

22R3 Customer Webinar Studio, Admin, Coder

Nov 3, 2022



CDMS Product Managers

Dennis Kochanski

Sr. Product Manager

Studio, Library, Retrospective Amendments



Mo Al-Adeeb

Sr. Product Manager

Coder, E2B Link



Eric Haas

Product Manager

Admin, User Mgmt



Lindsay Chan

Technical Product Manager

Extracts



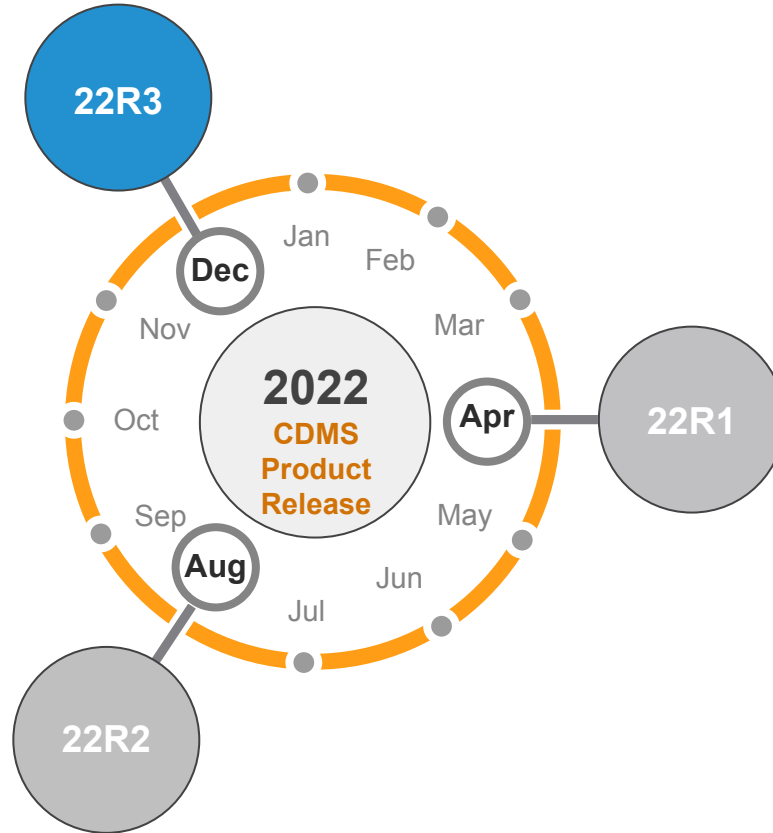
Natalie Moore

Product Manager

Rules



Veeva Vault Release Schedule



22R3 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	01 NOV	02	03 22R3 Release Webinar 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	04 22R3 Pre-Release Upgrade	05
06	07 Validation Docs	08	09	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	36
27	28	29	30	01 DEC	02 22R3 General Release Upgrade	03

— Customer
Validation



22R3 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 22R3 Release**



Validation Docs

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



22R3 Release

- All Customers Vaults upgraded to 22R3

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



Available Resources

<https://cdmshelp.veeva.com/lr/rn/general-releases/22r3/>

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

22R3 Feature Summary

Sites



- Bulk Signature
- Sign with Open Queries
- Data Entry Schedule Enhancements
- Protocol Deviation Enhancements
- Specify Other for Additive Review

Study Designer



- Library Keys in the SDS
- Library Report as CSV
- Multi-language Support
- Retrospective Amendment changes
- Cross-Form Derivations
- Previous Value Rules
- Form Linking Rule Enhancements
- Email Rule Enhancements

Admin



- Job Enhancements
- Rule Execution Enhancements
- User Import Warnings
- Vault Deployment Diff report - Support for MRS
- General Enhancements

Coding



- Coder UI Optimization
- Batch Upversioning Failure Tolerance
- Code Forms that Need Synonym Lists

Reports/Extracts



- Listings in Reports
- Listings Enhancements
- SDE Study Design Information
- SDE Length Standardization
- SDE Enhancements

Other



- CDMS - CTMS Study Pause
- APIs:
 - Retrieve Study Jobs
 - Support for Other Areas
 - Cleanup

Labs



- Lab Modifier for Unit Data Type
- Configurable Lab Queries
- Disable Pending Labs
- Labs Migration

E2BLink

(Formerly known as SafetyLink)



- Email Notifications on Failures
- Deployments & Validations



Study Designers / Coders /
Admin / APIs



Studio

Library Keys in the SDS

Overview

- This feature add options to the SDS to include system and library information for reference and traceability.
- Keys adds system keys for troubleshooting and reference
- Origin provides information about lineage of a definition

Use case

- Origin Keys can be used to tie a version of an object to an MDR
- Cross Vault Unique ID allows a user to look up validations that don't use names

Create Specification

Generate the following documents.

