



Statistical Center for HIV/AIDS
Research and Prevention

SCHARP

at **FRED HUTCH**

Welcome!

A few things to go over before we get started...

Medidata Rave Training

SCHARP

March 19, 2017
Karen Patterson
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Melissa Peda



SCHARP
at FRED HUTCH

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:

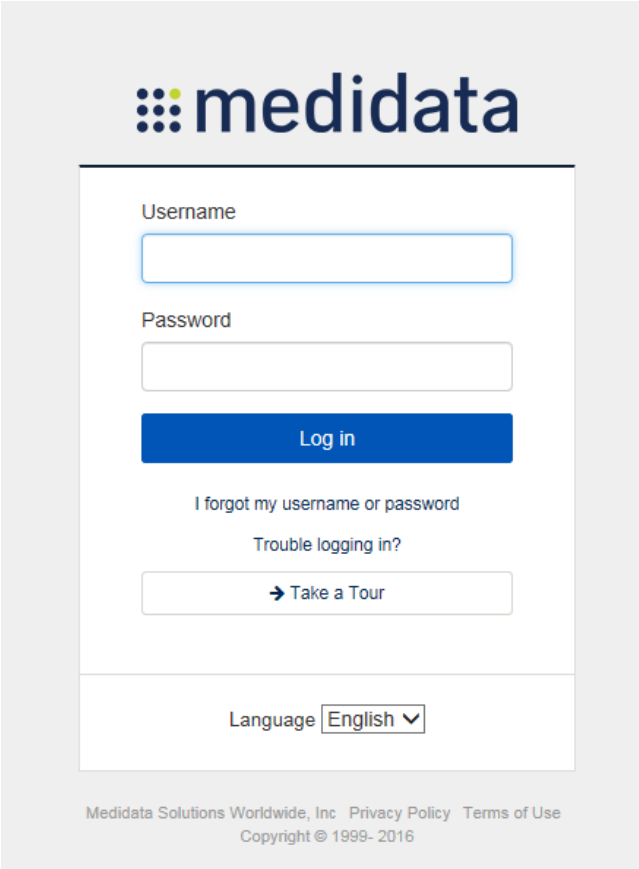
<u>Clinical Research Coordinator</u>	<u>Principal Investigator</u>
❖ Add participants into Rave	❖ Responsible for the overall conduct of a study
❖ Enter data	❖ Review and sign eCRFs
❖ Log adverse events and unscheduled visits	❖ Respond to queries
❖ Edit saved data	❖ Enter or edit subject data
❖ Answer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

- 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)



The screenshot shows the iMedidata login interface. At the top, the logo consists of a 3x3 grid of dots followed by the text "medidata". Below the logo is a login form with the following elements:

- A "Username" label above a text input field.
- A "Password" label above a text input field.
- A blue "Log in" button.
- Links for "I forgot my username or password" and "Trouble logging in?".
- A "Take a Tour" button with a right-pointing arrow.
- A "Language" dropdown menu currently set to "English".

At the bottom of the page, there is a footer with the text: "Medidata Solutions Worldwide, Inc. Privacy Policy Terms of Use Copyright © 1999- 2016".

Rave Navigation

The screenshot displays the iMedidata Portal interface. At the top left is the 'medidata' logo. Below it is a navigation bar with a home icon. The main content area is divided into several sections:

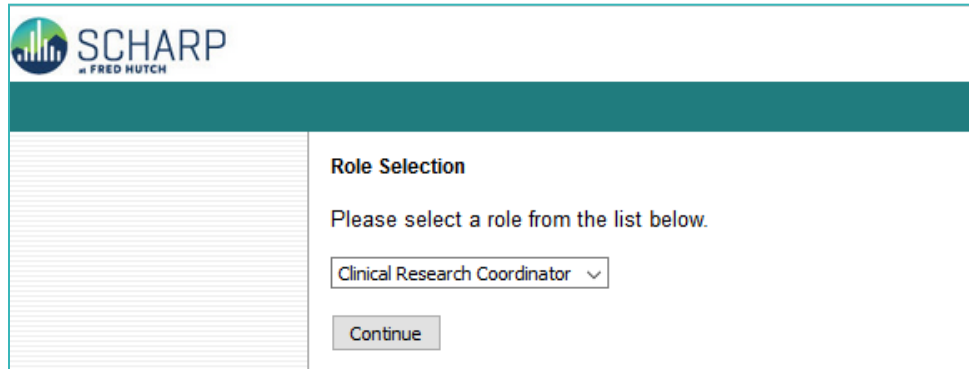
- Apps:** A section on the left stating 'You have zero (0) apps. Look here for apps linked to Studies, Sites, or Teams that you work in.'
- My Information:** A section below the Apps section.
- Account Details:** A link to 'MyMedidata'.
- Studies (2):** A central section with a search bar and two study cards. The first card is for 'MTN025' and the second is for 'MTN025 (TRAIN)'. Both cards feature a database icon and a red box highlighting the study name. Below each card is a message: 'Rave EDC Essentials for Clinical Research Coordinators is required for access'.
- Sites (2):** A section below the Studies section with a search bar and two site cards. The first card is for 'Seke South CRS' and the second is for 'Spilhaus CRS'. The second card features a person icon and a red box highlighting the site name.
- Tasks:** A vertical pane on the right side containing:
 - Invitations (0)
 - No Pending Invitations
 - eLearning (1) - highlighted in blue
 - Rave EDC Essentials for Clinical Research Coordinators

Two red arrows on the right side of the screenshot point to the 'Tasks' pane, specifically towards the 'Invitations (0)' and 'eLearning (1)' sections.

