DATA MANAGEMENT CENTER
NEWSLINE

Recorded Data Management Training

Recorded data management training is available on the Training Pages of the Frontier Science Portal. The Recorded Training tab provides links to videos of individual training sessions provided in recent DMC Introductory Workshops.

Introductory Workshop Training Sessions

- Adverse Event Reporting
- Study Enrollment System
- Who We Are
- DMC Portal Website Highlights
- 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

In addition to recorded sessions from the DMC Introductory Workshop, there are also recorded training exercises for the following topics:

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

Training materials can be downloaded to the right of the link to the training exercise video. To learn additional information about the DMC's training programs, please contact Mary Wojcik-Cross (wojcik@frontierscience.org).

frontier science foundation

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).

Adverse Event/Diagnosis Reporting When a Procedure is Also Completed

The specify lines for reporting diagnoses and adverse events is limited in characters, so please report the event that occurred as specifically as possible. If a procedure took place and needs to be reported, please report the procedure on a separate line or required surgery form, depending on the study.

For example, the DMC received a specify description that read:

<u>Surgery for resection of rectal adenocarcinoma, colostomy placed</u>

This description reported on an adverse event form has 3 events within it:

1. Surgical resection of rectal adenocarcinoma

2. Rectal adenocarcinoma

3. Colostomy placed

We are only able to code one event per specify line and when reporting an adverse event, we are looking for what the adverse event was, not how it was treated. This line would be queried to ask that one event is reported per line. The site in this case removed the surgical events and only reported the "rectal adenocarcinoma."

Reporting Death Outcomes

Please report the primary cause of death within the specify description. If the primary cause is unknown at the time of reporting, please state "unknown cause of death" within the specify description, and not just the term "unknown." If the participant experienced other conditions at the time of death, record them as contributing causes.

For example, we received a description reported on the death form of: <u>Unknown</u>

This description required a query to the site, asking what was unknown. Please remember that the DMC Medical Coders are only able to choose a code based off of what is stated in the specify description line. They are not able to take into consideration any other information when applying MedDRA codes. This is why the reported event must be as specific as possible. The site in this case updated the specify line to read "unknown cause of death."

Guidance for Reporting Complete Events

Events have multiple parts that are very important when choosing the most specific MedDRA Code. Please include as many as possible within the reported description that apply. The following is a list of what Medical Coders must consider when choosing a MedDRA Code:

Whether an event is:

1. Congenital or Acquired

2. Malignant or Benign

3. Age of Participant (neonatal, newborn, childhood, adolescent, etc.)

4. Infectious Agent (bacteria, virus or fungus specifically identified by testing)

5. Body Site Location

6. Modifiers (acute, chronic, intermittent, occasional)

Reminder about Unfreeze Requests

As a reminder, sites should not request that the DMC unfreeze data within a response to a CRA query. Instead, sites must issue a **DM from Site** query. In the query text, sites should describe how the data will be updated after the eCRF is unfrozen and provide a reason why the modification is required. This allows the SDMC to properly review the request prior to unfreezing the data. For more information, see *Guide to DM from Site Queries* available on the Medidata Rave Resources page, under the Site Staff Resources category, located towards the top of the page.

> **Site Staff Resources**
>
> Daily Quality Assurance in Rave
> Guide to DM from Site Queries
> How to Create Participant Casebooks (Data PDFs)
> Rave Reports
> Guide for New Studies Opening in Rave
> Guide for Migration to Rave
> Signing eCRFs in Rave: Quick Reference for Investigators

2022 DMC Introductory Workshop Schedule

The Data Management Center for the ACTG and IMPAACT networks is pleased to announce the 2022 Introductory Workshop schedule*:
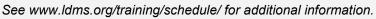
- **April 27—28, 2022**
- **October 26—27, 2022**

Email announcements will be circulated when registration opens for each workshop.

*See page 1 regarding the availability of recorded data management training sessions.

Web LDMS Introductory Training Webinars

The LDMS Training Team will conduct Introductory LDMS for the Web training webinars on the first Friday of each month.

See www.ldms.org/training/schedule/ for additional information.

