22R2 Customer Webinar
Studio, Admin, Coder

July 7, 2022

Veeva

CDMS Product Managers

Dennis Kochanski

Sr. Product Manager

Studio, Library

Eric Haas

Product Manager

Tools, User Mgmt

Mohammed Al-Adeeb

Sr. Product Manager

Coder, Safety Link

Lindsay Chan

Technical Product Manager

Extracts

Sharon Lin

Sr. Principal Product Manager

Local Labs, Randomization

Natalie Moore

Product Manager

Rules

Eric Emerton

Principal Product Manager

APIs

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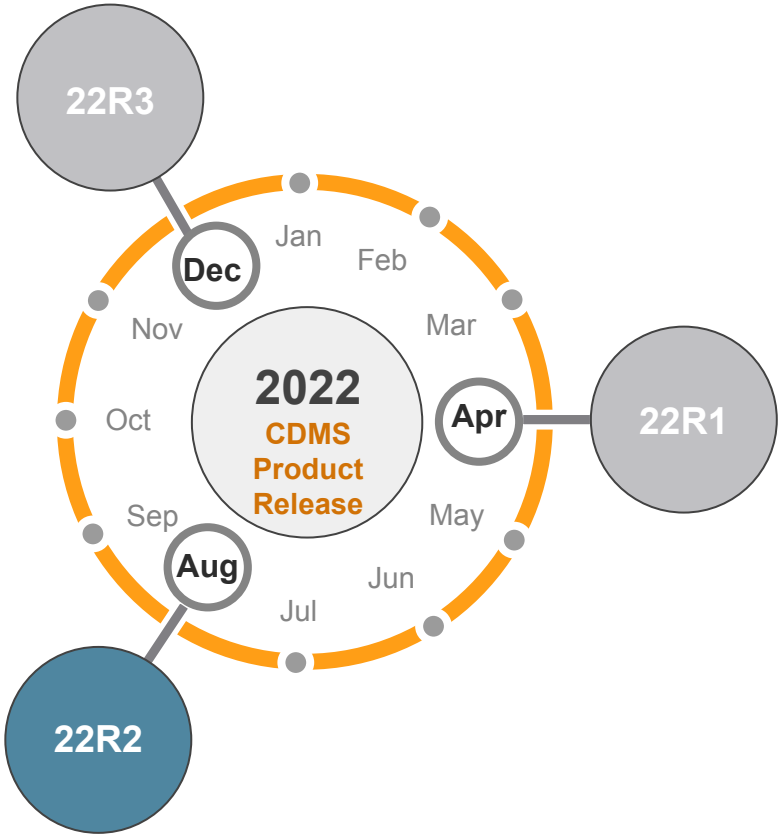
Veeva Vault Release Schedule



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22R2 Release Calendar

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

Customer Validation

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22R2 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 22R2 Release**

Validation Docs

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

22R2 Release

- All Customers Vaults upgraded to 22R2

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts

Available Resources

https://cdmshelp.veeva.com/lr/rn/general-releases/22r2/

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

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22R2 Feature Summary

Sites

- Data Entry updates
- Audit Trail Enhancements
- Assessment Enhancements
- Reassessments

Reports/Extracts

- Study Summary Metrics Report
- Event Progress Listing - Review Data
- Additive Review Listing
- Listings Enhancements
- SDE Enhancements
- Jobs Enhancements

Study Designer

- Property Panel Enhancements
- Object Usage Report
- Codelist Max Length
- General Rules Enhancements

Other

- CTMS Restricted Data Support
- CTMS Arms & Cohorts Support
- CDMS APIs

Admin

- Copy Study Data
- EDC Tools Study Settings
- Study Role Enhancements
- User Management Enhancements
- Learning Management Enhancements
- My Training Tab
- Vault Level Deployment to Template Vaults

Local Labs

- Global Versionless Labs
- Lab Header updates

Coding

- Dictionary Search Result Enhancement

Safety Link

- Mappable E2B ID E.i.9
- Follow-up vs Amendment

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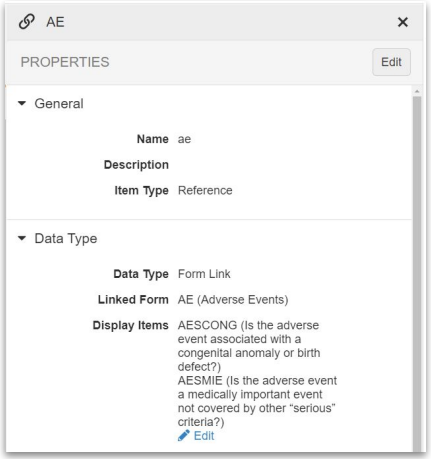
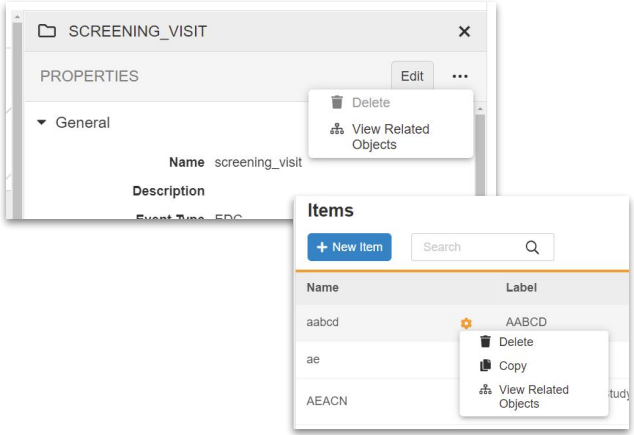
Studio

Property Panel Updates

- Overview
  - Updated the property panels to adopt a style similar to vault documents
  - Moved the actions from a property panel section
  - Removed Mandatory from Event and Form
- Use case

  Primarily this is to update the user experience standards displayed in studio. Mandatory was removed as it has no functionality in the system and caused user confusion.





