

DATA MANAGEMENT CENTER NEWSLINE

Network Meetings in Review

At the ACTG and IMPAACT Network Meetings, the DMC offered training on both DMC systems and Medidata Rave, as well as several study-specific training sessions. For site staff who couldn't attend these sessions, this edition of *Newsline* offers a quick summary of the main points of each presentation.



All presentations are available on the DMC Portal under Site Support > Training Pages > Presentations.

Daily QA in Rave

To perform daily quality assurance in *Rave*, check the Task Summary regularly. The Task Summary is the primary tool for receiving alerts about eCRFs with non-conformant data, open queries, sticky notes, and overdue data. The Task Summary is available at the Study, Site, and Subject levels. Click on the arrow beside each Task Summary item to see sites, subjects, or eCRFs that require action.

▼ Task Summary: Subject	Pages
▶ Requiring Signature	0
▶ NonConformant Data	0
▶ Open Queries	1
▶ Sticky Notes	0
▶ Overdue Data	0

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Daily QA in Rave (continued)

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Best practice is to view the Task Summary at the beginning of the day and prioritize data to be entered and queries to be addressed. For more information, see “Keying Data in Rave” (page 3).

eCRF Development for Study Teams

Difference between eData and Rave

In *eData*, forms are static, and the user interface is based on the print form. Although logical checks do appear as you key data, errors must be corrected in *Online Correct* or resolved in *Resolve*. Queries are handled separately through email, and delinquencies are listed in another separate report.

In *Rave*, eCRFs are dynamic and designed to be completed within a web browser. Printed CRF Notebooks will no longer be shipped to sites. Queries (including data checks) and delinquencies are all managed within the data capture system. To assist sites in completing forms, the Data Management Center has developed eCRF Completion Guides (covered in more detail in *eCRF Resources*).

What Study Teams Can Expect

A Study Build Team for *Rave* includes DMC Data Managers, a Study Builder, and an SDTM (CDISC) Specialist. They work with the study team to develop eCRFs for a new study.

In order to ensure that study build deadlines are met, it is vital for the study team to review eCRFs promptly, to maintain good communication with the Study Build Team, and to focus on the research questions of the study.



Adverse Events

In *Rave*, Adverse Events (AEs) are now captured on a log form, which allows users to capture updates to earlier data. It is necessary to define protocol AEs in section 7 of the protocol document.

eCRF Resources

Medidata Rave Resources

Most eCRF resources are available on the Portal under the Site Support category and the *Medidata Rave Resources* link. These include:

- **eCRF Completion Guides.** An eCRF Completion Guide is a “snapshot” of what each eCRF looks like within the system and what data it collects. It provides guidance on how to complete the eCRFs such as help text and data dictionaries (lists of answer choices). This document can help sites create source documentation.
- **Print Matrices.** A Print Matrix is a PDF containing all eCRFs used for the study. These are blank and contain no additional guidance. Included in the Print Matrix is a print-friendly version of the Specimen Tracking form that can be completed manually and sent to the processing laboratory.

- **Quick References.** *Medidata Rave Resources* also includes quick references such as a “Frequently Asked Questions” list, a “Guide for New Studies Opening in Rave,” the “Daily Quality Assurance in Rave” quick reference, the *Rave Reports* reference guide, and “Signing eCRFs in Rave: Quick Reference for Investigators,” among many others.

Grid View and Calendar View

When you view a participant (subject) in *Rave*, you can use *Calendar View* to see eCRFs listed by folder and expected visit date in a list, or *Grid View* to see a table correlating eCRF types (e.g., Laboratory Test Results) to visit folders. A link in the upper right-hand corner of the screen lets you toggle between the two views. The link shows the name of whichever view is not currently active.

Printing Completed eCRFs

At the bottom of each completed eCRF, there are links for a *Printable Version* and to *View PDF*. Each has benefits and disadvantages. The Printable Version shows queries on non-log forms, but it may truncate wide log forms, and it contains unnecessary “web view” formatting. The View PDF link shows the eCRF formatted cleanly in the style of Print Matrix, but it does not show queries.

Viewing Additional Log Lines

When you view a log form, by default, the log paginates after 20 entries. To view additional log lines, select the *My Profile* link in the upper right-hand corner of the *Rave* interface. In the *My Profile* section on the right, click *Edit*. Choose a higher number (such as 50), then click *Save*.

You can also select “Show All Log Lines” instead of a page number when the log is paginated.

If there are many entries on a log form, the headers may not be visible as you scroll down.

