## 20R2 Customer Webinar Studio & Admin

July 23, 2020

Revisions - July 28, 2020



## Revisions 07/28/20

#### Revisions to the Deck On 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



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# Veeva R&D and Quality SUMMITONLINE October 13–14, 2020





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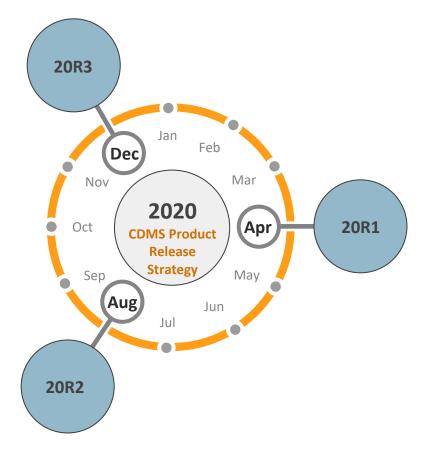
#### QUALITY & MANUFACTURING

REGULATORY





## 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	4	5	6	7	8
	Validation Docs 20R2 Pre - Release					
9	10	11	12	13	14	15
		AUG				
16	17	18	19	20	21	22
					20R2 General Release	

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



### 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



#### 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

CDB

• Locking/Freezing Enhancements

#### Study Designer



- Cascading Form Deletion
- Form Copy Enhancements
- Copy Codelists and Units
- Validation Script for Rule Changes
- Template Vaults

.

**Early Adopter** 

- 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

Labs





- 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 Beasons

#### Coding



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

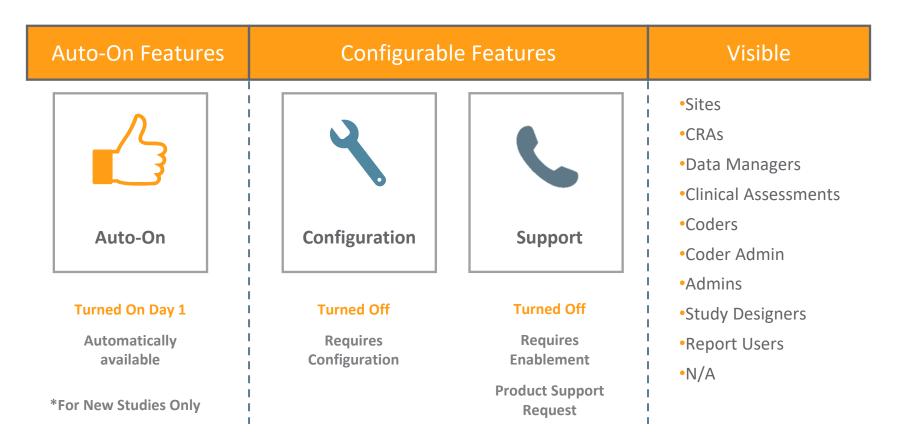
#### Extracts/Listings

- Extracts Data and Definition Enhancements
- Data Listings Restricted Data





20R3





## Studio (Study Designer)

## **Cascading Form Deletion**



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.

Delete	Θ
<ul> <li>This will delete this object and any objects that belong to it (that aren't used by other objects). This can only delete objects that have not been published yet. Unselecting the option will only delete this object. Click delete to continue.</li> <li>Include all related objects</li> <li>See Related Objects</li> <li>The following objects are targeted for deletion. Greyed out objects are referenced by other objects and will not be deleted but are here for reference.</li> </ul>	
Object     Type	
adverse_event (Adverse Event)     Form Definition	
R_DISPLAY_end_date_l_adverse_events_advers Rule Definition e_event_ENABLE	
adverse_event (AE) Medical Coding Item	
AE to ConMed Link Definition	

Cancel Delete



Visible

## 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.

Copy Fr	rom Study					O
	reate a copy Use existing	Update with Changes	Include	es		
Study	Cholecap_DEV1    Search forms	Q				1-20 of 61 < 1 / 4 >
	Name 🔺	Label	Repeating	External ID	Version	Description
	MHSR	SAE Relevant Medical History	No	MHSR	4	
	AEYN	Adverse Events YN?	No	AEYN	4	
	Multiple Timepoint Glucose Reading	Multiple Timepoint Glucose Reading	Yes	Multiple Timepoint Glucose Reading	4	

