22R3 Customer Webinar For All

Nov 3, 2022

Veeva

CDMS Product Managers

Margaret Wehner

Product Manager

Data Entry, Review UI, Reports

Sharon Lin

Director, Product Management

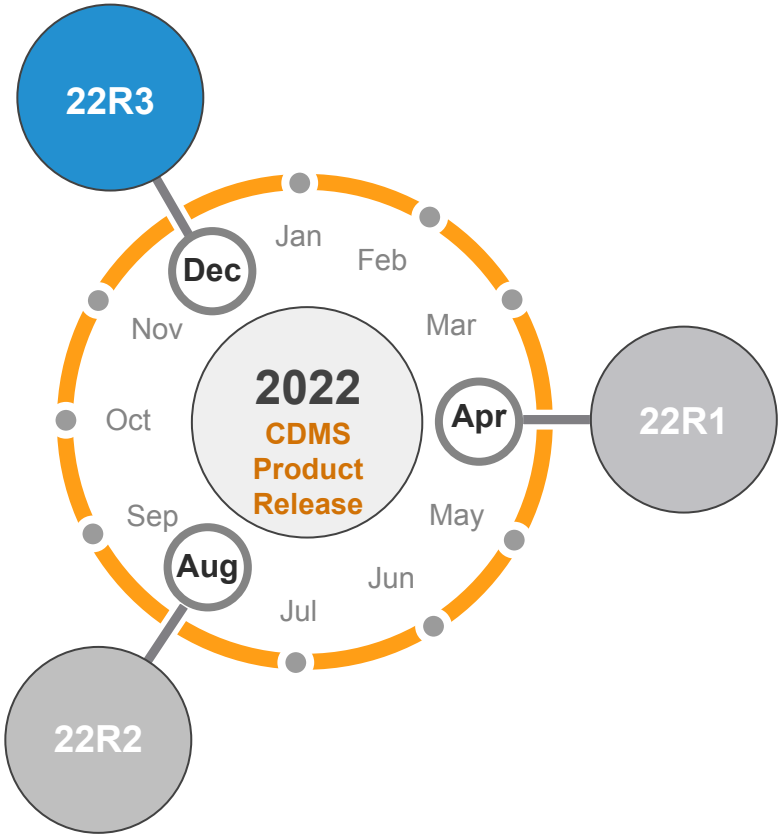
Local Labs

John Roeckel (JB)

Product Manager

Data Entry, Medical Assessments

Veeva Vault Release Schedule



22R3 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	01 NOV	02	03 **22R3 Release Webinar** 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	04 **22R3 Pre-Release Upgrade**	05
06	07 Validation Docs	08	09	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	36
27	28	29	30	01 DEC	02 **22R3 General Release Upgrade**	03

Customer Validation

22R3 Release Dates

Pre – Release

- **Clone of UAT**
- Special Request for DEV
- **Users**
- Added by Project Managers or Customers Success Managers
- **Available up to 6 weeks after 22R3 Release**

Validation Docs

- Located in VeevaDocs
- Validation Project Plan
- Business Requirements Documents
- Validation Impact Assessment
- Traceability Matrix
- IOQ Protocol
- System Release Memo

22R3 Release

- All Customers Vaults upgraded to 22R3

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts

Available Resources

https://cdmshelp.veeva.com/lr/rn/general-releases/22r3/

- Important Dates
- Notifications Opt-In
- Feature information
- Pre- Release Information
- Release Information
- Release Impact Assessment (RIA)

22R3 Feature Summary

Sites

- Bulk Signature
- Sign with Open Queries
- Data Entry Schedule Enhancements
- Protocol Deviation Enhancements
- Specify Other for Additive Review

Reports/Extracts

- Listings in Reports
- Listings Enhancements
- SDE Study Design Information
- SDE Length Standardization
- SDE Enhancements

Study Designer

- Library Keys in the SDS
- Library Report as CSV
- Multi-language Support
- Retrospective Amendment changes
- Cross-Form Derivations
- Previous Value Rules
- Form Linking Rule Enhancements
- Email Rule Enhancements

Other

- CDMS - CTMS Study Pause
- APIs:
  - Retrieve Study Jobs
  - Support for Other Areas
  - Cleanup

Admin

- Job Enhancements
- Rule Execution Enhancements
- User Import Warnings
- Vault Deployment Diff report - Support for MRS
- General Enhancements

Labs

- Lab Modifier for Unit Data Type
- Configurable Lab Queries
- Disable Pending Labs
- Labs Migration

Coding

- Coder UI Optimization
- Batch Upversioning Failure Tolerance
- Code Forms that Need Synonym Lists

E2BLink (Formerly known as SafetyLink)

- Email Notifications on Failures
- Deployments & Validations

Data Entry

Bulk Casebook Signature

- Overview

Principal Investigators will now have the ability to sign multiple casebooks at once rather than signing each individual casebook at a time.

A Signature History page will be available in data entry and review where users can view the signature history for all signing activities, bulk and non-bulk. This will be available regardless of whether or not bulk casebook signature is enabled in a vault.

Bulk Casebook Signature controlled at study and site level.

- Use case

As a PI, I want to sign multiple casebooks at a time, so that I can quickly sign off on all of my subjects at the end of the study.

Day 1 Impact to Clinical Teams

No

Visibility

Principal Investigator, Data Manager, Leader Data Manager

Configuration

Support - feature flag
EDC Tools - study and site settings

Dependencies

DM2

Sign with Open Queries

- Overview

Principal Investigators will now have the ability to sign forms and event dates that have open queries.

Controlled at the study level.

Bulk Casebook Signature behaves differently when Sign with Open Queries is also enabled for a study.

- Use case

As a PI, I want to sign forms with open queries, so that I can accept the data that I'm currently seeing, even if it'll change when the queries are addressed. This may be necessary for interim analysis, pharmacovigilance, or during other times in a study.

Day 1 Impact to Clinical Teams

No

Visibility

Principal Investigator, Leader Data Manager

Configuration

Support - feature flag
EDC Tools - study setting

Dependencies

DM2

Data Entry Schedule Enhancements

- Overview
  - Schedule panel improvements
    - Data entry page is responsive
    - Schedule tree is 1/3 of browser window
    - Common Form panel is 1/4 of schedule tree
    - Panels are sticky across sessions

