

20R2 Customer Webinar

Sites/CRAs/DMs/Coder

July 23, 2020





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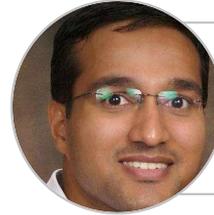
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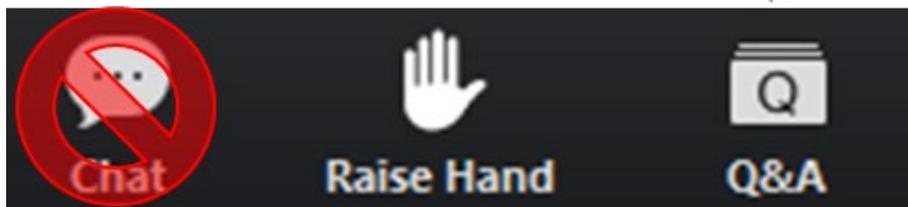
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'Q&A' to ask a
question



Veeva R&D and Quality

SUMMIT ONLINE

October 13–14, 2020



Develop new industry partnerships



Share best practices



Network with sponsors, CROs, & sites

CLINICAL

QUALITY & MANUFACTURING

REGULATORY

SAFETY

IT

Veeva Vault Release Schedule



20R2 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
19	20	21 JUL	22	23 20R2 Release webinar 9 AM PT - All Customers 10 AM PT - Studio & Admin	24	25
26	27	28	29	30	31	1
2	3 Validation Docs 20R2 Pre - Release	4	5	6	7	8
9	10	11 AUG	12	13	14	15
16	17	18	19	20	21 20R2 General Release	22

— Customer Validation



Pre-Release Environment

<https://login.veevavault.com>

- Clone of UAT
 - Special Request for Dev
- Users
 - Contact Veeva Post Implementation Manager to add users
- Available up to 4 weeks after the 20R2 upgrade

AUG

**Monday
3rd**



Validation Documents

- Validation Project Plan
- IOQ Protocols
- Business Requirements Documents
- Traceability Matrixes
- System Release Memo
- Executed OQ Scripts (unexecuted in Word format available upon request)

AUG

**Monday
3rd**



20R2 Go Live

- ALL customer vaults upgraded to 20R2
- EU starts at 2:00pm PT
- APAC & US starts at 5:00 PM PT
- May take up to 6 hours

AUG

**Friday
21st**



20R2 General Release Resources

- **Resources Available**
- <https://cdmshelp.veeva.com/lr/rn/general-releases/20r2/>
 - Important Dates
 - Notifications Opt-In
 - Feature information
 - Pre- Release Information
 - Release Information
 - Release Impact Assessment (RIA)



20R2 Feature Summary

Sites



- Restricted Data
- Delete Subject & Reset Event
- Study Closeout
- Translatable PDFs

CRAs/Data Managers



- Review UI Navigation Enhancement
- Review Functionality entirely in Review UI
- Performance Improvements
- Locking/Freezing Enhancements

Study Designer



- Cascading Form Deletion
- Form Copy Enhancements
- Copy Codelists and Units
- Validation Script for Rule Changes
- Template Vaults
- Relaxed Study Update Restrictions
- System Design Spec Enhancements
- Restricted Data Configuration
- Study Closeout Signature Def

Rules

- Query Future Dates for Events
- Query on Event Date out of Range
- Data Driven Review Plan
- Casebook Variables
- Rule Configurator
- Sequence Number in Expressions

Admin



- Dynamic Review Plans by Subject Status or Percentage
- Deploy Vault Level Configurations
- Vault Diff Report
- Delete Sites (Non-Production)
- Additional APIs
- Study Role Enhancements
- System Tools - Change Reasons

