

19R1 Pre-release

03 APRIL 2019

The Veeva logo consists of a white inverted triangle followed by the word "veeva" in a lowercase, sans-serif font.

19R1 CDMS Release Preview and Planning

April 3, 2019

veeva

Please use
'Q&A' to ask a
question



Raise Hand



Q&A

Foreword

- The content of this presentation is **subject to change** prior to the 19R1 Release

Please note the revision date on the title slide

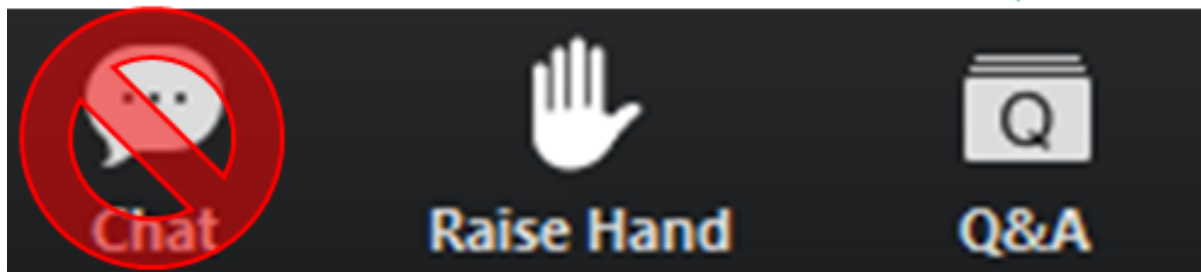
- Veeva encourages you to always reference Release documentation from our Release pages to ensure you are using the **latest information**

[Help](#) → [Release Notes](#) → [About the 19R1 Release](#)



Interact With Us!

Please use
'Q&A' to ask a
question



Vault CDMS 19R1 Presenter



David Gemzik

Product Manager

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Important Disclosures

The following is intended to outline Veeva's general product direction. It is intended for informational purposes only and does not form part of any contract. It is not a commitment to deliver any specific functionality and it should not be relied upon in making purchasing decisions. Features and functions described in this document will be released commercially only when and if they become available. The development, release, and timing of the features or functionality of Veeva's products remains at the sole discretion of Veeva.

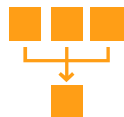


Reinventing Clinical Data Management

One product for coding, EDC, data cleaning, and data management

Vault CDMS

Coder
Clinical Coding



EDC
Data Capture & Monitoring



Data Workbench
Cleaning, Reporting, Export



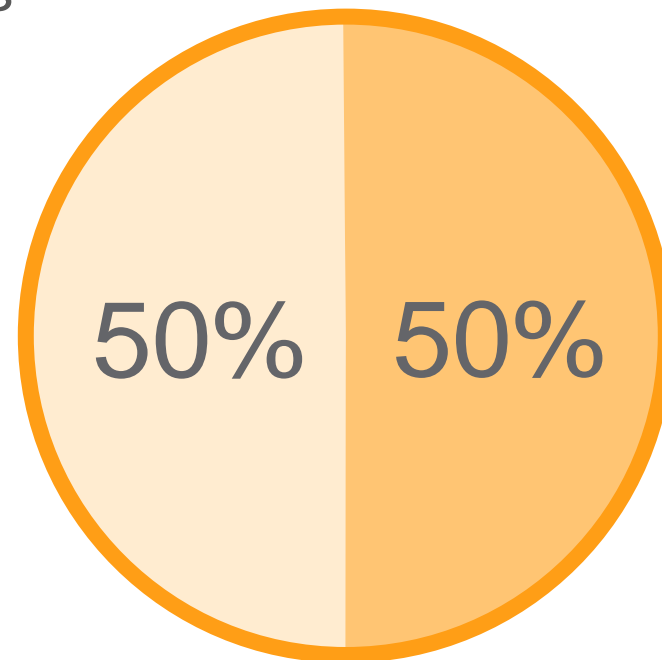
Vault Platform



Product Investment

50% Customer driven

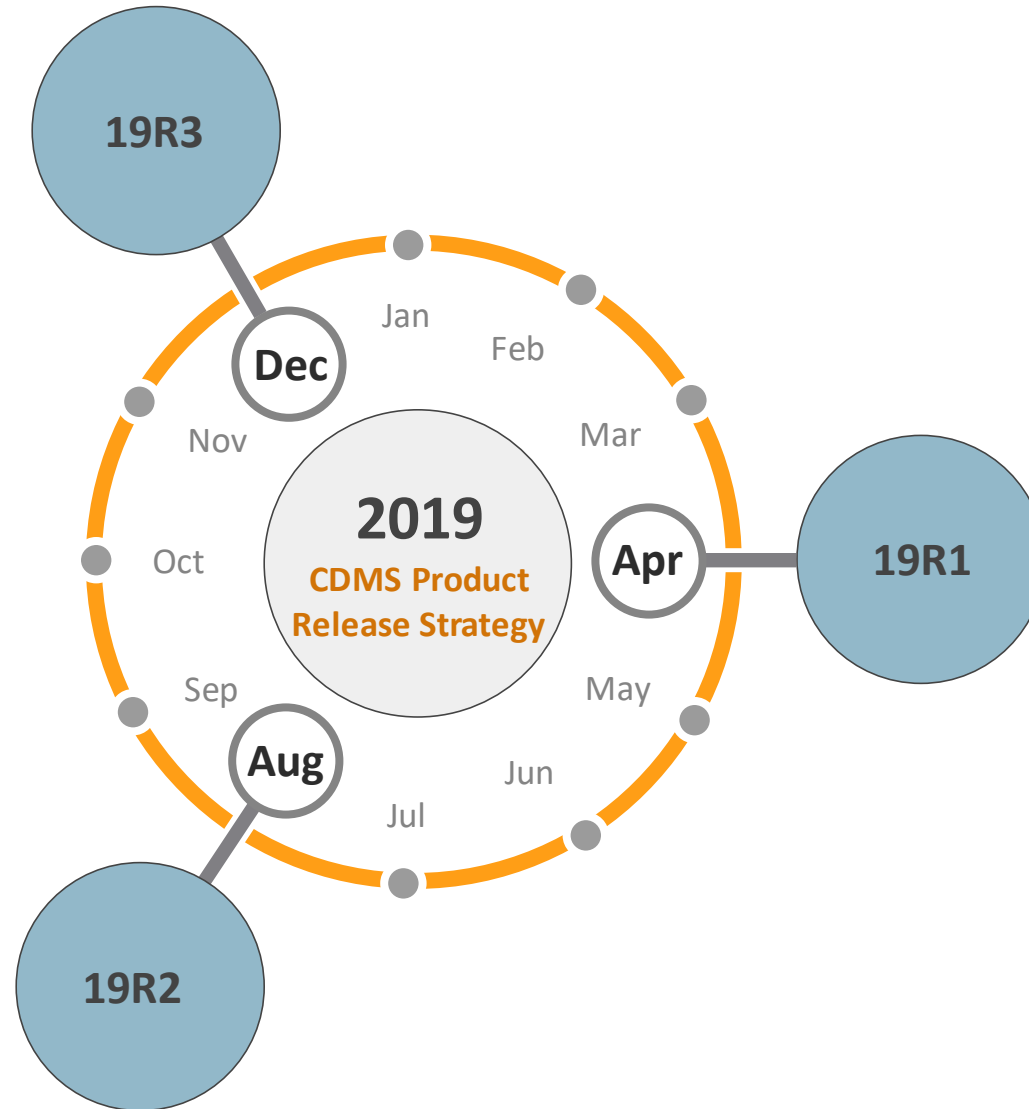
- 50% reserved development capacity
- Customer success focus
- 6-12 month horizon