- 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.

Rave Navigation

Once MTN-030 is selected, you will be prompted to select your Role (Investigator or CRC) before your home page displays.



The screenshot shows a web interface for SCHARP at FRED HUTCH. The header includes the SCHARP logo and the text "SCHARP at FRED HUTCH". Below the header, there is a "Role Selection" section with the instruction "Please select a role from the list below." A dropdown menu is currently set to "Clinical Research Coordinator" with a downward arrow. Below the dropdown is a "Continue" button.

Rave Navigation: Site Home Page

The screenshot shows the Rave navigation site home page. At the top, there is a navigation bar with a home icon, 'MTN030', and 'Pittsburgh CRS'. A 'TRAIN' button is visible. On the right, there are links for 'iMedidata', 'Messages', 'My Profile', 'Help', 'Home', and 'Logout', along with the user name 'User: Jennifer Berthiaume Clinical Data Manager (Data Manager)'. Below the navigation bar, there is a search bar labeled 'Subject' with a search icon and links for 'Advanced Search' and 'Labs'. A red box highlights a table of subjects, with a callout 'Participant (PTID) List' pointing to it. The table has two columns: 'Subject' and 'Subjects'. The 'Task Summary' section is also highlighted with a callout. The 'Icon Key' is located at the bottom left.

CRS

TRAIN

iMedidata Messages My Profile Help Home Logout
User: Jennifer Berthiaume Clinical Data Manager (Data Manager)

MTN030 Pittsburgh CRS

Subject

Advanced Search Labs

Subject	Subjects
702474817	2
702633483	0

Page 1 << < Page 1 of >>

Task Summary: Site

- Requiring Signature
- Requiring Translation
- Open Queries
- Answered Queries
- Requiring Review
- Ready for Entry Lock
- Ready for Data Lock
- Cancel Queries

