



Statistical Center for HIV/AIDS
Research and Prevention

SCHARP

at **FRED HUTCH**

MTN-036
Medidata Rave Training
SCHARP

Tanya Harrell & Jen Berthiaume



SCHARP
at FRED HUTCH

Presentation Overview

- ❑ Medidata Navigation, Functionality, and Features
- ❑ Query management
- ❑ SCHARP Data Reviews and PPD monitoring in Rave
- ❑ Study-specific considerations in Rave
- ❑ Resources

Rave Navigation

The screenshot displays the iMedidata portal interface. At the top left, the logo 'medidata' is visible. The main content area is divided into several sections: 'Apps' (showing zero apps), 'My Information' (user profile for Nyaradzo Mgodzi), 'Studies (2)' (listing MTN025 and MTN025 (TRAIN)), and 'Sites (2)' (listing Seke South CRS and Spilhaus CRS). A red box highlights the 'MTN025' study icon. On the right side, a 'Tasks' pane is visible, containing 'Invitations (0)', 'No Pending Invitations', 'eLearning (1)', and 'Rave EDC Essentials for Clinical Research Coordinators'. A red arrow points from a text box to the 'Invitations (0)' section.

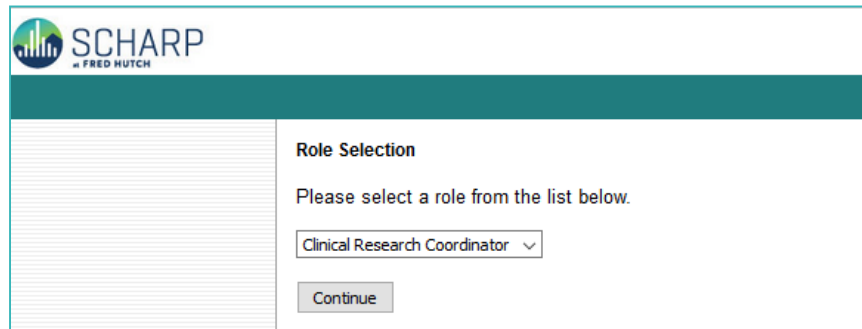
Accept
MTN-036
production
database
invitation

Once in the iMedidata Portal, select the MTN 036 study. **Do Not** select the MTN 036 TRAIN study.

- e-Learnings are located on the right side under the “Task” pane.

Rave Navigation

Once the MTN-036 Production database is selected, you may be prompted to select your Role 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 SCHARP at Fred Hutch interface. At the top left is the SCHARP logo. The main navigation bar includes a home icon, 'MTN026', and 'Test site 2'. A red 'REVIEW' button is visible. Below the navigation bar is a search area with a 'Subject' label, a search input field, and a magnifying glass icon. Below the search field are links for 'Advanced Search' and 'Add Subject'. A list of subjects is displayed, with a callout box labeled 'Participant (PTID) List' pointing to the list. On the right side, there is a 'Task Summary: Site' section with a dropdown arrow and four items: 'Requiring Signature', 'NonConformant Data', 'Open Queries', and 'Overdue Data'. A callout box labeled 'Task Summary' points to this section.

CRS

REVIEW

MTN026 Test site 2

Subject

Advanced Search Add Subject

Subject
999111643
999112734
999127899
999140807
999150225
999171299
999194113

Task Summary: Site


- Requiring Signature
- NonConformant Data
- Open Queries
- Overdue Data


Participant (PTID) List





















Task Summary

Icons within Rave

Home MTN026 Test site 2

Subject 





[Advanced Search](#)  [Add Subject](#)

Subject
 999111643
 999112734
 999127899
 999140807
 999150225
 999171299
 999194113
 999214760
 999234101
 999249446
 999271860
 999277951
 999334164
 999348596
 999398255
 999411960
 999430357
 999478554
 999508100
 999511449

Page 1 2 << < Page 1 of 2 > >>

[Icon Key](#)

Task Summary: Site

-  Requiring Signature
-  NonConformant Data
-  Open Queries
-  Overdue Data

Data Entry Icons

Data Entry Icons

Most users may see the following icons on forms:



Never Touched

- Data has not been entered/submitted.



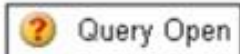
Complete

- Data has been entered/submitted.



Not Conformant

- Invalid data. Data will also be highlighted when it is not conformant.



Query Open

- A query is open on the data.



