

# 23R1 Customer Webinar Studio, Admin, Coder

March 23, 2023



# CDMS Product Managers

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Extracts



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Rules



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Safety Integrations, APIs



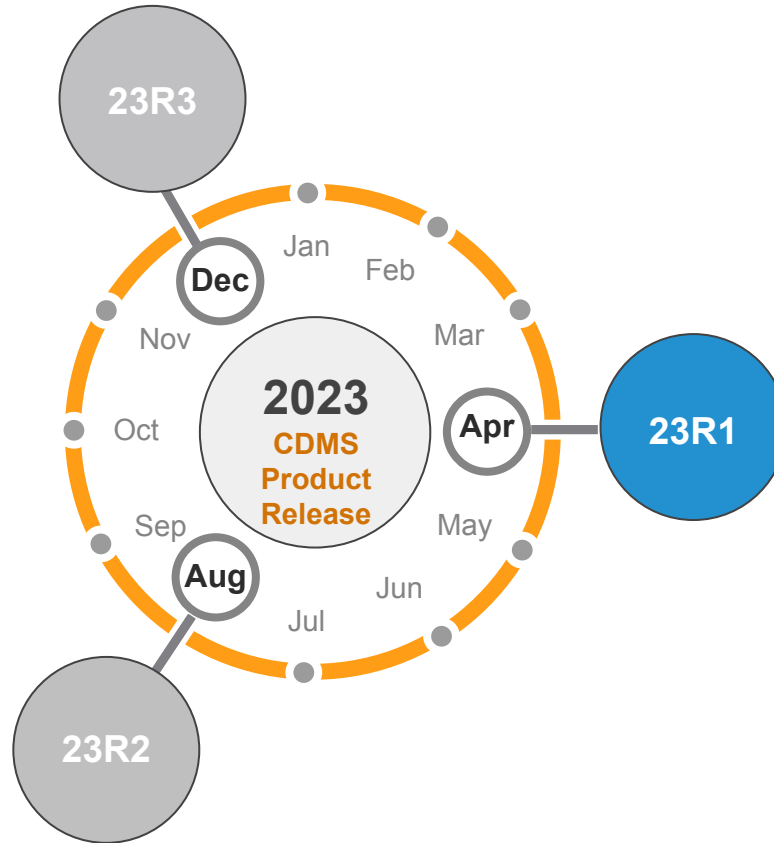
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Product Expert

EDC



# Veeva Vault Release Schedule



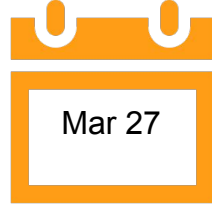
## 23R1 Release Calendar

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

— Customer  
Validation



# 23R1 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 23R1 Release**

## Validation Docs

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

## 23R1 Release

- All Customers Vaults upgraded to 23R1

### Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



## Available Resources

<https://cdmshelp.veeva.com/lr/rn/general-releases/23r1/>

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



# 23R1 Feature Summary

## Sites



- Form Submission Updates
- Site Closeout Enhancements
- General Enhancements

## Study Designer



- Rules - Sorting @PreviousEvent by Schedule
- SDS Enhancements
- Subject Status Date Enhancement

## Admin



- User Access Report
- Disable Manual Casebook Creation
- Role Management UI Enhancements
- Review Plan Assignment Enhancements
- General Enhancements

## Coding



- Sync Synonym Lists
- Coder Tools New Nav
- Coder Config Resilience

## Reports/Extracts



- Study Progress Listing Enhancements
- SDE New Lab Format
- Definition Names in Datasets
- SDE Enhancements

## Other



- CDMS APIs -Read Only via API
- CDMS APIs - Combination API (~23R1)

## Labs



- Lab Modifier support for Number Data Type
- Import Translations for Analytes/Units/Codelists

## Safety Integrations



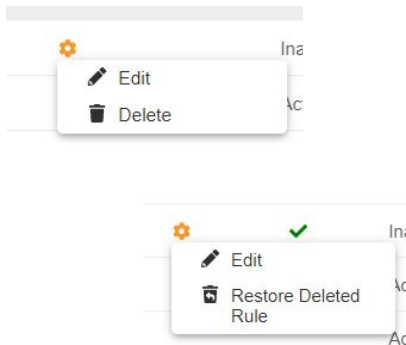
- Duration Rules for Case Data
- Crucial Alerting on Initial Form Submit / Case
- More Study Configuration



Studio

# Rules Archive

- Overview
  - Rule archive provides a method for “soft-deleting” rules - marking them as archived so they are excluded from the design and from rule execution. Rules can be deleted (moved to archived status) and restored when they have been archived.
- Use case
  - To remove rules no longer in use



User Defined Rules			
Invalid	Name	Archived	Rule Status
	<a href="#">Add_EG</a>	✓	Inactive
	<a href="#">AddAEAssessment</a>		Active





# General Quality of Life Enhancements

- Overview
  - Added a number of minor quality of life enhancements and bug fixes to include:
    - Fixed difference report returning a change to rule action order as modified
    - Skipped a number of validations when they applied to objects no in use
      - Mainly around linking and item groups
    - Improved Language Import and Export (to include logging and format)
    - Changed the default repeating value to 50 for new objects instead of 9999
    - Changed the “Future Date” edit change to “No Future Date” for clarity
    - Relaxed some study settings for update between versions to include moving ID generation to Manual or External post-go-live
    - Library can now update settings and signature
- Use case
  - Provide users with more control over certain aspects of the system and make the system easier to use

Day 1  
Impact to  
Clinical Teams

No

Visibility

Study Designer  
Librarian

Configuration

None

Dependencies

None



# SDS Enhancements

- Overview
  - Several enhancements that improve overall usability and fill gaps
    - Updated column headers and order to match UI
    - Added missing columns and removed unused columns
    - Updated formatting for improved filtering and searching
    - New columns on Form Definitions and Schedule Tree tabs for object and object relationship Last Modified timestamps
    - 'Include Rules' now checked by default
- Use case
  - Better alignment between SDS and Studio

Day 1  
Impact to  
Clinical Teams

No

Visibility

Study Designers,  
Librarians

Configuration

N/A

Dependencies

Available for  
existing studies





Rules

# @PreviousEvent Schedule Sorting

- Overview
  - Rules using **@PreviousEvent** identifiers can now be configured to sort Events in order of the Schedule configuration in Studio
  - **@PreviousEvent** rules that are sorted by Schedule can be configured to either ignore or include Did Not Occur Events.
- Use case
  - Builds on the feature added in 22R3 to support studies whose Events are not always chronologically linear
  - Study Designers can write fewer, more simplified rules to identify previous values
  - Alignment with Schedule ordering in Data Entry

Day 1  
Impact to  
Clinical Teams

No

## Visibility

Study Designers,  
Librarians

## Configuration

Studio

## Dependencies

Rules Engine v2

Available for  
existing studies



# @PreviousEvent Schedule Sorting

### New Rule

#### Details

**Name**  
prev\_value\_schedule

**Active**

**External ID**

**Description**  
Vital Signs Date should always be after the Previous Event's date (based on Schedule)

**Evaluate Rule When**  
Default

**Form**  
VS1

**Rule Execution**  
 Post-save Rule

**Rule Scope**  
 Within Current Event Group

**Dynamic Action Scope**  
Global

**Sort Events By**  
Schedule

**Handling Intentional Blanks**  
 Skip Intentionally Left Blank and Did Not Occur values

#### Expression

Check Syntax   Format   Formula Language Reference   View Rule Bindings

```
1 #define VSDAT @Form.VS1.VSDAT
2 #define PREVDAT @PreviousEvent.event_date__v
3
4 Not(IsBlank(VSDAT))
5 &&
6 Not(IsBlank(PREVDAT))
7 &&
8 VSDAT <= PREVDAT
```

#### Actions

Perform the following action(s) when the Expression evaluates to true.

