23R1 Customer Webinar
Studio, Admin, Coder

March 23, 2023

Veeva

CDMS Product Managers

Dennis Kochanski

Sr. Product Manager

Studio, Library, Retrospective Amendments

Mo Al-Adeeb

Sr. Product Manager

Coder, Local Labs

Eric Haas

Product Manager

Admin, User Mgmt

Lindsay Chan

Technical Product Manager

Extracts

Natalie Moore

Product Manager

Rules

Eric Emerton

Principal Product Manager

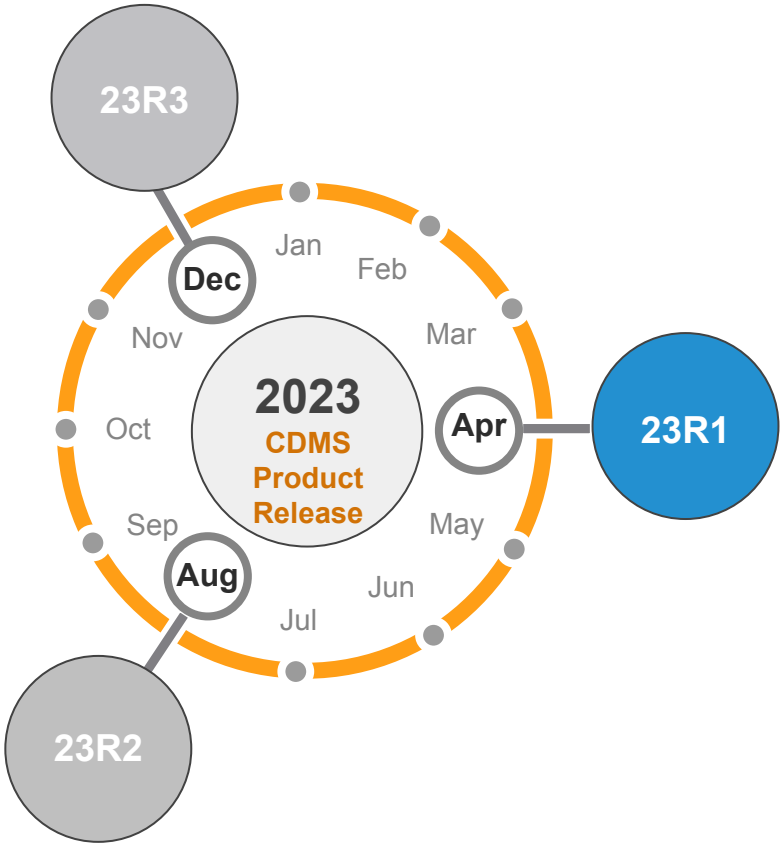
Safety Integrations, APIs

Kathy Tibaldi

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

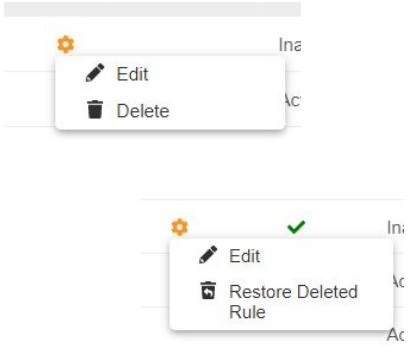
Safety Integrations

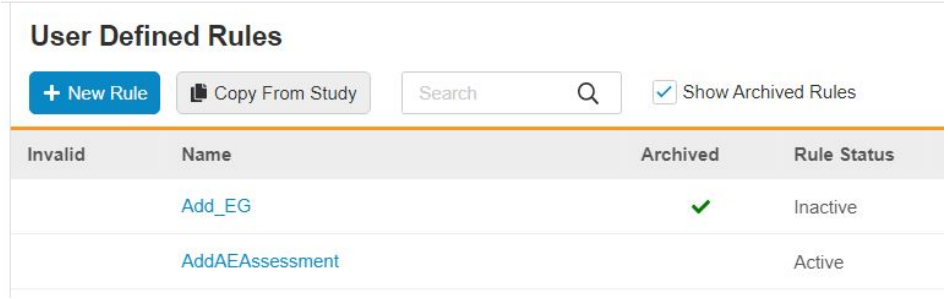
- Duration Rules for Case Data
- Crucial Alerting on Initial Form Submit / Case
- More Study Configuration

