

**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-up<sup>1</sup> for Women - 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	105	3	7	5	3	7
1. Women - Genetic Screening History Required and Expected	58	3	5	3	2	6
Completed	58 (100.0%)	3 (100.0%)	5 (100.0%)	3 (100.0%)	2 (100.0%)	6 (100.0%)

<sup>1</sup> 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-up<sup>1</sup> for Women - 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	105	4	6	3	13
1. Women - Genetic Screening History Required and Expected	58	2	4	1	8
Completed	58 (100.0%)	2 (100.0%)	4 (100.0%)	1 (100.0%)	8 (100.0%)

<sup>1</sup> 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-up<sup>1</sup> for Women - 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	105	15	2	4	13	6	14
1. Women - Genetic Screening History Required and Expected	58	10	0	0	3	2	9
Completed	58 (100.0%)	10 (100.0%)	0 (-%)	0 (-%)	3 (100.0%)	2 (100.0%)	9 (100.0%)

<sup>1</sup> 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.