

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

Mother Retention by Cohort, Visit, and Site

All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	133	114	154	157	558
Visit 3: Week 1 Phone Contact					
Expected ²	126	105	151	153	535
Completed ³	126 (100%)	103 (98%)	151 (100%)	151 (99%)	531 (99%)
Not Completed	0 (0%)	2 (2%)	0 (0%)	2 (1%)	4 (1%)
Missed	0 (0%)	1 (1%)	0 (0%)	2 (1%)	3 (1%)
Terminated Early	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (<1%)
Not Expected	7	9	3	3	22
Visit 4: Week 2 Bi-weekly Visit					
Expected ²	120	99	141	149	509
Completed ³	117 (98%)	88 (89%)	141 (100%)	148 (99%)	494 (97%)
Not Completed	3 (3%)	11 (11%)	0 (0%)	1 (1%)	15 (3%)
Missed	3 (3%)	10 (10%)	0 (0%)	1 (1%)	14 (3%)
Terminated Early	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (<1%)
Not Expected	13	15	13	7	48
Visit 5: Week 3 Phone Contact					
Expected ²	113	91	131	142	477
Completed ³	111 (98%)	85 (93%)	130 (99%)	142 (100%)	468 (98%)
Not Completed	2 (2%)	6 (7%)	1 (1%)	0 (0%)	9 (2%)
Missed	1 (1%)	4 (4%)	1 (1%)	0 (0%)	6 (1%)
Terminated Early	1 (1%)	2 (2%)	0 (0%)	0 (0%)	3 (1%)
Not Expected	20	23	23	14	80

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Mother Retention by Cohort, Visit, and Site

All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 6: Week 4 Bi-weekly Visit					
Expected ²	105	75	118	133	431
Completed ³	104 (99%)	63 (84%)	117 (99%)	132 (99%)	416 (97%)
Not Completed	1 (1%)	12 (16%)	1 (1%)	1 (1%)	15 (3%)
Missed	0 (0%)	10 (13%)	1 (1%)	1 (1%)	12 (3%)
Terminated Early	1 (1%)	2 (3%)	0 (0%)	0 (0%)	3 (1%)
Not Expected	28	39	36	23	126
Visit 7: Week 5 Phone Contact					
Expected ²	9	8	14	18	49
Completed ³	9 (100%)	5 (63%)	13 (93%)	18 (100%)	45 (92%)
Not Completed	0 (0%)	3 (38%)	1 (7%)	0 (0%)	4 (8%)
Missed	0 (0%)	2 (25%)	1 (7%)	0 (0%)	3 (6%)
Terminated Early	0 (0%)	1 (13%)	0 (0%)	0 (0%)	1 (2%)
Not Expected	19	31	42	23	115
Visit 8: Week 6 Bi-weekly Visit					
Expected ²	31	25	36	42	134
Completed ³	30 (97%)	21 (84%)	36 (100%)	42 (100%)	129 (96%)
Not Completed	1 (3%)	4 (16%)	0 (0%)	0 (0%)	5 (4%)
Missed	0 (0%)	3 (12%)	0 (0%)	0 (0%)	3 (2%)
Terminated Early	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	9	3	6	5	23

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Mother Retention by Cohort, Visit, and Site

All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 9: Week 7 Phone Contact					
Expected ²	38	25	38	40	141
Completed ³	37 (97%)	23 (92%)	36 (95%)	39 (98%)	135 (96%)
Not Completed	1 (3%)	2 (8%)	2 (5%)	1 (3%)	6 (4%)
Missed	0 (0%)	1 (4%)	2 (5%)	1 (3%)	4 (3%)
Terminated Early	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	15	4	9	7	35
Visit 10: Week 8 Visit					
Expected ²	82	59	95	103	339
Completed ³	81 (99%)	50 (85%)	95 (100%)	103 (100%)	329 (97%)
Not Completed	1 (1%)	9 (15%)	0 (0%)	0 (0%)	10 (3%)
Missed	0 (0%)	8 (14%)	0 (0%)	0 (0%)	8 (2%)
Terminated Early	1 (1%)	1 (2%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	23	13	13	15	64
Visit 11: Week 9 Phone Contact					
Expected ²	34	18	36	26	114
Completed ³	33 (97%)	15 (83%)	35 (97%)	26 (100%)	109 (96%)
Not Completed	1 (3%)	3 (17%)	1 (3%)	0 (0%)	5 (4%)
Missed	0 (0%)	1 (6%)	1 (3%)	0 (0%)	2 (2%)
Terminated Early	1 (3%)	2 (11%)	0 (0%)	0 (0%)	3 (3%)
Not Expected	27	14	20	26	87

