# 23R1 Customer Webinar For All

March 23, 2023

Veeva

# CDMS Product Managers

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Local Labs

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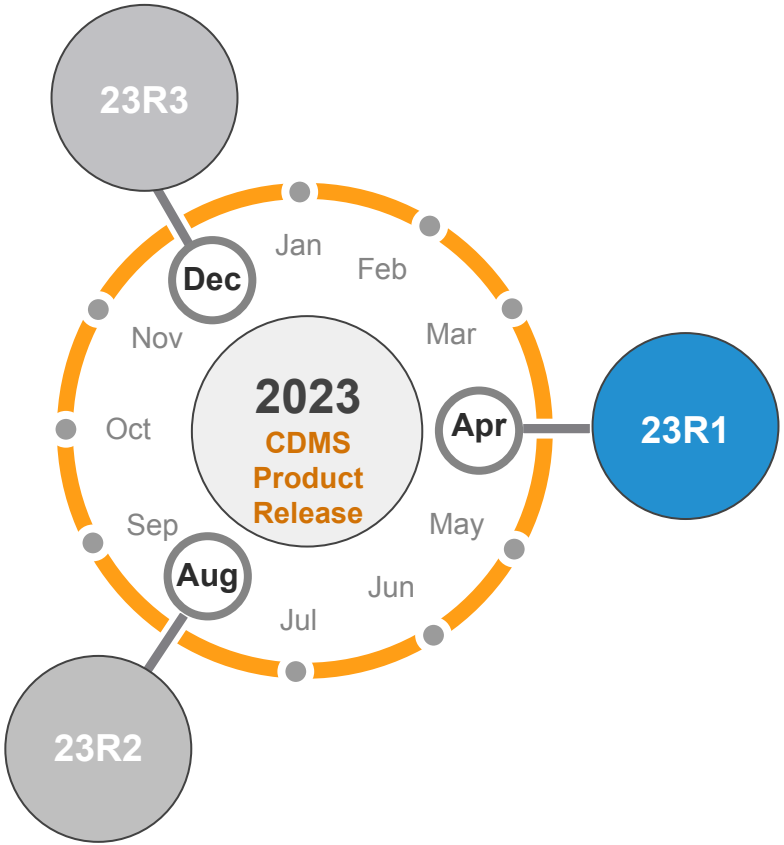
Product Expert

EDC

# Veeva Vault Release Schedule



# 23R1 Release Calendar

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

# Sites / CRAs / Data Managers

# Data Entry

# Form Submission Updates

## Submit Button

- Overview
  - The Complete button has been relabeled to be the Submit button
    - Functionally the button is the same
    - Users will click Submit when they're done entering data to submit the form
  - Messaging around autosave has also been updated
    - Data will still autosave after the user enters it and leaves the focus of the item

- Use case
  - Encourage users to submit the form
  - Make it clearer to site users when there are unsubmitted changes on the form

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites

**Configuration**

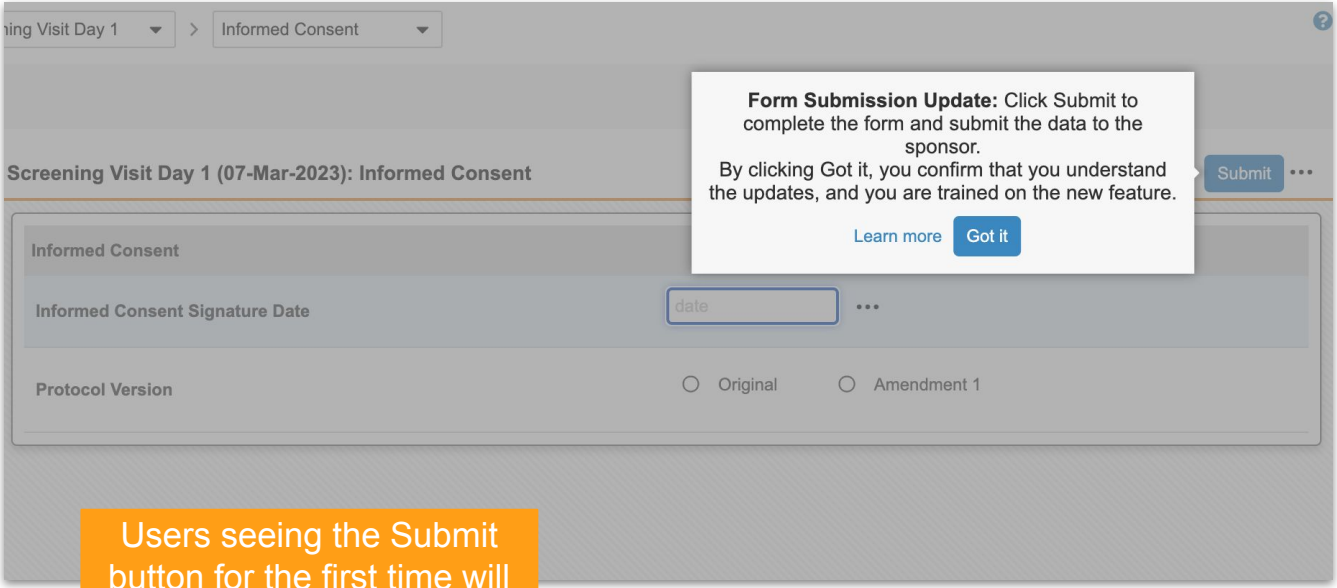
N/A

**Dependencies**

Available for all existing studies

# Form Submission Updates

## Submit Button




Users seeing the Submit button for the first time will be presented with a New Feature update, explaining the feature