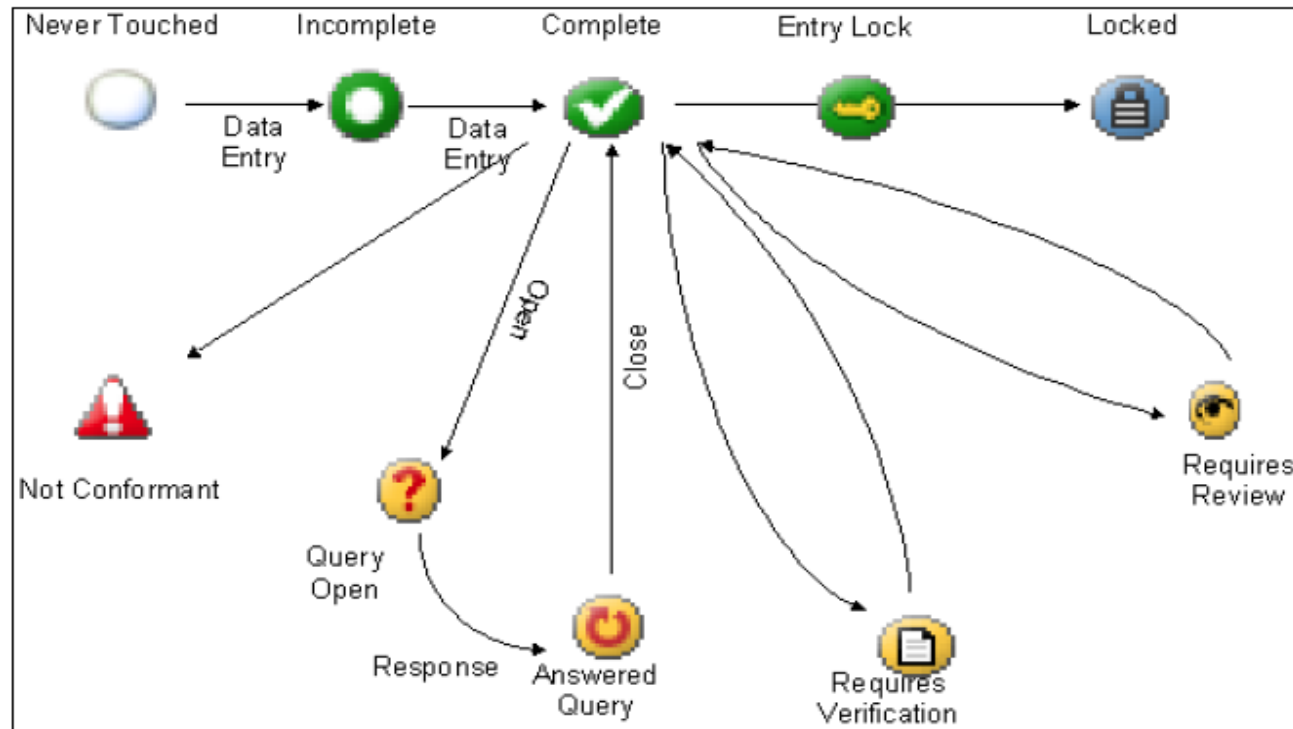
Icon Key

Icon Key

Site	Never Touched	Incomplete
Studies	Complete	Requires Verification
Study	Locked	Requires Review
Subject	Entry Lock	Query Open
Subject in doubt	Not Conformant	Answered Query
Form	Inactive	Requires Coding
Site Group	Overdue	Requires Signature
Home	Sticky Notes	Out of Range High
Comments	Data Changed	Out of Range Low
Edit	Protocol Deviation	Requires Translation
Study Status Deferred	Site Status Deferred	Requires First Pass DDE
Folder not available to the user	Add Marking	Requires Second Pass DDE
Task Summary Pop Up	Folder	Requires Reconciliation DDE
Requires Coder Coding		

Close Help Window

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



TRAIN

MTN030

Subject

[Advanced Search](#) [Labs](#)

Subject

- 821155688
- 821613133
- 821624636
- 821865211

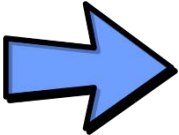
Page 1

<< < Page 1 of 1 > >>


[Icon Key](#)

Task Summary: Site	Subjects
▶ Requiring Signature	4
▶ Requiring Translation	0
▶ Open Queries	0
▶ Answered Queries	1
▶ Requiring Review	0
▶ Ready for Entry Lock	4
▶ Ready for Data Lock	0
▶ Cancel Queries	2


Task Summary: Site to Participant Level



Task Summary: Site	Subjects
▶ Requiring Signature	128
▶ ⚠ NonConformant Data	11
▶ ? Open Queries	102
▶ ✓ Overdue Data	23



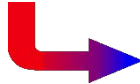
Task Summary: Site	Subjects
▶ Requiring Signature	128
▼ ⚠ NonConformant Data	11
123	
123164230	
123222497	
123398276	
123456789	
123860572	
123CAT888888	
123JEN123	
14JUL2016	
2016JUL14	
6043	



Task Summary: Subject	Pages
▶ Requiring Signature	3
▼ ⚠ NonConformant Data	1
Pre-Screening-Pre-Screening Outcome	
1	
▶ ? Open Queries	1
▼ ✓ Overdue Data	0

Task Summary: Site to Participant Level

Task Summary: Subject	Pages
▶ Requiring Signature	3
▼ ⚠ NonConformant Data	1
Pre-Screening-Pre-Screening Outcome	



SCHARP **REVIEW** IMedidata Messages My Profile Help Home Logout
User: Gina Escamilla Program Manager (Clinical Research Coordinator)

MTN025 Test site 1 123164230 Pre-Screening Pre-Screening Outcome

Pre-Screening Pre-Screening Outcome

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

CRF History

- 123164230 - Pre-Screening Outcome
- 123398276 - Pre-Screening Outcome
- 999386382 - Date of Visit
- 999476848 - Concomitant Medications
- 999476848 - Hematology
- 999117377 - Pregnancy Test
- 997932660 - Behavioral Risk Assessment
- 997387553 - Behavioral Risk Assessment
- 997387553 - Reasons for Not Enrolling
- 997387553 - Demographics
- 997156312 - Reasons for Not Enrolling
- 997156312 - Randomization
- 997156312 - Pre-Existing Conditions Y/N
- 997156312 - Demographics
- 997156312 - Behavioral Risk Assessment
- 999117377 - Behavioral Risk Assessment

1. What was this prior participant's ASPIRE PTID? Data Entry Error 3W4643345

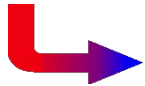
2. Was the participant contacted to participate in HOPE?
? List in study binder states participant was not contacted. Please clarify.
Opened To Site from CRA (12 Sep 2016)
 Yes No Data Entry Error

4. Did the participant conduct a screening visit for HOPE? Yes

5. Did the participant conduct a screening visit as part of the ...? MTN-025 main study

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 85 - Page Generated: 18 Sep 2016 18:10:05 Pacific Daylight Time

Save Cancel



Task Summary: Participant Level



REVIEW

MTN025 Test site 1 123398276

- 123398276
- Pre-Screening
- V1 - Screening (1)
- V2 - Enrollment (1)
- V3 - Month 1 (1)
- V4 - Month 2 (1)
- Ongoing Logs (1)

- CRF History
- 123164230 - Pre-Screening Outcome
 - 123398276 - Pre-Screening Outcome
 - 999386382 - Date of Visit
 - 999476848 - Concomitant Medications
 - 999476848 - Hematology
 - 999117377 - Pregnancy Test
 - 997932660 - Behavioral Risk Assessment
 - 997387553 - Behavioral Risk Assessment
 - 997387553 - Reasons for Not Enrolling
 - 997387553 - Demographics
 - 997156312 - Reasons for Not Enrolling

