

MTN 025 - HIV Open-label Prevention Extension (HOPE)
Data as of December 5, 2022

Screen-out Summary by Site - Main Study - First 7 Sites

	All Sites	Malawi - Blantyre	Malawi - Lilongwe	SA - CAPRISA eThekweni	SA - Cape Town	SA - MRC/ Botha's Hill	SA - MRC/ Chatsworth	SA - MRC/ Isipingo
Participants Screened	1643	93	78	145	84	115	85	105
Participants Enrolled ¹	1456 (89%)	85 (91%)	72 (92%)	130 (90%)	79 (94%)	98 (85%)	80 (94%)	88 (84%)
Participants not Enrolled	187 (11%)	8 (9%)	6 (8%)	15 (10%)	5 (6%)	17 (15%)	5 (6%)	17 (16%)
Participant did not complete all screening procedures	30 (2%)	0 (0%)	2 (3%)	4 (3%)	1 (1%)	3 (3%)	2 (2%)	1 (1%)
Participant is eligible but declined enrollment	8 (<1%)	1 (1%)	1 (1%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	2 (2%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible ²	149 (9%)	7 (8%)	3 (4%)	11 (8%)	3 (4%)	14 (12%)	3 (4%)	14 (13%)
Not previously enrolled in MTN-020 (ASPIRE)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to provide written informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV infected at Screening or Enrollment	45 (30%)	2 (29%)	2 (67%)	7 (64%)	3 (100%)	7 (50%)	3 (100%)	2 (14%)
Declines effective method of contraception at Enrollment and for duration of study participation	4 (3%)	1 (14%)	0 (0%)	2 (18%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Does not agree to not participate in other research studies for duration of study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Study product use permanently discontinued in response to AE or safety related concern with taking part in MTN-020 (ASPIRE) trial	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Plans for relocation/travel per participant report at Screening	6 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)
Grade 3 or higher Hemoglobin at Screening	3 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)	0 (0%)	0 (0%)
Grade 3 or high Pap results at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Currently taking PEP at Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participated in other research study involving drugs, medical devices, vaginal products, or vaccines within 60 days of Enrollment with the exception of MTN-020(ASPIRE)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pregnant at Screening/Enrollment or plans to become pregnant during study participation period	43 (29%)	2 (29%)	1 (33%)	1 (9%)	0 (0%)	2 (14%)	0 (0%)	5 (36%)
Currently breastfeeding	26 (17%)	0 (0%)	0 (0%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	4 (29%)
Diagnosed with UTI, PID, STI, or RTI which has not resolved or undergone complete treatment	4 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)	0 (0%)	1 (7%)
Grade 3 pelvic exam finding at Screening or has not improved to non-exclusionary grading or resolved within 56 days or Screening	2 (1%)	1 (14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

¹ Number of participants enrolled could differ from the accrual report since the data is taken from the Eligibility Criteria form and not the Enrollment form.

² Participants may be ineligible for more than one reason.

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	All Sites	Malawi - Blantyre	Malawi - Lilongwe	SA - CAPRISA eThekweni	SA - Cape Town	SA - MRC/ Botha's Hill	SA - MRC/ Chatsworth	SA - MRC/ Isipingo
Grade 3 or higher AST/ALT at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 3 or high Creatinine at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 3 or higher Platelet Count at Screening	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other, including IoR discretion	19 (13%)	2 (29%)	0 (0%)	0 (0%)	0 (0%)	3 (21%)	0 (0%)	1 (7%)

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Screen-out Summary by Site - Main Study - Last 7 Sites