Entry Lock

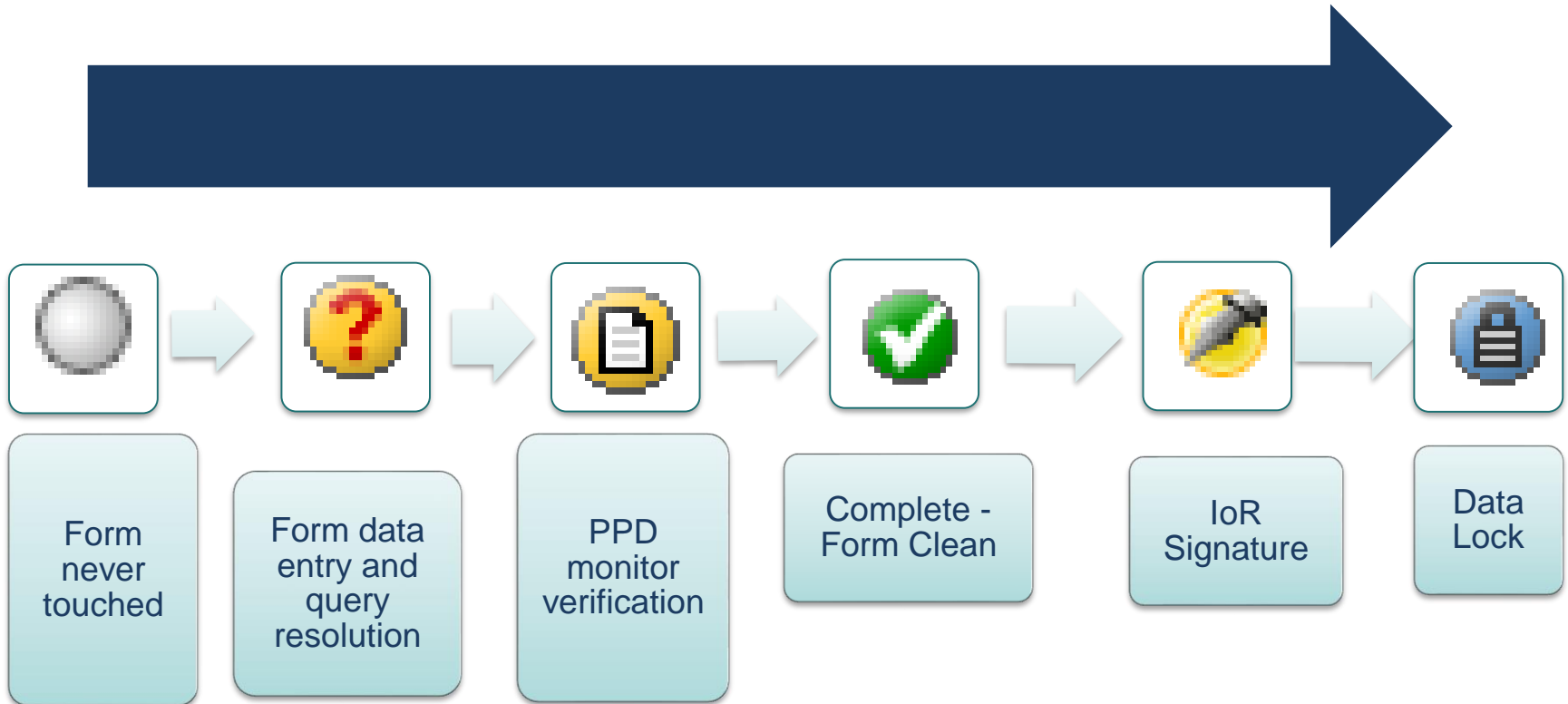
- Prohibits any changes to the data.



Locked

- Prevents any changes to the data, including markings, sticky notes, etc.

eCRF Workflow within Rave



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

Home MTN026 Test site 2

Subject

[Advanced Search](#) [+ Add Subject](#)

Subject
999111643
999112734
999127899
999140807
999150225
999171299
999194113
999214760
999234101
999249446
999271860
999277951
999334164
999348596
999398255
999411960
999430357
999478554
999508100
999511449

Page 1 2 << < Page 1 of 2 > >>

[Icon Key](#)

▼ Task Summary: Site

- ▶ Requiring Signature
- ▶ NonConformant Data
- ▶ Open Queries
- ▶ Overdue Data



Participant Grid View

The Participant Grid View:

- Displays participant folders and forms in a grid format
- Provides the status of specific forms
- Allows authorized Rave users to quickly perform activities such a freeze, sign-off, verify, and sign-off on multiple forms
 - E.g., Investigator role can quickly sign-off on multiple eCRFs for a given participant at the same time



Participant Grid View – Investigator Role

- ❑ Electronic form sign-off by the Site Investigator (IoR) to verify the completeness and accuracy of the study data should occur after all queries have been resolved on the form and prior to database lock as the study approaches close out and completion.

- ❑ To maximize efficiency, please hold off on providing Investigator sign-off for a participant casebook until instructed by SCHARP CDM(s).
 - Site Investigator sign off of a form or a participant casebook should **not** be completed until *after* data review by a PPD monitor or by a SCHARP Data Manager and all queries are resolved.

MTN-036

Query Management

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 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-specific 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

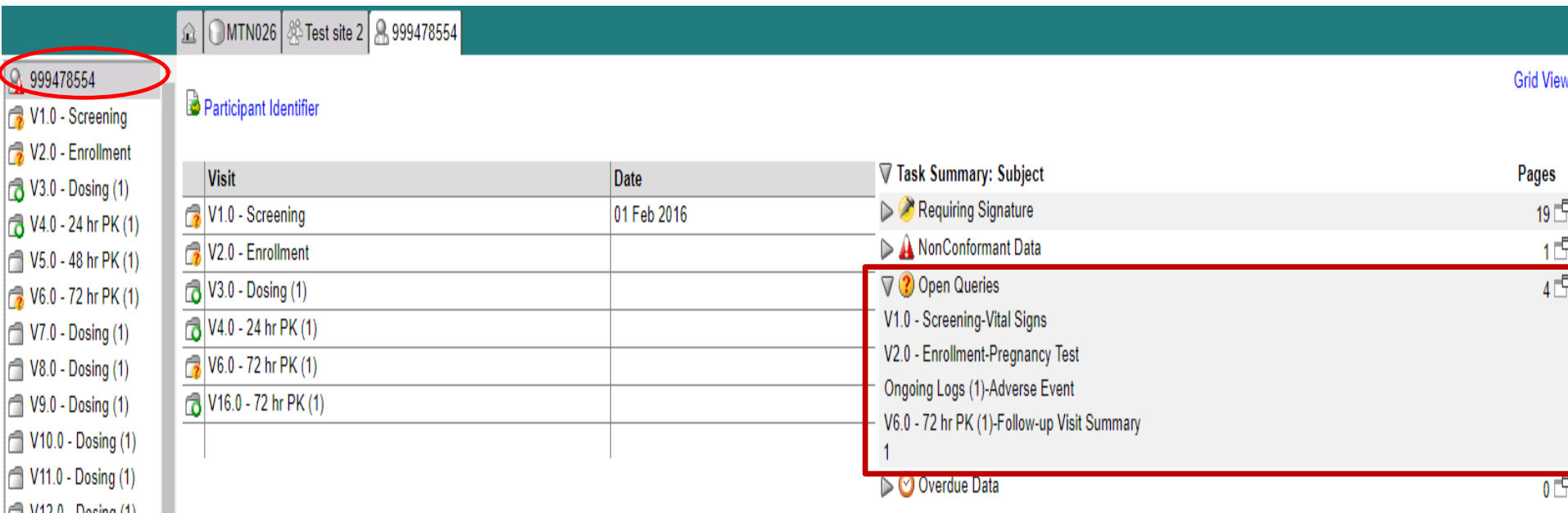
Philosophy of Query Management/ Data Cleaning and Evaluation

