

22R1 Customer Webinar For All

March 24, 2022



CDMS Product Managers

Margaret Wehner

Product Manager

Data Entry, Review
UI, Clinical
Assessments,
Reports



Quentin Paresys

Sr. Product
Manager

Rules



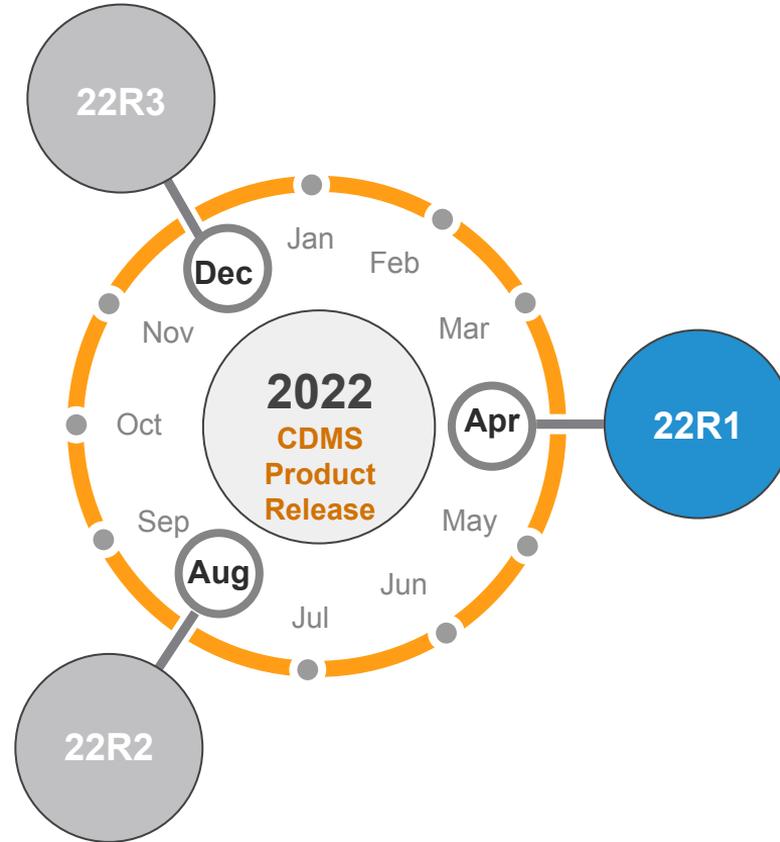
Sharon Lin

Principal
Product
Manager

Local Labs,
Randomization



Veeva Vault Release Schedule



22R1 Release Calendar

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

— Customer
Validation



22R1 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 22R1 Release**

Validation Docs

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

22R1 Release

- All Customers Vaults upgraded to 22R1

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



Available Resources

<https://cdmshelp.veeva.com/lr/rn/general-releases/21r2/>

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



22R1 Feature Summary

Sites



- Item to Form Linking
- Form Linking UI Improvements
- Additive Review
- Study Listings in Review Tab
- General EDC Enhancements

Reports/Extracts



- SDE Enhancements
- Unique Terms Report

Study Designer



- Library Classifications
- Event Window Enhancements
- Item to Form linking config
- General Library and Studio Enhancements
- Rules Enhancements
 - Comparison Rules
 - Standardized Dates in Emails
 - Query Scoping Repeating Objects
 - New Attributes
 - Updated Form Requirements

Other



- External FTP Connection
- CDMS APIs

Admin



- Study Environment Deletion
- Vault Config Report
- Study Role Updates
- Performance Enhancements

Local Labs



- Study/Site Initiated the Lab
- Update to Outdated Normals Report
- Audit Trail update

Coding



- Inactivate Coding Forms
- Reconstitute Code Request Job Enhancement

Safety Link



- Codelist Mapper
- Suspect ConMEDs

Randomization



- Option to Require Login Credential to Reveal Treatment

Additive SDV

Notice something questionable? Concerned about data quality?
CRAs can now SDV *more* than what was specified by the targeted review plan.