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Mother Retention by Cohort, Visit, and Site

All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 12: Week 10 Bi-weekly Visit					
Expected ²	24	9	24	19	76
Completed ³	23 (96%)	4 (44%)	24 (100%)	19 (100%)	70 (92%)
Not Completed	1 (4%)	5 (56%)	0 (0%)	0 (0%)	6 (8%)
Missed	0 (0%)	3 (33%)	0 (0%)	0 (0%)	3 (4%)
Terminated Early	1 (4%)	2 (22%)	0 (0%)	0 (0%)	3 (4%)
Not Expected	39	24	34	39	136
Visit 13: Week 11 Phone Contact					
Expected ²	21	8	26	25	80
Completed ³	20 (95%)	5 (63%)	26 (100%)	24 (96%)	75 (94%)
Not Completed	1 (5%)	3 (38%)	0 (0%)	1 (4%)	5 (6%)
Missed	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (3%)
Terminated Early	1 (5%)	2 (25%)	0 (0%)	0 (0%)	3 (4%)
Not Expected	43	21	34	42	140
Visit 14: Week 12 Visit					
Expected ²	40	36	51	65	192
Completed ³	40 (100%)	31 (86%)	51 (100%)	63 (97%)	185 (96%)
Not Completed	0 (0%)	5 (14%)	0 (0%)	2 (3%)	7 (4%)
Missed	0 (0%)	3 (8%)	0 (0%)	2 (3%)	5 (3%)
Terminated Early	0 (0%)	2 (6%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	26	8	17	8	59

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Mother Retention by Cohort, Visit, and Site

All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 15: Week 13 Phone Contact					
Expected ²	16	11	23	28	78
Completed ³	16 (100%)	9 (82%)	23 (100%)	26 (93%)	74 (95%)
Not Completed	0 (0%)	2 (18%)	0 (0%)	2 (7%)	4 (5%)
Missed	0 (0%)	2 (18%)	0 (0%)	2 (7%)	4 (5%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	16	5	12	14	47
Visit 16: Week 14 Bi-weekly Visit					
Expected ²	14	15	20	23	72
Completed ³	14 (100%)	12 (80%)	20 (100%)	23 (100%)	69 (96%)
Not Completed	0 (0%)	3 (20%)	0 (0%)	0 (0%)	3 (4%)
Missed	0 (0%)	2 (13%)	0 (0%)	0 (0%)	2 (3%)
Terminated Early	0 (0%)	1 (7%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	17	4	20	21	62
Visit 17: Week 15 Phone Contact					
Expected ²	16	11	17	25	69
Completed ³	16 (100%)	9 (82%)	17 (100%)	25 (100%)	67 (97%)
Not Completed	0 (0%)	2 (18%)	0 (0%)	0 (0%)	2 (3%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	2 (18%)	0 (0%)	0 (0%)	2 (3%)
Not Expected	12	7	15	21	55

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All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 18: Week 16 Visit					
Expected ²	25	25	27	34	111
Completed ³	25 (100%)	20 (80%)	27 (100%)	34 (100%)	106 (95%)
Not Completed	0 (0%)	5 (20%)	0 (0%)	0 (0%)	5 (5%)
Missed	0 (0%)	3 (12%)	0 (0%)	0 (0%)	3 (3%)
Terminated Early	0 (0%)	2 (8%)	0 (0%)	0 (0%)	2 (2%)
Not Expected	13	13	18	25	69
Visit 19: Week 17 Phone Contact					
Expected ²	12	9	12	19	52
Completed ³	12 (100%)	6 (67%)	12 (100%)	19 (100%)	49 (94%)
Not Completed	0 (0%)	3 (33%)	0 (0%)	0 (0%)	3 (6%)
Missed	0 (0%)	1 (11%)	0 (0%)	0 (0%)	1 (2%)
Terminated Early	0 (0%)	2 (22%)	0 (0%)	0 (0%)	2 (4%)
Not Expected	11	13	13	17	54
Visit 20: Week 18 Bi-weekly Visit					
Expected ²	9	13	10	16	48
Completed ³	8 (89%)	10 (77%)	9 (90%)	16 (100%)	43 (90%)
Not Completed	1 (11%)	3 (23%)	1 (10%)	0 (0%)	5 (10%)
Missed	1 (11%)	1 (8%)	1 (10%)	0 (0%)	3 (6%)
Terminated Early	0 (0%)	2 (15%)	0 (0%)	0 (0%)	2 (4%)
Not Expected	12	9	12	21	54

