21R2 Release Webinar
Studio, Admin, Coder

July 15, 2021

Veeva

CDMS Product Managers

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Migrations

21R2 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
11 JUL	12	13	14	15 **21R2 Release webinar** 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	16	17
18	19 **21R2 Pre-Release** Validation Docs	20	21	22	23	24
04	25	26	27	28	29	30
01 AUG	02	03	04	05	06	07
08	09 **21R2 General Release**	10	11	12	13	14

Customer Validation

21R2 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 21R2 Release**

Validation Docs

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

21R2 Release

- All Customers Vaults upgraded to 21R2

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)

21R2 Feature Summary

Sites

- Editable Grids
- Restrict users that can close system queries
- Support SSO pop up windows
- Misc. Enhancements

Local Labs

- Pending Approvals Count for Normals
- Incomplete State for missing units
- Override Normals Report
- Vault Diff Report for Analytes, Units, Codelist

Study Designer

- Annotated PDF Enhancements
- SDS Enhancements
- Cross Vault Copy
- Vault selector for Diff Reports

Rules

- Delayed execution
- Aggregate Identifiers & Functions
- Access Review Plans

Reports/Extracts

- Study Data Extracts Enhancements

Admin

- Multi-Role Security
- Review Plan Assignment Enhancements
- LMS Enhancements
- Study Role Enhancements
- New API Roles
- Delete Sites in Production

Other

- Protocol Deviations from CDMS to CTMS

Coding

- Japan Support
  - MedDRAJ
  - JDrug

Safety Link

- Multiple SAEs in a single case
- Support Null instances

Randomization

- Rule to send email when subject is randomized

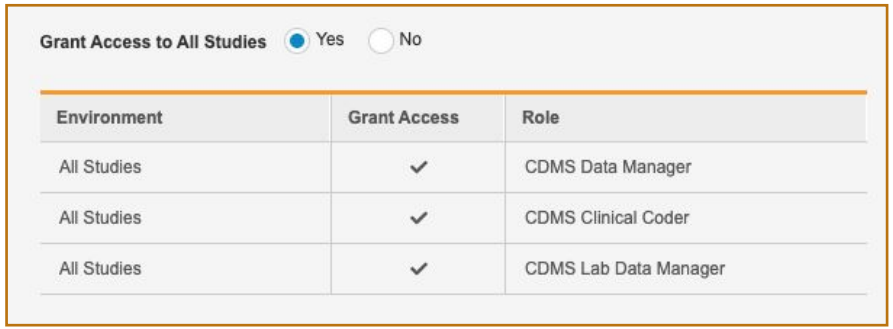
Multi-Role Security

Predefined Roles ensure individuals have all necessary functionality to perform their responsibilities without manual configuration, testing, and validation of permission settings

Multi-Role Security simplifies the setup and configuration of permissions for individuals who fulfill multiple roles, e.g. Data Manager and Coder

BENEFITS

- Simplifies configuration of roles and permissions
- Eliminates testing and validation work related to custom roles
- Ideal for small and mid-sized companies where individuals “wear many hats”
- Aligns with industry standards and Veeva best practices



Multi-Role Security

A phased implementation will roll-out availability across existing customers. New Vaults will have it automatically enabled.

