

# **ASPIRE Study Reports - What You Should Know**

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**Ted Livant – Network Lab**



# Topics Covered

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- Atlas web page
- Key Reports and why you need to look at them
  - Screen Out
  - Enrollment (Accrual)
  - Enrolled PTID Listing
  - Retention
  - Contraceptives
  - Missed Visit Listing
- Other study reports coming soon to Atlas or distributed via email
- LDMS Reconciliation Reports



# MTN-020 Atlas Web Page

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- Web address:

**atlas.scharp.org**

- No “www” needed

# atlas.scharp.org – Click on MTN!

The screenshot shows a web browser window with the URL <https://atlas.scharp.org/cpas/project/home/begin.view?> and a Google search bar. The website content includes a left-hand navigation menu, a main content area with a 'Welcome' header and 'ATLAS SCIENCE PORTAL' logo, a 'NEW! Atlas Password Policy' announcement, and a grid of project logos. A purple arrow points to the 'MTN' link in the navigation menu, and another purple arrow points to the 'MTN' logo in the project grid.

**Navigation Menu:**

- Home
- Announcements
- PROJECTS
  - Home
  - Collaborators
  - HPTN
  - MTN**
  - Support
  - VISC
- Sign In
- Home
- Permanent Link
- Help

**Main Content:**

Welcome

# ATLAS

SCIENCE PORTAL

**NEW! Atlas Password Policy**

**Project Logos:**

- CHAVI
- HIV VACCINE TRIALS NETWORK
- VISC
- MTN** (microbicide trials network)
- HPTN HIV PREVENTION TRIALS NETWORK
- MHRP

# Atlas Terms of Use – 2 Clicks needed



Atlas

Help

## Terms of Use

You must agree to terms of use to view data in this project.

You are about to enter a password-accessible site restricted to use by authorized members of MTN. Access to and information from this site should not be shared with unauthorized users. Your use of this site must be in accordance with the [Terms of Use of the ATLAS Science Portal](#).

I have read and understood the above provision, and signify my agreement.

I agree to these terms

AGREE



- 1. Click on the box to the left of “I agree...”,**
- 2. Click on “AGREE”**

# MTN Main Page – Support, DataFax Video, 020

← scharp.org https://atlas.scharp.org/cpas/project/MTN/begin.view? ☆ Google

**ATLAS** SCIENCE PORTAL | **Statistical Center for HIV/AIDS Research & Prevention SCHARP** Atlas


Search Atlas Help | Sign In

PROJECT FOLDERS

- MTN
  - 001
  - 002
  - 003 (VOICE)
  - 003B
  - 004
  - 005
  - 007
  - 008
  - 009
  - 012 and IPM
  - 010
  - 013 and IPM
  - 026
  - 015
  - 016
  - 020

**MTN** Portal

### Welcome to the MTN



**MTN 001** MTN 001 is a phase 2 adherence and pharmacokinetics study of oral and vaginal preparations of Tenofovir

**MTN 002** MTN 002 is a phase I study of the maternal single-dose pharmacokinetics and placental transfer of Tenofovir 1% vaginal gel among healthy term gravidas

**MTN 003 (VOICE)** MTN 003 (VOICE) is a 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 003B** The purpose of MTN-003B is to compare changes in bone mineral density (BMD) after one year among MTN-003 (VOICE) participants receiving oral Tenofovir and oral Truvada compared with oral placebo


#### Atlas Support

Click here to visit the Atlas Support page.


Or you can e-mail [atlas@scharp.org](mailto:atlas@scharp.org) directly.

#### DataFax Video

Download our video about SCHARP's DataFax system.



[ 250MB WMV format ]



