

23R1 Customer Webinar For All

March 23, 2023



CDMS Product Managers

Margaret Wehner

Product Manager
Data Entry, Review
UI, Reports



Sharon Lin

Director,
Product
Management
Local Labs



John Roeckel (JB)

Product Manager
Data Entry, Query
Handling, Medical
Assessments

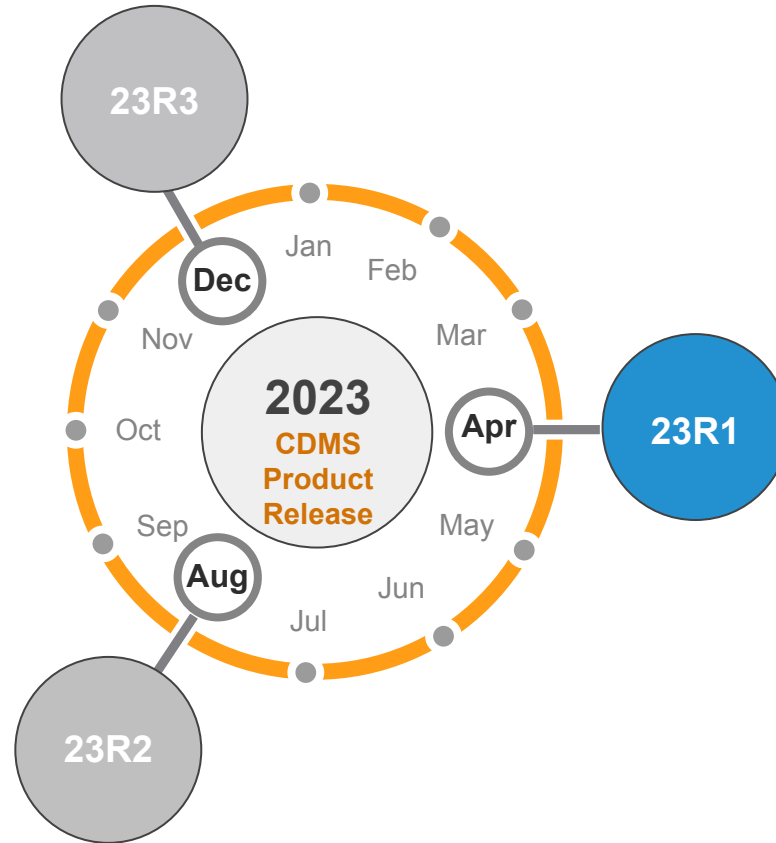


Kathy Tibaldi

Product Expert
EDC



Veeva Vault Release Schedule



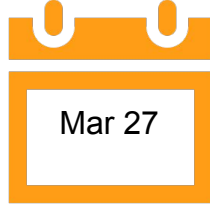
23R1 Release Calendar

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 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

The screenshot shows a web interface for a clinical trial form. At the top, there are two dropdown menus: 'Screening Visit Day 1' and 'Informed Consent'. Below them, the title 'Screening Visit Day 1 (07-Mar-2023): Informed Consent' is displayed. The form contains several fields: 'Informed Consent' (text input), 'Informed Consent Signature Date' (date input), and 'Protocol Version' (radio buttons for 'Original' and 'Amendment 1'). A blue 'Submit' button is located on the right side of the form. A white tooltip box is overlaid on the form, containing the text: 'Form Submission Update: Click Submit to complete the form and submit the data to the sponsor. By clicking Got it, you confirm that you understand the updates, and you are trained on the new feature.' The tooltip also includes a 'Learn more' link and a blue 'Got it' 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

The image displays two screenshots of a web form titled "Screening Visit Day 1 (01-Mar-2023): Informed Consent".

The top screenshot shows the form in its initial state. It features a "Submit" button in the top right corner. The form contains three main sections: "Informed Consent" (a grey header), "Informed Consent Signature Date" (a text input field containing the placeholder "date"), and "Protocol Version" (radio buttons for "Original" and "Amendment 1").

The bottom screenshot shows the form after an update. The "Submit" button has been replaced by "Unsubmitted changes" and a new "Submit" button. The "Informed Consent Signature Date" field now contains the value "01-Mar-2023". The "Protocol Version" section remains the same.