Visible

## **Copy Codelists and Units**

• Overview



Business Value

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

Copy From St	udy			Ø	С	opy From St	udy			0
How should dup Create a		Update with Changes				How should dup Create a Use exis		Update with Changes		
Study 1_Stan	dards_Librar • Search	Q		1-7 of 7		Study b b b_D	EV1 - Searc	Q		1-4 of 4
	Name 🔺	Description	External ID				Name 🔺	Unit Type Description	External ID	
	123		123				HEIGHT	Length	HEIGHT	
	abc		abc				TEMPERATURE	Temperature	TEMP	
	CL-AEACN		CLAEACN				unitTest		unitTest	
	CL-AEOUT		CLAEOUT				WEIGHT	Weight	WEIGHT	
	CL-AEREL		CLAEREL							
	CL-AESEV		CL.AESEV							
	CL-YN		CL.YN							
Show selected	1 (0)			Cancel Copy 0 Codelist(s)		Show selected	(0)			Cancel Copy 0 Unit(s)



Visible

## Validation Script for Rule Changes

#### • 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.

D C	D	E	-	0			1	К	L M	
Hote System Hideline bob @Formax.event	Action Typ	Message	. Form	Post Fe	· Passi · Tester	Failure Beason		3 Subject	Added Tels If Not, Specify Heason	
(Files)(beb)	Sara	1004								
#deline is_serious @Formae.is_serious			1							
is_seriors	Sond Email		×							
	Switz	this is a test for reset and its	inderst, and, prog., displ							
#deline date_1@Form.drining_items.Date			inder#_and_prog_displ	Next sick						
Ins	Add Event		test_crotte_eg	and the second second						
bBlask(parent1)	Guery	You have to fill this out!	iedark_eed_prog_displ	4						
#define dwfl@Form.jgt.cMf cMf	Add Form		indert_and_prog_disp_	Solutedig						
reced	iDustijeki Adrete ""unives @Francksi, unives defect connecesses@Francksika_hanskuttengeng defect aduk_10francksika_hanskuttengeng defect aduk_10francksika_hanskuttengeng idefect aduk_10francksika_hanspercht iDustigrentt iDustigrentt iDustigrentt	Bedric bit of Frans.const.         Brows           Bit bit bits.         Brows           Bedric bits.confexo 9Frans.cls.confexo         Brows           Bedric confexo 9Frans.cls.confexo         Brows           Bedric confex 9Frans.cls.confexo         Brows           Bedric confex 9Frans.cls.confexo         Bedric confex 9Frans.cls.confexo           Bedric confex 9Frans.cls.confexo         Bedric confex 9Frans.cls.confexo           Bedric confex 9Frans.cls.confexo         Bedric Confex 9Frans.cls.confexo           Bedric confex 9Frans.cls.confexo         Bedric Confex 9Frans.cls.confexo	Batchie bold Prima account         Design         annu           Viel Statubility         Statubility         Statubility         Statubility         Statubility           Viel Statubility         Statubility         Statubility         Statubility         Statubility         Statubility           Batchie obert, Statubility         Statubility         Statubility         Statubility         Statubility         Statubility           Batchie obert, Statubility         Statu	Bale Spars         Active Type         Monoge         Frame           Bale Spars         Active Type         Monoge         Frame         E           Bale Spars         Spars         Decry         ore         Scale         Scale </td <td>Bada para     Autors Type     Manage     Para     Para       Bala bada bada yana maximut     Bala yana     Para     Para     Para       Bala bada bada yana maximut     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana yana yana yana yana yana yana y</td> <td>Bade Sparse     Accise Type     Modes Type&lt;</td> <td>Biology     Prior     Prior</td> <td>Bada Space     Data Space     Data Space     Description     <thdescription< th=""> <thdescription< th=""> <thdescriptio< td=""><td>Bala Space     Data Space<td>Non-light     Non-light     Non-l</td></td></thdescriptio<></thdescription<></thdescription<></td>	Bada para     Autors Type     Manage     Para     Para       Bala bada bada yana maximut     Bala yana     Para     Para     Para       Bala bada bada yana maximut     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana     Bala yana     Bala yana     Para     Para     Para       Bala bada yana yana yana yana yana yana yana y	Bade Sparse     Accise Type     Modes Type<	Biology     Prior     Prior	Bada Space     Data Space     Data Space     Description     Description <thdescription< th=""> <thdescription< th=""> <thdescriptio< td=""><td>Bala Space     Data Space<td>Non-light     Non-light     Non-l</td></td></thdescriptio<></thdescription<></thdescription<>	Bala Space     Data Space <td>Non-light     Non-light     Non-l</td>	Non-light     Non-l