# MTN Main Page con't – Click on MTN-020

← scharp.org https://atlas.scharp.org/cpas/project/MTN/begin.view? ☆ ▾ ↻ Google

|                            |   |
|----------------------------|---|
| <b>MTN 009</b>             | MTN 009 is a prevalence of HIV-1 drug resistance within a female screening population for HIV prevention trials   |
| <b>MTN 012 and IPM 010</b> | MTN 012/IPM 010 is a male tolerance study of Dapivirine gel following multiple topical penile exposures   |
| <b>MTN 013 and IPM 026</b> | MTN-013/IPM-026 is a phase 1 multi-site, double-blinded, randomized, controlled trial looking at safety and pharmacokinetics of a Dapivirine/Maraviroc Vaginal Ring. This is a 4-arm study where participants will be randomized to receive either a Dapivirine Vaginal Ring, a Maraviroc Vaginal Ring, a Dapivirine/Maraviroc Vaginal Ring or a Placebo Ring |
| <b>MTN 015</b>             | MTN 015 is an observational cohort study of women following HIV-1 seroconversion in microbicide trials  |
| <b>MTN 016</b>             | MTN 016 (EMBRACE) is a prospective observational cohort investigation of exposures to study agents under investigation for HIV prevention   |
| <b>MTN 020</b>             | MTN-020 (ASPIRE) is a multi-center, randomized, double-blind, placebo-controlled phase 3 safety and effectiveness trial of a vaginal matrix ring containing Dapivirine for the prevention of HIV-1 infection in women   |
|                            | HPTN 035 is a phase II/Ib safety and effectiveness study of the vaginal microbicides BufferGel and 0.5% PRO2000/5 gel (P) for the prevention of HIV infection in women  |

>> Go the official Microbicide Trials Network site



# MTN-020 Main Page – Atlas Support Link; *consider bookmarking*

PROJECT FOLDERS

- MTN
  - 001
  - 002
  - 003 (VOICE)
  - 003B
  - 004
  - 005
  - 007
  - 008
  - 009
  - 011
  - 012 and IPM
  - 010
  - 013 and IPM
  - 026
  - 015
  - 016
  - 020**
  - HPTN 035

PROJECTS

- Sign In
- Home
- Permanent Link
- Help

020 Start Page

### Welcome to MTN 020

MTN-020 (ASPIRE) is A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Safety and Effectiveness Trial of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women.

MTN-020 will take place at 17 African sites and will enroll approximately 3,476 HIV-uninfected women. The study is expected to be completed in 2014.

### MTN 020 Open Reports

| Document:                      | Last Updated: |
|--------------------------------|---------------|
| Screen Out Report              | Current       |
| Enrollment Report              | Current       |
| Enrolled PTID Listing          | Current       |
| Retention Report               |               |
| Contraceptives Report          |               |
| Procedures Completion Report   |               |
| Data Management Quality Report |               |
| Data Summary Report            |               |

### MTN 020 Secure Reports (password required)

| Document:                    |
|------------------------------|
| Protocol Deviations Listings |
| PSRT (Safety) Reports        |

### Visit Packets and All CRFs

- Visit Packets

### MTN 020 Dashboard

**Statisticians:** Elizabeth Brown and Marla Husnik

**Project Managers:** Missy Cianciola and Jen Berthiaume

**Protocol Programmer:** Martha Doyle

**Data Coordinators:** Jennifer Schille and Claire Chapdu


**Document Specialist:** Stacie Kentop

**Lab Operations:** Deb Bassuk

**ACASI Programmer:** Lynda McVarish

**Clinical Affairs Safety Associate:** Maija Anderson

### iDataFax

 For iDataFax information and training videos, visit our [iDataFax site](#).  
(Atlas login required)

### Atlas Support

Click here to visit the Atlas Support page.

Or you can e-mail [atlas@ssharp.org](mailto:atlas@ssharp.org) directly.



# MTN-020 Main Page – Atlas Support Link

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## Atlas Support

Click here to visit the Atlas Support page.



Or you can e-mail [atlas@scharp.org](mailto:atlas@scharp.org) directly.

# MTN-020 Main Page – SCHARP Team, iDataFax

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## MTN 020 Open Reports

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| Screen Out Report              | Current              |
| Enrollment Report              | Current              |
| Enrolled PTID Listing          | Current              |
| Retention Report               |                      |
| Contraceptives Report          |                      |
| Procedures Completion Report   |                      |
| Data Management Quality Report |                      |
| Data Summary Report            |                      |

## MTN 020 Dashboard

|   |                                    |
|---|------------------------------------|
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| <b>ACASI Programmer:</b>                  | Lynda McVarish                     |
| <b>Clinical Affairs Safety Associate:</b> | Maija Anderson                     |

## iDataFax



For iDataFax information and training videos, visit our [iDataFax site](#).

(Atlas login required)



# SCHARP iDataFax – Requires You to be Logged In

Statistical Center for  
HIV/AIDS Research & Prevention  
**SCHARP**

Atlas

Search Atlas



Help ▾

missy@scharp.org ▾

iDataFax

Start Page

## iDataFax at SCHARP



### Welcome to SCHARP's resource center for iDataFax!

Using the iDataFax application will allow you to enter CRF data directly into SCHARP's DataFax server and view your site's data & queries.

