

21R3 Customer Webinar Studio, Admin, Coder

November 4, 2021



CDMS Product Managers

Dennis Kochanski

Sr. Product Manager

Studio, Library



Cory Etzcorn

Product Manager

Data Entry, Review
UI, Clinical
Assessments



Mohammed Al-Adeeb

Sr. Product Manager

Coder, Safety
Link



Rakesh Monassery

Sr. Product Manager

Tools, User
Mgmt



Lindsay Chan

Associate
Technical
Product
Manager

APIs, Extracts,
Integrations



Quentin Paresys

Sr. Product Manager

Rules



Sharon Lin

Principal
Product
Manager

Local Labs,
Randomization



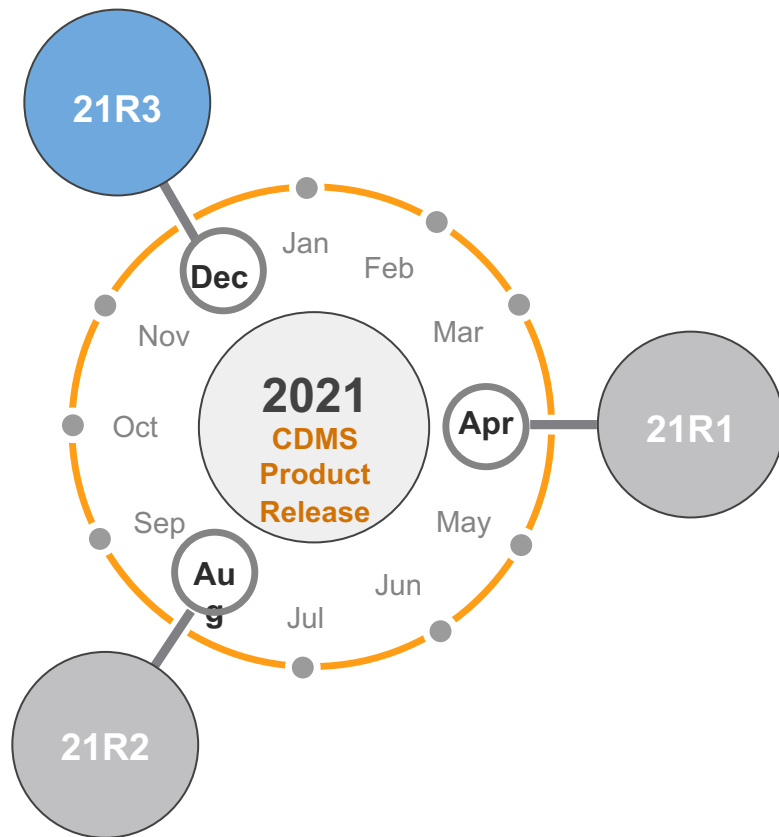
Margaret Wehner

Product Manager

Reports



Veeva Vault Release Schedule



21R3 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
NOV	1	2	3	4 21R3 Release webinar 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	5 21R3 Pre-Release Upgrade	6
	7	8 Validation Docs	9	10	11	12
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	01 DEC	02	03 21R3 General Release Upgrade	04

— Customer
Validation



21R3 Release Dates



Pre – Release

- **Clone of UAT**
- Special Request for DEV
- **Users**
- Added by Project Managers or Customers Success Managers
- **Available up to 6 weeks after 21R3 Release**



Validation Docs

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



21R3 Release

- All Customers Vaults upgraded to 21R3

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



Available Resources

<https://cdmshelp.veeva.com/lr/rn/general-releases/21r2/>

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

21R3 Feature Summary

Sites



- Repeating Item Group Actions
- Display Assigned Review Plan
- Core Listings in Review Tab
- Empty Form Link Indicator
- Misc General Enhancements

Study Designer



- Arms & Cohorts
- Progressive Display
- Repeating Item Group Enhancements
- Misc Enhancements

Rules

- New Aggregate Functions
- Previous/Next Identifiers

Admin



- Job Governor
- Audit Trail by Site & Filtering
- Validation Environment
- Error Console
- Enhancements
- Misc Study Role Enhancements

Coding



- Batch Upversioning Enhancements
- Misc JDrug Enhancements

Reports/Extracts



- Study Data Extracts Versioning
- Additional columns in SDE
- Study Data Extracts Misc Enhancements
- New Study Listings - Query Detail, Event/Form/Subject Progress

Randomization



- Rule to set Subject Status to Randomization Date

Other



- New Subject Statuses to align with CTMS
- Course completion in Training Report
- Veeva Learning Integration Enhancements
- Site Vault Integration
- Restricted Data Support in CTMS

Safety Link



- Long Narratives
- External Labs
- Support LLT
- Treatment Forms

Subject Groups: Arms, Cohorts, and Substudies

Simplify the management of arms, cohorts, and sub studies in complex trials

21R3: Create subject groupings and make them visible in casebooks, reporting, and exports