- ❑ Goal of system queries generated within EDC to is provide real time feedback and ensure clean data at point of data entry.
- ❑ Screening system queries will be applied to Enrolled participants at the time of Enrollment (as documented on the Eligibility Criteria CRF)
- ❑ Screening CRFs for screened-out participants will not undergo QC review with the exception of the Eligibility Criteria CRF

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 a participant with ID 999478554. The top navigation bar shows the site ID (MTN026), test site (Test site 2), and user ID (999478554). The participant ID is also highlighted in a red circle on the left. The main content area is titled 'Participant Identifier' and contains a table of visits. The 'Task Summary: Subject' section is expanded, showing a list of tasks with a red box highlighting the 'Open Queries' section. The 'Open Queries' section lists the following tasks:

Visit	Date	Task Summary: Subject	Pages
V1.0 - Screening	01 Feb 2016	Requiring Signature	19
V2.0 - Enrollment		NonConformant Data	1
V3.0 - Dosing (1)		Open Queries	4
V4.0 - 24 hr PK (1)		V1.0 - Screening-Vital Signs	
V5.0 - 48 hr PK (1)		V2.0 - Enrollment-Pregnancy Test	
V6.0 - 72 hr PK (1)		Ongoing Logs (1)-Adverse Event	
V7.0 - Dosing (1)		V6.0 - 72 hr PK (1)-Follow-up Visit Summary	
V8.0 - Dosing (1)		1	
V9.0 - Dosing (1)		Overdue Data	0
V10.0 - Dosing (1)			
V11.0 - Dosing (1)			
V12.0 - Dosing (1)			

Resolving Queries within Rave

□ Examples of System Queries:

1. Weight
? Data is required. Please complete.
Opened To Site from System (18 Sep 2016)
Data Entry Error [] kg ?

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 ?













3. Systolic BP
Data Entry Error [] ABC mmHg ?

Missing Data Query

Edit check Query

Non-Conformant Query

Query Text

1. Weight	55 kg    
2. Body Temperature	35 C    
3. Systolic BP	120 mmHg    

A Delta symbol appears when an item have been updated and the page has been saved.

Once you make the correction and save the page the line is no longer pink and the query icon goes away.

Resolving Queries within Rave

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 a system query text to document clarifying information regarding the data point or to request additional guidance from SCHARP on query resolution.

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.

Data Point - Were any new adverse events (AEs) reported at this visit?

Parent: Record - Follow-up Visit Summary

Siblings:

Audit

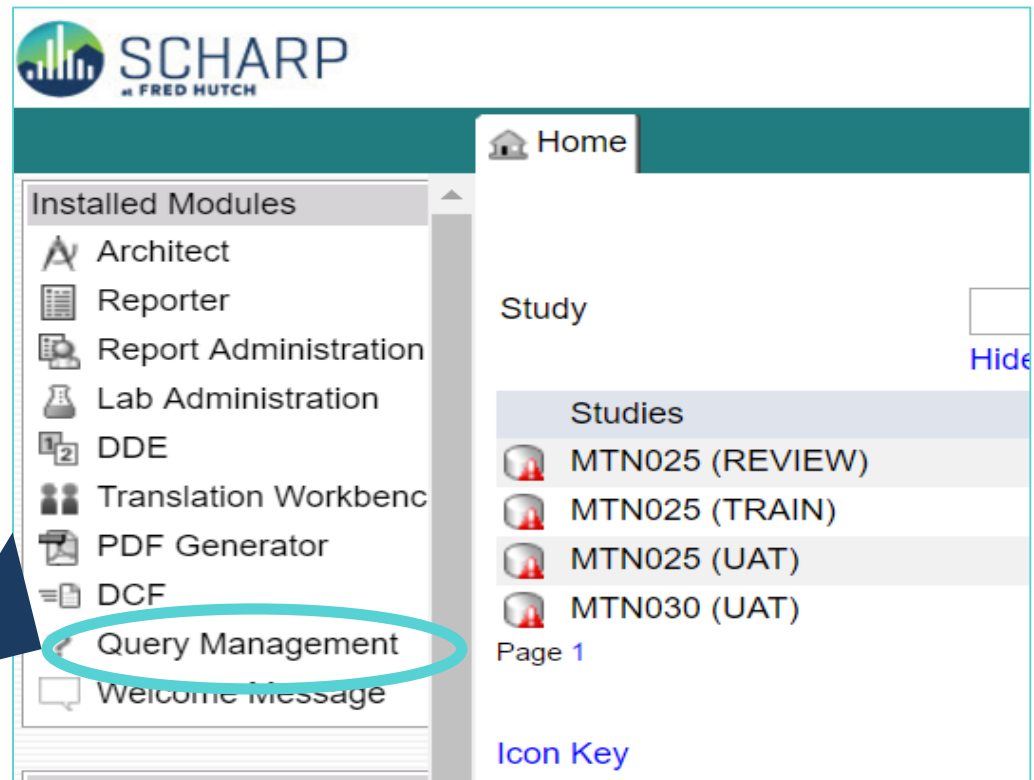
	User	Time
Query 'This item indicates that an AE was reported at this visit, however, no AE log form has been completed for this participant. Please review this item and update as applicable.' answered with 'A corresponding AE log page has been complete for this participant.' (Site from DM).	Richard Berman (1122 - r9berman3)	22 Aug 2017 12:00:29
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).	Richard Berman (1121 - r9berman2)	22 Aug 2017 11:56:37
Comment added 'If "yes", please complete Adverse Event Log in Ongoing Logs folder.'	System	22 Aug 2017 11:53:41
User entered 'Yes (Y)'	Richard Berman (1122 - r9berman3)	22 Aug 2017 11:53:41

CRF Version 501 - Page Generated: 22 Aug 2017 12:05:17 Pacific Daylight Time

RAVE Query Management Module

The Query Management module is a tool that allows you to search, view, and answer queries that have been placed by SCHARP and the system for your site.

