

DATA MANAGEMENT CENTER

NEWSLINE

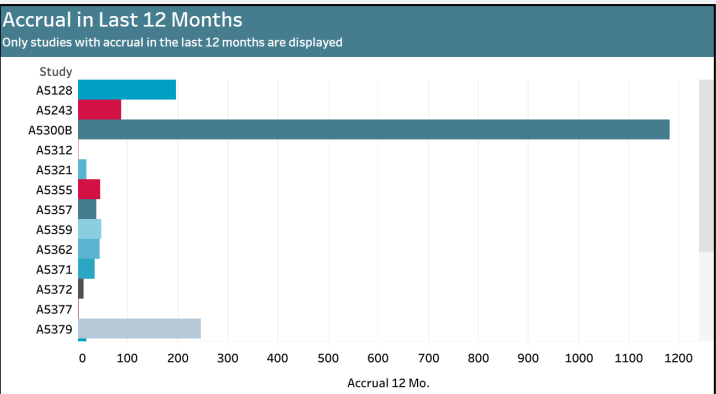
ACTG and IMPAACT Data Visualizations

The DMC is pleased to announce that two dynamic data dashboards have been promoted to the Frontier Science Portal using the data visualization software, Tableau. Each dashboard serves as a visual aid to represent site accrual and retention for the ACTG and IMPAACT networks. Accrual is broken down over a 12-month period by month.

Links and Applications Listed by Category		
Show Most Recently Used Items		
Calculators	Case Report Forms	Data Visualizations
Age Calculator	Annotated Forms	ACTG Accrual and Retention
Blood Volume Calculator	CRF Appendix Codes	
Calculator Utilities	Clinical Event Forms	
Week Calculator	Drug Code Lookup	
	Forms Instructions	
	Forms Management Utility	
	Forms Manual	
	Gender Identity Report Instructions	
	QOL/Adherence Forms	

Additional features are available to review accrual by study and site, including visualizations that display approved sites per study, site approval dates, and dates of first enrollment. Filters are provided to enhance the user experience and allow filtering by study to compare total accrual to target accrual, when available. Data are refreshed on a daily basis, reflecting enrollments completed the previous day. Users are also provided with an option to download a PDF of the dashboard with or without filters applied.

The DMC has additional dashboards planned for development and deployment over the coming grant year.



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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).

Clinical Data Management eLearning Update

Three new eLearnings have been added to the Training Pages of the Frontier Science Portal (Site Support > Training Pages > eLearning Courses): *External Data Transfers*, *Specimen Reconciliation*, and *Safety Data Management and Reporting*.

The New Investigator Topics section of the eLearning Courses tab currently features modules focused on the following content:

- *Data Freeze and Data Lock*
- *The Study Build Process*

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 ←

The General Clinical Data Management section features modules geared toward clinical site staff, with the following topics currently available:

- *Electronic Data Capture: Study Start-up and Planning Activities*
- *Data Standards Implementation*
- *Targeted Source Data Verification*
- *Ongoing Data Review*
- *External Data Transfers*
- *Specimen Reconciliation*
- *Safety Data Management and Reporting*

Data Freeze and Data Lock Timelines

Data Freeze is a temporary restriction on data entry or alteration. It is usually performed while a study is ongoing, for example, for a regulatory submission or participant transfer, but is also performed prior to a final data lock or early site closure. Data Freeze may also be referred to as a soft lock. Data Lock is a final permanent restriction on data entry or alteration, performed during study closure or early site closure. Any time a Data Freeze and Data Lock is performed, there are requirements for approval and signature collection from various stakeholders.

All data must be submitted by sites and laboratories and then reviewed by the DMC. Site Investigator of Record (IOR) electronic signatures are then collected on the frozen data.

Timelines for an interim data freeze are determined by the key stakeholders and are driven by the pharmaceutical company's regulatory submission deadlines and obligations. Timely completion of each step in the workflow ensures that those critical deadlines are met. Any shift in the timing of a data freeze or data lock could result in not meeting deadlines.