Participant Identifier

Visit	Date
V1 - Screening (1)	15 Jun 2016
V2 - Enrollment (1)	30 Jun 2016
V3 - Month 1 (1)	15 Jul 2016
V4 - Month 2 (1)	25 Aug 2016

Task Summary: Subject	Pages
Requiring Signature	17
NonConformant Data	1
Open Queries	5
V1 - Screening (1)-Vital Signs	
V2 - Enrollment (1)-Participant Date of Visit	
Ongoing Logs (1)-Adverse Experience	
Ongoing Logs (1)-Concomitant Medications	
V1 - Screening (1)-Baseline Medical History	
1	
Overdue Data	7

Add Event Add

Icon Key
CRF Version 57 - Page Generated: 18 Sep 2016 18:23:41 Pacific Daylight Time



Task Summary: Participant Level



REVIEW

MTN025 Test site 1 123398276 V1 - Screening (1) Vital Signs

- V1 - Screening (1)
- Participant Date of Visit
- Eligibility Criteria
- Demographics
- Baseline Medical History Y/N
- Baseline Medical History
- Pelvic Exam
- Physical Exam
- Vital Signs
- Concomitant Medication Y/N
- STI Test Results
- Laboratory Results

- CRF History
- 123398276 - Vital Signs
- 123398276 - Participant Date of Visit
- 123398276 - Adverse Experience Y/N
- 123398276 - Adverse Experience
- 123164230 - Pre-Screening Outcome

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

Exam date
? Data is required. Please complete.
Opened To Site from System (25 Jul 2016)

Data Entry Error

1. Weight	225 kg
2. Body Temperature	36 C
3. Systolic BP	150 mmHg
4. Diastolic BP	90 mmHg
5. Pulse	80 beats per minute
6. Respirations	70 breaths per minute
7. Height	120 cm

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 57 - Page Generated: 18 Sep 2016 18:31:39 Pacific Daylight Time

Save Cancel



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.

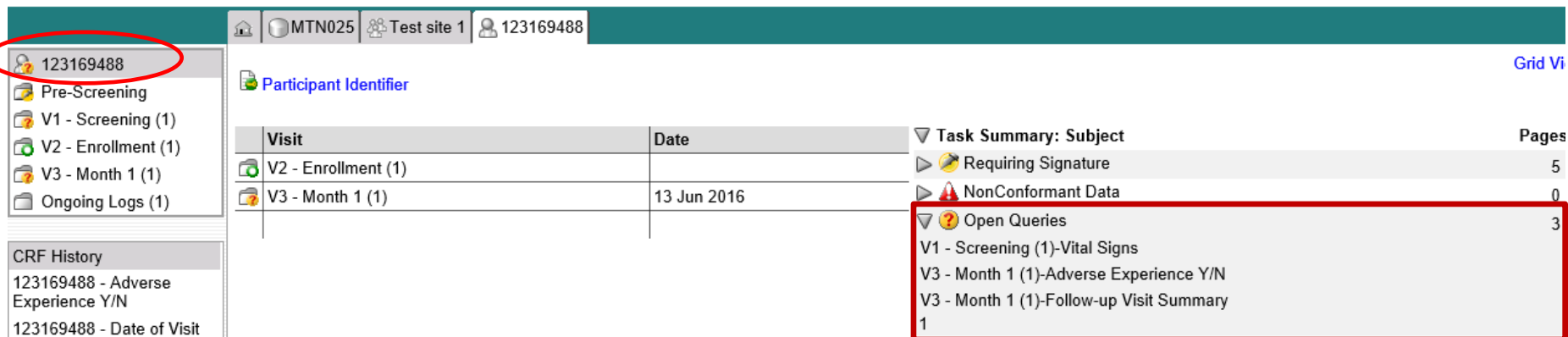
Manual Queries

- 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 - 



The screenshot displays the Rave interface for participant 123169488. The top navigation bar includes the site ID MTN025, the test site name 'Test site 1', and the participant ID 123169488. On the left sidebar, the participant ID 123169488 is circled in red. Below the sidebar, the 'Participant Identifier' section shows a table of visits:

Visit	Date
V2 - Enrollment (1)	
V3 - Month 1 (1)	13 Jun 2016

To the right, the 'Task Summary: Subject' section is expanded, showing a list of tasks. The 'Open Queries' section is highlighted with a red box and contains the following items:

- Open Queries (3)
- V1 - Screening (1)-Vital Signs
- V3 - Month 1 (1)-Adverse Experience Y/N
- V3 - Month 1 (1)-Follow-up Visit Summary
- 1

Resolving Rave System Queries

□ Examples of System Queries:

1. Weight ? Data is required. Please complete. Opened To Site from System (18 Sep 2016) [Data Entry Error] [] kg [?]	Missing Data Query
2. Body Temperature ? Data entered is out of range (> 42). Please correct. Opened To Site from System (18 Sep 2016) [Data Entry Error] [98.6] C [?]	Edit check Query
3. Systolic BP [Data Entry Error] [ABC] mmHg [!]	Non-Conformant Query

Query Text

1. Weight	55 kg [delta] [?]
2. Body Temperature	35 C [delta] [?]
3. Systolic BP	120 mmHg [delta] [?]

Once the data field is corrected and the page is saved, a delta symbol will appear above the item that has been update, 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)

Data Entry Error [] kg ? ? ?

