

DATA MANAGEMENT CENTER NEWSLINE

Medidata Rave Imaging

DAIDS has expanded Medidata Rave Imaging Solutions on select ACTG and IMPAACT clinical trials to include studies IMPAACT 2019, IMPAACT 2032, ACTG A5360, ACTG A5379, and ACTG A5404 in a phased approach. This implementation continues to be in accordance with the FDA issued guidance document entitled “FDA Conduct of Clinical Trials of Medical Products during COVID -19 Public Health Emergency,” and aligns with DAIDS remote monitoring strategy and expansion on the scope of remote source monitoring to include rSDV.

Sites participating in these studies will be invited as Rave Imaging is configured for each study. The invitation will be unique to each study configured and sent to participating sites when configuration for the study has been completed. Sites are required to take the eLearning entitled “Medidata Remote Source Review: Site Users Training” before accessing the module.

Recorded Data Management Training

Recorded data management training is available on the Training Pages of the Frontier Science Portal. The Recorded Training tab has links to videos of individual training sessions provided in recent DMC Introductory Workshops.

Introductory Workshop Training Sessions

- [Adverse Event Reporting](#)
- [Study Enrollment System](#)
- [Who We Are](#)
- [DMC Portal Website Highlights](#)
- [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](#)

To learn additional information about our training programs, please contact our Education Director, Mary Wojcik-Cross (wojcik@frontierscience.org or 716-834-0900 ext. 7466).



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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).

Introduction to JReview

What is JReview?

Installed Modules

Reporter

JReview is a tool that allows users to browse data, generate custom reports, and join tables, much like *TJoin* on the DMC Portal. It is necessary to have Java enabled on your browser. JReview can be accessed through Rave's Reporter module.

When should I use JReview over TJoin?

- JReview allows you to limit the population using patient selection criteria, without needing to filter after generating the report.
- Flexibility in date formats and limiting date ranges
- Able to generate PDF reports directly from the program
- Graphing feature
- Data are updated as soon as it is entered into an eCRF

Patient Selection Criteria

Use Patient Selection Criteria to limit the participants who appear in your retrieval. For example, you could limit your retrieval to only females. You are required to select forms and fields, and can select functions and operators. You are able to define multiple selection criteria.

Patient Selection Criteria - All Patients

Forms

- Antiretroviral History
- Automated Self-Administered 24-hour Di
- Bowel Symptom Assessment
- Comments
- MetricViews
- Concomitant Medications Log
- Concomitant Medications Log
- Death Report
- Diet History Questionnaire II (DHQII) Tr
- Eligibility Checklist Log
- Fatigue Symptom Assessment
- Food/Drink Intake Record
- HIV Plasma Viral Load
- Lab view
- Laboratory Findings

Fields

- _Define New Item_
- _Define New Range_
- BRTHDAT
- BRTHDAT DD
- BRTHDAT INT
- BRTHDAT MM
- BRTHDAT RAW
- BRTHDAT YYYY
- BRTHSEX
- CODER HIERARCHY
- DataPageName
- ELIGQANS
- ELIGQDMCO
- ELIGQNO
- ELIGQTX
- Folder

Functions

- actual value

Operator

- =
- <>
- <
- >
- <=
- >=
- begins with:
- is missing(NULL)
- is not missing(not NULL)

Update Browsers

ADD expression

Display Stats

Display Values

Item Compare

And/Or	Selection Criteria (Text)	Selection Criteria (SQL)
	Eligibility Checklist Log.BRTHSEX =F	T11.BRTHSEX ='F'

Value

F

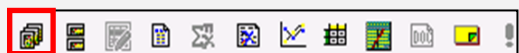
Select display values to see possible values for a field.

☐ Exclude patients meeting criteria?

☐ Append to criteria?

Criteria description:

Click on the Data Browser icon to review data for the participants meeting the selection criteria.

