MTN-036
Medidata Rave Training
SCHARP

Tanya Harrell & Jen Berthiaume
Presentation Overview

- Medidata Navigation, Functionality, and Features
- Query management
- SCHARP Data Reviews and PPD monitoring in Rave
- Study-specific considerations in Rave
- Resources
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.
Rave Navigation: Site Home Page

- CRS
- REVIEW
- Participant (PTID) List
- Task Summary
## Icons within Rave

### Rave Interface Example

#### Subject Table

<table>
<thead>
<tr>
<th>Subject Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>99911543</td>
</tr>
<tr>
<td>99912734</td>
</tr>
<tr>
<td>99912799</td>
</tr>
<tr>
<td>999140807</td>
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<td>999334164</td>
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</tr>
<tr>
<td>999508100</td>
</tr>
<tr>
<td>999511449</td>
</tr>
</tbody>
</table>

#### Icon Key

- **Task Summary:** Site
- **requiring Signature**
- **NonConformer Data**
- **Open Queries**
- **Overdue Data**
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

1. Form never touched
2. Form data entry and query resolution
3. PPD monitor verification
4. Complete - Form Clean
5. IoR Signature
6. Data Lock
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

<table>
<thead>
<tr>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>999111643</td>
</tr>
<tr>
<td>999112734</td>
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<tr>
<td>999127899</td>
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<td>999140807</td>
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<td>999150225</td>
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<td>999234101</td>
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<td>999249446</td>
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<td>999271860</td>
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<td>999277951</td>
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<td>999476354</td>
</tr>
<tr>
<td>999508100</td>
</tr>
<tr>
<td>999511449</td>
</tr>
</tbody>
</table>

**Icon Key**

- **Task Summary: Site**
- **requiring signature**
- **NonConformant Data**
- **Open Queries**
- **Overdue Data**
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 as 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

www.imedidata.com
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 is to 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 -
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
   - °C
   - ?

3. Systolic BP
   - Data Entry Error
   - mmHg
   - ?

Query Text

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weight</td>
<td>55 kg</td>
</tr>
<tr>
<td>2. Body Temperature</td>
<td>35 °C</td>
</tr>
<tr>
<td>3. Systolic BP</td>
<td>120 mmHg</td>
</tr>
</tbody>
</table>

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**

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**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 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.

---

<table>
<thead>
<tr>
<th>Audit</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.' answered with 'A corresponding AE log page has been complete for this participant.' (Site from DM).</td>
<td>Richard Berman (1122 - r9berman3)</td>
<td>22 Aug 2017 12:00:29</td>
</tr>
<tr>
<td>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).</td>
<td>Richard Berman (1121 - r9berman2)</td>
<td>22 Aug 2017 11:56:37</td>
</tr>
<tr>
<td>Comment added 'If &quot;yes&quot;, please complete Adverse Event Log in Ongoing Logs folder.'.</td>
<td>System</td>
<td>22 Aug 2017 11:53:41</td>
</tr>
<tr>
<td>User entered 'Yes (Y)'</td>
<td>Richard Berman (1122 - r9berman3)</td>
<td>22 Aug 2017 11:53:41</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>ID</th>
<th>Study ID</th>
<th>Version</th>
<th>Type</th>
<th>Data Details</th>
<th>Site from System</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>74113</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: A television</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74116</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: A refrigerator</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74119</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: A bad</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74101</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: Ethnic group or tribe</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74103</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: Number of cigarettes per day</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74107</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: Did the participant become pregnant since the end of ASPIRE?</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74110</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: Electricity or solar panels</td>
<td>Site from System</td>
<td>Open</td>
</tr>
<tr>
<td>74112</td>
<td>SCHARP</td>
<td>999274343</td>
<td>V1 - Screening</td>
<td>Demographics: A cassette player</td>
<td>Site from System</td>
<td>Open</td>
</tr>
</tbody>
</table>
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.
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.
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.
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
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

The image shows a screenshot of a web interface for Rave Reports. The interface is for Faulkner Hospital and includes several sections:

- **Last 10 subjects**: Lists the last 10 subjects with codes such as 1037 RLW, 1001 JDO, 1036 DWZ, 1036 CMM, 1034 JDO, 1033 MLT, 1032 PAC, 1031 SLL, 1007 JDO and 1030 ETN.

- **Resources**: Includes links to eLearning, eLearning (Japanese), FDA, GCP Guidelines, and Medidata Solutions.

- **Assigned Reports**: Shows a list of reports with two options: Page Status - Page Status Report and Query Summary - Query Summary Report.

The interface also includes a login section with options for My Profile, Help, Home, Logout, and User Login as Study Coordinator.
# Data Metric Tools in Rave

## Data queries report (by site)

### Query Details Report for MTN030 - REVIEW

| Subject | Folder | Form | Field | Log # | Query Status | Qry Open Date | Qry Open By | Query Text | Marking Gr. Name | Qry Respon Date | Response Text | Qry Responded | Qry Resolved By |
|---------|--------|------|-------|-------|--------------|---------------|-------------|------------|----------------|----------------|---------------|---------------|----------------|----------------|
| 999251834 | Pharmacy | Pharmacy Dispensation | DASTOTC1 | 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 | CVOAIDS | 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 | DVPLNLADRES | 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 | DVSSTDTC | 1 | Open | 10 Feb 2017 | System | Data is required. Please complete. | Site from System |
| 999169075 | Ongoing Logs | Protocol Deviation Log | DVTTERM | 1 | Open | 10 Feb 2017 | System | Data is required. Please complete. | Site from System |
| 999165327 | V2.0 - Enrollment | Hormone Tests | LBYN10 | 0 | Open | 02 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 |
| 999977068 | V2 - Enrollment | Baseline Medical History | 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.acccess@scharp.org
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
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**

- **Portrait View**
Discontinuations Folder

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 available for certain items on forms

- 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 data
  - Severity Grade
  - Relationship to Study Product?

Record rationale or alternative etiology in Comments section below.
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.

[Buttons: 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.
Resources: Within Rave

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

<table>
<thead>
<tr>
<th>Toll-free</th>
<th>Direct number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-866-MEDIDATA (633-4328)</td>
<td>1-973-659-6780</td>
</tr>
<tr>
<td>Toll-free fax</td>
<td>Direct fax</td>
</tr>
<tr>
<td>1-877-743-2350</td>
<td>1-973-954-5621</td>
</tr>
<tr>
<td>Email</td>
<td></td>
</tr>
<tr>
<td><a href="mailto:helpdesk@mdsol.com">helpdesk@mdsol.com</a></td>
<td></td>
</tr>
<tr>
<td>Hours</td>
<td></td>
</tr>
<tr>
<td>24 hours a day, 7 days a week</td>
<td></td>
</tr>
</tbody>
</table>

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