

21R1 Customer Webinar Studio, Admin, & Coder

March 25, 2021



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21R1 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
21 MAR	22	23	24	25 21R1 Release webinar 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	26 21R1 Pre-Release 5PM PT	27
28	29 Validation Docs	30	31	01 APR	02	03
04	05	06	07	08	09	10
11	12	13	14	15	16 21R1 General Release 5PM PT	17
18	19	20	21	22	23	24

— Customer
Validation



21R1 Release Dates



Pre – Release

- Starts at 5PM PT
- Clone of UAT
 - Special Request for DEV
- Users
 - Added by Project Managers or Customers Success Managers
- Available up to 4 weeks after 21R1 Release



Validation Docs

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



21R1 Release

- All Customers Vaults upgraded to 21R1
- EU starts at 2 PM PT
- APAC & US starts at 5 PM PT
- May take up to +/- 9 hours

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts



Resources Available

<https://cdmshelp.veeva.com/lr/rn/general-releases/21r1/>

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

21R1 Feature Summary

Sites



- Protocol Deviations
- SSO Integrations
- Minor Enhancements

Local Labs



- Re-Calculate Age
- Pending Lab Location Count

Study Designer



- Library Collection and Report

Rules

- Linked Forms with Rules
- Date Comparison Rule Enhancement
- Add Multiple Event Groups

Admin



- Vault Level User Mgmt.
- Job Enhancements

Reports/Extracts



- Study Data Extracts
- Site's /User Timezone

Coding



- Coder Approval Workflow
- Group Querying
- Preferred Base for Extracts

Safety Link



- Integrate to any 3rd Party Safety system including Vault Safety

Randomization



- Emergency Unmasking Report
- Exports and Filters

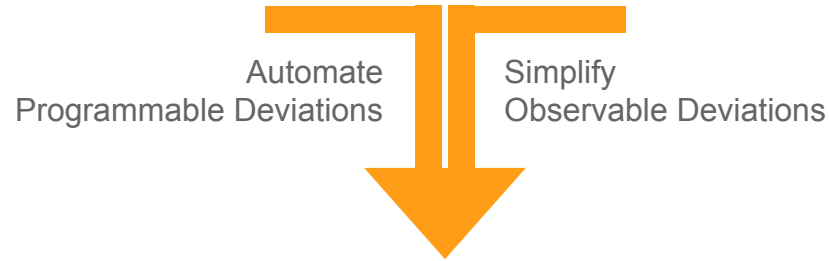
Other



- Procedure Notification for CTMS

Protocol Deviations

Fit-for-purpose design to collect, review, and manage PDs
eliminates complexity of work-arounds – tagging queries or hidden forms



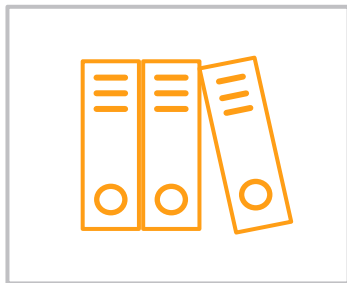
- ✓ Precision tracking, complete traceability
- ✓ Easy for sites and monitors to report deviations as soon as they are observed
- ✓ Greater clarity and usability with tracking at appropriate levels – by subject, visit, form, or field
- ✓ Facilitates managing downstream processes
- ✓ Will pass data directly to Vault CTMS (Planned 21R2)



Library Collections

Visibility and ease-of-use that support a robust standards program

Library collections



Faster study builds.
Controlled introductions
of new standards

Tracking of usage
and deviations



Visibility that helps
enforce adherence and
identify areas for
improvement

Dedicated interface
for librarians



Greater ease-of-use,
especially managing
multiple collections

CDMS Safety Link

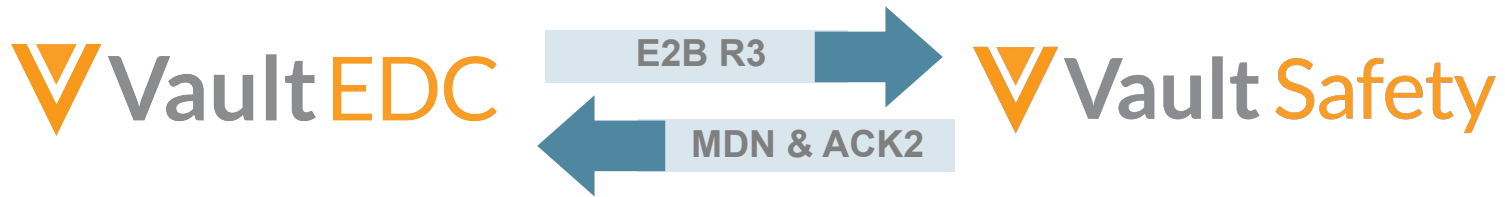
Automation increases speed and data quality with less effort