Query   Item   this form > VS1 > VSDAT   Vital Signs Date should always be after the Previous Event's date (based on Schedule)

When Sort Events By is Schedule, Skip ILB is configurable

Vault CDMS

Data Entry

SITE TASKS

Forms

Queries

Sort By: Schedule

Schedule

Event Date

Day 1  
Impact to  
Clinical Teams

No

Visibility  
Study Designers,  
Librarians

Configuration  
Studio

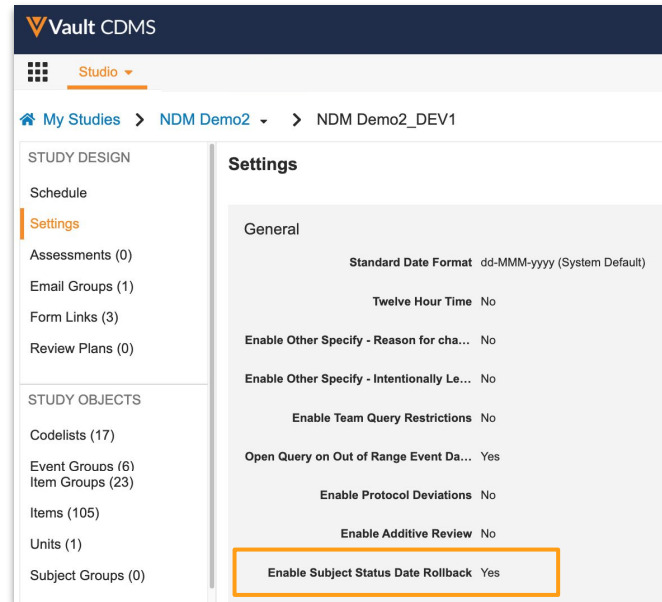
Dependencies  
Rules Engine v2

Available for  
existing studies

# Subject Status Date Rollback

- Overview
  - Added a study setting to enable rolling back historical Subject Status Dates when the associated Subject Status rule result changes from true to false
    - When set to No, behavior is the same as pre-23R1
- Use case
  - Remove erroneous data in CTMS

Note: Re-run subject status rules when enabling for a live study



Day 1  
Impact to  
Clinical Teams

No

Visibility

Study Designers,  
Librarians

Configuration

Studio

Dependencies

- DM2

- Available for  
existing studies

- Auto-on for  
new studies





Admin

# User Access Report

- Overview
  - New report type available in System Tools > Users
  - Produces a csv file containing a chronological audit log of user access activities from creation of vault to current date
  - Can be run on select studies or vault-wide in 6 month increments
  - Contains records of:
    - Study Role Assignment
    - Study Role Removal
    - Site Access Changes
    - Country Access Changes
    - Study Assigned (Role assignment + ‘Grant Access’)
    - Training Status Changed
    - Training Status Ignored
    - Training Status Respected
    - Grant Access
  - Existing User Access actions removed from User *Activity* Report
- Use case
  - Providing an easily accessible audit trail of user access covering the life of the vault

## Visibility

User Admin  
Super User  
Custom Roles  
w/ “View  
Users”

## Configuration

N/A

## Dependencies

Available on all  
vaults





# User Access Report

## System Tools

**Users**

Role Management | User Defined Permission Sets | Change Reasons | External Connections | Deployment

+ New User | Import From File | Search | Status: All | Selected 0 | 1-25 of 38 | 1 / 2 | Settings

Last Name	First Name	User Name	Email
val23r1	demo	DVAL23r1@eh.com	DVAL23r1@eh25c
ToAllSites		FSSTAS29@eh.com	FSSTAS29@erhaa
CaseSensitive		CVCS214@eh.com	CVCS214@veeva

- Reset password
- Send Welcome Email
- User Activity Report
- User Access Report
- Inactivate

**User Access Report**

From: 09/10/2022 | To: 03/10/2023

All Studies |  Select Studies

Cancel | Run

EXPORT

- CSV
- Excel
- User Activity Report
- User Training Report
- User Access Report

Role	Datetime	Name	Username	Email	Company	Study	Action	Old Value	New Value	Modified By
CDMS Clinical Research Associate	08/12/2022 4:32 PM MDT	Strd CDMS User Admin3	strdua719c@eh.com	strdua719b@eh.com		Simple Study1_VAL1	Study Role Assigned		CDMS Clinical Re	eric.sample@
CDMS Clinical Research Associate	08/12/2022 4:32 PM MDT	Strd CDMS User Admin3	strdua719c@eh.com	strdua719b@eh.com		Simple Study1_VAL1	Site Access Changed		All Sites	eric.sample@
CDMS Clinical Research Associate	08/12/2022 4:32 PM MDT	Strd CDMS User Admin3	strdua719c@eh.com	strdua719b@eh.com		Simple Study1_VAL1	Ignore Training Status Changed		LMS Ignored	eric.sample@
CDMS Clinical Research Associate	08/12/2022 4:32 PM MDT	Strd CDMS User Admin3	strdua719c@eh.com	strdua719b@eh.com		Simple Study1_VAL1	Assign Study		TRUE	eric.sample@
CDMS Clinical Research Associate	08/12/2022 4:32 PM MDT	Strd CDMS User Admin3	strdua719c@eh.com	strdua719b@eh.com		Simple Study1_VAL1	Grant Access		Enabled	eric.sample@
CDMS Safety Administrator	08/13/2022 11:23 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study2	Study Role Assigned		CDMS Safety Adr	eric.sample@
CDMS Safety Administrator	08/13/2022 11:23 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study2	Ignore Training Status Changed		LMS Ignored	eric.sample@
CDMS Safety Administrator	08/13/2022 11:23 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study2	Training Status Changed		Not Trained	eric.sample@
CDMS Safety Administrator	08/13/2022 11:23 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study2	Assign Study		TRUE	eric.sample@
CDMS Safety Administrator	08/13/2022 11:23 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study2	Grant Access		Enabled	eric.sample@
CDMS Safety Administrator	08/13/2022 11:23 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study2	Training Status Changed	Not Trained	Trained	System
CDMS Clinical Research Coordinat	08/13/2022 11:35 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study1_DEV1a	Site Access Changed	All Sites	001	eric.sample@
CDMS Clinical Research Coordinat	08/13/2022 11:40 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study1_DEV1a	Site Access Changed	001		eric.sample@
CDMS Clinical Research Coordinat	08/13/2022 11:40 AM MDT	Eric CRC61022b	ehCRC61022b@eh.com	eric.sample+5@veeva.com		Simple Study1_DEV1a	Country Access Changed		United States	eric.sample@

