

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 1

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	27	42	44	37	150
1. Social Benefits Assessment Required and Expected	26	33	42	36	137
Completed	26 (100.0%)	33 (100.0%)	42 (100.0%)	36 (100.0%)	137 (100.0%)
2. Social Harms Assessment Required and Expected	26	33	42	36	137
Completed	26 (100.0%)	33 (100.0%)	42 (100.0%)	36 (100.0%)	137 (100.0%)
3. IDI Required and Expected	8	11	14	13	46
Completed	8 (100.0%)	10 (90.9%)	14 (100.0%)	13 (100.0%)	45 (97.8%)
Not Completed	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	1 (2.2%)
4 Physical Exam Required and Expected	53	80	87	73	293
Completed	53 (100.0%)	80 (100.0%)	87 (100.0%)	73 (100.0%)	293 (100.0%)
5. Pelvic Exam Required and Expected	27	42	44	37	150
Completed	27 (100.0%)	42 (100.0%)	44 (100.0%)	37 (100.0%)	150 (100.0%)
6. Obstetric Abdominal Exam Required and Expected	76	113	136	122	447
Completed	76 (100.0%)	112 (99.1%)	136 (100.0%)	122 (100.0%)	446 (99.8%)
Not Completed	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
7. Dipstick UA (and/or Culture) Required and Expected	80	117	131	110	438
Completed	80 (100.0%)	117 (100.0%)	131 (100.0%)	110 (100.0%)	438 (100.0%)
8. HIV-1 Test Required and Expected	31	38	57	53	179
Completed	31 (100.0%)	37 (97.4%)	57 (100.0%)	53 (100.0%)	178 (99.4%)
Not Completed	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	1 (0.6%)
9. Hepatitis B Surface Antigen Test Required and Expected	27	42	44	37	150
Completed	27 (100.0%)	42 (100.0%)	44 (100.0%)	37 (100.0%)	150 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

**MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025**

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 1

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
10. Blood Serum Chemistry Required and Expected	80	117	130	110	437
Completed	79 (98.8%)	117 (100.0%)	130 (100.0%)	110 (100.0%)	436 (99.8%)
Not Completed	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
11. Hematology Required and Expected	80	117	130	110	437
Completed	77 (96.3%)	117 (100.0%)	130 (100.0%)	110 (100.0%)	434 (99.3%)
Not Completed	3 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.7%)
12. Syphilis Serology Required and Expected	53	75	86	73	287
Completed	53 (100.0%)	75 (100.0%)	86 (100.0%)	73 (100.0%)	287 (100.0%)
13. Dried Blood Spot for TFV-DP and FTC-TP drug levels Required and Expected (after Visit 2 Truvada group only)	31	47	75	53	206
Completed	30 (96.8%)	47 (100.0%)	75 (100.0%)	53 (100.0%)	205 (99.5%)
Not Completed	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
14. Plasma for DPV Drug levels Required and Expected (DPV group only)	20	21	35	43	119
Completed	19 (95.0%)	20 (95.2%)	35 (100.0%)	43 (100.0%)	117 (98.3%)
Not Completed	1 (5.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	2 (1.7%)
15. Plasma Archive Required and Expected	27	42	44	37	150
Completed	27 (100.0%)	42 (100.0%)	44 (100.0%)	37 (100.0%)	150 (100.0%)
16. NAAT (Pelvic) for GC/CT/Trich Required and Expected	53	75	86	73	287
Completed	53 (100.0%)	75 (100.0%)	86 (100.0%)	73 (100.0%)	287 (100.0%)
17. Vaginal pH Required and Expected	53	75	86	73	287
Completed	53 (100.0%)	75 (100.0%)	86 (100.0%)	73 (100.0%)	287 (100.0%)
18. Vaginal Swab(s) for Microbiota Required and Expected	75	104	134	121	434
Completed	74 (98.7%)	103 (99.0%)	134 (100.0%)	121 (100.0%)	432 (99.5%)
Not Completed	1 (1.3%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

**MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025**

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 1

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
19. Vaginal Gram Stain Required and Expected	75	104	134	121	434
Completed	74 (98.7%)	103 (99.0%)	134 (100.0%)	121 (100.0%)	432 (99.5%)
Not Completed	1 (1.3%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
20. Vaginal Swab(s) for Biomarkers Required and Expected	51	68	109	96	324
Completed	50 (98.0%)	67 (98.5%)	109 (100.0%)	96 (100.0%)	322 (99.4%)
Not Completed	1 (2.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (0.6%)
21. Creatinine Required and Expected	85	120	145	127	477
Completed	82 (96.5%)	118 (98.3%)	145 (100.0%)	126 (99.2%)	471 (98.7%)
Not Completed	3 (3.5%)	2 (1.7%)	0 (0.0%)	1 (0.8%)	6 (1.3%)
22. COVID-19 Behavioral Assessment Required and Expected	26	24	39	33	122
Completed	26 (100.0%)	24 (100.0%)	39 (100.0%)	33 (100.0%)	122 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

**MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025**

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 2

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	40	28	42	47	157
1. Social Benefits Assessment Required and Expected	38	24	41	47	150
Completed	38 (100.0%)	24 (100.0%)	41 (100.0%)	47 (100.0%)	150 (100.0%)
2. Social Harms Assessment Required and Expected	75	48	83	92	298
Completed	75 (100.0%)	48 (100.0%)	83 (100.0%)	92 (100.0%)	298 (100.0%)
3. IDI Required and Expected	10	7	6	8	31
Completed	9 (90.0%)	6 (85.7%)	6 (100.0%)	8 (100.0%)	29 (93.5%)
Not Completed	1 (10.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	2 (6.5%)
4 Physical Exam Required and Expected	115	75	126	139	455
Completed	115 (100.0%)	75 (100.0%)	126 (100.0%)	139 (100.0%)	455 (100.0%)
5. Pelvic Exam Required and Expected	40	28	42	47	157
Completed	40 (100.0%)	28 (100.0%)	42 (100.0%)	47 (100.0%)	157 (100.0%)
6. Obstetric Abdominal Exam Required and Expected	209	147	253	278	887
Completed	209 (100.0%)	147 (100.0%)	253 (100.0%)	278 (100.0%)	887 (100.0%)
7. Dipstick UA (and/or Culture) Required and Expected	155	104	167	186	612
Completed	155 (100.0%)	104 (100.0%)	167 (100.0%)	186 (100.0%)	612 (100.0%)
8. HIV-1 Test Required and Expected	93	65	115	127	400
Completed	93 (100.0%)	64 (98.5%)	115 (100.0%)	127 (100.0%)	399 (99.8%)
Not Completed	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
9. Hepatitis B Surface Antigen Test Required and Expected	40	28	42	47	157
Completed	40 (100.0%)	28 (100.0%)	42 (100.0%)	47 (100.0%)	157 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 2

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
10. Blood Serum Chemistry Required and Expected	155	104	167	186	612
Completed	155 (100.0%)	104 (100.0%)	167 (100.0%)	186 (100.0%)	612 (100.0%)
11. Hematology Required and Expected	155	104	167	186	612
Completed	147 (94.8%)	104 (100.0%)	167 (100.0%)	186 (100.0%)	604 (98.7%)
Not Completed	8 (5.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (1.3%)
12. Syphilis Serology Required and Expected	78	52	83	94	307
Completed	78 (100.0%)	52 (100.0%)	82 (98.8%)	94 (100.0%)	306 (99.7%)
Not Completed	0 (0.0%)	0 (0.0%)	1 (1.2%)	0 (0.0%)	1 (0.3%)
13. Dried Blood Spot for TFV-DP and FTC-TP drug levels Required and Expected (after Visit 2 Truvada group only)	82	55	101	103	341
Completed	78 (95.1%)	55 (100.0%)	96 (95.0%)	103 (100.0%)	332 (97.4%)
Not Completed	4 (4.9%)	0 (0.0%)	5 (5.0%)	0 (0.0%)	9 (2.6%)
14. Plasma for DPV Drug levels Required and Expected (DPV group only)	86	65	118	128	397
Completed	86 (100.0%)	64 (98.5%)	118 (100.0%)	128 (100.0%)	396 (99.7%)
Not Completed	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
15. Plasma Archive Required and Expected	40	28	42	47	157
Completed	40 (100.0%)	28 (100.0%)	42 (100.0%)	47 (100.0%)	157 (100.0%)
16. NAAT (Pelvic) for GC/CT/Trich Required and Expected	78	52	83	94	307
Completed	78 (100.0%)	52 (100.0%)	82 (98.8%)	94 (100.0%)	306 (99.7%)
Not Completed	0 (0.0%)	0 (0.0%)	1 (1.2%)	0 (0.0%)	1 (0.3%)
17. Vaginal pH Required and Expected	78	52	83	94	307
Completed	78 (100.0%)	52 (100.0%)	83 (100.0%)	94 (100.0%)	307 (100.0%)
18. Vaginal Swab(s) for Microbiota Required and Expected	207	143	252	278	880
Completed	203 (98.1%)	142 (99.3%)	252 (100.0%)	278 (100.0%)	875 (99.4%)
Not Completed	4 (1.9%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	5 (0.6%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 2

