# 20R1 Customer Webinar
# Studio & Admin

April 02, 2020

Veeva

Sharon Lin

Principal Product Manager, Veeva CDMS

Cory Etzcorn

Product Manager, Veeva CDMS


Veeva

# CDMS Product Team

## Dennis Kochanski
Senior Product Manager,
Vault CDMS

## Rakesh Monassery
Senior Product Manager,
Vault CDMS

## Mohammed Al-Adeeb
Senior Product Manager,
Vault CDMS

## Quentin Paresys
Product Manager,
Vault CDMS

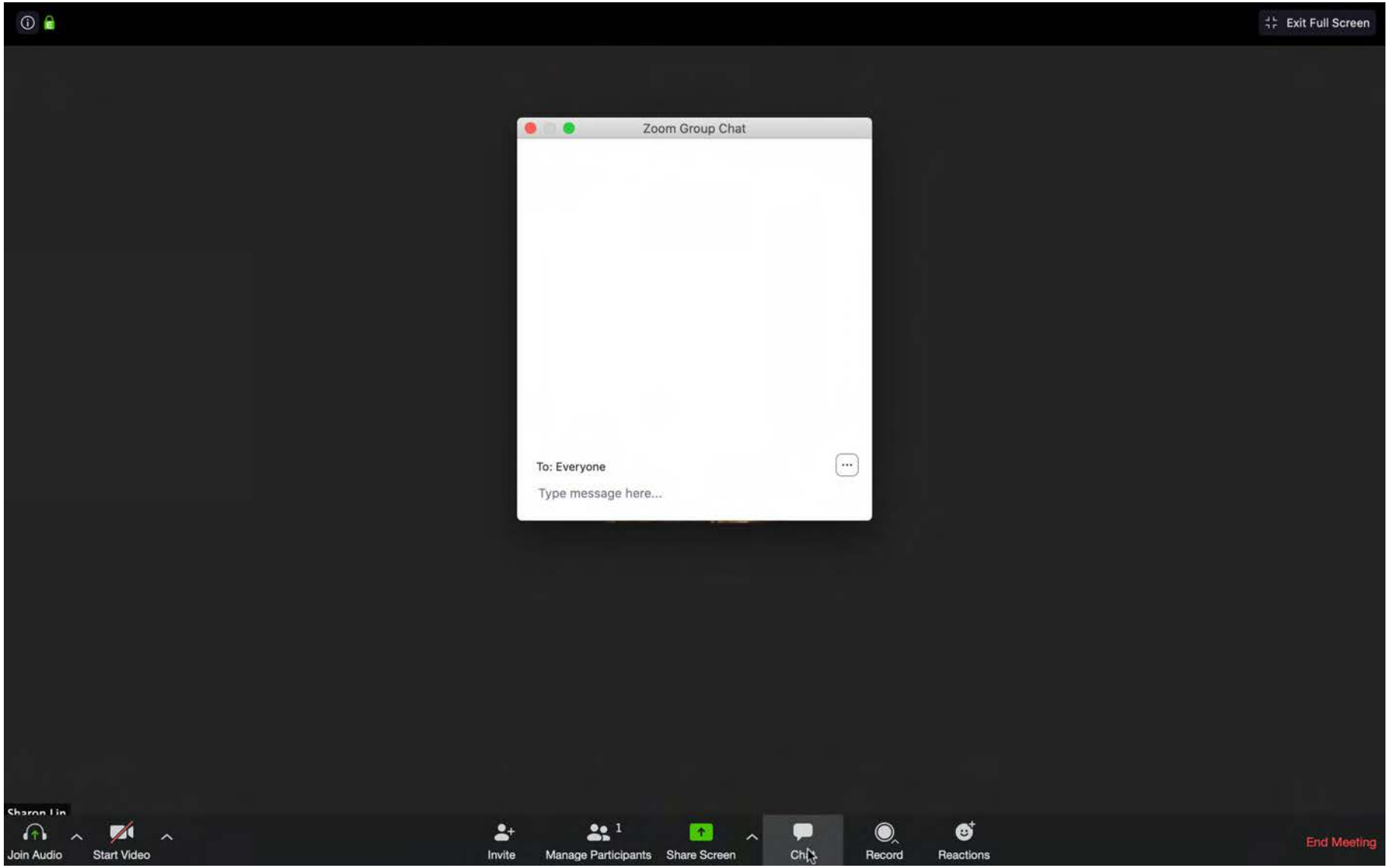
Copyright © Veeva Systems 2020

# 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.

Copyright © Veeva Systems 2020

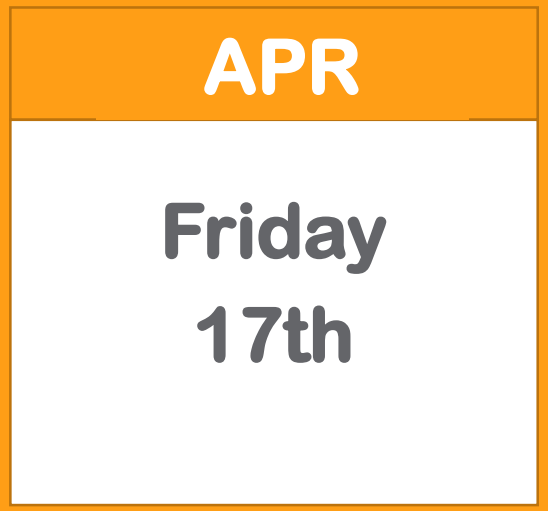
# Interact by using Chat




Copyright © Veeva Systems 2020

# 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




Copyright © Veeva Systems 2020

# 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*

Copyright © Veeva Systems 2020

# Agenda

| Thursday, April 02 |
| --- |
| 20R1 Features |
| Studio Demo |
| Rules and Review Plan Editor Demo |
| Admin Demo |
| Recap |

Copyright © Veeva Systems 2020

# 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**

- Form Linking
- Copy Rules from another Study
- ODM Import/Export for Automated Deployment Studies
- Progressive Display
- Item Indentation

**Review Plans**

- Reviews – "optional"
- setting
- Review Plan Templates

**Rules**

- Set Subject Status Dates
- Send Emails

**Rule Editor Enhancements**

- Expand/Collapse
- Search for Item by name or label on the right side
- Corresponding
- #define statement can be added to expression with one click

**NEW Functions**

- Power(), Sum(),Average()
- StartofDay(date, timezone)
- Today(timezone)
- Reciprocal Rules with @Form

**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

Copyright © Veeva Systems 2020

# 20R1 CDMS Features by Users

**Sites**
Data Entry Tab

**Coding**
Coding Tab

**Study Designer**
Studio

**Admin or Lead Data Mangers**
EDC Tools

Copyright © Veeva Systems 2020

# Feature Enablement Detail

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

Copyright © Veeva Systems 2020

# Studio (Study Designer)

# Form Linking

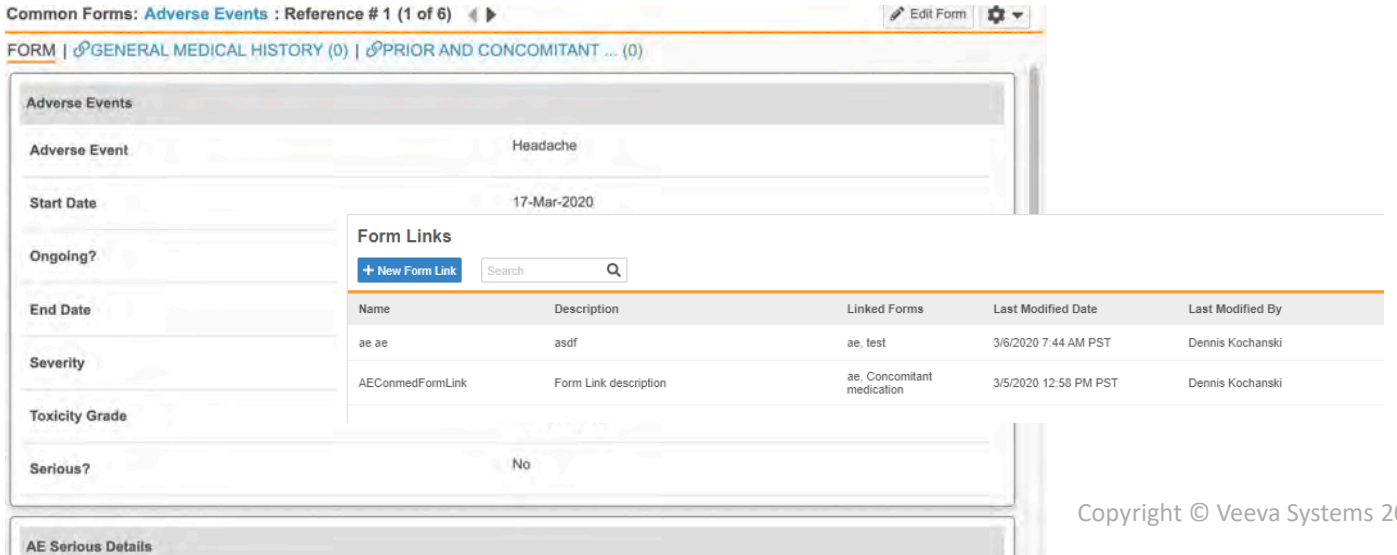
- Overview

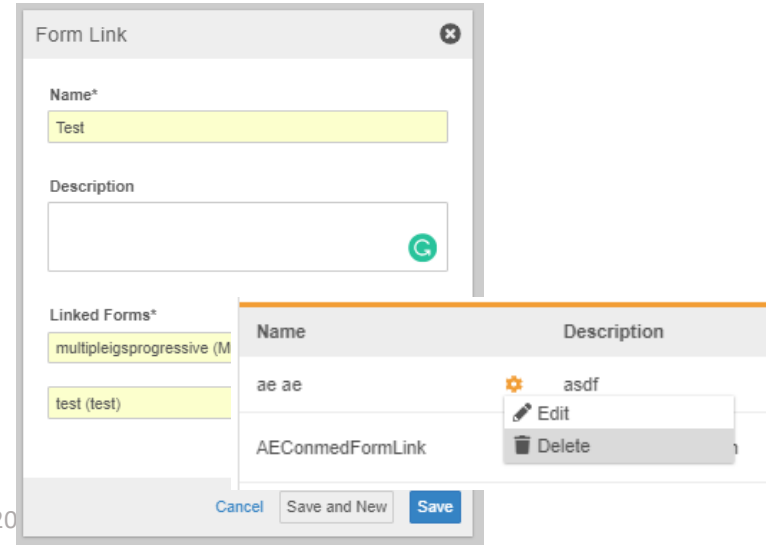
  Studio users can define links between forms, therefore allowing display of relationships. Most common use case AEs to ConMeds.

  - 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.




Copyright © Veeva Systems 2020

Automatic

Visible

STUDY DESIGNERS

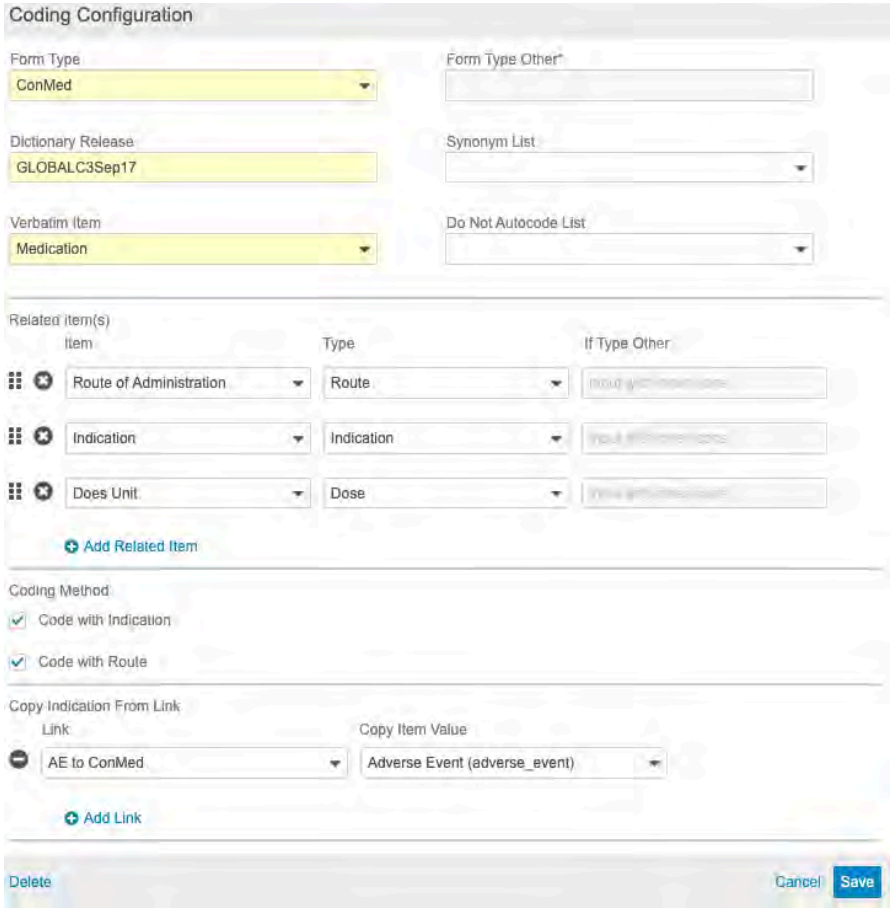
# Copy Indication from Link

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




Automatic

Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

# Progressive Display

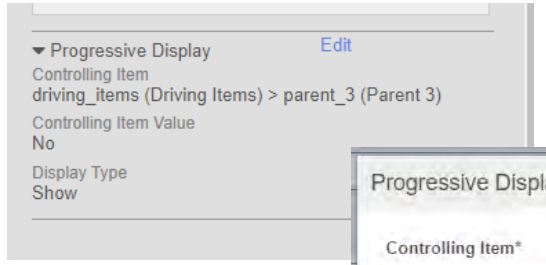
- Overview

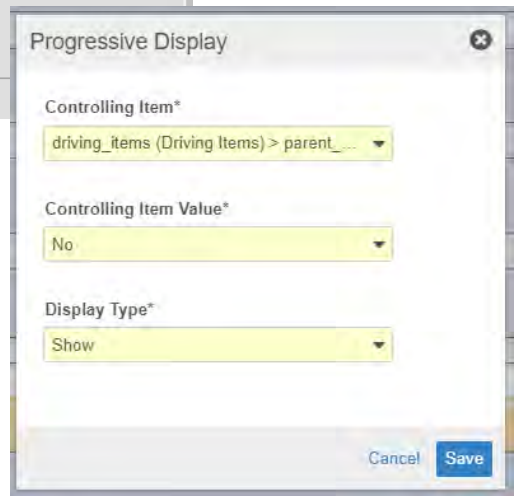
  Study designers can design a form that can dynamically display or hide items based on a data collection point as a user progresses through a form.

