Data Management Center
NEWSLINE

Demonstration Rooms at Network Meetings

The Data Management Center will host Demonstration Rooms during the upcoming ACTG and IMPAACT Network Meetings to provide training on Medidata Rave and TJoin, as well as refresher information for site data management metrics for Rave and various protocols. An assistance desk will also be staffed during the plenary session hours to field site data management questions.

The IMPAACT Demonstration Room will run from June 12–June 13. Presentations will focus on use of the Task Summary and Reporter modules for quality assurance, tips for keying data more efficiently, and rolling data freeze. Trainers will demonstrate the use of TJoin and JReview (a tool for creating customized reports in Rave). Refresher eCRF trainings and Q&A sessions will be held for the following protocols: PHOENix, 2009, 2010, 2016, and 2017.

In addition to the Medidata Rave quality assurance and site data management metrics for Rave sessions listed above, the ACTG Demonstration Room will offer a REPRIEVE Review and protocol tips for A5369 and A5375. The ACTG Demonstration Room will run June 18-19.

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

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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 (wojcik@frontierscience.org).

Data Management Center Demo Room

Wednesday, 12 June

12:00 p.m.   Assistance Desk (until 5:15pm)

Thursday, 13 June

8:00 a.m.   PHOENIx

9:00 a.m.   QA in Rave

9:30 a.m.   Rolling Data Freeze for 2019

10:00 a.m.   2010 Submission & Common Errors

11:00 a.m.   Rave Reports

12:00 p.m.   2016

1:00 p.m.   Rave Metrics

2:00 p.m.   2009

3:00 p.m.   JReview and TJoin

4:00 p.m.   2017

JReview & TJoin

Understand the basics of using the web-based TJoin program to retrieve your site's data and create customized reports, as well as specialized functions of Rave's built-in JReview module for creating customized site data reports.

2009

Review of common site questions and a chance to ask the data managers your questions.

2016

General overview and demonstration of CASI (Computer Assisted Self Interview) appearance and functionality for study questionnaires.

QA in Rave

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

Assistance Desk

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 Reports

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

Rave Metrics

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

PHOENIx

Demonstration of visit rollouts, TB forms completion, and time for live demo in Rave.

2017

Overview of IMPAACT 2017's most complicated eCRFs and participant log forms.

2010 Submission & Common Errors

Overview of common errors and preparations for upcoming data submission.

Rolling Data Freeze for 2019

Learn about how data will be reviewed and subsequently verified by site monitors, then periodically frozen for IMPAACT 2019. This new pilot, conducted with DAIDS, will integrate site, SDMC, and monitoring activities.

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IMPAACT
International Maternal Pediatric Adolescent AIDS Clinical Trials Group

Data Management Center Demo Room

Tuesday, 18 June

8:00 a.m.	Assistance Desk (until 12:00 p.m.)
1:00 p.m.	Rave Metrics
2:00 p.m.	QA in Rave
2:30 p.m.	Rolling Data Freeze for A5377
3:00 p.m.	Rave Reports
4:00 p.m.	TJoin

Wednesday, 19 June

9:00 a.m.	Rave Metrics
10:00 a.m.	Rave Overview
11:00 a.m.	REPRIEVE Review
12:00 p.m.	A5369 / Q & A
1:00 p.m.	QA in Rave
2:00 pm.	Rave Reports
3:00 p.m.	A5375
4:00 p.m.	TJoin

Assistance Desk

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 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.

A5369 / Q & A

Overview of visit rollout and eCRF completion.

TJoin

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

REPRIEVE Review

Review of upcoming changes to data capture requirements for participants in follow-up.

Rave Reports

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

Rave Metrics

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

A5375

Overview of the eCRFs for A5375.

QA in Rave

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

Rolling Data Freeze for A5377

Learn about how data will be reviewed and subsequently verified by site monitors, then periodically frozen for ACTG A5377. This new pilot, conducted with DAIDS, will integrate site, SDMC, and monitoring activities.

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ACTG AIDS CLINICAL TRIALS GROUP

Rave Metrics Overview

Monthly site evaluation report generation dates are posted on the Frontier Science Portal so sites can prepare and key eCRFs accordingly. IMPAACT reports can be expected on the first Tuesday of each month and ACTG reports on the first Thursday, although there are some exceptions. The established metrics are outlined below.

