

# 20R1 Customer Webinar Studio & Admin

April 02, 2020





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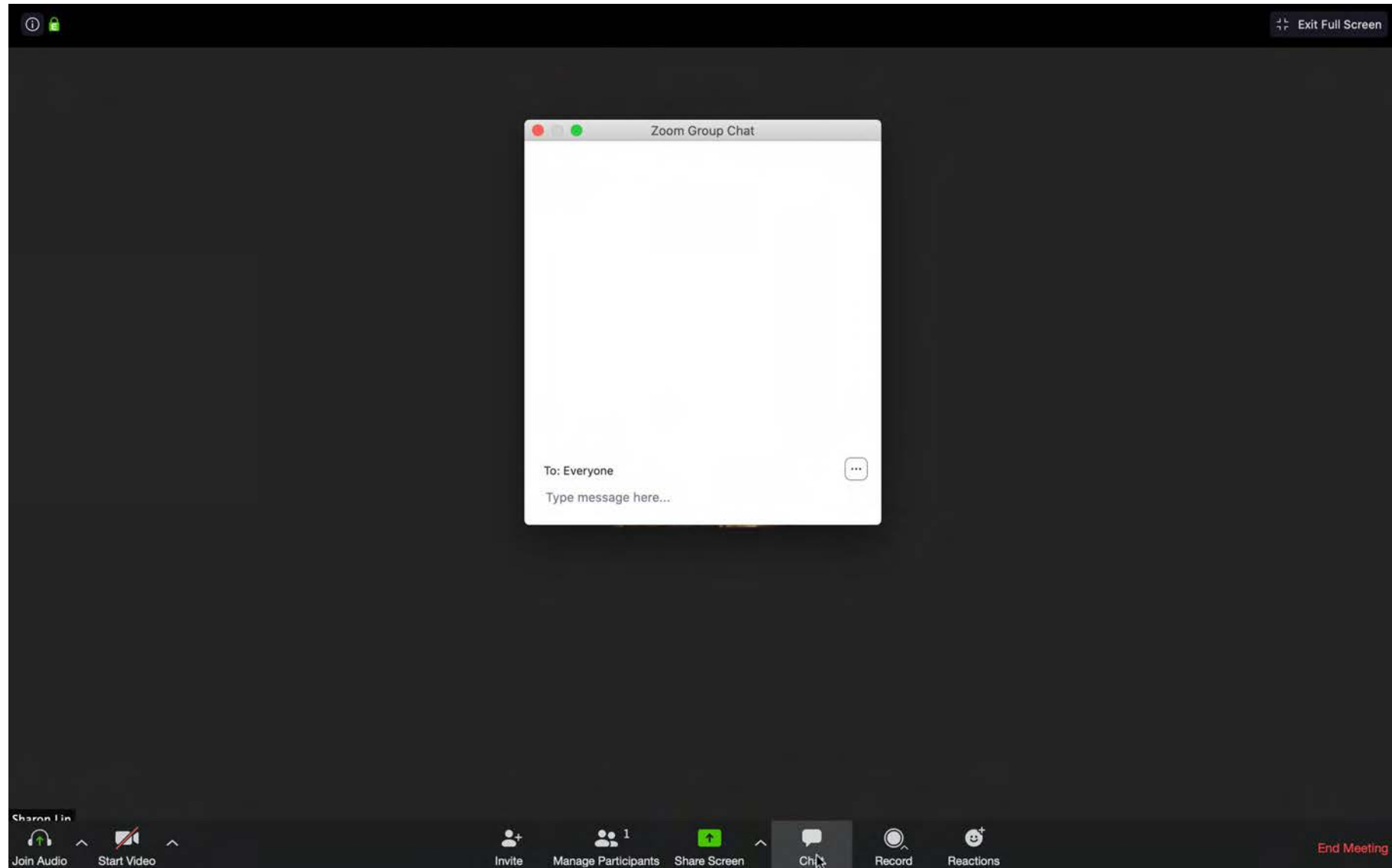
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# Important Disclosures

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 by using Chat



# 20R1 Go Live

- ALL customer vaults upgraded to 20R1
- EU starts at 2:00pm PT
- APAC & US starts at 5:00 PM PT
- May take up to 6 hours

**APR**

**Friday  
17th**



# 20R1 General Release Resources

## Resources Available

<https://cdmshelp.veeva.com/lr/rn/general-releases/20r1/>

- **20R1 Customer Release Preview Webinar Recording (Site Focused)**
- **Webinar Slides are available for download**
- **Abbreviated 7 min presentation for the Sites**
  - Important Dates
  - Notifications Opt-In
  - Feature information
  - Pre- Release Information
  - Release Information
  - Release Impact Assessment (RIA)

*\* Attending or Viewing the Site Focused Preview Webinar is a prerequisite for this Studio and Admin Webinar*



# Agenda

**Thursday, April 02**

20R1 Features

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Studio Demo

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Rules and Review Plan Editor Demo

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Admin Demo

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Recap

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# 20R1 Feature Summary

## Sites



- New Data Entry Interface
  - Progressive Display
  - Indenting
  - Form Linking
  - Copy Indication from Link
- Performance**
- Creation of Forms
  - First instance of Repeating Form (not automatically created)

## Study Designer



- |  |  |   |
|--|--|---|
| <ul style="list-style-type: none"> <li>• Form Linking</li> <li>• Copy Rules from another Study</li> <li>• ODM Import/Export for Automated Deployment Studies</li> <li>• Progressive Display</li> <li>• Item Indentation</li> </ul> <p><b>Review Plans</b></p> <ul style="list-style-type: none"> <li>• Reviews – “optional”</li> </ul> | <ul style="list-style-type: none"> <li>• setting</li> <li>• Review Plan Templates</li> </ul> <p><b>Rules</b></p> <ul style="list-style-type: none"> <li>• Set Subject Status Dates</li> <li>• Send Emails</li> </ul> <p><b>Rule Editor Enhancements</b></p> <ul style="list-style-type: none"> <li>• Expand/Collapse</li> <li>• Search for Item by name or label on the right side</li> <li>• Corresponding</li> </ul> | <ul style="list-style-type: none"> <li>• #define statement can be added to expression with one click</li> </ul> <p><b>NEW Functions</b></p> <ul style="list-style-type: none"> <li>• Power(), Sum(), Average()</li> <li>• StartofDay(date, timezone)</li> <li>• Today(timezone)</li> <li>• Reciprocal Rules with @Form</li> </ul> |
|--|--|---|

## Coding



### Automated Auto-coding

- Refresh button from Auto-coding
- Auto-Assign deprecated

## Admin



- Email Group Assignment
  - Deploy Custom Objects & Roles
  - Flexibility in creating PROD
  - CDMS-CTMS Spark Integration
  - APIs (support IRT)
  - User Activity Report
  - Sites –Active Version & Study Country
  - LDM – SDV/DMR Re-assignment Job
  - Federated ID for SSO
  - Vault CDMS Logo
- Roles and Permission**
- Study Designer Role(s)
  - Custom Object Permissions
  - Delete Custom Roles
  - Download Roles
  - New Permissions (Manage Study, View Coding, Workbench Tab..)
  - Remove Manage Study From Deployment Admin