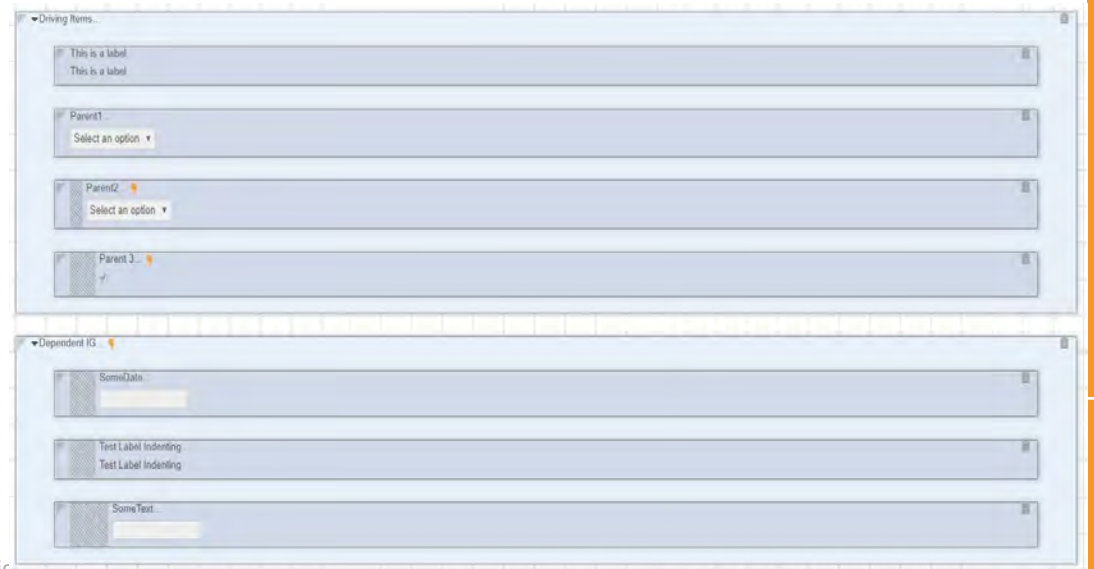
  Supports hide/show or enable/disable at the Item or Item Group level.

  **Must be a codelist or boolean item type*

| | |
|---|---|
| Show/Hide | Item/item group will display (show) upon data collection when criteria is met<br>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<br>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.

Copyrig

Automatic

Visible

STUDY DESIGNERS

# 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

Automatic

Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

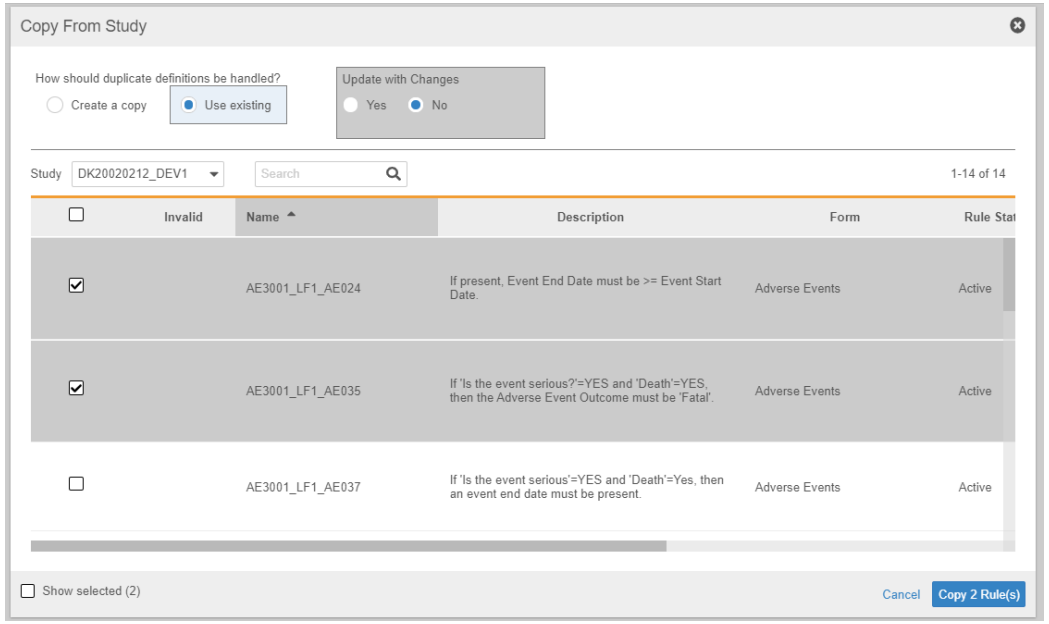
# Copy Rules From Another Study

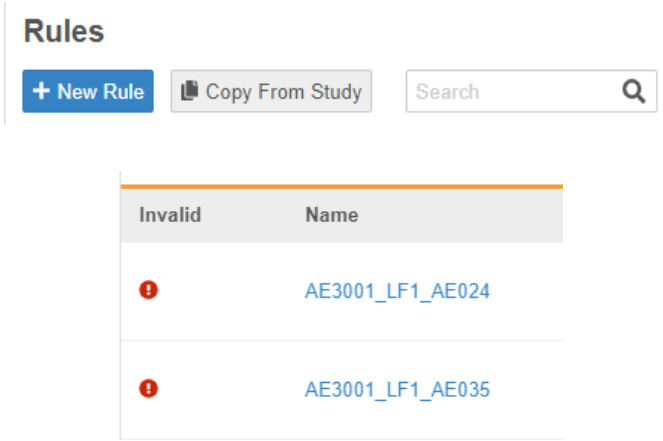
- Overview

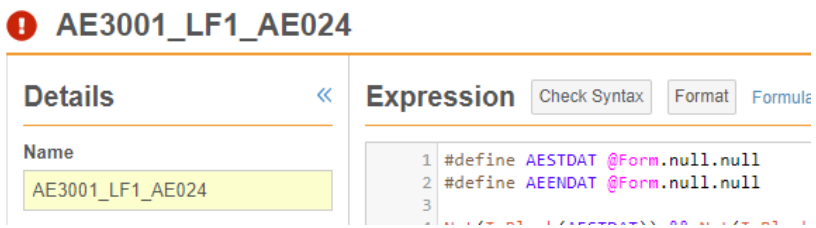
  Studio users can copy rules from another Study. Vault validates all identifiers in the copied rules and shows an indicator when a rule contains an invalid identifier.

- Business Value

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




Copyright © Vee

Automatic

Visible

STUDY DESIGNERS

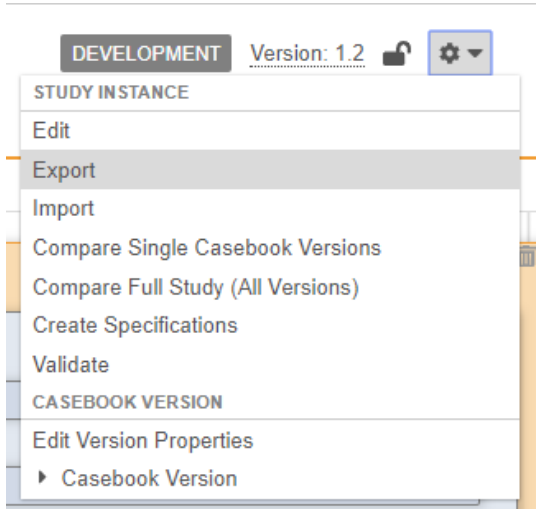
# ODM Import/Export for Automated Deployment Studies

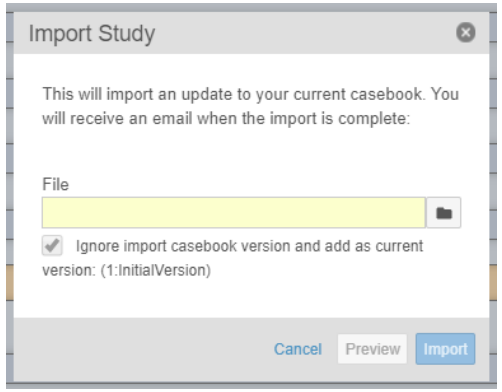
- Overview

  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 3rd party systems – decreasing study development time.



Automatic

Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

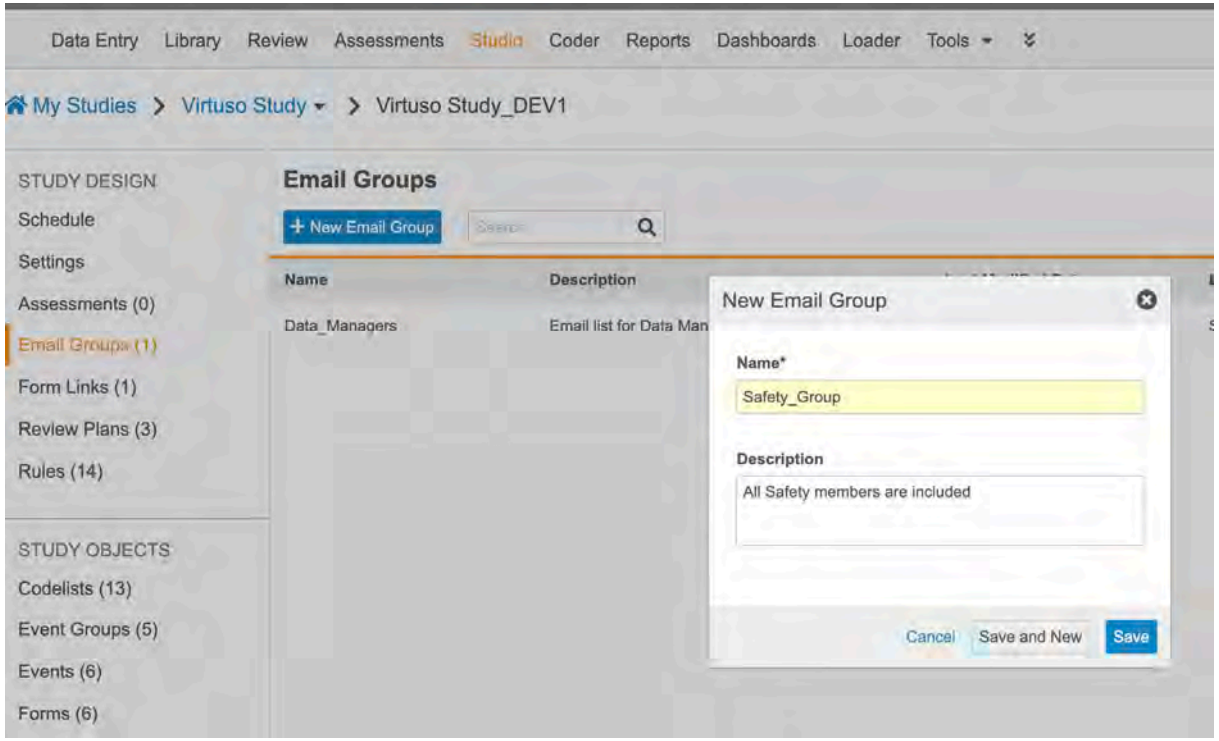
# Setup Email Group

- 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

Copyright © Veeva Systems 2020

# Studio Demo

Copyright © Veeva Systems 2020

# Rules

# Set Subject Status rules - Enhancement

Automatic

- 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.

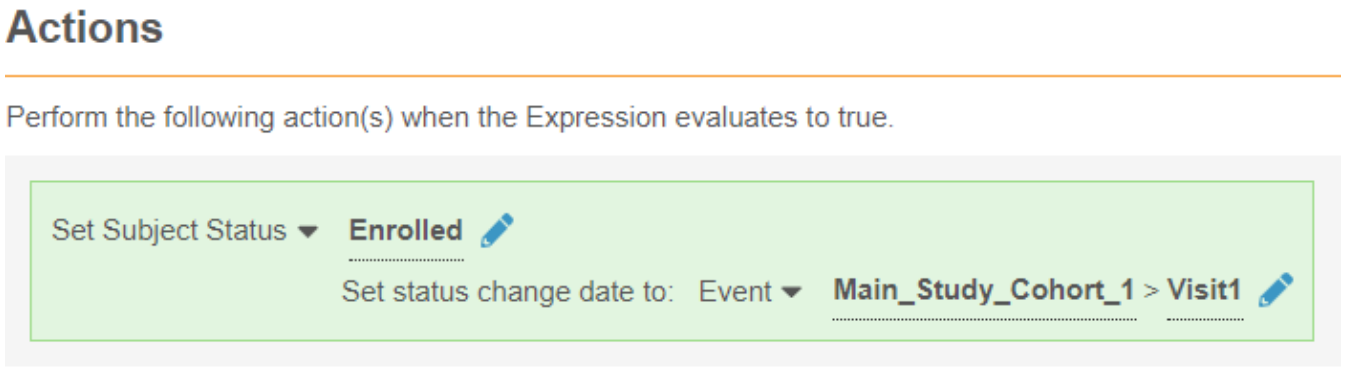
  E.g. if the subject moves to “Enrolled”, the system will populate the “Enrolled date” field with the selected event date or item date

  *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.




Visible

STUDY DESIGNERS

# 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).

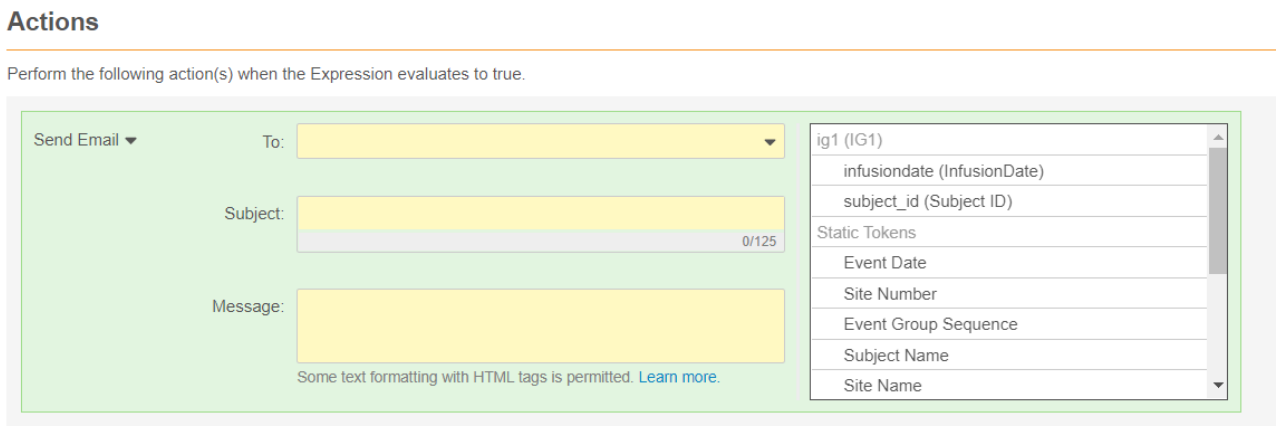
  Email Groups are created in Studio for automatic studies (studies using the new deployment model).

