MTN 038 - PK and Safety Study of a 90-Day Intravaginal Ring Containing Tenofovir
Data as of December 1, 2025

Screen-out Summary by Site

	Birmingham, AL	Pittsburgh, PA	San Francisco, CA	All Sites
Participants Screened[1]	15	27	21	63
Participants Enrolled[2, 3]	13 (87%)	21 (78%)	15 (71%)	49 (78%)
Participants not Enrolled	2 (13%)	6 (22%)	6 (29%)	14 (22%)
Participant did not complete all screening procedures[4]	0 (0%)	0 (0%)	1 (17%)	1 (7%)
Participant is eligible but did not enroll	0 (0%)	1 (17%)	0 (0%)	1 (7%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[5]	2 (100%)	5 (83%)	5 (83%)	12 (86%)
Not assigned female sex at birth	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not between the age of 18 through 45 years	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not able or willing to provide written informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not able or willing to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not able to communicate in spoken and written English	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not available for all visits or unwilling to comply with all study procedural requirements	0 (0%)	3 (60%)	0 (0%)	3 (25%)
Unwilling to abstain from receptive intercourse for 72 hours	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unwilling to use from male condoms for intercourse during the study	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unwilling to use an effective method of contraception before Enrollment and during study participation	0 (0%)	0 (0%)	1 (20%)	1 (8%)
Not in general good health at Screening and Enrollment	0 (0%)	0 (0%)	1 (20%)	1 (8%)
HIV-infected based on testing performed at Screening and Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Irregular menstrual cycles within 21 days at Screening	0 (0%)	0 (0%)	1 (20%)	1 (8%)
Unwilling to refrain from inserting any non-study vaginal products or objects into the vagina or rectum	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant over the age of 21 has not had a satisfactory PAP within the past 3 years	1 (50%)	0 (0%)	0 (0%)	1 (8%)
Participation in any other research study after Screening and during the study	0 (0%)	1 (20%)	0 (0%)	1 (8%)
Pregnant at Screening or Enrollment or plans to become pregnant	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Diagnosed with symptomatic urinary tract infection(UTI) or reproductive tract infection(RTI)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Diagnosed with an acute STI requiring treatment per current CDC guideliness	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Has a clinically apparent Grade 2 or higher pelvic exam finding	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Known adverse reaction to any component of the study product including polyurethane	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Chronic and/or recurrent vaginal candidiasis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Non-therapeutic injection drug use in the past 12 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Last pregnancy outcome less than 90 days prior to Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Gynecologic or genital procedure 45 days or less prior to Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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

Source: SCHARP (Gayathri) - /trials/mtn/p038/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (02DEC2025,6:38)

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	Birmingham, AL	Pittsburgh, PA	San Francisco, CA	All Sites
Currently breastfeeding or planning to breast feed	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participation in any other research study in the 60 days prior to Enrollment	0 (0%)	1 (20%)	0 (0%)	1 (8%)
Use of PrEP for HIV prevention or PEP for HIV for HIV exposure within 3 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher AST or ALT laboratory abnormalities	0 (0%)	0 (0%)	1 (20%)	1 (8%)
Grade 1 or higher Hemoglobin laboratory abnormalities	1 (50%)	0 (0%)	0 (0%)	1 (8%)
Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Positive Hepatitis B surface antigen result	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other conditions	0 (0%)	0 (0%)	3 (60%)	3 (25%)

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[3] Percentage of participants screened.
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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	San Francisco, CA	Poor venous access
2		concern re participant veracity
3		Ppt w/ unusual shaped, lobular cervix. Anterior cervical trunk w/ additional tissue present that is petal-shaped. D/t abnormal appearance and no records on assessment/tx, study participation unsafe