21R2	21R3
Initial Customers	Targeted Broad Availability
	

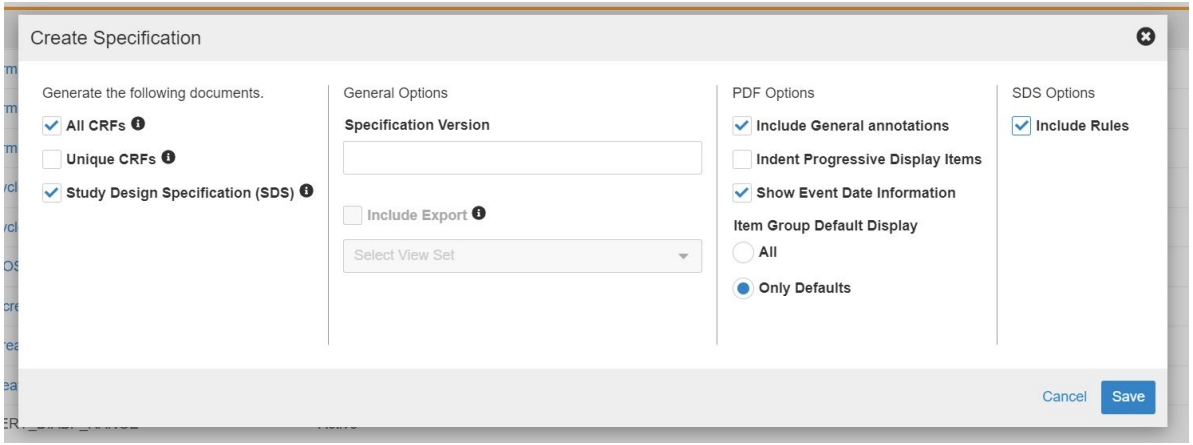
Feature Enablement

Impact to Clinical Team	**On Day 1 of the Release, will the Study Clinical Team (Sites, CRAs, Data Managers) see it?** Options: Yes or No
Visibility	**On Day 1 of the Release, which users see it?** Options: Sites, CRAs, Data Managers, Study Designers, Study Admin (Deploy, Safety, User), Coders, Coder Admin, Lab Manager, Randomization Manager
Configuration	**Is Configuration required to use the Feature?** Options: Studio, Tools, Coder Admin, Labs, Randomization, Vault Owner in Business Admin, Support
Dependencies	**Are there dependencies to use the Feature?** Examples: Labs must be enabled, Randomization must be enabled, Only Studies that have not deployed to Production...

Studio

Study Specification Enhancements

- Overview
  - As part of the SDS and PDF changes, improvements were made to the Create Specifications Screen
    - Combined PDF options to reduce clicks
    - Added support for new features
- Business Value
  - Improved usability



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration Studio

Dependencies

N/A

PDF Enhancements

- Overview
  - Added better support for EDC features and improved usability to include:
    - A summary page
    - A specification version
    - Better support for default Item Groups
    - Codelist and Unit names in the annotations
    - Disable rules in the annotations
    - Additional Item Group annotations
    - Layout and formatting improvements
    - Event annotations
- Business Value
  - Improved efficiency

Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

Studio

Dependencies

N/A

SDS Enhancements

- Overview
  - Made general enhancements to the SDS to improve usability and add support for new features
    - Added Event Group, Event, and Form names on the Schedule tree
    - Added Event Group on the grid
    - Carried down labels on Form Definitions
    - Added rule bindings to capture rule execution for Rules
    - Removed system rules from the rules tab to reduce noise
    - Added a Local Lab Configuration tab
    - Added a Summary Sheet
- Business Value
  - Improved efficiency

Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

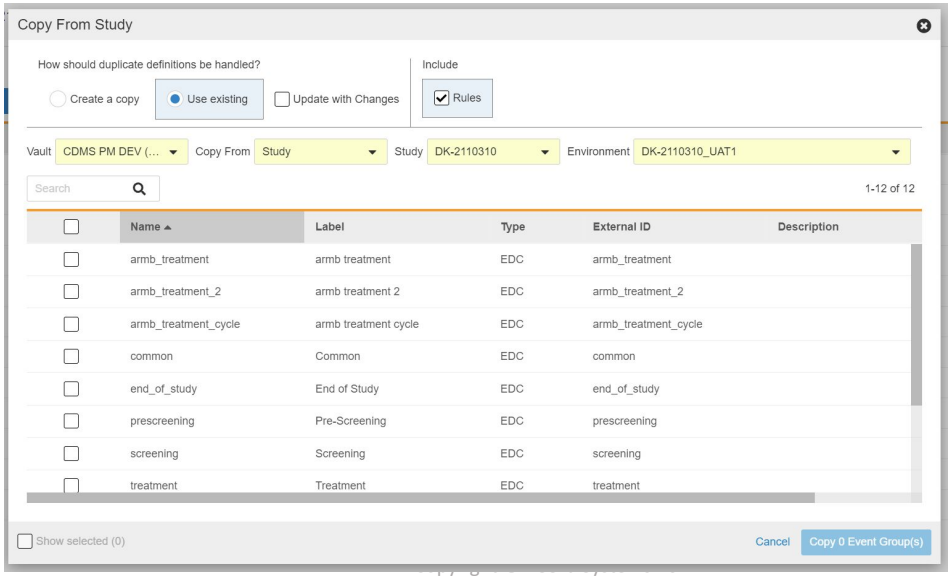
Studio

Dependencies

N/A

Cross Vault Copy

- Overview
  - Allows users to copy objects across vaults that they have access to
- Business Value
  - Improved study build times and better support for standardization



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

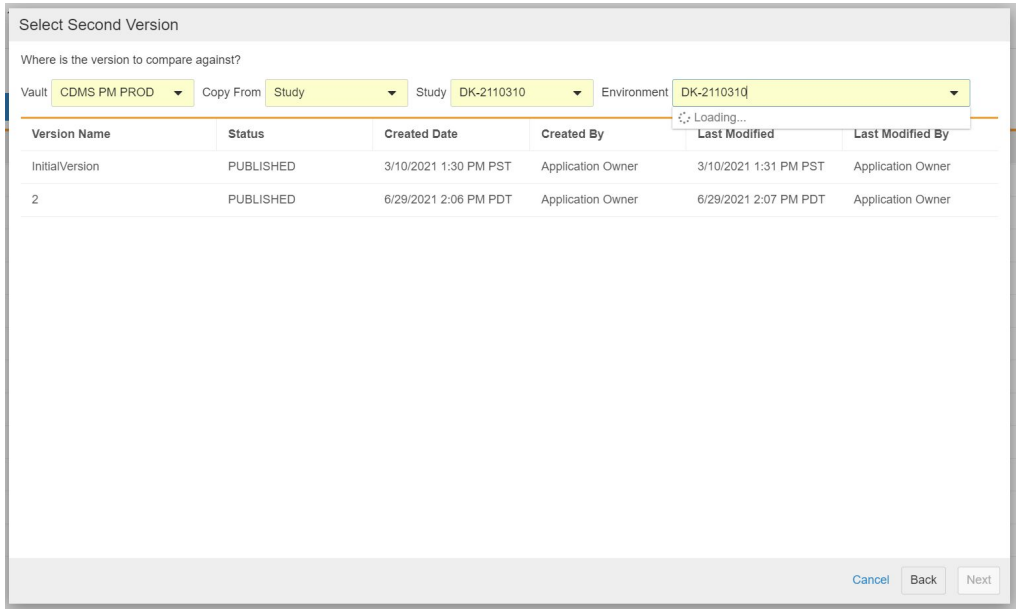
Studio

Dependencies

N/A

SSO Support for Cross Vault Comparisons

- Overview
  - Removed the login required for comparing differences across two vaults
- Business Value
  - Decreased user management effort, better Study Designer user experience



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

Studio

Dependencies

N/A

Asynchronous execution for rules

- Overview

  A new “Asynchronous” parameter can be selected when creating a query rule. When such a rule is triggered, the system will put it in a queue for processing. The triggering action (e.g. form submit) will not wait for the result of the rule evaluation to complete, thus improving performance.

  Asynchronous queries will be created in the background and displayed in the application on the next “page refresh” after their creation, for example navigating to a new form.

  Note: Send email, create protocol deviation, override review plan and create assessment rules will be set as “Asynchronous” by the system. Those actions are already asynchronous, so there is no change in functionality.