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
19. Vaginal Gram Stain Required and Expected	207	143	252	278	880
Completed	203 (98.1%)	142 (99.3%)	252 (100.0%)	278 (100.0%)	875 (99.4%)
Not Completed	4 (1.9%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	5 (0.6%)
20. Vaginal Swab(s) for Biomarkers Required and Expected	168	120	218	231	737
Completed	164 (97.6%)	119 (99.2%)	214 (98.2%)	231 (100.0%)	728 (98.8%)
Not Completed	4 (2.4%)	1 (0.8%)	4 (1.8%)	0 (0.0%)	9 (1.2%)
21. Creatinine Required and Expected	155	104	167	186	612
Completed	155 (100.0%)	104 (100.0%)	167 (100.0%)	186 (100.0%)	612 (100.0%)
22. COVID-19 Behavioral Assessment Required and Expected	78	52	83	94	307
Completed	78 (100.0%)	52 (100.0%)	83 (100.0%)	94 (100.0%)	307 (100.0%)
23. Baseline Behavioral Assessment Required and Expected	40	28	42	47	157
Completed	40 (100.0%)	28 (100.0%)	42 (100.0%)	47 (100.0%)	157 (100.0%)
24. Follow-up Behavioral Assessment Required and Expected	37	24	41	45	147
Completed	37 (100.0%)	24 (100.0%)	41 (100.0%)	45 (100.0%)	147 (100.0%)
25. Post-PO Behavioral Assessment Required and Expected	38	24	40	47	149
Completed	38 (100.0%)	24 (100.0%)	40 (100.0%)	47 (100.0%)	149 (100.0%)
26. Ring Adherence Required and Expected	50	33	56	64	203
Completed	50 (100.0%)	33 (100.0%)	56 (100.0%)	64 (100.0%)	203 (100.0%)
27. Tablet Adherence Required and Expected	25	14	26	28	93
Completed	25 (100.0%)	14 (100.0%)	26 (100.0%)	28 (100.0%)	93 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 3

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	66	44	68	73	251
1. Social Benefits Assessment Required and Expected	66	35	67	72	240
Completed	66 (100.0%)	35 (100.0%)	67 (100.0%)	72 (100.0%)	240 (100.0%)
2. Social Harms Assessment Required and Expected	183	105	192	217	697
Completed	183 (100.0%)	105 (100.0%)	192 (100.0%)	217 (100.0%)	697 (100.0%)
3. IDI Required and Expected	10	8	0	3	21
Completed	10 (100.0%)	8 (100.0%)	0 (-%)	3 (100.0%)	21 (100.0%)
4 Physical Exam Required and Expected	299	196	318	377	1190
Completed	299 (100.0%)	196 (100.0%)	318 (100.0%)	377 (100.0%)	1190 (100.0%)
5. Pelvic Exam Required and Expected	66	44	68	73	251
Completed	66 (100.0%)	44 (100.0%)	68 (100.0%)	73 (100.0%)	251 (100.0%)
6. Obstetric Abdominal Exam Required and Expected	452	282	478	530	1742
Completed	452 (100.0%)	282 (100.0%)	478 (100.0%)	530 (100.0%)	1742 (100.0%)
7. Dipstick UA (and/or Culture) Required and Expected	292	185	298	332	1107
Completed	292 (100.0%)	185 (100.0%)	297 (99.7%)	331 (99.7%)	1105 (99.8%)
Not Completed	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.2%)
8. HIV-1 Test Required and Expected	296	189	301	378	1164
Completed	269 (90.9%)	173 (91.5%)	300 (99.7%)	348 (92.1%)	1090 (93.6%)
Not Completed	27 (9.1%)	16 (8.5%)	1 (0.3%)	30 (7.9%)	74 (6.4%)
9. Hepatitis B Surface Antigen Test Required and Expected	66	44	68	73	251
Completed	66 (100.0%)	44 (100.0%)	68 (100.0%)	73 (100.0%)	251 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 3

