                       | 1 | 186 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders | Peri-engrafment respiratory distress syndrome           | 1 | 186 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Pneumothorax  | 1 | 186 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism                                      | 3 | 186 | 3 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders | Respiratory insufficiency                               | 3 | 186 | 3 | 2 | 1 | 1 |
| Respiratory, thoracic and mediastinal disorders | Thromboembolic event, pulmonary embolism                | 1 | 186 | 1 | 1 | . | . |

|  |   |   |     |   |   |   |   |
|--|---|---|-----|---|---|---|---|
| Skin and subcutaneous tissue disorders | Rash/desquamation   | 1 | 186 | 1 | . | . | . |
| Vascular disorders                     | Bleeding  | 1 | 186 | 1 | 1 | . | . |
| Vascular disorders                     | Collaps   | 1 | 186 | 1 | . | . | . |
| Vascular disorders                     | Deep vein thrombosis  | 1 | 186 | 1 | 1 | . | . |
| Vascular disorders                     | Deep venous thrombosis                                      | 1 | 186 | 1 | 1 | . | . |
| Vascular disorders                     | Infection with grade 4 neutrophils                          | 1 | 186 | 1 | 1 | . | . |
| Vascular disorders                     | Thromboembolic event  | 1 | 186 | 1 | 1 | . | . |
| Vascular disorders                     | Thrombosis  | 2 | 186 | 2 | 2 | . | . |
| Vascular disorders                     | Thrombus mass in the right jugular vein&inf vena subclavion | 1 | 186 | 1 | . | . | . |

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|-------------|--|
| ssoccd      | Soccode  |
| aeterm      | Event term                                       |
| affected    | Subjects affected number                         |
| exposed     | Subjects exposed number                          |
| occurrences | Occurrences all number                           |
| occurrel    | Occurrences causally related to treatment number |
| fatality    | Fatalities number                                |
| fatalrel    | Fatalities causally related to treatment number  |

|   | ssoccd  | aeterm | affected | exposed | occurrences | occurrel | fatality | fatalrel |
|---|---|--------|----------|---------|-------------|----------|----------|----------|
| Blood and lymphatic system disorders                        | Neutropenic fever                                   |        | 2        | 17      | 2           | 2        | .        | .        |
| Gastrointestinal disorders                                  | Gingivostomatitis                                   |        | 1        | 17      | 1           | 1        | .        | .        |
| Gastrointestinal disorders                                  | Ileus/ileum   |        | 1        | 17      | 1           | 1        | .        | .        |
| Gastrointestinal disorders                                  | Pancreatitis  |        | 1        | 17      | 1           | 1        | .        | .        |
| Gastrointestinal disorders                                  | Stomach antral vascular ectasia                     |        | 1        | 17      | 1           | 1        | .        | .        |
| General disorders and administration site conditions        | Mucositis   |        | 1        | 17      | 1           | 1        | .        | .        |
| Immune system disorders                                     | GvH disease   |        | 1        | 17      | 1           | .        | 1        | .        |
| Immune system disorders                                     | GvHD  |        | 1        | 17      | 1           | .        | .        | .        |
| Infections and infestations                                 | Perianal abscess                                    |        | 1        | 17      | 1           | 1        | .        | .        |
| Infections and infestations                                 | Septic shock  |        | 1        | 17      | 1           | 1        | .        | .        |
| Infections and infestations                                 | Viral infection                                     |        | 1        | 17      | 1           | 1        | .        | .        |
| Investigations  | Liver dysfunction                                   |        | 1        | 17      | 2           | 2        | .        | .        |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Admission based on ebv lymphoproliferative disorder |        | 1        | 17      | 1           | 1        | 1        | 1        |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | Neoplasm malignant                                  |        | 1        | 17      | 1           | .        | 1        | .        |
| Nervous system disorder                                     | Acute serotenergic syndrome                         |        | 1        | 17      | 1           | .        | .        | .        |
| Nervous system disorder                                     | Insult  |        | 1        | 17      | 1           | 1        | .        | .        |
| Renal and urinary disorders                                 | Renal failure                                       |        | 1        | 17      | 1           | 1        | .        | .        |
| Respiratory, thoracic and mediastinal disorders             | Lung embolism                                       |        | 1        | 17      | 1           | .        | .        | .        |
| Respiratory, thoracic and mediastinal disorders             | Lungembolism  |        | 1        | 17      | 1           | .        | .        | .        |
| Respiratory, thoracic and mediastinal disorders             | Pleural effusion                                    |        | 1        | 17      | 1           | 1        | .        | .        |
