21R3 Customer Webinar for ALL

November 04, 2021

Veeva

CDMS Product Managers

Sharon Lin

Principal
Product
Manager

Local Labs,
Randomization

Cory Etzcorn

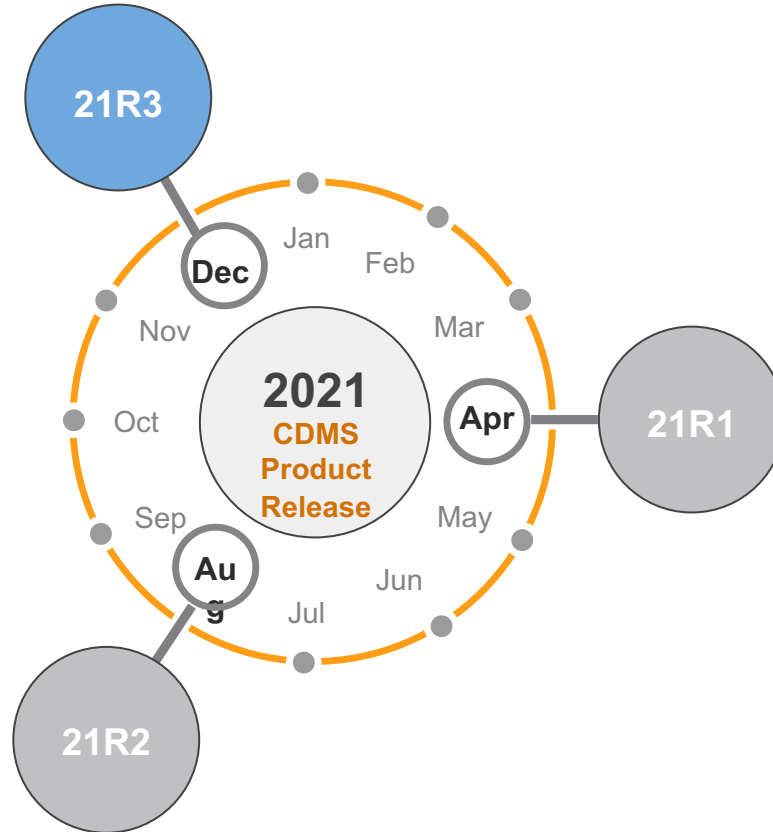Product Manager

Data Entry, Review
UI, Clinical
Assessments

**Quentin
Paresys**

Sr. Product
Manager

Rules

Veeva Vault Release Schedule

21R3 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
NOV	1	2	3	4 **21R3 Release webinar** **9 AM PT - All Customers** **10 AM PT - Studio, Admin, Coder**	5 **21R3 Pre-Release Upgrade**	6
7	8 **Validation Docs**	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	01 **DEC**	02	03 **21R3 General Release Upgrade**	04

━━━ Customer Validation

21R3 Release Dates

NOV 05

NOV 08

DEC 03

Pre – Release

- **Clone of UAT**
- Special Request for DEV
- **Users**
- Added by Project Managers or Customers Success Managers
- **Available up to 6 weeks after 21R3 Release**

Validation Docs

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

21R3 Release

- All Customers Vaults upgraded to 21R3

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)

21R3 Feature Summary

Sites

- Repeating Item Group Actions
- Display Assigned Review Plan
- Core Listings in Review Tab
- Empty Form Link Indicator
- Misc General Enhancements

Reports/Extracts

- Study Data Extracts Versioning
- Additional columns in SDE
- Study Data Extracts MIsc Enhancements
- New Study Listings - Query Detail, Event/Form/Subject Progress

Study Designer

- Arms & Cohorts
- Progressive Display
- Repeating Item Group Enhancements
- Misc Enhancements

Rules

- New Aggregate Functions
- Previous/Next Identifiers

Randomization

- Rule to set Subject Status to Randomization Date

Admin

- Job Governor
- Audit Trail by Site & Filtering
- Validation Environment
- Error Console Enhancements
- Misc Study Role Enhancements

Other
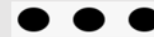
- New Subject Statuses to align with CTMS
- Course completion in Training Report
- Veeva Learning Integration Enhancements
- Site Vault Integration
- Restricted Data Support in CTMS

Coding

- Batch Upversioning Enhancements
- MIsc JDrug Enhancements

Safety Link

- Long Narratives
- External Labs
- Support LLT
- Treatment Forms

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

Repeating Item Group Actions

- Overview

  Repeating Item Groups (form view and editable grids) now display an actions menu for Site users to perform actions on an instance. The following actions are available:

  - **Intentionally Left Blank:** Sets all Items within the instance as ILB with the selected reason
  - **Unset Intentionally Left Blank:** Unsets ILB on all Items within the instance
  - **Reset Section/Row:** Clears all Items within the instance
  - **Remove Section/Row:** Removes the section/row. A few key notes to keep in mind:
    - Sections/Rows can only be removed if they are blank. Once data has been entered, the site user should ILB if the section/row if no longer needed.
    - Sections/Rows can only be removed in sequential order. The highest sequence number must be removed first before the second highest can be removed, etc.