Day 1  
Impact to  
Clinical Teams

No

Visibility  
User Admin  
Super User  
Custom Roles  
w/ "View  
Users"

Configuration

N/A

Dependencies

Available on all  
vaults



# Disable Manual Casebook Creation

- Overview
  - New setting in EDC Tools - Study Settings
  - Default value is “No” - casebook creation is unchanged
  - “Yes” - the New Casebook button will be disabled in Data Entry for that study
    - Casebook creation via API still supported
  - Can be toggled on and off
- Use case
  - Support for casebook creation via external integration (IRT, etc.) only

Day 1  
Impact to  
Clinical Teams

No

## Visibility

Lead Data  
Managers,  
Librarians,  
Study  
Designers

## Configuration

EDC Tools >  
Study Settings

## Dependencies

Available on all  
vaults



# Disable Manual Casebook Creation

Day 1  
Impact to  
Clinical Teams

No

My Studies > Simple Study2 > Simple Study2\_DEV1 DEVELOPMENT Version: 1.3

EDC Tools **Study Settings** Cancel Save

SETUP

Study Settings

Study Countries (1)

Sites (2)

Learning Systems

Email Group Assignment

Review Plan Assignment Criteria

Review Plan Manual Assignment

Assessments

Enable Absorb Learning System  Yes  No

Include Absorb Course Details in the Training Report  Yes  No

Connect to Vault CTMS  Yes  No

CTMS Study Link ID

**Disable Manual Casebook Creation**  Yes  No

Visibility

Lead Data  
Managers,  
Librarians,  
Study  
Designers

Configuration

EDC Tools >  
Study Settings

Dependencies

Available on all  
vaults

Data Entry Library Review Assessments Studio Coder Reports Dashboards Loader

SITE TASKS

Forms

Queries

DEV1 > 955 > Search Subject

+ New Casebook Subject Status: All Signature completed: All

Subject	Last Event	Next Event
SCR-0010	Prescreening Visit (19-Oct-2022)	Screening Visit
SCR-0009	Prescreening Visit (10-Feb-2023)	Screening Visit
SCR-0008	Prescreening Visit (19-Oct-2022)	Screening Visit
SCR-0007	Prescreening Visit (10-Feb-2023)	Screening Visit

This action cannot be performed because casebook creation has been disabled for this study



# Role Management UI Enhancements

- Overview

- Usability enhancements to the System Tools - Role Management page
- Permission dependencies displayed via tooltip when creating or editing a custom role
- Permissions in grid are now grouped into the following sections:
  - Data Entry
  - Queries
  - Review
  - Assessments
  - Study Admin
  - Coder
  - Study Design
  - Library
  - Protocol Deviations
  - Labs
  - Randomization (if applicable)
  - Site Closeout
  - CDB (if applicable)

- Use case

- Enhanced navigability and UX in Role Management

Day 1  
Impact to  
Clinical Teams

No

## Visibility

LDM  
User Admin  
Super Users  
Custom role w/  
*Manage Study  
Roles*

## Configuration

N/A

## Dependencies

Available on all  
vaults



# Role Management UI Enhancements

Day 1  
Impact to  
Clinical Teams

No

Role Management

Show:  All Roles  Active Roles

+ New Role

	Administration							
	CDMS Deployment Administrator	CDMS Randomization Manager	CDMS Safety Administrator	CDMS Super User	CDMS User Administrator	Copy Study Data	Copy Study Data Only	L Custom User Ad
Number of Users	0	0	0	1	2	0	1	0
Manage Role	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Study Countries	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
View Study Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Edit Study Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Manage Review Plan Assignment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Review Plan Assignment Criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Review Plan Manual Assignment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Deployments	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Cancel Save

This permission cannot be removed because the following dependent permissions are selected:

- Copy Study Data to PPT
- Edit Study Sites

Role Management

Show:  All Roles  Active Roles

+ New Role

	Administration			
	CDMS Deployment Administrator	CDMS Randomization Manager	CDMS Safety Administrator	CDMS Super User
Number of Users	0	0	0	1
Manage Role	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Study Countries	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
View Study Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Edit Study Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Manage Review Plan Assignment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Review Plan Assignment Criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Review Plan Manual Assignment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manage Deployments	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Assessments

View Medical Assessments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Edit Medical Assessments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Manage Assessments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Study Administration

Manage Study Lock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Manage Jobs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Visibility

LDM  
User Admin  
Super Users  
Custom role w/  
Manage Study  
Roles

Configuration

N/A

Dependencies

Available on all  
vaults



# Review Plan Assignment Enhancements

- Overview

- The single Review Plan Assignment tab with subtabs has been moved to two individual tabs:
  - Review Plan Assignment Criteria
  - Review Plan Manual Assignment
- Two new permissions have been created to provide more granular access to the respective tabs:
  - Manage Review Plan Assignment Criteria
  - Manage Review Plan Manual Assignment
- New permissions are not granted to any standard roles but are available for use with custom roles
- In Assignment Criteria, Site can be searched by name or number

- Use case

- Enhanced usability of Review Plan Assignment, and opportunity for precise access to subsections

Day 1  
Impact to  
Clinical Teams

No

## Visibility

LDM  
Librarians  
Study  
Designers  
Super Users

## Configuration

New  
permissions  
available for  
use with  
custom roles

## Dependencies

Available on all  
vaults



# Review Plan Assignment Enhancements

Day 1  
Impact to  
Clinical Teams

No

Visibility

LDM  
Librarians  
Study  
Designers  
Super Users

Configuration

New  
permissions  
available for  
use with  
custom roles

Dependencies

Available on all  
vaults

EDC Tools

Review Plan Assignment Criteria

+ New Assignment Criteria Reorder Assignment Job

Review Task	Study Countries
SDV	
SDV	

SETUP

Study Settings

Study Countries (1)

Sites (2)

Learning Systems

Email Group Assignment

Review Plan Assignment Criteria

Review Plan Manual Assignment Rule

EDC Tools

Review Plan Manual Assignment

Search Q Site Status: All Study C

Site Number	Site Name
955	Denver Health
956	Swedish Hospital

SETUP

Study Settings

Study Countries (1)

Sites (2)

Learning Systems

Email Group Assignment

Review Plan Assignment Criteria

Review Plan Manual Assignment

Review Plan

Review Task\*  
DMR

Assignment to Subjects with Status  
Pre Screen

Base Plan  
DMR None

Override ⓘ

Override Plan

Override Subject Ordinals

Override Coverage Percentage %

Assignment Criteria ⓘ

Assign Plans to Casebooks In

Each site

Specific countries

Specific sites

Sites

d

- 001 Denver Health
- 020 Anschutz Medical Center
- 030 Porter Hospital
- 040 St Anthony's



