



MTN-016 Annual Meeting

17 March 2015

Agenda

- Introductions
- EMBRACE Implementation Update
 - Malawi Activation
 - Accrual Progress
 - Considerations for end of ASPIRE
- MTN-016 Publications Update

Implementation Updates

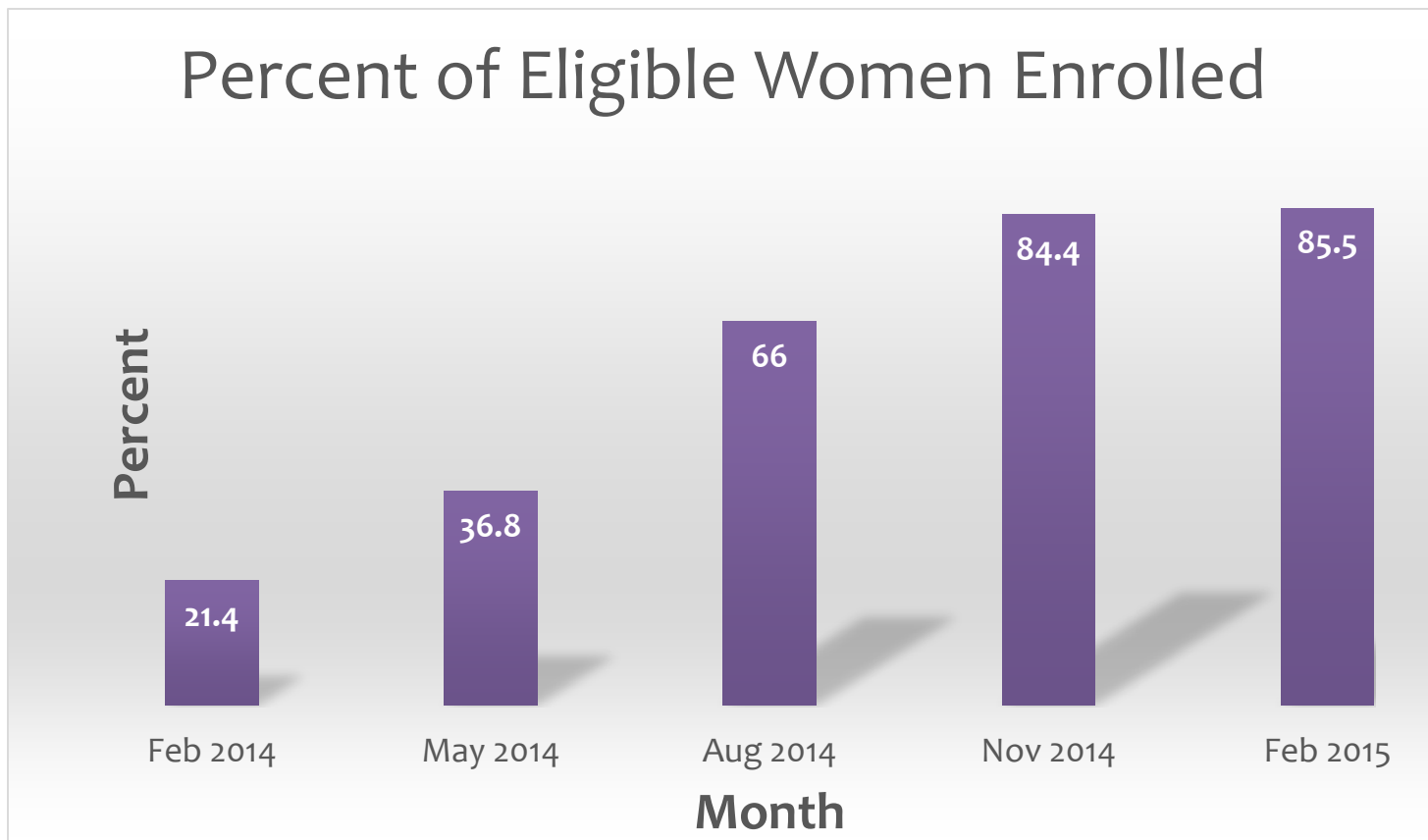
- Activation Progress at Lilongwe and Blantyre:
 - Lilongwe
 - CONGRATULATIONS on study activation on 31 December 2014. What a great way to end the year!
 - Blantyre
 - Activation requirements nearly complete, but regulatory approvals still pending.

Implementation Updates

- Accrual Progress:
 - Overall Accrual into MTN-016:
 - Total Women Enrolled: 388 (84.5% of eligible ppts)
 - Total Infants Enrolled: 328 (93.4% of live births)
 - ASPIRE-specific Accrual into MTN-016:
 - Women Enrolled: 71 (85.5% of eligible ppts)
 - Infants Enrolled: 45 (90% of live births)

Implementation Updates

- Accrual from ASPIRE



End of ASPIRE Considerations

- Re-approach eligible women/babies not previously enrolled in MTN-016
- Review MTN-016 visit schedule and logistics with participants
- Discuss strategies for maintaining contact with participants between appointments
 - If central locator being used: make certified copy for archive with ASPIRE binder; maintain moving forward during MTN-016 visits
- Strategize how site will find out about pregnancy outcomes for women who are still pregnant at the end of 020
- Unanticipated Problems Related to Study Participation continue to be reported to DAIDs MO (see safety monitoring SSP section), although there is no AE reporting in MTN-016

Proposed Publications

- Primary analysis:
 - One manuscript addressing the VOICE pregnancies that includes both VOICE and MTN-016 data (baseline data from MTN-016, as well as adverse pregnancy and delivery outcomes for women and adverse neonatal outcomes for infants)
- Study design:
 - Including what makes MTN-016 and this pregnancy registry unique
- Infant follow-up:
 - Growth, health, and developmental milestones during the first year of life

Publications Brainstorm

- MTN-016 management team also encourages site-driven publications. What additional research interests/ideas do you have?
 - Research question/objective
 - Brief rationale
 - Key variables
- Full concept proposals can be submitted to the MTN-016 publications committee at mtn016pubcommittee@mtnstopshiv.org

Questions?

