

20R3 Customer Webinar

Study Designer, Admin, and Coder

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20R3 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
01	02	03 NOV	04	05	06	07
08	09	10	11	12 20R3 Release webinar 9 AM PT - All Customers 10 AM PT - Studio & Admin 11 AM PT - Randomization	13	14
15	16 Validation Docs 20R3 Pre - Release	17	18	19	20	21
22	23	24	25	26	27	28
29	30	01 DEC	02	03	04 20R3 General Release 5PM PT	05

 Customer Validation



20R3 Feature Summary

Sites



- Query Teams

Study Designer



- Schedule Editor
- Status - After Deployment

Rules

- Events - Did Not Occur and Change Reason Supported in Send Email

Admin



- Veeva Learning Integration Enhancements
- Rule Execution Enhancements
- Deployment Enhancements
- Query Team Administration
- Labs Security
- Randomization Security
- API Access Permission
- Lists the Study Role assigned to the user
- Set the Form Status for Retro Amendments
- Miscellaneous

Coding



- Batch Upversioning
- Autocoding Source
- Subject Source
- Third Party Coding Support
- Certain Coding Config moved to Coder Tools

Safety Link

- SAE Form
- First Send & Follow Up
- E2B with ACK2

Other

- Additional APIs

Local Labs



- Data Driven Normals
- Visual Indicators when out of Normal Range
- Manual Override of Auto-Populated Normals
- Pre-Defined Units
- Downloaded Reference Range Template
- Analyte Library
- LOINC Code Support
- Unit Conversions
- Centralizing Tracking of Reference Ranges
- Import Lab Locations and Normals
- Reference Range Effective Dates
- Approve Lab Normals
- Approve Lab Locations
- Outdated Normals Report
- Update all Outdated Normals Job
- Pending Lab Location Report
- Update all Pending Locations Job

Randomization



- Support Different Randomization Types
- Support Diff Randomization IDs
- Amendments to Randomization for changes to Strata
- Append Randomization List for Increased Enrollment Size
- Blinded Studies
- Define Rules when Subjects are Ready to Randomize
- Emergency Unblinding
- Email notification for Unblinding
- Unblinding Report
- Treatment Reveal
- Automatic System Queries for changes to Strata variables
- Configurable manual entry of Kit/Device ID

Feature Enablement Detail

Auto-On Features	Configurable Features		Visible
 Auto-On	 Configuration	 Support	<ul style="list-style-type: none">• Sites• CRAs• Data Managers• Clinical Assessments• Coders• Coder Admin• Admins• Study Designers• Report Users• N/A
Turned On Day 1 Automatically available	Turned Off Requires Configuration	Turned Off Requires Enablement Product Support Request	





Local Labs

Features: Studio

Enabling Local Labs	Study setting that needs to be turned on for each study that wants to use Local Labs.
Lab Panel creation	<p>Once a study has been set up to use Local Labs, lab panels can be created using analytes configured in the Analyte Library.</p> <p>On Save of a lab panel, lab units and codelists used in the selected analytes will be copied to Studio.</p>
Lab Form creation	<p>Adding a lab panel to a form will automatically create a lab form.</p> <p>A lab form contains a fixed item group called the lab header that collects the sample collection date time, the lab location and the age of the subject.</p>
Other functionalities	<p>Lab forms will appear in the SDS and be considered in the dif report</p> <p>Lab forms cannot currently be copied between studies.</p>