## Data Workbench



Early Adopter

## Local Labs



20R3



# 20R1 CDMS Features by Users

**Sites**  
Data Entry Tab



**Coding**  
Coding Tab



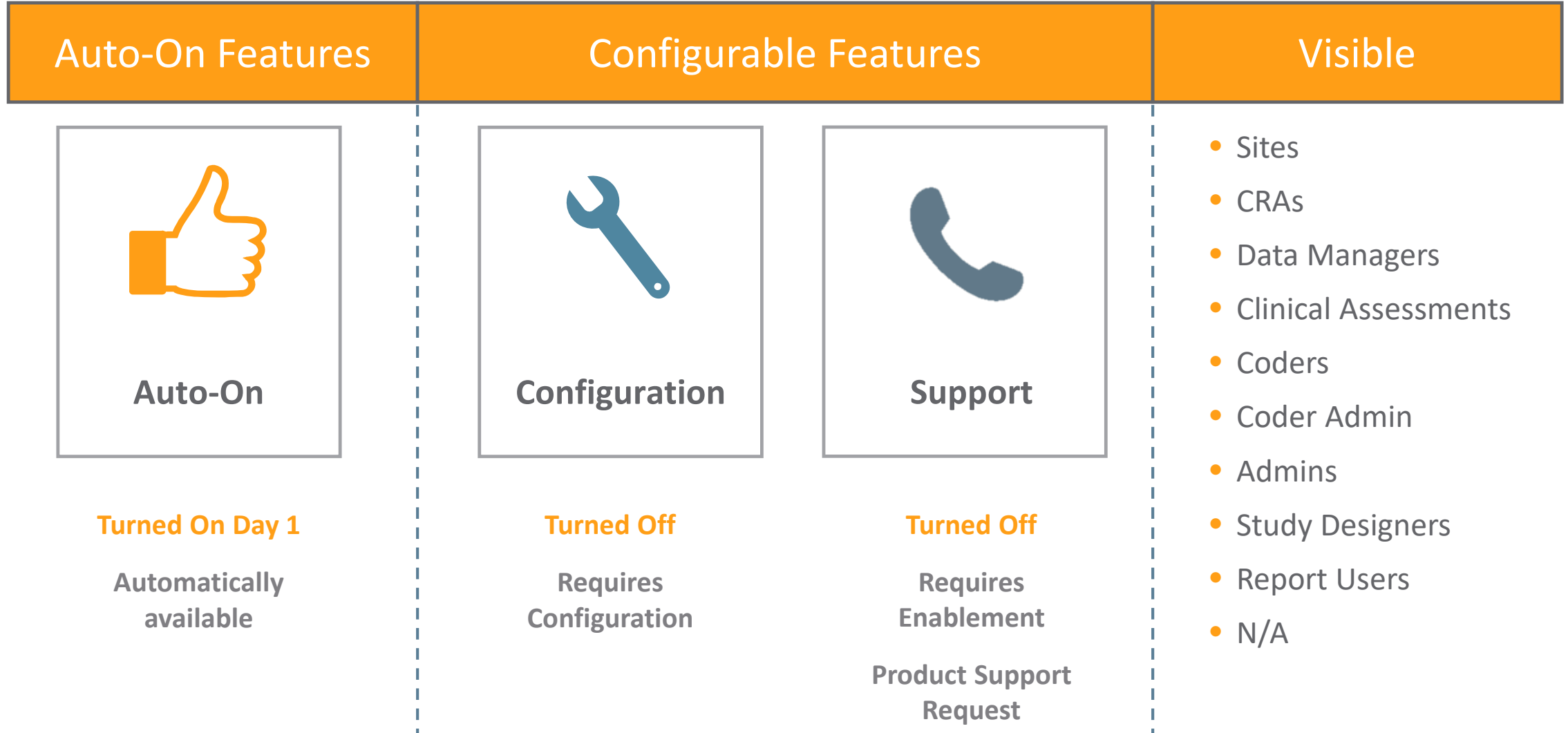
**Study Designer**  
Studio



**Admin or Lead Data  
Mangers**  
EDC Tools



# Feature Enablement Detail





Studio (Study Designer)



Automatic

# Form Linking

- Overview

Studio users can define links between forms, therefore allowing display of relationships. Most common use case AEs to ConMeds.

- Link Multiple Forms – AE to ConMed to MedHistory
- Link to same Form – AE to AE
- Forms must be Repeating

- Business Value

Provides a better picture of relationships via forms.

Common Forms: Adverse Events : Reference # 1 (1 of 6) Edit Form

FORM | GENERAL MEDICAL HISTORY (0) | PRIOR AND CONCOMITANT ... (0)

Adverse Events

Adverse Event Headache

Start Date 17-Mar-2020

Ongoing?

End Date

Severity

Toxicity Grade

Serious? No

**Form Links**

+ New Form Link Search

Name	Description	Linked Forms	Last Modified Date	Last Modified By
ae ae	asdf	ae, test	3/6/2020 7:44 AM PST	Dennis Kochanski
AEConmedFormLink	Form Link description	ae, Concomitant medication	3/5/2020 12:58 PM PST	Dennis Kochanski

Form Link

Name\* Test

Description

Linked Forms\*

Name	Description
multipleigprogressive (M	
test (test)	
AEConmedFormLink	asdf

Edit Delete

Cancel Save and New Save

# Copy Indication from Link



Automatic

- Overview

Configure which form to copy the indication from, so sites have easy access to the indication through a couple of clicks. Most common example will be copying an Indication from an Adverse Event to a ConMed.

- Business Value

This will allow Sites to easily select an accurate Indication value, and so that the Form may be Coded correctly by the Coding team.

The screenshot displays the 'Coding Configuration' interface with the following sections:

- Form Type:** ConMed
- Form Type Other:** (empty)
- Dictionary Release:** GLOBALC3Sep17
- Synonym List:** (empty)
- Verbatim Item:** Medication
- Do Not Autocode List:** (empty)

Related Item(s)	Item	Type	If Type Other
<input checked="" type="checkbox"/>	Route of Administration	Route	Route of Administration
<input checked="" type="checkbox"/>	Indication	Indication	Indication
<input checked="" type="checkbox"/>	Dose Unit	Dose	Dose

[Add Related Item](#)

**Coding Method**

- Code with Indication
- Code with Route

**Copy Indication From Link**

Link	Copy Item Value
AE to ConMed	Adverse Event (adverse_event)

[Add Link](#)

Buttons: Delete, Cancel, Save

Visible

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DESIGNERS





# Progressive Display

- Overview

Study designers can design a form that can dynamically display or hide items based on a data collection point as a user progresses through a form.

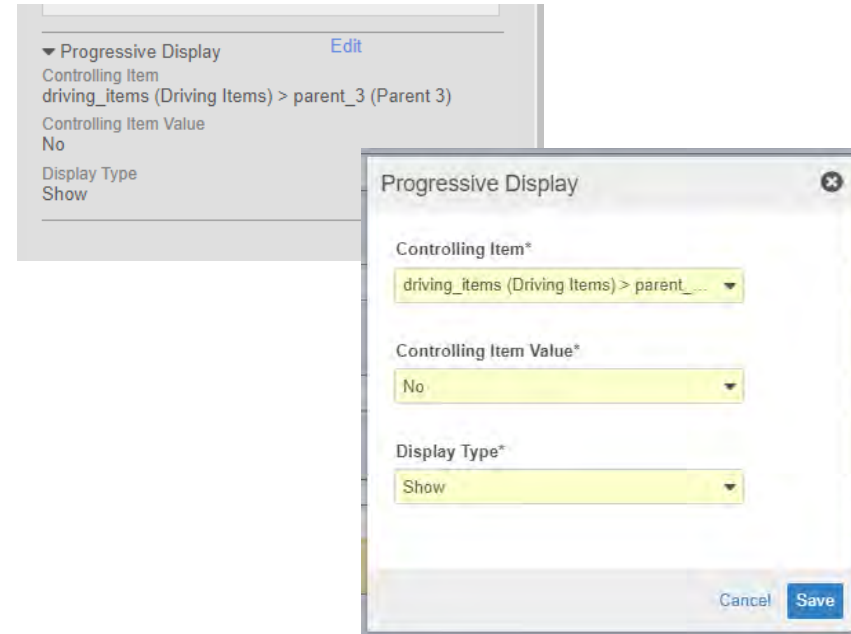
Supports hide/show or enable/disable at the Item or Item Group level.

*\*Must be a codelist or boolean item type*

Show/Hide	Item/item group will display (show) upon data collection when criteria is met Item/item group will not display (hide) if data collection criteria is not met
Enable /Disable	Item/item group will display (enabled) upon data collection criteria being met Item/item group will display grayed out (disable) if data collection criteria is not met

- Business Value

Allows for easy configuration of dynamic form elements without the need to write rules.





Automatic

# Item Indentation

- Overview

Study designers can indent Items on a Form using the new Indent Level property. Can be used in conjunction with composite items and columns.

- Business Value

Indenting provides the site with a better user experience by visual grouping

▼ Display Override

Label  
tx1

Short Label  
tx1

Indent Level  
3 ▼

0

1

2

3

Visible

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# Copy Rules From Another Study



Automatic

- Overview

Studio users can copy rules from another Study. Vault validates all identifiers in the copied rules and shows an indicator when a rule contains an invalid identifier.

- Business Value

Allows for rule logic to be reused as a template reducing development time for new studies.

Copy From Study

How should duplicate definitions be handled?  
 Create a copy  Use existing

Update with Changes  
 Yes  No

Study: DK20020212\_DEV1 Search 1-14 of 14

<input type="checkbox"/>	Invalid	Name	Description	Form	Rule Stat
<input checked="" type="checkbox"/>		AE3001_LF1_AE024	If present, Event End Date must be >= Event Start Date.	Adverse Events	Active
<input checked="" type="checkbox"/>		AE3001_LF1_AE035	If 'Is the event serious?'=YES and 'Death'=YES, then the Adverse Event Outcome must be 'Fatal'.	Adverse Events	Active
<input type="checkbox"/>		AE3001_LF1_AE037	If 'Is the event serious?'=YES and 'Death'=Yes, then an event end date must be present.	Adverse Events	Active

Show selected (2) Cancel Copy 2 Rule(s)

Rules

+ New Rule Copy From Study Search

Invalid	Name
	AE3001_LF1_AE024
	AE3001_LF1_AE035

AE3001\_LF1\_AE024

Details << Expression Check Syntax Format Formula

Name  
AE3001\_LF1\_AE024

```
1 #define AESTDAT @Form.null.null
2 #define AEENDAT @Form.null.null
3
```