- Business Value

  With the introduction of link and aggregate identifiers, rules can look across more and more data points and aggregation of data points.

  This can potentially increase the amount of time it takes to run all the rule evaluations on form submit. To preserve performance, query rules can be run asynchronously.

Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

Studio

Dependencies

N/A

Error console for asynchronous rules

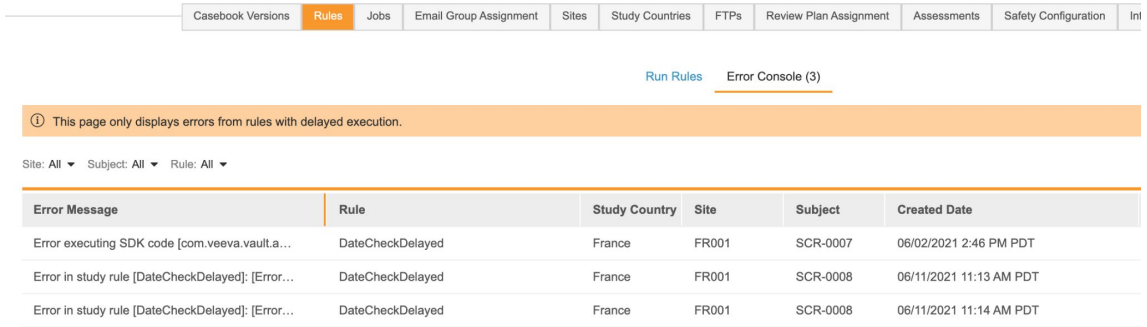
- Overview

  When an asynchronous rule fails, the error message and the location of the error (e.g. which form submit triggered the rule) will be recorded. An error console is accessible in the Rules tab of EDC Tools for users with the Run Rules permission.

  Users with the Run Rules permission for the study where the failure occurred will also receive an email notification that a rule failed. Vault Owners are excluded from that notification.

- Business Value

  With the introduction of asynchronous rules, rule failures will not be observable directly in the application and need to be recorded for review by system administrators or study designers.



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

Studio

Dependencies

N/A

Aggregate identifiers and functions

- Overview

  The rule editor now allows study designers to use an asterisk within brackets in an identifier, to indicate that the values returned for that identifier need to be considered as an array of values.

  Aggregate identifiers cannot be used “standalone” and have to be wrapped in a function that can handle aggregates, like Sum(), Min(), …

  Aggregate identifiers can currently be of all data types, except Boolean and Time.

  Example: Max(@Form.PK[*].Measurement) -> Max([5, 15, 32]) -> 32

- Business Value

  There are use cases where study designers want to consider the data entered as an array of values, instead of evaluating each data point individually, so that they can find a minimum/maximum, find a specific value, sum all values, etc.

Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration Studio

Dependencies

N/A

Admin

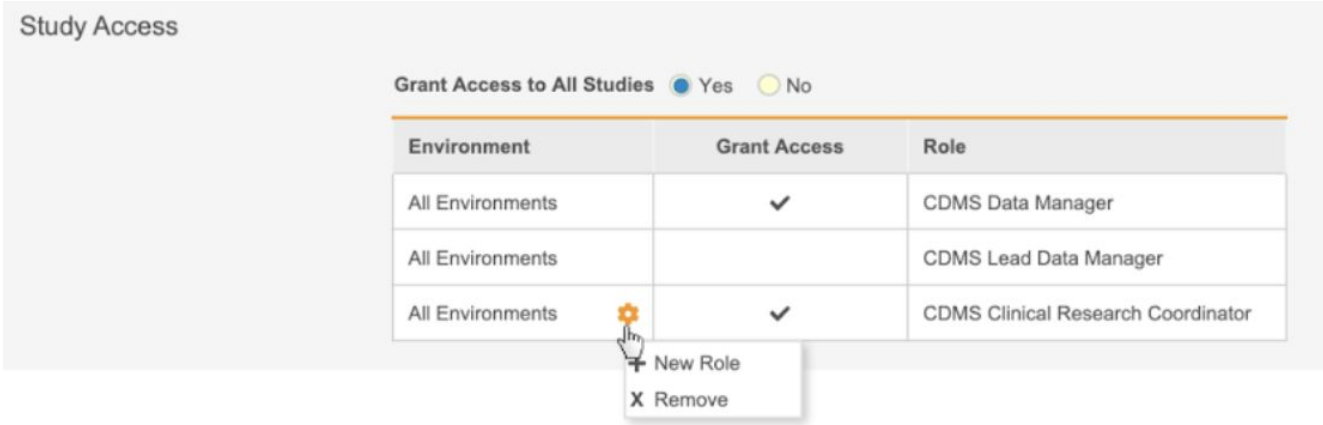
Multi-Role Security

- Overview

  Vault CDMS extends the current security model to allows users to have multiple Study Roles in the same Study. A user can have up to 15 distinct roles in a vault, either across the same study or across multiple studies. This model leverages the Role Based Security feature. If you have more than one Application Role in a study, resulting access to a study is the combination of all your permission across the roles. All users will now share a common security profile, CDMS All Access.

- Business Value

  Users can have multiple roles in a study.



Day 1 Impact to Clinical Teams

No

Visibility

User Admin

Configuration

Support

Dependencies

N/A

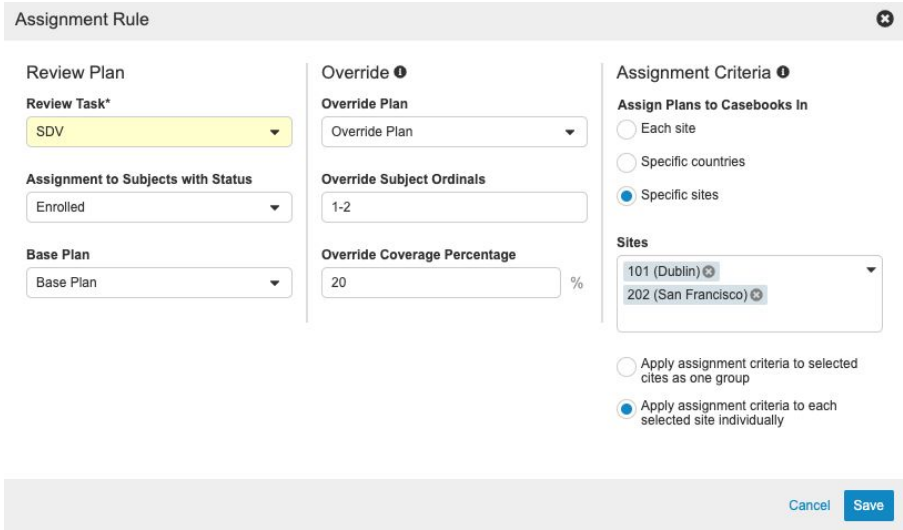
Multiple Sites in Review Plan Assignment

- Overview

  With Targeted SDV (Source Data Verification) and DMR (Data Management Review), your organization can define SDV or DMR requirements for a subject in a Review Plan. You can now configure overrides for Each Site, For Group of Sites or Countries.

- Business Value

  Users can assign plans to selected Sites Individually or as a Group.



Day 1 Impact to Clinical Teams

Yes

Visibility

Data Managers

Configuration

EDC Tools

Dependencies

N/A

Early Study Access

- Overview

  If a Casebook Definition does not yet exist for a Study, the Active Version field on Sites is no longer required. This allows users to configure and begin training for a Study before a study design is complete. The Get Enrollment check now occurs every 12 hours, instead of every 24 hours. Vault checks for enrollment at 12:00 AM and 12:00 PM, based on the vault's timezone.

- Business Value

  Users can now create a Site or User without needing a study design.