50% Veeva Innovation

- Strategic direction
- Leading the industry
- 12-24 month horizon

Veeva Vault Release Schedule



Key Dates

Task	Date
19R1 Regression Testing	3/6/19 - 3/22/19
19R1 Validation prerelease begins	Monday 3/18/19 - 3/29/19
19R1 Customer prerelease Vaults	Monday 4/1/19 - 4/19/19
Stabilization Sprint and final build	4/9/19
19R1 Production	Friday 4/19/19



Casebooks to Data Entry

Auto On

All Users

“Casebooks” button label is now “Data Entry”

The screenshot shows the Vault EDC SBX interface. The top navigation bar includes the Vault EDC logo, 'SBX', a 'Subjects' dropdown, a search bar for 'Search Subjects', 'EDC Services - Internal', and a user profile for 'David M. Gemzik'. Below this is a secondary navigation bar with 'Data Entry' highlighted in an orange box, followed by 'Review', 'Studio', 'Reports', 'Dashboards', 'Loader', 'Coder', 'Tools', and 'Reference Object'. An 'ADMIN' link with an external icon is on the far right. The main content area shows a breadcrumb trail: 'Home > Gemzik 02 > 101 > Search Subject'. Below the breadcrumb is a '+ New Casebook' button and filters for 'Subject Status: All' and 'Signature completed: All'. A table displays two subjects:

Subject	Last Event Date	Next Event Date	Subject Status	Signature completed
SCR-0002	Event 1 (11-Mar-2019)		Pre Screen	No
SCR-0001	Event 1 (29-Nov-2018)		Pre Screen	No

On the left side, there are sections for 'STUDY TASKS' (1 task), 'Forms' (0 forms), and 'Review' (0 reviews).



Improving the Monitoring Experience

Auto On

All Reviewer Users

Filter for open tasks

Rapid Review and Navigation

No More Page Turns UX

The screenshot displays the Vault EDC SBX interface. At the top, there is a navigation bar with 'Vault EDC SBX', a search bar for 'Subjects', and user information 'EDC Services - Internal' and 'David M. Gemzik'. Below this is a secondary navigation bar with tabs for 'Data Entry', 'Review', 'Studio', 'Reports', 'Dashboards', 'Loader', 'Coder', 'Tools', and 'Reference Object'. The main content area shows a breadcrumb trail: 'Veterans Stadium > Subject: SCR-0019 > Visit 1'. Below the breadcrumb, there are filters for 'Subject: SCR-0019' and 'Visit 1', along with 'Schedule Task Filter' and 'Item Task Filter' toggle switches. A table lists tasks with columns for Name, a question mark icon, a speech bubble icon, a checkmark icon, and a purple checkmark icon. The tasks are: 'Screening Event 23-Sep-2018' (1, -, green circle, purple circle), 'Visit 1 24-Sep-2018' (-, -, orange circle, purple circle), 'Dosing' (-, -, green checkmark, purple circle), and 'Log' (4, -, green circle, purple circle). To the right of the table is a 'Dosing' section with a 'View As Site' link. It contains a 'Dosing Information (1 of 1)' table with a highlighted row 'Hows it is going?' and a 'Radio button' for 'Yes' with a green checkmark and a purple circle.



eSignature – Clear Signatures

Auto On

eSig Users

Signature can be cleared by Signer

The screenshot displays the Veeva eSignature interface for a specific form. The breadcrumb navigation shows the path: Gemzik Study 01 > 100 > SCR-0019 > Visit 1 > Dosing. The form title is "Visit 1 (24-Sep-2018): Dosing". A status bar indicates "Electronic Signature saved" and shows progress for SDV (100%) and DMR (0%). A "Signed" record is shown: "Signed 13-Mar-2019 by David M. Gemzik" with a "Clear Signature" link. The form content includes a "Dosing Information (1 of 1)" section with a question "How's it is going?" and a "Radio button" with a "Yes" option. An "ACTIONS" menu is open, listing options: "Clear Form Signature", "Intentionally Left Blank", "Freeze Form", and "Lock Form". The "Clear Form Signature" option is highlighted with an orange box. Other menu sections include "EXPORT" (Export Blank PDF, Detail PDF) and "VIEW" (Form History). The left sidebar shows navigation icons for Study Tasks (88), Forms (0), Review (26), and Queries (13).