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	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 21: Week 19 Phone Contact					
Expected ²	6	16	10	11	43
Completed ³	6 (100%)	13 (81%)	10 (100%)	11 (100%)	40 (93%)
Not Completed	0 (0%)	3 (19%)	0 (0%)	0 (0%)	3 (7%)
Missed	0 (0%)	1 (6%)	0 (0%)	0 (0%)	1 (2%)
Terminated Early	0 (0%)	2 (13%)	0 (0%)	0 (0%)	2 (5%)
Not Expected	9	10	13	15	47
Visit 22: Week 20 Visit					
Expected ²	8	14	12	13	47
Completed ³	8 (100%)	11 (79%)	12 (100%)	13 (100%)	44 (94%)
Not Completed	0 (0%)	3 (21%)	0 (0%)	0 (0%)	3 (6%)
Missed	0 (0%)	2 (14%)	0 (0%)	0 (0%)	2 (4%)
Terminated Early	0 (0%)	1 (7%)	0 (0%)	0 (0%)	1 (2%)
Not Expected	9	8	9	12	38
Visit 23: Week 21 Phone Contact					
Expected ²	4	9	7	8	28
Completed ³	4 (100%)	8 (89%)	7 (100%)	8 (100%)	27 (96%)
Not Completed	0 (0%)	1 (11%)	0 (0%)	0 (0%)	1 (4%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	1 (11%)	0 (0%)	0 (0%)	1 (4%)
Not Expected	9	12	10	9	40

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	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 24: Week 22 Bi-weekly Visit					
Expected ²	2	2	4	3	11
Completed ³	2 (100%)	2 (100%)	4 (100%)	3 (100%)	11 (100%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	11	16	11	13	51
Visit 25: Week 23 Phone Contact					
Expected ²	1	1	5	3	10
Completed ³	1 (100%)	1 (100%)	5 (100%)	3 (100%)	10 (100%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	6	13	7	6	32
Visit 26: Week 24 Visit					
Expected ²	2	0	2	3	7
Completed ³	2 (100%)	0 (-%)	2 (100%)	3 (100%)	7 (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	5	7	6	2	20

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	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 27: Week 25 Phone Contact					
Expected ²	0	0	2	1	3
Completed ³	0 (-%)	0 (-%)	2 (100%)	1 (100%)	3 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	5	1	2	3	11
Visit 28: Week 26 Bi-weekly Visit					
Expected ²	0	0	1	1	2
Completed ³	0 (-%)	0 (-%)	1 (100%)	1 (100%)	2 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	2	0	2	3	7
Visit 29: Week 27 Phone Contact					
Expected ²	0	0	1	1	2
Completed ³	0 (-%)	0 (-%)	1 (100%)	1 (100%)	2 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	1	0	1	2	4

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Visit 30: Week 28 Bi-weekly Visit					
Expected ²	0	0	1	0	1
Completed ³	0 (-%)	0 (-%)	1 (100%)	0 (-%)	1 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (-%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (-%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (-%)	0 (0%)
Not Expected	1	0	0	1	2
Visit 31: Week 29 Phone Contact					
Expected ²	0	0	0	0	0
Completed ³	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not Completed	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Missed	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Terminated Early	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not Expected	1	0	0	1	2
Visit 101: PPO Visit					
Expected ²	133	114	154	156	557
Completed ³	130 (98%)	94 (82%)	152 (99%)	152 (97%)	528 (95%)
Not Completed	3 (2%)	20 (18%)	2 (1%)	4 (3%)	29 (5%)
Missed	2 (2%)	13 (11%)	2 (1%)	4 (3%)	21 (4%)
Terminated Early	1 (1%)	7 (6%)	0 (0%)	0 (0%)	8 (1%)
Not Expected	0	0	0	0	0

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Visit 102: 1 week PPO phone contact⁴					
Expected ²	3	20	2	4	29
Completed ³	2 (67%)	4 (20%)	2 (100%)	4 (100%)	12 (41%)
Not Completed	1 (33%)	16 (80%)	0 (0%)	0 (0%)	17 (59%)
Missed	0 (0%)	8 (40%)	0 (0%)	0 (0%)	8 (28%)
Terminated Early	1 (33%)	8 (40%)	0 (0%)	0 (0%)	9 (31%)
Not Expected	130	94	152	152	528
Visit 103: Study Exit Visit					
Expected ²	133	114	154	156	557
Completed ³	130 (98%)	92 (81%)	150 (97%)	155 (99%)	527 (95%)
Not Completed	3 (2%)	22 (19%)	4 (3%)	1 (1%)	30 (5%)
Missed	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (<1%)
Terminated Early	3 (2%)	21 (18%)	4 (3%)	1 (1%)	29 (5%)
Not Expected	0	0	0	0	0