Day 1 Impact to Clinical Teams

No

Visibility

Study designers, Librarians

Configuration

N/A

Dependencies

N/A

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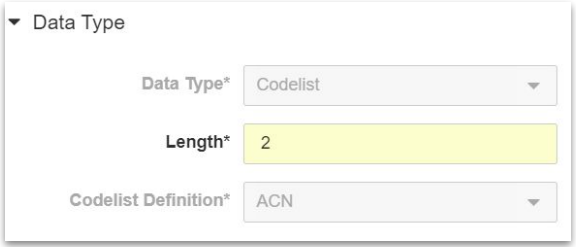
Codelist Length

- Overview
  - Added the ability to set the length for Codelist Items
  - Added validations if they are not the correct length for the Longest coded value in the codelist
    - Can turn off the Warning with a study setting (not in the UI)

- Use case

  CDB creates a SAS dataset, currently the dataset sets the length based on the length of the item. Currently users have no control over that item length so the system will now allow users to set the value.



Category	Section	Error Name	Description	Object
Error	Codelist	Item length is shorter than Codelist	The item max length is shorter than the longest length (11) of the coded value in the codelist items for this codelist	Item Definition:AEREL
Warning	Codelist	Item length is longer than the longest codelist item	The item length of the current item is longer than the length (11) of the longest code in the codelist items for the associated codelist	Item Definition:CMDOSFRM

Day 1 Impact to Clinical Teams

No

Visibility

Study designers, Librarians

Configuration

N/A

Dependencies

N/A

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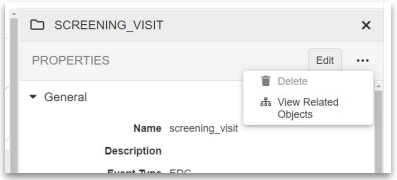
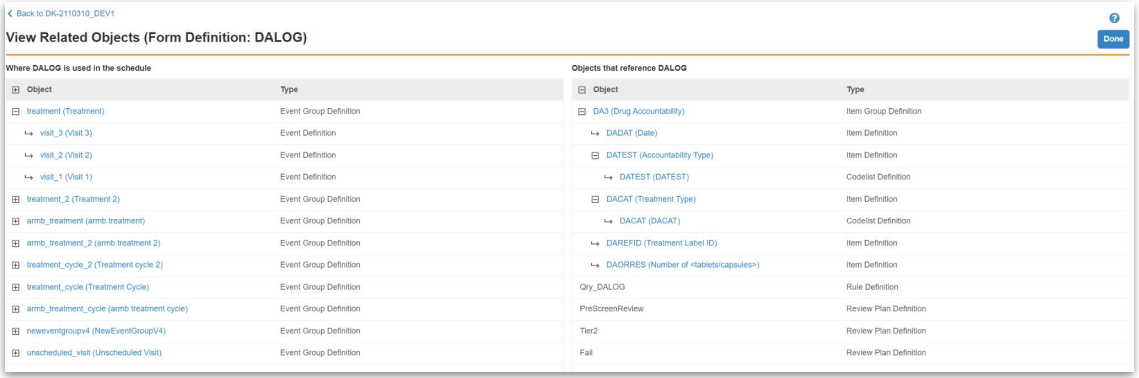
Object Usage

- Overview
  - Users can now view all places a definition is used or what definitions belong to that definition
  - Accessible through the definition actions
  - Available for Event Group, Event, Form, Item Group, Item, Codelist, Unit
- Use case

  Allows users to review potential impact for changes as well as find all uses of an object.





Day 1 Impact to Clinical Teams

No

Visibility

Study designers, Librarians

Configuration

N/A

Dependencies

N/A

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Rules

Rule Enhancements

- Overview
  - Fixed an issue where Event Groups were being deleted upon Event reset in a very particular use case
    - This does not impact the behavior of existing rules and just prevents casebooks from getting into an invalid state (missing event)
  - Results of Inactive Dynamic Rules are now ignored when deciding if a dynamic objects needs to be added or removed
    - This addresses the issue where an old rule was run to add/remove a dynamic object but a new rule was then added to add/remove that same object and the first rule was inactivated.
    - The old rule's result was interfering with the new rule's result in some cases and preventing the object from being correctly added or removed.

Day 1 Impact to Clinical Teams

No

Visibility

Study designers, Librarians

Configuration

N/A

Dependencies

N/A

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Admin

Copy Study Data from Production

- Overview
  - In EDC Tools, deployment administrators can now create a new environment type named "Post Production Test" (PPT).
  - A user with the new Copy Study Data to PPT permission in Production can then copy a select number of casebooks (no more than 100) from Production to the new PPT environment.
  - Copied Production data will consist of execution data (including restricted data, if applicable) and will not include CDB.
  - Once these casebooks have been copied to the PPT environment, a retrospective amendment may be run on this snapshot of Production data for the purpose of testing and validating the amendment.
- Use Case
  - Historically, LDM's and associated roles did not have the ability to test a post-production change with real data before the change was applied to Production.
  - With this feature, admin users can now test a retrospective amendment or other post-go-live changes without immediately committing to that change directly in Production