- Assign study arms, cohorts, and sub studies to subjects via rule logic
- See arm and cohort assignments in the subject casebook and reports
- Export grouping information for easier accounting and reporting on subject status



Use grouping information to drive casebook behavior in complex trials

New Rule: Compare Values from Previous or Next

No trigger or sequence numbers needed. Just define an anchor and specify +1/-1



Create a query if the subject's weight changes by more than 5 % from the prior visit

Veeva has virtually eliminated
the need for custom functions or
Veeva-triggers in Vault EDC

New
functions in
the Rules
Engine

- Count
- Countif
- NoBlanks
- AllEqual
- IsAnyBlank
- GetAllMatches

Feature Enablement

Impact to Clinical Team	On Day 1 of the Release, will the Study Clinical Team (Sites, CRAs, Data Managers) see it? Options: Yes or No
Visibility	On Day 1 of the Release, which users see it? Options: Sites, CRAs, Data Managers, Study Designers, Study Admin (Deploy, Safety, User), Coders, Coder Admin, Lab Manager, Randomization Manager
Configuration	Is Configuration required to use the Feature? Options: Studio, Tools, Coder Admin, Labs, Randomization, Vault Owner in Business Admin, Support
Dependencies	Are there dependencies to use the Feature? Examples: Labs must be enabled, Randomization must be enabled, Only Studies that have not deployed to Production...





Studio

Librarians and Study Designers - Adding Collections/Studies

- Overview

Librarians and Study Designers can now add Collections and Studies without being a Vault Owner. The user does need to have “All Study” access on the DEV vault.

- Business Value


Can move away from Vault Owner users for better access control

Grant Access to All Studies ☒ Yes ☐ No

Environment	Grant Access	Role	LMS Training Status	Ignore LMS Status, Assume Trained
All Studies	✓	CDMS Study Designer		

My Studies > Select Study ▾

+ New Study



Or



Arms and Cohorts

- Overview

Studies can now track Arm, Cohort, and Substudy assignment at the subject level. Studies can be implemented with any combination of the three subject groupings. Designers will write rules to assign them to a subject and the assignments are viewable on the casebook.

- Business Value

Can track subject grouping assignments at the casebook level.

Subject Groups

Label	Code	Type	External ID	Last Modified Date	Last Modified By
Arm A	arm_a	Arm	arma	6/11/2021 10:00 AM PDT	Dennis Kochanski
ArmB	arm_b	Arm	armb	10/15/2021 10:30 AM PDT	Dennis Kochanski
Cohort 1	cohort_1	Cohort	cohort1	10/22/2021 4:29 PM PDT	Dennis Kochanski
Cohort 2	cohort_2	Cohort	cohort2	10/22/2021 4:29 PM PDT	Dennis Kochanski

New Subject Group

Label* SubStudy 1

Code* substudy1

Type* Substudy

External ID substudy1

Cancel Save and New Save

New Rule

Details

Name arm1

Active

External ID

Description

Evaluate Rule When Default

Form ent

Rule Execution Post-save Rule

Rule Scope Within Current Event Group

Dynamic Action Scope Global

Blank Handling

Expression

```
1. define arm1 @form_arm1.arm1;
2. arm1 = "arm_a";
3. arm1 = "arm_a";
```

Actions

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

Assign Subject Latest Arm Arm A

Current Casebook

Version Latest Arm Arm A

Subject	Version	Arm
SCR-0010	1	Arm A

Sort By: Schedule + New Event

START OF STUDY

Screening 26-Sep-2021

Day 1
Impact to
Clinical Teams

No

Visibility
Study
Designers
Librarians

Configuration
N/A

Dependencies
None



Progressive Display Enhancements

- Overview

Users can now drive progressive display configuration from the driving item and set multiple dependent items in a single screen.

- Business Value

Speeds study development.

Add Dependent Definitions

Controlling Item: SEX

Controlling Item Value: F0

Display Type: Enable

Dependent Definitions

Available Definitions:

- DM (Demographics) > BRTHDAT (Date of Birth)
- DM (Demographics) > AGE (Age at Time of Informed Consent)
- DM (Demographics) > AGEU (Age Units)
- DM (Demographics) > ETHNIC (Ethnicity)
- DM (Demographics) > RACEOTH (If Other, Specify)

Selected Definitions: 7 selected

- RP (Childbearing Potential) > RP_LBL1 (Record any contraceptive medication the subject is taking on the Prior and Concomitant Medications form.)
- RP (Childbearing Potential) > RP_LBL2 (Check all that apply)
- RP (Childbearing Potential) > PREMENRNC (Premenarche)
- RP (Childbearing Potential) > SURGSTER (Surgically Sterile)
- RP (Childbearing Potential) > MENOPAUS (Postmenopausal)
- RP (Childbearing Potential) > NCBPOTH (Other)
- RP (Childbearing Potential) > NREASOTH (If Other, Specify)

Cancel Save

Progressive Display

This item is controlled by another item

Controlling Item: MENOPAUS (Postmenopausal)

