Welcome!

A few things to go over before we get started…
Medidata Rave Overview

- Medidata Rave and EDC
- User roles
- Query management
- PPD monitoring in Rave
- Resources
What is Medidata Rave?

Industry-leading electronic data capture (EDC) and management platform for the capture, management and reporting of clinical, operational and safety data.

– Hosted on-line with a web-based interface
Medidata Rave – What and Why?

• SCHARP has selected Medidata Solutions as our partner for EDC (Rave).

• Medidata Rave Features Include:
  
  • Sites can enter data straight from source document into Rave
  
  • Sites can check and resolve errors, inconsistencies, missing data, etc., in real time at the point of site data entry
  
  • Communication, query guidance applied by DM to sites directly within Rave (rather than via email)
  
  • Audit trail captures all changes made to an eCRF within Rave
Why Electronic Data Capture (EDC)?

**DATA ACCURACY**
- Real-time data & consistency checks
- Legible entries
- Automatic calculations
- Better data management quality performance

**ORGANIZATION**
- User-friendly navigation
- Search and filter options
- Unified database
- Reports
- Greater visibility

**EFFICIENT DATA MANAGEMENT**
- Data entry at sites
- SDMC data entry process
- Real-time data access
- Unified database
- Less time managing queries

**DATA SECURITY**
- Data protected
- Data backed-up
- User and role-specific permissions

**REGULATORY COMPLIANCE**
- Validated system
- Data integrity
- 21 CFR Part 11 (Electronic Records, Electronic Signatures)
- Electronic source data verification (monitors)
- CDISC standards
- Submission-ready data
Medidata User Roles

- There are 2 types of Rave site user roles:

<table>
<thead>
<tr>
<th>Clinical Research Coordinator</th>
<th>Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>❖ Add participants into Rave</td>
<td>❖ Responsible for the overall conduct of a study</td>
</tr>
<tr>
<td>❖ Enter data</td>
<td>❖ Review and sign eCRFs</td>
</tr>
<tr>
<td>❖ Log adverse events and unscheduled visits</td>
<td>❖ Respond to queries</td>
</tr>
<tr>
<td>❖ Edit saved data</td>
<td>❖ Enter or edit subject data</td>
</tr>
<tr>
<td>❖ Answer queries</td>
<td></td>
</tr>
</tbody>
</table>

- User roles are based on user function within Rave. They do not necessarily correspond to a CRS role.
Rave Navigation

To access Rave, first log into the iMedidata Portal

• iMedidata portal will provide access to all types of studies implemented at a site for which you have access (e.g., HVTN, MTN, HPTN)
Once in the iMedidata Portal, select the study that you wish to access.

Required e-Learnings database invitations are located on the right side under the “Task” pane.
Once MTN-030 is selected, you will be prompted to select your Role (Investigator or CRC) before your home page displays.
Rave Navigation: Site Home Page

- CRS
- Participant (PTID) List
- Task Summary
- Icon Key
Icon Progressions
Task Summary

• Shows any pending tasks associated with the study based on user role

• Pending tasks are items needing prompt attention:
  – Requiring signatures
  – Non-conformant data
  – Open queries
  – Overdue data

• Site and Participant level
## Task Summary: Site Level

### Task Summary: Site

<table>
<thead>
<tr>
<th>Task</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requiring Signature</td>
<td>4</td>
</tr>
<tr>
<td>Requiring Translation</td>
<td>0</td>
</tr>
<tr>
<td>Open Queries</td>
<td>0</td>
</tr>
<tr>
<td>Answered Queries</td>
<td>1</td>
</tr>
<tr>
<td>Requiring Review</td>
<td>0</td>
</tr>
<tr>
<td>Ready for Entry Lock</td>
<td>4</td>
</tr>
<tr>
<td>Ready for Data Lock</td>
<td>0</td>
</tr>
<tr>
<td>Cancel Queries</td>
<td>2</td>
</tr>
</tbody>
</table>