Access the RAVE Query Management module from the Installed Modules sidebar on your Medidata homepage



The screenshot displays the SCHARP at Fred Hutch Medidata homepage. The top navigation bar includes a 'Home' button. A sidebar on the left lists 'Installed Modules' with the following items: Architect, Reporter, Report Administration, Lab Administration, DDE, Translation Workbench, PDF Generator, DCF, Query Management (circled in red), and Welcome Message. The main content area shows a 'Study' section with a 'Hide' button and a list of studies: MTN025 (REVIEW), MTN025 (TRAIN), MTN025 (UAT), and MTN030 (UAT). The page number 'Page 1' and an 'Icon Key' link are also visible.

RAVE Query Management Module

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

[? Query Management](#)

Advanced Search

Study*

Site Group*

Site

Subject

Folder

Form

Marking Group

Query Status

Search

Exact Search

Query ID

Search

OR

Search Results

Select Action

<input type="checkbox"/>	Query Site	Subject	Folder	Form	Field	Field Data	Query Text	Marking Group	Query Status
<input type="checkbox"/>	81989	SCHARP	999179756	V3 - Month 1 (1)	Pelvic Exam	Were any new pelvic finding AEs reported at this visit?	Yes	A pelvic finding AE has been reported at the visit, however no AE has been specified on this for...	Site from System Answered
<input type="checkbox"/>	81957	SCHARP	999179756	V2 - Enrollment (1)	Family Planning	Date Regimen Started:	UN NOV 2015	there is an entry for a family planning/contraception method. But there is no entry for the date...	Site from System Answered

The module screen is divided into three sections: the Advanced Search, Exact Search, and Search Results panels.

RAVE Query Management Module

The Advanced Search panel can be used to search for all queries by:

- Study*
- Site*
- Specific form or folder
- Marking Group (site from system, site from DM, etc.)
- Query status (Answered, Open, or Both)

*Note that the study and the site group must be specified to perform a search.

Advanced Search OR

Study* MTN025 (TRAIN) ▼

Site Group* World ▼

Site SCHARP ▼

Subject ▼

Folder ▼

Form ▼

Marking Group Site from System ▼

Query Status Both ▼

Search

RAVE Query Management Module

- The Search Results panel returns all queries that match the parameters specified in the Advanced Search panel.
- Using this panel, one or more queries can be selected to perform certain actions.
- The first column, “Query”, indicates the unique ID assigned to each query generated in the database
- The “Field Data” provides the data value entered for that field or item

Search Results										
Select Action ▾ Submit										
<input type="checkbox"/>	Query	Site	Subject	Folder	Form	Field	Field Data	Query Text	Marking Group	Query Status
<input type="checkbox"/>	81989	SCHARP	999179756	V3 - Month 1 (1)	Pelvic Exam	Were any new pelvic finding AEs reported at this visit?	Yes	A pelvic finding AE has been reported at the visit, however no AE has been specified on this for...	Site from System	Answered
<input type="checkbox"/>	81957	SCHARP	999179756	V2 - Enrollment (1)	Family Planning	Date Regimen Started:	UN NOV 2015	there is an entry for a family planning/contraception method. But there is no entry for the date...	Site from System	Answered

RAVE Query Management Module

- If the search returns multiple pages of results, pagination links are located in the bottom-left corner of the search results. Click a page to go to that specific page.

<input type="checkbox"/>	74113	SCHARP	999274343	V1 - Screening (1)	Demographics	A television	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74116	SCHARP	999274343	V1 - Screening (1)	Demographics	A refrigerator	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74119	SCHARP	999274343	V1 - Screening (1)	Demographics	A bed	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74101	SCHARP	999274343	V1 - Screening (1)	Demographics	Ethnic group or tribe	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74103	SCHARP	999274343	V1 - Screening (1)	Demographics	Number of cigarettes per day	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74107	SCHARP	999274343	V1 - Screening (1)	Demographics	Did the participant become pregnant since the end of ASPIRE?	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74110	SCHARP	999274343	V1 - Screening (1)	Demographics	Electricity or solar panels	Data is required. Please complete.	Site from System	Open
<input type="checkbox"/>	74112	SCHARP	999274343	V1 - Screening (1)	Demographics	A cassette player	Data is required. Please complete.	Site from System	Open

1 2 3 4 5 6 7 8 9 10 ...

RAVE Query Management Module

Search Results									
Select Action ▾									
Query Site	Subject	Folder	Form	Field	Field Data	Query Text	Marking Group	Query Status	
81989	SCHARP	999179756	V3 - Month (1)	Pelvic Exam	Were any new pelvic finding AEs reported at this visit? Yes	A pelvic finding AE has been reported at the visit, however no AE has been specified on this for...	Site from System	Answered	
81957	SCHARP	999179756	V2 - Enrollment (1)	Family Planning	Date Regimen Started:				

MTN025 SCHARP 999179756 V3 - Month 1 (1) Pelvic Exam

- V3 - Month 1 (1)
 - Date of Visit
 - Follow-up Visit Summary
 - Ring Adherence Y/N
 - Pregnancy Test Result
 - Concomitant Medication Y/N
 - Adverse Experience Y/N
 - Physical Exam
 - Pelvic Exam**
 - Ring Collection and Insertion
 - Additional Study Procedures Y/N

CRF History
999179756 - Pelvic Exam

blister

pustule

peeling

ecchymosis

GENERAL/OTHER

odor (vaginal)

condyloma

adnexal masses (based on bimanual exam; not pregnancy or infection-related)

uterine masses (based on bimanual exam)

uterine tenderness

adnexal tenderness

abnormal blood or bleeding

Other abnormal findings

Were any new pelvic finding AEs reported at this visit?

? A pelvic finding AE has been reported at the visit, however no AE has been specified on this form. Please review and this item and update. Opened To Site from System (21 Feb 2017)

AE Completed

...

- To access an eCRF from the Search Results panel, select the form name hyperlink provided.
- The system then will navigate you to the specific eCRF within RAVE

RAVE Query Management Module

Once a query has been addressed, you can return to the Query Management module by clicking the “Go back to Query Management” Link and continue addressing queries.