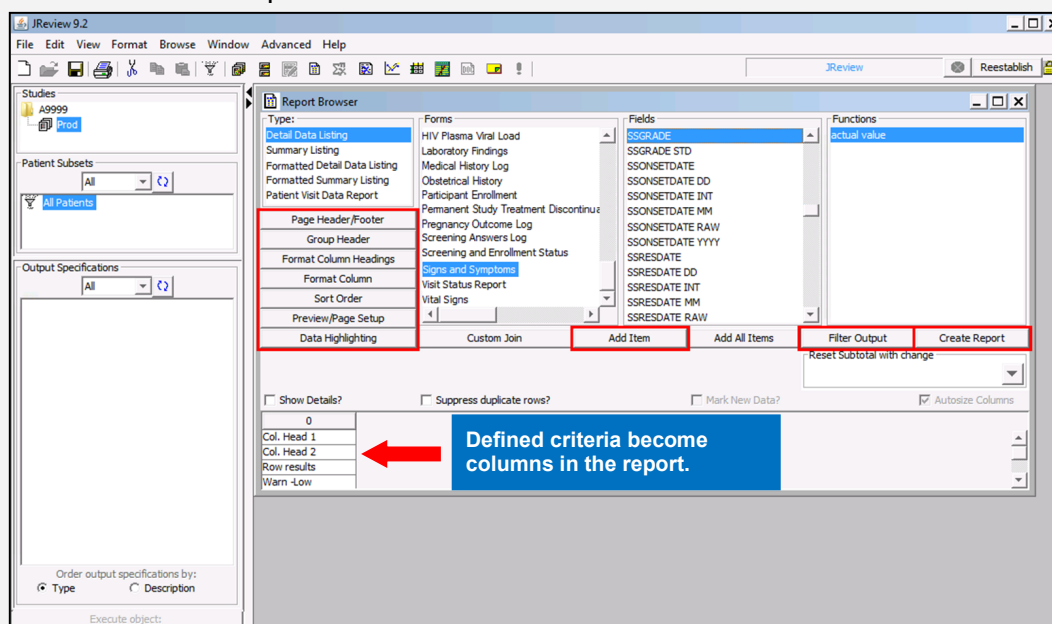


Introduction to JReview (cont'd)

Report Browser



Allows you to retrieve data in a tabular format that can be exported into Microsoft® Excel or formatted into a customized PDF report.



Where can I find further information?

- eLearnings are available from Medidata
- Medidata Rave Resources on the DMC Portal (included under the Site Support category) includes a link to the DMC's *Rave Reports* reference guide, which includes information on JReview and other modules within
- The Training Pages on the DMC Portal (also included under the Site Support category) includes a presentation on JReview and a recorded session from the DMC Introductory Workshop

Site Support
[Computing Manual](#)
[Computing Requirements](#)
[DMC Contacts](#)
[Email Address Book Download](#)
[Email Address Lookup](#)
[Medidata Rave Resources](#)
[Newslines](#)
[Training Pages](#)

Employee Spotlight: Matt Foreman, Study Builder

Matt Foreman began working at Frontier Science in August 2019, as a Rave Study Builder for the ACTG & IMPAACT projects. Matt holds a B.S. in Computer Science from Indiana University of Pennsylvania, in addition to a M.S. in Telecommunications from the University of Pittsburgh. Matt spent much of his career working for a major telecommunications provider, holding various positions around the Northeast.

Matt settled in the Buffalo area in 2014, following his husband Wes, who was drawn to Buffalo through a career opportunity. Matt enjoys spending his time practicing yoga, caring for the yard/garden, bicycling, reading, and vegetarian cooking.



LOINC Codes within SDTM Datasets

The FDA requires the submission of LOINC (Logical Observation Identifiers Names and Codes) codes within CDISC SDTM datasets for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs), and for certain investigational new drugs (INDs) for studies that started after March 15, 2020.

To facilitate the mapping of LOINC codes into SDTM and ensure data integrity, clinical laboratory eCRFs have been updated to now collect specimen type. If you have any questions about how to complete this new field, please contact your Protocol Data Manager.

Specify Lines and Medical Coding in Medidata Rave

The Medical Coding Department at Frontier Science is responsible for coding adverse events and reported medications using various standardized dictionaries. The MedDRA dictionary is used to code reported adverse events. The WHODrug Global B3 dictionary is used for reported, concomitant, and study drug medications. Frontier Science's Appendix 3 is also utilized when applying codes to all submitted medications.

Code choices are made solely based on what has been reported in the specify description field. The description line is reviewed and assigned one MedDRA code or one drug code per description line. If more than one event or drug name is reported in one specify line, the Medical Coders will send a query asking the site to report each event or medication on separate specify lines in order to capture the complexity of the event or the different medications being taken. By doing this, the Medical Coders can then assign a MedDRA code or drug code to each. Otherwise, the event or drug name may be assigned a vague, less descriptive code to encompass both events.

Query Text

Please report only one event per 'Adverse Event' field. Therefore, report 'enlarged uvula' in one field and 'erythematous uvula' in another field. Thank you.

Keep in mind that if a diagnosis and its characteristic signs or symptoms are reported, the Medical Coders will code the diagnosis. For example, if “due to” is reported, the Medical Coders will code the diagnosis and be unable to code the other part without it being reported on a separate specify line.

For example, regarding an adverse event reporting, if a site is reporting “2nd & 3rd degree burns” on one line, it should be split into two separate description lines. MedDRA considers 2nd degree burns and 3rd degree burns as different medical concepts and therefore, they each have their own MedDRA code. Without splitting the 2nd and 3rd degree burns, the Medical Coders would have to assign the less specific code of “thermal burns” to this line.

With respect to medication reporting, if two different drugs are taken at the same time, report one drug per specify line. For example, if taking Tivicay and Kaletra at the same time each day, report each one on its own specify line, as these are not combined into one pill. They are two separate pills taken at the same time.

If a true combination pill, such as dolutegravir/lamivudine/tenofovir disoproxil fumarate, is reported, because this is one pill with three different drugs compounded together, it is correct to report on one specify line.

2021

JANUARY

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NOVEMBER

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DECEMBER

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MARK YOUR CALENDARS

Data Management Introductory Workshops

- October 26—28, 2021

See *Frontier Science Portal Training Pages* for additional information.

LDMS Introductory Workshops

- May 14, 2021
- August 13, 2021
- November 05, 2021

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