It is important to be responsive to queries prior to a data freeze or data lock in order to provide sufficient time for the reverification of modified data by monitors.

The following may cause a shift in the timeline for data freeze or data lock and should be avoided:

- Completing QA of data after data freeze or data lock
- Not signing off on eCRFs by the deadline set by the DMC

Employee Spotlight: John Binkowski, IMPAACT Protocol Data Manager

John Binkowski began working at Frontier Science as a Protocol Data Manager in 2020. He holds a Bachelor of Science in Bioinformatics from Canisius College and a Master of Arts in Biological Sciences from the University at Buffalo.

John works on protocol data management for IMPAACT on several protocols, including 2032, P1112, P1115, as well as BHP Tatelo. He became part of the DMC Training Team last year and recently joined the Cure Scientific Committee as the data manager representative. John was born and raised in the Buffalo area. He enjoys supporting the local sports teams, watching soccer, reading, and spending time with his fiancée and dogs.



Required Use of the LDMS Storage Module

In order to maintain accurate storage information on all specimens, it is required that all labs use the LDMS Storage module to track the storing of specimens. If you have a storage score of less than 100%, you can expect a query from the DMC that will need to be resolved. Queries regarding use of the Storage Module are intended to be helpful. Taking advantage of the **Specimens not in Storage** report can be a useful step in your lab's specimen processing workflow.

The **Specimens not in Storage** report, accessed in the Reports module in LDMS, can be used to identify potential gaps. This report lists specimens that are available in a laboratory's database but have not had a storage location assigned on the Storage page.

Specimens Not in Storage Report										
Searched on: Project = FRONTIER AND Non ACTG Prot/ID2 = STUDY3 AND Derivative = CEL										
Project/Prot: FRONTIER STUDY3										
Specimen ID	Global Spec ID	Pid/ID1	Collection Date	Pri	Add	Der	Sub A/D	VID	Volume	Condition
9999-000BVB00-005	123456ABC	123456ABC	31/May/2022	BLD	EDT	CEL	DMS	4.00 Vst	3e^6 CEL	SAT
9999-000BVB00-006	123456ABC	123456ABC	31/May/2022	BLD	EDT	CEL	DMS	4.00 Vst	3e^6 CEL	SAT
9999-000BVB00-007	123456ABC	123456ABC	31/May/2022	BLD	EDT	CEL	DMS	4.00 Vst	3e^6 CEL	SAT
9999-000BVB00-008	123456ABC	123456ABC	31/May/2022	BLD	EDT	CEL	DMS	4.00 Vst	3e^6 CEL	SAT
9999-000FKA00-004	8082022A	8082022A	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FKA00-005	8082022A	8082022A	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FKA00-006	8082022A	8082022A	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FLG00-004	8082022B	8082022B	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FLG00-005	8082022B	8082022B	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FLG00-006	8082022B	8082022B	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FMJ00-004	8082022C	8082022C	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FMJ00-005	8082022C	8082022C	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT
9999-000FMJ00-006	8082022C	8082022C	08/Aug/2022	BLD	EDT	CEL	DMS	1.00 Ent	3e^6 CEL	SAT

Required Entry of LDMS PBMC Processing Tracking Fields

Looking for ways to reduce the number of Lab Queries you receive from the DMC? Check your daily LDMS entries for errors using the **Specimen Processing Report**. The Specimen Processing Report can be accessed in the **Reports** modules in LDMS. At first glance, this report may seem like just a running log of samples accessioned in LDMS, but the Specimen Processing Report is much more than that.

In addition to the index of specimens, this report also contains relevant processing data for the primary and aliquot specimens, such as: Total Cell Count, Frozen Date & Time, Processing Date & Time, Processed By (tech initials), etc. Results can be filtered to display only viable PBMCs (Derivative=CEL), and can be filtered further by date.