| Skin and subcutaneous tissue disorders                      | Rash - allergic reaction                            |        | 1        | 17      | 1           | 1        | .        | .        |
| Vascular disorders  | Thrombosis left arm                                 |        | 1        | 17      | 1           | .        | .        | .        |
| Vascular disorders  | Vena jugularis thrombosis left                      |        | 1        | 17      | 1           | 1        | .        | .        |

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|             |  |
|-------------|--|
| ssoccd      | Soccode  |
| aeterm      | Event term                                       |
| affected    | Subjects affected number                         |
| exposed     | Subjects exposed number                          |
| occurrences | Occurrences all number                           |
| occurrel    | Occurrences causally related to treatment number |
| fatality    | Fatalities number                                |
| fatalrel    | Fatalities causally related to treatment number  |

|                                      | ssoccd                              | aeterm | affected | exposed | occurrences | occurrel | fatality | fatalrel |
|--------------------------------------|-------------------------------------|--------|----------|---------|-------------|----------|----------|----------|
| Blood and lymphatic system disorders | Anemia                              |        | 1        | 171     | 1           | 1        | .        | .        |
| Blood and lymphatic system disorders | Febrile Neutropenia                 |        | 3        | 171     | 3           | 3        | .        | .        |
| Blood and lymphatic system disorders | Febrile neutropenia                 |        | 11       | 171     | 13          | 13       | .        | .        |
| Blood and lymphatic system disorders | Fever Neutropenia                   |        | 1        | 171     | 1           | 1        | .        | .        |
| Blood and lymphatic system disorders | Neutropenic fever                   |        | 6        | 171     | 6           | 6        | .        | .        |
| Blood and lymphatic system disorders | Pancytopenia                        |        | 2        | 171     | 2           | 1        | .        | .        |
| Cardiac disorders                    | Acute coronary syndrome             |        | 1        | 171     | 1           | 1        | .        | .        |
| Cardiac disorders                    | Atrial flutter                      |        | 1        | 171     | 1           | .        | .        | .        |
| Cardiac disorders                    | Cardiac arrest                      |        | 1        | 171     | 1           | 1        | .        | .        |
| Cardiac disorders                    | Cardiac arrest seizure              |        | 1        | 171     | 1           | .        | .        | .        |
| Endocrine disorders                  | Adrenal insufficiency               |        | 1        | 171     | 1           | .        | .        | .        |
| Gastrointestinal disorders           | Acute pancreatitis                  |        | 1        | 171     | 1           | 1        | .        | .        |
| Gastrointestinal disorders           | Constipation                        |        | 2        | 171     | 2           | 2        | .        | .        |
| Gastrointestinal disorders           | Drug induced stomatitis             |        | 1        | 171     | 1           | .        | .        | .        |
| Gastrointestinal disorders           | Gastro intestinal bleeding          |        | 1        | 171     | 1           | 1        | .        | .        |
| Gastrointestinal disorders           | High esophageal ulceration          |        | 1        | 171     | 1           | .        | .        | .        |
| Gastrointestinal disorders           | Intestinal Mucositis                |        | 1        | 171     | 1           | 1        | .        | .        |
| Gastrointestinal disorders           | Ischemic colitis                    |        | 1        | 171     | 1           | .        | .        | .        |
| Gastrointestinal disorders           | Left sacro ileitis                  |        | 1        | 171     | 1           | 1        | .        | .        |
| Gastrointestinal disorders           | Mucocutaneous ulcer small intestine |        | 1        | 171     | 1           | .        | .        | .        |

|  |  |   |     |    |   |   |   |
|--|--|---|-----|----|---|---|---|
| Gastrointestinal disorders                           | Mucositis, oral  | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Nausea   | 2 | 171 | 2  | 1 | . | . |
| Gastrointestinal disorders                           | Nausea and vomiting  | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Oesophageal reflux   | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Oral mucositis   | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Pancreatitis   | 2 | 171 | 2  | 2 | . | . |
| Gastrointestinal disorders                           | Paralytic ileus  | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Stomatitis and ulcerative oesophagitis with herpes infection | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Vomiting   | 2 | 171 | 2  | 2 | . | . |
| Gastrointestinal disorders                           | Vomiting, diarrhea, weight loss                              | 1 | 171 | 1  | 1 | . | . |
| Gastrointestinal disorders                           | Vomitting  | 1 | 171 | 1  | 1 | . | . |
| General disorders and administration site conditions | Atypical pain thorax   | 1 | 171 | 1  | . | . | . |
| General disorders and administration site conditions | Death  | 1 | 171 | 1  | . | 1 | . |