Coding



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

Extracts/Listings

- Extracts Data and Definition Enhancements
- Data Listings - Restricted Data

CDB



Early Adopter

Labs



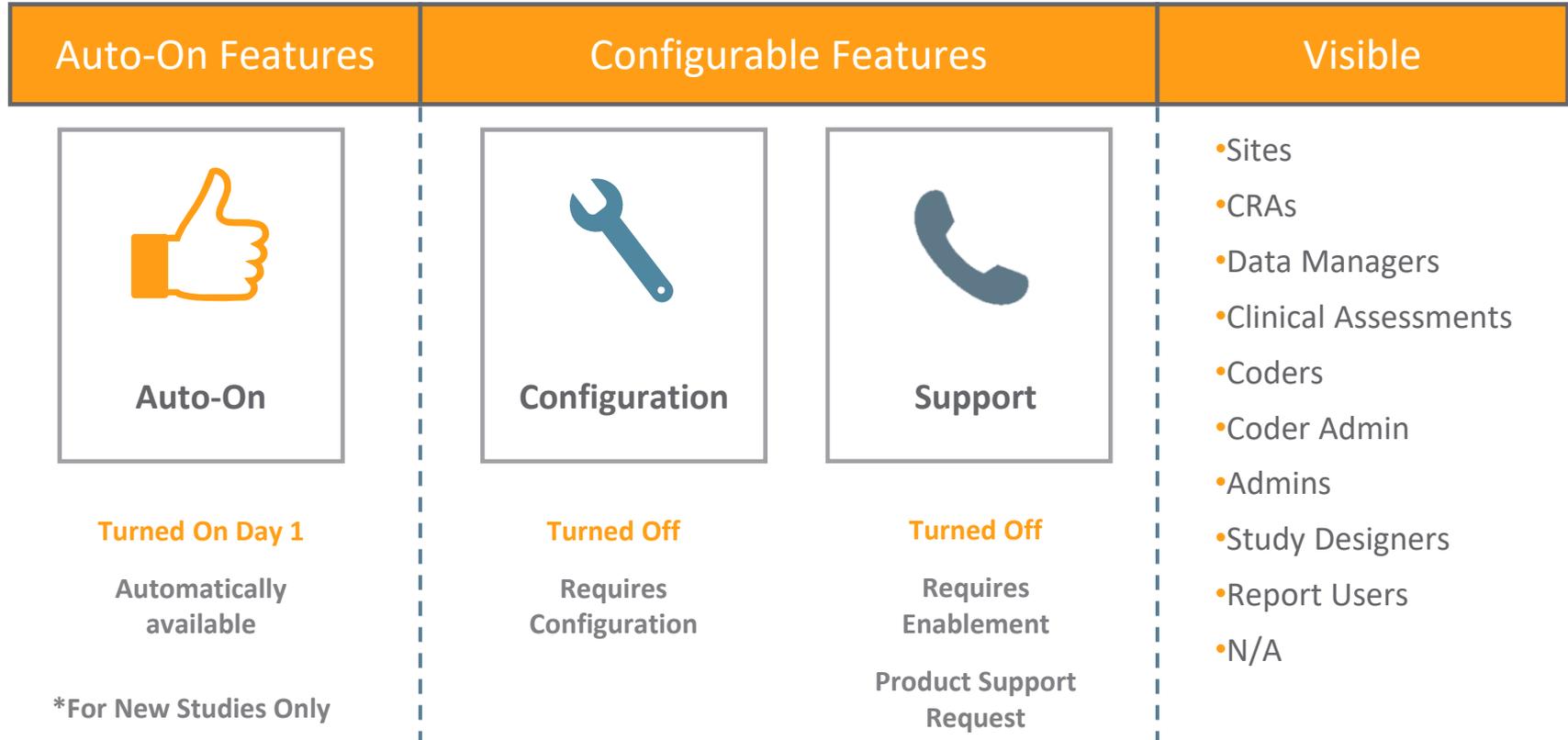
20R3

Randomization



20R3

Feature Enablement Detail





Sites



Configuration

NEW STUDIES ONLY

Visible

SITES, CRAs, DATA MANAGERS, REPORT USERS

Restricted Data

Overview

Study designers can configure a study to restrict (hide) Forms.

As a user with Restricted Data Access, an icon will display next to any Forms, Events, or Subjects marked as restricted to raise awareness that visibility is restricted dependent on a Role/Permission. When viewing a casebook as a user without the Restricted Data Access permission, all Forms marked as Restricted will be hidden within Data Entry and the Review tabs.

