

veeva

19R2 Release Webinar

New Features

July 17, 2019

veeva

Please use
'Q&A' to ask a
question



Raise Hand



Q&A



veeva

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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.



Foreword

- The content of this presentation is **subject to change** prior to the 19R2 Release

Please note the date on the title slide

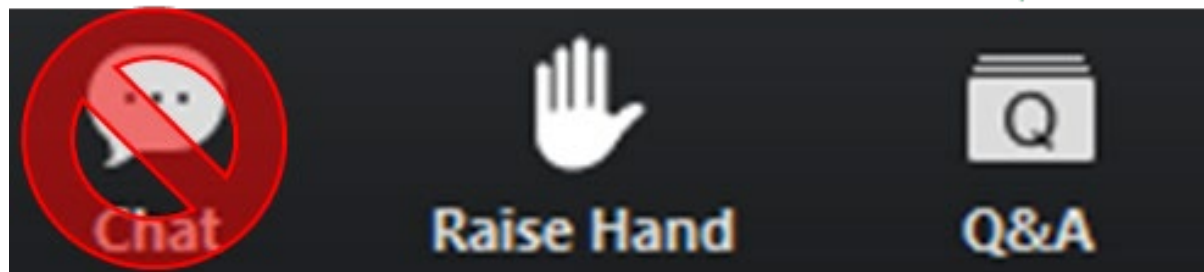
- Veeva encourages you to always reference Release documentation from our Release pages to ensure you are using the **latest information**

Help → Release Notes → About the 19R2 Release

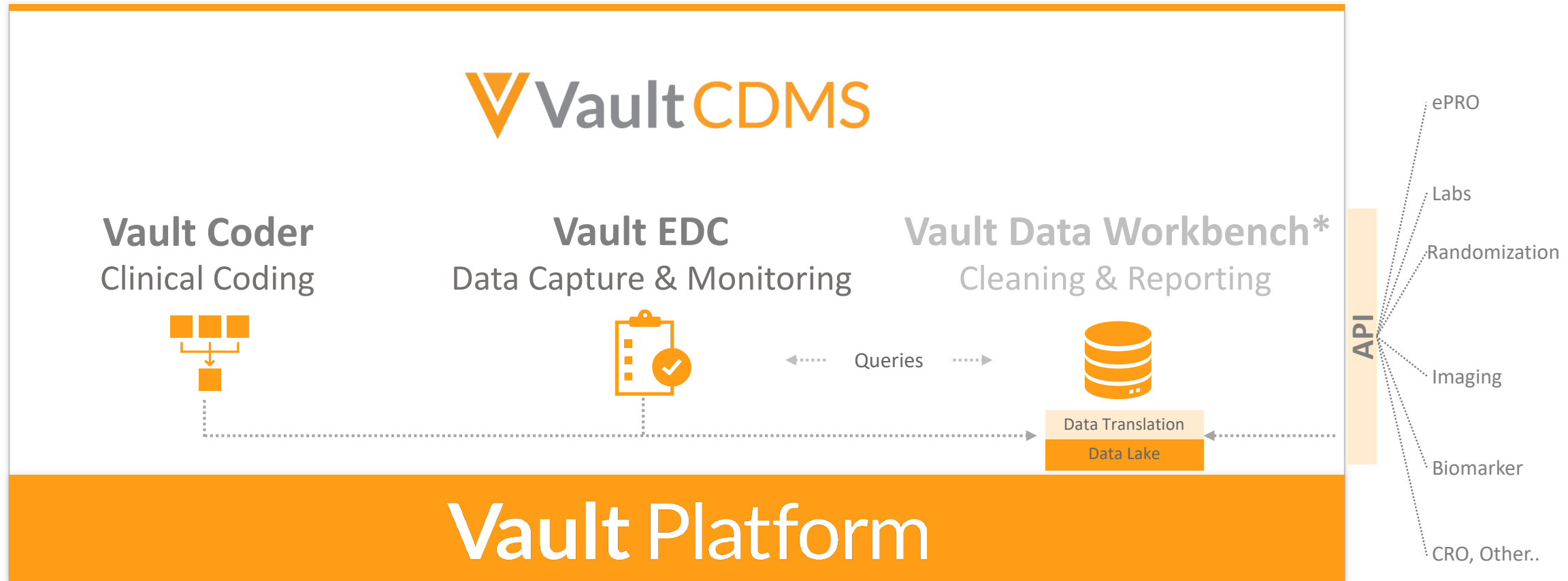


Interact With Us!

