MTN-016 Protocol Team Meeting

MTN Regional Meeting
24 September 2018
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:30-4:40</td>
<td>Welcome and Introductions</td>
</tr>
<tr>
<td>4:40-4:50</td>
<td>Operational Update</td>
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<td>4:50-5:00</td>
<td>Publication Update</td>
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<tr>
<td>5:00-5:15</td>
<td>Lessons learned for MTN-042/MTN-043</td>
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<tr>
<td>5:15-5:30</td>
<td>MTN-016 looking ahead</td>
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## MTN-016/HOPE Accrual (site report through 31Aug2018)

<table>
<thead>
<tr>
<th>MTN-016 Accrual</th>
<th>N (%)</th>
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<tbody>
<tr>
<td># Parent Study Pregnancies*</td>
<td>65*</td>
</tr>
<tr>
<td># Eligible for MTN-16</td>
<td>45</td>
</tr>
<tr>
<td># Pending Enrollment</td>
<td>3</td>
</tr>
<tr>
<td># Eligible but Not Enrolled</td>
<td>11</td>
</tr>
<tr>
<td># Enrolled</td>
<td>31 (68.9%)</td>
</tr>
<tr>
<td># Infants Enrolled</td>
<td>19</td>
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*Note that according to Atlas there have been 72 pregnancies. FHI will conduct a final reconciliation of numbers following last HOPE termination visit on 10 October.*
MTN-016 Retention

- Woman Quarterly Visit Retention: 84-100%
- Infant Visit Retention:
  - Newborn: 89%
  - Month 1: 81%
  - Visit 6: 50%
  - Month 12: 0% (only 1 ppt expected so far, but visit was missed)
- Question: Retention seems to be dropping for infant visits over time. What strategies can we employ to combat this?
Publication Update
Pregnancy Incidence and Outcomes in Women Receiving Tenofovir-based PrEP in the VOICE Trial


• **Status:**
  
  – Initially submitted to JAIDS: not accepted for publication
  
  – Submitted to BMC Pregnancy and Childbirth (March 2018)
Pregnancy and infant outcomes among women using the dapivirine vaginal ring in early pregnancy


• **Status:**
  – Accepted for publication by JAIDS
Lessons Learned for MTN-042/MTN-043

- **MTN-042**: Phase 3b, Randomized, Open Label Safety Trial of Dapivirine Vaginal Ring (VR) and Oral TRUVADA Use in Pregnancy
- **MTN-043**: Phase 3B, Open Label, Safety, Pharmacokinetic, Mother-infant Pair Study of Dapivirine Vaginal Ring (VR) and Oral TRUVADA Use in Breastfeeding
Lessons Learned for MTN-042/MTN-043: Brainstorm

- **Retention:**
  - What retention challenges might sites face with pregnant women or mother/infant pairs?
  - What strategies might be particularly effective when working with these populations?

- **Engagement ideas:**
  - Mothers
  - Partners
  - Extended family
MTN-016 Looking Ahead

- Pregnancy follow-up in future MTN Protocols
- MTN-016 closeout timelines
- Community messaging
MTN-016 Looking Ahead

• MTN-016 visits should continue until all HOPE mothers/infants complete their final visits
  – Potential for HOPE pregnancy in final days of follow-up

• Sites that are no longer seeing participants can close out the study
  – FHI 360 will follow-up with close-out guidance

• For future MTN studies, all follow-up will be in parent protocol rather than MTN-016
Site Discussion

• Managing community and ethics committee expectations
  – MTN-016 was necessary but not anymore?
  – How will MTN assure safety for mothers and infants?
Questions?