Reports will automatically filter out Restricted records for user without access.

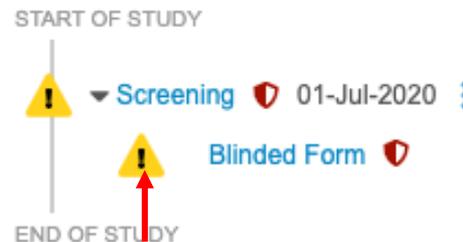
Note: The system will only allow restricted users to reset/delete data they have access to. Restricted Forms will be “Marked for Removal” if a user action triggers the removal of a Restricted Form that contains data. Unrestricted users can then reset these forms to remove them from the casebook.

Business Value

This feature will ensure that studies with blinded vs. unblinded data are supported with CDMS.

Restricted Icon

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Marked for Removal



Restricted Access

New Studies ONLY - (Data Model v2 in 20R2)

NO Restricted Access Permission	w/ Restricted Access Permissions
Forms mark Restricted cannot be seen	Form mark Restricted can be seen and has a shield icon indicating that is was restricted
Delete an object (subject/Reset a Cycle/Reset a Visit) and there was a restricted form - the user view looks like it was all removed	Delete an object (subject/Reset a Cycle/Reset a Visit) and there was a restricted form - Object is “Marked for removal” with a yellow triangle and exclamation point. Banner appears - Form needs to be reset.
Reports and Dashboards - Restricted forms and Queries on restricted forms will not be included. Data Listings, Query Reports, Form reports, ie.. the Query and Form counts will be different than a user with Restricted Access.	Reports and Dashboards - Restricted forms and Queries on restricted forms will be included. Data Listings, Query Reports, Form reports, ie.. the Query and Form counts will be different than a user with Restricted Access.



Delete Subject & Event Reset Enhancements

- Overview

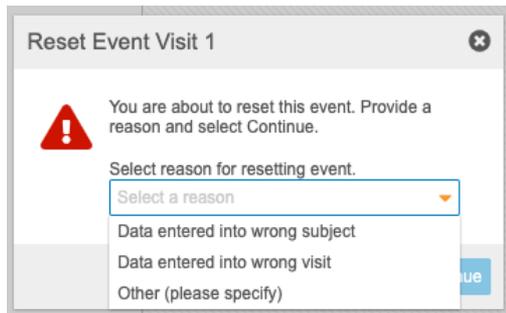
When resetting an Event, site users must now select a Reason for Change in addition to typing in “RESET” to confirm the Event reset.

When deleting a Subject, site users with permission must now type in “DELETE” to confirm the Subject deletion.

Note: The system will also delete forms that contain data if they are not locked and frozen. This eliminates the need to reset each event prior to Subject deletion. For studies that contain Restricted Data, the system will only reset/delete forms that the user has access to.

- Business Value

These enhancements add an additional layer of friction to ensure the site user does not unintentionally delete data. Additionally, these enhancements provide sites with a more streamlined process for deleting Subjects.



Reset Event Visit 1

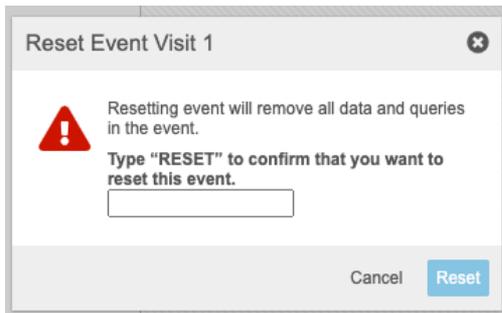
! You are about to reset this event. Provide a reason and select Continue.

Select reason for resetting event.