Error Responsiveness – This metric assesses site responsiveness to Site from System queries (errors). These are queries automatically triggered on the eCRF in pink/red, immediately after saving/submitting the record. The expectation is that Site from System queries (errors) will be answered within 3 days, 95% of the time.

This metric is calculated by the following equation:
$$\frac{Number\ of\ Errors\ Answered\ Within\ 3\ Days}{Total\ Number\ of\ Errors}$$

Based on reviewing data over a period of several months, the majority of errors were addressed by site staff within 3 calendar days. A separate error rate will no longer be calculated for Rave data.

Query Responsiveness – This metric assesses site responsiveness to Site from DM and Site from Coder queries. These are queries manually entered by DMC staff after review of the submitted data. The expectation is that Site from DM and Site from Coder queries will be answered within 2 weeks, 90% of the time.

This metric is calculated by the following equation:
$$\frac{Number\ of\ Queries\ Responded\ to\ Within\ 2\ Weeks}{Total\ Number\ of\ Queries}$$

The Query Responsiveness metric is unchanged from the Query Responsiveness metric from the eData Site Data Management report.

Data Completeness – This metric assesses the current form status of Rave eCRFs that are not marked as overdue. The expectation is that the percent of forms entered will be 95% or higher.

This metric is calculated by the following equation:
$$\frac{Number\ of\ eCRFs\ Entered}{Total\ Number\ of\ eCRFs\ Entered + Overdue}$$

ACTG Data Timeliness – This metric assesses the amount of time to key eCRFs based on the participant's visit date. The expectation is that visit tracking and study event tracking eCRFs will be keyed within 21 days, 90% of the time. These forms are designated as key forms since they control how the full set of eCRFs are rolled out dynamically in Rave for a study visit.

This metric is calculated by the following equation:
$$\frac{Number\ of\ Key\ eCRFs\ Entered\ Within\ 21\ Days}{Total\ Number\ of\ Key\ eCRFs}$$

IMPAACT Data Timeliness – This metric assesses the amount of time to key eCRFs based on the participant's visit date. The expectation is that visit tracking and study event tracking eCRFs will be keyed within 14 days, 90% of the time. These forms are designated as key forms since they control how the full set of eCRFs are rolled out dynamically in Rave for a study visit.

This metric is calculated by the following equation:
$$\frac{Number\ of\ Key\ eCRFs\ Entered\ Within\ 14\ Days}{Total\ Number\ of\ Key\ eCRFs}$$

Regulatory – This metric assesses monthly data received from DAIDS regarding the timeliness of Serious Adverse Event (SAE) submission. SAEs must be reported to DAIDS within 3 days. This metric differs from other data management metrics in that it includes all studies in Rave and eData and spans the previous 12 months. A site is categorized as either *Meets Standard* (<100%) or *Does Not Meet Standard* (100%).

In addition to the metrics described above, ACTG studies have a **Retention** metric that assesses the percentage of participants retained on study. Only data for the current grant year are reported for this category.

For general questions regarding the Rave metrics, please contact:

　　ACTG: ACTG.SITEDATAMGMTRPT.QUESTIONS@fstrf.org

　　IMPAACT: IMPAACT.SITEDATAMGMTRPT.QUESTIONS@fstrf.org

ACTG Site Laboratory Evaluation Reports Pilot

The Data Management Center pilot of the monthly evaluation reports for each ACTG Site Processing Laboratory has been underway for the past several months. The evaluation metrics are listed below, followed by a brief description and target for each metric. Please note that recent metric updates are highlighted in italics.

Query Responsiveness – The percentage of queries <u>responded to</u> within 14 days of receipt. The metric target is 90%.