My Studies > Labrinone

Search | Environment Type: All

Environment	Highest Casebook Version	Study Build	Environment Type	Reason for Change	Last Deployment Date	Vault
Labrinone_DEV1	1	1	DEVELOPMENT (1 of 2)			cdmspmdev
Labrinone_UAT1		1	UAT (1 of 5)			cdmspmdev
Labrinone_TRN1		1	TRAINING (1 of 2)			cdmspmdev
Labrinone		1	PRODUCTION (1 of 1)			cdmspmdev

Day 1 Impact to Clinical Teams

Yes

Visibility

Data Managers, User Administrators

Configuration

EDC Tools

Dependencies

N/A

Study Role Enhancements

- Overview

  We made several improvements to the available permissions and standard Study Roles. We added the following new permissions:

  - **View Users**: Controls the ability to view Users
    - Assigned to the standard CDMS User Administrator role and any custom Study Roles that have the Manage Users permission assigned
  - **View Query**: Controls the ability to view EDC Queries
    - Assigned to the following standard Study Roles and any custom Study Roles that have the Open Query, Answer Query, Close Query, or Close All Query permissions assigned:
  - **View Study Sites**: Controls the ability to view Sites
    - Assigned to the CDMS Lead Data Manager, CDMS Study Designer, CDMS Librarian, and CDMS User Administrator roles and any custom Study Roles that have the Edit Study Sites assigned.

We relabeled the following permissions:

- Manage Study Sites as **Edit Study Sites**
- Manage Users as **Edit Users**
- View Query (existing permission for viewing queries in Workbench) as **View CDB Query**

Day 1 Impact to Clinical Teams

Yes

Visibility

Study Admin

Configuration

System Tools

Dependencies

N/A

Study Role Enhancements (contd)

We granted the View Casebook permission to all Study Roles, both standard and custom, that have the Data Entry permission assigned.

We granted the View Casebook, Schedule Reports, and Reports Dashboards Tab permissions to the CDMS Auditor Read Only study role.

We created the following new standard Study Roles:

- **CDMS Super User**: Users with this study role can access all areas of the application and perform all actions within those areas. This role is in the Administration query team. This role is only available in non-production environments.
- **CDMS API Read Only**: Users with this study role have read-only access to the CDMS API. This role is in the Other query team.
- **CDMS API Read Write**: Users with this study role have read and write access to the CDMS API. This role is in the Other query team.

Day 1 Impact to Clinical Teams

Yes

Visibility

Study Admin

Configuration

System Tools

Dependencies

N/A

API Enhancements

We have 3 new APIs.

- Retrieve All Users API (new version)
  - **GET** /api/v21.2/app/cdm/users?study_name={study_name}&user_name={user_name}

- Open Query by Item Record ID
  - **POST** /api/{version}/app/cdm/items/actions/openquery

- Open Query by Event Record ID
  - **POST** /api/{version}/app/cdm/events/actions/openquery

Day 1 Impact to Clinical Teams

Yes

Visibility

Study Admin

Configuration

N/A

Dependencies

N/A

CDMS to CTMS Connection: Protocol Deviations

- Overview

  Protocol Deviations created in Vault CDMS can now be configured to flow into Vault CTMS via the Spark Connection. Once configured, creating or updating a Protocol Deviation in CDMS (either programmatically or manually) triggers an action in CTMS to either update or create the matching Protocol Deviation in CTMS.

  Note: Protocol deviation data only flows one direction (into CTMS) with the Spark Connection. Any updates made in CTMS don't transfer back into CDMS.

- Business Value

  Protocol Deviation records created in CDMS can now flow automatically into CTMS for a centralized location for managing Protocol Deviations.