eSignature – Sign UX

Auto On

eSig Users

Sign Form Button added for UX improvement

Vault EDC SBX

Subjects Search Subjects

Data Entry Review Studio Reports Dashboards Loader Coder Tools Reference Object

Gemzik Study 01 100 SCR-0019 Search Event Search Form

Subject SCR-0019

Select the events to be signed and click Continue. Clear All Continue Cancel

START OF STUDY

- Screening Event 23-Sep-2018
- Visit 1 24-Sep-2018

END OF STUDY

EDC Services - Internal David M. Gemzik ADMIN

ence Object ADMIN

Dosing

SDV (100%) DMR (0%) Sign Form Edit Form

SDV DMR

Sign Casebook Button – Sign multiple Events



Freeze and Lock Event Dates

Feature Flag

Reviewers

Freeze or Lock the Event Date

The screenshot displays the Vault EDC SBX interface. At the top, the navigation bar includes 'Vault EDC SBX', a search bar for 'Subjects', and user information 'EDC Services - Internal' and 'David M. Gemzik'. Below this is a secondary navigation bar with options like 'Data Entry', 'Review', 'Studio', 'Reports', 'Dashboards', 'Loader', 'Coder', 'Tools', and 'Reference Object'. The main content area shows a breadcrumb trail: 'Veterans Stadium > Subject: SCR-0019 > Screening Event'. A table on the left lists tasks for 'Subject: SCR-0019', including 'Screening Event 23-Sep-2018', 'Visit 1 24-Sep-2018', 'Log', and 'PD (4)'. The 'Screening Event 23-Sep-2018' row is highlighted, and a context menu is open over the date '23-Sep-2018', showing options: 'Freeze Event Date', 'Lock Event Date', and 'Event Date History'. The right side of the interface shows a 'Screening Event' view with a table for 'Event Date' and a 'Screening' section with 'View As Site' and an 'Enrollment' status of 'Yes'.

Name	?	!	✓	✓
Screening Event 23-Sep-2018	1	-	✓	✓
Visit 1 24-Sep-2018	-	-	✓	✓
Log	4	-	✓	✓
PD (4)	4	-	✓	✓

Event Date: 23-Sep-2018

- Freeze Event Date
- Lock Event Date
- Event Date History

Screening View As Site

Enrollment: Yes



Intentionally Left Blank

Auto On

Data Entry Users

Marking Form ILB sets all Items ILB

The screenshot shows the Vault EDC interface for a study named 'Gemzik Study 01'. The breadcrumb navigation is: Home > Gemzik Study 01 > 100 > SCR-0019 > Visit 1 > Dosing. The form title is 'Visit 1 (24-Sep-2018): Dosing'. The form content includes a section 'Dosing Information (1 of 1)' with a question 'How's it going?'. Below this is a 'Radio button' field. A yellow warning box at the bottom of the form says 'Form not done'. On the right side of the form, there are two status indicators: 'SDV (0%)' and 'DMR (0%)', along with buttons for 'Sign Form', 'Edit Form', and a settings gear. A vertical orange line connects the 'Marking Form ILB sets all Items ILB' text to the 'Form not done' warning. A horizontal orange line is drawn across the form. A box on the right highlights the SDV and DMR status indicators, with a vertical orange line connecting it to the text 'Marking Form ILB removes completed DMR or SDV'.

Marking Form ILB removes completed DMR or SDV



Data Entry UI

Auto On

Data Entry Users

Vault EDC SBX

Data Entry Review Studio Reports Dashboards

STUDY TASKS >> Home > Gemzik Study 01 > 100 > SCR-0019

Subject SCR-0019

Forms

Sort By Schedule Event Date

START OF STUDY

- Screening Event 23-Sep-2018
 - Screening
- Visit 1 24-Sep-2018
 - Dosing

New Event button is Gray color as opposed to Blue

Schedule Sort is now Radio Button as opposed to picklist

+ New Event

COMMON FORMS

PD (4)

