

**MTN 016 - HIV Prevention Agent Pregnancy Exposure Registry (EMBRACE)**

**Report Generation Date: June 2, 2020**

**Retention Evaluation Date: May 26, 2020**

**Study Retention of Infants by Visit and Site: South Africa Sites (Group 1)**

	All Sites	South Africa Aurum	South Africa Bothas Hill	South Africa eThekweni	South Africa Isipingo	South Africa Overport	South Africa Chatsworth
Participants Enrolled	403	2	17	27	13	7	24
<b>Newborn Visit</b>							
Participants Expected	350	2	11	26	9	5	21
Participants Retained	317 (91%)	1 (50%)	10 (91%)	22 (85%)	9 (100%)	5 (100%)	18 (86%)
Participants Who Missed the Visit	33 (9%)	1 (50%)	1 (9%)	4 (15%)	0 (0%)	0 (0%)	3 (14%)
Participants Lost to Follow-up or Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 1 Visit</b>							
Participants Expected	370	2	17	26	12	5	22
Participants Retained	330 (89%)	1 (50%)	13 (76%)	25 (96%)	10 (83%)	4 (80%)	21 (95%)
Participants Who Missed the Visit	39 (11%)	1 (50%)	4 (24%)	1 (4%)	2 (17%)	1 (20%)	1 (5%)
Participants Lost to Follow-up or Terminated Early	1 (<1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 6 Visit</b>							
Participants Expected	394	2	17	27	13	6	24
Participants Retained	352 (89%)	2 (100%)	16 (94%)	26 (96%)	11 (85%)	5 (83%)	23 (96%)
Participants Who Missed the Visit	38 (10%)	0 (0%)	1 (6%)	1 (4%)	2 (15%)	1 (17%)	0 (0%)
Participants Lost to Follow-up or Terminated Early	4 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
<b>Month 12 Visit</b>							
Participants Expected	403	2	17	27	13	7	24
Participants Retained	348 (86%)	1 (50%)	16 (94%)	25 (93%)	9 (69%)	6 (86%)	23 (96%)
Participants Who Missed the Visit	42 (10%)	1 (50%)	1 (6%)	2 (7%)	4 (31%)	0 (0%)	0 (0%)
Participants Lost to Follow-up or Terminated Early	13 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (14%)	1 (4%)

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**Study Retention of Infants by Visit and Site: South Africa Sites (Group 2)**

	All Sites	South Africa PHRU	South Africa Tongaat	South Africa Umkomaas	South Africa Verulam	South Africa WRHI	South Africa Emavundleni Ctr
Participants Enrolled	403	7	29	9	16	36	5
<b>Newborn Visit</b>							
Participants Expected	350	7	20	9	8	34	3
Participants Retained	317 (91%)	6 (86%)	20 (100%)	9 (100%)	7 (88%)	27 (79%)	2 (67%)
Participants Who Missed the Visit	33 (9%)	1 (14%)	0 (0%)	0 (0%)	1 (13%)	7 (21%)	1 (33%)
Participants Lost to Follow-up or Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 1 Visit</b>							
Participants Expected	370	7	25	9	11	34	4
Participants Retained	330 (89%)	6 (86%)	23 (92%)	6 (67%)	5 (45%)	30 (88%)	4 (100%)
Participants Who Missed the Visit	39 (11%)	1 (14%)	2 (8%)	2 (22%)	6 (55%)	4 (12%)	0 (0%)
Participants Lost to Follow-up or Terminated Early	1 (<1%)	0 (0%)	0 (0%)	1 (11%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 6 Visit</b>							
Participants Expected	394	7	29	9	13	36	4
Participants Retained	352 (89%)	5 (71%)	26 (90%)	7 (78%)	10 (77%)	35 (97%)	4 (100%)
Participants Who Missed the Visit	38 (10%)	2 (29%)	3 (10%)	1 (11%)	3 (23%)	1 (3%)	0 (0%)
Participants Lost to Follow-up or Terminated Early	4 (1%)	0 (0%)	0 (0%)	1 (11%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 12 Visit</b>							
Participants Expected	403	7	29	9	16	36	5
Participants Retained	348 (86%)	5 (71%)	28 (97%)	8 (89%)	11 (69%)	34 (94%)	4 (80%)
Participants Who Missed the Visit	42 (10%)	1 (14%)	1 (3%)	0 (0%)	5 (31%)	1 (3%)	1 (20%)
Participants Lost to Follow-up or Terminated Early	13 (3%)	1 (14%)	0 (0%)	1 (11%)	0 (0%)	1 (3%)	0 (0%)