# ODM Import/Export for Automated Deployment Studies



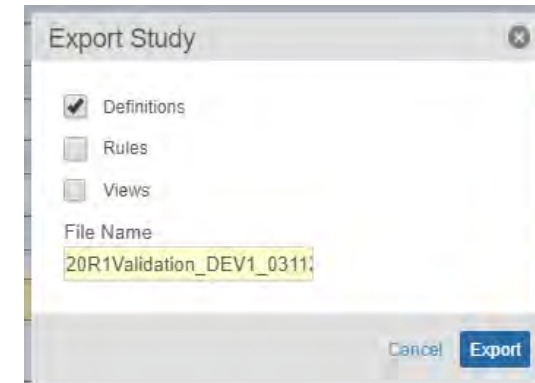
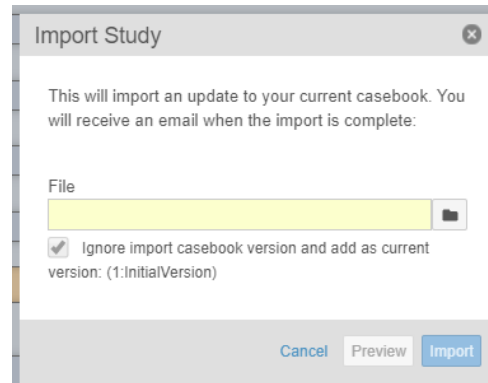
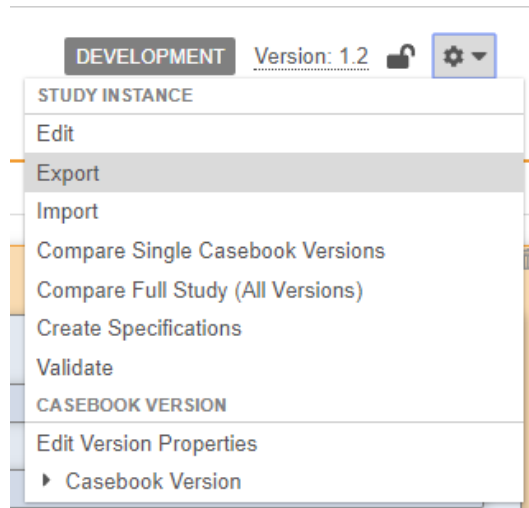
Automatic

- Overview

ODM import and export functionality is available for use in automated deployment Studies (new deployment model).

- Business Value

Allows for the import of study designs from disconnected vaults, for importing standards or studies from 3<sup>rd</sup> party systems – decreasing study development time.



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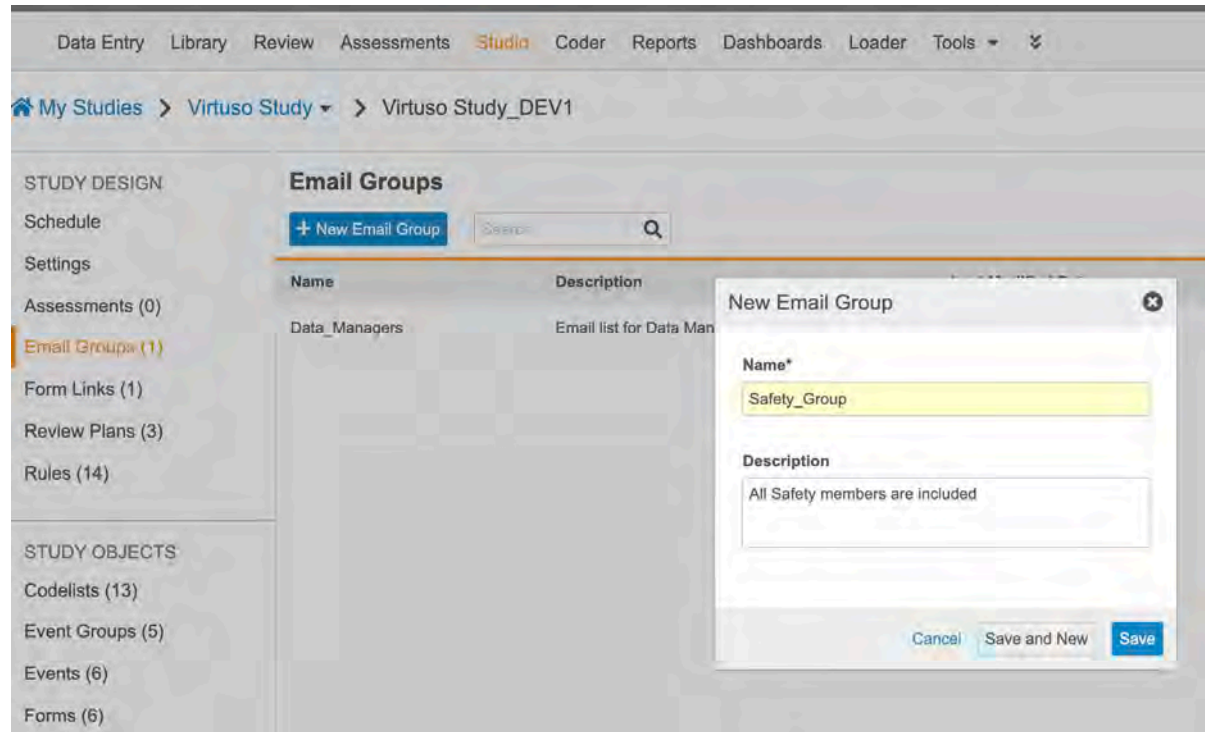
# Setup Email Group

- Overview

Define Email groups In Studio for Automatic Studies (new deployment model). This will help categorize the diff groups that emails should be sent out for notifications.

- Business Value

Helpful for commonly used email groups



Automatic

ONLY  
AUTOMATIC  
STUDIES

Visible

STUDY  
DESIGNERS



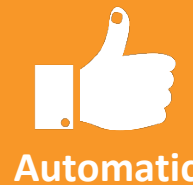


# Studio Demo



Rules

# Set Subject Status rules - Enhancement



- Overview

Study Designers will now select an event date or an item date when creating a Set Subject Status rule.

When the subject is moved to the status specified in the rule, the value of the selected date is used to set the corresponding field of the Subject status.

E.g. if the subject moves to “Enrolled”, the system will populate the “Enrolled date” field with the selected event date or item date

*Note: make sure the date being set has a value, it has to be used in the expression.*


- Business Value


This feature is needed for the integration of Vault CDMS with Vault CTMS.

It can also be helpful for reporting to establish a timeline for the subjects in a study by recording each status change date.

## Actions

Perform the following action(s) when the Expression evaluates to true.

Set Subject Status ▾ **Enrolled** 

Set status change date to: Event ▾ **Main\_Study\_Cohort\_1 > Visit1** 



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# Send Email rules

- Overview

Study Designers now have access to the “Send Email” rule action in which an email should be sent based on a rule, as well as defining the Subject and Message of that email.

Tokens can be used in Subject and Message to include data from the current form (with some limitations) and data from the study (e.g. Subject, PI name, Study country, Site name, etc).

Email Groups are created in Studio for automatic studies (studies using the new deployment model).

*Note: Due to technical limitations, the Subject of the email is limited to 125 characters.*

*Tokens pertains to the selected form, and not available across forms. It also can not be in a repeating item group.*

- Business Value

This feature adds a new rule action in the Rule Editor to configure Send Email rules. Such configuration had to be done through business admin (backend) in 19R3.

**Actions**

Perform the following action(s) when the Expression evaluates to true.

Send Email ▼

To:

Subject:  0/125

Message:

Some text formatting with HTML tags is permitted. [Learn more.](#)

ig1 (IG1)
infusiondate (InfusionDate)
subject_id (Subject ID)
Static Tokens
Event Date
Site Number
Event Group Sequence
Subject Name
Site Name



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Automatic

# Rule Editor enhancements

- Overview

The Rule Details panel can now be collapsed/expanded to give more room to the expression editor.

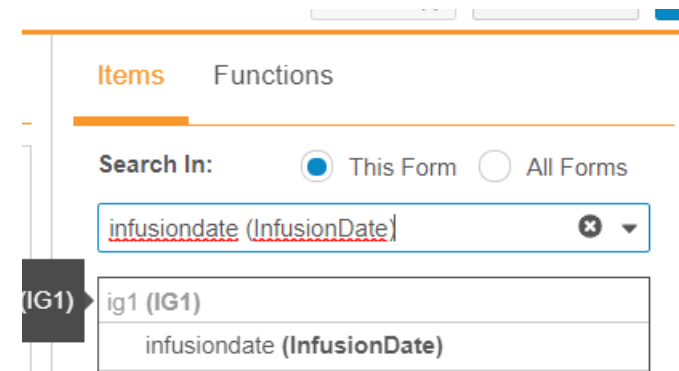
Study Designers have access to an “Items” tab on the right side of the editor, next to the Functions tab. It allows them to search for an item (by name or label) in the selected form or in the overall schedule.

Once the item has been found, the corresponding #define statement can be added to the expression with one click. The variable will be created with the item name and the reference will either use @Form or a fully qualified \$ path, depending on the option selected.

- Business Value

This feature provides the ability to look for an item directly in the rule editor, without having to refer to an external document to find where it might be located. It also provides a quick way to insert variables without having to type.

Overall, it should make writing rules faster and easier.