- Use case
  - More space devoted to data entry

Day 1 Impact to Clinical Teams

Yes

Visibility

Sites

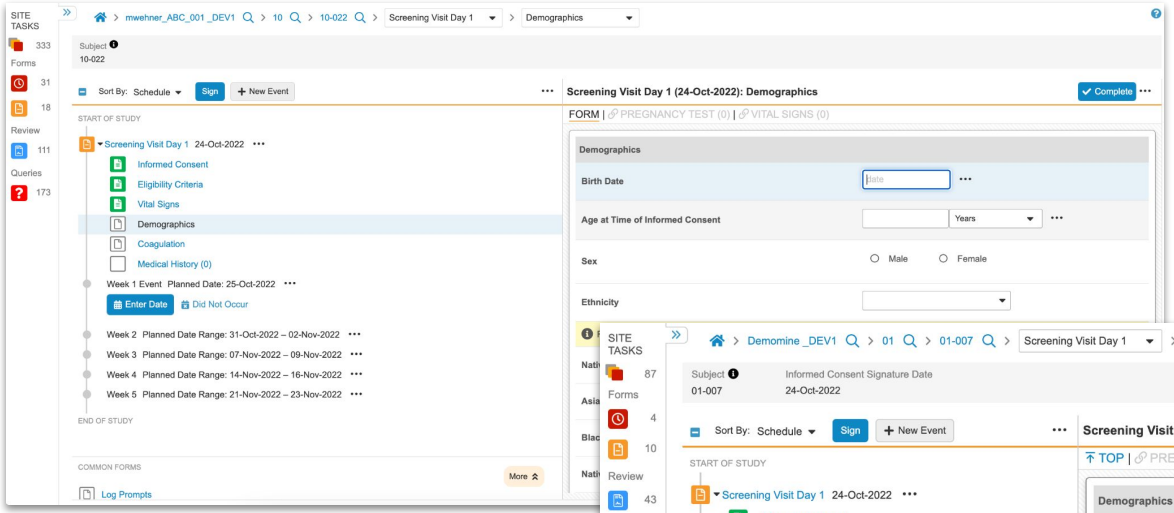
Configuration

N/A

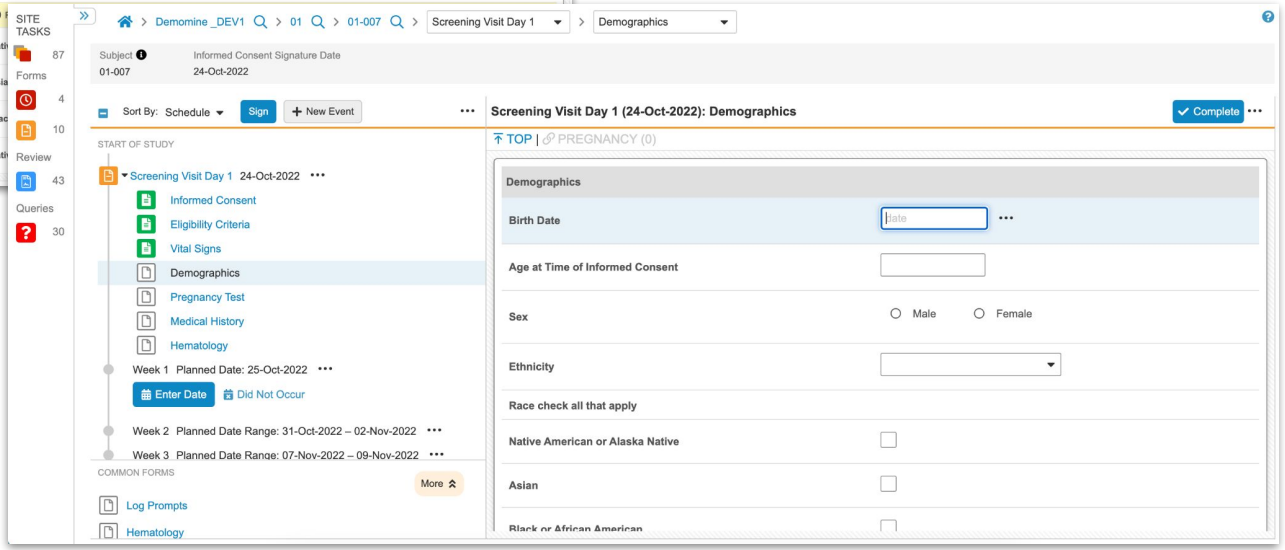
Dependencies

Data Entry V2

Data Entry Schedule Enhancements



22R2



22R3

Other Data Entry Enhancements

- Delimiter always shows for composite items
- Global lab units and codelists are visible in data entry UI grids
- Units are visible in form link details in PDFs

- Use case
  - Consistent user experience

Day 1 Impact to Clinical Teams

Yes

Visibility

Sites, CRAs, Data Managers

Configuration

N/A

Dependencies

None

Review

Protocol Deviation Enhancements

- Overview
  - Improved search for protocol deviations
    - No longer requires exact match or case sensitive
  - Protocol Deviation ID now appears in grid and export
  - Export improvements
    - Excel export option
    - Export filtered view
    - Unambiguous date format
      - yyyy-mm-dd
  - Inactive deviations are hidden in Review
  - Display status in Review