Reduces manual processes and duplicate data entry	Complete, high-quality information	On-time transmission	Keeps safety system current without a lot of noise	Fit for purpose reports
<p>Sites simply submit SAE forms, and the systems do the rest.</p>	<p>Data is drawn from multiple forms, each of which get SDV'd and reviewed:</p> <ul style="list-style-type: none">AE, ConMeds,Medical History,Demographics, andIn Case of Death.	<p>Comply with FDA requirements.</p> <p>SAEs will always be transmitted within the configured time.</p>	<p>Follow-ups are sent automatically.</p> <p>Configurable windows for bundling updates increases the completeness and quality of data sent</p>	<p>Purpose-built reports to track status of transmissions and support reconciliation (e.g. with direct entries into Safety systems)</p>



CDMS Safety Link

Automate transmission of new SAE cases and related updates



No Coding
Easily configurable
connections

Easier to Manage
No AS2 gateway
No certification mgmt
No IP address white labeling

Builds Foundation
Supports future visibility
and case management
enhancements



Feature Enablement

DAY
1

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, EDC Tools, Coder Admin, Labs, Randomization, Vault Owner in Business Admin, Support



Dependencies

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

Protocol Deviations - Configuration

- Overview

Studies can now enable a new Protocol Deviations feature for creating deviations and linking to study data within Vault CDMS. This feature is behind a study setting that defaults to off for existing and new studies, but can be toggled on at any point.

Once enabled, study designers can configure categories, dependent subcategories, and severity options to be utilized when Protocol Deviations are created. CRAs and Data Managers can manually create a Protocol Deviation via the Review tab, and/or study designers can configure rules to programmatically create PD records when certain criteria is met.

Study Documentation has been updated to include protocol Deviation configurations and user defined “Create Protocol Deviation” rules.

- Business Value

Sponsors now have the ability to create, review, and export protocol deviations in the same system as they collect clinical data. Programmatic Protocol Deviation creation also reduces manual effort on CRAs/DMs to document all deviations.

Day 1
Impact to
Clinical Teams

No

Visibility

Study
Designers

Configuration

Studio

Dependencies

N/A



Linked Rules

- Overview

- The rule editor allows study designers to access data from a linked form only, instead of having to consider all matching forms for a subject.

I.e. a rule can now be written to only check against ConMed forms linked to an AE form, instead of having to write a rule looking at all ConMed forms.

- Business Value

- The form link feature was introduced to allow site users to indicate relationships between forms. Once a relationship has been established, checks need to be run to verify that the data in the linked forms matches what is expected: for example, that the start date of an adverse event is after the start date of a linked concomitant medication.

This feature should remove the need for some of the triggers currently being written.

Expression [Formula Language Reference](#) [View Rule Bindings](#)

```
1 #define AESTDAT $Adverse_Events.Adverse_Events.Adverse_Event.AE_Details.AE_Start_Date
2 #define CMSTDAT $Adverse_Events.Adverse_Events.Adverse_Event/Concomitant_medications.Details_CM.CM_Start_Date
3
4 Not(IsBlank(AESTDAT)) && Not(IsBlank(CMSTDAT)) &&
5 AESTDAT < CMSTDAT
```

No

Visibility
Study
Designer

Configuration
Studio

Dependencies
Grammar v2



Study Data Extracts

- Overview

This report will allow Lead Data Managers to have access to all Clinical Data in a form including system data (e.g., operational, queries, etc.) in EDC tools. Users will have the option to download the data as a SAS or CSV file and send to an external connection if they wish. *In addition, all DateTime fields will be shown in Site Timezone, UTC Timezone, and User Timezone in the Study Data Extracts, Core Listings, and Data and Definition Export jobs.*

- Business Value

Users have access to the SAS version of all Clinical Data in a form, including system data without using utilities.