Optional site response to query

2. Body Temperature
? Data entered is out of range (> 42). Please correct.
Opened To Site from System (18 Sep 2016)

Data Entry Error [98.6] C ? ? ?

Optional site response to query

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)

Data Entry Error

Yes No



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

🔄 A corresponding AE log page has been completed for this participant.

Field Audit Trail

- All changes that have been 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.

Data Point - Has the participant experienced any new adverse events or are there any updates to previously reported AEs? If 'Y', please update the Adverse Experience log.		
Parent: Record - Adverse Experience Y/N		
Siblings:		
Audit	User	Time
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. ' answered with 'A corresponding AE log page has been completed for this participant.' (Site from DM).	Jennifer Berthiaume (28 - jberthia@scharp.org2)	18 Sep 2016 19:00:41
User opened 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).	Jennifer Berthiaume (29 - jberthia@scharp.org3)	18 Sep 2016 18:32:20
User entered 'Yes (Y)'	Jennifer Berthiaume (28 - jberthia@scharp.org2)	18 Sep 2016 18:30:58

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

The screenshot displays the SCHARP home screen. The top navigation bar includes 'Home' and a search box. Below the navigation bar, there are sections for 'Translation Workbench', 'PDF Generator', 'DCF', 'Query Management', and 'Welcome Message'. A 'Last 10 subjects' list is visible, followed by a 'Resources' section. The 'Resources' section is circled in red and contains the following links: AE Grading Table v2 NOV2014, Atlas portal, Female Genital Grading Table v1 NOV2007, HPTN, HVTN, Male Genital Grading Table v1 NOV2007, MTN, and Rectal Grading Table v1 NOV2007. Other sections include 'Studies' with a list of study identifiers, 'Icon Key', and 'Messages'.

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

 medidata

 Help ▾

 Gina Escamilla (gina1113) ▾

Resources: Within Rave

Once within a study, you can click on the “Help” button on any page to access information relevant to that page.

The screenshot displays the Rave EDC interface. At the top, there is a navigation bar with the 'medidata' logo, 'Spaces', a search bar for 'Search All Spaces', a help icon, and a 'Log In' button. Below this, the current space is identified as 'Pre-release Knowledge Space (Staging)'. A search bar for 'Search This Space' is also present.

The main content area is titled 'Rave EDC (Staging)' and 'About Subject Management in Rave EDC'. It indicates the article was last modified on Aug 11, 2016, and has 0 comments. The article text states: 'Every study has a required form designated as the primary form, where data entry must be completed before a subject can be added to Rave EDC. The fields on the primary form can be used to derive the subject's name within the study. When the form is submitted, the new subject is added to the site within the study.'

A note box contains the text: 'Note: The sponsor defines the primary form's name and fields.'

Below the note, the article lists 'In this article:' with two sub-topics: 'Subject Home' and 'Restrictions to Access Subjects'.

The 'Subject Home' section explains: 'Upon successfully saving the primary form, the Subject home page opens. The Subject home page summarizes the information for each subject.'

An inset window shows a 'Subject Summary' table with columns for 'Week', 'Date', and 'Task Summary'. The table lists data for 'Week 1' through 'Week 3' with corresponding dates and task names like 'Preparation Signature', 'Non-Confidential Data', 'Preparation Coding', 'Preparation Transcription', 'Open Queries', 'Unresolved Queries', 'Sticky Notes', 'Preparation Review', 'Preparation Validation', 'Overdue Data', 'Ready for Entry Lock', 'Ready for Data Lock', and 'Critical Queries'. Below the table are 'Sign and Save' and 'Add Over' buttons.

On the right side of the article, there are two sections: 'Rave EDC FAQs' and 'More about Subject Maintenance'. Both sections contain a placeholder for content by label, with the text 'There is no content with the specified labels' and an icon of a document with a keyhole.

