Veeva

19R2 Release Webinar
New Features

July 17, 2019

Veeva

Please use 'Q&A' to ask a question

Chat   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
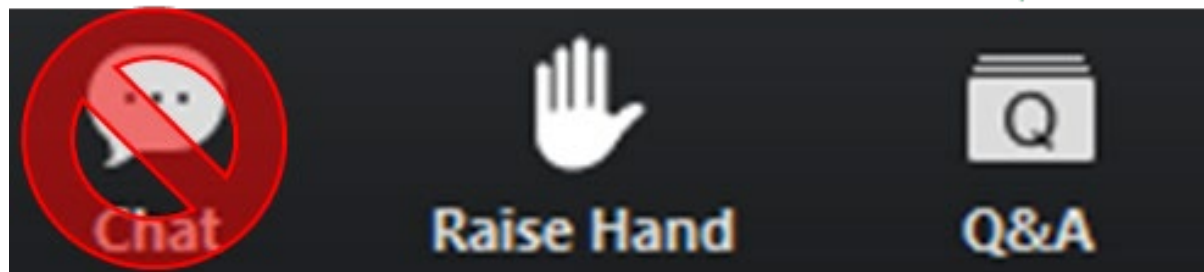
  Please note the date on the title slide

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

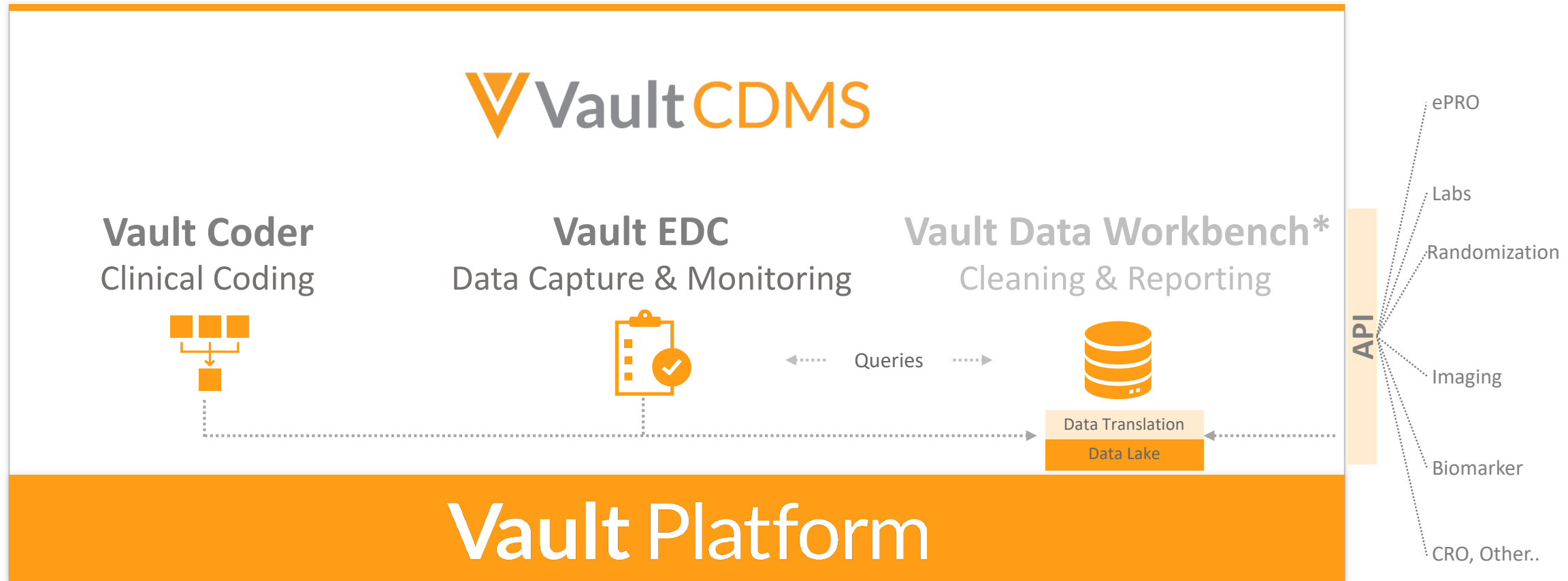 Help → Release Notes → About the 19R2 Release