Added "No records to display" message when no repeating Item Groups present

Screening (06-Feb-2019): Eligibility

Dis the subject meet all Inclusion/Exclusion criteria? Yes No

Unmet criteria

No records to display

+ New Section



Data Review Dashboards

Auto On

All Users

Monitoring Dashboard

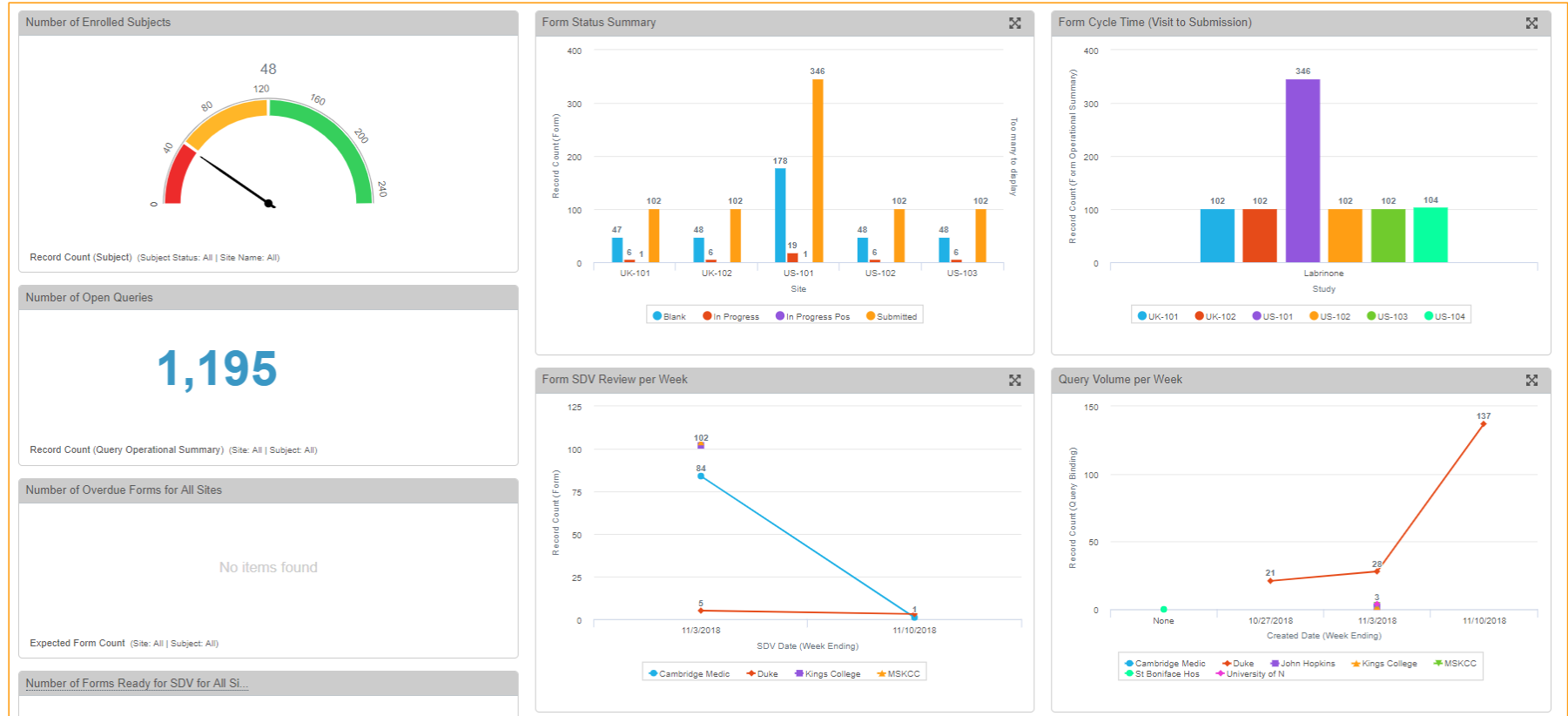
- Site and monitor performance metrics

Data Management Dashboard

- Data cleaning progression metrics

Study Design Dashboard

- Evaluating study design quality and areas of issue



In this release, this feature is Auto On and no longer is enabled through configuration



Query Enhancements

Auto On

All Users

The screenshot shows the Vault EDC interface for subject SCR-0019. The breadcrumb trail is: Gemzik Study 01 > 100 > SCR-0019 > Screening Event > Screening. The main content area shows a 'Screening Event (23-Sep-2018): Screening' form. The 'Enrollment' field is set to 'Yes'. Below it, a 'Derived' field is empty. A 'Boolean' field is set to 'False'. A 'Radio button' field is highlighted with a red box and a validation error message: 'A value is required for this item.' The error message includes a 'System' timestamp '25/09/2018 11:28 PDT' and a 'Rule name (R_QUERY_Radio button_REQ)'.

Text limit from 255 to 500

Rule Name available in info pop up



Audit Trail Export

Auto On

All Users

Vault EDC SBX

Subjects Search Subjects EDC Services - Internal David M. Gemzik

Data Entry Review Studio Reports Dashboards Loader Coder Tools Reference Object ADMIN

Gemzik Study 01

Casebook Versions Query Rules Jobs Users Sites Study Countries Connections

Job History Job Schedule (0)

+ New Job Status: All Type: All

New Job

Type: Audit Trail Export

Frequency: Run Now

Cancel Save

EDC Tools job to export audit trail

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Audit Timestamp	Audit User	Study	Site	Subject	Event Group	Event Group	Event	Event Sequel	Form	Item Group	Item Group	Item	Object	Record ID	Record Name	Audit Description		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021										Subject	SCR-0021		Casebook : SCR-0021 crea		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021										Subject	SCR-0021		Subject : SCR-0021 crea		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021										Casebook	SCR-0021		Casebook : SCR-0021 crea		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1						Event Group		Screening Gr	Event Group : VV-00003		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1				Event	VV-000040	Screening Ev	Event : VV-000040 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	Form	VV-000037	Screening	Form : VV-000037 creat		
2018-09-27 19:46:	System on behal	Gemzik Stud Veterans Sta	SCR-0021										Subject	SCR-0021		"Casebook Status" chan		
2018-09-27 19:46:	System on behal	Gemzik Stud Veterans Sta	SCR-0021										Casebook	SCR-0021		"Casebook Status" chan		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		Screening	Item Group : VV-000037		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		Enrollment	Item : VV-000132 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		Derived	Item : VV-000133 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		URL	Item : VV-000134 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		Boolean	Item : VV-000135 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		Radio button	Item : VV-000136 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		Date	Item : VV-000137 creat		
2018-09-27 19:46:	Nimish Patel	Gemzik Stud Veterans Sta	SCR-0021		EG.SCREEN		1	EV.SCREEN	1	FRM.SCREEN		1	IG.SCREEN		derived	Item : VV-000138 creat		



