

MTN-016: EMBRACE Annual Meeting 2014



Agenda

3:30-3:35	Welcome and Introduction	Rich Beigi/ Samuel Kabwigu
3:35-3:50	Implementation and Accrual Status	Rachel Scheckter
3:50-4:10	Site Presentations on Enrollment Challenges and Successes in MTN-016	MRC (Umkomaas) and UZ-UCSF (Spilhaus)
4:10-4:25	Capturing primary endpoints under protocol v2.0	Lisa Noguchi
4:25-4:30	Questions and Closing Remarks	Rich Beigi/ Samuel Kabwigu



Implementation Update

- Follow-up of participants from two parent protocols currently ongoing:
 - MTN-008
 - MTN-020

MTN-008

- **Expanded Safety of Tenofovir 1% Gel in Pregnancy and Lactation**
 - Two Sites:
 - Pitt CRS (58 women, 54 infants)
 - UAB CRS (30 women, 28 infants)
 - MTN-016 enrollment is complete. Last infant visits anticipated for September 2014.

MTN-020: ASPIRE

- **A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Safety and Effectiveness Trial of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women**
- 15 activated sites for ASPIRE, 12 of these are already implementing MTN-016
 - Cape Town training completed 31 Oct-1 Nov 2013 and site should be activated by end of Q1 2014.



Protocol v2.0

- Finalized on 11 February 2014
- Distributed to sites 14 February 2014

- Next steps:
 - All sites preparing revised ICFs to submit along with Protocol Summary of Changes and Protocol Version 2.0 for IRB approval
 - While approval is pending, update SOPs, Visit Checklists, DoA
 - Management team to update SSP, study tools
 - Blantyre and Lilongwe to begin activation preparations

MTN-016 Accrual from ASPIRE

Site	WOMEN				
	# Parent Study Pregnancies*	# eligible for 016†	Eligible, but Pending Enrollment	# women enrolled	# Eligible, but Not Enrolled§
South Africa: Durban MRC- Botha's Hill	3	1	1	0	0
South Africa: Durban MRC- Chatsworth	5	3	1	0	2
South Africa: Durban MRC- Isipingo	4	3	0	0	3
South Africa: Durban MRC- Tongaat	8	3	0	1	2
South Africa: Durban MRC- Umkomaas	3	2	0	2	0
South Africa: Durban MRC- Verulam	8	4	0	0	4
eThekwini (CAPRISA Durban)	5	1	0	1	0
South Africa: Johannesburg WRHI	6	1	1	0	0
South Africa: Cape Town					
Uganda: Kampala	7	4	4	0	0
Zimbabwe: Harare - Spilhaus	2	2	0	2	0
Zimbabwe - Chitungwiza - Seke South	1	0	0	0	0
Zimbabwe - Chitungwiza - Zengeza	4	4	4	0	0
TOTAL (MTN-020)	56	28	11	6	11



Accrual from ASPIRE

- To be eligible for MTN-016, women must have a known confirmed pregnancy while participating in one of the MTN-016 parent protocols.
- Pregnancy rate in past prevention trials
 - Partners PrEP-10%
 - CAPRISA 004- 4%
 - Fem-Prep- 9%
 - VOICE 7.8%
- Pregnancy rate in ASPIRE to date-3%

ASPIRE vs. VOICE

Including 11 pending enrollments

		WOMEN			
	Site	# Parent Study Pregnancies*	# eligible for 016†	# women enrolled	# Eligible, but Not Enrolled§
MTN-020	TOTAL (MTN-020)	56	28	17 (60.7%)	11 (39.3%)
MTN-003	TOTAL (MTN-003)	424	261	213 (81.6%)	47 (18.0%)

- Trends:
 - Rate of parent study pregnancies much lower in ASPIRE than in VOICE
 - Percent of eligible, but not enrolled women more than double in ASPIRE than in VOICE
 - Percent of eligible and enrolled women from ASPIRE is only about one fourth what this was in VOICE.
- Lower pregnancy rate in parent protocol is a positive trend, but a lower pregnancy rate *plus* lower enrollment rate of eligible participants limits our ability to achieve the study objectives of MTN-016.



Moving Forward

- Continue revisiting MTN-016 with eligible participants who have not enrolled
- Provide refresher trainings for site staff that help make MTN-016 a priority (trainings to prepare for roll-out of v2.0 are a good opportunity for this)
- Identify challenges and successes related to MTN-016 accrual
- Communicate with each other and the management team about what is working well and what is needed to maximize enrollment