



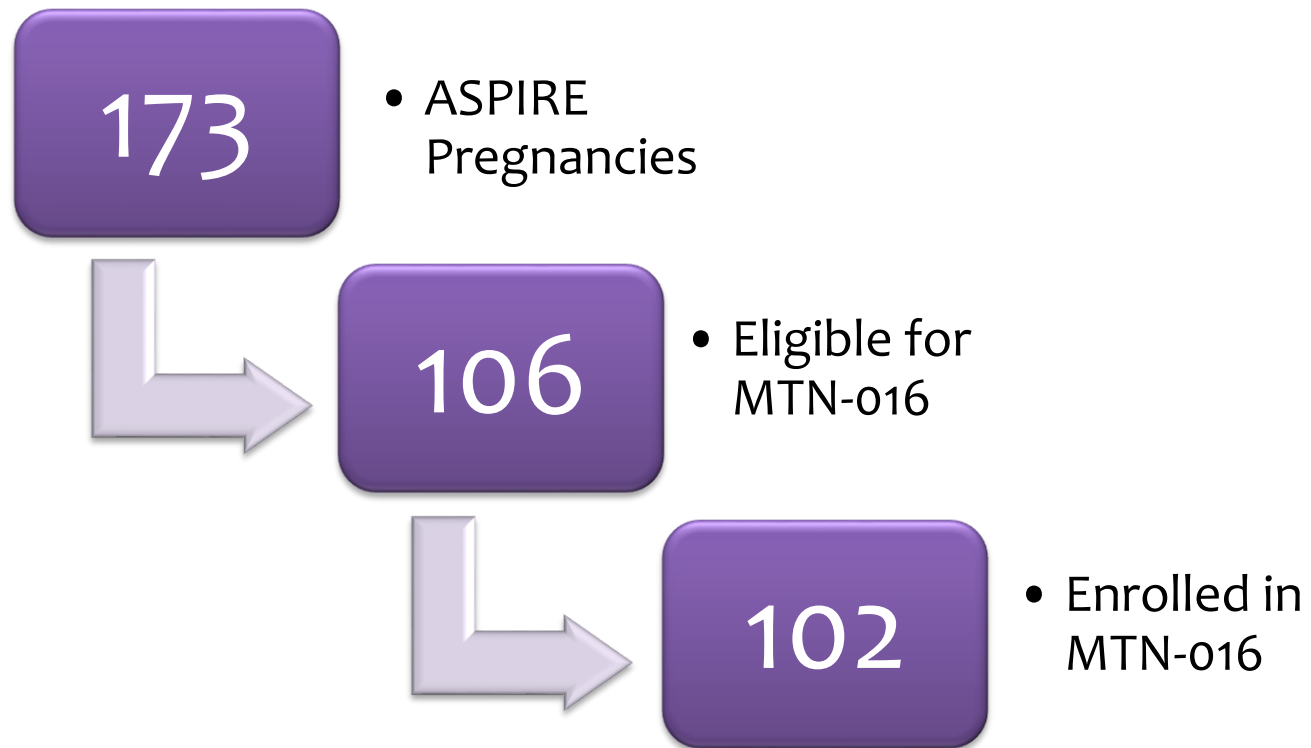
MTN-016 Regional Meeting 2015

6 October 2015
Cape Town, South Africa

Agenda

- Introductions
- EMBRACE Implementation Update
 - Accrual
 - Retention challenges/successes
- HOPE and MTN-016
- Publications update
- Data Communique Review