- Use case
  - Better user experience for protocol deviations

Day 1 Impact to Clinical Teams

No

Visibility

CRA, Data Manager, Lead Data Manager

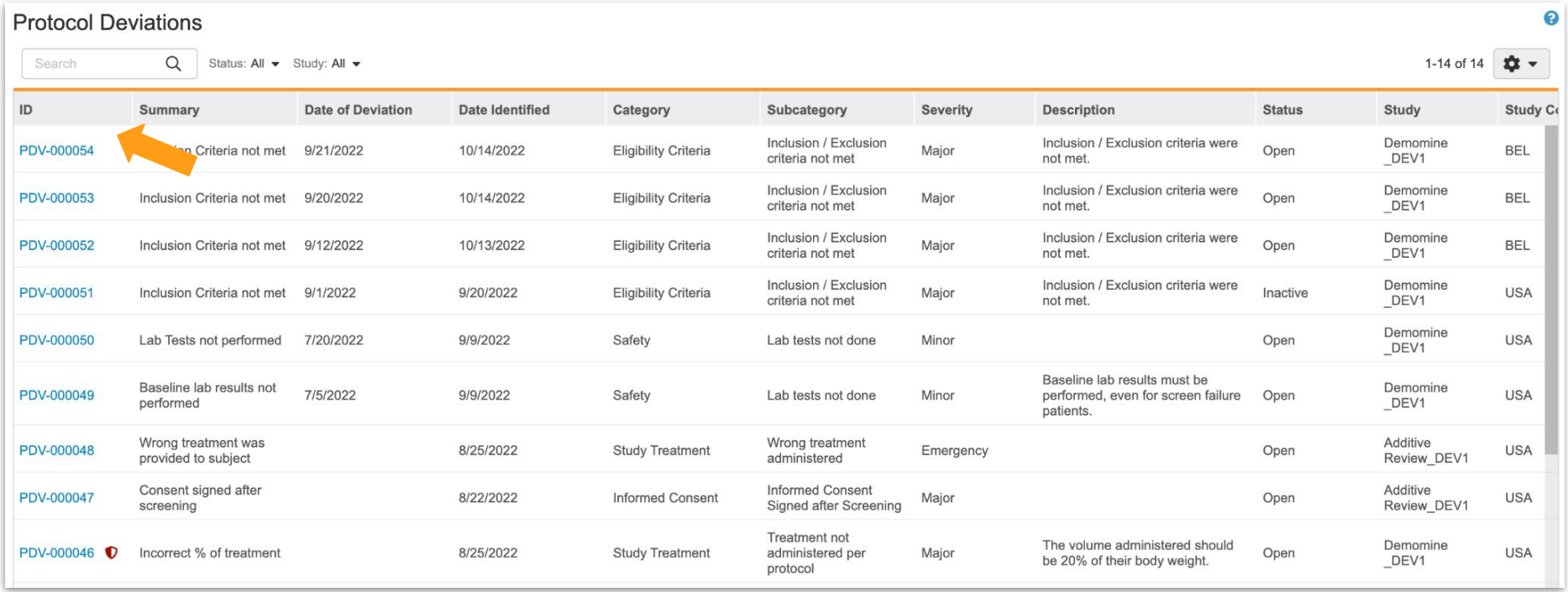
Configuration

N/A

Dependencies

Protocol Deviations

Protocol Deviation Enhancements

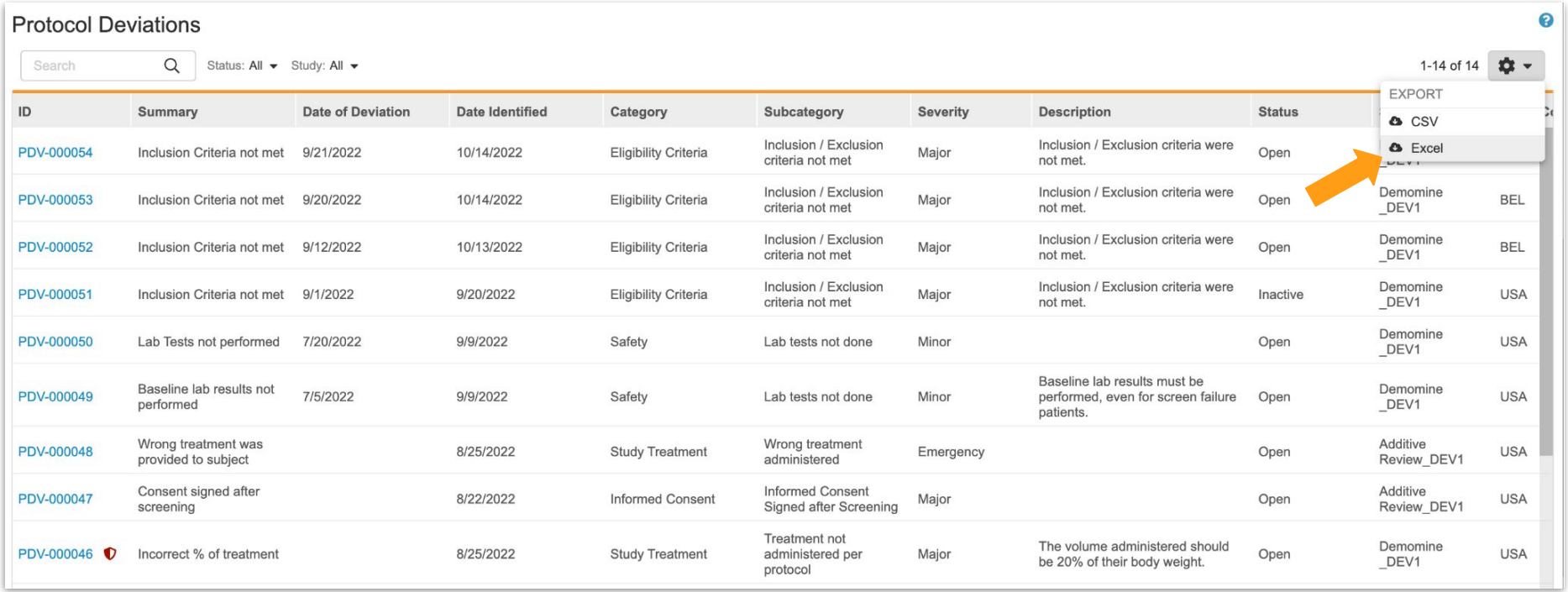


Protocol Deviations

Search | Status: All | Study: All | 1-14 of 14

ID	Summary	Date of Deviation	Date Identified	Category	Subcategory	Severity	Description	Status	Study	Study C
PDV-000054	Criteria not met	9/21/2022	10/14/2022	Eligibility Criteria	Inclusion / Exclusion criteria not met	Major	Inclusion / Exclusion criteria were not met.	Open	Demomine _DEV1	BEL
PDV-000053	Inclusion Criteria not met	9/20/2022	10/14/2022	Eligibility Criteria	Inclusion / Exclusion criteria not met	Major	Inclusion / Exclusion criteria were not met.	Open	Demomine _DEV1	BEL
PDV-000052	Inclusion Criteria not met	9/12/2022	10/13/2022	Eligibility Criteria	Inclusion / Exclusion criteria not met	Major	Inclusion / Exclusion criteria were not met.	Open	Demomine _DEV1	BEL
PDV-000051	Inclusion Criteria not met	9/1/2022	9/20/2022	Eligibility Criteria	Inclusion / Exclusion criteria not met	Major	Inclusion / Exclusion criteria were not met.	Inactive	Demomine _DEV1	USA
PDV-000050	Lab Tests not performed	7/20/2022	9/9/2022	Safety	Lab tests not done	Minor		Open	Demomine _DEV1	USA
PDV-000049	Baseline lab results not performed	7/5/2022	9/9/2022	Safety	Lab tests not done	Minor	Baseline lab results must be performed, even for screen failure patients.	Open	Demomine _DEV1	USA
PDV-000048	Wrong treatment was provided to subject		8/25/2022	Study Treatment	Wrong treatment administered	Emergency		Open	Additive Review_DEV1	USA
PDV-000047	Consent signed after screening		8/22/2022	Informed Consent	Informed Consent Signed after Screening	Major		Open	Additive Review_DEV1	USA
PDV-000046	Incorrect % of treatment		8/25/2022	Study Treatment	Treatment not administered per protocol	Major	The volume administered should be 20% of their body weight.	Open	Demomine _DEV1	USA

Protocol Deviation Enhancements



Protocol Deviations

Search | Status: All | Study: All | 1-14 of 14

EXPORT
CSV
Excel

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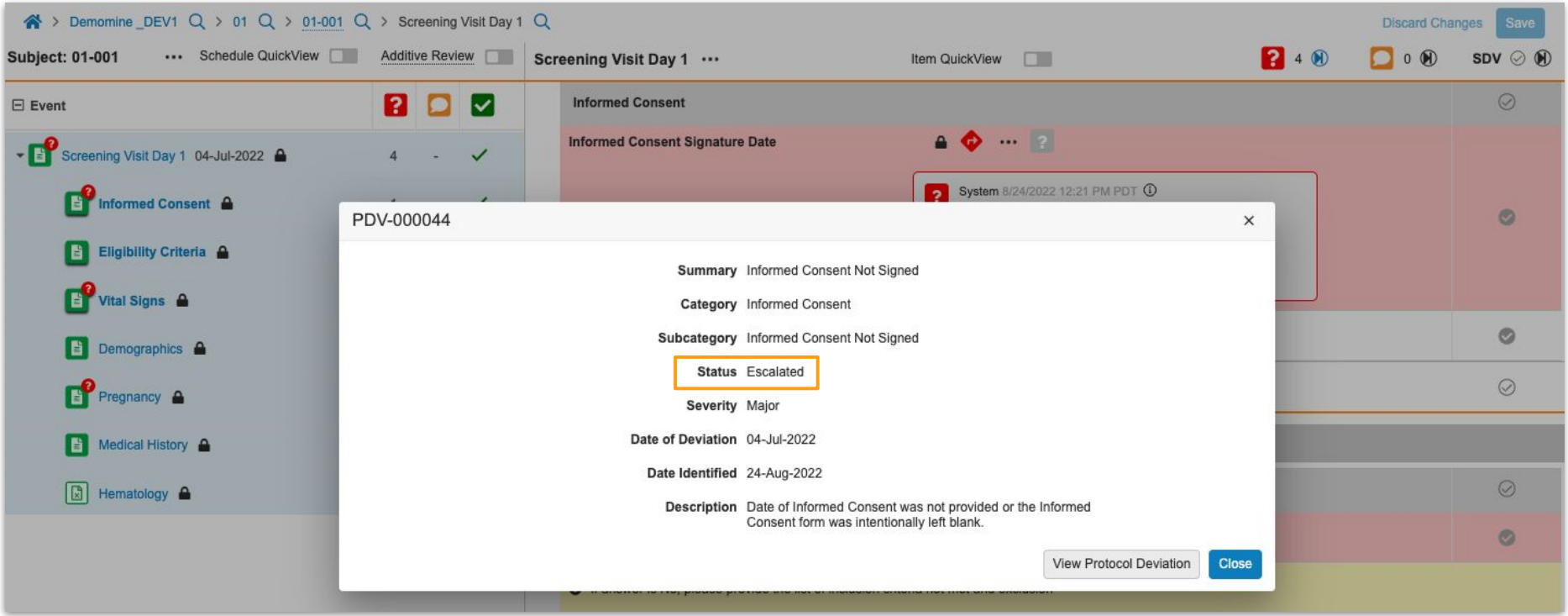
Protocol Deviation Enhancements



Additive Review - Other Specify

- Overview
  - Reviewers can provide a custom reason for Additive Review
  - Based on the **Enable Other Specify - Reason for change** setting in Studio

- Use case
  - Allows CRAs and Data Managers to explain why they're performing additive review, if the reason is not already listed

