Data Management Center Overview

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IMPAACT DMC Director

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IMPAACT

International Maternal Pediatric Adolescent AIDS Clinical Trials Network

ANNUAL MEETING

2024

Key Messages

- This session provides an overview of the Data Management Center and its role within the IMPAACT network.

Frontier Science

- Not-for-profit statistical and data management organization focused on medical research
- Established in 1975 in Amherst, New York
- Suzanne Siminski, MS, MBA, Chief Executive Officer

Mission

To advance the application of statistical science and practice, and data management techniques in science, healthcare, and education.

Frontier Science Offices

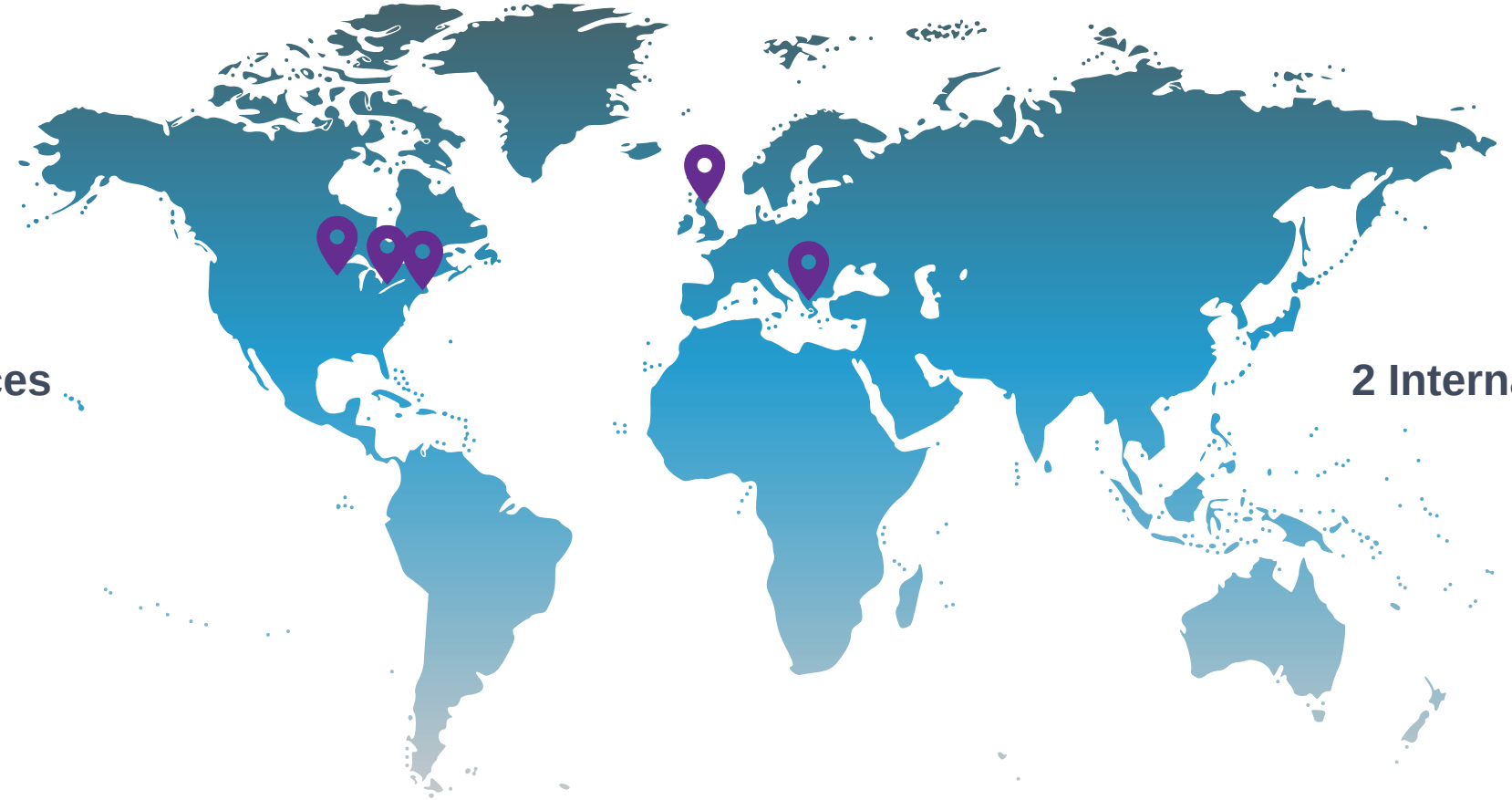
Amherst NY

Boston MA

Madison WI

Athens Greece

Kincraig Scotland



3 US Offices

2 International Affiliates

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Data Management Center

The Data Management Center (DMC) for the ACTG, IMPAACT, PHACS and other clinical trials projects is located at Frontier Science Foundation in Amherst, New York.

- Frontier Science
- DMC
- Data Center
- Frontier Science Amherst

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IMPAACT DMC Leadership

Marlene Cooper

ACTG/IMPAACT
DMC Director

Carrie Fry

ACTG/IMPAACT DMC
Associate Director

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Key DMC Responsibilities

- Members of the protocol team