Select a reason

- Data entered into wrong subject
- Data entered into wrong visit
- Other (please specify)

Continue

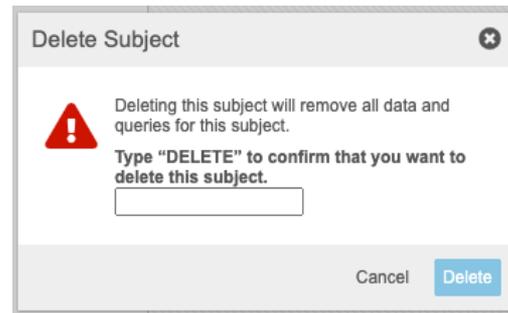


Reset Event Visit 1

! Resetting event will remove all data and queries in the event.

Type “RESET” to confirm that you want to reset this event.

Cancel Reset



Delete Subject

! Deleting this subject will remove all data and queries for this subject.

Type “DELETE” to confirm that you want to delete this subject.

Cancel Delete



AUTOMATIC

Translatable PDFs

- Overview

All PDF generated by Vault are now translatable in the Blank, Detail, Annotated, and Clinical Assessment PDFs. Vault will use the user’s language that was set in their user record to determine the language in which to create the PDF.

Note: User entered text will continue to display as it was entered into the system and will not translate automatically. For example if Form name was entered in English, it will display and print as English.

- Business Value

Translatable PDFs will ensure documents are in the Sites Native language.

被験者: SCR-0003					
イベント	フォーム	イベント日付	ステータス	署名済み	クエリ
Visit 1		23-Jun-2020	進行中	未署名	
	Common Identifier Variables: Subject Identifier		送信済み	未署名	
	Disposition: Minor/Incapacitated Adult Informed Consent		空白	未署名	
	Disposition: Study Informed Assent		空白	未署名	
	Demographics		空白	未署名	
	Subject Status: Visit 1		送信済み	未署名	
	Pre-Existing Conditions and Medical History		空白	未署名	
	Prespecified Medical History: Migraine		空白	未署名	
	Columbia-Suicide Severity Rating Scale (C-SSRS) Children's Baseline/Screening - Categories		空白	未署名	
	Self-Harm Supplement Form		空白	未署名	
	Vital Signs: Visit 1		空白	未署名	
	Substance Use: Alcohol		空白	未署名	
	Substance Use: Tobacco		空白	未署名	
	Female Reproductive Status: Menstrual Status		空白	未署名	
Visit 2			予定	未署名	

Visible

SITES, CRAs,
DATA
MANAGERS





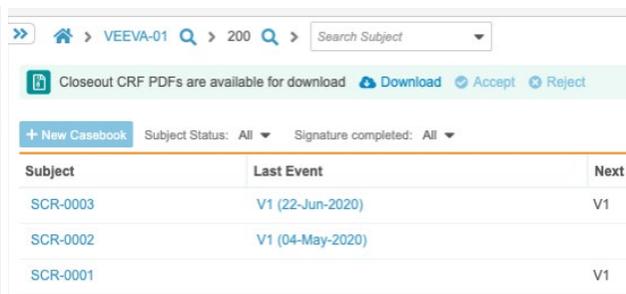
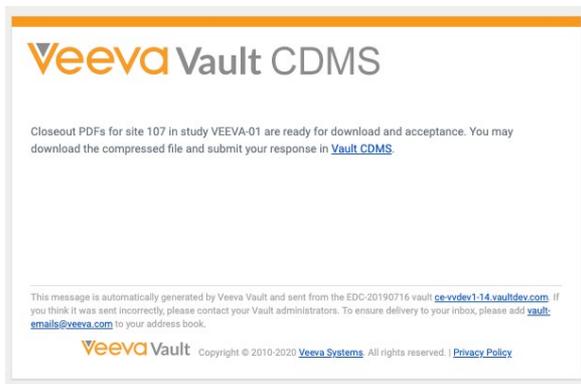
Study Closeout

