Data Management Center
NEWSLINE

NETWORK MEETINGS

The DMC will host Demo Rooms during the upcoming ACTG and IMPAACT Network Meetings to provide training on *Medidata Rave* and *TJoin*, as well as eCRF and questionnaire refresher information for various protocols. In addition, the proposed new site data management metrics for Rave will be outlined.

The IMPAACT Demo Room will run from June 18 – June 19. Presentations will focus on use of the *Task Summary* and *Reporter* modules for quality assurance, as well as tips for keying data more efficiently. Trainers will also demonstrate the use of *TJoin* for both legacy systems and *Rave*, and *JReview*, a tool for creating customized reports in *Rave*. Refresher eCRF trainings and Q&A sessions will be held for the following protocols: 2008, 2009, 2010, Cohort 2, and 2015.

In addition to *Medidata Rave* quality assurance sessions listed above, the ACTG Demo Room will offer training on the *Subject Enrollment System*, *TJoin*, REPRIEVE: *OpenClinica* and Adjudicated Events, and protocol tips for A5359 and A5360. The ACTG Demo Room will run June 20 – 21.

Session schedules and descriptions can be found on the next two pages. Sessions are open to all attendees, regardless of network.

INSIDE THIS ISSUE

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.

frontier
science foundation

2018 IMPAACT Demo Room

Monday, 18 June	
8:00 a.m.	Rave Metrics
9:00 a.m.	Rave Overview
10:00 a.m.	Daily QA in Rave
11:00 a.m.	2009 Refresher Training / Q&A
12:00 p.m.	Walk-in Assistance
1:00 p.m.	JReview
2:00 p.m.	TJoin
3:00 p.m.	2014 Cohort 2 Training
4:00 p.m.	Rave Reports

Tuesday, 19 June	
8:00 a.m.	JReview
9:00 a.m.	Rave Overview
10:00 a.m.	2015 Refresher Training / Q&A
11:00 a.m.	2010 Refresher Training / Q&A
12:00 p.m.	Walk-in Assistance
1:00 p.m.	TJoin
2:00 p.m.	Daily QA in Rave
3:00 p.m.	2008 Refresher Training / Q&A
4:00 p.m.	Rave Metrics

2008 Refresher Training / Q&A

Overview of IMPAACT 2008's most complicated eCRFs and other data management considerations.

2009 Refresher Training / Q&A

Review of the 2009 eCRFs and data collection forms schedules for sites newly enrolling into the study.

2010 Refresher Training / Q&A

Overview of IMPAACT 2010's most complicated eCRFs and other data management considerations.

2015 Refresher Training / Q&A

Overview of IMPAACT 2015's most complicated eCRFs and other data management considerations.

Daily QA in Rave

Learn about best practices and available tools for daily quality assurance in Medidata Rave.

Rave Overview

Learn how to enter data in Rave, how to use the Task Summary for quality assurance and control, and how to access resources for eCRF completion.

2014 Cohort 2 Training

Data Management Considerations and eCRF Overview for Cohort 2.

TJoin

Understand the basics of using the web-based TJoin program to retrieve your site's data and create customized reports.

Rave Reports

Learn to use Medidata Rave Reporter to keep track of queries, sticky notes, and to access completed forms.

Walk-in Assistance

Do you have a question about data management? Meet with a training team member to discuss your question or issue. All questions are welcome!

Rave Metrics

Overview of the proposed new site data management system scoring for Rave.

JReview

Overview of specialized functions of Rave's built-in JReview module for creating customized site data reports.

2018 ACTG Demo Room

Wednesday, 20 June	
8:00 a.m.	Rave Metrics
9:00 a.m.	Rave Overview
10:00 a.m.	Daily QA in Rave
11:00 a.m.	Subject Enrollment System
12:00 p.m.	Rave Reports
1:00 p.m.	TJoin
2:00 p.m.	OpenClinica for REPRIEVE
3:00 p.m.	A5360 Protocol Tips
4:00 p.m.	A5359 Questionnaires & Misc

Thursday, 21 June	
10:00 a.m.	Rave Metrics
11:00 a.m.	REPRIEVE Adjudicated Events Overview
12:00 p.m.	TJoin
1:00 p.m.	Closed
2:00 p.m.	
3:30 p.m.	Rave/Subject Enrollment System for Clinical Trial Specialists (3:30 – 5:30 p.m.)