- Develop materials for data collection and participant enrollment
- Initialize the study database
- Maintain the software (LDMS) for biospecimen tracking
- Review study data and send queries
- Develop software and reports to support and monitor studies
- Support clinical site and laboratory staff
- Manage incoming and outgoing data requests following network guidelines
- Work with Statisticians to prepare data for analysis

Data Management Team

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Protocol Data Managers

During study development:

- Coordinate data collection (eCRF) design
- Develop enrollment materials
- Design study-specific software and/or reports

During study accrual and follow-up:

- Serve as primary DMC liaison to study team
- Consult with and assist sites as needed
- Review data; write queries to sites
- Generate reports for the study team

During analysis:

- Assist study teams in preparations for analysis and publication

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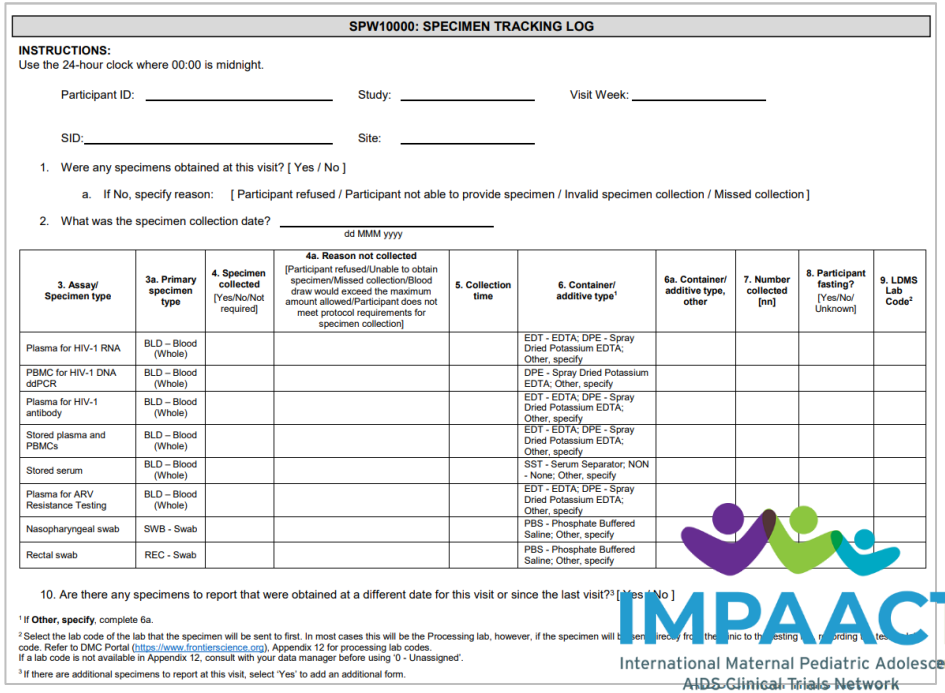
Data Manager Assistants

- Assist PDMs with QA/QC of data
- Send & reply to site queries

Laboratory Data Managers

- Work with the Protocol Data Manager to develop specimen tracking forms and assay result forms and templates
- Manage protocol laboratory data
- Assist programmers in developing new features of the LDMS
- Provide LDMS training to laboratories



SPW10000: SPECIMEN TRACKING LOG

INSTRUCTIONS:
Use the 24-hour clock where 00:00 is midnight.