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Mother Retention by Cohort, Visit, and Site

Cohort 1 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	27	42	44	37	150
Visit 3: Week 1 Phone Contact					
Expected ²	21	33	41	33	128
Completed ³	21 (100%)	31 (94%)	41 (100%)	33 (100%)	126 (98%)
Not Completed	0 (0%)	2 (6%)	0 (0%)	0 (0%)	2 (2%)
Missed	0 (0%)	1 (3%)	0 (0%)	0 (0%)	1 (1%)
Terminated Early	0 (0%)	1 (3%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	6	9	3	3	21
Visit 4: Week 2 Bi-weekly Visit					
Expected ²	15	27	32	29	103
Completed ³	14 (93%)	23 (85%)	32 (100%)	29 (100%)	98 (95%)
Not Completed	1 (7%)	4 (15%)	0 (0%)	0 (0%)	5 (5%)
Missed	1 (7%)	3 (11%)	0 (0%)	0 (0%)	4 (4%)
Terminated Early	0 (0%)	1 (4%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	12	15	12	7	46
Visit 5: Week 3 Phone Contact					
Expected ²	8	19	22	22	71
Completed ³	7 (88%)	15 (79%)	22 (100%)	22 (100%)	66 (93%)
Not Completed	1 (13%)	4 (21%)	0 (0%)	0 (0%)	5 (7%)
Missed	1 (13%)	3 (16%)	0 (0%)	0 (0%)	4 (6%)
Terminated Early	0 (0%)	1 (5%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	19	23	22	14	78

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Cohort 1 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 6: Week 4 Bi-weekly Visit					
Expected ²	3	5	10	14	32
Completed ³	3 (100%)	2 (40%)	10 (100%)	14 (100%)	29 (91%)
Not Completed	0 (0%)	3 (60%)	0 (0%)	0 (0%)	3 (9%)
Missed	0 (0%)	2 (40%)	0 (0%)	0 (0%)	2 (6%)
Terminated Early	0 (0%)	1 (20%)	0 (0%)	0 (0%)	1 (3%)
Not Expected	24	37	34	22	117
Visit 7: Week 5 Phone Contact					
Expected ²	3	2	3	12	20
Completed ³	3 (100%)	0 (0%)	3 (100%)	12 (100%)	18 (90%)
Not Completed	0 (0%)	2 (100%)	0 (0%)	0 (0%)	2 (10%)
Missed	0 (0%)	1 (50%)	0 (0%)	0 (0%)	1 (5%)
Terminated Early	0 (0%)	1 (50%)	0 (0%)	0 (0%)	1 (5%)
Not Expected	14	30	40	22	106
Visit 101: PPO Visit					
Expected ²	27	42	44	36	149
Completed ³	26 (96%)	38 (90%)	43 (98%)	36 (100%)	143 (96%)
Not Completed	1 (4%)	4 (10%)	1 (2%)	0 (0%)	6 (4%)
Missed	1 (4%)	3 (7%)	1 (2%)	0 (0%)	5 (3%)
Terminated Early	0 (0%)	1 (2%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	0	0	0	0	0

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Mother Retention by Cohort, Visit, and Site

Cohort 1 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 102: 1 week PPO phone contact⁴					
Expected ²	1	4	1	0	6
Completed ³	1 (100%)	2 (50%)	1 (100%)	0 (-%)	4 (67%)
Not Completed	0 (0%)	2 (50%)	0 (0%)	0 (-%)	2 (33%)
Missed	0 (0%)	1 (25%)	0 (0%)	0 (-%)	1 (17%)
Terminated Early	0 (0%)	1 (25%)	0 (0%)	0 (-%)	1 (17%)
Not Expected	26	38	43	36	143
Visit 103: Study Exit Visit					
Expected ²	27	42	44	36	149
Completed ³	26 (96%)	33 (79%)	42 (95%)	36 (100%)	137 (92%)
Not Completed	1 (4%)	9 (21%)	2 (5%)	0 (0%)	12 (8%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (4%)	9 (21%)	2 (5%)	0 (0%)	12 (8%)
Not Expected	0	0	0	0	0

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Mother Retention by Cohort, Visit, and Site

Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	40	28	42	47	157
Visit 3: Week 1 Phone Contact					
Expected ²	39	28	42	47	156
Completed ³	39 (100%)	28 (100%)	42 (100%)	45 (96%)	154 (99%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	2 (4%)	2 (1%)
Missed	0 (0%)	0 (0%)	0 (0%)	2 (4%)	2 (1%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	1	0	0	0	1
Visit 4: Week 2 Bi-weekly Visit					
Expected ²	39	28	42	47	156
Completed ³	37 (95%)	25 (89%)	42 (100%)	47 (100%)	151 (97%)
Not Completed	2 (5%)	3 (11%)	0 (0%)	0 (0%)	5 (3%)
Missed	2 (5%)	3 (11%)	0 (0%)	0 (0%)	5 (3%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	1	0	0	0	1
Visit 5: Week 3 Phone Contact					
Expected ²	39	28	42	47	156
Completed ³	38 (97%)	27 (96%)	42 (100%)	47 (100%)	154 (99%)
Not Completed	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	1	0	0	0	1

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Mother Retention by Cohort, Visit, and Site

Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 6: Week 4 Bi-weekly Visit					
Expected ²	36	26	41	46	149
Completed ³	35 (97%)	22 (85%)	41 (100%)	45 (98%)	143 (96%)
Not Completed	1 (3%)	4 (15%)	0 (0%)	1 (2%)	6 (4%)
Missed	0 (0%)	3 (12%)	0 (0%)	1 (2%)	4 (3%)
Terminated Early	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	4	2	1	1	8
Visit 7: Week 5 Phone Contact					
Expected ²	6	6	11	6	29
Completed ³	6 (100%)	5 (83%)	10 (91%)	6 (100%)	27 (93%)
Not Completed	0 (0%)	1 (17%)	1 (9%)	0 (0%)	2 (7%)
Missed	0 (0%)	1 (17%)	1 (9%)	0 (0%)	2 (7%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	5	1	2	1	9
Visit 8: Week 6 Bi-weekly Visit					
Expected ²	31	25	36	42	134
Completed ³	30 (97%)	21 (84%)	36 (100%)	42 (100%)	129 (96%)
Not Completed	1 (3%)	4 (16%)	0 (0%)	0 (0%)	5 (4%)
Missed	0 (0%)	3 (12%)	0 (0%)	0 (0%)	3 (2%)
Terminated Early	1 (3%)	1 (4%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	9	3	6	5	23

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Mother Retention by Cohort, Visit, and Site

Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 9: Week 7 Phone Contact					
Expected ²	24	24	32	39	119
Completed ³	23 (96%)	22 (92%)	32 (100%)	38 (97%)	115 (97%)
Not Completed	1 (4%)	2 (8%)	0 (0%)	1 (3%)	4 (3%)
Missed	0 (0%)	1 (4%)	0 (0%)	1 (3%)	2 (2%)
Terminated Early	1 (4%)	1 (4%)	0 (0%)	0 (0%)	2 (2%)
Not Expected	15	4	9	7	35
Visit 10: Week 8 Visit					
Expected ²	17	17	29	30	93
Completed ³	16 (94%)	15 (88%)	29 (100%)	30 (100%)	90 (97%)
Not Completed	1 (6%)	2 (12%)	0 (0%)	0 (0%)	3 (3%)
Missed	0 (0%)	1 (6%)	0 (0%)	0 (0%)	1 (1%)
Terminated Early	1 (6%)	1 (6%)	0 (0%)	0 (0%)	2 (2%)
Not Expected	22	11	11	15	59
Visit 11: Week 9 Phone Contact					
Expected ²	11	14	21	19	65
Completed ³	10 (91%)	12 (86%)	21 (100%)	19 (100%)	62 (95%)
Not Completed	1 (9%)	2 (14%)	0 (0%)	0 (0%)	3 (5%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (9%)	2 (14%)	0 (0%)	0 (0%)	3 (5%)
Not Expected	26	13	18	26	83

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Mother Retention by Cohort, Visit, and Site

Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 12: Week 10 Bi-weekly Visit					
Expected ²	4	5	9	5	23
Completed ³	3 (75%)	2 (40%)	9 (100%)	5 (100%)	19 (83%)
Not Completed	1 (25%)	3 (60%)	0 (0%)	0 (0%)	4 (17%)
Missed	0 (0%)	1 (20%)	0 (0%)	0 (0%)	1 (4%)
Terminated Early	1 (25%)	2 (40%)	0 (0%)	0 (0%)	3 (13%)
Not Expected	31	22	26	39	118
Visit 13: Week 11 Phone Contact					
Expected ²	2	2	4	1	9
Completed ³	1 (50%)	0 (0%)	4 (100%)	1 (100%)	6 (67%)
Not Completed	1 (50%)	2 (100%)	0 (0%)	0 (0%)	3 (33%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	1 (50%)	2 (100%)	0 (0%)	0 (0%)	3 (33%)
Not Expected	27	19	25	39	110
Visit 101: PPO Visit					
Expected ²	40	28	42	47	157
Completed ³	38 (95%)	23 (82%)	42 (100%)	47 (100%)	150 (96%)
Not Completed	2 (5%)	5 (18%)	0 (0%)	0 (0%)	7 (4%)
Missed	1 (3%)	2 (7%)	0 (0%)	0 (0%)	3 (2%)
Terminated Early	1 (3%)	3 (11%)	0 (0%)	0 (0%)	4 (3%)
Not Expected	0	0	0	0	0