Keying Data in Rave

Rave Interface

The *Rave* interface is designed to allow users to key data and perform quality assurance without leaving *Rave*. Icons appear on subjects, folders, eCRFs, and individual data items to indicate the status of the data within. An *Icon Key* link is available on most pages. The most important icons are as follows:

	Never Touched		Complete		Non-Conformant
	Overdue		Sticky Note		Incomplete
	Query Open		Answered Query		

Dynamic Folders and eCRFs

Both folders and eCRFs may become available dynamically. Each visit is associated with a folder, and visit folders roll out one at a time. For each visit, you will key a Visit Tracking eCRF to indicate that the visit occurred. If the visit did occur, a Study Event Tracking eCRF rolls out. When you com-

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Keying Data (continued)

(Continued from page 3)

plete and save this eCRF, if the participant will continue on study, the next visit becomes available.

Depending on how you respond to certain questions, other questions may appear on the same eCRF or other eCRFs may become available to be keyed. When a question response triggers a new eCRF, a sticky note appears on the triggering eCRF to notify you.

You may also be prompted to complete a new eCRF or update an existing eCRF in the participant-level log folder. It is very important to keep these logs up to date.

Keying Tips

Use the following tips to minimize switching between keyboard and mouse:

- Use tab to navigate between questions
- Use arrow keys to navigate between radio button responses to a single question
- Use space bar to select answers for radio buttons
- Begin typing in drop-down menus to select the desired response

Adding and Inactivating Log Lines

A log form is designed to collect data in a tabular format. To add a new log line, at the bottom of the log, select *Add a new Log line*.

To inactivate a log line, at the bottom of the log, select *Inactivate*. Select the line number for the log line that you want to inactivate from the first drop-down menu, then select a reason for inactivation from the second drop-down menu. Click *Inactivate*. Inactive lines appear with a strikethrough.

Inactivating Pages

To inactivate an entire eCRF, in the upper right, select the *Inactivate Page* link. Select a reason for inactivation.

Modifying Entered Data and Responding to Queries

To modify data, click the pencil icon to the right of the response that you want to update. Change the data and select reason for modification, then scroll to the bottom of the eCRF and click *Save*.

Queries (both automatically generated and sent by a protocol data manager) appear in red or pink on eCRFs, and the data entry fields appear as available for keying. Correct the data, select a reason for modification, and enter a comment in the comment field provided. *Do not* enter data in this field. If you need to indicate that the data are already correct as entered, do so here.

Site staff are expected to respond to queries in *Rave* within two weeks, just like in *eData*. Keep in mind that you may need to update a field on a different eCRF in order to resolve your query.

All changes to data, including queries and query responses, are logged in the audit trail. Click the data status icon to see the audit trail.

Adding Additional Events

Some unexpected circumstances—such as an unscheduled visit, additional laboratory results, or virologic failure—may require you to add additional events for a participant. Navigate to the subject

QA Tips for eData Studies

The Monthly Report and the Site Data Management Report

The Site Data Management Report is a report sent monthly that provides site scores on several data management measures. This should not be confused with the Monthly Report, which is available on the Portal and provides an unscored summary of data management issues that need to be addressed. However, these two reports are related, and eliminating issues on your Monthly Report will improve your Site Data Management Report score. You can access the last twelve months' worth of Monthly Reports on the Portal under the QA Tools Category and the *Monthly QA Report* link.

In addition to several other types of reports, this report addresses three major issues: delinquencies, unanswered queries, and unresolved errors.

Delinquencies

The term “delinquency” refers to data that is expected in the database but is not present. The Delinquency System determines which forms are expected based on the participant’s randomization date and the Data Collection Forms Schedule (DCFS) for the protocol. Using the randomization date, it calculates an ideal visit schedule, then it consults the DCFS to see which forms are expected at each visit date. Depending on your responses to some questions, the Delinquency System may expect additional forms as indicated on the triggering form and the DCFS.

Most forms are expected three weeks (21 days) after the ideal visit date. However, 48- and 72-hour forms are expected one week (7 days) after the ideal visit date. If they have not been exported to the database by that calculated date, they are identified as potentially delinquent. The delinquency system does not take protocol visit windows into account, so items may appear as delinquent when they are in fact on time. These generally do not influence your Site Data Management Report score.