Participant ID: _____ Study: _____ Visit Week: _____

SID: _____ Site: _____

1. Were any specimens obtained at this visit? [Yes / No]
   a. If No, specify reason: [Participant refused / Participant not able to provide specimen / Invalid specimen collection / Missed collection]
2. What was the specimen collection date? _____ (dd MMM yyyy)

3. Assay/ Specimen type	3a. Primary specimen type	4. Specimen collected [Yes/No/Not required]	4a. Reason not collected [Participant refused/Unable to obtain specimen/Missed collection/Blood draw would exceed the maximum amount allowed/Participant does not meet protocol requirements for specimen collection]	5. Collection time	6. Container/ additive type[1]	6a. Container/ additive type, other	7. Number collected [nn]	8. Participant fasting? [Yes/No/ Unknown]	9. LDMS Lab Code[2]
Plasma for HIV-1 RNA	BLD – Blood (Whole)				EDT - EDTA; DPE - Spray Dried Potassium EDTA; Other, specify				
PBMC for HIV-1 DNA ddPCR	BLD – Blood (Whole)				DPE - Spray Dried Potassium EDTA; Other, specify				
Plasma for HIV-1 antibody	BLD – Blood (Whole)				EDT - EDTA; DPE - Spray Dried Potassium EDTA; Other, specify				
Stored plasma and PBMCs	BLD – Blood (Whole)				EDT - EDTA; DPE - Spray Dried Potassium EDTA; Other, specify				
Stored serum	BLD – Blood (Whole)				SST - Serum Separator; NON - None; Other, specify				
Plasma for ARV Resistance Testing	BLD – Blood (Whole)				EDT - EDTA; DPE - Spray Dried Potassium EDTA; Other, specify				
Nasopharyngeal swab	SWB - Swab				PBS - Phosphate Buffered Saline; Other, specify				
Rectal swab	REC - Swab				PBS - Phosphate Buffered Saline; Other, specify				

10. Are there any specimens to report that were obtained at a different date for this visit or since the last visit?[3] [Yes / No]

[1] If **Other, specify**, complete 6a.

[2] Select the lab code of the lab that the specimen will be sent to first. In most cases this will be the Processing lab, however, if the specimen will be sent directly from the clinic to the testing lab recording the test, select the lab code. Refer to DMC Portal (https://www.frontierscience.org), Appendix 12 for processing lab codes.
If a lab code is not available in Appendix 12, consult with your data manager before using '0 - Unassigned'.

[3] If there are additional specimens to report at this visit, select 'Yes' to add an additional form.

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Core Support Team

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Data Modeling Specialists

- Per the FDA, all network studies are required to prepare study data sets in CDISC format
- Annotate all electronic case report form fields using CDISC data standards
- Map study data into CDISC defined data sets
- Maintain all required documentation about the CDISC data modeling and mapping process

cdisc®

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Programming, Database and IT Operations

Software Engineering

- Develop programs on the DMC Portal to support the network and studies
- Design websites and data visualizations

