

Date: May 1, 2014
To: MTN 016 Protocol Team
From: SCHARP
RE: **MTN 016 Visit Adherence, Completion of Procedures by Site Report**

Purpose

To summarize, overall and by site, completion of required and expected follow-up visit procedures.

Definition of Required and Expected Procedures

Refer to the protocol and/or the Study-Specific Procedures Manual for required procedures at each follow-up visit.

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 Case Report Form (CRF), the procedures for that visit will not be included as expected.

Definition of Completed Procedures

Completion of a procedure is defined by specific data elements on the CRF. For example, for laboratory assays, the assay is counted as completed if a result is present on the appropriate CRF. For other procedures, a completion date, completion time, and/or response of “yes” or “stored” on the appropriate CRF may be the indication that the procedure was completed.

MTN 016 - HIV Prevention Agent Pregnancy Exposure Registry (EMBRACE)
Data as of April 3, 2019

Visit Adherence: Completion of Procedures During Follow-up¹ for Infants - South Africa Sites (Group 1) Parent Protocol MTN 020

	All Sites	South Africa Bothas Hill	South Africa eThekweni	South Africa Isipingo	South Africa Chatsworth	South Africa Tongaat
Participants Enrolled	99	3	5	5	3	7
1. Infant - Weight Required and Expected	46	2	3	3	2	6
Completed	46 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	2 (100.0%)	6 (100.0%)
2. Infant - Length Required and Expected	46	2	3	3	2	6
Completed	46 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	2 (100.0%)	6 (100.0%)
3. Infant - Head Circumference Required and Expected	46	2	3	3	2	6
Completed	45 (97.8%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	2 (100.0%)	6 (100.0%)
Not Completed	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
4. Infant - Physical Exam Required and Expected	5	0	0	0	0	0
Completed	5 (100.0%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
5. Infant - Developmental Screening Test Required and Expected	5	0	1	0	0	1
Completed	5 (100.0%)	0 (-%)	1 (100.0%)	0 (-%)	0 (-%)	1 (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 Case Report Form (CRF), the procedures for that visit will not be included as expected.

MTN 016 - HIV Prevention Agent Pregnancy Exposure Registry (EMBRACE)
Data as of April 3, 2019

Visit Adherence: Completion of Procedures During Follow-up¹ for Infants - South Africa Sites (Group 2) Parent Protocol MTN 020

	All Sites	South Africa Umkomaas	South Africa Verulam	South Africa Emavundleni Ctr	South Africa WRHI
Participants Enrolled	99	4	6	3	14
1. Infant - Weight Required and Expected	46	4	3	0	10
Completed	46 (100.0%)	4 (100.0%)	3 (100.0%)	0 (-%)	10 (100.0%)
2. Infant - Length Required and Expected	46	4	3	0	10
Completed	46 (100.0%)	4 (100.0%)	3 (100.0%)	0 (-%)	10 (100.0%)
3. Infant - Head Circumference Required and Expected	46	4	3	0	10
Completed	45 (97.8%)	4 (100.0%)	2 (66.7%)	0 (-%)	10 (100.0%)
Not Completed	1 (2.2%)	0 (0.0%)	1 (33.3%)	0 (-%)	0 (0.0%)
4. Infant - Physical Exam Required and Expected	5	0	0	0	5
Completed	5 (100.0%)	0 (-%)	0 (-%)	0 (-%)	5 (100.0%)
5. Infant - Developmental Screening Test Required and Expected	5	1	0	0	1
Completed	5 (100.0%)	1 (100.0%)	0 (-%)	0 (-%)	1 (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 Case Report Form (CRF), the procedures for that visit will not be included as expected.

**MTN 016 - HIV Prevention Agent Pregnancy Exposure Registry (EMBRACE)
Data as of April 3, 2019**

Visit Adherence: Completion of Procedures During Follow-up¹ for Infants - Non-South Africa Sites Parent Protocol MTN 020

	All Sites	Uganda MU-JHU	Malawi Blantyre	Malawi Lilongwe	Zimbabwe Seke South	Zimbabwe Spilhaus	Zimbabwe Zengeza
Participants Enrolled	99	15	1	5	11	5	12
1. Infant - Weight Required and Expected	46	3	0	0	2	3	5
Completed	46 (100.0%)	3 (100.0%)	0 (-%)	0 (-%)	2 (100.0%)	3 (100.0%)	5 (100.0%)
2. Infant - Length Required and Expected	46	3	0	0	2	3	5
Completed	46 (100.0%)	3 (100.0%)	0 (-%)	0 (-%)	2 (100.0%)	3 (100.0%)	5 (100.0%)
3. Infant - Head Circumference Required and Expected	46	3	0	0	2	3	5
Completed	45 (97.8%)	3 (100.0%)	0 (-%)	0 (-%)	2 (100.0%)	3 (100.0%)	5 (100.0%)
Not Completed	1 (2.2%)	0 (0.0%)	0 (-%)	0 (-%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
4. Infant - Physical Exam Required and Expected	5	0	0	0	0	0	0
Completed	5 (100.0%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
5. Infant - Developmental Screening Test Required and Expected	5	0	0	0	0	1	0
Completed	5 (100.0%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)	1 (100.0%)	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 Case Report Form (CRF), the procedures for that visit will not be included as expected.