  *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.




Automatic

ONLY AUTOMATIC STUDIES

Visible

STUDY DESIGNERS

# Rule Editor enhancements

- Overview

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

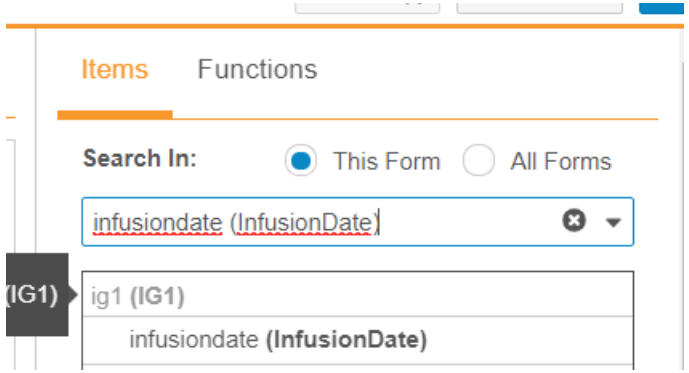
  Study Designers have access to an “Items” tab on the right side of the editor, next to the Functions tab. It allows them to search for an item (by name or label) in the selected form or in the overall schedule.

  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.




Automatic

Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

# 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.

Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

# Reciprocal rules

- 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.

**Automatic**

**ONLY NEW RULES**

**Visible**

**STUDY DESIGNERS**

Copyright © Veeva Systems 2020

# 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.

Copyright © Veeva Systems 2020

# Review Plan Editor

# Optional Setting in the Review Plan Editor

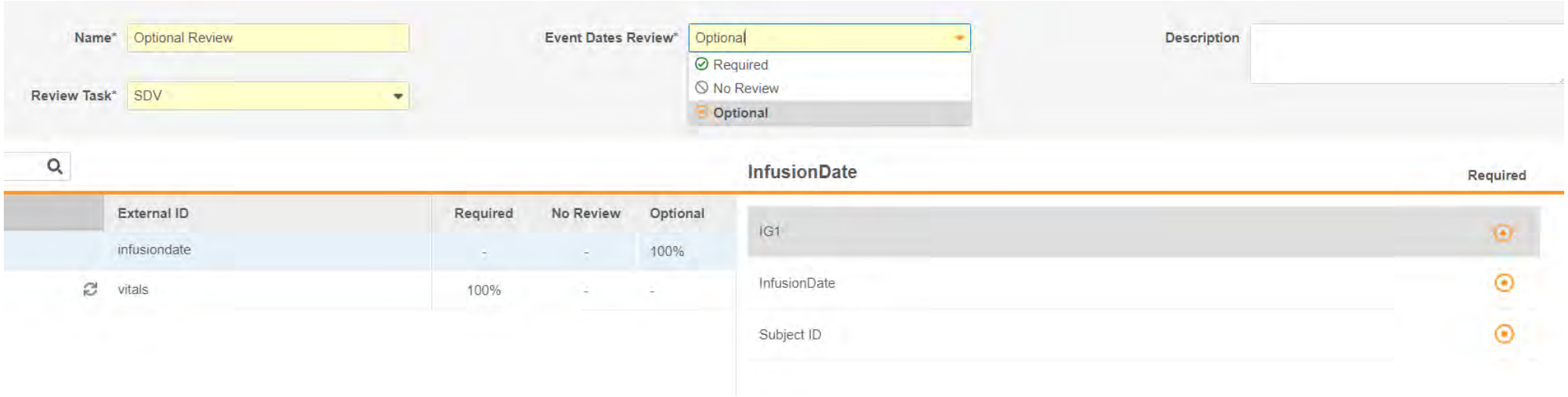
Automatic

- 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.




Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

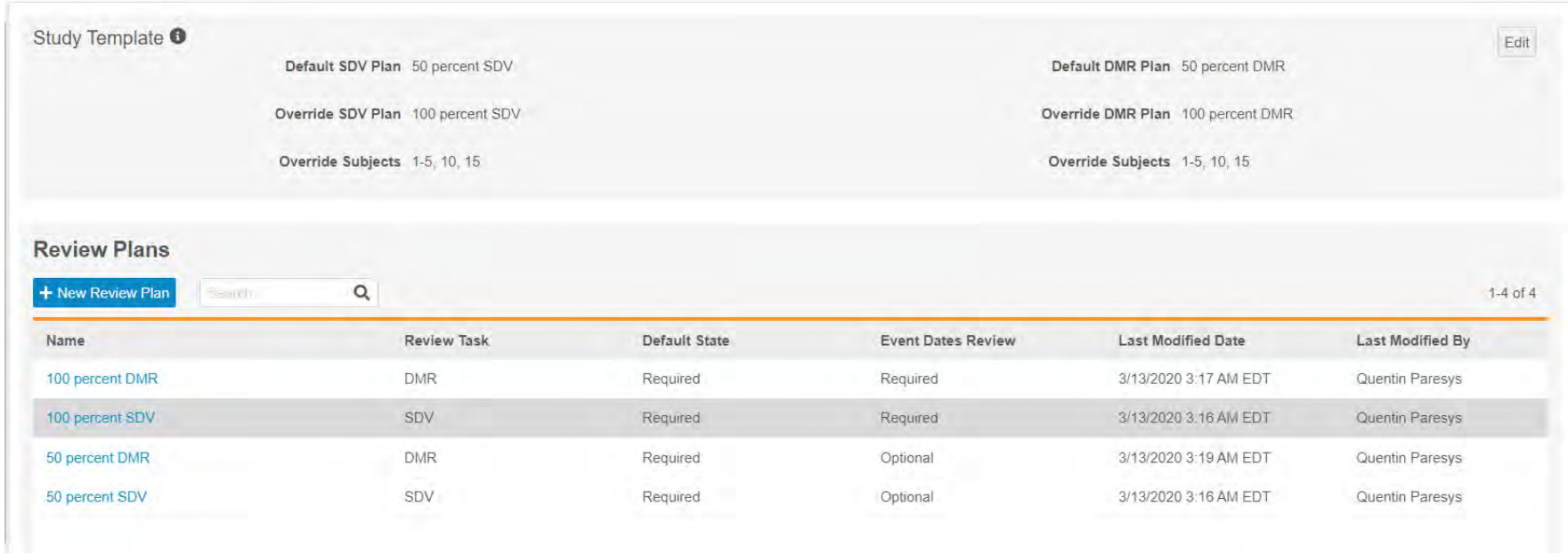
# Study templates for Review Plans

- 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.




Automatic

Visible

STUDY DESIGNERS

Copyright © Veeva Systems 2020

# Rules & Review Plan Editor Demo

Copyright © Veeva Systems 2020

# Admin

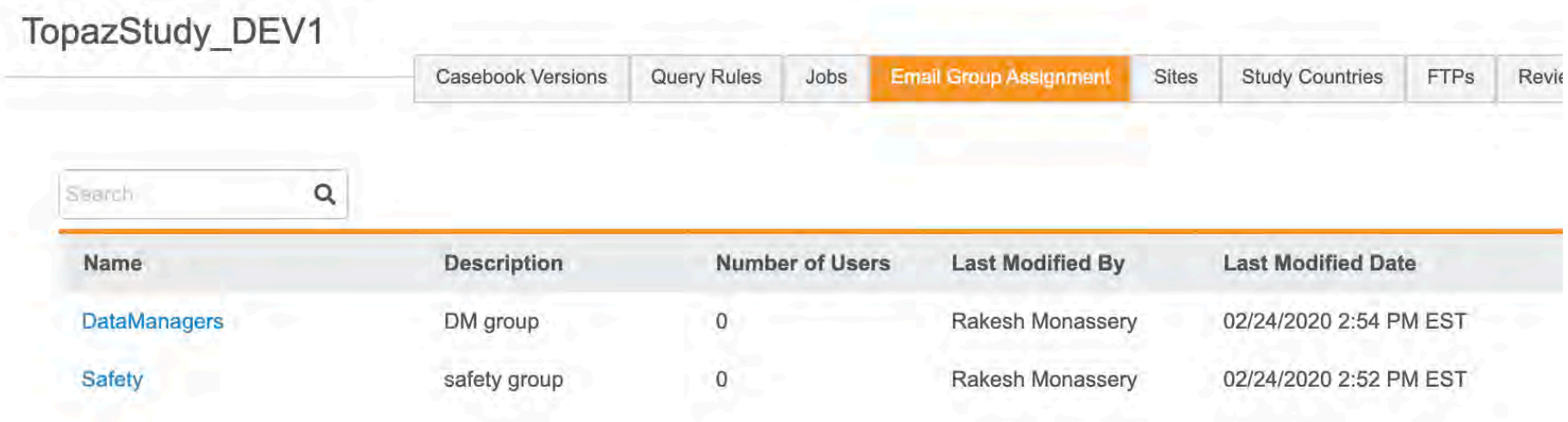
# Email Group Assignment

- 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.




Automatic

Visible

ADMIN

Copyright © Veeva Systems 2020

# Automated Deployments – Custom Roles & Objects

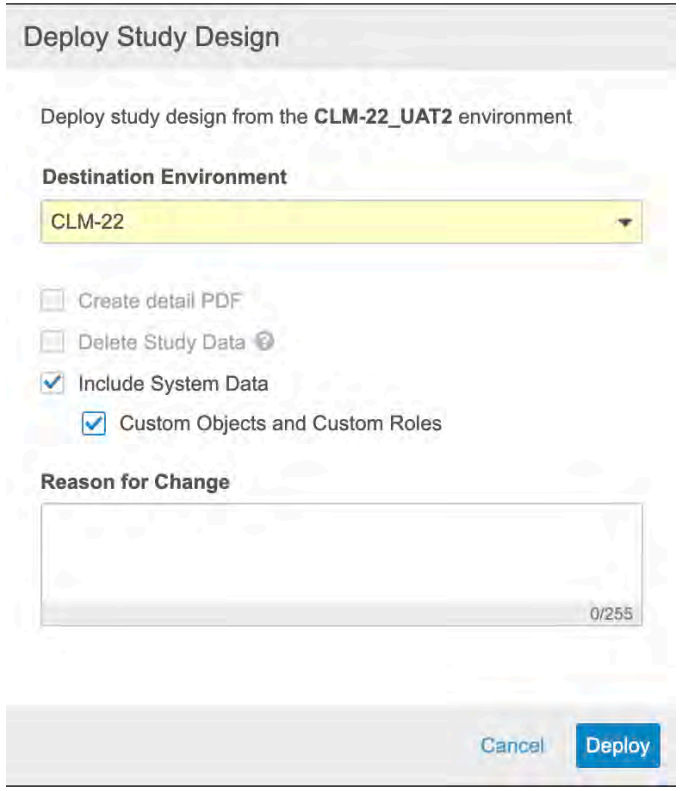
Automatic

- 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.




Visible

ADMIN

# Create a PRD Environment after Study Creation

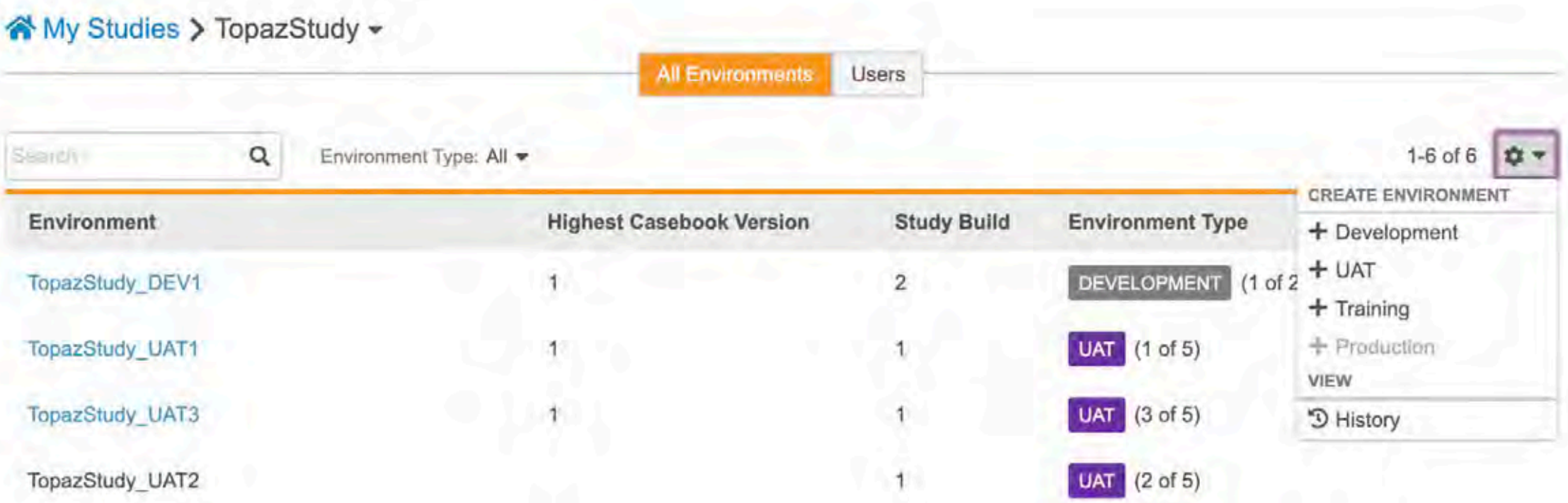
Automatic

- 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.




Visible

ADMIN

# CDMS-CTMS Spark Integration

- 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.

