20R2 Customer Webinar

Studio & Admin

July 23, 2020

Revisions - July 28, 2020

Veeva

Revisions 07/28/20

Revisions to the Deck 0n 07/28/20:

- Casebook Variables Feature changed from “New Studies Only” to “Existing studies”
- Rules Configurator Feature changed from “New Studies Only” to “Existing studies”
- Restricted Data Permission - typo change from Data Manager to Deployment Administrator.
- Updated Validation Documentation availability

Sharon Lin

Principal Product Manager, Veeva CDMS

Cory Etzcorn

Product Manager, Veeva CDMS

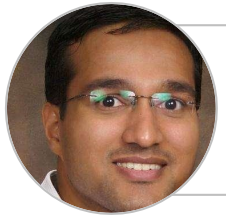
Veeva

CDMS Product Team

Dennis Kochanski
Senior Product Manager,
Vault CDMS

Mohammed Al-Adeeb
Senior Product Manager,
Vault CDMS

Quentin Paresys
Product Manager,
Vault CDMS

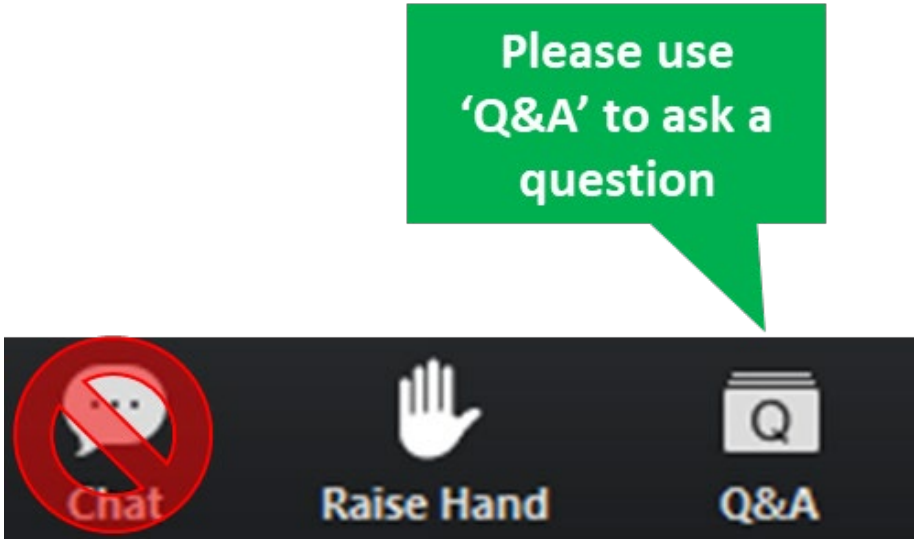


Rakesh Monassery
Senior Product Manager,
Vault CDMS

Important Disclosures

The following is intended to outline Veeva's general product direction. It is intended for informational purposes only and does not form part of any contract. It is not a commitment to deliver any specific functionality and it should not be relied upon in making purchasing decisions. Features and functions described in this document will be released commercially only when and if they become available. The development, release, and timing of the features or functionality of Veeva's products remains at the sole discretion of Veeva.

Interact With Us!



Veeva R&D and Quality

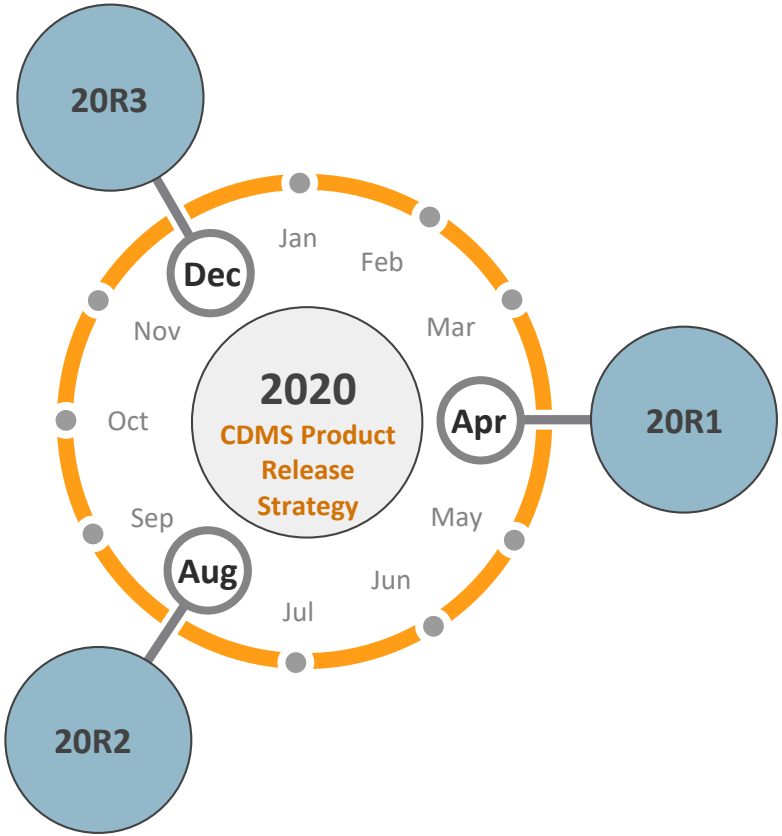
SUMMIT ONLINE

October 13–14, 2020

- Develop new industry partnerships
- Share best practices
- Network with sponsors, CROs, & sites

CLINICAL | QUALITY & MANUFACTURING | REGULATORY | SAFETY | IT

Veeva Vault Release Schedule



20R2 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
19	20	21 JUL	22	23 **20R2 Release webinar** 9 AM PT - All Customers 10 AM PT - Studio & Admin	24	25
26	27	28	29	30	31	1
2	3 **Validation Docs** **20R2 Pre - Release**	4	5	6	7	8
9	10	11 AUG	12	13	14	15
16	17	18	19	20	21 **20R2 General Release**	22