Features: Lab Module

Analyte Library	Vault provides a preloaded master list of all commonly used analytes.
LOINC Code Support	Comply with the FDA guidance to report LOINC codes with lab results by adding the appropriate LOINC codes within your analyte master list
Background Unit Conversions	Vault maintains a library of unit conversion ratios and generates standardized results and units to accompany the original results and units in data extractions
Centralizing Tracking of Reference Ranges	Enter lab normal information once and share it across all of your studies and sites.
Rapid Setup for Lab Locations and Normals	Lab locations and normal ranges are uploaded from a spreadsheet template
Reference Range Effective Dates	Effective dates for lab normals ensure the correct ranges are displayed for the given collection date.
Approve Lab Normals	If configured, Normals that are entered must be approved before Sites can use it
Review and Approve Pending lab locations	Sites can enter new Lab Locations, and Manager can review and approved for addition in the Centralized Lab Locations and Normals
Outdated Lab Normals Report/and Job	Report that shows Sites that are using outdated lab normals
Pending Lab Location Report/and Job	Identify new labs to add the System's centrally managed Lab Location
Select Default Month Day for Birthdate	If Birth year is only allowed to be collected, set a default month/day to be used to determine age



Enablement



Automatic

- Local Labs will be automatically enabled for all customer Vaults
 - Labs tab will be available
 - Labs standard roles and permissions will be available
 - Labs must be enabled in Studio

- Local Labs can be turned on for existing studies
 - Current lab forms deprecation must be considered





Local Labs Demo



Studio (Study Designer)



Automatic

Schedule Editor

- Overview

Studio users can build the study schedule in a grid similar to the time and events schedule in the Protocol document. Users can still switch back to the drag and drop view of the schedule. Form design remains in the drag and drop editor.

- Business Value

This provides a method to quickly build and review the structure of the study reducing study build times.

The screenshot displays the 'Schedule Editor' interface. On the left, a sidebar lists 'STUDY DESIGN' (Schedule, Settings, Assessments, Email Groups, Form Links, Review Plans, View Sets) and 'STUDY OBJECTS' (Codelists, Event Groups, Events, Forms, Item Groups, Items, Units). Below these are 'RULES' (Casebook Variables, Comparison Rules, User Defined Rules). The main area is a grid titled 'Schedule' with columns for 'Screening', 'Treatment', and 'Follow Up'. The grid contains rows for various study events like 'Indent and Prog Disp 2', 'Lab', 'Prog With Default', 'AE', 'All Data Types', and 'Concomitant medication'. A 'Properties' panel on the right shows settings for the selected event, including 'Event Type', 'Mandatory', 'Dynamic', and 'Default Display'. The bottom of the screen shows the 'Vault' logo and 'Privacy Policy' link.

Visible

VISIBLE TO
ALL STUDY
DESIGNERS





Automatic

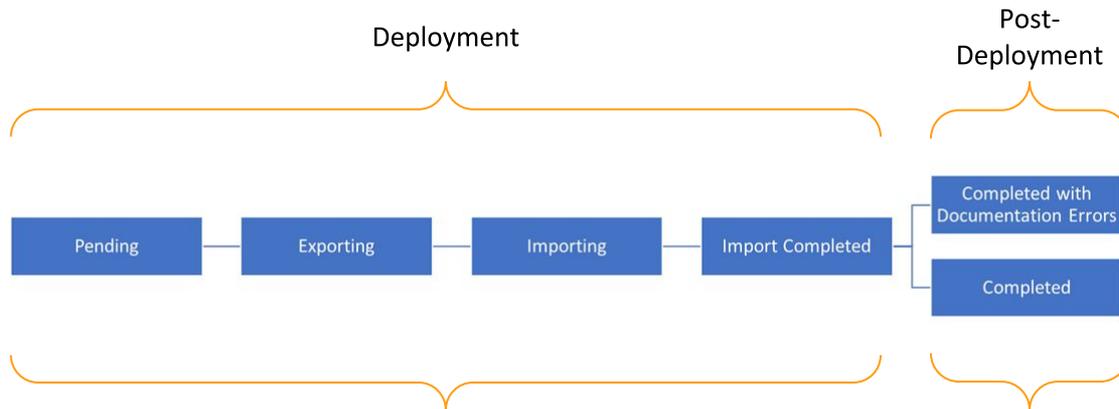
AFTER DEPLOY STATUS

- Overview

Deployment Administrators will be able to track a clear delineation between the completion of the deployment Export and Import, and the post deployment documentation creation. This is viewable in deployment history.