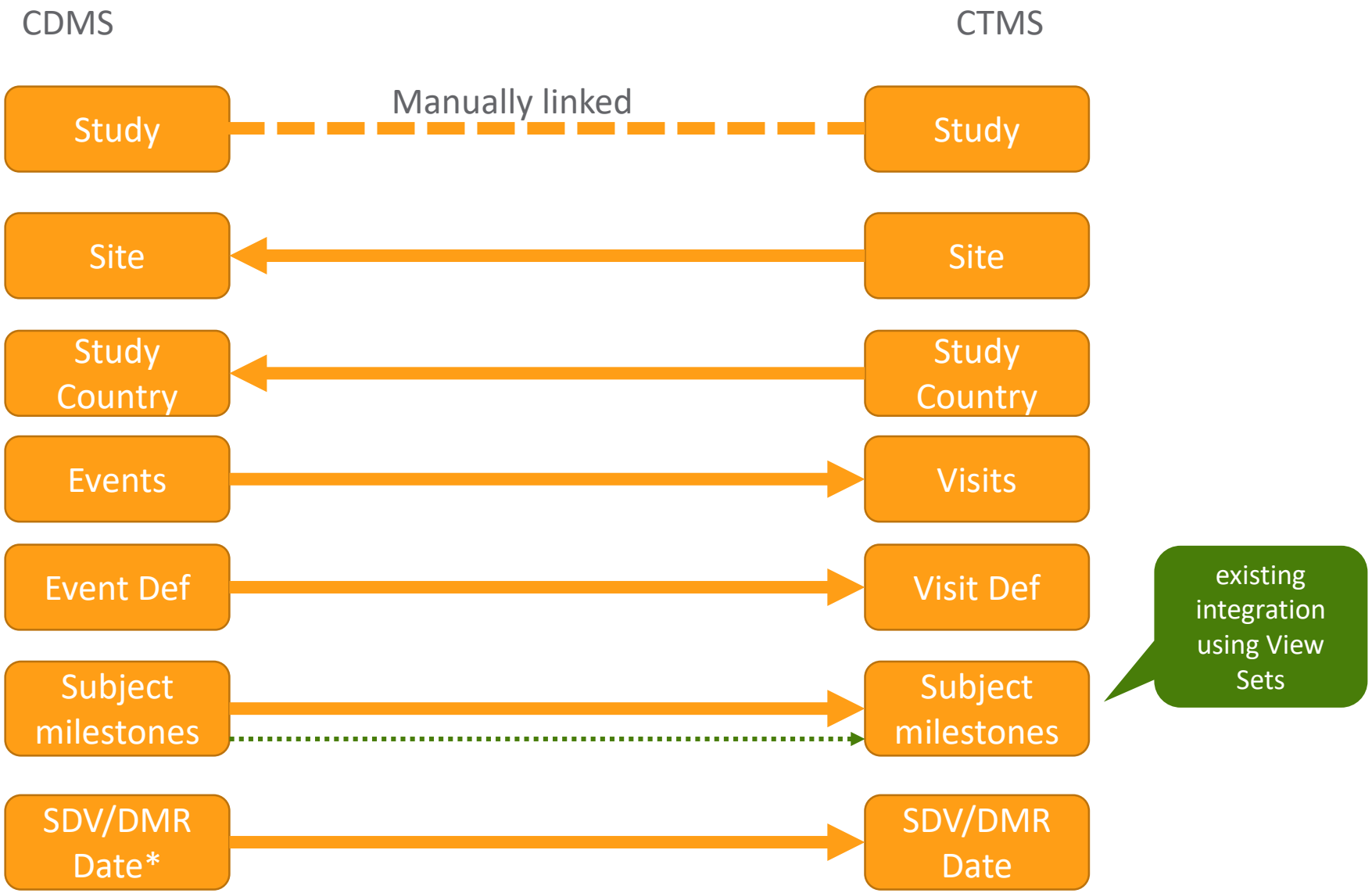
Configuration

Visible

N/A

Copyright © Veeva Systems 2020

# CDMS-CTMS Spark Integration




Configuration

Visible

N/A

Copyright © Veeva Systems 2020

# Study Designer & Designer Read Only Role

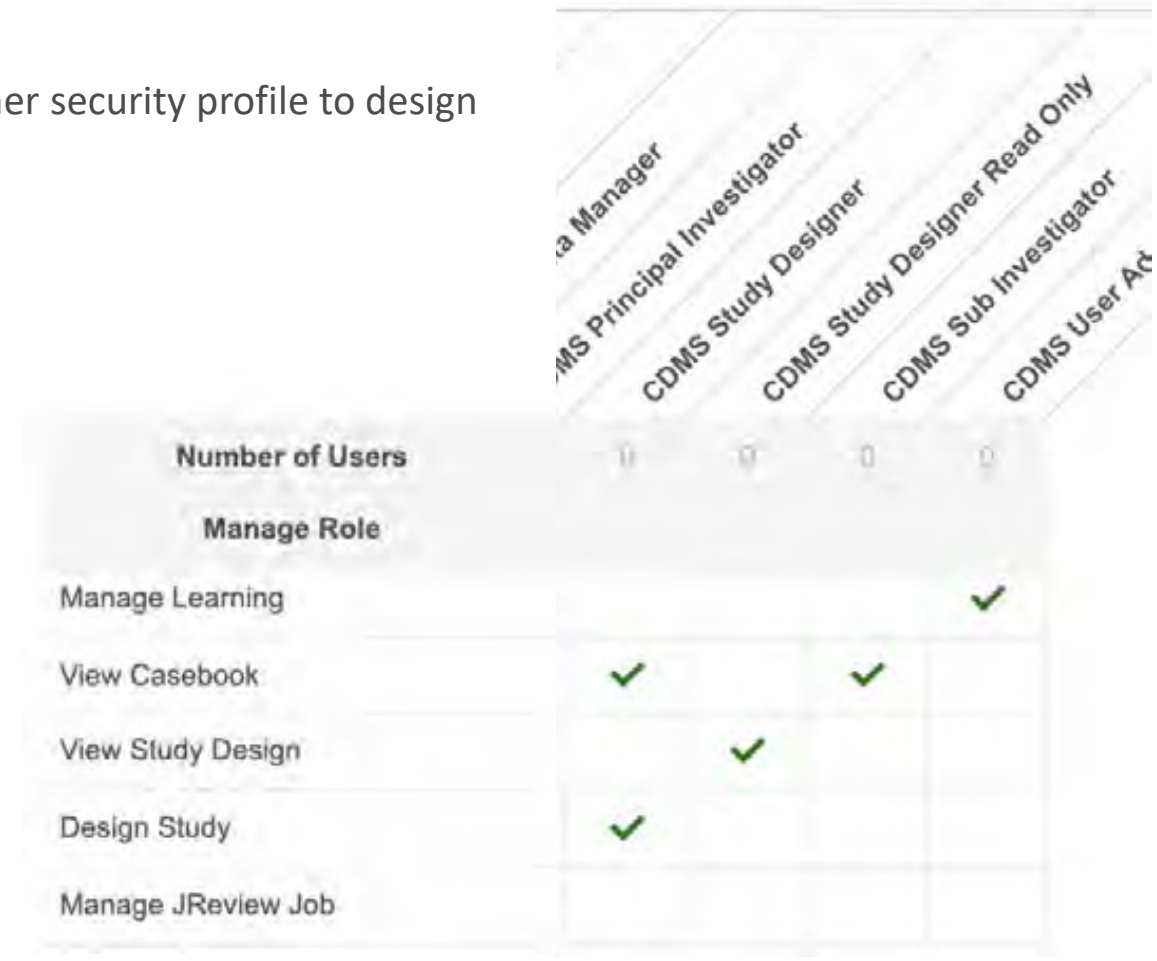
- Overview

  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 |




Configuration

Visible

ADMIN

# Permission Updates

- 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

**Automatic**

**Visible**

**ADMIN**

Copyright © Veeva Systems 2020

# Manage Custom Object Permissions in Role Management

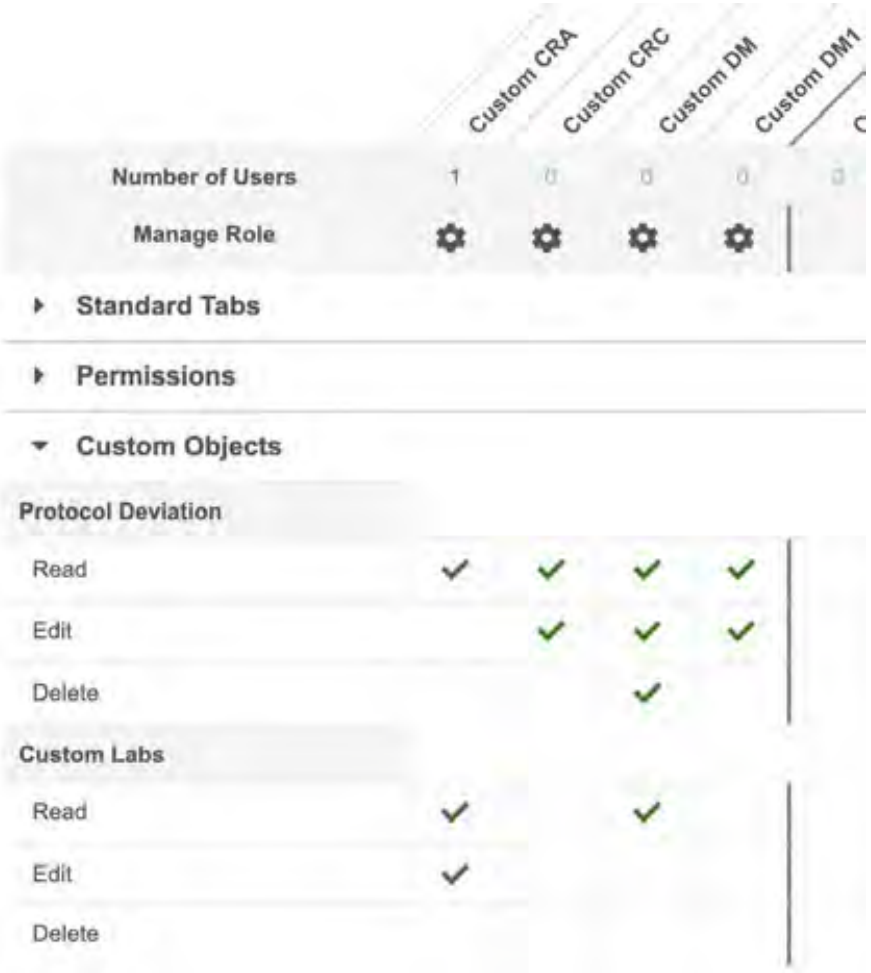
- Overview

  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




Automatic

Visible

ADMIN

Copyright © Veeva Systems 2020

# 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.

Visible

ADMIN

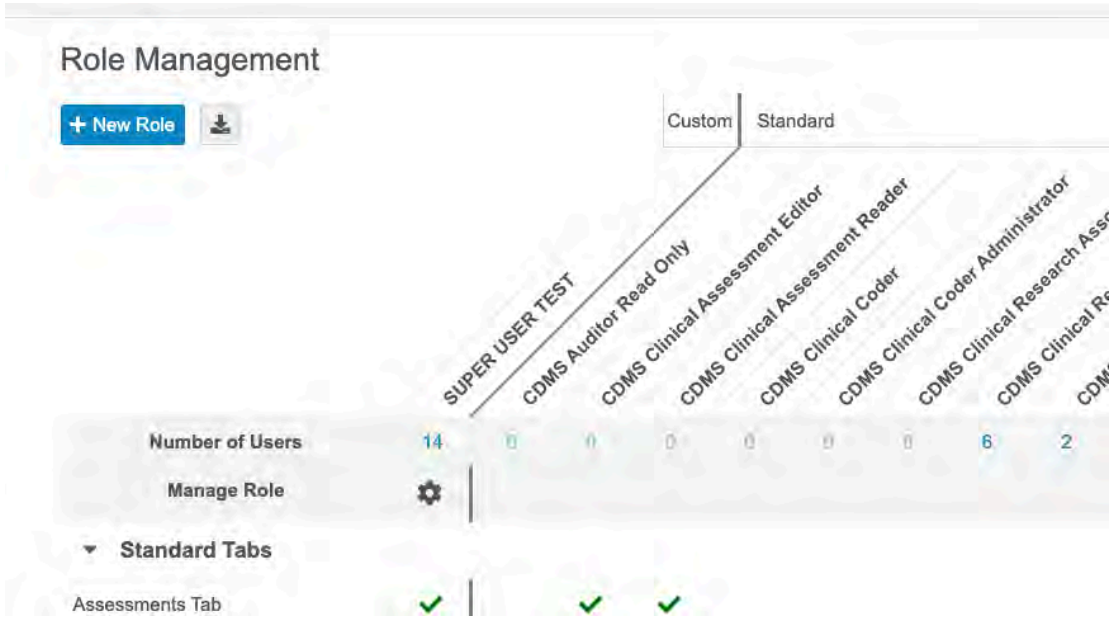
# Download Study Role

- 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.




Automatic

Visible

ADMIN

Copyright © Veeva Systems 2020

# Provide Federated ID during User Creation (UI)

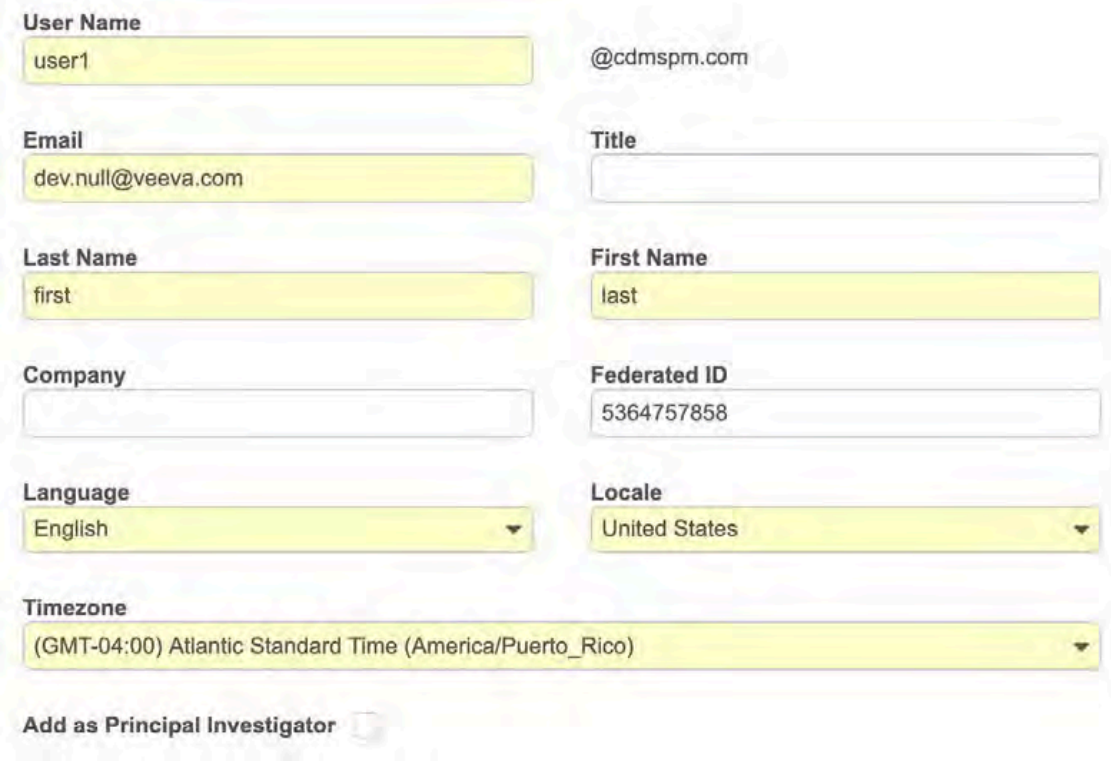
Automatic

- 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.