- Overview

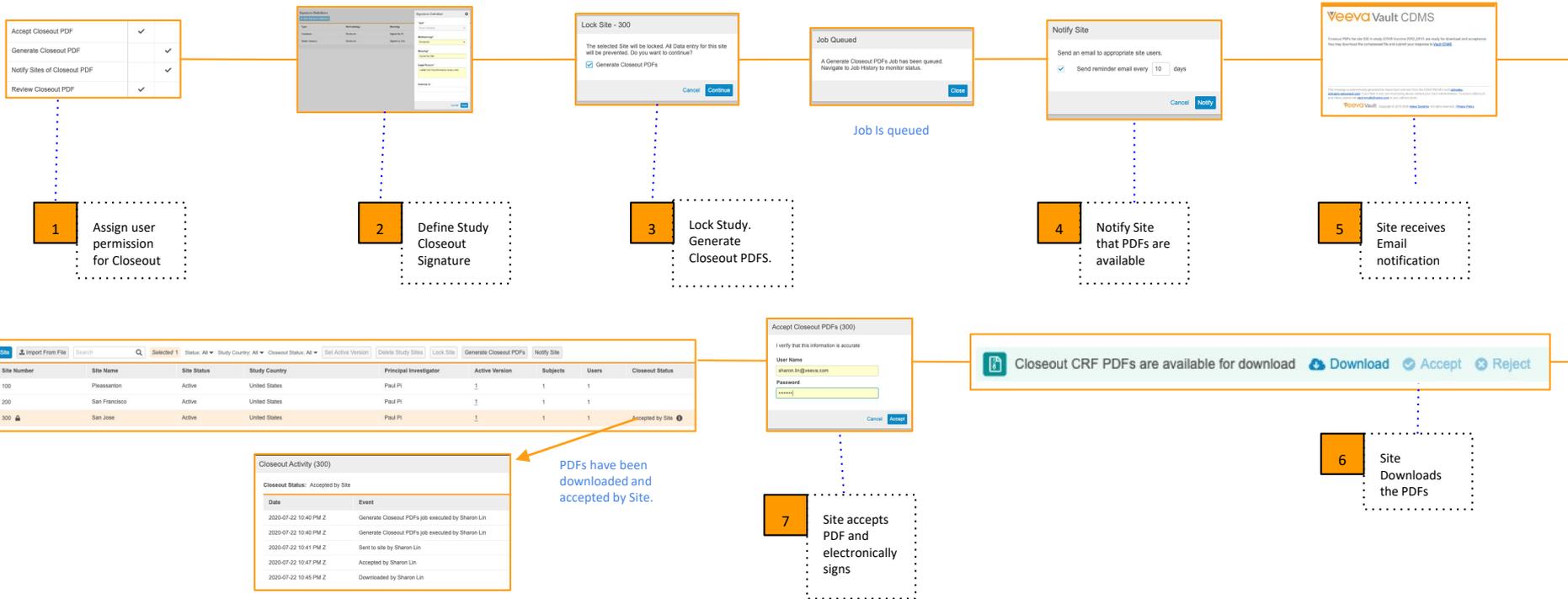
Sponsors can make Closeout PDFs available to site users at the end of a study. Site users are notified via email when Closeout PDFs are available and can be reminded on an automated basis to log in and accept the file based on a cadence set by the sponsor. When ready, Sites can easily download and accept/reject Closeout PDFs. The downloading of PDFs will always be available throughout the entirety of the study.

- Business Value

Sites can easily download and accept end of study PDFs within the same system they used throughout the study.



Study Closeout Process



Site Number	Site Name	Principal Investigator	Active Version	Subjects	Users	Closeout Status
<input type="checkbox"/> 100	Pleasanton	Paul Pl	1	1	1	
<input type="checkbox"/> 200	San Francisco	Paul Pl	1	1	1	
<input checked="" type="checkbox"/> 300	San Jose	Paul Pl	1	1	1	Accepted by Site

Date	Event
2020-07-22 10:40 PM Z	Generate Closeout PDFs job executed by Sharon Lin
2020-07-22 10:40 PM Z	Generate Closeout PDFs job executed by Sharon Lin
2020-07-22 10:41 PM Z	Sent to site by Sharon Lin
2020-07-22 10:47 PM Z	Accepted by Sharon Lin
2020-07-22 10:45 PM Z	Downloaded by Sharon Lin