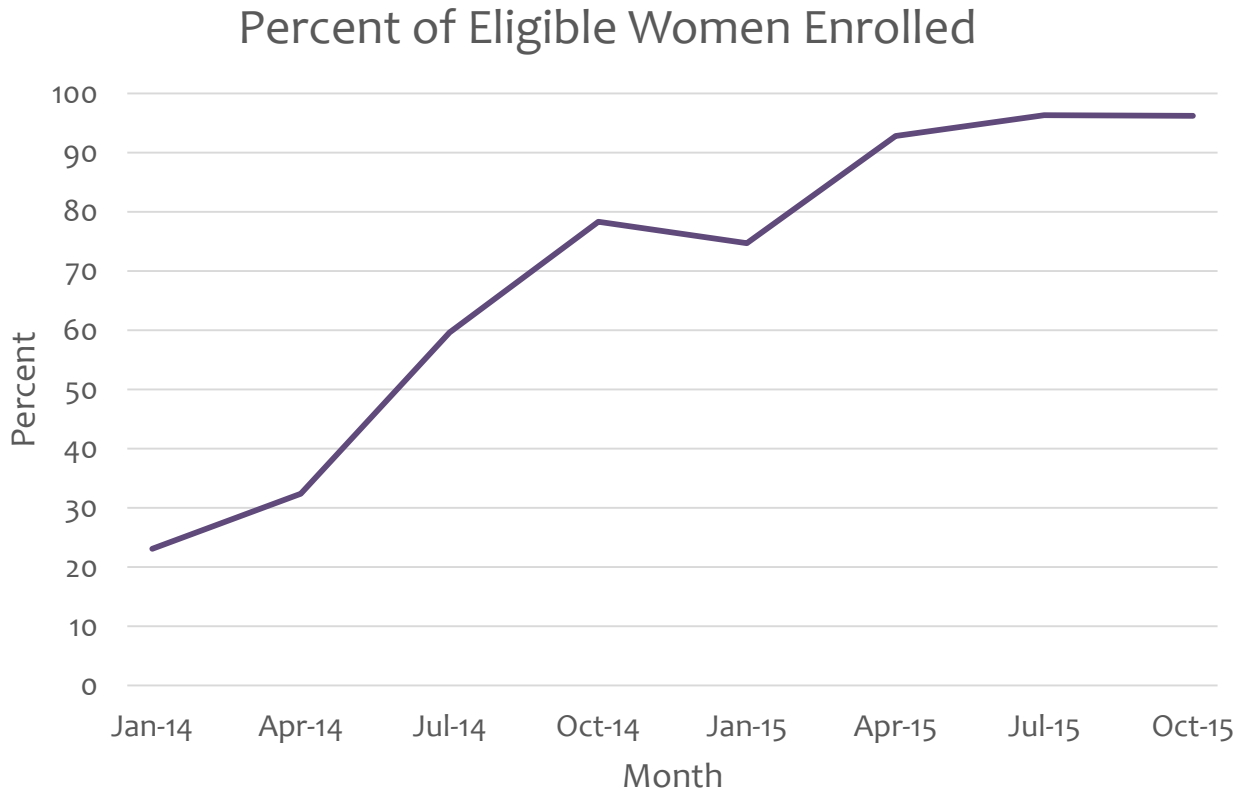
Implementation Updates - Accrual



- 96.2% of eligible women from ASPIRE were enrolled in EMBRACE.

Implementation Updates - Accrual

- ASPIRE 2014 Accrual Improvements:



Implementation Updates - Accrual

- 76/77 Eligible Infants have been enrolled in MTN-016
- 21 women enrolled in MTN-016 have pregnancy outcomes pending
- Last pregnancy outcome expected in early February 2016. Final MTN-016/ASPIRE infant visit anticipated in February 2017.

Implementation Updates

- Retention:
 - Women:
 - 100% woman retention in Q1 2015; 88% woman retention in Q2 2015
 - Infants
 - Newborn visit: 87% retained
 - Month 1: 86% retained
 - Month 6: 98% retained
 - Month 12: 88% retained
- Challenges/successes experienced with participant retention now that ASPIRE is over?

Looking forward to HOPE...