Visible

ADMIN

# User Activity Report

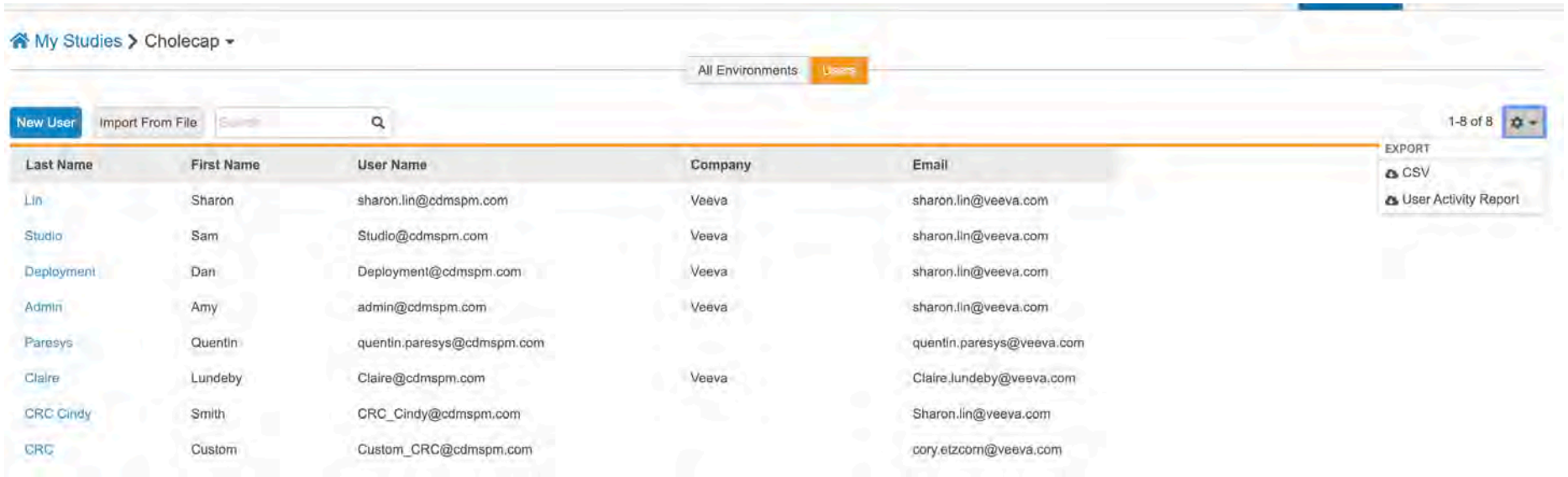
Automatic

- 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.




Visible

ADMIN

Copyright © Veeva Systems 2020

# Active Version & Study Country during Site Creation

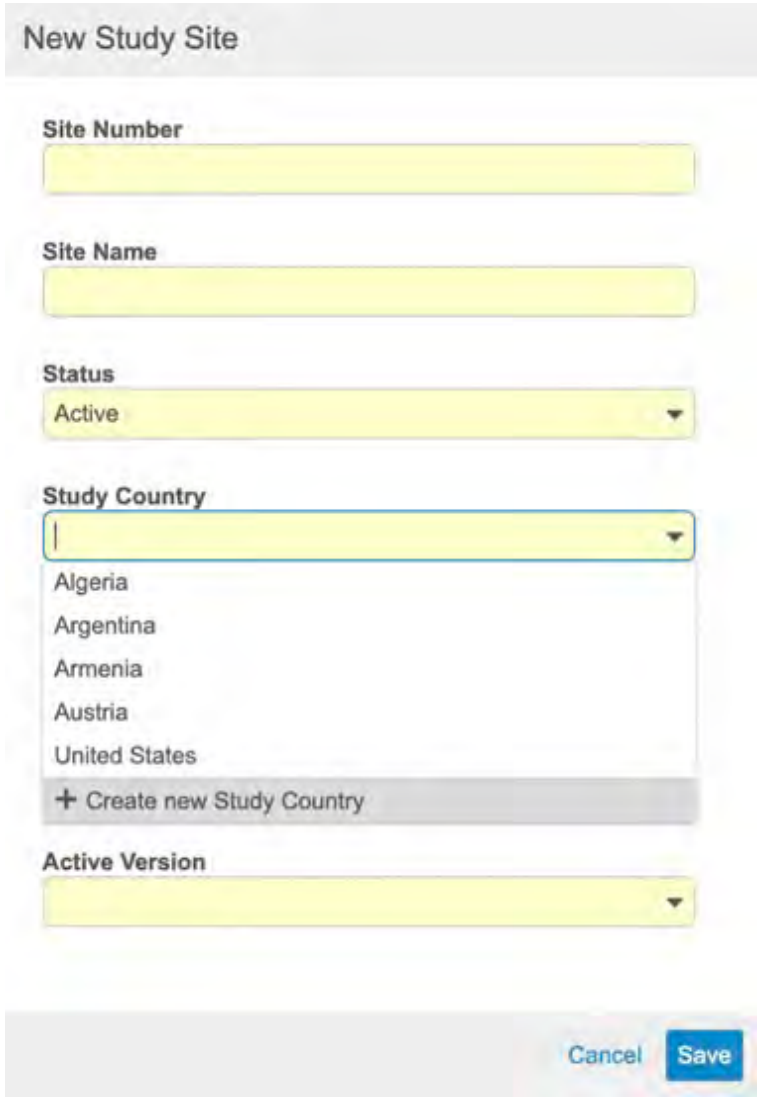
Automatic

- 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.




Visible

ADMIN

Copyright © Veeva Systems 2020

# Site-level SDV & DMR Re-assignment

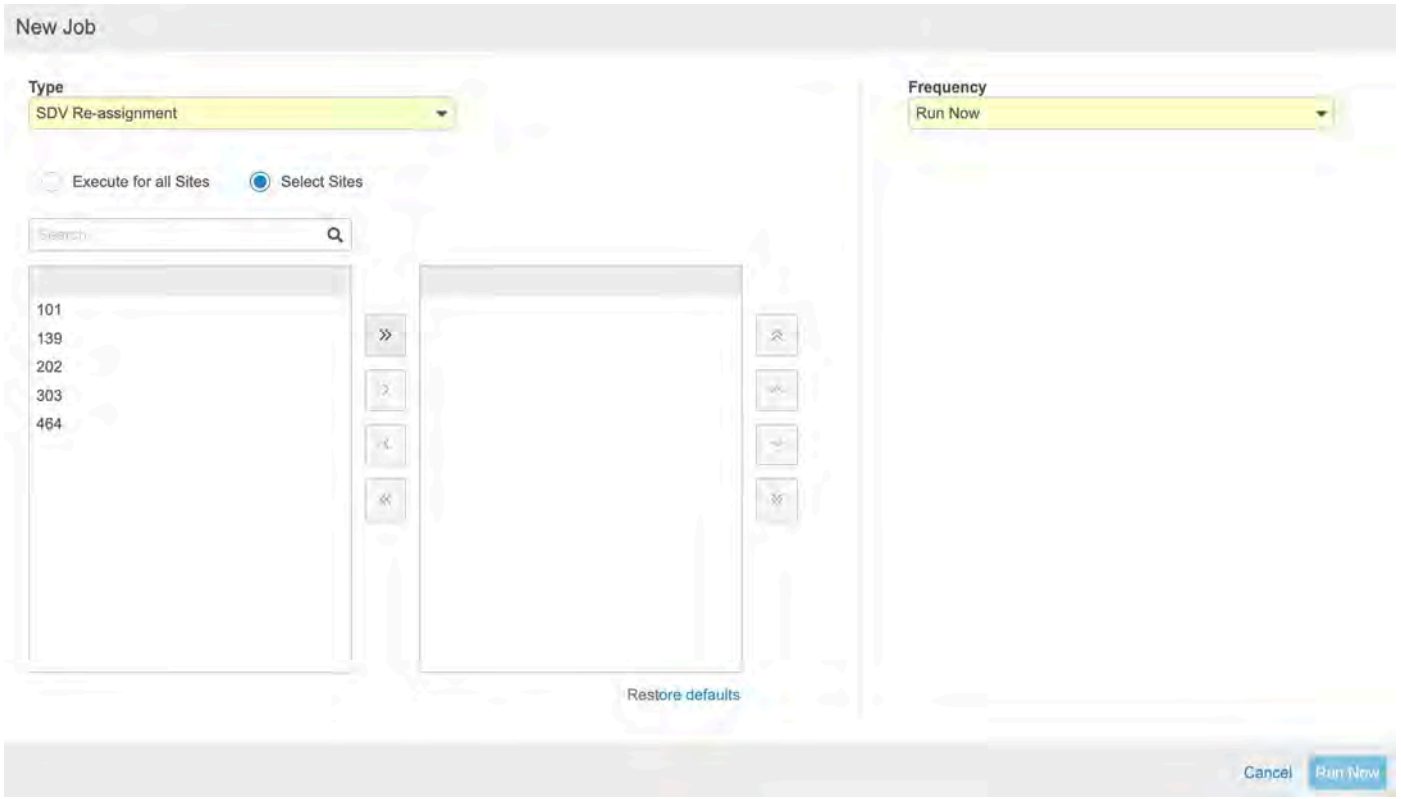
Automatic

- 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.