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites

**Configuration**

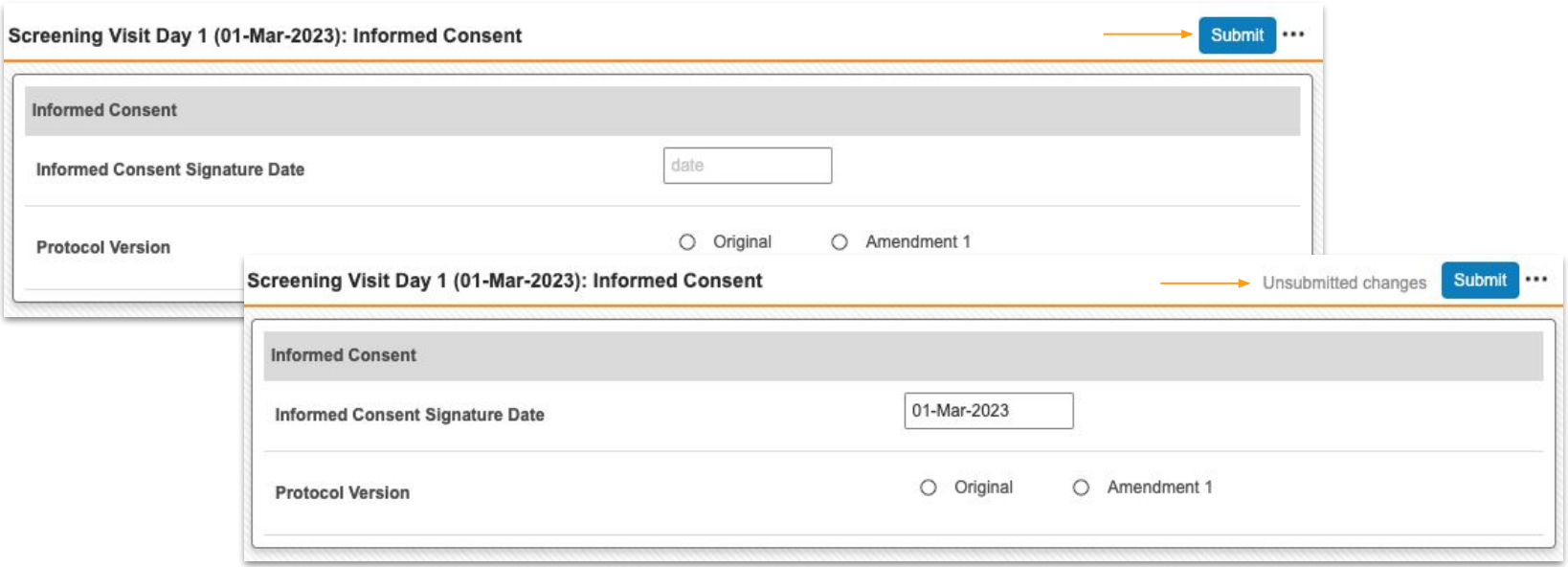
N/A

**Dependencies**

Available for all existing studies

# Form Submission Updates

## Submit Button




**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites

**Configuration**

N/A

**Dependencies**

Available for all existing studies

# Form Submission Updates

## Form Not Submitted Dialog

- Overview
  - When a user navigates away from an In Progress form, they will see a **Form Not Submitted** confirmation dialog
  - The user will have three options:
    1. Submit the form
    2. Continue editing the form
    3. Leave the form

- Use case
  - Encourage users to submit the form

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites

**Configuration**

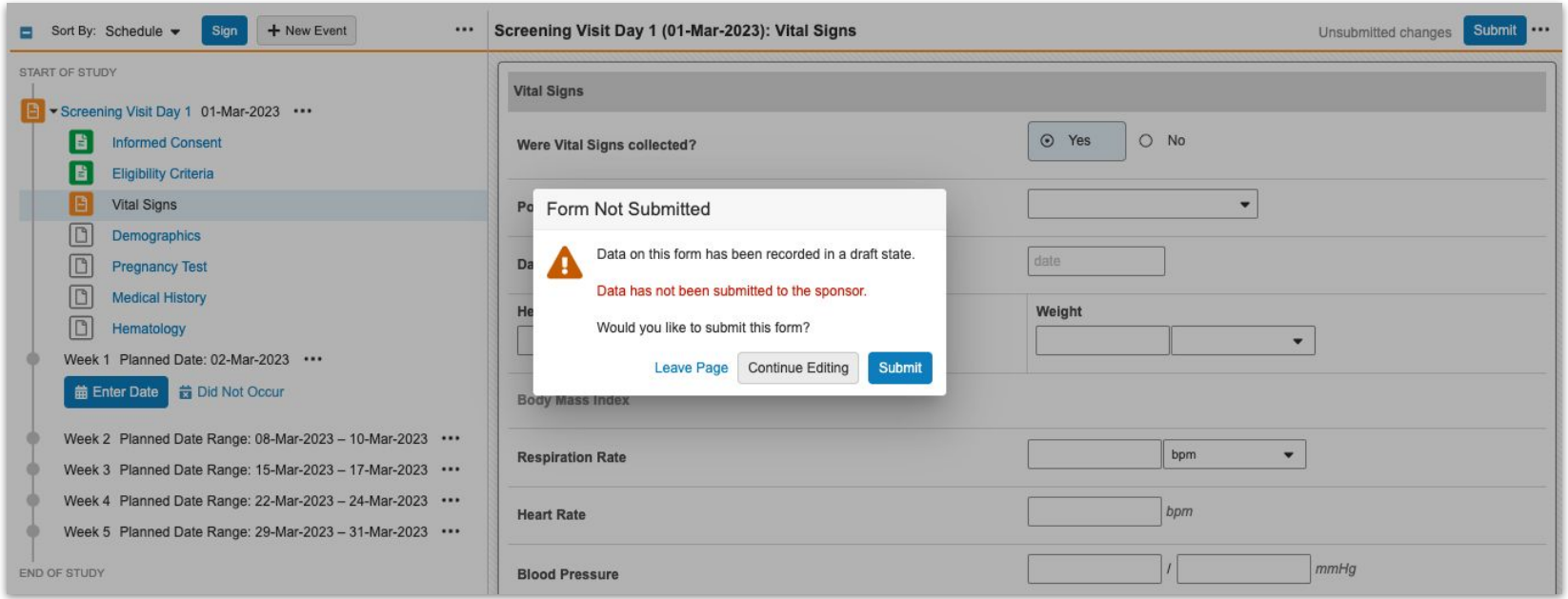
Support - Automatically enabled but can be disabled on request

**Dependencies**

**Available for all existing studies**

# Form Submission Updates

## Form Not Submitted Dialog




**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites

**Configuration**

Support - Automatically enabled but can be disabled on request

**Dependencies**

Available for all existing studies

# Site Closeout without Restricted Data

- Overview
  - When a site does not have any restricted forms, the Closeout PDFs will no longer be marked as restricted
  - Lead data managers will no longer need a custom role to generate non-restricted Closeout PDFs
  - Site users will be able to download & accept the Closeout PDFs without requiring the Restricted Data Access permission
  - Improved messaging about site closeout
- Use case
  - Allows site users to download and accept Closeout PDFs if their site does not have any restricted data

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites, Principal Investigator, Lead Data Manager