### Icon Key

- **MTN030**

### Advanced Search

- **Subject**

### Labs
## Task Summary: Site to Participant Level

<table>
<thead>
<tr>
<th>Task Summary: Site</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requiring Signature</td>
<td>128</td>
</tr>
<tr>
<td>NonConformant Data</td>
<td>11</td>
</tr>
<tr>
<td>Open Queries</td>
<td>102</td>
</tr>
<tr>
<td>Overdue Data</td>
<td>23</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task Summary: Site</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requiring Signature</td>
<td>128</td>
</tr>
<tr>
<td>NonConformant Data</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>123</td>
</tr>
<tr>
<td></td>
<td>123164230</td>
</tr>
<tr>
<td></td>
<td>12322497</td>
</tr>
<tr>
<td></td>
<td>123398276</td>
</tr>
<tr>
<td></td>
<td>123456789</td>
</tr>
<tr>
<td></td>
<td>123860572</td>
</tr>
<tr>
<td></td>
<td>123CAT888888</td>
</tr>
<tr>
<td></td>
<td>123JEN123</td>
</tr>
<tr>
<td></td>
<td>14JUL2016</td>
</tr>
<tr>
<td></td>
<td>2016JUL14</td>
</tr>
<tr>
<td></td>
<td>6043</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task Summary: Subject</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requiring Signature</td>
<td>3</td>
</tr>
<tr>
<td>NonConformant Data</td>
<td>1</td>
</tr>
<tr>
<td>Pre-Screening-Pre-Screening Outcome</td>
<td>1</td>
</tr>
<tr>
<td>Open Queries</td>
<td>1</td>
</tr>
<tr>
<td>Overdue Data</td>
<td>0</td>
</tr>
</tbody>
</table>
Task Summary: Site to Participant Level

- **Task Summary: Subject**
  - Requiring Signature: 3
  - Nonconformant Data: 1
  - Pre-Screening Pre-Screening Outcome

**REVIEW**

Subject: 123164230
Page: Pre-Screening Outcome - Pre-Screening

1. What was this participant's ASPIRE PTSD?

2. Was the participant contacted to participate in HOPE?
   - List in study binder states participant was not contacted. Please clarify.
   - Open to site from CRF (13 Sep 2016)

3. Did the participant conduct a screening visit for HOPE?

4. Did the participant conduct a screening visit as part of the...

Printable Version | View PDF | Icon Key

CRF Version 05 - Page Generated: 18 Sep 2016 18:10:05 Pacific Daylight Time

MTN-025 main study
Task Summary: Participant Level

<table>
<thead>
<tr>
<th>CRF History</th>
</tr>
</thead>
<tbody>
<tr>
<td>123164230 - Pre-Screening Outcome</td>
</tr>
<tr>
<td>123398276 - Pre-Screening Outcome</td>
</tr>
<tr>
<td>999386382 - Date of Visit</td>
</tr>
<tr>
<td>999476848 - Concomitant Medications</td>
</tr>
<tr>
<td>998117377 - Hematology</td>
</tr>
<tr>
<td>999302650 - Behavioral Risk Assessment</td>
</tr>
<tr>
<td>997385553 - Behavioral Risk Assessment</td>
</tr>
<tr>
<td>997387553 - Reasons for Not Enrolling</td>
</tr>
<tr>
<td>999705312 - Demographics</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task Summary: Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit</td>
</tr>
<tr>
<td>V1 - Screening (1)</td>
</tr>
<tr>
<td>V2 - Enrollment (1)</td>
</tr>
<tr>
<td>V3 - Month 1 (1)</td>
</tr>
<tr>
<td>V4 - Month 2 (1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Open Queries</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1 - Screening (1) - Vital Signs</td>
</tr>
<tr>
<td>V2 - Enrollment (1) - Participant Date of Visit</td>
</tr>
<tr>
<td>Ongoing Logs (1) - Adverse Experience</td>
</tr>
<tr>
<td>Ongoing Logs (1) - Concomitant Medications</td>
</tr>
<tr>
<td>V1 - Screening (1) - Baseline Medical History</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Icon Key</th>
</tr>
</thead>
</table>
### Vital Signs

**Subject:** 123398276  
**Page:** Vital Signs - V1 - Screening (1)

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>225 kg</td>
</tr>
<tr>
<td>Body Temperature</td>
<td>36 °C</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>150 mmHg</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>90 mmHg</td>
</tr>
<tr>
<td>Pulse</td>
<td>80 beats per minute</td>
</tr>
<tr>
<td>Respiration</td>
<td>70 breaths per minute</td>
</tr>
<tr>
<td>Height</td>
<td>120 cm</td>
</tr>
</tbody>
</table>
Query Management within Rave

Data, clinical, and coding queries are applied, reviewed, answered, and resolved within the Rave database.

