

21R1 Customer Webinar All Customers

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CDMS Product Managers

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Product Manager
Data Entry, Review UI, Clinical Assessments



21R1 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
21 MAR	22	23	24	25 21R1 Release webinar 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	26 21R1 Pre-Release 5PM PT	27
28	29 Validation Docs	30	31	01 APR	02	03
04	05	06	07	08	09	10
11	12	13	14	15	16 21R1 General Release 5PM PT	17
18	19	20	21	22	23	24

— Customer
Validation



21R1 Release Dates



Pre – Release

- Starts at 5PM PT
- Clone of UAT
 - Special Request for DEV
- Users
 - Added by Project Managers or Customers Success Managers
- Available up to 4 weeks after 21R1 Release

Validation Docs

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

21R1 Release

- All Customers Vaults upgraded to 21R1
- EU starts at 2 PM PT
- APAC & US starts at 5 PM PT
- May take up to +/- 9 hours

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



Resources Available

<https://cdmshelp.veeva.com/lr/rn/general-releases/21r1/>

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



21R1 Feature Summary

Sites



- Protocol Deviations
- SSO Integrations

Local Labs



- Re-Calculate Age
- Pending Lab Location Count

Study Designer



- Library Collection and Report

Rules

- Linked Forms with Rules
- Date Comparison Rule Enhancement
- Add Multiple Event Groups

Admin



- Vault Level User Mgmt.
- Job Enhancements

Reports/Extracts



- Study Data Extracts
- Site's /User Timezone

Coding



- Coder Approval Workflow
- Group Querying
- Preferred Base for Extracts

Safety Link



- Integrate to any 3rd Party Safety system including Vault Safety

Randomization



- Emergency Unmasking Report
- Exports and Filters

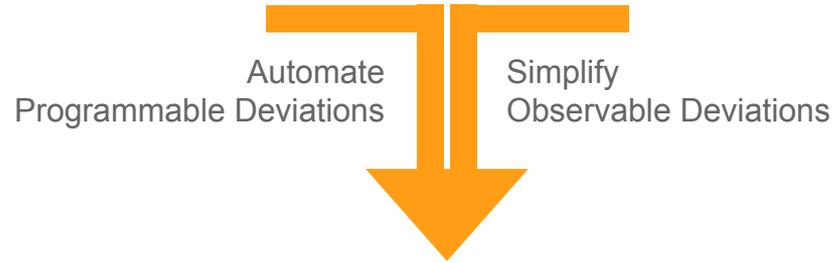
Other



- Procedure Notification for CTMS

Protocol Deviations

Fit-for-purpose design to collect, review, and manage PDs
eliminates complexity of work-arounds – tagging queries or hidden forms



- ✓ Precision tracking, complete traceability
- ✓ Easy for sites and monitors to report deviations as soon as they are observed
- ✓ Greater clarity and usability with tracking at appropriate levels – by subject, visit, form, or field
- ✓ Facilitates managing downstream processes
- ✓ Will pass data directly to Vault CTMS (Planned 21R2)



Feature Enablement

DAY
1

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, EDC Tools, Coder Admin, Labs, Randomization, Vault Owner in Business Admin, Support



Dependencies

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

Recalculate Age

- Overview

For studies with Local Labs enabled, there is a new button to Recalculate Age. Only used when the age is incorrect because a change was made to the Birthdate/Year or Collection Date and Time.

- Business Value

This will save Sites from extra clicks of clearing the Age and Collection date/time field.

Screening (06-Jan-2021): Lab Form - Chemistry

Sample Collection Date and Lab Location

Collection Date Time	05-Jan-2021  10:00	- OR -	<input type="checkbox"/> Lab Tests Not Performed
Lab Location	UCSF Labs3 : 34893 Parkway San Francisco, CA 94133, United States 	Refresh Lab Normals	
Age	25  YEARS	Sex	Female Recalculate Age



Pending Lab Location Count

- Overview

For studies with Local Labs enabled, there is a counter located the Pending Lab Location Tab. This will let users know how many Pending Lab Locations need to get approved or merged.

- Business Value

This will allow awareness of how many Pending Labs need to be reviewed.

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

Approved Locations Pending Locations (3)

[+ New Lab](#) [Import Lab Locations](#) [Import Normal Ranges](#) Search Country: All ▾ 1-9 of 9 [Settings](#)

Lab ID	Lab Name	Address	Country	Status	In Use
6783	UCSF Labs3	34893 Parkway San Francis...	United States	Approved	IN USE
7393	NY Presbyterian	35953 Sixth Street NY, NY 0...	United States	Approved	IN USE
5853	London Hospital	38 Queen Street London NW...	United Kingdom	Approved	IN USE

Day 1
Impact to
Clinical Teams

Yes

Visibility

Data Manager,
Lead Data
Manager, Lab
Manager

Configuration

N/A

Dependencies

Labs Enabled



SSO Authentication for eSignatures

- Overview

Vault CDMS now supports Single Sign-On authentication when prompted to re-authenticate after logging into Vault. Users with a Single Sign-On security policy will be prompted to authenticate with their SSO provider's credentials when:

- Signing at the Form level
- Signing at the Casebook level
- Accepting Study Closeout PDFs
- Randomization - Emergency Unmasking
- Randomization - Reveal Treatment
- Randomization - Redispense Kit/Device
- Randomization - Verify List
- Randomization - Invalidating Randomization
- Local Labs - Updating Normal Ranges in Use

Note: There is no impact on users configured with a non-SSO security policy. The workflows mentioned above will continue to prompt the user for their Vault username and password.

- Business Value

This feature provides the ability for Sponsors to manage users via an existing Single Sign-On provider and allows users to utilize their existing SSO credentials to perform tasks within Vault CDMS.

Day 1
Impact to
Clinical Teams

No

Visibility

Vault Owners

Configuration

Vault Owner in
Business
Admin

Dependencies

N/A



Protocol Deviations

- Overview

Studies can now enable a new Protocol Deviations feature for creating deviations and linking them to study data within Vault CDMS.

When enabled, CRAs and Data Managers can manually create a Protocol Deviation via the Review tab, and/or studies can define logic via the rules engine to programmatically create PD records when certain criteria is met. Categorizations and severity classifications are customizable at a study level.

A listing of Protocol Deviation records across Sites and Studies can be reviewed and updates can be made to change review statuses and provide resolutions. A CSV export is available to extract the Protocol Deviation records out of the system.

- Business Value

Sponsors now have the ability to create, review, and export protocol deviations in the same system as they collect clinical data. Programmatic Protocol Deviation creation also reduces manual effort on CRAs/DMs to document all deviations.

Day 1
Impact to
Clinical Teams

No

Visibility
Study
Designers

Configuration
Studio

Dependencies
N/A



Dedicated DEMO

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





Thank you