- Business Value

Provides better insight into the deployment process to provide more information and reduce confusion.



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ALL DEPLOYMENT
ADMINISTRATORS





Studio Demo



Rules

New Event properties



Automatic

- Overview

- Study Designers can now access two new properties for Events in the rule editor:
 - Did_not_occur__v: returns true if the event was marked as did not occur
 - Change_reason__v: returns the “did not occur” reason selected
- Both values are also available as tokens for the “Send Email” rule action

- Business Value

- This feature broadens the scope of rules that can be written using the rule editor

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ALL STUDY
DESIGNERS**





Admin

Veeva Learning Integration



Configuration

- Overview

Site users who haven't completed their assigned training can now view the training status and navigate to Absorb from the Data Entry tab. Also, users will now see all the studies they have access to. Lead data managers can now set up learning systems in new studies more easily by copying a Role to Curriculum mapping from another Study in their vault. By default, the curriculum list is now sorted in ascending order. Lead data managers can now delete an existing Learning System from EDC Tools > Learning Systems.

- Business Value

Site users can in real time see the training status for a study and get study access sooner than usual. Lead data managers can more easily manage their role to curriculum mappings.

The screenshot shows the Veeva Vault CDMS SBX interface. At the top, there is a header with the Veeva logo and 'Vault CDMS SBX'. Below the header is a search bar for 'Subjects' with a search icon. The main content area is titled 'Data Entry'. On the left, there is a 'STUDY TASKS' sidebar with a 'Choose a study' dropdown. The main area displays a notification: 'You must complete training in order to access your studies.' with a 'Go to Training' button. Below the notification, there are filters for 'Study Status: All' and 'Study Phase: All'. A table lists studies with columns for 'Study', 'Study Phase', 'Screen Failed %', 'Study Status', and 'My Access Refresh'. The table contains four rows: 'AI Study A LDM' (Training Required), 'How to dunk_DEV1' (Valid), 'TopazStudy_UAT1' (0% Screen Failed, Valid), and 'TopazStudy_UAT3' (Valid).

Study	Study Phase	Screen Failed %	Study Status	My Access Refresh
AI Study A LDM				Training Required
How to dunk_DEV1				Valid
TopazStudy_UAT1		0%		Valid
TopazStudy_UAT3				Valid

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Rule Execution Enhancements



- Overview

Lead Data Managers can now view all Rules (except for Add Assessment, Set Item Value, and Send Email rules) in their study. Users can click on each rule to view additional details, including the rule's criteria expression. They can use the Advanced Filters to narrow their list of rules. They can preview or execute rules on all Subjects or select individual subject casebooks in which to execute rules. **Note that users may only select 50 Rules and 500 Casebooks during execution.**

- Business Value

This feature allows lead data managers to run a rule that may not have fired. They can also run rules of types other than Query Rules after performing a retrospective amendment.

▼Advanced Filters

Veeva Vault - EDC Tools

Rule Actions Add Assessment Add Form Ready to Randomize
 Add Event Override Review Plan Set Subject Status
 Add Event Group Query

Last Modified Date All Date Range -

[Find Rules](#)

Search Rule Status: All ▾ Selected 0

<input type="checkbox"/>	Name	Rule Status	Form	Rule Action	External ID	Last Modified	Last Modified By
<input type="checkbox"/>	A_Form	Inactive	Local Laboratory Te...	Add Event Group	A_Form	09/09/2020 7:10 PM EDT	Rakesh Monassery
<input type="checkbox"/>	AAA1	Active	Demographics	Override Review Plan	AAA1	07/06/2020 8:02 PM EDT	Rakesh Monassery



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Deployment Enhancements



- Overview

Deployment administrators can now add custom roles, object tabs, reports, and dashboards to the deployment list from within System Tools, without needing to access Business Admin. Deployments can now include custom object tabs, so users no longer need to configure these in every vault. Vault adds custom object tabs to the deployment list when the tab's object is added to the deployment list.

