

DATA MANAGEMENT CENTER NEWSLINE

Participant-Level Logs

In *Rave*, many data items that are being tracked throughout the course of a study are captured on participant-level log eCRFs that are not associated with a specific visit folder. Participant-level logs collect data such as adverse events, study treatment, and concomitant medications in a table format. On these eCRFs, sites make entries for items (such as events or drugs) when prompted, then update that entry or make new entries as needed.

You will receive a sticky note on the Study Event Tracking eCRF when a participant-level log needs to be updated. You can use the Sticky Note Report in the Reporter module as a to-do list to see which logs need to be updated.

When you make your first entry, you will complete a log line on the eCRF. Depending on how much information needs to be provided, the log may be a “portrait” or “landscape” log. Portrait logs are used when a lot of information needs to be provided per line. The questions appear as a list when you add the log line, and when you save, your answers appear as a row in the table. For a landscape log, you enter data directly in the table. When you have completed the necessary participant-level logs, acknowledge the sticky note.

At each visit, the Study Event Tracking eCRF will ask you whether any data items on these participant-level logs have changed. If so, you will receive a new sticky note reminding you to update the log.

When a data item concludes—for example, when the participant discontinues a medication—update the existing log line to indicate the end date. If the participant starts taking the same medication again, add a new log line.

When a data item changes—such as when an event changes grade—modify the existing log line to indicate when the event at the previous grade ended, then add a new log line to report the event at the new grade. **Do not** modify the existing log line to change diagnoses, grades, or doses.

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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.

Quash a Query

Writing It Out

When reporting drugs, it is important never to abbreviate drug names. Always spell them out fully.

Example: The participant is taking isoniazid. This medication is commonly reported on this study, and the data keyer would like to abbreviate it as “INH” on eCRFs. However, “INH” might also refer to inhibostamin, Inhibace, or even an inhalant.

Right:

# Medication [200]?	Primary disease indication?
1 isoniazid	Active TB

Wrong:

# Medication [200]?	Primary disease indication?
1 INH	Active TB

One Pill Per Line

Medications taken in combination can be tricky to report. A good rule of thumb is to report one pill per specify line.

Example: In addition to study drug, the participant is taking a background regimen of two antiretroviral pills: darunavir and a pill with combined atazanavir/ritonavir. Report each pill on its own line.

# Medication [200]?	Primary disease indication?	Secondary disease indication	Medication indication
1 darunavir	HIV	None of the above	Optimized background regimen
2 atazanavir/ritonavir	HIV	None of the above	Optimized background regimen

Specifying Tenofovir

For the drug Tenofovir, always specify the type (Tenofovir Disoproxil Fumarate or Tenofovir alafenamide) in the description.

Example: The clinic nurse reported that the participant’s antiretroviral regimen includes the drug Tenofovir. The data keyer followed up to confirm that the participant was taking Tenofovir alafenamide.

Right:

1. Treatment Name [200]?	2. Start date
Tenofovir alafenamide	12 Feb 2018

Wrong:

1. Treatment Name [200]?	2. Start date
Tenofovir	12 Feb 2018

If Tenofovir is reported as part of a combination medication (for example, a single pill containing a type of Tenofovir, emtricitabine, and rilpivirine), it is also necessary to specify which type of Tenofovir (for example, “Tenofovir Disoproxil Fumarate/emtricitabine/rilpivirine”).

LDMS Training Resources

The Laboratory Data Management System (LDMS) website (<https://www.ldms.org>) offers links to numerous training resources that can help familiarize laboratory staff with the LDMS. These resources include training events, documents, and YouTube videos.

On the Training menu, there is a schedule of upcoming workshops and webinars and a link to register for training. More information about the content and format of training events is also available through the Training menu.



On the Resources menu, users can access LDMS user manuals, general and project-specific documentation, training materials such as workbooks and quizzes, and LDMS video tutorials. Video tutorials include "Completing PBMC Processing Information," "Locating Specimens Not Stored," "Shipping for REPRIEVE," "Specimen Management for REPRIEVE," "Storage Management for REPRIEVE," and "Specimens Not in Storage Report." These tutorials are also on the Frontier Science YouTube channel: <https://www.youtube.com/user/FSTRFfilms>

Electronic Signatures in Rave

The DMC has implemented electronic signatures for all ACTG and IMPAACT *Rave* studies. The timing of signature, though, is important: site investigators should **not** sign off on eCRFs in *Rave* directly after the eCRFs are keyed. **Instead, they should wait for a notification to sign from the DMC.**



Complete



Requires Signature

Staff at your sites who are assigned the Clinical Research Coordinator - IVRS role in *Rave* will see the "Requires Signature" icon when an item (such as a visit, eCRF, or data field) is successfully completed for these studies. However, although these items will display in the task summary as requiring signature right after they are keyed, they are not yet ready to sign. First, the Protocol Data Managers at the DMC need to review the data and send any necessary queries; depending on the study, site monitors may also need to verify the data. Any data changes will break the signature, and the investigator will have to sign off again.

The DMC collects signatures at intervals throughout the course of the study (such as at interim analyses) and at study closure. Your DMC Protocol Data Manager will notify you when it is time to sign eCRFs.

