

20R1 Customer Webinar

March 25, 2020





veeva

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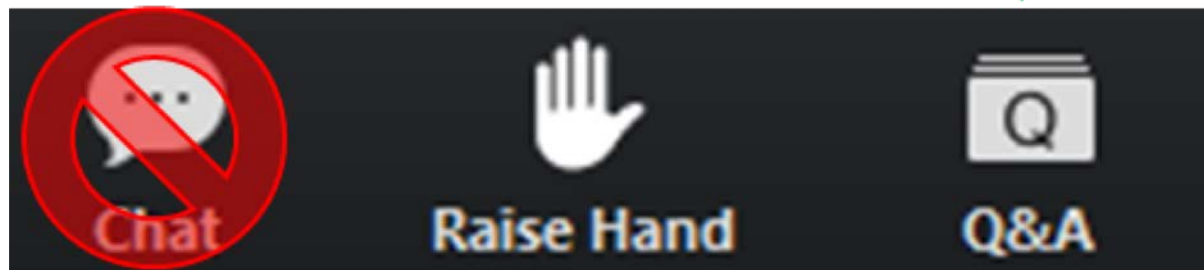
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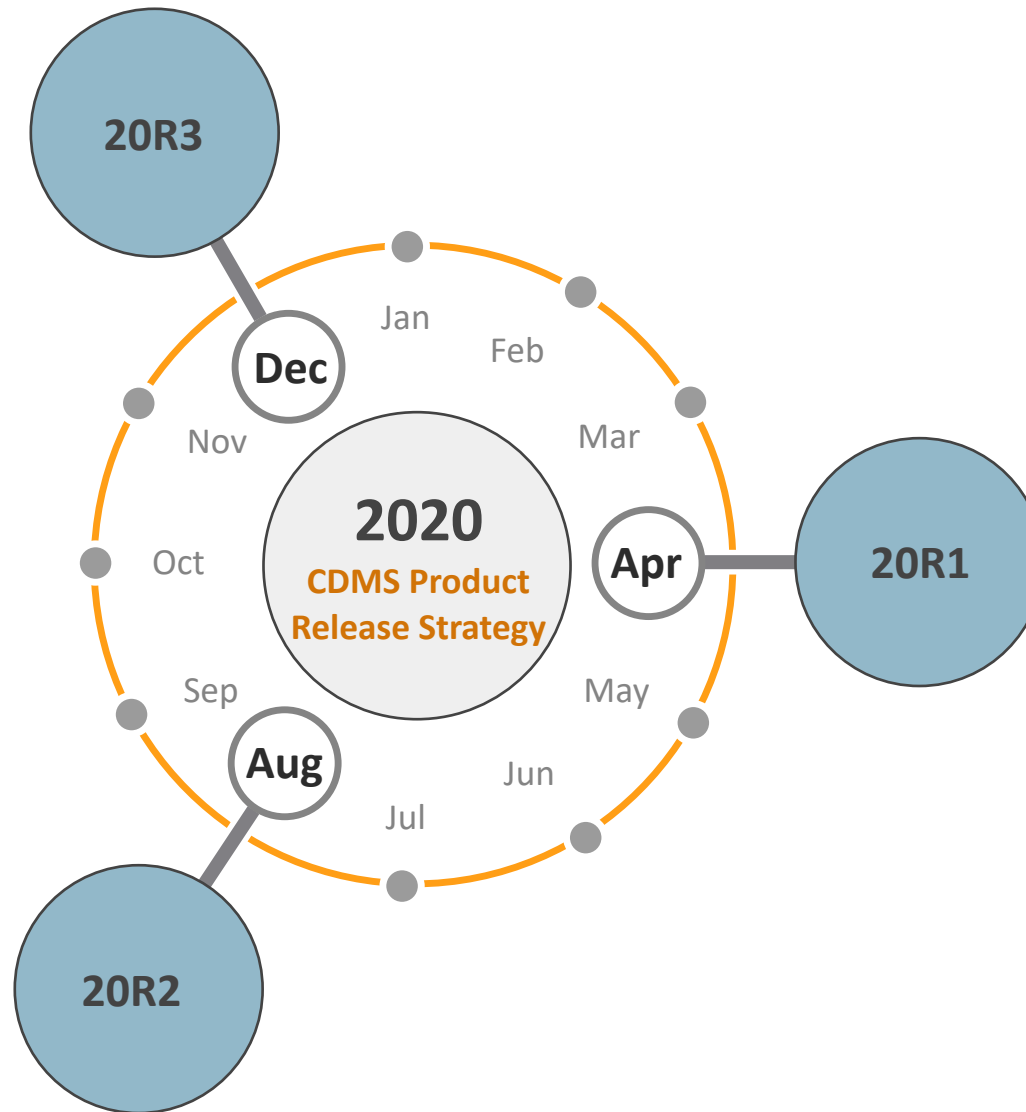


Interact With Us!