- Business Value

The ability to add custom roles, reports, and dashboards to the deployment safelist from System Tools, without needing to access Business Admin, increases customer independence.

System Tools

Role Management	Custom Roles Manage Custom Roles <input type="text" value="Search"/>
Change Reasons	
External Connections	
Deployment	
DEPLOYMENT LIST	
Custom Objects	
Custom Roles	
Custom Reports	
Custom Dashboards	

Label	Name
SAE Assessment Editor	sae_assessment_editor__c
SAE Assessment Rea...	sae_assessment_reader__c
Verteo Investigator	verteo_investigator__c

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Query Teams Administration

- Overview

With this release, the ability and inability for a user to close a manual query created by another user can be enforced within a study. Vault groups Study Roles into Teams at the vault level. All vaults have a set of standard teams to choose from when assigning user-defined roles to teams. Standard roles are automatically placed into their corresponding teams. A team can contain multiple roles, but each role can only belong to one team. A new permission to override query team restrictions, Close All Queries, which controls the ability to close a query regardless of the team that created it. By default, this permission is assigned to the CDMS Lead Data Manager standard study role.

- Business Value

This feature provides the ability limit which a user can close another user's query, which can prevent certain queries from getting closed prior to getting seen and acted on by the correct team.

Role Management Show: All Roles Active Roles

[+ New Role](#)

	Administration				Cli...			Coding			Data Management		
	CDMS Deployment Administrator	CDMS Randomization Manager	CDMS User Administrator	Regional CRA	CDMS Clinical Research Associate	CDMS Clinical Coder	CDMS Clinical Coder Administrator	API Integration User Raikesh	CDMS Clinical Assessment Editor	CDMS Clinical Assessment Reader	CDMS Data Manager	CDMS Data and Defir	CDMS L
Number of Users	0	0	0	0	1	4	0	2	0	0	11	0	0
Manage Role	▼	▼	▼	⚙	▼	▼	▼	⚙	▼	▼	▼	▼	▼

▼ Standard Tabs



Labs Security

- Overview
 - Created 10 permissions for Labs.
 - Created “CDMS Lab Data Manager” study role.

Role Management Show: All Roles

[+ New Role](#)

	Data Management					
	Assessment Editor	CDMS Clinical Assessment Reader	CDMS Data Manager	CDMS Data and Definition Export	CDMS Lab Data Manager	CDMS Lead Data Manager
	11	0	0	1	1	0
View Lab Locations and Normals						
Edit Lab Locations and Normals						
Manage Site Lab Assignment						
Manage Lab Units and Codelists						
Manage Lab Study Settings						
Lab Mass Update						
View All Lab Settings						
View Lab Analyte Library						
Edit Lab Analyte Library						
Approve Lab Normals						



Automatic

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Randomization Security

- Overview

- Created 10 permissions for Randomization.
- Created “CDMS Randomization Manager” study role.

Role Management Show:

[+ New Role](#) 

	CDMS Deployment Administrator	CDMS Randomization Manager	CDMS User Administrator	Regional C...	Administ...
Number of Users	0	0	0	0	1
Manage Role	▼	▼	▼	⚙️	▼
Randomize Subject					
Emergency Unmasking					
Configure Randomization		✓			
Manage Randomization List		✓			
Randomization (System use only)					
View Randomization Enrollment		✓			
View Unmasked Data					
View Randomization Kit/Device		✓			
Reveal Treatment					
Invalidate Randomization					



