DATA MANAGEMENT CENTER
NEWSLINE

frontier
science foundation

INSIDE THIS ISSUE

Protocol Email Group Process Update

As part of our ongoing efforts to streamline and modernize our systems, Frontier Science is working to update the system used to generate protocol email groups. Protocol email group membership will then be determined by Medidata Rave access rather than enrollment privileges.

An individual will be automatically added to the protocol group if they have one of the following roles in Medidata Rave for that study:

- Investigator - IVRS
- Clinical Research Coordinator (CRC) - IVRS
- Read Only

In order to ensure no one is inadvertently removed from the protocol groups during this update, we will be migrating all active members from the previous system to the new system. An individual that falls outside of this scope can still be added manually to the protocol group via a request to User Support. Sites will be notified prior to the implementation of this change in production.

Studies Added to the Specimen Repository Website

Page 2

The Specimen Repository Website includes a data visualization tool with the goal of making specimens available to investigators for new and innovative research.

The website, *www.specimenrepository.org*, is a collaborative project among the ACTG, IMPAACT, and HVTN networks.

ACTG DNA specimens now searchable

For ACTG studies that had co-enrollment in the A5128 and A5243 protocols, the Specimen Repository Website is now displaying the available DNA specimens from those two protocols that are stored at the ACTG DNA Repository and can be used for human genetic research.

The details on these specimens can be found in the section *Select Below for Additional Summaries...* by selecting either 'Unique Participants with DNA Specimens by Study' or 'DNA Amounts for Unique Participants with DNA Specimens' from the drop down.

The summaries of available DNA specimens and participants are listed by the main protocol that they were enrolled in.

Studies Added to the Specimen Repository Website, cont'd

AIEDRP specimens now searchable:

Available specimens from the Acute Infection and Early Disease Research Program (AIEDRP) are now searchable on the Specimen Repository Website. AIEDRP was established to develop and evaluate data from studies of participants with acute or recent HIV infection. The specimens from the three available AIEDRP studies can be found under their associated ACTG protocols AIN501/A5216, AIN503/A5217, and CORE01/A5228.

A5216 (AIN501) - A Randomized Phase II Study of the Safety, Immunologic and Virologic Effects of Cyclosporine A in Conjunction with Trizivir ® and Kaletra ® versus Trizivir ® and Kaletra ® Alone during Primary HIV-1 Infection

A5217 (AIN503) - A Randomized Study of Treatment with Tenofovir DF/Emtricitabine, and Lopinavir/Ritonavir versus no Therapy in Newly Infected HIV-1 Infected Subjects to Determine Whether Potent Antiretroviral Therapy Alters the Virologic Setpoint

A5228 (CORE01) - Acute HIV Infection and Early Disease Research Program (AIEDRP) AIEDRP CORE01 Database Protocol

Studies Added to the Specimen Repository Website, cont'd

IMPAACT PROMISE specimens now searchable for the following components:

IMPAACT 1077BF - Breastfeeding Version of the PROMISE Study: Promoting Maternal and Infant Survival Everywhere

> 1077BA - Breastfeeding Version of PROMISE - Antepartum Component
> 1077BL - Breastfeeding Version of PROMISE - Late Presenters Component
> 1077BM - Breastfeeding Version of PROMISE - Maternal Health Component
> 1077BP - Breastfeeding Version of PROMISE - Postpartum Component

IMPAACT 1077FF - Formula Feeding Version of the PROMISE Study: Promoting Maternal and Infant Survival Everywhere

> 1077FA - Formula Feeding Version of PROMISE - Antepartum Component
> 1077FM - Formula Feeding Version of PROMISE - Maternal Health Component

Employee Spotlight: Chelsea Krotje Stotz, IMPAACT Chief Data Manager

Chelsea Krotje Stotz 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 University. She joined the Data Management Center in 2016 and has recently accepted the role of IMPAACT Chief Data Manager. In her new role, Chelsea leads the clinical data management components of the project, overseeing the IMPAACT data management staff, and coordinating the day-to-day clinical data management operations for the project.

In addition to her studies, Chelsea is a member of the Data Management Center Training Team and is one of the two PDMs responsible for reviewing and distributing the IMPAACT Monthly Site Data Management Reports. She is also one of our Global Library Managers for the ACTG and IMPAACT networks, coordinating the development, review, and finalization of generic eCRFs with SDMC and network representatives.

One of her favorite things about working at Frontier Science is seeing the impact that our clinical trials make on the lives of many people around the world.