THANK YOU

**Site Presentation:
EDC Experiences and Lessons
Learned
MU-JHU, Uganda CRS**



SCHARP
at FRED HUTCH

Rave Training Exercises



SCHARP
at FRED HUTCH

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:*

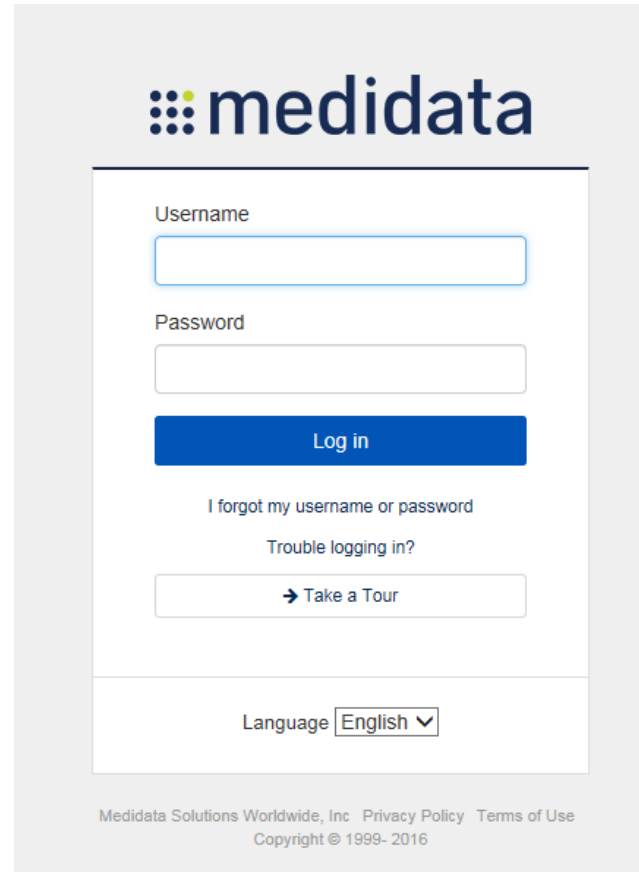
MTN2017

<http://www>



Log in to your iMedidata Account

- Log in to iMedidata Portal (www.imedidata.com)



The screenshot shows the iMedidata login page. At the top, the logo consists of a 3x3 grid of dots followed by the word "imedidata". Below the logo is a white login form with a blue border. The form contains the following elements: a "Username" label above a text input field; a "Password" label above a text input field; a blue "Log in" button; a link "I forgot my username or password"; a link "Trouble logging in?"; a button "→ Take a Tour"; and a "Language" dropdown menu currently set to "English". At the bottom of the page, there is a footer with the text: "Medidata Solutions Worldwide, Inc. Privacy Policy Terms of Use Copyright © 1999- 2016".

Access the MTN-030 TRAIN Study



Pre Release sign up for iMedidata will begin March 13, 2017 and end on March 20, 2017. Going forward, we will no longer be posting pre-release signups through this banner. To sign up for this and future pre-releases, and to keep informed of other product release information, please subscribe to our 2017 product release newsletters through the [Stay Informed page](#).

Apps

[RAVE EDC](#)

scharp

[RAVE Architect Security](#)

scharp

[BALANCE](#)

scharp

[RAVE Modules](#)

scharp

Studies (69)



MTN030 (DEV)

[Rave EDC](#)
[Rave Architect Security](#)
[Rave Modules](#)



MTN030 (FUNCTE

ST)
[Rave EDC](#)
[Rave Architect Security](#)
[Rave Modules](#)



MTN030 (REVIEW

)
[Rave EDC](#)
[Rave Architect Security](#)
[Rave Modules](#)



MTN030 (TRAIN)

[Rave EDC](#)
[Rave Architect Security](#)
[Rave Modules](#)

Tasks

Invitations (0)

No Pending Invitations


eLearning (0)

No Pending eLearning


Select applicable site within the TRAIN

TRAIN





Home MTN030

Find  ▶ Task Summary: Study

[Advanced Search](#)

Site Group 

Include Sub Site Groups

Site	Site Group	Site Number
 Annual Meeting	World	Annual Meeting
 Birmingham RAVE	World	31788
 Pittsburgh CRS	World	1001
 Test site 1	World	999123

Page 1 << < Page 1 of 1 > >>

[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

REVIEW

iMedidata Messages My Profile Help Home Logout
User: Melissa Peda (Clinical Research Coordinator)

MTN030 test2 New Subject

Subject Status: New

Subject: **New Subject**
Page: **Participant Identifier**

Participant ID:

[Printable Version](#) [Icon Key](#)

CRF Version 298 - Page Generated: 15 Mar 2017 12:42:31 Pacific Daylight Time

Save Cancel

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!

MTN030 test2 999672409 V1.0 - Screening Demographics

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

Date of Birth 24 DEC 1984

Age Years

Sex at Birth
? Data is required. Please complete.
Opened To Site from System (15 Mar 2017)
Data Entry Error

Ethnicity
? Data is required. Please complete.
Opened To Site from System (15 Mar 2017)
Data Entry Error
 Hispanic or Latino Not Hispanic or Latino

Race (mark all that apply)

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Other race

Other race, specify:

Highest education level completed
? Data is required. Please complete.
Opened To Site from System (15 Mar 2017)
Data Entry Error

Number of children (live births)

Relationship status
? Data is required. Please complete.
Opened To Site from System (15 Mar 2017)
Data Entry Error

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!

MTN030 test2 999672409 V1.0 - Screening Eligibility Criteria

Subject: 999672409

Page: Eligibility Criteria - V1.0 - Screening

Did the participant meet all eligibility criteria?