Day 1 Impact to Clinical Teams

No

Visibility

Deployment Admin, Lead Data Manager, Super User, Vault Owner

Configuration

N/A

Dependencies

Data Model 2

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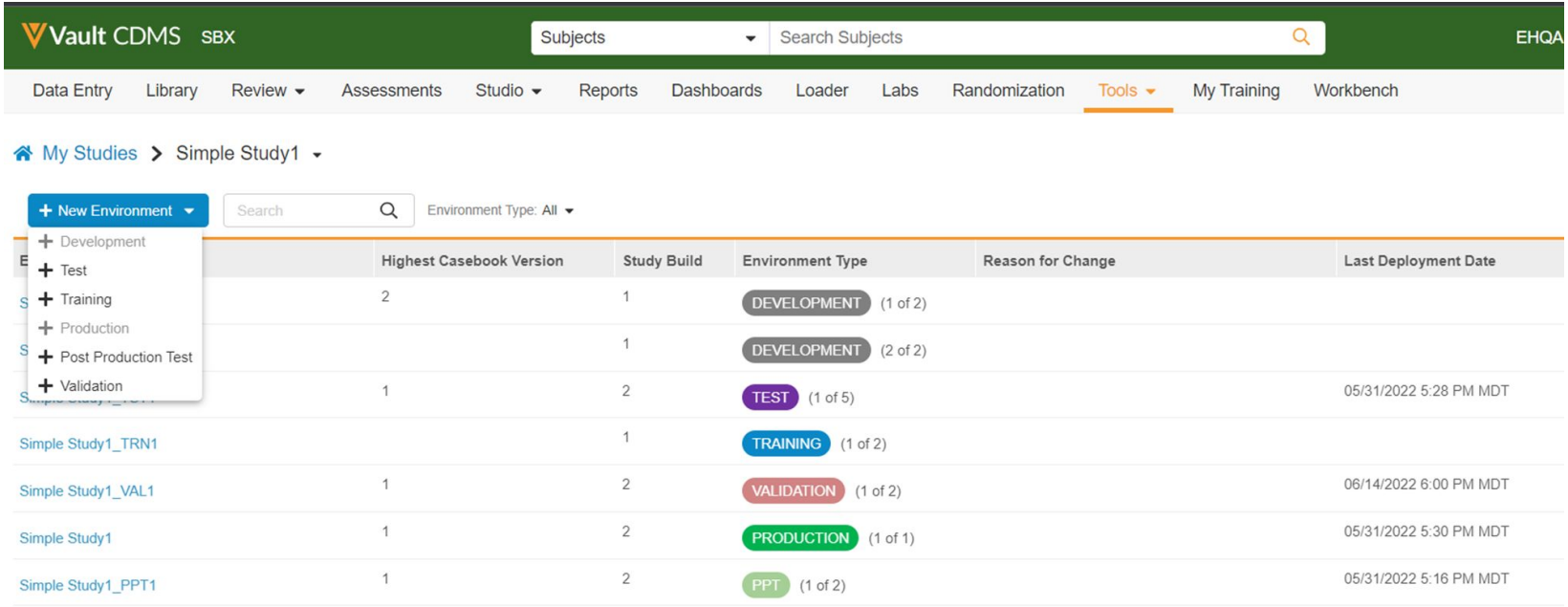
Copy Study Data from Production
Post Production Test Environment



Day 1 Impact to Clinical Teams

No

Visibility

Deployment Admin, Lead Data Manager, Super User, Vault Owner

Configuration

N/A

Dependencies

Data Model 2

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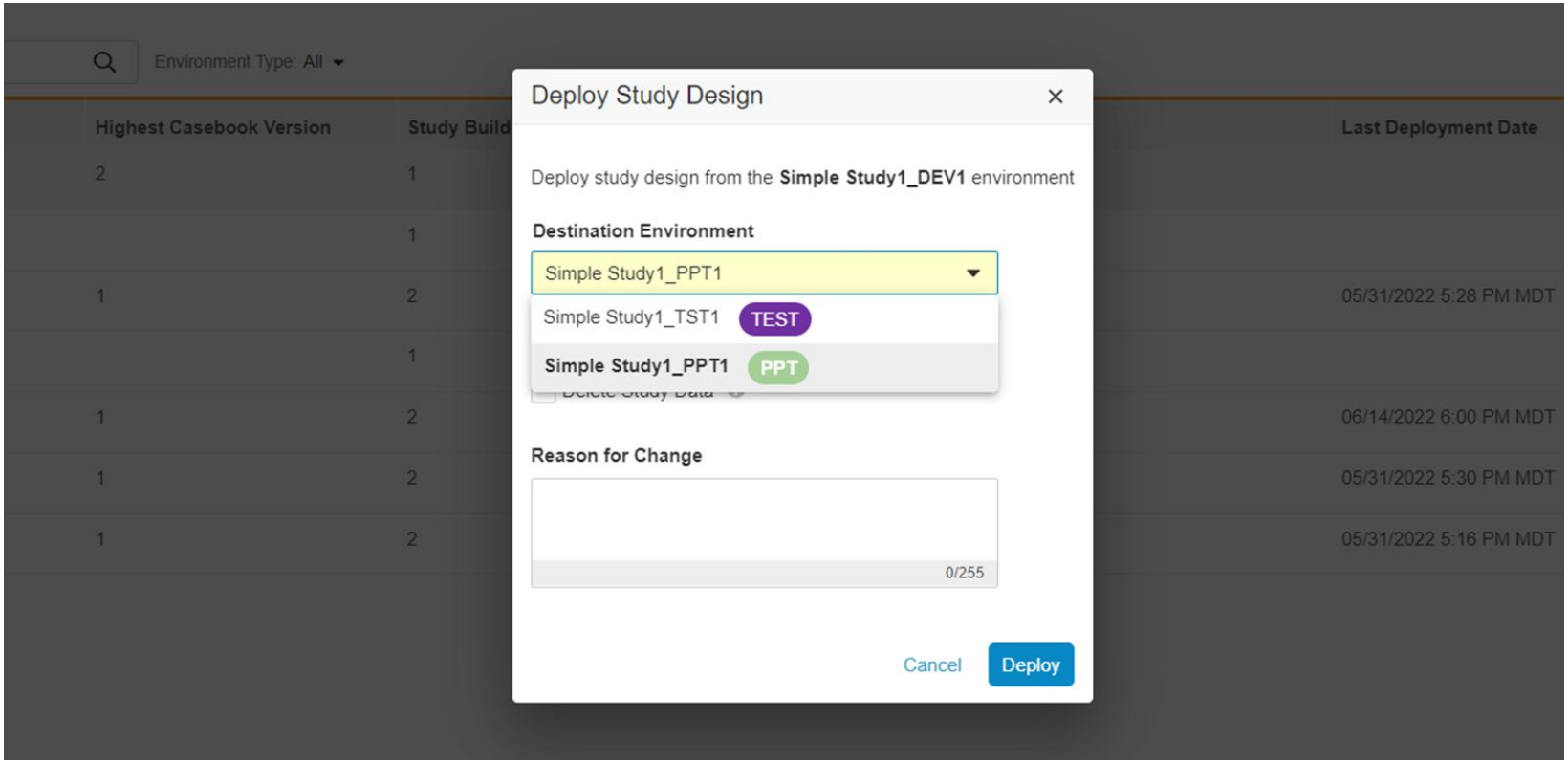
Copy Study Data from Production
Deployment to PPT