MTN025 SCHARP 999179756 V3 - Month 1 (1) Pelvic Exam

V3 - Month 1 (1)
Date of Visit
Follow-up Visit Summary
Ring Adherence Y/N
Pregnancy Test Result
Concomitant Medication: Y/N
Adverse Experience Y/N
Physical Exam
Pelvic Exam
Ring Collection and Insertion
Additional Study Procedures Y/N

◀ Go back to Query Management ✕

Subject: 999179756
Page: Pelvic Exam - V3 - Month 1 (1)

Exam date	01 MAR 2016
Pelvic exam assessment	Abnormal findings

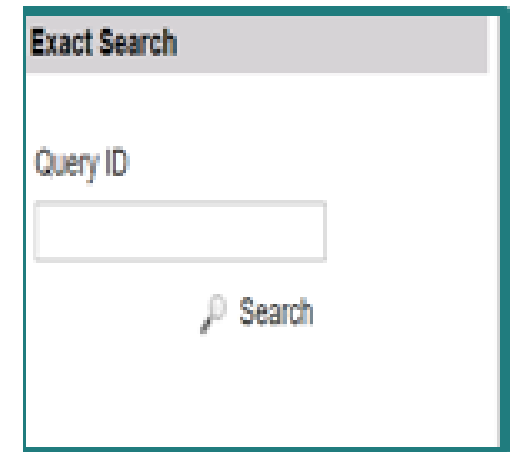
Abnormal findings. Mark all that apply.

VULVAR

vulvar edema	<input type="checkbox"/>
vulvar erythema	<input type="checkbox"/>


RAVE Query Management Module

- The Exact Search panel allows users to search for a single, specific query using the query ID.
- To conduct an exact search, you must enter the complete Query ID in order to return the query
- The query matching the ID that you have search for is displayed in the Search Results panel



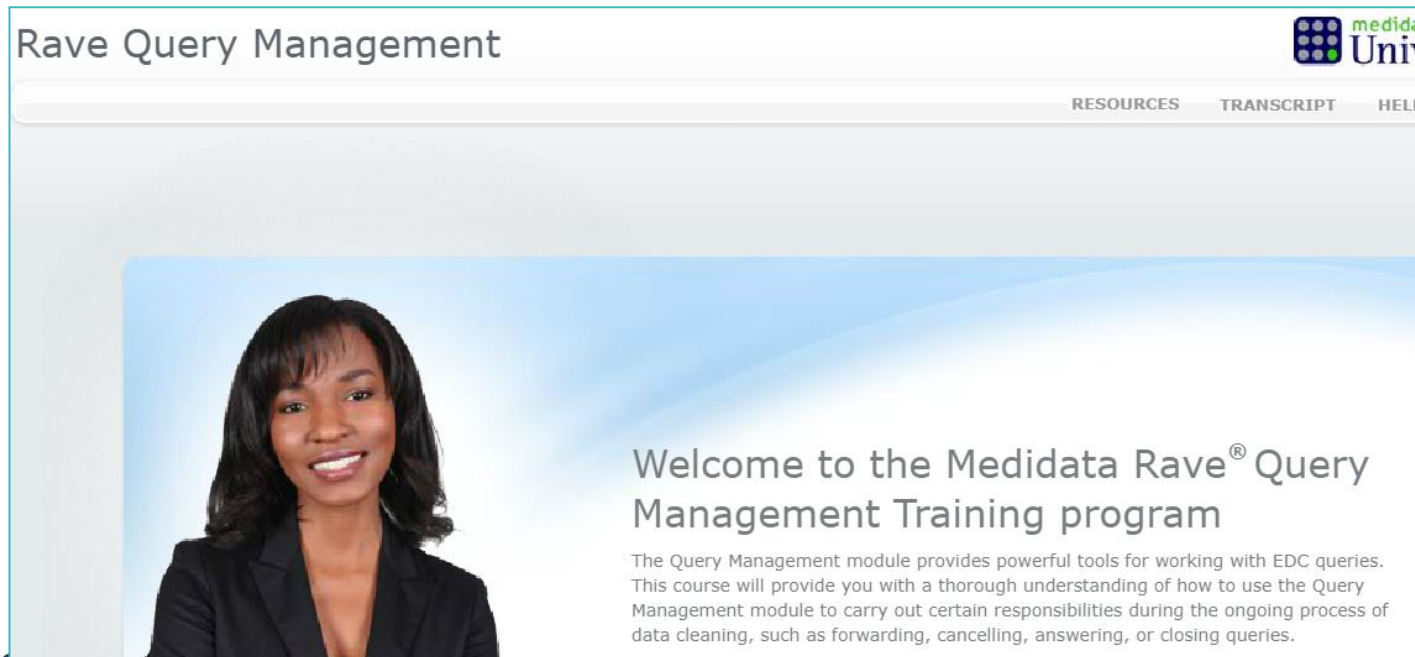
Exact Search

Query ID

 Search

RAVE Query Management eLearning

- Complete the RAVE Query Management eLearning assigned to you as this training will provide you with additional tips for resolving queries using this module
- This eLearning should take approx. 25 minutes