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# New functions in the Rule Editor



Automatic

- Overview

Study Designers can now use the following functions in the Rule Editor:

- Power(number1, number2): Returns the result of the first number to the power of the second number
- StartOfDay(date, timezone): Returns the beginning of the specified day as a datetime in the specified timezone
- Today(timezone): Returns the current date in the specified timezone
- Sum(number): Returns the sum of all the numbers provided
- Average(number): Returns the average of all the numbers provided

- Business Value

These functions broaden the scope of expressions that can be written in the rule editor.

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# Reciprocal rules



Automatic

- Overview

Reciprocal rules change the way the expression engine is evaluating rules containing a fully qualified reference and a reference to a re-used form (using @Form).

Before 20R1, if a rule was comparing a fully qualified reference (e.g. an event date or an informed consent date) against items referenced using @Form (meaning that the same rule would apply to everywhere that form is used), changing the value of the fully qualified reference would not trigger the rule again. The rule had to be triggered from every instance of the @Form reference instead.

In 20R1, such a rule can be triggered from both sides.

*Note: This behavior is only available for newly created rules. Existing rules will stay on the old behavior. Copied or deployed rules will also stay on the old behavior.*

*If a study needs to be copied from an existing one and also needs to use reciprocal rules, the reciprocal\_\_v field on the rule definition object can be manually modified (bulk change also possible through Business Admin bulk action or Vault Loader)*

- Business Value

Since only one side of the rule was working, sites had to manually update all forms impacted by that rule to, for example, get rid of queries that were no longer relevant (since they changed the data).

This feature removes that manual process and allows for a better site experience.

ONLY NEW  
RULES

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# Example: Reciprocal Rule

## PRE – 20R1

### Create a Rule

If Dosing Date on Dosing Form is less (earlier) than Consent Date, then fire a query on Dosing Form Date.

### Site Data Entry:

Consent Date = March 15, 2020

Visit 1. Dosing Date = March 02, 2020 (Query fired)

Visit 2. Dosing Date = March 09, 2020 (Query Fired)

Query fired on both Dosing Forms since the Dosing Date came before the consent date

### Site Corrects Consent Date

Consent Date = March 01, 2020

Query does not close even though date was corrected.

- Query has to be manually closed
- or the form resubmitted and then query will close.

## 20R1

### Create a Rule

Same

### Site Data Entry:

Same

### Site Corrects Consent Date

Consent Date = March 01, 2020

Query closes.





# Review Plan Editor



Automatic

# Optional Setting in the Review Plan Editor

- Overview

The Optional mode can now be set in the Review Plan Editor.

- Business Value

Some customers have expressed the need to configure an “optional” review for certain forms and items. This is now available for event dates, forms and items in the Review Plan Editor.

The screenshot shows the Review Plan Editor interface. At the top, there are configuration fields: 'Name\*' is 'Optional Review', 'Event Dates Review\*' is 'Optional' (with a dropdown menu showing 'Required', 'No Review', and 'Optional'), and 'Description' is empty. Below these is 'Review Task\*' set to 'SDV'. A search bar is visible on the left. The main area displays a table of items with columns for 'External ID', 'Required', 'No Review', and 'Optional'. The 'InfusionDate' item is highlighted, showing 100% Optional. To the right, a list of items includes 'IG1', 'InfusionDate', and 'Subject ID', each with a status icon.

External ID	Required	No Review	Optional
infusiondate	-	-	100%
vitals	100%	-	-

Visible

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# Study templates for Review Plans



Automatic

- Overview

Study Designers can add study level templates for review plans, so that every newly created site will inherit those plans. Default and override values can be defined, as well as the subject numbers for overrides. The plan assignment can still be modified after creation for each site in EDC Tools.

- Business Value

This feature removes the need to manually configure review plans for each created site if the Review Plan is generally the same for each new site.

The screenshot displays the 'Study Template' configuration interface. It includes fields for Default and Override values for SDV and DMR plans, and Override Subjects. Below this is a 'Review Plans' section with a '+ New Review Plan' button, a search bar, and a table of existing plans.

Name	Review Task	Default State	Event Dates Review	Last Modified Date	Last Modified By
100 percent DMR	DMR	Required	Required	3/13/2020 3:17 AM EDT	Quentin Paresys
100 percent SDV	SDV	Required	Required	3/13/2020 3:16 AM EDT	Quentin Paresys
50 percent DMR	DMR	Required	Optional	3/13/2020 3:19 AM EDT	Quentin Paresys
50 percent SDV	SDV	Required	Optional	3/13/2020 3:16 AM EDT	Quentin Paresys

Visible

STUDY  
DESIGNERS





# Rules & Review Plan Editor Demo



Admin



# Email Group Assignment



Automatic

- Overview

Assign study or non-study users to an Email Group created in Studio.

- Business Value

Users within and outside the study will receive an email notification when certain conditions are met.

TopazStudy\_DEV1

Casebook Versions Query Rules Jobs **Email Group Assignment** Sites Study Countries FTPs Review

Search

Name	Description	Number of Users	Last Modified By	Last Modified Date
<a href="#">DataManagers</a>	DM group	0	Rakesh Monassery	02/24/2020 2:54 PM EST
<a href="#">Safety</a>	safety group	0	Rakesh Monassery	02/24/2020 2:52 PM EST

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ADMIN





# Automated Deployments – Custom Roles & Objects

- Overview

Deployment of custom Vault objects and custom Study Roles can be included as part of study deployments.

- Business Value

Removes the need to manually reconfigure or use VPK to deploy custom Study Roles and custom objects in each environment.

Deploy Study Design

Deploy study design from the **CLM-22\_UAT2** environment.

**Destination Environment**

CLM-22

Create detail PDF

Delete Study Data ⓘ

Include System Data

Custom Objects and Custom Roles

**Reason for Change**

0/255

Cancel Deploy



# Create a PRD Environment after Study Creation



Automatic

- Overview

Deployment administrators can now create a Production-type environment (Study Instance record) from EDC Tools > Environments.

- Business Value

Deployment administrators can now create a production environment if one wasn't already created for their study.

My Studies > TopazStudy

All Environments Users

Search Environment Type: All 1-6 of 6

Environment	Highest Casebook Version	Study Build	Environment Type
TopazStudy_DEV1	1	2	DEVELOPMENT (1 of 2)
TopazStudy_UAT1	1	1	UAT (1 of 5)
TopazStudy_UAT3	1	1	UAT (3 of 5)
TopazStudy_UAT2		1	UAT (2 of 5)

CREATE ENVIRONMENT

- + Development
- + UAT
- + Training
- + Production

VIEW

History

Visible

ADMIN

# CDMS-CTMS Spark Integration



Configuration

- Overview

With the Veeva Vault CTMS Connection, you can easily leverage operational data from your EDC vault for operational reporting within your CTMS vault.

- Business Value

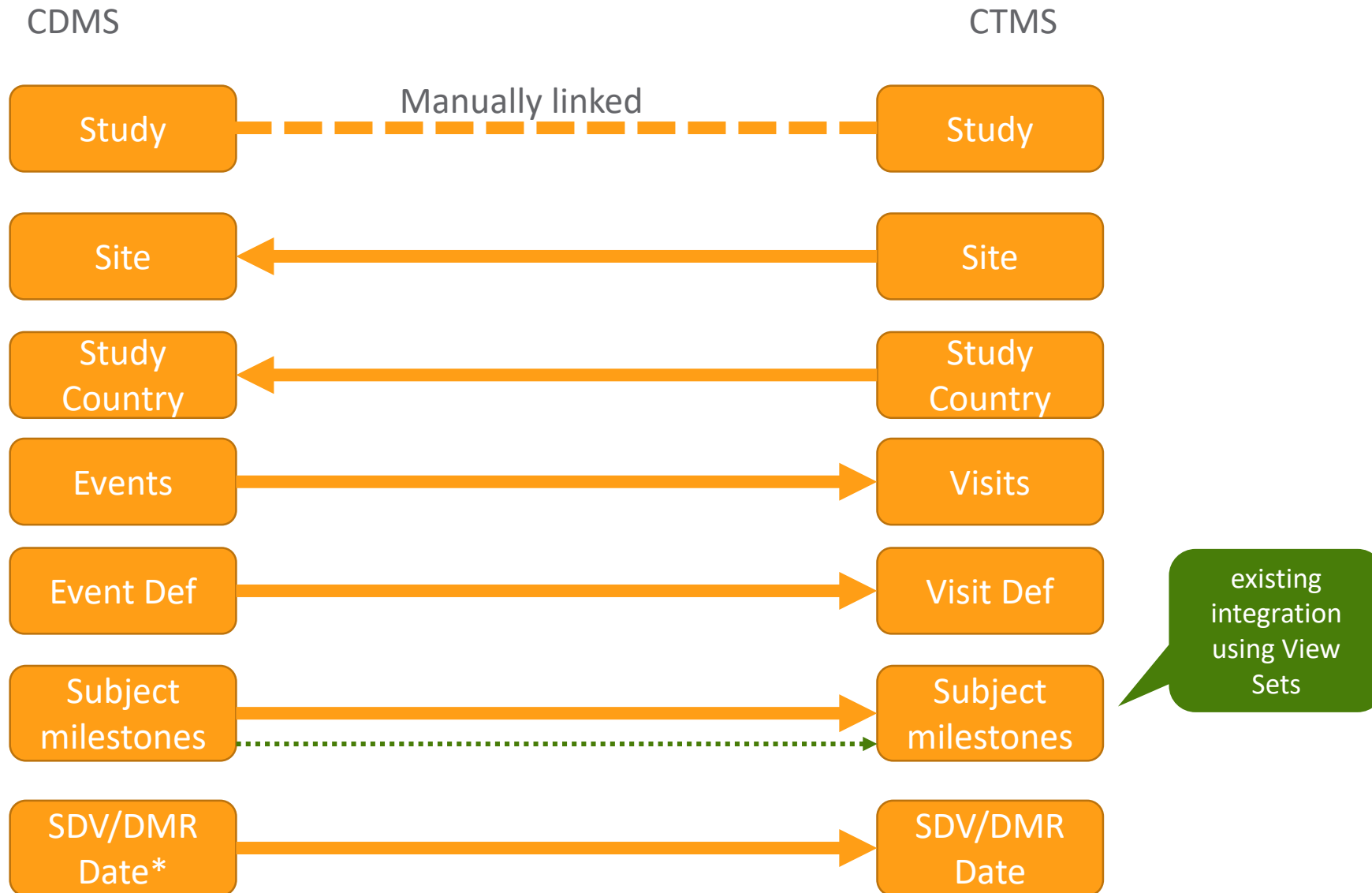
Automated and near real time data sync between Clinical Operations and Data Management.

