MTN 039 - Safety and PK Study of TAF/EVG Administered Rectally
Data as of December 5, 2022

Screen-out Summary by Site

	Pittsburgh	Birmingham	All Sites
Participants Screened[1]	13	14	27
Participants Enrolled[2, 3]	11 (85%)	12 (86%)	23 (85%)
Participants not Enrolled	2 (15%)	2 (14%)	4 (15%)
Participant did not complete all screening procedures[4]	0 (-%)	0 (-%)	0 (-%)
Eligible/Not enrolled[4]	1 (50%)	0 (-%)	1 (25%)
Reason participant not enrolled is missing	0 (-%)	0 (-%)	0 (-%)
Participant not eligible[5]	1 (50%)	2 (100%)	3 (75%)
Not individuals who are 18 years or older at Screening	0 (-%)	0 (-%)	0 (-%)
Not able and/or willing to provide written informed consent	0 (-%)	0 (-%)	0 (-%)
HIV-1/2 infected at Screening and Enrollment and/or not willing to receive HIV test results	0 (-%)	0 (-%)	0 (-%)
Not able and/or willing to provide adequate locator information	0 (-%)	0 (-%)	0 (-%)
Not able to communicate in spoken and written English	0 (-%)	0 (-%)	0 (-%)
Not available for all visits and able or not willing to comply with all requirements	0 (-%)	0 (-%)	0 (-%)
Not in general good health	0 (-%)	0 (-%)	0 (-%)
No history of consensual RAI at least once at screening	0 (-%)	0 (-%)	0 (-%)
Not willing to not take part in other researches	0 (-%)	0 (-%)	0 (-%)
Not willing to comply with abstinence and other protocol requirements	0 (-%)	0 (-%)	0 (-%)
Positive pregnancy test at screening or enrollment for participants of childbearing potential	0 (-%)	0 (-%)	0 (-%)
Didn't use and do not intend to use effective method of contraception	0 (-%)	0 (-%)	0 (-%)
Grade 1 or higher Hemoglobin at Screening	0 (-%)	0 (-%)	0 (-%)
Grade 1 or higher Platelet count at Screening	0 (-%)	0 (-%)	0 (-%)
Grade 1 or higher Aspartate aminotransferase (AST) or Alanine transaminase (ALT) at Screening	1 (100%)	0 (-%)	1 (33%)
Serum creatinine > 1.3x site ULN	0 (-%)	0 (-%)	0 (-%)
International normalized ratio (INR) >1.5× site ULN	0 (-%)	0 (-%)	0 (-%)
History of inflammatory bowel disease per participant report	0 (-%)	0 (-%)	0 (-%)
Positive hepatitis B surface antigen (HBsAg) test result	0 (-%)	0 (-%)	0 (-%)
Anticipated use of and/or unwillingness to abstain from Anticoagulant medications during study participation	0 (-%)	0 (-%)	0 (-%)
Anticipated use of and/or unwillingness to abstain from Rectally-admin istered medications during study participation	0 (-%)	0 (-%)	0 (-%)
Known adverse reaction to any of the components of the study product	0 (-%)	0 (-%)	0 (-%)
Use of PrEP for HIV prevention within 3 months prior to Enrollment, and/or anticipate/unwilling to abstain from PrEP during study	0 (-%)	0 (-%)	0 (-%)
Use of PEP for potential HIV exposure within the 6 months prior to Enrollment	0 (-%)	0 (-%)	0 (-%)

[1] Number of participants screened is based on the Inclusion Exclusion eCRF, and may differ from the Enrollment report, which is instead based on the Scr Date of Visit eCRF.
[2] Number of participants enrolled is based on the Inclusion Exclusion eCRF, so could differ from the Enrollment report, which is instead based on the Enrollment eCRF.
[3] Percentage of participants screened.
[4] Percentage of participants not enrolled.
[5] Participants may be ineligible for more than one reason.

Source: SCHARP (yjiao) - /trials/mtn/p039/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (06DEC2022,6:43)

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Condomless RAI or penile-vaginal intercourse with a partner known or unsure to be HIV-positive in 6 months prior to Enrollment	0 (-%)	0 (-%)	0 (-%)
History of transactional sex in the 12 months prior to Enrollment	0 (-%)	0 (-%)	0 (-%)
Non-therapeutic injection drug use in the 12 months prior to Enrollment	0 (-%)	0 (-%)	0 (-%)
Participation in research studies involving products such as drugs, medical devices or vaccines within 30 days of Enrollment	0 (-%)	0 (-%)	0 (-%)
Diagnosis or treatment of an anogenital STI in the 3 months prior to enrollment	0 (-%)	2 (100%)	2 (67%)
At screening or enrollment, active pharyngeal, anorectal infection or RTI requiring treatment per current CDC guidelines	0 (-%)	0 (-%)	0 (-%)
At Screening or Enrollment, current symptomatic UTI	0 (-%)	0 (-%)	0 (-%)
Pregnant or breastfeeding at either Screening or Enrollment or intends to become pregnant or start breastfeeding	0 (-%)	0 (-%)	0 (-%)
Last pregnancy outcome 90 days or less prior to Screening	0 (-%)	0 (-%)	0 (-%)
Has a condition that, per IoR/designee, would preclude informed consent, make study unsafe, complicate interpretation	0 (-%)	0 (-%)	0 (-%)

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