

**MTN 036 - Pharmacokinetics and safety study of extended duration Dapivirine vaginal rings
Data as of December 1, 2025**

Screen-out Summary by Site

	Birmingham, AL	San Francisco, CA	All Sites
Participants Screened	38	52	90
Participants Enrolled ^{1, 2}	25 (66%)	24 (46%)	49 (54%)
Participants not Enrolled	13 (34%)	28 (54%)	41 (46%)
Participant did not complete all screening procedures ³	3 (23%)	10 (36%)	13 (32%)
Participant is eligible but did not enroll	0 (0%)	2 (7%)	2 (5%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)
Participant not eligible ⁴	10 (77%)	16 (57%)	26 (63%)
Not assigned female sex at birth	0 (0%)	0 (0%)	0 (0%)
Age not between 18 through 45 years (inclusive) at Screening	0 (0%)	0 (0%)	0 (0%)
Not able and willing to provide written informed consent	3 (27%)	0 (0%)	3 (11%)
Not able and willing to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)
Not able to communicate in spoken and written English	0 (0%)	0 (0%)	0 (0%)
Not available for all visits and able and willing to comply with all study procedural requirements	1 (9%)	1 (6%)	2 (7%)
Not willing to comply with abstinence and other protocol requirements	0 (0%)	1 (6%)	1 (4%)
Not willing to use male condoms for penile-vaginal intercourse (PVI) and penile-rectal intercourse for the duration of study participation	0 (0%)	0 (0%)	0 (0%)
Not using an effective method of contraception for at least 30 days prior to Enrollment, and intending to continue use of an effective method for the duration of study participation	1 (9%)	2 (13%)	3 (11%)
Not in general good health at Screening and Enrollment	0 (0%)	1 (6%)	1 (4%)
HIV-uninfected based on testing performed at Screening and Enrollment	0 (0%)	0 (0%)	0 (0%)
No regular menstrual cycles with at least 21 days between menses at Screening	0 (0%)	1 (6%)	1 (4%)
Not willing to refrain from inserting any non-study vaginal products or objects into the vagina for the 24 hours preceding the Enrollment visit and for the duration of study participation	0 (0%)	0 (0%)	0 (0%)
No documentation of a satisfactory Pap within the past 3 years	1 (9%)	2 (13%)	3 (11%)
Does not agree not to participate in other research studies involving drugs, medical devices, vaginal products or vaccines for the duration of study participation	1 (9%)	1 (6%)	2 (7%)
Pregnant at Screening or Enrollment or plans to become pregnant during the study period	0 (0%)	0 (0%)	0 (0%)
Diagnosed with a UTI or reproductive tract infection (RTI) at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)

¹ Number of participants enrolled is based on the Eligibility Criteria eCRF, so could differ from the accrual report, which is instead based on the Randomization eCRF.

² Percentage of participants screened.

³ Percentage of participants not enrolled.

⁴ Participants may be ineligible for more than one reason.

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Diagnosed with an acute STI requiring treatment at Screening or Enrollment	2 (18%)	1 (6%)	3 (11%)
Has a clinically apparent Grade 2 or higher pelvic exam finding at Screening or Enrollment	0 (0%)	1 (6%)	1 (4%)
Known adverse reaction to any of the study products (ever)	0 (0%)	0 (0%)	0 (0%)
Chronic and/or recurrent vaginal candidiasis	0 (0%)	0 (0%)	0 (0%)
Non-therapeutic injection drug use in the 12 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Last pregnancy outcome less than 90 days prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 45 days before Enrollment	0 (0%)	0 (0%)	0 (0%)
Currently breastfeeding or planning to breastfeed during the study period	0 (0%)	0 (0%)	0 (0%)
Participation in any other research study involving drugs, medical devices vaginal products or vaccines, 60 days prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Use of pre-exposure prophylaxis (PrEP) for HIV prevention and/or post-exposure prophylaxis (PEP) for potential HIV exposure within the 3 months prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from PrEP during trial participation	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher AST or ALT laboratory abnormalities at Screening Visit	0 (0%)	2 (13%)	2 (7%)
Grade 1 or higher hemoglobin laboratory abnormalities at Screening Visit	1 (9%)	1 (6%)	2 (7%)
Has any other condition that would preclude informed consent, make study participation unsafe, complicate the interpretation of study outcome data, or otherwise interfere with achieving the study objective including any significant uncontrolled active or chronic medical condition	1 (9%)	2 (13%)	3 (11%)

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Birmingham, Al	Poor venous access
2	San Francisco, CA	UTERINE PROLAPSE THAT WOULD INTERFERE WITH RING PLACEMENT
3		PI concern due to housing instability