Visible

ADMIN

# CDMS 20R1 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 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

Automatic

Visible

ADMIN

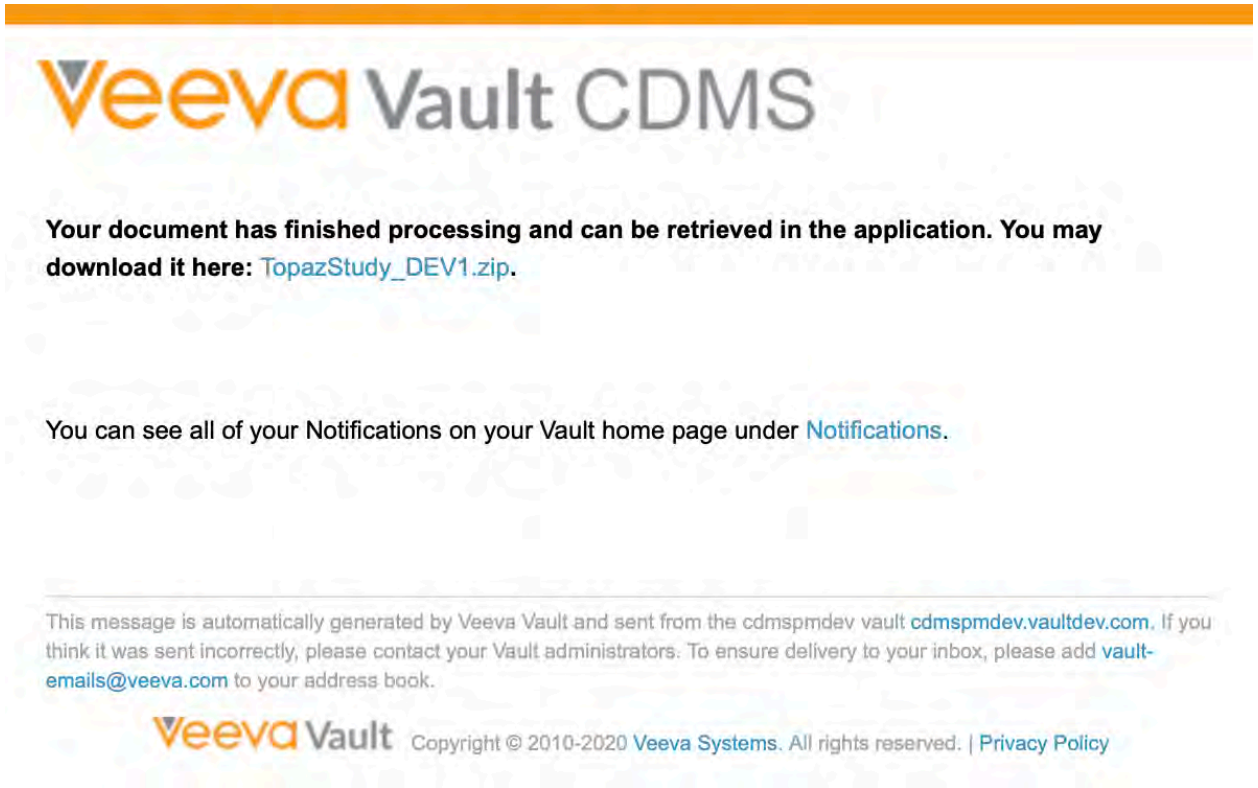
Copyright © Veeva Systems 2020

# Emails Use Vault CDMS Logo

Automatic

- Overview

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




Visible

N/A

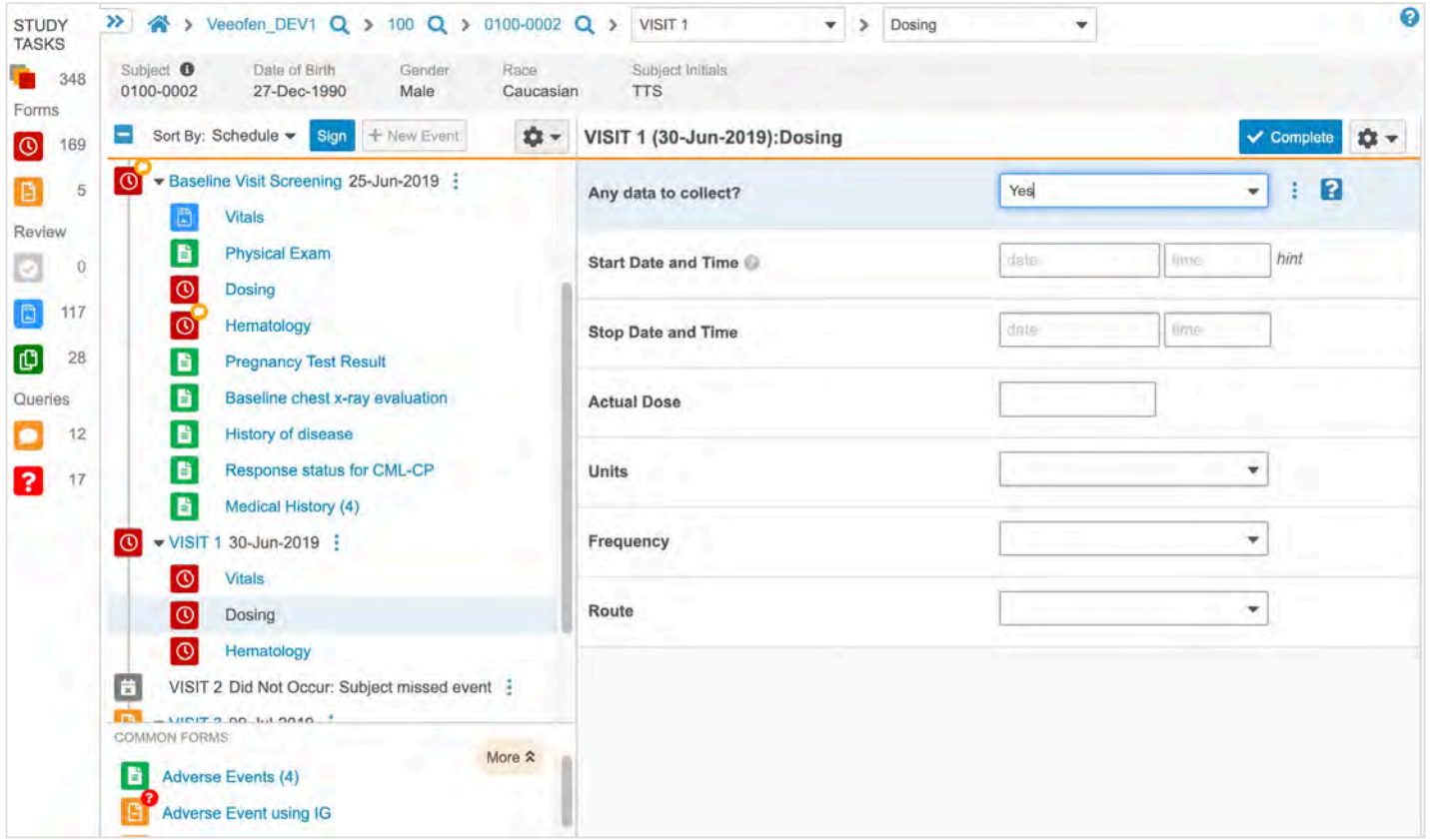
Copyright © Veeva Systems 2020

# Admin Demo

Copyright © Veeva Systems 2020

# Recap

# New Data Entry Interface

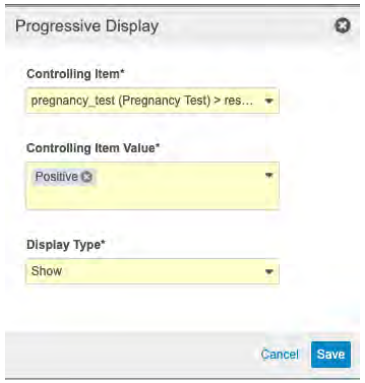


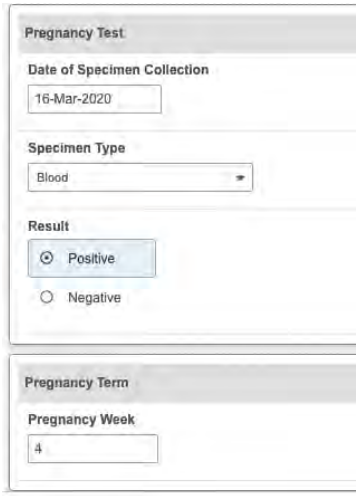

- Automatically enabled for New studies
- Existing Studies must be enabled

Copyright © Veeva Systems 2020

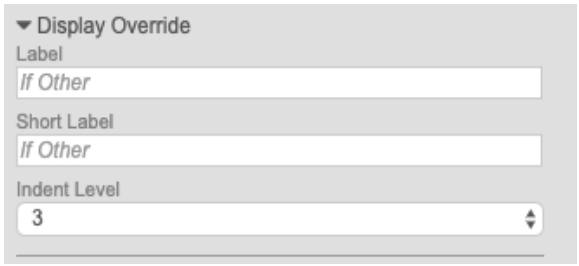
# Form Enhancements

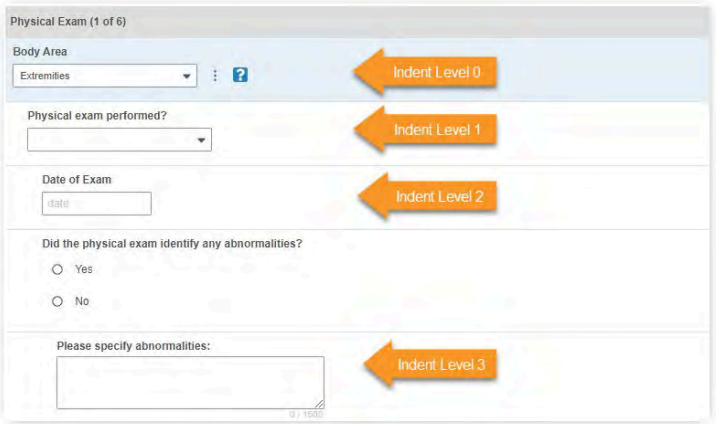
## Progressive Display




## Indenting

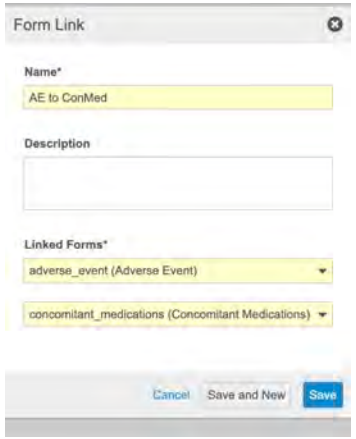


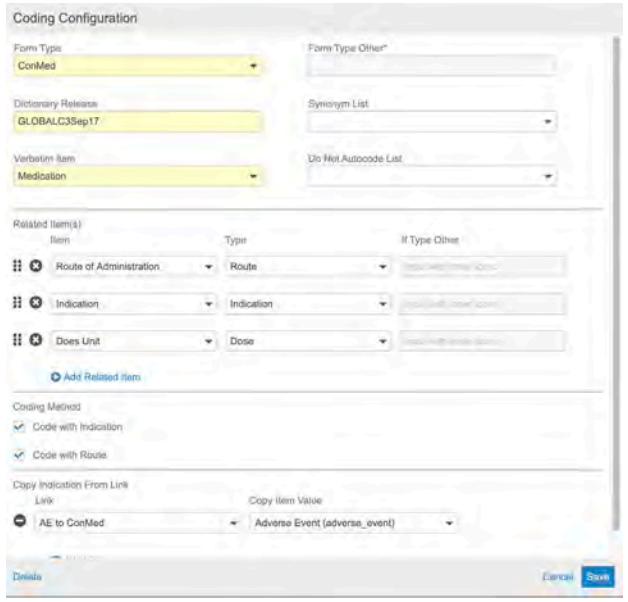



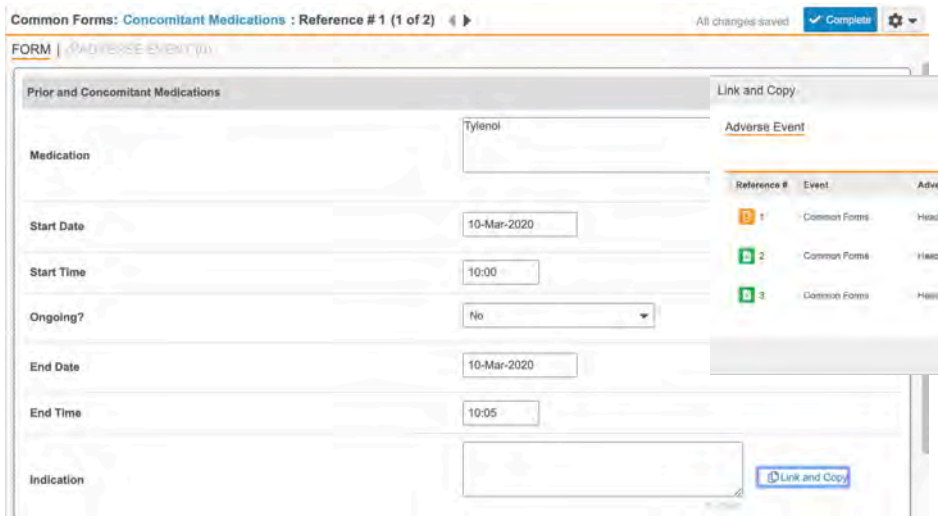

Copyright © Veeva Systems 2020

# Linking Forms and Copy Indications

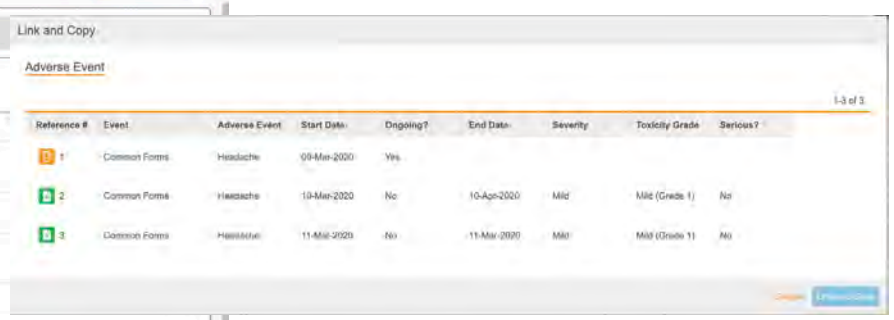
## Form Linking





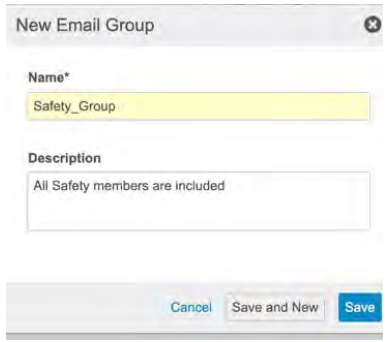



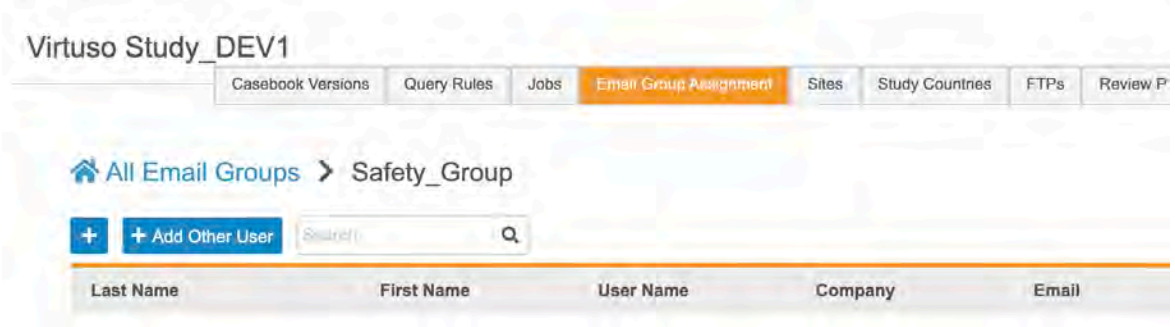

## Copy Indication Link



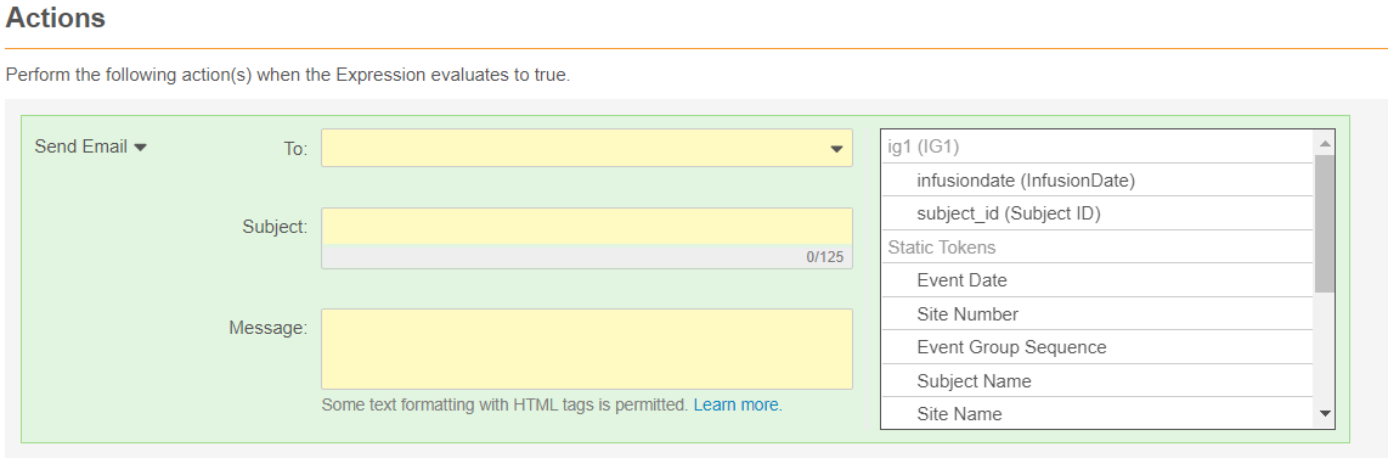

Copyright © Veeva Systems 2020

# Email Groups



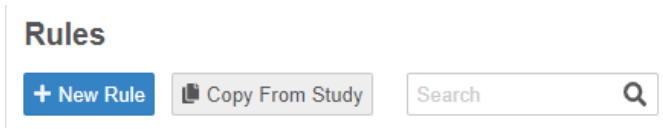

- Define Email Group in Studio
- Add users to Email group in EDC Tools
- Create a rule that triggers an email to the Group *(eg. Serious Adverse Event occurs, an email gets sent to the Safety Email group)*