Please use
'Q&A' to ask a
question



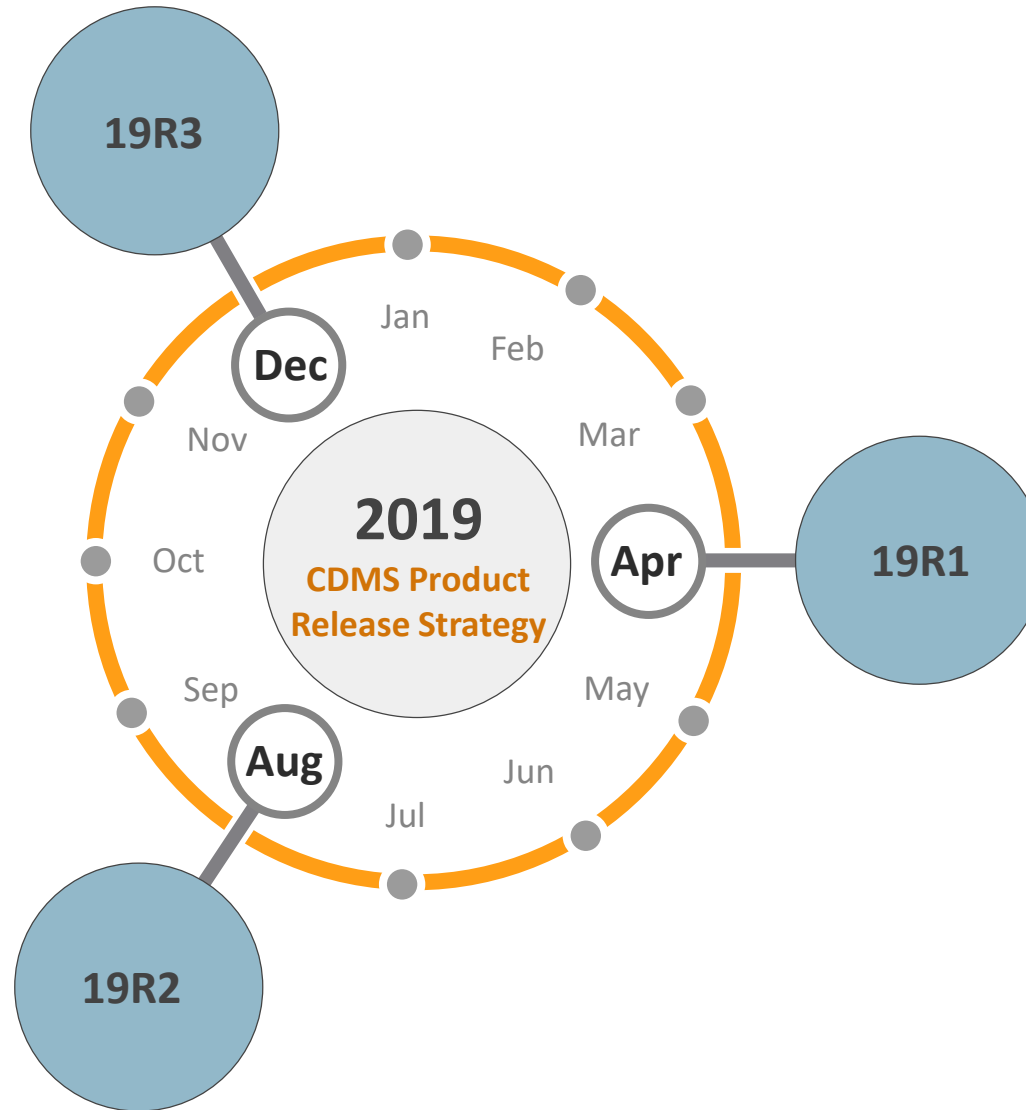
Reinventing Clinical Data Management



**Vault Data Workbench is currently under development*



Veeva Vault Release Schedule



19R2 Release Calendar

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

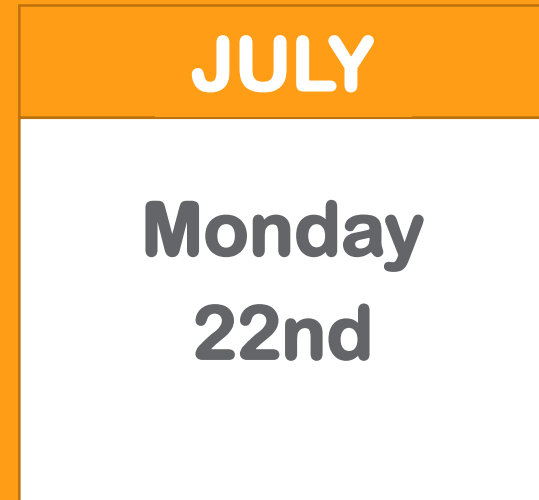
— Customer Validation



Pre-Release Environment

<https://login.veevavault.com>

- Clone of Production and UAT
 - Data and Configuration is copied
- Users are not copied
 - Contact Veeva Project Manager to add users
- Available up to 4 weeks after the 19R2 upgrade



Validation Documents

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

JULY

**Tuesday
23rd**



19R2 Go Live

- ALL customer vaults upgraded to 19R2
- EU starts at 2:00pm PT
- APAC & US starts at 5:00 PM PT
- May take up to 6 hours

AUGUST

**Friday
9th**



19R2 General Release Resources

- **Resources Available**

- <https://cdmshelp.veeva.com/pr/rn/general-release/19r2/>

- Important Dates
- Pre-Release FAQ
- Release Impact Assessment
- What's new in 19R2
- Feature Enablement Details

🏠 / General Release / About the 19R2 Release

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Resources

- [About Vault Releases](#)
- [Veeva Trust Site](#)

About the 19R2 Release

This page can help you understand the schedule for the coming release and the list of features included. Dates are subject to change.

Important Dates

- **July 17:** Preview webinar ([Register here](#))
- **July 22:** Validation package available on VeevaDocs
- **July 22:** Pre-release vaults available
- **August 2:** Release to all limited release PODs
- **August 9:** Release to all general release PODs

Notifications Opt-In

As a valued member of our community, providing you with control over the communications you receive from Veeva is important to us. Please allow us to send you pre-release environment notifications and other industry related information. From your user profile within Vault, verify that the **Product Announcements** checkbox is selected.

Feature Information

- **What's New in 19R2** (*Published July 1*) provides detailed explanations of each feature.
- **19R2 Feature Enablement Details** (*Published July 1*) includes information on how new features are enabled.

Pre-Release Information

- **Pre-Release FAQ** answers common questions about "pre-release".
- **Known Issues in 19R2 Pre-Release** (*Available July 22*) lists known issues in the 19R2 pre-release.