Rave Query Management

medidata
Univ

RESOURCES TRANSCRIPT HELP

Welcome to the Medidata Rave® Query Management Training program

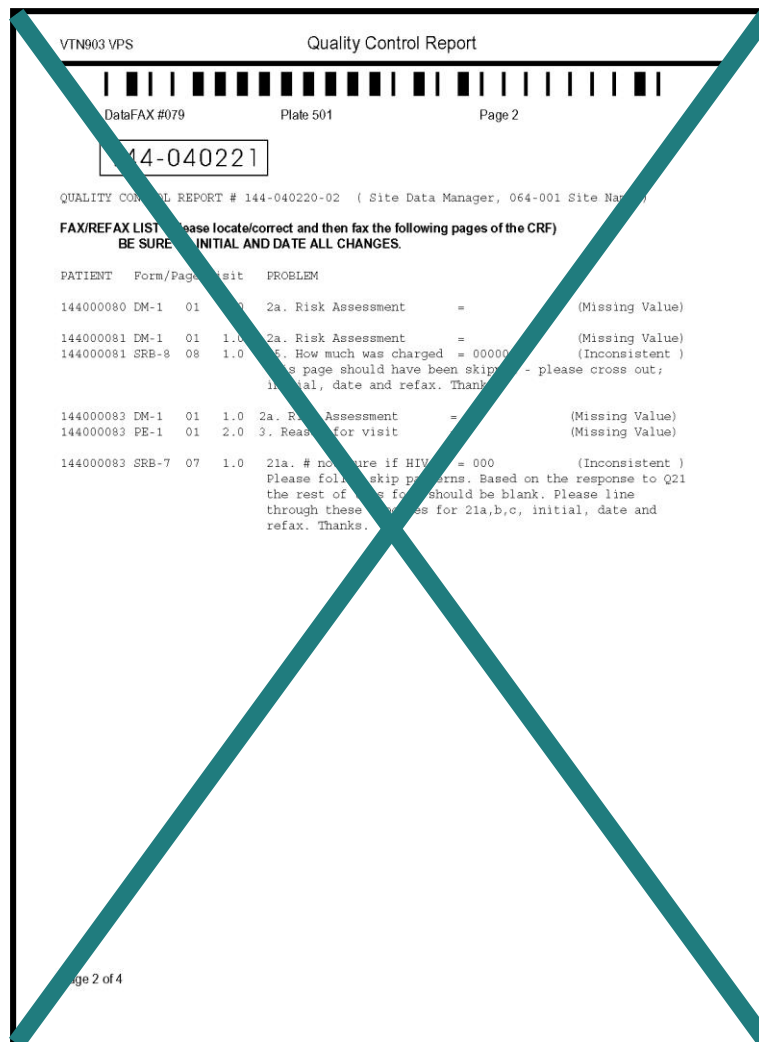
The Query Management module provides powerful tools for working with EDC queries. This course will provide you with a thorough understanding of how to use the Query Management module to carry out certain responsibilities during the ongoing process of data cleaning, such as forwarding, cancelling, answering, or closing queries.

MTN-036 Routine Study Reports

- Rave reports
 - Query Detail
 - Query Summary
 - Page Status Comprehensive
 - Productivity
- Emailed Report
 - LDMS Specimen Monitoring
- ATLAS Reports
 - Screen Out
 - Enrollment
 - Retention Report/Graph
 - Visit Adherence (Procedures Completion)
 - Missed Visit Summary Report
 - Missed Visit Site Listings
 - Data Management Quality (DMQ) Report
 - Data Summary Report
 - CASI

Rave Query Reports

QC Reports will no longer be sent via email to each study site once a month for site review.



Rave Reports

Medidata Rave

https://ravedemo562.mdsol.com/MedidataRAVE/(adneh45n03qapubxwv4ac45)/SharedPages/FrameSet.aspx?Frame=/MedidataRAVE

Medidata RAVE Demos

medidata
Medidata Solutions Worldwide

Messages My Profile Help Home Logout
User: Study Coordinator

MJB00002 Faulkner Hospital

Welcome Study Coordinator , Your enrollment target for this site is 150.
You currently have 38 subjects enrolled. Thank you for your participation in this important MJB Clinical Trial.

There have been no failed logins
Password Expires Never

Last 10 subjects:

- 1037 RLW
- 1001 JDD
- 1036 DWZ
- 1035 CMM
- 1034 JDD
- 1033 MLT
- 1032 PAC
- 1031 SLL
- 1007 JDD
- 1030 ETN

Resources:

- eLearning
- eLearning (Japanese)
- FDA
- GCP Guidelines
- Medidata Solutions

Subject

Subject
1001 JDD
1002 ERT
1004 JDD
1005 AJK
1006 KDK
1007 JDD
1008 JKL
1009 MJD
1010 JDD
1011 JYY

Page 1 2 3 4 <<Page 1 of 4>>

Icon Key

Messages
No Messages

Reports

- Page Status - Page Status Report
- Query Summary - Query Summary Report

Task Summary: Site

Task	Subjects
NonConformant Data	0
Open Queries	12
Sticky Notes	1
Overdue Data	7

Assigned Reports

medidata Rave

Click Here for Customer Support Information

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Data Metric Tools in Rave

Data queries report (by site)

Query Details Report for MTN030 - REVIEW

15 Mar 2017

test2 - World

Subject	Folder	Form	Field	Log #	Query Status	Qry Open Date	Qry Open By	Query Text	Marking Gr. Name	Qry Respon Date	Response Text	Qry Respond ed	Qry Resolv edDate	Qry ResolvedBy
999251834	Pharmacy	Pharmacy Dispensation	DASTDTC1	0	Open	10 Mar 2017	System	Data entered is non-conformant. Please correct.	Site from System					
999180741	Discontinuations	Treatment Discontinuation	DSTRTYN	0	Open	13 Mar 2017	System	Data is required. Please complete.	Site from System					
999169075	Ongoing Logs	Protocol Deviation Log	DVDAIDS	1	Open	10 Feb 2017	System	Data is required. Please complete.	Site from System					
999169075	Ongoing Logs	Protocol Deviation Log	DVIRB	1	Open	10 Feb 2017	System	Data is required. Please complete.	Site from System					
999169075	Ongoing Logs	Protocol Deviation Log	DVPLNADRES	1	Open	10 Feb 2017	System	Data is required. Please complete.	Site from System					
999169075	Ongoing Logs	Protocol Deviation Log	DVPLNPRVNT	1	Open	10 Feb 2017	System	Data is required. Please complete.	Site from System					
999169075	Ongoing Logs	Protocol Deviation Log	DVSTDTC	1	Open	10 Feb 2017	System	Data is required. Please complete.	Site from System					
999169075	Ongoing Logs	Protocol Deviation Log	DVTERM	1	Open	10 Feb 2017	System	Data is required. Please complete.	Site from System					
999165337	V2.0 - Enrollment	Hormone Tests	LBYN10	0	Open	03 Feb 2017	System	Data is required. Please complete.	Site from System					
New Subject	Subject Level	Baseline Medical History	MHDTC	1	Open	05 Aug 2016	System	Data is required. Please complete.	Site from System					
999977087	V2 - Enrollment	Baseline Medical History Log	MHDTC	1	Open	17 Aug 2016	System	Data is required. Please complete.	Site from System					

