

DATA MANAGEMENT CENTER

NEWSLINE

Checklist Correction Request Workflow Changes

Over the course of the next several months, the DMC will be preparing to retire the Eligibility Correction Request and the Screening Correction Request programs located on the Frontier Science Portal for the **ACTG and IMPAACT projects**.

Once implemented, 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 new response/value must be indicated within the text of the query, along with the reason for the correction.

A formal notification will be sent prior to the final retirement of the programs and the relevant training materials available on the Frontier Science Portal will be updated. The program links will remain on the Frontier Science Portal following the program's retirement as a means to remind site staff to use the new workflow, but will not provide access to the checklist correction request programs.

Clinical Data Management eLearning Update

Site Support

Computer Account Report

Computing Manual

Computing Requirements

DMC Contacts

Email Address Book Download

Email Address Lookup

Medidata Rave Resources

Newslines

Protocol Deviation Reporting System

Training Pages

A *Case Report Form Completion Guidelines* eLearning has been added to General Clinical Data Management section of the Training Pages on the Frontier Science Portal (Site Support > Training Pages > eLearning Courses). In addition, an *Introduction to Estimands* eLearning will soon join the New Investigator Topics section.



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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).

Employee Spotlight: Rebecca Dirschberger, IMPAACT Protocol Data Manager



Rebecca (Becky) Dirschberger began working at Frontier Science in 2020. She holds a Bachelor of Science in Health Promotion from SUNY Oswego and a Master of Public Health from Daemen University.

Becky is a Protocol Data Manager for several IMPAACT protocols, including 2014, 2009, 2034, 2040, 2016, and 2028. She became a member of the DMC Training Team, DMC Generics Group, and Study Build Working Group last year, and is the data manager representative for the Lab Data Committee and Pharmacology Working Group.

Becky was born and raised in Buffalo, New York and loves the Buffalo Bills. In her free time, she enjoys hiking, kayaking, and spending time with her dogs at the dog park with her boyfriend.

Reporting Combined Medications

Reporting medications correctly is extremely important in data collection. Combination medications are common and should be reported appropriately. A combination medication, or a fixed-dose combination medication, is a medicine that includes two or more active ingredients in a single dosage form. Individual medications that are taken at the same time are not considered combination medications.

For accurate WHODrug coding, fixed-dose combination medications must be reported on one log line on the eCRF. This should be done even if the medication consists of several active ingredients that have different dose amounts.

A fixed-dose combination medication should NEVER be reported on separate log lines with a different active ingredient indicated on each line.

Example 1:

Incorrect Method of Reporting:

- **Aluvia; Lopinavir** (on one log line)
- **Aluvia; Ritonavir** (on one log line)

Correct Reporting Options:

- **Aluvia** (Drug Trade name for fixed-dose medication only on one log line) **OR**
- **Lopinavir 100mg; Ritonavir 25mg** (all active ingredients on one log line)

Example 2:

Incorrect Method of Reporting:

- **Clear Cough Syrup; Ammonium Chloride** (on one log line)
- **Clear Cough Syrup; Diphenhydramine HCl** (on one log line)
- **Clear Cough Syrup; Sodium Citrate** (on one log line)

Correct Reporting Options:

- **Clear Cough Syrup** (Drug Trade name for fixed-dose medication only on one log line) **OR**
- **Ammonium Chloride; Diphenhydramine HCL; Sodium Citrate** (all active ingredients on one log line)

Contact dmc.coding.issues@fstfrf.org with questions related to reporting medications.

DMC Training Options

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.

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

| Overview | Training Schedule | Meet the Trainers | Presentations | Recorded Training | eLearning Courses |
|--|-------------------|-------------------|---------------|-------------------|-------------------|
| Introductory Workshop Training Sessions <ul style="list-style-type: none"> 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 | | | | | |
| Training Workshop Exercises <p>The associated training topic presentation for the desired exercise (see above) should be viewed prior to participation in the exercise. Download/Print the training materials listed after the exercise topic before viewing the exercise recording.</p> <ul style="list-style-type: none"> Rave eCRFs and Grading Laboratory Toxicities Exercise [Exercise Overview, DAIDS Toxicity Table Version 2.1, LBW10002 CRF] Study Enrollment System Mock Enrollment Exercise [Study Enrollment System Mock Enrollment Exercise Handout] TJoin for Rave Exercise [TJoin Scenario 1 Blank, TJoin Scenario 1 Answer Key, TJoin Scenario 1 A5371 Annotated Print Matrix, Master Tables Reference, TJoin Scenario 2 Blank, TJoin Scenario 2 Answer Key] | | | | | |

In addition, eLearnings geared toward New Investigators and General Clinical Data Management are available on the eLearning Courses tab.

| Overview | Training Schedule | Meet the Trainers | Presentations | Recorded Training | eLearning Courses |
|--|-------------------|-------------------|---------------|-------------------|-------------------|
| New Investigator Topics <p>Please Note: A Completion Report can be generated after successful completion of the assessment included in each eLearning in this category. Click on Your Score to generate the report.</p> <ul style="list-style-type: none"> Data Freeze and Data Lock (eLearning transcript) The Study Build Process (eLearning transcript) | | | | | |
| General Clinical Data Management <p>Please Note: A Certificate and Completion Report can be generated after successful completion of the assessment included in each eLearning. Please use the following steps to generate the documents:</p> <ul style="list-style-type: none"> Completion Report: click on Your Score on the displayed certificate Certificate: Click on the course title on the displayed certificate Electronic Data Capture: Study Start-Up and Planning Activities (eLearning transcript) Case Report Completion Guidelines (eLearning transcript) Data Standards Implementation (eLearning transcript) Targeted Source Data Verification (eLearning transcript) Clinical Coding (eLearning transcript) Ongoing Data Review (eLearning transcript) External Data Transfers (eLearning transcript) Specimen Reconciliation (eLearning transcript) Safety Data Management and Reporting (eLearning transcript) | | | | | |

2023

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DECEMBER

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MARK YOUR CALENDARS

2023 Data Management Introductory Workshops

- January 31—February 2
- April 25—27*
- October 17—19*

*tentative schedule

Web LDMS Introductory Trainings

- First Friday of Each Month

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

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