Day 1 Impact to Clinical Teams

No

Visibility

Deployment Admin, Lead Data Manager, Super User, Vault Owner

Configuration

N/A

Dependencies

Data Model 2

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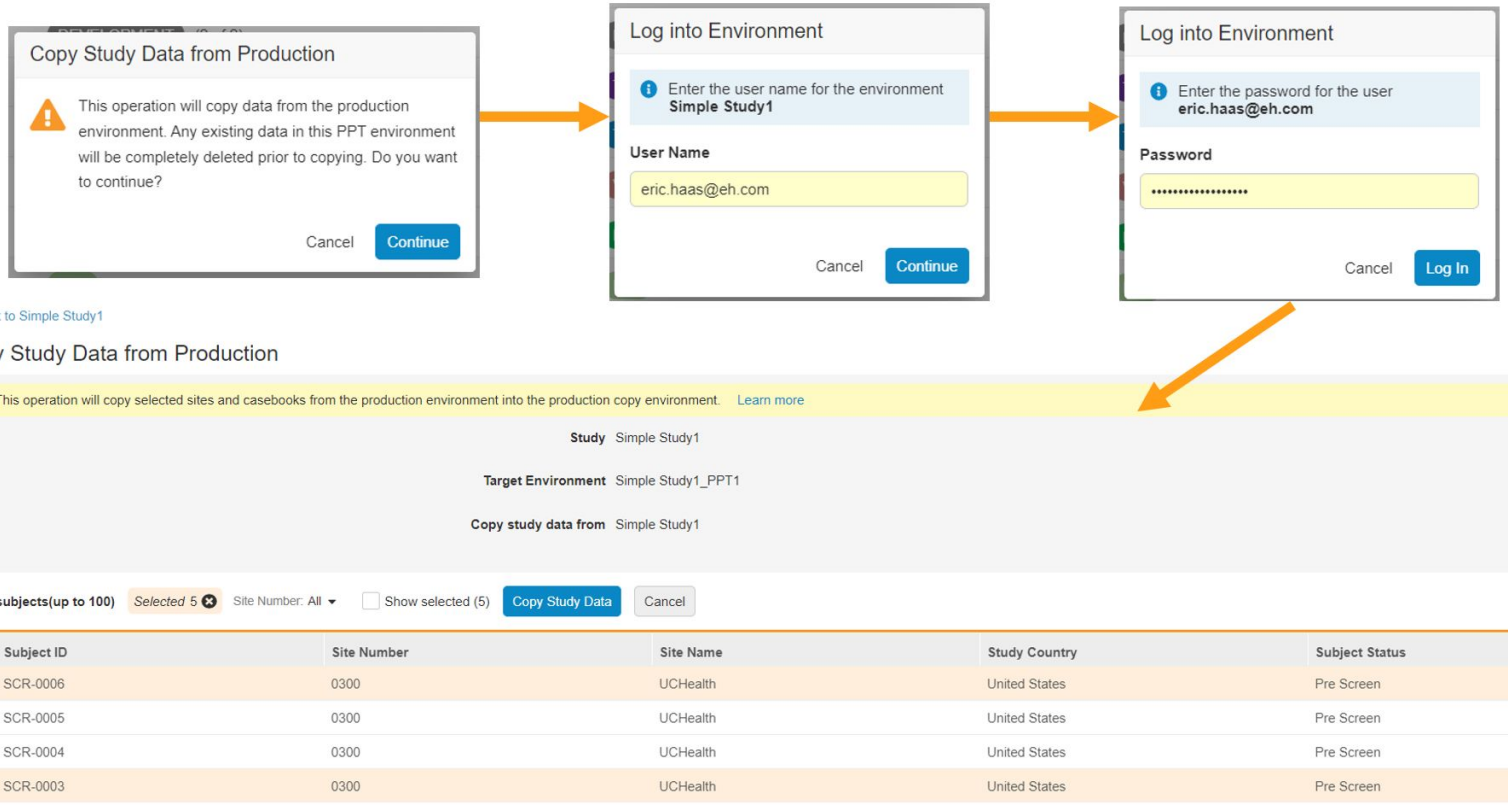
Copy Study Data from Production
Authentication and Casebook Selection



Day 1 Impact to Clinical Teams

No

Visibility

Deployment Admin, Lead Data Manager, Super User, Vault Owner

Configuration

N/A

Dependencies

Data Model 2

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My Training Tab

- Overview
  - *My Training* is a new main navigation tab that provides applicable users a convenient and straightforward mechanism to manage their training requirements and study access. From the My Training tab, users can:
    - Quickly determine whether they have any outstanding training for a given role
    - Click a link to open the learning portal in a new tab
    - Fetch their individual status from the LMS in real time

- Use Case
  - Previously, a user's training requirements, training status, and study access could be unclear without simultaneously inspecting the external training system transcript.
  - In addition, some platform users may have seen a vague error message when accessing the platform before all training requirements were met.
  - The addition of the My Training Tab eliminates these ambiguities by providing a central location to view and manage training and study access.