There are two main types of queries applied to eCRFs within Rave:

- **System Queries**
  - Automatically generated and placed in real time by Rave EDC when a page is saved with data that is missing (left blank) or when a data point does not conform to a pre-specified edit check.

- **Manual Queries**
  - Opened by a SCHARP Data Manager, Clinical Coder, or PPD Monitor upon manual review of the data for clarification on or correction to a specific item.
Query Management within Rave

Use the Task Summary to identify open queries for all participants at your site or for a given participant.

Participants, forms and fields with outstanding queries applied will be designated with the “Query Open” icon - 📌
Resolving Rave System Queries

Examples of System Queries:

1. Weight
   - Data is required. Please complete. (18 Sep 2016)
   - Data Entry Error
   - kg
   - Missing Data Query

2. Body Temperature
   - Data entered is out of range (> 42). Please correct. (18 Sep 2016)
   - Data Entry Error
   - °C
   - Edit check Query

3. Systolic BP
   - Data Entry Error
   - mmHg
   - Non-Conformant Query

Once the data field is corrected and the page is saved, a delta symbol will appear above the item that has been updated, the line is no longer pink and the query icon goes away.
Resolving Rave System Queries

1. Weight
   - Data is required. Please complete. Opened To Site from System (18 Sep 2016)
   - Optional site response to query
   - Data Entry Error: kg

2. Body Temperature
   - Data entered is out of range (> 42). Please correct. Opened To Site from System (18 Sep 2016)
   - Optional site response to query
   - Data Entry Error: 98.6 C

3. Systolic BP
   - Data Entry Error: ABC mmHg

**NOTE:** An **OPTIONAL** text field is provided beneath the system query text to document clarifying information regarding the data point or to request additional guidance from SCHARP on query resolution.
Resolving Rave Manual Queries

Example of a Manual Query:

Subject: 123169488
Page: Adverse Experience Y/N - V3 - Month 1 (1)

Has the participant experienced any new adverse events or are there any updates to previously reported AEs?

If 'Yes', complete or update the Adverse Experience log.

This item indicates that an AE was reported at this visit, however, no AE log form has been completed for this participant. Please review this item and update as applicable.
Opened To Site from DM (18 Sep 2016)

Yes / No

Data Entry Error

Subject: 123169488
Page: Adverse Experience Y/N - V3 - Month 1 (1)

Has the participant experienced any new adverse events or are there any updates to previously reported AEs?

If 'Yes', complete or update the Adverse Experience log.

This item indicates that an AE was reported at this visit, however, no AE log form has been completed for this participant. Please review this item and update as applicable.
Opened To Site from DM (18 Sep 2016)

Yes / No

A corresponding AE log page has been completed for this participant.
Field Audit Trail

- All changes that have made to a specific item on an eCRF can be viewed via the audit trail.
- To access an item’s audit trail, navigate to the completed form and click the data status icon.
- Audit trail within Rave will show each user who enters data, responds to queries, etc.

<table>
<thead>
<tr>
<th>Data Point - Has the participant experienced any new adverse events or are there any updates to previously reported AEs?</th>
<th>User</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Query: 'This item indicates that an AE was reported at this visit, however, no AE log form has been completed for this participant. Please review this item and update as applicable.' (Site from DM).</td>
<td>Jennifer Berthiaume</td>
<td>18 Sep 2016</td>
</tr>
<tr>
<td></td>
<td>(28 - jberthia@scharp.org2)</td>
<td>19:00:41</td>
</tr>
<tr>
<td>User opened query: 'This item indicates that an AE was reported at his visit, however, no AE log form has been completed for this participant. Please review this item and update as applicable.' (Site from DM).</td>
<td>Jennifer Berthiaume</td>
<td>18 Sep 2016</td>
</tr>
<tr>
<td></td>
<td>(29 - jberthia@scharp.org3)</td>
<td>18:32:20</td>
</tr>
<tr>
<td>User entered 'Yes (Y)'</td>
<td>Jennifer Berthiaume</td>
<td>18 Sep 2016</td>
</tr>
<tr>
<td></td>
<td>(28 - jberthia@scharp.org2)</td>
<td>18:30:58</td>
</tr>
</tbody>
</table>
SCHARP Data Reviews

SCHARP Data Managers:

• Review protocol endpoint data
• Review and resolve answered queries
• Place, review, and resolve manual queries based on ongoing data review

SCHARP CSA:

• Reviews clinical CRFs such as AE log CRFs on an ongoing basis
• Places, reviews, and resolves manual queries based on ongoing clinical data review
PPD Monitoring - Source Data Verification (SDV)

• DAIDS, SCHARP, & PPD review Study Monitoring Plan to determine on which CRFs and fields to place SDV boxes within Rave.