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Mother Retention by Cohort, Visit, and Site

Cohort 2 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 102: 1 week PPO phone contact⁴					
Expected ²	2	5	0	0	7
Completed ³	1 (50%)	0 (0%)	0 (-%)	0 (-%)	1 (14%)
Not Completed	1 (50%)	5 (100%)	0 (-%)	0 (-%)	6 (86%)
Missed	0 (0%)	2 (40%)	0 (-%)	0 (-%)	2 (29%)
Terminated Early	1 (50%)	3 (60%)	0 (-%)	0 (-%)	4 (57%)
Not Expected	38	23	42	47	150
Visit 103: Study Exit Visit					
Expected ²	40	28	42	47	157
Completed ³	38 (95%)	24 (86%)	41 (98%)	47 (100%)	150 (96%)
Not Completed	2 (5%)	4 (14%)	1 (2%)	0 (0%)	7 (4%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	2 (5%)	4 (14%)	1 (2%)	0 (0%)	7 (4%)
Not Expected	0	0	0	0	0

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Enrolled	66	44	68	73	251
Visit 3: Week 1 Phone Contact					
Expected ²	66	44	68	73	251
Completed ³	66 (100%)	44 (100%)	68 (100%)	73 (100%)	251 (100%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	0	0	0	0	0
Visit 4: Week 2 Bi-weekly Visit					
Expected ²	66	44	67	73	250
Completed ³	66 (100%)	40 (91%)	67 (100%)	72 (99%)	245 (98%)
Not Completed	0 (0%)	4 (9%)	0 (0%)	1 (1%)	5 (2%)
Missed	0 (0%)	4 (9%)	0 (0%)	1 (1%)	5 (2%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	0	0	1	0	1
Visit 5: Week 3 Phone Contact					
Expected ²	66	44	67	73	250
Completed ³	66 (100%)	43 (98%)	66 (99%)	73 (100%)	248 (99%)
Not Completed	0 (0%)	1 (2%)	1 (1%)	0 (0%)	2 (1%)
Missed	0 (0%)	1 (2%)	1 (1%)	0 (0%)	2 (1%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	0	0	1	0	1

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 6: Week 4 Bi-weekly Visit					
Expected ²	66	44	67	73	250
Completed ³	66 (100%)	39 (89%)	66 (99%)	73 (100%)	244 (98%)
Not Completed	0 (0%)	5 (11%)	1 (1%)	0 (0%)	6 (2%)
Missed	0 (0%)	5 (11%)	1 (1%)	0 (0%)	6 (2%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	0	0	1	0	1
Visit 9: Week 7 Phone Contact					
Expected ²	14	1	6	1	22
Completed ³	14 (100%)	1 (100%)	4 (67%)	1 (100%)	20 (91%)
Not Completed	0 (0%)	0 (0%)	2 (33%)	0 (0%)	2 (9%)
Missed	0 (0%)	0 (0%)	2 (33%)	0 (0%)	2 (9%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	0	0	0	0	0
Visit 10: Week 8 Visit					
Expected ²	65	42	66	73	246
Completed ³	65 (100%)	35 (83%)	66 (100%)	73 (100%)	239 (97%)
Not Completed	0 (0%)	7 (17%)	0 (0%)	0 (0%)	7 (3%)
Missed	0 (0%)	7 (17%)	0 (0%)	0 (0%)	7 (3%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	1	2	2	0	5

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 11: Week 9 Phone Contact					
Expected ²	23	4	15	7	49
Completed ³	23 (100%)	3 (75%)	14 (93%)	7 (100%)	47 (96%)
Not Completed	0 (0%)	1 (25%)	1 (7%)	0 (0%)	2 (4%)
Missed	0 (0%)	1 (25%)	1 (7%)	0 (0%)	2 (4%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	1	1	2	0	4
Visit 12: Week 10 Bi-weekly Visit					
Expected ²	20	4	15	14	53
Completed ³	20 (100%)	2 (50%)	15 (100%)	14 (100%)	51 (96%)
Not Completed	0 (0%)	2 (50%)	0 (0%)	0 (0%)	2 (4%)
Missed	0 (0%)	2 (50%)	0 (0%)	0 (0%)	2 (4%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	8	2	8	0	18
Visit 13: Week 11 Phone Contact					
Expected ²	19	6	22	24	71
Completed ³	19 (100%)	5 (83%)	22 (100%)	23 (96%)	69 (97%)
Not Completed	0 (0%)	1 (17%)	0 (0%)	1 (4%)	2 (3%)
Missed	0 (0%)	1 (17%)	0 (0%)	1 (4%)	2 (3%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	16	2	9	3	30