Day 1 Impact to Clinical Teams

Yes

Visibility

All

Configuration

LMS Enabled > Curricula Mapped to Role > Study Role assigned

Dependencies

LMS Integration

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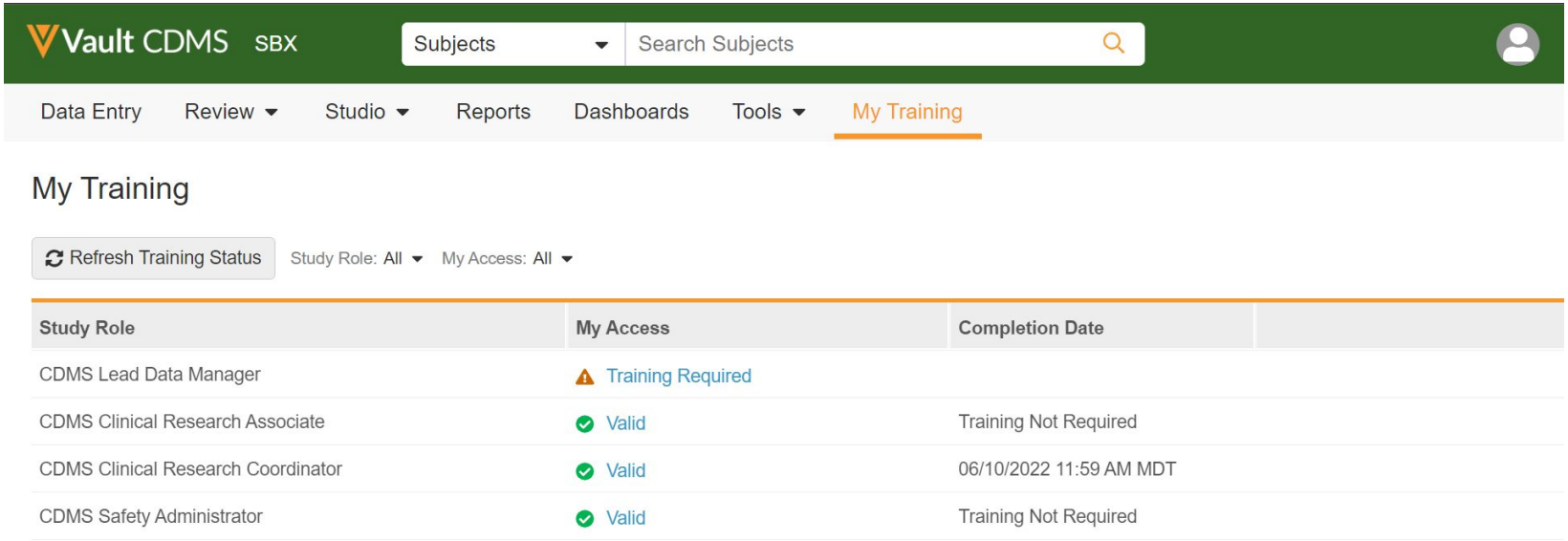
My Training Tab



Day 1 Impact to Clinical Teams

Yes

Visibility

All

Configuration

LMS Enabled > Curricula Mapped to Role > Study Role assigned

Dependencies

LMS Integration

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EDC Tools New Navigation Pattern

- Overview
  - With this release, we revamp the navigation pattern and UI of EDC Tools pages to provide an exceptional user experience. Enhancements include:
    - Moving all tabs to a left navigation panel
    - Providing study instance environment type, build version, and lock status throughout EDC Tools
    - Tab stickiness when navigating away and back to EDC Tools
    - Enhanced layout of Jobs, Casebook Versions, Review Plans and Rules subtabs

- Use Case
  - Previously, EDC Tools used a layout distinct from other CDMS components. These enhancements unify the look and feel of the platform, and make it easier to navigate and perform critical study configuration and processes.

Day 1 Impact to Clinical Teams

Yes

Visibility

All Tools users

Configuration

N/A

Dependencies

None

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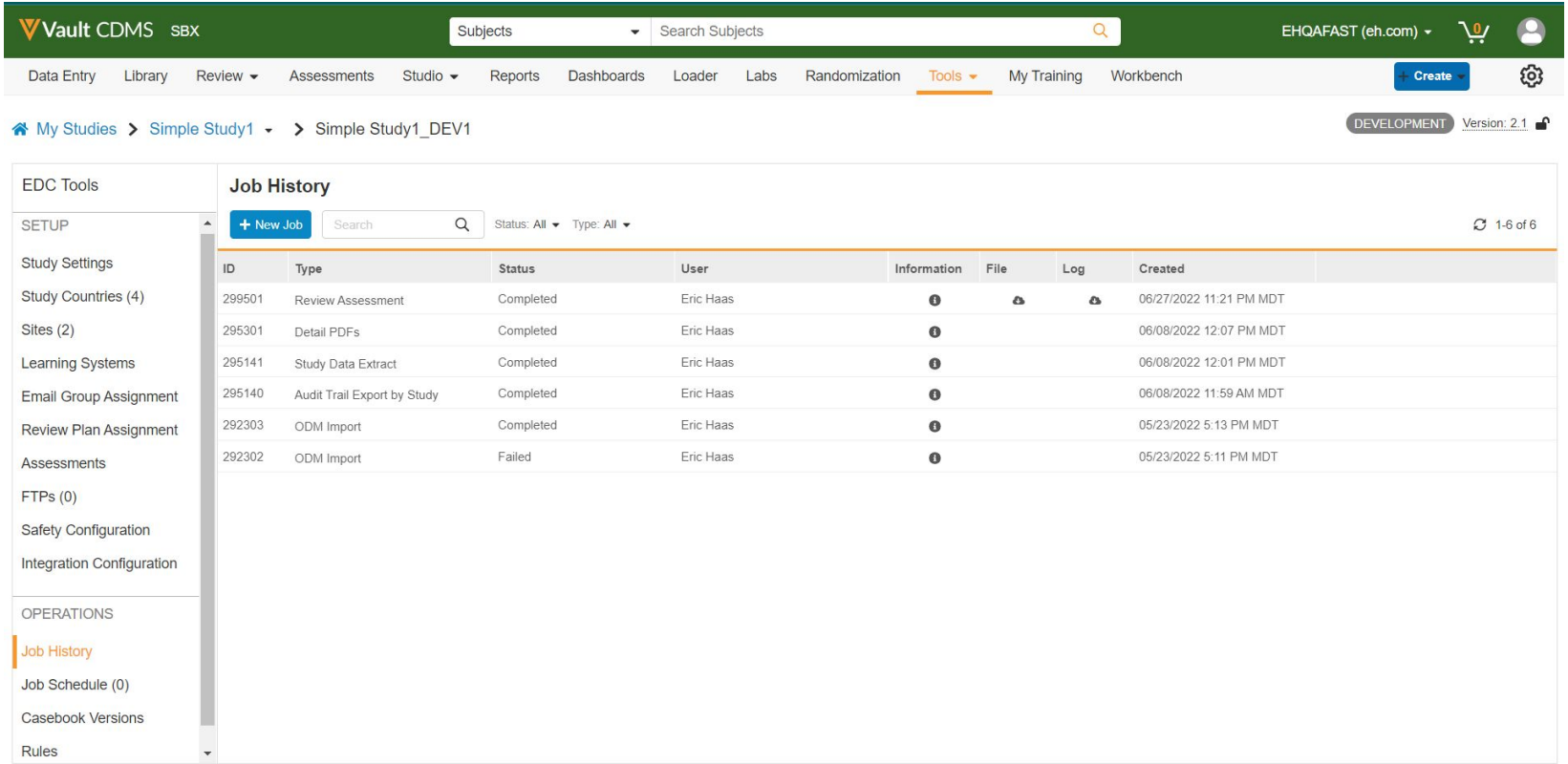
EDC Tools New Navigation Pattern



