

21R2 Release Webinar For All Customers

July 15, 2021



CDMS Product Managers

Dennis Kochanski

Sr. Product Manager
Studio, Library



Rakesh Monassery

Sr. Product Manager
Admin, User Mgmt, LMS



Mohammed Al-Adeeb

Sr. Product Manager
Coder, Safety Link



Lindsay Chan

Associate Technical Product Manager
APIs, Extracts, Integrations



Quentin Paresys

Sr. Product Manager
Rules, Reports



Sharon Lin

Principal Product Manager
Local Labs, Randomization



Abhi Yeleswarapu

Product Manager
Migrations



Cory Etcorn

Product Manager
Data Entry, Review UI, Clinical Assessments



21R2 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
11 JUL	12	13	14	15 21R2 Release webinar 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	16	17
18	19 21R2 Pre-Release Validation Docs	20	21	22	23	24
04	25	26	27	28	29	30
01 AUG	02	03	04	05	06	07
08	09 21R2 General Release	10	11	12	13	14

— Customer
Validation



21R2 Release Dates



Pre – Release

Validation Docs

21R2 Release

- **Clone of UAT**
- Special Request for DEV
- **Users**
- Added by Project Managers or Customers Success Managers
- **Available up to 6 weeks after 21R2 Release**

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

- All Customers Vaults upgraded to 21R2

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



Available Resources

<https://cdmshelp.veeva.com/lr/rn/general-releases/21r2/>

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



21R2 Feature Summary

Sites



- Editable Grids
- Restrict users that can close system queries
- Support SSO pop up windows
- Misc. Enhancements

Local Labs



- Pending Approvals Count for Normals
- Incomplete State for missing units
- Override Normals Report
- Vault Diff Report for Analytes, Units, Codelist

Study Designer



- Annotated PDF Enhancements
- SDS Enhancements
- Cross Vault Copy
- Vault selector for Diff Reports

Rules

- Delayed execution
- Aggregate Identifiers & Functions
- Access Review Plans

Reports/Extracts



- Study Data Extracts Enhancements

Admin



- Multi-Role Security
- Review Plan Assignment Enhancements
- LMS Enhancements
- Study Role Enhancements
- New API Roles
- Delete Sites in Production

Other



- Protocol Deviations from CDMS to CTMS

Coding



- Japan Support
- MedDRAJ
- JDrug

Safety Link



- Multiple SAEs in a single case
- Support Null instances

Randomization



- Rule to send email when subject is randomized

Feature Enablement

Impact to Clinical Team	On Day 1 of the Release, will the Study Clinical Team (Sites, CRAs, Data Managers) see it? Options: Yes or No
Visibility	On Day 1 of the Release, which users see it? Options: Sites, CRAs, Data Managers, Study Designers, Study Admin (Deploy, Safety, User), Coders, Coder Admin, Lab Manager, Randomization Manager
Configuration	Is Configuration required to use the Feature? Options: Studio, Tools, Coder Admin, Labs, Randomization, Vault Owner in Business Admin, Support
Dependencies	Are there dependencies to use the Feature? Examples: Labs must be enabled, Randomization must be enabled, Only Studies that have not deployed to Production...





Sites / CRAs / Data
Managers

Normals Pending Approval Counts

- Overview

For studies with Local Labs and approvals enabled, there is a new column that will indicate how many Normals are waiting to be approved.

- Business Value

This will bring awareness of how many Lab Normals need to be reviewed.

Lab Locations & Normal Ranges

[All Lab Locations](#) > Select Lab Location ▾

		Approved Locations		Pending Locations (0)			
Lab ID	Lab Name ▲	Address	Country	Status	In Use	Normals Pending	Normals Incomplete
LDH	London Hospital	484 Weaver Street London, UK	United Kingdom	Approved	IN USE	19	1
NYP	New York Presbyterian	393 9th Ave New York City, NY	United States	Approved	IN USE	2	0
UCSF	University of San Francisco	3739 Parnassus Drive San F...	United States	Approved	IN USE	1	0

Day 1
Impact to
Clinical Teams

Yes

Visibility

Data Manager,
Lab Manager

Configuration

Approvals
have to be
enabled

Dependencies

Labs Approval
Enabled



Normals Incomplete Counts

- Overview

Lab Normal Ranges are considered incomplete when a normal is missing data e.g. units. There will be a new column called “Incomplete Normals” that will provide a count of all incomplete data. It is a system generated status, and users will not be able to select the status.

