MTN 017 - Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel
Data as of September 9, 2015

Screen-out Summary by Site

	Peru Lima	Puerto Rico San Juan	South Africa Cape Town	Thailand Bangkok	Thailand Chiang Mai	USA Boston	USA Pittsburgh	USA San Francisco	All Sites
Participants Screened	55	13	40	32	55	12	45	97	349
Participants Enrolled[1]	38 (69%)	7 (54%)	18 (45%)	24 (75%)	30 (55%)	7 (58%)	33 (73%)	38 (39%)	195 (56%)
Participants not Enrolled	17 (31%)	6 (46%)	22 (55%)	8 (25%)	25 (45%)	5 (42%)	12 (27%)	59 (61%)	154 (44%)
Participant did not return (refused or lost contact)	3 (5%)	2 (15%)	1 (3%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)	5 (5%)	12 (3%)
Participant is eligible but declined enrollment	1 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	3 (1%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[2]	13 (24%)	3 (23%)	21 (53%)	8 (25%)	24 (44%)	5 (42%)	12 (27%)	52 (54%)	138 (40%)
Participant < 18 years old	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant unable to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2%)	1 (1%)
Participant not able or willing to provide informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not male at birth	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant unavailable to return for all study visits, or comply with study requirements	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	1 (20%)	1 (8%)	4 (8%)	7 (5%)
Participant not in general good health per loR/designee	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	3 (6%)	4 (3%)
Participant has not had consensual RAI in the last 3 months	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Participant unwilling to abstain from receptive/insertive sex with another study participant	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant unwilling to abstain from participation in other research studies	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PEP exposure in the 12 weeks prior to screening, or anticipated use during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is HIV-positive	3 (23%)	0 (0%)	3 (14%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)	0 (0%)	8 (6%)
Participant declines use of study-provided condoms	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	2 (4%)	3 (2%)
Participant has symptoms suggestive of acute seroconversion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (4%)	2 (1%)
Participant use, anticipated use, or unwillingness to abstain from contraindicated medications/products	0 (0%)	0 (0%)	0 (0%)	2 (25%)	1 (4%)	0 (0%)	0 (0%)	2 (4%)	5 (4%)
Participant does not meet laboratory eligibility criteria	4 (31%)	2 (67%)	11 (52%)	2 (25%)	16 (67%)	0 (0%)	4 (33%)	11 (21%)	50 (36%)
Participant does not meet other clinical eligibility criteria	5 (38%)	0 (0%)	4 (19%)	1 (13%)	2 (8%)	0 (0%)	3 (25%)	12 (23%)	27 (20%)

[1] Number of participants enrolled could differ from the accrual report since the data is taken from the ECI-1 CRF and not the ENR-1 CRF.
[2] Participants may be ineligible for more than one reason.

Source: SCHARP (janne) - /trials/mtn/p017/reporting/progress/code/t_screen_out_site.sas, SAS Version 9.4 (10SEP2015,5:06)

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Other reason, including investigator decision	1 (8%)	1 (33%)	2 (10%)	4 (50%)	3 (13%)	4 (80%)	4 (33%)	19 (37%)	38 (28%)

[1] Number of participants enrolled could differ from the accrual report since the data is taken from the ECI-1 CRF and not the ENR-1 CRF.
[2] Participants may be ineligible for more than one reason.

Source: SCHARP (janne) - /trials/mtn/p017/reporting/progress/code/t_screen_out_site.sas, SAS Version 9.4 (10SEP2015,5:06)

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Peru - Lima	chronic kidney disease
2	Puerto Rico - San Juan	questionable allergy to product and exposure to a test dose during screening (not prior)
3	South Africa - Cape Town	chronic diarrhoea needing investigations
4		high risk profile for HIV acquisition.
5	Thailand - Bangkok	the participant could not be enrolled because the site's enrollment target was met
6		has conditions make study participantion unsafe.
7		The participant may be at risk for Tenofovir product use
8		he was found anal fistula opening on screening and may interfere with achieving the study objecti...
9	Thailand - Chiang Mai	persistent high blood pressure
10		issues methamphetamine abuse can cause problems with retention.
11		the investigator decision ineligibility due to LFT was borderline abnormal which may be unsafe to...
12	USA - Boston	psrt consult suggest screen fail
13		anal exophytic wart requiring removal per investigation and PSRT.
14		extensive history of anal fissures, most recently 3 months ago
15		per participant report anticipates sex with HIV positive partner; risk of need for PEP considered.
16	USA - Pittsburgh	participant's weight is too high
17		history of anal HPV/surgery
18		lack of reliable transportation to clinic
19		hemmorrhoids and anoidysplasia
20	USA - San Francisco	did not complete screening procedures prio to site meeting enrollment target.
21		high risk lifestyle
22		concerns about ability to adhere to the protocol.
23		study staff concerned with participants ability to adhere to study requirements
24		concerns about participant's ability to adhere to protocol requirements
25		symptomatology related to PrEP use
26		PSRT decision
27		investigator decision
28		investigator decision
29		has condition that might complicate interpretation of study data
30		inappropriate comments to staff.
31		staff concerns about participant's ability to meet protocol requirements.
32		investigator decision
33		staff concern about truthfullness
34		staff concern about participant's ability to comply with protocol.

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
35		concert re-retention
36		site met enrollment target prior to participants anticipated enrollment vist
37		retention concerns
38		staff concerned about ability to comply with protocol.