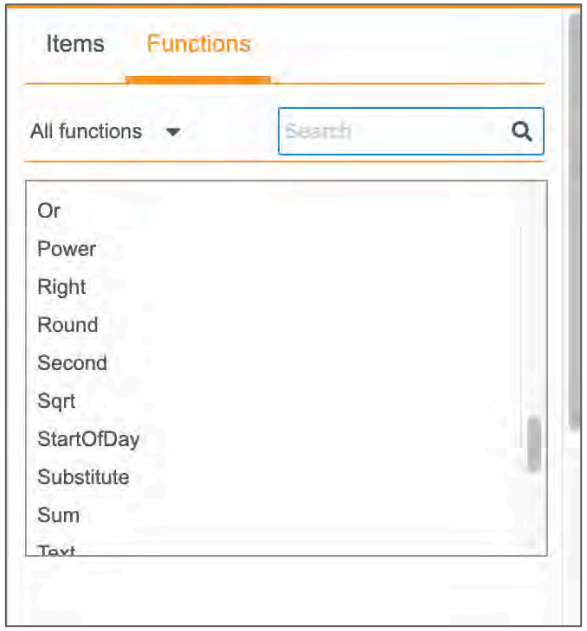

Copyright © Veeva Systems 2020

# Rule Enhancements

## Copy Rules

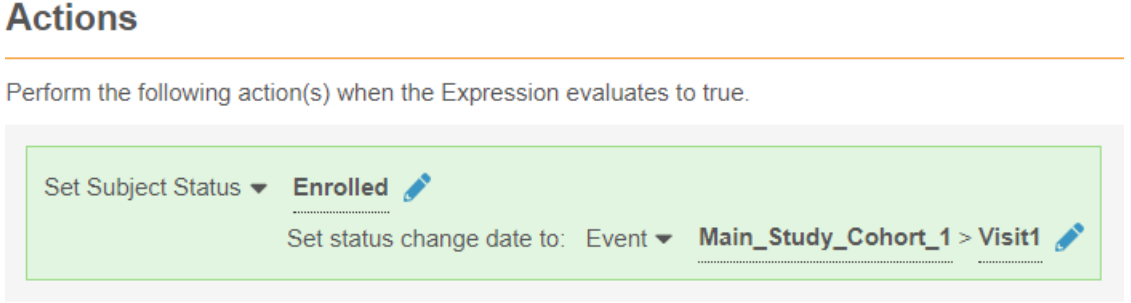



## New Rule Functions

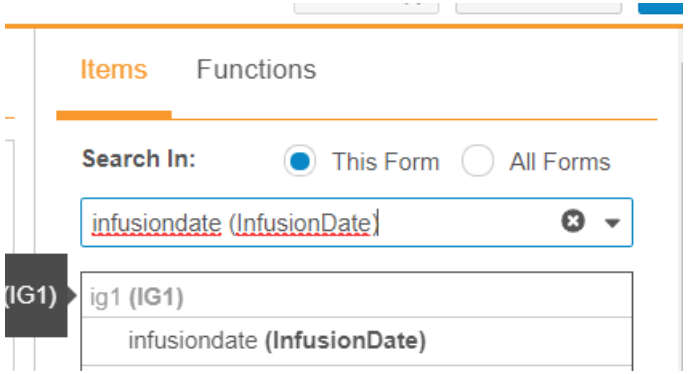



- Power()
- Sum()
- Average()
- StartofDay( date, timezone)
- Today(time zone)

## Define what dates are associated to the Subject Status

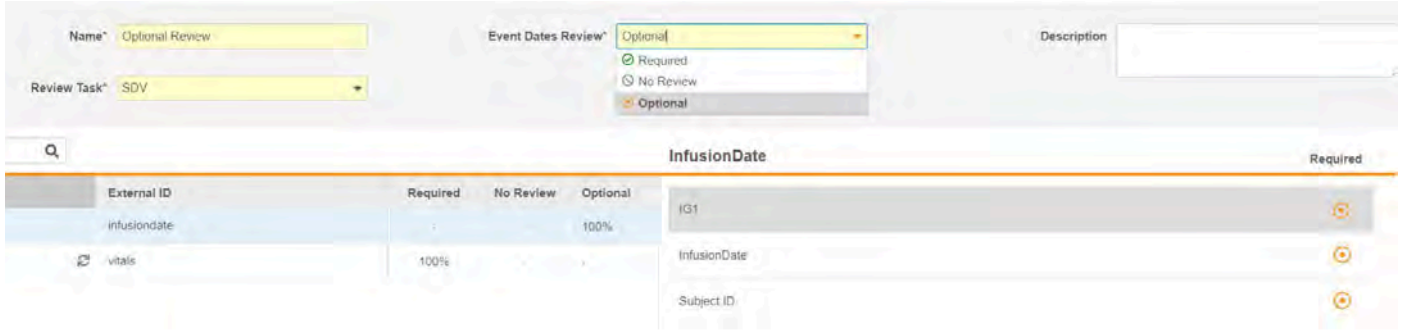


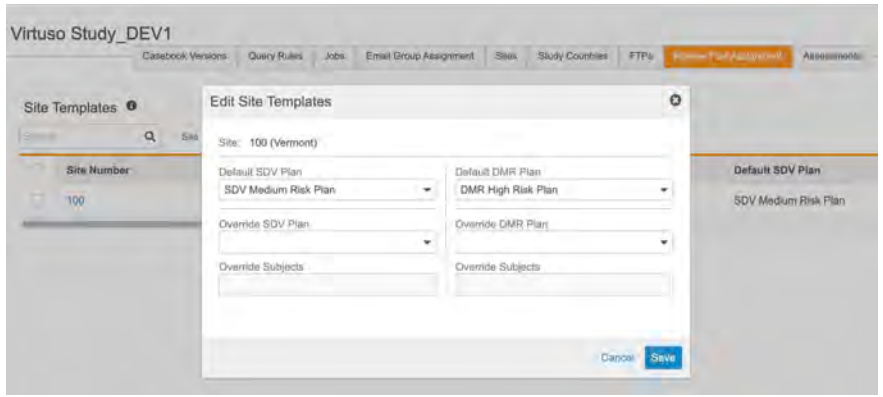

## New Items tab and Enhanced UI for Faster Rule Creation

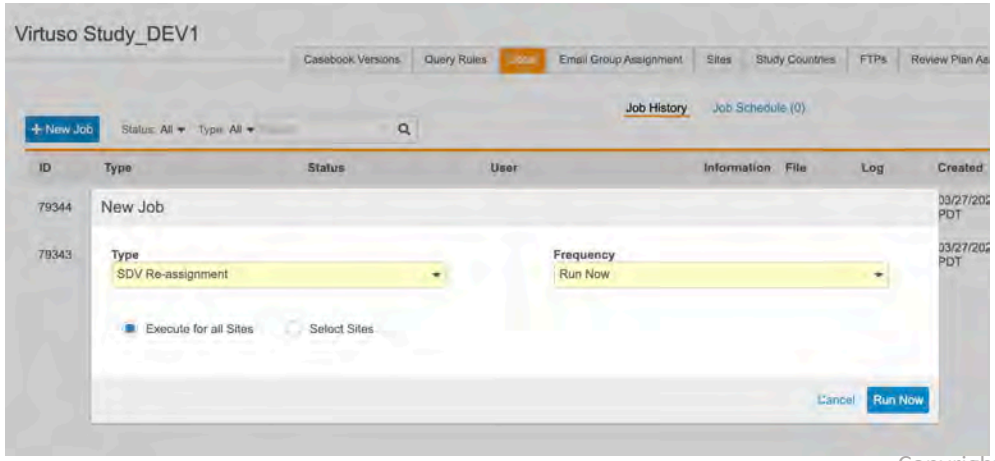



Copyright © Veeva Systems 2020

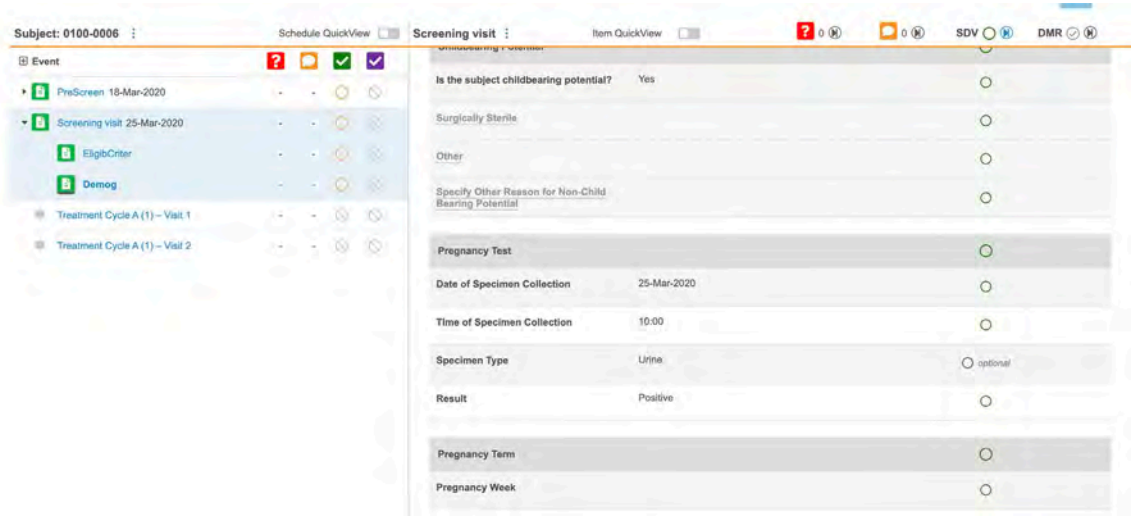
# Optional Review Plans & Jobs



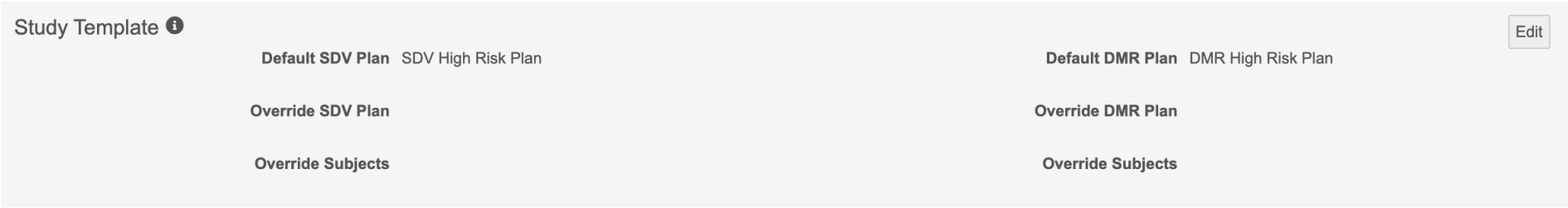



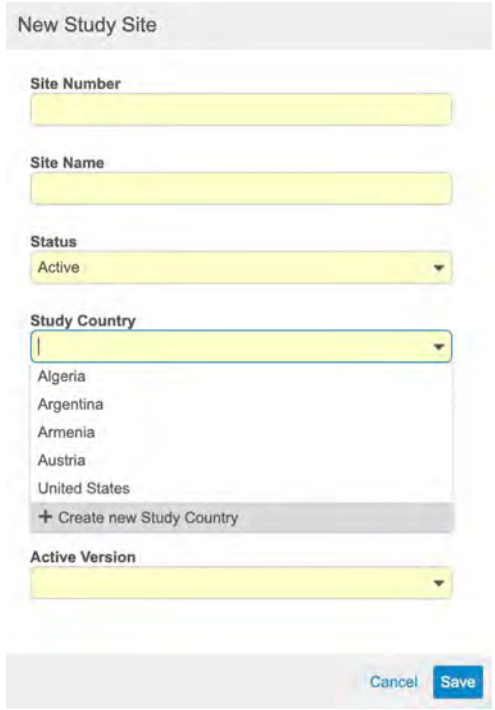

- Create Review Plan with optional Reviews in Studio
- Assign Review Plan to Site in EDC Tools – Review Plan Assignment
- Run job – SDV Reassignment or DMR Reassignment for all sites or select sites to execute Review Plan




Copyright © Veeva Systems 2020

# Review Plan Template & New Sites



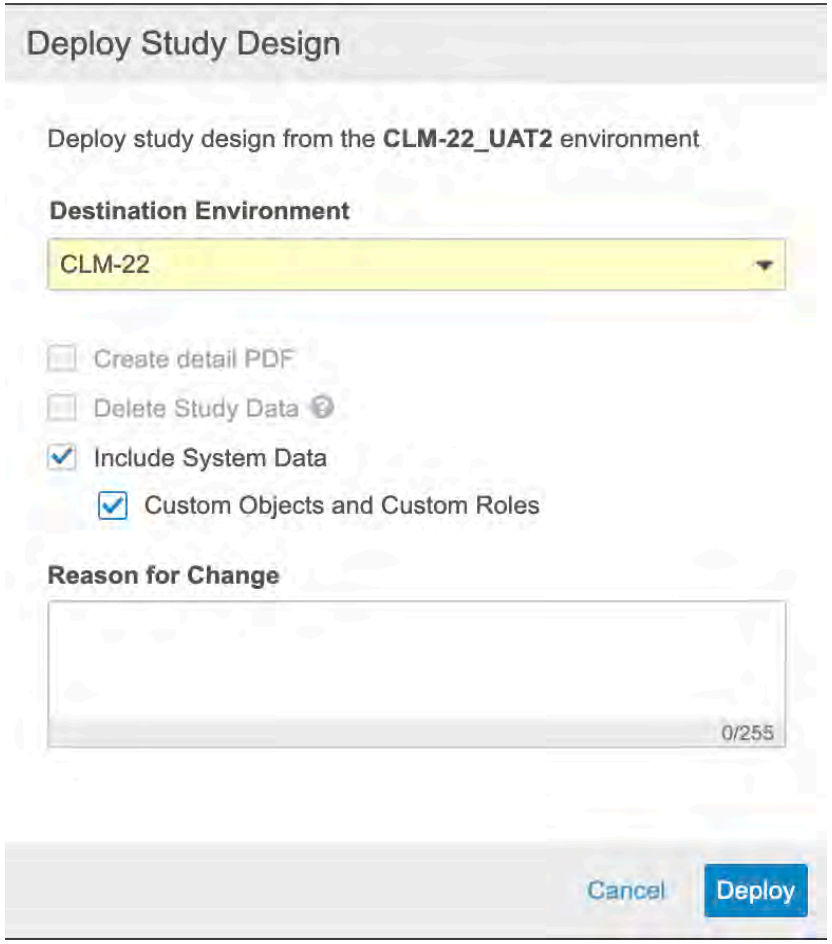




- Create a Review Plan Template in Studio so any new site inherits the Review Plan
- Adding a new Site in EDC Tools can add a new Study Country and select active Casebook version at the same time. (*these were previously separated*)