# General Admin Enhancements

- Overview
  - ‘Manage Jobs’ permission granted to *CDMS Clinical Research Associate* & *CDMS Data Manager* roles to support Listings
  - Study Access automatically removed when a user is inactivated
  - Prevent custom role from being removed in target vault after deploying
  - Study deploy from DEV to VAL
  - Changes to user’s future Activation Date accommodated in User Import
  - Warning when a permission set references a deleted Tab
  - Accommodate changes to Production data during a *Copy Study Data to PPT* operation
  - Augmented warning on adding a cross-vault user via User Import
- Use case
  - Continue providing usability and QoL enhancements to Study Administration in CDMS

Day 1  
Impact to  
Clinical Teams

Yes

## Visibility

CRA  
DM  
Deployment  
Admin  
User Admin  
Super User

## Configuration

N/A

## Dependencies

Available on all  
vaults







Extracts

# Study Data Extract New Lab Format

- Overview

- In the *23R1 version* of the SDE, there will be a new lab format which replaces the existing format for forms configured with Local Labs. Users can still retrieve the previous format in older SDE versions.
- This format pivots the data so that the dataset is tall vs. wide, with a shared set of columns for each Analyte. The Analytes are listed in a column called LBTEST.
- Some of the columns' Data Types and SAS Types will be changed to text/char to account for multiple Analyte types sharing the same column for their values.

- Use Case

- Previously, clinical lab forms could have hundreds of columns, making the dataset very wide and unreadable / not consumable. Now, the datasets are more easily parsable with a common set of columns, and users do not have to scroll as far horizontally to read all of the data.

Day 1  
Impact to  
Clinical Teams

No

Visibility

LDMs

Configuration

N/A

Dependencies

Available for all  
existing studies



# Study Data Extract Definition Names in Datasets

- Overview

- In the *23R1 version* of the SDE, Event Group, Event, Form, Item Group and Item definition names have been added to the clinical datasets and various System datasets.
- System Datasets impacted:
  - SYS\_EVT
  - SYS\_FORM
  - SYS\_ILB
  - SYS\_LINKS
  - SYS\_Q
  - SYS\_PD
  - SYS\_ASM

- Use Case

- Users are able to more easily map definition names to Labels when ingesting the data. Previously, Labels were primarily displayed in the SDE, which aren't guaranteed to be unique.



# Study Data Extract Enhancements

- Overview

- In the *23R1 version* of the SDE, the following general enhancements were made:
  - Boolean formatting override: users can choose the output format of booleans
    - The default format is “Y/N”
  - CSV column headers will be deduplicated
    - The system will deduplicate CSV column headers (in addition to SAS column headers which it does today) by appending a `_2`, `_3`, and so forth to column headers. Users running the SAS export option will see an additional “SAS Column” in the Study definitions file that reflects any SAS column header transformations that may occur.
  - The `casebook_schedule.csv`, `casebook_definition_summary.csv`, `item_definitons.csv`, `event_definitions.csv` and `form_definitions.csv` files in the definitions folder of the SDE will be in order of the casebook schedule in Studio.
  - The Query Last Closed Date (LASTCLOSEDDT) column was added to the SYS\_Q dataset.

- Use Case

- These enhancements provide usability improvements to the SDE.





Coder

# Sync Synonym List

- Overview

Users can designate one *Synonym List* and *Do Not Autocode List* to perform all autocoding and suggestions actions for two vaults. *Autocoding and Suggestions* will be consistent across all Studies that span the vaults.

There are some limitations to consider: Coders cannot *Propagate Code* from the secondary Vault. The Propagate Code action from the primary Vault will apply the decision to the Synonym List and the Forms on the primary Vault but it will not apply to the Forms on the secondary Vaults. Finally, Coder Managers cannot use the feature Apply to Synonym List from the secondary Vault.

- Use case

Autocoding and Suggestions will be consistent across all Studies that span two Vaults.



# Coder Tools New Navigation

- Overview

The main navigation in Coder Tools is now on the left panel.

- Use case

This new UI experience is scalable as we add more features to Coder Tools.

## Coder Tools

SETUP	<b>Study Settings</b>														
Default Study Settings	<a href="#">My Studies</a> > Select a Study ▾														
<b>Study Settings</b>	<input type="text" value="Search"/> <input type="button" value="Q"/> Organization: All ▾ <span style="float: right;">1-15 of 15</span>														
Synonym Lists (11)															
Do Not Autocode Lists (2)															
OPERATIONS															
Upversioning															
Jobs															
	<table border="1"><thead><tr><th>Name</th><th>Organization</th></tr></thead><tbody><tr><td>Aabrinone_DEV1</td><td>Bryce Pharma</td></tr><tr><td>Jabrinone_DEV1</td><td>Bryce Pharma</td></tr><tr><td>Kabrinone_DEV1 </td><td>Bryce Pharma</td></tr><tr><td>Labrinone_DEV1</td><td>Bryce Pharma</td></tr><tr><td>Library_DEV1</td><td>Bryce Pharma</td></tr><tr><td>Nabrinone_DEV1</td><td>Bryce Pharma</td></tr></tbody></table>	Name	Organization	Aabrinone_DEV1	Bryce Pharma	Jabrinone_DEV1	Bryce Pharma	Kabrinone_DEV1	Bryce Pharma	Labrinone_DEV1	Bryce Pharma	Library_DEV1	Bryce Pharma	Nabrinone_DEV1	Bryce Pharma
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Aabrinone_DEV1	Bryce Pharma														
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Kabrinone_DEV1	Bryce Pharma														
Labrinone_DEV1	Bryce Pharma														
Library_DEV1	Bryce Pharma														
Nabrinone_DEV1	Bryce Pharma														

No

Visibility  
Coder Admin

Configuration  
N/A

Dependencies  
None



# Coder Config Resilience

- Overview

With this release, Study designers can still see coding configurations for Form and Item Definitions from an deleted or orphaned Verbatim Item Definition or orphaned or deleted a related coding Item Definition. Study Designers can then select a new Item Definition or make the mapping not required (in the case of Related Coding Item Definitions only). Users can also delete the Coding Configuration on the Form Definition entirely.

- Use case

Study Designers will have options to fix the Coding Configuration instead of requiring assistance from Veeva Support.