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**Study Retention of Infants by Visit and Site: Non-South Africa Sites (Group 1)**

	<b>All Sites</b>	<b>Uganda MU-JHU</b>	<b>United States Birmingham: UAB</b>	<b>United States Pittsburgh: Pitt CRS</b>
Participants Enrolled	403	41	29	72
<b>Newborn Visit</b>				
Participants Expected	350	37	29	60
Participants Retained	317 (91%)	34 (92%)	29 (100%)	59 (98%)
Participants Who Missed the Visit	33 (9%)	3 (8%)	0 (0%)	1 (2%)
Participants Lost to Follow-up or Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 1 Visit</b>				
Participants Expected	370	37	29	61
Participants Retained	330 (89%)	32 (86%)	29 (100%)	55 (90%)
Participants Who Missed the Visit	39 (11%)	5 (14%)	0 (0%)	6 (10%)
Participants Lost to Follow-up or Terminated Early	1 (<1%)	0 (0%)	0 (0%)	0 (0%)
<b>Month 6 Visit</b>				
Participants Expected	394	41	29	68
Participants Retained	352 (89%)	40 (98%)	22 (76%)	56 (82%)
Participants Who Missed the Visit	38 (10%)	1 (2%)	6 (21%)	11 (16%)
Participants Lost to Follow-up or Terminated Early	4 (1%)	0 (0%)	1 (3%)	1 (1%)
<b>Month 12 Visit</b>				
Participants Expected	403	41	29	72
Participants Retained	348 (86%)	38 (93%)	21 (72%)	55 (76%)
Participants Who Missed the Visit	42 (10%)	3 (7%)	7 (24%)	14 (19%)
Participants Lost to Follow-up or Terminated Early	13 (3%)	0 (0%)	1 (3%)	3 (4%)

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**Study Retention of Infants by Visit and Site: Non-South Africa Sites (Group 2)**

	<b>All Sites</b>	<b>Zimbabwe Seke South</b>	<b>Zimbabwe Spilhaus</b>	<b>Zimbabwe Zengeza</b>	<b>Malawi Blantyre</b>	<b>Malawi Lilongwe</b>
Participants Enrolled	403	28	19	22	0	0
<b>Newborn Visit</b>						
Participants Expected	350	28	19	22	0	0
Participants Retained	317 (91%)	24 (86%)	17 (89%)	18 (82%)	0 (-%)	0 (-%)
Participants Who Missed the Visit	33 (9%)	4 (14%)	2 (11%)	4 (18%)	0 (-%)	0 (-%)
Participants Lost to Follow-up or Terminated Early	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (-%)
<b>Month 1 Visit</b>						
Participants Expected	370	28	19	22	0	0
Participants Retained	330 (89%)	27 (96%)	17 (89%)	22 (100%)	0 (-%)	0 (-%)
Participants Who Missed the Visit	39 (11%)	1 (4%)	2 (11%)	0 (0%)	0 (-%)	0 (-%)
Participants Lost to Follow-up or Terminated Early	1 (<1%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (-%)
<b>Month 6 Visit</b>						
Participants Expected	394	28	19	22	0	0
Participants Retained	352 (89%)	25 (89%)	18 (95%)	21 (95%)	0 (-%)	0 (-%)
Participants Who Missed the Visit	38 (10%)	3 (11%)	1 (5%)	1 (5%)	0 (-%)	0 (-%)
Participants Lost to Follow-up or Terminated Early	4 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (-%)	0 (-%)
<b>Month 12 Visit</b>						
Participants Expected	403	28	19	22	0	0
Participants Retained	348 (86%)	25 (89%)	19 (100%)	20 (91%)	0 (-%)	0 (-%)
Participants Who Missed the Visit	42 (10%)	1 (4%)	0 (0%)	0 (0%)	0 (-%)	0 (-%)
Participants Lost to Follow-up or Terminated Early	13 (3%)	2 (7%)	0 (0%)	2 (9%)	0 (-%)	0 (-%)