Visible

N/A



# CDMS-CTMS Spark Integration



Configuration

Visible

N/A





# Study Designer & Designer Read Only Role

- Overview

The CDMS Study Designer role and CDMS Study Designer Read Only role is intended for creating and testing study designs.

- Business Value

A user no longer needs to have the Vault Owner security profile to design their study.

PRD	—	CDMS Study Designer Read Only
UAT	CDMS Study Designer	CDMS Study Designer Read Only
DEV	CDMS Study Designer	CDMS Study Designer Read Only

	CDMS Principal Investigator	CDMS Study Designer	CDMS Study Designer Read Only	CDMS Sub Investigator	CDMS User Act
Number of Users	0	0	0	0	
Manage Role					
Manage Learning					✓
View Casebook	✓		✓		
View Study Design		✓			
Design Study	✓				
Manage JReview Job					

Visible

ADMIN



# Permission Updates



Automatic

- Overview

- View Form Linking and Edit Form Linking
- Manage Study Role Permission
- View Code
- Workbench Tab ( \*if enabled for your Vault)
- Removed "Manage Study Lock" Permission from CDMS Deployment Administrator- Only CDMS Lead Data Manager

- Business Value

- More defined permissions will allow users to create a custom role to select the relevant individual permissions for a desired role

Visible

**ADMIN**



# Manage Custom Object Permissions in Role Management



Automatic

- Overview

User Administrators can now manage Custom Objects with Read, Edit, and Delete permissions

\*Permission set required on the Security profile

- Business Value

This provides User admins the capability to define their own permissions for Custom Objects in Role Management

The screenshot displays a table with columns for 'Number of Users' and 'Manage Role' for various Custom Objects: Custom CRA, Custom CRC, Custom DM, and Custom DM1. Below this, there are expandable sections for 'Standard Tabs', 'Permissions', and 'Custom Objects'. Under 'Custom Objects', there are two sub-sections: 'Protocol Deviation' and 'Custom Labs'. Each sub-section lists 'Read', 'Edit', and 'Delete' permissions with checkmarks indicating their status for each object.

	Custom CRA	Custom CRC	Custom DM	Custom DM1
Number of Users	1	0	0	0
Manage Role	⚙️	⚙️	⚙️	⚙️
▶ Standard Tabs				
▶ Permissions				
▼ Custom Objects				
<b>Protocol Deviation</b>				
Read	✓	✓	✓	✓
Edit		✓	✓	✓
Delete			✓	
<b>Custom Labs</b>				
Read	✓		✓	
Edit	✓			
Delete				

Visible

ADMIN





# Allow Deletion of Custom Study Roles



Automatic

- Overview

User Administrators can now delete custom Study Roles (in DEV) that don't have any users assigned that role.

- Business Value

Unused Study Roles can build up over time and create confusion when assigning roles to users.



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ADMIN





Automatic

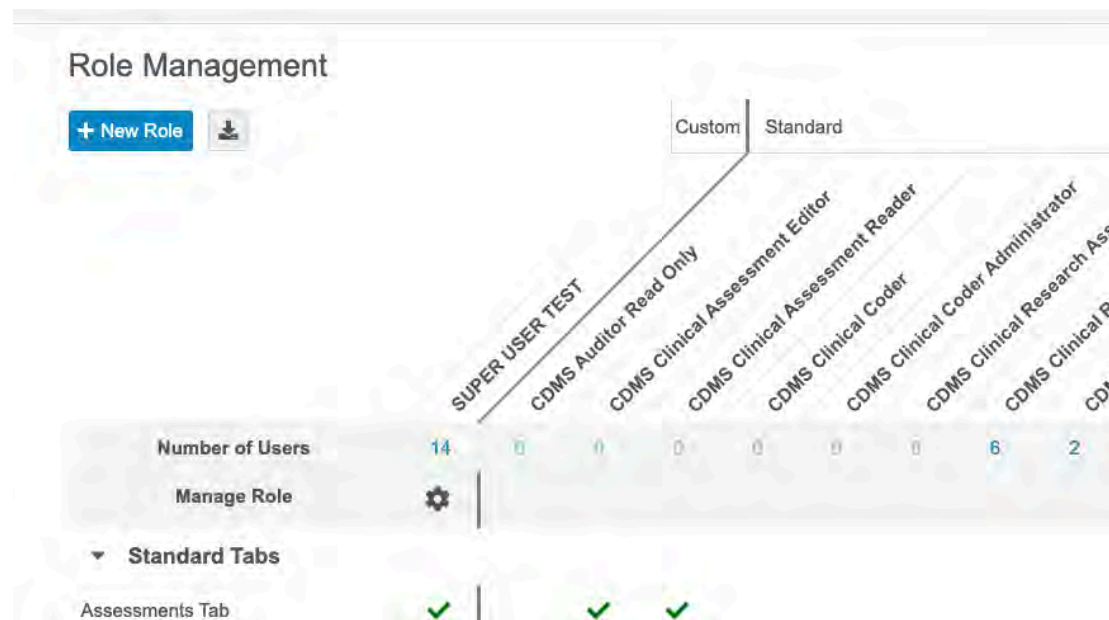
# Download Study Role

- Overview

Users with access to Tools > Role Management can now download an Excel™ file with a report of which permissions are assigned to which Study Role.

- Business Value

Allows for easy documentation of an organization's Study Role permissions.



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ADMIN



# Provide Federated ID during User Creation (UI)



Automatic

- Overview

When creating and editing users from EDC Tools > Users, user administrators can now provide a Federated ID.

- Business Value

This change allows users to provide a Federated ID for a user account when creating users manually, empowering organizations to leverage single sign-on (SSO) with Vault.

The screenshot shows a user creation form with the following fields and values:

<b>User Name</b> user1	@cdmspm.com
<b>Email</b> dev.null@veeva.com	<b>Title</b> 
<b>Last Name</b> first	<b>First Name</b> last
<b>Company</b> 	<b>Federated ID</b> 5364757858
<b>Language</b> English	<b>Locale</b> United States
<b>Timezone</b> (GMT-04:00) Atlantic Standard Time (America/Puerto_Rico)	
<b>Add as Principal Investigator</b> <input type="checkbox"/>	

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Automatic

# User Activity Report

- Overview

The User Activity Report lists user actions and user login attempts in chronological order for a given time period.

- Business Value

Customers can track who had access to the system, thereby ensuring availability and compliance with data privacy and security regulations.

The screenshot shows a web interface for a 'User Activity Report'. At the top, there is a breadcrumb 'My Studies > Cholecap' and a filter for 'All Environments' with a 'Using' button. Below this is a toolbar with 'New User', 'Import From File', and a search bar. The main content is a table with columns: Last Name, First Name, User Name, Company, and Email. The table lists eight users. To the right of the table is an 'EXPORT' menu with options for 'CSV' and 'User Activity Report'. A '1-8 of 8' indicator is also visible.