Configuration

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General Enhancements



Automatic

- Overview

- Vault allows deletion of a Review Plan Assignment Criteria if it's used for assigning a plan to a casebook.
- Users can now select a Form Status when initiating a retrospective amendment. They can choose to set the impacted Forms in the In Progress Post Submit or Submitted statuses.
- Site Name is no longer requires uniqueness within the Study.
- We added hover text for the Delete Study Data and Delete Site Data job in EDC Tools > Job History.
- System Tools > External Connections now only displays the Absorb connection, and not the vault connections required for automatic deployments.
- Added the new API Access permission to control the ability to access the API. This permission is automatically assigned to the CDMS Data Manager and CDMS Lead Data Manager study roles.
- All study roles that are assigned the Manage Study Site permission are now automatically assigned the Manage Study Countries permission.
- Added a new Study Role column to the user listing in EDC Tools > Users, which lists the Study Role assigned to the User.
- Added the ability to show All Roles or only Active Roles in the Role Management table.

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Admin Demo



Coding



Automatic

Batch Upversioning

- Overview

Prior to this release, upversioning applied to a single Form at a time and one Synonym List at a time. With Batch Upversioning, all Forms can be Upversioned at once along with their assigned Synonym List.

Coder Admins have the option to select a subset of Forms or to not include the Synonym List in their batch upversioning action.

- Business Value

Coder Admins will save a lot of time when they upversion their studies once or twice a year, depending on their schedule.

If you upversion a subset of Forms of a Synonym List and the Synonym list is being upversioned as well, then a duplicate Synonym List is generated and assigned to the non-upversioned Forms to avoid disrupting the Coders that continue to code those Forms.

Coder Tools

Study	Form	Dictionary	Status	Synonym List
<input type="checkbox"/> Labrinone_DEV1	Medical History	MedDRA 22.0	Active	MedDRA Syn List
<input type="checkbox"/> New Third Party Study_UAT1	AE	MedDRA 22.0	Active	MedDRA Syn List
<input type="checkbox"/> Relaxing Coder Deployments Test_DEV1	AE	MedDRA 22.0	Active	MedDRA Syn List
<input type="checkbox"/> What How Bifurcation DEV1	AE	MedDRA 22.0	Active	MedDRA Syn List

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CODER ADMIN



Autocoding Attribution

- Overview

The Code Request object now stores the autocoding source, which can be either the Dictionary or the Synonym List. If the request was autocoded from the synonym list, then the Code Request record stores the name of the Synonym List and the reference to the Synonym. Users can view this information in any Vault Report that includes coding data by adding columns titled Autocoding Source, Autocoding Synonym List, and Autocoding Synonym List Record. Users can also add a custom dashboard components that compare the efficiency of autocoding from the dictionary to the efficiency of autocoding from the synonym list.

- Business Value

Coders can now trace the Synonym responsible for autocoding particular records. They can also begin to understand the maturity and performance of their Synonym Lists.

MedDRA Coding Report 
Clinical Coding Request and assigned codes (if assigned) for MedDRA based forms

Refresh Edit 

▼ PROPERTIES
 Report Type Template: Clinical Coding

▼ FILTERS (2) 

Verbatim	SAE	Coding Status	Autocoding Source	Autocoding Synonym List	Autocoding Synonym List Record	Autocoding Type	LLT Code	LLT	PT Code
Dry Skin		Autocoded	Dictionary			Exact Match	10013786	Dry skin	10013786
Sinus Infection		Autocoded	Dictionary			Exact Match	10040745	Sinus infection	10040753
Osteo-arthritis of neck		Autocoded	Dictionary			Exact Match	10031160	Osteo-arthritis of neck	10041591
Back Pain	No	Autocoded	Synonym List	MedDRA 23.0 Syn List	VV-000014	Exact Match	10048412	Back pain aggravated	10003988
Back Pain		Autocoded	Synonym List	MedDRA 23.0 Syn List	VV-000014	Exact Match	10003988	Back pain	10003988

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CODER ADMIN





Automatic

Subject Search

- Overview

The Code Request Listing now includes columns and filters for Site and Subject. This allows coders to search for a specific Subject or set of Subjects to apply coding for the first time or to reevaluate coding. Note that these filters aren't available when in Group mode.

