

22R1 Customer Webinar Studio, Admin, Coder

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Rules



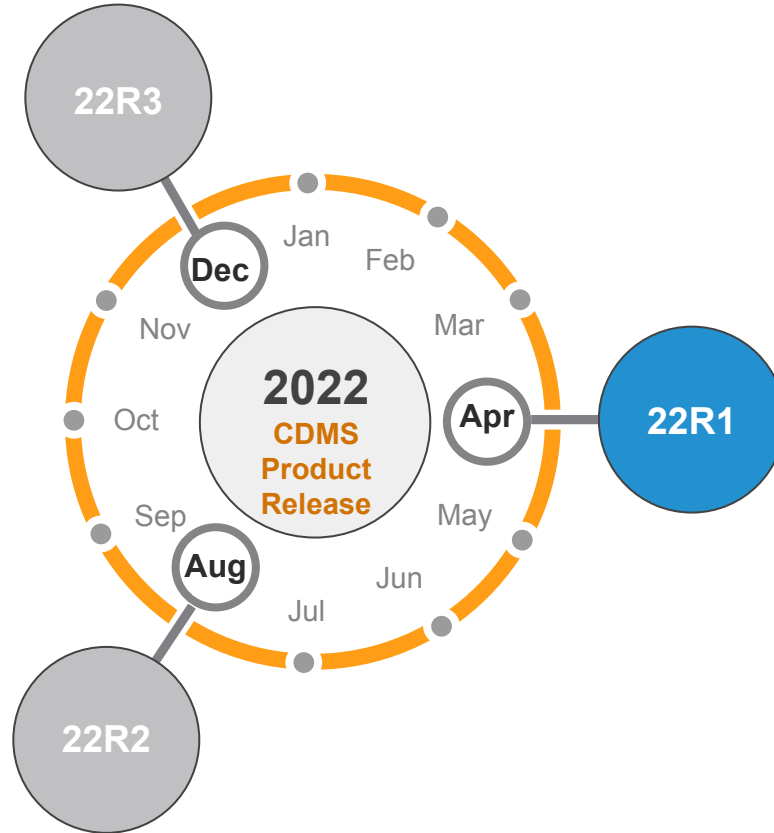
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Local Labs, Randomization



Veeva Vault Release Schedule



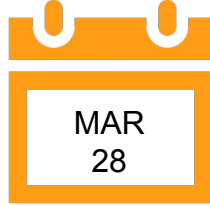
22R1 Release Calendar

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

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

Library Classification

Improve the adoption of library templates by making it easy to find them

Phase:

- Phase 1
- Phase 2
- Phase 3

Therapeutic Area:

- Endocrinology
- Immunology
- Oncology
- ...

Region:

- Argentina
- Australia
- Belgium
- Brazil
- ...

Attributes:

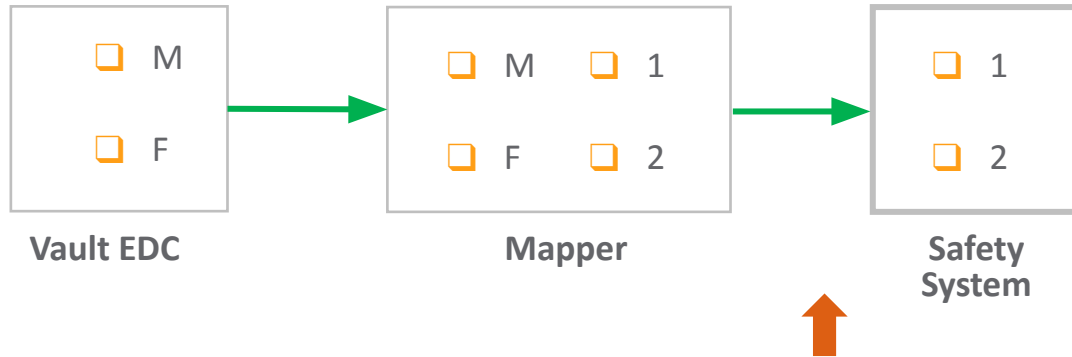
- Geriatric
- Pediatric
- Randomized
- Not Randomized



Safety Codelist Mapper

Easily Support E2B Codelist Codes

Patient Gender Example:



Vault CDMS now transfers the mapped code values to the safety system.