Day 1 Impact to Clinical Teams

No

Visibility

CRA, Data Manager, Lead Data Manager

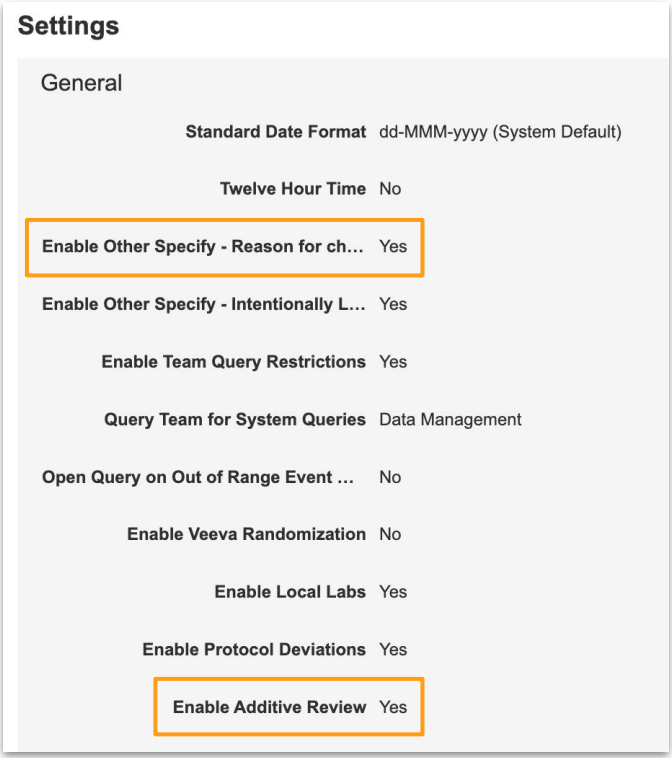
Configuration

Studio

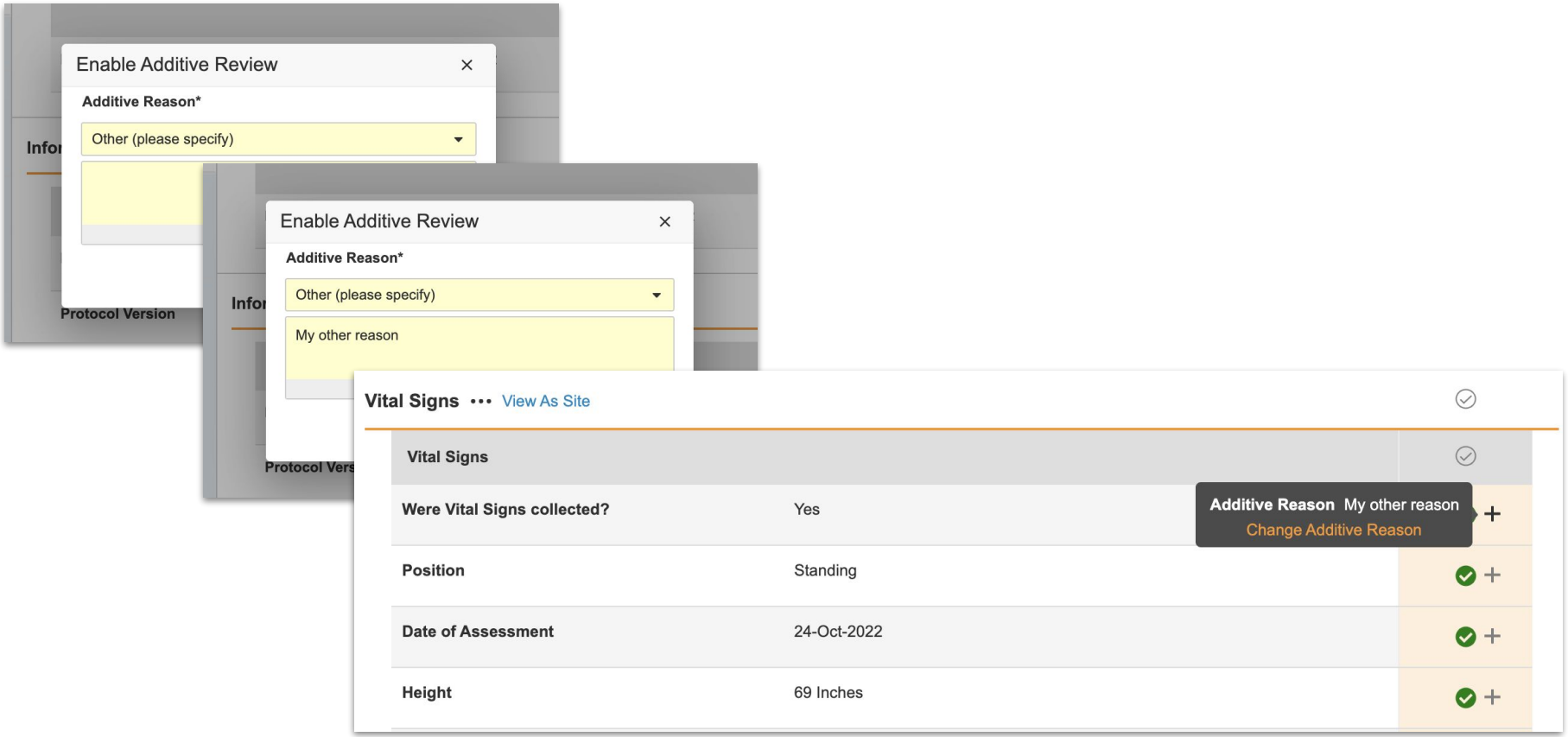
Dependencies

Additive Review

Additive Review - Other Specify



Additive Review - Other Specify



Reports

Study Progress Listings in Reports

- Overview
  - The four study progress listings are now available in the Reports tab
    - Standard report template for each listing
  - Users can create custom reports based on the listings and customize:
    - Tabular or Matrix
    - Visible columns
    - Filters
    - Conditional fields
  - Users can create dashboards based on the listings
  - User will need to schedule a daily job to refresh the data in Reports
    - One daily job per listing
    - Exception: Priority studies can schedule 3 daily jobs