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.

Visible

Automatic





## **Relaxed Study Update Restrictions**

#### • 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

## System Design Specs (SDS) Enhancements

• 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



## **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 <u>all</u> 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.

✓ General Description	
Repeating	
Restricted	



NEW STUDIES ONLY

Visible

Studies on Data Model v2 (post 20R2)

## **Study Closeout Signature Definition**

#### • 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			
Туре	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





## Studio Demo



## Rules

## Query future dates for events



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 <u>all</u> 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

Automatic

## 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.

Standard Date Format	dd-MMM-yyyy (System Default)
oundula paro i onnat	
Twelve Hour Time	No Yes
Enable Other Specify - Reason for change	No Yes
Enable Other Specify - Intentionally Left Blank	No      Yes
Open Query on Out of Range Event Dates	• No Ves
Offset Event	
visit1	-
Open Query	
Inherit	~
Inherit	
Yes	
No	



**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

STUDY DESIGN	Casebook Variables									
Schedule	Search Q	Search Q								
Settings	Name	Label	Data Type	Study Reference	Last Modified Date	Last Modified By				
Assessments (0)	birth_date	Birth Date			7/22/2020 10:05 AM PDT	System				
Email Groups (2)	enrolled_date	Enrolled Date			7/22/2020 10:05 AM PDT	System				
Form Links (1)	informed_consent_date	Informed Consent Date			7/22/2020 10:05 AM PDT	System				
Review Plans (3)	randomization_date	Randomization Date			7/22/2020 10:05 AM PDT	System				
STUDY OBJECTS	study_treatment_end_date	Study Treatment Stop Date			7/22/2020 10:05 AM PDT	System				
Codelists (13)	study_treatment_start_date	Study Treatment Start Date			7/22/2020 10:05 AM PDT	System				
Event Groups (6)	termination_date	Termination Date			7/22/2020 10:05 AM PDT	System				
Events (7)	treatment_start_date	Treatment Start Date			7/22/2020 10:05 AM PDT	System				
Forms (7)	withdrawn_date	Withdrawn Date			7/22/2020 10:05 AM PDT	System				
Item Groups (15)										
Items (48)										
Units (1)										
RULES										
Casebook Variables (9)										
Comparison Rules										
Custom Rules (15)										

#### • Business Value

It separated the distinct Rules for easier navigation

Visible

Studies on Data Model v2 (post 20R2)

## Data Driven Review Plan Assignment

#### • 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 <u>instance</u>, based on the evaluation of an expression, giving more control over the review mode that needs to be applied to a form.

Form adverse_event	Actions
Rule Scope 0 Within Current Event Group	Perform the following action(s) when the Expression evaluates to true.
Blank Handling 0	Override Review Plan ▼ SDV ▼ Override default plan with: All required  View plan



Visible

## **Casebook variables**

#### Overview

**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 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

Search Q			
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		

#### Casebook Variables

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Studies on Data Model v2 (post 20R2)





## Rule Configurator (Comparison Rules)

#### • 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.

Comparison Rules								
Search Q Data	Type: Date 👻	Show: All Items	•					
Name	Label	Data Type	Operator	Compare To				
▼ screening	Screening							
▼ screening	Screening							
▼ IC	Informed Consent							
▼ IC	Informed Consent							
ICDAT	Informed Consent Date	Date	cannot be before	screening(Screening)				