| General disorders and administration site conditions | Edema  | 1 | 171 | 1  | 1 | . | . |
| General disorders and administration site conditions | Febrile non-neutropenia                                      | 1 | 171 | 1  | . | . | . |
| General disorders and administration site conditions | Fever  | 3 | 171 | 3  | 1 | . | . |
| General disorders and administration site conditions | Fever (maybe neutropenic)                                    | 1 | 171 | 1  | 1 | . | . |
| General disorders and administration site conditions | Fever E.C.I.   | 1 | 171 | 1  | 1 | . | . |
| General disorders and administration site conditions | Fever unk. origin  | 1 | 171 | 1  | 1 | . | . |
| General disorders and administration site conditions | Malaise  | 2 | 171 | 2  | 2 | . | . |
| General disorders and administration site conditions | Mucositis  | 4 | 171 | 6  | 6 | . | . |
| General disorders and administration site conditions | Post punctional pain   | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Drug-induced hepatitis                                       | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Hepatic impairment   | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Hepatotoxicity   | 2 | 171 | 2  | 2 | . | . |
| Hepatobiliary disorders                              | Liver disturbances   | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Liver failure  | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Liver function disorder                                      | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Liver function disorders                                     | 1 | 171 | 1  | 1 | . | . |
| Hepatobiliary disorders                              | Liver funtion disorder                                       | 1 | 171 | 1  | 1 | . | . |
| Immune system disorders                              | Acute GvHD   | 1 | 171 | 1  | . | . | . |
| Immune system disorders                              | Allergic reaction  | 1 | 171 | 1  | 1 | . | . |
| Immune system disorders                              | Allergic reaction Dasatinib                                  | 1 | 171 | 1  | . | . | . |
| Immune system disorders                              | Graft versus host disease (acute)                            | 1 | 171 | 1  | . | 1 | . |
| Immune system disorders                              | GvHD   | 1 | 171 | 2  | . | . | . |
| Immune system disorders                              | GvHD skin  | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Appendicular abcess  | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Aspergillus pneumonia  | 1 | 171 | 1  | 1 | 1 | 1 |
| Infections and infestations                          | Bacteremia   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | CMV reactivation   | 1 | 171 | 2  | . | . | . |
| Infections and infestations                          | CNS baceraemia   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | CNS bacteremia   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | CNS bacteriaemia   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | CVC infection (hickman)                                      | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Candida infection mouth                                      | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Catheter related infection                                   | 2 | 171 | 2  | 2 | . | . |
| Infections and infestations                          | Clostridium difficile colitis                                | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | E coli urinary tract infection and e faecalis                | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | E.Coli urinary tract infection                               | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | E.coli bacteriemie   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Escherichia coli sepsis                                      | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Fatal ongoing sepsis   | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Gastro enteritis   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Herpes Simplex infection                                     | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Hickman infection  | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Infection  | 2 | 171 | 2  | 2 | . | . |
| Infections and infestations                          | Infection - candidaemia                                      | 1 | 171 | 1  | 1 | 1 | 1 |
| Infections and infestations                          | Infection Gastro-intestinal NOS: Candida                     | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Infection central venous catheter                            | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Infection lung pneumocystis jirovecii                        | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Infection with grade 4 neutropenia                           | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Infection with normal neutrophils (anc)                      | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Lung infection   | 2 | 171 | 2  | 2 | . | . |
| Infections and infestations                          | Mucormycosis (zygomycosis) of sinus                          | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Neutropene sepsis  | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | PJP Pneumonia  | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Pansinusitis   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Perianal abcess  | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Pharyngitis  | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Pneumococcus pneumonia                                       | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Pneumonia  | 9 | 171 | 11 | 9 | 1 | 1 |
