

**Statistical Center for HIV/AIDS Research and Prevention  
HPTN 057i Safety Summary**

**ALL ADVERSE EXPERIENCES BY BODY SYSTEM AND SEVERITY**

**All Locations -- All Parts -- All Groups -- All Vaccinations  
Number of Enrolled Participants: 47  
Data as of October 25, 2007**

Body System	MedDRA Term	Mild		Moderate		Severe		Life Threat.		Total/Incidence	
		N	%	N	%	N	%	N	%	N	%
<i>Participants with one or more AE</i>		9	(19.1%)	20	(42.6%)	13	(27.7%)	3	(6.4%)	45	(95.7%)
<i>Blood and lymphatic system disorders</i>		3	(6.4%)	3	(6.4%)	1	(2.1%)	1	(2.1%)	8	(17.0%)
	<i>Anaemia</i>	3	(6.4%)	2	(4.3%)	1	(2.1%)	1	(2.1%)	7	(14.9%)
	<i>Neutropenia</i>	0	(0.0%)	2	(4.3%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
<i>Congenital, familial and genetic disorders</i>		1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Congenital hand malformation</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Congenital syphilis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Eye disorders</i>		1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Conjunctivitis</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Ophthalmia neonatorum</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Gastrointestinal disorders</i>		1	(2.1%)	1	(2.1%)	1	(2.1%)	0	(0.0%)	3	(6.4%)
	<i>Abdominal distension</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	<i>Constipation</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Nausea</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>General disorders and administration site condit</i>		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Vessel puncture site haematoma</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Infections and infestations</i>		3	(6.4%)	10	(21.3%)	7	(14.9%)	0	(0.0%)	20	(42.6%)
	<i>Abscess</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	<i>Abscess limb</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Gastroenteritis</i>	4	(8.5%)	1	(2.1%)	1	(2.1%)	0	(0.0%)	6	(12.8%)
	<i>Impetigo</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Malaria</i>	1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Neonatal infection</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Pneumonia</i>	0	(0.0%)	2	(4.3%)	2	(4.3%)	0	(0.0%)	4	(8.5%)

(Continued)

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Body System	MedDRA Term	Mild		Moderate		Severe		Life Threat.		Total/Incidence	
		N	%	N	%	N	%	N	%	N	%
<i>Infections and infestations</i>	<i>Respiratory tract infection</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Sepsis</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	<i>Sepsis neonatal</i>	1	(2.1%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	2	(4.3%)
	<i>Upper respiratory tract infection</i>	3	(6.4%)	10	(21.3%)	1	(2.1%)	0	(0.0%)	14	(29.8%)
	<i>Viral upper respiratory tract infection</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Injury, poisoning and procedural complications</i>		1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Arthropod bite</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Soft tissue injury</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Investigations</i>		11	(23.4%)	25	(53.2%)	5	(10.6%)	2	(4.3%)	43	(91.5%)
	<i>Alanine aminotransferase increased</i>	2	(4.3%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	<i>Aspartate aminotransferase increased</i>	17	(36.2%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	18	(38.3%)
	<i>Blood albumin decreased</i>	13	(27.7%)	3	(6.4%)	2	(4.3%)	0	(0.0%)	18	(38.3%)
	<i>Blood alkaline phosphatase increased</i>	3	(6.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	<i>Blood calcium decreased</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Blood calcium increased</i>	18	(38.3%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	19	(40.4%)
	<i>Blood creatinine increased</i>	1	(2.1%)	3	(6.4%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	<i>Blood phosphorus decreased</i>	9	(19.1%)	5	(10.6%)	1	(2.1%)	1	(2.1%)	16	(34.0%)
	<i>Haemoglobin decreased</i>	8	(17.0%)	10	(21.3%)	1	(2.1%)	0	(0.0%)	19	(40.4%)
	<i>Neutrophil count decreased</i>	7	(14.9%)	6	(12.8%)	1	(2.1%)	0	(0.0%)	14	(29.8%)
	<i>Platelet count decreased</i>	4	(8.5%)	8	(17.0%)	1	(2.1%)	1	(2.1%)	14	(29.8%)
	<i>Pregnancy, puerperium and perinatal conditions</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2
<i>Jaundice neonatal</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)

(Continued)