Goal Achieved: Death to Custom Functions!

Necessary functionality should exist within the product itself

- Veeva has been working diligently to natively support all common scenarios where customers typically relied on custom functions.
- As of 22R2, customers should no longer need Custom Triggers to achieve their business requirements and Veeva intends to no longer develop them for new studies.
- While most do not need custom triggers today, as of 22R2, all remaining customers will be asked to utilize productized methods to meet their business requirements.
- Customers will no longer be burdened with the added cost and complexity of Custom Triggers. This is good for our customers and for the industry.



Goal Achieved: Death to Custom Functions!

Common Questions

- **What about existing studies?** No change or action is needed. We will leave existing Custom Trigger capabilities in place.
- **What's Next?** Meet with your CSM to discuss how existing triggers will be replaced by productized functionality in your next study.
- **What about exceptions?** If unmet needs emerge, we will endeavor to add productized solutions for those scenarios in subsequent releases.
As of 22R2, Veeva will no longer perform Custom Trigger development.





Studio

Item Form Linking (Studio Config)

- Overview
 - Added a new item type called “Form Link”
 - Study Designers can define what display items are shown in EDC
 - Only available in Data Model 2 studies
- Use case
 - Supports the EDC feature for Form Linking, allowing users to associate the current form or item group to another form and display item values from that form

Day 1
Impact to
Clinical Teams

No

Visibility

Study
designers,
Librarians

Configuration

Studio

Dependencies

Data Model 2



Item Form Linking (Rules)

- Overview

Rules support accessing data from a form linked through an item, similar to what is already available for form to form links.

The identifier uses the same / concept to access the linked form.

- Use case

This allows data checks to be performed between linked forms.



Item Form Linking

Schedule Adverse Events

COMPONENTS

Create ▾

- Item Group
- Checkbox
- Codelist
- Form Link
- Date
- Label
- Number
- Text
- Unit
- Url

Display Items

Select at least one or up to five items to display

Linked Form* CM (Concomitant Medications)

Search Items

Available Items

- ig_CM > CMDOSU (Dose Unit)
- ig_CM > CMENDAT (End Date)
- ig_CM > CMINDIC (Indication)
- ig_CM > CMONGO (Ongoing?)

Selected Items

- ig_CM > CMTRT (Medication)
- ig_CM > CMSTDAT (Start Date)
- ig_CM > CMDOSE (Dose)
- ig_CM > CMFREQ (Frequency)
- ig_CM > CMROUTE (Route)

Cancel Save

Day 1
Impact to
Clinical Teams

No

Visibility
Study
Designers,
Librarians

Configuration
Studio

Dependencies
Data Model 2



Event Window Enhancements

- Overview

- Added Event Group to the Event Offset selection
- Added “Previous” Event as a selection - this drives the planned date from the last date in the schedule
- Allow users to now override the 1st Event in a repeating Event Group to calculate planned dates for cycles
- In EDC calculated planned dates for Unscheduled events will no longer display
- UI now restricts configuration on/using Unscheduled and out of Event Group events in repeating events

- Use case

Simplifies window definitions with the introduction of “Previous”. Adds support for planned date calculation in Event cycles.