Release Information

- **19R2 Release Impact Assessment** (*Updated June 28*) analyzes the impact of new features. If you need an editable version, we also provide an **MS Excel™ version**.
- **19R2 Fixed Issues** (*Available August 9*) documents issues that affected previous versions or pre-release and are fixed in 19R2.
- **19R2 Known Issues** (*Available August 9*) documents issues introduced in 19R2 which are not yet fixed.

For details about new features in the Vault Platform in 19R2, see the [Vault Release Notes](#).



Agenda

WEDNESDAY, JULY 17

CDMS Investments

19R2 Feature Value Add

Site Demo

CRA and Data Manager Demo

Coder Demo

Q&A



19R2 Investments

Investments were made to advance the CDMS application

Sites



- Casebook Confirmation
- Subject Deletion
- Unknown Time
- Tabular View

CRA's and Data Managers



- Last Event/Next Event
- Syncing Panes
- Review Navigation
- Form Level Review
- Intuitive Icons
- Save Button

Coding



- Select/De-Select All
- Query Status Filter
- Dictionary Search
- Dashboard
- Unique Term Report

Admin



- Review Plan Assignment
- Custom Study Role Management
- Subject Transfers
- Import Sites

Study Designer



- Coding Configuration
- Study Settings
- Diff Viewer Enhancements
- Review Plan Editor

Foundation



- Clinical Assessments
- Click Button Deployment
- Data Workbench

19R2 Feature Value Add

Optimized User Experience	Sites Review	Tabular Data View Latest casebook version, Event Tree view with synchs with right form details, Previous Event/Next Event, Increased modal box, new Icons, Form Level Reviews
	Coding	Coding: Select/De-select all checkboxes, Summary view exposed through icon
Cleaner Data	Sites	Confirmation for creating new casebooks Delete subjects when permission is enabled Allow unknown time
Accessible Data	Reviews	Reviews have last event date and next event date Reviews includes casebook versions
Targeted Reviews	Review	Review Editor to design custom Review Plans Assign SDV/DMR Review Plans to Site/Casebooks
Improved Performance	Coding	Dictionary search results have been improved
Focused Data	Coding	Query Status Filter
Dictionary Search Efficiencies	Coding	Search results display when coding without ATCs Drug names with diff preferred names will be grouped together Search up to 10 Key words Support special ASCII characters
Better Reporting	Coding Studio	Dashboard, Unique Term Report Diff Viewer Report

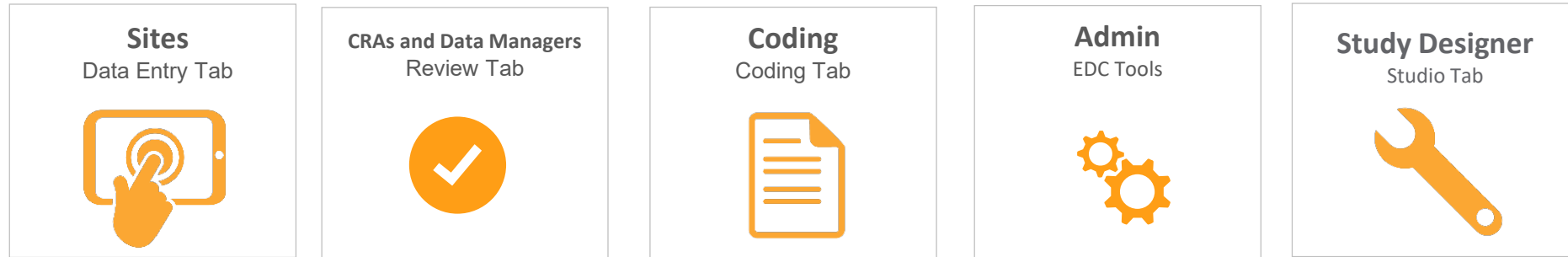


19R2 Feature Value Add (cont'd)