Enhanced Role Access Model

Feature Flag

All Users

1. Object Access

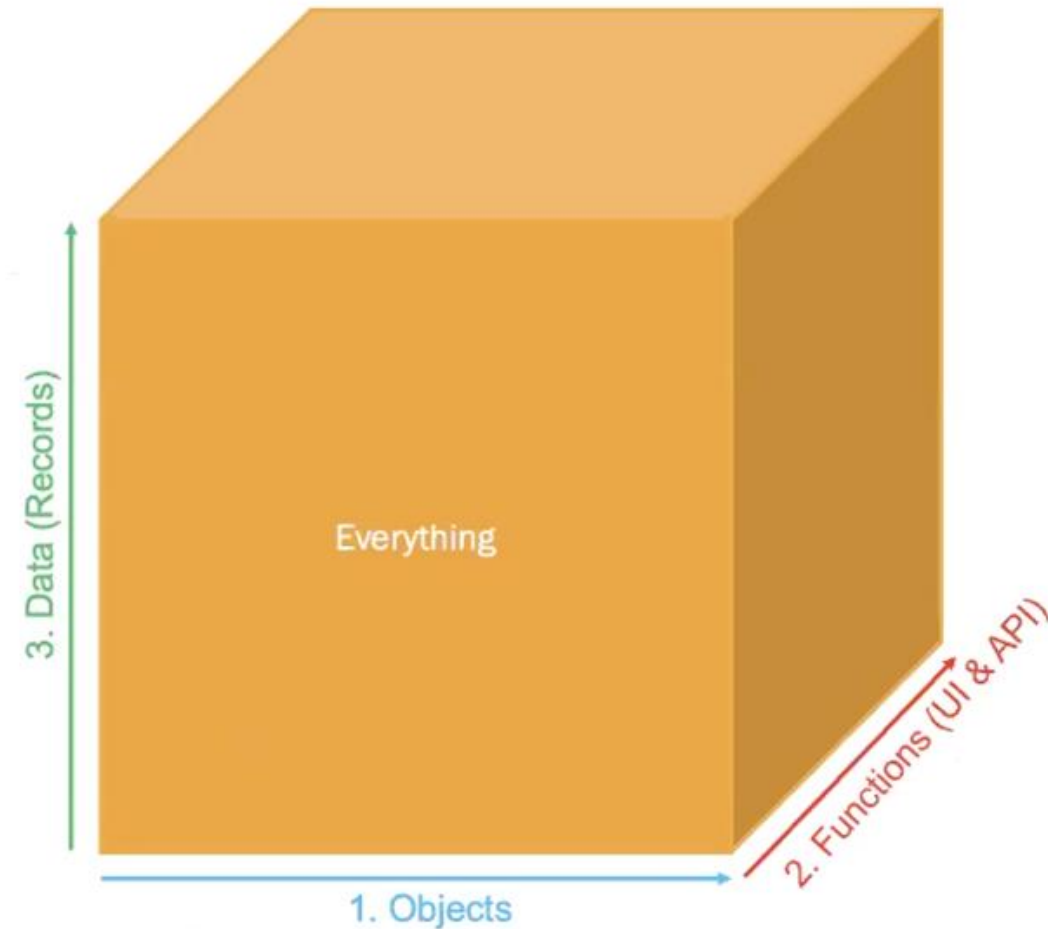
Which Objects Can you see? and
What Operations can you do?
Create, Read, Update, & Delete (CRUD)

2. Function Access

What functions in the product can you access?
Eg. Through the UI Tabs, Buttons, or APIs

3. Record Access

Which object instances can you see?
(by Study ID, Country ID, or Site ID, etc.)
And anything related to them
(Forms, Items, Queries, etc)



Application Role by Study

Feature Flag

All Users

CDMS Application Roles

1. CDMS Principal Investigator
2. CDMS Sub Investigator New
3. CDMS Clinical Research Coordinator
4. CDMS Clinical Research Associate
5. CDMS Auditor (Read Only)
6. CDMS Data Manager
7. CDMS Clinical Coder
8. CDMS Clinical Coder Administrator
9. CDMS Study Designer New
10. CDMS User Administrator New

New Application Roles (one per Study)

	Permission Set	Access Type	Comments
1	Data Entry Tab Access	Function	
2	Review Tab Access	Function	
3	Coder Tab Access	Function	
4	Coder Tools Tab Access	Function	Access to tabs only, nothing else
5	EDC Tools Tab Access	Function	
6	Reports Tab Access	Function	
7	Studio Tab Access	Function	
8	CDMS All Objects Read Only	Object	No access to tab. Read only access to all objects.
9	CDMS Execution Objects Full Access	Object	No access to tab. Full CRUD access to all execution objects.
10	CDMS Definition Objects Full Access	Object	No access to tab. Full CRUD access to all definition objects.
11	User Administration Access	Function	Access to manage users in Admin tab.
12	Jobs Access	Function	Access to EDC Jobs and OOB Jobs objects.
13	Job Schedule Access	Function	Access to Jobs permissions in Admin tab and EDC Schedule Job object.
14	API Access	Function	Access to API in Application tab in a permission set. No additional tab or object access.

New Security Profile Permission Sets



Application Role Functions – per Study

Feature Flag

All Users

Application Role Functions

Name ^	Open Query	Answer Query	Close Query	Data Entry	Edit DMR	View DMR	View SDV	Edit SDV	Sign
CDMS Auditor Read Only	No	No	No	No	No	Yes	Yes	No	No
CDMS Clinical Coder	Yes	No	Yes	No	No	No	No	No	No
CDMS Clinical Coder Administrator	Yes	No	Yes	No	No	No	No	No	No
CDMS Clinical Research Associate	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No
CDMS Clinical Research Coordinator	No	Yes	No	Yes	No	No	No	No	No
CDMS Data Manager	Yes	No	Yes	No	Yes	Yes	Yes	No	No
CDMS Principal Investigator	No	Yes	No	Yes	No	No	No	No	Yes
CDMS Sub Investigator	No	Yes	No	Yes	No	No	No	No	No
CDMS User Administrator	No	No	No	No	No	No	No	No	No

Application Roles

Complete list available in CDMS Documentation
<https://cdmshelp.veeva.com/lr/user-administration/cdms-application-roles/>



Coder: UI Enhancements

Auto On

Coder Users

Vault EDC CDM Demo LR 3 Connie C

Coder Reports Dashboards

All Bryce Pharma Cholecap ConMed Requests

Study: Cholecap Dictionary: GLOBALB3Sep18 Form: ConMed Sponsor: Bryce Pharma Therapeutic Area: General 51-100 of 121 < 2 / 3 > STATUS All Autoassign

Verbatim	Search Verbatims...	Indication	Route	Status	Assigned Code	Suggestions	Age (D)
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			34
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			27
<input checked="" type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			15
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			14
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			9
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			9
<input type="checkbox"/>	Sudafed	Allergies	Oral	OPEN			7
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	38
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	35
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	34
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	27
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	30

OXYCODONE

ASSIGNED CODE

No Assigned Code

QUERIES (0) PROPERTIES NOTES (0)

No Query History

Submit a Query... Close

Verbatim(s) Selected: 1 Add to Synonym List? Yes No Synonym List(s): BrycePharma WhoDrug B3 ConMed List Uncode