Yes  

If No, specify type of eligibility criteria not met.

Was the participant enrolled?

Yes  

Why was the participant not enrolled?

If eligible, but participant declined enrollment, specify reason

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CRF Version 298 - Page Generated: 15 Mar 2017 10:11:58 Pacific Daylight Time

Save

Cancel

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

REVIEW

[iMedidata](#) [Messages](#) [My Profile](#) [Help](#) [Home](#) [Logout](#)
 User: **Melissa Peda** (Clinical Research Coordinator)

[MTN030](#) [test2](#) [999672409](#) [V3.0 - Day 1](#) [Follow-up Visit Summary](#)

Subject: 999672409

Page: Follow-up Visit Summary - V3.0 - Day 1

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 exit/terminate the study at this visit?	No			
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	Yes			
Is the participant taking any concomitant medications that have not been previously reported? If yes, complete the Concomitant Medications Log.	Yes			
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviation Log.	No			
What study procedures were completed at this visit:				
Ring adherence assessment?	Yes			
Ring collection?	No			
Ring insertion or removal?	Yes			
Vital signs?	No			
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			

V3.0 - Day 1

- Follow-up Visit Summary
- Pharmacokinetics
- Ring Adherence
- Vaginal Bleeding Assessment
- Ring Insertion and Removal

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

SCHARP
FRED HUTCH

REVIEW

IMEdata Messages My Profile Help Home Logou
User: **Melissa Peda** (Clinical Research Coordinator)

MTN030 test2 999672409

999672409 [Grid View](#)

Participant Identifier

Visit	Date
-------	------

Task Summary: Subject

Task	Pages
Requiring Signature	4
NonConformant Data	0
Open Queries	2
Overdue Data	0

Add Event Interim Visit Add

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

REVIEW

[medidata](#) [messages](#) [my Profile](#) [help](#) [Home](#) [Logout](#)
 User: **Melissa Peda** (Clinical Research Coordinator)

[MTN030](#) [test2](#) [999672409](#) [Interim Visit \(1\)](#) [Interim Visit Summary](#)

Subject: **999672409**
 Page: **Interim Visit Summary - Interim Visit (1)**

Visit date	13 MAR 2017		
Interim visit code	Data Entry Error	5.1	
Was study product use permanently discontinued (scheduled or early) at this visit?	No		
Did the participant exit/terminate the study at this visit?	No		
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	Yes		
Is the participant taking any concomitant medications that have not been previously reported? If yes, complete the Concomitant Medications Log.	Yes		
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviation Log.	No		
Reason for interim visit: (Mark all that apply)			
AE report or follow-up	<input checked="" type="checkbox"/>		
Return of ring or need for a new ring	<input type="checkbox"/>		
Completion of missed visit procedures	No		
If yes, for which visit are procedures being made up?			
Other	<input type="checkbox"/>		
If Other, specify			
What study procedures were completed at this visit:			
Ring adherence assessment?	No		
Ring collection?	No		
Ring insertion or removal?	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!



REVIEW

MTN030 test2 999672409

- 999672409
- V1.0 - Screening
- V2.0 - Enrollment
- V3.0 - Day 1
- V4.0 - Day 2
- V5.0 - Day 3
- V6.0 - Day 7
- V7.0 - Day 14
- V8.0 - Day15
- V9.0 - Day16
- Discontinuations
- Ongoing Logs
- Pharmacy
- Interim Visit (1)

Participant Identifier









Visit	Date
-------	------

Task Summary: Subject	Pages
Requiring Signature	5
NonConformant Data	1
Open Queries	2
Overdue Data	0

Add Event









Exercise #5: Let's resolve some queries!

- Navigate to Open queries
- Click on V1.0 – Screening- Demographics

Task Summary: Subject	Pages
▶  Requiring Signature	5 
▶  NonConformant Data	1 
▼  Open Queries	2 
V1.0 - Screening-Demographics	
V2.0 - Enrollment-Randomization	
1	
▶  Overdue Data	0 

Exercise #5: Let's resolve some queries!

- Navigate to Open queries
- Click on V1.0 – Screening- Demographics

Task Summary: Subject	Pages
▶  Requiring Signature	5 
▶  NonConformant Data	1 
▼  Open Queries	2 
V1.0 - Screening-Demographics	
V2.0 - Enrollment-Randomization	
1	
▶  Overdue Data	0 

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!