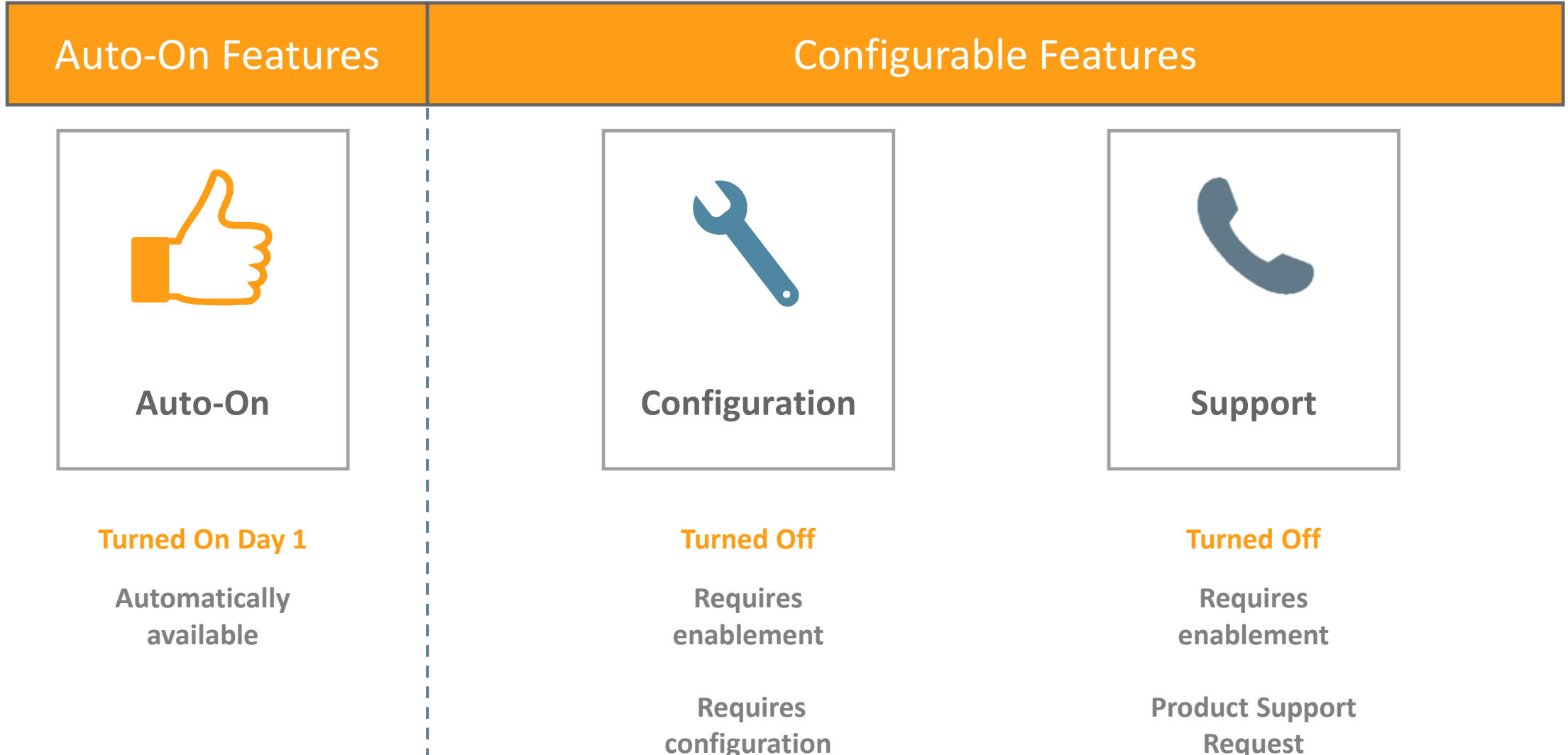
Simplified User Role Management	Admin	Custom Study Role Management
Instantaneous Study Changes	Admin	Retrospective Amendments <ul style="list-style-type: none">• Event (Visit) changes• Changes to Max/Min of Item Groups• Unknown Date/Time Subject Transfers
Faster Site Setup	Admin	Bulk Import Sites
Faster Study Build	Studio	Coding Configuration Compare diff casebook versions within a Study or to another study Import Study Casebook Designs and start with Version 1 New Study Configuration Setting tab: Date/ Time Setting, Add signature/define signature, Configure Subject ID format



19R2 CDMS Features by Users



Feature Enablement Detail





Sites

Casebook Confirmation



Automatic

- Overview

Users will be asked to confirm if they want to create a casebook.

- Business Value

Sites were accidentally creating casebooks, and this will help minimize the casebooks created in error.

The screenshot shows a Veeva system interface with a table of study subjects and a confirmation dialog box. The table has columns for Subject, Last Event, Next Event, Subject Status, and Signature completed. The dialog box asks for confirmation to create a new casebook.

Subject	Last Event	Next Event	Subject Status	Signature completed
SCR-0003	VISIT 1 (01-Jul-2019)	VISIT 2 (04-Jul-2019 – 07-Jul-2019)	Pre Screen	No
0100-0002	VISIT 1 (30-Jun-2019)	VISIT 2 (04-Jul-2019 – 07-Jul-2019)	In Screening	No
0100-0001	VISIT 2 (20-Jun-2019)	VISIT 3 (03-Jul-2019 – 04-Jul-2019)	In Screening	No

Create Casebook

Confirm that you want to create a new casebook.

Cancel Create

Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS



Delete Subjects



Configurable

- Overview

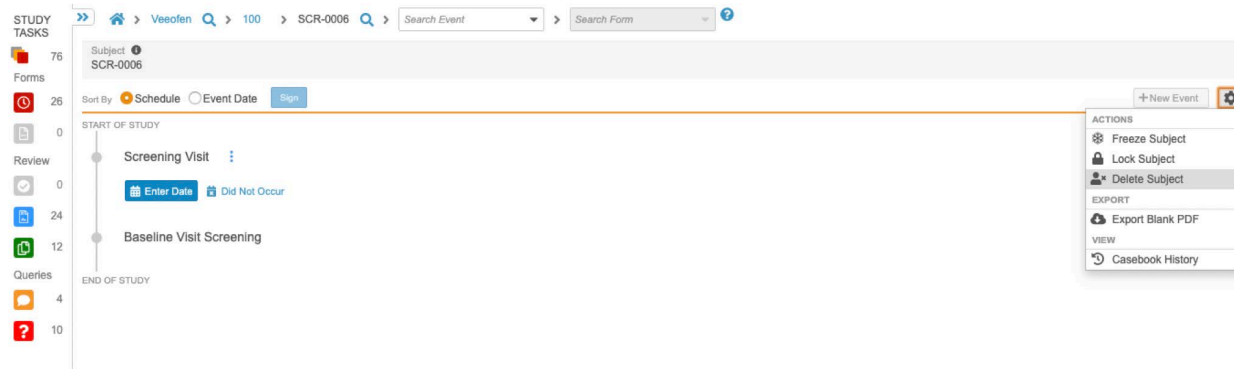
Users will be able to delete subjects if they were granted permission

- Business Value

This will give users the authority to correct any mistakes with erroneous subjects

- Consideration

- Subject must contain no data. If there is data, data must be deleted (form reset) before subject can be deleted.
- Only available with the new 19R2 security model.



Feature Risk

HIGH

Default Impact

**VISIBLE TO
USERS WITH
PERMISSION**





Configurable

Allow Unknown Time

- Overview

Users can now enter a “?” in the time field for date/time field when configured to support as unknown

- Business Value

Patients do not remember the time when the headache occurred and instead of requiring a time a “?” can be entered, and instead of them making up an inaccurate time, the unknown is allowed.