LDMS Export Timeliness – The percentage of 7-day intervals that Windows LDMS laboratories have exported at least once. The metric target is 80%. *Web LDMS laboratories are not evaluated by this metric.*

PBMC Shipping Storage Compliance – The percentage of PBMCs shipped to the ACTG Biorepository or stored on LN2 within 5 weeks of collection. The metric target is 95%. *This metric now excludes specimens that never existed, such as specimens with the following condition codes: SNC (Sample Not Collected), SNP (Sample Not Processed), or QNS (Quantity Not Sufficient).*

Percent Shipped to the Repository – The percentage of specimens older than 6 months shipped to the ACTG Biorepository. The metric target is 95%. *This metric excludes specimens shipped back to the laboratory from the repository, have a test assigned to them or are testing remnants (with an appropriate condition code), as well as specimens from archived studies and specimens expected to be stored on site until requested to ship per a protocol's Lab Processing Chart. The following derivatives are also excluded from this evaluation:*

> *LDMS Derivative Code: Description*
> *CCC: Cryopreserved Cells from a Culture, Viable*
> *CDP: Dry Pellet from a Culture, Non-Viable*
> *MCS: Microbiology Culture Slant*
> *PCC: Culture Supernatant and Cells*
> *PLP: Supernatant & Cells from a Quantitative Culture*
> *SPQ: Supernatant from a Quantitative Culture*
> *STK: Quantitative Culture Held beyond 14 Days*
> *SUP: Culture Supernatant*
> *MTB: MTB Isolates*

Shipment Evaluation Score – The shipment evaluation score as evaluated by the ACTG Biorepository at BRI. The metric target is 90. *This metric includes specimens from studies intended for archive that were <u>already</u> shipped by the laboratory, so laboratories will get credit for what they previously were expected to ship.*

Please note, each of these metrics are now project-specific. Laboratories and sites affiliated with both ACTG and IMPAACT projects will get separate reports that evaluate records, shipments and queries for the project in question only. The project is indicated in the email that is sent with the report.

The monthly evaluation report received by the laboratory will indicate a green check or red X to indicate whether the laboratory met the metric target.

Target to meet: 80 %	Target to meet: 90 %
meets target ✔	does not meet target ✖

New Appendices:
The report has been recently updated to include Appendices that list records for each metric where the target was not met with 100% completeness, and displays all records or instances where the target was not met. This may, for example, display a date range for which LDMS exports were not made as expected, or will display a list of queries that were not responded to within the 14 days of receipt.

If you have any questions regarding these reports, please contact the Frontier Science Laboratory Data Division at fstrf.labdiv@fstrf.org for assistance.

ACTG and IMPAACT Specialty Laboratory Evaluation Reports

ACTG and IMPAACT specialty testing laboratories are now receiving monthly reports for the Query Responsiveness and Export Timeliness metrics through the new Evaluation Reports system. These metrics were previously sent to specialty laboratories on a quarterly basis. Assay data submission timeliness reports will continue to be sent on their original quarterly schedules.

LDMS Assistance Desk at Network Meetings

The LDMS Training Team will host an Assistance Desk at the upcoming IMPAACT and ACTG Network Meetings. Trainers will be available to offer quick software demonstrations and to answer your questions.

The desk will be staffed from 8am to 4pm on the following dates:

IMPAACT: June 12th & 13th

ACTG: June 19th & 20th

LDMS Training

Two remaining 2019 Introductory Workshops are scheduled to take place at the Frontier Science office in Amherst, New York:

- **Friday, August 9th**
- **Friday, November 8th**

The one-day training will cover the use of the LDMS web platform. The training will include a full demonstration of all functions within the web application, with a hands-on component for participants.

Ad hoc training requests to fit your laboratory's needs are also welcome. Training requests can be submitted via the LDMS website:

https://www.ldms.org/training/

TRAINING ▾

Training

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LDMS End-User Validation

As part of the development of the LDMS software, Frontier Science performs validation to ensure the software is functioning as intended. The suite of documents recording this process is maintained by Frontier Science and is available to laboratories when requested. However, the validation process does not end there. It is the responsibility of the lab to perform its own validation to confirm the software functions as intended within the end user's environment.

Frontier Science has created a suite of templates to assist our laboratories with creating and maintaining end-user validation documentation for the LDMS. Developer and end-user documentation packets, as well as a training presentation on this topic, can be requested from the LDMS website:

https://www.ldms.org/resources/validation/

A recent training presentation on this topic is available via the URL provided above, while a recorded webinar can be viewed on the Frontier Science YouTube channel: FSTRFfilms.

Laboratory Query System

The Query System, a secure communication tool for resolving laboratory queries for ACTG, IMPAACT, REPRIEVE, and VQA, is available on the Frontier Science Portal.

