

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Report Generation Date: December 2, 2025
Data as of: December 1, 2025¹
Infant Retention by Cohort, Visit, and Site

All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	132	106	153	155	546
Visit 201: PPO Visit					
Expected ²	132	106	153	155	546
Completed ³	129 (98%)	93 (88%)	151 (99%)	150 (97%)	523 (96%)
Not Completed	3 (2%)	13 (12%)	2 (1%)	5 (3%)	23 (4%)
Missed	2 (2%)	11 (10%)	2 (1%)	4 (3%)	19 (3%)
Terminated Early	1 (1%)	2 (2%)	0 (0%)	1 (1%)	4 (1%)
Not Expected	0	0	0	0	0
Visit 202: 1 week PPO phone contact⁴					
Expected ²	3	14	2	5	24
Completed ³	2 (67%)	5 (36%)	2 (100%)	4 (80%)	13 (54%)
Not Completed	1 (33%)	9 (64%)	0 (0%)	1 (20%)	11 (46%)
Missed	0 (0%)	7 (50%)	0 (0%)	0 (0%)	7 (29%)
Terminated Early	1 (33%)	2 (14%)	0 (0%)	1 (20%)	4 (17%)
Not Expected	129	92	151	150	522
Visit 203: 6 week PPO visit					
Expected ²	132	106	153	155	546
Completed ³	129 (98%)	89 (84%)	149 (97%)	153 (99%)	520 (95%)
Not Completed	3 (2%)	17 (16%)	4 (3%)	2 (1%)	26 (5%)
Missed	0 (0%)	11 (10%)	4 (3%)	1 (1%)	16 (3%)
Terminated Early	3 (2%)	6 (6%)	0 (0%)	1 (1%)	10 (2%)
Not Expected	0	0	0	0	0

¹ This report includes data received at SCHARP through this date.

² A visit is considered expected only once the participant's visit window has closed.

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⁴ The 1 week PPO phone contact visit is not expected if the PPO visit was both completed and completed 1-14 days after the pregnancy outcome date.

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All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 204: 6 month PPO visit					
Expected ²	132	106	153	155	546
Completed ³	129 (98%)	86 (81%)	151 (99%)	151 (97%)	517 (95%)
Not Completed	3 (2%)	20 (19%)	2 (1%)	4 (3%)	29 (5%)
Missed	0 (0%)	12 (11%)	2 (1%)	1 (1%)	15 (3%)
Terminated Early	3 (2%)	8 (8%)	0 (0%)	3 (2%)	14 (3%)
Not Expected	0	0	0	0	0
Visit 205: 12 month PPO visit					
Expected ²	132	106	153	155	546
Completed ³	129 (98%)	79 (75%)	148 (97%)	144 (93%)	500 (92%)
Not Completed	3 (2%)	27 (25%)	5 (3%)	11 (7%)	46 (8%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	3 (2%)	27 (25%)	5 (3%)	11 (7%)	46 (8%)
Not Expected	0	0	0	0	0

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Infant Retention by Cohort, Visit, and Site

Cohort 1 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	27	40	44	36	147
Visit 201: PPO Visit					
Expected ²	27	40	44	36	147
Completed ³	26 (96%)	37 (93%)	43 (98%)	36 (100%)	142 (97%)
Not Completed	1 (4%)	3 (8%)	1 (2%)	0 (0%)	5 (3%)
Missed	1 (4%)	2 (5%)	1 (2%)	0 (0%)	4 (3%)
Terminated Early	0 (0%)	1 (3%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	0	0	0	0	0
Visit 202: 1 week PPO phone contact⁴					
Expected ²	1	3	1	0	5
Completed ³	1 (100%)	3 (100%)	1 (100%)	0 (-%)	5 (100%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)
Not Expected	26	37	43	36	142
Visit 203: 6 week PPO visit					
Expected ²	27	40	44	36	147
Completed ³	26 (96%)	33 (83%)	42 (95%)	36 (100%)	137 (93%)
Not Completed	1 (4%)	7 (18%)	2 (5%)	0 (0%)	10 (7%)
Missed	0 (0%)	5 (13%)	2 (5%)	0 (0%)	7 (5%)
Terminated Early	1 (4%)	2 (5%)	0 (0%)	0 (0%)	3 (2%)
Not Expected	0	0	0	0	0

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Infant Retention by Cohort, Visit, and Site

Cohort 1 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 204: 6 month PPO visit					
Expected ²	27	40	44	36	147
Completed ³	26 (96%)	32 (80%)	43 (98%)	36 (100%)	137 (93%)
Not Completed	1 (4%)	8 (20%)	1 (2%)	0 (0%)	10 (7%)
Missed	0 (0%)	4 (10%)	1 (2%)	0 (0%)	5 (3%)
Terminated Early	1 (4%)	4 (10%)	0 (0%)	0 (0%)	5 (3%)
Not Expected	0	0	0	0	0
Visit 205: 12 month PPO visit					
Expected ²	27	40	44	36	147
Completed ³	26 (96%)	29 (73%)	42 (95%)	36 (100%)	133 (90%)
Not Completed	1 (4%)	11 (28%)	2 (5%)	0 (0%)	14 (10%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (4%)	11 (28%)	2 (5%)	0 (0%)	14 (10%)
Not Expected	0	0	0	0	0