The screenshot shows a web-based data entry interface for a clinical trial. The breadcrumb trail indicates the user is in the 'Dosing' section for 'VISIT 1' of study 'SCR-0003'. The main form is titled 'VISIT 1 (01-Jul-2019): Dosing'. A tooltip is visible over the time input field of the 'Start Date and Time' section, indicating that a question mark '?' can be used to denote an unknown time. The form includes various input fields for data collection, dates, and doses.

Feature Risk

Low

Default Impact

VISIBLE TO ALL USERS





Configurable

Tabular Data View

- Overview

Users can now view data in a tabular (column/row) format for repeating item groups.

- Business Value

There are certain form views that are better displayed in a tabular view, this may be a log of events that has occurred like Medical History and Physical Exam.

The screenshot shows a web interface for a clinical trial form. The main content area displays a table titled "Physical Exam (4)". The table has four columns: "#", "Body System", "Result", and "Abnormal Findings". The data rows are as follows:

#	Body System	Result	Abnormal Findings
1	Head	Normal ?	No Findings ?
2	Chest	Normal	No Findings ?
3	Neck	Normal	No Findings ?
4	Abdomen	Normal ?	ZeroNo Findings ?

Feature Risk

Low

Default Impact

VISIBLE TO ALL USERS





Site Demo



CRAAs/Data Manager



Automatic

Accessible Data

- Overview

New columns were added to the Review Subject Listings page – Last Event and Next Event.

Casebook versions have been added

- Business Value

This provides a quick and easy way to access relevant data.

Home > Ronald Reagan UCLA Medical Center > Search Subject

Study	Site Number	Principal Investigator
Veeofen	100	Doogie Howser

Frozen: All Locked: All

Subject	Last Event	Next Event	Open Queries	Answers
SCR-0006	Subject Status: In Screening Date of Birth: 02-Jul-2000	Screening Visit		
0100-0003	Gender: Male Race: Hispanic Latino Subject Initials: wbt Casebook Version: 4 1 (01-Jul-2019)	VISIT 2 (04-Jul-2019 – 07-Jul-2019)		
0100-0002	1 (30-Jun-2019)	VISIT 2 (04-Jul-2019 – 07-Jul-2019)	8	
0100-0001	VISIT 2 (20-Jun-2019)	VISIT 3 (03-Jul-2019 – 04-Jul-2019)	2	

Home > Ronald Reagan UCLA Medical Center > Subject: 0100-0003 > Search Event

Subject: 0100-0003

Subject Status: In Screening
Date of Birth: 02-Jul-2000
Gender: Male
Race: Hispanic Latino
Subject Initials: wbt
Casebook Version: 4

Event

- Screening Visit 24-Jun-2019
- Baseline Visit 25-Jun-2019
- VISIT 1 01-Jul-2019
- VISIT 2 Planned Date Range: 04-Jul-2019 – 07-Jul-2019
- VISIT 3 Planned Date Range: 09-Jul-2019 – 10-Jul-2019
- Common Log Forms

Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS



Enhanced User Experience



Automatic

- Overview

Tree Visits and Forms is highlighted and synched with Right Pane Form Details.

Form level Reviews

Icon changes

View as Site window screen has increased to a larger view

- Business Value

Improve the quality of the Reviewer's interaction with the application allowing them to complete task faster.

The screenshot shows the application interface for a 'Screening Visit'. On the left, there is a list of events for Subject: 0101-0009. The 'Screening Visit 04-Jul-2019' event is expanded, showing a list of forms: Eligibility Criteria, Demographics, Physical Exam, MH and PE YN, Substance Use, and Enrollment. On the right, the 'Eligibility Criteria' form is displayed. It includes a question 'Did the subject meet all eligibility criteria?' with a 'Yes' response, and another question 'Was the subject enrolled in the study?' with a 'Yes' response. There are also fields for 'Person who granted waiver for subject enrollment' and 'Date of Waiver'. A message box at the bottom states 'Inclusion Criteria Not Met and Exclusion Criteria Met' with 'No data found' below it.

The screenshot shows the 'Demographics' form for Subject: 0100-0000. It includes fields for 'Subject Initials' (wcc), 'Date of Birth' (02-Jul-2000), 'Gender' (Male), and 'Race' (Hispanic Latino).

Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS





Automatic

Save Button

- Overview

Any changes made to the SDV/DMR must be saved. Any changes made to SDV/DMR that are unsaved are indicated with a yellow background.

- Business Value

This ensures consistency in the Rollup status (left nav) when users are clicking review checkboxes too fast.

The screenshot shows the Vault EDC interface for a 'Screening Visit' record. The 'Save' button is highlighted in yellow, indicating it is unsaved. The interface includes a navigation menu on the left, a main content area with a table of events, and a detailed view of the selected 'Screening Visit' event. The 'Event Date' is 04-Jul-2019. The 'Eligibility Criteria' section shows that the subject met all criteria, and the subject was enrolled in the study. The 'Person who granted waiver for subject enrollment' and 'Date of Waiver' fields are also visible.

