

22R3 Customer Webinar For All

Nov 3, 2022



CDMS Product Managers

Margaret Wehner

Product Manager

Data Entry, Review
UI, Reports



Sharon Lin

Director,
Product
Management

Local Labs



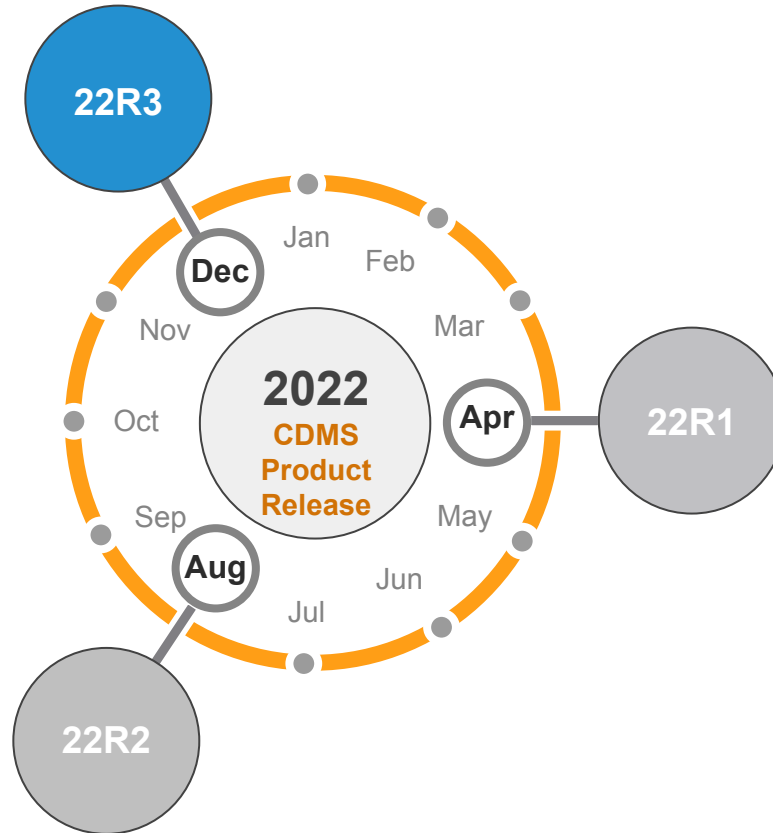
John Roeckel (JB)

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	26
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

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

Admin



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

Coding



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

Reports/Extracts



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

Other



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

Labs



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

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.

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

This screenshot shows a data entry interface for a clinical trial. On the left, a 'SCHEDULE' sidebar lists study events: 'Screening Visit Day 1' (24-Oct-2022), 'Week 1 Event' (25-Oct-2022), and 'Weeks 2-5' with date ranges. The 'Screening Visit Day 1' event is selected, and its 'Demographics' form is displayed on the right. The form includes fields for Birth Date, Age at Time of Informed Consent, Sex, and Ethnicity. A 'Sign' button is visible above the form.

22R2

This screenshot shows a similar data entry interface but with a different study schedule. The 'Screening Visit Day 1' event (24-Oct-2022) is selected, and its 'Demographics' form is displayed. This form includes additional fields for 'Race check all that apply', 'Native American or Alaska Native', 'Asian', and 'Black or African American'. A 'Sign' button is visible above the form.

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



Status: All

Study: All

1-14 of 14



ID	Summary	Date of Deviation	Date Identified	Category	Subcategory	Severity	Description	Status	Study	Study Co
PDV-000054	Inclusion 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

ID	Summary	Date of Deviation	Date Identified	Category	Subcategory	Severity	Description	Status		
PDV-000054	Inclusion Criteria not met	9/21/2022	10/14/2022	Eligibility Criteria	Inclusion / Exclusion criteria not met	Major	Inclusion / Exclusion criteria were not met.	Open		
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

EXPORT
 CSV
 Excel



Protocol Deviation Enhancements

The screenshot displays a user interface for a clinical trial. The main header shows the subject ID '01-001' and the event 'Screening Visit Day 1'. A modal window is open, displaying details for a protocol deviation (PDV-000044). The deviation is categorized as 'Informed Consent Not Signed' with a status of 'Escalated' and a severity of 'Major'. The date of deviation is 04-Jul-2022, and it was identified on 24-Aug-2022. The description states: 'Date of Informed Consent was not provided or the Informed Consent form was intentionally left blank.' The modal window includes buttons for 'View Protocol Deviation' and 'Close'.