Included	Not Included
Raw Clinical Data in a form (Data entered by the site)	Does not include Listings currently in Utilities (Planned Feature)
Inclusion of 2 additional time zones on all Clinical Data DateTime Fields (Site Entered and User executing the job)	Protocol deviations
System Dataset (e.g., operational data, queries, SDV, DMR, Locked, Frozen Status, ILB etc.)	Assessments
Users will have the option to download the data as a SAS or CSV export file and send to an external connection	Custom objects

Yes

Visibility
Lead Data
Manager

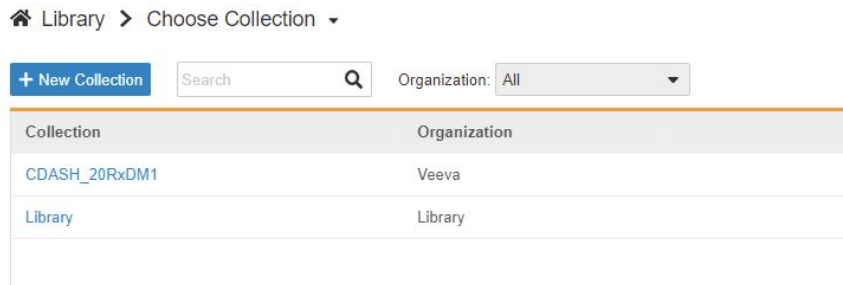
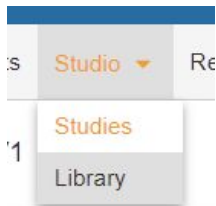
Configuration
N/A

Dependencies
N/A



Library

- The first of a series of library features, the first is comprised of the following:
 - A Library tab and the ability to create Library Collections
 - Casebook definition source tracking and basic reporting
 - Librarian Role
- Business Value
 - Provide a secure way to maintain standards
 - Track lineage to understand what is being used from the library and where deviations are occurring





Admin

Procedure Notifications for Vault CTMS

- Overview

EDC can now transmit mapped submitted Procedures to Vault CTMS, used for payments when this integration is enabled. Customers must map Procedures on a study-by-study basis in EDC Tools. EDC creates a Procedure record when a procedure-mapped Form is submitted by a data entry user. Then, EDC sends a message, via Spark, to CTMS to inform the system that a Procedure was created. In addition, to form submission, the integration is able to update the status of deleted and reset Forms. Customers can map form deletion and reset to the appropriate statuses in EDC Tools.

- Business Value

EDC can now provide CTMS with payment related information extending platform capabilities and adding value to customers.

History and physical

Details

Name
History and physical

Integration Type
Procedures

Casebook Reference ⓘ
Event Group
Any

Event
Any

Form
VS (Vital Signs)

Field Mappings

Search

Field Name	Label	Data Type	Required	Reference Type	Reference Value
procedure_definition__v	Procedure Definition	Text (128)	✓	Static Value	History and physical
procedure_status__v	Procedure Status	Picklist	✓	Map Values to System Actions	3 actions mapped
visit_name__v	Visit Name	Text (128)			
procedure_date__v	Procedure Date	Date	✓	Study Reference	VSDAT (Assessment.Date)

No

Visibility
Study Admin

Configuration
EDC Tools

Dependencies

Vault
Connections
and CTMS



Vault Level User Management

- Overview

User management is now at the vault level. User administrators may create user accounts and assign study access to any studies in that vault from one location (Tools > System Tools > Users). They can also reset a user's password, resend a welcome email, and active or inactivated users. The User Activity Report is also available from this page. This feature moves all user management activities from EDC Tools > Users to Tools > System Tools > Users.

- Business Value

User administrators can now change a user account's status and reset a user's password without Vault Owner level access.

System Tools

The screenshot shows the 'System Tools' interface with a sidebar on the left containing 'Users', 'Role Management', 'Change Reasons', 'External Connections', 'DEPLOYMENT LIST', 'Custom Objects', and 'Custom Roles'. The main area is titled 'Users' and includes a '+ New User' button, an 'Import From File' button, and a search bar. Below is a table of users with a context menu open over the 'Darzi' user row.

<input type="checkbox"/>	Last Name	First Name	User Name
<input type="checkbox"/>	Tiedman	Lacey	lacey.tiedman@verteopharma.com
<input type="checkbox"/>	Darzi		amir.darzi@verteopharma.com
<input type="checkbox"/>	Schultz		tschultz@verteopharma.com
<input type="checkbox"/>	Woods	Tiana	twoods@verteopharma.com

The context menu for the 'Darzi' user includes the following options:

- Reset password
- Send Welcome Email
- User Activity Report
- Inactivate



Job Enhancements

- Overview

Users can cancel an in progress **Core Listing, Retrospective Amendment, Labs Mass Updates, or Data and Definition Export** job.