Feature Risk



LOW

Default Impact

VISIBLE TO ALL USERS



Review Tab designed for CRAs/Data Manager

CRAs and Data Managers Review Tab 	VS	Sites Data Entry Tab 
<ul style="list-style-type: none">• Comprehensive View focusing on Reviews• Quick and Easy Navigation to view Visit/ Forms• Centralized location of all Queries and Reviews• Filter View of “To Dos”• Toggle between Site View/Monitor View		<ul style="list-style-type: none">• Designed for Site Data Entry• Multiple Clicks to Review Visits/ Forms• Click into each Form to see the Query• No Filter• Only Site View

**Please contact Support to enable the Review Tab*





CRA and Data Manager Demo



Coding

Enhanced User Experience



Automatic

- Overview

Coders can select or deselect all coding items in the Coding Listings Panel

Summary is exposed through an icon

- Business Value

Having a select/de-select all makes it easier for user to select a lot of coding items at once instead of clicking multiple times

Cleaner look with the summary moved behind the icon

Study: Labriona
Topic: GLOALB3Mar19
Form: ConMed
Sponsor: Bryca Pharma
Therapeutic Area: Oncology

Coding Status: All Query Status: All

Verbatim	Indication	Route	Coding Status	Assigned Code	Suggestions
<input type="checkbox"/>	Cetirizine	Headache	Intravenous	UNCODED	
<input checked="" type="checkbox"/>	Dimorph	Hives	Oral	UNCODED	
<input checked="" type="checkbox"/>	Ibuprofen	Headache	Oral	UNCODED	
<input checked="" type="checkbox"/>	Lidocaine	Skin Irritation	Topical	UNCODED	LIDOCAINE
<input type="checkbox"/>	Lidocaine	Skin Irritation	Topical	UNCODED	LIDOCAINE
<input type="checkbox"/>	Lidocaine	Skin Irritation	Topical	UNCODED	LIDOCAINE
<input type="checkbox"/>	Lidocaine	Skin Irritation	Topical	UNCODED	LIDOCAINE
<input type="checkbox"/>	Lidocaine	Skin Irritation	Topical	UNCODED	LIDOCAINE

Verbatim(s) Selected: 3 Add to Synonym List? Y Synonym List(s):WHODrug B3 Uncode

Dimorph

Code Options	Drug Name	Preferred Name	Drug Code
	DIMORPHANTHUS MANDSHURICUS	ARALIA ELATA VAR. MANDSHURICA	06528001005
	DIMORPHOLAMINE	DIMORPHOLAMINE	00733101001
	DIMORPHLAMINE,LIDOCAINE	DIMORPHLAMINE,LIDOCAINE	12180501001
	DIMORPHLAMINE,LIDOCAINE HYDROCHLORIDE	DIMORPHLAMINE,LIDOCAINE HYDROCHLORIDE	12180502001

Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS



Query Status Filter



Automatic

- Overview

Coders will be able to filter based on the different query statuses

- Business Value

Coder can stay focused with the task at hand and choose to see only open queries, or only responded queries.

The screenshot displays the 'All Veeva Clinical Coding ConMed Requests' interface. At the top, there are filters for 'Coding Status: All' and 'Query Status: All'. A search bar is present above a table of queries. The table has columns for 'Indication', 'Route', 'Coding Status', 'Assigned Code', and 'Suggestions'. The 'Dimorph' query is selected. A 'Suggestions' panel is open, showing a list of drug names and their corresponding drug codes. A tooltip is visible over the 'Dimorph' query, providing details: 'Study: Labrinone Dictionary: GLOBALB3Marr19 Form: ConMed Sponsor: Bryco Pharma Therapeutic Area: Oncology'. The 'Assigned Code' field for the selected query is empty, showing 'No Assigned Code'. The 'SUGGESTIONS' panel shows a search for 'Dimorph' with search columns for 'Drug Name', 'Preferred Name', and 'Drug Code'. The suggestions list includes:

Code Options	Drug Name	Preferred Name	Drug Code
	DIMORPHANTHUS MANDSHURICUS	ARALIA ELATA VAR. MANDSHURICA	06528001005
	DIMORPHOLAMINE	DIMORPHOLAMINE	00733101001
	DIMORPHOLAMINE:LIDOCAINE	DIMORPHOLAMINE:LIDOCAINE	12180501001
	DIMORPHOLAMINE:LIDOCAINE HYDROCHLORIDE	DIMORPHOLAMINE:LIDOCAINE HYDROCHLORIDE	12180502001

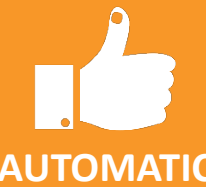
Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS





Dictionary Search Efficiencies

- Overview

Search results that may contain the same drug name but diff preferred names will appear "together" on the top of the search results.

Search up to 10 key words

Supports Special ASCII characters

- Business Value

Coders will gain efficiencies by the enhanced search features.

Verbatim(s) Selected: 0 Add to Synonym List? Synonym List(s): WHODrug B3

Search Columns: Drug Name Preferred Name Drug Code

Code Options	Drug Name	Preferred Name	Drug Code
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE	LIDOCAINE	00033401001
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE [CHLORHEXIDINE;LIDOCAINE]	CHLORHEXIDINE;LIDOCAINE	13160001005
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE [LIDOCAINE HYDROCHLORIDE]	LIDOCAINE HYDROCHLORIDE	00033402023
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE & FLUORESCIN MINIMS SPECIFIC	FLUORESCIN SODIUM;LIDOCAINE HYDROCHLORIDE	12183502023

Verbatim(s) Selected: 7 Add to Synonym List? Synonym List(s): WHODrug B3

Search Columns: Drug Name Preferred Name Drug Code

Code Options	Drug Name	Preferred Name	Drug Code
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE HYDROCHLORIDE MONOHYDRATE;MYROXYLON BALSAMUM VAR. PEREIRAE BALSAM;PHENOXYETHANOL;THYMOL	LIDOCAINE HYDROCHLORIDE MONOHYDRATE;MYROXYLON BALSAMUM VAR. PEREIRAE BALSAM;PHENOXYETHANOL;THYMOL	12416002001
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE [CHLORHEXIDINE;LIDOCAINE]	CHLORHEXIDINE;LIDOCAINE	13160001005
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE [LIDOCAINE HYDROCHLORIDE]	LIDOCAINE HYDROCHLORIDE	00033402023
<input type="button" value="Code + Next"/> <input type="button" value="Code"/>	LIDOCAINE	LIDOCAINE	00033401001