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

The screenshot displays a clinical trial form titled "Screening Visit Day 1 (01-Mar-2023): Vital Signs". The interface includes a sidebar with a list of form sections: Informed Consent, Eligibility Criteria, Vital Signs (highlighted), Demographics, Pregnancy Test, Medical History, and Hematology. The main form area contains fields for "Were Vital Signs collected?" (Yes/No), "Date", "Weight", "Body Mass Index", "Respiration Rate", "Heart Rate", and "Blood Pressure". A modal dialog box titled "Form Not Submitted" is overlaid on the form, containing the following text: "Data on this form has been recorded in a draft state. Data has not been submitted to the sponsor. Would you like to submit this form?". The dialog box has three buttons: "Leave Page", "Continue Editing", and "Submit".

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

Day 1
Impact to
Clinical Teams

Yes

The screenshot shows the Veeva Studio interface for a study named 'Closeout Study_DEV1'. The 'Forms' table is displayed, listing various forms used in the study. The 'Restricted' column is highlighted with an orange box, and all entries in this column are 'No'. The table includes columns for Name, Label, External ID, Repeating, Repeat Maximum, Restricted, and Description.

Name	Label	External ID	Repeating	Repeat Maximum	Restricted	Description
AE	Adverse Events	AE	Yes	25	No	
CM	Prior/Concomitant Medication	CM	Yes	25	No	
DM	Demographics	DM	No		No	
EOS	End of Study	EOS	No		No	
EXOR	Exposure Oral	EXOR	No		No	
IC	Informed Consent	IC	No		No	
IEEL	Eligibility Criteria	IEEL	No		No	
LOGSYN	Log Prompts	LOGSYN	No		No	
MH	Medical History	MH	No		No	
PK	Pharmacokinetic	PK	No		No	
		PREG	No		No	

Only applicable to sites
without restricted form
definitions

Visibility

Sites, Principal
Investigator,
Lead Data
Manager

Configuration

N/A

Dependencies

Only
applicable for
sites without
restricted data



Site Closeout without Restricted Data

Day 1
Impact to
Clinical Teams

Yes

The screenshot shows the 'Tools' section of the Veeva EDC interface. A modal dialog titled 'Lock Site - 101' is open, displaying the following text: 'The selected Site will be locked. All Data entry for this site will be prevented. Do you want to continue?' Below the text is a checkbox labeled 'Generate Closeout PDFs' which is checked. At the bottom of the dialog are 'Cancel' and 'Continue' buttons. In the background, a table lists sites with columns: Site Number, Site Name, Site Status, Study Country, and Principal Investigator. The first row shows site 101 at UCSF, with Principal Investigator Doctor Frankenstein.

Site Number	Site Name	Site Status	Study Country	Principal Investigator
101	UCSF			Doctor Frankenstein

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

Visibility

Sites, Principal Investigator, Lead Data Manager

Configuration

N/A

Dependencies

Only applicable for sites without restricted data



Site Closeout without 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

The screenshots show the 'Data Entry' interface for 'Closeout Study_DEV1'. The top screenshot shows a notification: 'Closeout CRF PDFs are available for download' with 'Download', 'Accept', and 'Reject' buttons. The middle screenshot shows a notification: 'Closeout CRF PDFs were downloaded on 03/09/2023 8:19 PM CST by Doctor Frankenstein' with 'Download', 'Accept', and 'Reject' buttons. The bottom screenshot shows a table with the following data:

Subject	Last Event	Next Event	Subject Status	Signature completed
0101-0004	Screening Visit Day 1 (01-Feb-2023)	Week 1 (02-Feb-2023)	Enrolled	No
	Follow Up Visit 1 (01-Feb-2023)	Week 2 (86 days overdue)	Enrolled	No
	Screening Visit Day 1 (10-Nov-2022)	Follow Up Visit 1	Screen Failure	No
	Week 1 (02-Nov-2022)	Week 2 (120 days overdue)	Enrolled	No

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



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

Closeout CRF PDFs are available for download

This action cannot be performed because the Closeout PDFs must be downloaded first