Database Administrators & Specialists

- Maintain study central database

IT Computing Staff

- Maintain the DMC's computing networks

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Medical Coders

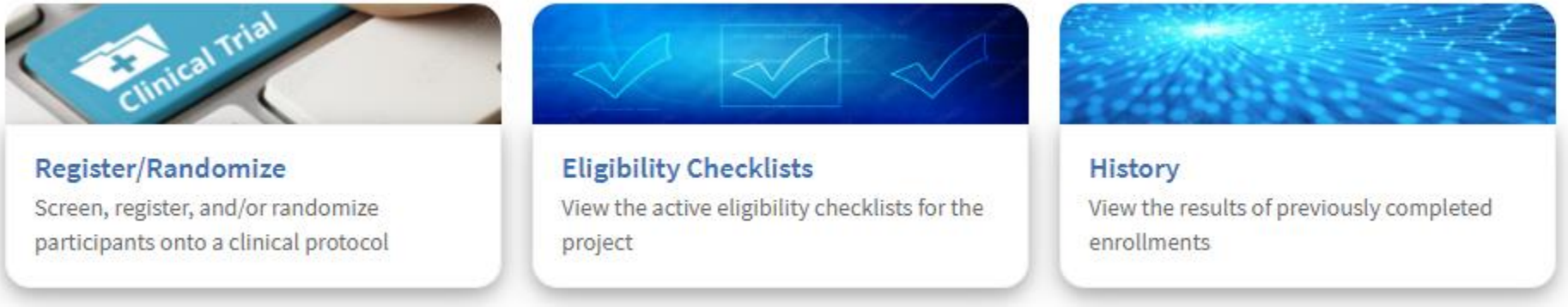
- Review and assign standard codes to collected data

MedDRA Medical Dictionary for Regulatory Activities

Uppsala Monitoring Centre WHODrug Global

Randomization Support Staff

- Work with the Protocol Data Manager to set up the study enrollment screens
- Assist site staff with any enrollment issues



EDC Study Build Department

EDC = Electronic Data Collection

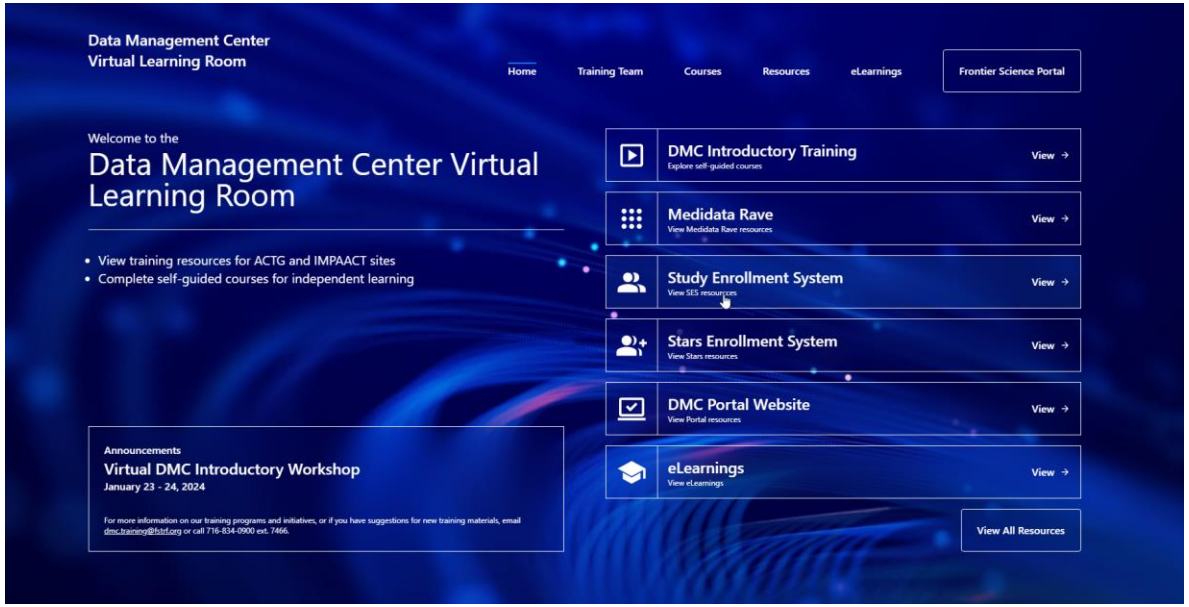
Study Builders

- Manage the global library of standardized eCRFs that are used across studies
- Work with Protocol Data Manager to design study-specific eCRFs
- Implement data checks on eCRFs so sites get feedback in real-time as data are being keyed

Education & User Support

Education and Training

- Run Introductory Workshops for site staff
- Maintain the DMC Virtual Learning Room
  - Recorded trainings
  - eLearnings
  - Exercises



User Support

- Provide assistance to clinical site and laboratories 24 hours a day, 7 days a week

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THANKS!

Any questions?

You can find me at cooper@frontierscience.org

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