- Business Value

This feature provides a quick and easy way to filter Code Requests for one or more Subjects.

Coder > Subject Search_DEV1 - ConMed

Sponsor	Study	Form	Dictionary	Synonym List
Bryce Pharma	Subject Search_DEV1	ConMed	GLOBALB3Mar20	WHODrug Syn List

Coding Status: All Query Status: All Site: All Subject: All Refresh 1-7 of 7

<input type="checkbox"/> Verbatim	Search Verbatims...	Indication	Search	Assigned Code	Suggestions	Site	Subject
<input type="checkbox"/>	Advil	Headache	<input type="checkbox"/> 0101-0001			101	0101-0002
<input type="checkbox"/>	Cetirizine Hydrochloride	Hives	<input type="checkbox"/> 0101-0002			102	0102-0001
<input type="checkbox"/>	Flonase	Sneezing	<input type="checkbox"/> 0101-0003			102	0102-0002
<input type="checkbox"/>	Prilosec	Bloating	<input type="checkbox"/> 0102-0001			102	0102-0003
<input type="checkbox"/>	Tylenol	Headache	<input type="checkbox"/> 0102-0003			101	0101-0001
<input type="checkbox"/>	Zyrtec	Sneezing	Oral OPEN			102	0102-0001
<input type="checkbox"/>	Zyrtec		OPEN			102	0102-0002

Visible

CODER





"How to Code" Coding Configurations Moved to Coder Tools from Studio

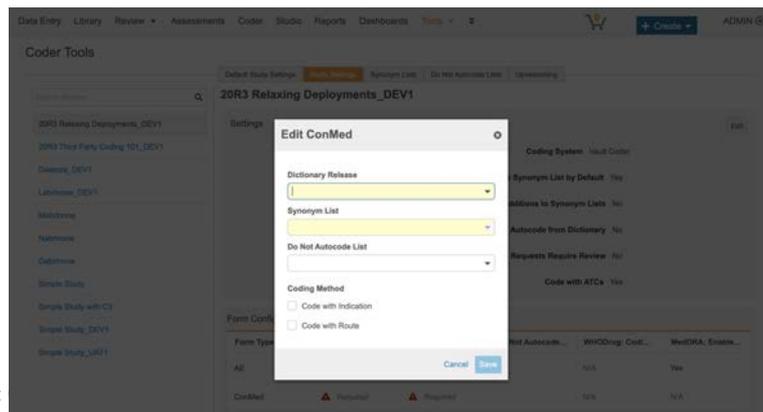
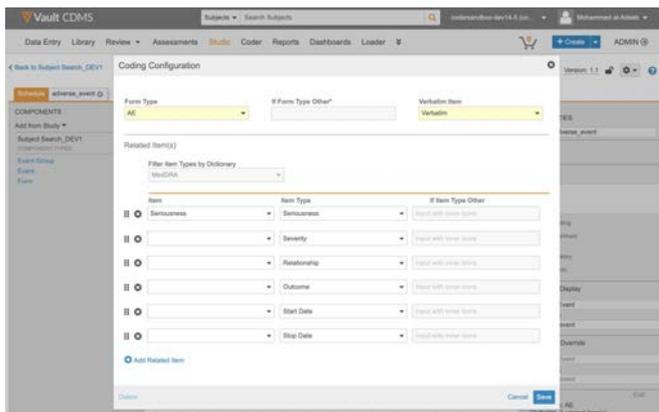
- Overview

While Studio will continue to be the location where we define the Verbatim and Related Items, it's no longer where we will define "how to code": the Dictionary Release, Synonym List, Do Not Autocode Lists, and Coding Methods. All "how to code" configurations now only reside in Coder Tools.