Day 1 Impact to Clinical Teams

Yes

Visibility

All Tools users

Configuration

N/A

Dependencies

None

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EDC Tools Study Settings

- Overview
  - With this release, we added a new landing page in EDC Tools, Study Settings, where users can manage the following study-level settings:
    - Enable Absorb Learning System
    - Include Absorb Course Details in the Training Report
    - Connect to Vault CTMS
    - CTMS Study Link ID

- Use Case
  - With this change, administrators can manage study settings that were previously only accessible from Business Admin. Bringing this functionality into the familiar EDC Tools tab provides enhanced usability and speed.

Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Manager, Librarian, Study Designer, User Administrator

Configuration

N/A

Dependencies

None

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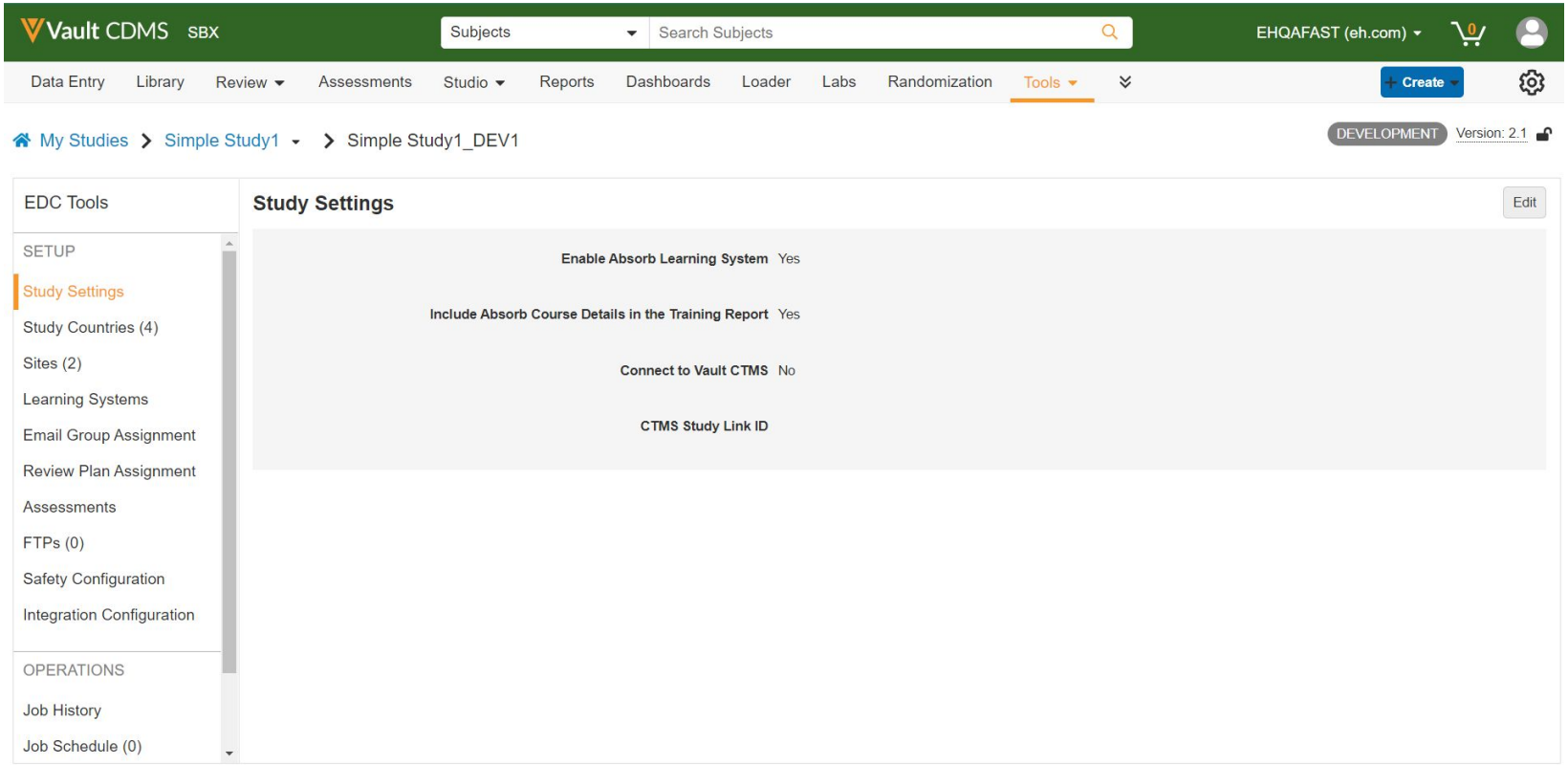
EDC Tools Study Settings



Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Manager, Librarian, Study Designer, User Administrator

Configuration

N/A

Dependencies

None

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Study Role Enhancements

- Overview
  - With this release, we have granted the *View Study Design* and *View Library* permissions to the CDMS API Read Only and CDMS API Read Write roles.
  - The *Copy Study Data to PPT* permission has been created and added to the CDMS Super User role
  - The *Edit Study Settings* permission has been created and added to the following roles:
    - CDMS Lead Data Manager
    - CDMS Super User Role
    - CDMS Librarian
    - CDMS Study Designer
    - CDMS User Administrator

Day 1 Impact to Clinical Teams

Yes

Visibility

User Administrators

Configuration

N/A

Dependencies

None

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User Management Enhancements

- Overview
  - The following fields are now available for editing in System Tools > Users:
    - Domain Admin
    - Service Availability Notifications
    - Product Announcement Emails
  - These fields can also be modified via user import and will be required in import sheets post-22R2.