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Infant Retention by Cohort, Visit, and Site

Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	39	26	42	47	154
Visit 201: PPO Visit					
Expected ²	39	26	42	47	154
Completed ³	38 (97%)	24 (92%)	42 (100%)	47 (100%)	151 (98%)
Not Completed	1 (3%)	2 (8%)	0 (0%)	0 (0%)	3 (2%)
Missed	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Terminated Early	0 (0%)	1 (4%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	0	0	0	0	0
Visit 202: 1 week PPO phone contact⁴					
Expected ²	1	3	0	0	4
Completed ³	1 (100%)	0 (0%)	0 (-%)	0 (-%)	1 (25%)
Not Completed	0 (0%)	3 (100%)	0 (-%)	0 (-%)	3 (75%)
Missed	0 (0%)	1 (33%)	0 (-%)	0 (-%)	1 (25%)
Terminated Early	0 (0%)	2 (67%)	0 (-%)	0 (-%)	2 (50%)
Not Expected	38	23	42	47	150
Visit 203: 6 week PPO visit					
Expected ²	39	26	42	47	154
Completed ³	38 (97%)	23 (88%)	41 (98%)	47 (100%)	149 (97%)
Not Completed	1 (3%)	3 (12%)	1 (2%)	0 (0%)	5 (3%)
Missed	0 (0%)	0 (0%)	1 (2%)	0 (0%)	1 (1%)
Terminated Early	1 (3%)	3 (12%)	0 (0%)	0 (0%)	4 (3%)
Not Expected	0	0	0	0	0

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Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 204: 6 month PPO visit					
Expected ²	39	26	42	47	154
Completed ³	38 (97%)	18 (69%)	42 (100%)	47 (100%)	145 (94%)
Not Completed	1 (3%)	8 (31%)	0 (0%)	0 (0%)	9 (6%)
Missed	0 (0%)	5 (19%)	0 (0%)	0 (0%)	5 (3%)
Terminated Early	1 (3%)	3 (12%)	0 (0%)	0 (0%)	4 (3%)
Not Expected	0	0	0	0	0
Visit 205: 12 month PPO visit					
Expected ²	39	26	42	47	154
Completed ³	38 (97%)	15 (58%)	40 (95%)	41 (87%)	134 (87%)
Not Completed	1 (3%)	11 (42%)	2 (5%)	6 (13%)	20 (13%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (3%)	11 (42%)	2 (5%)	6 (13%)	20 (13%)
Not Expected	0	0	0	0	0

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Infant Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	66	40	67	72	245
Visit 201: PPO Visit					
Expected ²	66	40	67	72	245
Completed ³	65 (98%)	32 (80%)	66 (99%)	67 (93%)	230 (94%)
Not Completed	1 (2%)	8 (20%)	1 (1%)	5 (7%)	15 (6%)
Missed	0 (0%)	8 (20%)	1 (1%)	4 (6%)	13 (5%)
Terminated Early	1 (2%)	0 (0%)	0 (0%)	1 (1%)	2 (1%)
Not Expected	0	0	0	0	0
Visit 202: 1 week PPO phone contact⁴					
Expected ²	1	8	1	5	15
Completed ³	0 (0%)	2 (25%)	1 (100%)	4 (80%)	7 (47%)
Not Completed	1 (100%)	6 (75%)	0 (0%)	1 (20%)	8 (53%)
Missed	0 (0%)	6 (75%)	0 (0%)	0 (0%)	6 (40%)
Terminated Early	1 (100%)	0 (0%)	0 (0%)	1 (20%)	2 (13%)
Not Expected	65	32	66	67	230
Visit 203: 6 week PPO visit					
Expected ²	66	40	67	72	245
Completed ³	65 (98%)	33 (83%)	66 (99%)	70 (97%)	234 (96%)
Not Completed	1 (2%)	7 (18%)	1 (1%)	2 (3%)	11 (4%)
Missed	0 (0%)	6 (15%)	1 (1%)	1 (1%)	8 (3%)
Terminated Early	1 (2%)	1 (3%)	0 (0%)	1 (1%)	3 (1%)
Not Expected	0	0	0	0	0

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	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 204: 6 month PPO visit					
Expected ²	66	40	67	72	245
Completed ³	65 (98%)	36 (90%)	66 (99%)	68 (94%)	235 (96%)
Not Completed	1 (2%)	4 (10%)	1 (1%)	4 (6%)	10 (4%)
Missed	0 (0%)	3 (8%)	1 (1%)	1 (1%)	5 (2%)
Terminated Early	1 (2%)	1 (3%)	0 (0%)	3 (4%)	5 (2%)
Not Expected	0	0	0	0	0
Visit 205: 12 month PPO visit					
Expected ²	66	40	67	72	245
Completed ³	65 (98%)	35 (88%)	66 (99%)	67 (93%)	233 (95%)
Not Completed	1 (2%)	5 (13%)	1 (1%)	5 (7%)	12 (5%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (2%)	5 (13%)	1 (1%)	5 (7%)	12 (5%)
Not Expected	0	0	0	0	0

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