Subject	Last Event	Next Event
0101-0004	Screening Visit Day 1 (01-Feb-2023)	Week 1 (02-Feb-2023)
0101-0003	Follow Up Visit 1 (01-Feb-2023)	Week 2 (86 days overdue)

Closeout CRF PDFs are available for download

This action cannot be performed because you do not have the required permissions

Subject	Last Event	Next Event
04-005	Screening Visit Day 1 (21-Sep-2022)	
04-004	Screening Visit Day 1 (20-Sep-2022)	

Closeout CRF PDFs were accepted on 03/09/2023 8:20 PM CST by Doctor Frankenstein

This action cannot be performed because the Closeout PDFs has already been accepted

Subject	Last Event	Next Event
0101-0004	Screening Visit Day 1 (01-Feb-2023)	Week 1 (02-Feb-2023)
0101-0003	Follow Up Visit 1 (01-Feb-2023)	Week 2 (86 days overdue)

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

Day 1
Impact to
Clinical Teams

Yes

Visibility
Sites

Configuration

N/A

Dependencies

Labs enabled

Available for all
existing Lab
studies

Screening Visit Day 1 (01-Nov-2022): Coagulation

Sample Collection Date and Lab Location

Collection Date Time: date 13:30

Lab Location: choose lab

Age: [input] [dropdown]

Sex: Male

ACTIONS

- Intentionally Left Blank

EXPORT

- Export Blank PDF
- Detail PDF

VIEW

- Form Audit Trail

Complete

22R3

Screening Visit Day 1 (07-Mar-2023): Hematology

Sample Collection Date and Lab Location

Collection Date Time: date 13:30

Lab Location: choose lab

Age: [input] [dropdown]

Sex: [input]

EXPORT

- Export Blank PDF
- Detail PDF

VIEW

- Form Audit Trail

Submit

23R1



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 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 surrounded by a grey border. A black tooltip above the field reads 'The value of this item is not editable. It has been set by another system.' A yellow callout bubble points to the Gender field with the text 'After the API Attempt - in open status, and notification to end user about field read only'. The Birth Year field contains the value '1978'. The interface includes a left sidebar with a study event tree, a top navigation bar with filters, and a bottom status bar.

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

CRA's, DM's

Configuration

N/A

Dependencies

Query Teams
& Multi-Role
Security
enabled



Query Teams & Multi-Role Security

The screenshots illustrate the process of configuring a query team for multi-role security. The interface shows a data table with fields like 'Were Vital Signs collected?', 'Position', 'Date of Assessment', 'Height', and 'Weight'. A 'Body Mass Index' field is also present at the bottom. A 'Query Team' dialog box is shown, allowing selection of a role (e.g., 'Clinical') and providing instructions to verify against the source. The final state shows the query team configuration applied to the data table.