Customer Validation

Pre-Release Environment

https://login.veevavault.com

- Clone of UAT
  - Special Request for Dev
- Users
  - Contact Veeva Post Implementation Manager to add users
- Available up to 4 weeks after the 20R2 upgrade

AUG
Monday 3rd

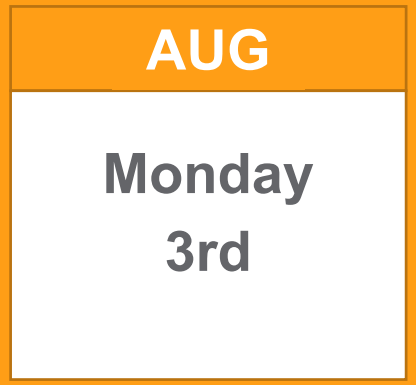
Validation Documents

On Monday, Aug 3

- Validation Project Plan
- IOQ Protocol
- Business Requirements Documents
- Validation Impact Assessment

On Monday, Aug 10

- Traceability Matrix
- System Release Memo
- Executed OQ Scripts (unexecuted in Word format available upon request)



20R2 Go Live

- ALL customer vaults upgraded to 20R2
- EU starts at 2:00pm PT
- APAC & US starts at 5:00 PM PT
- May take up to 6 hours

AUG
Friday 21st

- **Resources Available**
- https://cdmshelp.veeva.com/lr/rn/general-releases/20r2/
  - Important Dates
  - Notifications Opt-In
  - Feature information
  - Pre- Release Information
  - Release Information
  - Release Impact Assessment (RIA)

20R2 Feature Summary

Sites

- Restricted Data
- Delete Subject & Reset Event
- Study Closeout
- Translatable PDFs

CRAs/Data Managers

- Review UI Navigation Enhancement
- Review Functionality entirely in Review UI
- Performance Improvements
- Locking/Freezing Enhancements

Study Designer

- Cascading Form Deletion
- Form Copy Enhancements
- Copy Codelists and Units
- Validation Script for Rule Changes
- Template Vaults
- Relaxed Study Update Restrictions
- System Design Spec Enhancements
- Restricted Data Configuration
- Study Closeout Signature Def

Rules

- Query Future Dates for Events
- Query on Event Date out of Range
- Data Driven Review Plan
- Casebook Variables
- Rule Configurator
- Sequence Number in Expressions

Admin

- Dynamic Review Plans by Subject Status or Percentage
- Deploy Vault Level Configurations
- Vault Diff Report
- Delete Sites (Non-Production)
- Additional APIs
- Study Role Enhancements
- System Tools - Change Reasons

Coding

- Upversioning Impact Report
- Group Coding Enhancements
- Navigation Enhancements
- Reconstitute Code Request Job Enhancement
- Coding Data viewable by LDM and DM

Extracts/Listings

- Extracts Data and Definition Enhancements
- Data Listings - Restricted Data

CDB  **Early Adopter**

Labs  **20R3**

Randomization  **20R3**

Auto-On Features	Configurable Features		Visible
 **Auto-On**	 **Configuration**	 **Support**	•Sites •CRAs •Data Managers •Clinical Assessments •Coders •Coder Admin •Admins •Study Designers •Report Users •N/A
Turned On Day 1 **Automatically available** ***For New Studies Only**	**Turned Off** **Requires Configuration**	**Turned Off** **Requires Enablement** **Product Support Request**	

Studio (Study Designer)

Cascading Form Deletion

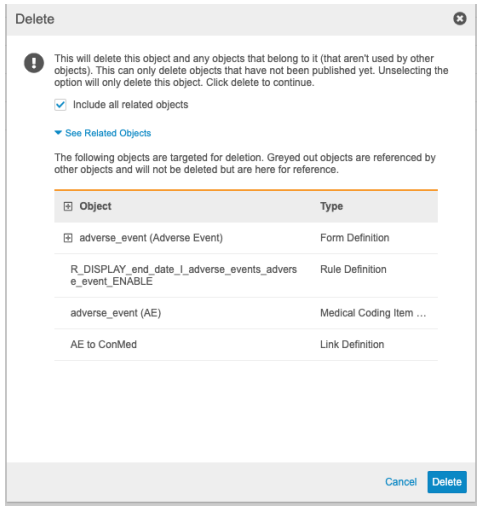
- Overview

  During form deletion, there is an option to “include all related objects” and delete any related objects associated to that form. But if that related object is associated to another object it will not be deleted.

  This is useful when you have copied a form, and there were objects such as item groups, items, or rules that were associated with it that does not apply to your current study.

- Business Value

  This provides a method to clean up a study before the initial deployment – avoiding issues with deployments and study amendments.



Automatic

Visible

VISIBLE TO ALL STUDY DESIGNERS

Form Copy Enhancements

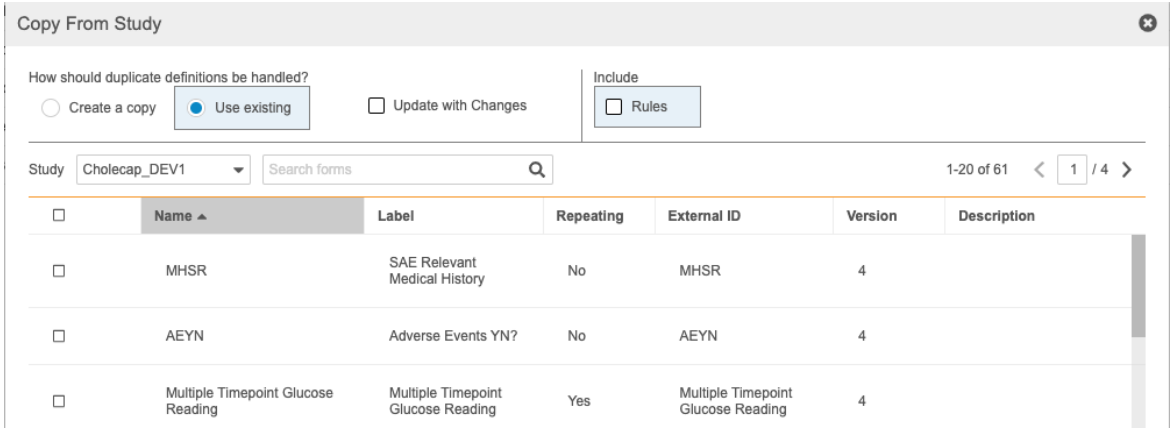
- Overview

  The default setting when copying form is now to “use existing”

  Coding configuration is now copied. And there is a coding validation check, to see if the verbatim and related item is still available.