Last Name	First Name	User Name	Company	Email
Lin	Sharon	sharon.lin@cdmspm.com	Veeva	sharon.lin@veeva.com
Studio	Sam	Studio@cdmspm.com	Veeva	sharon.lin@veeva.com
Deployment	Dan	Deployment@cdmspm.com	Veeva	sharon.lin@veeva.com
Admin	Amy	admin@cdmspm.com	Veeva	sharon.lin@veeva.com
Paresys	Quentin	quentin.paresys@cdmspm.com		quentin.paresys@veeva.com
Claire	Lundeby	Claire@cdmspm.com	Veeva	Claire.lundeby@veeva.com
CRC Cindy	Smith	CRC_Cindy@cdmspm.com		Sharon.lin@veeva.com
CRC	Custom	Custom_CRC@cdmspm.com		cory.etzcom@veeva.com

Visible

ADMIN



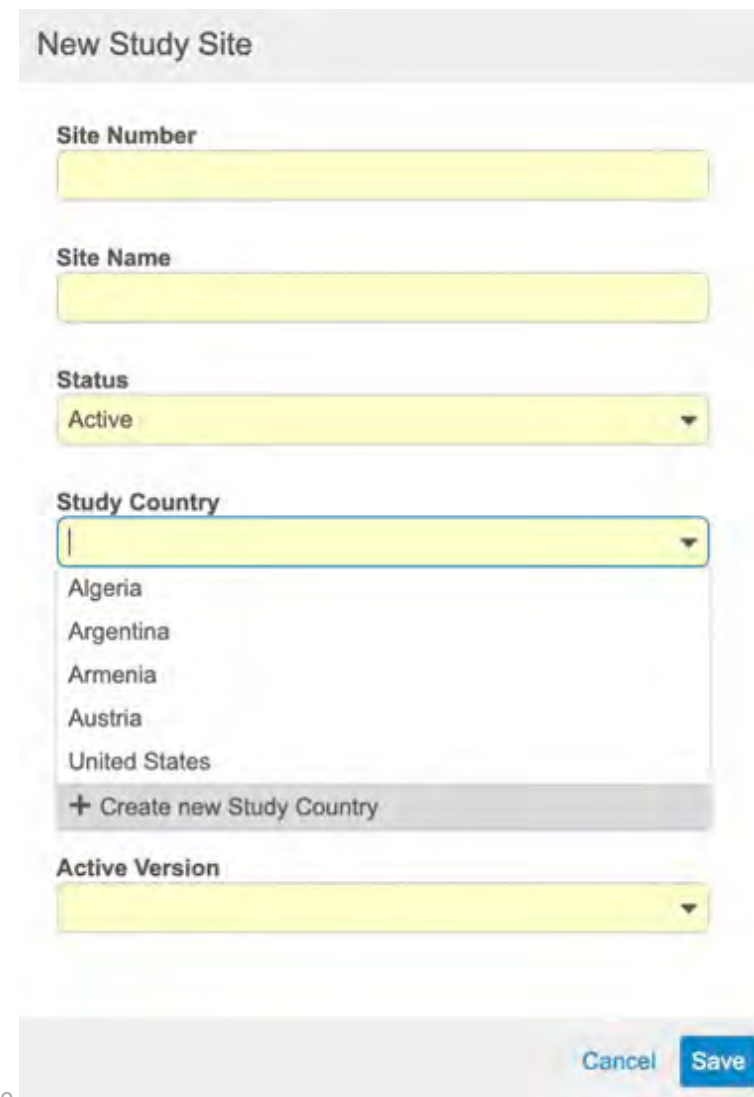
# Active Version & Study Country during Site Creation

- Overview

Lead data managers can now create a Study Country when creating a new Site. An active casebook version can also be set during Site creation.

- Business Value

This removes the extra step of adding a Study Country to the Study before creating a Site.



**New Study Site**

**Site Number**

**Site Name**

**Status**  
Active

**Study Country**  
  
Algeria  
Argentina  
Armenia  
Austria  
United States  
+ Create new Study Country

**Active Version**

Cancel Save

# Site-level SDV & DMR Re-assignment



Automatic

- Overview

Lead data managers can now run the SDV Re-assignment and DMR Re-assignment jobs at the site level.

- Business Value

Run Review Plan jobs as needed at a Site level.

The screenshot shows a 'New Job' configuration window. At the top, the title is 'New Job'. Below it, there are two dropdown menus: 'Type' set to 'SDV Re-assignment' and 'Frequency' set to 'Run Now'. Below these are two radio buttons: 'Execute for all Sites' (unselected) and 'Select Sites' (selected). A search bar is located below the radio buttons. The main area contains two lists of site IDs. The left list contains 101, 139, 202, 303, and 464. The right list is empty. Between the lists are navigation buttons: a double right arrow, a single right arrow, a single left arrow, and a double left arrow. Below the right list are four buttons: a double right arrow, a single right arrow, a single left arrow, and a double left arrow. At the bottom center, there is a 'Restore defaults' link. At the bottom right, there are 'Cancel' and 'Run Now' buttons.

Visible

ADMIN



# CDMS 20R1 API



Automatic

- 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 Set Subject Status and Create Event Groups.

- List of 20R1 APIs

- Set Subject Status API
- Unset Subject Status API
  - Updates subject status to current status
- Create Event Group API

Visible

ADMIN



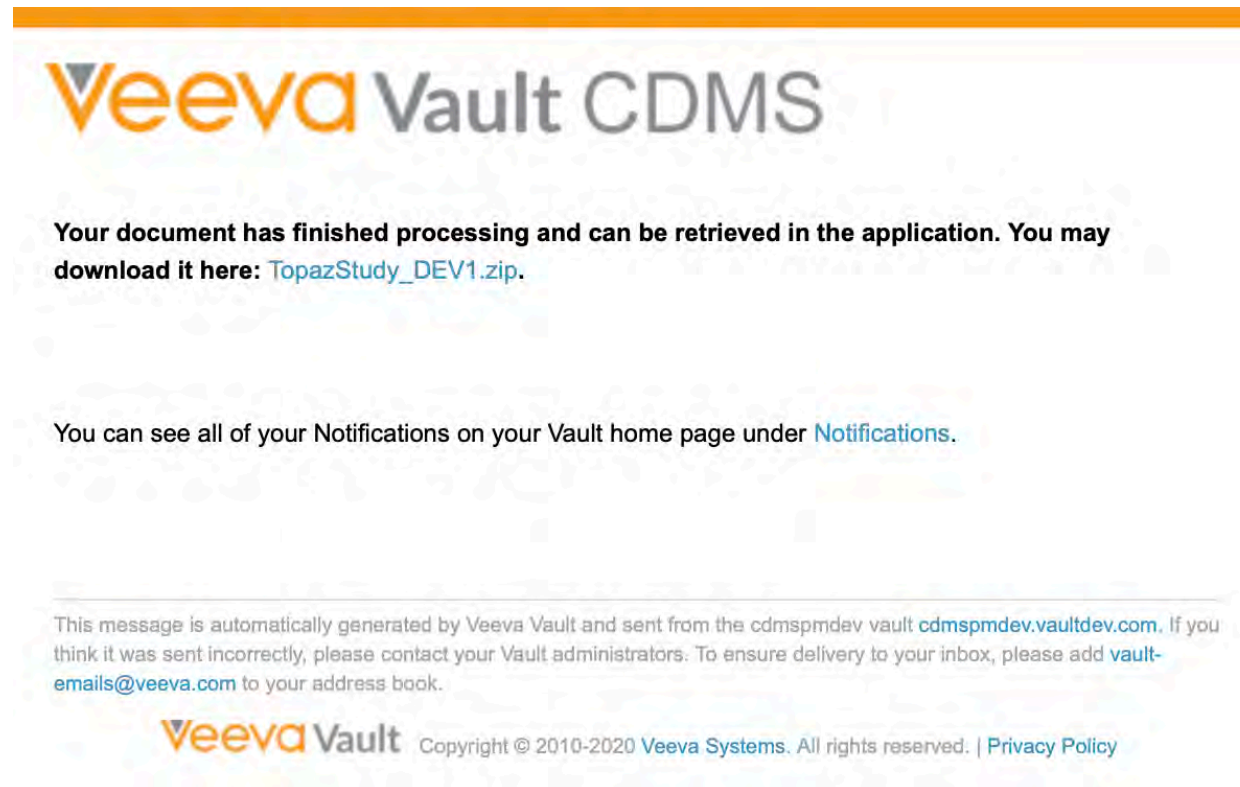
# Emails Use Vault CDMS Logo



Automatic

- Overview

All email notifications sent from Vault CDMS now include the Vault CDMS logo.



Visible

N/A







# Admin Demo



Recap

# New Data Entry Interface

The screenshot displays the Veeva New Data Entry Interface for a subject named TTS (0100-0002) during VISIT 1 (30-Jun-2019). The interface is divided into several sections:

- STUDY TASKS:** A sidebar on the left showing various tasks categorized by status: Forms (348), Review (169), Queries (5), and a question mark icon (17).
- Subject Information:** Subject 0100-0002, Date of Birth 27-Dec-1990, Gender Male, Race Caucasian, Subject Initials TTS.
- Event Selection:** A list of events for VISIT 1 (30-Jun-2019) is shown, including Vitals, Dosing, Hematology, and Hematology. The 'Dosing' event is selected.
- Event Details:** The 'Dosing' event details are displayed, including:
  - Any data to collect? (Yes)
  - Start Date and Time (date and time fields)
  - Stop Date and Time (date and time fields)
  - Actual Dose (text field)
  - Units (dropdown menu)
  - Frequency (dropdown menu)
  - Route (dropdown menu)
- COMMON FORMS:** A section at the bottom showing 'Adverse Events (4)' and 'Adverse Event using IG'.