Employee Spotlight: Sara Sieczkarski, Protocol Data Manager

Sara Sieczkarski has been working at the Data Management Center as a Protocol Data Manager since 2018. She holds a BA in Biology and Religion from Wellesley College and a PhD in Microbiology from Cornell University. Prior to joining Frontier Science, Sara held a position as a science teacher for an independent high school in Buffalo, New York.

Currently, Sara is a Protocol Data Manager for several ACTG studies, including A5359, A5368, and A5404. In addition, she is also the DMC representative on the Antiretroviral Therapy Strategies Transformative Science Group (ARTS TSG). Sara has also been a member of the DMC Training Team since 2020. When not working, Sara enjoys reading, quilting, and spending time with her family.

Eligibility Checklists: Review and Corrections

When sites are entering data from a paper copy of the eligibility checklist into the Study Enrollment System (SES), be sure to double-check the answers against the paper copy before submitting to the DMC. This reduces the chance of needing to request a correction to the eligibility checklist. If a correction to an eligibility checklist is required, site staff must submit an **Eligibility Correction Request.**

Utilities
DataView
Deconsent Utility
Eligibility Correction Request
File Exchange Utility
IMPAACT Credentials Utility
Mother/Infant PID Mapping
Participant Calendar
Participant Transfer Request
Screening Correction Request
TJoin

The Eligibility Correction Request utility can be accessed on the Frontier Science Portal, under the Utilities category. All fields in the utility are required, including Study, Patid, Step, and the affected question with the reason for changes. If more than one correction to an eligibility checklist is needed, additional rows can be added. You must also indicate whether or not skip logic is affected by the data change.

Eligibility Checklist Correction Request

This program will submit an eligibility checklist correction request to the DMC protocol data manager. Sites can request five corrections for the same study/patid/step combination with one submission.

All fields are required.

Study: _____
Patid: _____
Step: _____

[Add Row]

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

[Submit] [Reset]

The primary Protocol Data Manager (PDM) for the study will receive the request via email. The PDM then completes a Data Correction Request Form (DCRF), using the information received via the Eligibility Correct Request, and forwards it to the site. It is the responsibility of site staff to review, sign, and date the DCRF before sending it back to the PDM. After receiving the signed DCRF, the PDM is able to make the updates to the data in the clinical database and *Medidata Rave*, if appropriate, and sends the corrected Eligibility Checklist back to the site.

Most Common Checklist Errors:
The types of errors most commonly seen by the Data Management Center are listed below. While minor typographical errors can be corrected fairly easily, other errors are very complex. Errors on these data elements can severely impact stratification and potentially eligibility on a study.

Pay close attention to the following data elements:
- PID
- Date of birth
- Biological sex at birth
- Date/Time of Informed Consent
- Reproductive potential
- HIV-1 infection status
- Dates lab specimens were obtained
- Lab results
  - Conversion/Unit
  - Upper vs. lower limit of normal

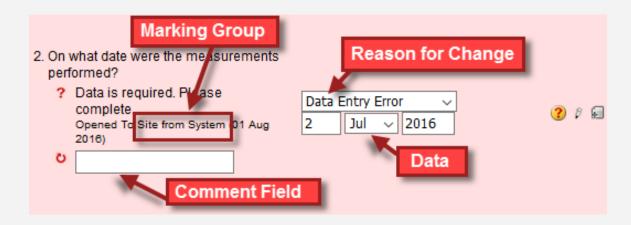**When completing the checklists, please do the following:**
- Double-check each response before going on to the next question
  - Compare against source documentation
  - Are there any typographical errors?
  - Are lab-related eligibility results keyed/converted to the correct unit?
- Prior to clicking "Enroll," perform a thorough review of the entire checklist

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," respectively). 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 dropdown 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 dropdown 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: Sites may receive multiple queries throughout the day, so sites should monitor the task summary frequently. The DMC may also re-query on the same item.

2022

JANUARY

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25	26	27	28	29	30	31

MARK YOUR CALENDARS

Data Management Introductory Workshops

- April 27—28, 2022
- October 26—27, 2022

Web LDMS Introductory Trainings

- First Friday of Each Month

See https://www.ldms.org/training/schedule/
for more information

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ACTG and IMPAACT

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Email: **user.support@fstrf.org**

LDMS User Support

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https://www.ldms.org/contact