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





Day 1 Impact to Clinical Teams

No

Visibility

Study Designer
Librarian

Configuration

None

Dependencies

None

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

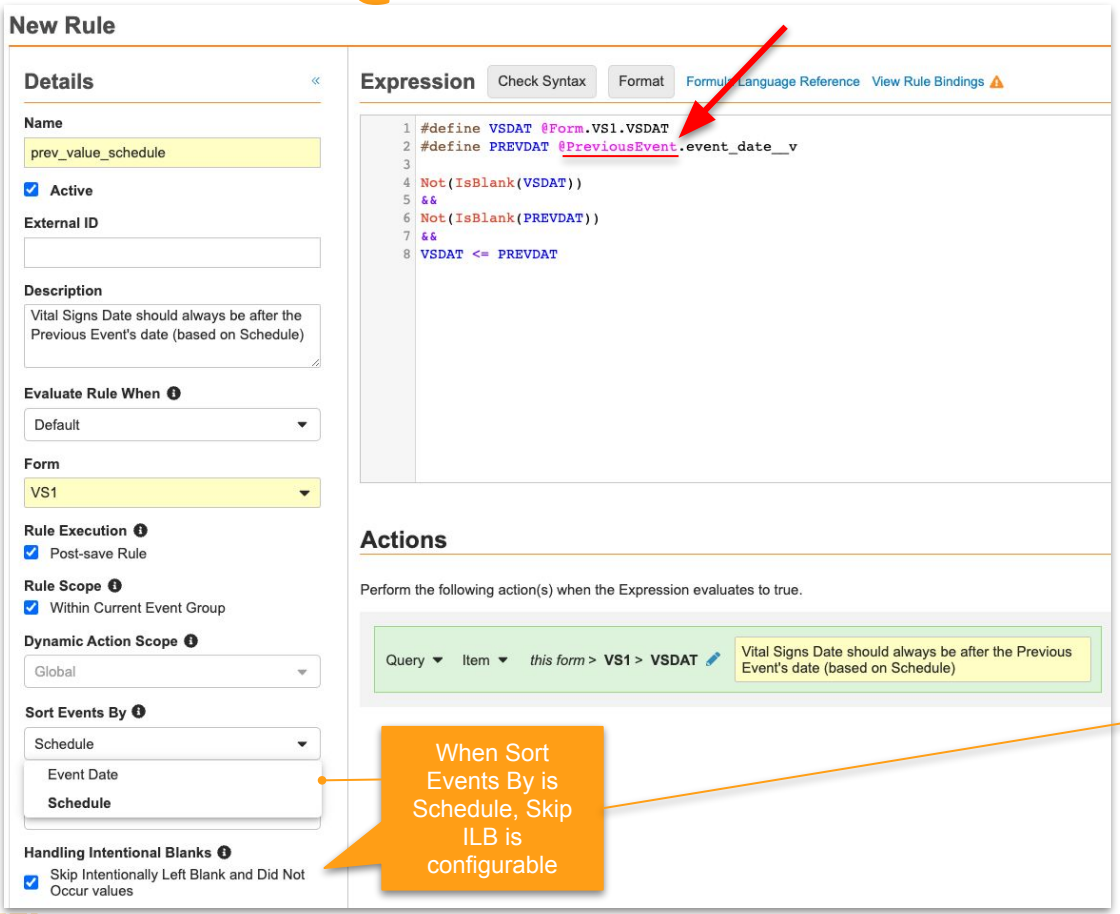
Studio

Dependencies

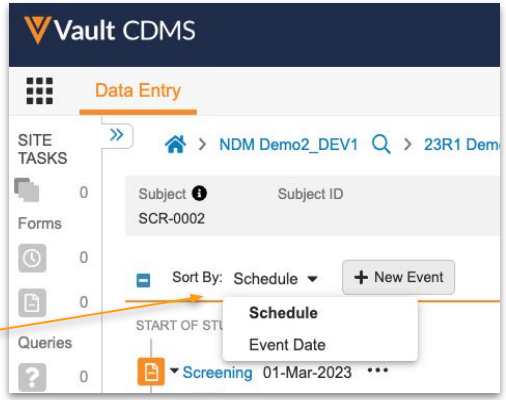
Rules Engine v2

Available for existing studies

@PreviousEvent Schedule Sorting



When Sort Events By is Schedule, Skip ILB is configurable



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers, Librarians

Configuration

Studio

Dependencies

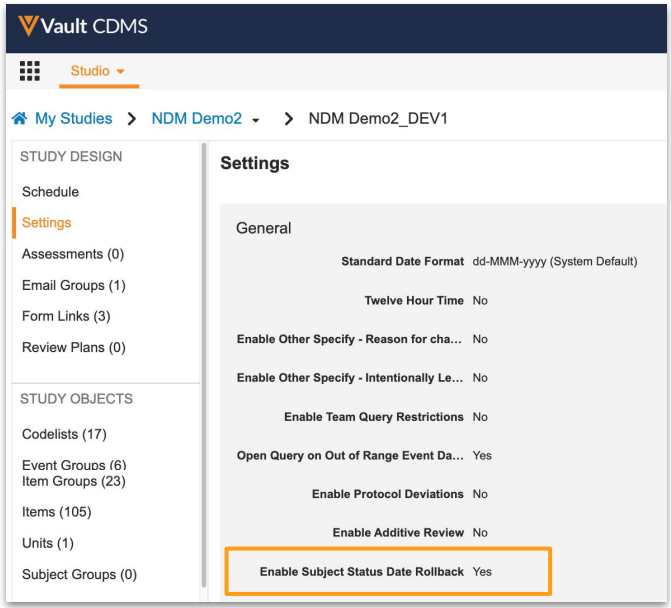
Rules Engine v2

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

Day 1 Impact to Clinical Teams

No

Visibility

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

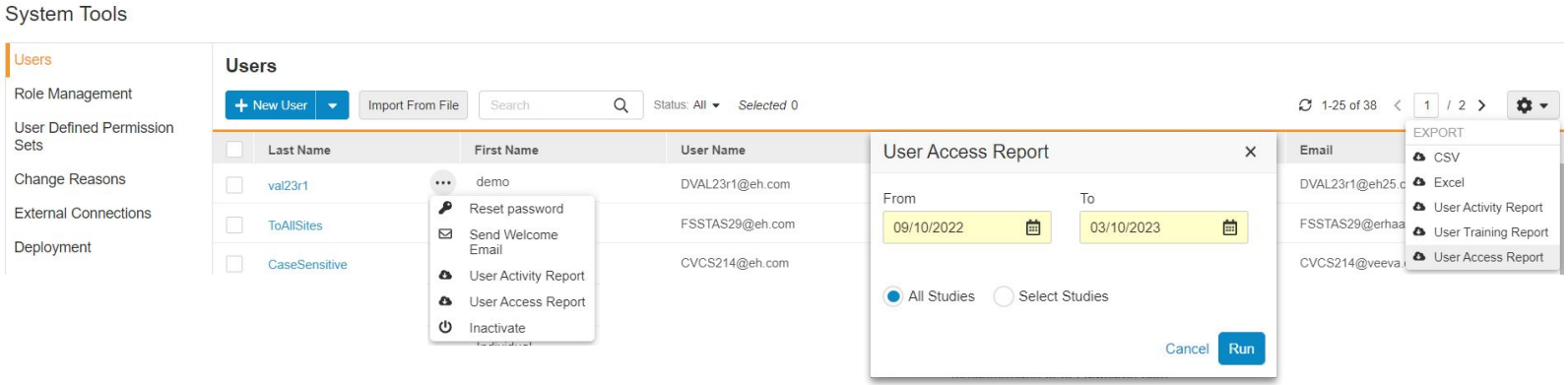
Configuration

N/A

Dependencies

Available on all vaults

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 Res	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 Adm	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@
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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
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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

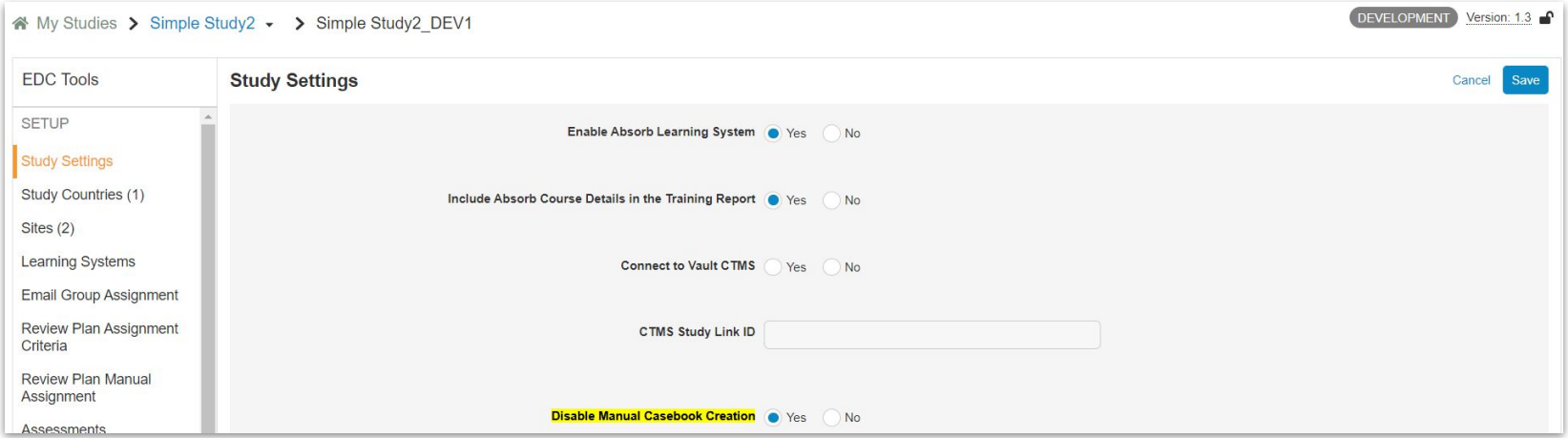
Configuration

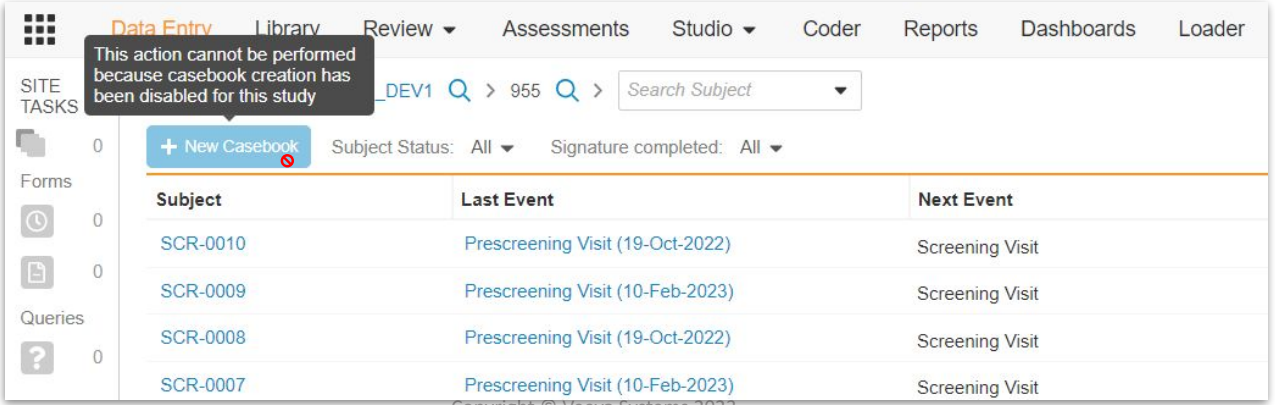
EDC Tools > Study Settings

Dependencies

Available on all vaults

Disable Manual Casebook Creation





Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Managers, Librarians, Study Designers