- Automatically enabled for New studies
- Existing Studies must be enabled

# Form Enhancements

## Progressive Display

Progressive Display

Controlling Item\*  
pregnancy\_test (Pregnancy Test) > res...

Controlling Item Value\*  
Positive

Display Type\*  
Show

Cancel Save

Pregnancy Test

Date of Specimen Collection  
16-Mar-2020

Specimen Type  
Blood

Result  
 Positive  
 Negative

Pregnancy Term

Pregnancy Week  
4

## Indenting

Display Override

Label  
If Other

Short Label  
If Other

Indent Level  
3

Physical Exam (1 of 6)

Body Area  
Extremities ? ← Indent Level 0

Physical exam performed? ← Indent Level 1

Date of Exam  
date ← Indent Level 2

Did the physical exam identify any abnormalities?  
 Yes  
 No

Please specify abnormalities: ← Indent Level 3

# Linking Forms and Copy Indications

### Form Linking

**Form Link**

**Name\***  
AE to ConMed

**Description**

**Linked Forms\***  
 adverse\_event (Adverse Event)  
 concomitant\_medications (Concomitant Medications)

Cancel Save and New Save

Common Forms: Adverse Events : Reference # 1 (1 of 6)

FORM | GENERAL MEDICAL HISTORY (0) | PRIOR AND CONCOMITANT ... (0)

Adverse Events	
Adverse Event	Headache
Start Date	17-Mar-2020
Ongoing?	No
End Date	17-Mar-2020
Severity	Mild
Toxicity Grade	Mild (Grade 1)
Serious?	No

AE Serious Details

### Coding Configuration

Form Type: ConMed

Dictionary Release: GLOBALG3Sep17

Verbatim Item: Medication

Related Item(s):  
 Route of Administration: Route  
 Indication: Indication  
 Does Unit: Dose

Coding Method:  
 Code with Indication  
 Code with Route

Copy Indication From Link:  
 Link: AE to ConMed  
 Copy Item Value: Adverse Event (adverse\_event)

Cancel Save

### Common Forms: Concomitant Medications : Reference # 1 (1 of 2)

FORM | ADVERSE EVENT (0)

Prior and Concomitant Medications

Medication: Tylenol

Start Date: 10-Mar-2020

Start Time: 10:00

Ongoing?: No

End Date: 10-Mar-2020

End Time: 10:05

Indication

Link and Copy

Reference #	Event	Adverse Event	Start Date	Ongoing?	End Date	Severity	Toxicity Grade	Serious?
1	Common Forms	Headache	09-Mar-2020	Yes				
2	Common Forms	Headache	10-Mar-2020	No	10-Apr-2020	Mild	Mild (Grade 1)	No
3	Common Forms	Headache	11-Mar-2020	No	11-Mar-2020	Mild	Mild (Grade 1)	No

Link and Copy



# Email Groups

New Email Group ✕

Name\*  
Safety\_Group

Description  
All Safety members are included

Cancel Save and New Save

Virtuso Study\_DEV1

Casebook Versions Query Rules Jobs **Email Group Assignment** Sites Study Countries FTPs Review P

All Email Groups > Safety\_Group

+ Add Other User Search

Last Name	First Name	User Name	Company	Email
-----------	------------	-----------	---------	-------

- Define Email Group in Studio
- Add users to Email group in EDC Tools
- Create a rule that triggers an email to the Group (eg. *Serious Adverse Event occurs, an email gets sent to the Safety Email group*)

## Actions

Perform the following action(s) when the Expression evaluates to true.

Send Email ▼ To:

Subject:  0/125

Message:

Some text formatting with HTML tags is permitted. [Learn more.](#)

ig1 (IG1)

- infusiondate (InfusionDate)
- subject\_id (Subject ID)
- Static Tokens
- Event Date
- Site Number
- Event Group Sequence
- Subject Name
- Site Name



# Rule Enhancements

## Copy Rules

### Rules

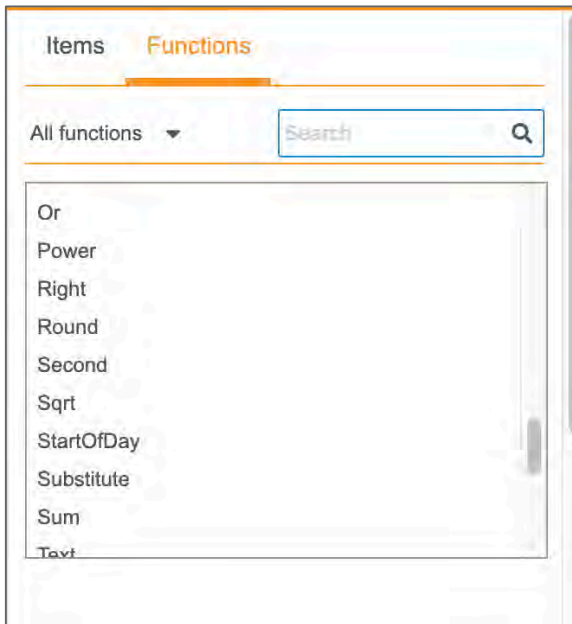
+ New Rule

Copy From Study

Search



## New Rule Functions



- Power()
- Sum()
- Average()
- StartOfDay( date, timezone)
- Today(time zone)

## Define what dates are associated to the Subject Status

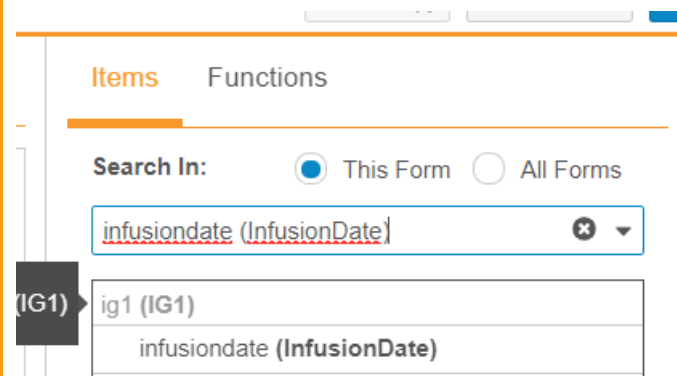
### Actions

Perform the following action(s) when the Expression evaluates to true.

Set Subject Status ▾ **Enrolled** ✎

Set status change date to: Event ▾ **Main\_Study\_Cohort\_1 > Visit1** ✎

## New Items tab and Enhanced UI for Faster Rule Creation



# Optional Review Plans & Jobs

- Create Review Plan with optional Reviews in Studio
- Assign Review Plan to Site in EDC Tools – Review Plan Assignment
- Run job – SDV Reassignment or DMR Reassignment for all sites or select sites to execute Review Plan

External ID	Required	No Review	Optional	InfusionDate
infusiondate			100%	IG1
vitals	100%			InfusionDate
				Subject ID





# Review Plan Template & New Sites

Study Template ⓘ

<b>Default SDV Plan</b> SDV High Risk Plan	<b>Default DMR Plan</b> DMR High Risk Plan
<b>Override SDV Plan</b>	<b>Override DMR Plan</b>
<b>Override Subjects</b>	<b>Override Subjects</b>

Edit

New Study Site

Site Number

Site Name

Status  
Active

Study Country  
  
Algeria  
Argentina  
Armenia  
Austria  
United States  
+ Create new Study Country

Active Version

Cancel Save

- Create a Review Plan Template in Studio so any new site inherits the Review Plan
- Adding a new Site in EDC Tools can add a new Study Country and select active Casebook version at the same time. (*these were previously separated*)

# Deployments and Environments

## Deploy Custom Objects & Custom Roles

### Deploy Study Design

Deploy study design from the **CLM-22\_UAT2** environment

#### Destination Environment

CLM-22

- Create detail PDF
- Delete Study Data
- Include System Data
  - Custom Objects and Custom Roles

#### Reason for Change

0/255

Cancel Deploy

## Add Production Environments at a later time

My Studies > TopazStudy

All Environments Users

Search

Environment Type: All

1-6 of 6

Environment	Highest Casebook Version	Study Build	Environment Type
TopazStudy_DEV1	1	2	DEVELOPMENT (1 of 2)
TopazStudy_UAT1	1	1	UAT (1 of 5)
TopazStudy_UAT3	1	1	UAT (3 of 5)
TopazStudy_UAT2	1	1	UAT (2 of 5)

CREATE ENVIRONMENT

- + Development
- + UAT
- + Training
- + Production

VIEW

History



# Role Management

## Permission Updates

- View Form Linking and Edit Form Linking
- Manage Study Role Permission
- View Code
- Workbench Tab ( \*if enabled for your Vault)
- Removed "Manage Study Lock" Permission from CDMS Deployment Administrator