- Business Value

  Reduces development time for new studies.



Automatic

Visible

VISIBLE TO ALL STUDY DESIGNERS

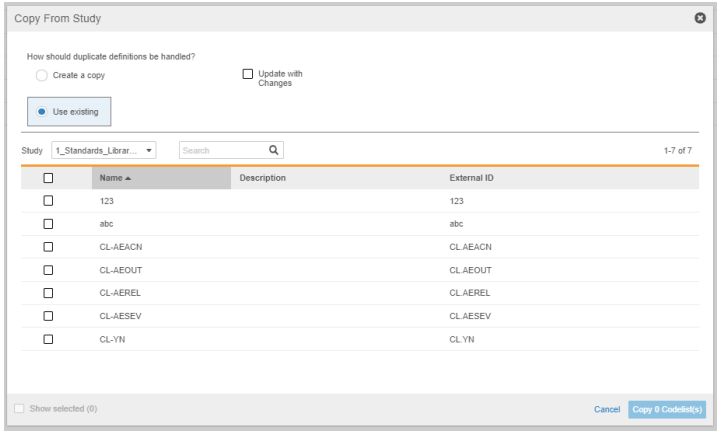
Copy Codelists and Units

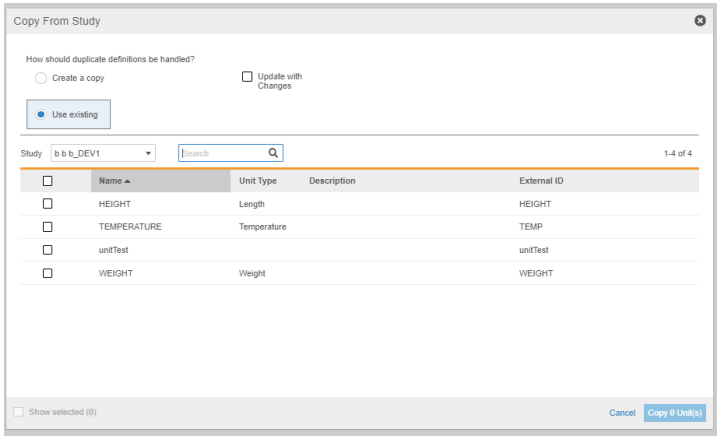
- Overview

  Ability to copy Codelists and Units

- Business Value

  Decreases study development time for new studies. Provides a better facility for standardization.





Automatic

Visible

VISIBLE TO ALL STUDY DESIGNERS

Validation Script for Rule Changes

Automatic

- Overview

  Users can now create a validation script that documents rules that have changed between study environments. When you run the single casebook comparison, and select “Create a Validation Test Script”. A Validation Script spreadsheet will be created, with additional columns.

  Additional Columns added to help with Validation:

  Pass/ Fail, Tester, Failure Reasons, Subject, Added to Log, If Not Specify Reason

- Business Value

  Reduces the effort to manually build test plans/scripts for custom rules.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Rule	Rule Description	Rule Syntax	Action Type	Message	Form	Post To	Pass?	Tester	Failure Reason	Subject	Added To Log	If Not, Specify Reason
2	test		#define:bob @Form.ae.event isBlank(bob)	Query	error	ae							
3	AEEmail	Sends an email when an ae is entered	#define:is_serious @Form.ae.is_serious is_serious	Send Email		ae							
4	indext_prog_display_q		#define:testtrxquery @Form.driving_items.testtrxquery testtrxquery	Query	this is a test for ticket sad lib	indext_sed_prog_displa y							
5	AddEventText_Visit		#define:date_1 @Form.driving_items.Date Not(IsBlank(date_1))	Add Event		indext_sed_prog_displa y	$test_visit						
6	Add_EG		true	Add Event		test_create_eg							
7	TestDrinkenPop		#define:parent1 @Form.driving_items.parent1 isBlank(parent1)	Query	You have to fill this out!	indext_sed_prog_displa y							
8	dmchsrcdig		#define:child @Form.igf.child child	Add Form		indext_sed_prog_disp_ 2	$dmchsrcdig						
9													

Visible

VISIBLE TO ALL STUDY DESIGNERS

Template Vaults

- Overview

  While provisioning a Vault, you can identify a Template Vault that houses all your standards so you can copy those standards into any Vault.

  This provides an easy method to create a new study from a vault where standards are managed.

  Template vaults will never be available for deployment

- Business Value

  Reduces the dependence on Export/Import and provides a way to secure template/standards in a separate vault but still provide access for the creation of new studies from those standards.

Automatic

Visible

VISIBLE TO ALL STUDY DESIGNERS

Relaxed Study Update Restrictions

Automatic

- Overview

  Users can now change non-repeating to repeating (on Event Group, Form, and Item Group) and Non-dynamic to Dynamic (Event and Form).

- Business Value

  Provides better support for post-go-live changes, putting more control in the hands of the study designer and reducing the requirements to have Veeva do updates via the Change Control process.

Visible

VISIBLE TO ALL STUDY DESIGNERS

System Design Specs (SDS) Enhancements

Automatic

- Overview

  SDS now includes:

  - New formatting
  - A Review Tab for Review Plans
  - An Assessments Tab for Assessments
  - Better documentation about Dynamic creation of Event Groups, and disabled rules
  - Layout Information (like Item Group - Header Visible and Visual group)
  - Additional Rule information (blank handling, scope, and dynamic scope)

- Business Value

  More information in the SDS provides for more complete document for review, validation and sign-off or for troubleshooting designs.