Ethnicity

? Data is required. Please complete.
Opened To Site from System (15 Mar 2017)

🔄 ⌘

Data Entry Error ▾

Hispanic or Latino Not Hispanic or Latino



Subject: 999704772

Page: Demographics - V1.0 - Screening



Date of Birth

24 DEC 1984



Age

Years



Sex at Birth

Female



Ethnicity

Not Hispanic or Latino



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

Relationship status

? Data is required. Please complete.
Opened To Site from System (15 Mar 2017)

Updated

Married   



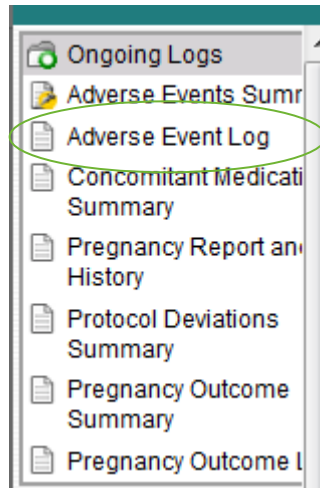
Exercise #6: Ongoing Logs

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

IMedidata Messages My Profile Help Home Logout
 User: Melissa Peda (Clinical Research Coordinator)

MTN030 test2 999672409 Ongoing Logs Adverse Event Log

Subject: 999672409
 Page: Adverse Event Log - Ongoing Logs

#	Date reported to site	Adverse Event (AE)	Onset Date	Is the AE still ongoing?	Outcome Date	Severity Grade	Relationship to Study Product?	Action Taken with Study Product	Other action(s) taken	Medication	New/prolonged hospitalization	Therapeutic procedure/surgery	Diagnostic procedure	Other	Other, specify	Outcome	Is this a Serious Adverse Event?	Has or will this AE be reported as an EAE?	If y EAE nu
1	13 MAR 2017	BACTERIAL VAGINOSIS	12 MAR 2017	Yes	-	Grade 2 (Moderate)	Not Related	dose not changed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	not recovered/resolved	No	No	-

Add a new Log line deactivate

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CRF Version 298 - Page Generated: 15 Mar 2017 10:58:57 Pacific Daylight Time

Save Cancel

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

REVIEW

iMedidata Messages My Profile Help Home Logou
User: Melissa Peda (Clinical Research Coordinator)

MTN030 test2 999672409 Ongoing Logs Adverse Event Log

Subject: 999672409
Page: Adverse Event Log - Ongoing Logs

#reported to site	Date	Adverse Event (AE)	Onset Date	Is the AE still ongoing?	Outcome Date	Severity Grade	Relationship to Study Product?	Action Taken with Study Product	Other action(s) taken	Medication	New/prolonged hospitalization?	Therapeutic procedure/surgery?	Diagnostic procedure?	Other	Other, specify	Outcome	Is this a Serious Adverse Event?	Has or will this AE be reported as an EAE?
1	13 MAR 2017	BACTERIAL VAGINOSIS	12 MAR 2017	Yes	-	Grade 2 (Moderate)	Not Related	dose not changed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	not recovered/resolved	No	No
2	10 MAR 2017	INCREASED ALT	10 MAR 2017	No	12 MAR 2017	Grade 2 (Moderate)	Not Related	dose not changed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	recovered/resolved	No	No

Add a new Log line Inactivate

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CRF Version 298 - Page Generated: 15 Mar 2017 10:59:08 Pacific Daylight Time

Exercise #6: Ongoing Logs

MTN030 test2 999672409 Ongoing Logs Adverse Event Log

Subject: 999672409
Page: Adverse Event Log - Ongoing Logs

Date #reported to site	Adverse Event (AE)	Onset Date	Is the AE still ongoing?	Outcome Date	Severity Grade	Relationship to Study Product?	Action Taken with Study Product	Other action(s) taken	Medication	New/prolonged hospitalization	Therapeutic procedure/surgery	Diagnostic procedure	Other	Other, specify	Outcome	Is this a Serious Adverse Event?	Has or will this AE be reported as an EAE?
1 13 MAR 2017	BACTERIAL VAGINOSIS	12 MAR 2017	Yes	-	Grade 2 (Moderate)	Not Related	dose not changed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	not recovered/resolved	No	No
2 10 MAR 2017	INCREASED ALT	10 MAR 2017	No	12 MAR 2017	Grade 2 (Moderate)	Not Related	dose not changed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	recovered/resolved	No	No

2 INACT_L - Log line not required Inactivate Cancel

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CRF Version 298 - Page Generated: 15 Mar 2017 11:00:39 Pacific Daylight Time

Save Cancel

REVIEW

MTN030 test2 999672409 Ongoing Logs Adverse Event Log

Subject: 999672409
Page: Adverse Event Log - Ongoing Logs

Date #reported to site	Adverse Event (AE)	Onset Date	Is the AE still ongoing?	Outcome Date	Severity Grade	Relationship to Study Product?	Action Taken with Study Product	Other action(s) taken	Medication	New/prolonged hospitalization	Therapeutic procedure/surgery	Diagnostic procedure	Other	Other, specify	Outcome	Is this a Serious Adverse Event?	Has or will this AE be reported as an EAE?
1 13 MAR 2017	BACTERIAL VAGINOSIS	12 MAR 2017	Yes	-	Grade 2 (Moderate)	Not Related	dose not changed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	not recovered/resolved	No	No
2 10 MAR 2017	INCREASED ALT	10 MAR 2017	No	12 MAR 2017	Grade 2 (Moderate)	Not Related	dose not changed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	recovered/resolved	No	No

Add a new Log line Inactivate Reactivate

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Save Cancel



Questions?

THANK YOU