Demomine_DEV1 > 01 > 01-001 > Screening Visit Day 1

Subject: 01-001 Schedule QuickView Additive Review Screening Visit Day 1 Item QuickView

Discard Changes Save

Event

Screening Visit Day 1 04-Jul-2022 4 - ✓

Informed Consent

Eligibility Criteria

Vital Signs

Demographics

Pregnancy

Medical History

Hematology

Informed Consent Signature Date

System 8/24/2022 12:21 PM PDT

PDV-000044

Summary Informed Consent Not Signed

Category Informed Consent

Subcategory Informed Consent Not Signed

Status Escalated

Severity Major

Date of Deviation 04-Jul-2022

Date Identified 24-Aug-2022

Description Date of Informed Consent was not provided or the Informed Consent form was intentionally left blank.

View Protocol Deviation Close

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

Settings

General

Standard Date Format dd-MMM-yyyy (System Default)

Twelve Hour Time No

Enable Other Specify - Reason for ch... Yes

Enable Other Specify - Intentionally L... Yes

Enable Team Query Restrictions Yes

Query Team for System Queries Data Management

Open Query on Out of Range Event ... No

Enable Veeva Randomization No

Enable Local Labs Yes

Enable Protocol Deviations Yes

Enable Additive Review Yes



Additive Review - Other Specify

The image displays a software interface with two overlapping 'Enable Additive Review' dialog boxes and a 'Vital Signs' table. The dialog boxes show a dropdown menu for 'Additive Reason*' with 'Other (please specify)' selected, and a text input field containing 'My other reason'. The 'Vital Signs' table has a header 'Vital Signs' with a 'View As Site' link and a checkmark. The table contains the following data:

Vital Signs		✓
Were Vital Signs collected?	Yes	✓ +
Position	Standing	✓ +
Date of Assessment	24-Oct-2022	✓ +
Height	69 Inches	✓ +

A tooltip is visible over the 'Were Vital Signs collected?' row, showing 'Additive Reason My other reason' and a 'Change Additive Reason' link.





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

CRA's & DMs

Configuration

Support

Dependencies

None



Study Progress Listings in Reports

New Job

Type

Form Progress Listing

Include Restricted Data

Include Item Counts

Frequency

Daily

Name

Daily Form Report

Run at

6:00 AM

Active Periods

6

i Scheduled jobs will be removed once the number of active periods has been reached.

Send data to Vault Reports

Cancel Schedule



Study Progress Listings in Reports

Data Entry Library Review Assessments Studio Coder **Reports** Dashboards Loader Labs Randomization Tools My Training Custom Tab Create

STUDY SELECTOR ?
All Studies 🔍

Views ✎

- All Reports
- Recently Viewed Reports
- Favorites
- My Reports
- Flash Reports

Filters ✎

- REPORT TYPE
- TAGS
- CREATED DATE
- LAST RAN

All Reports ? Save View As

+ Create 1-25 of 60 < 1 / 3 > ...

Name	Report Type	Description	Tags	Created By	Created Date	Lifecycle State	Runs As	Schedule
★ Standard Template: Form SDV Detail (v2)	Form with Event, Study Site, Subject, Form Summary	Use this version of the "Form SDV Detail" report for studies that started after 19R3 release.		System	9/12/2022 1:16 PM EDT	Active		
★ Subject Progress Listing	Template: Subject Progress Listing	Listing of all subjects and their progress in the study	Veeva	System	9/12/2022 1:16 PM EDT	Active		
★ Event Progress Listing	Template: Event Progress Listing	Listing of all events and their progress in the study	Veeva	System	9/12/2022 1:16 PM EDT	Active		
★ Query Detail Listing	Template: Query Detail Listing	Detailed listing of all queries in the study	Veeva	System	9/12/2022 1:16 PM EDT	Active		
★ Form Progress Listing	Template: Form Progress Listing	Listing of all forms and their progress in the study	Veeva	System	9/12/2022 1:16 PM EDT	Active		
★ SDV Progress for Forms	Template: Form Progress Listing			David Data Manager	9/16/2022 10:30 AM EDT	Active		
★ Standard Template: Site Queries	Template: Study Site with Query Binding	v1.0		System	9/12/2022 1:16 PM EDT	Active		



Study Progress Listings in Reports

Data Entry Library Review Assessments Studio **Coder** Reports Dashboards Loader Labs Randomization Tools My Training Custom Tab Create

[Back to reports](#)