Visible

VISIBLE TO ALL STUDY DESIGNERS

Restricted data configuration

- Overview

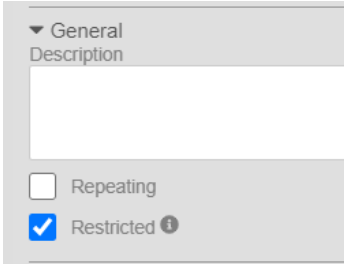
  For studies created after 20R2 using Data Model version 2, a new checkbox will be available at the Form Properties panel that will mark a Form as Restricted.

  This setting is at the Form level, meaning that it will apply to **all** uses of that Form across the schedule.

  Restricted Forms cannot be used for Coding configuration.

- Business Value

  This feature allows Study Designers to configure which forms need to be restricted in the schedule, so that they only show for users with Restricted Data access.



Automatic

NEW STUDIES ONLY

Visible

Studies on Data Model v2 (post 20R2)

Study Closeout Signature Definition

Automatic

- Overview

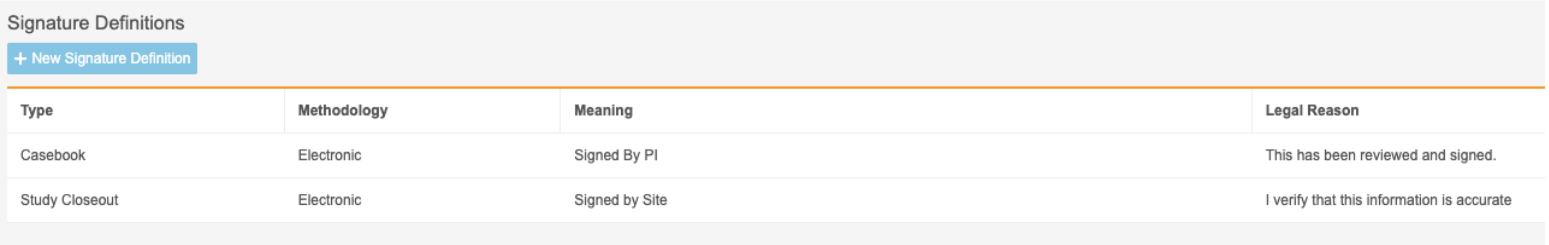
  Study Closeout Signature Definition is used to assign the language to be associated when the electronic signature occurs for the closeout PDFs.

  Only one Study Closeout signature can exist for each study.

  Signature can be edited, but not be deleted.

- Business Value

  This feature allows Study Designers the flexibility to use sponsor's own legal language.


Signature Definitions

+ New Signature Definition

Type	Methodology	Meaning	Legal Reason
Casebook	Electronic	Signed By PI	This has been reviewed and signed.
Study Closeout	Electronic	Signed by Site	I verify that this information is accurate

Visible

VISIBLE TO ALL STUDY DESIGNERS

Studio Demo

Rules

Query future dates for events

Automatic

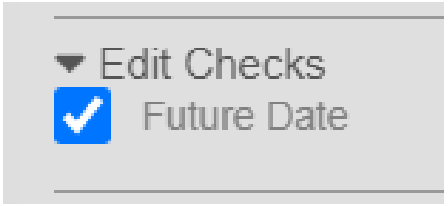
- Overview

  A new setting was added on Events to indicate if a query needs to be automatically fired if an event date is entered in the future.

  This setting is at the Event level, meaning that it will apply to **all** uses of that Event across the schedule.

- Business Value

  This feature removes the need to write a rule to check if an event date is in the future. It will automatically create a univariate rule and create a query if needed in Data Entry.



Visible

VISIBLE TO ALL STUDY DESIGNERS

Query on event date out of range

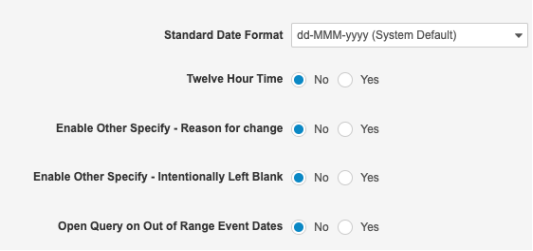
- Overview

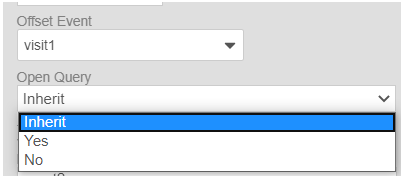
  Studio now allows Study Designers to define if a query needs to be opened when an event date is entered out of the planned range.

  A new study setting option was added to allow setting this parameter at a study level, meaning that all event dates with a planned date range will inherit that setting by default (Yes/No)

  When an offset event is defined for an event, a new choice will appear, giving the Study Designer 3 options:

  - Inherit: Look at the study configuration to determine if a query needs to be opened
  - Yes: Always open a query, regardless of the study configuration
  - No: Never open a query, regardless of the study configuration





- Business Value

  Before 20R2, EDC could only display a warning that a visit date was entered out of the planned range. Some sponsors might want to create a query to prompt a review if a site still enters a visit date out of range.

Automatic

NEW STUDIES ONLY

Visible

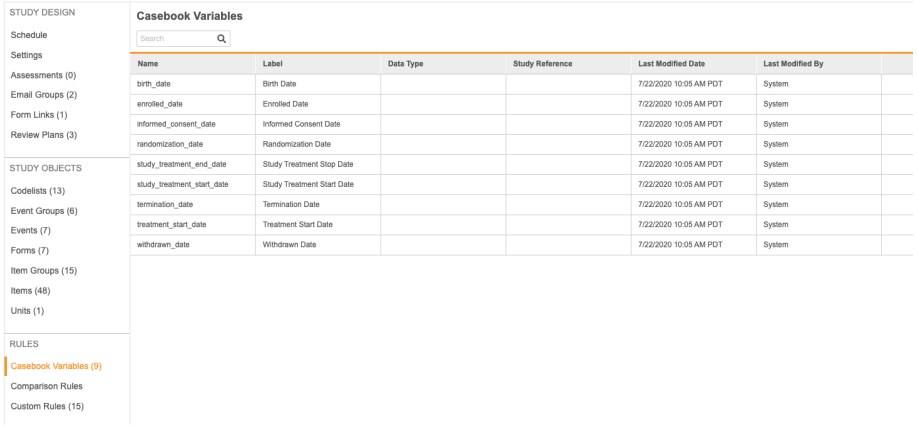
Studies on Data Model v2 (post 20R2)

Rule Navigation Layout

- Overview

  The Rules tab is now split into 3 tabs in a specific Rules section.

