



MTN-016 Protocol Team Meeting

MTN Regional Meeting
24 September 2018



MTN-016 Meeting Agenda

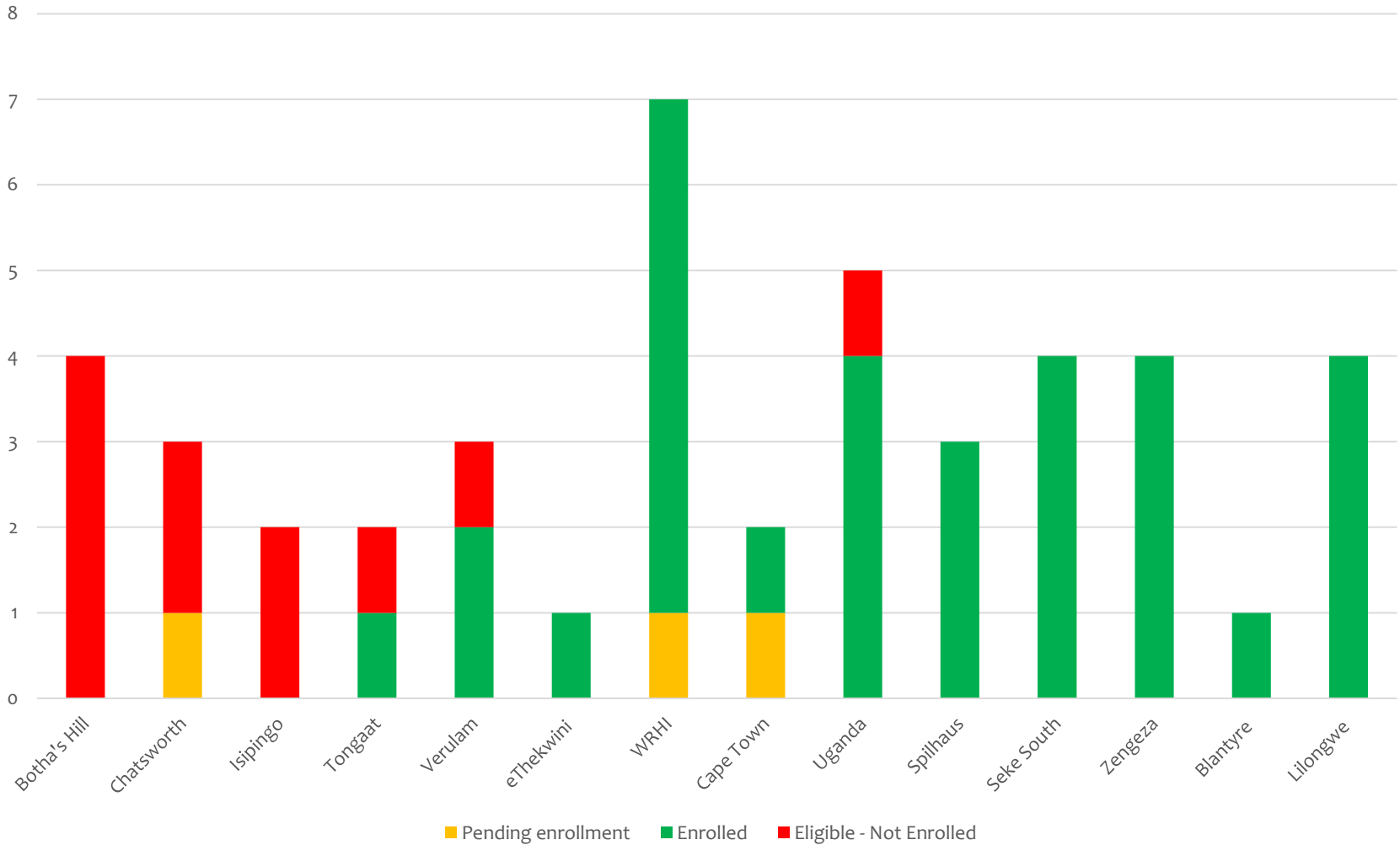
4:30-4:40	Welcome and Introductions
4:40-4:50	Operational Update
4:50-5:00	Publication Update
5:00-5:15	Lessons learned for MTN-042/MTN-043
5:15-5:30	MTN-016 looking ahead

MTN-016/HOPE Accrual (site report through 31Aug2018)

MTN-016 Accrual	N (%)
# Parent Study Pregnancies*	65*
# Eligible for MTN-16	45
# Pending Enrollment	3
# Eligible but Not Enrolled	11
# Enrolled	31 (68.9%)
# Infants Enrolled	19

**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 Uptake By Site



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



VOICE Primary Manuscript

Pregnancy Incidence and Outcomes in Women Receiving Tenofovir-based PrEP in the VOICE Trial

Katherine Bunge, Jennifer Balkus, Lisa Noguchi, Jason Pan, Jeanna Piper, Jeanne Marrasso, Mike Chirenje, Samuel Kabwigu, Barbra Richardson, Craig Hendrix, Mark Marzinke, D. Heather Watts, Kenneth Kintu, Gita Ramjee, Felix Muhlana, Gonasagrie Nair, Marthinette Taljaard, Thesla Palanee-Phillips, Ravindre Panchia, James Rooney, Jill L. Schwartz, Kristine Torjesen, Kailazarid Gomez, Rachel Scheckter, Rich Beigi, and the VOICE team

- **Status:**
 - **Initially submitted to JAIDS: not accepted for publication**
 - **Submitted to BMC Pregnancy and Childbirth (March 2018)**

ASPIRE/MTN-016 Manuscript

Pregnancy and infant outcomes among women using the dapivirine vaginal ring in early pregnancy

Bonus Makanani and Jennifer E. Balkus, Yuqing Jiao, Lisa M. Noguchi, Thesla Palanee-Phillips, Yamikani Mbilizi, Jothi Moodley, Kenneth Kintu, Krishnaveni Reddy, Samuel Kabwigu, Nitesha Jeenariain, Ishana Harkoo, Nyaradzo Mgodzi, Jeanna Piper, Helen Rees, Rachel Scheckter, Richard Beigi and Jared M. Baeten

- **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?