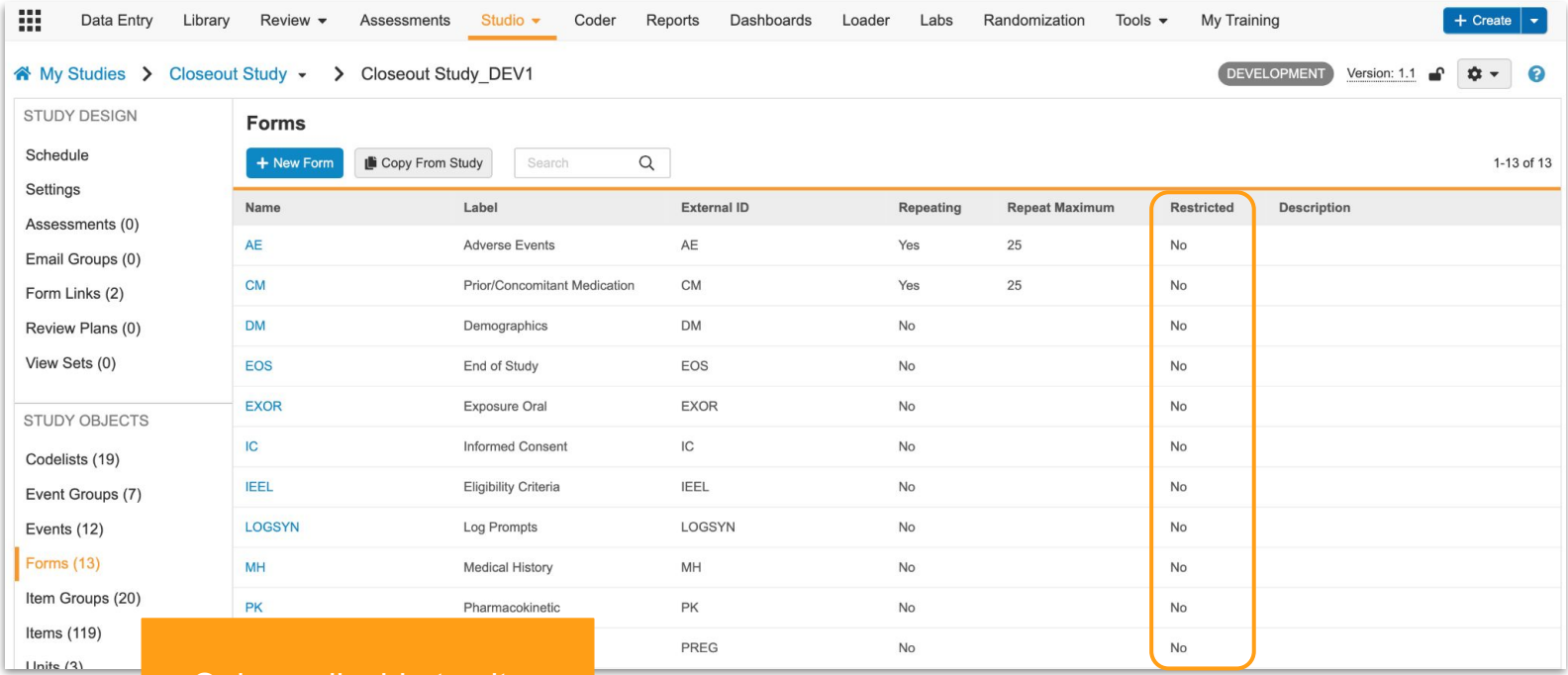
**Configuration**

N/A

**Dependencies**

**Only applicable for sites without restricted data**

# Site Closeout without Restricted Data




Only applicable to sites without restricted form definitions

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites, Principal Investigator, Lead Data Manager

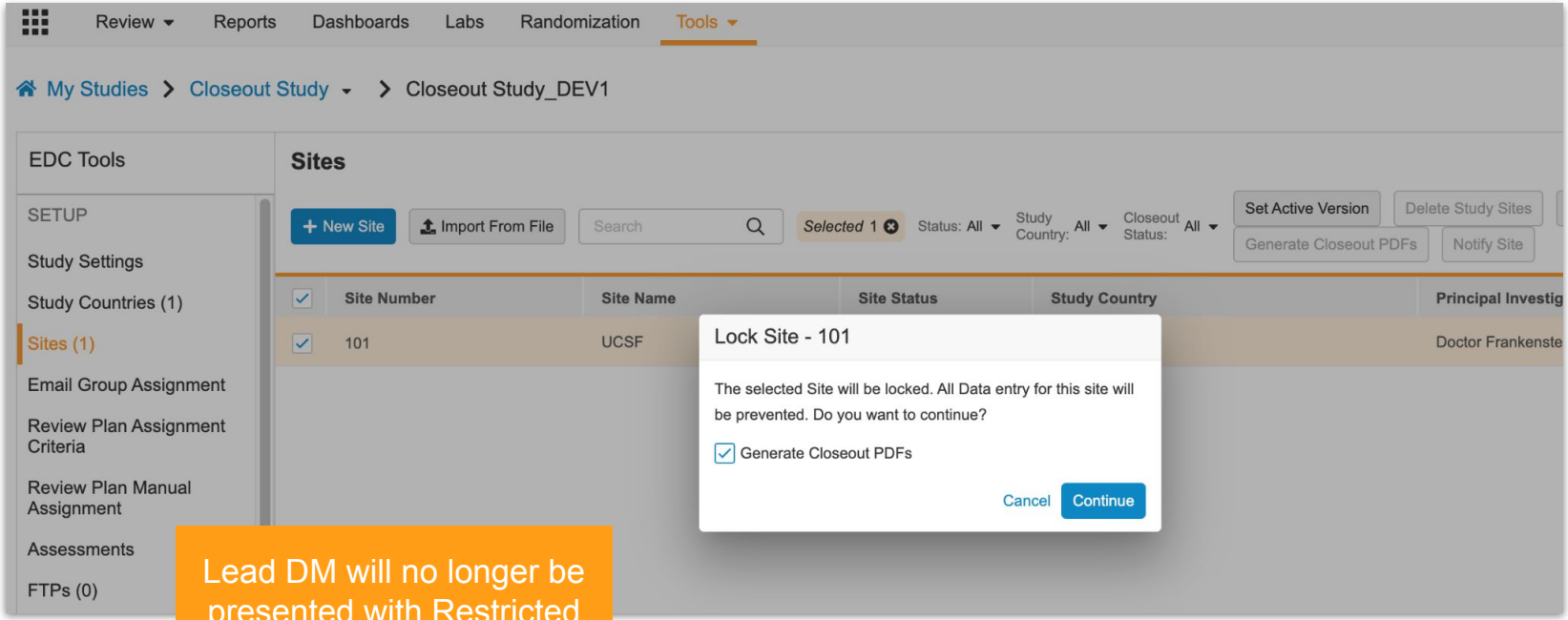
**Configuration**

N/A

**Dependencies**

Only applicable for sites without restricted data

# Site Closeout without Restricted Data




Lead DM will no longer be presented with Restricted Data warning when generating Closeout PDFs

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites, Principal Investigator, Lead Data Manager