Day 1 Impact to Clinical Teams

No

Visibility

Vault Owners

Configuration

Business Admin

Dependencies

Vault CTMS

Reports

Study Data Extracts Enhancements

- Overview

Enhancements to the SDE including:

- Option to use the External ID instead of item names as column headers
- Option to split clinical Datetime item columns into two separate Date and Time columns
- Option to include forms marked intentionally left blank in clinical datasets
- Option to exclude blank forms from clinical datasets
- Option to specify the Zip File Name of their SDE export file
- Option to specify the FTP external connection directory path
- Support for custom objects extraction after configuration in Business Administration

Changes to the SDE:

- If a clinical dataset is set up for form linking, there will be a LINKEDTO column displaying information about the forms linked to that dataset
- Type and Length columns were added to Definitions file
- For clinical datetimes, the Datetime in the Site's timezone and the Datetime in the User running the job's timezone will be **treated as text and will no longer be using the SAS formats** such as DATETIME22.3., and TIME5. The change to text was due to inconsistencies we were finding with SAS conversions in handling different timezones
- Subject Status Dates were added to the SYS_SUB file

- Business Value

Users will have more flexibility regarding customizing their SDE export by being able to include additional columns, as well as the ability to choose where the file goes within their FTP connection. There will also be custom object support to allow custom object information to be extracted.

Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Managers

Configuration

N/A

Dependencies

N/A

Study Data Extracts Enhancements

- Overview

  New System Datasets

- Business Value

  Users have access to new dataset files when Assessments, Local Labs, Protocol Deviations, and Randomization modules are enabled

Description	Dataset Name
Assessments System Dataset	SYS_ASM
Assessments Replies System Dataset	SYS_ASMR
Protocol Deviations System Dataset	SYS_PD
Randomization Enrollment System Dataset	SYS_RAND
Lab Normal Ranges System Dataset	SYS_LABRANGES
Lab Locations System Dataset	SYS_LABLOC
Lab Analytes System Dataset	SYS_ANALYTES

Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Managers

Configuration

N/A

Dependencies

N/A

Coder

MedDRAJ

- Overview

  Vault Coder offers MedDRAJ to code and autocode Japanese Adverse Events and Medical History terms. It can autocode from the Dictionary and the Synonym List.

  Coders can search the Dictionary using Kanji, Hiragana, and Katakana scripts to code in Japanese. Both full-width and half-width are supported.

  All Listings and Extracts are capable of displaying MedDRAJ coding.

  MedDRAJ Synonym Lists can generate relevant Japanese suggestions. Coder Admins can upversion both MedDRAJ Forms and Synonym Lists.

- Business Value

  Japanese language studies are more holistically supported in CDMS.

Day 1 Impact to Clinical Teams

No

Visibility

Coder Administrator

Configuration

Coder Tools

Dependencies

N/A

JDrug

- Overview

  Vault Coder offers JDrug to code and autocode Japanese medications. It can autocode from the Dictionary and the Synonym List.

  Coders can search the Dictionary using Kanji, Hiragana, and Katakana scripts to code in Japanese. Both full-width and half-width are supported.

  All Listings and Extracts are capable of displaying MedDRAJ coding.

  JDrug Synonym Lists can generate relevant Japanese suggestions.

- Business Value

  Japanese language studies are more holistically supported in CDMS.

Day 1 Impact to Clinical Teams

No

Visibility

Coder
Administrator

Configuration

Coder Tools

Dependencies

N/A

Safety Link

Multiple SAEs per Case

- Overview

  Safety Link can now be configured to include multiple Serious Adverse Events in a single Safety Case. This is helpful when capturing a series of related SAEs. For example, if a subject was hospitalized for a heart attack and then, a week later, had a stroke during the same hospital visit, both of those SAEs would be included in the same Safety Case.

- Business Value

  Combining SAEs into a single Safety Case reduces the need for manual data entry in the safety system.

Day 1 Impact to Clinical Teams

No

Visibility

Safety Admin

Configuration

Safety

Dependencies

N/A

Integration Enhancements

- Overview

  Safety Link now offers the ability to indicate that the Investigational Product is blinded. It is able to identify the MedDRA version and is configurable to use a NullFlavor of 99999999 for coding.

- Business Value

  These updates offer enhanced integrations with safety systems.