☐ All CRFs
 ☐ Unique CRFs
 ☒ Study Design Specification (SDS)

General Options

Specification Version

☐ Include Export

PDF Options

☐ Include General annotations
 ☐ Indent Progressive Display Items
 ☐ Show Event Date Information

SDS Options

☐ Include Rules
 ☒ Include Keys
 ☒ Include Origin

Select View Set

AT	AU	AV	AW	AX	AY
Private Key	Cross Vault Unique ID	Origin Name	Origin Type	Origin Definition Name	Origin Key
ErX122eRq9cTjjo51a8g	16833:00Z000000020001:0PC000000040013	BAD_202002041_DEV2	Study	test_repeating	16833:00Z000000020001:0PC000000030013
nZlIQ0z7TAa8RlpcP2tgag	16833:00Z000000020001:0PD000000040014	BAD_202002041_DEV2	Study	repeating_form	16833:00Z000000020001:0PC00000003R014
B1FWXikg5SmY0tAFIuaeOQ	16833:00Z000000020001:0PE00000007W060	BAD_202002041_DEV2	Study	create_date	16833:00Z000000020001:0PE00000006H097
UM_HyR3IS4QF36c7-Km-Q	16833:00Z000000020001:0PE00000007W097	BAD_202002041_DEV2	Study	single_unit	16833:00Z000000020001:0PE00000006H097
rtQ0K32BT-WWno9mwQ3F2Q	16833:00Z000000020001:0PC000000040001	BAD_202002041_DEV2	Study	indent_and_prog_display	16833:00Z000000020001:0PC000000030001
na2beShpQHml_322K5vVQ	16833:00Z000000020001:0PD000000040003	BAD_202002041_DEV2	Study	driving_items	16833:00Z000000020001:0PD00000003R003
KoHP2aq9ydy0a2rPSG56w	16833:00Z000000020001:0PE00000007W123	BAD_202002041_DEV2	Study	dyn_text	16833:00Z000000020001:0PE000000073001
Jgh1JicRkCuf-jlBeaMIQ	16833:00Z000000020001:0PE00000007W041	BAD_202002041_DEV2	Study	date	16833:00Z000000020001:0PE00000006H041
h3yPhgldw5gDAU4IHREw	16833:00Z000000020001:0PE00000007W096	BAD_202002041_DEV2	Study	derivedval	16833:00Z000000020001:0PE00000006H096
OZHFgySDuDM7gvQpHVQ	16833:00Z000000020001:0PE00000007W042	BAD_202002041_DEV2	Study	testtruequery	16833:00Z000000020001:0PE00000006H042
Ja_tRCnNT09fJF5KTMaww	16833:00Z000000020001:0PE00000007W083				
-NTNAd_QQeJ4FfeD5T0Mg	16833:00Z000000020001:0PE00000007W084				
asbX0vpeQa19VqPkeS5g5w	16833:00Z000000020001:0PE00000007W014	BAD_202002041_DEV2	Study	this_is_a_label	16833:00Z000000020001:0PE00000006H014



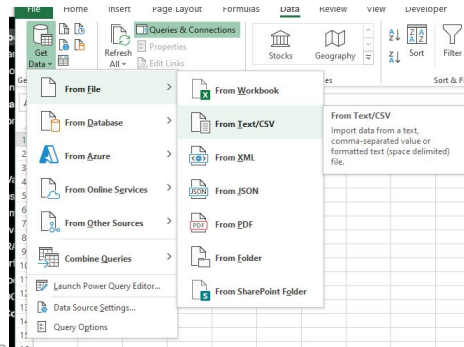
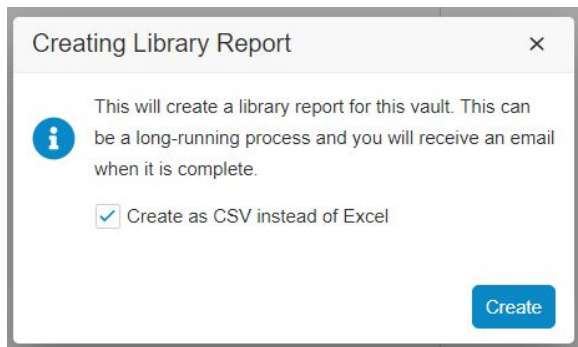
Library Report as a CSV