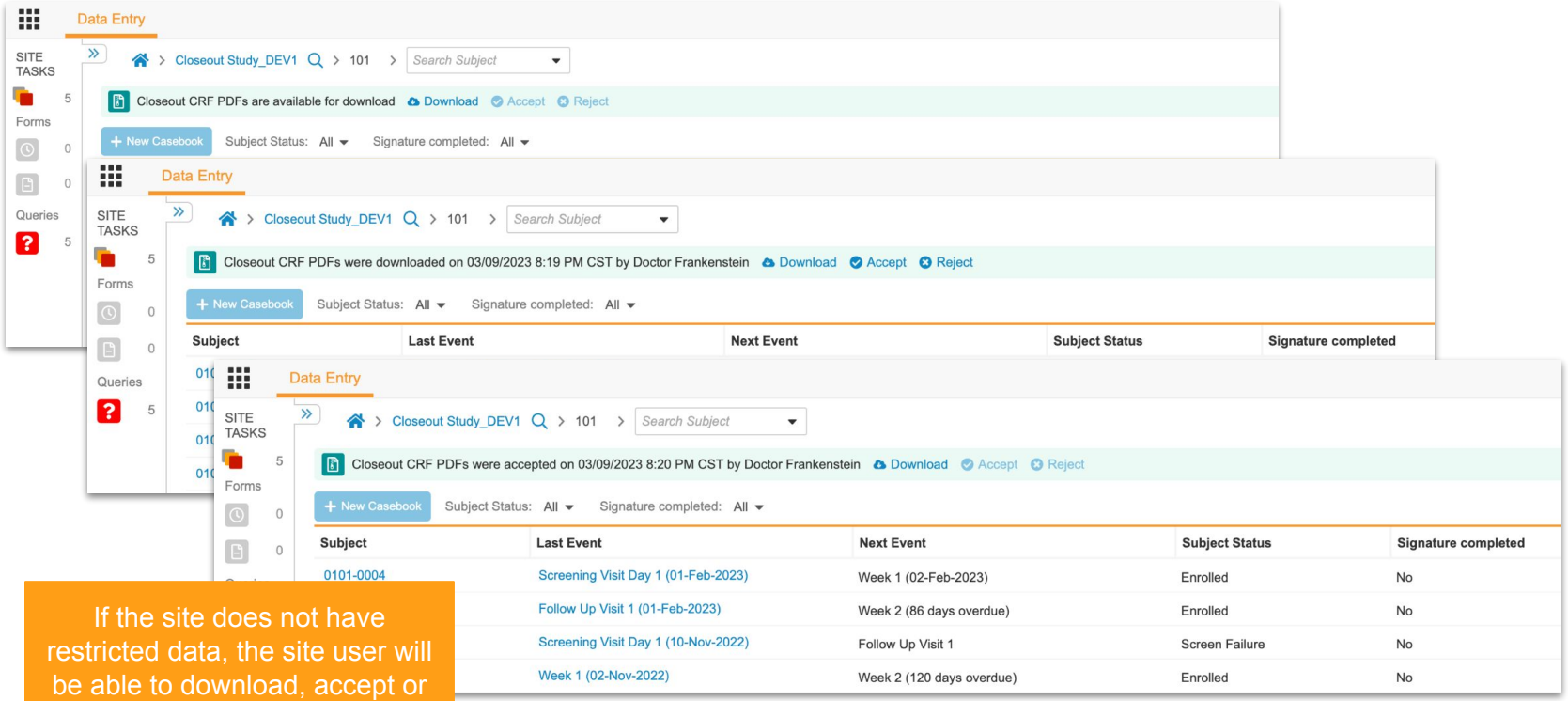
**Configuration**

N/A

**Dependencies**

**Only applicable for sites without restricted data**

# Site Closeout without Restricted Data




If the site does not have restricted data, the site user will be able to download, accept or reject the Closeout PDFs without restricted data access

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites, Principal Investigator, Lead Data Manager

**Configuration**

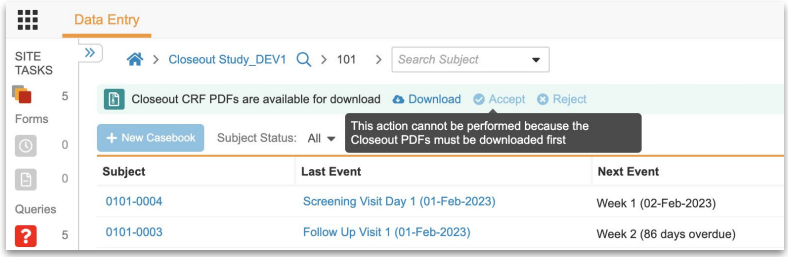
N/A

**Dependencies**

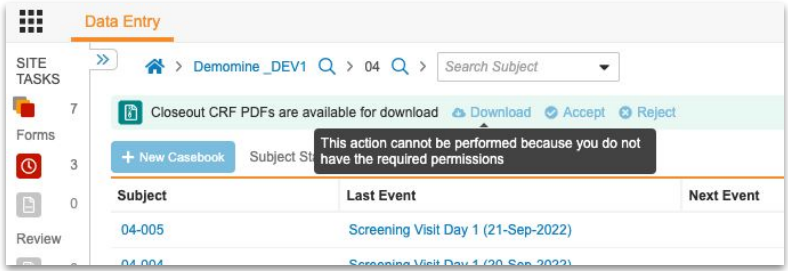
Only applicable for sites without restricted data

# Site Closeout - Updated Messaging

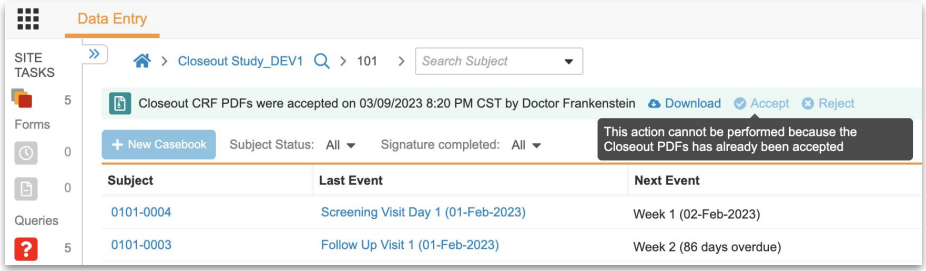
Inform users to first download the PDFs before accepting or rejecting the files




Inform users if they are missing the required permissions to download, accept or reject the files




Inform users if they are missing the required permissions to download, accept or reject the files




**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites, Principal Investigator, Lead Data Manager

**Configuration**

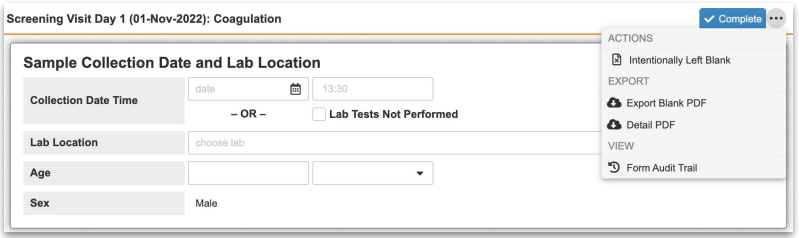
N/A

**Dependencies**

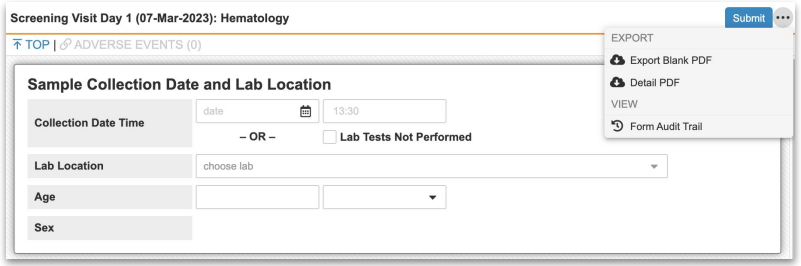
Available for all existing studies

# Lab Forms - ILB Update

- Overview
  - On Lab Forms, the form action “Intentionally Left Blank” has been removed
  - Site users should use the form option “Lab Tests Not Performed” instead
    - This is a lab specific ILB
    - The selected reason will still populate in the ILB reason in exports & reportings
- Use case
  - Removed redundant form options




22R3




23R1

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Sites

**Configuration**

N/A

**Dependencies**

Labs enabled

Available for all existing Lab studies

# 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, and re-sends can be problematic, depending on the other vendor
    - Event dates - through an integration - can be mistakenly update by CDMS site users
    - UAT of study can be problematic, as read only field might control 'next visit' (toggle in UAT, then before Prod deploy → build number dilemma)
  - **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