  - Casebook Variables
  - Comparison Rules
  - Custom Rules



- Business Value

  It separated the distinct Rules for easier navigation

Automatic

Visible

Studies on Data Model v2 (post 20R2)

Data Driven Review Plan Assignment

Automatic

- Overview

Review Plan can be assigned based on data entered using a rule, which can than override an already assigned plan. Prior to 20R2, only one review plan could be assigned for each form, meaning that items would have the same review mode (required, optional, no review), regardless of the data entered on the form. But now, with this new rule action, if a serious event occurred on the Adverse Event Form, the Review Plan will change to SDV the form. If there was no serious adverse event, stay with the assigned plan and don't SDV the Adverse Event form.

In the Rule Editor for studies using grammar version 2, a new rule action "**Override default plan with**" is available for Data Driven Plan Assignment

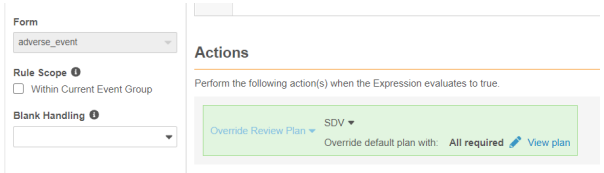
The form that will be targeted by the override is the one selected on the left side of the rule editor (in Rule Details)

Study Designers must select a review task (SDV or DMR) and the override plan to assign in the rule action.
They can also view the review modes that would be applied by the override plan for the selected form.

Note: Once a rule with this action has been saved, the form or action type can no longer be changed.
This is to prevent inconsistencies if the rule was changed (no cleanup mechanism for existing rule results).

- Business Value

This feature allows a new review plan to be assigned for a specific form instance, based on the evaluation of an expression, giving more control over the review mode that needs to be applied to a form.



Visible

VISIBLE TO ALL STUDY DESIGNERS

Casebook variables

- Overview

  Casebook Variables provide a quick way of identifying key items in the schedule that are common in most studies and used as a reference point. For example birthdate or Informed Consent Date.

  The new Casebook Variables are static, and cannot be modified. 9 Casebook Variables are provided for all new studies. They can be mapped to items that are date/datetime or event dates.

  Only items/events that are non-repeating objects can be assigned to Casebook Variables.

  Casebook Variables can be referenced in the rule editor through @Var, as well as in Comparison rules

- Business Value

  - It makes it easier to define Comparison Rules against items that are often referenced and compared against (e.g. Informed Consent date, Birth Date)

Casebook Variables

Search

Name	Label	Data Type	Study Reference
birth_date	Birth Date		
enrolled_date	Enrolled Date		
informed_consent_date	Informed Consent Date		
randomization_date	Randomization Date		
study_treatment_end_date	Study Treatment Stop Date		
study_treatment_start_date	Study Treatment Start Date		
termination_date	Termination Date		
treatment_start_date	Treatment Start Date		
withdrawn_date	Withdrawn Date		

Automatic

Visible

Studies on Data Model v2 (post 20R2)

Rule Configurator (Comparison Rules)

Automatic

- Overview

  The Rule Configurator allows quick simple comparisons between dates OR between datetimes.

  Comparison Rules are limited to date and datetime comparisons.

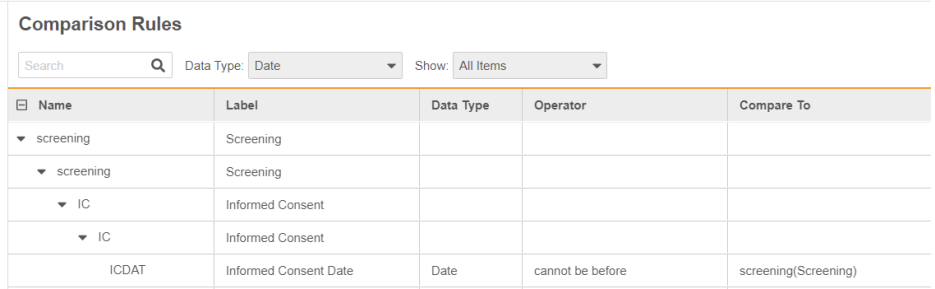
  There is an expandable grid view of the schedule showing all date or datetime items.

  Items can be compared against other items, event dates or Casebook Variables.

  The query message is generated by the system based on the labels of the items used in the comparison and the operator (cannot be before, cannot be equal, etc.).

- Business Value

  It provides a simple, intuitive way of comparing dates without creating a rule expression.



Visible

Studies on Data Model v2 (post 20R2)

Sequence number in expressions

Automatic

- Overview

  A sequence number can be specified in identifiers for repeating event groups, forms and item groups
  E.g. $CYCLE[3].DAY8.LBCHEM.LB[5].RESULT

  For example, compare the visit dates between cycle 1 and cycle 2 or compare values between second and third instances of an item group.

  Sequence numbers can also be specified in **rule actions**, but only for **query** and **set item value** rules.
  Meaning that a query can be attached to an item in a specific instance of a repeating item group.

  It can be used **in the expression** for all rule action types.

- Business Value

  This feature provides a way for Study Designers to write rules that can target a specific instance of an object

  This feature also helps reduce the number of triggers that need to be written to look at specific values in repeating objects of the schedule.

