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
• 96.2% of eligible women from ASPIRE were enrolled in EMBRACE.
Implementation Updates - Accrual

• ASPIRE 2014 Accrual Improvements:

Percent of Eligible Women Enrolled

Month
Percent
0 10 20 30 40 50 60 70 80 90 100
Implementation Updates - Accrual

- 76/77 Eligible Infants have been enrolled in MTN-016
- 21 women enrolled in MTN-016 have pregnancy outcomes pending
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 pregnancy 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?

- 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

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