Labs can use this report to review newly logged specimens and verify that all required fields are completed; confirming the following:

- Processing Date
- Processing Time
- Processed By [Tech Initials]
- Total Cell Count
- Frozen Date
- Frozen Time

Adding the step of generating and reviewing the Specimen Processing Report to a lab's workflow is a great way to find missing data and reduce queries. For more information about PBMC requirements, please refer to the [Cross-Network PBMC Processing SOP](#).

Specimen Processing Report													
Searched on: Project = FRONTIER AND Non ACTG Prot/ID2 = STUDY3 AND SID/ID3 = 3A AND Derivative = CEL													
Primary Spec ID	Global Spec ID	Other Spec ID	PRI	ADD	Volume	Spec Date	Spec Time	Rec Date	Rec Time	Total Cell Count	Proc Date	Proc Time	Proc By
	9999-000FKA00-000		BLD	EDT	10.00 ML	08/Aug/2022		08/Aug/2022					FL
PID/ID1	Project/Prot	SID/ID3			VID		Clinic	OPID					
8082022A	FRONTIER STUDY3	3A			1.00 Ent								
Aliq Spec ID	Global Spec ID	Other Spec ID	DER	Sub A/D	Volume	Project/Prot			Frozen Date	Frozen Time	Proc Date	Proc Time	Proc By
	9999-000FKA00-004		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
	9999-000FKA00-005		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
	9999-000FKA00-006		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
Primary Spec ID	Global Spec ID	Other Spec ID	PRI	ADD	Volume	Spec Date	Spec Time	Rec Date	Rec Time	Total Cell Count	Proc Date	Proc Time	Proc By
	9999-000FLG00-000		BLD	EDT	10.00 ML	08/Aug/2022		08/Aug/2022					FL
PID/ID1	Project/Prot	SID/ID3			VID		Clinic	OPID					
8082022B	FRONTIER STUDY3	3A			1.00 Ent								
Aliq Spec ID	Global Spec ID	Other Spec ID	DER	Sub A/D	Volume	Project/Prot			Frozen Date	Frozen Time	Proc Date	Proc Time	Proc By
	9999-000FLG00-004		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
	9999-000FLG00-005		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
	9999-000FLG00-006		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
Primary Spec ID	Global Spec ID	Other Spec ID	PRI	ADD	Volume	Spec Date	Spec Time	Rec Date	Rec Time	Total Cell Count	Proc Date	Proc Time	Proc By
	9999-000FMJ00-000		BLD	EDT	10.00 ML	08/Aug/2022		08/Aug/2022					FL
PID/ID1	Project/Prot	SID/ID3			VID		Clinic	OPID					
8082022C	FRONTIER STUDY3	3A			1.00 Ent								
Aliq Spec ID	Global Spec ID	Other Spec ID	DER	Sub A/D	Volume	Project/Prot			Frozen Date	Frozen Time	Proc Date	Proc Time	Proc By
	9999-000FMJ00-004		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
	9999-000FMJ00-005		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				
	9999-000FMJ00-006		CEL	DMS	3e+06 CEL	FRONTIER STUDY3			08/Aug/2022				

cont'd on next page

Required Entry of LDMS PBMC Processing Tracking Fields (cont'd)

In addition to the Specimen Processing Report, Frontier Science User Support also can work with labs to set up a custom report in the data retrieval (Windows) or customized report (Web) modules to identify records that have missing fields. You simply add the fields of interest in the report and, without too much filtering, see what is missing!