The screenshot displays the Vault CDMS interface for a subject named '001-005'. The main view is for 'Screening Visit Day 1'. On the left, an 'Event' list shows 'Screening Visit Day 1' (19-Jan-2022) with a red question mark icon, and subsequent weeks (Week 1-5) with orange and green status icons. The 'Vital Signs' table on the right lists various parameters with their values and status indicators (green checkmarks and plus signs). A tooltip is shown over the 'Additive Reason' column, containing the text 'Additive Reason Source quality' and 'Change Additive Reason'.

Vital Signs		⊙
Were Vital Signs collected?	Yes	⊙ +
Date of Assessment	19-Jan-2022	⊙ +
Position	Supine	⊙ +
Height	69 Inches	⊙ +
Weight	175 Pounds	⊙ +
Body Mass Index	25.8	⊙ +
Systolic Blood Pressure	150	⊙ +
Diastolic Blood Pressure	90 mmHg	⊙ +
Heart Rate	45	⊙ +





Sites / CRAs / Data
Managers

Item Form Linking

- Overview

With this feature, study designers can add a new form link item type and set up Display Items in Studio.

In EDC, users will be able to link an individual item to a form, and data from the linked form will be visible in the Display Items within the form link item.

Form links items and the linked data will be available in clinical dataset.

- Use case

Allows for more specificity when linking, providing downstream teams with more context as to why data is linked.



Item Form Linking

The image shows a clinical form with several sections: Procedure, Another Medication Given, Linked Medication, Other, and Outcome. The 'Another Medication Given' section is checked and linked to a 'Concomitant Medications' table. The table lists three medications: Advil, Nyquil, and Melatonin. A detailed view of the 'Another Medication Given' section shows the linked medication details: Advil, 25mg, Twice Daily, Oral.

Reference #	Medication	Start Date	Dose	Frequency	Route
1	Advil	14-Mar-2022	25	Twice Daily	Oral
2	Nyquil				
3	Melatonin				

Another Medication Given

Linked Medication

Form Concomitant Medications

Reference # 1

Medication Advil

Start Date 14-Mar-2022

Dose 25

Frequency Twice Daily

Route Oral

[Change](#) [Clear](#)

Other

Day 1
Impact to
Clinical Teams

No

Visibility
Study
Designers

Configuration
Studio

Dependencies
Data Model 2



Form Linking V2

- Overview

For studies using Form Linking V2, form links will appear in a new section at the bottom of the data entry form.

Users can add, edit and view links on the same page as the form data.

Users can quickly navigate to the link section using jump links at the top of the page.

- Use case

Site users were missing or forgetting to link forms when linking was performed in a separate tab at the top of the page. This allows linking to be done on the same page as data entry.

No

Visibility

Study
Designer

Configuration

Studio - New
Studies
Vault Owner in
Business Admin for
existing studies

Dependencies

Form Linking
must be
enabled



Form Linking V2

Screening Visit (01-Mar-2022): Demographics Edit Form ...

[TOP](#) | [PREGNANCY TEST \(1\)](#) ←

i Race check all that apply

Asian ...

Black or African American

Native American or Alaska Native

Native Hawaiian or Other Pacific Islander

White

Other

Childbearing Potential

Is the subject of childbearing potential? Yes

i If Yes, please link the pregnancy test result.

[Pregnancy Test \(1\)](#)

[Edit Links](#) ... 1-1 of 1

Reference #	Event	Event Date	Was the sample	Date of Specimen	Specimen Type	Result
1	Screening Visit	01-Mar-2022	Yes	01-Mar-2022	Urine	Negative

Day 1
Impact to
Clinical Teams

No

Visibility
Vault Owners

Configuration
Studio - New
Studies
Vault Owner in
Business Admin for
existing studies

Dependencies

Form Linking
must be
enabled



Additive Review

- Overview

CRA and Data Managers can SDV or DMR items that are not required by the patient's review plan.

When enabled, they will choose a reason why they're additively reviewing data, which will be applied to any items additively reviewed.

- Use case

CRA and Data Managers can now record and track their additional SDV and DMR work within CDMS.