Suggestions Dictionary

Oxycodone Search Columns: Drug Name Preferred Name ATC4 ATC3 ATC2 ATC1 Drug Code

Code Options	Drug Name	Preferred Name	ATC4	ATC3	ATC2	ATC1	Drug Code
	OXYCODONE	OXYCODONE	N02AA NATURAL OPIUM ALKALOIDS	N02A OPIOIDS	N02 ANALGESICS	N NERVOUS SYSTEM	00045601001
	OXICODONA [OXYCODONE]	OXYCODONE	N02AA NATURAL OPIUM ALKALOIDS	N02A OPIOIDS	N02 ANALGESICS	N NERVOUS SYSTEM	00045601007
	OXYCODONE PECTINATE	OXYCODONE PECTINATE	N02AA NATURAL OPIUM ALKALOIDS	N02A OPIOIDS	N02 ANALGESICS	N NERVOUS SYSTEM	00045602001

Smoother resizing of Coding Panel

User preferences for Filters and Columns are remembered

Popout Coding Panel



Grouping Code Requests

Auto On

Coder Users

Toggle switches between Group and List Modes

In Group Mode, identical Code Requests are displayed as one line item

Vault EDC

Subjects Search Subjects

Mohammed Al-Adeeb ADMIN

Data Entry Studio **Coder** Reports Dashboards Loader Tools

All Bryce Pharma Labrinone ConMed Requests

Study: Labrinone Dictionary: GLOBALB3Sep18 Form: ConMed Sponsor: Bryce Pharma Therapeutic Area:

STATUS All Autoassign

<input type="checkbox"/>	Verbatim	Search Verbatims...	Indication	Route	Status	Assigned Code	Suggestions	Age (D)
<input type="checkbox"/>	Advil (4)		Headache	Oral	OPEN			N/A N/A N/A
<input checked="" type="checkbox"/>	Cetirizine (6)	Q	Hives	Oral	OPEN			N/A N/A N/A
<input type="checkbox"/>	Penzital (1)		Pancreatic Insu...	Oral	OPEN			N/A N/A N/A
<input type="checkbox"/>	Tylenol (3)		Headache	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL]	N/A N/A N/A
<input type="checkbox"/>	Tylenol (1)		Headache	Oral	CODED	N02BE TYLENOL [PARACETAM...		N/A N/A N/A
<input type="checkbox"/>	Zitrac (1)		Bacterial Infecti..	Oral	OPEN			N/A N/A N/A

1-6 of 6

CETIRIZINE

ASSIGNED CODE

No Assigned Code

QUERIES PROPERTIES NOTES

You cannot query a group. Switch to the List Mode to query a code request in this group. [Learn More](#)

Suggestions Dictionary

Verbatim(s) Selected: 6 Add to Synonym List? Yes Synonym List(s): BP ConMed WHODrug B3 Sep 18 List Uncode

Cetirizine Search Columns: Drug Name Preferred Name ATC4 ATC3 ATC2 ATC1 Drug Code

Code Options	Drug Name	Preferred Name	ATC4	ATC3	ATC2	ATC1	Drug Code
	CETIRIZINE	CETIRIZINE	R06AE PIPERAZINE DERIVATIVES	R06A ANTIHISTAMINES FOR SYSTEMIC USE	R06 ANTIHISTAMINES FOR SYSTEMIC USE	R RESPIRATORY SYSTEM	00884301001
	CETIRIZINE	CETIRIZINE	S01GX OTHER ANTIALLERGICS	S01G DECONGESTANTS AND ANTIALLERGICS	S01 OPHTHALMOLOGICALS	S SENSORY ORGANS	00884301001
	CETRIZIN [CETIRIZINE HYDROCHLORIDE]	CETIRIZINE HYDROCHLORIDE	R06AE PIPERAZINE DERIVATIVES	R06A ANTIHISTAMINES FOR SYSTEMIC USE	R06 ANTIHISTAMINES FOR SYSTEMIC USE	R RESPIRATORY SYSTEM	00884302113



Access Audit Trail

Auto On

Coder Users

Inspect Audit Trail for each Code Request

The screenshot displays the Vault EDC interface. At the top, there are navigation tabs: Data Entry, Studio, Coder, Reports, Dashboards, Loader, and Tools. The main header shows 'All Bryce Pharma Labrinone ConMed Requests'. Below this, there is a table with columns: Verbatim, Indication, Route, Status, Assigned Code, and Suggestions. A row for 'Tylenol' is selected, and an 'Audit History' modal window is open over it. The modal window contains a table with the following data:

Timestamp (M/d/yyyy h:mm a z)	User Name	Event Description
1/10/2019 6:24 PM PST	Mohammed Al-Adeeb	Coded: The code request was coded to 0020001005 - Tylenol, 00020001001 - PARACETAMOL
1/10/2019 6:22 PM PST	Mohammed Al-Adeeb	Posted Note: "I coded this non-traditional way for this non-traditional reason."
1/10/2019 6:19 PM PST	Connie Coder	Site Responded to Query: "Yes and I've updated it."
1/10/2019 6:12 PM PST	Mohammed Al-Adeeb	Query to Site: "Can you take a look at the Indication?"
1/10/2019 5:38 PM PST	System	Medical Coding Request : VV-000009 created

The background interface also shows a 'TYLENOL' section with 'ASSIGNED CODE' (TYLENOL [PARACETAMOL]), 'QUERIES (1)', and 'NOTES (1)'. A note from Mohammed Al-Adeeb is visible: '10-Jan-2019 06:22:11 PM PST I coded this non-traditional way for this non-traditional reason.'



Query and Notes Enhancements

Auto On

Coder Users

Updates in real-time with Query and Notes updates from Coder

Close Query without Entering Text

Expand Query & Notes Text Field

Vault EDC CDM Demo LR 3 Connie Coder

Coder Reports Dashboards

All Bryce Pharma Cholecap ConMed Requests

Study: Cholecap Dictionary: GLOBALB3Sep18 Form: ConMed Sponsor: Bryce Pharma Therapeutic Area: General 51-100 of 121 < 2 / 3 > STATUS All Autoassign

Verbatim	Search Verbatims...	Indication	Route	Status	Assigned Code	Suggestions	Age (D)
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			34
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			27
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			30
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			15
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			14
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			9
<input type="checkbox"/>	Oxycodone	Pain	Oral	OPEN			9
<input checked="" type="checkbox"/>	Sudafed	Allergies	Oral	OPEN			7
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	38
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	35
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	34
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	27
<input type="checkbox"/>	Tylenol	Pain	Oral	AUTOCODED	N02BE TYLENOL [PARACETAM...	N02BE TYLENOL [PARACETAMOL], N02BE ...	30

SUDAFED

ASSIGNED CODE

No Assigned Code

QUERIES (1) **PROPERTIES** **NOTES (0)**

06-Mar-2019 08:28:31 AM EST - Connie Coder

Please confirm medication brand

Ed Smith - 06-Mar-2019 12:25:07 PM EST

this is correct.