CODING

Feature Risk

MEDIUM

Default Impact

None



Dashboard



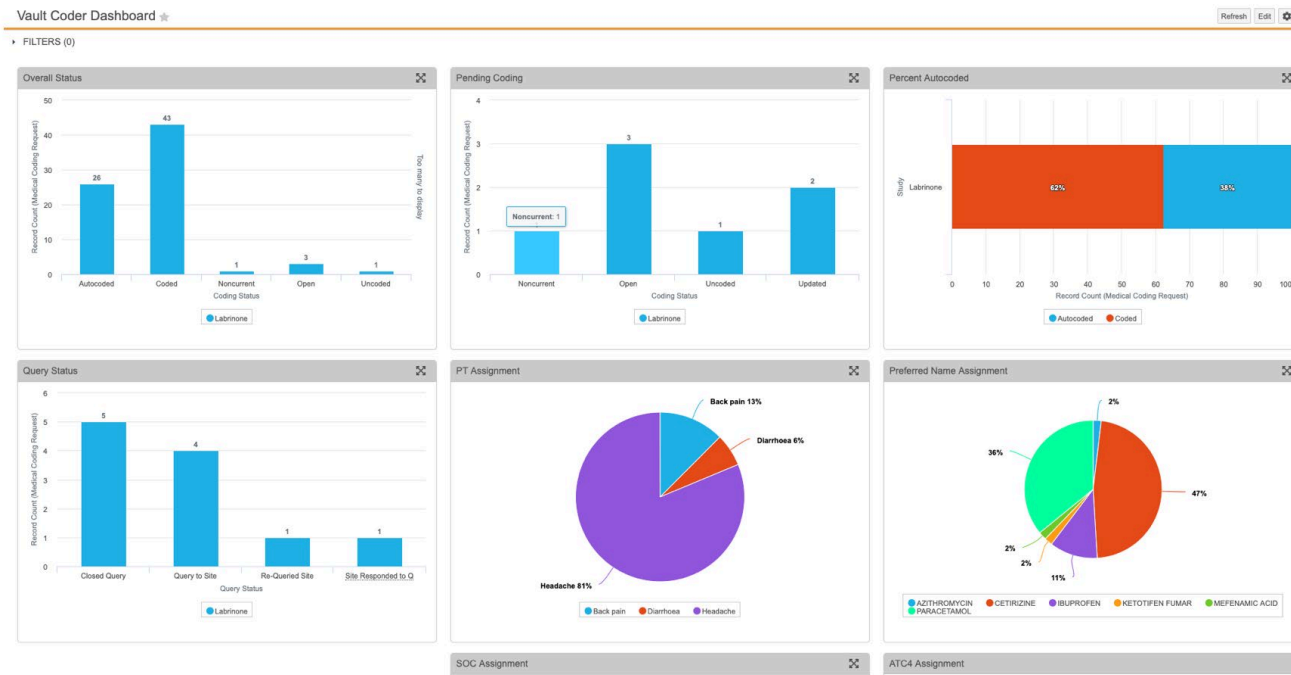
Support

- Overview

Coding dashboard that provides an overall review of the Coding progress

- Business Value

Comprehensive, graphical Visualization of Coding status and progress



CODING

Feature Risk

LOW

Default Impact

None



Unique Term Report



Support

- Overview

The Unique term report contains all the unique coded terms.

- Business Value

This allows Coding Manager to focus on new coding patterns and history of coding.

New Term	Dictionary Release	Form Name	Record Count	Verbatim	Lowest Level Term	Preferred Term	High Level Term	High Level Group Term	System Organ Class	Primary Path	Comments for Report Review
	MedDRA 22.0	AE	5	ANEMIA	ANEMIA	ANAEMIA	ANAEMIAS NEC	ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION	BLOOD AND LYMPHATIC SYSTEM DISORDERS	Yes	
	MedDRA 22.0	MH	1	ANEMIA	ANEMIA	ANAEMIA	ANAEMIAS NEC	ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION	BLOOD AND LYMPHATIC SYSTEM DISORDERS	Yes	
*	MedDRA 22.0	AE	6	ASYSTOLE	ASYSTOLE	CARDIAC ARREST	VENTRICULAR ARRHYTHMIAS AND CARDIAC ARREST	CARDIAC ARRHYTHMIAS	CARDIAC DISORDERS	Yes	
*	MedDRA 22.0	AE	22	CARDIAC ARREST	CARDIAC ARREST	CARDIAC ARREST	VENTRICULAR ARRHYTHMIAS AND CARDIAC ARREST	CARDIAC ARRHYTHMIAS	CARDIAC DISORDERS	Yes	
	MedDRA 22.0	MH	1	EAR PAIN	EAR PAIN	EAR PAIN	EAR DISORDERS NEC	AURAL DISORDERS NEC	EAR AND LABYRINTH DISORDERS	Yes	
	MedDRA 22.0	AE	1	EAR RINGING	EAR RINGING	TINNITUS	INNER EAR SIGNS AND SYMPTOMS	INNER EAR AND VIIIITH CRANIAL NERVE DISORDERS	EAR AND LABYRINTH DISORDERS	Yes	
*	MedDRA 22.0	AE	1	INFLUENZA	INFLUENZA	INFLUENZA	INFLUENZA VIRAL INFECTIONS	VIRAL INFECTIOUS DISORDERS	INFECTIONS AND INFESTATIONS	Yes	
	MedDRA 22.0	MH	1	RUBELLA	RUBELLA	RUBELLA	RUBELLA VIRAL INFECTIONS	VIRAL INFECTIOUS DISORDERS	INFECTIONS AND INFESTATIONS	Yes	
	MedDRA 22.0	AE	1	VIRAL ILLNESS	VIRAL INFECTION	VIRAL INFECTION	VIRAL INFECTIONS NEC	VIRAL INFECTIOUS DISORDERS	INFECTIONS AND INFESTATIONS	Yes	
	MedDRA 22.0	MH	1	SHOULDER LABRAL TEAR	GLENOID LABRAL TEAR	CARTILAGE INJURY	BONE AND JOINT INJURIES NEC	BONE AND JOINT INJURIES	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Yes	
	MedDRA 22.0	MH	1	MENISCUS TEAR	MENISCUS TEAR	MENISCUS INJURY	BONE AND JOINT INJURIES NEC	BONE AND JOINT INJURIES	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Yes	
	MedDRA 22.0	MH	1	DISPLACED LEFT SACRAL ALA FRACTURE	FRACTURE DISPLACEMENT	FRACTURE DISPLACEMENT	FRACTURES AND DISLOCATIONS NEC	BONE AND JOINT INJURIES	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Yes	
	MedDRA 22.0	AE	1	ELEVATED TEMP	BODY TEMPERATURE INCREASED	BODY TEMPERATURE INCREASED	PHYSICAL EXAMINATION PROCEDURES AND ORGAN SYSTEM STATUS	PHYSICAL EXAMINATION AND ORGAN SYSTEM STATUS TOPICS	INVESTIGATIONS	Yes	