Configuration

EDC Tools > Study Settings

Dependencies

Available on all vaults

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*

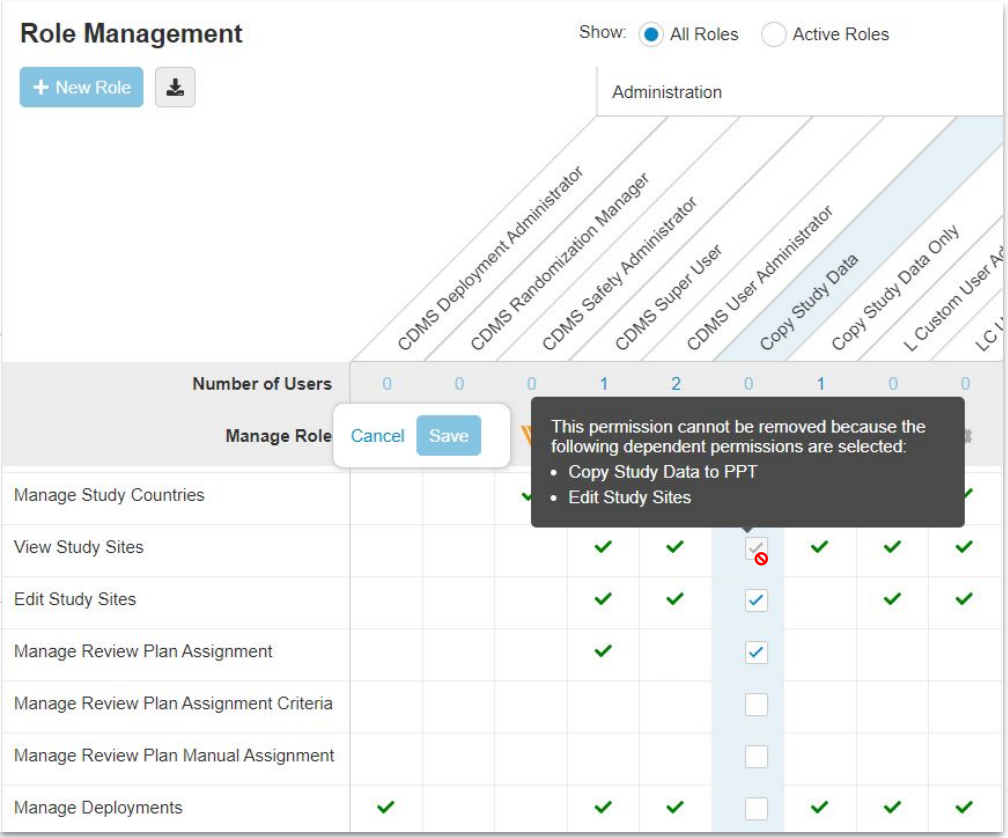
Configuration

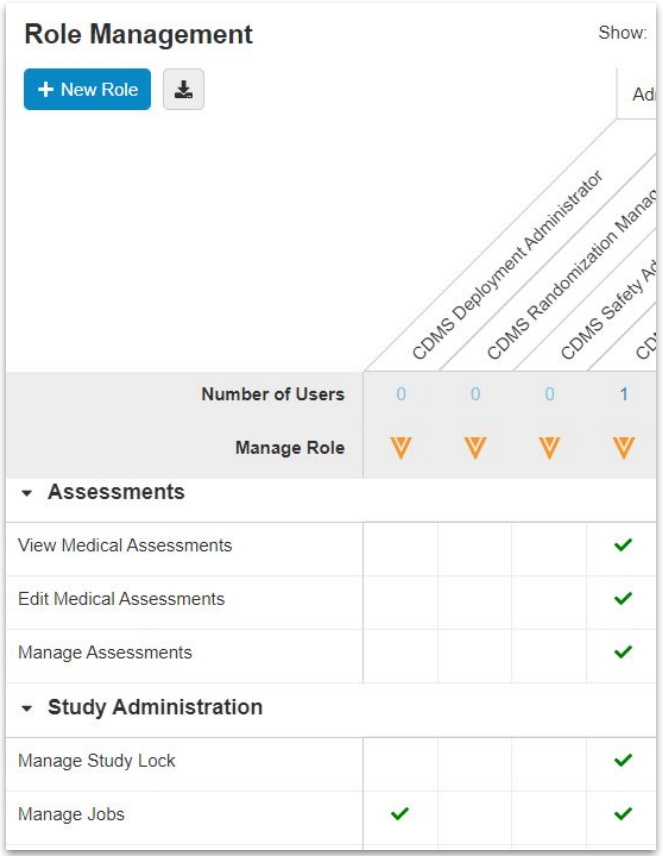
N/A

Dependencies

Available on all vaults

Role Management UI Enhancements





Day 1 Impact to Clinical Teams

No

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

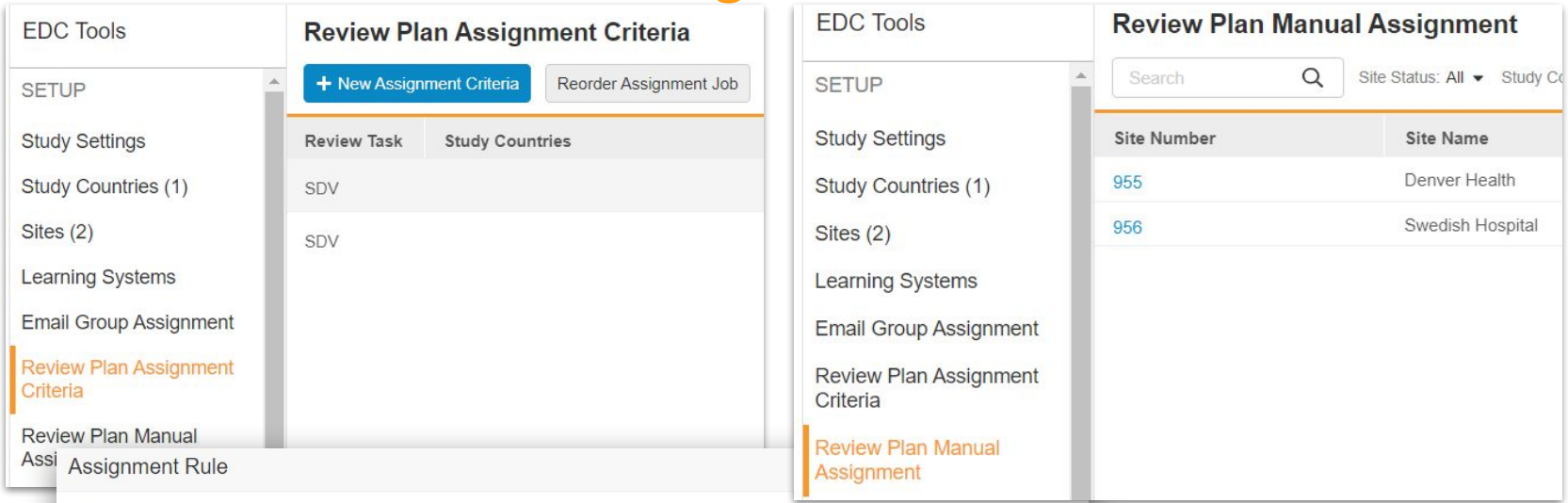
Configuration

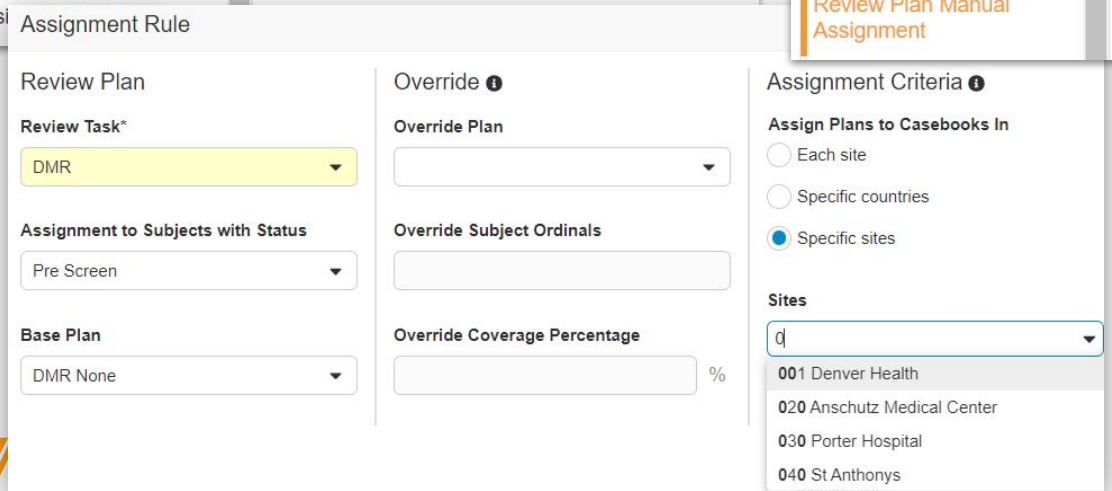
New permissions available for use with custom roles

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

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.

Day 1 Impact to Clinical Teams

No

Visibility

LDMs

Configuration

N/A

Dependencies

Available for all existing studies

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.

Day 1 Impact to Clinical Teams

No

Visibility

LDMs

Configuration

N/A

Dependencies

Available for all existing studies

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.

Day 1 Impact to Clinical Teams

No

Visibility

Coder Admin

Configuration

Contact Veeva

Dependencies

None

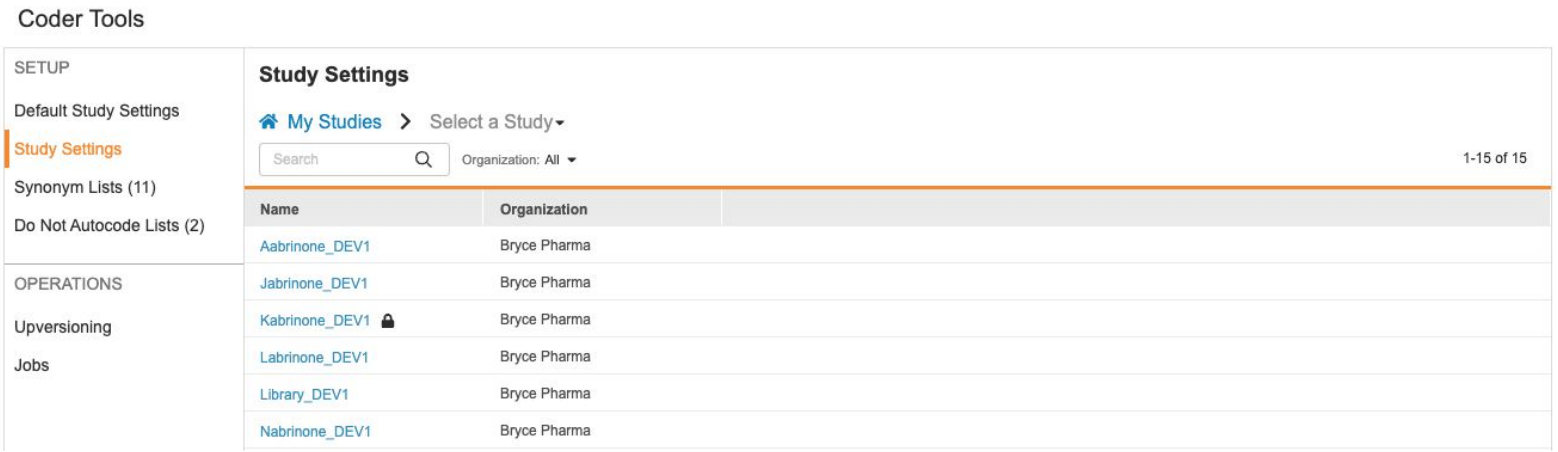
Coder Tools New Navigation

- 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.