To begin using iDataFax:

1. If you have not already received your iDataFax account information, notify your primary site contact.
2. View the SCHARP iDataFax [training videos](#).
3. Visit the [Getting Started](#) page to download and install iDataFax.

## iDataFax Support

Visit the [iDataFax FAQ](#) page.

Contact your Primary Site Contact for help.

Email [support@scharp.org](mailto:support@scharp.org).

## Quick Links

- [Getting Started](#)
- [iDataFax Training videos](#)
- [iDataFax Quick Reference](#)
- [Using iDataFax Guide \(pdf\)](#)
- [Frequently Asked Questions](#)

# MTN-020 Main Page – Open Reports Section

***Click on “Current” under “Last Updated” to open report***

MTN-020 will take place at 17 African sites and will enroll approximately 3,476 HIV-uninfected women. The study is expected to be completed in 2014.

## MTN 020 Open Reports

| <b>Document:</b>               | <b>Last Updated:</b>    |
|--------------------------------|-------------------------|
| Screen Out Report              | <a href="#">Current</a> |
| Enrollment Report              | <a href="#">Current</a> |
| Enrolled PTID Listing          | <a href="#">Current</a> |
| Retention Report               |                         |
| Contraceptives Report          |                         |
| Procedures Completion Report   |                         |
| Data Management Quality Report |                         |
| Data Summary Report            |                         |



**Protocol Programmer:** Martha D  
**Data Coordinators:** Jennifer  
Claire C  
**Document Specialist:** Stacie K  
**Lab Operations:** Deb Bas  
**ACASI Programmer:** Lynda M  
**Clinical Affairs Safety Associate:** Maija An

## iDataFax



For iDataFax information training videos, visit

*Contraceptive and other listed reports to be added*



# Screen Out Report – Page 2

- Gives text when “4n - other, specify” was marked as reason participant did not enroll on ECI

MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of 25 September 2012

## Screen-Out Report "Other" Reason for Ineligibility

| Site                  | Text from item 4n - Other Reason For Ineligibility   |
|-----------------------|--|
| SA - MRC/Botha's Hill | ppt has renal disease.   |
| SA - MRC/Chatsworth   | gynecologic procedure less than 90 days<br>ppt experiences anxiety during blood draws.<br>pregnancy outcome 2 months ago<br>uncontrolled blood pressure/prefers tubal ligation<br>uncontrolled diabetes mellitus<br>vaginal pain due to condom use |
| SA - MRC/Isipingo     | dysfunctional uterine bleeding<br>uncontrolled/chronic condition   |
| Uganda - Kampala      | Participant not likely to be retainable<br>inadequate locator information<br>indeterminate hiv rapid results<br>participant likely not to be retainable  |

# Screen Out Report – Page 3

- Provides “key” to column labels on page 1
  - tells you what reason 4a is, 4b, etc.

MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of 25 September 2012

## Screen-Out Report Ineligibility Reasons

| Reason(s) for ineligibility   |
|---|
| 4a. Participant < 18 or > 45 years old  |
| 4b. Plans for relocation/travel   |
| 4c. Participant is pregnant or planning to become pregnant                                    |
| 4d. Participant is breastfeeding  |
| 4e. Participant has not had vaginal sex in the last 3 months                                  |
| 4f. Participant has enrolled in another research study in the last 60 days                    |
| 4g. Participant has participated in VOICE or other HIV prevention trial in the past 12 months |
| 4h. PEP exposure in the last 6 months   |
| 4i. Participant is HIV-positive   |
| 4j. Participant declines effective method of contraception                                    |
| 4k. Participant has a grade 2 or higher pelvic exam finding                                   |
| 4l. Participant does not meet laboratory eligibility criteria                                 |
| 4m. Participant does not meet other clinical eligibility criteria                             |
| 4n. Other reason, including investigator decision   |





# Screen Out Report – Why Look at it?

- Provides insight on reasons why participants at your site are not enrolled
- May help you focus recruitment efforts
- May bring up issues that should be discussed with Protocol Leadership, especially if a site is sees 1 reason resulting in a large number of screen outs

# Enrollment Report – What It Is

- By site
  - Activation Date
  - 1<sup>st</sup> Enrollment Date
  - Last (most recent) Enrollment Date
  - Duration of Accrual in Days
    - Each calendar day included
    - Starts with date of first enrollment
  - Accrual Target – does not include unassigned slots
  - Total Screened
  - Total Enrolled
  - Screening to Enrollment Ratio
  - Average Enrollment per Day
  - Percent Enrollment (percent of listed target)