Controlling Item Value: F0

Display Type: Enable

The value of this item controls other definitions

Dependent Definition	Type	Controlling Item Value	Display Type
MENOPAUS (Postmenopausal)	Item	F0	Enable
NCBPOTH (Other)	Item	F0	Enable
NREASOTH (If Other, Specify)	Item	F0	Enable
PREMENRNC (Premenarche)	Item	F0	Enable
RP_LBL2 (Check all that apply)	Item	F0	Enable
SURGSTER (Surgically Sterile)	Item	F0	Enable

+ Add Dependent Definition

Cancel Save

Day 1
Impact to
Clinical Teams

No

Visibility

Study
Designers

Librarians

Configuration
N/A

Dependencies

None



Empty Form Link Indicator

- Overview

Study Designers can enable a new “Warn When Empty” setting when creating or updating Form Links within Studio. When enabled, Form Link tabs with zero links added will be highlighted in Red in Data Entry & Review.

All existing Form Links will be defaulted to “No” to not impact current studies. This setting can be toggled on for any Form Link (existing or new) in DEV and deployed to UAT/PROD.

- Business Value

Site users can be reminded to add a Form Link before leaving the Form.

The screenshot shows the Studio interface. On the left is a sidebar with a 'STUDY DESIGN' menu containing 'Schedule', 'Settings', 'Assessments (0)', 'Email Groups (1)', and 'Form Links (1)'. The main area displays the 'Form Links' table with a '+ New Form Link' button and a search bar. The table has columns for Name, Description, Linked Forms, Warn When Empty, and Last Modified Date. One row is visible: 'AE-to-CM' with description 'AE_Reg, CM', 'Warn When Empty' set to 'Yes', and a last modified date of '10/27/2021 7:59 PM EDT'. Below the table, a status bar shows 'Common Forms: Adverse Events : Reference # 1 (1 of 1)' and 'All changes saved'. A form tab is visible at the bottom, labeled 'FORM | PRIOR AND CONCOMITANT ... (0)', with a red border indicating it is empty.

Name	Description	Linked Forms	Warn When Empty	Last Modified Date
AE-to-CM	AE_Reg, CM	AE_Reg, CM	Yes	10/27/2021 7:59 PM EDT

The 'Form Link' configuration modal is shown. It includes fields for 'Name*' (AE to CM), 'Description', and 'Linked Forms*' (a dropdown menu with 'AE_Reg (Adverse Events)' and 'CM (Prior and Concomitant Medications)' selected). There is a 'Warn When Empty' section with radio buttons for 'Yes' (selected) and 'No'. At the bottom are 'Cancel', 'Save and New', and 'Save' buttons.

Day 1
Impact to
Clinical Teams

No

Visibility
Study
Designers

Configuration
Studio

Dependencies
N/A



Rules: Set Subject Status to Randomization Date

- Overview

For studies with Randomization enabled, a rule can be created to set a subject status to Randomization Date

- Business Value

Automatically control and define what gets associated with the the subject status

The screenshot displays the configuration interface for a rule in Veeva Systems. On the left, the 'Evaluate Rule When' dropdown is set to 'Randomized'. Under 'Rule Execution', the 'Post-save Rule' checkbox is unchecked. The 'Rule Scope' is set to 'Within Current Event Group' (checked). The 'Dynamic Action Scope' is set to 'Global'. The 'Blank Handling' dropdown is empty. The main 'Actions' section, titled 'Perform the following action(s) when the Expression evaluates to true.', contains a single action: 'Set Subject Status' with a dropdown menu open showing 'Randomized', 'Event', 'Item', and 'Randomize Date'. The 'Randomize Date' option is highlighted. The background of the action card is green.



Previous/Next for repeating objects

- Overview

Study designers can now target the previous or next instance of a repeating object without having to specify sequence numbers.

This is done by using [-1] or [+1] in identifiers like:

- @Form[-1].ItemGroup.Item
- @Form.ItemGroup[-1].Item

This feature is only available for repeating objects and does not yet support other numbers like [-/+2]

- Business Value

This feature allows more flexibility in rule writing and reduces the total number of rules.

```
1 #define WEIGHT2 @EventGroup[-1].evV2.VS.igVS.WEIGHT
2 #define WEIGHT1 @EventGroup.evV1.VS.igVS.WEIGHT
3
4 Not(IsAnyBlank(WEIGHT1, WEIGHT2))
5 &&
6 (WEIGHT1 > (WEIGHT2 + 0.1*WEIGHT2))
7 ||
8 (WEIGHT1 < (WEIGHT2 - 0.1*WEIGHT2))
```



New functions

- Overview

Study designers have access to a wider array of functions:

- **Count(array)**: returns the number of instances of the aggregate identifier, even nulls
- **NoBlanks(value/array, value/array, ...)**: returns an array of all arguments without null values
- **AllEqual(value/array, value/array, ...)**: returns true if all arguments have the same value
- **CountIf(value, value/array, value/array)**: returns the number of times the first value can be found in the other arguments
- **IsAnyBlank(value/array, value/array, ...)**: returns true if any of the values in the arguments is null/blank
- **GetAllMatches(lookup_value, lookup_aggregate, return_aggregate)**: Returns an array of values from the third parameter that are found in the same instances where the value (first parameter) can be found in the second parameter.
- Update to the **Text()** function to make the format optional

- Business Value

This feature allows more flexibility in rule writing.