Day 1 Impact to Clinical Teams

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

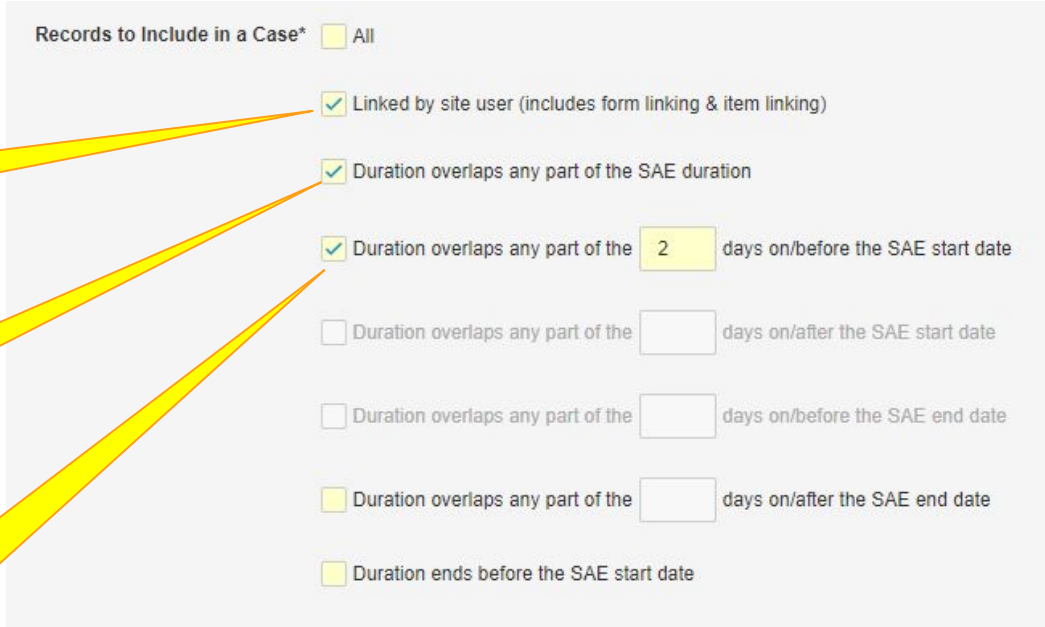
Study by Study -
Study Designers
Safety Admin

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

Day 1 Impact to Clinical Teams

No

Visibility

Safety Admin
Study Designers (Paired Safety System)

Configuration

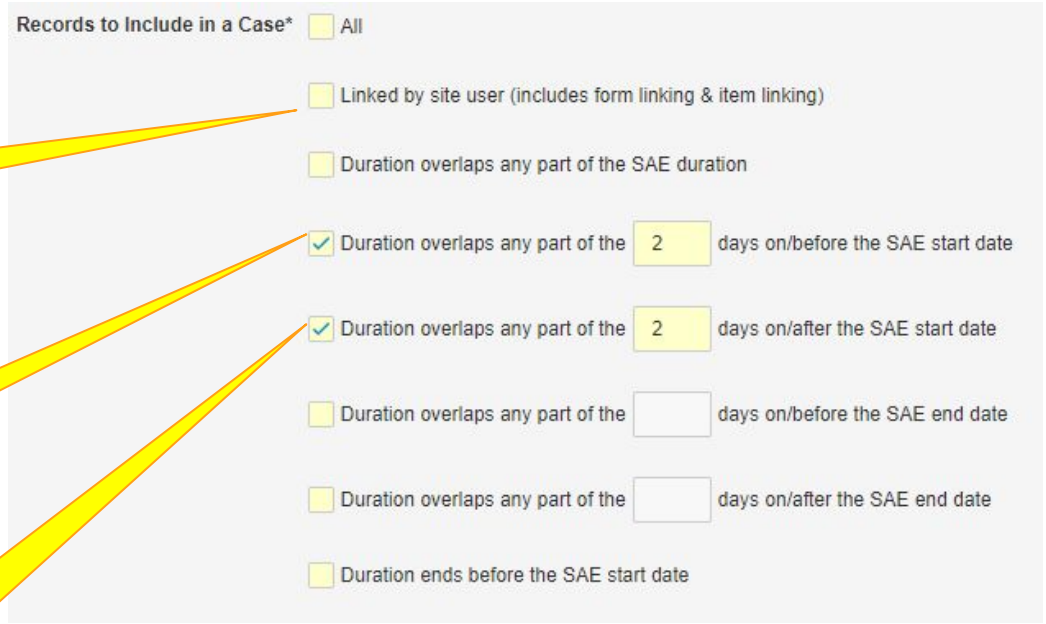
Study by Study - Study Designers Safety Admin

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)

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)

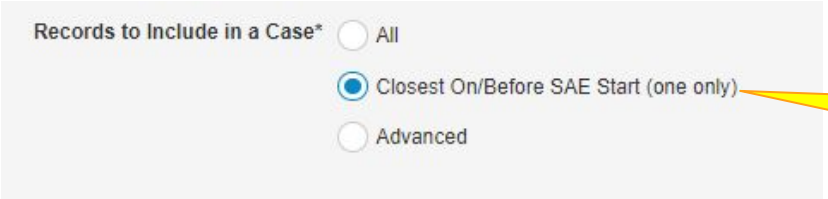
Configuration

Study by Study - Study Designers Safety Admin

Dependencies

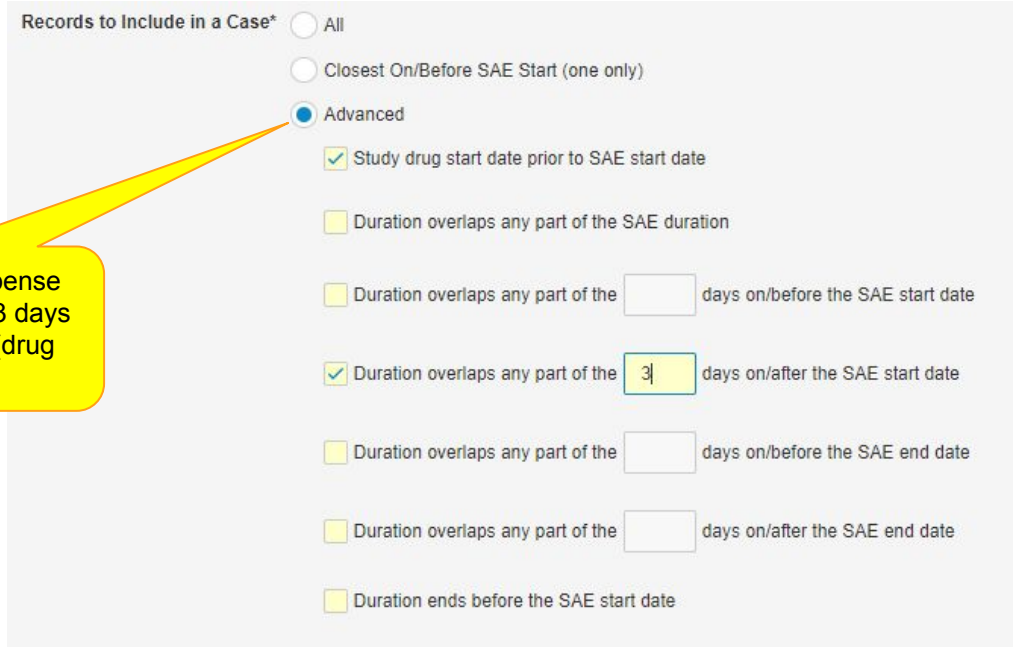
Available for all existing studies

Duration Inclusion Rules for Related Safety Data



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

Study Drug Rules



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

Day 1 Impact to Clinical Teams

No

Visibility

Safety Admin
Study Designers (Paired Safety System)