ELIGIBILITY CRITERIA REMINDER

Prior to enrolling a participant with the Subject Enrollment System, you must always confirm the eligibility criteria for the protocol. It is easier (and much safer!) not to enroll a participant who is ineligible than to remove an enrollment after it is completed.

CONTACT INFORMATION

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



Employee Spotlight: Jenna Kearly

What is your name and job title?

Jenna Kearly, Medidata Project Lead.

Where are you from?

I was born in upper Michigan but grew up in Cheektowaga, NY.

What is your education?

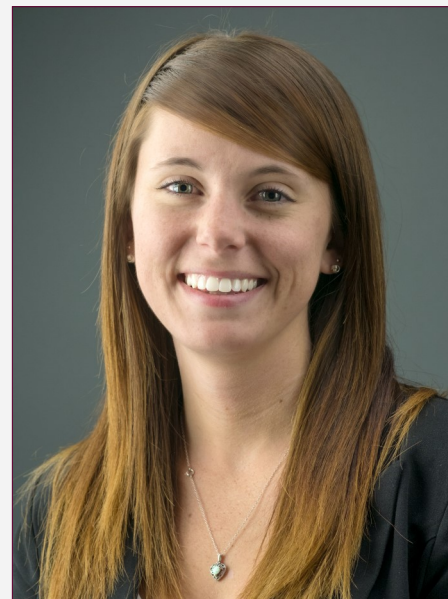
I have a B.S. in Pharmacology and Psychology, as well as an MPH in Epidemiology from the University at Buffalo.

How long have you worked at Frontier Science?

It will be four years in August.

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

I am typically in and out of meetings, coordinating efforts for new and conversion study builds in *Rave*, collaborating with PDMs, SDTM Specialists and Study Builders, and triaging questions from internal and external staff regarding Medidata *Rave* and the study build process.



Jenna Kearly, Medidata Project Lead.

What is your favorite part about working at Frontier Science?

Every day is different; it keeps things exciting, and I never get bored. I enjoy facing and overcoming new challenges, and the people that I work with make anything seem possible.

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

It was a little over a year ago, but becoming the Medidata Project Lead was a big accomplishment for me. I can't begin to explain how much I have learned and grown over the last year, and I continue to learn more every day.

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

I think that we will see an increase in trials focused on vaccines and prevention, while continuing work to reduce pill burden and side effects among those living with HIV/AIDS.

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

At the dog park with our English setter, Toby, or catching up on some housework. If the Buffalo Bills or Sabres are playing, though, that usually takes priority over the housework!

What are your passions/interests outside of the workplace?

I love to read; I attend a monthly brunch book club with some girlfriends. I enjoy cooking and trying out new recipes I find on Pinterest. I also love to travel and see new and exciting places.

What was the last book you read?

The Woman in Cabin 10 by Ruth Ware.

April DMC Introductory Workshop

A Data Management Introductory Workshop has been scheduled for the ACTG and IMPAACT networks on April 11-13, 2018 at the Data Management Center in Amherst, NY. This is a three-day, interactive workshop for coordinators, data managers, or clinical staff involved with data management.

Please note: Additional training for study-specific items can be added and the workshop extended for any participants wanting study-specific assistance. Those requests should be sent to Mary Wojcik-Cross (wojcik@fstrf.org) as soon as possible to make arrangements. A link to the full agenda, registration, and local hotel accommodations has been posted on the top center of the Frontier Science Portal website (www.frontierscience.org) on the ACTG and IMPAACT project tabs.



Attendees of the January DMC Introductory Workshop. **Back row:** Cale Reid (HANC), Will Smith (Emory University), Annalyn Reyes (De La Salle Health Science Inst.), Karina Tazca (Asociación Civil Impacta Salud y Educación), and Bruno Martel (Socios En Salud Sucursal). **Front Row:** Angela Nunez (Bronx-Lebanon Hospital), Charisma James (Bronx-Lebanon Hospital), Carolina Morán (Socios En Salud Sucursal), and Isabel Valverde (Socios En Salud Sucursal).

May Regional Introductory Workshop

Registration is now open for two May 2018 DMC Regional Introductory Workshops. One workshop will take place on May 21-22 in Blantyre, Malawi at the Blantyre CRS (locally known as the Johns Hopkins Research Project, and the other will take place on 24-25 May in Johannesburg, South Africa at Wits Helen Joseph CRS.

A link to the full agenda, registration, and local hotel accommodations has been posted on the top center of the Frontier Science Portal website (www.frontierscience.org) on the ACTG and IMPAACT project tabs.

Seating is limited. Additional details and registration instructions are available during the registration process. Please receive leadership approval to attend prior to completing the registration form.

MARK YOUR CALENDARS

FOR 2018

Data Management Introductory Workshops

April 11-13

October 17-19

IMPAACT Network Meeting

June 16-19

ACTG Network Meeting

June 20-24

Webinar Series

See DMC Portal Training Pages for schedule

CONTACT

Data Management Center

Frontier Science and Technology
Research Foundation, Inc.

4033 Maple Road
Amherst, NY 14226, USA

Phone: +001 716-834-0900

Fax: +001 716-834-8432

or +001 716 834 8675



ACTG and IMPAACT

Randomization Assistance

Phone: +001 716-834-0900 x7301

Email: rando.support@fstrf.org

User Support

Phone: +001 716-834-0900 x7302

Email: user.support@fstrf.org

JANUARY

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