Use the following tips to avoid delinquencies:

- Keep to the “ideal” schedule as closely as possible
- Follow the DCFS at key time points such as Off Treatment, Off Study, Step Change, Labor and Delivery, and Virologic Failure visits
- Always use the correct form week based on the DCFS
- Key all forms triggered by your other responses
- Always report missed visits on the appropriate CRF
- Set clear expectations for when forms must be turned in
- Use DMC Portal resources such as the Delinquency Viewer, Participant Record History, Participant Calendar, and Visit Forecaster

Unanswered Queries

DMC staff send queries via email to clarify data for eData studies. Common queries include dates for stopping medications, resolution dates for signs/symptoms and diagnoses, incorrect codes, insufficient information on a Specify line, and longitudinal queries (data changes over time). You can respond to a query by email or using the Unanswered Query Report on the Portal.

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QA Tips for eData Studies (continued)

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You are expected to respond to a query within two weeks. IMPAACT sites who respond within one week will receive the highest allowable score for query responsiveness on the Site Data Management Report.

Unresolved Errors

The terms “error,” “computerized data check,” “logical check,” and “warning” all refer to a data check programmed to appear automatically within Rave. Site staff must either correct the data using *Online Correct* in *eData* or indicate why the data are correct as entered using *Resolve* on the Portal. Do not perform both actions.

Site staff are expected to correct or resolve computerized data checks within two weeks.

Other helpful resources on the Portal include the Unresolved Error List and the Warnings program.

Rave Reports

The following table shows the main reports in the *Rave Reporter* module. For more information, see *Rave Reports* on the Portal (Site Support > Medidata Rave Resources).

Report Name	Purpose
360 Query Management Report	Combines other query-focused reports and offers visualization tools.
Audit Trail Report	Retrieves the audit trail (modification history) of a study.
Enrollment Report	Shows number of participants with status “Enrolled,” “Screening,” or “Screen Failed” and offers a graph showing enrollment, screening, and screening failure over time.
JReview	Allows users to generate custom reports. Similar to <i>TJoin</i> on the DMC Portal.
Page Status Report v 2.0	Indicates how many eCRFs are <i>Expected Total</i> , <i>Expected To Date</i> , <i>Entered</i> , or <i>Overdue</i> , as well as how many queries are either <i>Open</i> or <i>Answered</i> . Includes a drill down feature.
Productivity Report	Reports on activities and actions performed by users. Includes # of pages entered, # of pages with open or acknowledged sticky notes, and # of pages with queries.
Query Aging Report	Provides an overview of how long it takes for queries to reach a status of “Answered,” “Closed,” or “Cancelled.” Does not include open queries.
Query Details Report	Retrieves all queries that a site has received, including full text of query, query status, status date, query response, and marking group (query sender).
Query Summary Report	Provides the number of queries by status, as well as the total number. Totals are broken down by marking group (query sender).
Sticky Note Report	Retrieves all sticky notes that a site has received, including the full text of the sticky note, date received, status, and acknowledging user.
Subject CRF Versions Report	Indicates the CRF Version (study build deployment) active for each participant.
Subject PDF Report	Retrieves PDFs of eCRFs for a select participant.

TJoin

Database Structure

The following information is applicable to *eData* studies.

The Central Database at the DMC is a *relational database*, which means that it stores CRF data in a tabular format so that records can be compared. Each CRF corresponds to a table that is named after the CRF (for example, f0031 or 1bw0054). If you picture a spreadsheet, each field on a CRF corresponds to a column, and each individual record corresponds to a row. Fields on CRFs have field names, which you can view using Annotated Forms or the Codebook Generator on the Portal.

Very long CRFs may be split into multiple tables, such as the ACTG Event Report Form (evw0206a, evw0206b, and evw0206c).

-1	Site reported that value is unknown or nothing has changed since last report.
-2	Data item left blank by site or by form skip logic.
-3	Site entered an out-of-range value for a coded data item (e.g., entering 7 for 1-Yes, 2-No)
-4	The field in the record was not on the form at the time that the record was entered.

We use negative numbers to represent unknown or missing values:

Master Tables

In addition to the CRF-based tables, there are five Master Tables that contain administrative data: patient (participant demographic data), scase (participant's status on study), step (participant's status on step), itrack (institutions where the participant has been seen), and curent (participant's current site).

TJoin

TJoin allows users to create custom reports by joining together tables in the Central Database. This program is available on the DMC Portal in the Utilities category. The TJoin interface includes six tabs: Source, Selection, Join, Criteria, Layout, and Output.

On the Source tab, select whether you wish to create a new retrieval or load a saved retrieval.

On the Selection tab, choose the study, then select the tables that you wish to include in your retrieval and the fields that you want from each table.