Configuration

Study by Study - Study Designers
Safety Admin

Dependencies

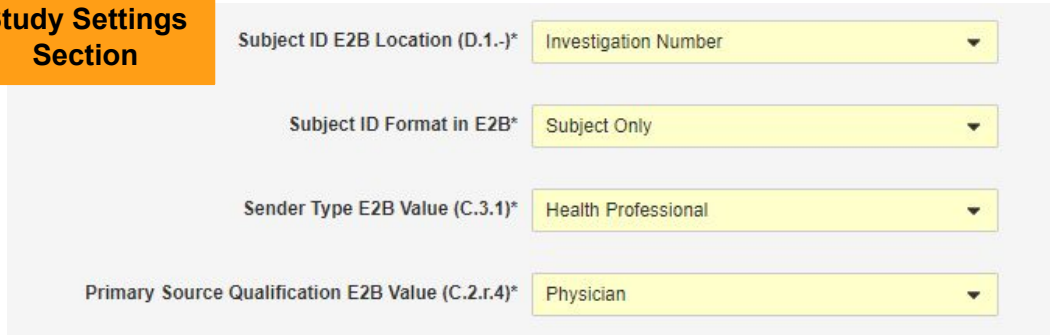
Available for all existing studies

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



CM Section

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

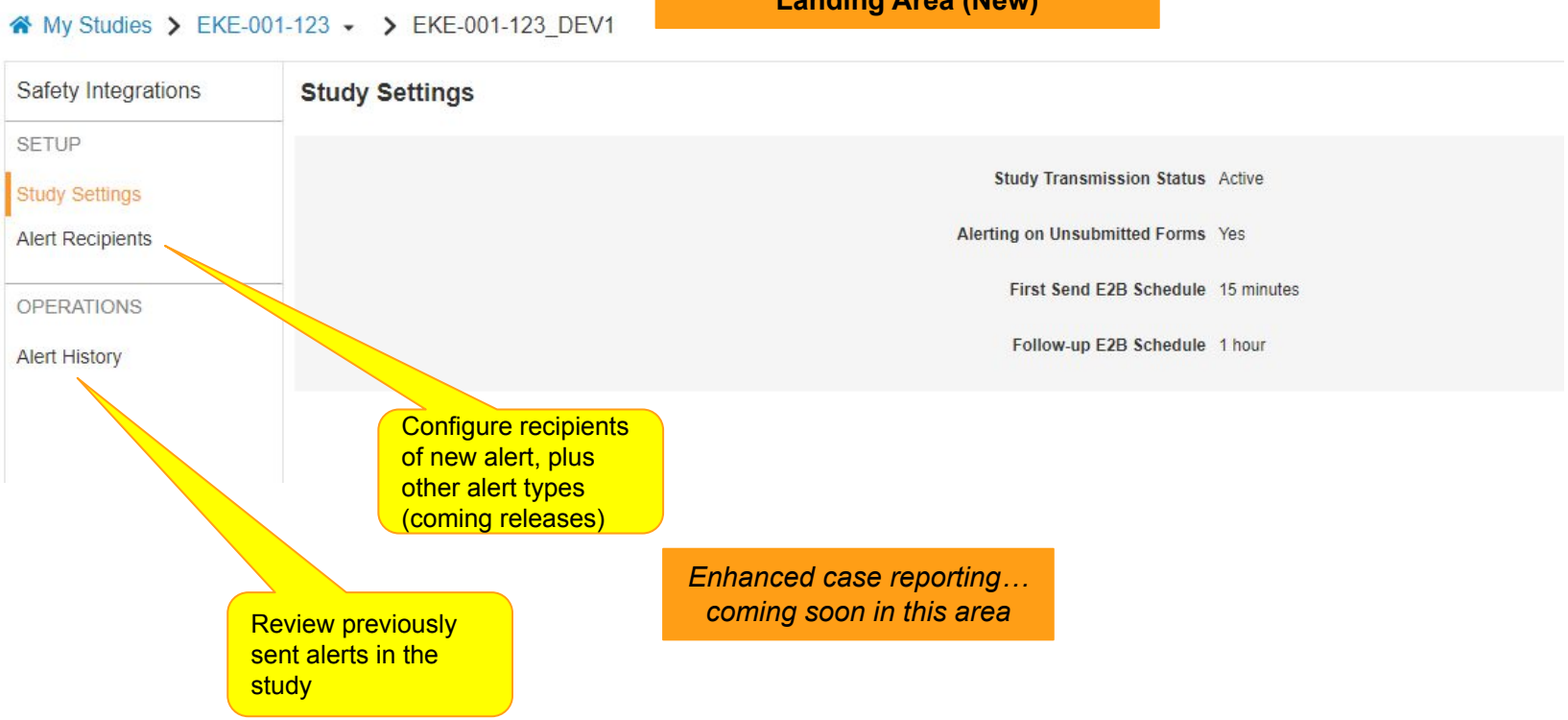
Study by Study -
Study Designers
Safety Admin

Dependencies

Available for all existing studies

Enhanced Alerting on Important First Submit

Safety Administrator, Lead DM - Landing Area (New)



Day 1 Impact to Clinical Teams

Yes

Visibility

DM / CRA
Site Users (if turned on)

Configuration

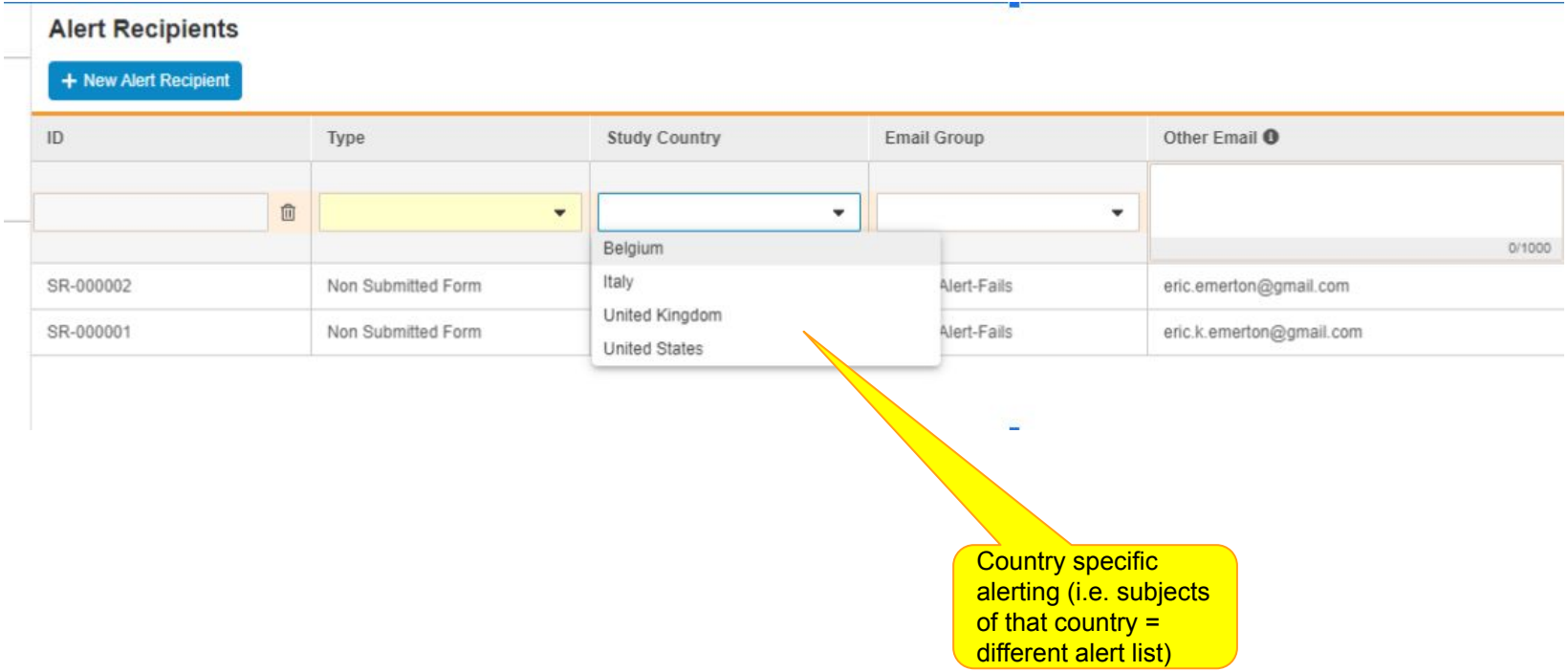
Study by Study - Study Designers
Safety Admin

Dependencies

Available for all existing studies

Enhanced Alerting on Important First Submit

Configure Recipients



Day 1 Impact to Clinical Teams

Yes

Visibility

DM / CRA
Site Users (if turned on)