**If Site is unlocked, Closeout Process starts all over*





Sites Demo



CRA's / Data Managers

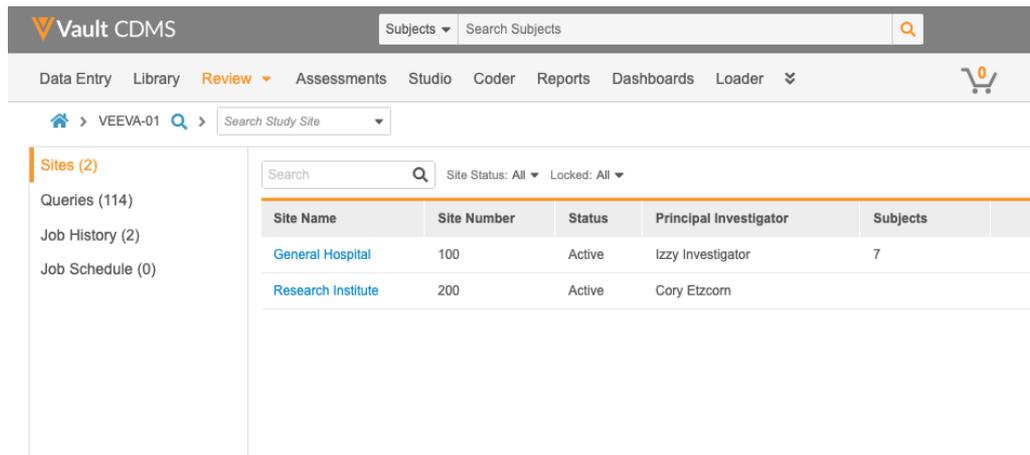
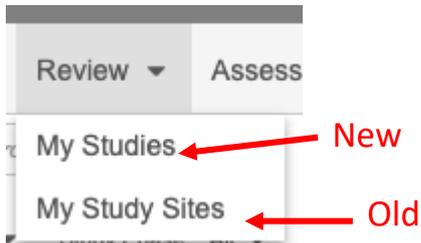
Review UI Navigation Enhancements

- Overview

The Review tab now contains “My Studies” and “My Study Sites” sub-tabs. “My Studies” introduces a new navigational pattern to the Review UI that behaves similarly to the Data Entry tab. Users select a Study, then work with the selected study’s Sites, Queries, and Jobs. “My Study Sites” continues to provide the same experience users have today. As part of these enhancements, the Queries and Study Jobs tabs were removed from “My Study Sites” and are only available within the new navigational pattern.

- Business Value

The “My Studies” sub-tab provides the user with an alternative navigation pattern they are more familiar with.



The screenshot shows the Vault CDMS interface. The top navigation bar includes 'Vault CDMS', 'Subjects', and a search bar. The main navigation bar includes 'Data Entry', 'Library', 'Review', 'Assessments', 'Studio', 'Coder', 'Reports', 'Dashboards', and 'Loader'. The 'Review' tab is selected, and the 'My Studies' sub-tab is active. The breadcrumb trail shows 'VEEVA-01' and 'Search Study Site'. The main content area displays a table of study sites.

Site Name	Site Number	Status	Principal Investigator	Subjects
General Hospital	100	Active	Izzy Investigator	7
Research Institute	200	Active	Cory Etzcoom	



Review Functionality is in the Review Tab



AUTOMATIC

- Overview

All review functions typically performed by CRAs, monitors, and data managers have been removed from the Data Entry tab. Going forward, all review functions must be performed in the Review tab. These functions include:

- Source Data Verification (SDV)
- Data Management Review (DMR)
- Freezing
- Locking
- Opening & Closing Queries

- Business Value

The Review tab offers a more streamlined user experience for review actions.

Visible

**CRAs, DATA
MANAGERS**



Performance Improvements



AUTOMATIC

• Overview

The Freeze & Lock icons have been removed from the Data Entry screen, but actions will still be disabled when Frozen or Locked. Vault will continue to display the current Freeze/Lock status of each Casebook, Event, Event Date, Form, and Item in the Review Tab.

New reports will be available for studies created after 20R2 as old Freeze/Lock reports will no longer work.