A Form will be unavailable to a Coder until a Coder Admin completes those configurations in Coder Tools. This applies to all study environments; including UAT, Training, Production, as well as in customer preview (pre-release) environments.

- Business Value

Now that Dictionary Releases are no longer controlled in Studio, there is more flexibility for deployments after customers Upversion on Production.



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STUDY
DESIGNER
&
CODER ADMIN



Copyright

Third Party Coding Support

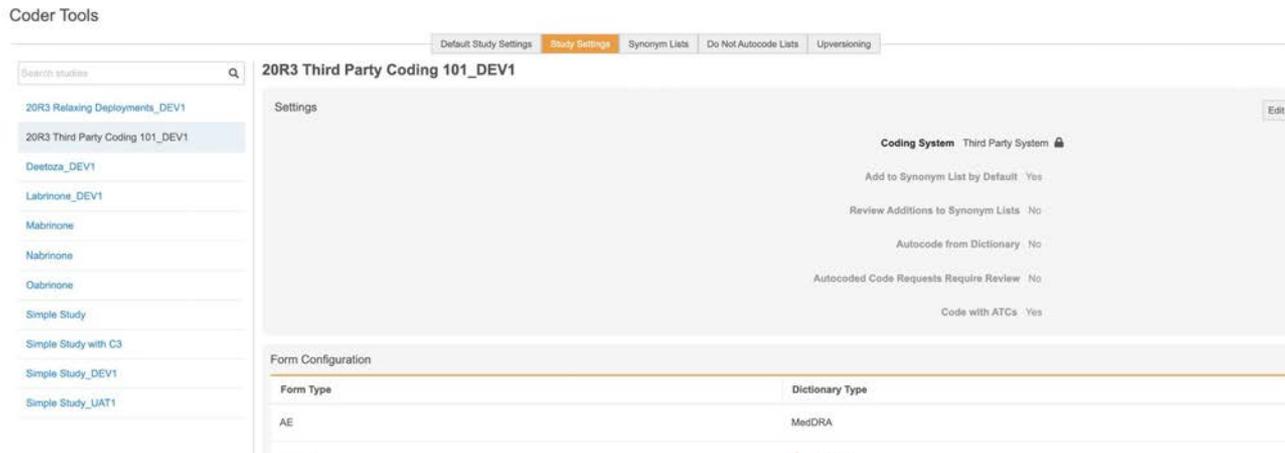
- Overview

Vault CDMS can now support third-party Coding systems. This will only be available on new Studies and requires the use of APIs to get the Code Requests, and the ability to get, post, and close Coding Queries.

While a Study is using a third-party Coding system, a Coder or Coder Admin can still navigate to the Coding page to see a listing of all the Coding Requests and view their Audit Trails. They will not be able to perform any coding or querying in the UI, all that must happen in the Third Party system.

- Business Value

Use Vault EDC with your own Coding System.



The screenshot shows the 'Coder Tools' interface. At the top, there are tabs for 'Default Study Settings', 'Study Settings' (which is active), 'Synonym Lists', 'Do Not Autocode Lists', and 'Upversioning'. Below the tabs is a search bar and a list of studies. The selected study is '20R3 Third Party Coding 101_DEV1'. The main content area shows the 'Settings' for this study, with a sub-section for 'Coding System' set to 'Third Party System'. Below this, there are several toggle options: 'Add to Synonym List by Default' (Yes), 'Review Additions to Synonym Lists' (No), 'Autocode from Dictionary' (No), 'Autocoded Code Requests Require Review' (No), and 'Code with ATCs' (Yes). At the bottom, there is a 'Form Configuration' table with two columns: 'Form Type' and 'Dictionary Type'. The table contains one row with 'AE' in the 'Form Type' column and 'MedDRA' in the 'Dictionary Type' column.

Visible

**CODER ADMIN
&
API User**





Coding Demo



Questions

Dedicated DEMO

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





Thank you