- Use case
  - Listings can be customized and filtered

Day 1 Impact to Clinical Teams

NO

Visibility

CRAs & DMs

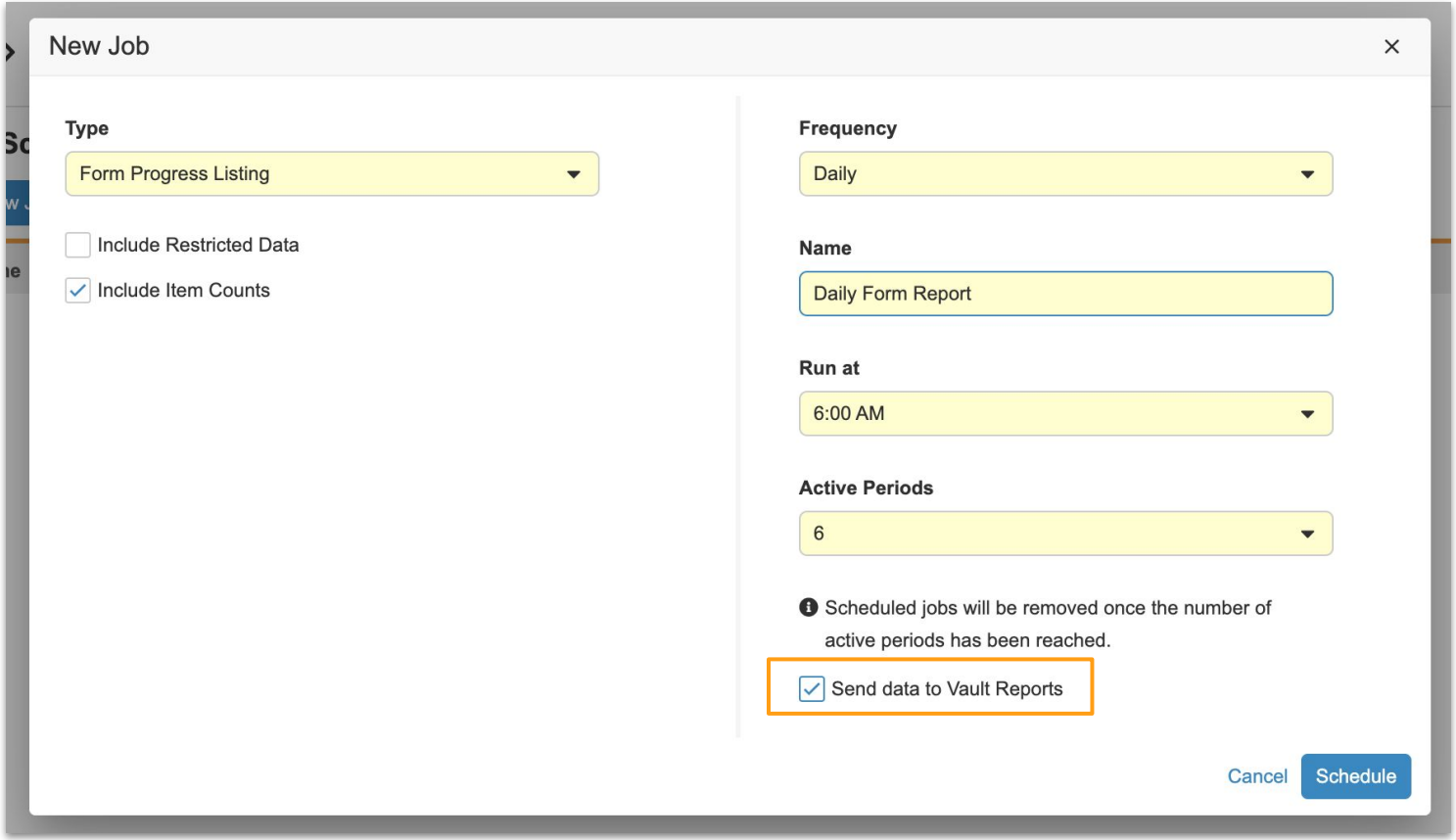
Configuration

Support

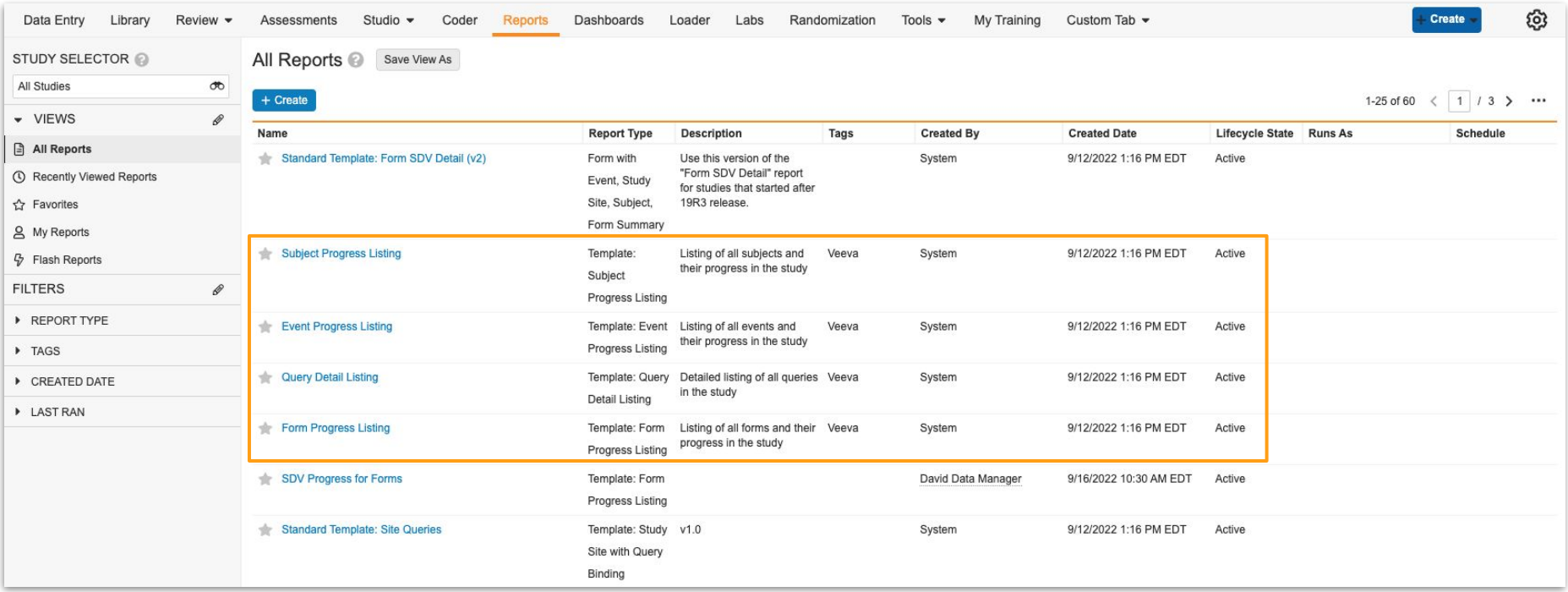
Dependencies

None

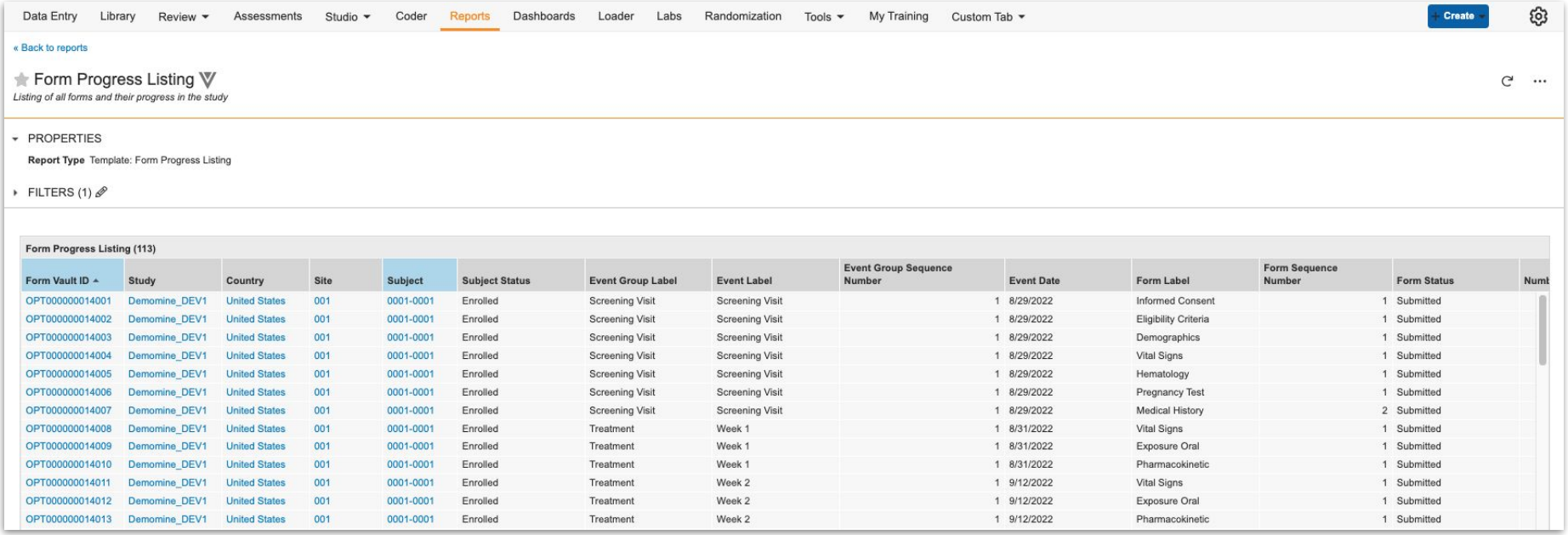
Study Progress Listings in Reports



Study Progress Listings in Reports

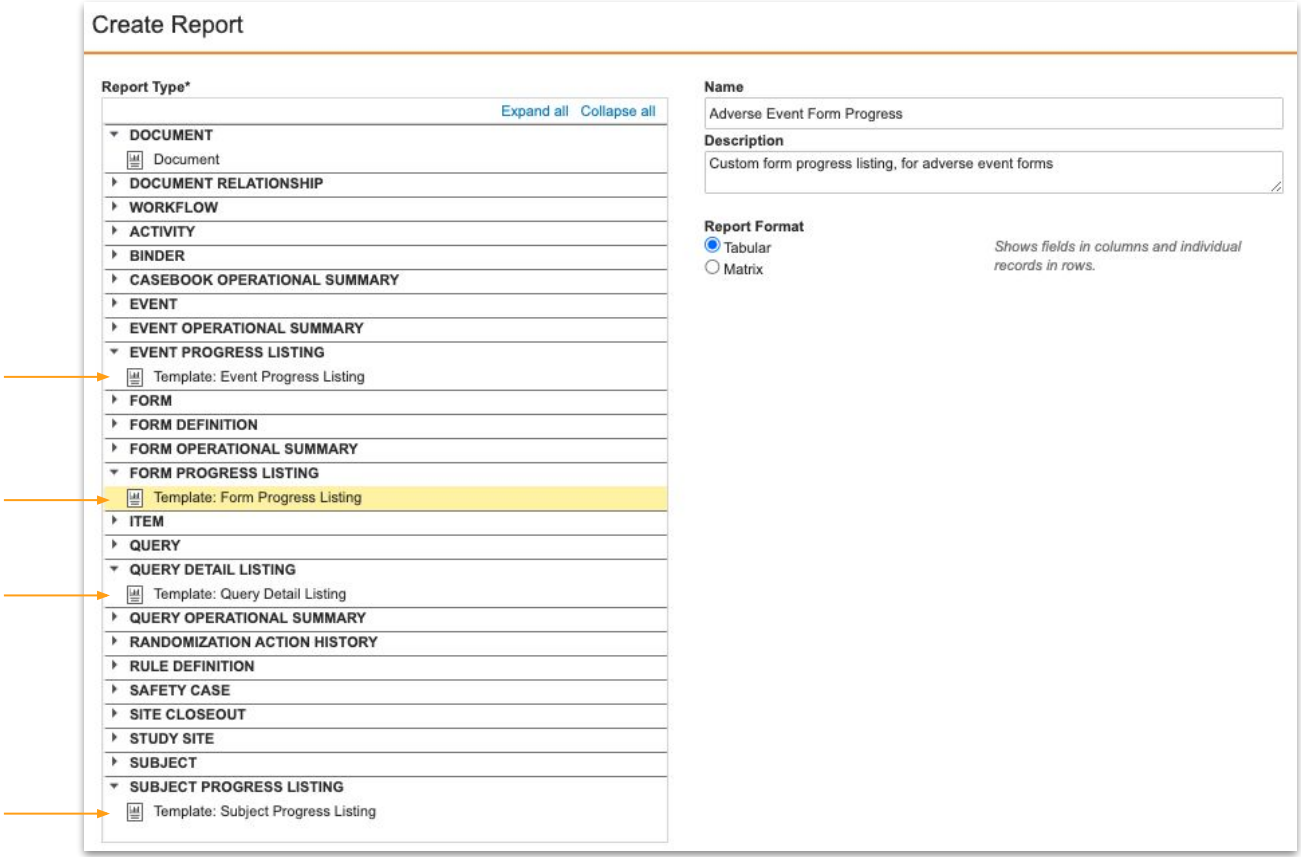


Study Progress Listings in Reports



Form Vault ID	Study	Country	Site	Subject	Subject Status	Event Group Label	Event Label	Event Group Sequence Number	Event Date	Form Label	Form Sequence Number	Form Status	Numb
OPT000000014001	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Informed Consent	1	Submitted	
OPT000000014002	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Eligibility Criteria	1	Submitted	
OPT000000014003	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Demographics	1	Submitted	
OPT000000014004	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Vital Signs	1	Submitted	
OPT000000014005	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Hematology	1	Submitted	
