

**MTN 035 - Rectal Microbicide Acceptability, Tolerability, and Adherence
Data as of December 1, 2025**

Screen-out Summary by Site

	Birmingham	Blantyre	Chiang Mai	Hillbrow, WRHI	Lima, San Miguel	Pittsburgh	San Francisco	All Sites
Participants Screened ¹	45	38	33	32	38	35	36	257
Participants Enrolled ^{2, 3}	33 (73%)	31 (82%)	30 (91%)	30 (94%)	30 (79%)	33 (94%)	30 (83%)	217 (84%)
Participants not Enrolled	12 (27%)	7 (18%)	3 (9%)	2 (6%)	8 (21%)	2 (6%)	6 (17%)	40 (16%)
Participant did not complete all screening procedures ⁴	3 (25%)	0 (-%)	0 (-%)	1 (50%)	0 (-%)	0 (-%)	2 (33%)	6 (15%)
Participant is eligible but did not enroll	0 (-%)	1 (14%)	1 (33%)	0 (-%)	2 (25%)	1 (50%)	0 (-%)	5 (13%)
Reason participant not enrolled is missing	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ⁵	9 (75%)	6 (86%)	2 (67%)	1 (50%)	6 (75%)	1 (50%)	4 (67%)	29 (73%)
Not between the age of 18 through 35 years and men/transgender	1 (11%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	1 (3%)
Unable or unwilling to provide written informed consent	1 (11%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	1 (3%)
Not HIV-uninfected at Screening and Enrollment after testing	1 (11%)	1 (17%)	0 (-%)	0 (-%)	3 (50%)	0 (-%)	0 (-%)	5 (17%)
Unable or unwilling to provide adequate locator information	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable or unwilling to comply with all study requirements	1 (11%)	0 (-%)	0 (-%)	0 (-%)	1 (17%)	0 (-%)	0 (-%)	2 (7%)
Not in good health at Screening or Enrollment	1 (11%)	0 (-%)	0 (-%)	1 (100%)	0 (-%)	0 (-%)	0 (-%)	2 (7%)
No history of consensual RAI or not expecting frequent enough RAI during study	1 (11%)	3 (50%)	0 (-%)	0 (-%)	2 (33%)	0 (-%)	1 (25%)	7 (24%)
Unwilling to not participate in other research studies during study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Does not have a negative pregnancy test at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Does not use effective contraceptive method before and during study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
History of inflammatory bowel disease at screening	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Current anorectal condition that would impede product placement/tolerability	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	1 (25%)	1 (3%)
Unwilling to abstain from non-study rectal-administrated product use during study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Known adverse reaction to any components of the study products	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in other research study within 30 days of enrollment visit	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in research studies involving rectal products (ever)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Use of PEP within the 3 month prior to enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Engagement in unprotected RAI/RVI with HIV-positive partner	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Engagement in unprotected RAI/RVI with partner with unknown HIV status	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Non-therapeutic injection drug use in the 12 month prior to enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Clinical evidence or reported anorectal or reproductive tract infection	3 (33%)	2 (33%)	2 (100%)	0 (-%)	0 (-%)	1 (100%)	1 (25%)	9 (31%)
Pregnant or breastfeeding at screening/enrollment or planning for pregnancy	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Last pregnancy outcome 90 days or less prior to screening	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	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.

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Screen-out Summary by Site

	Birmingham	Blantyre	Chiang Mai	Hillbrow, WRHI	Lima, San Miguel	Pittsburgh	San Francisco	All Sites
Has a condition that preclude informed consent or affect study outcome/objectives	2 (22%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	1 (25%)	3 (10%)

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.

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Data as of November 30, 2025**

Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Birmingham	
2		
3	San Francisco	