Day 1
Impact to
Clinical Teams

No

Visibility

Study
designers,
Librarians

Configuration

Studio

Dependencies

N/A



Library Classifications

- Overview

- Introduces a set of Classification Types and values to be applied to Form definitions
- Classification values are managed by the Librarian
- Study designers will be able to search by classification when copying forms from the library
- Examples of classifications: Therapeutic Area, Region

- Use case

Allows Librarians to classify Forms so Study Designers can easily determine which forms they should be pulling into their studies - simplifying the study build process



General Library Enhancements

- Overview

Added two minor enhancements to the library functionality:

- Libraries will now “adopt” an object copied into the library from another study
 - The Origin Key (viewable in the Library Report) will now reflect that library for the newly copied object
 - This doesn’t change any other existing versions of that object
- The Library Report will show that a Form was changed if any of its children were changed so it is easier to determine Form changes in studies using Library Forms
 - This includes Item Groups, Items, Codelists, & Units

- Use case

- Allows adoption of study objects into the Library w/o requiring a CC to for Veeva to update the Origin Key of the adoption objects
- Provides Librarian with an easier method to identify Forms that are being altered by Study Designers so they have better insights into how the library is being used



General Studio Enhancements

- Overview
 - Removed System Rules from the User Defined Rules list
- Use case
 - System rules couldn't be maintained directly by users, this reduces the amount of noise visible through the User Defined Rules list

Day 1
Impact to
Clinical Teams

No

Visibility

Study
designers,
Librarians

Configuration
Studio

Dependencies

N/A



Comparison rules enhancement

- Overview

The Comparison Rules grid now has an “Override Query Message” column that allows the definition of a query message to be used instead of the default message.

The Comparison rules tab also shows the number of comparison rules created.

- Use case

The query message generated by comparison rules is very generic since it uses the event/item labels and doesn't always provide a good understanding of what needs to be modified to resolve the query.

Allowing users to define the message allows for more customization and more accurate querying.

Data Type: Date (88) Show: All Items

Label	Data Type	Operator	Compare To	Query Text Override
Baseline				
Cycle 1				

RULES

Casebook Variables (1)
Comparison Rules (88)
User Defined Rules (489)

No

Visibility

Study
designers,
Librarians

Configuration
Studio

Dependencies

Data model 2



Standardize dates in email notifications

- Overview

Date and datetime items included in email rules are standardized using the date format and twelve-hour time parameters defined in Studio. Datetimes are also displayed in the Site's timezone.

This feature should have no impact on most emails configured, since dates and datetime are already stored with the right format when coming from Data Entry.

- Use case

Some dates and datetimes that can be included in email rules, like the randomization date coming from Veeva randomization, were using a different format than the items entered in Data Entry. That format was harder to read and caused confusion for users.

Day 1
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Clinical Teams

Yes

Visibility

All

Configuration

Studio

Dependencies

N/A



Query scoping for repeating objects

- Overview

Studies created after 22R1 will benefit from enhanced query scoping for repeating objects. Existing studies can turn it on through business admin.

When the same identifier is used multiple times in an expression with a different scope (i.e. one with a sequence number and one without) and the action identifier targets the same identifier, the system will favor opening the query on the expression identifier that is a closest match to the action identifier.

This also applies to rules where there is a scope mismatch between the expression and the action for the same identifier.

- Use case

In some cases where a rule expression contained the same identifier with a different scope in a repeating object (i.e. one with a sequence number and one without), the system would not be able to open the query on the instance actually triggering the query.



New attributes and functions for rules

- Overview

New attributes:

- On item: `unit__v`, `translated_unit__v`, `change_reason__v`
- On @Casebook: `subject_name__v`

Functions:

- `Median()`: returns the median value of an aggregate or multiple identifiers
- `IsBlank(aggregate)`: the function now correctly supports aggregate identifiers
- `Networkdays()`: returns the number of workdays between two dates
- `Workday()`: returns a work day X number of days after a specified date

- Use case

This feature adds support for more options to the rule editor for writing expressions.

Day 1
Impact to
Clinical Teams

No

Visibility
Study
designers,
Librarians

Configuration
Studio

Dependencies

N/A



Updated form requirements in rule editor

- Overview

The Form dropdown in the Rule Details panel is now only required if:

- The expression or action contains an @Form identifier
- The action is Set item value, Send email, Disable, Override review plan

- Use case

Some fully qualified expressions and expressions without form reference were still requiring a form to be entered in the Rule Details panel, leading to the rule being triggered incorrectly.

