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

Percent of Eligible Women Enrolled

<table>
<thead>
<tr>
<th>Month</th>
<th>Percent of Eligible Women Enrolled</th>
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<tbody>
<tr>
<td>Feb 2014</td>
<td>21.4</td>
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<tr>
<td>May 2014</td>
<td>36.8</td>
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<tr>
<td>Aug 2014</td>
<td>66</td>
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<tr>
<td>Nov 2014</td>
<td>84.4</td>
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<tr>
<td>Feb 2015</td>
<td>85.5</td>
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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?