MTN-016
Data Management Considerations Overview

SSP Sections
13 & 15
SSP Section 13 - Contents

• The Data Management section of the MTN-016 SSP contains information on:
  – The SCHARP MTN-016 team
  – DataFax overview, including data entry/quality control procedures at SCHARP (13.1)
  – Form completion requirements (13.2)
  – 016-specific data collection information, including PTIDs, study visit timing, visit windows, visit codes, pregnancy cycles, CRF completion schedule, site review of CRFs, faxing CRFs (13.3)
  – Form and label supply; form storage (13.4)
  – Completion of interviewer-administered forms (13.5)
  – Additional form completion instructions (13.6)
  – Images of each MTN-016 case report form (13.7)
MTN-016 PTIDs

• The PTIDs used for this study are nine digits and formatted as “WWW-XXXX-Y-Z”

• The PTID consists of four parts:
  – the site number (WWW)
  – the participant number (XXXX)
  – a numerical check digit (Y)
  – the cohort number (Z)

• The cohort number is used to identify each participant as the woman (0) or infant (1,2,3, etc.)
MTN-016 PTIDs cont.

- Woman PTID structure

```
  3 0 2 - 1 2 3 4 - 8 - 0

  Site Number    Participant Number    Chk    Cohort
```

- Infant PTID structure

The Infant PTID is identical to it’s mother’s PTID with the exception of the last digit, the cohort number.

```
  3 0 2 - 1 2 3 4 - 8 - 1

  Site Number    Participant Number    Chk    Cohort
```
• SCHARP will provide the PTID list for the women PTIDs
• SCHARP will provide the linkage log for infant PTIDs, but PTIDs will need to be recorded as infants enroll into MTN-016
MTN-016 CRF Supplies

- SCHARP will provide the initial supply of CRFs needed for the study
- CRFs provided as visit packets (e.g. Woman Screening and Enrollment Visit)
- Bulk “as needed” CRFs are also provided (e.g. Infant Concomitant Medications Log)
- Site can print additional visit packets and forms as needed using the Atlas web page
Here are the form packets used in MTN-016 for the women:
  – Woman Screening and Enrollment
  – Woman Quarterly
  – Woman Subsequent Consent
  – Woman Termination/Study Exit

Printed on white paper

Note: there is no form packet for the Pregnancy Outcome visit (only a PO form is required)
MTN-016 CRF Supplies, cont.

• Here are the form packets used in MTN-016 for the infants:
  – Infant Newborn/Initial Visit
  – Infant Month 1 Visit
  – Infant Month 6 Visit
  – Infant Month 12 Visit (Infant Termination)

• Infant CRFs are printed on green paper
MTN-016 Other Supplies

- SCHARP does not provide 2 or 4-ring binders
- SCHARP will provide templates that can be used to create 016 binder cover and spine label inserts
- SCHARP will provide Microsoft Word templates (macros) which can be used to make PTID specimen labels needed for 016
  - SCHARP will provide bulk blank labels
- Additional CRFs can be printed directly from the MTN Atlas webpage
MTN-016 SCHARP Study Reports

• The Study Reporting Plan section of the SSP (section 15) describes all of the study reports produced by SCHARP

• This section also contains information on how reports are distributed (via email attachment or the MTN Atlas webpage)

• Discuss Data QC Reports, Site Data Management Quality Reports in this presentation
• SCHARP will send you separate QC Reports for Women and Infant data
• Format and content of these reports is the same as for other studies (VOICE)
• SCHARP *is not* performing “cross-checking” of data between VOICE and MTN 016
Data Management Quality Reports

- Reports are used to identify data management issues/patterns
- Please contact Corey with any questions about this report (I may be contacting you as well, depending on the situation)
- Reports are produced monthly
- Will be available via the MTN 016 Atlas webpage
• Click on MTN-016
• Under “MTN-016 Open Reports” section, you will see the Site Data Management Quality Report
MTN-016 Reports on Atlas, cont.

- Some 016 reports will be in the open section, some will be in the secure section (e.g. Major Malformations Assessment Reports)
- A login and password is required for secure study reports, and access is maintained by SCHARP
- SSP Section 15 details which reports are open and which are secure
- Questions about Atlas? Email atlas@scharp.org