Visible

Studies on Data Model v2 (post 20R2)

## Sequence number in expressions

#### • 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

Automatic





## Admin

### Study Closeout



#### • 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.

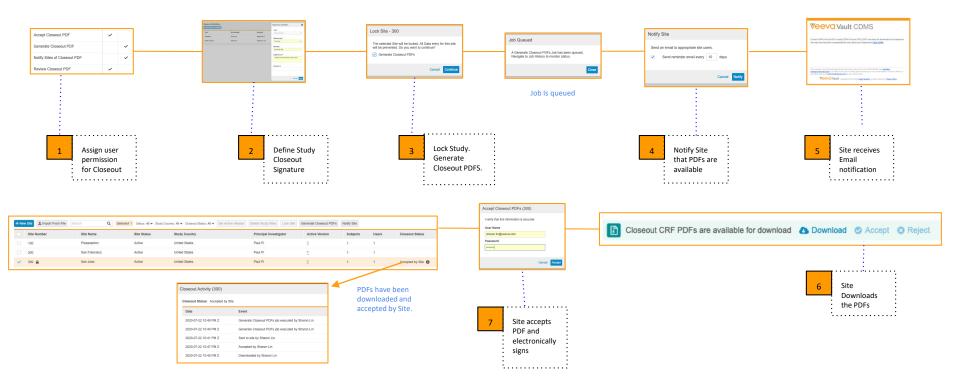
Lock Site - 200	Closeout Activity (201)	
The selected Site will be locked. All Data entry for this site will be prevented. Do you want to continue?	Closeout Status: Awaiting Site F ③ 10 days until next reminder	Response Stop Reminders
Cancel Continue	Date	Event
	2020-07-10 02:10 PM Z	Generate Closeout PDFs job executed by Cory Etzcorn
Notify Site Send an email to appropriate site users. Send reminder email every 10 days	2020-07-10 02:10 PM Z	Sent to site by Cory Etzcorn
Cancel Notify		
	Copyright © V	eeva Systems 2020

Visible

Θ

ADMIN, REPORT USERS

### **Study Closeout Process**



#### \*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.

<b>∛Vault</b> CD	MS			Subjects 👻 Search Subject	5			Q		cdmspmc	lev (cdmspm.com)	<ul> <li>Rakes</li> </ul>	n Monassery 👻
Data Entry L	Data Entry Library Review - Assessments Studio Coder Reports Dashboards Loader Labs Randomization Tools - 🗧 🖌 ADMIN 🕀												
TopazStudy_	TopazStudy_DEV1RM												
		Casebook Versions	Query Rules Jobs	Email Group Assignment	Sites S	tudy Countries	FTPs	Review Plan Assignment	Assessments	Learning Systems			
				Ass	ignment Criteri	ia Manual Assi	gnment						
+ New Assignme	+ New Assignment Criteria Reorder Assignment Job Search Q Review Task: All -												
Review Task	Study Countries	Sites	Subject	Status Base Revi	ew Plan		Overrid	le Review Plan	Overr	ide Subject Ordinals	Override	Minimum Coverage	Percentage
SDV	Brazil			IC Plan			Override	e SDV Plan	1-2		40%		
SDV	Brazil		In Scree	ening InScreenin	g Plan								



ONLY

Visible ADMIN

**NEW STUDIES** 

## Minimum Coverage Percentage (MCP)

Casebooks	МСР	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	0	<b>v</b>
Assignment by Subject Status	•	$\bigcirc$
Assignment by Subject Ordinal	<b>O</b>	<b>O</b>
Manual Assignment	$\bigcirc$	$\bigcirc$
Assignment by Country (all Sites within the country)	<b>e</b>	<b>O</b>

#### 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...)

System Tools

- Deployment Vault level deployments \_
- Custom Objects Deploy custom Objects
- **Business Value** •
  - Simple user interface for Vault Level Settings