## Custom Object Permissions


	Custom CRA	Custom CRC	Custom DM	Custom DM1
Number of Users	1	0	0	0
Manage Role	⚙️	⚙️	⚙️	⚙️
▶ Standard Tabs				
▶ Permissions				
▼ Custom Objects				
Protocol Deviation				
Read	✓	✓	✓	✓
Edit		✓	✓	✓
Delete			✓	
Custom Labs				
Read	✓		✓	
Edit	✓			
Delete				

## Delete Custom Roles

	Custom CRA	Custom CRC	Custom DM	Custom DM1	CDMS Auditor Read	CDMS v
Number of Users	1	0	0	0	0	0
Manage Role	⚙️	⚙️	⚙️	⚙️	⚙️	⚙️
▶ Standard Tabs						
▶ Permissions						
▼ Custom Objects						

Context menu for Custom CRA: Edit, Rename, Delete

## Study Designer Role(s)

+ New Role 

Download Study Roles

	CDMS Principal Investigator	CDMS Study Designer	CDMS Study Designer Read Only	CDMS Sub Investigator	CDMS User Act
Number of Users	0	0	0	0	0
Manage Role					
Manage Learning					✓
View Casebook	✓		✓		
View Study Design		✓			
Design Study	✓				
Manage JReview Job					

# User – Federated ID & Activity Report

## Federated ID for Single Sign On

**User Name**  
user1 @cdmspm.com

**Email**  
dev.null@veeva.com

**Title**

**Last Name**  
first

**First Name**  
last

**Company**

**Federated ID**  
5364757858

**Language**  
English

**Locale**  
United States

**Timezone**  
(GMT-04:00) Atlantic Standard Time (America/Puerto\_Rico)

Add as Principal Investigator

## User Activity Report

My Studies > Cholecap

All Environments **Users**

New User Import From File Search

1-5 of 8

Last Name	First Name	User Name	Company	Email
Lin	Sharon	sharon.lin@cdmspm.com	Veeva	sharon.lin@veeva.com
Studio	Sam	Studio@cdmspm.com	Veeva	sharon.lin@veeva.com
Deployment	Dan	Deployment@cdmspm.com	Veeva	sharon.lin@veeva.com
Admin	Amy	admin@cdmspm.com	Veeva	sharon.lin@veeva.com
Paresys	Quentin	quentin.paresys@cdmspm.com		quentin.paresys@veeva.com
Claire	Lundeby	Claire@cdmspm.com	Veeva	Claire.lundeby@veeva.com
CRC Cindy	Smith	CRC_Cindy@cdmspm.com		Sharon.lin@veeva.com
CRC	Custom	Custom_CRC@cdmspm.com		cory.etzcom@veeva.com

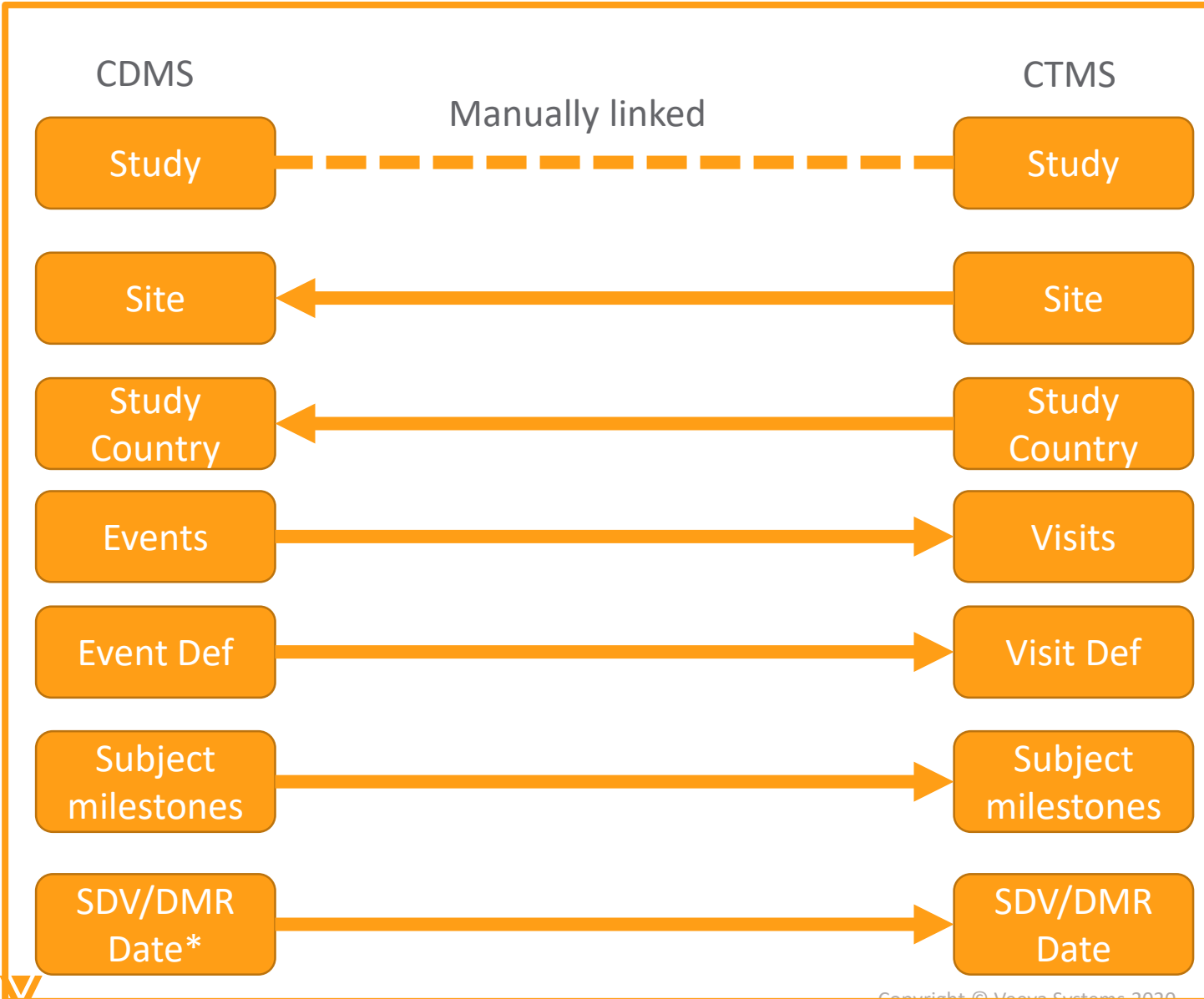
EXPORT  
CSV  
User Activity Report



# CTMS Spark Integration & APIs



Configuration



## CDMS APIs to support integration to IRTs

- Set Subject Status API
- Unset Subject Status AP
  - Updates subject status to current status
- Create Event Group API

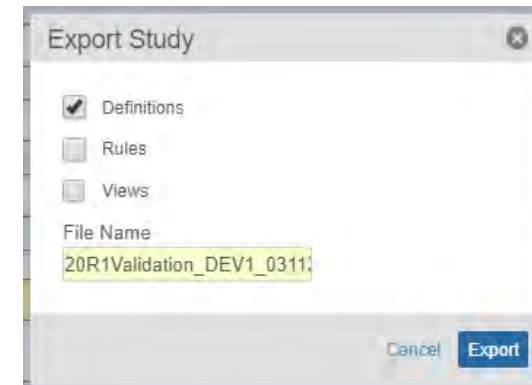
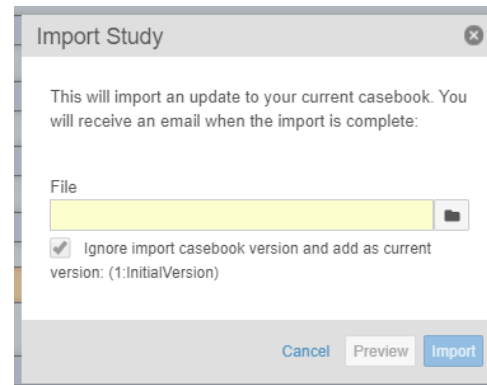
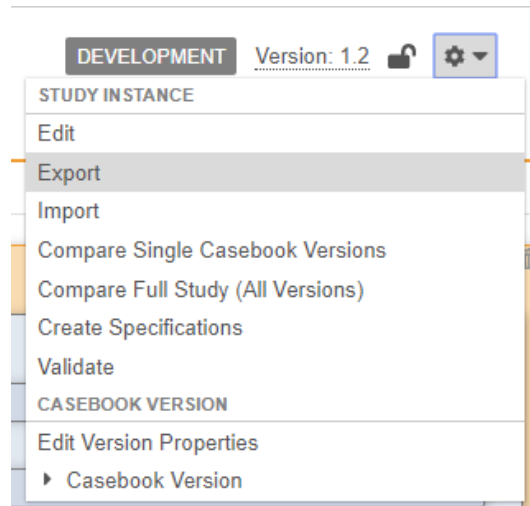
Visible

N/A

# ODM Import/Export Data into Study

Bring in external 3<sup>rd</sup> party standards or from a disconnected Vault

- only in Automated Deployment Studies in Studio





Thank you