

# MTN-016

## Safety Monitoring and Reporting



# Objectives

- Apply safety assessment and reporting processes for both woman and their infants participating in MTN-016.

# Safety Reporting Scenario

Grace reports to the clinic for her monthly VOICE visit. At her last visit, she had both her scheduled VOICE visit and her first quarterly EMBRACE visit. Her pregnancy test is negative.

# Safety Monitoring and Reporting

- Unanticipated problems/events related to MTN-016

## **PARTICIPATION:**

- Is the problem/event and **participation in MTN-016** related in time?
- Is the problem/event and **participation in MTN-016** directly associated or more likely due to some other cause?
- If yes, IoR to report to:
  - Appropriate IRB/EC
  - MTN-016 DAIDS Medical Officer

# Safety Monitoring and Reporting

**What if an MTN-016 participant has what appears to be an SAE or EAE?**

- Any SAE or EAE that is considered reportable in the parent protocol should be reported via the safety reporting system utilized by the parent protocol.

# Safety Monitoring and Reporting

## Considerations for the woman:

- All AEs related to the woman as per MTN-003 reporting guidelines
- Fetal loss is **NOT** reportable as an AE in VOICE (per MTN-003 LoA #1)
  - However, medical conditions resulting from or in fetal loss are reportable.

## Considerations for the infant:

- Congenital anomalies
  - Record as part of MTN-003 and MTN-016 Pregnancy Outcome
  - Complete MTN-003 and EAE reporting form

# Safety Monitoring and Reporting

## Social Harms

- Confirm whether related to MTN-016 participation or to the parent protocol
- Report on the relevant CRF
- Consult the MTN-016 team as needed

# Safety Reporting Scenario

Grace reports to the clinic for her monthly VOICE visit.

At her last visit, she had both her scheduled VOICE visit and her first quarterly EMBRACE visit.

Her pregnancy test returns negative.

# Safety Reporting Scenario

- This would be an interim visit for EMBRACE.