

# MTN 016 Study

← Approximate duration of study participation for woman= 1- 40 weeks

Approximate duration of study participation for infants = 1 year →

## WOMAN SCREENING & ENROLLMENT (1.0)

- Eligibility Assessment
- **WOMAN S&E INFORMED CONSENT**
- PTID Assignment
- Locator Information\*
- Medical record release
- Woman Enrollment
- Woman Demographics
- Parent Protocol Participation
- Genetic Screening History
- Update Medical History\*
- Concomitant Medication
- Pregnancy Report & History
- Ultrasound Results
- Confirm estimated date of delivery & procedure for notifying staff of labor
- Schedule & Reimburse
- As Indicated-----
- Schedule/ Review U/S
- Pregnancy Outcome

= Datafax CRF  
\*May obtain certified copies from VOICE & review/update



## WOMAN QUARTERLY VISIT (2.0, 3.0, 4.0)

- Update Locator Information\*
- Update Medical History\*
- Update Con. Medication
- Update Genetic Screening History
- Update Pregnancy Report & History
- Ultrasound Results
- Woman Follow-up Visit
- Confirm estimated date of delivery & procedure for notifying staff of labor
- Schedule & Reimburse
- As Indicated-----
- Schedule/ Review U/S
- Social Harms Assess.
- Pregnancy Outcome
- Woman Missed Visit

**Coordinate with monthly VOICE visits.  
Visit Window = +/- 45 days**



## POST-DELIVERY

- Follow Quarterly Visit or Interim Visit Procedures
- Pregnancy Outcome

### NEWBORN/ INITIAL VISIT (1.0)

- Eligibility Assessment
- **INFANT S&E INFORMED CONSENT**
- Infant PTID Assignment
- Update Locator Information
- Medical Record Release
- Infant Enrollment
- Infant Medical History
- Infant Con. Med
- Infant Visit Form
- Infant Physical Exam
- If Suspected Abnormalities:
  - Major Malformation Worksheet
  - Major Malformation Assessment
  - If consented, Photographs
- Schedule & Reimburse
- As Indicated-----
- **INFANT TESTING INFORMED CONSENT**
- Infant HIV Test Results
- LDMS Specimen Tracking
- Infant Missed Visit
- Social Harms Assess.

**Visit Window = within 10 days of delivery**



### INFANT MONTH 1 VISIT (2.0)

- Update Locator Information
- Update Infant Medical History
- Update Infant Con. Med
- Infant Visit Form
- Infant Physical Exam
- If Suspected Abnormalities:
  - Major Malformation Worksheet
  - Major Malformation Assessment
  - If consented, Photographs
- Schedule & Reimburse
- As Indicated-----
- Infant HIV Test Results
- LDMS Specimen Tracking
- Infant Missed Visit
- Social Harms Assess.

**Visit Window = +/- 2 weeks**



### INFANT MONTH 6 & 12 VISIT (3.0 & 4.0)

- Update Locator Information
- Update Infant Medical History
- Update Infant Con. Med
- Infant Visit Form
- Infant Physical Exam
- If Suspected Abnormalities:
  - Major Malformation Worksheet
  - Major Malformation Assessment
  - If consented, Photographs
- Denver Developmental Assessment
- Infant Developmental Screening
- Schedule (M6) & Reimburse
- As Indicated-----
- Infant HIV Test Results
- LDMS Specimen Tracking
- Infant Missed Visit
- Social Harms Assess.
- Infant Termination (M12)
- Infant End of Study Inventory (M12)

**Visit Window = +/- 1 month**



**INCLUSION CRITERIA: WOMEN**

1. Able and willing to provide written informed consent
2. During participation in a parent protocol, has/had a known confirmed pregnancy, meeting at least one of the following sets of criteria in A or B:
  - A: Two consecutive monthly study visits with positive pregnancy tests, OR
  - B: One or more of the following assessments:
    - Auscultation of fetal heart tones
    - Positive pregnancy test in the presence of clinically confirmed enlarged uterus
    - Positive pregnancy test in the presence of missed menses\* by participant report
    - Clinical assessment of fetal movement
    - Demonstration of pregnancy by ultrasound
3. Able and willing to provide adequate locator information

*Note: Participants do not have to be currently enrolled or engaged in follow-up in a parent protocol to participate in MTN-016.*  
*\* Missed menses = no menses ≥60 days from first day of last menses. Amenorrheic or irregularly cycling women: use other listed criteria*

**EXCLUSION CRITERIA: WOMEN**

1. Has any condition that in the opinion of the investigator or designee, would complicate interpretation of study outcome data, make participation in the study unsafe, or otherwise interfere with achieving the study objectives.
2. Pregnancy outcome was diagnosed > one year ago.

**INCLUSION CRITERIA: INFANTS**

- Has written informed consent provided by parent(s)/guardian.
- Born to MTN-016 participant mother from pregnancy concurrent with participation in parent study.

**EXCLUSION CRITERIA: INFANTS**

- Has any condition that, in the opinion of the investigator or designee, would complicate interpretation of study outcome data, make participation in the study unsafe, or otherwise interfere with achieving the study objectives.
- Is greater than 1 year old.

**WOMAN SUBSEQUENT PREGNANCY (1.0)**

- Eligibility Assessment
- Confirm MTN-016 PTID Previously Assigned
- **WOMAN S&E INFORMED CONSENT**
- Update Locator Information\*
- Medical record release
- Woman Subsequent Consent
- Genetic Screening History
- Update Medical History\*
- Update Con. Medication
- Pregnancy Report & History
- Ultrasound Results
- Schedule & Reimburse

-----As Indicated-----

- Schedule/ Review U/S
- Pregnancy Outcome
- Social Harms Assess.

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**WOMAN INTERIM VISIT**

- Update Locator Information\*
- Woman Interim Visit

-----As Indicated-----

- Update Medical History\*
- Update Con. Medication
- Update Genetic Screening History
- Update Pregnancy Report & History
- Ultrasound Results
- Social Harms Assess.
- Pregnancy Outcome



**INFANT INTERIM VISIT**

- Update Locator Information
- Infant Interim Visit

-----As Indicated-----

- Update Infant Medical History
- Update Infant Con. Med
- Infant Physical Exam
- If Suspected Abnormalities:**
- Major Malformation Worksheet
- Major Malformation Assessment
- If consented, Photographs
- Denver Developmental Assessment
- Infant Developmental Screening
- Infant HIV Test Results
- LDMS Specimen Tracking
- Social Harms Assess.