	All Sites	SA - MRC/ Tongaat	SA - MRC/ Verulam	SA - WRHI	Uganda - Kampala	Zimbabwe - Seke South	Zimbabwe - Spilhaus	Zimbabwe - Zengeza
Participants Screened	1643	71	99	136	185	137	153	157
Participants Enrolled ¹	1456 (89%)	53 (75%)	79 (80%)	100 (74%)	172 (93%)	130 (95%)	139 (91%)	151 (96%)
Participants not Enrolled	187 (11%)	18 (25%)	20 (20%)	36 (26%)	13 (7%)	7 (5%)	14 (9%)	6 (4%)
Participant did not complete all screening procedures	30 (2%)	1 (1%)	0 (0%)	6 (4%)	4 (2%)	4 (3%)	2 (1%)	0 (0%)
Participant is eligible but declined enrollment	8 (<1%)	0 (0%)	0 (0%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible ²	149 (9%)	17 (24%)	20 (20%)	29 (21%)	8 (4%)	3 (2%)	12 (8%)	5 (3%)
Not previously enrolled in MTN-020 (ASPIRE)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to provide written informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV infected at Screening or Enrollment	45 (30%)	7 (41%)	2 (10%)	2 (7%)	2 (25%)	1 (33%)	2 (17%)	3 (60%)
Declines effective method of contraception at Enrollment and for duration of study participation	4 (3%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Does not agree to not participate in other research studies for duration of study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Study product use permanently discontinued in response to AE or safety related concern with taking part in MTN-020 (ASPIRE) trial	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Plans for relocation/travel per participant report at Screening	6 (4%)	1 (6%)	0 (0%)	2 (7%)	0 (0%)	1 (33%)	1 (8%)	0 (0%)
Grade 3 or higher Hemoglobin at Screening	3 (2%)	0 (0%)	2 (10%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 3 or high Pap results at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Currently taking PEP at Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participated in other research study involving drugs, medical devices, vaginal products, or vaccines within 60 days of Enrollment with the exception of MTN-020(ASPIRE)	1 (1%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pregnant at Screening/Enrollment or plans to become pregnant during study participation period	43 (29%)	6 (35%)	9 (45%)	6 (21%)	1 (13%)	1 (33%)	8 (67%)	1 (20%)
Currently breastfeeding	26 (17%)	3 (18%)	7 (35%)	10 (34%)	1 (13%)	0 (0%)	0 (0%)	0 (0%)
Diagnosed with UTI, PID, STI, or RTI which has not resolved or undergone complete treatment	4 (3%)	0 (0%)	0 (0%)	0 (0%)	2 (25%)	0 (0%)	0 (0%)	0 (0%)
Grade 3 pelvic exam finding at Screening or has not improved to non-exclusionary grading or resolved within 56 days or Screening	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)

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	All Sites	SA - MRC/ Tongaat	SA - MRC/ Verulam	SA - WRHI	Uganda - Kampala	Zimbabwe - Seke South	Zimbabwe - Spilhaus	Zimbabwe - Zengeza
Grade 3 or higher AST/ALT at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 3 or high Creatinine at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 3 or higher Platelet Count at Screening	1 (1%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other, including IoR discretion	19 (13%)	0 (0%)	1 (5%)	9 (31%)	2 (25%)	0 (0%)	1 (8%)	0 (0%)

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Listing of Other Reasons for Ineligibility by Site - Main Study