Day 1
Impact to
Clinical Teams

No

Visibility

Study
Designer

Configuration
Studio

Dependencies

Review Rollup
V2



Additive Review

Day 1
Impact to
Clinical Teams

No

Subject: 0001-0001 Schedule QuickView Additive Review Screening Visit Item QuickView SDV

Event	?	🗨️	✓
Screening Visit 01-Mar-2022	-	-	○
Consent	-	-	○
Eligibility Criteria	-	-	○
Medical History (2)	-	-	○
Demographics	-	-	○
Pregnancy Test	-	-	○
Vitals	-	-	✓
Visit 1	-	-	⊘
Visit 2	-	-	⊘
Log Forms	-	-	○

Demographics View As Site PREGNANCY TEST (1)

Demographics		
Birth Date	01-Jan-1989	✓
Age	32 △	✓ +
Sex	Female	✓ +
Race check all that apply		
Asian	<input type="checkbox"/>	+
Black or African American	<input type="checkbox"/>	○ +
Native American or Alaska Native	<input type="checkbox"/>	○ +
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>	○ +
White	<input checked="" type="checkbox"/>	○ +

Additive Reason Source quality
Change Additive Reason

Visibility
Study
Designer

Configuration
Studio

Dependencies
Review Rollup
V2



Study Listings in Review

- Overview

CRAs and Data Managers are now able to run and schedule the below study listings from the Review Tab:

1. Event Progress Listing
2. Form Progress Listing
3. Query Details Listing
4. Subject Progress Listing

Users can filter by study country or site.

Available for users with access to the Review tab and Manage Jobs permission.

- Use Case

CRAs and Data Managers can now access the study listings without needing access to EDC Tools.

Day 1
Impact to
Clinical Teams

No

Visibility
CRAs and Data
Managers

Configuration
Manage Jobs
permission

Dependencies

N/A



Study Listings in Review

Day 1
Impact to
Clinical Teams

No

Visibility
CRAs and Data
Managers

Configuration
Manage Jobs
permission

Dependencies

N/A

The screenshot displays the Veeva Systems interface for managing study listings. The main view is titled 'Listings & Exports' and shows a table of listings with columns for ID and Type. A 'New' button is visible, and a dropdown menu is open, listing various listing types such as 'Core Listing', 'Data Export (Legacy)', 'Detail PDFs', 'Event Progress Listing', 'Form Progress Listing', 'Query Detail Listing', and 'Subject Progress Listing'. The 'Event Progress Listing' option is selected. A 'New' dialog box is open, showing the configuration for a new listing. The 'Type' is set to 'Event Progress Listing'. The 'Frequency' is set to 'Run Now'. The 'Include Restricted Data' checkbox is unchecked. The 'Execute for all countries and sites' radio button is selected. The 'Available Sites' list includes '02 Seattle Grace', '11 Hammersmith', and '21 Melbourne Clinic'. The 'Selected Sites' list includes '01 UCSF'. The 'Run Now' button is highlighted.

Review Reports Dashboards Labs Tools

22R1 Testing Study_DEV1 Search Study Site

Sites (4)
Queries (3)
Listings & Exports (4)
Job Schedule (4)

Listings & Exports

ID	Type
366918	Subject Progress Listing
367013	Query Detail Listing
3670	
3670	

New

Type
Event Progress Listing

Include Restricted Data

Execute for all countries and sites
 Select countries
 Select sites

Search

Available Sites
02 Seattle Grace
11 Hammersmith
21 Melbourne Clinic

Selected Sites 1 selected
01 UCSF

Frequency
Run Now

Cancel Run Now



Study Listings in Review

Day 1
Impact to
Clinical Teams

No

Visibility
CRAs and Data
Managers

Study	Country	Site	Subject	Subject Status	Most recent visit	Date of most recent visit	Next Event	Entry Complete	SDV Plan	SDV Complete	DMR Plan	DMR Complete	Frozen	Locked	Signed
22R1 Testing Study_DEV1	United States	1	0001-0001	Enrolled	Screening Visit	2022-03-01	Visit 1	No	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0002	Screen Failure	Screening Visit	2022-03-02		No	Full SDV	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0003	Enrolled	Visit 2	2022-03-10		Yes	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0004	Enrolled	Screening Visit	2022-03-02	Visit 1	No	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0005	Enrolled	Screening Visit	2022-03-01	Visit 1	Yes	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0006	Enrolled	Screening Visit	2022-03-18	Visit 1	No	Full SDV	No	Data Manager Review	No	No	No	No