Visible

VISIBLE TO ALL STUDY DESIGNERS

Admin

Study Closeout

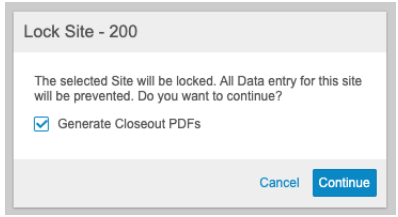
Automatic

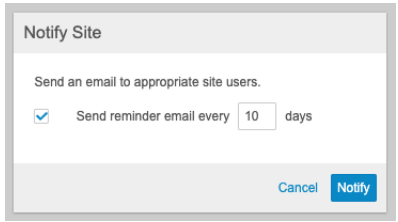
- Overview

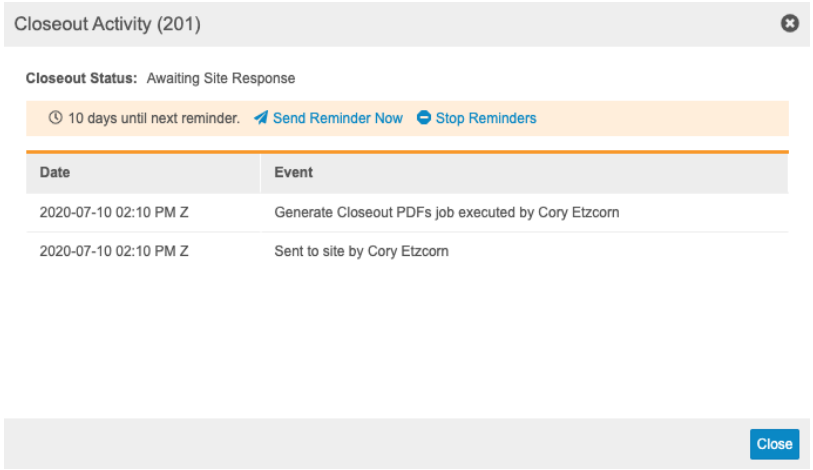
  Sponsors can generate Closeout PDFs at the end of a study from EDC Tools when locking a site(s). Once ready, the Closeout PDFs can be made available to site users for download and acceptance. The system supports automated and manual email notifications to remind sites who haven't completed the acceptance. Throughout the closeout process, Sponsors can track site status within EDC Tools and within the new Study Closeout Status standard report.

- Business Value

  Sponsors no longer need to rely on external systems to send and track Closeout PDFs for acceptance at the end of each study.





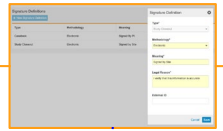


Visible

ADMIN, REPORT USERS

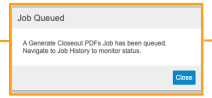
Study Closeout Process

1 Assign user permission for Closeout

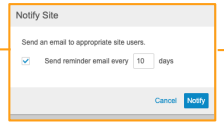


2 Define Study Closeout Signature

3 Lock Study. Generate Closeout PDFS.

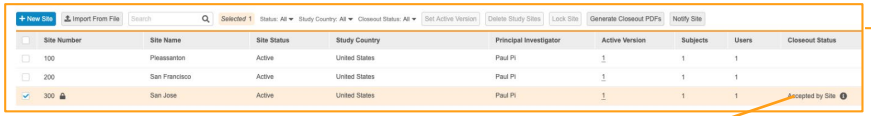


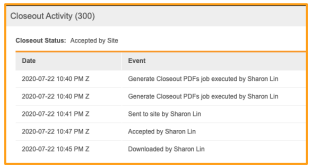
Job Is queued



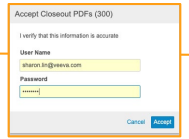
4 Notify Site that PDFs are available

5 Site receives Email notification

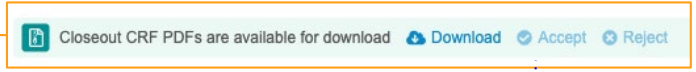




PDFs have been downloaded and accepted by Site.



7 Site accepts PDF and electronically signs



6 Site Downloads the PDFs

**If Site is unlocked, Closeout Process starts all over*

Dynamic Review Plans by Status or Percentage

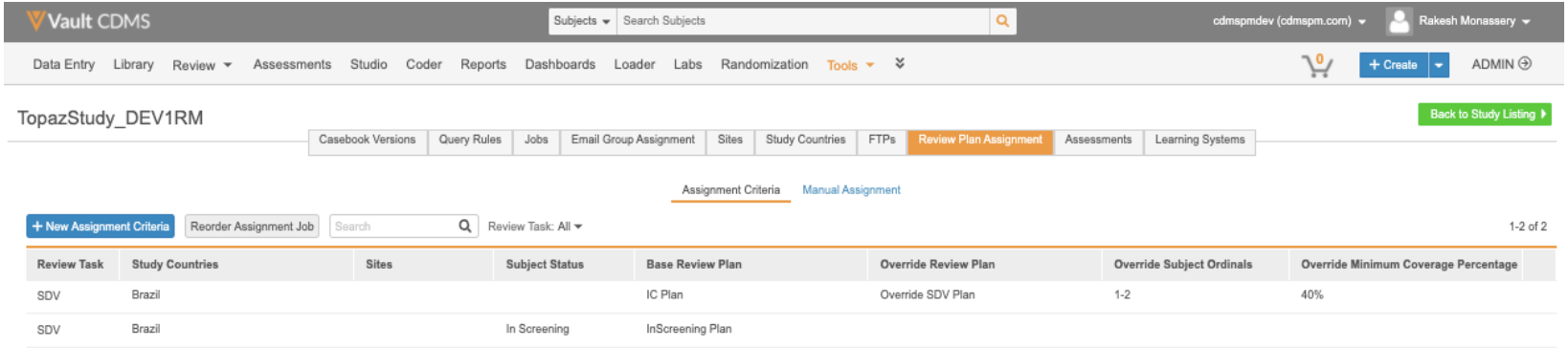
- Overview

  Plans can be defined by Study Country, Study Site, Subject Status, or a minimum percentage of subjects for assignment. A combination of all the above can occur to help customize your Review plan.

