



# MTN 016 Concept

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MTN Regional Meeting  
October, 2014



# Background

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- Reproductive age women are a primary target population for an effective microbicide
- Early pregnancy exposures will be inevitable once an agent is approved



# Purpose

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- To compare pregnancy outcome and specific infant outcomes (mortality, growth, and neurodevelopment) between participants randomized to active study agents and their corresponding placebos



# Hypothesis

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- There will be no difference in rates of adverse pregnancy outcomes (e.g., preterm delivery, stillbirth, ectopic pregnancy, or spontaneous abortion) between active and placebo groups.
- There will be no difference in rates of adverse neonatal outcomes (congenital anomalies or growth restriction at birth) or poor infant outcomes (i.e., neurodevelopmental delay or growth delay at one year).

# Data Analysis

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- Demographics of study population
  - Entire MTN-016 cohort derived from VOICE
    - Maternal age at enrollment
    - Parity
    - HIV infection while
    - Educational status at VOICE enrollment
    - Gestational age at enrollment
    - Gestational age at pregnancy outcome
    - Length of exposure to study product during pregnancy
    - Adherence to study product



# Compare

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- Rates of pregnancy outcomes across groups
- Rate of poor neonatal outcomes across groups
- Rates of infant death or growth lag across groups



# Challenges

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- Defining adherence
  - Use the same definition as the primary paper?
  - Based on drug level at time of pregnancy diagnosis
- Defining “groups”
  - Should the two oral products be lumped together?



# Importance of Exposed Group

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- Add to the data available from HIV seropositive mothers
- Add to the data available from HIV seronegative mothers (Partners)
- Inform prescribing guidelines regarding pregnancy testing





# Importance of placebo

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- Will provide baseline pregnancy outcome data in this population
  - Partners Prep
  - Challenge of pregnancy studies



# Timeline

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- Additional blood samples analyzed at JHU- complete
- Data analysis at SCHARP
- 2 month turn around for manuscript



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