Obs	Site	Reason
1	Malawi - Blantyre	RECENT DEEP VEIN THROMBOSIS FOR WHICH SHE WAS TREATED WITH ANTICOAGURANTS AND CANNOT USE HORMONAL CONTRACEPTIVES. SHE IS ONLY USING CONDOMS AT THE MOMENT.
2		SHE HAS A GRADE 3 HYPERTENSION AND HAS BEEN REFERRED FOR REVIEW BY MEDICAL SPECIALISTS
3	SA - MRC/Botha's Hill	PARTICIPANT DEMISED
4		IOR DISCRETION ON 14 NOV 16 - PARTICIPANT REQUIRES COLPOSCOPY FOR A GRADE 2 HGSIL PAP SMEAR RESULT. IOR DISCRETION TO NOT ENROLL UNTIL COLPOSCOPY IS DONE. SCREENING WINDOW CLOSED ON 26 DEC 16.
5		SUSPECTED UNDIAGNOSED DIABETES MELLITUS TYPE 2
6	SA - MRC/Isipingo	GRADE 2 ABNORMAL PELVIC FINDING - BOOKED FOR SURGICAL MANAGEMENT AT LOCAL HOSPITAL. PARTICIPANT WAS IN ADDITION REFERRED FOR TREATMENT FOR GRADE 3 ELEVATED BLOOD PRESSURE AND COMMENCED TREATMENT.
7	SA - MRC/Verulam	EXCESSIVE ALCOHOL CONSUMPTION
8	SA - WRHI	HSIL ON PAP. REFERRED FOR COLPOSCOPY.PAP SMEAR REPORT IS HSIL WHICH IS GRADE 2.PARTICIPANT DID NOT RETURN FOR VISIT COMPLETION WITHIN THE SCREENING/ENROLMENT WINDOW.
9		ATYPICAL GLANDULAR EPITHELIAL CELLS ON PAP. REFERRED FOR COLPOSCOPY. PAP SMEAR SHOWED ATYPICAL GLANDULAR EPITHELIAL CELLS WHICH IS GRADE1
10		PARTICIPANT DIAGNOSED WITH SCHIZOPRENIA IN 2015. PSRT CONSULTED AND RECOMMENDATION WAS TO LEARN DETAILS OF CONDITION AND MEDICATION PRIOR TO ENROLMENT. WINDOW CLOSED BEFORE THIS COULD HAPPEN.
11		HSIL ON PAP. REFERRED FOR COLPOSCOPY. PAP SMEAR RESULY WAS HSIL WHICH IS GRADE 2. PARTICIPANT DID NOT RETURN FOR VISIT COMPLETION WITHIN THE SCREENING/ENROLMENT WINDOW.
12		HSIL ON PAP. HSIL IS GRADE 2. REFERRED FOR COLPOSCOPY. SMEAR REPEATED 28 JUNE 2017 SHOWED NEGATIVE FOR INTRAEPITHELIAL LESION.19 JULY 2017 PARTICIPANT REPORTED SHE WAS PREGNANT.
13		ELEVATED BLOOD PRESSURE. ASC-H ON PAP. DID NOT RETURN. PAP SMEAR COULD NOT EXCLUDE HSIL WHICH IS GRADE2.
14		ASC-H ON PAP. REFERRED FOR COLPOSCOPY. ASC-H IS GRADE 1.
15		ASC-H ON PAP. REFERRED FOR COLPOSCOPY. 01 SEPTEMBER 2017 PARTICIPANT HAD NOT GONE FOR THE COLPOSCOPY.ASC-H IS GRADE 1
16		PSRT GUIDANCE: PPT IS HYPERTENSIVE AND ON ORAL CONTRACEPTIVES
17	Uganda - Kampala	DUE TO PSYCHIATRIC ILLNESS NOT YET UNDER CONTROL
18		SCREENING WINDOW CLOSED DESPITE ATTEMPTS TO CONTACT PARTICIPANT TO COME COMPLETE SCREENING PROCEDURES.DECLINED SYPHILIS TREATMENT AND HER GC/CT SAMPLE DRAW FOR TESTING NOT DONE AS SHE DID NOT RETURN
19	Zimbabwe - Spilhaus	INELIGIBLE FOR CLINICAL REASONS, SIGNIFICANT CARDIOVASCULAR FINDINGS, PREFERRED FOR EVALUATION AND MANAGEMENT BY PHYSICIAN

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	All Sites	Malawi - Blantyre	Malawi - Lilongwe	SA - CAPRISA eThekweni	SA - Cape Town	SA - MRC/ Botha's Hill	SA - MRC/ Chatsworth	SA - MRC/ Isipingo
Participants Screened	121	11	9	2	12	0	2	27
Participants Enrolled ¹	120 (99%)	11 (100%)	9 (100%)	2 (100%)	12 (100%)	0 (0%)	2 (100%)	27 (100%)
Participants not Enrolled	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant did not complete all screening procedures	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible ²	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not previously enrolled in MTN-020 (ASPIRE)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to provide written informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to perform the Decliner Population study procedures	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Did not decline MTN-025 (main) study trial participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other, including IoR discretion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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Participants Screened	121	3	12	24	4	6	0	9
Participants Enrolled ¹	120 (99%)	3 (100%)	12 (100%)	23 (96%)	4 (100%)	6 (100%)	0 (0%)	9 (100%)
Participants not Enrolled	1 (1%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant did not complete all screening procedures	1 (1%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible ²	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not previously enrolled in MTN-020 (ASPIRE)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to provide written informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unable/unwilling to perform the Decliner Population study procedures	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Did not decline MTN-025 (main) study trial participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other, including IoR discretion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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