  For example for subjects that have a Screen Failure, to have no Review Plans and Enrolled Status to have with 30% minimum percentage coverage.

- Business Value

  This feature allows customers to verify a subset of Subjects and focus on critical data points.



Automatic

NEW STUDIES ONLY

Visible

ADMIN

Minimum Coverage Percentage (MCP)

Casebooks	MCP	Site 101 – Plan A, at least 30%
1	0%	Plan A
2	50.00%	
3	33.33%	
4	25.00%	Plan A
5	40.00%	
6	33.33%	
7	28.57%	Plan A
8	37.50%	
9	33.33%	
10	30.00%	
11	27.27%	Plan A
12	33.33%	
13	30.77%	

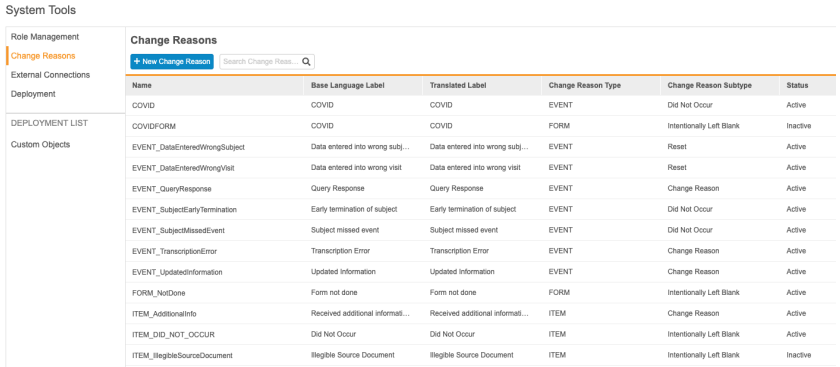
Version 1 vs Version 2

	Version 1	New Studies Version 2
Minimum Coverage Percentage	⛔	✅
Assignment by Subject Status	⛔	✅
Assignment by Subject Ordinal	✅	✅
Manual Assignment	✅	✅
Assignment by Country (all Sites within the country)	⛔	✅

Cannot migrate a Study from version 1 to version 2.

System Tools

- Overview
  - New subtab under Tools called “System Tools”
  - Role Management is now under the System Tools
  - Change Reasons - Define the Drop down list for each object (Intentionally Left Blank, Reset, Did not occur…)
  - Deployment - Vault level deployments
  - Custom Objects - Deploy custom Objects
- Business Value
  - Simple user interface for Vault Level Settings



Automatic

Visible

ADMIN

Vault Deployments

Automatic

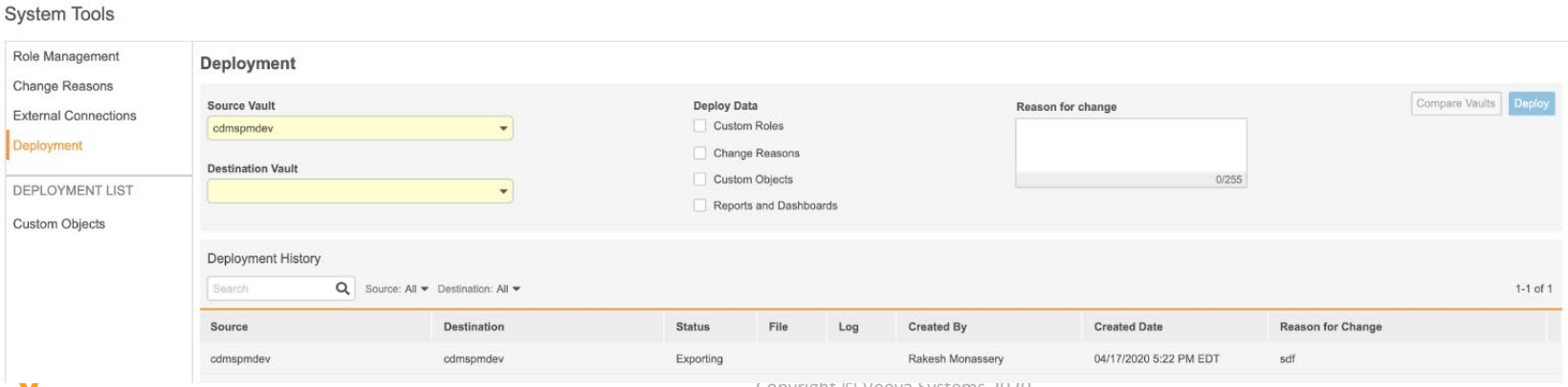
- Overview

  Users can deploy vault-level configuration from your development or sandbox vault to UAT and Production. This includes Custom Roles, Change Reasons, Custom Objects, Reports, and Dashboards.

  This is in addition to the existing deployment of the Study environments.

- Business Value

  Provides an easy and automated way to deploy vault-level configurations between customer vaults.