Day 1  
Impact to  
Clinical Teams

No

Visibility

Coder Admin

Configuration

N/A

Dependencies

None







E2BLink (Safety Integrations)

# Duration Inclusion Rules for Related Safety Data

- Overview
  - **Before release:** only **site linked** form data included to safety transfer / cases
  - **At release:** (via study design)
    - Auto include related safety case data (ConMed, Med History, Labs,..)
    - Disallow site linking inclusion (per preference)
    - Auto include 'All' (as/when necessary)
    - Study drug/product dispense rules
    - **Close** Adverse Events → auto include to existing safety case
    - Study by study configurable, i.e. one study needs CM(s) within 3 days, another within 60 days
- Use case (for a study...)
  - Concomitant Medications - Ongoing + within 7 days of the SAE Start
  - Medical History - All (then review / decide in case processing)
  - Related AEs - +/- 2 days of the SAE
  - Study Drug - Any that overlaps the SAE Start <-> End. (e.g. restart dose)

Day 1  
Impact to  
Clinical Teams

No

## Visibility

Safety Admin  
Study Designers  
(Paired Safety  
System)

## Configuration

Study by Study -  
Study Designers  
Safety Admin

## Dependencies

Available for all  
existing studies



# Duration Inclusion Rules for Related Safety Data

## Non Study Drug Rules (Con Meds Example)

"Site deems relevant"  
- linked in Data Entry

Captures any ongoing  
at SAE Start

Taking Aspirin 'near',  
but ended before the  
SAE Start

Records to Include in a Case\*  All

- Linked by site user (includes form linking & item linking)
- Duration overlaps any part of the SAE duration
- Duration overlaps any part of the  days on/before the SAE start date
- Duration overlaps any part of the  days on/after the SAE start date
- Duration overlaps any part of the  days on/before the SAE end date
- Duration overlaps any part of the  days on/after the SAE end date
- Duration ends before the SAE start date

Day 1  
Impact to  
Clinical Teams

No

### Visibility

Safety Admin  
Study Designers  
(Paired Safety  
System)

### Configuration

Study by Study -  
Study Designers  
Safety Admin

### Dependencies

Available for all  
existing studies



# Duration Inclusion Rules for Related Safety Data

## Non Study Drug Rules (Close AEs)

No site linking

Other AEs within 2  
days before the SAE  
(serious or not)

Other AEs within 2  
days **after** the SAE  
(serious or not)

Records to Include in a Case\*  All

Linked by site user (includes form linking & item linking)

Duration overlaps any part of the SAE duration

Duration overlaps any part of the  days on/before the SAE start date

Duration overlaps any part of the  days on/after the SAE start date

Duration overlaps any part of the  days on/before the SAE end date

Duration overlaps any part of the  days on/after the SAE end date

Duration ends before the SAE start date

### Example:

\* Severe Headache (SAE #1) - Monday

\* Stroke (SAE #2) - Wednesday

→ Two 'candidates' - Follow-up to Monday's, plus a standalone for Wednesday's → safety user decides downstream

Day 1  
Impact to  
Clinical Teams

No

### Visibility

Safety Admin  
Study Designers  
(Paired Safety  
System)

### Configuration

Study by Study -  
Study Designers  
Safety Admin

### Dependencies

Available for all  
existing studies



# Duration Inclusion Rules for Related Safety Data

Day 1  
Impact to  
Clinical Teams

No

Records to Include in a Case\*  All  
 Closest On/Before SAE Start (one only)  
 Advanced

Pre 23R1 behavior -  
single dispense, closest  
on/before the SAE Start

## Study Drug Rules

Records to Include in a Case\*  All  
 Closest On/Before SAE Start (one only)  
 Advanced

- Study drug start date prior to SAE start date
- Duration overlaps any part of the SAE duration
- Duration overlaps any part of the  days on/before the SAE start date
- Duration overlaps any part of the  days on/after the SAE start date
- Duration overlaps any part of the  days on/before the SAE end date
- Duration overlaps any part of the  days on/after the SAE end date
- Duration ends before the SAE start date

Or...fine tune, any dispense  
before, + those within 3 days  
on/after the SAE start (drug  
restart)

### Visibility

Safety Admin  
Study Designers  
(Paired Safety  
System)

### Configuration

Study by Study -  
Study Designers  
Safety Admin

### Dependencies

Available for all  
existing studies



# New Configurable Study Behaviors

- Overview
  - = **At release:** Configurable
  - = **Before release:** Certain study level settings (E2BR3) were **not** configurable (static)
- Use cases (values to safety)
  - Subject Number format (composite, Country-Site-Subject, or just Subject)
  - Subject Number location in E2B (1 of 5 locations)
  - Sender organization type - e.g. Health Professional, Pharma Company, etc.
  - Qualification type - Medical Professional, Other Health Care Professional etc.
  - Behavior when site user indicates **Suspect** concomitant medication, as relates to study drug classification

## Study Settings Section

Subject ID E2B Location (D.1.-)\* Investigation Number

Subject ID Format in E2B\* Subject Only

Sender Type E2B Value (C.3.1)\* Health Professional

Primary Source Qualification E2B Value (C.2.r.4)\* Physician

## CM Section

Study Drug Classify when ConMed Suspect (G.k.1) \* Always Suspect

Day 1  
Impact to  
Clinical Teams

No

## Visibility

Safety Admin  
Study Designers  
(Paired Safety  
System)

## Configuration

Study by Study -  
Study Designers  
Safety Admin

## Dependencies

Available for all  
existing studies



# Enhanced Alerting on Important First Submit

- Overview
  - **Before release:**
    - End user could answer 'Yes' to all important 'Serious?'
    - But (!!) - not initially submit the form
    - The 'Yes' was the **start** of the clock for reporting to agencies
    - Result? → Delayed send to the safety system (and the agency as result)
  - **After release:**
    - Hourly check for all studies and situation above
    - Alert at the one hour mark - to **end user** + configurable mail list(s) / users
- Use cases
  - Urgent alerts sent near real time for necessary actions / completion by the site user

Day 1  
Impact to  
Clinical Teams

No

## Visibility

Safety Admin  
Study Designers  
DM / CRA

## Configuration

Study by Study -  
Study Designers  
Safety Admin

## Dependencies

Available for all  
existing studies



# Enhanced Alerting on Important First Submit

Day 1  
Impact to  
Clinical Teams

Yes

**Safety Administrator, Lead DM -  
Landing Area (New)**

My Studies > EKE-001-123 > EKE-001-123\_DEV1

Safety Integrations	<b>Study Settings</b>
SETUP	
Study Settings	Study Transmission Status Active
Alert Recipients	Alerting on Unsubmitted Forms Yes
OPERATIONS	First Send E2B Schedule 15 minutes
Alert History	Follow-up E2B Schedule 1 hour

Configure recipients of new alert, plus other alert types (coming releases)

Review previously sent alerts in the study

*Enhanced case reporting... coming soon in this area*

Visibility  
DM / CRA  
Site Users (if turned on)

Configuration  
Study by Study -  
Study Designers  
Safety Admin

Dependencies  
Available for all existing studies





# Enhanced Alerting on Important First Submit

## Configure Recipients

### Alert Recipients

+ New Alert Recipient

ID	Type	Study Country	Email Group	Other Email ⓘ
SR-000002	Non Submitted Form	Alert-Fails	eric.emerton@gmail.com	0/1000
SR-000001	Non Submitted Form	Alert-Fails	eric.k.emerton@gmail.com	

Country specific alerting (i.e. subjects of that country = different alert list)

Day 1  
Impact to  
Clinical Teams

Yes

### Visibility

DM / CRA  
Site Users (if  
turned on)