- Overview

- Provides users the ability to export the Library Report as a format other than Excel
- Due to the volume of records exported in this file, some vaults may exceed the excel limits of one million records
- This will be accompanied with filters in future versions
- If there are more than 800,000 records in the definition histories, CSV will be automatically selected
- Though the extension is .CSV, this is a tab delimited file
- Excel can still be used - leveraging the Datamodel functionality to Get Data

- Use case

- Large vaults can cross the million record threshold for support in Excel



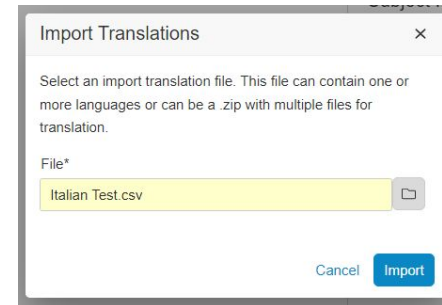
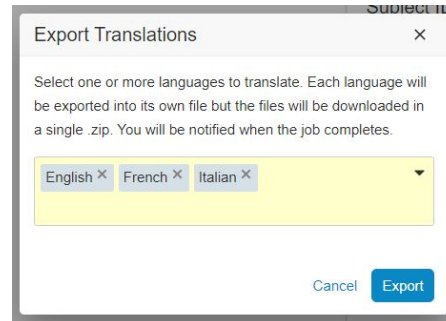
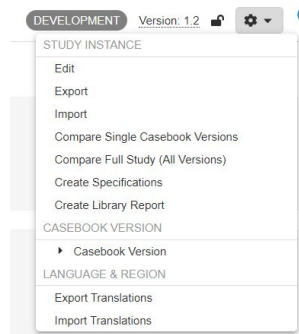
Multi-Language Support

• Overview

- This feature allows users to export and import translations specific to that study and study version
- Files are tab delimited but saved as CSV
- Includes all of the study labels but does not include vault level labels (like custom reasons for change)
- Translations are copied with definitions and are deployed with casebook versions

• Use case

- Simplifies support for multi-language studies
- Allows for standards stored in the library to include translations



Retrospective Amendment Changes

- Overview

- In this version a number of Retrospective Amendment changes have been made
 - Event selection for retro is now locked to the first event in the schedule
 - Additional warnings on versioned definitions in studio are displayed for deleted definition relationships
 - Deployment will show an additional warning if there are deleted relationships detected
 - Retro Amendments will now NOT ALLOW an amendment job to be processed when there is existing data and a relationship deletion
- We are introducing a process in which approved relationship deletion can go through Veeva to allow the retro amendment job to process - this will be described in help for the retro amendment.
- Long term the system will reintroduce these changes with a way to archive the data associated with destructive changes

- Use case

- Users can make post-go-live changes to study designs that accidentally remove data from the study - these changes are to stop this process

Day 1
Impact to
Clinical Teams

No

Visibility

Lead
Datamanager,
Super User

Configuration

None

Dependencies

None





Rules

Cross Form Derivations

- Overview

- New component type called Derived items, considered “display items”
- Always up to date, regardless of the status of the form
- Carry forward values or calculate a value based on other forms
- Can be visible or not visible in both Data Entry and Extracts (must be displayed in at least one)

- Use case

- Need to access values from across the casebook for a derivation

Studio:

COMPONENTS

Create ▾

- Item Group
- ☒ Checkbox
- Codelist
- Form Link
- Date
- f(*) Derived**
- Label

▼ Target

Baseline pulse rate measurement
Derived value

f(*) DERIVED_ITEM

PROPERTIES Cancel Save

▼ General

Name* derived_item

Description

Item Type* Derived

Display Visibility* Include in Data Entry Include in Extracts

▼ Data Type

Data Type* Text

Length* 250

Rule Action:

Set Derived Value ▾ Select item

EDC:

Derived Item 1 No value to display

Value when form was last submitted 105

Rule Name DRV1 110 ...