Identifier changes

- Overview

Study designers have more options in identifiers:

- Aggregates are now available for **booleans** and **time** items
- Some existing attributes are now supported on fully qualified identifiers
 - **Intentionally_left_blank__v** and **change_reason__v** for \$ identifiers
- **Submit_counter__v** available on forms (floating and fully qualified): returns the number of times the form has been submitted (including the one that triggered the rule)
- Only for **send email rules**:
 - **Has_value_changed__v** for items: returns true if the value of the item has changed between the previous form submit and the form submit that triggered the rule evaluation
 - **Previous_submit_value__v** for items: returns the value of the item at the time of the previous form submit

- Business Value

This feature allows more flexibility in rule writing.





Admin

Deployment - Validation Environments

- Overview

This release introduced a new environment type, Validation. Any existing Studies using the automatic deployment model are eligible to use this environment type. A Study can have up to **TWO** validation environments. Deployment administrators can deploy from UAT environments to validation environments. In Studio, Vault has a dedicated environment-type badge for validation environments. Study designers and librarians can use validation environments as a source copying a study or comparing casebook versions. The following environment-level actions are available for validation environments in EDC Tools:

- Delete Study Data
- Rename
- Delete
- Lock

- Business Value

This feature provides a specified environment for conducting validation activities.

Day 1
Impact to
Clinical Teams

No

Visibility

Study
Administrator,
Study
Designers,
Librarians

Configuration

N/A

Dependencies

N/A



Deployment - Migration Environments

- Overview

This release introduced a new environment type, *Migration*. Any existing *Studies* using the automatic deployment model are eligible to use this environment type on vaults where “Enable Data Migration” feature flag is enabled. A *Study* can have up to **THREE** migration environments. Deployment administrators can deploy from development environments to migration environments. In Studio, Vault has a dedicated environment-type badge for migration environments. Study designers and librarians can use migration environments as a source copying a study or comparing casebook versions. The following environment-level actions are available for migration environments in EDC Tools:

- Delete Study Data
- Rename
- Delete
- Lock

- Business Value

This feature provides a specified environment-type for the migration of data from external systems into Vault CDMS.

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Manager,
Librarian, Study
Designer,
Deployment
Administrator

Configuration

Support

Dependencies

Enable Data
Migration
Feature Flag



Veeva Learning Integration Enhancements

- Overview

- User administrators can now assign training to users with Access to All Studies (vault-wide userse) and users with Access to All Study Environments (study-wide users).
- When updating the Curriculum to Role Mapping for a Study Environment, users can now copy their changes to the mapping to one or more Studies.
- With this release, you can now generate the training report across one or more Studies from System Tools.

- Business Value

These enhancements support regulatory compliance by preventing vault-wide and study-wide users from accessing Vault CDMS before completing the appropriate training and increasing the reporting ability on the training progress of users across Studies.

Day 1
Impact to
Clinical Teams

No

Visibility
Lead Data
Manager, User
Administrator

Configuration
N/A

Dependencies

LMS
Enablement



Veeva Learning Integration Enhancements

- Overview

- We updated the Training Report to include additional columns.
 - Courses Assigned
- The additional columns will be displayed after enabling the feature in Biz Admin via Vault Owner (lms.coursedrilldownenabled)

- Business Value

These enhancements support regulatory compliance by preventing vault-wide and study-wide users from accessing Vault CDMS before completing the appropriate training and increasing the reporting ability on the training progress of users across Studies.

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Manager, User
Administrator

Configuration

Yes - Vault
Owner

Dependencies

LMS
Enablement



Study Role Enhancements - EDC

- Overview

With this release, we made the following functional enhancements to standard Study Roles and their permissions:

- The **CDMS Clinical Research Associate** role now has the View Casebook permission (*Defect fix only in 3.0*)
- We renamed Manage Study Deployments to **Manage Deployments**.
- The CDMS Lead Data Manager role has the **Manage Study Priority** by default.

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Manager, User
Administrator

Configuration

N/A

Dependencies

N/A



Study Role Enhancements - CDB

- Overview

With this release, we made the following functional enhancements to standard Study Roles and their permissions:

- In support of future enhancements, we added the **Browse View** permission and assigned it to the CDMS Data Manager, CDMS Lead Data Manager, and CDMS Super User roles.
- In support of future enhancements, we added the following permissions and assigned them to the CDMS Super User role - **Browse View, Create View, Modify View, Delete View, and Manage Key Mappings**

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Manager, User
Administrator

Configuration

N/A

Dependencies

CDB



Study Role Enhancements - Randomization

- Overview

With this release, we made the following functional enhancements to standard Study Roles and their permissions:

- All standard and user defined roles that have the **Manage Randomization List** now need access to all Sites to perform those functions.