| Infections and infestations                          | Pneumonia with humaan metapneumovirus                        | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Possible aspergillosis                                       | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Pseudomonal sepsis   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Pulmonary aspergillosis                                      | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | Respiratory syncytical virus infection                       | 1 | 171 | 1  | . | . | . |
| Infections and infestations                          | S. aureus bacteremia   | 1 | 171 | 1  | 1 | . | . |
| Infections and infestations                          | Sepsis   | 3 | 171 | 3  | 2 | 1 | 1 |

|   |   |   |     |   |   |   |   |
|---|---|---|-----|---|---|---|---|
| Infections and infestations                                 | Septic arthritis at right sacroiliac joint        | 1 | 171 | 1 | . | . | . |
| Infections and infestations                                 | Septic shock                                      | 4 | 171 | 5 | 2 | 1 | 1 |
| Infections and infestations                                 | Severe sepsis                                     | 1 | 171 | 1 | 1 | . | . |
| Infections and infestations                                 | Severe sepsis (septic shock)                      | 1 | 171 | 1 | . | . | . |
| Infections and infestations                                 | Sinusitis   | 1 | 171 | 3 | 3 | . | . |
| Infections and infestations                                 | Spondylodiscitis Th10 + Th6-8                     | 1 | 171 | 1 | 1 | . | . |
| Infections and infestations                                 | Spondylodiscitis cervical                         | 1 | 171 | 1 | . | . | . |
| Infections and infestations                                 | Staphylococcus epidermidis septicemia             | 1 | 171 | 1 | 1 | . | . |
| Infections and infestations                                 | Urinary Tract Infection                           | 1 | 171 | 1 | . | . | . |
| Infections and infestations                                 | Varicella zoster infection                        | 1 | 171 | 1 | 1 | . | . |
| Infections and infestations                                 | Viral pulmoanry infection                         | 1 | 171 | 1 | . | . | . |
| Injury, poisoning and procedural complications              | Femur fracture                                    | 1 | 171 | 1 | . | . | . |
| Injury, poisoning and procedural complications              | Radiation pneumonitis                             | 1 | 171 | 1 | . | . | . |
| Injury, poisoning and procedural complications              | Spontaneous rupture of the spleen                 | 1 | 171 | 1 | 1 | . | . |
| Injury, poisoning and procedural complications              | Subcapital fracture left hip                      | 1 | 171 | 1 | . | . | . |
| Injury, poisoning and procedural complications              | Transfusion reaction                              | 1 | 171 | 1 | . | . | . |
| Injury, poisoning and procedural complications              | Vascular access complication                      | 1 | 171 | 1 | 1 | . | . |
| Investigations  | ALAT increased                                    | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Abnormal liver values                             | 1 | 171 | 1 | . | . | . |
| Investigations  | Acute elevated liverenzymes                       | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Blood bilirubin increased                         | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Cytomegalovirus                                   | 1 | 171 | 1 | . | . | . |
| Investigations  | Grade IV ^AST/^ALT liver functiontest             | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Hepatic enzyme disorder                           | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Increased ALAT (>10 ULN)                          | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Increased liver enzymes                           | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Increased liverenzymes                            | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Investigations: ASAT and ALAT increased           | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Liver enzymes severely elevated                   | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Transaminases elevated                            | 1 | 171 | 1 | 1 | . | . |
| Investigations  | Triglyceridemia                                   | 1 | 171 | 1 | 1 | . | . |
| Metabolism and nutrition disorders                          | Anorexia  | 1 | 171 | 1 | . | . | . |
| Metabolism and nutrition disorders                          | Diabetes  | 1 | 171 | 1 | 1 | . | . |
| Metabolism and nutrition disorders                          | Hypertriglyceridemia                              | 1 | 171 | 1 | 1 | . | . |
| Metabolism and nutrition disorders                          | Hypokalemia                                       | 1 | 171 | 1 | . | . | . |
| Metabolism and nutrition disorders                          | Hyponatrium, SIADH                                | 1 | 171 | 1 | 1 | . | . |
| Musculoskeletal and connective tissue disorders             | Backpain  | 1 | 171 | 1 | 1 | . | . |
| Musculoskeletal and connective tissue disorders             | Bone pain   | 1 | 171 | 1 | 1 | . | . |
| Musculoskeletal and connective tissue disorders             | Hospital admission for bone pain                  | 1 | 171 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders             | Pain hip  | 1 | 171 | 1 | . | . | . |