Day 1
Impact to
Clinical Teams

No

Visibility

Study Designers,
Librarians, Sites,
CRAs, Data
Managers

Configuration

Studio

Dependencies

DM2



Previous Value Rules

- Overview

- Ability to reference the previous Event or Form in a casebook in Query rules
- @PreviousEvent variable, used with @Form
- Events are sorted by Event Date
- @PreviousEvent rules are post-save, and are triggered when any Event is entered, added, reset, or changed
- Also added support for skipping ILB values in [-1] and [+1] rules for repeating objects

- Use case

- Studies need to reference past values, such as dates or dosing information, that do not necessarily occur in a set pattern in the study

Expression [Check Syntax](#) [Format](#) [Formula Language Refe](#)

```
1 @  
  @Casebook  
  @Event  
  @EventGroup  
  @Form  
  @PreviousEvent  
  @Site  
  @Study  
  @StudyCountry  
  @User  
  @Var
```

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



Form Linking Rule Enhancements

- Overview
 - Rules with link identifiers “/” can now also include identifiers outside the context of the main form or linked form
 - Rules that reference outside identifiers are executed post-save
- Use case
 - Needed to be able to reference more values in a rule

Day 1
Impact to
Clinical Teams

No

Visibility

Study Designers,
Librarians

Configuration

Studio

Dependencies

DM2



Email Rule Enhancements

- Overview
 - Send Email Rules that include codelist values in the email subject or body now include the codelist label in addition to the coded value
- Use case
 - Readability for email recipients



Day 1
Impact to
Clinical Teams

Yes

Visibility

Email Group
Recipients

Configuration

N/A

Dependencies

N/A





Admin

Job Enhancements

- Overview

- This release provides users insight into the status of Jobs, by introducing a new status, Queued, and providing metrics on the completion of In Progress Jobs.
 - Queued indicates a Job has been triggered but has not begun processing
 - In Progress Jobs now provide a percent complete in the Status column
 - Hovering on Status displays last activity time
- The 23hr limit on Jobs has been effectively removed

- Use case

- Previously, the Retrospective Amendment on a very large study could take days to complete. This release improves the user experience by reducing the time taken to run Retro Amendment and other Jobs and removes the need to create multiple Job records because of timeout issues

Job History		
<div><div>+ New Job</div><div><input type="text" value="Search"/></div><div>Status: All ▼ Type: All ▼</div></div>		
ID	Type	Status
320601	Audit Trail Export by Study	Queued
318401	Data and Definition Export	Completed

Job History		
<div><div>+ New Job</div><div><input type="text" value="Search"/></div><div>Status: All ▼ Type: All ▼</div></div>		
ID	Type	Status
320450	Study Data Extract	In Progress...20%

Last Activity Time: 10/24/2022 12:39 PM MDT

Day 1
Impact to
Clinical Teams

No

Visibility

Deployment
Admin
LDM
Study Designer

Configuration

N/A

Dependencies

N/A



Rule Execution Enhancements

- Overview

- Eliminated the 500 casebook restriction during rule execution
- Double the limit on Rule selection during rule execution to 100

- Use case

- Enhancing the user experience when running rule Jobs by removing or limiting the number of distinct Jobs that must be run post-amendment.

EDC Tools	Rules						
SETUP	Run Rules Error Console (0)						
Study Settings	Advanced Filters						
Study Countries (4)	Search Rule Status: Active Selected 100 Run Rules						
Sites (2)	You may only select 100 records						
Learning Systems	<input checked="" type="checkbox"/>	Name	Rule Status	Form	Rule Action	External ID	Last Modified
Email Group Assignment	<input checked="" type="checkbox"/>	R_QUERY_EXREF...	Active		Query	R_QUERY_EXREFID...	07/12/2022 8:42 PM MDT
Review Plan Assignment	<input checked="" type="checkbox"/>	R_QUERY_EXSTD...	Active		Query	R_QUERY_EXSTDAT...	07/12/2022 8:42 PM MDT
Assessments	<input checked="" type="checkbox"/>	R_QUERY_EXSTD...	Active		Query	R_QUERY_EXSTDAT...	07/12/2022 8:42 PM MDT
FTPs (0)	<input checked="" type="checkbox"/>	R_QUERY_EXSTM...	Active		Query	R_QUERY_EXSTMID...	07/12/2022 8:42 PM MDT
Safety Configuration	<input checked="" type="checkbox"/>	R_QUERY_EXSTT...	Active		Query	R_QUERY_EXSTTIM...	07/12/2022 8:42 PM MDT
Integration Configuration	<input checked="" type="checkbox"/>	R_QUERY_EXTDP...	Active		Query	R_QUERY_EXTDPRP...	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_EXTVP...	Active		Query	R_QUERY_EXTVPRP...	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_EXVDI...	Active		Query	R_QUERY_EXVDID_R...	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_Obesity...	Active		Query	R_QUERY_Obesity_Tr...	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_PCIBY...	Active		Query	R_QUERY_PCIBYN_R...	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_RFICD...	Active		Query	R_QUERY_RFICDAT_FD	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_RFICD...	Active		Query	R_QUERY_RFICDAT...	07/12/2022 8:42 PM MDT
	<input checked="" type="checkbox"/>	R_QUERY_Screeni...	Active	Informed Consent	Query	R_QUERY_Screening...	07/12/2022 8:42 PM MDT

