Data Management Center
NEWSLINE

The Protocol Deviation Reporting System

In accordance with the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency and due to the anticipated increase in the number of protocol deviations experienced at sites as a result of the ongoing pandemic, the Data Management Center (DMC) at Frontier Science developed and deployed a Protocol Deviation Reporting System (PDRS) to facilitate the collection of mass protocol deviations. The PDRS can be used to report protocol deviations that apply to multiple studies or multiple participants enrolled on a study. Individual, participant-level protocol deviations should continue to be reported per Network or study guidelines. While the PDRS is being introduced in the context of reporting deviations due to the COVID-19 pandemic, it is anticipated that this utility will be used in the future for other reportable deviations impacting large numbers of participants or if the deviation does not involve specific participants. Sites should retrospectively enter mass protocol deviations dating back to March 15, 2020.

The Protocol Deviation Reporting System can be accessed from the Frontier Science DMC Portal under the ACTG and IMPAACT Network tabs. Protocol deviations should be reported by the communicating staff member, which may be the Investigator of Record or other designee. Within the utility, users are provided with a data entry screen to report the site, study, site awareness date, deviation start and end date, the type of deviation, and a summary of the deviation that occurred. The user can also indicate whether the deviation was reported to the local IRB/EC, and if the deviation was a result of the COVID-19 pandemic.

This new utility is intended to supplement existing participant-level network and study deviation workflows by providing a mechanism for mass deviation reporting and is not a replacement for current participant-level deviation reporting procedures. If you have any questions regarding accessing the PDRS or have technical issues with the system, please contact Frontier Science User Support at usersprt@fstrf.org. If you have any questions about how to report protocol deviations for your study, please contact the study team email group.

Inside This Issue

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).

Using the Protocol Deviation Reporting System

The home screen of the Protocol Deviation Reporting System (PDRS) displays a table which lists previously reported deviations. Each deviation has **View**, **Update**, and **Delete** buttons to the right, which allow the user to view the details of a deviation, update a deviation, or delete a deviation.

Users click the **Report Deviation** button to initiate a new protocol deviation report.

The following user interface appears, which displays the data entry fields.

The user may enter protocol deviations for multiple studies, but only for one site at a time.

If the user enters multiple studies, the deviation is automatically entered for all participants. If the user needs to select only certain participants, each study must be reported separately.

If a protocol deviation must be changed after submission, the user may update a deviation by clicking the **Update** button that appears to the right of a previously submitted deviation on the program's home screen. This brings up the same data entry fields that were originally entered. After changing the fields, a reason must be entered for why the changes were made.

From the home screen, a user may also choose to delete a deviation by clicking the **Delete** button to the right of a previously submitted deviation. A reason must be entered for why the deviation was deleted.

Protocol deviations can be printed by clicking the **View** button to the right of a previously submitted deviation on the home screen. This brings up a detailed listing of the deviation. Click the **PDF** button at the bottom of the protocol deviation pop-up to generate a print friendly, PDF-formatted report of the deviation.

Rave eCRF and LDMS Data Consistency

It is important that specimen collection dates, times, and other data items are consistent between sites and labs to ensure laboratory data integrity and accuracy. The DMC is continuously checking data to ensure consistency between the Rave specimen tracking eCRFs and LDMS. Specimen collection date and time errors are among the most frequent types of discrepancies that are identified between the sites and labs.

Sites and laboratories often need to work together to resolve eCRF-LDMS discrepancies. If the site finds that an error occurred in their records, they are responsible for correcting the eCRF in Rave. If the error lies within data entered into LDMS, the processing lab needs to correct the LDMS entry and enter aliquot comments so that any aliquot label discrepancies will be explained on the shipping manifest. When data corrections are made on specimens that have already been shipped (e.g., to a testing lab or repository), it is very important that the shipping laboratory notify the receiving lab of the correction in writing.