Each time your laboratory has a query requiring a response, you will receive an email notification containing a link to the Query System. To view and respond to queries, click the link contained in the email notification or the Query System link that is available on the Frontier Science Portal (www.frontierscience.org/portal).

Systems
Data Submission System (DSS)
Order Entry Program
Query System ⬅
Resolve
Subject Enrollment
eData Distributions

Access the Query System via the project tab(s) for which your laboratory has a query. Queries with a status of "New" or "Responded Data Center" require your investigation and response. Repeat the process on each project tab for which your laboratory performs work and has a query. Laboratories are reminded to resolve (as much as possible) and respond to queries within 2 weeks (1 week for VQA queries).

When responding to a query, please be sure to address the highlighted issue. Invalid responses, such as "*I am working on it*" or "*We will investigate and get back to you*" are not necessary and are discouraged. Such invalid responses will not be counted when response times are evaluated. Please keep in mind that laboratories are evaluated on their response time and not on resolution time.

To register for a Frontier Science Portal account, visit www.frontierscience.org/register. To be added as a query recipient for your laboratory to receive Query System notifications, or to modify your laboratory contacts that will receive these notifications, visit www.frontierscience.org/portal and click on the Submit Contact Changes link. If you are not receiving notifications from the automated query system, please check your spam email folder. To ensure delivery of query email notifications, add qryadmin@fstrf.org to your email address book.

Within the Query System, laboratories can generate a report of their query responsiveness for each project for which work is performed and laboratory queries received:

- Click the Filter button.
- Enter criteria to limit/filter queries.
- Click Submit. The results of your Filter will then appear on the screen.
- Choose Export from the drop down menu. Click Submit.
- Choose a format for the report.

A user manual is available via the Help button in the upper right hand corner of the Query System. Please contact user.support@fstrf.org with any account or permissions questions.

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CONTACT INFORMATION

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

Employee Spotlight: Loren Wright-Whitson

What is your name and job title?

Loren Wright-Whitson, ACTG Protocol Data Manager.

Where are you from?

I grew up in Lockport, NY.

What is your education?

I have a B.B.A in Accounting, an M.B.A in Healthcare Administration, and an M.A. in Biological Sciences.

How long have you worked at Frontier Science?

I have been working at Frontier Science for a little over two years.

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

As a Protocol Data Manager, my daily schedule can include responding to site staff questions about data collection, discussing protocol progress on team calls, reviewing clinical data, sending out queries, and working across various Frontier Science departments to complete projects.

What is your favorite part about working at Frontier Science?

Everyone at Frontier Science is incredibly helpful! I really enjoy working with everyone to meet new challenges and objectives.

What changes have you seen over your years of working at Frontier Science?

Since I have started working at Frontier Science, the most prevalent change has been the transition of managing studies in *eData* to *Medidata Rave*.

How do you think things will change over the next five years in HIV/AIDS clinical trials?

I hope to see more clinical trials focused on the emerging challenge of addressing health needs of older adults living with HIV. I am also excited for clinical trials implementing the next generation HIV vaccines, as well as injectable ARV treatments.

It's the weekend. Where can we find you?

With my husband, at our horse farm!

What are your passions/interests outside of the workplace?

Outside of work, I enjoy spending time with my dogs, cats, and horses. I have been riding horses since I was a small child, and have shown all across the country at major competitions. I was nationally ranked at the age of 13, and have since enjoyed numerous opportunities to train under the guidance of Olympic showjumpers and World Cup competitors.

What is the best part of your job?

I find it truly rewarding to work with study teams and help implement clinical trials at sites around the world that aim to improve the quality of life of people living with HIV through new prevention and treatment strategies.

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

From 2009-2011, I was part of a national pipeline training program for the U.S. show jumping team.

What was the last book you read?

"My Own Country: A Doctor's Story of a Town and Its People in the Age of AIDS," by Abraham Verghese.

2019

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MARK YOUR CALENDARS

Data Management Introductory Workshop

October 23 -25, 2019

Regional Data Management Introductory Workshop (Moshi, Tanzania)

August 5-7, 2019

Webinar Series

See DMC Portal Training Pages for schedule

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ACTG and IMPAACT

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