MTN 033 - Rectal PK Study of Dapivirine (DPV) Gel
Data as of December 1, 2025

Screen-out Summary by Site

	Pittsburgh, PA	All Sites
Participants Screened[1]	17	17
Participants Enrolled[2, 3]	16 (94%)	16 (94%)
Participants not Enrolled	1 (6%)	1 (6%)
Participant did not complete all screening procedures[4]	1 (100%)	1 (100%)
Participant is eligible but did not enroll	0 (-%)	0 (-%)
Reason participant not enrolled is missing	0 (-%)	0 (-%)
Participant not eligible[5]	0 (-%)	0 (-%)
Not man or transgender woman and not 18 years or older at Screening	0 (-%)	0 (-%)
Not able and/or willing to provide written informed consent	0 (-%)	0 (-%)
HIV-1/2 infected at Screening and Enrollment and/or not willing to receive HIV test results	0 (-%)	0 (-%)
Not able and/or willing to provide adequate locator information	0 (-%)	0 (-%)
Not available to return for all study visits and/or not willing to comply with study requirements	0 (-%)	0 (-%)
Not in general good health at Screening and/or Enrollment	0 (-%)	0 (-%)
Per participant report, no history of consensual RAI at least once in the past calendar year	0 (-%)	0 (-%)
Not willing to not take part in other research studies for the duration of the study participation	0 (-%)	0 (-%)
Not willing to be sexually abstinent when prohibited and as specified per protocol	0 (-%)	0 (-%)
Grade 1 or higher Hemoglobin at Screening	0 (-%)	0 (-%)
Grade 1 or higher Platelet count at Screening	0 (-%)	0 (-%)
Grade 2 or higher White blood count at Screening	0 (-%)	0 (-%)
Grade 1 or higher Aspartate aminotransferase (AST) or Alanine transaminase (ALT) at Screening	0 (-%)	0 (-%)
Serum creatinine greater than 1.3x the site laboratory ULN	0 (-%)	0 (-%)
INR greater than 1.5x the site laboratory ULN	0 (-%)	0 (-%)
Positive for hepatitis C antibody	0 (-%)	0 (-%)
Positive for hepatitis B surface antigen	0 (-%)	0 (-%)
History of inflammatory bowel disease per participant report	0 (-%)	0 (-%)
Known adverse reaction to latex or polyurethane (ever)	0 (-%)	0 (-%)
Anticipated use of and/or unwillingness to abstain from Anticoagulant medications during study participation	0 (-%)	0 (-%)
Anticipated use of and/or unwillingness to abstain from Aspirin (greater than 81 mg/day) during study participation	0 (-%)	0 (-%)
Anticipated use of and/or unwillingness to abstain from NSAIDS during study participation	0 (-%)	0 (-%)
Anticipated use of and/or unwillingness to abstain from any other drugs associated with increased likelihood of bleeding	0 (-%)	0 (-%)
Not willing to abstain from rectally-administered medications or products containing N-9 or corticosteroids	0 (-%)	0 (-%)

[1] Number of participants screened is based on the Inclusion Exclusion eCRF and may differ from the Enrollment Report which is 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 (Calins) - /trials/mtn/p033/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (02DEC2025,6:33)

MTN 033 - Rectal PK Study of Dapivirine (DPV) Gel
Data as of December 1, 2025

Screen-out Summary by Site

		Pittsburgh, PA	All Sites
	Anticipated use of and/or unwillingness to abstain from CYP3A incuder(s) and/or inhibitor(s)	0 (-%)	0 (-%)
	Anticipated use of and/or unwillingness to abstain from Hormone-replacement therapy in tablet, injectable or gel form	0 (-%)	0 (-%)
	Known adverse reaction to any of the components of the study product, applicator or coital stimulation device	0 (-%)	0 (-%)
	Use of PrEP for HIV prevention within 1 month prior to or after Enrollment	0 (-%)	0 (-%)
	Use of PEP for potential HIV exposure within the 6 months prior to Enrollment	0 (-%)	0 (-%)
	Use of systemic immunomodulatory medications within the 6 months prior to Enrollment and/or anticipated use	0 (-%)	0 (-%)
	RAI and/or penile-valiginal sex with partner who is known to be HIV-positive in the 6 months prior to enrollment	0 (-%)	0 (-%)
	Non-therapeutic injection drug use in the 12 months prior to Enrollment	0 (-%)	0 (-%)
	Participation in research studies within 30 days of the Enrollment Visit	0 (-%)	0 (-%)
	Per participant report at Screening, treatment for anogenital STI within past 3 months	0 (-%)	0 (-%)
	At Screening, active anorectal infection or RTI requiring treatment per current CDC Guidelines	0 (-%)	0 (-%)
	At Enrollment, active anorectal infection or RTI requiring treatment per current CDC Guidelines or symptomatic UTI	0 (-%)	0 (-%)
	Other condition that could preclude informed consent or interfere with study objectives	0 (-%)	0 (-%)

[1] Number of participants screened is based on the Inclusion Exclusion eCRF and may differ from the Enrollment Report which is 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 (Calins) - /trials/mtn/p033/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (02DEC2025,6:33)