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

DMC Virtual Learning Room
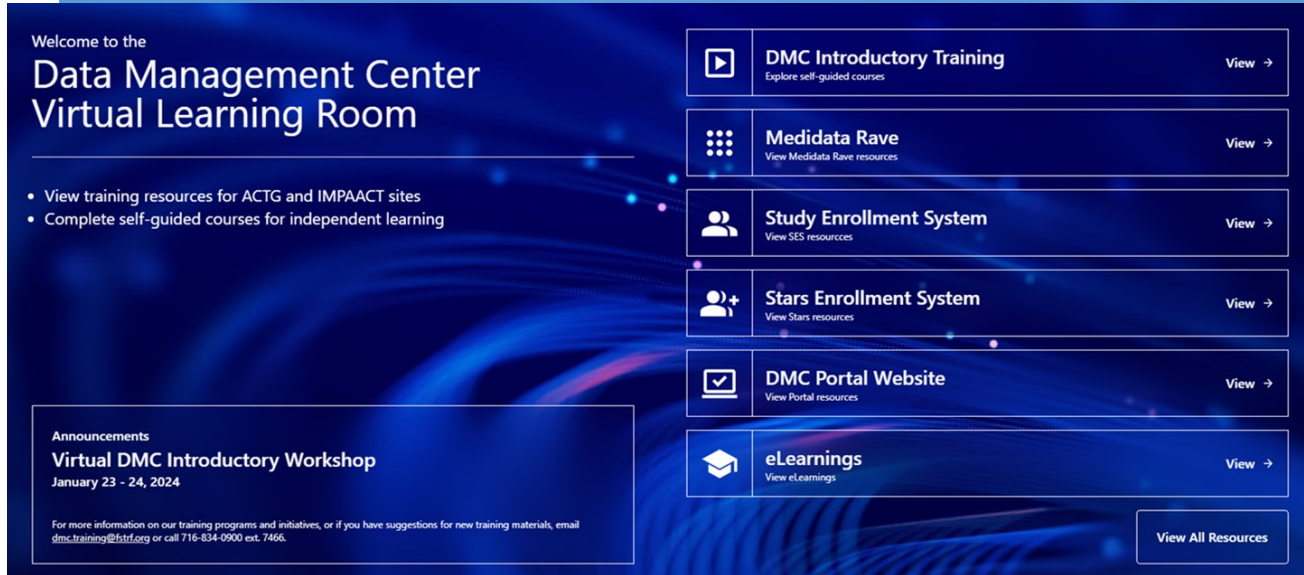
The Data Management Center's Virtual Learning Room has replaced the Training Pages on the Frontier Science Portal.

The new link is available under the *Site Support* category of the ACTG and IMPAACT Portal pages, offers a redesigned format, on-demand self-guided courses for independent learning, and many training resources to assist clinical sites.

Menu items include the following:

Home: Links to some of our fundamental topics required for site establishment and new hires and announcements

Training Team: Meet the DMC Training Team

Courses: Get started with quick self-guided courses that offer a quiz and certificate option

Resources: Search/View various training resources

eLearnings: View available Investigator and General Clinical Data Management eLearnings

Frontier Science Portal: Return to the Frontier Science Portal

The *Courses* page provides access to quick self-guided courses organized by topic.

Each course provides access to all available resources for that topic, including training presentations, videos, and any related documents.

Successful completion of the included quiz provides the user with a certificate.
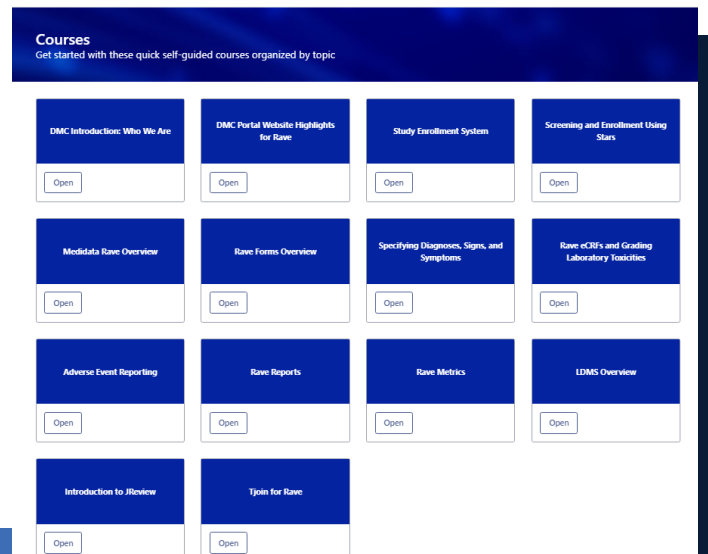
NEWSLINE

January 2024

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February 2024

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August 2024

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September 2024

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October 2024

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November 2024

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December 2024

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MARK YOUR CALENDARS

2024 Virtual DMC Introductory Workshops

- August 19-22
- October 22-24

2024 Monthly LDMS Webinar Schedule

www.ldms.org/training/schedule

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