VOLUME 34, ISSUE 3 AUGUST 2023

# DATA MANAGEMENT CENTER

# NEWSLINE

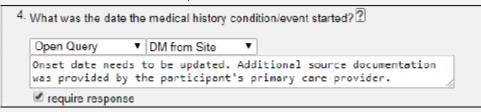
# Correction Request Workflow Changes to be Implemented

The DMC is prepared to retire the Eligibility Correction Request and the Screening Correction Request programs from the Frontier Science Portal for the ACTG and IMPAACT projects.

Beginning September 25th, site users will be required to open DM from Site queries on the appropriate question(s) (i.e. log line(s)) on the Eligibility Checklist Log or Screening Answers Log eCRF in Rave to initiate corrections for ACTG and IMPAACT studies. The relevant training materials available on the Frontier Science Portal have been updated. The program links will remain on the Frontier Science Portal as a means to remind site staff to use the new workflow, but will not provide access to the checklist correction request programs.

### **Creating a DM from Site Query**

- 1. Navigate to a Study > Site > Subject > Form.
- Click the icon to the right of the field for which you want to add a DM from Site query.
- 3. Select **Open Query** from the dropdown of marking types.
- 4. Select **DM from Site** from the dropdown of marking groups.
- 5. Enter the query text (up to 1000 characters) in the text box. The new response/value must be indicated within the text of the query, along with the reason for the correction. If a question needs to be removed as a result of a skip logic change, or calculation questions are affected by the original data correction, a DM from Site query must be opened on each question that needs to be updated. If a question needs to be added as a result of a skip logic change, the new question number and response must be included within the query text on the original question.
- 6. **Require Response** is selected by default. This must remain checked in order to track the PDM's response.



7. Click Save. The saved query will have a pink background.

See Guide for DM from Site Queries link on Medidata Rave Resources page

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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 (wojcik@frontierscience.org).

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# Employee Spotlight: Austin Glick, ACTG Coordinating Data Manager



Austin Glick began working at Frontier Science in 2020 and became an ACTG Coordinating Data Manager in 2022. He holds a BS in Biomedical Sciences from the Rochester Institute of Technology and works on protocol data management for numerous ACTG protocols, including A5300B (PHOENIX), A5355, A5362, A5380, and A5386.

Austin serves as a Global Librarian for the Generics group, which collaborates with members at the Statistical Data Management Center and the ACTG and IMPAACT Networks to develop and manage standardized generic forms for use across Network studies, and also serves as a Co-Chair on the ACTG Data Management Committee. Austin participates in a number of working groups and committees, including the Site Operations Subcommittee, DMC Generics, and the DMC Training Team.

Prior to joining Frontier Science, Austin worked as a Study Coordinator on Gastrointestinal Oncology Clinical Trials. Outside of work, Austin is pursuing a Master of Public Health (MPH) degree from the University at Buffalo. He enjoys watching and attending Buffalo Bills games, hiking, reading, and spending time with family and friends.

## Monthly Web LDMS Introductory Training Webinars

The LDMS Training Team has scheduled the Monthly Web LDMS Introductory Training Webinar Series for 2023. We encourage new and current/active Web LDMS Users to attend. The schedule is also available on the LDMS website with accompanying registration information: <a href="https://www.ldms.org/training/schedule/">https://www.ldms.org/training/schedule/</a>

There will be two training sessions per month:

- 8:00am 10:30am (Session 1)
- 12:00pm 2:30pm (Session 2)

An email communication containing registration information will be distributed to all Web LDMS users, 1-2 weeks prior to each training. Registrants will receive the webinar details via email and will be added to a virtual calendar event. As a reminder, training times are in Eastern Time (GMT-5) to accommodate LDMS trainers from the Amherst, New York, USA office.

Each session will cover the same features of the Web LDMS platform, from a project-agnostic perspective and a training certificate will be distributed to webinar participants. This

# 2023 Monthly Web LDMS Introductory Training Webinar Series

Month	Date
September	September 8, 2023
October	TBD
November	TBD

webinar series will be recorded and posted to our Frontier Science YouTube Channel (@FSTRFfilms). Laboratories are welcome to schedule additional or project-specific training webinars with the LDMS Training Team by contacting us directly via *Idms.training@frontierscience.org*.

## Q&A Tables at IMPAACT Network Annual Meeting

The DMC and LDMS training teams will host Q&A tables at the IMPAACT Network Annual Meeting on Tuesday, October 24th and Wednesday, October 25th, 1-5pm each day.





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## **DMC Training Pages**

The Training Pages on the Frontier Science Portal offer options for on-demand introductory data management training. These options are beneficial for new staff, or those requiring a refresher in a certain topic area.

### Webinars

- Protocol Deviation Reporting System
- Protocol Deviation Reporting System for ACTG Sites
- QA in Rave

### Introductory Workshop Training Sessions

- Adverse Event Reporting
- · Study Enrollment System
- Who We Are
- . DMC Portal Website Highlights for Rave
- LDMS Overview
- · Medidata Rave Overview
- TJoin for Rave
- · Rave Forms Overview
- · Specifying Diagnoses, Signs, and Symptoms
- · Rave eCRFs and Grading Laboratory Toxicities
- Rave Reports
- · Introduction to JReview
- Rave Metrics

### **Training Workshop Exercises**

- Rave eCRFs and Grading Laboratory Toxicities Exercise
- Study Enrollment System Mock Enrollment Exercise
- TJoin for Rave Exercise

# Computer Account Report Computing Manual DMC Contacts Email Address Book Download Email Address Lookup Medidata Rave Resources Newslines Protocol Deviation Reporting System Protocol Deviation Review Utility Training Pages

### DMC Introductory Workshop

- Adverse Event Reporting
- DMC Introduction: Who We Are
- DMC Portal Website Highlights
- Introduction to JReview
- LDMS Overview
- Medidata Rave Overview
- · Rave eCRFs and Grading Laboratory Toxicities
- Rave Forms Overview
- Rave Metrics
- Rave Reports
- · Specifying Diagnoses, Signs, and Symptoms
- Study Enrollment System
- TJoin for Rave

The **Recorded Training** tab hosts webinars, recordings of live DMC Introductory Workshop sessions, as well as exercises in certain topic areas that can be performed to further understanding. The **Presentations** tab features PDFs of the content. Questions regarding content can be directed to the Education and Training Director, via wojcik@frontierscience.org.

### General Clinical Data Management

- · Electronic Data Capture: Study Start-Up and Planning Activities
- Case Report Completion Guidelines
- Data Standards Implementation
- Targeted Source Data Verification
- Clinical Coding
- Ongoing Data Review
- · External Data Transfers
- Specimen Reconciliation
- Safety Data Management and Reporting

### **New Investigator Topics**

- Data Freeze and Data Lock
- . The Study Build Process
- Introduction to Estimands

In addition, eLearnings geared toward New Investigators and General Clinical Data Management are available on the *eLearning Courses* tab. Volume 34, Issue 3 Page 4

## 2023

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### MARK YOUR CALENDARS

## 2023 Data Management Introductory Workshops

• October 17-19 (virtual)

### **Web LDMS Introductory Trainings**

First Friday of Each Month
 See https://www.ldms.org/training/schedule/
 for more information

### **CONTACT**

### **Data Management Center**

Frontier Science Foundation 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: <u>user.support@fstrf.org</u> LDMS User Support

Phone: +001 716-834-0900 x7311 Email: <a href="mailto:ldmshelp@fstrf.org">ldmshelp@fstrf.org</a> https://www.ldms.org/contact