### Configuration

Study by Study -  
Study Designers  
Safety Admin

### Dependencies

Available for all  
existing studies



# Enhanced Alerting on Important First Submit

## Review Alerts

### Alert History

Study Country: All ▾ Type: All ▾

ID	Study Country	Site	Subject	Type	Email Group	Other Email	User
<a href="#">SA-000002</a>	United Kingdom	201	SCR-0001	Non Submitted Form			Eric Emerton
<a href="#">SA-000003</a>	United Kingdom	201	SCR-0001	Non Submitted Form		eric.k.emerton@gmail.com	

#### Safety Alert Detail: SA-000002

**Send Attempt** 1/27/2023 10:03 AM EST

**Type** Non Submitted Form

**Other Email**

**Subject Line** EKE-001-123\_DEV1: Safety Alert (Form Unsubmitted) - Subject SCR-0001

**Study Country** United Kingdom

**Site** 201

**Subject** SCR-0001

**Form** Adverse Events (5)

**Email Body** [Copy to Clipboard](#)

Study: EKE-001-123\_DEV1  
Study Country: United Kingdom  
Site: 201 : London Genreal  
Subject: SCR-0001  
Form: Adverse Events  
Form Sequence: 5  
Created By: Eric Emerton

WARNING: The referenced subject/form form satisfies AE seriousness criteria, but has not been submitted yet, or some required information is missing for the first send. For safety reporting reasons, a site user should return to the form and complete necessary information and use the Submit button once complete.

Close

Day 1  
Impact to  
Clinical Teams

Yes

Visibility

DM / CRA  
Site Users (if  
turned on)

Configuration

Study by Study -  
Study Designers  
Safety Admin

Dependencies

Available for all  
existing studies



# Enhanced Alerting on Important First Submit

Alert  
Email

Veeva Vault <vault-emails@veeva.com>  
to me ▾

Fri, Jan 27, 10:03 AM ☆

**Veeva Vault CDMS**

Study: EKE-001-123\_DEV1  
Study Country: United Kingdom  
Site: 201 : London Genreal  
Subject: SCR-0001  
Form: Adverse Events  
Form Sequence: 5  
Created By: Eric Emerton

**WARNING:** The referenced subject/form form satisfies AE seriousness criteria, but has not been submitted yet, or some required information is missing for the first send. For safety reporting reasons, a site user should return to the form and complete necessary information and use the **Submit** button once complete.

This email was sent to you by Veeva Vault, the first cloud-based suite of content management applications for the global life sciences industry. Learn more at [www.veeva.com/vault](http://www.veeva.com/vault) if you think it was sent incorrectly, please contact your Vault administrators. To ensure delivery to your inbox, please add [vault-emails@veeva.com](mailto:vault-emails@veeva.com) to your address book.

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Day 1  
Impact to  
Clinical Teams

Yes

Visibility

DM / CRA  
Site Users (if  
turned on)

Configuration

Study by Study -  
Study Designers  
Safety Admin

Dependencies

Available for all  
existing studies





APIs

# CDMS API: Data Read Only via API

- Overview
  - **Before release:**
    - Study design for IRT / other data → use of **read only** field(s)
    - Users can/would mistakenly 'reset' forms with integrated data
    - Event dates - through an integration - can be mistakenly update by site users
    - UAT of study can be problematic, as read only field might control 'next visit' Forces the 'Editable for UAT' -> 'Turn Read Only' (on go live day) issue
  - **After release:**
    - Fields can (optionally) be left non read only, in study design. When the API sets, its then locks down the value
    - Protection against mistaken reset of forms (leaves integrated data intact)
    - Event Date lockdown of value (if set by API)
- Use cases
  - Data that can be integrated for some sites vs. entered by others, in the same study.
  - Dilemma with Dev -> UAT -> Prod and increment of build number → no longer an issue, should one leave fields open through Dev/UAT/Prod

\* Only if the integration vendor moves 'forward' in API version

Day 1  
Impact to  
Clinical Teams

No

Visibility

DM / CRA  
Site Users \*

Configuration

Study Designers  
Limited or  
automatic

Dependencies

Available for all  
existing studies \*



# CDMS API: Data Read Only via API

## Form Data

The image displays two screenshots of the CDMS API interface for a 'Screening (01-Mar-2023): Demographics' form. The top screenshot shows the form with empty input fields for Gender and Birth Year. A yellow callout bubble points to the Gender field with the text 'Before the API Attempt'. The bottom screenshot shows the same form after an API attempt. The Gender field now contains the value 'Male' and is accompanied by a black tooltip that reads 'The value of this item is not editable. It has been set by another system.' A yellow callout bubble points to this tooltip with the text 'After the API Attempt - in open status, and notification to end user about field read only'. The interface includes a left sidebar with a study event tree, a top navigation bar with filters, and a main content area with a 'Submit' button.

Day 1  
Impact to  
Clinical Teams

No

Visibility

DM / CRA  
Site Users \*

Configuration

Study Designers  
Limited or  
automatic

Dependencies

Available for all  
existing studies \*



# CDMS API: Data Read Only via API

## Form Data

### Item Audit Trail

Timestamp	Username	Event Description
3/10/2023 9:20:19 AM EST	Eric Emerton (eric.emerton@eke.com)	Item set as owned by another system.
3/10/2023 9:20:18 AM EST	Eric Emerton (eric.emerton@eke.com)	Value entered "Male (M)". Reason for change: "Changes prior to submit"
3/10/2023 9:20:18 AM EST	System on behalf of Eric Emerton (eric.emerton@eke.com)	Item : VV-020450 created

Audit trail indication

Submit ...

ACTIONS

- Intentionally Left Blank
- Reset Form

EXPORT

- Export Blank PDF
- Detail PDF

VIEW

- Form Audit Trail

Reset Form Function

Sort By: Schedule Sign + New Event ...

### Screening (01-Mar-2023): Demographics

START OF STUDY

- Screening 01-Mar-2023
  - Informed Consent
  - Demographics
  - Visit Signs Screening
  - Medical History

Demographics	
Gender	Male
Birth Year	1978

Blank form..  
...but...  
→ data **maintained** (assuming other editable fields on form for site user entry)

Day 1  
Impact to  
Clinical Teams

No

Visibility  
DM / CRA  
Site Users \*

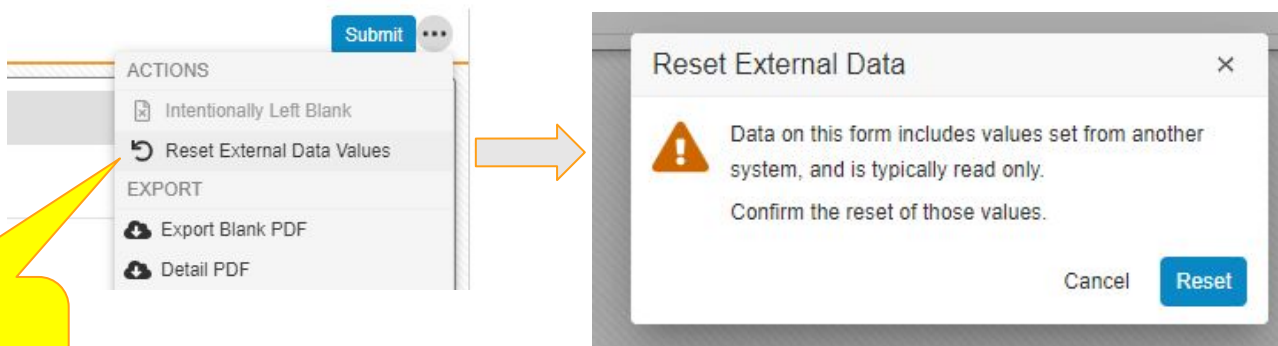
Configuration  
Study Designers  
Limited or  
automatic