On the Join tab, if you are retrieving data from more than one table, indicate how you would like these tables to be joined. An "inner join" only retrieves data where there is a match in both tables. For example, if you pull data from patient and the table for a pregnancy form, participants who have not had a pregnancy form completed will not be included. An "outer join" retrieves data even when there is no match. In the previous example, selecting a "left outer join" would include all participants, even those without the pregnancy form. This can be useful for seeing when forms were not completed.

On the Criteria tab, use operators (such as >, <, and =) and values to filter data for your retrieval. You can also add additional criteria to set a data range.

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TJoin (continued)

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On the Layout tab, modify column placement to change the order of columns in your output from left to right and modify sort order to change the order of rows from top to bottom.

On the Output tab, you may run or save the retrieval. If you run the retrieval, you can choose the format of the output file (such as Excel, CSV, or text) and select features such as header rows. If you save the retrieval, you can select it later from the Source tab and run it again or modify it as needed.

Using TJoin for Rave

Data entered in *Rave* are also loaded into the Central Database. For conversion studies (studies moving from *eData* to *Rave*), you can retrieve data the same way you do for *eData* studies. For studies starting in *Rave*, use the following tips:

- Use eCRF Completion Guide instead of Annotated Forms to find field and table names.
- Most table names begin with “rave_” followed by Form ID.
- Negative numbers are not used.
- Master Tables are still available.
- When retrieving dates, use the date field with the “_raw” suffix.
- To retrieve log lines, include the grouprepeat field in your retrieval.
- To retrieve week, include the event field. It retrieves a string that includes S## (step), W### (week), H# (hour), and Q# (sequence).

2008

IMPAACT 2008 is a “legacy-style” study built in *Rave*. This study uses generic forms familiar from *eData* studies, reformatted into *Rave* eCRFs. Although Portal programs and reports will be available for 2008, all queries will be received and responded to in *Rave*.

The eCRFs for this study are not final and may change before the study opens. Check *Medidata Rave Resources* periodically for the eCRF Completion Guide and Print Matrix.

Protocol Deviations

2008 uses the Protocol Deviation eCRF (DEV0001) to collect information about protocol deviations. These might include inappropriate enrollments, study product management errors, breaches of confidentiality, or informed consent deviations. Although data managers cannot advise sites about whether an incident should be considered a protocol deviation, they can help with questions related to the form. Refer to the IMPAACT Manual of Operations for information on what constitutes a reportable protocol deviation.

eCRFs

The Initiation of Study Defined Medication/Regimen (ADM0022) eCRF is only completed for Arm 1 participants to record VRC01. Document all cART on the IMPAACT 2008 cART Regimen Record.

For the Hematologies (PE6814) and Chemistries (PE6819) eCRFs, the results of all protocol-specified screening and entry laboratory tests that are performed in real time at site laboratories will be entered into eCRFs.

For the Signs and Symptoms (PE6834) and Diagnoses (PE6854) eCRFs, enter all signs, symptoms, and diagnoses identified from 30 days prior to entry (or from birth for infants who are less than 30 days of age at entry up until study entry. The same eCRF data is required for infants in both study arms.

For Event Evaluation (PE6867), evaluate the following laboratory test results, signs, symptoms, or diagnoses for infants on both study arms:

- Grade 3 or higher
- Meeting criteria for EAE reporting
- Resulting in deferral or discontinuation of study product administration
- Resulting in any change of cART regimen (including ARV holds, replacements, discontinuations, additions, and dose modifications)

For many eCRFs, the 16-week mark is a watershed in how data are reported.

eCRFs	Through Week 16	After Week 16
PE0412	Report all non-ARV concomitant medications	Report only immunizations, immunosuppressive medications, and treatments administered through injection to the legs where VRC01 has been administered.
PE6814, PE6819, PE6834, and PE6854	Enter all Grade 1 or higher laboratory results (PE6814 and PE6819), signs/symptoms (PE6834), and diagnoses (PE6854)	Enter all Grade 2 or higher laboratory results (PE6814 and PE6819), signs/symptoms (PE6834), and diagnoses (PE6854)
PE6814, PE6819, PE6834, PE6854, and PE6867	Enter eCRFs within 48 hours of clinical findings becoming available	Enter eCRFs within standard timeframes unless otherwise requested by the CMC

IMPAACT 2008 cART Regimen Record (TXW0309) is a log form, meaning that it needs to be updated periodically each time the participant's regimen changes. This includes initial doses, modifications, interruptions, and permanent discontinuations.