OPT000000014006	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Pregnancy Test	1	Submitted	
OPT000000014007	Demomine_DEV1	United States	001	0001-0001	Enrolled	Screening Visit	Screening Visit	1	8/29/2022	Medical History	2	Submitted	
OPT000000014008	Demomine_DEV1	United States	001	0001-0001	Enrolled	Treatment	Week 1	1	8/31/2022	Vital Signs	1	Submitted	
OPT000000014009	Demomine_DEV1	United States	001	0001-0001	Enrolled	Treatment	Week 1	1	8/31/2022	Exposure Oral	1	Submitted	
OPT000000014010	Demomine_DEV1	United States	001	0001-0001	Enrolled	Treatment	Week 1	1	8/31/2022	Pharmacokinetic	1	Submitted	
OPT000000014011	Demomine_DEV1	United States	001	0001-0001	Enrolled	Treatment	Week 2	1	9/12/2022	Vital Signs	1	Submitted	
OPT000000014012	Demomine_DEV1	United States	001	0001-0001	Enrolled	Treatment	Week 2	1	9/12/2022	Exposure Oral	1	Submitted	
OPT000000014013	Demomine_DEV1	United States	001	0001-0001	Enrolled	Treatment	Week 2	1	9/12/2022	Pharmacokinetic	1	Submitted	

Study Progress Listings in Reports



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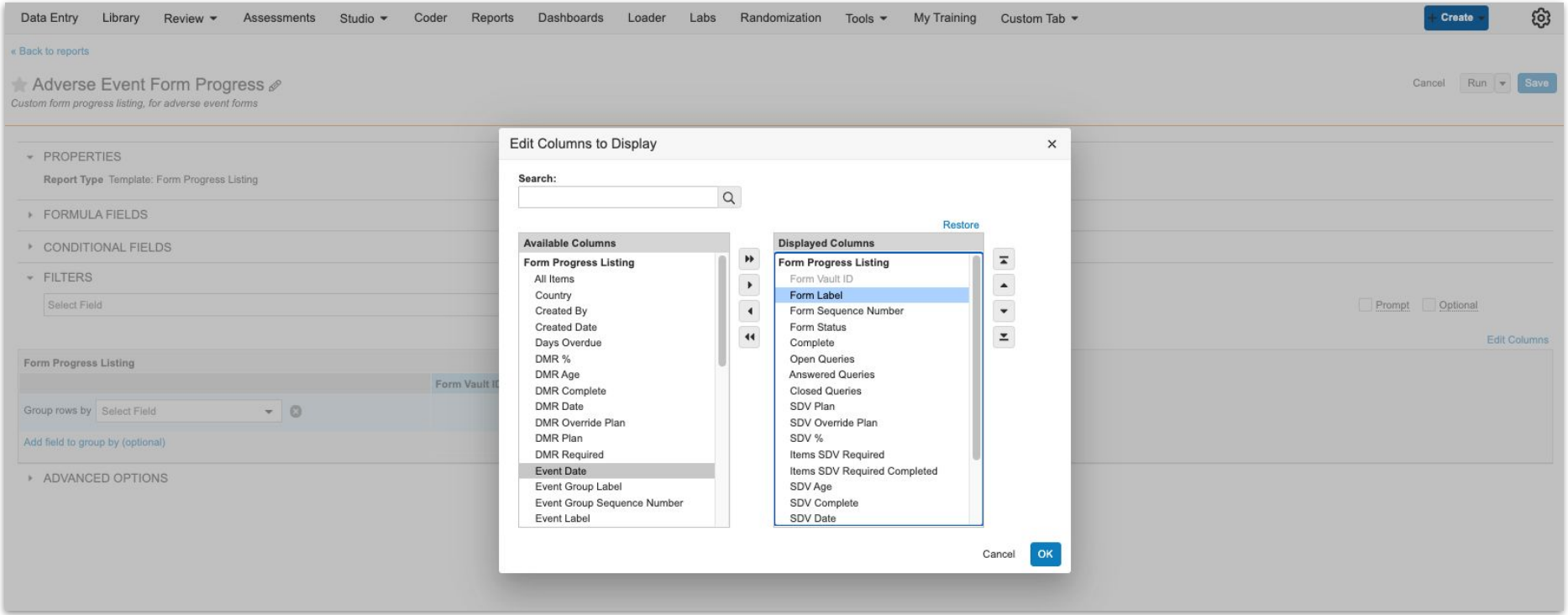
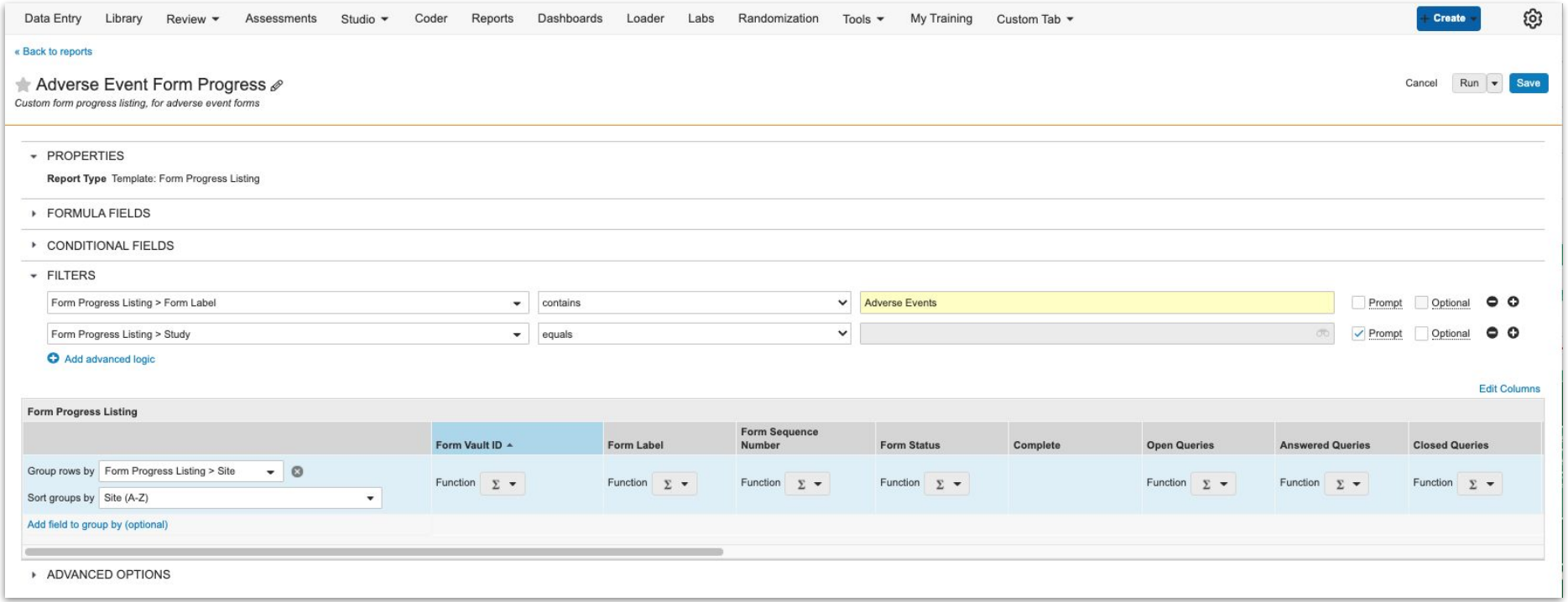
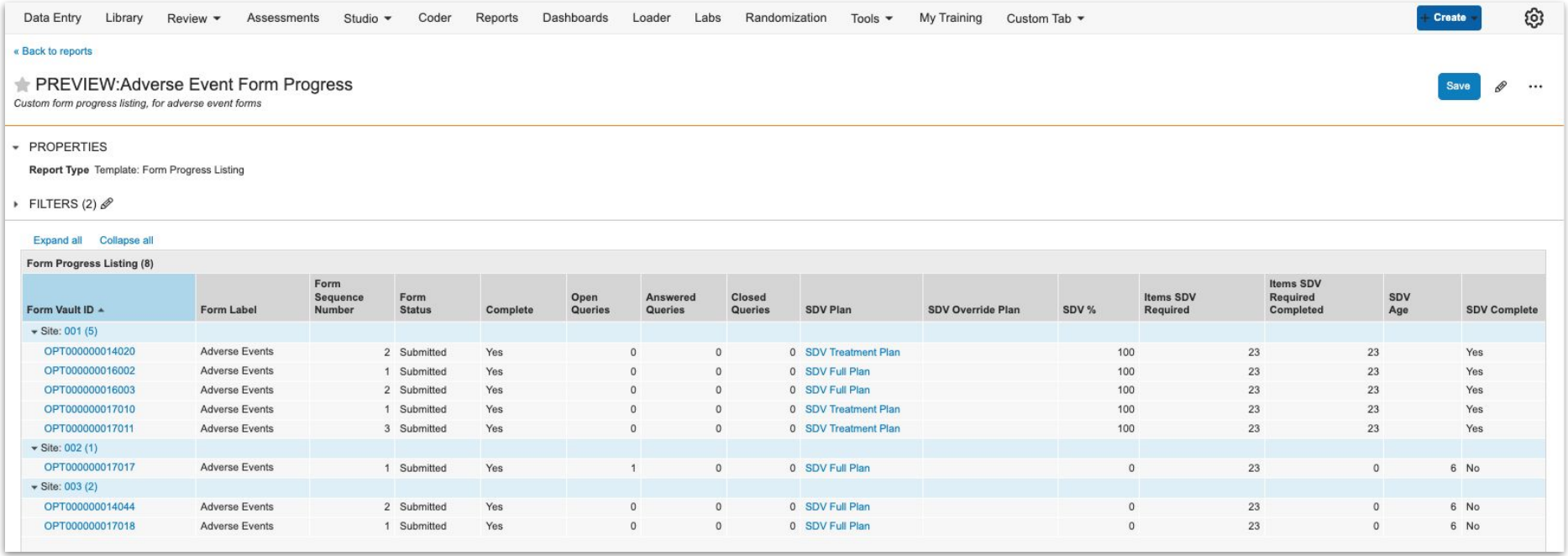