Dependencies  
Available for all  
existing studies \*



# CDMS API: Data Read Only via API

## Form Data



For the rare need to actually reset the integrated data...  
(**ONLY** available at the form = blank status + 2nd action to perform)

Day 1  
Impact to  
Clinical Teams

No

## Visibility

DM / CRA  
Site Users \*

## Configuration

Study Designers  
Limited or  
automatic

## Dependencies

Available for all  
existing studies \*





# CDMS API: Data Read Only via API

## Event Dates

The screenshot shows a CDMS API interface with a timeline view. At the top, there is a 'Sort By: Schedule' dropdown, a 'Sign' button, and a '+ New Event' button. Below this, a horizontal line marks the 'START OF STUDY'. A vertical timeline axis on the left has markers at 0, 30, and 4. An event titled 'Screening' is scheduled for '01-Mar-2023'. A dropdown menu is open for this event, showing 'ACTIONS' with options: 'Edit Event Date', 'Reset Event', 'VIEW', and 'Event Audit Trail'. A black tooltip with white text reads: 'This event date is not editable. It has been set by another system.' A yellow callout box points to the 'Edit Event Date' option.

Event dates controlled by another system - no editing possible

Day 1  
Impact to  
Clinical Teams

No

Visibility

DM / CRA  
Site Users \*

Configuration

Study Designers  
Limited or  
automatic

Dependencies

Available for all  
existing studies \*



# CDMS API: Combination Form Data API

- Overview
  - **Before release:**
    - Situational issues in integrations - mixed form usage (some values by integration, some by site)
    - Is the form open or submitted? → additional inspection / API calls
    - Integration flow is a string of API calls, in specific order - e.g. add a form, open (if submitted), set data, submit it, etc.
    - Need to conditionally include reason for change in some situations, not others
  - **After release:**
    - One API - that will perform the 4 to 5 actions in one call down the value
    - CDMS API determines when/if necessary to open the form for edit
    - CDMS API will auto add a change reason (stock text) when/if necessary
- Use cases
  - General CDMS API integrations (e.g. IRT vendors)