Feature Risk

LOW

Default Impact

None



Unique Terms Report

1. Select a Date Range
2. If new coding assignment is only available in the Date Range, will be flagged for review.

2. Record count for the coding assignment.

3. Blank column for comments to track and share

New Term	Dictionary Release	Form Name	Record Count	Verbatim	Lowest Level Term	Preferred Term	High Level Term	High Level Group Term	System Organ Class	Primary Path	Comments for Report Review
	MedDRA 22.0	AE	5	ANEMIA	ANEMIA	ANAEMIA	ANAEMIAS NEC	ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION	BLOOD AND LYMPHATIC SYSTEM DISORDERS	Yes	
	MedDRA 22.0	MH	1	ANEMIA	ANEMIA	ANAEMIA	ANAEMIAS NEC	ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION	BLOOD AND LYMPHATIC SYSTEM DISORDERS	Yes	
*	MedDRA 22.0	AE	6	ASYSTOLE	ASYSTOLE	CARDIAC ARREST	VENTRICULAR ARRHYTHMIAS AND CARDIAC ARREST	CARDIAC ARRHYTHMIAS	CARDIAC DISORDERS	Yes	
*	MedDRA 22.0	AE	22	CARDIAC ARREST	CARDIAC ARREST	CARDIAC ARREST	VENTRICULAR ARRHYTHMIAS AND CARDIAC ARREST	CARDIAC ARRHYTHMIAS	CARDIAC DISORDERS	Yes	
	MedDRA 22.0	MH	1	EAR PAIN	EAR PAIN	EAR PAIN	EAR DISORDERS NEC	AURAL DISORDERS NEC	EAR AND LABYRINTH DISORDERS	Yes	
	MedDRA 22.0	AE	1	EAR RINGING	EAR RINGING	TINNITUS	INNER EAR SIGNS AND SYMPTOMS	INNER EAR AND VIIIITH CRANIAL NERVE DISORDERS	EAR AND LABYRINTH DISORDERS	Yes	
*	MedDRA 22.0	AE	1	INFLUENZA	INFLUENZA	INFLUENZA	INFLUENZA VIRAL INFECTIONS	VIRAL INFECTIOUS DISORDERS	INFECTIONS AND INFESTATIONS	Yes	
	MedDRA 22.0	MH	1	RUBELLA	RUBELLA	RUBELLA	RUBELLA VIRAL INFECTIONS	VIRAL INFECTIOUS DISORDERS	INFECTIONS AND INFESTATIONS	Yes	
	MedDRA 22.0	AE	1	VIRAL ILLNESS	VIRAL INFECTION	VIRAL INFECTION	VIRAL INFECTIONS NEC	VIRAL INFECTIOUS DISORDERS	INFECTIONS AND INFESTATIONS	Yes	
	MedDRA 22.0	MH	1	SHOULDER LABRAL TEAR	GLENOID LABRAL TEAR	CARTILAGE INJURY	BONE AND JOINT INJURIES NEC	BONE AND JOINT INJURIES	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Yes	
	MedDRA 22.0	MH	1	MENISCUS TEAR	MENISCUS TEAR	MENISCUS INJURY	BONE AND JOINT INJURIES NEC	BONE AND JOINT INJURIES	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Yes	
	MedDRA 22.0	MH	1	DISPLACED LEFT SACRAL ALA FRACTURE	FRACTURE DISPLACEMENT	FRACTURE DISPLACEMENT	FRACTURES AND DISLOCATIONS NEC	BONE AND JOINT INJURIES	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Yes	
	MedDRA 22.0	AE	1	ELEVATED TEMP	BODY TEMPERATURE INCREASED	BODY TEMPERATURE INCREASED	PHYSICAL EXAMINATION PROCEDURES AND ORGAN SYSTEM STATUS	PHYSICAL EXAMINATION AND ORGAN SYSTEM STATUS TOPICS	INVESTIGATIONS	Yes	





Coding Demo



Questions



Thank you