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Impact to
Clinical Teams

No

Visibility

Study
designers,
Librarians

Configuration
Studio

Dependencies

N/A





Admin

Study Environment Deletion

- Overview

- The Delete action in the Actions menu for Study Environments has been renamed to Delete Environment. Users can use this action to delete a Study Environment. Users must enter the Study Name to complete deletion.
- In addition, Vault will automatically back up the Study Design before deleting the study environment. The backed-up file will be available in Deployment History. Study Data will not be backed-up. While we backup study design during deletion, Restore option is only available on Development Study Instances.
- Users can download the backup of the study design for a deleted study environment and use it to restore the study design. An EDC Tools user can select the Restore action from an environment's Actions menu. Then, they can select Restore from File in the Restore Study Design dialog and select the backup file. Note that this action only restores the study's design. It doesn't restore the study data. There is no change in the Restore from Environment flow.

- Use Case

Customer who accidentally deleted their Development Study environment will now be able to Restore the Study Design.

Restore Study Design

Restore from Environment Restore from File

Restore Study Design for **WONDERDRUG_DEV1** from File

Reason for Change

0/255

Cancel Restore



Vault Configuration Report

- Overview

With Vault Configuration Reports, you can generate a Microsoft Excel report containing configuration information, including Vault Settings, Study Configuration, Roles, Change Reason Configuration, Security Policies, Report Types, Report, and Dashboards components for a vault. Vault Configuration Reports include a Summary about the vault.

- Vault Settings - Display the Lab Analytes per Study, Multi-Role Security, Randomization, and Workbench settings.
- Study Configuration - Displays the configuration for every vault study the user has access to.
- Roles - Display the standard and user-defined roles in the worksheet.
- Change Reason Configuration - displays the standard and user-defined vault changes reasons.
- Security Policies - displays the password requirements, expiration period, reuse policy, security question policy etc.
- Report Types - display all standard and user-defined report types.
- Reports - display all standard and user-defined reports with their User and Group sharing settings user has access to.
- Dashboards - display all standard and user-defined dashboards with their User and Group sharing settings user has access to.

- Use Case

This feature is useful for tracking and documenting a vault's configuration before and after any configuration projects.

Day 1
Impact to
Clinical Teams

No

Visibility
Deployment
Administrators

Configuration
N/A

Dependencies
N/A



Study Role Enhancements

- In support of the Library Classification feature, we added the following permissions:
 - **View Classification** - CDMS Study Designer, CDMS Study Designer Read Only, CDMS Librarian, CDMS Super User
 - **Edit Classification** - CDMS Librarian, CDMS Super User
- The CDMS API Read Write role now has the **Manage Jobs** permission.
- In support of the CDB feature, we added the **Approve Import** permission and assigned it to the CDMS Lead Data Manager.
- In support of the Vault Configuration Report feature, we added the **Vault Configuration Report** permission and assigned it to the CDMS Super User and CDMS Deployment Administrator.
- We added the **View Lab Locations and Normals** permission to the CDMS Clinical Research Associate.
- If "Data Entry" is selected, then "Edit Form Linking" permission will be automatically selected.
- If "Vault Configuration Report" is selected, then "System Tools Tab", "Manage Jobs" permission will be automatically selected.
- If Edit Users is selected, then all the standard tabs are selected in the Role Management UI.