Medidata Rave Reports

- Site IoR, Study Coordinator, and Data Manager will have access to these reports
- The Reporter eLearning module will automatically be added to your homepage to complete (no email is sent from iMedidata)
- Should additional data team staff members need access to these reports, please send this request to sc.medidata.access@scharp.org

The screenshot displays the Medidata user interface. The top navigation bar includes the Medidata logo, a home icon, and user information for Nyaradzo Mgodi (nmmgodi). The main dashboard 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 for the user Nyaradzo Mgodi (nmmgodi), showing locale (sna) and location (Harare), with links for Account Details and MyMedidata.
- Studies (2):** A central section with two cards for "MTN025" and "MTN025 (TRAIN)". Both cards indicate that "Rave EDC Essentials for Clinical Research Coordinators" is required for access.
- Sites (2):** A section at the bottom with two cards for "Seke South CRS" and "Spilhaus CRS".
- Tasks:** A right-hand sidebar containing "Invitations (0)" (with "No Pending Invitations"), a circled "eLearning (1)" link, and "Rave EDC Essentials for Clinical Research Coordinators".

SCHARP Data Reviews

SCHARP Data Managers:

- Review protocol endpoint data
- Review and resolve answered system 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

MTN-036

Medidata Rave Database Considerations



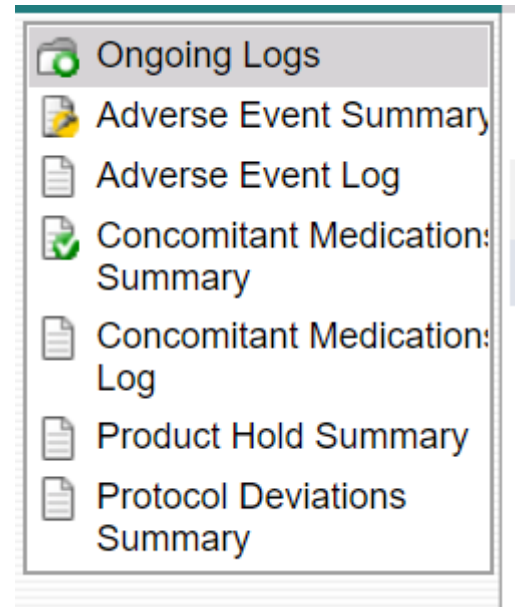
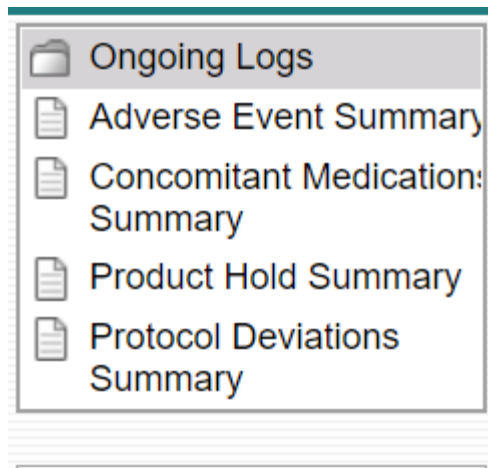
SCHARP
at FRED HUTCH

Ongoing Logs Folder

- Adverse Events Summary
- Concomitant Medications Summary
- Product Hold Summary
- Protocol Deviations Summary

Ongoing Logs Folder

- Selecting 'Yes' to any of the Summary prompt questions within this folder will dynamically populate the actual form for completion.







Things to know about Log forms

- Landscape View

Subject: 999425057

Page: Baseline Medical History - V1 - Screening (1)

#	Date medical history collected	Description of medical history condition/event	Is condition/event gradable?	Toxicity (Severity) Grade	Date medical condition/event started	Is the condition ongoing?	Date medical condition/event ended/resolved	
1	1 SEP 2014	VAGINAL ABRASION	Yes	Grade 2 (Moderate)	UN JUN 2012	Yes	-	 
2	1 SEP 2014	HEADACHE	No	-	31 AUG 2014	Yes	-	 

[Add a new Log line](#) Inactivate

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















CRF Version 113 - Page Generated: 20 Sep 2016 17:07:22 Pacific Daylight Time

- Portrait View

Subject: 999425057

Page: Baseline Medical History - V1 - Screening (1)

Currently viewing line 1 of 2.
[Click here to return to "Complete View".](#)

Date medical history collected	1 SEP 2014	 
Description of medical history condition/event	VAGINAL ABRASION	 
Is condition/event gradable?	Yes	 
Toxicity (Severity) Grade	Grade 2 (Moderate)	 
Date medical condition/event started	UN JUN 2012	 
Is the condition ongoing?	Yes	 
Date medical condition/event ended/resolved		 

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Discontinuations Folder

Home MTN036 Test site 2 999174900 Discontinuations (1) Study Discontinuation

- Discontinuations (1)
- Study Discontinuation
- Product Discontinuation

CRF History

999174900 - Study Discontinuation

Subject: **999174900**
Page: **Study Discontinuation - Discontinuations (1)**

Date of study exit

Did the participant complete the study?

If participant completed the study, end of form.

Primary reason for non-completion

If withdrawal of consent by participant, investigator decision, or other, specify:

If death, enter date of death

Was termination associated with an adverse event?

If yes, select applicable Adverse Event

Help Text

Help text available for certain items on forms

Subject: 999111643

Page: Adverse Event - Ongoing Logs (1)

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Date reported to site

Adverse Event (AE)

Onset date


At which visit was this AE first reported?