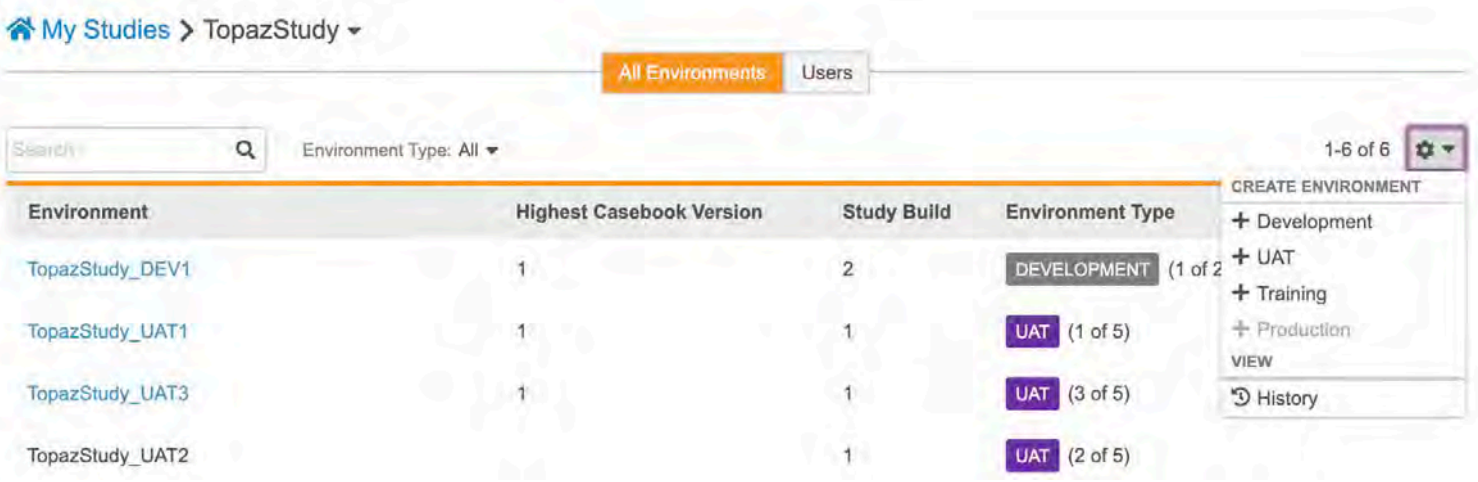
Copyright © Veeva Systems 2020

# Deployments and Environments

## Deploy Custom Objects & Custom Roles




## Add Production Environments at a later time



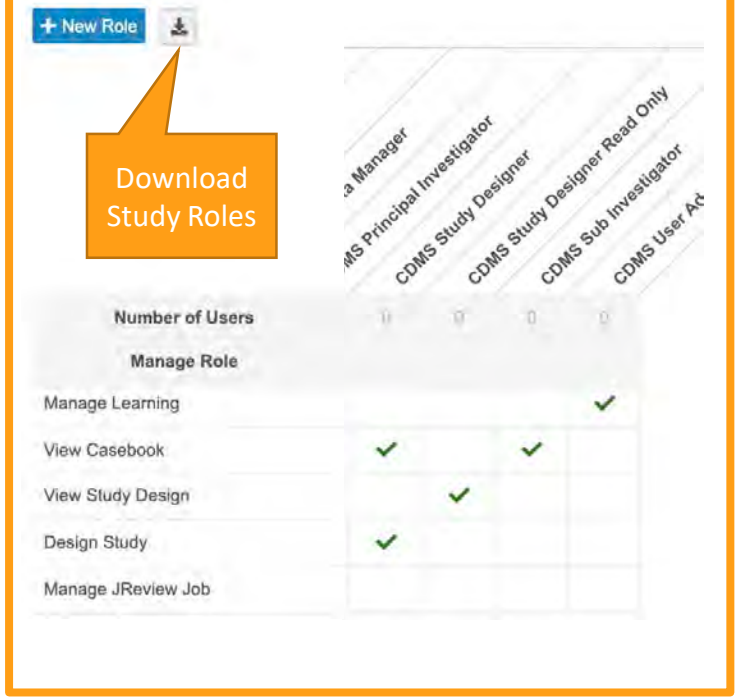

Copyright © Veeva Systems 2020

# Role Management

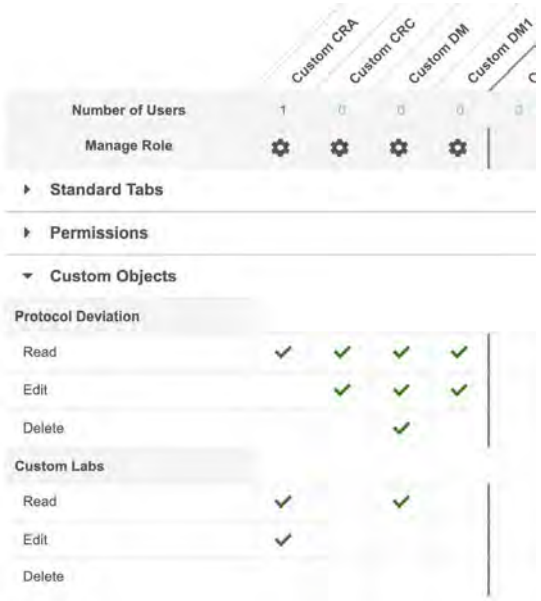
## Permission Updates

- 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

## Study Designer Role(s)




## Custom Object Permissions




## Delete Custom Roles

Copyright © Veeva Systems 2020

# 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

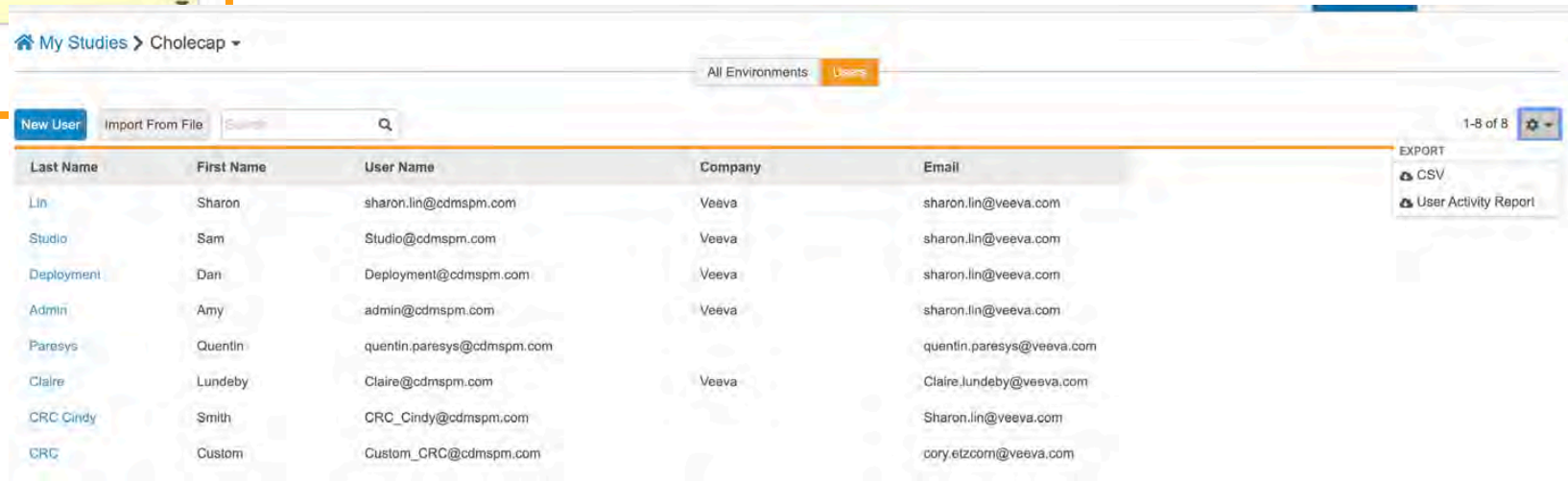
**Language**
English

**Locale**
United States

**Timezone**
(GMT-04:00) Atlantic Standard Time (America/Puerto_Rico)

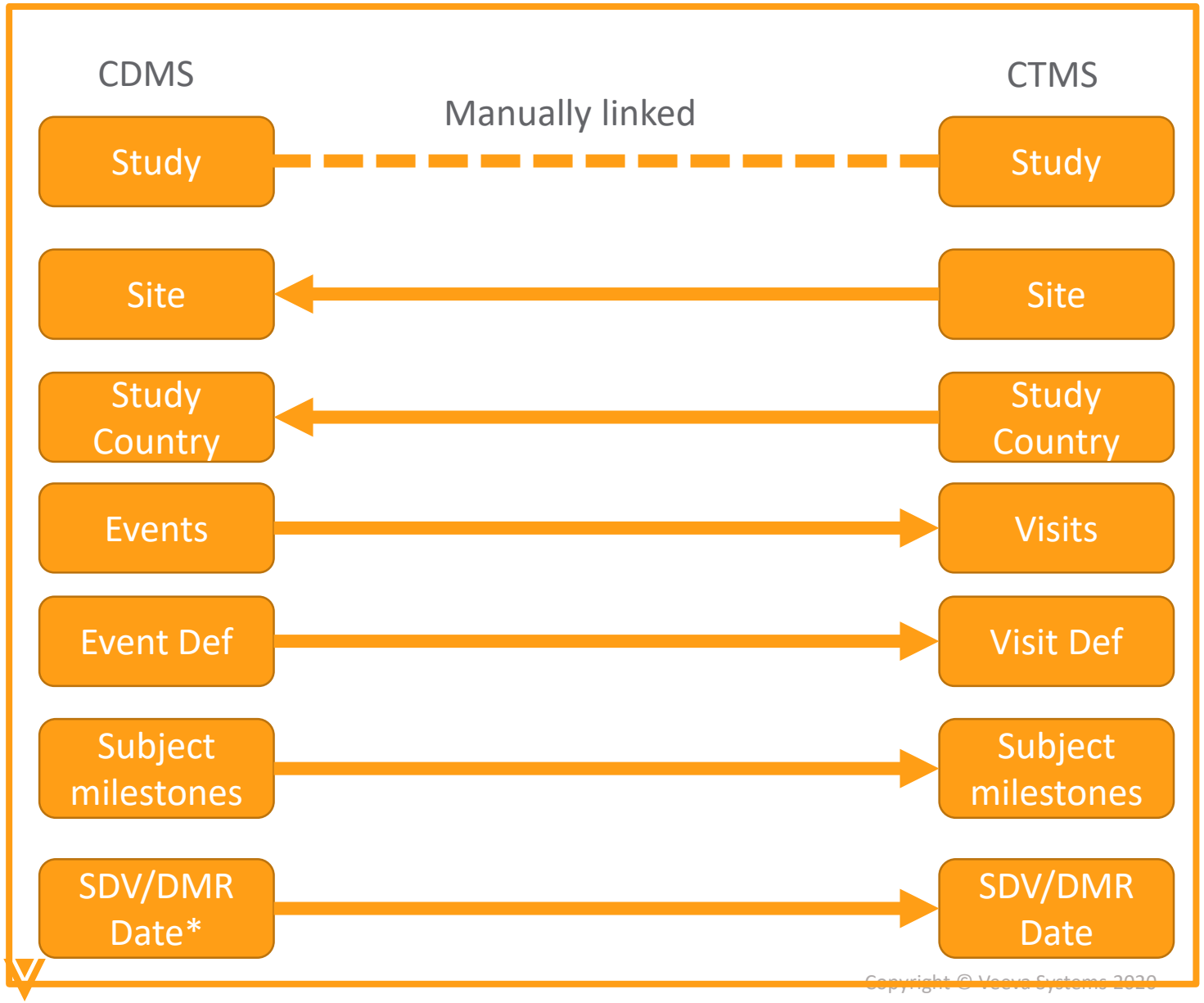
**Add as Principal Investigator**

## User Activity Report




Copyright © Veeva Systems 2020

# CTMS Spark Integration & APIs




**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

Configuration

Visible

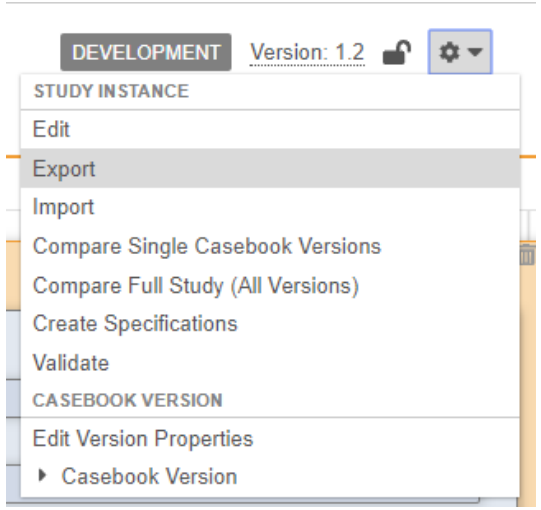
N/A

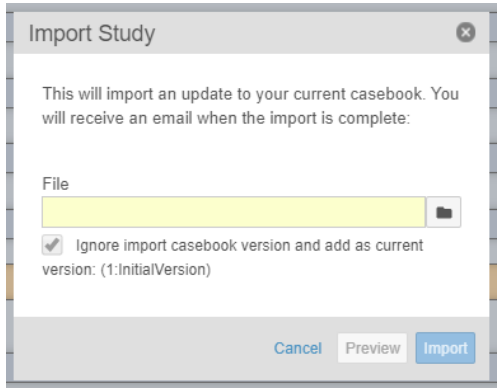
Copyright © Veeva Systems 2020

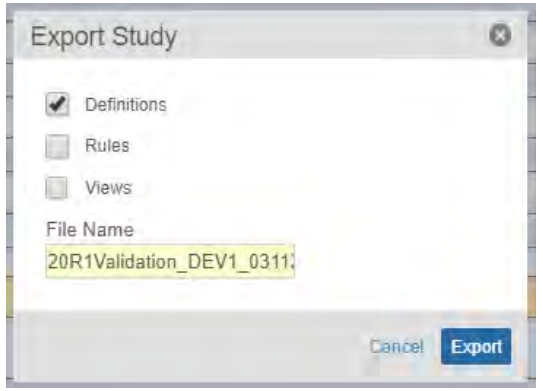
# ODM Import/Export Data into Study

Bring in external 3rd party standards or from a disconnected Vault

- only in Automated Deployment Studies in Studio




Copyright © Veeva Systems 2020

# Thank you