Day 1
Impact to
Clinical Teams

No

Visibility
Multiple

Configuration
On

Dependencies
N/A



CDMS APIs

- Overview:
 - Pagination Framework
 - Enabled on Retrieve Users, Retrieve Subjects, Retrieve Queries
 - Create User API - supports the new Vault User Import framework. Not backward compatible.
 - Open Coding Query API
 - Retrieve Queries
 - Added the ability to filter by the coding item definition
 - Retrieve Subjects
 - Added support for 22R1 SDE enhancements in the Start Job API (Include Randomization Treatment, Dataset Configurator, External FTPS support)
 - Added support for the Form Progress Listing job to Include Item Counts in the Start Job API
- Use Case:
 - These enhancements increase performance of the API infrastructure, and allow users to retrieve more study information and perform query actions for coding specific queries

Day 1
Impact to
Clinical Teams

No

Visibility

CDMS API
Read Write
User

Configuration

N/A

Dependencies

N/A



External FTPS

- Overview:
 - EDC now supports outbound connections between EDC and External FTPS servers to send export files such as the Study Data Extract and Code Request Export. There is an enhanced UI in the EDC Tools FTPs tab and a connection type for CDB Workbench as well.
 - Protocol is Explicit FTP over TLS (FTPES) in Passive mode
 - Veeva supports by default TCP port 21 for the control channel and ports 56000-56100 for the data channel
 - Both the control port and data channel ports are required for Passive Mode Explicit FTPS
 - If a customer's FTPS server cannot be configured to the Veeva port range, they must submit a ticket to request Veeva to open up their custom port range for the IP address of their server
- Use Case:
 - Allows for customers to send export files to their own external FTPS servers instead of only to Veeva Vault FTPS servers.

The screenshot shows a 'New FTP' configuration window. It includes the following fields and values:

- FTP Name: MYFTP
- FTP Type: External FTPS
- User Name: user@mydomain.com
- Password: [Redacted]
- Host: mydomain.com
- Confirm Password: [Redacted]
- Port: 21
- Destination Path: /files

At the bottom, there are buttons for 'Test Connection', 'Cancel', and 'Save'.





Reports/Extracts

SDE Enhancements

- The SDE includes the following features in 22R1:
 - Option to include randomization treatment in the SDE (for users with Randomization enabled)
 - Users must either have their study unmasked, or if the study is masked, the user running the job must have the View Unmasked Data permission
 - When checked, the SYS_RANDOM dataset will include three new columns: TREATMENTNAME, TREATMENTLABEL, TREATMENTARM
 - Dataset configurator: option to select clinical and system datasets, or custom objects
 - Users can select which clinical datasets, system datasets, or custom objects they want to include in their export
 - Users must include at least one of the three in order to run the job
- Use Case:
 - Users can include more information about Randomization data, as well as be able to customize the SDE further by selecting individual datasets, which also speeds up job performance.



SDE Enhancements

New Job ×

Type
Study Data Extract

SDE Version ⓘ
Version 22R1

Restricted Data Options

Include Restricted Data Include Randomization Treatment

Clinical Data Options

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
 Exclude blank forms

Data to Export

Export all System Datasets Export all Clinical Datasets Include Custom Objects

System Datasets (1) Clinical Datasets (0) Custom Objects (0)

Search

Available System Datasets	Selected System Datasets
Lab Analytes System Dataset (SYS_ANALYTES)	Form System Dataset (SYS_FORM)
Assessments System Dataset (SYS_ASM)	
Assessments Replies System Dataset (SYS_ASMR)	
Event System Dataset (SYS_EVT)	
Intentionally Left Blank System Dataset (SYS_ILB)	
Lab Locations System Dataset (SYS_LABLOC)	

Export Options

Zip File Name ⓘ

Cancel Run Now

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Clinical Teams

No

Visibility
Lead Data
Manager

Configuration
N/A

Dependencies
N/A



SDE Enhancements

- General Enhancements:

- In the SDE versions 22R1 and later, datetime items in the Site’s timezone will now use the SAS format DATETIME22.3.
- The SDE zip file will be compressed for SAS in versions 22R1 and later, and any version prior to 22R1 can be compressed by enabling the feature flag “Enable sas artifact compression”
- The following columns have increased Lengths and SAS lengths in the 22R1 version of the SDE:

Dataset Name	Column	Length	SAS Length
SYS_LABLOC	LABID	128	\$512
SYS_LABRANGES	LABID	128	\$512
SYS_PD	PDRES	500	\$2000
SYS_PD	ITEM	500	\$2000
SYS_Q	ITEM	500	\$2000
SYS_ILB	ITEM	500	\$2000

No

Visibility
Lead Data
Manager

Configuration
N/A

Dependencies
N/A



Reconstitute Code Request Job Enhancements

- Overview

This enhancement allows users to run the Reconstitute Code Requests job on all forms and select coding forms.