Interact With Us!
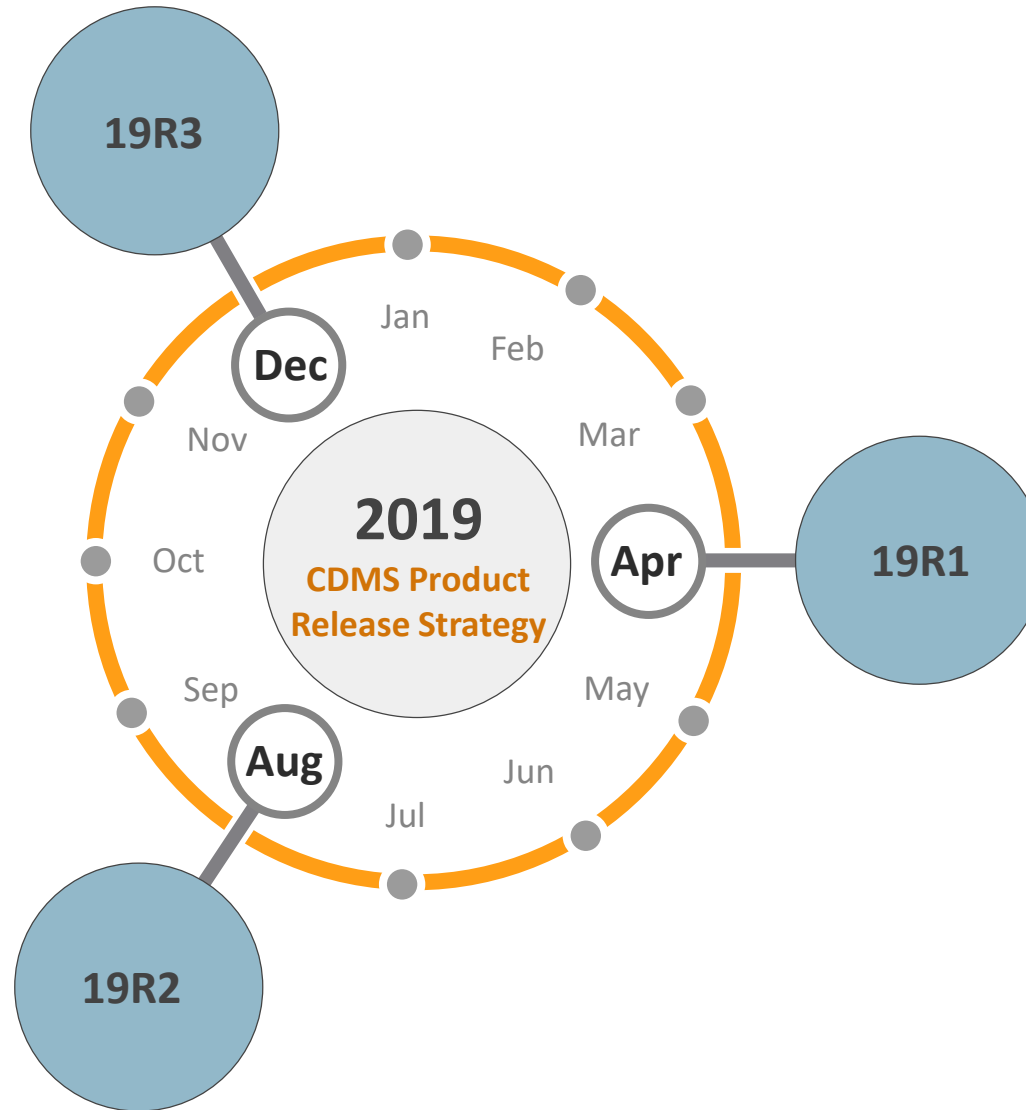

Please use 'Q&A' to ask a question

Reinventing Clinical Data Management

Vault Data Workbench is currently under development

Veeva Vault Release Schedule

2019
CDMS Product Release Strategy

19R3 · Dec · 19R1 · Apr · 19R2 · Aug

Jan · Feb · Mar · May · Jun · Jul · Sep · Oct · Nov

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

JULY

Monday 22nd
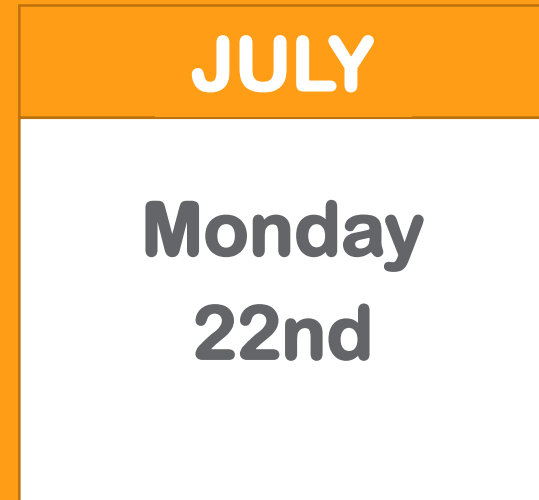
Validation Documents

- 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

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