- Use Case
  - With this change, Domain Administrators can create other Domain Admins, and User Administrators can enable service availability and product announcement emails directly through the User Management UI rather than Admin.

Day 1 Impact to Clinical Teams

Yes

Visibility

User Administrators
Domain Administrators

Configuration

N/A

Dependencies

None

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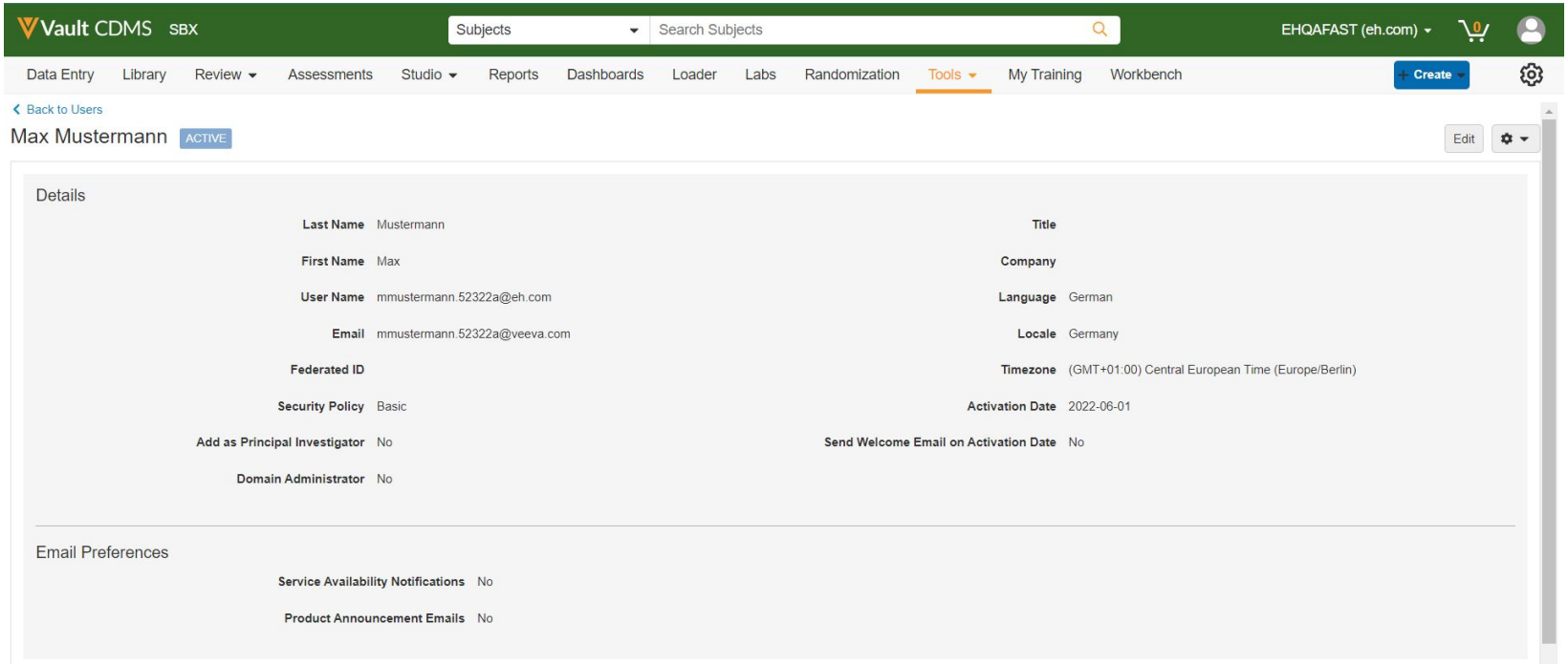
User Management Enhancements



Day 1 Impact to Clinical Teams

Yes

Visibility

User Administrators
Domain Administrators

Configuration

N/A

Dependencies

None

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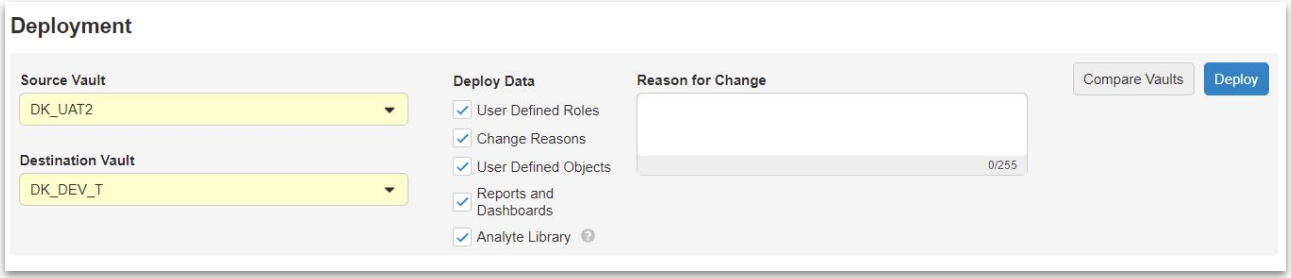
Vault Level Deployments - Template Vaults

- Overview
  - Vault level deployments can now deploy from UAT to a Template vault
  - This includes Vault Level Objects such as: User Defined Roles, Change Reasons, User Defined Objects, Reports and Dashboards, and the Analyte Library
- Use Case
  - Allows CROs to create a Template with validated Vault Level Objects to be available for cloning new CRO Sponsor vaults. Template vaults are connected to the CRO DEV/UAT as a template vault so studies created in DEV are not provisioned to them.