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Manager, User
Administrator

Configuration

N/A

Dependencies

Randomization



Audit Trail Export Filtering & Performance Improvements

- Overview

When running Audit Trail Export jobs, filters can be applied to only include audit entries during a certain time period and/or activity of certain users.

- **Date Range:** A start date, end date, or both can be applied to only include audit entries before a given date, after a given date, or within a date range. The audit trail export files will only include entries that meet the date range criteria.
- **Users:** One or more users from the Vault can be selected. The audit trail export files will only include audit entries for the selected users and “System on behalf of” that user.

Additionally, Audit Trail Exports and Detail PDFs with Audits now run **significantly** faster.

- Business Value

Users can now generate an Audit Trail Export that only includes a subset of audit trail entries based on their specific needs.

The screenshot shows a 'New Job' dialog box with the following fields:

- Type:** A dropdown menu with 'Audit Trail Export by Study' selected.
- Frequency:** A dropdown menu with 'Run Now' selected.
- Filter by:**
 - Date Range:** Two date input fields (MM/DD/YYYY) separated by 'to'.
 - User:** A dropdown menu.

At the bottom right, there are 'Cancel' and 'Run Now' buttons.



Audit Trail Export By Site

- Overview

A new “Audit Trail Export By Site” job has been added to the list of available job types in EDC Tools. Lead Data Managers can now easily export audit trails for up to 10 sites in a single job.

- Business Value

Users no longer need to run a full Study audit trail export or select Subjects individually to retrieve the audit information for an entire Site.

The screenshot shows a 'New Job' dialog box with the following fields and options:

- Type:** A dropdown menu with 'Audit Trail Export By Site' selected.
- Frequency:** A dropdown menu with 'Run Now' selected.
- Filter by:**
 - Date Range:** Two date input fields (MM/DD/YYYY) separated by 'to', each with a calendar icon.
 - User:** A dropdown menu.
- Run on:**
 - Site:** A dropdown menu with a list of sites: '100 General Hospital', '200 Research Institute', and '300 Northwest Clinic'.

At the bottom right, there are 'Cancel' and 'Run Now' buttons.

Day 1
Impact to
Clinical Teams

No

Visibility
Lead Data
Manager

Configuration
N/A

Dependencies
N/A



Extract Job Governor

- Overview

Production Studies can be marked as “priority” by users with the “Manage study priority” permission (LDM by default). Extract jobs for these studies will run in a priority queue. Priority lasts for 7 days and can be re-applied when it expires.

When a production study gets locked, an expiration date will be set on all scheduled jobs for 7 days after the lock date.

Scheduled jobs in non-production instances will require selecting a number of “active periods” at the time of creation and will drive the expiration date of the job.

Ad-hoc extract jobs	Scheduled extract jobs
<ul style="list-style-type: none">No limitation on the number of jobsIf an extract job is running, an extract job of the same type cannot be started until the previous job is done.	<ul style="list-style-type: none">50 jobs per Vault2 SDE per Study2 Listings of each type per Study

- Business Value

The job governor feature was implemented to ensure that the system has enough resources to run all extract jobs across a whole Vault, but also to ensure that studies with upcoming deadlines can get data out faster than normal.

Day 1

Impact to
Clinical Teams

No

Visibility

Lead Data
Manager

Configuration

N/A

Dependencies

N/A



CDMS APIs

- New CDMS API Enhancements in 21R3
 - Updated Retrieve Queries API
 - Jobs API
 - Supports the SDE, Data and Definition Export, Core Listings, Form Progress Listing, Query Detail Listing, Subject Progress Listing, Event Progress Listing
 - Retrieve Sites API
- Please visit the developer portal: <https://developer-cdms.veevavault.com/> for more information on the latest API updates

Day 1
Impact to
Clinical Teams

No

Visibility

API Users

Configuration

N/A

Dependencies

N/A





Reports/Extracts

Study Data Extracts Enhancements

- Overview

Enhancements to the SDE including:

- **SDE Versioning**
 - Users can select which version of the SDE they want to run
 - Each version will have new features and enhancements
 - Versions are named based on the release (e.g. 21R2, 21R3)
 - Currently scheduled jobs will be stamped with the 21R2 version of the SDE
- **Additional Columns**
 - The following datasets have new columns in the 21R3 version:
 - SYS_EVT
 - SYS_FORM
 - SYS_ILB
 - SYS_Q
 - SYS_SUB
- **Job History Information**
 - The Job History grid in EDC Tools will display information about the SDE job being run in the information icon, including the Version, Export File Type, and Options selected
- **Other**
 - Consistent Key Columns in clinical datasets to match System Datasets: SITENUM, EVENTEID
 - Coding column headers will not have spaces

- Business Value

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

N/A

The SDE supports backward compatibility so users can maintain their existing export configurations or gain new features by running the latest version of the SDE