Configuration

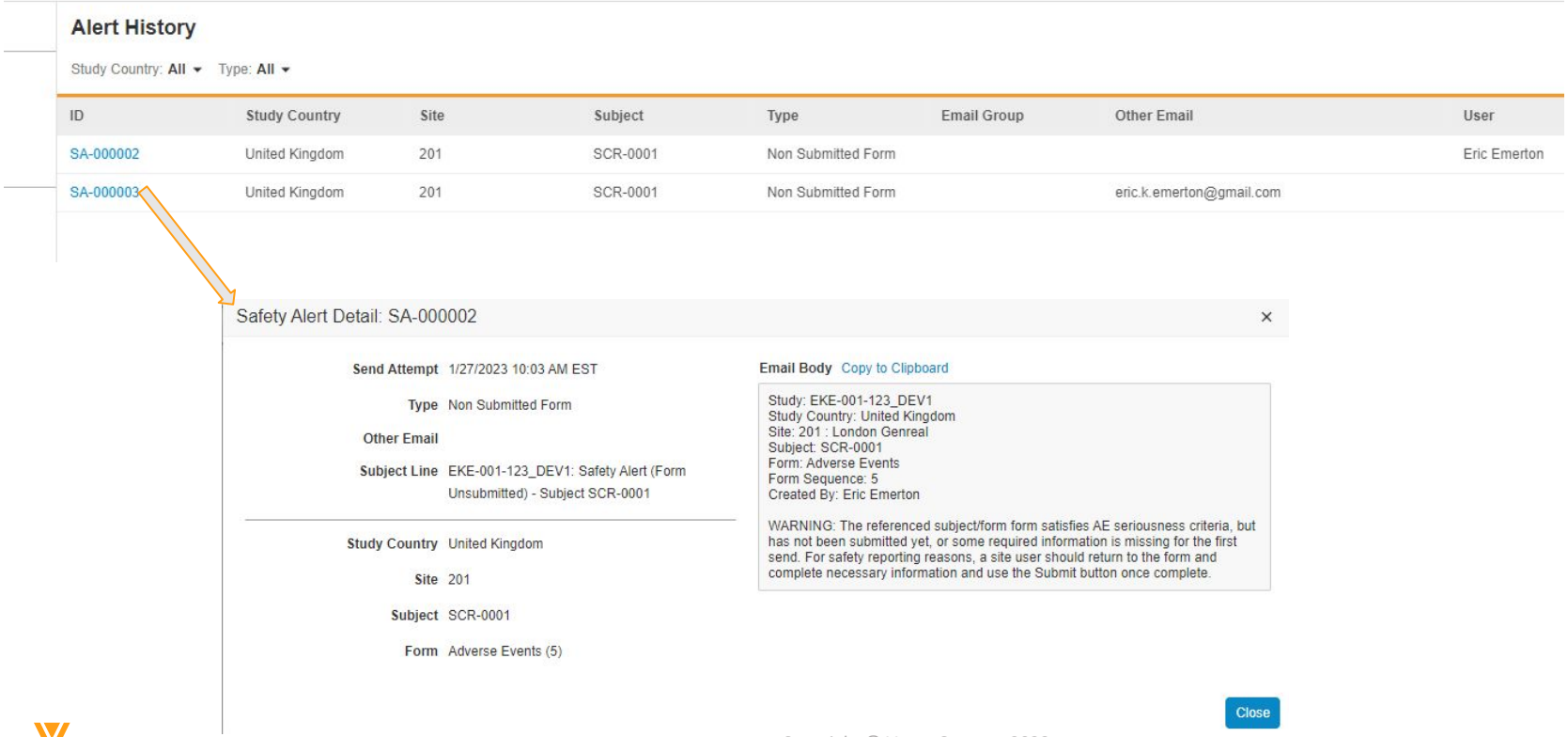
Study by Study - Study Designers
Safety Admin

Dependencies

Available for all existing studies

Enhanced Alerting on Important First Submit

Review Alerts



Day 1 Impact to Clinical Teams

Yes

Visibility

DM / CRA
Site Users (if turned on)

Configuration

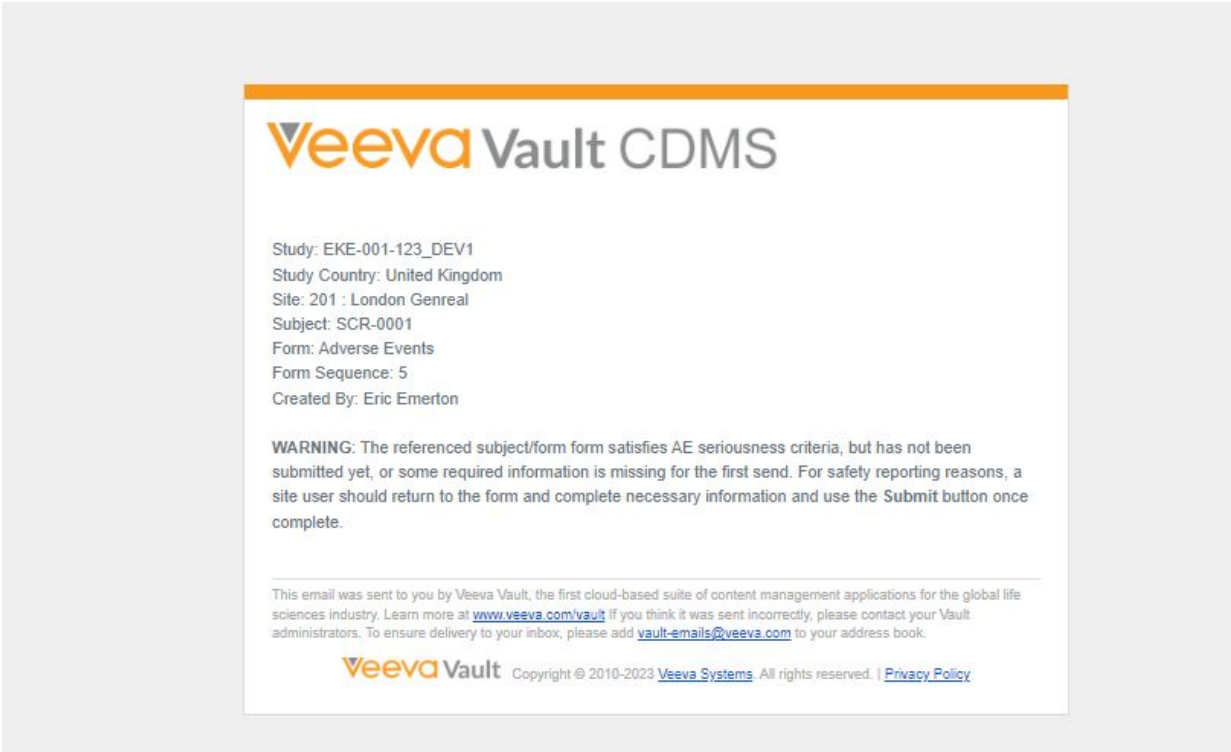
Study by Study -
Study Designers
Safety Admin

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 If you think it was sent incorrectly, please contact your Vault administrators. To ensure delivery to your inbox, please add vault-emails@veeva.com to your address book.

Veeva Vault

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 entact)
    - 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