# Enrollment Report – A Look

MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)  
Data as of 25 September 2012

## Accrual Summary by Site

| Site                   | Activation Date | First Enrollment Date | Last Enrollment Date* | Duration of Accrual** (days) | Enrollment Target*** | Total Screened | Total Enrolled | Screen/Enroll Ratio | Average Enrolled per Day | Percent Enrolled |
|------------------------|-----------------|-----------------------|-----------------------|------------------------------|----------------------|----------------|----------------|---------------------|--------------------------|------------------|
| Malawi - Blantyre      | -               | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| Malawi - Lilongwe      | -               | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| SA - Cape Town         | 04SEP2012       | 19SEP2012             | 20SEP2012             | 7.0                          | 150                  | 2              | 2              | 1.0                 | 0.3                      | 1.3%             |
| SA - CAPRISA eThekweni | 13SEP2012       | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| SA - MRC/Botha's Hill  | 28AUG2012       | 10SEP2012             | 20SEP2012             | 16.0                         | 216                  | 29             | 11             | 2.6                 | 0.7                      | 5.1%             |
| SA - MRC/Chatsworth    | 28AUG2012       | 11SEP2012             | 21SEP2012             | 15.0                         | 216                  | 21             | 8              | 2.6                 | 0.5                      | 3.7%             |
| SA - MRC/Isipingo      | 28AUG2012       | 19SEP2012             | 19SEP2012             | 7.0                          | 216                  | 7              | 2              | 3.5                 | 0.3                      | 0.9%             |
| SA - MRC/Tongaat       | 28AUG2012       | 17SEP2012             | 19SEP2012             | 9.0                          | 216                  | 18             | 4              | 4.5                 | 0.4                      | 1.9%             |
| SA - MRC/Verulam       | 28AUG2012       | 13SEP2012             | 20SEP2012             | 13.0                         | 216                  | 30             | 7              | 4.3                 | 0.5                      | 3.2%             |
| SA - MRC/Umkomaas      | 28AUG2012       | 14SEP2012             | 17SEP2012             | 12.0                         | 216                  | 13             | 3              | 4.3                 | 0.3                      | 1.4%             |
| SA - WRHI              | -               | -                     | -                     | -                            | 200                  | -              | -              | -                   | -                        | -                |
| Uganda - Kampala       | 19JUL2012       | 21AUG2012             | 24SEP2012             | 36.0                         | 200                  | 47             | 31             | 1.5                 | 0.9                      | 15.5%            |
| Zambia - Lusaka        | -               | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| Zimbabwe - Seke South  | -               | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| Zimbabwe - Spilhaus    | -               | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| Zimbabwe - Zengeza     | -               | -                     | -                     | -                            | 150                  | -              | -              | -                   | -                        | -                |
| Overall                | 19JUL2012       | 21AUG2012             | 24SEP2012             | 36.0                         | 2896                 | 167            | 68             | 2.5                 | 1.9                      | 2.3%             |



# Enrollment Report – Why Look At It

- Three “words” .....

**12 Months**

**3476**

# Enrolled PTID Listing – What It Is

MTN 020: ASPIRE  
List of Enrolled Participants by Site

Data as of September 26, 2012

| Site                  | Participant ID | Enrollment Date |
|-----------------------|----------------|-----------------|
| SA - Cape Town        | 330-00001-1    | 19-SEP-2012     |
|                       | 330-00003-5    | 20-SEP-2012     |
| SA - MRC/Botha's Hill | 310-50002-6    | 11-SEP-2012     |
|                       | 310-50003-1    | 10-SEP-2012     |
|                       | 310-50004-4    | 12-SEP-2012     |
|                       | 310-50005-9    | 18-SEP-2012     |
|                       | 310-50006-7    | 12-SEP-2012     |
|                       | 310-50007-8    | 13-SEP-2012     |
|                       | 310-50008-0    | 14-SEP-2012     |
|                       | 310-50009-3    | 14-SEP-2012     |
|                       | 310-50011-0    | 20-SEP-2012     |
|                       | 310-50017-3    | 18-SEP-2012     |
|                       | 310-50018-5    | 20-SEP-2012     |
| SA - MRC/Chatsworth   | 308-40004-3    | 19-SEP-2012     |
|                       | 308-40007-9    | 11-SEP-2012     |
|                       | 308-40008-4    | 12-SEP-2012     |
|                       | 308-40009-2    | 19-SEP-2012     |
|                       | 308-40011-4    | 18-SEP-2012     |
|                       | 308-40013-7    | 18-SEP-2012     |
|                       | 308-40021-1    | 19-SEP-2012     |
| 308-40031-5           | 21-SEP-2012    |                 |