Study Data Extracts Enhancements

- New columns added to datasets in the 21R3 version

Dataset	Column	Change
Clinical Datasets	SITENUM, EVENTEID	- Changed column name from SITE and EVENTID
SYS_FORM	EGROUP, EVENTEID, FORMEID, SDVREQ, SDVLAST, DMRREQ, LSTSGNDT	- Added Event Group, Event External Id, Form External ID, SDV Required, Datetime of last SDV modification, DMR Required, Last Signature Date
SYS_EVT	EGROUP, EVENTEID, LASTMODDT, WINSTAT, DAYSOW, EXPFORMS, FORMEOD	- Added Event Group, Event External Id, Last Modified Date/Time of the Event Date, Scheduled Window Status, Days Outside Window, Expected Number of Forms, Number of days past due
SYS_ILB	EGROUP, FORMEID, EVENTEID, ITEMDEF, LABANALYTENAME (if Labs are enabled)	- Added Event Group, Renamed COLNAME to FORMEID, Added Event External Id, Item Definition, Analyte Name
SYS_Q	EGROUP, EVENTEID, FORMEID, QCHGDATA	- Added Event Group, Event External Id, Form External ID, Whether the data changed after query creation
SYS_SUB	CNSNTDT, STARTTRTDT, STARTFLLWUPDT, LOSTFLLWUPDT	- Added Initial Consent Date, Started Treatment Date, Started Follow Up Date, Lost to Follow Up Date



Study Data Extracts Enhancements

- SDE Versioning Dropdown

New Job

Type

Study Data Extract

☐ Include Restricted Data

SDE Version ⓘ

Version 21R3

Version 21R3

Version 21R2

Clinical Data Options

☐ Use Item External ID instead of Item Name for column headers

☐ Include separate Date and Time columns for Datetime items

☐ Include forms intentionally left blank

☐ Exclude blank forms

Export Options

Zip File Name ⓘ

.zip

Export File Type

External Connection

Frequency

Run Now

Cancel

Run Now

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

N/A



Study Listings

- Overview

- Four new study listings are available from EDC Tools:
 1. Form Progress Listing
 2. Query Detail Listing
 3. Subject Progress Listing
 4. Event Progress Listing
- Requires access to EDC Tools, Manage Jobs and all sites
- Can be used to track the progress of the subject or site over the course of the study
- Includes:
 - SDV/DMR data for a form or subject
 - Frozen, Locked or Signed statuses for forms, events & subjects
 - Query details, such as status, comments/answers, and dates
 - Event dates and windows

- Business Value

Users will now have real time access to the most requested listings in EDC Tools.

Day 1
Impact to
Clinical Teams

No

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

N/A



Study Listings

Casebook Versions Rules **Jobs** Email Group Assignment Sites Study Countries FTPs Review Plan Assignment Assessments Safety Configuration Integration Configuration

[+ New Job](#) Status: All Type: All [Job History](#) [Job Schedule \(3\)](#) 1-25 of 68 1 / 1

ID	Type	Status	User	Information	File	Log	Created
539427	Form Progress Listing	Completed	Margaret Wehner				10/26/2021 12:07 PM PDT
539131	Study Data Extract	Completed	Margaret Wehner				10/25/2021 11:55 AM PDT
539130	Event Progress Listing	Completed	Margaret Wehner				10/25/2021 11:54 AM PDT
536811	Query Detail Listing	Completed	Margaret Wehner				10/21/2021 4:30 PM PDT
537415	Core Listing						
536003	Query Detail Listing						
536808	Core Listing						
536807	Study Data Extract						
536805	Event Progress Listing						
535312	Query Detail Listing						
535309	Subject Progress Listing						
535307	Query Detail Listing	Completed	Margaret Wehner				10/18/2021 4:33 PM PDT
535308	Event Progress Listing	Completed	Margaret Wehner				10/18/2021 4:33 PM PDT
535303	Event Progress Listing	Completed	Margaret Wehner				10/18/2021 3:47 PM PDT
533514	Form Progress Listing	Completed	Margaret Wehner				10/15/2021 4:49 PM PDT

New Job

Type
Form Progress Listing
☐ Include Restricted Data
☐ Include Item Counts

Frequency
Run Now
Daily
Weekly
Monthly

[Cancel](#) [Run Now](#)