Users can refresh the Job History without refreshing the entire page.

After 21R1, any output or job log files are now available for download for up to 6 months. The previous window was 15 days. Any earlier jobs remain on the 15-day window.

- Business Value

Lead data managers can now cancel long-running jobs.

Day 1
Impact to
Clinical Teams

Yes

Visibility

Study Admin

Configuration

EDC Tools

Dependencies

N/A



Protocol Deviations - Security

- Overview

- **Permissions**

- **View Protocol Deviations:** Ability to view Protocol Deviations from Review > Protocol Deviations (CDMS Clinical Research Associate, CDMS Data Manager, CDMS Lead Data Manager, and CDMS Auditor Read Only)
- **Edit Protocol Deviations:** Ability to edit Protocol Deviations (CDMS Data Manager, CDMS Lead Data Manager, and CDMS Clinical Research Associate)
- **Create Protocol Deviations:** Ability to create manual Protocol Deviations (CDMS Data Manager, CDMS Lead Data Manager, and CDMS Clinical Research Associate)

- **Role Changes**

- No new Role

- **Business Value**

Sponsors can create and review protocol deviations in the same system as they collect clinical data.



Library - Security

- Overview

- **Permissions**

- **View Library (New)**
 - **Design Library (New)**

- **Role Changes**

- **CDMS Librarian (New)** - available only in non-Production environments
 - **CDMS Study Designer** and **CDMS Study Designer Read Only** has access to a Collection, but they can't edit them.

- Business Value

Sponsors can View and Create Library Collections.

Day 1
Impact to
Clinical Teams

No

Visibility

Study Admin

Configuration

System Tools

Dependencies

N/A



Safety - Security

- Overview

- **New Permissions**

- **Manage Safety Configuration (New)**
- **Design Library**

- **Role Changes**

- **CDMS Safety Administrator (New)** - EDC Tools Tab, Studio Tab, Reports Tab, Systems Tab, View Study Design, Manage Safety Configuration
- **CDMS Study Designer** - Manage Safety Configuration

- Business Value

Sponsors can Manage Safety Configuration.

Day 1
Impact to
Clinical Teams

No

Visibility

Study Admin

Configuration
System Tools

Dependencies

N/A



CDB - Security

- Overview

- **New Permissions**

- Edit CQL, Modify Listing, Create Listing, Delete Listing, Generate CSV, Public Access, View Listings, View Queries, View Export, Create Export Definition, Generate Export Package, Delete Export Definition, View Export Packages, View Import, Download Import Package, View Admin

- **Role Changes**

- **CDB Data Provider (New)** - Workbench Tab, Restricted Data Access, API Access
- **CDMS User Administrator** - Workbench Tab, View Admin
- **CDMS Lead Data Manager** - Edit CQL, Modify Listing, Create Listing, Generate CSV, Public Access, View Listings, View Queries, View Export, Create Export Definition, Generate Export Package, View Export Packages, View Import, Download Import Package
- **CDMS Data Manager** - Edit CQL, Modify Listing, Create Listing, Generate CSV, Public Access, View Listings, View Queries, View Export, Create Export Definition, Generate Export Package, View Export Packages, View Import, Download Import Package

- Business Value

These new permissions offer more granular control over which user roles can perform which functions in CDB.



Coder - Security

- Overview

- **New Permissions**

- **Approve Code (New)** - granted to CDMS Coder Manager and CDMS Coder Administrator.

- **Role Changes**

- **CDMS Coder Manager (New)** - Coder Tab, Reports & Dashboard Tab, Open Query, Close Query, Schedule Reports, View Code, Approve Code, Assign Code

- Business Value

These new permissions offer Coder Manager the ability to perform Approval Workflow.

Day 1
Impact to
Clinical Teams

No

Visibility

Study Admin

Configuration

System Tools

Dependencies

N/A



Repeating Events to CTMS

- Overview

When Events come over to CTMS via the Spark Connection, each event has the same name. For example - For an Oncology study, you might have Day 1, Day 5, Day 15, and then another Day 1, Day 5, Day 15 for the same subject. Some customers might create separate events while others use the same event across repeating Event groups. CTMS integration now sends Repeating and Non-Repeating Event Group information.

- Business Value

Events coming over to CTMS via the Spark Connection will now have a Repeating Event Group Label.