All injections of study product must be recorded on IMPAACT 2008 Study Product Record (VCW0078). If the dose is split into two injections, add a log line and record each separately.

Other eCRFs for this study include Master Specimen Tracking (F3008), Immunization History (HXW0021), Infant Exposure to Antiretrovirals in Utero (HXW0220), Infant Exposure to Antiretrovirals While Breastfeeding (HXW0221), Infant Feeding Practices (QLW300), Specimen Consent/Deconsent Tracking for Non-Protocol Defined Testing (TRK0103), and IMPAACT 2008 Genetic Testing and Residual CSF Consent (TRK0180).

2010

IMPAACT 2010 is a new study opening in Rave. This study screens potential participants prior to enrollment. For each mother/infant pair, only one screening number is assigned to the pair. This study allows multiple screening attempts; if a pair fails screening and is screened again, a new screening number is assigned. When screening failure occurs, sites should complete the IMPAACT 2010 Screening Failure and Non-Enrollment Results eCRF (SCR10001) as soon as possible for every failure.

Study-specific questionnaires will be available on the Forms Management Utility on the Portal. Some questionnaires require translation into local languages and were sent to sites via email. Contact the Protocol Data Manager with any questions you may have regarding translation and back-translation.

eCRFs will roll out for each visit and each event based on the data keyer's responses to questions on Visit Tracking (ADM10011), Study Event Tracking (Maternal) (SVW10001), and Study Event Tracking (Infant) (SVW10000). Many important eCRFs, including logs, roll out in a participant-level folder that is not associated with a specific visit.

When reporting the study-defined drugs indicated in Section 5 of the protocol, use the Treatment Log (TXW10001). When reporting any other medications, including ARVs, use the Concomitant Medications Log (CMW10001). These are log forms and should be updated periodically when the participant's medication is modified.

Other log forms include the Medical History Log (MHW10001) and the Adverse Events Log (ADE10002). On these logs, each event has its own line, which must be updated when events begin or resolve or when new information becomes available. See the protocol, particularly Sections 6 and 7, for details about reportable events both on-study and in the participant's medical history.

If an infant has a congenital anomaly, update ADE10002 before completing Congenital Anomalies (DXW10000). A detailed narrative is required; if you need more space, add a log line to DXW10000. Submit photos related to congenital anomalies through the File Exchange Utility on the Portal.

Some eCRFs, including the Pregnancy Outcome Log (EVW100013) and the Delivery Record (EVW10018), must be completed under the mother's PID. The infant's PID is entered as data. If a multiple birth occurs, add as many log lines as needed to EVW10018.

When completing the Newborn Exam (EVW10016), use only information taken immediately after birth. This is separate from the regularly-scheduled examinations taken at the Delivery Visit.

Breastfeeding, Formula, and Complementary Food Record (QLW10011) is designed to capture firm time periods for different stages of the transition to complementary food. If an infant returns to a stage that was considered complete, such as when the infant is weaned but then begins to suckle again, the weaning information needs to be updated. This eCRF is available in the participant-level folder so that it can be updated at any time during the study.

Other eCRFs for 2010 include Targeted Pregnancy Diagnoses (DXW10001), Labor Record (EVW10015), Infant Feeding Method (QLW10010), Vital Signs (VSW10000), and Vital Signs - Infant (VSW10001).

A5354

General Tips for *Rave*

Non-conformant data includes data that does not match the type specified for the field (such as letters instead of numbers), some out-of-range values (the 32nd of December), and text entry fields where the response contains too many characters. In *Rave*, data marked as non-conformant is considered blank, and as a result, queries may appear indicating that required fields cannot be left blank. We recommend that you address non-conformant data first, then see if the query disappears.

Responses to certain questions on Study Event Tracking eCRFs add a log at the participant level. If the log is left blank, when the next visit is keyed, a “No” response to the same triggering question will delete the log. We recommend that you always key log data promptly to prevent this scenario from occurring. A Protocol Data Manager can add a log manually if needed.

A5354 eCRF Tips

A common query on the Adherence Assessment eCRF is, “It is indicated that the Adherence Assessment was performed but no reason has been provided. Please reconcile.” This is because the lower section of the eCRF has been left blank. A response to the question about reason for missed doses is expected. If the participant left this question blank, indicate this in the query response.