Rave Metrics

Overview of the proposed new site data management system scoring for Rave.

Rave Reports

Learn to use Medidata Rave Reporter to keep track of queries, sticky notes, and to access completed forms.

OpenClinica for REPRIEVE

Overview of REPRIEVE and how the OpenClinica CTDMS is used in this protocol.

REPRIEVE Adjudicated Events Overview

Overview of the adjudication event process for A5332 REPRIEVE.

Daily QA in Rave

Learn about best practices and available tools for daily quality assurance in Medidata Rave.

Rave/SES for Clinical Trial Specialists

Rave Overview and Subject Enrollment System refresher for the Clinical Trials Specialist.

Subject Enrollment System

Overview of the Subject Enrollment System.

TJoin

Understand the basics of using the web-based TJoin program to retrieve your site's data and create customized reports.

A5360 Protocol Tips

Overview of A5360 with tips for how to anticipate and solve common problems.

Rave Overview

Learn how to enter data in Rave, how to use the Task Summary for quality assurance and control, and how to access resources for eCRF completion.

A5359 Questionnaires & Misc

Overview of the questionnaires used in A5359 and other data management considerations.

Double-Check Eligibility Checklist Responses

The DMC has seen many sites reporting errors for eligibility data. To ensure eligibility data integrity and avoid enrollment of ineligible participants, it is best practice to thoroughly review the answers to the Eligibility Checklist prior to enrollment. As nearly all Eligibility Checklist responses are reviewed by site monitors, by checking this data prior to submission you will also avoid monitoring findings. If you discover an error in an Eligibility Checklist that was submitted to the DMC, you will need to complete an Eligibility Correction Request. This request form is available under the Utilities category on the FSTRF Portal and allows for the modification of question responses, by entry of the Question Number, Original Value, New Value, Reason (for change), and whether Skip Logic will be affected by the correction.

Utilities
A5288 ARV Cohort Selection
DataView
Deconsent Utility
Eligibility Correction Request

All fields are required.

Study: [ ]
Patid: [ ]
Step: [ ]

Add Row

Question number	Original value	New value	Reason	Skip logic affected by correction?
[ ]	[ ]	[ ]	[ ]	☐

Submit   Reset

Once you've submitted the Eligibility Correction Request, an email is automatically sent to the primary protocol data manager (PDM). Depending on the request, the protocol team may need to be involved. For example, if stratification or treatment are involved, or if in fact the participant is not eligible. The PDM completes the Data Correction Request Form and sends it back to the site for review, signature, and date. Once the PDM receives the completed form signed by your site, the changes can be completed in the central database, and if needed, *Medidata Rave*. Please do your best to avoid these types of errors by double checking your Eligibility Checklist responses prior to submission to the DMC.

Common Eligibility Checklist Errors are noted below. Did you double check the following?
⇒ Birth Date
⇒ Dates of Test Results
⇒ RNA results

Viewing Log Lines in Rave

By default, *Rave* displays 20 lines per page on the screen. With this default, the column header of a log form will be viewable on the screen at all times, but there is the potential of multiple pages requiring responses. If this is the case, you will see Paginate at the lower right portion of the form, along with numbered links to the additional pages. If you desire to see all log lines on one page, you can select Show All Lines from the selection box in the lower right side of the log form.

Paginate   ⌄   1 2
Paginate
Show All Lines

As an alternative, you can increase the number of lines per page setting in My Profile:

🅘 iMedidata   ✉ Messages   🔳 My Profile   ❓ Help   🏠 Home   🗗 Logout

- Click My Profile at the top right of the screen
- Click Edit in the My Profile section
- Select 50+ Lines Per Page
- Click Save

My Profile
Lines Per Page: 20
      → ✎ Edit

My Profile
Lines Per Page: 50 ⌄
      → ✓ Save ✗ Cancel

Employee Spotlight: Christina (Tia) Reding

What is your job title?

IMPAACT Protocol Data Manager.

Where are you from?

I was born and raised in Buffalo, NY.

What is your education?