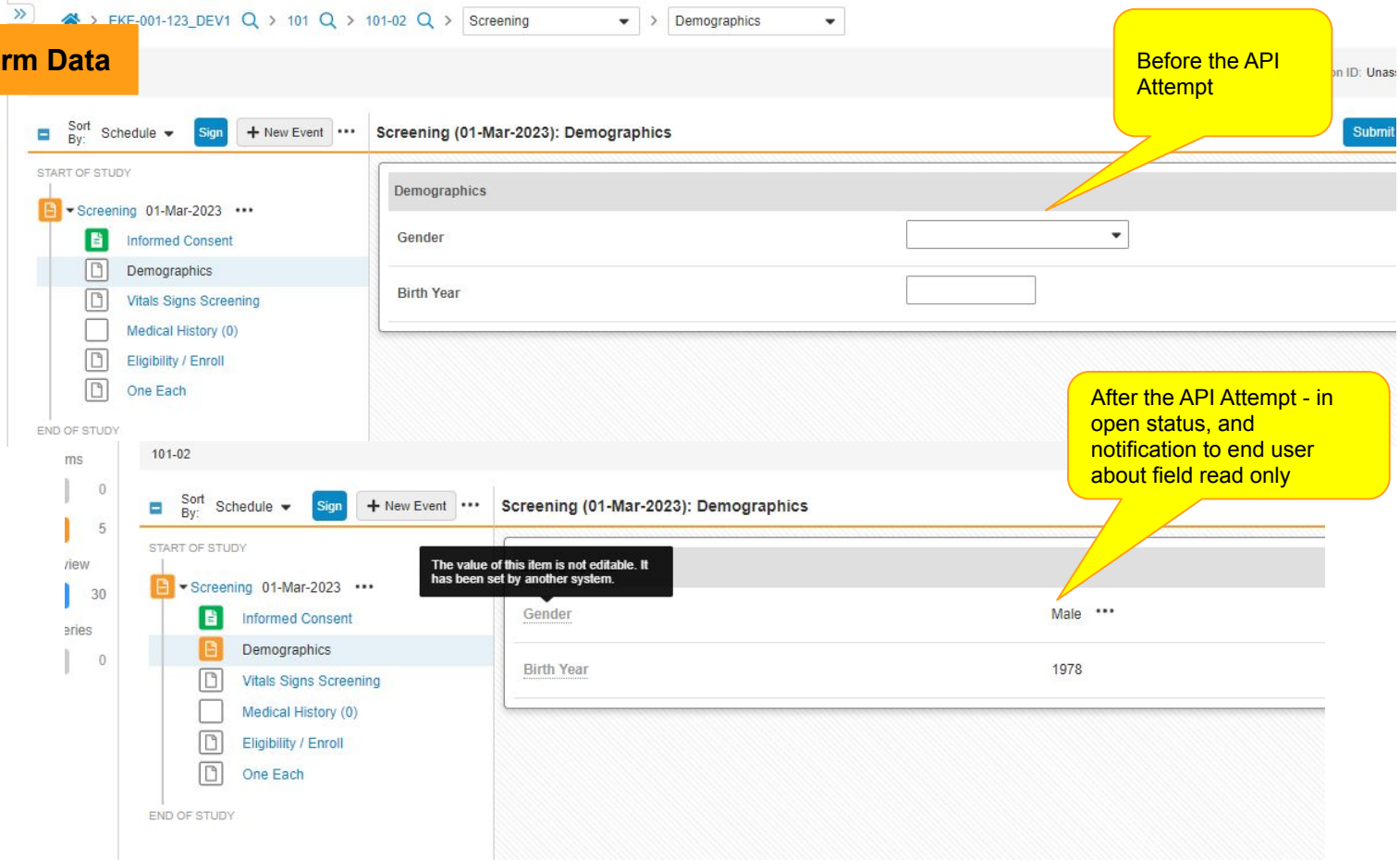
**Dependencies**

**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 *

# Review

# Query Teams & Multi-Role Security

- Overview
  - When a user with multiple roles opens a query, the system will now stamp the selected query team
  - This team will be reflected in the Query UI and in the query reports
- Use case
  - Improved query UI and reporting for multi-role security

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs

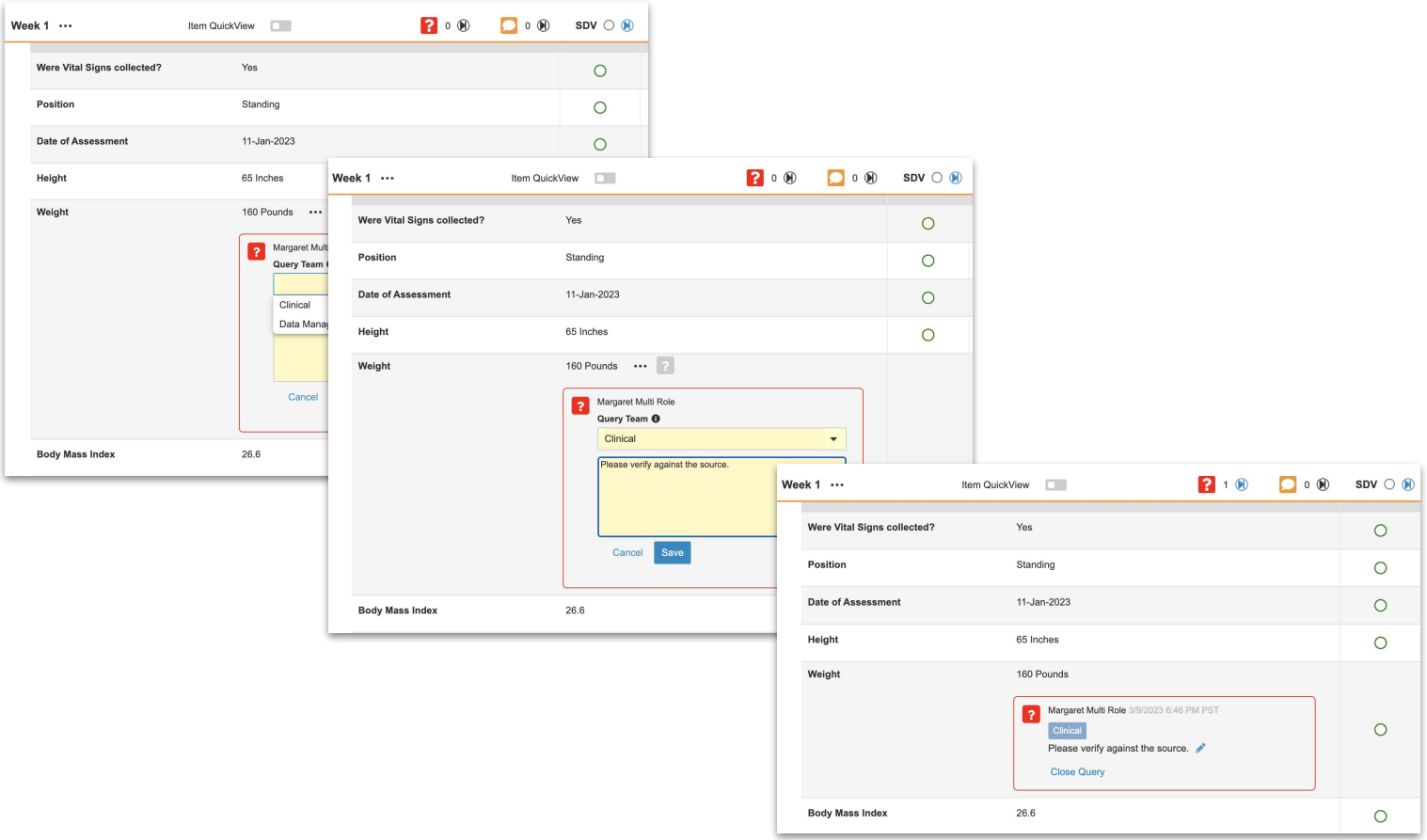
**Configuration**

N/A

**Dependencies**

Query Teams & Multi-Role Security enabled

# Query Teams & Multi-Role Security




**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs

**Configuration**

N/A

**Dependencies**

Query Teams & Multi-Role Security enabled

# Reports

# Study Progress Listing Updates

- Overview
  - Only applicable for priority studies using the Progress Listings in Reports
  - When the study's priority expires, the additional scheduled reports that are sending data to Vault Reports will also automatically expire