★ **Form Progress Listing** Refresh More

Listing of all forms and their progress in the study

▼ PROPERTIES

Report Type Template: Form Progress Listing

▶ FILTERS (1)

Form Progress Listing (113)

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	Num
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

Create Report

[Expand all](#) [Collapse all](#)

Report Type*

- DOCUMENT
 - Document
- DOCUMENT RELATIONSHIP
- WORKFLOW
- ACTIVITY
- BINDER
- CASEBOOK OPERATIONAL SUMMARY
- EVENT
- EVENT OPERATIONAL SUMMARY
- EVENT PROGRESS LISTING
 - Template: Event Progress Listing
- FORM
 - FORM DEFINITION
 - FORM OPERATIONAL SUMMARY
 - FORM PROGRESS LISTING
 - Template: Form Progress Listing
- ITEM
- QUERY
- QUERY DETAIL LISTING
 - Template: Query Detail Listing
- QUERY OPERATIONAL SUMMARY
- RANDOMIZATION ACTION HISTORY
- RULE DEFINITION
- SAFETY CASE
- SITE CLOSEOUT
- STUDY SITE
- SUBJECT
- SUBJECT PROGRESS LISTING
 - Template: Subject Progress Listing

Name

Adverse Event Form Progress

Description

Custom form progress listing, for adverse event forms

Report Format

Tabular *Shows fields in columns and individual records in rows.*

Matrix



Study Progress Listings in Reports

The screenshot displays the Veeva system interface for editing a report. The main window shows the report configuration for "Adverse Event Form Progress". A modal dialog titled "Edit Columns to Display" is open, allowing the user to select which columns to show in the report.

Report Configuration:

- Report Type: Form Progress Listing
- Group rows by: Select Field

Available Columns:

- Form Progress Listing
- All Items
- Country
- Created By
- Created Date
- Days Overdue
- DMR %
- DMR Age
- DMR Complete
- DMR Date
- DMR Override Plan
- DMR Plan
- DMR Required
- Event Date
- Event Group Label
- Event Group Sequence Number
- Event Label

Displayed Columns:

- Form Progress Listing
- 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
- SDV Date

The dialog includes a search bar, a "Restore" button, and navigation arrows between the column lists. The "OK" button is highlighted in blue.

Study Progress Listings in Reports

Data Entry Library Review Assessments Studio Coder Reports Dashboards Loader Labs Randomization Tools My Training Custom Tab [Create](#)

[Back to reports](#)

★ Adverse Event Form Progress

Custom form progress listing, for adverse event forms

Cancel Run Save

▼ PROPERTIES

Report Type Template: Form Progress Listing

▶ FORMULA FIELDS

▶ CONDITIONAL FIELDS

▼ FILTERS

Form Progress Listing > Form Label contains Adverse Events Prompt Optional

Form Progress Listing > Study equals Prompt Optional

[Add advanced logic](#)

[Edit Columns](#)

Form Progress Listing									
	Form Vault ID	Form Label	Form Sequence Number	Form Status	Complete	Open Queries	Answered Queries	Closed Queries	
Group rows by	Form Progress Listing > Site	Function	Function	Function	Function	Function	Function	Function	Function
Sort groups by	Site (A-Z)								

[Add field to group by \(optional\)](#)

▶ ADVANCED OPTIONS



Study Progress Listings in Reports

Data Entry Library Review Assessments Studio Coder Reports Dashboards Loader Labs Randomization Tools My Training Custom Tab [Create](#)

[Back to reports](#)

★ **PREVIEW: Adverse Event Form Progress** [Save](#)

Custom form progress listing, for adverse event forms

▼ PROPERTIES
Report Type Template: Form Progress Listing

► FILTERS (2)