• During site monitoring visits, PPD monitors use the Task Summary on the Rave homepage to identify forms required for review.

• PPD monitors use SDV boxes to document their reviews within the study database.

• PPD monitors can place manual queries for the site to review and address
Resources Within Rave

Resource Pane: bottom left-side of home screen

- Displays a list of internet links that are standard across HVTN, HPTN, and MTN studies.

- AE Grading Table v2
- SCHARP Atlas portal
- Female Genital Grading Table v1
- HPTN website
- HVTN website
- Male Genital Grading Table v1
- MTN website
- Rectal Grading Table v1
Resources Within Rave

iMedidata Portal: Help menu on upper right corner provides access to these functions:

- **Help On This Page** – Click to open Online Help for the current application page in a new tab.
- **Knowledge Space Home** – Click to open the top level Help page in a new tab.
- **Show Me Videos** – Click to open a new tab where you can view a short instructional video about iMedidata.
- **Help center** – Click to open a page that allows you to view documentation and helpful tips as well as to report a problem.
Resources: Within Rave

Once within a study, you can click on the “Help” button on any page to access information relevant to that page.
THANK YOU
Site Presentation: EDC Experiences and Lessons Learned
MU-JHU, Uganda CRS
Rave Training Exercises
Logistics

- The following exercises are intended for site staff who will be entering data and resolving queries within Rave.
- If you do not have CRC access or have a user account but wish to observe, you are welcome to join your site colleagues.
- Don’t forget to save data!
- SCHARP staff are available to assist as needed! Ask us questions during the exercises!
- This is for training purposes only!
WELCOME TO THE BETHESDA NORTH MARRIOTT

YOUR WIRELESS NETWORK NAME IS: MARRIOTT_CONFERENCE

YOUR WIRELESS PASSWORD IS: MTN2017
Log in to your iMedidata Account

- Log in to iMedidata Portal (www.imedidata.com)
Access the MTN-030 TRAIN Study
Select applicable site within the TRAIN

<table>
<thead>
<tr>
<th>Site</th>
<th>Site Group</th>
<th>Site Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Meeting</td>
<td>World</td>
<td>Annual Meeting</td>
</tr>
<tr>
<td>Birmingham RAVE</td>
<td>World</td>
<td>31788</td>
</tr>
<tr>
<td>Pittsburgh CRS</td>
<td>World</td>
<td>1001</td>
</tr>
<tr>
<td>Test site 1</td>
<td>World</td>
<td>999123</td>
</tr>
</tbody>
</table>

Icon Key
Exercise #1: PTID Generation

Objective: Generate one PTID
1. Generate a PTID (hint: there are two steps)
2. Record PTID on a piece of paper
Exercise #1: PTID Generation

- Add subject
- Click “Save” on Participant Identifier page
Exercise #2: Let’s enroll a participant!

Objectives:
To become familiar with…
  • Randomization
  • Form and folder dynamics
  • System queries – viewing and resolving

• Use the PTID generated in Exercise #1
• Navigate to the V1.0 – Screening folder
  • Navigate to the Demographics eCRF
    • Enter the Date of Birth ONLY and SAVE the form
    • System queries will trigger – we will come back and resolve these!
### Exercise #2: Let’s enroll a participant!

**Subject:** 999672409  
**Page:** Demographics - V1.0 - Screening

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
<td>24 DEC 1984</td>
</tr>
<tr>
<td>Age</td>
<td>24 DEC 1984</td>
</tr>
<tr>
<td>Sex at Birth</td>
<td>Male</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Not Hispanic or Latino</td>
</tr>
</tbody>
</table>
| Race (mark all that apply)    | American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, White, Other race
| Highest education level completed | Not Hispanic or Latino     |
| Number of children (live births) | Not Hispanic or Latino     |
| Relationship status           | Not Hispanic or Latino     |
Exercise #2: Let’s enroll a participant!

• Navigate to the Eligibility Criteria eCRF within the V1.0 – Screening folder
  • *Did the participant meet all eligibility criteria…?* Yes
  • “If No, specify type of eligibility criteria not met: Leave blank
  • “Was the participant enrolled? Yes
  • “Why was the participant not enrolled? Leave blank
Exercise #2: Let’s enroll a participant!

