

MTN-016

HIV Prevention Agent Pregnancy Exposure Registry

Protocol Co-Chairs:

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MTN-016

EMBRACE:

**Evaluation of Maternal and Baby
Outcomes Registry After
Chemoprophylactic Exposure**

Study Population

- Participants who become or became pregnant during HIV prevention trials, or who have or had planned exposures in pregnancy safety studies, provided pregnancy outcome was <1 year from the date of the EMBRACE Screening/Enrollment Visit
 - Target enrollment = 500 women

- The infants resulting from those pregnancies, provided infants have not yet reached their 1 year birth date.
 - Target enrollment = 300 live infants

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Primary Objectives

- Pregnancy loss: mothers exposed/not exposed to an active study agent
- Major malformations: infants exposed/not exposed to active study agent *in utero*

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Secondary Objectives

- ❑ Adverse pregnancy outcomes
- ❑ Growth parameters: infants exposed/not exposed to active study agent *in utero*
- ❑ Major malformations: infants exposed/not exposed to active study agent *in utero*

Exploratory Objectives

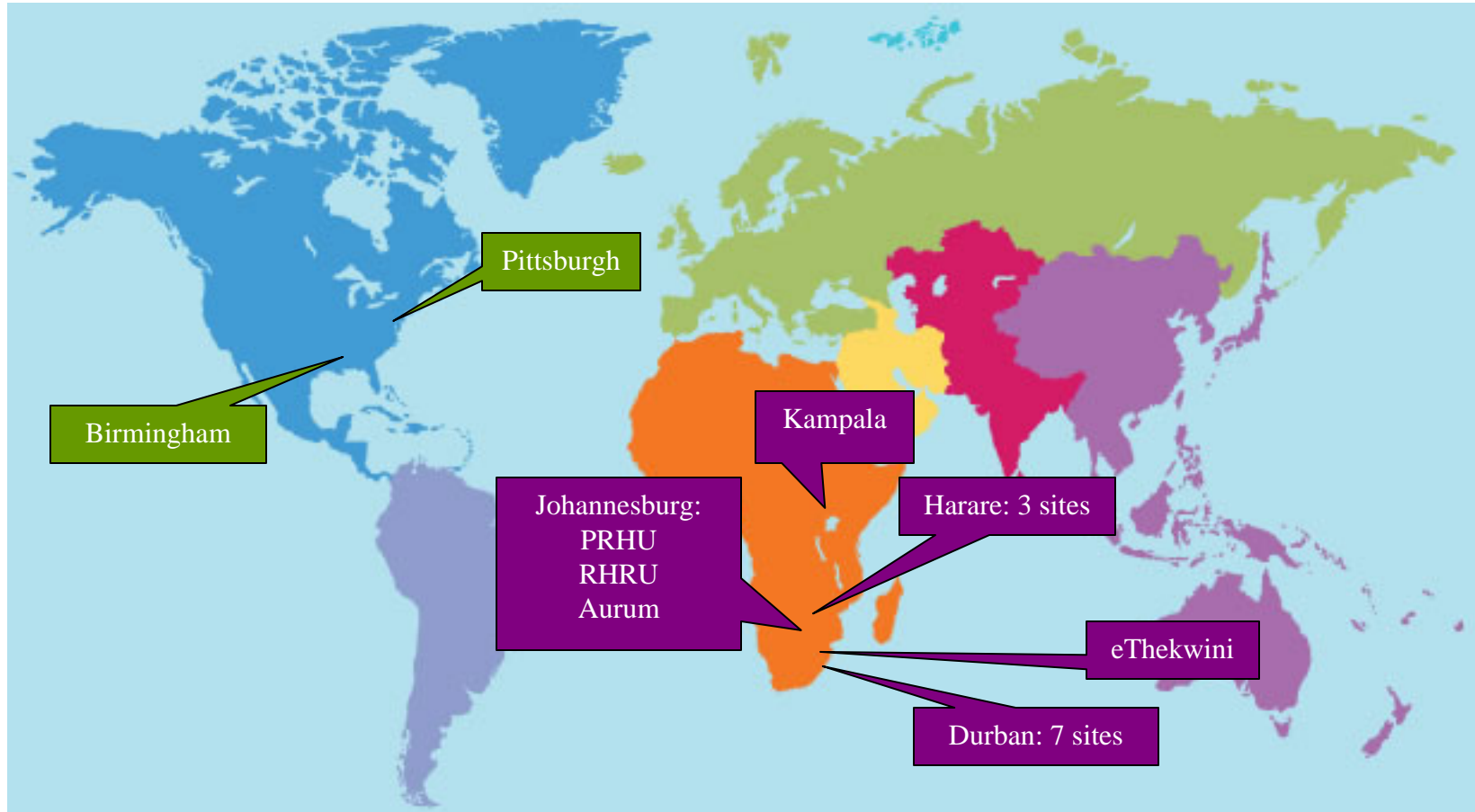
- ❑ Select risks of prevention agents by trimester of exposure
- ❑ Prevalence/persistence of HIV drug mutations in HIV-infected infants
- ❑ Developmental screening: infants exposed/not exposed to active study agent *in utero*

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Expected MTN parent protocols:

- MTN-002: Ph 1 Maternal Single-Dose PK and Placental transfer of Tenofovir 1% Vaginal gel among Healthy Term Gravidas
 - N = 16 mother-infant pairs
- MTN-008: Expanded Safety Investigation of Tenofovir 1% Gel in Pregnancy and Lactation
 - N = 90 mother-infant pairs
- **MTN-003: VOICE**
 - **Expected to contribute the remainder**

MTN016 Participant Contributors



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Main Maternal Inclusion Criterion

- During participation in parent protocol, has/had known confirmed pregnancy

Maternal Exclusion Criteria

- Any condition that would complicate study outcome data
- Pregnancy outcome diagnosed > 1 yr ago

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Main Infant Inclusion Criterion

- Born to mother enrolled in EMBRACE

Infant Exclusion Criteria

- Any condition that would complicate study outcome data
- Has reached 1 year birth date

MTN 016: EMBRACE

Maternal Visit Schedule

- Screening/Enrollment
- Quarterly
- (Pregnancy Outcome)

Infant Visit Schedule

- Newborn/Initial Visit
- Months 1, 6 and 12



MTN-016 Sites: 12 of 17

- Pittsburgh, US
- Zimbabwe – 3 sites
- MRC, Durban, SA – 7 sites
- Uganda

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- RHRU
 - PHRU
 - eThekwini
 - Aurum
 - Birmingham, Alabama, US

GOAL

All 17 sites activated prior to January, 2011

PREFERABLY ... NOVEMBER 30, 2010