For the Laboratory Test Results eCRF, a response is required for the “Test Performed” question for every test reported. If the test is not required to be performed at the visit or does not meet the reporting requirements, select “Not required.” If you select “No” (not performed), you must enter a reason. We also recommend that you key the leading questions first before completing the log portion of the eCRF. This will allow the units to display in the drop-down menus in the log portion. As a final note, for this study, it is only required to enter limits of normal for tests where this value is used to calculate toxicity grade.

On the HIV-1 Plasma Viral Load eCRF, if the viral load is reported via LDMS, only answer questions 1 and 3. If you receive a query on question 9 anyway, no action is required on your part. The DMC will cancel the query.

On the Concomitant Medications Log, total daily dose and dose unit are not required for non-ARVs.

The DMC will be checking for discrepancies between the eligibility checklist inclusion criteria and results reported on the Documentation of AHI eCRF and other associated eCRFs.

P1108

Like 2008, P1108 is a “legacy-style” study built in *Rave*. Although Portal programs and reports will be available for P1108, all queries will be received and responded to in *Rave*. Like 2008, P1108 uses the Protocol Deviation (DEV0001) eCRF to capture protocol deviations. For more information, see “2008” (page 8).

eCRFs

IMPAACT P1108 Electrocardiogram Results (DGW0112) is used to document ECG performance,

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P1108 (continued)

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transmission to Quintiles, and site interpretation. Where prompted to select a visit description, choose the correct visit from the drop-down menu. Enter a new log line for each ECG performed; three are expected.

For IMPAACT P1108 Lactate-Pyruvate Ratio Results (LBW0160), record Lactate-Pyruvate ratio results obtained from ARUP. Local lactate will instead be recorded on the Chemistries eCRF.

On the IMPAACT P1108 Historical Microbiology (LBW0162) eCRF, document tuberculosis (TB) microbiology results from specimens collected before entering the study. Submit one eCRF per specimen. Complete one for the participant and another for any known adult MDR-TB source case(s) if the participant is bacteriologically negative at screening (i.e. the MDR-TB diagnosis was made clinically).

TB results related to specimens collected on-study should instead be collected on IMPAACT P1108 TB Microbiology for Study Specimens (LBW0163). Again, submit one eCRF per specimen.

IMPAACT P1108 Pharmacokinetics - Sparse (PKW0403) is collected at most study visits; IMPAACT P1108 Pharmacokinetics - Intensive (PKW0404) is collected at Week 2. Prior to the Week 2 visit, site staff should make expectations for the evaluation clear. Refer to the P1108 Manual of Procedures for guidance on the difference between a full meal and a light snack for the food intake record. During this evaluation, dosing of Bedaquiline (BDQ) should be directly observed.

For IMPAACT P1108 Treatment Record (TXW0308), Bedaquiline is hard-coded into the first log line. Add log lines as needed to capture additional medications in a background regimen.

Chest X-Rays

To submit CXR data, use the File Exchange Utility on the Portal. Upload the appropriate file and enter all required data for the file. Be sure to complete a Chest X-Ray Evaluation (TBW0095) and to update it as needed to reflect file uploads to the File Exchange Utility.

REPRIEVE DM Training: OpenClinica Overview

REPRIEVE (ACTG study A5332) is conducted in *OpenClinica* and has a Mechanistic Substudy (A5333S) the PREPARE substudy (A5361S).

Screening and Enrollment

When screening potential participants, be aware that you will need to complete Screening Outcome (SCR0034) upon successful enrollment, screening failure, or expiration of the screening number at 90 days.

When enrolling participants, use the most recent version of the protocol that you are IRB-approved to use. When you complete the Enrollment Checklist, pay special attention to the substudy enrollment order. Participants enrolling in both substudies must be enrolled in A5333S before enrolling in A5361S.

Changing or Deleting Data

To change a single data point for a single participant on one form, follow the “Changing Previously Saved Data” video in the REPRIEVE Training Videos section of the Portal. If you need to have an entire form deleted, contact reprieve.dmc@fstrf.org and ask for the form to be deleted.

Premature Discontinuation

For A5332, If the participant is continuing on study but will discontinue study medication permanently, complete Premature Study Medication Discontinuation. If the participant is being taken off study, complete Premature Study Discontinuation. If these occur at a scheduled visit (M1-M72), complete the appropriate Premature Discontinuation visit in place of the scheduled visit. See Section 8 of the protocol for more information about discontinuations.

For A5333S, if the participant completes the Month 24 assessment, also complete Off Study (RP0001) in the A5333S PRN visit. If the participant discontinues A5333S prior to the Month 24 assessment, complete the Premature Study Discontinuation visit and the Off Study (RP0001) eCRF in the A5333S PRN visit.