- Use case
  - Automatically expire additional jobs when study's priority expires

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

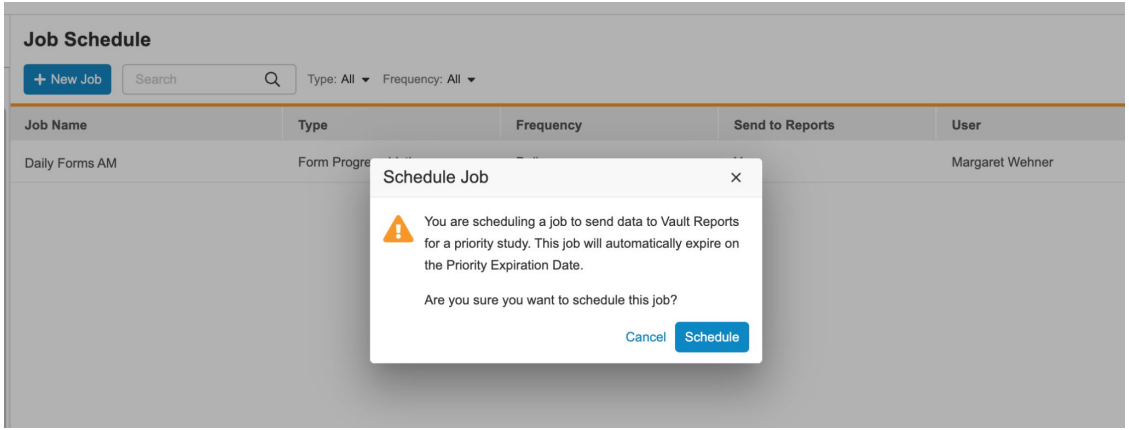
**Configuration**

N/A

**Dependencies**

**Progress Listings enabled in Reports**

# Study Progress Listing Updates




New warning when scheduling an additional “Send to Reports” jobs

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

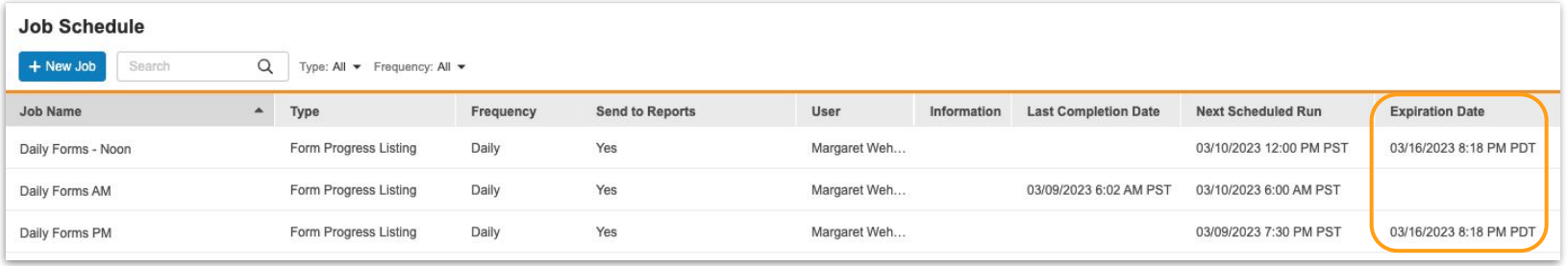
**Configuration**

N/A

**Dependencies**

Progress Listings enabled in Reports

# Study Progress Listing Updates




The job's expiration date will equal the study's priority expiration date

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

**Configuration**

N/A

**Dependencies**

Progress Listings enabled in Reports

# Study Progress Listing Updates

- Overview
  - New columns added to all progress listings
    - Applicable to EDC Tools, Review and Reports versions
  - The SDV and DMR % columns in the following listings will now round to the nearest integer
    - Form Progress Listing
    - Event Progress Listing
    - Study Summary Metrics Report

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

**Configuration**

N/A

**Dependencies**

Available for all existing studies

# Subject Progress Listing Updates

- New Columns
  - SDV Completion Date
    - Date when all forms where SDV is required was SDV Completed
  - DMR Completion
    - Date when all forms where DMR is required was DMR Completed

| D | E | F | G | H | I | J | K | L | M | N | O | P |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject | Subject Statu | Restricted Su | Most recent v | Date of most | Next Event | Entry Complete | SDV Plan | SDV Complete | Forms SDV Completion Date | DMR Plan | DMR Complete | Forms DMR Completion Date |
| 03-001 | Enrolled | No | Week 1 | 10/4/22 | Week 3 | No | Full SDV Plan | No | 10/3/22 17:30 | DMR | No | 1/12/23 1:38 |
| 03-002 | In Screening | No | Screening Vis | 10/1/22 | | No | | Yes | | DMR | No | |
| 03-003 | Enrolled | No | Screening Vis | 1/19/23 | Week 1 | No | Treatment SDV Plan | No | | DMR | No | |

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

**Configuration**

N/A

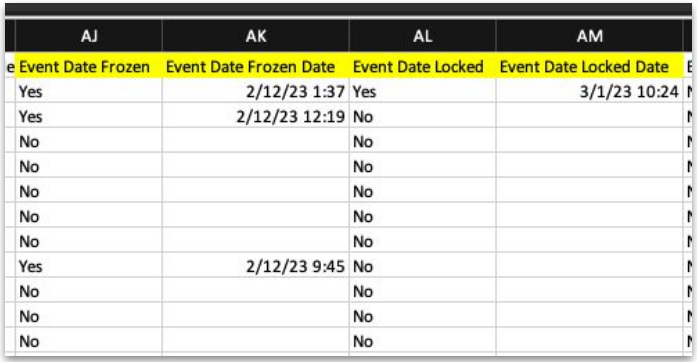
**Dependencies**

Review Rollup V2 only

Available for existing studies

# Event Progress Listing Updates

- New Columns
  - Event Date Frozen
    - Is the event date frozen?
  - Event Date Frozen Date
    - When the event date was frozen
  - Event Date Locked
    - Is the event date locked?
  - Event Date Locked Date
    - When the event date was frozen



| AJ | AK | AL | AM |
|---|---|---|---|
| Event Date Frozen | Event Date Frozen Date | Event Date Locked | Event Date Locked Date |
| Yes | 2/12/23 1:37 | Yes | 3/1/23 10:24 |
| Yes | 2/12/23 12:19 | No | |
| No | | No | |
| No | | No | |
| No | | No | |
| No | | No | |
| No | | No | |
| Yes | 2/12/23 9:45 | No | |
| No | | No | |
| No | | No | |
| No | | No | |