Configuration
Manage Jobs
permission

Dependencies

N/A



General EDC Enhancements

- Removed redundant information in repeating form headers

Log Forms: Adverse Events : Reference # 1 (1 of 4) ◀ ▶
21R3

Log Forms: Adverse Events: Reference #1 of 4 < >
22R1

Day 1
Impact to
Clinical Teams

Yes

Visibility

Site Users,
CRAs, Data
Managers

Configuration

N/A

Dependencies

N/A



General EDC Enhancements

- Review users can now jump to the previous/next instance of a repeating form in Review

Adverse Events: Reference # 1 (1 of 4) : [View Summary](#) [View As Site](#)

Adverse Events	
Adverse Event	Headache

21R3

Adverse Events: Reference #1 of 2 ▲ ▼ ... [View Summary](#) [View As Site](#)

Adverse Events	
Adverse Event	Stroke

22R1

Yes

Visibility
CRAs, Data
Managers

Configuration
N/A

Dependencies
N/A



General EDC Enhancements

- Assessors can View Summary for repeating forms in Assessments

Serious Adverse Event

Study	Site Number	Subject	Event	Form	Status
mwehner_ABC_001_DEV1	10	10-005	Log Forms	Adverse Events (5) 🟡	Open

Schedule

- Screening Visit Day 1 05-Feb-2022
- Log Forms 🟡
- Adverse Events (10) 🟡

Adverse Events: Reference # 1 (1 of 10)

Adverse Events
Adverse Event
Rash
Start Date
05-Feb-2022

21R3

Serious Adverse Event

Study	Site Number	Subject	Event	Form	Status
Demomine_DEV1	01	01-005	Log Forms	Adverse Events (2) 🟡	Open

Schedule

- Log Forms 🟡
- Adverse Events (1) 🟡

Adverse Events: Reference #2 of 2 🟡 ▲ ▾ [View Summary](#)

Adverse Events
Adverse Event
Death

22R1

Day 1
Impact to
Clinical Teams

Yes

Visibility
Assessors

Configuration
N/A

Dependencies
N/A



General EDC Enhancements

- Visible non-repeating Item Group headers will now display in the Detail PDF

Screening Visit (18-Mar-2022): Demographics Edit Form

TOP | PREGNANCY TEST (1)

Demographics

Birth Date 07-Aug-1991

Age 30

Sex Female

Race check all that apply

Asian

Black or African American

Native American or Alaska Native

Native Hawaiian or Other Pacific Islander

White

Other

Childbearing Potential

Is the subject of childbearing potential? Yes

If Yes, please link the pregnancy test result.

Event: Screening Visit
Event Date: 18-Mar-2022
Form: Demographics
Version: 1

Item	Value
Demographics	
Birth Date	07-Aug-1991
Age	30
Sex	Female
Race check all that apply	
Asian	
Black or African American	
Native American or Alaska Native	
Native Hawaiian or Other Pacific Islander	
White	true
Other	
Childbearing Potential	
Is the subject of childbearing potential?	Yes
If Yes, please link the pregnancy test result.	
If No, specify the reason below and record any necessary information on the Medical History form. (select all that apply)	
Premenarchal	
Surgically Sterile	
Postmenopausal	
Other	

Day 1
Impact to
Clinical Teams

Yes

Visibility
Site Users,
CRAs, Data
Managers

Configuration
N/A

Dependencies
N/A





Local Labs

Lab Initiated by Study/Site

- Overview

For studies with Local Labs and approvals enabled, there is a new column in Approved and Pending Locations that will indicate which Study/Site initiated the Lab

- Use case

Allow managers to be able to search for Labs via the Study or Site that created it

Lab Locations & Normal Ranges

[All Lab Locations](#) > Select Lab Location ▾

						Approved Locations	Pending Locations (1)		
<input type="checkbox"/>	Lab ID	Lab Name	Address	Country	Status	In Use	Initiated By Study	Initiated By Site	
<input type="checkbox"/>	PEN-00004	Test1	test	Afghanistan	Merged		21R3 Jasmine Sudy_DEV1	SF	
<input type="checkbox"/>	PEN-00007	1234	test	Afghanistan	Merged		21R3 Jasmine Sudy_DEV1	SF	
<input type="checkbox"/>	PEN-00005	Site Entered Lab	test	Algeria	Merged		21R3 Jasmine Sudy_DEV1	SF	
<input type="checkbox"/>	PEN-00006	2sie-entered	test	Afghanistan	Merged		21R3 Jasmine Sudy_DEV1	SF	
<input type="checkbox"/>	PEN-00009	test	test	Afghanistan	Merged	IN USE	21R3 Jasmine Sudy_DEV1	NY	
<input type="checkbox"/>	PEN-00010	SiteAdded	test	Afghanistan	Merged	IN USE	21R3 Jasmine Sudy_DEV1	SF	
<input type="checkbox"/>	PEN-00011	test	test	Afghanistan	Pending	IN USE	21R3 Jasmine Sudy_DEV1	SF	