CRAs and Data Managers

- Last Event/Next Event
- Synching 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

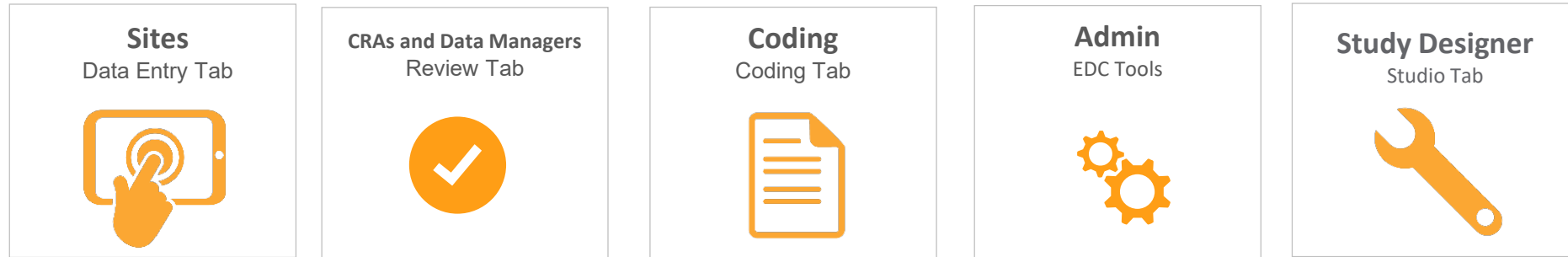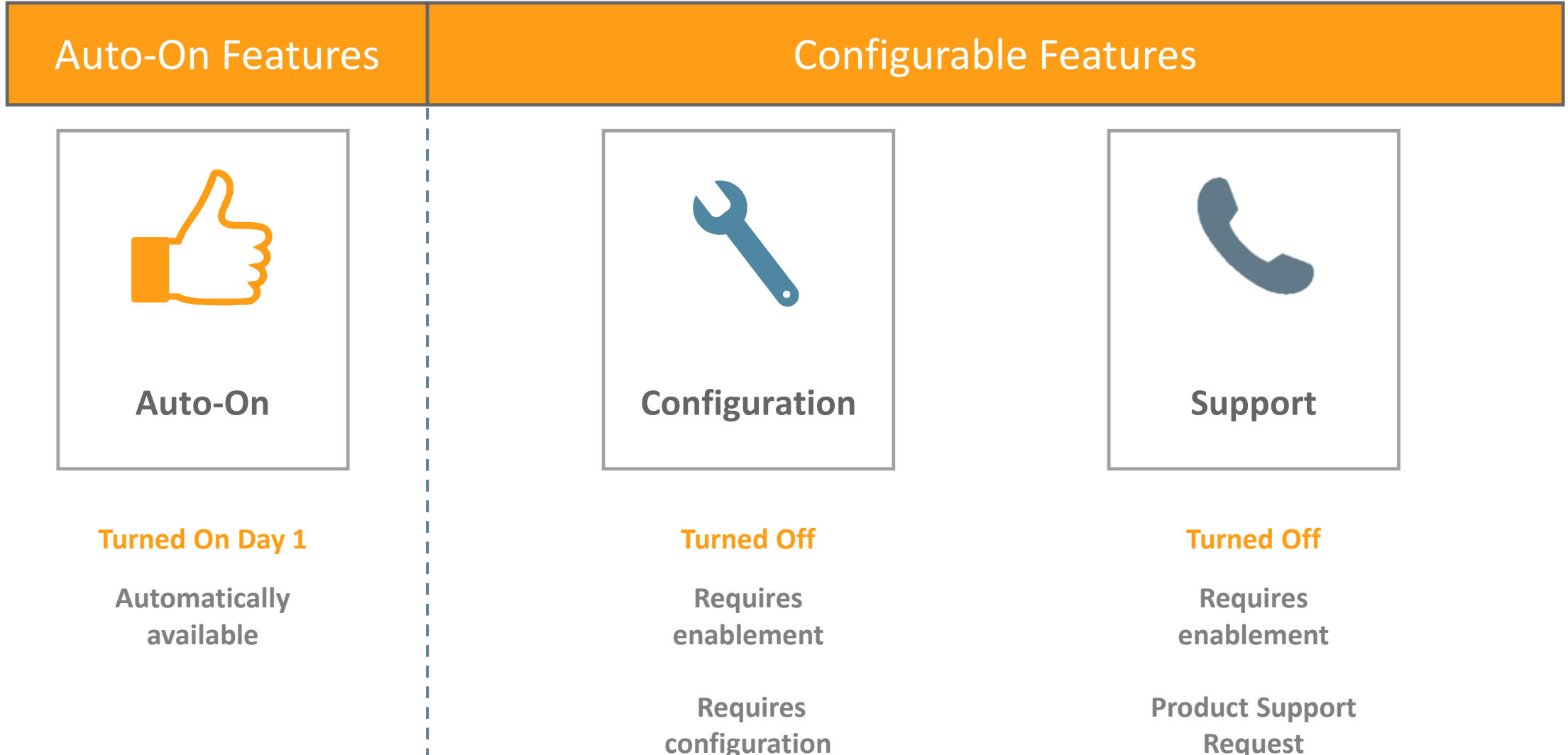|		
Optimized User Experience	**Sites**	Tabular Data View
	Review	Latest casebook version, Event Tree view with synchs with right form details, Previous Event/Next Event, Increased modal box, new Icons, Form Level Reviews
	Coding	Coding: Select/De-select all checkboxes, Summary view exposed through icon
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 • 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