Day 1
Impact to
Clinical Teams

No

Visibility

LDM
Librarian

Configuration

N/A

Dependencies

N/A



User Import Warnings

- Overview

- When importing a batch of users, the Import Preview now displays a warning if there are changes present to an existing user's profile details:
 - Language
 - Locale
 - Time Zone
 - Security Policy

- Use case

- Previously, changes to a user's profile details via import would proceed without informing the User Administrator, leading to unintended changes. These enhancements aim to reduce these accidental updates.

Preview  0  1  0

Import Status: All ▼

Import Status	User Name	Email
 Warning: Locale will be updated., Language will be updated.	strdua719c@eh.com	strdua719b@eh.com

Day 1
Impact to
Clinical Teams

No

Visibility

User
Administrators

Configuration

N/A

Dependencies

N/A



Vault Deployment Diff Report - Support for MRS

- Overview
 - The Vault Diff/Comparison Report's *User Defined Roles* section now:
 - Lists all custom role differences between Vaults (for whitelisted roles)
 - Displays standard and user-defined permission set differences per role
 - Introduces a new *User Defined Permission Sets* sheet that:
 - Displays Tab, Object and Object Field permission differences per user-defined permission set
- Use case
 - Previously, in vaults using Multi-Role Security, the Vault Diff Report's *User Defined Roles* section did not accurately reflect custom roles, instead displaying differences in the Security Profiles. With this release we have restored the practicality of this section of the report, regardless of security model.

Deployment

Source Vault

EHQAFast

Destination Vault

EHQAFast-PRD

Deploy Data

☒ User Defined Roles

☐ Change Reasons

☐ User Defined Objects

☐ Reports and Dashboards

☐ Analyte Library ?

Reason for Change

New Roles and Permissions

25/255

Compare Vaults

Deploy

Day 1
Impact to
Clinical Teams

No

Visibility

Deployment
Admin
User Admin

Configuration

N/A

Dependencies

N/A



Vault Deployment Diff Report - Support for MRS

Day 1
Impact to
Clinical Teams

No

Visibility

Deployment
Admin
User Admin

Configuration

N/A

Dependencies

N/A

Study Role	Type	Component	EHQA	EHQ
Copy Study Data Only	Permission	Manage Deployments	Yes	No
Copy Study Data Only	Permission	Restricted Data Access	Yes	No
Copy Study Data Only	Permission	View Casebook	Yes	No
Copy Study Data Only	Permission	View Code	Yes	No
Copy Study Data Only	Permission	View DMR	Yes	No
Copy Study Data Only	Permission	View Form Linking	Yes	No
Copy Study Data Only	Permission	View Integration Mappings	Yes	No
Copy Study Data Only	Permission	View Lab Locations and Normals	Yes	No
Copy Study Data Only	Permission	View Medical Assessments	Yes	No
Copy Study Data Only	Permission	View Protocol Deviations	Yes	No
Copy Study Data Only	Permission	View SDV	Yes	No
Copy Study Data Only	Permission	View Study Design	Yes	No
Copy Study Data Only	User Defined Permissi	PPT Custom Perm	Yes	No
Data Entry Only	Permission	Accept Closeout PDF	Yes	No
Data Entry Only	Permission	Answer Query	Yes	No
Data Entry Only	Permission	Data Entry	Yes	No
Data Entry Only	Permission	Data Entry Tab	Yes	No
Data Entry Only	Permission	Edit Form Linking	Yes	No
Data Entry Only	Permission	Generate Blank PDF	Yes	No
Data Entry Only	Permission	Generate Detail PDF	Yes	No
Data Entry Only	Permission	Randomize Subject	Yes	No
Data Entry Only	Permission	Review Closeout PDF	Yes	No
Data Entry Only	Permission	View Casebook	Yes	No
Data Entry Only	Permission	View Form Linking	Yes	No
Data Entry Only	Permission	View Lab Locations and Normals	Yes	No
Data Entry Only	Permission	View Query	Yes	No
►	Summary	User Defined Roles	User Defined Permission Sets	User Defined