Day 1
Impact to
Clinical Teams

Yes

Visibility

Data Manager,
Lab Manager

Configuration

N/A

Dependencies

Labs Enabled



Outdated Normals Report - New Columns

- Overview

There are 2 new columns in the Outdated Normals Report - Lab Name (Title) and Lab ID

- Use case

When the eCRFs have outdated normals, this report will show what Lab Name and ID was selected on the form that shows a different lab normal than what was selected on the eCRF

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	Study	Study Site	Subject	Event Group Label	Event Group Sequence Number	Event Label	Form Label	Form Sequence Number	Lab ID	Lab Title	Lab Panel	Analyte Definition Label	Normal Low	Norm. High
1	21R3 Jasmin SF		SCR-0001	Screening	1	Screenings	Lab Form Blo	1	CopyUCSF	COPY Univ of San Francisco	Blood Gases	pH		
2	21R3 Jasmin SF		SCR-0001	Screening	1	Screenings	Lab Form Se	1	UCSF	Univ of San Francisco	Serology	Hepatitis B		
3	21R3 Jasmin SF		SCR-0003	Screening	1	Screenings	Lab Form Se	1	UCSF	Univ of San Francisco	Serology	Hepatitis B		
4														
5														
6														

Yes

Visibility

Data Manager,
Lab Manager

Configuration

N/A

Dependencies

Labs Enabled



Audit Trail - added column

- Overview

The Audit trail history in the Lab Normals has an added column - Analyte Name

- Use case

This makes the consolidated audit trail more consumable showing which analyte the change referred to

Lab Locations & Normal Ranges

Lab ID: 7393, Lab Name: NY Presbyterian, Lab Address: 35953 Sixth Street NY, NY 01283

1-20 of 22 < 1 / 2 > ⚙️

Analyte Name (Label)	Effective Begin Date	Sex	Lower Age	Upper Age	Age Unit	Lower Normal	Upper Normal	Measurement Unit
Alanine Aminotransferase (Alani...	11/05/2021							
Alanine Aminotransferase (Alani...	10/02/2021							
Alanine Aminotransferase (Alani...	09/04/2021							
Alanine Aminotransferase (Alani...	09/04/2021							
Albumin (Albumin)	10/03/2021							
Albumin (Albumin)	02/07/2021							
Basophils_Absolute (Basophils A...	04/07/2021							
Bilirubin (Bilirubin)	11/03/2021							
Chloride - Serum (Chloride - Serum)	09/04/2021							
CO2 (CO2)	10/19/2021							
Eosinophils_Absolute (Eosinophi...	03/04/2021							
Glucose (Glucose)	04/07/2021							

Audit History

Timestamp (Mid/yyyy h:mm a z)	User Name	Analyte Name (Label)	Event Description
11/5/2021 2:08:00 PM PDT	Sharon Lin (sharon.lin@sharonqa.com)	Bilirubin (Bilirubin)	"Lower Normal" changed from "0.3" to "0.30"
11/5/2021 2:08:00 PM PDT	Sharon Lin (sharon.lin@sharonqa.com)	Bilirubin (Bilirubin)	"Lab Reference Range Status" changed from "Pending Approval" to "Active"
11/5/2021 2:08:00 PM PDT	Sharon Lin (sharon.lin@sharonqa.com)	Bilirubin (Bilirubin)	"Upper Normal" changed from "1.2" to "1.20"

Close

Day 1
Impact to
Clinical Teams

Yes

Visibility
Data Manager,
Lab Manager

Configuration
N/A

Dependencies
Labs Enabled



Dedicated DEMO

For a dedicated demo of any
these features,
please contact your
Account Executive OR
Customer Success Manager





Thank you