Local Sample Storage Help for ACTG & IMPAACT LDMS Laboratories

In follow-up to the network's instructions for labs to store samples locally on site, including PBMCs, knowing shipments to the Repository are not allowed during the COVID-19 pandemic, Frontier Science has published various LDMS guidance documents to answer any questions labs might have about how best to track local storage in their LDMS. The document *PBMC Storage Guidance*, located on the LDMS website using either the *ACTG Resources* or *IMPAACT Resources* links below, details proper procedures in LDMS for moving PBMC samples from -70 freezers into LN2 tanks, knowing sites will be required to hold on to these samples locally for the time being. Specifically, the document reinforces the steps for how to configure storage containers, levels, and freezers; how to create new freezers, how to move samples, and a review of the various reports for reporting on this information.

Instructions are included for both our web and Windows LDMS applications.

[ACTG Resources](#)

[IMPAACT Resources](#)

In addition, included below are helpful links available on our website that might help address some of the questions labs have recently inquired about specific LDMS procedures. Please remember: we have A LOT of helpful materials on the LDMS website (www.ldms.org), including detailed manuals.

During the evolving COVID-19 situation, Frontier Science continues to maintain 24/7 support. User Support is accessible by email at **ldmshelp@fstrf.org** or by phone at (716) 834-0900 x7311. Support can also be requested via our website at: https://www.ldms.org/contact/

Windows LDMS resources/links on website

[Various storage reports available](#) (including MOVE report)

[How to MOVE samples](#)

[Defining and configuring Freezers](#) (with proper temperature)

[Various Training materials and existing reference guides](#) (under Windows category)

Web LDMS resources/links on website

[Various storage reports available](#) (including MOVE report)

[How to MOVE samples](#)

[Defining and configuring Freezers](#) (with proper temperature)

[Various Training materials and existing reference guides](#) (under Web category)

IMPAACT Protocol Data Manager: Chelsea Krotje Stotz

Chelsea Krotje Stotz joined the Data Management Center in 2016 and serves as a protocol data manager for several IMPAACT protocols, including 2002, 2008, 2010/VESTED, 2014, and 2015. She holds a Bachelor of Science in Biology from the State University of New York at Geneseo and a Master's in Public Health from Daemen College.

Chelsea participates in the IMPAACT Complications Scientific Committee and recently became a member of the Data Management Center's training team. She also serves on a cross-network data standardization group with the Office of HIV/AIDS Network Coordination. In addition, Chelsea is one of the data managers who oversees the Monthly Site Data Management Report metrics for studies in Medidata Rave.

When not working, Chelsea enjoys gardening, painting, sewing, and spending time with family and friends.

Recorded Data Management Training Available on the Frontier Science Portal

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 Recorded Training page was recently added to the Training Pages on the Frontier Science Portal. This page provides links to individual training sessions recorded during scheduled Data Management Center training events, and currently contains the April 2020 Introductory Workshop sessions and the May 2020 Protocol Deviation Reporting System webinar.

For more information on our training programs and initiatives, or if you have suggestions for new training materials, please contact our Education Coordinator, Mary Wojcik-Cross(wojcik@frontierscience.org or 716-834-0900 ext. 7466).

LDMS Introductory Trainings to be Held Virtually

In response to travel restrictions due to the ongoing COVID-19 pandemic, the LDMS Training team will be hosting our 2020 Web LDMS Introductory trainings virtually. All LDMS users are invited to attend, although the material is geared towards new users. The invites are sent to users at laboratories who are utilizing the web version of LDMS. Please feel free to share the invitation with any new staff members who may not have LDMS login credentials. After the webinar, every attendee will receive a certificate of attendance. Only registered users will receive this document.

In addition to these webinars, Frontier Science has our online tutorials and other training materials readily available on the LDMS public website (www.ldms.org). These can be found in the Resources tab on the LDMS website. Prior to attending the webinar, be sure to download a copy of the LDMS training workbook to reference during the presentations.

The schedule of upcoming trainings is available on the LDMS website: www.ldms.org/training/schedule/

2020

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MARK YOUR CALENDARS

Data Management Introductory Workshops

- October 21-22 *(virtual)*

Data Management Webinars

- August 13: Rave Metrics
- September 10: QA in Rave
- October 8: TJoin for Rave

See Frontier Science Portal Training Pages for additional information.

LDMS Introductory Workshops

- August 21 *(virtual)*
- November 13 *(virtual)*

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: user.support@fstrf.org