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

**Configuration**

N/A

**Dependencies**

Data Model 2 only

Available for existing studies

# Form Progress Listing Updates

- New Columns
  - Intentionally Left Blank
  - Intentionally Left Blank Reason

| J | K | L | M | N | O | P | Q |
|---|---|---|---|---|---|---|---|
| Form Label | Form Sequen | Form Status | Number of Su | Restricted Fo | Complete | Intentionally Left Blank | Intentionally Left Blank Reason |
| Informed Consent | 1 | Submitted | 1 | No | Yes | | |
| Eligibility Criteria | 1 | Submitted | 1 | No | Yes | | |
| Vital Signs | 1 | Submitted | 1 | No | Yes | | |
| Demographics | 1 | Submitted | 1 | No | Yes | | |
| Pregnancy Test | 1 | Submitted | 1 | No | Yes | | |
| Medical History | 1 | Submitted | 1 | No | Yes | Yes | Form not done |
| Log Prompts | 1 | Blank | 0 | No | No | | |
| Vital Signs | 1 | Blank | 0 | No | No | | |
| Restricted Data | 1 | Blank | 0 | No | No | | |
| Vital Signs | 1 | Submitted | 1 | No | Yes | | |
| Exposure Oral | 1 | Submitted | 1 | No | Yes | | |
| Pharmacokinetic | 1 | Submitted | 1 | No | Yes | | |
| Informed Consent | 1 | Submitted | 1 | No | Yes | | |
| Eligibility Criteria | 1 | Submitted | 1 | No | Yes | | |
| Vital Signs | 1 | Submitted | 1 | No | Yes | Yes | COVID 19 |
| Demographics | 1 | Submitted | 1 | No | Yes | | |
| Pregnancy Test | 1 | Submitted | 1 | No | Yes | Yes | Form not done |
| Medical History | 1 | Submitted | 1 | No | Yes | | |
| Informed Consent | 1 | Submitted | 1 | No | Yes | | |
| Eligibility Criteria | 1 | Blank | 0 | No | No | | |
| Vital Signs | 1 | Blank | 0 | No | No | | |
| Demographics | 1 | Blank | 0 | No | No | | |
| Pregnancy Test | 1 | Blank | 0 | No | No | | |
| Medical History | 1 | Blank | 0 | No | No | | |

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

**Configuration**

N/A

**Dependencies**

Available for all existing studies

# Query Detail Listing Updates

- New Columns
  - Form Status
  - Number of Query Messages

| L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Form Status | Item Group L | Item Group S | Item OID | Item Label | Query ID | Query Status | Query Team | Days Unresol | Manual Quer | Query Rule | Original Que | Latest Query | Latest Query | Number of Query Messages |
| Submitted | Informed Cor | 1 | RFICDAT | Informed Cor | VV-001123 | Open | Data Manage | 174.13 | No | R_QUERY_RF | A value is req | A value is required for this | | 1 |
| Submitted | Vital Signs | 1 | WEIGHT | Weight | VV-001124 | Closed | Data Manage | 0.1 | No | R_QUERY_WI | Value is out of range | | | 2 |
| Submitted | Vital Signs | 1 | SYSBP | Systolic Bloo | VV-001125 | Open | Data Manage | 174.01 | No | R_QUERY_SY | A value is req | A value is required for this | | 1 |
| Submitted | Vital Signs | 1 | DIASBP | Diastolic Bloo | VV-001126 | Open | Data Manage | 174.01 | No | R_QUERY_DI | A value is req | A value is required for this | | 1 |
| Submitted | Pregnancy Te | 1 | PREGRSLT | Result | VV-001127 | Open | Data Manage | 174.01 | No | PREG_001 | Result must r | Confirmed | | 2 |
| Submitted | Adverse Even | 1 | AESTDAT | Start Date | VV-001139 | Closed | Data Manage | 56.24 | No | AE_001 | Start Date mu | Ok, closing q | Event occurri | 3 |
| | | | | | VV-001140 | Closed | | 0 | Yes | | This looks incorrect. Please clarify. | | | 2 |
| | | | | | VV-001141 | Closed | | 0 | Yes | | Please clarify | | This is correc | 3 |
| In Progress Post Submit | Vital Signs | 1 | VSPERF | Were Vital Si | VV-001154 | Closed | Data Manage | 0 | No | R_QUERY_VS | A value is required for this item. | | | 2 |
| In Progress Post Submit | Vital Signs | 1 | VSPOS | Position | VV-001155 | Open | Data Manage | 160.3 | No | R_QUERY_VS | A value is req | correct | | 2 |
| In Progress Post Submit | Vital Signs | 1 | HR | Heart Rate | VV-001156 | Closed | Data Manage | 0 | No | R_QUERY_HR | A value is required for this item. | | | 2 |
| In Progress Post Submit | Vital Signs | 1 | WEIGHT | Weight | VV-001157 | Open | Data Manage | 160.3 | No | R_QUERY_WI | Value is out c | comment | | 2 |
| In Progress Post Submit | Vital Signs | 1 | DIASBP | Diastolic Bloo | VV-001158 | Open | Data Manage | 160.3 | No | R_QUERY_DI | A value is req | A value is required for this | | 1 |
| In Progress Post Submit | Vital Signs | 1 | BMI | Body Mass In | VV-001159 | Open | Data Manage | 160.3 | No | R_QUERY_BM | A value is req | A value is required for this | | 1 |
| In Progress Post Submit | Vital Signs | 1 | VSDAT | Date of Asses | VV-001160 | Open | Data Manage | 160.3 | No | R_QUERY_VS | A value is req | A value is required for this | | 1 |
| In Progress Post Submit | Vital Signs | 1 | HEIGHT | Height | VV-001161 | Open | Data Manage | 160.3 | No | R_QUERY_HE | A value is req | A value is required for this | | 1 |
| In Progress Post Submit | Vital Signs | 1 | SYSBP | Systolic Bloo | VV-001162 | Open | Data Manage | 160.3 | No | R_QUERY_SY | A value is req | A value is required for this | | 1 |
| Submitted | Adverse Even | 1 | AESER | Serious? | VV-001163 | Open | Data Manage | 137.16 | No | AE_02 | Adverse Even | Adverse Event is Serious, h | | 1 |

**Day 1 Impact to Clinical Teams**

No

**Visibility**

CRAs, DMs, LDMs

**Configuration**

N/A

**Dependencies**

Available for all existing studies

# Assessments

# Assessment Enhancements

- Overview
  - Added the audit trails for assessments and assessment responses to the UI and assessment PDFs
  - Added the audit trail for the supplemental data to the assessment PDFs
  - Improved the audit trail export to include the full audit trail for assessments and assessment responses

**Day 1 Impact to Clinical Teams**

Yes

**Visibility**

Assessment Editor, Assessment Reader

**Configuration**

None

**Dependencies**

**N/A**

# Local Labs

# Lab Modifier Support for Number Data Type

- Overview
  - In 22R3, we released the Lab Modifier for Unit Data Type, and this release (23R1) we support the number data type
- Use case
  - Support lab results with numbers that are >, >=, <=, or < (eg. >1)

**Analyte Library**

Edit Analytes | Import Analytes | Search Analytes... | Created By: All | Modified By: All | In Use: All

| Analyte | Label | Data Type | Measurement Type | Codelist | Lab Modifier |
|---|---|---|---|---|---|
| Monocytes_Absolute | Monocytes Absolute | Unit | Absolute | | |
| Monocytes_Percent | Monocytes % | Unit | Percent | | |
| pH | pH | Number | | | ✓ |