- Should HOPE move forward, any women who become pregnant during participation will be eligible for MTN-016
- Updated study tools (e.g. visit checklists) and operational considerations will be issued for this cohort as needed
- Consider strategies for accrual of all eligible participants into MTN-016/HOPE cohort from “Day 1” – think about what strategies worked in ASPIRE and continue these in HOPE

Publications Update

- Pregnancy outcomes from VOICE (VOICE data only) likely submitted as letter
 - Status: Being drafted
 - Lead: Katie Bunge
- Infant growth and development paper
 - Status: Background research, data analysis pending
 - Lead: Kristine Torjesen, Rachel Scheckter, Laura McKinstry
- Design paper
 - Status: Draft out for review to subset of co-authors
 - Lead: Felix Mhlanga

Data Communique #5: Infant Enrollment in MTN-016

Laura McKinstry & Rachel Scheckter

MTN-016 Team Meeting

MTN Regional Meeting

Cape Town, South Africa

October 2015



Definition of Infant Enrollment

- Specific guidance has been provided in Data Communique #5, issued 14SEP15. SSP Sections 4 and 13 have been updated accordingly.
- An infant is now considered enrolled when s/he:
 - Is born alive
 - Has been consented into the study and
 - Has completed at least 1 study visit
- This means that:
 - Stillborn infants cannot be enrolled into the study
 - Infants who die shortly after birth, before attending a study visit, cannot be enrolled into the study
 - Infants who are born alive but never attend a study visit cannot be enrolled into the study

How does this affect sites?



Statistical Center for
HIV/AIDS Research & Prevention
SCHARP

MTN-016 Data Communiqué #5

14 September 2015

This is official study documentation for MTN-016. Please circulate it among relevant staff for their review, print it, and place it in your MTN-016 SSP Manual in the Data Communiqués section.
This document is considered part of the MTN-016 SSP manual.

UPDATES

1. Definition of Infant Enrollment

The MTN-016 management team, with the input of the MTN-016 statisticians and DAIDS Medical Officer, have re-defined infant enrollment as an infant that 1) is born alive, 2) was consented into the study, and 3) attended at least 1 study visit. This means that a) stillborn infants cannot be enrolled into the study; b) infants who die shortly after birth, before attending a study visit, cannot be enrolled into the study, and c) infants who are born alive but never attend a study visit cannot be enrolled in the study. If a site has already enrolled an infant into MTN-016 that falls into one of these 3 categories, that infant will need to be un-enrolled and the mother's Pregnancy Outcome CRF may need to be updated.

Specific form instructions are as follows:

1) Stillborn infants who were enrolled into the study:

- Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant, by drawing a single diagonal line across the form, writing "delete" above the diagonal line, and initialing and dating the correction.
- Check to make sure the Mother's Pregnancy Outcome CRF lists the outcome, in item 5, as

□ You may have enrolled an infant at your site who now needs to be un-enrolled

CRF Guidance 1

- For stillborn infants enrolled into the study:
 - Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant
 - Make sure the Mother's Pregnancy Outcome CRF lists the outcome, in item 5, as "stillbirth/intrauterine fetal demise (> 20 weeks)"
 - Make sure a brief narrative of the pregnancy outcome was provided in item 6
 - Record, in the site-specific Infant Enrollment Log that the infant was not enrolled into MTN-016 and the reason why

CRF Guidance 2

- For infants born alive but died shortly after birth (before a study visit) who were enrolled:
 - Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant
 - **Update the mother's Pregnancy Outcome form by recording, in item 6, "live birth but infant died X days after birth"**
 - **Record any additional information in item 6 about the cause of death and the date of the infant's death**
 - Item 5 on the Mother's Pregnancy Outcome form for this scenario does not need to be updated. It should still indicate that there was a "live birth"
 - Record, on the site-specific Infant Enrollment Log that the infant was not enrolled into MTN-016 and the reason why

CRF Guidance 3

- For infants born alive but never attended a study visit who were enrolled:
 - Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant
 - Record, on the site-specific Infant Enrollment Log that the infant was not enrolled into MTN-016 and the reason why

Questions

- For CRF completion questions contact:

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- For other questions contact:

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