Study Progress Listings in Reports

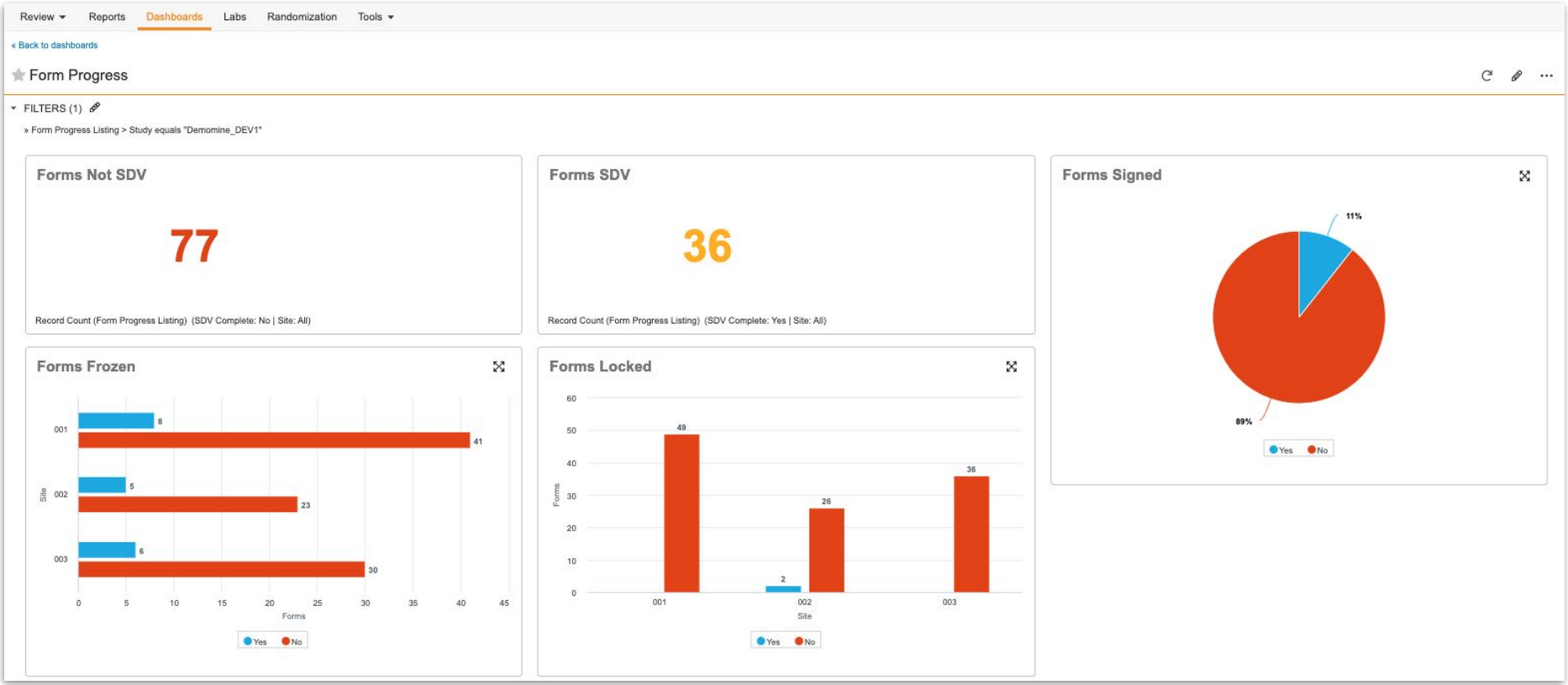


Study Progress Listings in Reports



Form Vault ID	Form Label	Form Sequence Number	Form Status	Complete	Open Queries	Answered Queries	Closed Queries	SDV Plan	SDV Override Plan	SDV %	Items SDV Required	Items SDV Required Completed	SDV Age	SDV Complete
Site: 001 (5)														
OPT000000014020	Adverse Events	2	Submitted	Yes	0	0	0	SDV Treatment Plan		100	23	23		Yes
OPT000000016002	Adverse Events	1	Submitted	Yes	0	0	0	SDV Full Plan		100	23	23		Yes
OPT000000016003	Adverse Events	2	Submitted	Yes	0	0	0	SDV Full Plan		100	23	23		Yes
OPT000000017010	Adverse Events	1	Submitted	Yes	0	0	0	SDV Treatment Plan		100	23	23		Yes
OPT000000017011	Adverse Events	3	Submitted	Yes	0	0	0	SDV Treatment Plan		100	23	23		Yes
Site: 002 (1)														
OPT000000017017	Adverse Events	1	Submitted	Yes	1	0	0	SDV Full Plan		0	23	0	6	No
Site: 003 (2)														
OPT000000014044	Adverse Events	2	Submitted	Yes	0	0	0	SDV Full Plan		0	23	0	6	No
OPT000000017018	Adverse Events	1	Submitted	Yes	0	0	0	SDV Full Plan		0	23	0	6	No