Permission Set	Type	Component	EHQAFA	EHQA
PPT Custom Perm	Object Permission	customObj1	Read	
PPT Custom Perm	Object Permission	Lab Location	Read	
PPT Custom Perm	Object Field Permission	customObj1 - customObj1_field2	Read	
PPT Custom Perm	Object Field Permission	customObj1 - customObj1_field1	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Status	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Name	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Link	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Last Modified Date	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Last Modified By	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Created Date	Read	
PPT Custom Perm	Object Field Permission	customObj1 - Created By	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Study Country	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Status	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Secondary Email	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Primary Email	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Link	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Last Modified Date	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Last Modified By	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Lab Title	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Lab Status	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Lab Location Status	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Lab ID	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Initiated By Study	Read	
PPT Custom Perm	Object Field Permission	Lab Location - Initiated By Site	Read	
PPT Custom Perm	Tab Permission	Lab Location Tab1	Read	
PPT Custom Perm	Tab Permission	Lab Location Tab2	Read	



General Enhancements

- Overview

- PI field no longer required when creating a Site (UI and Import)
- Tooltip in User Management to clarify “Add as PI” option
- Site lock status displayed in Review Plan Assignment
- Use multi-select across “Active Versions by Site” pages when selecting sites for a Retro Amendment
- Display “All Sites” in Training Report - Site Access column for users with All Sites access
- Warning on adding conflicting Site and Country for users access in import: country will be ignored
- Standard 30 day retention policy for Job files

- Use case

- The PI person object is not required in the Data Model, and forcing users to choose or create a PI for a site has led to confusion and frustration. In the same vein, the “Add as PI” field in User Management has been confused with the actual *PI role*.
- Improve the user experience when managing and interacting with sites across the product.
- Previously, there was no unified retention policy for EDC Jobs, and obsolete Job files were taking up large amounts of space.

Day 1
Impact to
Clinical Teams

No

Visibility

User Admin
LDM
Librarian
Study Designer

Configuration

N/A

Dependencies

N/A



General Enhancements

Day 1
Impact to
Clinical Teams

No

Visibility
User Admin
LDM
Librarian
Study Designer

Configuration
N/A

Dependencies
N/A

Adding a user as a Principal Investigator allows them to be selected as the PI for a site. **This field has no bearing on the user's study role.**

Add as Principal Investigator

☐ Yes ☒ No

New Study Site

Site Number

040

Site Name

Swedish Medical

Status

Active

Study Country

United States

Principal Investigator

Review Plan Assignment

Search



Site Status: All

Study Country: All

Site Number

Site Name

001

Denver Health

020



Anschutz Medical Center

030

030 Porter Hospital

EDC Tools

SETUP

Study Settings

Study Countries (1)

Sites (46)

Email Group Assignment

Review Plan Assignment

Casebook Versions

All Versions

Active Versions by Site

Amendment History

Search



Site Status: All

Country: All

Selected 25

New Retrospective Amendment

1-25 of 46

1 / 2

<input checked="" type="checkbox"/>	Site Number	Site Name	Study Country	Principal Investigator	Site Status	Active Version
<input checked="" type="checkbox"/>	30	Denver Health	All 25 sites on this page are selected. Select all 46 sites.			1
<input checked="" type="checkbox"/>	31	UC Health	United States	Navn Navnesen	Active	1
<input checked="" type="checkbox"/>	32	Swedish General	United States	Navn Navnesen	Active	1
<input checked="" type="checkbox"/>	33	Methodist	United States	Navn Navnesen	Active	1





Extracts

Study Data Extracts Study Design Information

• Overview

- In the 22R3 version of the SDE, users have the option to include Study Design CSV files in their extract.
- These files will live in a new folder called *definitions* and include the following:
 - export_options.csv
 - <StudyName>-Definitions.csv (existing Study Definitions file)
 - casebook_definitions.csv
 - casebook_schedule.csv
 - casebook_definition_summary.csv
 - event_definitions.csv
 - event_group_repeat_overrides.csv
 - form_definitions.csv
 - item_definitions.csv
 - codelist_definitions.csv
 - unit_codelist_definitions.csv
 - protocol_deviations.csv (if protocol deviations are enabled)
 - protocol_deviations_relationships.csv (if protocol deviations are enabled)
 - medical_coding_items.csv (if medical coding forms are enabled)
 - medical_coding_related_items.csv (if medical coding forms are enabled)
 - medical_coding_copy_indication_from_links.csv (if medical coding forms are enabled)

• Use case

- Users will be able to obtain definition information to correlate with the clinical and operational data the SDE provides. This will also start the retirement of the Data and Definition export job (with removal in 23R2).