I have a B.S. in Natural Science and Health Science, as well as an MPH in Epidemiology with a focus on global infectious diseases from Daemen College.

How long have your worked at Frontier Science?

It will be two years in July.

What does a typical day for you at Frontier Science look like?

As a Protocol Data Manager, I interact with multiple departments within Frontier Science on a daily basis that may include Database Operations, Study Builders, SDTM Specialists, Lab Data Managers, etc. This is great because it provides the opportunity to understand that carrying out clinical trials is a group effort with many moving parts that all contribute to the end goal. On any given day, I can go from discussing protocol progress with statisticians and study chairs to talking with site staff across the world regarding data collection. It's wonderful to be able to participate in so many aspects of what is necessary for the successful execution of clinical trials.

What is your favorite part about working at Frontier Science?

I love the people I work with at Frontier Science. We have such knowledgeable and helpful staff whose contributions make anything possible. I also truly enjoy interacting with the site staff involved in my studies. It's great to know that you are working together with people around the world towards a common goal.

What was your greatest work-related accomplishment of the past year?

This May I was provided the opportunity to travel to Africa and conduct Regional Training at two network sites: Blantyre, Malawi and Johannesburg, South Africa. It was amazing to be able to meet clinical research site staff and put a face to some of the names that I interact with on a daily basis!

What are your passions/interests outside of the workplace?

I am a huge animal, nature, and travel lover! My personal "zoo" currently consists of a dog, a cat, two sugar gliders, and two horses. I also love traveling at any opportunity I get. I find experiencing other landscapes and ways of life to be enriching and rewarding.

What is the best part of your job?

As someone who has studied public health, being able to contribute to clinical trials that are advancing HIV/AIDS treatment and prevention strategies and improving the lives of those who are at risk or affected by HIV/AIDS is extremely rewarding.

One thing that people would be surprised to know about me:

I ride horses both recreationally and competitively as a hunter-jumper. I've been taking riding lessons since I was 7 years old and have taken both of my horses to competitive horse shows around the U.S. I hope to one day have my own horse barn.
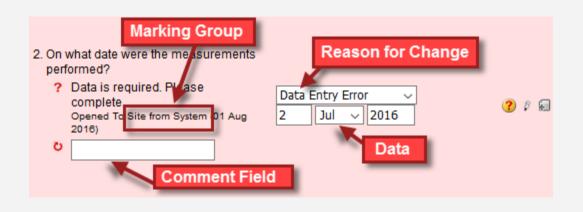
What was the last book you read?

A travel book for South Africa in preparation of my trip to Africa for Regional DMC Training.

Resolving Queries in Rave

In *Rave*, queries appear in the Task Summary with a question mark icon and are highlighted on eCRFs in pink or red. A query may indicate an error in the eCRF data that need to be corrected, but in some cases, the queried data are correct.

Queries can include both automated data checks (labeled "Site from System") and questions sent by data managers or coders ("Site from DM" or "Site from Coder"). These categories of query are called *marking groups.* To decide how to resolve a query, first look at the marking group.

When should I enter a comment in response to a query in Rave?

For **Site from System** queries:

- If the data entered in *Rave* are <u>incorrect</u>, correct the data field in question. Complete the drop-down menu indicating the reason for change. DO NOT enter a comment OR a data change in the comment field.
- If the data entered are <u>correct</u>, complete the comment field explaining why. DO NOT enter data changes here.

For **Site from DM** and **Site from Coder** queries:

- If the data entered in *Rave* are <u>incorrect</u>, correct the data field in question. Complete the drop-down menu indicating reason for change. Enter a comment in the comment field explaining the change. This is important to capture for the Audit Trail. DO NOT enter data changes here.
- If the data entered are <u>correct</u>, complete the comment field explaining why. DO NOT enter data changes here.

Remember: You may receive multiple queries from the site throughout the day, so keep your eye on the Task Summary! The DMC may also re-query you on the same item.

JANUARY

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MARK YOUR CALENDARS
FOR 2018

IMPAACT Network Meeting
June 16-19

ACTG Network Meeting
June 20-24

Data Management Introductory Workshops
October 17-19

Webinar Series
See DMC Portal Training Pages for schedule

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