| Musculoskeletal and connective tissue disorders             | Pain right flank                                  | 1 | 171 | 1 | 1 | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | (Blood and lymf syst.disorders) relapse B-ALL     | 1 | 171 | 1 | . | . | . |
| Neoplasm benign, malignant and unspecif. (inc. cysts/polyp) | EBV + lyphomatoid granulomatosis                  | 1 | 171 | 1 | . | . | . |
| Nervous system disorder                                     | (post punction) headache                          | 1 | 171 | 1 | . | . | . |
| Nervous system disorder                                     | Admission for dizziness                           | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | CNS hemorrhage (subdural haematoma chron+acute)   | 1 | 171 | 1 | . | . | . |
| Nervous system disorder                                     | CSF leak  | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Cerebral encephalopathy                           | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Cortical vein thrombosis (left)                   | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Encephalopathy                                    | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Headache  | 3 | 171 | 3 | 1 | . | . |
| Nervous system disorder                                     | Hypesthesia lower body                            | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Idiopathic cranial hypertension                   | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Pain neurology headache                           | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Periferal motor tremor neuropathy (PNP)           | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Peripheral motor neuropathie                      | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Posterior reversible encephalopathy syndrome      | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Radicular syndrome                                | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Reversible posterior leukoencephalopathy syndrome | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Sinus thrombosis left                             | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Sinus trombosis                                   | 1 | 171 | 1 | 1 | . | . |
| Nervous system disorder                                     | Stroke (heamorrhagic)                             | 1 | 171 | 1 | 1 | 1 | 1 |
| Nervous system disorder                                     | Thrombosis cerebral vein                          | 1 | 171 | 1 | 1 | . | . |
| Psychiatric disorders                                       | Confusion   | 1 | 171 | 1 | 1 | . | . |
| Psychiatric disorders                                       | Mania   | 1 | 171 | 1 | 1 | . | . |
| Renal and urinary disorders                                 | Acute renal insufficiency                         | 1 | 171 | 1 | 1 | . | . |
| Renal and urinary disorders                                 | Acute renal toxicity                              | 1 | 171 | 1 | . | . | . |
| Renal and urinary disorders                                 | Kidney failure                                    | 1 | 171 | 1 | . | . | . |
| Renal and urinary disorders                                 | Kidney stone                                      | 1 | 171 | 1 | . | . | . |
| Renal and urinary disorders                                 | Obstruction ureter urolithiase                    | 1 | 171 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders             | Bronchopulmonary hemorrhage                       | 1 | 171 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders             | Bronchopulmonary hemorrhage                       | 1 | 171 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders             | Dyspnea   | 1 | 171 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders             | Hypoxemia   | 1 | 171 | 1 | . | . | . |
| Respiratory, thoracic and mediastinal disorders             | Pneumonia   | 1 | 171 | 1 | 1 | . | . |
| Respiratory, thoracic and mediastinal disorders             | Pulmonary embolism                                | 3 | 171 | 3 | 2 | . | . |
| Respiratory, thoracic and mediastinal disorders             | Respiratoire insufficiency                        | 1 | 171 | 1 | 1 | 1 | 1 |
| Respiratory, thoracic and mediastinal disorders             | Respiratory arrest                                | 1 | 171 | 1 | . | 1 | . |

|   |                            |   |     |   |   |   |   |
|---|----------------------------|---|-----|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | Respiratory failure        | 1 | 171 | 1 | 1 | 1 | 1 |
| Respiratory, thoracic and mediastinal disorders | Respiratory insufficiency  | 2 | 171 | 2 | 1 | 1 | . |
| Skin and subcutaneous tissue disorders          | Decubitus                  | 1 | 171 | 1 | . | . | . |
| Surgical and medical procedures                 | Cholecystectomy            | 1 | 171 | 1 | . | . | . |
| Surgical and medical procedures                 | Nefrectomy left            | 1 | 171 | 1 | . | . | . |
| Vascular disorders                              | Deep venous thrombosis     | 1 | 171 | 1 | . | . | . |
| Vascular disorders                              | Deep venous thrombosis DVT | 1 | 171 | 1 | 1 | . | . |
| Vascular disorders                              | Thromboembolic event       | 1 | 171 | 1 | . | . | . |
| Vascular disorders                              | Thrombosis right arm       | 1 | 171 | 1 | . | . | . |
| Vascular disorders                              | Tromboembolic event        | 1 | 171 | 1 | . | . | . |
| Vascular disorders                              | Veno occlusive disease     | 1 | 171 | 1 | 1 | . | . |