A5361S Schedule

The A5361 schedule is tied to the schedule for A5332 and A5333S. Month 12 and Month 24 always synchronize, regardless of when the participant enrolled to the substudy.

	A5332/A5333S	A5361S
Participant enrolls into A5332, A533S, and A5361S simultaneously	A5332/A5333S Entry	A5361S Entry
	A5332/A5333S M12	A5361S M12
	A5332/A5333S M24	A5361S M24
Participant enrolls into A5361S at A5332 M1, M4, or M8	A5332/A5333S Entry	A5361S Entry
	A5332 M1/4/8	A5361S M12
	A5332/A5333S M24	A5361S M24
Participant enrolls into A5361S at A5332 M12	A5332/A5333S Entry	A5361S Entry and M12
	A5332/A5333S M12	A5361S M24
	A5332/A5333S M24	A5361S M24
Participant enrolls into A5361S at A5332 M16 or M20	A5332/A5333S Entry	Mark A5361S M12 as skipped
	A5332/A5333S M12	A5361S Entry
	A5332 M16/20	A5361 M24
	A5332/A5333S M24	A5361 M24
Participant enrolls into A5361S at A5332 M24	A5332/A5333S Entry	Mark A5361S M12 as skipped
	A5332/A5333S M12	A5361 Entry and M24
	A5332/A5333S M24	A5361 Entry and M24

Form Versions

Some updated forms are tied to specific criteria in a Letter of Amendment. The previous versions are available for sites that have not yet received IRB approval.

Quash a Query

Combination drugs and drugs taken in combination

Combination drugs are those that are combined into one pill and should be recorded on one line.

Example: A participant is taking the combination medication Emtricitabine/Tenofovir (Truvada) as a single pill. Record Truvada as drug description on the CRF.

Specify Drug [70]	Status ¹	Route ²	Drug Formulation ³	Date Started/Date Stopped (dd/mmm/yyyy)
a. TRUVADA	5	0 3	1 1	2 8 FEB 2014 2 6 JUN 2014

Medications that are given in a combination regimen—even if they are provided in a blister pack together—should be recorded on separate lines.

Example: A participant is taking Tenolam and Nevirapine as separate pills. Record each of these on separate lines on the CRF. DO NOT record as Tenolam/Nevirapine on the same line.

Specify Drug [70]	Status ¹	Route ²	Drug Formulation ³	Date Started/Date Stopped (dd/mmm/yyyy)
a. NEVIRAPINE	5	0 3	1 1	2 9 AUG 2014 3 0 JAN 2015
b. TENOLAM	5	0 3	1 1	2 9 AUG 2014 3 0 JAN 2015

Responding to Queries

All queries require responses; however, not all responses are created equal. Insufficient responses may affect your monthly Site Data Management Report.

Do:

- Provide specific information from source documentation that confirms or clarifies your data
- Indicate if you will correct your data based on a query
- Confirm any additional forms that need to be submitted or adjusted as a result of a query
- Adhere to the two-week response time.

Don't:

- Respond saying that you will reply later
- Respond saying that you are not sure, but you are checking into the query
- Respond saying that the person who normally responds is on vacation



CONTACT INFORMATION

Contact information for DMC staff for specific protocols can be found on the DMC Portal (<http://www.fstrf.org/portal>) under Site Support > DMC Contacts > ACTG or IMPAACT Data Managers and Laboratory Data Managers by Study.

REMINDER: DATA CORRECTION FORMS

When you receive a data correction form, be sure to sign and return it as soon as possible. It's important for the Data Management Center to have your approval before moving forward with data corrections.



Site Operations Subcommittee (SOS)



Mentoring Program for Study Coordinators and Data Managers

The purpose and goal of the SOS Mentoring Program is to provide support to new ACTG Study Coordinators and Data Managers that are assuming the functions and responsibilities of their positions. The program provides advice and guidance from ACTG staff experienced with conducting and/or managing clinical trials. To learn more about the mentoring program visit the ACTG website- <https://member.actgnetwork.org/netcom/comm/35#profile=2>.

We are seeking volunteers to become mentors in our program. If you would like to be a mentor complete the Study Coordinator or Data Manager **Mentor Information form**.

If you are a new study coordinator or data manager and you would like to request a mentor, complete the **Mentor Request form**.

All documents for the Mentoring Program can be found on the SOS webpage of the ACTG website (via the link above -> Site Operations SC -> Documents -> Mentoring Forms).