Day 1 Impact to Clinical Teams

No

Visibility

Deployment Admin, Lead Data Manager, Super User, Vault Owner

Configuration

N/A

Dependencies

None

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Extracts

Study Data Extracts Enhancements

- Overview

  In the 22R2 Version of the Study Data Extract, the following changes were made to fix incorrect data types:
  - The column CASEBDEF has a SAS Type of numeric in the SYS_EVT, SYS_SITE, and SYS_SUB datasets.
  - The column MANUAL has a Type of boolean in the SYS_Q dataset.
  - The column NSUBMITS has a Type of integer and a SAS Type of numeric in the SYS_ASM dataset.
  - The column IGSEQ has a Type of integer and a SAS Type of numeric, the column INACBYSYS has a Type of boolean, and the column LASTINACDT has a Type of datetime and a SAS Type of numeric in the SYS_PD dataset.
  - The column LABMODIFIER has a Type of boolean in the SYS_LABRANGES dataset.
  - The columns LABMODIFIER and LABSYSMANAGED have Types of boolean, and the column LABPREC has a Type of integer and a SAS Type of numeric in SYS_ANALYTES

- Use Case

  Users will be able to ingest the correct Data Type (Type) and SAS Type in their downstream programs and when utilizing SAS.

Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Managers

Configuration

N/A

Dependencies

N/A

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Study Data Extracts Enhancements

- Overview

  In the 22R2 Version of the Study Data Extract and the Core Listings Job, the Clinical Datasets and the SYS_LINKS (SDE only) dataset have additional columns to support Item to Form Linking released in 22R1:

  SYS_LINKS:
  - IGROUP: Item Group Label
  - IGROUPDEF: Item Group Definition Name
  - IGSEQ: Item Group Sequence
  - ITEM: Item Label
  - ITEMDEF: Item Definition Name

  Clinical Data:
  - [Form Link Item Definition Name]_LINKID: Item Form Link VOF ID

  Core Listings Clinical Data:
  - [Form Link Item Label] ([Item Group Name.Item Definition Name])_LINKID

- Use Case

  Users with Item To Form Linking enabled will have more information about the items linked on a form which they can use to relate datasets to each other.

Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Managers

Configuration

N/A

Dependencies

N/A

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Other Job Enhancements

- The following enhancements have been made to the Job Options dialog:
  - Job Type dropdown is disabled when editing scheduled jobs
  - The Restore Defaults button is no longer available for shuttles
  - Updated look and feel for radio buttons
- Use Case:
  - Consistency with UI/UX patterns

Day 1 Impact to Clinical Teams

No

Visibility

Lead Data Manager

Configuration

N/A

Dependencies

N/A

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Coder

Dictionary Search Results Enhancement

- Overview

Coders will be able to find more relevant results when searching phrases that include single characters such as the “E” in “Vitamin E," phrases with terms that include special characters such as “+Immu” in “+Immu boost," and phrases that include popular terms such as “carbonate” in “calcium carbonate." The Dictionary search can also return more accurate results when the search phrase includes non-relevant terms. For example, searching “Abdominal” in “Abdominal surgical scar." Coders can also search for exact match results only with the use of double quotes.

- Use case

Coders will find more relevant dictionary results in specific search phrases. They can also make use of double quotes for exact match only results.

Day 1 Impact to Clinical Teams

No

Visibility

Coder

Configuration

N/A

Dependencies

NA

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Safety Link

E.i.9 Country Where the Event Occurred

- Overview

The E2B ID E.i.9 ‘Identification of the Country Where the Reaction / Event Occurred’ is now mappable by Safety Link.

- Use case

When an SAE occurred outside of the site’s country, Safety Link can now automate the reporting of this site-reported value.

Day 1 Impact to Clinical Teams

No

Visibility

Safety Administrator

Configuration

EDC Tools

Dependencies

NA

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Follow Up as Label

- Overview

With this release, all follow ups generated by Safety Link are labeled as “Follow-Up”, instead of “Amendment”. This label is used in reports. In the E2B ID C.1.11.1 “Report Nullification / Amendment”, is now null, where previously it used the value “2”, which is reserved for amendments.

- Use case

While safety systems are correctly processing follow-ups from Safety Link, Safety Link now correctly labels a Follow-Up as a “Follow-Up” and not as an “Amendment”.

Day 1 Impact to Clinical Teams

No

Visibility

Safety Administrator

Configuration

EDC Tools

Dependencies

NA

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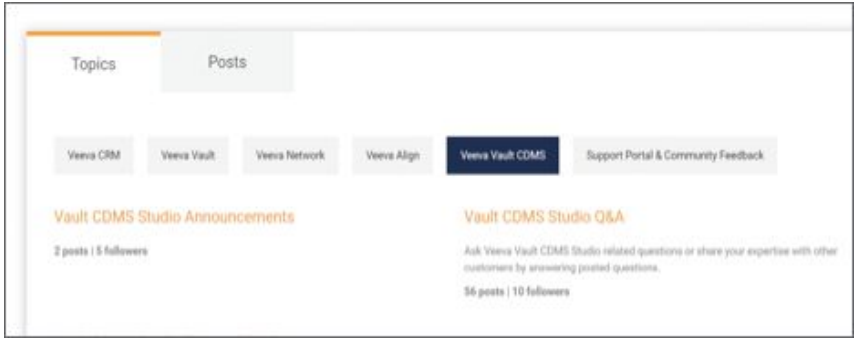
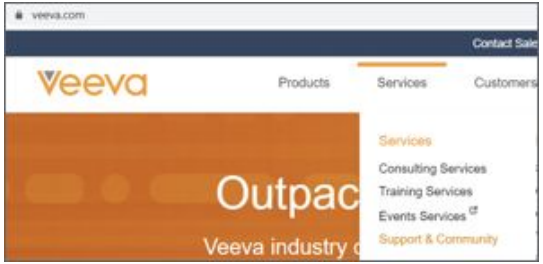
Closing / QnA

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





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Dedicated DEMO

For a dedicated demo of any these features,

please contact your

Account Executive OR

Customer Success Manager

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Thank you