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
10. Blood Serum Chemistry Required and Expected	292	185	298	332	1107
Completed	290 (99.3%)	185 (100.0%)	296 (99.3%)	331 (99.7%)	1102 (99.5%)
Not Completed	2 (0.7%)	0 (0.0%)	2 (0.7%)	1 (0.3%)	5 (0.5%)
11. Hematology Required and Expected	292	185	298	332	1107
Completed	287 (98.3%)	185 (100.0%)	296 (99.3%)	330 (99.4%)	1098 (99.2%)
Not Completed	5 (1.7%)	0 (0.0%)	2 (0.7%)	2 (0.6%)	9 (0.8%)
12. Syphilis Serology Required and Expected	132	79	135	145	491
Completed	131 (99.2%)	79 (100.0%)	134 (99.3%)	145 (100.0%)	489 (99.6%)
Not Completed	1 (0.8%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	2 (0.4%)
13. Dried Blood Spot for TFV-DP and FTC-TP drug levels Required and Expected (after Visit 2 Truvada group only)	128	78	136	140	482
Completed	128 (100.0%)	78 (100.0%)	136 (100.0%)	140 (100.0%)	482 (100.0%)
14. Plasma for DPV Drug levels Required and Expected (DPV group only)	258	157	272	316	1003
Completed	258 (100.0%)	157 (100.0%)	272 (100.0%)	316 (100.0%)	1003 (100.0%)
15. Plasma Archive Required and Expected	66	44	68	73	251
Completed	66 (100.0%)	44 (100.0%)	68 (100.0%)	73 (100.0%)	251 (100.0%)
16. NAAT (Pelvic) for GC/CT/Trich Required and Expected	132	79	135	145	491
Completed	131 (99.2%)	79 (100.0%)	134 (99.3%)	145 (100.0%)	489 (99.6%)
Not Completed	1 (0.8%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	2 (0.4%)
17. Vaginal pH Required and Expected	132	79	135	145	491
Completed	131 (99.2%)	79 (100.0%)	134 (99.3%)	145 (100.0%)	489 (99.6%)
Not Completed	1 (0.8%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	2 (0.4%)
18. Vaginal Swab(s) for Microbiota Required and Expected	452	273	477	529	1731
Completed	452 (100.0%)	273 (100.0%)	476 (99.8%)	529 (100.0%)	1730 (99.9%)
Not Completed	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Visit Adherence: Completion of Procedures During Enrollment and Follow-up¹ by Site - Mothers Cohort 3

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
19. Vaginal Gram Stain Required and Expected	452	273	477	529	1731
Completed	452 (100.0%)	272 (99.6%)	476 (99.8%)	529 (100.0%)	1729 (99.9%)
Not Completed	0 (0.0%)	1 (0.4%)	1 (0.2%)	0 (0.0%)	2 (0.1%)
20. Vaginal Swab(s) for Biomarkers Required and Expected	386	235	410	456	1487
Completed	386 (100.0%)	235 (100.0%)	408 (99.5%)	456 (100.0%)	1485 (99.9%)
Not Completed	0 (0.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)	2 (0.1%)
21. Creatinine Required and Expected	277	175	287	311	1050
Completed	275 (99.3%)	175 (100.0%)	286 (99.7%)	310 (99.7%)	1046 (99.6%)
Not Completed	2 (0.7%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	4 (0.4%)
22. COVID-19 Behavioral Assessment Required and Expected	132	79	134	145	490
Completed	132 (100.0%)	79 (100.0%)	134 (100.0%)	145 (100.0%)	490 (100.0%)
23. Baseline Behavioral Assessment Required and Expected	66	44	68	73	251
Completed	66 (100.0%)	44 (100.0%)	68 (100.0%)	73 (100.0%)	251 (100.0%)
24. Follow-up Behavioral Assessment Required and Expected	117	69	125	145	456
Completed	117 (100.0%)	69 (100.0%)	125 (100.0%)	145 (100.0%)	456 (100.0%)
25. Post-PO Behavioral Assessment Required and Expected	66	35	66	72	239
Completed	66 (100.0%)	35 (100.0%)	66 (100.0%)	72 (100.0%)	239 (100.0%)
26. Ring Adherence Required and Expected	224	144	237	277	882
Completed	224 (100.0%)	144 (100.0%)	237 (100.0%)	277 (100.0%)	882 (100.0%)
27. Tablet Adherence Required and Expected	53	27	59	59	198
Completed	53 (100.0%)	27 (100.0%)	59 (100.0%)	59 (100.0%)	198 (100.0%)

¹ Protocol-required follow-up visit procedures are expected only once the visit window has closed, and only for participants who attend the visit. If a participant misses a visit, as documented by a Missed Visit eCRF, the procedures for that visit will not be included as expected.