Study Progress Listings in Reports



Study Progress Listings Enhancements

- Form Progress Listing
  - New column for All Items
  - Freeze, Lock and Sign Dates for DM1 studies
- Query Detail Listing
  - The user's current role will now show for studies not using Query Teams
- Restricted Data
  - When Include Restricted is not selected, the Subject Progress and Event Progress Listings will only count non-restricted forms
- Study Summary Metrics Report
  - Site number is now included

Day 1 Impact to Clinical Teams

NO

Visibility

CRAs & DMs

Configuration

N/A

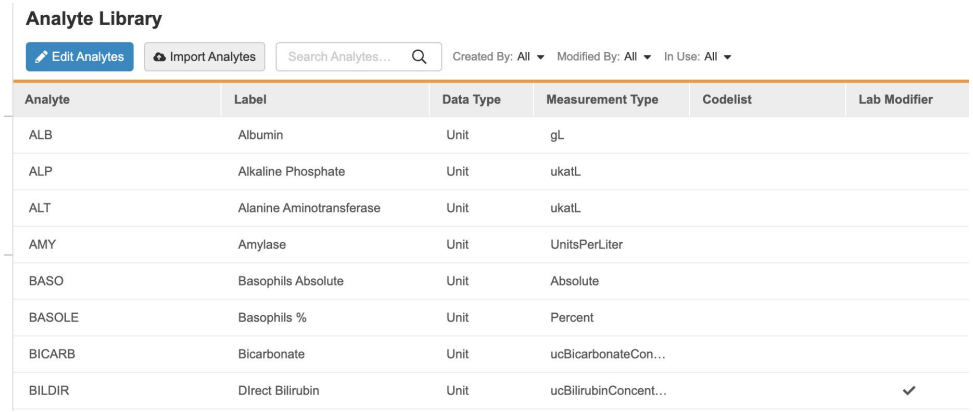
Dependencies

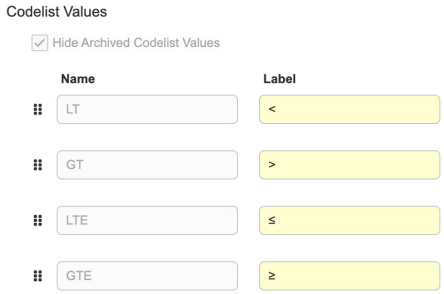
None

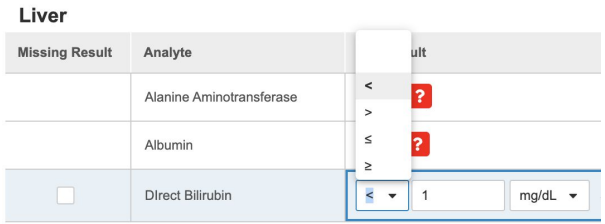
Local Labs

Lab Modifier for Unit Data Type

- Overview
  - Analytes can be configured to have a Lab Modifier, and when Lab Results contain the lab modifier, it will be used to calculate the out of range indicator.
  - There is also a new flag indicator - Inconclusive. When selecting a lab modifier causes the possibility to be within range or out of range.
- Use case
  - Be able to support Lab Results with a >, <, ≥, ≤







Day 1 Impact to Clinical Teams

NO

Visibility

Lab Data Manager, Data Manager, Lead Data Manager

Configuration

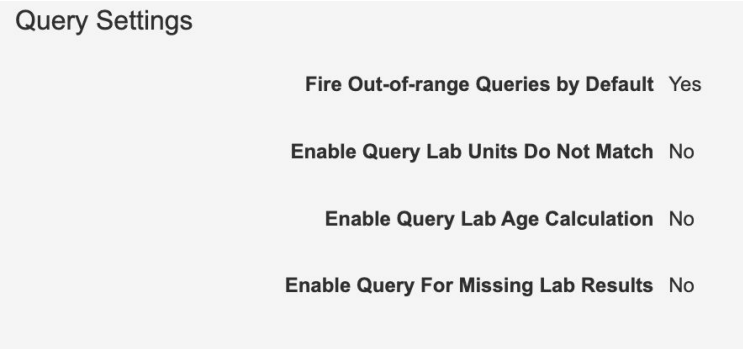
Lab Module - Only Unit Data Types

Dependencies

Global Labs Version DM2

Configurable Lab Queries

- Overview
  - Following System Lab Queries can be disabled
    - Lab Units do not Match
    - Lab Age Calculation
    - Missing Lab Results
- Use case
  - Lab Units do not Match - g/l is the same as g/L
  - Lab Age Calculation - Only birth year is collected and depending on the month the age is not accurate
  - Missing Lab Results - Some lab tests are optional



Day 1 Impact to Clinical Teams

NO

Visibility

Lab Data Manager, Data Manager, Lead Data Manager

Configuration

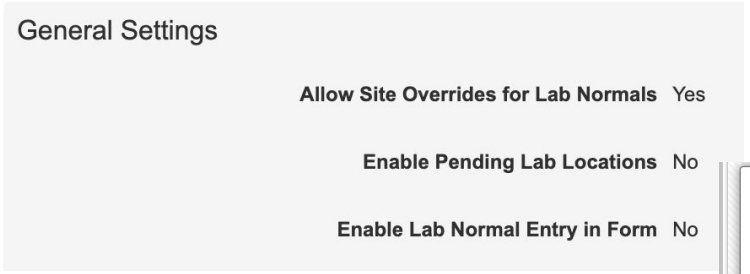
Lab Module - System Settings

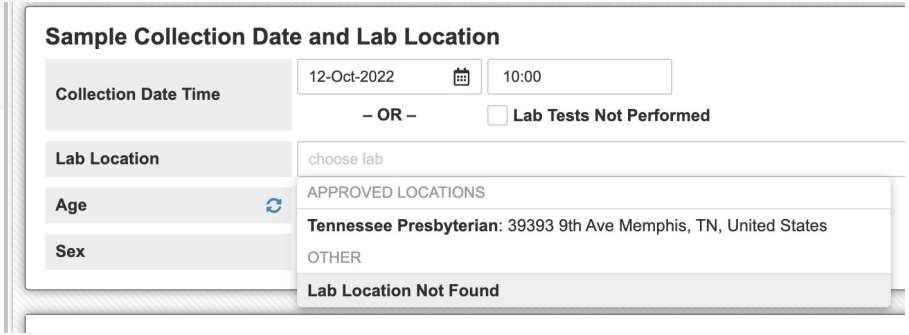
Dependencies

None

Disable Pending Labs

- Overview
  - Disable Sites to create new Pending Labs
  - Disable Sites from Entering Lab Normals in the Form for Pending Labs
- Use case
  - Prevent Sites from initiating any new Local Lab location entry, it is only done via Data Managers from Local Lab Module
  - Prevent Sites from entering Lab Normals for Pending Labs





Day 1 Impact to Clinical Teams

NO

Visibility

Lab Data Manager, Data Manager, Lead Data Manager

Configuration

Lab Module - System Settings

Dependencies

None

New Global Labs Version

Feature	Global Versionless (new model)	Study Level Version (old model)
Increasing Precision and Length	Config only in Labs	Config in Labs. Must be increased in Studio in New Casebook Version, Deployment, Retro-amendment
Lab Units	Config only in Labs	Config in Labs. Must be synched to Studio in New Casebook Version, Deployment, Retro-amendment
Lab Codelists	Config only in Labs	Config in Labs. Must be synched to Studio in New Casebook Version, Deployment, Retro-amendment
Lab Unit/Codelist Archive (hide)	Config only in Labs	Config in Labs. Must be hidden in Studio in New Casebook Version, Deployment, Retro-amendment
Lab Unit Conversions change post go live	Update conversion in Labs. Run Mass update - Update Translated Values	Config in Labs - Create a new lab unit item with the new lab unit conversion. Must be synched to Studio in New Casebook Version, Label the old unit item do not use. Deployment, Retro-amendment.
Lab Unit Standard change post go live	Update Standard in Labs. Run Mass update - Update Translated Values	Config in Labs - Create a new lab unit with the new lab unit standard. Must be synched to Studio in New Casebook Version, Label the old unit item do not use. Deployment, Retro-amendment.
Lab Modifier (<,>,≤,≥)	Config in Labs	Not Available
Disable Unit selection for Lab Results when Lab Normals are Present	Same	Same
Audit Trail for Translated Values	Same	Same

Dedicated DEMO

For a dedicated demo of any these features,

please contact your

Account Executive OR

Customer Success Manager

Thank you