\* Only if the integration vendor moves 'forward' in API version

Day 1  
Impact to  
Clinical Teams

No

Visibility

Integration /  
Other Vendors

Configuration

Other Veeva  
Vendors  
integration to  
CDMS

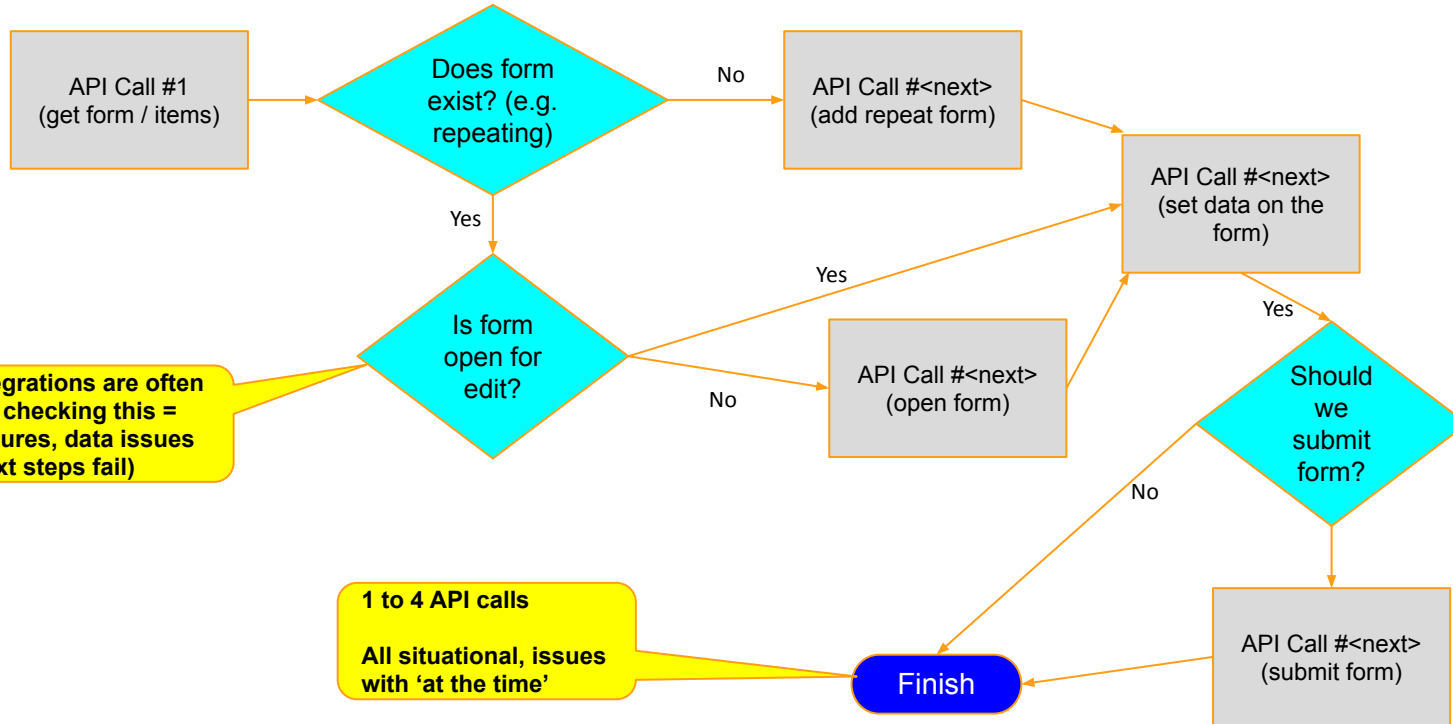
Dependencies

Available for all  
existing studies \*



# CDMS API: Combination Form Data API

**Before Release:**



Day 1  
Impact to  
Clinical Teams

No

Visibility

Integration /  
Other Vendors

Configuration

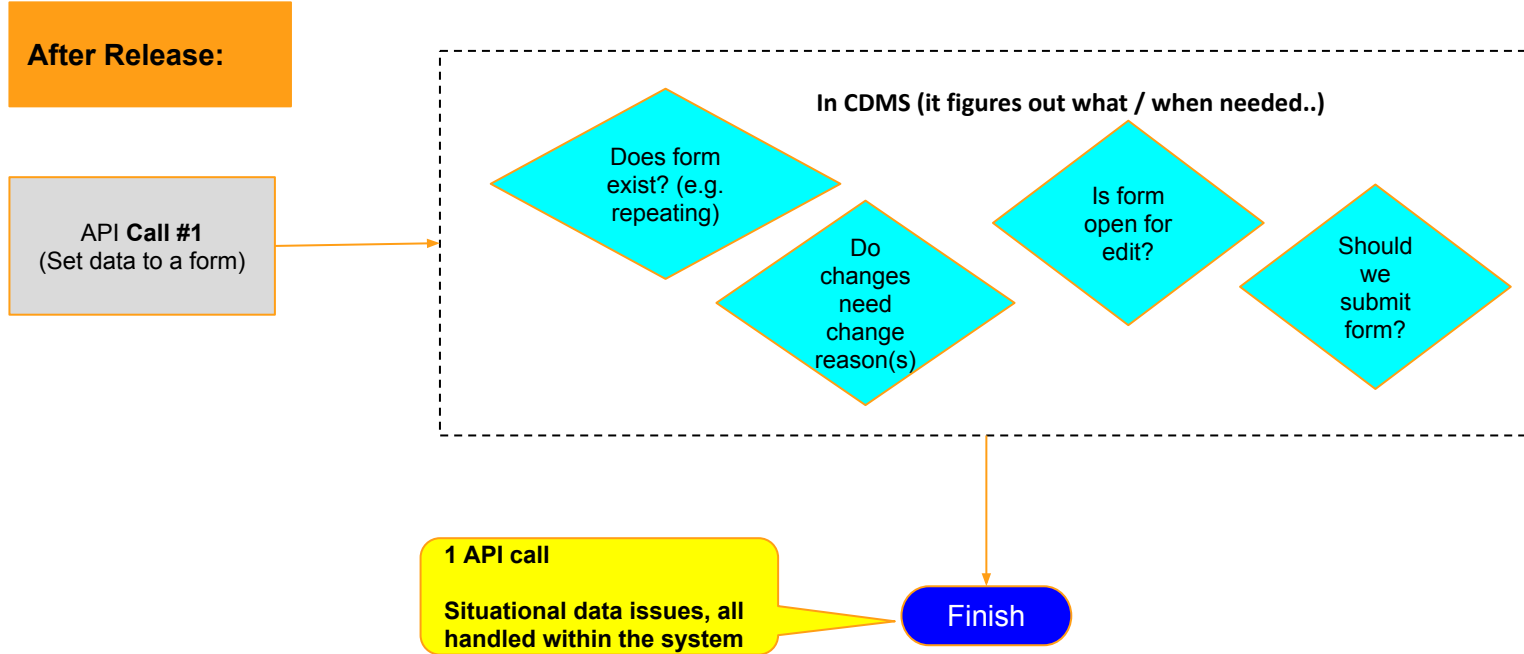
Other Veeva  
Vendors  
integration to  
CDMS

Dependencies

Available for all  
existing studies \*



# CDMS API: Combination Form Data API



Day 1  
Impact to  
Clinical Teams

No

Visibility

Integration /  
Other Vendors

Configuration

Other Veeva  
Vendors  
integration to  
CDMS

Dependencies

Available for all  
existing studies \*



# Evolving Customer Success

veeva

# Customer Success Update

## Customer Success Evolution

- We are creating a new role: **Product Experts** (former CSMs) as part of the **Product team**
- **Significant increase** in the investment and **quality of product-related content**
- **Customers better connected** with each other and supported by our Product organization **through Veeva Connect**

## Product Expert Benefit

- Gives customers **greater access to the Product organization**
- Creates more **engaged asynchronous communication**, including enhanced self-serve documentation
- **Expands learnings & relationships through Veeva Connect**



# Partnering for Customer Success



# Release Education Changes After 23R1

## Release Notes



Investing in content & communications

## Video Demos



Video demos of key features

## Veeva Connect



Engaging through Veeva Connect

Starting with 23R2 we will have improved Release Education Material instead of release webinars  Stay Tuned!





# SDE: New Lab Form Format

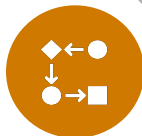
CDMS improves the formatting of the Lab Form Extract in 23R1

## FEATURE HIGHLIGHTS

- Clinical forms configured with Local Labs are formatted to decrease the number of columns
- Dynamically generated Lab columns are shared across all Lab Analytes on the form instead of multiple columns per analyte

## BUSINESS IMPACT

- Easier to review Lab data
- Provides better support for ingestion of Lab data into downstream systems
- No longer need to transpose the data



The screenshot shows the 'New Job' configuration page in the SDE system. The interface includes a sidebar with navigation options like 'CSM', 'Job Scheduling', and 'Job Name'. The main content area is divided into several sections: 'Type' (Study Data Extract), 'SDE Version' (Version 22R3), 'Restricted Data Options' (Include Restricted Data), 'Clinical Data Options' (Use Item External ID, Include separate Date and Time columns, Include forms intentionally left blank, Exclude blank forms), 'Data to Export' (Export all System Datasets, Export all Clinical Datasets, Include Custom Objects), 'Export Options' (Include Study Design), and 'Zip File Name' (with a .zip extension). On the right side, there are settings for 'Frequency' (Weekly), 'Name' (Scheduled SDE), 'Run at' (1:00 AM), 'Repeat on' (S M T W T F S), and 'Active Periods' (15). A note at the bottom right states: 'Scheduled jobs will be removed once the number of active periods has been reached.'



## BENEFITS

- Lab forms are more readable for viewing clinical data
- Rows are now combined into standard columns for test name, result, high and low range values, etc.
- Usability is improved for filtering across analytes, e.g. all high results, missing results

## ENABLEMENT

- Auto-on with the 23R1 version of the SDE
- Existing Scheduled Jobs can be updated to take advantage of the new format
- [Editing a Scheduled Job](#)



# Veeva Connect Communities

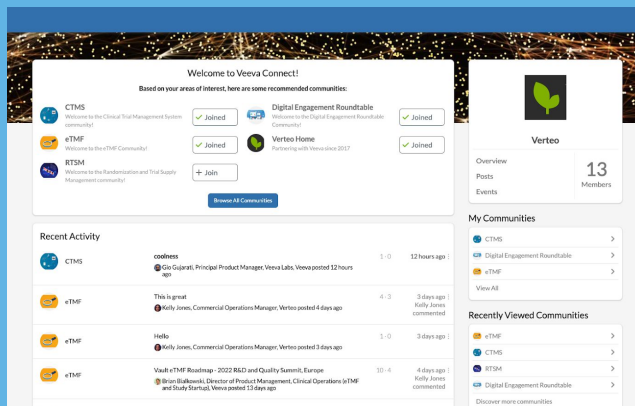


**Vision:** Create an enjoyable and efficient **community for life sciences** by bringing customers closer together with Veeva through *simple* and *authentic communication*





# Getting Access



- VeevaConnect.com
- Accessible by Veeva Customers
  - Work email address, and authentication code
- No username and password required



# Clinical Data Communities



CDB



EDC



RTSM





Questions



Thank you