Submit a Query... Close

Verbatim(s) Selected: 1 Add to Synonym List? Yes No Synonym List(s): BrycePharma WhoDrug B3 ConMed List Uncode

Code Options	Synonym List	Drug Name	Preferred Name	ATC4	ATC3	ATC2	ATC1	Drug Code
Unable to find suggestions. Try searching the dictionary.								



Support for Codelist Coding Properties

Auto On

Coder Users

Support for Codelist based Coding Properties

Vault EDC CDM Demo LR 3 Connie Coder

Coder Reports Dashboards

All Bryce Pharma Cholecap ConMed Requests

Study: Cholecap Dictionary: GLOBALB3Sep18 Form: ConMed Sponsor: Bryce Pharma Therapeutic Area: General 1-50 of 121 < 1 / 3 > STATUS All Autoassign

Verbatim	Indication	Route	Status	Assigned Code	Suggestions	Age (D)
Aleve	Pain	Oral	AUTOCODED	G02CC ALEVE	G02CC ALEVE, M02AA ALEVE	27
Aleve	Pain	Oral	AUTOCODED	G02CC ALEVE	G02CC ALEVE, M02AA ALEVE	6
Aleve	Pain	Oral	CODED	G02CC ALEVE	G02CC ALEVE, M02AA ALEVE	35
AMBIEN			CODED	N05CF AMBIEN	N05CF AMBIEN	35
Ambien			CODED	N05CF AMBIEN	N05CF AMBIEN	35
Aspirin	Pain	Oral	AUTOCODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	30
Aspirin	Pain	Oral	AUTOCODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	28
Aspirin	Pain	Oral	AUTOCODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	28
Aspirin	Pain	Oral	AUTOCODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	20
Aspirin	Pain	Oral	AUTOCODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	14
Aspirin	Pain	Oral	AUTOCODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	9
Aspirin	Pain	Oral	CODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	35
Aspirin	Pain	Oral	CODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	35
Aspirin	Pain	Oral	CODED	A01AD ASPIRIN [ACETYSALIC...	A01AD ASPIRIN [ACETYSALICYLIC ACID]	35

ALEVE

ASSIGNED CODE

Drug Name: ALEVE
 Preferred Name: NAPROXEN SODIUM
 ATC4: G02CC ANTIINFLAMMATORY PRODU...
 ATC3: G02C OTHER GYNECOLOGICALS
 ATC2: G02 OTHER GYNECOLOGICALS
 ATC1: G GENITO URINARY SYSTEM A...

QUERIES (0) PROPERTIES NOTES (0)

INDICATION	ROUTE	DURATION
Pain	Oral	0 days
SITE	SUBJECT	REQUEST AGE
US-101	US-101-0110	6 days
SYNONYM LIST(S)	STOP LIST	

Verbatim(s) Selected: 1 Add to Synonym List? Yes No Synonym List(s): BrycePharma WhoDrug B3 ConMed List

Suggestions Dictionary

Aleve Search Columns: Drug Name Preferred Name ATC4 ATC3 ATC2 ATC1 Drug Code

Code Options	Drug Name	Preferred Name	ATC4	ATC3	ATC2	ATC1	Drug Code
	ALEVE	NAPROXEN SODIUM	G02CC ANTIINFLAMMATORY PRODUCTS	G02C OTHER GYNECOLOGICALS	G02 OTHER GYNECOLOGICALS	G GENITO URINARY SYSTEM	00256202018
	ALEVE	NAPROXEN SODIUM	M01AE PROPIONIC ACID DERIVATIVES	M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	M01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	M MUSCULO-SKELETAL SYSTEM	00256202018
	ALEVE	NAPROXEN SODIUM	M02AA ANTIINFLAMMATORY PREPARATIONS, NON-	M02A TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	M02 TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	M MUSCULO-SKELETAL SYSTEM	00256202018

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Autocode from Dictionary

Auto On

Coder Admin

The screenshot shows the Vault EDC Coder Tools interface. At the top, there is a navigation bar with 'Vault EDC' logo, 'Subjects' dropdown, 'Search Subjects' input, and a search icon. The user 'Mohammed Al-Adeeb' is logged in, and 'ADMIN' is visible in the top right. Below the navigation bar, there are tabs for 'Application Settings', 'Study Settings', 'Synonym Lists', and 'Stop Lists'. The 'Study Settings' tab is active, showing settings for the 'Labrinone' study. A search bar on the left lists 'LTS' and 'Labrinone'. The settings for 'Labrinone' include: 'Add to Synonym List by Default' (Yes), 'Review Additions to Synonym Lists' (No), 'Autocode from Dictionary' (Yes, highlighted with an orange box), 'Autocoded Code Requests Require Review' (Yes), and 'Code With ATCs' (No, with a lock icon). Below the settings is a 'Form Configuration' table.