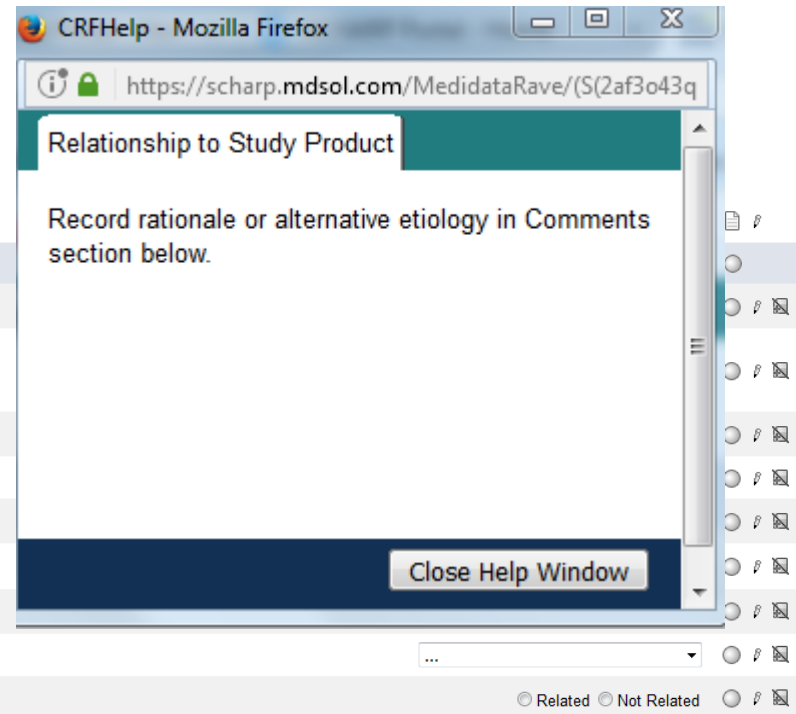
If 'Interim visit' is chosen, provide interim visit code

Is the AE still ongoing?

If no, outcome date

Severity Grade

Relationship to Study Product 



CRFHelp - Mozilla Firefox

https://scharp.mdsol.com/MedidataRave/(S(2af3o43q

Relationship to Study Product

Record rationale or alternative etiology in Comments section below.

Close Help Window

... Related Not Related

Saving Data on a Page/Leaving a Page

- Navigating away from the page before clicking the “Save” button will *not* save any data
- Once data has been entered and the “Save” button has been clicked, then any data entered will be saved

This page is asking you to confirm that you want to leave - data you have entered may not be saved.

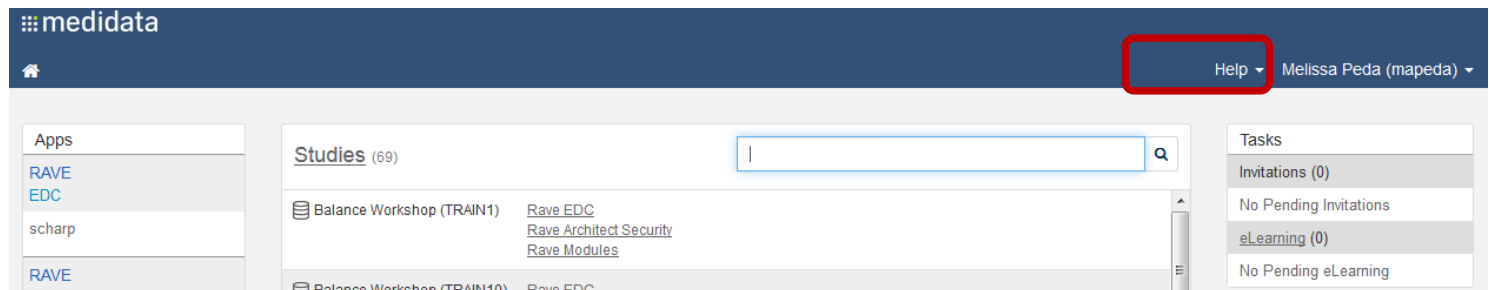
Leave Page

Stay on Page

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



The screenshot displays the iMedidata portal interface. At the top, a dark blue header bar contains the text "medidata" on the left and a user profile "Melissa Peda (mapeda)" on the right. A red rectangular box highlights the "Help" dropdown menu in the top right corner. Below the header, the main content area is divided into several sections: "Apps" on the left with links for RAVE, EDC, and scharp; "Studies (69)" in the center with a search bar and a list of items including "Balance Workshop (TRAIN1)" and "Balance Workshop (TRAIN10)"; and "Tasks" on the right with sub-sections for "Invitations (0)", "eLearning (0)", and "No Pending Invitations/eLearning".

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', and a 'Log In' button. Below this, the current space is identified as 'Pre-release Knowledge Space (Staging)'. The main content area shows an article titled 'About Subject Management in Rave EDC' with a sub-header 'Rave EDC (Staging)'. The article text explains that every study has a required primary form and provides a note that the sponsor defines the primary form's name and fields. Below the text, there are links for 'Subject Home' and 'Restrictions to Access Subjects'. A section titled 'Subject Home' describes how the subject home page summarizes information for each subject. At the bottom of the article, there is a table with columns for 'Subject ID', 'Visit', 'Date', and 'Task Summary Subject'. The table contains data for three visits: Visit 1 (21 Jun 2007), Visit 2 (28 Feb 2007), and Visit 3 (30 Mar 2007). To the left of the article is a sidebar with a search bar and a list of navigation links, including 'Getting Started in Rave EDC', 'About Subject Management in Rave E...', and 'Rave EDC FAQs'. To the right of the article are two content boxes, each with the text 'Content by label' and 'There is no content with the specified labels'.

MTN-036 SCHARP Resources

MTN website

- SSP
- Specimen Label Macros (Avery label and gram stain label)
- Visit Calendar Tool

MTN Atlas Portal (<https://atlas.scharp.org/cpas/project/MTN/036/begin.view?>)

- eCRF Medidata Rave Output
- Pelvic Exam Diagrams
- CRF Completion Guidelines (CCGs)
- Medidata Rave Materials

Medidata Rave Materials

[Medidata Rave User Request Form](#)

[Medidata Rave Training Manual](#)

[iMedidata Access Guide](#)

[Medidata Rave Start-up Information](#)

Questions

Medidata related (i.e., Rave or iMedidata offline, or for password reset)

Toll-free 1-866-MEDIDATA (633-4328)	Direct number 1-973-659-6780
Toll-free fax 1-877-743-2350	Direct fax 1-973-954-5621
Email helpdesk@mdsol.com	
Hours 24 hours a day, 7 days a week	

For MTN-036 database questions, contact SCHARP CDM Tanya Harrell (tharrell@scharp.org)

Questions?



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THANK YOU