VOLUME 30, ISSUE 1

JANUARY 2019

DATA MANAGEMENT CENTER NEWSLINE

Rave Metrics Pilot Has Ended

The Rave Metrics Pilot came to an end with the December Rave Monthly Site Data Management Report. The Rave Metric reports are now considered official, but we appreciate sites bringing questions or concerns to our attention as the reports evolve.

A Regulatory metric was recently added to the reports. This metric reports 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 the data management metrics as it includes all studies in Rave *and* eData, and spans the previous 12 months. Additionally, different assessments are assigned to this metric: *Meets Standard* vs. *Does Not Meet Standard*

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Lab Audit Preparedness—Resources Available from Frontier Science

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. Both developer and end-user documentation packets can be requested from the LDMS website: https://www.ldms.org/resources/validation/

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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.

Rave Metrics Pilot Has Ended, cont'd

Metric Assessment Range	Does Not Meet Standard	Meets Standard
Regulatory	<100%	100%
Retention *ACTG ONLY*	<90%	90-100%

A Retention metric has been added to the reports for ACTG studies only. This metric assesses the percentage of participants retained on study. Only data for the current grant year will be reported for this category.

IMPAACT reports can generally be expected on the first Tuesday of each month and ACTG reports on the first Thursday, although there are some exceptions. The complete schedule for the reports can be found on the Frontier Science Portal under ***QA Tools***, listed as the ***Rave QA Report Schedule***.

Study-specific questions regarding the reports should be sent to the study's protocol data manager. Any changes in contact information for site staff who should receive the Rave Metric reports should be sent to User Support as soon as they occur: user.support@fstrf.org.

For general questions regarding the Rave metrics, please contact:

ACTG: ACTG.SITEDATAMGMTRPT.QUESTIONS@fstrf.org

IMPAACT: IMPAACT.SITEDATAMGMTRPT.QUESTIONS@fstrf.org

Lab Audit Preparedness—Resources Available from Frontier Science, cont'd

Reporting

There are several reports available in the Reports module of the LDMS to respond to requests that might occur in an audit. To create a customized report, use Data Retrieval (Windows) or Custom Report Builder (Web).

Specimen Log Report
This report provides the user with a list of all of the specimens that the laboratory has logged into its LDMS. The report also provides the primary and associated aliquot information for a given specimen.

Storage Detail Report
This report provides a detailed summary of the exact specimens and location of all the aliquots that are stored in a container held within a laboratory's storage structure hierarchy.

User Permissions
This report provides the user with a summary of all users in the LDMS and lists their current permissions within the LDMS.

Transaction Log (Audit Trail)
This log is a historical record of all transactions performed by users in your LDMS database and can be generated from the Reports module in the Admin category.
Please note this report is currently available in Web and will be available in the 13.0 release of Windows LDMS.

Completing the Concomitant Medication and Treatment Logs

The Concomitant Medication and Treatment Logs work differently in Rave than in the legacy system. Incorrectly completing these logs may lead to queries. In Rave, **Start date** and **End date** for medications must be completed on the same log line. Always update the existing log line for the medication/treatment. Do not start a new entry for discontinuation of a medication/treatment, as you would in the legacy system.

Correct Method of Completion:

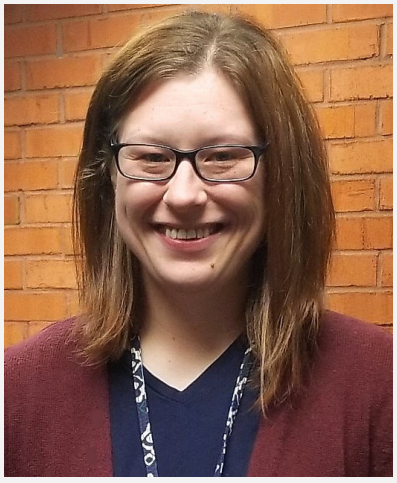
	1. Medication name	2. Primary disease category	3. Primary indication	5. Frequency	6. Start date	7. Started prior to study?	8. Ongoing	9. End date	
1	ferrous sulfate	General concomitant medication	Prophylaxis	Daily; Per Day	15 Jan 2018	Yes	No	31 Jan 2018	
2	ferrous sulfate	General concomitant medication	Prophylaxis	3 times per day	31 Jan 2018	No	Yes		
3	folic acid	General concomitant medication	Prophylaxis	Daily; Per Day	15 Jan 2018	Yes	No	26 Mar 2018	

Note: The second log line for ferrous sulfate denotes a change in Frequency and is therefore correct.

Incorrect Method of Completion:

1. Medication name [70]	2. Primary disease category	3. Primary indication	5. Frequency	6. Start date	7. Started prior to study?	8. Ongoing	9. End date
nevirapine	HIV	Prophylaxis	Daily; Per Day	19 May 2018	No	Yes	
End date ? Data is required. Please complete. Opened To Site from System (23 May 2018 ongoing							
NEVIRAPINE	HIV	Prophylaxis	Daily; Per Day	19 May 2018	No	No	23 Aug 2018

Employee Spotlight: Kayla Denson



What is your name and job title?

Kayla Denson – IMPAACT Coordinating Data Manager

Where are you from?

Baltimore, Maryland.

What is your education?

I have a BS in Biological Sciences from York College of Pennsylvania, an MBA in Management from Frostburg State University, and a PhD in Cell and Molecular Biology from University at Buffalo.

How long have your worked at Frontier Science?

I started working at Frontier Science in February 2017.

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

No two days are the same. I am the Protocol Data Manager for multiple enrolling studies, as well as several that are currently in development. For my enrolling studies, I spend time each day answering questions from sites and reviewing data. For my developing studies, I hold regular study build meetings with my EDC Study Builder, SDTM Specialist, and Laboratory Data Manager to develop the randomization and data collection materials that will be needed.

What is your favorite part about working at Frontier Science?

My favorite part about working at Frontier Science is the collaborative environment. Everyone is friendly and supportive, and I get to work with a variety of colleagues from different departments on a daily basis.

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

In the past year, I have been fortunate to be involved in the development of the new data management metrics for studies in Medidata Rave.

What changes have you seen during your time working at Frontier Science?

I started working at Frontier Science just as IMPAACT began to utilize Medidata Rave. It has been a rewarding experience working with sites to help them make a successful transition from using eData to Rave.

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

I recently attended the Society of Clinical Data Management Annual Conference in Seattle. A large focus of the meeting was how clinical trials are changing due to new advances in technology. One of the most interesting ideas presented there was the possibility of transitioning to almost fully virtual trials using new technology such as wearable devices and the ability to conduct virtual visits with participants.

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

At local events around Buffalo or hiking with my friends.

What are your passions/interests outside of the workplace?

I love photography and use my three pugs as my subjects quite frequently. They have over 8,000 followers on Instagram!

What is the best part of your job?

The best part of my job is having the ability to interact with the diverse group of people who are involved in the IMPAACT Network's clinical trials. It really gives me an appreciation for the immense amount of work that goes into each study.

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

I play in a competitive dodgeball league and my team was undefeated this season.

What was the last book you read?

I'm currently reading *How to Survive a Plague* by David France, which is about the early years of the AIDS epidemic.

2019

JANUARY

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MARK YOUR CALENDARS

Data Management Introductory Workshops

April 10 -12, 2019

October 23 -25, 2019

Webinar Series

See DMC Portal Training Pages for schedule

CONTACT

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ACTG and IMPAACT

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