Form Type	Dictionary	Synonym List	Stop List
AE	MedDRA 21.1	BP MedDRA 21.1 Syn List	BP AE Stop List
ConMed	GLOBALB3Sep18	BP ConMed WHODrug B3 Sep 18 List	
Medical History	GLOBALB3Mar19	BP ConMed WHODrug B3 Mar 19 List	
Medical History	MedDRA 21.0	BP MH MedDRA 21.0 List	

Set to Yes will Autocode from Dictionary after the Synonym List (Default is No)



Import & Export Syn & Stop Lists

Auto On

Coder Admin

Vault EDC Subjects CDM Demo LR 3 Mohammed Al-A ADMIN

Data Entry Review Studio Coder Reports Dashboards Protocol Deviations Loader Tools Study Files

Coder Tools

Application Settings Study Settings **Synonym Lists** Stop Lists

New Synonym List

1-2 of 2

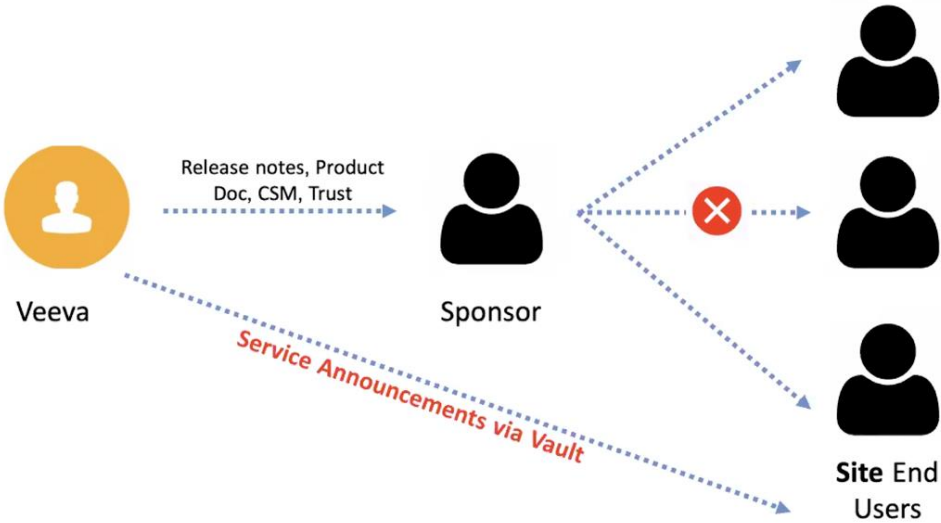
Name	Dictionary	Status	Includes ATCs	Synonyms	Synonyms Pending Approval
BrycePharma MedDRA 21.1 AE List	MedDRA 21.1	Active	-	82	9
BrycePharma WhoDrug B3 ConMed List	Edit Import Synonyms Export Upversion	Active	Yes	63	0

Import & Export Synonym Lists

Service Announcements

Auto On

All Users



The screenshot shows a Veeva Vault EDC interface. At the top, a blue header contains the Veeva logo and "Vault EDC". Below the header is a notification banner with a red exclamation mark icon and the text: "This release preparation event will prepare your instance for the 19R1 major release upgrade. While this event was posted to TRUST, no further TRUST notifications about it will be sent." Below this is another notification banner with a yellow warning icon and the text: "Upcoming Service Notification - Please be advised that Veeva Vault EDC will be unavailable from 6:00pm to 06:30pm on Feb 14th, 2019". Below the notifications is a table with the following columns: Study Number, Study Phase, Screen Failed %, and Study Status. The table contains three rows of data.

Study Number	Study Phase	Screen Failed %	Study Status
Clinical Coding			
NEW-STUDY-DESIGNER-USER			
QA Master-add2211		0%	



CTMS Integration

- CTMS users of the Vault CTMS & Vault EDC integration open a Casebook from their CTMS vault, the Casebook now opens in the Review tab of Vault EDC.



Auto Enablement

- <https://cdmshelp.veeva.com/lr/rn/general-release/19r1/enablement/>

The screenshot shows the Veeva Vault CDMS Help page for "Feature Enablement Details for 19R1". The page includes a navigation bar with "Vault CDMS Help", "EDC", "Coder", "Release Notes", and "Resources" menus, along with a search box. The breadcrumb trail is "General Release / Feature Enablement Details for 19R1". The main heading is "Feature Enablement Details for 19R1" with sub-headers "On This Page" (containing "Feature Enablement Details for 19R1" and "Enablement Legend") and "Resources" (containing "About Vault Releases" and "Veeva Trust Site"). A paragraph of text explains that the following list includes information on how enablement works and which applications include the feature. Below this is a table with columns "Feature", "Enablement", and "Application".

Feature	Enablement	Application
CDMS		
Service Announcements	Auto-on ¹	Coder, EDC
Data Entry		
Renamed "Casebooks" Tab to "Data Entry"	Auto-on	EDC
Clear Signature Action	Auto-on	EDC
Casebook Schedule UI Enhancements	Auto-on	EDC
Data Entry UI Enhancements	Auto-on	EDC
eSignature Enhancements	Auto-on	EDC
Query Enhancements	Auto-on	EDC
Intentionally Left Blank Enhancements	Auto-on	EDC
Data Review		
Freeze & Lock Event Dates	Support	EDC

Feature Information

- [What's New in 19R1](#) (Published March 11) provides detailed explanations of each feature.
- [19R1 Feature Enablement Details](#) (Published March 11) includes information on how new features are enabled.

Veeva Vault Help lists the Features and their Auto Enablement



Validation Impact Assessment Document

- Veeva QMS Document to be provided by your project manager

Retrieved from QMS Vault on 24 Jul 2018 (Local)

Validation Impact Assessment



Approvals

Doc ID:	QV-12910		
Name	Title	Signature	Date
Computer Systems Validation			
Shruti Burli	Director, Computer Systems Validation	<i>Approval by Electronic Signature in QMS Vault</i>	
System Owner			
Ray Letulle	SVP, Products, Vault EDC	<i>Approval by Electronic Signature in QMS Vault</i>	
Quality			
Jacques Mourrain	VP, Global Quality & Compliance	<i>Approval by Electronic Signature in QMS Vault</i>	

1 Purpose

The purpose of this Validation Impact Assessment is to synopsise the method and analysis necessary to evaluate the impact of software changes associated with the EDC 18R2 General Release (GR) using data provided by Product Management and in Jira tickets for this release. This document is intended to summarize development activity at a high level. Refer to the Project IOQ and Validation Summary Report for this release for what was in scope, was validated, and what issues were encountered.

2 Scope

This assessment covers the deployment of EDC 18R2 GR. The assessment evaluates enhancements since the last validated GR.

2.1 Limitations / Exclusions



Pre Release Vault login – April 1st

- Use the same URL to login to your prerelease vault : <https://login.veevavault.com>
- Your username directs you to the pre-release vault.





Questions