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 14: Week 12 Visit					
Expected ²	40	36	51	65	192
Completed ³	40 (100%)	31 (86%)	51 (100%)	63 (97%)	185 (96%)
Not Completed	0 (0%)	5 (14%)	0 (0%)	2 (3%)	7 (4%)
Missed	0 (0%)	3 (8%)	0 (0%)	2 (3%)	5 (3%)
Terminated Early	0 (0%)	2 (6%)	0 (0%)	0 (0%)	2 (1%)
Not Expected	26	8	17	8	59
Visit 15: Week 13 Phone Contact					
Expected ²	16	11	23	28	78
Completed ³	16 (100%)	9 (82%)	23 (100%)	26 (93%)	74 (95%)
Not Completed	0 (0%)	2 (18%)	0 (0%)	2 (7%)	4 (5%)
Missed	0 (0%)	2 (18%)	0 (0%)	2 (7%)	4 (5%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	16	5	12	14	47
Visit 16: Week 14 Bi-weekly Visit					
Expected ²	14	15	20	23	72
Completed ³	14 (100%)	12 (80%)	20 (100%)	23 (100%)	69 (96%)
Not Completed	0 (0%)	3 (20%)	0 (0%)	0 (0%)	3 (4%)
Missed	0 (0%)	2 (13%)	0 (0%)	0 (0%)	2 (3%)
Terminated Early	0 (0%)	1 (7%)	0 (0%)	0 (0%)	1 (1%)
Not Expected	17	4	20	21	62

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 17: Week 15 Phone Contact					
Expected ²	16	11	17	25	69
Completed ³	16 (100%)	9 (82%)	17 (100%)	25 (100%)	67 (97%)
Not Completed	0 (0%)	2 (18%)	0 (0%)	0 (0%)	2 (3%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	2 (18%)	0 (0%)	0 (0%)	2 (3%)
Not Expected	12	7	15	21	55
Visit 18: Week 16 Visit					
Expected ²	25	25	27	34	111
Completed ³	25 (100%)	20 (80%)	27 (100%)	34 (100%)	106 (95%)
Not Completed	0 (0%)	5 (20%)	0 (0%)	0 (0%)	5 (5%)
Missed	0 (0%)	3 (12%)	0 (0%)	0 (0%)	3 (3%)
Terminated Early	0 (0%)	2 (8%)	0 (0%)	0 (0%)	2 (2%)
Not Expected	13	13	18	25	69
Visit 19: Week 17 Phone Contact					
Expected ²	12	9	12	19	52
Completed ³	12 (100%)	6 (67%)	12 (100%)	19 (100%)	49 (94%)
Not Completed	0 (0%)	3 (33%)	0 (0%)	0 (0%)	3 (6%)
Missed	0 (0%)	1 (11%)	0 (0%)	0 (0%)	1 (2%)
Terminated Early	0 (0%)	2 (22%)	0 (0%)	0 (0%)	2 (4%)
Not Expected	11	13	13	17	54

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Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 20: Week 18 Bi-weekly Visit					
Expected ²	9	13	10	16	48
Completed ³	8 (89%)	10 (77%)	9 (90%)	16 (100%)	43 (90%)
Not Completed	1 (11%)	3 (23%)	1 (10%)	0 (0%)	5 (10%)
Missed	1 (11%)	1 (8%)	1 (10%)	0 (0%)	3 (6%)
Terminated Early	0 (0%)	2 (15%)	0 (0%)	0 (0%)	2 (4%)
Not Expected	12	9	12	21	54
Visit 21: Week 19 Phone Contact					
Expected ²	6	16	10	11	43
Completed ³	6 (100%)	13 (81%)	10 (100%)	11 (100%)	40 (93%)
Not Completed	0 (0%)	3 (19%)	0 (0%)	0 (0%)	3 (7%)
Missed	0 (0%)	1 (6%)	0 (0%)	0 (0%)	1 (2%)
Terminated Early	0 (0%)	2 (13%)	0 (0%)	0 (0%)	2 (5%)
Not Expected	9	10	13	15	47
Visit 22: Week 20 Visit					
Expected ²	8	14	12	13	47
Completed ³	8 (100%)	11 (79%)	12 (100%)	13 (100%)	44 (94%)
Not Completed	0 (0%)	3 (21%)	0 (0%)	0 (0%)	3 (6%)
Missed	0 (0%)	2 (14%)	0 (0%)	0 (0%)	2 (4%)
Terminated Early	0 (0%)	1 (7%)	0 (0%)	0 (0%)	1 (2%)
Not Expected	9	8	9	12	38