**not available in Pre-Release until July 30th*

- Business Value

This will bring awareness of how many Lab Normals were not able to complete data entry because of the units not being available.

Lab Locations & Normal Ranges
[All Lab Locations](#) > Select Lab Location ▾

Approved Locations Pending Locations (2)

+ New Lab Import Lab Locations Import Normal Ranges Search Country: All ▾

Lab ID	Lab Name	Address	Country	Normals Incomplete	Normals Pending	Status
lab1	lab1	asdf	Albania	4	2	Approved
asdf	asdf	asdf	Bulgaria	0	0	Approved
approved1	pending1	asdf	Australia	0	0	Approved
approved2	pending2	asdf	Argentina	0	0	Approved
labs2_approved1	labs2_approved1	adsf	Algeria	0	0	Approved
rand1	rand1	rand1	Bosnia and Herzegovina	0	0	Approved
labs2_approved2	labs2_pending2	asdf	Algeria	0	0	Approved



Concatenate Analyte Name w/Label

- Overview

For studies with Local Labs, the Analyte Name is concatenated with the Label

- Business Value

This will allow users who enter Normals to see the Label name with the Analyte name in the event that they don't know the name (Name: ALB vs Label: Albumin)

Labs

SYSTEM SETTINGS

Analyte Library

System General Settings

LAB SETTINGS

Lab Locations & Normal Ranges

Reports Mass Updates

STUDY SETTINGS

Study General Settings

Site Lab Assignment

Lab Locations & Normal Ranges

[All Lab Locations](#) > 3483

Lab ID	Lab Name	Lab Address
3483	Cleveland Clinic Labs	3494 Melon Drive C

[+ Add New Normal Range](#) [Done](#)

Analyte Name (Label)	Effective Begin
ALB (Albumin)	
Amylase (Amylase)	
BICARB (Bicarbonate)	
BILDIR (Bilirubin)	
CAION (Calcium Serum - Total)	
CA (Calcium Serum - Ionized)	
CA_U (Calcium - Urine)	
CEA (CEA)	
CO2 (Carbon Dioxide)	
CHOL_U (Chloride - Urine)	



Labs: Override Normal Report

- Overview

For studies with Local Labs enabled, there is a new Report called Override Normal. This will show where the Sites have an entered an Override Normal Value on the Lab Form.

- Business Value

This report would be used as an indicator that the Lab Normals entered into the Lab Locations is incorrect, thus the Override Value.

Sample Collection Date and Lab Location

Collection Date Time: 04-Jun-2021 10:00 - OR - Lab Tests Not Performed

Lab Location: UCSF Labs3 : 34893 Parkway San Francisco, CA 94133, United States [Refresh Lab Normals](#)

Age: 29 Years Sex: Fem... [Recalculate Age](#)

chemistry

Missing Result	Analyte	Lab Result	Normal	Normal Override	Flag	Clinical Significance
	Sodium	100 mEq/L	125 - 150.00 mEq/L	130 - 150 mEq/L	↓ Low	Clinically Significant
	Potassium-Serum	4.0 mEq/L	3.500 - 5.50 mEq/L	3.0 - 6.0 mEq/L		
	Chloride - Serum	100 mEq/L	94.00 - 106.00 mEq/L			
	CO2	25 mEq/L	23.00 - 29.00 mEq/L	24 - 30 mEq/L		



Vault Diff Report for Analytes, Codelist, Units

- Overview

For studies with Local Labs, you can compare differences between Vaults for the Analyte Library, Units, and Codelists.

- Business Value

Be able to compare to see the differences between the Vaults before doing a deployment

	A	B	C	D	E	F	G	H	I	J	K
	Analyte Name	Type	CDMS PM DEV	CDMS PM PROD							
1	Analyte Name	Type	CDMS PM DEV	CDMS PM PROD							
2	Alkaline Phosphatase	In Use	true	false							
3	Amylase	In Use	true	false							
4	Calcium Serum - Ionized	In Use	true	false							
5	Creatinine - Serum	In Use	true	false							
6											
7											
8											
9											
10											
11											
12											
13											
14											

No



Editable Grids

- Overview

Study Designers can now configure any repeating item group to display as an “Editable Grid” in Data Entry. When enabled, site users can enter data in a tabular/spreadsheet format allowing for quick data entry and viewing multiple rows of data without scrolling up/down. The Editable Grid can be configured to include up to 16 items and supports all item types except labels.