Day 1
Impact to
Clinical Teams

NO

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

22R3 SDE



Study Data Extracts Length Standardization

- Overview

- In the 22R3 version of the SDE, the Length and SAS Length of text columns are driven from Vault object lengths and from the Studio UI limitations.
 - For example, the STUDYID column comes from the Study Name field, which is 128 characters.
- Some general patterns that apply:
 - Booleans are Length 5 characters
 - Vault Picklist Labels are Length 100 characters
 - User Fields (Created By, Modified By) are Length 201 characters
 - Vault IDs are Length 100 characters
 - Note: for HVO objects, the Length may be 15 characters
 - SAS Lengths are 4x the character Length to provide enough space for UTF-8 encoding and are represented in Bytes

- Use case

- The SDE lengths are driven from Studio and Vault limitations in order to prevent data truncation in SAS and to help users allocate enough space for fields during ingestion. If the Studio limit or Vault length are updated, the SDE will reflect that.

Day 1
Impact to
Clinical Teams

NO

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

22R3 SDE



Study Data Extracts Enhancements

- Overview

- In the 22R3 version of the SDE, the following enhancements have been made:
 - The SYS_PD dataset now includes the Labels for the Category, Subcategory, and Severity. It also includes the Form Sequence, Form Internal Vault ID, and the Protocol Deviation Internal Vault ID.
 - The SDE supports the use of the Lab Modifier on studies with Global Labs enabled with the addition of two columns for the Lab Modifier Code and its Decode.
 - The Core Listings and Data and Definition Export (soon to be deprecated) jobs were also updated to support Lab Modifier with an additional column.
 - The SDE supports the Bulk Casebook Signature feature in EDC with a new column called BULKCASEBOOKSIGNATURE added to the SYS_SITE dataset.
 - The DLASTMOD (Datetime of last data change) column in the clinical datasets is now being populated from the most recent *value last modified* date for items on a form
 - Note: This applies to *all* SDE versions

- Use case

- The SDE includes enhancements which support cross-functional features and improves clinical data consumption.

Day 1
Impact to
Clinical Teams

NO

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

22R3 SDE





Coder

Coder UI Optimizations

- Overview

We have optimized white space allowing Coders to see all the rich data without the need to scroll on the page to see it.

- Collapsible Properties Panel: users can collapse and expand the Properties Panel as necessary while coding
- Removed the Info Banner and placed on the content on other areas of the page, and moved the pagination to site above the Verbatims table.

Also made it easier to see manage the Dictionary Panel's viewport.

- Use case

As a Coder I now see more verbatim data and coding options on the screen. I don't need to scroll around the page to find the data that I'm looking for to perform my task of understanding the Verbatim and selecting or verifying the best code.



Batch Upversioning Failure Tolerance

- Overview

During Batch Upversioning while Forms and Synonym Lists are not expected to fail upversioning, in the worst circumstance if any do then Coders and Coder Admins can easily identify which Forms and Synonym Lists failed Upversioning both on the Coder Homepage and the Verbatims page. Meanwhile, Coders are able to continue coding these Forms until a Coder Admin restarts Upversioning.

When a Synonym List failed upversioning then it cannot be assigned to any Forms. While a Form is in this status, a Synonym List can be assigned to the Form.

- Use case

Batch Upversioning failed for some Forms and/or the Synonym List. Meanwhile Coders can continue their coding activities on these Forms until Upversioning restarts on the Forms.

Day 1
Impact to
Clinical Teams

Yes

Visibility

Coder &
Coder Admin

Configuration

N/A

Dependencies

N/A



Code Forms that Need Synonym Lists

- Overview

If a Form does not have an assigned Synonym List then the Coder may continue to code the Form until one is assigned. Forms with the Needs Synonym List status will not Autocode or have Suggestions off of the Synonym List, meanwhile it can still receive Autocoding from the Dictionary.