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Report Generation Date: December 2, 2025

Data as of: December 1, 2025¹

Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 23: Week 21 Phone Contact					
Expected ²	4	9	7	8	28
Completed ³	4 (100%)	8 (89%)	7 (100%)	8 (100%)	27 (96%)
Not Completed	0 (0%)	1 (11%)	0 (0%)	0 (0%)	1 (4%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	1 (11%)	0 (0%)	0 (0%)	1 (4%)
Not Expected	9	12	10	9	40
Visit 24: Week 22 Bi-weekly Visit					
Expected ²	2	2	4	3	11
Completed ³	2 (100%)	2 (100%)	4 (100%)	3 (100%)	11 (100%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	11	16	11	13	51
Visit 25: Week 23 Phone Contact					
Expected ²	1	1	5	3	10
Completed ³	1 (100%)	1 (100%)	5 (100%)	3 (100%)	10 (100%)
Not Completed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	6	13	7	6	32

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 26: Week 24 Visit					
Expected ²	2	0	2	3	7
Completed ³	2 (100%)	0 (-%)	2 (100%)	3 (100%)	7 (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	5	7	6	2	20
Visit 27: Week 25 Phone Contact					
Expected ²	0	0	2	1	3
Completed ³	0 (-%)	0 (-%)	2 (100%)	1 (100%)	3 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	5	1	2	3	11
Visit 28: Week 26 Bi-weekly Visit					
Expected ²	0	0	1	1	2
Completed ³	0 (-%)	0 (-%)	1 (100%)	1 (100%)	2 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	2	0	2	3	7

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 29: Week 27 Phone Contact					
Expected ²	0	0	1	1	2
Completed ³	0 (-%)	0 (-%)	1 (100%)	1 (100%)	2 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
Not Expected	1	0	1	2	4
Visit 30: Week 28 Bi-weekly Visit					
Expected ²	0	0	1	0	1
Completed ³	0 (-%)	0 (-%)	1 (100%)	0 (-%)	1 (100%)
Not Completed	0 (-%)	0 (-%)	0 (0%)	0 (-%)	0 (0%)
Missed	0 (-%)	0 (-%)	0 (0%)	0 (-%)	0 (0%)
Terminated Early	0 (-%)	0 (-%)	0 (0%)	0 (-%)	0 (0%)
Not Expected	1	0	0	1	2
Visit 31: Week 29 Phone Contact					
Expected ²	0	0	0	0	0
Completed ³	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not Completed	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Missed	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Terminated Early	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not Expected	1	0	0	1	2

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Mother Retention by Cohort, Visit, and Site

Cohort 3 Only

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Visit 101: PPO Visit					
Expected ²	66	44	68	73	251
Completed ³	66 (100%)	33 (75%)	67 (99%)	69 (95%)	235 (94%)
Not Completed	0 (0%)	11 (25%)	1 (1%)	4 (5%)	16 (6%)
Missed	0 (0%)	8 (18%)	1 (1%)	4 (5%)	13 (5%)
Terminated Early	0 (0%)	3 (7%)	0 (0%)	0 (0%)	3 (1%)
Not Expected	0	0	0	0	0
Visit 102: 1 week PPO phone contact⁴					
Expected ²	0	11	1	4	16
Completed ³	0 (-%)	2 (18%)	1 (100%)	4 (100%)	7 (44%)
Not Completed	0 (-%)	9 (82%)	0 (0%)	0 (0%)	9 (56%)
Missed	0 (-%)	5 (45%)	0 (0%)	0 (0%)	5 (31%)
Terminated Early	0 (-%)	4 (36%)	0 (0%)	0 (0%)	4 (25%)
Not Expected	66	33	67	69	235
Visit 103: Study Exit Visit					
Expected ²	66	44	68	73	251
Completed ³	66 (100%)	35 (80%)	67 (99%)	72 (99%)	240 (96%)
Not Completed	0 (0%)	9 (20%)	1 (1%)	1 (1%)	11 (4%)
Missed	0 (0%)	1 (2%)	0 (0%)	0 (0%)	1 (<1%)
Terminated Early	0 (0%)	8 (18%)	1 (1%)	1 (1%)	10 (4%)
Not Expected	0	0	0	0	0

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