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<i>Body System</i>	<i>MedDRA Term</i>	<i>Mild</i>		<i>Moderate</i>		<i>Severe</i>		<i>Life Threat.</i>		<i>Total/Incidence</i>	
		<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
<i>Reproductive system and breast disorders</i>		0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Genital ulceration</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Respiratory, thoracic and mediastinal disorders</i>		2	(4.3%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	3	(6.4%)
	<i>Cough</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Nasal congestion</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Respiratory distress</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
<i>Skin and subcutaneous tissue disorders</i>		0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Dermatitis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Heat rash</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)

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Body System	MedDRA Term	Not Related		Probably Not Related		Possibly Related		Probably Related		Total/Incidence	
		N	%	N	%	N	%	N	%	N	%
<i>Participants with one or more AE</i>		6	(12.8%)	5	(10.6%)	29	(61.7%)	5	(10.6%)	45	(95.7%)
<i>Blood and lymphatic system disorders</i>		2	(4.3%)	4	(8.5%)	2	(4.3%)	0	(0.0%)	8	(17.0%)
	<i>Anaemia</i>	2	(4.3%)	4	(8.5%)	1	(2.1%)	0	(0.0%)	7	(14.9%)
	<i>Neutropenia</i>	1	(2.1%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	2	(4.3%)
<i>Congenital, familial and genetic disorders</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Congenital hand malformation</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Congenital syphilis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Eye disorders</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Conjunctivitis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Ophthalmia neonatorum</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Gastrointestinal disorders</i>		3	(6.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	<i>Abdominal distension</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Constipation</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Nausea</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>General disorders and administration site condit</i>		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Vessel puncture site haematoma</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Infections and infestations</i>		20	(42.6%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	20	(42.6%)
	<i>Abscess</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Abscess limb</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Gastroenteritis</i>	6	(12.8%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	6	(12.8%)
	<i>Impetigo</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Malaria</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Neonatal infection</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)

(Continued)

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Body System	MedDRA Term	Not Related		Probably Not Related		Possibly Related		Probably Related		Total/Incidence	
		N	%	N	%	N	%	N	%	N	%
<i>Infections and infestations</i>	<i>Pneumonia</i>	4	(8.5%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	<i>Respiratory tract infection</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Sepsis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Sepsis neonatal</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Upper respiratory tract infection</i>	14	(29.8%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	14	(29.8%)
	<i>Viral upper respiratory tract infection</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Injury, poisoning and procedural complications</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Arthropod bite</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Soft tissue injury</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Investigations</i>		4	(8.5%)	5	(10.6%)	29	(61.7%)	5	(10.6%)	43	(91.5%)
	<i>Alanine aminotransferase increased</i>	2	(4.3%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	3	(6.4%)
	<i>Aspartate aminotransferase increased</i>	3	(6.4%)	1	(2.1%)	13	(27.7%)	1	(2.1%)	18	(38.3%)
	<i>Blood albumin decreased</i>	1	(2.1%)	0	(0.0%)	17	(36.2%)	0	(0.0%)	18	(38.3%)
	<i>Blood alkaline phosphatase increased</i>	2	(4.3%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	3	(6.4%)
	<i>Blood calcium decreased</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Blood calcium increased</i>	12	(25.5%)	4	(8.5%)	1	(2.1%)	2	(4.3%)	19	(40.4%)
	<i>Blood creatinine increased</i>	0	(0.0%)	1	(2.1%)	3	(6.4%)	0	(0.0%)	4	(8.5%)
	<i>Blood phosphorus decreased</i>	1	(2.1%)	1	(2.1%)	14	(29.8%)	0	(0.0%)	16	(34.0%)
	<i>Haemoglobin decreased</i>	12	(25.5%)	2	(4.3%)	5	(10.6%)	0	(0.0%)	19	(40.4%)
	<i>Neutrophil count decreased</i>	7	(14.9%)	5	(10.6%)	1	(2.1%)	1	(2.1%)	14	(29.8%)
	<i>Platelet count decreased</i>	3	(6.4%)	1	(2.1%)	9	(19.1%)	1	(2.1%)	14	(29.8%)

(Continued)

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		N	%	N	%	N	%	N	%	N	%
<i>Pregnancy, puerperium and perinatal conditions</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Jaundice neonatal</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
<i>Reproductive system and breast disorders</i>		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Genital ulceration</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Respiratory, thoracic and mediastinal disorders</i>		2	(4.3%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	<i>Cough</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Nasal congestion</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Respiratory distress</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Skin and subcutaneous tissue disorders</i>		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Dermatitis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Heat rash</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)

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