<table>
<thead>
<tr>
<th>Subject: 999672409</th>
<th>Page: Eligibility Criteria - V1.0 - Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the participant meet all eligibility criteria?</td>
<td>Yes</td>
</tr>
<tr>
<td>If No, specify type of eligibility criteria not met.</td>
<td></td>
</tr>
<tr>
<td>Was the participant enrolled?</td>
<td>Yes</td>
</tr>
<tr>
<td>Why was the participant not enrolled?</td>
<td></td>
</tr>
<tr>
<td>If eligible, but participant declined enrollment, specify reason</td>
<td></td>
</tr>
</tbody>
</table>

Printable Version  View PDF  Icon Key
Exercise #2: Let’s enroll a participant!

- Navigate to the V2.0 – Enrollment folder
- Navigate to the Randomization eCRF
Exercise #2: Let’s enroll a participant!

• Is the participant ready to be randomized? **Yes**
• *Ignore system query (Balance will be linked to Rave module and Randomization Date and Time will automatically populate in live study database)*
Exercise #3: Enrolled participant – Follow-up

- Navigate to the V3.0 – Day 1 Folder
- Complete the Follow-up Visit Summary eCRF
  - Was this visit completed? Yes
  - Visit Date 10 MAR 2017
  - Was study product use permanently discontinued? No
  - Did the participant exit/terminate the study? No
  - Were any new AE reported at this visit? No
  - Is the participant taking any con meds…? No
  - Have any protocol deviations been reported…? No
  - What study procedures were completed at this visit:
    - Select ‘Yes’ for the following:
      - Ring Adherence Assessment
      - Ring Insertion or Removal
      - Vaginal Bleeding Assessment
      - PK Specimen collection?
    - Select ‘No’ for remaining forms
Exercise #3: Enrolled participant – Follow-up

<table>
<thead>
<tr>
<th>Subject: 999672409</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page: Follow-up Visit Summary - V3.0 - Day 1</td>
</tr>
</tbody>
</table>

- **Was this visit completed?** Yes
- **Visit date:** 10 MAR 2017
- **Was study product use permanently discontinued (scheduled or early) at this visit?** No
- **Did the participant withdraw the study at this visit?** No
- **Were any new adverse events (AEs) reported at this visit?** Yes
- **Is the participant taking any concomitant medications that have not been previously reported?** Yes
- **Have any protocol deviations been reported at this visit?** No

**What study procedures were completed at this visit:**

- **Ring adherence assessment?** Yes
- **Ring collection?** No
- **Ring insertion or removal?** No
- **Vital signs?** Yes
- **Physical exam?** No
- **Pelvic exam?** No
- **Vaginal Bleeding Assessment?** Yes
- **Gram stain collection?** No
- **Pregnancy test?** No
- **CBC testing (includes platelets and differential)?** No
- **Serum creatinine, AST, ALT, or albumin test(s)?** No
- **Sex hormone-binding globulin (SHBG), serum progesterone, or serum estradiol test(s)?** No
- **HIV test(s)?** No
- **STI test(s) (other than HIV)?** No
- **PK specimen collection?** Yes
Exercise #4: Let’s add an interim visit

• Navigate back to the participant’s homepage
• How do we add an interim visit?
Exercise #4: Let’s add an interim visit
Exercise #4: Let’s add an interim visit

- Navigate to Interim Visit folder
- Complete Interim Visit Summary eCRF
  - Visit Date **13 MAR 2017**
  - Interim visit code: 5.1
  - Was study product use permanently discontinued? **No**
  - Did the participant exit/terminate the study? **No**
  - Were any new AE reported at this visit? **Yes**
  - Is the participant taking any con meds…? **Yes**
  - Have any protocol deviations been reported…? **No**
  - Reason for interim visit:
    - Check ‘AE report or follow-up’
    - Leave ‘return of ring or need for new ring’ and ‘other’ blank
    - Completion of missed visit procedures – leave blank
    - **Select ‘Yes’ for the following study procedures completed:**
      - Vital Signs, Pelvic Exam, Pregnancy Test
    - **Select ‘No’ for remaining forms**
Exercise #4: Let's add an interim visit

<table>
<thead>
<tr>
<th>Visit date</th>
<th>13 MAR 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim visit code</td>
<td>5.1</td>
</tr>
</tbody>
</table>

