

HPTN 077 - A Phase IIa Safety, Tolerability and Acceptability Study of an Investigational Injectable HIV Integrase Inhibitor, GSK1265744, for PrEP in HIV Uninfected Men and Women
Data as of 15NOV18

Table 1 - Type of Protocol Deviations and Enrollment Violations by Site

	UNC AIDS CRS	UCLA CRS	San Francisco	GWU CRS	Soweto CTU	Vulindlela CRS	Lilongwe UNC	Rio de Janeiro	Overall
Participants Enrolled	42	18	23	23	18	24	18	34	200
Number of Protocol Deviations and Enrollment Violations	1	0	9	3	5	21	1	0	40
Type of Protocol Deviations and Enrollment Violations									
Inappropriate enrollment	1 (100%)	0 (-%)	1 (11%)	0 (0%)	0 (0%)	4 (19%)	1 (100%)	0 (-%)	7 (18%)
Failure to follow trial randomization or blinding procedures	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Study product management deviation	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)	2 (10%)	0 (0%)	0 (-%)	2 (5%)
Study product dispensing error	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Conduct of non-protocol procedure	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)	8 (38%)	0 (0%)	0 (-%)	8 (20%)
Breach of confidentiality	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Physical assessment deviation	0 (0%)	0 (-%)	4 (44%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	4 (10%)
Lab assessment deviation	0 (0%)	0 (-%)	1 (11%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	2 (5%)
Use of non-IRB/EC-approved materials	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Informed assent/consent process deviations	0 (0%)	0 (-%)	1 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	1 (3%)
Other	0 (0%)	0 (-%)	2 (22%)	2 (67%)	5 (100%)	7 (33%)	0 (0%)	0 (-%)	16 (40%)