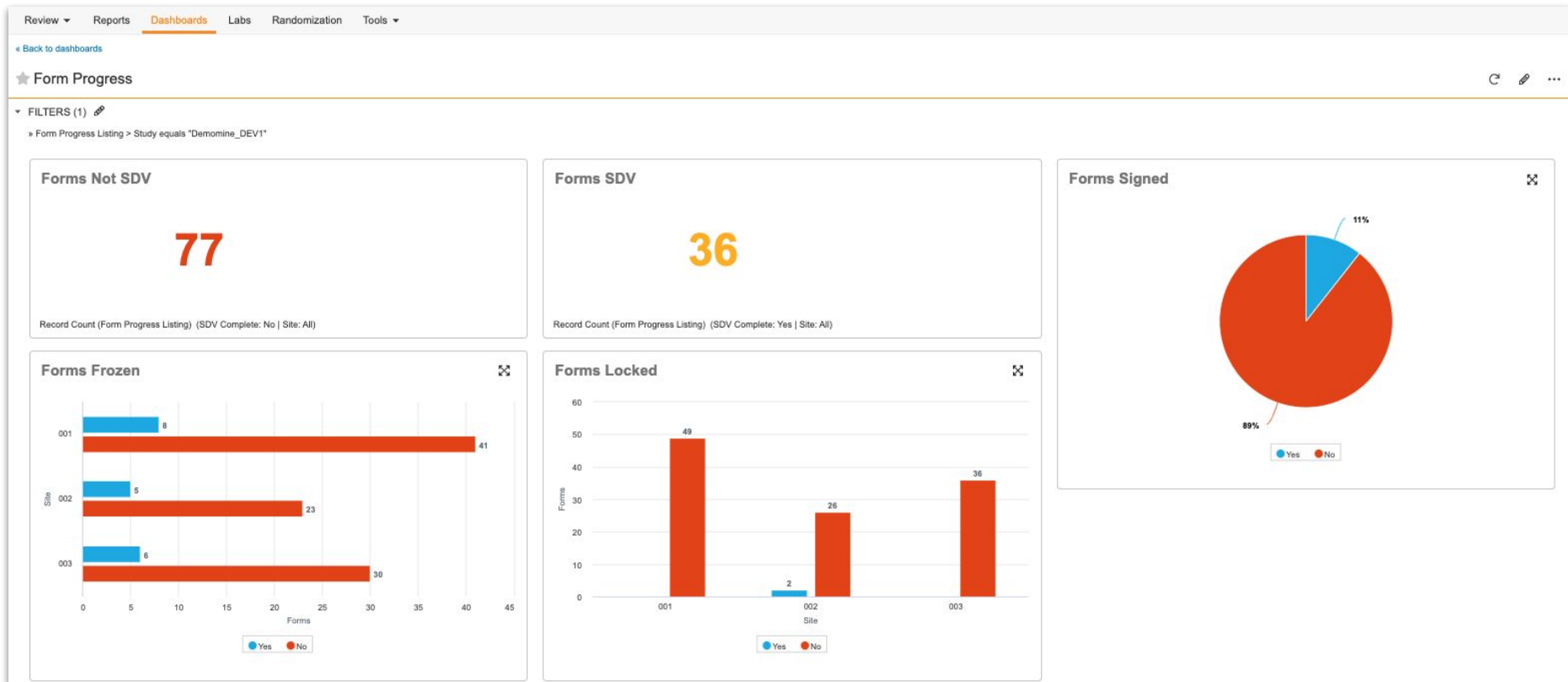
[Expand all](#) [Collapse all](#)

Form Progress Listing (8)

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

CRA's & 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 $>$, $<$, \geq , \leq

Analyte Library

Created By: All
Modified By: All
In Use: All

Analyte	Label	Data Type	Measurement Type	Codelist	Lab Modifier
ALB	Albumin	Unit	gL		
ALP	Alkaline Phosphate	Unit	ukatL		
ALT	Alanine Aminotransferase	Unit	ukatL		
AMY	Amylase	Unit	UnitsPerLiter		
BASO	Basophils Absolute	Unit	Absolute		
BASOLE	Basophils %	Unit	Percent		
BICARB	Bicarbonate	Unit	ucBicarbonateCon...		
BILDIR	Direct Bilirubin	Unit	ucBilirubinConcent...		✓

Codelist Values

Hide Archived Codelist Values

Name	Label
LT	<
GT	>
LTE	≤
GTE	≥

Liver

Missing Result	Analyte	Result
	Alanine Aminotransferase	< ?
	Albumin	≤ ?
<input type="checkbox"/>	Direct Bilirubin	≤ 1 mg/dL

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

Query Settings

Fire Out-of-range Queries by Default	Yes
Enable Query Lab Units Do Not Match	No
Enable Query Lab Age Calculation	No
Enable Query For Missing Lab Results	No

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

General Settings

Allow Site Overrides for Lab Normals Yes

Enable Pending Lab Locations No

Enable Lab Normal Entry in Form No

Sample Collection Date and Lab Location

Collection Date Time 12-Oct-2022 10:00
– OR – Lab Tests Not Performed

Lab Location choose lab

Age  APPROVED LOCATIONS

Sex OTHER
Tennessee Presbyterian: 39393 9th Ave Memphis, TN, United States

Lab Location Not Found

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