- **Went any new adverse events (AEs) reported at this visit?**
  - Yes

- **Did the participant withdraw from the study at this visit?**
  - No

- **Have any protocol deviations been reported at this visit?**
  - No

**Reason for interim visit (Mark all that apply):**

- AE report or follow-up: Yes
- Completion of missed visit procedures: No
- If yes, which visit are procedures being made up? No
- Other: No

**What study procedures were completed at this visit:***

- Ring adherence assessment: No
- Ring collection: No
- Vital signs: Yes
- Physical exam: No
- Pelvic exam: Yes
- Vaginal Bleeding Assessment: No
- Gram stain collection: No
- Pregnancy test: Yes
Exercise #5: Let’s resolve some queries!

• Navigate to Task Summary on your Participant’s homepage
Exercise #5: Let’s resolve some queries!
Exercise #5: Let’s resolve some queries!

- Navigate to Open queries
- Click on V1.0 – Screening- Demographics
Exercise #5: Let’s resolve some queries!

- Navigate to Open queries
- Click on V1.0 – Screening-Demographics
Exercise #5: Let’s resolve some queries!

- Resolve system queries that triggered on following fields
  - Enter test data
    - Sex at Birth
    - Ethnicity
    - Highest education level completed
    - Relationship status
    - Do you currently have a primary sex partner?

*Do not need to provide a response for updating system queries (Only if data will not conform to expectations)*
Exercise #5: Let’s resolve some queries!
Exercise #5a: Let’s resolve some queries!

- Let’s update a field
- What icon would you click to edit a field? (e.g. data entry error)
Exercise #5a: Let’s resolve some queries!

- Click the pencil icon for ‘relationship status’ and change response and resave the form.
Exercise #6: Ongoing Logs

Objectives:

• Learn how to update records in the Ongoing Logs folder
• Practice entry of AE
Exercise #6: Ongoing Logs

- Navigate to the Ongoing Logs folder
- Adverse Events Summary: Yes
- Navigate to the Adverse Event Log eCRF
Exercise #6: Ongoing Logs

- **Complete Adverse Event eCRF**
  - Date reported to site = 13 Mar 2017
  - Fill in description for AE
  - Onset date = 12 MAR 2017
  - Is the AE still ongoing? Yes
  - Outcome Date *Leave blank*
  - Severity Grade = Grade 1
  - Relationship to study product = Not related
  - Action taken with Study Product = Dose not changed
  - Other action(s) taken – Check Medication (leave other items blank)
  - Outcome = Not recovered/resolved
  - Is this a SAE = No
  - Has/will this AE be reported as an EAE = No
  - Was this AE a worsening of baseline medical condition = No
  - Comments = Not related to study product
Exercise #6: Ongoing Logs

- Let’s add another AE
- Navigate to Adverse Event Log
- How do we add another AE?
# Exercise #6: Ongoing Logs

## Review

<table>
<thead>
<tr>
<th>Date reported to site</th>
<th>Adverse Event (AE)</th>
<th>Onset Date</th>
<th>Is the AE still ongoing?</th>
<th>Outcome</th>
<th>Severity Grade</th>
<th>Relationship to Study Product</th>
<th>Action Taken with Study Product</th>
<th>Other Action(s) taken</th>
<th>Medication</th>
<th>New/prolonged hospitalization</th>
<th>Therapeutic procedure/surgery</th>
<th>Diagnostic procedure</th>
<th>Other</th>
<th>Other Specific</th>
<th>Outcome</th>
<th>Is this a Serious AE?</th>
<th>Has this AE been reported as an SAE?</th>
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</thead>
<tbody>
<tr>
<td>13 MAR 2017</td>
<td>BACTERIAL VAGINOSIS</td>
<td>12 MAR 2017</td>
<td>Yes</td>
<td>—</td>
<td>Grade 2 (Moderate)</td>
<td>Not Related</td>
<td>dose not changed</td>
<td>None</td>
<td>✔</td>
<td>✔</td>
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<td>No</td>
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Add a new Log line
Exercise #6: Ongoing Logs

- Enter test date on Adverse Event Log eCRF and Save form
Exercise #6: Ongoing Logs

- After log line 2 has been entered and saved, notice the Landscape view
- Let’s inactivate a log line
### Exercise #6: Ongoing Logs

#### Table of Ongoing Logs

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Questions?
THANK YOU