Role Management Change Reasons External Connections Deployment	Change Reasons + New Change Reason Elseich Change Reason										
	Name	Base Language Label	Translated Label	Change Reason Type	Change Reason Subtype	Status					
epioymeni	COVID	COVID	COVID	EVENT	Did Not Occur	Active					
EPLOYMENT LIST	COVIDFORM	COVID	COVID	FORM	Intentionally Left Blank	Inactive					
Custom Objects	EVENT_DataEnteredWrongSubject	Data entered into wrong subj	Data entered into wrong subj	EVENT	Reset	Active					
	EVENT_DataEnteredWrongVisit	Data entered into wrong visit	Data entered into wrong visit	EVENT	Reset	Active					
	EVENT_QueryResponse	Query Response	Query Response	EVENT	Change Reason	Active					
	EVENT_SubjectEarlyTermination	Early termination of subject	Early termination of subject	EVENT	Did Not Occur	Active					
	EVENT_SubjectMissedEvent	Subject missed event	Subject missed event	EVENT	Did Not Occur	Active					
	EVENT_TranscriptionError	Transcription Error	Transcription Error	EVENT	Change Reason	Active					
	EVENT_UpdatedInformation	Updated Information	Updated Information	EVENT	Change Reason	Active					
	FORM_NotDone	Form not done	Form not done	FORM	Intentionally Left Blank	Active					
	ITEM_AdditionalInfo	Received additional informati	Received additional informati	ITEM	Change Reason	Active					
	ITEM_DID_NOT_OCCUR	Did Not Occur	Did Not Occur	ITEM	Intentionally Left Blank	Active					
	ITEM_IllegibleSourceDocument	Illegible Source Document	Illegible Source Document	ITEM	Intentionally Left Blank	Inactive					

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### Vault Deployments



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.

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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.

,													
Role Management	Deployment												
Change Reasons External Connections Deployment DEPLOYMENT LIST	Source Vault cdmspmdev Destination Vault	•	Custo	m Roles ge Reasons	ards	Re	ason for change 0/255		Compare Vaults Deploy				
Custom Objects										Visible			
	Deployment History								_				
	Search Q S	ource: All 👻 Destination: All 👻							1-1 of 1	ADMIN			
	Source	Destination	Status	File	Log	Created By	Created Date	Reason for Change					
	cdmspmdev	cdmspmdev	Exporting			Rakesh Monassery	04/17/2020 5:22 PM EDT	sdf					
				Convrig	nt (C) Ve	eva Systems 2020							

#### System Tools

### Vault Difference Report



#### 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.

Role Management	Deployment									
Change Reasons External Connections Deployment DEPLOYMENT LIST Custom Objects	Source Vault cdmspmdev Destination Vault	Custor Chang Custor	Deploy Data Custom Roles Change Reasons Custom Objects Reports and Dashboards			Reason for change Compare Vaults				
	Deployment History Search Q	Source: All 👻 Destination: All 👻							1-1 of 1	Visible
	Source	Destination	Status	File	Log	Created By	Created Date	Reason for Change		ADMI
	cdmspmdev	cdmspmdev	Exporting			Rakesh Monassery	04/17/2020 5:22 PM EDT	sdf		ADIVIT

#### System Tools



• 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.

opaz	zStudy_DEV1RM						
		Casebook Versions	Query Rules	Jobs	Email Group Assignment	Sites Study Countries	
+ Nev	v Site	Search	<b>Q</b> Sele	ected 0	Status: All 🔻 Study Country	r: All ▼ Closeout Status: All ▼	
	Site Number	Site Name			Site Status	Study Country	
	101	Dublin			Terminated	Argentina	
	139 🔒	asdsad			Active	Argentina	
	202	Dummy Site			Active	United States	
	303	SITE SITE			Active	Armenia	
	AAAA101	<ul> <li>Delete Site Data</li> <li>Delete</li> </ul>			Active	Brazil	
	AUS101	CLOSEOUT	DSEOUT Active		Active	Australia	
		Lock					

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# **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		Grant Access to All Sites	O No O Yes
Design Study		Country Access	
Manage Sites		Site Access	
Manage Revie	ew 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.

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## Study Role Enhancements (contd.)

- 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

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#### 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/

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# Thank you!