Day 1
Impact to
Clinical Teams

No

Visibility
Lead Data
Managers

Configuration
N/A

Dependencies
N/A



Study Listings

Day 1
Impact to
Clinical Teams

No

Form Label	Form Sequence Number	Form Status	Number of Submits	Complete	Days Overdue	Items with Values	Items with Value Change	SDV Plan	SDV Override Plan	SDV Required	Items SDV Required Completed	Items SDV Required	SDV %	SDV Age	SDV Date
Informed Consent	1	Submitted	1	Yes	No	2	0	Treatment SDV Plan	Yes	Yes	2	2	100		9/28/21 0:35
Eligibility Criteria	1	Submitted	1	Yes	No	1	0	Treatment SDV Plan	Yes	Yes	1	1	100		9/28/21 0:35
Vital Signs	1	Submitted	1	Yes	No	7	0	Treatment SDV Plan	No	Yes	4	5	80	34	
Demographics	1	Submitted	2	Yes	No	7	2	Treatment SDV Plan	Yes	Yes	1	1	100		9/28/21 0:35
Coagulation	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Pregnancy Test	1	Submitted	1	Yes	No	4	0	Treatment SDV Plan	No	Yes	3	4	75	34	
Log Prompts	1	Submitted	2	Yes	No	2	1	Treatment SDV Plan	No	No	0	0			
End of Study	1	Submitted	1	Yes	No	2	0	Treatment SDV Plan	No	Yes	0	5	0	35	
Informed Consent	1	Submitted	1	Yes	No	2	0	Treatment SDV Plan	Yes	Yes	2	2	100		9/28/21 0:31
Eligibility Criteria	1	Submitted	1	Yes	No	1	0	Treatment SDV Plan	Yes	Yes	1	1	100		9/28/21 0:31
Vital Signs	1	Submitted	1	Yes	No	7	0	Treatment SDV Plan	No	Yes	4	5	80	35	
Demographics	1	Submitted	3	Yes	No	7	3	Treatment SDV Plan	Yes	Yes	1	1	100		9/28/21 0:31
Coagulation	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Log Prompts	1	Submitted	1	Yes	No	3	0	Treatment SDV Plan	No	No	0	0			
Vital Signs	1	Submitted	3	Yes	No	7	1	Treatment SDV Plan	No	Yes	3	5	60	35	
Exposure Oral	1	Submitted	5	Yes	No	7	1	Treatment SDV Plan	No	Yes	4	9	44	34	
Pharmacokinetic	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Vital Signs	1	Submitted	1	Yes	No	7	0	Treatment SDV Plan	No	Yes	2	5	40	35	
Pharmacokinetic	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Exposure Oral	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Vital Signs	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Pharmacokinetic	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Exposure Oral	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Vital Signs	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Pharmacokinetic	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Exposure Oral	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Vital Signs	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			
Pharmacokinetic	1	Blank	0	No	No	0	0	Treatment SDV Plan	No	No	0	0			

Visibility

Lead Data
Managers

Configuration

N/A

Dependencies

N/A





Coder

Batch Upversioning Enhancements

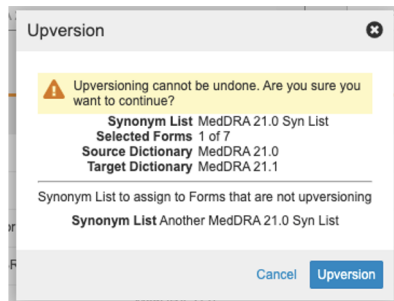
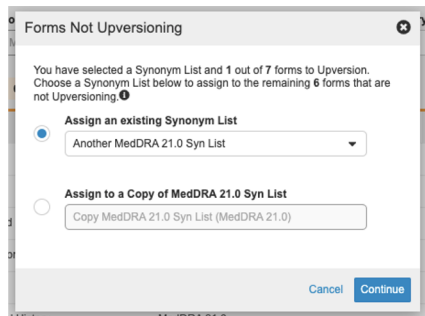
- Overview

The Batch Upversioning experience is more intuitive in the ability to determine if you want just Forms or both Forms and Synonym Lists to Upversion, it displays a dialog to confirm Upversioning before running the job, and finally if the Synonym List is Upversioning along with some but not all assigned Forms, then an option is provided to assign a Synonym List to the not Upversioning Forms.

In addition, anytime the system Upversions, it will generate an Impact Report. The report is emailed to the user that initiated the job. Finally, Coder Admins now have the ability to delete a Synonym List.

- Business Value

Coder Admins have a more intuitive experience navigating Batch Upversioning, have several options to continue Upversioning and not disrupt the coding experience on the not Upversioning Forms, and finally they have more tools to manage Synonym Lists.



Day 1
Impact to
Clinical Teams

No

Visibility
Coder
Administrator

Configuration
Coder Tools

Dependencies

N/A



JDrug Upversioning & Suggestions

- Overview

With JDrug, Coder Admins are able to Upversion, view an Impact Report, use the Code All Forms and Synonym Lists feature (AKA Propagate Code), and import/export a JDrug Synonym List. While the system was able to generate autocoding on JDrug, it is now able to generate Suggestions it as well.

- Business Value

Coders and Coder Admins have access to more comprehensive set features when coding with JDrug.

