

**MTN 043 - B-PROTECTED: Mother-Infant Pair Study of Dapivirine Ring and PrEP in Breastfeeding
Data as of November 13, 2023**

Screen-out Summary by Site - Mothers

	Malawi Blantyre	Zimbabwe Zengeza	Uganda Kampala	SA Johannesburg	All Sites
Mothers Screened ¹	48	80	85	50	263
Mothers Enrolled ^{2, 3}	39 (81%)	67 (84%)	55 (65%)	36 (72%)	197 (75%)
Mothers not Enrolled	9 (19%)	13 (16%)	30 (35%)	14 (28%)	66 (25%)
Participant did not complete all screening procedures ⁴	0 (-%)	1 (8%)	0 (-%)	1 (7%)	2 (3%)
Participant is eligible but declined enrollment ⁴	0 (-%)	1 (8%)	6 (20%)	0 (-%)	7 (11%)
Reason participant not enrolled is missing(Incomplete screening) ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ^{4, 5}	9 (100%)	11 (85%)	24 (80%)	13 (93%)	57 (86%)
Not 18 years or older at Screening	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not between 6 to 12 weeks postpartum at Enrollment	0 (-%)	1 (9%)	0 (-%)	2 (15%)	3 (5%)
Not currently exclusively breastfeeding or unwilling to continue during the study	1 (11%)	0 (-%)	0 (-%)	1 (8%)	2 (4%)
Not consistently using an effective contraceptive currently or continue during the study	3 (33%)	0 (-%)	0 (-%)	1 (8%)	4 (7%)
Unable or unwilling to comply with all study requirements.	2 (22%)	0 (-%)	0 (-%)	0 (-%)	2 (4%)
Not providing written informed consent to be screened for and to take part in the study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not providing written informed consent for the breastfed infant.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Does not have intention to stay within study catchment area during study.	0 (-%)	1 (9%)	0 (-%)	2 (15%)	3 (5%)
HIV-infected based on HIV testing performed by study staff at Screening or Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unwilling to be randomized to either study product.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Breastfeeding infant ineligible for enrollment in the study.	0 (-%)	1 (9%)	2 (8%)	0 (-%)	3 (5%)
Known adverse reaction to any of the study products	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Known adverse reaction to latex and polyurethane (ever).	0 (-%)	1 (9%)	0 (-%)	0 (-%)	1 (2%)
Use of post-exposure prophylaxis (PEP) for HIV exposure in 6 months prior to Enrollment.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Use of vaginal medications(s) or other vaginal products in five days prior to Enrollment.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Use of non-therapeutic injection drug use in the 12 months prior to Enrollment.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
History of exposure to any investigational drugs during pregnancy, including MTN-042.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
At Screening or Enrollment, has a positive HIV test.	0 (-%)	1 (9%)	1 (4%)	1 (8%)	3 (5%)
At Screening or Enrollment, Grade 2 or higher breast or genitourinary findings.	0 (-%)	0 (-%)	1 (4%)	0 (-%)	1 (2%)
At Screening or Enrollment, has a positive urinary pregnancy test.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Positive for hepatitis B surface antigen (HBsAg).	1 (11%)	1 (9%)	1 (4%)	0 (-%)	3 (5%)
AST/ALT >= Grade 2.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Creatinine >= Grade 1.	0 (-%)	0 (-%)	1 (4%)	0 (-%)	1 (2%)

¹ Number of mothers screened is based on the Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report total screened which is based on the Screening Date of Visit eCRF.

² Number of mothers enrolled is based on the Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report which is based on the Randomization eCRF.

³ Percentage of mothers screened.

⁴ Percentage of mothers not enrolled.

⁵ Participants may be ineligible for more than one reason.

**MTN 043 - B-PROTECTED: Mother-Infant Pair Study of Dapivirine Ring and PrEP in Breastfeeding
Data as of November 13, 2023**

Screen-out Summary by Site - Mothers

	Malawi Blantyre	Zimbabwe Zengeza	Uganda Kampala	SA Johannesburg	All Sites
Estimated creatinine clearance >= Grade 2.	1 (11%)	2 (18%)	10 (42%)	0 (-%)	13 (23%)
Diagnosed with UTI, PID, STI or RTI, requiring treatment per WHO Guidelines.	1 (11%)	0 (-%)	0 (-%)	3 (23%)	4 (7%)
Any significant uncontrolled active or chronic disease/condition.	0 (-%)	3 (27%)	0 (-%)	4 (31%)	7 (12%)
Has any condition that would preclude study participation.	0 (-%)	0 (-%)	9 (38%)	1 (8%)	10 (18%)
Participation in any research study 30 days before enrollment.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Currently participating in other research studies.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Expected to participate in other research studies during study.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

¹ Number of mothers screened is based on the Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report total screened which is based on the Screening Date of Visit eCRF.

² Number of mothers enrolled is based on the Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report which is based on the Randomization eCRF.

³ Percentage of mothers screened.

⁴ Percentage of mothers not enrolled.

⁵ Participants may be ineligible for more than one reason.

**MTN 043 - B-PROTECTED: Mother-Infant Pair Study of Dapivirine Ring and PrEP in Breastfeeding
Data as of November 13, 2023**

Screen-out Summary by Site - Infants

	Malawi Blantyre	Zimbabwe Zengeza	Uganda Kampala	SA Johannesburg	All Sites
Infants Screened ¹	48	80	85	49	262
Infants Enrolled ^{2, 3}	39 (81%)	67 (84%)	55 (65%)	36 (73%)	197 (75%)
Infants not Enrolled	9 (19%)	13 (16%)	30 (35%)	13 (27%)	65 (25%)
Participant did not complete all screening procedures ⁴	0 (-%)	2 (15%)	1 (3%)	1 (8%)	4 (6%)
Participant is eligible but declined enrollment ⁴	8 (89%)	7 (54%)	27 (90%)	9 (69%)	51 (78%)
Reason participant not enrolled is missing(Incomplete screening) ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ^{4, 5}	1 (11%)	4 (31%)	2 (7%)	3 (23%)	10 (15%)
Not exclusively breastfed at Screening/Enrollment	1 (100%)	0 (-%)	0 (-%)	1 (33%)	2 (20%)
Not generally healthy at Screening/Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not between the ages of 6 and 12 weeks postpartum at Enrollment	0 (-%)	1 (25%)	0 (-%)	2 (67%)	3 (30%)
Has any condition that precludes eligibility or interferes with achieving study objectives	0 (-%)	3 (75%)	1 (50%)	1 (33%)	5 (50%)
Birth weight less than 2000g.	0 (-%)	0 (-%)	1 (50%)	0 (-%)	1 (10%)
Participation in any research study involving drugs, vaccines, or medical devices since birth.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Currently, participating in other research studies.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Expected to participate in other research studies during study participation.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

¹Number of infants screened is based on the Infant Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report total screened which is based on the Screening Date of Visit eCRF.

² Number of infants enrolled is based on the Infant Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report which is based on the Randomization eCRF.

³ Percentage of infants screened.

⁴ Percentage of infants not enrolled.

⁵ Participants may be ineligible for more than one reason.