Clear All

Saved Queries

Processing Details

Save

Delete

All Fields

Add COUNT Field

Specimen ☒

Storage ☒

Shipping ☒

Name	Description	Category	Display
Address Assigned	Has a destination address been assigned?	Shipping	<input type="checkbox"/>
Destination Lab ID	Lab ID of the receiving lab	Shipping	<input type="checkbox"/>
Has Shipped	Is specimen shipped?	Shipping	<input type="checkbox"/>
Import Date	Date shipment was imported (received)	Shipping	<input type="checkbox"/>
Intended Ship Category	Intended shipment category	Shipping	<input type="checkbox"/>
Intended Ship Date	Intended shipping date for a marked item	Shipping	<input type="checkbox"/>
Intended Ship Lab ID	Intended destination lab for a marked item	Shipping	<input type="checkbox"/>
Marked For Shipment	Specimen either marked for shipment, or in container marked for shipment	Shipping	<input type="checkbox"/>
Original Shipment	Shipment identifier from		

Fields to Display

Up

Down

Name	Remove
Collection Time	<input type="button" value="X"/>
Received Date	<input type="button" value="X"/>
Received Time	<input type="button" value="X"/>
Processing Date	<input type="button" value="X"/>
Processing Time	<input type="button" value="X"/>
Processing Tech Initials	<input type="button" value="X"/>
Cell Count	<input type="button" value="X"/>
Frozen Date	<input type="button" value="X"/>
Frozen Time	<input type="button" value="X"/>

Distinct ☐

Sort Results By

Up

Down

Name	Remove
Project	<input type="button" value="X"/>
ID1	<input type="button" value="X"/>
ID2	<input type="button" value="X"/>
Global Specimen ID	<input type="button" value="X"/>

Selection Criteria

Upload Global Specimen Ids File

#	Name	Operator	Value	
1	Project	=	FRONTIER	<input type="button" value="Remove"/>
2	ID2	=	STUDY3	<input type="button" value="Remove"/>
3	ID3	=	3A	<input type="button" value="Remove"/>
4	Derivative	=	CEL	<input type="button" value="Remove"/>

Valid sentence items: AND, OR, (,), and numbers corresponding to the grid rows above.
For example, assuming 3 criteria in the grid above, you could use "(1 OR 2) AND 3"

criteria sentence

File Type:

Include Headers: ☒

Preview Report

Showing first 100 results

Project	ID1	ID2	Derivative	Global Specimen ID	Collection Date	Collection Time	Received Date	Received Time	Processing Date	Processing Time	Processing Tech Initials	Cell Count	Frozen Date	Frozen Time
FRONTIER	8082022A	STUDY3	CEL	9999-000FKA00-004	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022A	STUDY3	CEL	9999-000FKA00-005	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022A	STUDY3	CEL	9999-000FKA00-006	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022B	STUDY3	CEL	9999-000FLG00-004	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022B	STUDY3	CEL	9999-000FLG00-005	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022B	STUDY3	CEL	9999-000FLG00-006	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022C	STUDY3	CEL	9999-000FMJ00-004	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022C	STUDY3	CEL	9999-000FMJ00-005	08/Aug/2022		08/Aug/2022						08/Aug/2022	
FRONTIER	8082022C	STUDY3	CEL	9999-000FMJ00-006	08/Aug/2022		08/Aug/2022						08/Aug/2022	

Close

Additional information about LDMS, including a detailed user manual, can be found at <https://www.ldms.org/>.

2022

JANUARY

S	M	T	W	T	F	S
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2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
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30	31					

MARCH

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MAY

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JULY

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31						

SEPTEMBER

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NOVEMBER

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FEBRUARY

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APRIL

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JUNE

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AUGUST

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OCTOBER

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30	31					

DECEMBER

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25	26	27	28	29	30	31

MARK YOUR CALENDARS

Data Management Introductory Workshops

October 19—21, 2022

Web LDMS Introductory Trainings

- First Friday of Each Month

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

CONTACT

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ACTG and IMPAACT

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Email: user.support@fstfrf.org

LDMS User Support

Phone: +001 716-834-0900 x7311

Email: ldms-help@fstfrf.org<https://www.ldms.org/contact>