MTN 034 - Reversing the Epidemic in Africa with Choices in HIV Prevention (REACH)
Data as of December 5, 2022

Screen-out Summary by Site

	SA Cape Town	SA Johannesburg	Uganda Kampala	Zimbabwe Spilhaus	All Sites
Participants Screened[1]	86	106	109	95	396
Participants Enrolled[2, 3]	60 (70%)	67 (63%)	60 (55%)	60 (63%)	247 (62%)
Participants not Enrolled	26 (30%)	39 (37%)	49 (45%)	35 (37%)	149 (38%)
Incomplete screening[4]	17 (65%)	6 (15%)	21 (43%)	13 (37%)	57 (38%)
Participant is eligible but declined enrollment	0 (-%)	3 (8%)	1 (2%)	2 (6%)	6 (4%)
Reason participant not enrolled is missing	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible[5]	9 (35%)	30 (77%)	27 (55%)	20 (57%)	86 (58%)
Not between the age of 16 through 21 years	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not able or willing to provide written informed consent	0 (-%)	0 (-%)	0 (-%)	1 (5%)	1 (1%)
Not able or willing to provide adequate locator information	0 (-%)	0 (-%)	2 (7%)	0 (-%)	2 (2%)
Not able or willing to comply with all study procedural requirements	0 (-%)	11 (37%)	8 (30%)	3 (15%)	22 (26%)
Per participant report at Screening, not post-menarche	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not HIV-uninfected based on testing performed at Screening and Enrollment	0 (-%)	2 (7%)	8 (30%)	3 (15%)	13 (15%)
No history of at least one episode of sexual intercourse in participant's lifetime	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Positive pregnancy test at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	1 (5%)	1 (1%)
Unwilling to use an effective method of contraception before Enrollment and during study	2 (22%)	6 (20%)	2 (7%)	3 (15%)	13 (15%)
Unwilling to abstain from inserting anything into the vagina 72 hours prior to each study visit	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unwilling to not participate in other research studies for the duration of study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to become pregnant during the study participation period	0 (-%)	0 (-%)	1 (4%)	1 (5%)	2 (2%)
Intends to access and/or use oral PrEP outside the context of study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to relocate away from the study site	1 (11%)	2 (7%)	2 (7%)	4 (20%)	9 (10%)
Intends to travel away from the study site that would interfere with product resupply	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Has a positive HIV test at screening or enrollment	2 (22%)	0 (-%)	7 (26%)	3 (15%)	12 (14%)
Diagnosed with UTI, PID, STI or RTI requiring treatment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
At Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Clinical evidence or report of known adverse reaction to any of the study products (ever)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Clinical evidence or report of known adverse reaction to latex and polyurethane (ever)	0 (-%)	6 (20%)	1 (4%)	0 (-%)	7 (8%)
Clinical evidence or report of symptoms suggestive of acute HIV infection	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Clinical evidence or report of injection drug use in the 12 months prior to Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Clinical evidence or report of use of HIV PEP or PrEP in the 3 months prior to Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

[1] Number of participants screened is based on the Eligibility 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 Eligibility 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 (Calins) - /trials/mtn/p034/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (06DEC2022,6:40)

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Clinical evidence or report of current breastfeeding	1 (11%)	0 (-%)	2 (7%)	2 (10%)	5 (6%)
Clinical evidence or report of last pregnancy outcome within 8 weeks or less of Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in any other research study within 60 days of enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Uncontrolled active or chronic physiological disorder or infectious disease	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Positive for hepatitis B surface antigen (HBsAG) at Screening Visit	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Hemoglobin Grade 2 or higher at Screenining Visit	2 (22%)	3 (10%)	0 (-%)	1 (5%)	6 (7%)
Calculated creatinine clearance less than 60 mL/min by the Schwartz Equation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Other condition that could preclude informed consent or interfere with study objectives	1 (11%)	1 (3%)	2 (7%)	1 (5%)	5 (6%)

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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	SA - Cape Town	Interferes with achieving Study Objectives. Unable to Perform Pelvic Examination Successfully.
2	SA - Johannesburg	In light of participants recurrent bleeding noted on numerous occasions during pelvic exams and the inability to complete enrolment within enrolment window.
3	Uganda - Kampala	participant had history of sexual abuse through rape and she was still traumatized by the rape incident. she was also still very frightened to have pelvic examinations and deemed ineligible for study
4		MOTHER OF THIS PARTICPANT WAS AGAINST HER PARTICIPATION IN THE STUDY AND SHE WAS UNWILLING TO COME AND GET MORE INFORMATION ABOUT THE STUDY. HER PARTICIPATION WOULD PREDISPOSE HER TO SOCIAL HARMS
5	Zimbabwe - Spilhaus	Misreading of her finger prints made checking for co-enrollment impossible.