Sites	CRAs and Data Managers	Coding	Admin	Study Designer
Data Entry Tab	Review Tab	Coding Tab	EDC Tools	Studio Tab

Feature Enablement Detail

Auto-On Features	Configurable Features	
Auto-On	**Configuration**	**Support**
Turned On Day 1	**Turned Off**	**Turned Off**
Automatically available	**Requires enablement**	**Requires enablement**
	Requires configuration	**Product Support Request**

Sites

Casebook Confirmation

- 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.

Delete Subjects

- 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.
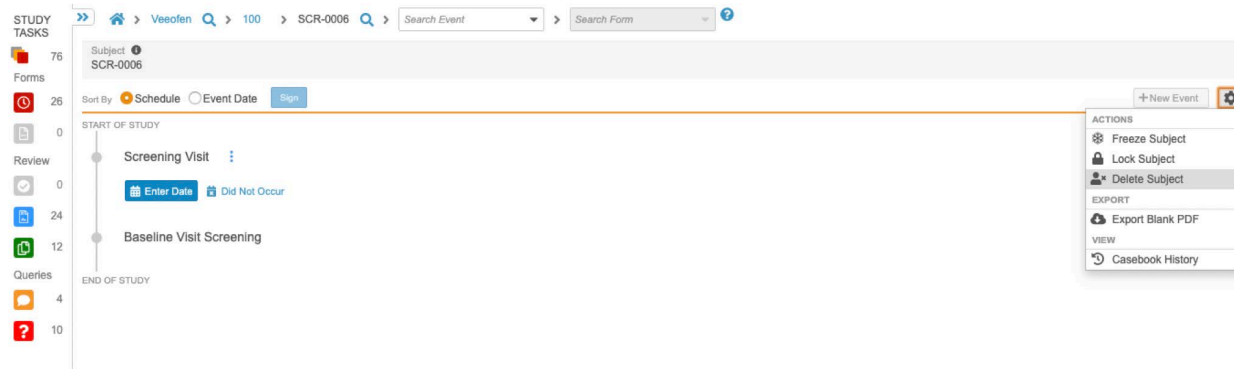
Feature Risk

HIGH

Default Impact

VISIBLE TO USERS WITH PERMISSION

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.

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.