- Use case

This feature improves performance of the job and allows users more flexibility around which forms they want to run the job for, which is particularly useful for large Studies

The screenshot shows a 'New Job' configuration window. At the top, the job type is set to 'Reconstitute Code Requests'. Below this, there are two radio buttons: 'Execute on all forms' (unselected) and 'Select forms' (selected). A search bar is present above two panels: 'Available Forms' and 'Selected Forms'. The 'Available Forms' panel lists 'ConMed (concomitant_medication)'. The 'Selected Forms' panel shows 'AE (adverse_events)' as the selected form. Navigation arrows are visible between the panels. At the bottom right, there are 'Cancel' and 'Run Now' buttons.



Unique Terms Report

- Overview

In Coder Tools, there is a new section for Jobs, where Coder Admins can run the Unique Terms Report.

This report will include unique coding records from across multiple studies. Users will select a From Date, and new data coded from that date will be highlighted in the report.

Coder Admins can use this report to track trends in coding data and identify any differences that deviate from the pattern.

- Use Case

Coder Admins no longer need to generate the Unique Terms Report in Utilities, as it is now available within CDMS.

Day 1
Impact to
Clinical Teams

No

Visibility
Coder Admin

Configuration
N/A

Dependencies
Coding



Unique Terms Report

Coder Tools

Default Study Settings | Study Settings | Synonym Lists | Do Not Autocode Lists | Upversioning | **Jobs**

New Job

Type: Unique Terms Report

Frequency: Run Now

Set Job Options

Unique Terms Report

*Coding decisions that were made since the entered From Date will be starred in the new report

From Date
03/16/2022

Dictionary
MedDRA
MedDRAJ
WHODrug
JDrug

Available Studies
DM1_SubjectProgress_DEV1
22R1 Testing Study_DEV1

Selected Studies

Cancel Run Now

Day 1
Impact to
Clinical Teams

No

Visibility
Coder Admin

Configuration
N/A

Dependencies
Coding



Unique Terms Report

Day 1
Impact to
Clinical Teams

No

New Term	Dictionary Release	Form Name	Record Count	Verbatim	Lowest Level Term	Preferred Term	High Level Term	High Level Group Term	System Organ Class	Primary Package	Comments for Report Review
*	MedDRA 25.0	Medical History	1	HIGH CHOLESTEROL	High cholesterol	Blood cholesterol increased	Cholesterol analyses	Lipid analyses	Investigations	Y	
*	MedDRA 25.0	Medical History	1	BREAST CANCER	Breast cancer	Breast cancer	Breast and nipple neoplasms malignant	Breast neoplasms malignant and unspecified (incl nipple)	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Y	
	MedDRA 25.0	Medical History	1	CANCER	Cancer	Neoplasm malignant	Neoplasms malignant site unspecified NEC	Miscellaneous and site unspecified neoplasms malignant and unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Y	
	MedDRA 25.0	AE	3	HEADACHE	Headache	Headache	Headaches NEC	Headaches	Nervous system disorders	Y	
	MedDRA 25.0	AE	1	MIGRAINE	Migraine	Migraine	Migraine headaches	Headaches	Nervous system disorders	Y	
*	MedDRA 25.0	Medical History	1	ASTHMA	Asthma	Asthma	Bronchospasm and obstruction	Bronchial disorders (excl neoplasms)	Respiratory, thoracic and mediastinal disorders	Y	
*	MedDRA 25.0	Medical History	1	PSORIASIS	Psoriasis	Psoriasis	Psoriatic conditions	Epidermal and dermal conditions	Skin and subcutaneous tissue disorders	Y	
	MedDRA 25.0	AE	1	RASH	Rash	Rash	Rashes, eruptions and exanthems NEC	Epidermal and dermal conditions	Skin and subcutaneous tissue disorders	Y	
*	MedDRA 25.0	AE	1	ACNE	Acne	Acne	Acnes	Skin appendage conditions	Skin and subcutaneous tissue disorders	Y	
*	MedDRA 25.0	Medical History	1	ACNE	Acne	Acne	Acnes	Skin appendage conditions	Skin and subcutaneous tissue disorders	Y	

