

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 December 2, 2025**

Visit Adherence: Completion of Procedures During Follow-up¹ for Women - South Africa Sites (Group 1) Parent Protocol MTN 025

	All Sites	South Africa Bothas Hill	South Africa eThekwini	South Africa Isipingo	South Africa Chatsworth
Participants Enrolled	20	0	1	0	0
1. Women - Genetic Screening History Required and Expected	20	0	1	0	0
Completed	20 (100.0%)	0 (-%)	1 (100.0%)	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.

MTN 016 - HIV Prevention Agent Pregnancy Exposure Registry (EMBRACE)
Data as of December 2, 2025

Visit Adherence: Completion of Procedures During Follow-up¹ for Women - South Africa Sites (Group 2) Parent Protocol MTN 025

	All Sites	South Africa Tongaat	South Africa Verulam	South Africa Emavundleni Ctr	South Africa WRHI
Participants Enrolled	20	0	2	0	6
1. Women - Genetic Screening History Required and Expected	20	0	2	0	6
Completed	20 (100.0%)	0 (-%)	2 (100.0%)	0 (-%)	6 (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 December 2, 2025**

Visit Adherence: Completion of Procedures During Follow-up¹ for Women - Non-South Africa Sites Parent Protocol MTN 025

	All Sites	Uganda MU-JHU	Malawi Blantyre	Malawi Lilongwe	Zimbabwe Seke South	Zimbabwe Spilhaus	Zimbabwe Zengeza
Participants Enrolled	20	3	1	3	0	2	2
1. Women - Genetic Screening History Required and Expected	20	3	1	3	0	2	2
Completed	20 (100.0%)	3 (100.0%)	1 (100.0%)	3 (100.0%)	0 (-%)	2 (100.0%)	2 (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.