By site:  
list of each  
PTID enrolled  
with Date of  
Enrollment



## Enrolled PTID Listing – Why Look at It

- May be useful to make sure info in Participant Tracking Database is current
  - All PTIDs are “enrolled” in PTD
- May be other site-specific uses

# Retention Report – What It Is

- Report is currently draft (in progress)
- By site
  - Total enrolled
  - By Visit Month
  - **# Expected (window closed)**
  - **# Completed based on HIV testing**
  
- In order to keep seroconverters by site masked, will count seroconverters as expected and completed
- Deaths are not included in “expected” or “completed”
- Participants who withdraw consent will continue to be expected



# Retention Report – A Look

**\*\*DRAFT\*\* MTN-020 (ASPIRE): Number of Participants Retained by Visit and Site \*\*DRAFT\*\***  
**For Data Entered as of 24 SEP 2012**

|   | Site 1 Name | Site 2 Name | Site 3 Name | Site 4 Name | Total |
|---|-------------|-------------|-------------|-------------|-------|
| <b>Number Enrolled</b>                  | 183         | N           | N           | N           | N     |
| <b>Month 1 Expected (window closed)</b> | 110         | N           | N           | N           | N     |
| <b>Completed based on HIV testing</b>   | 105 (95%)   | N (%)       | N (%)       | N (%)       | N (%) |
| <b>Month 2 Expected (window closed)</b> | 82          | N           | N           | N           | N     |
| <b>Completed based on HIV testing</b>   | 79 (96%)    | N (%)       | N (%)       | N (%)       | N (%) |
| <b>Month 3 Expected (window closed)</b> | 67          | N           | N           | N           | N     |
| <b>Completed based on HIV testing</b>   | 64 (96%)    | N (%)       | N (%)       | N (%)       | N (%) |

Note: Seroconverters are counted as “completed”. Deaths are not counted as “expected”.  
 Participants who withdraw consent are counted as “expected”.

# Retention Report – Why Look At It

- Without high retention, may not be able to answer with confidence whether the ring works to prevent HIV
  
- In order to say the whether the product works,
  - need to know participants' HIV status
  - Need participants to have/use the product
  
- Low retention means we may not see an effect, even if the product actually works



# Missed Visit Listing - What It Is

- Site-specific
- Provided to each site monthly via email
- Plan to provide in Excel format
- Lists name/date of last completed visit
- Name of missed visit and when window closed
- Date next required visit window closes
- # of consecutive visits missed
- # of total visits missed

# Missed Visit Listing – A Look

| Participant ID | Last Completed Scheduled Visit |            | Most Recent Scheduled Visit Missed |                     | Next Scheduled Visit |                     | Consecutive Visits Missed | Total Visits Missed |
|----------------|--------------------------------|------------|------------------------------------|---------------------|----------------------|---------------------|---------------------------|---------------------|
|                | Visit                          | Visit Date | Visit                              | End of Visit Window | Visit                | End of Visit Window |                           |                     |
| 320-00376-8    | Month 3                        | 21FEB2011  | Month 9                            | 15AUG2011           | Month 10             | 12SEP2011           | 6                         | 7                   |
| 320-00431-6    | Month 8                        | 06JUL2011  | Month 9                            | 09AUG2011           | Month 10             | 06SEP2011           | 1                         | 1                   |
| 320-00434-3    | Month 6                        | 19APR2011  | Month 10                           | 22AUG2011           | Month 11             | 19SEP2011           | 4                         | 4                   |
| 320-00525-2    | Month 2                        | 27JAN2011  | Month 9                            | 28AUG2011           | Month 10             | 25SEP2011           | 7                         | 7                   |



## Missed Visit Listing – Why Look At It

- Try to prevent chronic defaulters before they happen
- Try to minimize # of consecutive visits missed by a participant – avoid large time gaps between HIV testing and product supply
- FHI 360 will also see these reports, and will follow-up with sites on retention challenges

# Contraceptives Report - What It Is

- By site and by visit
  - Percent of participants using a given contraceptive method at t
  - Enrollment (baseline)
  - During a set time frame, i.e. calendar month
    - Example: September, 2012 Report will list all methods used by participants during that month, then a November 2012 Report will be created, then December, etc.

