

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

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

**All Locations -- All Parts -- All Groups -- All  
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>											
<i>Blood and lymphatic system disorders</i>											
	<i>Anaemia</i>	4	(8.5%)	2	(4.3%)	0	(0.0%)	1	(2.1%)	7	(14.9%)
<i>Cardiac disorders</i>											
	<i>Palpitations</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Gastrointestinal disorders</i>											
	<i>Diarrhoea</i>	4	(8.5%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	<i>Ileus paralytic</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Toothache</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Vomiting</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>General disorders and administration site condit</i>											
	<i>Malaise</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Pyrexia</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Infections and infestations</i>											
	<i>Dysentery</i>	2	(4.3%)	11	(23.4%)	1	(2.1%)	0	(0.0%)	14	(29.8%)
	<i>Endometritis</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Gastroenteritis</i>	0	(0.0%)	4	(8.5%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	<i>Gastroenteritis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Hordeolum</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	<i>Lochial infection</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Malaria</i>	0	(0.0%)	2	(4.3%)	5	(10.6%)	0	(0.0%)	7	(14.9%)
	<i>Oral candidiasis</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Postoperative wound infection</i>	0	(0.0%)	1	(2.1%)	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>Syphilis</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)

(Continued)

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		N	%	N	%	N	%	N	%	N	%	
Infections and infestations	<i>Tinea capitis</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
	<i>Upper respiratory tract infection</i>	0	(0.0%)	3	(6.4%)	0	(0.0%)	0	(0.0%)	3	(6.4%)	
	<i>Vaginal candidiasis</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
Injury, poisoning and procedural complications		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
	<i>Postoperative fever</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
Investigations		9	(19.1%)	5	(10.6%)	3	(6.4%)	0	(0.0%)	17	(36.2%)	
	<i>Alanine aminotransferase increased</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)	
	<i>Aspartate aminotransferase increased</i>	4	(8.5%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(8.5%)	
	<i>Blood albumin decreased</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)	
	<i>Blood bilirubin increased</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
	<i>Blood creatinine increased</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)	
	<i>Blood phosphorus decreased</i>	1	(2.1%)	2	(4.3%)	0	(0.0%)	0	(0.0%)	3	(6.4%)	
	<i>Haemoglobin decreased</i>	3	(6.4%)	2	(4.3%)	1	(2.1%)	0	(0.0%)	6	(12.8%)	
	<i>Neutrophil count decreased</i>	4	(8.5%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(8.5%)	
	<i>Platelet count decreased</i>	1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)	
	<i>White blood cell count decreased</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)	
	Musculoskeletal and connective tissue disorders		2	(4.3%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
		<i>Arthralgia</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
		<i>Arthritis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Musculoskeletal pain</i>		0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
Nervous system disorders		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)	
	<i>Headache</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	Mild		Moderate		Severe		Life Threat.		Total/Incidence	
		N	%	N	%	N	%	N	%	N	%
<i>Pregnancy, puerperium and perinatal conditions</i>		1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Postpartum haemorrhage</i>	1	(2.1%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Retained products of conception</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Reproductive system and breast disorders</i>		1	(2.1%)	2	(4.3%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	<i>Breast engorgement</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Breast pain</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Uterine cervical laceration</i>	0	(0.0%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	1	(2.1%)

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

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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>		11	(23.4%)	3	(6.4%)	11	(23.4%)	2	(4.3%)	27	(57.4%)
<i>Blood and lymphatic system disorders</i>		2	(4.3%)	2	(4.3%)	3	(6.4%)	0	(0.0%)	7	(14.9%)
	<i>Anaemia</i>	2	(4.3%)	2	(4.3%)	3	(6.4%)	0	(0.0%)	7	(14.9%)
<i>Cardiac disorders</i>		0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	<i>Palpitations</i>	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
<i>Gastrointestinal disorders</i>		4	(8.5%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	<i>Diarrhoea</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Ileus paralytic</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Toothache</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Vomiting</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>General disorders and administration site condit</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Malaise</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Pyrexia</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Infections and infestations</i>		14	(29.8%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	14	(29.8%)
	<i>Dysentery</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Endometritis</i>	4	(8.5%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	<i>Gastroenteritis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Hordeolum</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Lochial infection</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Malaria</i>	7	(14.9%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	7	(14.9%)
	<i>Oral candidiasis</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Postoperative wound 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%)

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		N	%	N	%	N	%	N	%	N	%
Infections and infestations	Syphilis	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	Tinea capitis	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	Upper respiratory tract infection	3	(6.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	Vaginal candidiasis	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
Injury, poisoning and procedural complications		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	Postoperative fever	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
Investigations		5	(10.6%)	2	(4.3%)	8	(17.0%)	2	(4.3%)	17	(36.2%)
	Alanine aminotransferase increased	0	(0.0%)	0	(0.0%)	2	(4.3%)	0	(0.0%)	2	(4.3%)
	Aspartate aminotransferase increased	0	(0.0%)	0	(0.0%)	4	(8.5%)	0	(0.0%)	4	(8.5%)
	Blood albumin decreased	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	Blood bilirubin increased	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	Blood creatinine increased	0	(0.0%)	0	(0.0%)	1	(2.1%)	0	(0.0%)	1	(2.1%)
	Blood phosphorus decreased	0	(0.0%)	0	(0.0%)	1	(2.1%)	2	(4.3%)	3	(6.4%)
	Haemoglobin decreased	4	(8.5%)	1	(2.1%)	1	(2.1%)	0	(0.0%)	6	(12.8%)
	Neutrophil count decreased	3	(6.4%)	1	(2.1%)	0	(0.0%)	0	(0.0%)	4	(8.5%)
	Platelet count decreased	0	(0.0%)	0	(0.0%)	2	(4.3%)	0	(0.0%)	2	(4.3%)
	White blood cell count decreased	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	Musculoskeletal and connective tissue disorders		3	(6.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3
Arthralgia		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
Arthritis		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
Musculoskeletal pain		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)

(Continued)

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		N	%	N	%	N	%	N	%	N	%
<i>Nervous system disorders</i>		1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Headache</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Pregnancy, puerperium and perinatal conditions</i>		2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Postpartum haemorrhage</i>	2	(4.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(4.3%)
	<i>Retained products of conception</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
<i>Reproductive system and breast disorders</i>		3	(6.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(6.4%)
	<i>Breast engorgement</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Breast pain</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)
	<i>Uterine cervical laceration</i>	1	(2.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(2.1%)

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