Day 1 Impact to Clinical Teams

No

Visibility

DM / CRA
Site Users *

Configuration

Study Designers
Limited or automatic

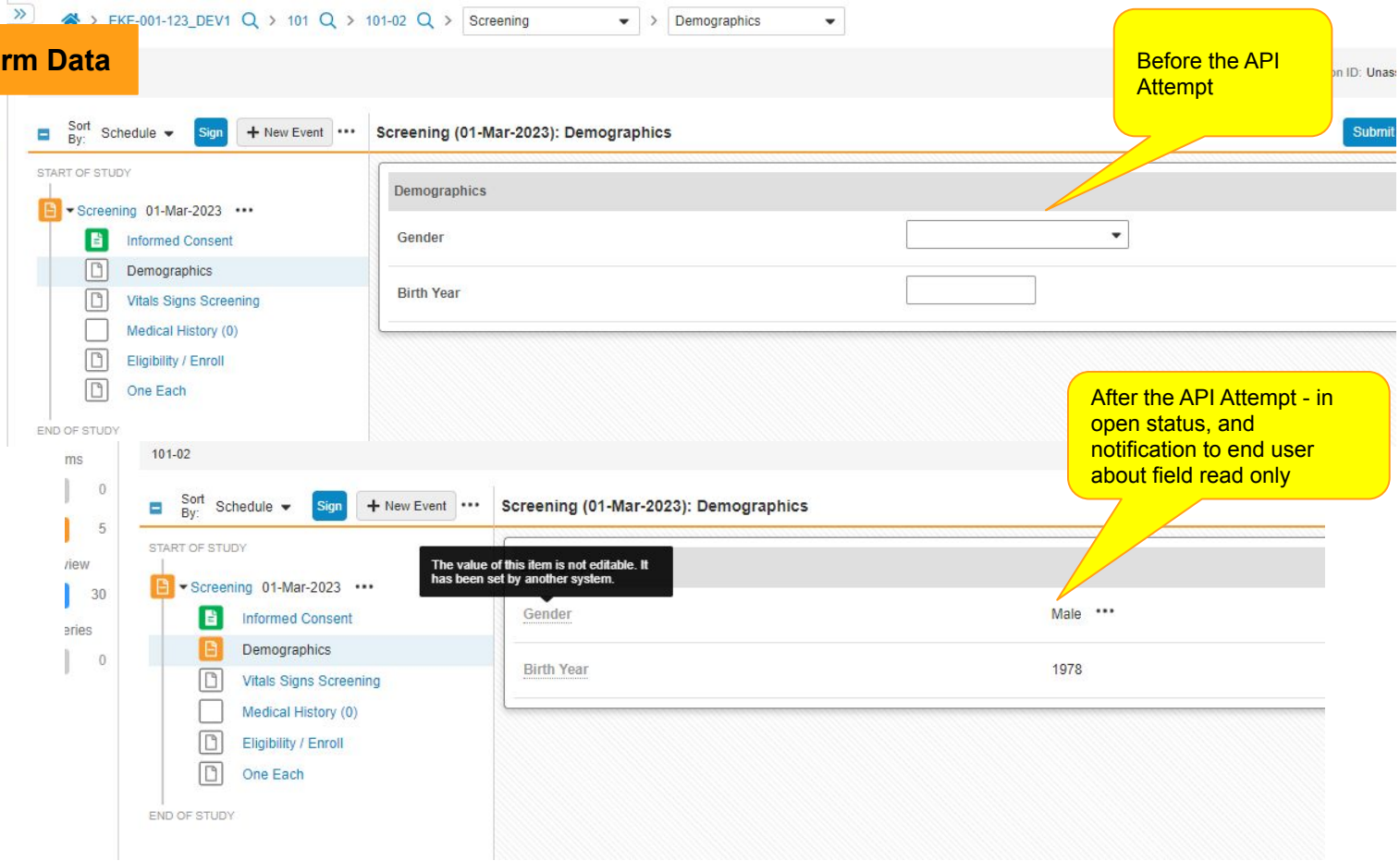
Dependencies

Available for all existing studies *

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

CDMS API: Data Read Only via API

Form Data



Day 1 Impact to Clinical Teams

No

Visibility

DM / CRA
Site Users *

Configuration

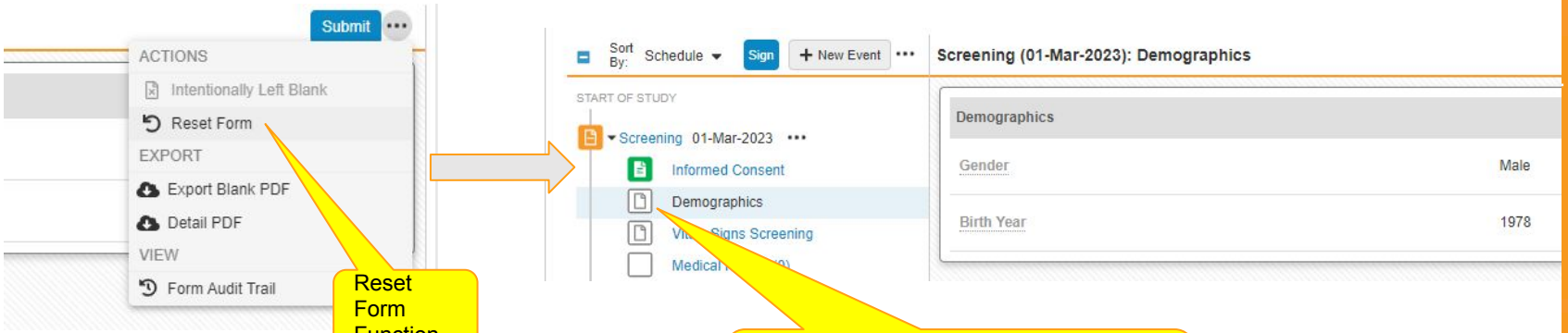
Study Designers
Limited or automatic

Dependencies

Available for all existing studies *

CDMS API: Data Read Only via API

Form Data



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

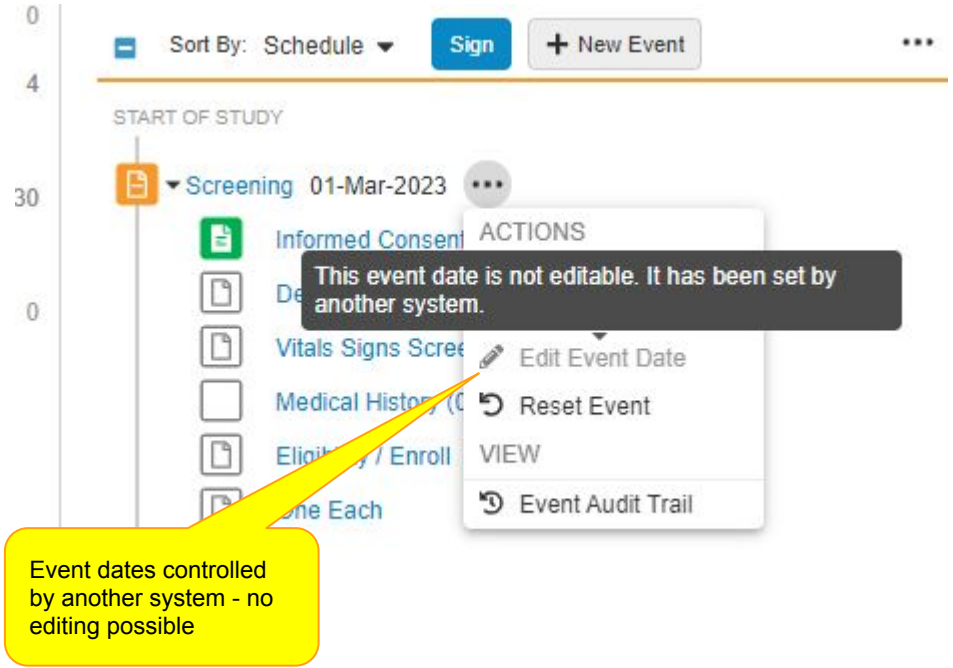
Study Designers
Limited or automatic

Dependencies

Available for all existing studies *

CDMS API: Data Read Only via API

Event Dates



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)

Day 1 Impact to Clinical Teams

No

Visibility

Integration / Other Vendors

Configuration

Other Veeva Vendors integration to CDMS

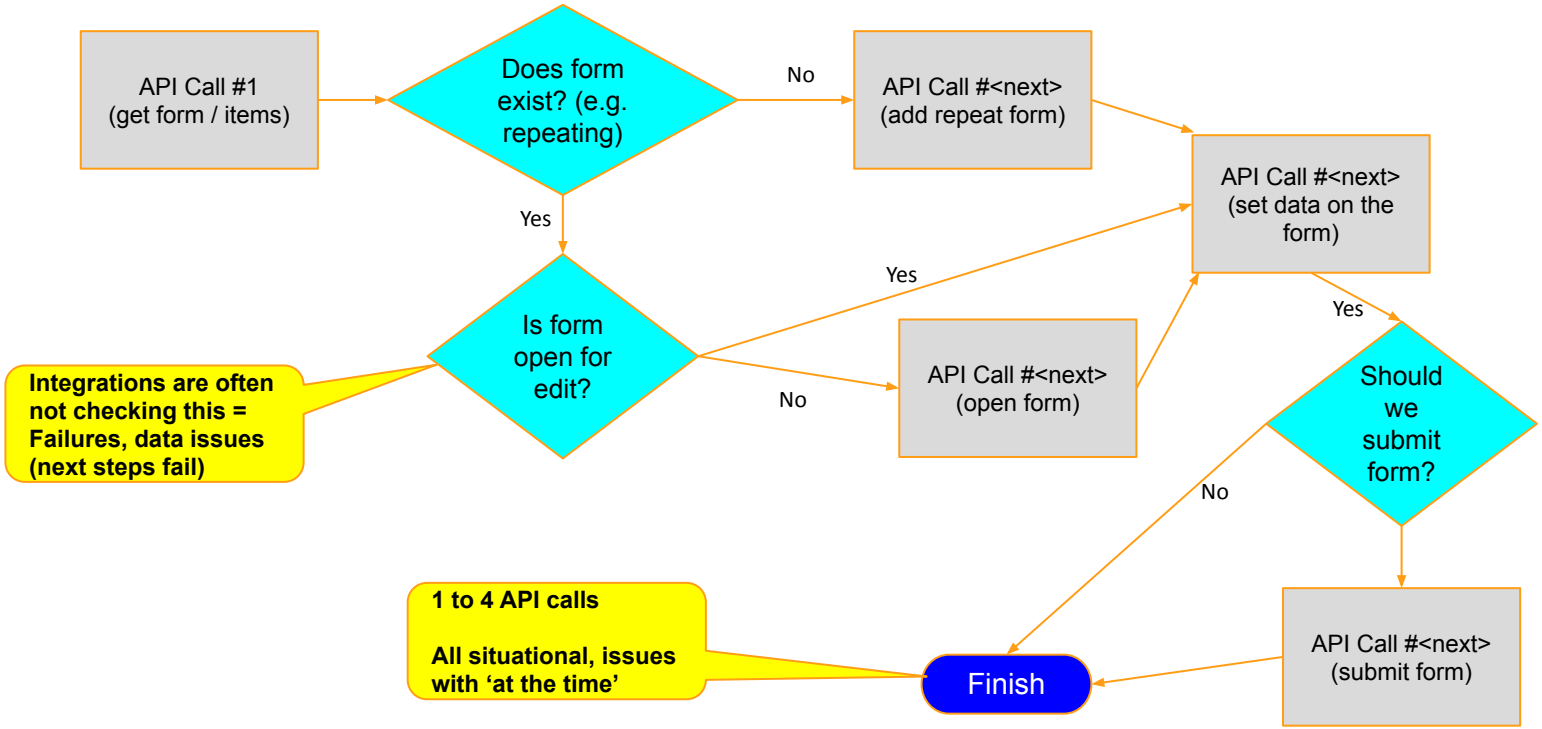
Dependencies

Available for all existing studies *

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

CDMS API: Combination Form Data API

Before Release:



Day 1 Impact to Clinical Teams

No

Visibility

Integration / Other Vendors

Configuration

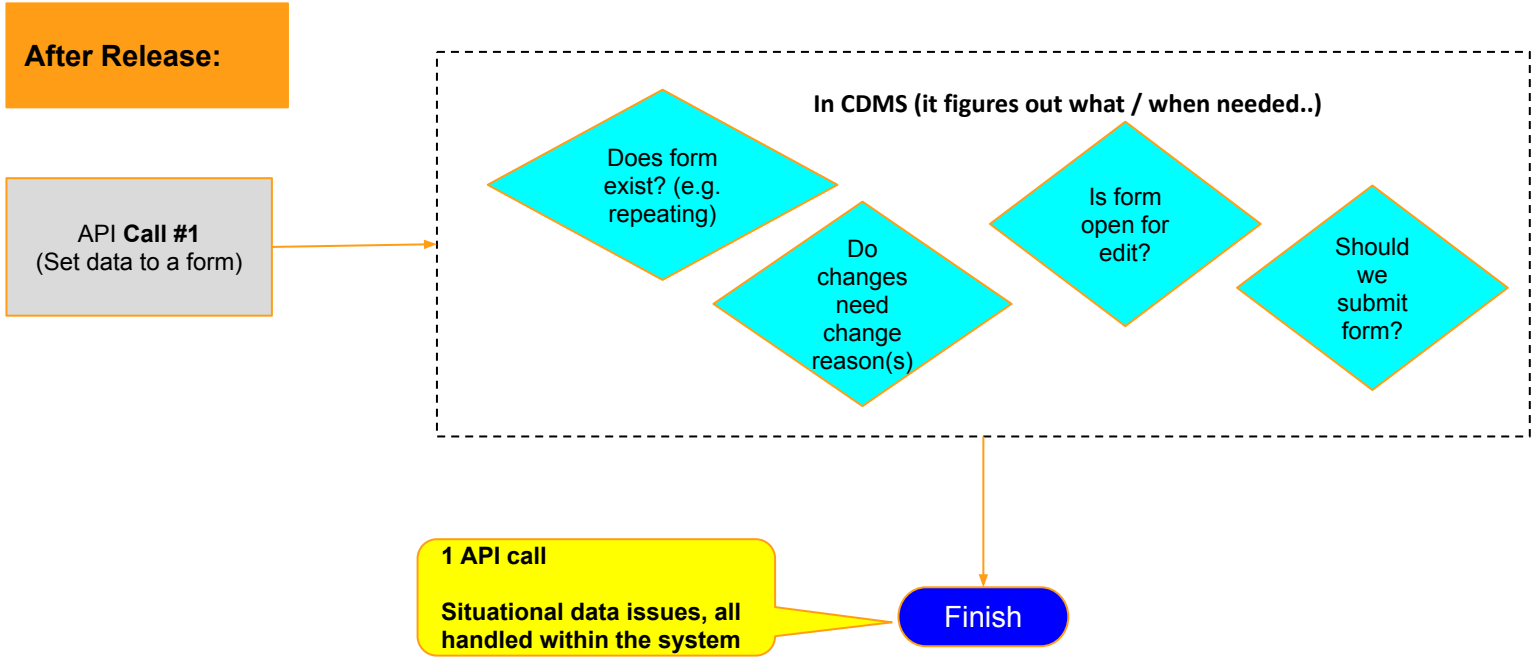
Other Veeva Vendors integration to CDMS

Dependencies

Available for all existing studies *

CDMS API: Combination Form Data API

After 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 *

Evolving Customer Success

Veeva

Customer Success Update

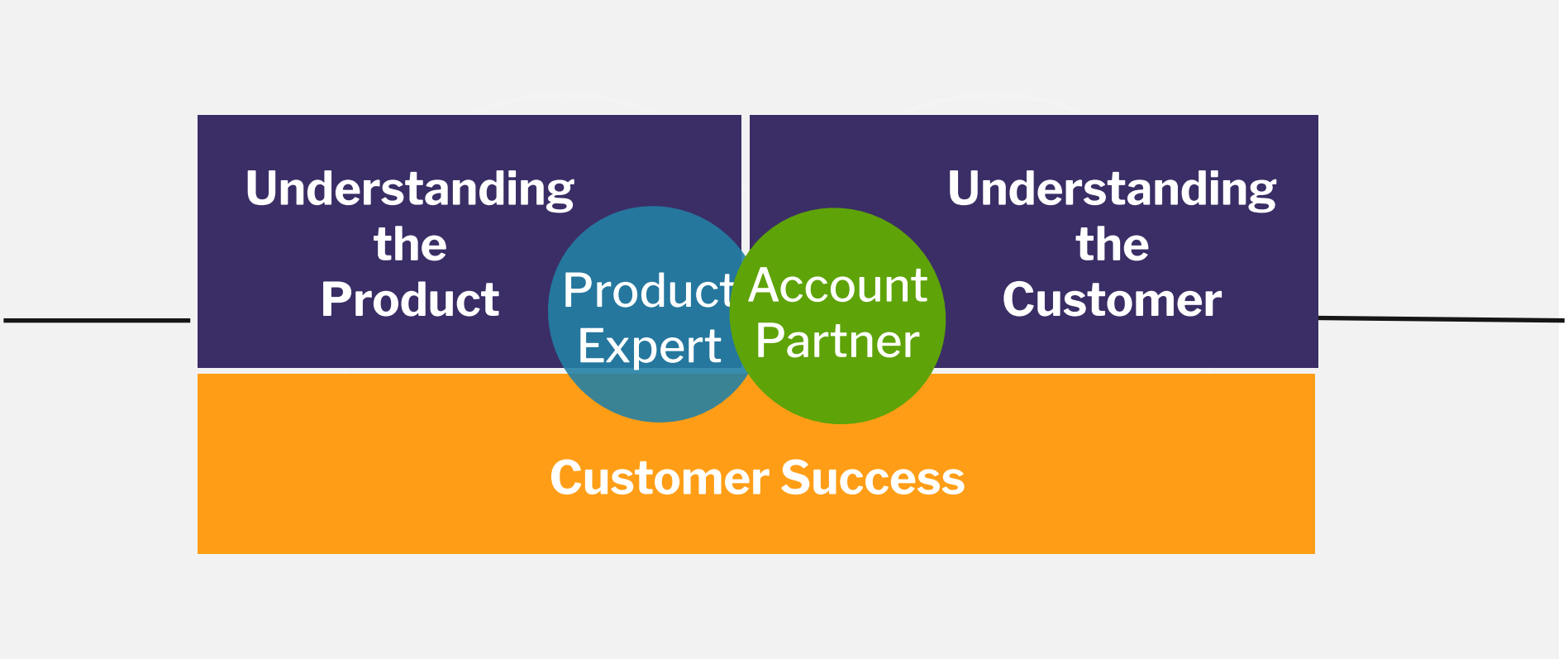
Customer Success Evolution

- 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

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

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

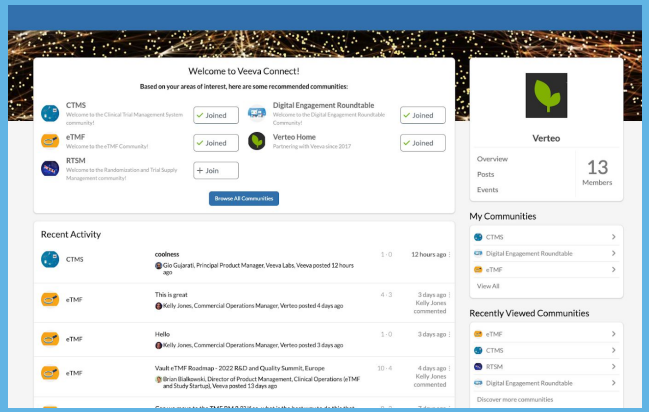
ENABLEMENT

- 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

Veeva

Questions

Thank you