# Contraceptives Report – A Look

|   | All Sites  | Malawi - Blantyre | Malawi - Lilongwe |
|---|------------|-------------------|-------------------|
| Participants Enrolled                           | 68         | 0                 | 0                 |
| Participants with Baseline Family Planning Form | 68         | 0                 | 0                 |
| Current Method of Contraception                 | 68         | 0                 | 0                 |
| None  | 0          | 0 (-%)            | 0 (-%)            |
| Spermicide                                      | 0          | 0 (-%)            | 0 (-%)            |
| Diaphragm                                       | 0          | 0 (-%)            | 0 (-%)            |
| Sponge  | 0          | 0 (-%)            | 0 (-%)            |
| Intrauterine device                             | 4 (5.9%)   | 0 (-%)            | 0 (-%)            |
| Oral contraceptives                             | 10 (14.7%) | 0 (-%)            | 0 (-%)            |
| Injectable contraceptives                       | 44 (64.7%) | 0 (-%)            | 0 (-%)            |
| Patch   | 0          | 0 (-%)            | 0 (-%)            |
| Implants  | 7 (10.3%)  | 0 (-%)            | 0 (-%)            |
| Female condoms                                  | 0          | 0 (-%)            | 0 (-%)            |
| Natural methods                                 | 0          | 0 (-%)            | 0 (-%)            |
| Male condoms                                    | 4 (5.9%)   | 0 (-%)            | 0 (-%)            |
| Sterilization                                   | 3 (4.4%)   | 0 (-%)            | 0 (-%)            |
| Partner has a vasectomy                         | 0          | 0 (-%)            | 0 (-%)            |
| Other   | 0          | 0 (-%)            | 0 (-%)            |





# Contraceptives Report – Why Look At It

- Allow us to see how well we are doing with expanding the mix of contraceptives used by study participants



# Other Reports Coming To Atlas

- Procedures Completion
- Data Management Quality
- Data Summary
  
- Secure (permission required, access limited)
  - PSRT
  - SMC



# Coming Soon via email

- QC Reports – discuss more on Wednesday
- Clinical QC
- Ongoing AE
- Ongoing Product Hold
- Ongoing Social Harms
- LDMS Reconciliation Reports



# LDMS Reconciliation Reports

- Why you need to look at them
  - The reports reconcile information between the CRF's and LDMS entry so that specimen storage data is accurate.
  - The reports look for errors in LDMS codes so this information is correct.
  - The reports help identify specimens collected during screening for participants that are not enrolled.
  - The reports can catch problems with specimen management so they can be corrected.



# LDMS Reconciliation Reports

- What the reports show:
  - Specimen stored on CRF, no LDMS match
  - Specimen stored in LDMS, no CRF match
  - LDMS code errors
  - Non-enrollee list
  - No storage information



# LDMS Reconciliation Reports

- How to address items on the various reports
  - Look at error report first. Check SSP lab section to verify where error is first.
  - Next cross check discrepancy list. Correcting errors will frequently remove item from discrepancy list.



# LDMS Reconciliation Reports

- How to address items on the various reports
  - Discrepancies:
    - Review LDMS and CRF information, chain of custody
    - Make corrections as needed
    - Export LDMS, data fax new or corrected CRF's
    - Do not refax CRF's if no corrections made.
    - If discrepancies cannot be identified, indicate this on the excel sheet and submit for guidance



# LDMS Reconciliation Reports

- How to address items on the various reports
  - Non enrollees
    - Verify with clinic that participant is deferred
    - Option 1: destroy samples. Does not require NL approval unless participant is enrolled
    - Option 2: mark specimen as “never store” and maintain in LDMS
    - Note that these specimens cannot be tested locally or shipped to the NL





# LDMS Reconciliation Reports

- Will require communication between the lab and clinic staff
- The source of discrepancies can be in the lab or the clinic
- Sites should can have systems in place to review specimen storage more frequently then SCHARP reports
- Look for trends to prevent future issues



# LDMS Reconciliation Reports

## □ Communications

- The reports come from SCHARP directly to the site; make sure the correct people at your site/contract lab are on the email list
- Send your corrective action to the NL with SCHARP copied
- The NL will routinely address the corrective action first and consult SCHARP as needed.

**What are your questions?**