Visibility
Coder Admin

Configuration
N/A

Dependencies
Coding





Coder

Inactivate Coding Forms

- Overview

With this release, Study Designers are able to delete Coding Configurations from the Control Center Vault even if it has Coding Requests. They can then deploy this Coding Configuration deletion to downstream Studies (for example, UAT and Prod).

When the Coding Configuration is deleted, it is inactivated in the Vault. The respective Coding Form and Coding Requests will not be viewable in Coder, Coder Tools, or in any Listings, Extracts, or CDB Listings. They will be viewable in Vault Reports. To take the next step and delete the inactive Coding Requests from the Vault, users must run the new *Delete Inactive Coding Requests* job.

The Studio Diff can detect changes if the Coding Configuration is inactivated in the source and target. The Studio SDS will include this definition status.

Once a Coding Form is inactivated, the Study Administrator can run a job from EDC Tools to delete the inactivated Code Requests.

- Use case

A Coding Form can be removed from the PROD Study before and after the Study is live.





Safety Link

Suspected ConMed



- Overview

In some cases a Safety Case is caused by a ConMed and not the Study Drug. This feature allows the Site to indicate if a Linked Concomitant Medication to the SAE is just a Concomitant Medication or that it is suspected of causing the SAE. When the Site makes this determination, then the Safety Link will generate the E2B XML, transmit the SAE along with this value to the Safety System, and any administered Study Drug in the XML will be marked at "Interacting".


Item to Form Linking is required to capture this and it provides a convenient way for it to still be Reviewed (SDVed and DMRed), available in Extracts and CDB, and tracked in the Audit Trail.

- Use case

When the ConMed causes (or is suspected of causing) the SAE, this is the way the Site will indicate that.

Linked Concomitant Medications (2)						
#	Linked Concomitant Medica	Medication	Indication	Route	G.k.1 Drug Role	
1 ...	Concomitant Medications (#1) 	Tylenol	Headache	Oral	Concomitant Medication	
2 ...	Concomitant Medications (#2) 	Advil	Headache	Oral	<input type="text" value=""/> ...	




Suspect
Concomitant Medication


 + New Row



Suspected ConMed

- Date Entry Experience




Linked Concomitant Medications (3)						
#	Linked Concomitant Medica	Medication	Indication	Route	G.k.1 Drug Role	
1 ...	Concomitant Medications (#1)  	Tylenol	Headache	Oral	Concomitant Medication	
2 ...	Concomitant Medications (#2)  	Advil	Headache	Oral	Suspect	
3 ...	Select ...					

 + New Row

Demographics

Concomitant Medications

1-3 of 3

	Reference #	Medication	Indication	Route	
<input type="radio"/>	 1	Tylenol	Headache	Oral	
<input type="radio"/>	 2	Advil	Headache	Oral	
<input checked="" type="radio"/>	 3	Zyrtec	Hives	Oral	

Cancel Save

Day 1
Impact to
Clinical Teams

No

Visibility
Sites

Configuration
Studio

Dependencies
Item to Form
Linking



Codelist Mapper

- Overview

Study designers can now use CDASH codelist codes when designing *Codelist* items, and a safety administrator can configure Safety Link to map those codes to the appropriate values for the E2B XML. When Safety Link generates the E2B XML file for a *Safety Case*, Vault translates the CDASH codes into the appropriate E2B codes, allowing the safety system to interpret those values correctly.