Additionally, improvements were made to the Lab Panel grid for Local Labs within Data Entry to improve usability.

- Business Value

Editable Grids/Tabular Data Entry allows for site users to more efficiently enter data into repeating item groups.

#	MH Category (Required)	If Other, Specify	Date of Onset	Ongoing?	End Date
1	Cardiovascular		15-Jul-2021	Yes	
2	Dermatological		13-Jul-2021	Yes	
3	Drug Allergy		01-Jul-2021	No	02-Jul-2021
4	Other, Specify	Other	03-Jul-2021	Yes	
5	Respiratory		15-Jul-2021	No	14-Jul-2021

The screenshot shows a calendar pop-up for the date 15-Jul-2021. The calendar displays the month of July 2021 with the 15th highlighted. Navigation arrows and a 'Today July 15, 2021' indicator are visible at the bottom of the calendar.



Data Entry: Default Unit When Only One Exists

- Overview

Unit items configured with a single option no longer require the user to manually select the value each time they enter a unit value. When only a single option is configured, Data Entry will display it as the default. Upon autosave, both the value and the unit will save without requiring the site to click into the unit dropdown.

Note: The unit does not save until a valid value is entered and an autosave occurs.

- Business Value

Data Entry efficiency and removes the need to use hint labels for single unit items.



The image shows a data entry form with a label 'Unit' above a text input field and a dropdown menu. The dropdown menu is currently displaying 'g/dL' and has a small downward arrow on its right side. The text input field is empty.



Pop-Up Window Support for CDMS SSO Authentication

- Overview

Vault CDMS now supports SSO eSignatures in a pop-up window in addition to an iFrame (added in 21R1). When “Authenticate SAML eSignatures in a pop-up window rather than an iFrame.” is enabled on the SAML profile, users will be prompted to enter their credentials in a separate pop-up window vs. an iFrame within the same browser tab.

- Business Value

Supporting the pop-up setting provides more flexibility in SAML Profile configurations for authentication occurring within Vault CDMS.

Day 1
Impact to
Clinical Teams

No

Visibility

Domain
Admins

Configuration

Business
Admin

Dependencies

SSO Policy +
SAML Profile



Query Teams for System Queries

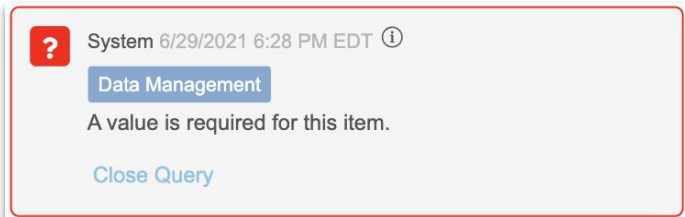
- Overview

Study Designers now have the ability to specify a Query Team in Studio to apply to all queries created by the system (User Defined Rules, Required checks, etc.). When configured, all system queries will be tagged with the specified team upon creation. Only users with the Close Query on that same Query Team will be able to close the query.

This is an optional configuration when enabling the Query Teams functionality.

- Business Value

Sponsors can now restrict which users can close queries that were created by the System.



Review: Expanded Repeating Form Layout with View Summary

- Overview

With this release, all Repeating Form instances will now appear in the Review tab in the same layout as non-Repeating Forms in that each instance is loaded as the user scrolls down through the Event. The initial grid view will no longer display. A “View Summary” link is available in the Form Header for each instance to provide the grid view of all instances present for the Repeating Form. Clicking into any row of the “View Summary” pop-up will auto-scroll to the selected instance.

- Business Value

In addition to performance improvements of the, the View Summary feature allows users to quickly navigate to a specific instance rather than scrolling up or down on the page.

Reference #	✓	✗	Adverse Event	Start Date	Ongoing?	End Date	Severity	Serious?	Is the adverse ev
1	○	○	Seizure	01-Jun-2021	No	17-Jun-2021	Mild	Yes	Yes
2	○	○	Migrane	01-May-2021	Yes		Moderate	Yes	No
3	○	○	Headache	29-Jun-2021	Yes		Mild	Yes	
4	○	○	Heart Attack	07-Apr-2021	No	08-Apr-2021	Mild	Yes	



Dedicated DEMO

For a dedicated demo of any
these features,
please contact your
Account Executive OR
Customer Success Manager





Questions



Thank you