Day 1
Impact to
Clinical Teams

No

Visibility
Study Admin

Configuration
N/A

Dependencies
Vault
Connections
and CTMS





Coder

Select All Forms for Batch Upversioning

- Overview

In Batch Upversioning, users can now select more than twenty (20) forms to batch upversion using the new “Select All Forms on All Pages” option.

- Business Value

This change allows easier and faster batch upversioning, especially for updates to large, live Studies.

Day 1
Impact to
Clinical Teams

No

Visibility

Coders

Configuration

Coder Tools

Dependencies

N/A



Preferred Base for Reports & Extracts

- Overview

Coder now supports the storing of Preferred Base. The Preferred Base further normalizes WHODrug Coding by storing the Preferred Name without the Salt or Ester. Common Salts or Esters are “Hydrochloride”, “Sodium”, or “Bromide”. This data is needed by downstream reporting teams.

Verbatim	Drug Name	Preferred Name	Preferred Base
Cetirizine	Cetirizine	Cetirizine	Cetirizine
Zyrtec	Zyrtec	Cetirizine Hydrochloride	Cetirizine

This feature is enabled by a Study Setting. When enabled, then Coders will find values for Preferred Base in Vault Reports. Also Lead Data Managers will find Preferred Base columns in Core Listings, Study Extract, and the Data and Definition Extract.

- Business Value

Reduce time and effort on downstream reporting teams and have Coder fully normalize the data.

Day 1
Impact to
Clinical Teams

No

Visibility

Coder,
Lead Data
Manager,
&
Data & Def
Extract

Configuration

Coder Tools

Dependencies

N/A



Group Queries

- Overview

Coders can open queries on a Code Request Group while in Group view. Opening a query on a Group opens a query on each Code Request in the Group.

As part of this feature, we added a Study Setting that expands the Grouping criteria to include Query Status. When enabled, this will update the groupings and in addition it will prominently displays the Query Status column in the Group View allowing Coders to decide whether or not they will Query the Sites.

- Business Value

Coders can now use Group view to both code and query. By expanding the grouping criteria to include Query Status, Coders are able to view the three most important pieces of information in the view: Verbatim, Coding Status, and Query Status.



Approval Workflow

- Overview

When manual coding needs to be reviewed by a more experienced member of the team, you can enable the Approval Workflow. It is a Study Setting. When enabled, all manual coding must be approved.

After a coder assigns a code, the Coding Status changes to Pending Approval. Then, a Coding Manager can either approve or reject it. Approving changes the Coding Status to Coded, and Rejecting changes it to Rejected. Coding Managers can be required to add a rejection reason for every rejection. Vault posts these reasons as a Note on the respective Code Requests.

The Coding Manager has the option to apply their approval or rejection to the matching Synonyms in the *Synonym List*. Doing so marks the matching Synonym as approved or rejected.

This workflow can only be performed while in Group view.

- Business Value

Organizations can have more experienced coders review coding decisions.

Day 1
Impact to
Clinical Teams

No

Visibility

Coder
Managers

Configuration
Coder Tools

Dependencies

N/A





Randomization

Unmasking Report

- Overview

For studies with Randomization enabled, there is a report that will list every time an emergency unmasking occurred.

- Business Value

This will provide visibility in who, when, and why an unblinding occurs

[« Back to reports](#)

Unmasking Report

Shows all users that did an emergency unmasking

Refresh Edit 

▼ PROPERTIES

Report Type Randomization Action History

▶ FILTERS (2) 

Randomization Action History (2)							
Name ^	Study	Site	Subject	Action	Unmasked By	Unmask Date	Reason
VV-000014	20R3_Lab_Testing_DEV1	SF	00SF-0018	Unmask	Sharon Lin	2/18/2021 12:16 PM PST	Adverse Event
VV-000015	20R3_Lab_Testing_DEV1	SF	00SF-0018	Unmask	Sharon Lin	2/23/2021 9:59 AM PST	AE

Day 1
Impact to
Clinical Teams

Yes

Visibility

Lead Data
Manager

Configuration

N/A

Dependencies

Randomization
Enabled



Search, Filter, Export Randomization Listings

- Overview

For studies with Randomization enabled, lists can be exported

- Business Value

An easy way to export data.

	Export	Filter	Search
Randomization List	X		
Enrollment List	X	Rand Status	
Device	X	Status	Device ID
Unmasked Data	X	Record Status	Rand ID

Day 1
Impact to
Clinical Teams

Yes

Visibility

Lead Data
Manager,
Randomization
Manager

Configuration

N/A

Dependencies

Randomization
Enabled



Dedicated DEMO

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





Thank you