Day 1 Impact to Clinical Teams

No

Visibility

Safety Admin

Configuration

Safety

Dependencies

N/A

Randomization

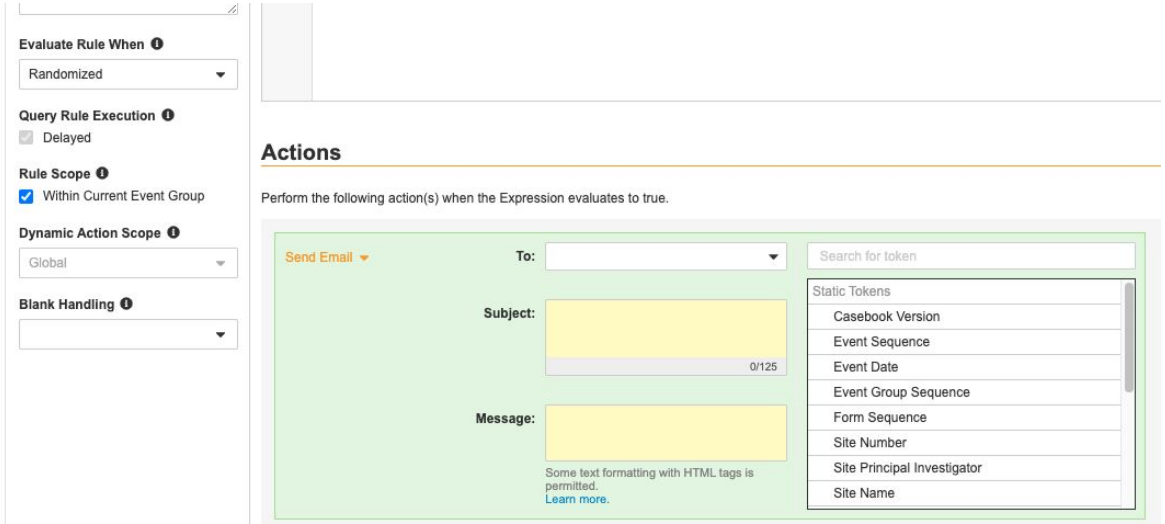
Rules: Send email once Subject is Randomized

- Overview

  For studies with Randomization enabled, a rule to can be created for an email to be sent once subject is Randomized

- Business Value

  Notify relevant parties by email when subject is randomized



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

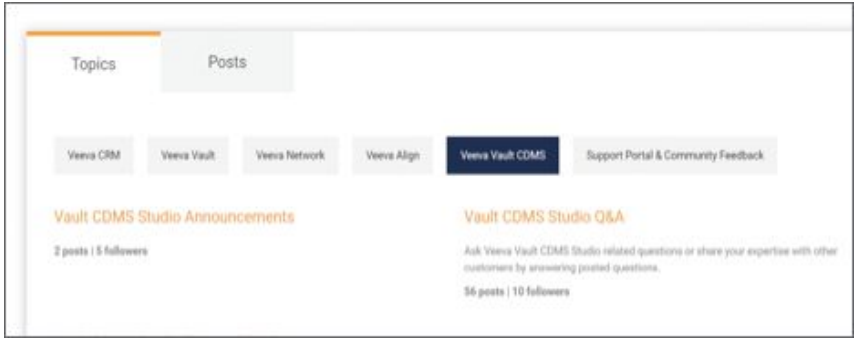
N/A

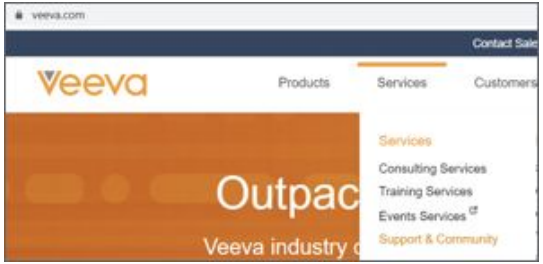
Dependencies

Randomization Enabled

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