

***** List of reported NON-SERIOUS AE's *****

-> group == Arm1: Experimental (1 arm only)

ssoc	System organ class	aeterm	affected	exposed	occurrences
aeterm	Adverse Event term				
affected	Subjects affected number				
exposed	Subjects exposed number				
occurrences	Occurrences all number				
	ssoc				
blood/bone marrow	Bone marrow cellularity		1	54	1
blood/bone marrow	Catheter related		1	54	1
blood/bone marrow	Febrile neutropenia		1	54	1
blood/bone marrow	Hemoglobin		19	54	24
blood/bone marrow	Hemoglobine		3	54	3
blood/bone marrow	Infection, pneumonia		1	54	1
blood/bone marrow	Leucocytes		1	54	1
blood/bone marrow	Leucopenia		2	54	2
blood/bone marrow	Leukocytes		9	54	11
blood/bone marrow	Leukocytosis		1	54	1
blood/bone marrow	Leukocyts		1	54	1
blood/bone marrow	Leukopenia		3	54	4
blood/bone marrow	Neutorpenia		1	54	1
blood/bone marrow	Neutropenia		3	54	4
blood/bone marrow	Neutrophils		13	54	16
blood/bone marrow	Pancytopenia		1	54	1
blood/bone marrow	Platelets		26	54	30
blood/bone marrow	Thrombocytopenia		1	54	1
blood/bone marrow	Thrombopenia		2	54	3
blood/bone marrow	Trombocytopenia		1	54	1
cardiac arrhythmia	Atrial flutter		1	54	1
cardiac arrhythmia	Hemoglobin		1	54	1
cardiac arrhythmia	Supraventricular arrhythmia		1	54	2
cardiac general	Hypertension		5	54	5
cardiac general	Left ventricual systdic dysfun		1	54	1
cardiac general	Left ventricular systiolic dys		1	54	1
cardiac general	Symptomatic CHF		1	54	1
cardiac general	Vasovagal episode		1	54	1
coagulation	Febrile neutropenia		1	54	1
coagulation	Thrombotic microangiopathy		2	54	3
constitutional symptoms	Fatigue		3	54	3
dermatology/skin	Rash		2	54	2
endocrine	ADH (Si ADH)		1	54	1
endocrine	Diabetes		2	54	2
gastrointestinal	Anorexia		7	54	8
gastrointestinal	Ascites		1	54	1
gastrointestinal	Diarrhea		1	54	1
gastrointestinal	Nausea		1	54	1
gastrointestinal	Nausea --> TPV		1	54	1
gastrointestinal	Typhilitis		1	54	1
hemorrhage/bleeding	Venous catheter bleeding		1	54	1
infection	Bacteremia		4	54	5
infection	CMV reactivation		4	54	6
infection	Catheter related		1	54	1
infection	Cellutitis		1	54	1
infection	Cmv reactivation		1	54	1
infection	Cmv reactivsation		1	54	1
infection	EBV-reactivation-infection-		1	54	1
infection	Febrile neutrope nia		1	54	1
infection	Febrile neutropenia		28	54	37
infection	Fungal infection pulmonary		1	54	1
infection	Fungal infection sinus		1	54	1
infection	Fungal infection skin		1	54	1
infection	Infection		5	54	8
infection	Infection (throat)		1	54	1
infection	Infection gr. 3/4 ANC		1	54	1

infection	Infection, blood	2	54	3
infection	Infection, catheter related	1	54	1
infection	Infection, colon	1	54	1
infection	Infection, gastrointestinal	1	54	2
infection	Infection, oral cavity	1	54	1
infection	Infection, catheter related	1	54	1
infection	Infection, oral cavity-gums	1	54	1
infection	Infection, sinus (fungal)	1	54	1
infection	Infection, urinary tract NOS	1	54	1
infection	Infection-bladder	1	54	1
infection	Infection-catheter related	1	54	1
infection	Infection/catheter related/ANC	1	54	1
infection	Infection/lung	1	54	1
infection	Neutropenic fever	1	54	1
infection	Other: EBV reactivation	1	54	1
infection	Perianal infection	1	54	3
infection	Pneumonia	2	54	2
infection	Pneumonia (fungal)	1	54	1
infection	Pseudomonas aeruginosa	1	54	1
infection	Sinusitis	1	54	1
infection	Urinary tract	1	54	1
infection	Urinary tract NOS	1	54	1
metabolic/laboratory	Bilirubin increased	1	54	1
metabolic/laboratory	Bilirubin>3.0-10.0xULN	1	54	1
metabolic/laboratory	Bilirubine	1	54	1
metabolic/laboratory	GammaGT	1	54	1
metabolic/laboratory	Glucose	1	54	1
metabolic/laboratory	Glucose, serum high	1	54	1
metabolic/laboratory	Hyperglycemia	3	54	3
metabolic/laboratory	Hypocalcemia	3	54	4
metabolic/laboratory	Hypokalemia	1	54	1
metabolic/laboratory	Hypomagnesemia	3	54	4
metabolic/laboratory	Liver dysfunction	1	54	1
neurology	Depression	1	54	1
neurology	Dizziness	1	54	1
neurology	Neuropathy	1	54	1
neurology	Seizure	1	54	1
neurology	Tremor	1	54	1
ocular/visual	Keratoconjunctivitis	1	54	1
ocular/visual	Retina bleeding	1	54	1
ocular/visual	Retinal detachment	1	54	1
pain	Pain joints	1	54	1
pain	Pain, renal/genito urinary	1	54	1
renal/genitourinary	Renal failure	1	54	1
vascular	Peripheral arterial ischemia	1	54	1
vascular	Thrombosis	1	54	1
vascular	Thrombosis (*)	1	54	1
vascular	Thrombosis/embolism	2	54	2