- Business Value

  Site users can now remove unintentionally added Repeating Item Group instances. Additionally, Site users can perform bulk actions on a Repeating Item Group instance vs. clicking into each Item individually.

Day 1 Impact to Clinical Teams

Yes

Visibility

Sites

Configuration

N/A

Dependencies

N/A

Unsetting ILB Restores Default Data

- Overview

  Unsetting Intentionally Left Blank on an Item, Item Group, or Form will automatically restore defaulted data (if configured) on a Repeating Item Group. Full Form resets are no longer needed to restore these defaulted values.

- Business Value

  Site users no longer need to reset the entire Form for defaulted data to be restored.

Visibility

Sites

Configuration

N/A

Dependencies

N/A

Empty Form Link Indicator

- Overview

  Study Designers can enable a new "Warn When Empty" setting on a Form Link to highlight the Form Link tab in Data Entry and Review when zero form links have been added. Once a Form Link has been added, the red highlight is no longer displayed.

  Note: This is purely a visual indicator and does not prevent additional actions from occurring.

- Business Value

  Site users can be reminded to add a Form Link before leaving the Form.

Visibility

Study Designers

Configuration

Studio

Dependencies

N/A

Display Review Plan Name in Review Tab

- Overview

    SDV and DMR Review Plan Names are now displayed in the Review tab. The system also now highlights if an Override Review Plan has been applied to a Form instance via Override Review Plan rules. These columns are displayed for roles with "View SDV" and/or "View DMR" permissions.

- Business Value

    CRAs and Data Managers no longer need to reference custom reports to view which Review Plan a Subject is assigned to.

	Day 1 Impact to Clinical Teams
	Yes
Visibility	CRAs, Data Managers, Lead Data Managers
Configuration	N/A
Dependencies	Review Plan Assignment V1+

Display Historical SDV/DMR Values

- Overview

  Items and Event Dates with SDV/DMR values set while Optional or Required will continue to display the SDV/DMR checkmark if the Review Plan criteria and/or assignment is updated to make it Not Required. If the SDV/DMR value is later unset, the SDV/DMR icon will no longer be displayed upon saving (respecting the current Review Plan).

  Note: This change only impacts the user interface in the Review tab. Standard Reports and Reporting Objects will continue to behave the same as they did prior to this 21R3 release.

- Business Value

  Users no longer need to reference the audit trail to find Items and/or Event Dates previously set as SDV/DMR prior to the Review Plan update to make them no longer required.

Day 1 Impact to Clinical Teams

Yes

Visibility

CRAs, Data Managers, Lead Data Managers

Configuration

N/A

**Dependencies**

N/A

Core Listings in Review Tab

- Overview

  Roles with access to the Job Schedule and Job History tabs within the Review tab can now run Core Listing jobs on the Site(s) they have access to.

  To view the Job Schedule and Job History tabs, a user must have the "Manage Jobs" permission.

- Business Value

  Users no longer need to have full access to EDC Tools and all jobs to run Core Listings.

Day 1
Impact to
Clinical Teams

Yes

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

Requires
Manage Jobs
permission
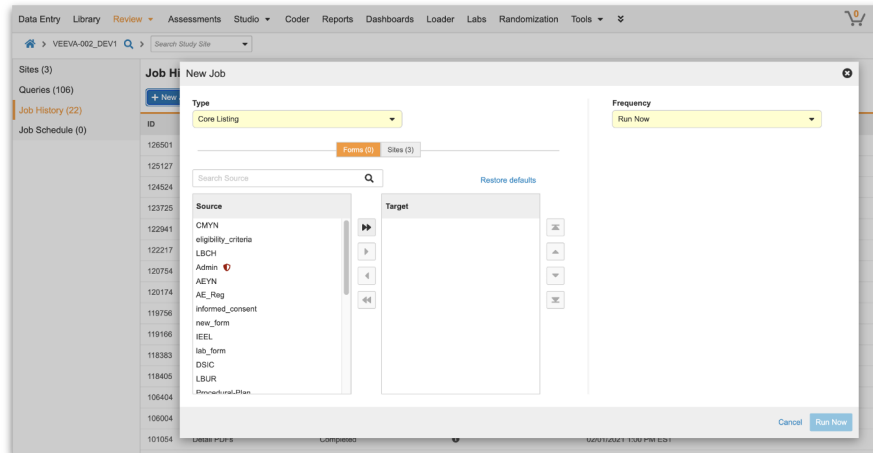
Protocol Deviations Study Filter

- Overview

  A multi-select Study filter as been added to the Protocol Deviations grid in Review -> Protocol Deviations.

- Business Value

  Protocol Deviations can now be viewed in the context of a single Study, or select Studies.

Day 1 Impact to Clinical Teams

Yes

Visibility

CRAs, Data Managers, Lead Data Managers

Configuration

N/A

Dependencies

N/A

Dedicated DEMO

For a dedicated demo of any these features,

please contact your

Account Executive OR

Customer Success Manager

Thank you