This feature allows Coder more freedom and flexibility to complete their tasks while Coder Administrators are administering Synonym Lists.

- Use case

Coder Administrator needs more time to manage the Synonym List prior to assigning it to Forms, meanwhile Coders may proceed with their coding activities.

Day 1
Impact to
Clinical Teams

Yes

Visibility

Coder &
Coder Admin

Configuration

N/A

Dependencies

N/A





E2BLink

Email Notifications on Failures

- Overview

E2BLink captures up to five email addresses to send email notifications when the Transmission fails via the Safety to CDMS Connector or via the AS2 Gateway to a third party Safety System. It can fail for several reasons: if the configuration is incorrect, if the target system is offline, or if the connection profile is set to Inactive.

E2BLink will also send an email prior to the expiration of the AS2 Gateway Encryption Certificates. It sends email alerts three months prior, one month prior, and the day the certificates expire, giving your team enough time to respond and load new certificates.

- Use case

If a Safety Message fails to deliver or if the validity of the configuration is going to expire soon because of to be expiring Encryption Certificates, then E2BLink will send an email notification to a group of emails.

Day 1
Impact to
Clinical Teams

Yes

Visibility
Safety Admin

Configuration
N/A

Dependencies
N/A



Deployments & Validations

- Overview

E2BLink's Safety Configurations now must be configured on a DEV Study Instance and then deployed using Studio Deployments to downstream Study Instances such as UAT and PROD.

Now that the DEV environment is the only environment that allows configurations, customers will enjoy a controlled and uniform configuration across the Study Environments. Allowing for transparency for what is available in the E2B Link Safety Configuration during the UAT phases and Prod phases of the Study.

During the Studio Deployment, the validation file now includes validation checks of the Safety Configuration. If there is a situation in the configuration that would prevent the E2B XML from being generated or from including expected relevant case data, then that will show up in the validation file as either an error or a warning.

- Use case

To configure E2BLink on UAT or PROD, it must first be configured on DEV and then deployed to the downstream environments. As part of the deployment, Studio will validate the E2BLink configuration to ensure it up-to-date with the latest Study Design version since that an change independent of E2BLink configurations.

Day 1
Impact to
Clinical Teams

Yes

Visibility

Study Designer
& Safety Admin

Configuration

N/A

Dependencies

N/A

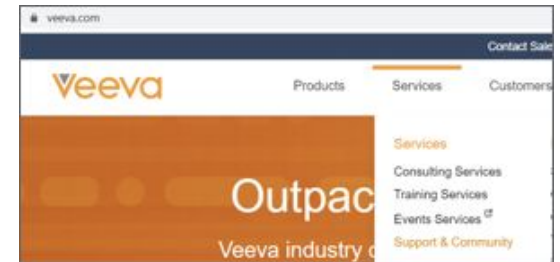
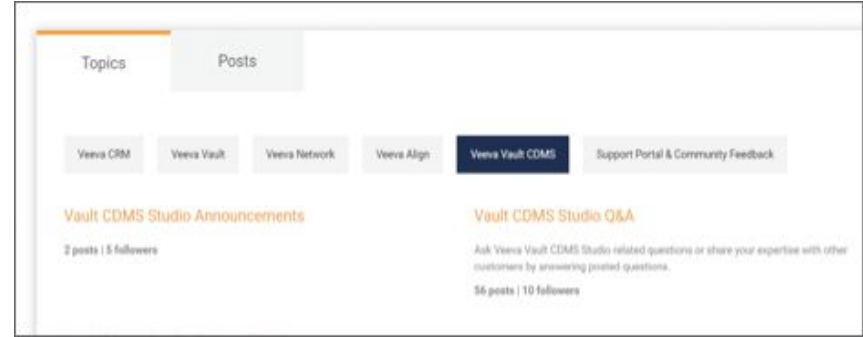




Closing / QnA

CDMS User Community

- Interactive support community of trained Studio users
 - Customers and Veeva consultants
- Peer-to-peer communication
 - Discuss and share ideas
 - Q&A
 - Rule syntax, tips
 - Announcements
 - Useful links, webinar recordings
 - Voting
 - Replies from User Community network
- Monitored daily by Veeva for accuracy
- How to find it:
 - Part of Veeva's Support Portal
 - Veeva.com **Services > Support & Community > Community**
 - **Vault Community** link at the bottom of CDMS Help pages
- Follow each area to get involved



Dedicated DEMO

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





Thank you