

MTN-016

Data Management Considerations Overview



SSP Sections
13 & 15

SSP Section 13 - Contents

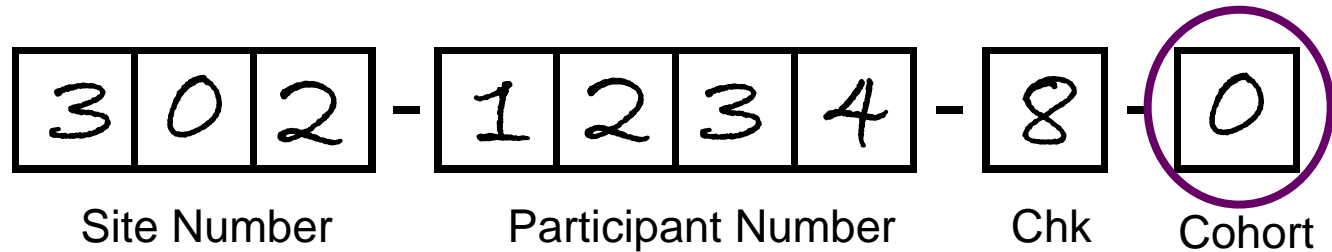
- The Data Management section of the MTN-016 SSP contains information on:
 - The SCHARP MTN-016 team
 - DataFax overview, including data entry/quality control procedures at SCHARP (13.1)
 - Form completion requirements (13.2)
 - 016-specific data collection information, including PTIDs, study visit timing, 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.)

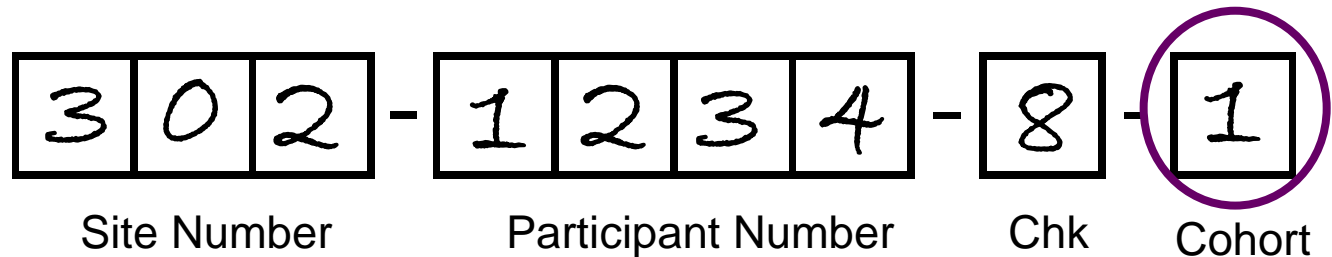
MTN-016 PTIDs *cont.*

- Woman PTID structure



- Infant PTID structure

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



MTN-016 PTIDs *cont.*

- 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

MTN-016 CRF Supplies, *cont.*

- 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

MTN-016 Data Quality Control (QC) Reports

- 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

MTN-016 Reports on Atlas

The screenshot shows a web browser window displaying the ATLAS SCHARP website. The page title is "MTN: /MTN - Mozilla Firefox". The address bar shows the URL "https://atlas.scharp.org/cpas/project/MTN/begin.view?". The page header includes the ATLAS logo, the SCHARP logo (Statistical Center for HIV/AIDS Research & Prevention), and the text "Atlas". The user is identified as "Laura McKinstry" with links for "My Account" and "Sign Out".

The main content area is titled "MTN" and includes a "Welcome to the MTN" message. A banner for "MTN SCHARP Reports" (microbicide trials network) is displayed. Below the banner, a list of projects is shown:

- MTN 001** Phase 2 Adherence and Pharmacokinetics Study of Oral and Vaginal Preparations of Tenofovir.
- MTN 002** Phase I Study of the Maternal Single-Dose Pharmacokinetics and Placental Transfer of Tenofovir 1% Vaginal Gel among Healthy Term Gravidas.
- MTN 003** Phase 2B Safety and Effectiveness Study of Tenofovir 1% Gel, Tenofovir Disoproxil Fumarate Tablet and Emtricitabine/Tenofovir Disoproxil Fumarate Tablet for the Prevention of HIV Infection in Women.
- MTN 004** A safety and acceptability study looking at the candidate microbicide VivaGel (SPL7013 Gel) in 40 sexually active, HIV-negative women ages 18 to 24.
- MTN 015** MTN 015 is an Observational Cohort Study of Women following HIV-1 Seroconversion in Microbicide Trials.
- HPTN 035** HPTN 035 is a Phase II/IIb Safety and Effectiveness Study of the Vaginal Microbicides BufferGel and 0.5% PRO2000/5 Gel (P) for the Prevention of HIV Infection in Women.

At the bottom of the list, there is a link: ">> Go the official Microbicide Trials Network site".

The left sidebar contains "Project Folders" with a tree view showing "MTN" expanded to show folders "001", "002", "003", "004", "015", "HPTN 035", and "HPTN 059". Below this is a "Projects" section with links for "Home", "Permanent Link", "Support", and "Help".

The right sidebar contains an "Atlas Support" section with a "[print]" link and text: "Click here to visit the Atlas Support page." and "Or you can e-mail atlas@scharp.org directly."

The browser status bar at the bottom shows "Done" and "atlas.scharp.org".

- 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