Instructions of how to submit the forms will be on the ACTG webpage also. If you have any questions about the program, please contact us at actg.sos@fstrf.org.

ACTG STUDY COORDINATORS AND DATA MANAGERS MENTORING PROGRAM

The Site Operations Sub-committee (SOS) would like to broadcast the AIDS Clinical Trials Group (ACTG) Study Coordinators and Data Managers Mentoring Program. This program provides support to new ACTG Study Coordinators and Data Managers by pairing them with an ACTG Study Coordinator or Data Manager who is experienced with conducting and/or managing clinical trials. The goal of this program is to provide advice and guidance to new Study Coordinators and Data Managers while they are assuming the functions and responsibilities of their positions. The SOS committee will need experienced Study Coordinators and Data Managers willing to be mentors and would welcome requests for mentors from new Study Coordinators and Data Managers. To get started, please email us at actg.sos@fstrf.org.

SUBMIT AN ARTICLE TO THE DMC NEWSLINE

The DMC Newsline encourages readers to submit articles, news releases, and event listings. Materials submitted are subject to editorial review. Please email information in Microsoft® Office Word format to the Editor, Mary Wojcik-Cross, at wojcik@fstrf.org.

MARK YOUR CALENDARS

FOR 2017

Data Management Beyond the Basics Workshop

September 14-15

Data Management Introductory Workshops

November 1-3

CONTACT

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ACTG and IMPAACT

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JANUARY

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

FEBRUARY

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APRIL

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MAY

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JUNE

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JULY

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23	24	25	26	27	28	29
30	31					

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SEPTEMBER

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17	18	19	20	21	22	23
24	25	26	27	28	29	30

OCTOBER

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22	23	24	25	26	27	28
29	30	31				

NOVEMBER

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19	20	21	22	23	24	25
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DECEMBER

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17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Electronic Signatures in *Rave*

Electronic signatures are now being required to comply with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. As of October 1, for ACTG and IMPAACT, this means applying an electronic signature in *Rave*.

Remember, your electronic signature indicates that you verify the information entered on the eCRF is correct. Only sign an eCRF when you are satisfied that this is true.*

Who Is Authorized to Sign an eCRF?

To be authorized to sign eCRFs, investigators must meet three criteria:

- Must be listed on FDA Form 1572 for the site (sections 1 and 8) or DAIDS Investigator of Record agreement.
- Must be a clinician, such as a medical doctor or nurse.**
- Must make a “direct and significant contribution to the data,” which means he or she has direct responsibility for treating or evaluating research participants.

How Do I Sign an eCRF?

Log into *iMedidata* and select the *Rave* link for the desired study. If you have multiple roles in the system, select the “Investigator—IVRS” role. Access eCRFs requiring signature via the Task Summary. At the study level, select the right-pointing arrow for “Requiring Signature” to show sites with eCRFs to sign. At the site level, clicking this arrow shows subjects; at the subject level, it shows the eCRFs themselves.

Select the eCRF from the Task Summary. The eCRF displays. At the bottom of the screen, select *Sign and Save*.

You will be asked to enter your username and password to verify that the information entered on the eCRF is correct.

When and How Do I Sign a Batch of eCRFs?

Signatures will be expected at specific protocol milestones, generally corresponding to a data lock or freeze. You can apply signatures in a batch for each participant; you cannot apply them on the site level. The DMC will notify sites when a study milestone is met and the investigator needs to sign.

In *Rave*, navigate to the subject level. There, you can sign for all eCRFs collected at one visit, one eCRF collected at multiple visits, or all eCRFs at once.

In the upper right-hand corner, select the *Grid View* link. In Grid View, you may select a folder (visit) by clicking a column header, select an eCRF by clicking a row header, or select “All.” Selected cells will be highlighted. Next, click *Sign and Save* and enter your credentials.

Sign and Save							
✓ All	AG0006	Screening	Entry (1)	Week 1 (1)	Week 2 (1)	Eligibility Checklist (1)	✓ All
Participant Enrollment							Participant Enrollment
Visit Tracking							Visit Tracking
Vital Signs							Vital Signs

You can also sign all eCRFs at once in Calendar View. Under the table of visits and dates, you will see “For all applicable Forms sign below” and a *Sign and Save* button. Click this button and enter your credentials.

* You can sign eCRFs with outstanding queries or non-conformant data, but modifying the data to correct the error requires a new electronic signature.

** Limited exceptions for certain studies (i.e. behavioral studies) where there may not be a medical doctor on site.