Visible

ADMIN

Vault Difference Report

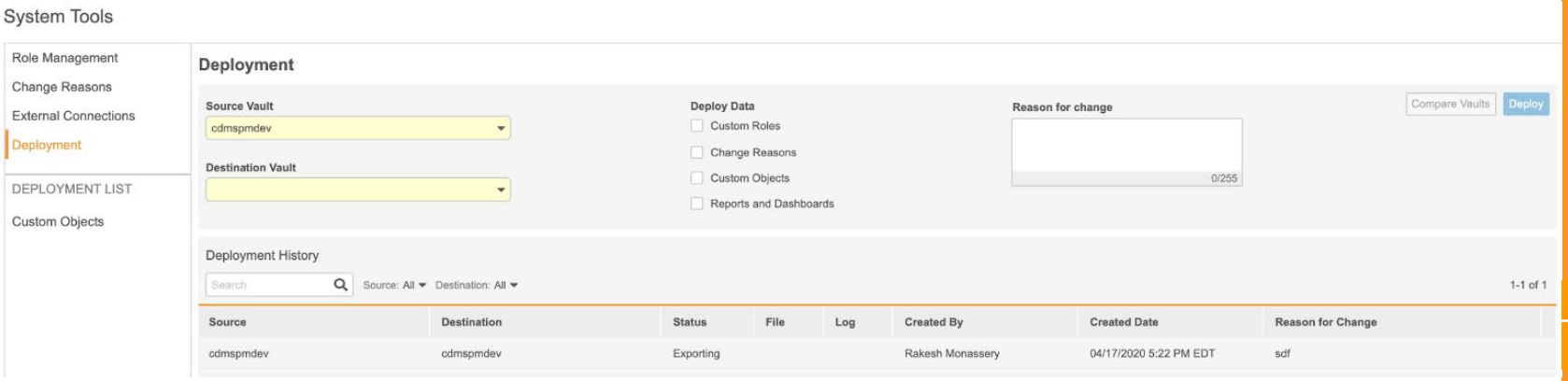
Automatic

- Overview

  Users can run a report to show the differences between two vaults, which is similar to the Study Diff Report but at the Vault level. The report includes any changes to configuration of custom Study Roles, Custom Vault Objects, Reports, Dashboards, and User Managed Groups.

- Business Value

  By comparing vaults, users can more easily identify changes that a deployment will apply.



Visible

ADMIN

Delete Site (non-Production environment)

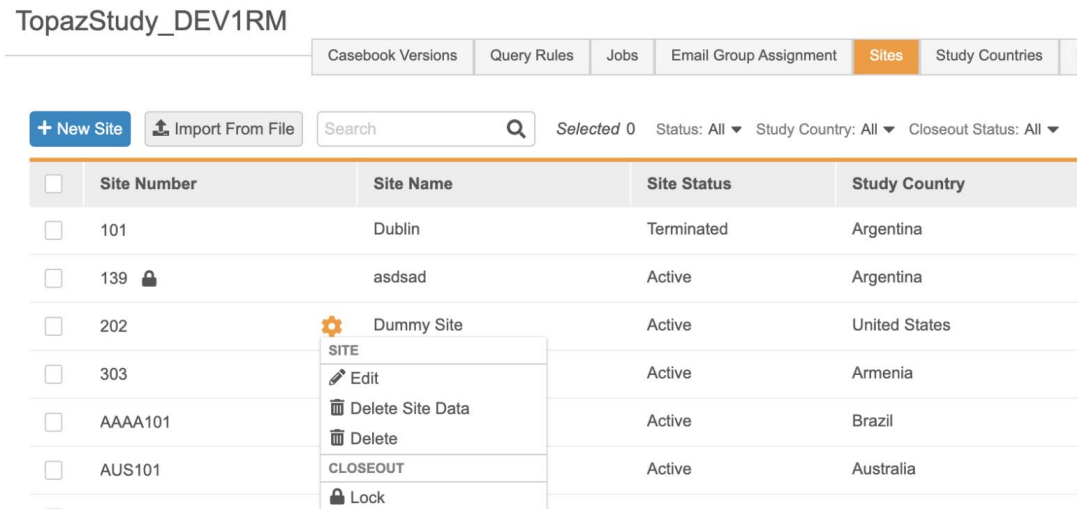
Automatic

- Overview

  In non-production environments, users will have the ability to delete Sites that are no longer required in a Study.

- Business Value

  Removing unwanted Sites makes the study easier to manage.

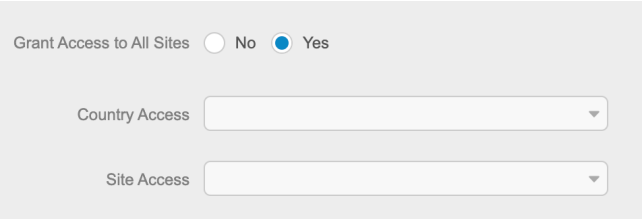


Visible

ADMIN

Study Role Enhancements

- Overview
  - For 20R2, User Defined (aka Custom) role with "**Manage Review Plan Assignment**" permission will automatically be granted access to **execute Jobs**.
  - Any Study Role (Standard or User Defined) that contains the below permission will be granted **Access to All Sites** in a Study.
    - Assign Code
    - Design Study
    - Manage Sites
    - Manage Review Plan Assignment



  - The **CDMS Data Manager, CDMS Lead Data Manager, CDMS User Administrator** roles now have access to the **CDB application**.
  - The **CDMS User Administrator** standard role now has the **Manage Study Sites and Manage Study Countries permissions.**
  - The **CDMS Deployment Administrator, CDMS Lead Data Manager, CDMS Study Designer, CDMS Study Design Read Only** now have access to **Restricted Data permission**.
  - User Defined role with "**Manage Amendments**" and "**Manage Study Deployments**" permission will be granted access to "**Restricted Data**" permission.

Automatic

Visible

ADMIN

Study Role Enhancements (contd.)

Automatic

- Overview
  - The **CDMS Study Designer** standard role now has the following permissions:
    - Manage Review Plan Assignment
    - View Form Linking & Edit Form Linking
    - View Study Design
    - Manage Email Group Assignment
  - The **CDMS User Administrator** now has "**Manage Study Deployment**" permission.
  - The **CDMS Lead Data Manager** role now has the **Generate Closeout PDF** and **Notify Sites of Closeout PDF** study closeout permissions
  - The **CDMS Principal Investigator** and **CDMS Clinical Research Coordinator** roles now have the **Accept Closeout PDF** and **Review Closeout PDF** study closeout permissions:
  - The **CDMS Data Manager** and **CDMS Lead Data Manager** roles now have **View Code** permission.
  - **JReview** role is now called **Data and Definition Export**

Visible

ADMIN

CDMS 20R2 API

- Overview

  CDMS API (Application Programming Interface) allows users to interact with and retrieve data from the CDMS application.

- Business Value

  Provide IRTs the ability to Retrieve study data.

- List

  - Get Event Data API
  - Get Form Data API

- API Documentation

  - https://developer-cdms.veevavault.com/

Automatic

Visible

N/A

Thank you!