- Frozen Form Summary (v2) - *to be used in place of Standard Template: Frozen Form Summary*
- Locked Form Summary (v2) - *to be used in place of Standard Template: Locked Form Summary*
- Frozen Event Summary
- Locked Event Summary
- Frozen Casebook Summary
- Locked Casebook Summary
- Comprehensive Form Summary (v2) - *to be used in place of Standard Template: Comprehensive Form Summary*

For Studies created after 20R2, new reports have been added for reporting on Form, Event, and Casebook signed status. Previously used signature reports will no longer work.

- Form Signature Summary (v2) - *to be used in place of Standard Template: Form Signature Summary*
- Event Signature Summary
- Casebook Signature Summary
- Comprehensive Form Summary (v2) - *to be used in place of Standard Template: Comprehensive Form Summary*

• Business Value

These changes provide better overall system performance when freezing/locking and when applying signatures and viewing signature statuses

NEW STUDIES
ONLY

Visible

SITES, CRAs,
DATA
MANAGERS,
REPORT USERS



Locking & Freezing Enhancements



AUTOMATIC

NEW STUDIES
ONLY

Visible

SITES, CRAs,
DATA
MANAGERS,
REPORT USERS

- Overview

Parent/Child Relationships with Locking and Freezing

When you Lock or Freeze at the Parent Level, all the children beneath the Parent inherits that action. With the new enhancement you can unlock or unfreeze just one of the children below the parent after the inheritance.

For example, lock a Subject (parent), all the Forms (children) will be locked for that Subject. But now you can go in and unlock just one of those forms. Same for Freezing, Freeze a Form (parent), and all the items (child) will get frozen. But now I can just unfreeze one of the items.

- Business Value

This will provide more flexibility for targeted use cases.

Eligibility Criteria [View As Site](#)

Frozen	
Does Subject Meet Eligibility Requirements	Yes ❄️
Is Subject enrolled in Study	Yes ❄️ ⋮ ?
Person who Granted Waiver for subject enrollment	❄️
Date of Waiver	❄️

ACTIONS

- Unfreeze Item

VIEW

- Item Audit Trail





Sites & CRAs / Data Managers Demo



Coding

Upversioning Impact Report

- Overview

The Upversioning Impact Report provides a preview of upversioning to a dictionary release before having to commit to that upversioning. You may generate it for any Form or Synonym List.

- Business Value

This report can inform your decision to upversion to a particular dictionary release or to skip it. This can be helpful if your Study is locking soon and you want to evaluate the size of the impact on coding. It can also be valuable to understand what the changes are in the new dictionary releases and how the changes impact your coding paradigm and therapeutic area. Monitors can find this report as a useful summary to track and understand PT, SOC, and ATC changes. In some cases, Monitors may want to challenge the new coding paths.

Upversioning_Impact_Report_MedDRA_23_0_Form_04142020_1030 ☆ ⓘ

File Edit View Insert Format Data Tools Add-ons Help Last edit was seconds ago

100% \$ % .0_ .00 123 ▾ Default (Aut... 10 ▾ B I T A ▾

	A	B	C	E	F	G	H	I	J	K	L	M	N	O	As
1	Assigned Code in Target Release														As
2	Impact	Verbatim	Count	LLT Code	LLT	PT Code	PT	HLT Code	HLT	HLGT Code	HLGT	SOC Code	SOC	Primary Path	LL
3	Remapped	Collodion	20	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
4	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
5	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
6	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
7	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
8	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
9	Nonrecurrent	Collodion	3												10
10	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
11	Remapped	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10
12	Autocoded	Collodion	3	10002960	Collodion	10002960	Apicectomy	10012317	Dental and gingival therapeutic procedures	10019190	Head and neck therapeutic procedures	10042613	Surgical and medical procedures	Y	10

Visible

CODER ADMIN



Navigation Enhancements

- Overview

All Coder pages now have breadcrumbs to improve navigation and this allows Coders to switch between Coding Forms while on the Verbatims Page. In addition, the homepage now has filters so that Coding Forms can be filtered by Study, Form, and Dictionary Release. Lastly, the Verbatims Page displays an informational banner that clearly displays the major attributes of the Coding Form.