Item	CDASH Codelist Code	E2B Codelist Code	E2B Codelist Label
Sex	M	1	Male
	F	2	Female
Action Taken	DRUG WITHDRAWN	1	Drug withdrawn
	DOSE REDUCED	2	Dose reduced
	DOSE INCREASED	3	Dose increased
	DOSE NOT CHANGED	4	Dose not changed
	UNKNOWN	0	Unknown
	DRUG INTERRUPTED	0	Unknown
	NOT APPLICABLE	9	Not applicable



Codelist Mapper

Patient Characteristics Fields				
E2B ID ↕	E2B Element	E2B Data Type	Mapped Item	Translate Values for E2B XML
D.2.1	Date of Birth (value)	Datetime	date_of_birth (Date of Birth)	
D.2.2a	Age at time of onset of reaction/event (number)	Number (5)		
D.2.2b	Age at time of onset of reaction/event (unit)	Text (50)		
D.5	Sex	Number (1)	sex (Sex) ▼	No values mapped ☰

Translate Values for E2B XML

E2B ID D.5

E2B Element Sex

E2B Data Type Number (1)

Mapped Item sex (Sex)

Codelist Sex (Sex) [Reset All](#)

Codelist Code	Codelist Label	E2B XML Value
M	Male	<input type="text"/>
F	Female	<input type="text"/>

Day 1
Impact to
Clinical Teams

No

Visibility
Safety Admin

Configuration
EDC Tools

Dependencies

NA





Randomization

Option to Require Login Credential to Reveal Treatment

- Overview

There is a new configuration option in Randomization setting that Site users will not have to enter login credentials to see the treatment

- Use case

There is a lot of clicking for some Sites when they have to enter login credentials for every subject to see a treatment.

Randomization Settings

Study Settings

Randomize by	Study
Randomization Type	Simple
Dynamic Site Assignment	No
Allow Unbalanced Randomization	No
Mask Treatment Data	Yes
Email Notification on Unmasking Data	
<u>Require Reveal Treatment Credentials</u>	Yes

Reveal Treatment [X]

This action will reveal the treatment assigned to the subject

Enter user name and password to reveal treatment

User Name*

Password*

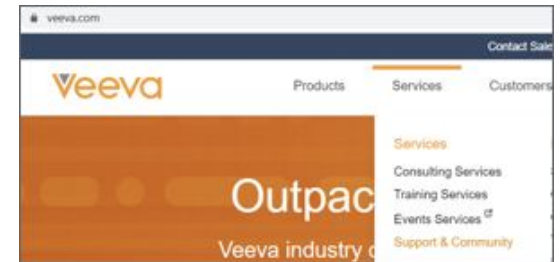
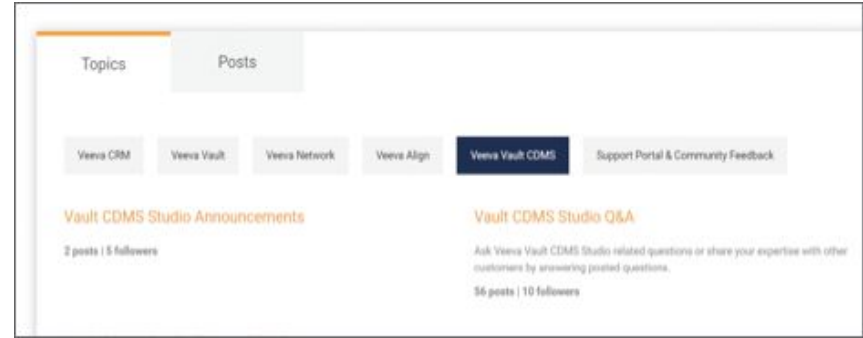
Cancel Reveal

No



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