Site Demo

CRAs/Data Manager

Accessible Data

Automatic

- 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.

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.

Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS

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.

Automatic

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

CRAs and Data Managers	Sites
• Comprehensive View focusing on Reviews	• Designed for Site Data Entry
• Quick and Easy Navigation to view Visit/ Forms	• Multiple Clicks to Review Visits/ Forms
• Centralized location of all Queries and Reviews	• Click into each Form to see the Query
• Filter View of "To Dos"	• No Filter
• Toggle between Site View/Monitor View	• 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

Feature Risk

LOW

Default Impact

VISIBLE TO ALL USERS

Query Status Filter

- 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.

Automatic

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.

Dashboard

- Overview

  Coding dashboard that provides a overall review of the Coding progress

- Business Value

  Comprehensive, graphical Visualization of Coding status and progress

Support

CODING

Feature Risk

LOW

Default Impact

None

Unique Term Report

- 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.

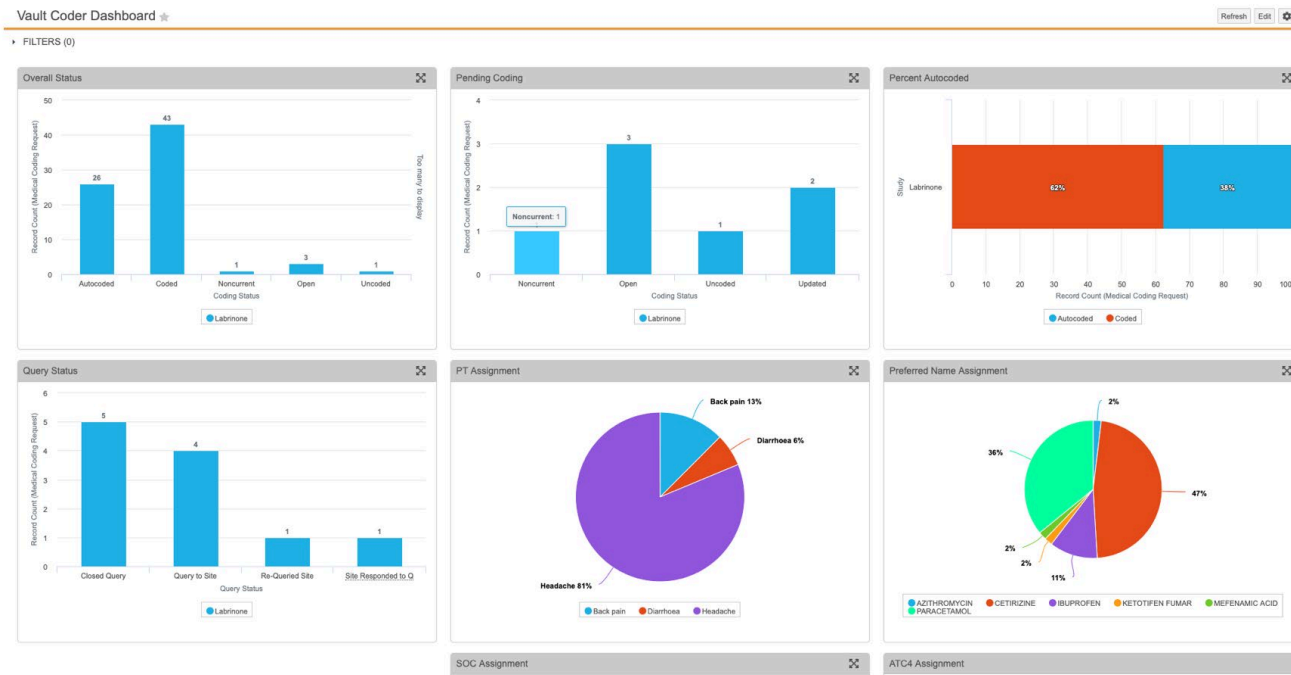| New Term	Dictionary Release	Form Name	Record Count	Verbatim	Lowest Level Term	Preferred Term	High Level Term	High Level Group Term	System Organ Class	Primary Path	Comments for Report Review
	MedDRA 22.0	AE	5	ANEMIA	ANEMIA	ANAEMIA	ANAEMIAS NEC	ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION	BLOOD AND LYMPHATIC 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 VIIITH 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	

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 VIIITH 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