- Business Value

The navigational enhancements allow Coders to get to where they need quicker and with less clicks.

Home Coder

Study: All ▼ Dictionary: All ▼ Form: All ▼

Sponsor	Study	Form	Status	Dictionary
Bryce Pharma	Labrinone_DEV1	ConMed	Needs Synony...	
Bryce Pharma	Labrinone_DEV1	AE	Active	M

Home Coder > Mabrinone - AE ▼

Sponsor	Study	Form	Dictionary	Synonym List(s)
Bryce Pharma	Mabrinone	AE	MedDRA 22.1	BP AE MedDRA 22.1 List

Coding Status: All ▼ Query Status: All ▼

<input type="checkbox"/>	Verbatim	Search Verbatims...	Seriousness	Coding Status
<input type="checkbox"/>	ACETATE INTOLERANCE		No	CODED
<input type="checkbox"/>	ANEURYSM		No	CODED



Reconstitute Code Requests Job Enhancement



Automatic

- Overview

Previously you had to run the Autocoding and Suggestions Job after running the Reconstitute Code Request Job. Now, running the Reconstitute Code Request Job will not only create and update Code Request based on new coding configurations, it will also attempt to autocode any of them that are pending coding.

- Business Value

Users no longer have to remember to run the Autocoding and Suggestions Job right after running the Reconstitute Code Request Job. The system will take care of that for them.

Visible

Lead Data
Manager



LDM and DM Can View Coding Data

- Overview

Lead Data Manager and Data Manager now have the permissions to read Coding data. They will be able to generate and view coding data in Reports, Dashboards, and any Extracts.

- Business Value

LDM and DM can now inspect coding progress and decisions.

All Reports ? Save View As

▼ **Filters** (1) [Clear All Filters](#)

» Report Type: **Template: Clinical Coding** ✕

[+ Create](#)

Name	Report Type	Description	Tags
MedDRA Coding Report ★	Template: Clinical Coding	Clinical Coding Request and assigned codes (if assigned) for MedDRA based forms	Standard Coder Reports
WHODrug Coding Report ★	Template: Clinical Coding	Clinical Coding Request and assigned codes (if assigned) for WHODrug based forms	Standard Coder Reports
Dashboard: Coding Statuses ★	Template: Clinical Coding	Report of all coding statuses used in the Dashboard.	Standard Coder Reports
Dashboard: Pending Queries ★	Template: Clinical Coding	Report of queries that are either pending a response from the Site or action from the Coder used in the Dashboard.	Standard Coder Reports

Visible

Data Managers





Coding Demo



Extracts & Listings

Data and Definition Export Enhancements



- Overview

This job provides a full data and definition extract and can be used for third-party reporting system integrations, such as JReview. Enhancements include: if users have permissions for restricted data access, then they can configure the export to include or not include restricted data. If the export includes restricted data, then the export contents will tag which definitions and data are restricted. In addition, it includes External IDs and SDTM Names, when available, for all definitions so that end users can map to the desired label.

- Business Value

Restricted data is further protected by making it optional to include it in the export contents. End users will be able to map to objects using External ID and SDTM Name. Third party systems can ingest the data with less pre-processing.

Mohammed Al-Adeeb 06/15/2020 11:34 PM PDT

New Job

Type
Data and Definition Export

Frequency
Run Now

Include Restricted Data

Cancel Run Now

Visible

Data and
Definition
Extract User



Data Listings with Restricted Data



Automatic

- Overview

Users with restricted data access will see restricted forms in the Data Listings configuration and will be able to include them in the extract.

Users without restricted data access will not be able to extract any data from restricted forms through Data Listings. Those forms will not be available in the job configuration.

Restricted files contained in the downloaded zip file will be prefixed with “RESTRICTED” to indicate that they contain restricted data.

- Business Value

Restricted data is available and protected when needed to review and analyze data.

Visible

Lead Data
Managers





Extract and Listings Demo



Thank you!