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

CRA's, DM's,
LDM's

Configuration

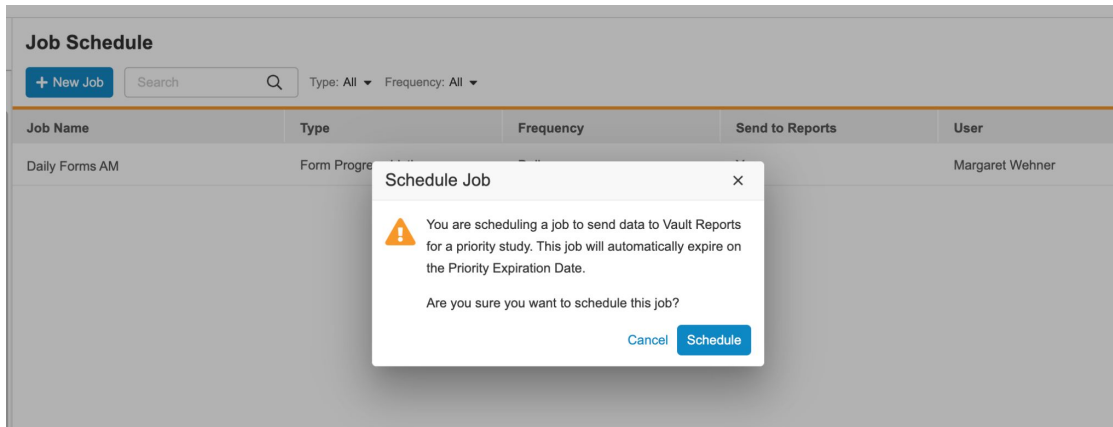
N/A

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

Day 1
Impact to
Clinical Teams

No

Job Schedule

[+ New Job](#) Type: All Frequency: All

Job Name	Type	Frequency	Send to Reports	User	Information	Last Completion Date	Next Scheduled Run	Expiration Date
Daily Forms - Noon	Form Progress Listing	Daily	Yes	Margaret Weh...			03/10/2023 12:00 PM PST	03/16/2023 8:18 PM PDT
Daily Forms AM	Form Progress Listing	Daily	Yes	Margaret Weh...		03/09/2023 6:02 AM PST	03/10/2023 6:00 AM PST	
Daily Forms PM	Form Progress Listing	Daily	Yes	Margaret Weh...			03/09/2023 7:30 PM PST	03/16/2023 8:18 PM PDT

Visibility
CRAs, DMs,
LDMs

Configuration
N/A

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

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 Status	Restricted Subject	Most recent Visit	Date of most recent Visit	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 Visit	10/1/22		No		Yes		DMR	No	
03-003	Enrolled	No	Screening Visit	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	
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 Si	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 Quei	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 rec	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 rec	A value is required for this		1	
Submitted	Vital Signs	1	DIASBP	Diastolic Bloc	VV-001126	Open	Data Manage	174.01	No	R_QUERY_DI	A value is rec	A value is required for this		1	
Submitted	Pregnancy Te	1	PREGSLT	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 incorrec	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 rec	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 Bloc	VV-001158	Open	Data Manage	160.3	No	R_QUERY_DI	A value is rec	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_BN	A value is rec	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 rec	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 rec	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 rec	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](#) 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.*

Labs

SYSTEM SETTINGS

- Analyte Library
- System General Settings
- Language & Region**

LAB SETTINGS

- Lab Locations & Normal Ranges
- Reports Mass Updates

Language & Region

Export Translation File Template

Select at least one language to translate and export. The export file includes individual files for each language contained in a single .zip file. Vault will send you an email notification when the job completes.

Spanish ×

Import Translation File

Select a translation file to import.

Select a File

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

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 interface. The job is named 'Study Data Extract' and is set to 'Version 22R3'. The 'Restricted Data Options' section has 'Include Restricted Data' unchecked. The 'Clinical Data Options' section has 'Use Item External ID instead of Item Name for column headers', 'Include separate Date and Time columns for Datetime Items', 'Include forms intentionally left blank', and 'Exclude blank forms' all unchecked. The 'Data to Export' section has 'Export all System Datasets' and 'Export all Clinical Datasets' checked, and 'Include Custom Objects' unchecked. The 'Export Options' section has 'Include Study Design' checked. The 'Zip File Name' field is empty with a '.zip' extension. The right-hand side shows 'Frequency' set to 'Weekly', 'Name' set to 'Scheduled SDE', 'Run at' set to '1:00 AM', 'Repeat on' set to 'S M T W T F S', and 'Active Periods' set to '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

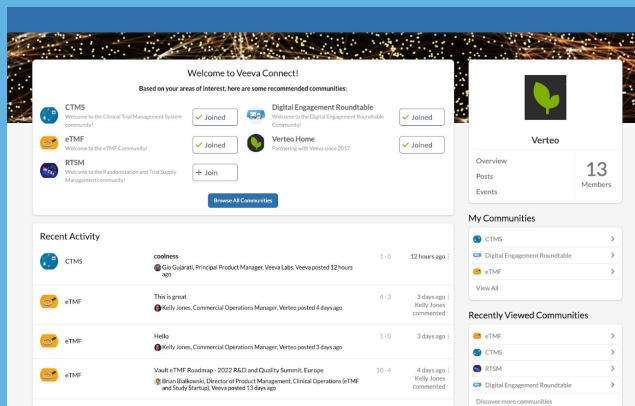


Vision: Create an enjoyable and efficient **community for life sciences** by bringing customers closer together with Veeva through *simple* and *authentic communication*





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