**Day 1 Impact to Clinical Teams**

No

**Visibility**

Lab Manager, Data Manager, Lead Data Manager, Study Designer

**Configuration**

Yes

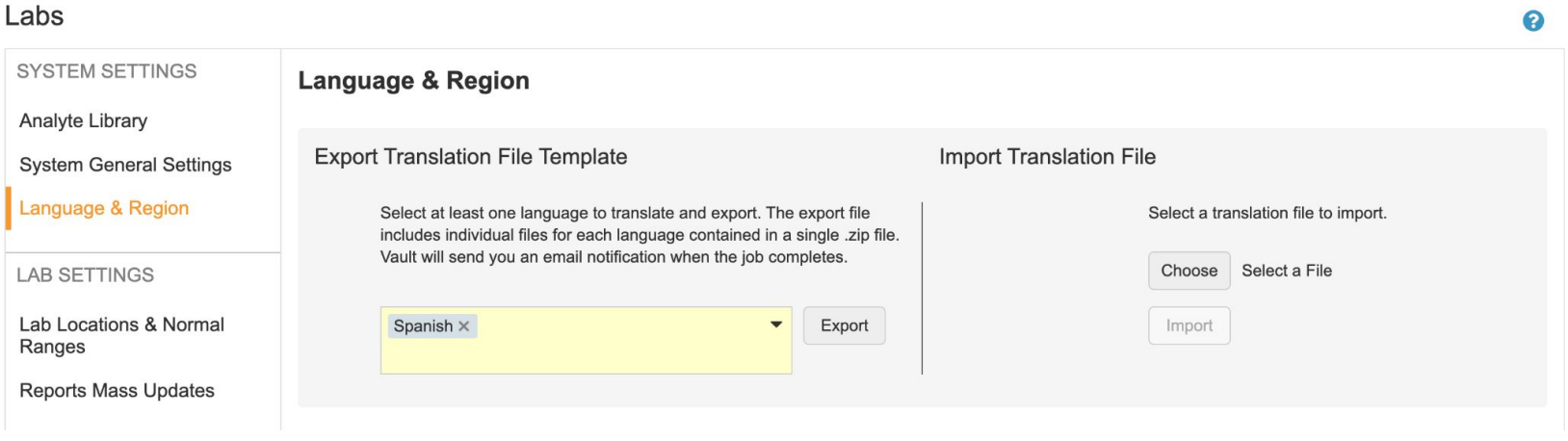
**Dependencies**

**Available for existing Global Lab studies**

# Lab Translations for Analytes, Units, and Codelists

- Overview
  - Support of additional languages for Analytes, Units, and Codelists, in the Lab Module
- Use case
  - Studies have Sites throughout the world want to see Analytes/Units/Codelists other than English

**Analyte Translations in EDC Data Entry are only inherited when adding a new lab panel, any subsequent translations after lab panel creation will have to be done manually through Studio.*




**Day 1 Impact to Clinical Teams**

No

**Visibility**

Lab Manager, Data Manager, Lead Data Manager, Study Designer

**Configuration**

Yes

**Dependencies**

**Available for all existing Lab studies**

# Evolving Customer Success

Veeva

# Customer Success Update

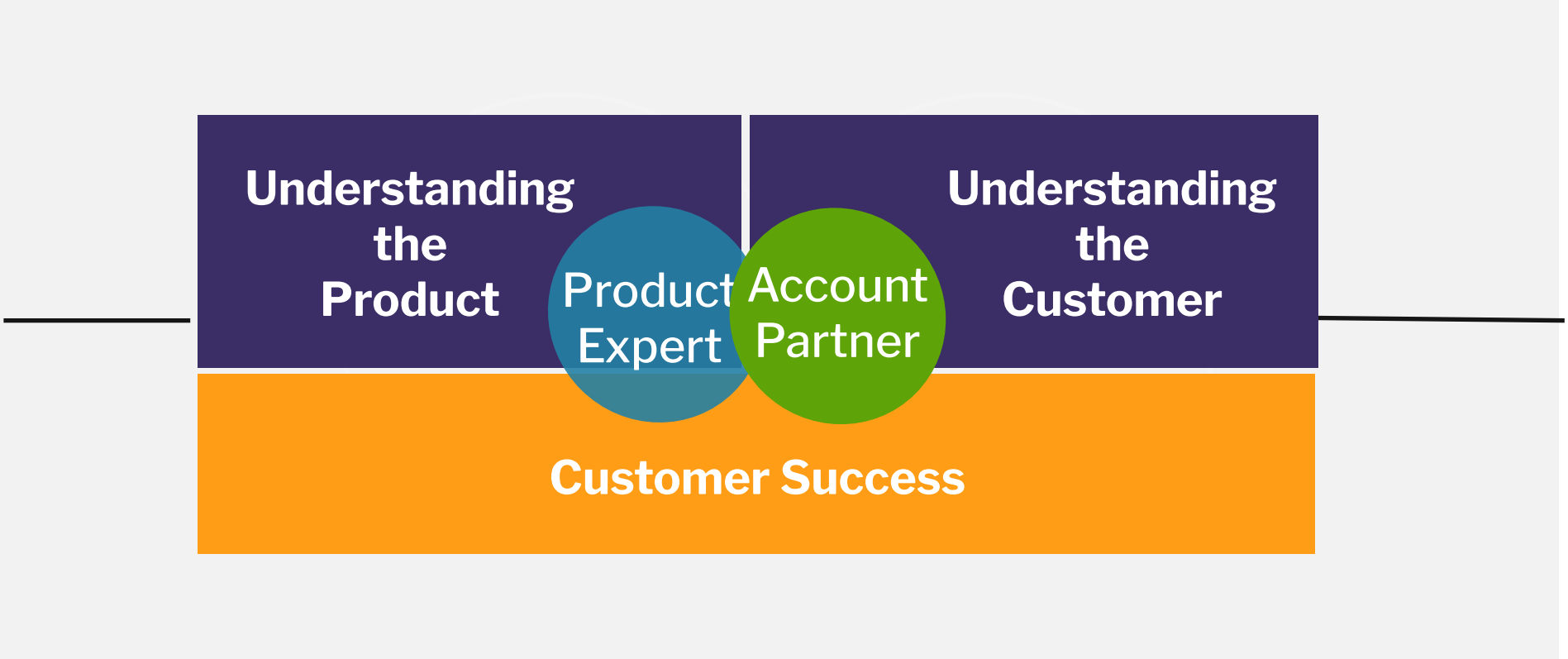
## Customer Success Evolution

- 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

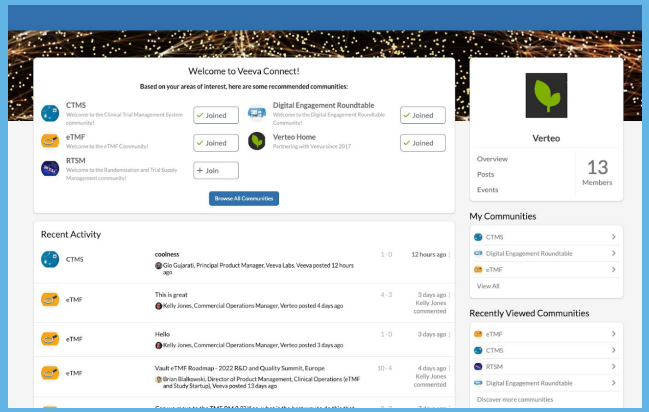
## ENABLEMENT

- 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