Preview Impact

Upversion

Upversion

☒ Synonym List and Forms ☐ Forms

Synonym List

JDrug April 2021 Syn List

Source Dictionary

JDrug April 2021

Target Dictionary

JDrug October 2021

Search

Study: All Form: All Selected 2

1-2 of 2

<input checked="" type="checkbox"/>	Study	Form	Dictionary	Status	Synonym List
<input checked="" type="checkbox"/>	Sandbox Testing Study_TRN1	New Form for BRD Testing	JDrug April 2021	Active	JDrug April 2021 Syn List
<input checked="" type="checkbox"/>	What How Bifurcation_TRN1	ConMed	JDrug April 2021	Active	JDrug April 2021 Syn List

Day 1
Impact to
Clinical Teams

No

Visibility
Coder
Administrator

Configuration
Coder Tools

Dependencies
N/A





Safety Link

Long Narratives

- Overview

CRCs can transfer up to 100,000 characters for the Case Narrative field and up to 20,000 characters for the Reporter's Comments field on the SAE form. Vault then includes the entirety of these field values in the XML file for transfer to the safety system.

- Business Value

With long narratives, Safety Link doesn't limit the Narrative field length and transfers all of its contents to the safety system.

Narrative Item Group (1 of 2) :

i If you need more space to write the narrative, add another item

Narrative new

This event is related to Treatment A because of ABC reason.

59 / 1500

test

Narrative Item Group (2 of 2) :

i If you need more space to write the narrative, add another item

Narrative new

And the event is not related to Treatment B because of XYZ reason.

66 / 1500

test

+ New Section

Day 1
Impact to
Clinical Teams

No

Visibility
Safety Admin

Configuration
Safety

Dependencies
N/A



External Unscheduled Lab Forms

- Overview

Safety Admins can map an external unscheduled lab Form Definition in Safety Configurations. If sites link an external unscheduled lab Form Instance to an SAE (using Form Linking), then Safety Link will generate a follow-up message to the Safety System. The transmitted E2B XML will include item values from this lab Form such as lab name, result, result unit, lab date, normal low, normal high, and more.

- Business Value

Safety Link can transfer more data to safety systems.

Day 1
Impact to
Clinical Teams

No

Visibility
Safety Admin

Configuration
Safety

Dependencies
N/A



Study Drug Treatment Forms

- Overview

Safety admins can map Study Drug Treatment Forms in Safety Configurations. When Safety Link generates a First Send or a Follow Up, it will include the one Treatment Form instance that was administered most recently prior to the AE Start Date.

If a newly submitted Treatment Form meets the above criteria, this generates a follow up message and the transmitted E2B XML file will include the Item values for this new Form.

- Business Value

Safety Link can transfer more data to safety systems.

Day 1
Impact to
Clinical Teams

No

Visibility
Safety Admin

Configuration
Safety

Dependencies
N/A



Coding Values in E2B XML

- Overview

With this release, Vault automatically includes the coding values assigned in Vault Coder to an SAE in the E2B transfer to the safety system. If the coding values are later changed, Vault generates a follow up message to the safety system.

- Business Value

Safety Link can yet transfer more data to safety systems.

Day 1
Impact to
Clinical Teams

No

Visibility
Safety Admin

Configuration
Safety

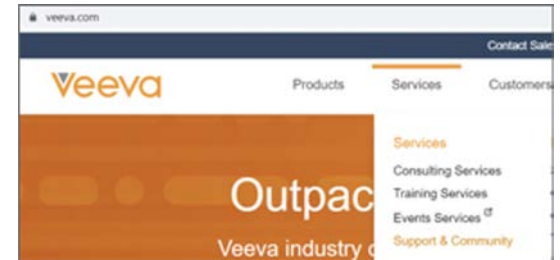
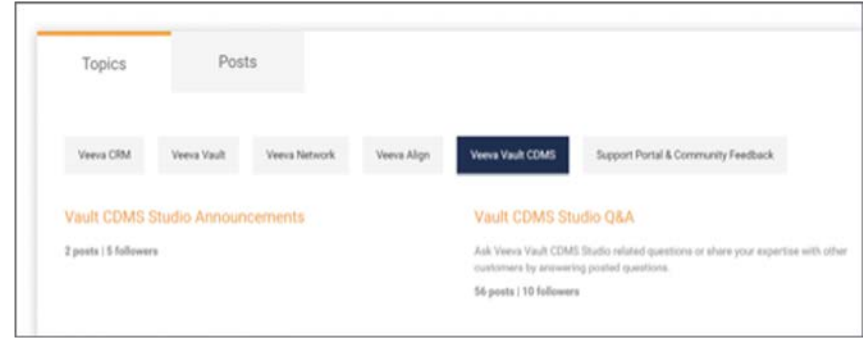
Dependencies

N/A



CDMS User Community

- Support community of trained Studio users
 - Customers and Veeva consultants
- Peer-to-peer communication
 - Discuss and share ideas
 - Q&A
 - Rule syntax, tips
 - Announcements
 - Useful links, webinar recordings
 - Voting
 - Replies from User Community network
- Monitored daily by Veeva for accuracy
- How to find it:
 - Part of Veeva's Support Portal
 - Veeva.com **Services > Support & Community > Community**
 - **Vault Community** link at the bottom of CDMS Help pages
- Follow each area to get involved



Dedicated DEMO

For a dedicated demo of any
these features,
please contact your
Account Executive OR
Customer Success Manager





Thank you