Please use
'Q&A' to ask a
question



Veeva Vault Release Schedule



20R1 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
22	23	24 MAR	25 20R1 Release webinar	26	27	28
28	30 Validation Docs 20R1 Pre - Release	31	1	2	3	4
5	6	7	8	9	10	11
12	13	14 APR	15	16	17 20R1 General Release	18

 Customer Validation



Pre-Release Environment

<https://login.veevavault.com>

- Clone of UAT ONLY
- Users
 - Contact Veeva Post Implementation Manager to add users
- Available up to 4 weeks after the 20R1 upgrade

MAR

**Monday
30th**



Validation Documents

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

MAR

**Monday
30th**



20R1 Go Live

- ALL customer vaults upgraded to 20R1
- EU starts at 2:00pm PT
- APAC & US starts at 5:00 PM PT
- May take up to 6 hours

APR

**Friday
17th**



20R1 General Release Resources

- **Resources Available**
- <https://cdmshelp.veeva.com/lr/rn/general-releases/20r1/>
 - Important Dates
 - Notifications Opt-In
 - Feature information
 - Pre- Release Information
 - Release Information
 - Release Impact Assessment (RIA)



20R1 Feature Summary

Sites



- New Data Entry Interface
- Progressive Display
- Indenting
- Form Linking
- Copy Indication from Link

Performance

- Creation of Forms
- First instance of Repeating Form (not automatically created)

Study Designer



- | | | |
|--|---|---|
| <ul style="list-style-type: none"> • Form Linking • Copy Rules from another Study • ODM Import/Export for Automated Deployment Studies • Progressive Display • Item Indentation | <ul style="list-style-type: none"> • setting • Review Plan Templates | <ul style="list-style-type: none"> • #define statement can be added to expression with one click |
| <ul style="list-style-type: none"> • Reviews – “optional” | <p>Rules</p> <ul style="list-style-type: none"> • Set Subject Status Dates • Send Emails <p>Rule Editor Enhancements</p> <ul style="list-style-type: none"> • Expand/Collapse • Search for Item by name or label on the right side • Corresponding | <p>NEW Functions</p> <ul style="list-style-type: none"> • Power(), Sum(), Average() • StartofDay(date, timezone) • Today(timezone) • Reciprocal Rules with @Form |

Coding



Automated Auto-coding

- Refresh button from Auto-coding
- Auto-Assign deprecated

Admin



- Email Group Assignment
 - Deploy Custom Objects & Roles
 - Flexibility in creating PROD
 - CDMS-CTMS Spark Integration
 - APIs (support IRT)
 - User Activity Report
 - Sites –Active Version & Study Country
 - LDM – SDV/DMR Re-assignment Job
 - Federated ID for SSO
 - Vault CDMS Logo
- Roles and Permission**
- Study Designer Role(s)
 - Custom Object Permissions
 - Delete Custom Roles
 - Download Roles
 - New Permissions (Manage Study, View Coding, Workbench Tab)
 - Remove Manage Study From Deployment Admin

Data Workbench



Early Adopter




Local Labs



20R3



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	



Sites

New Data Entry Interface



AUTOMATIC

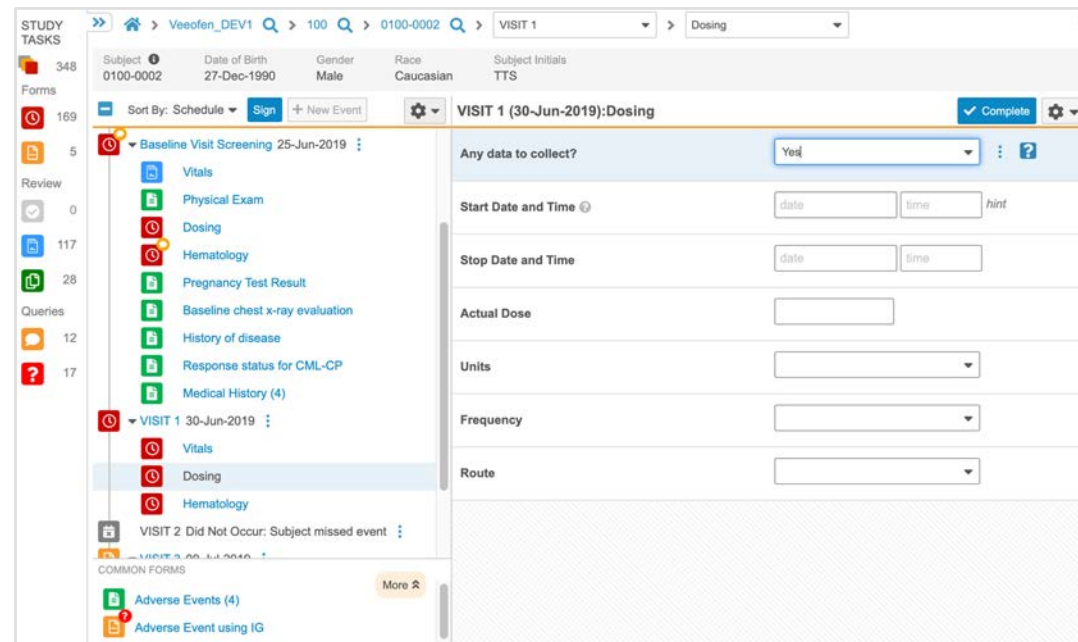
- Overview

The Data Entry tab has been updated based on feedback from Sites. The new navigation provides the site user a better and more streamlined experience.

- Combines two different pages, the event/form schedule and form display, into a single page therefore minimizing the number of clicks necessary to navigate across forms.
- Resize the event/form or form display panels to focus on the priority at the moment

- Business Value

An improved user experience and better navigation.



NEW STUDIES
*must be enabled
for existing studies

Visible

SITES





Progressive Display

- Overview

Study designers now have additional control on how a form is presented to users.

- Ability to hide/show, disable/enable fields
- Driven by the value of the previous field

Business Value

Allows user to focus on the fields that are relevant





Indenting

- Overview

Indenting fields provides another choice for a better cosmetic appearance.

- Items can be indented up to 3 different levels

- Business Value

More options on designs of form for better viewing

Physical Exam (1 of 6)

Body Area
Extremities ⋮ ? ← Indent Level 0

Physical exam performed?
 ← Indent Level 1

Date of Exam
date ← Indent Level 2

Did the physical exam identify any abnormalities?
 Yes
 No

Please specify abnormalities:
 ← Indent Level 3
0 / 1500





Form Linking

- Overview

Create Relationships between forms such as Adverse Event and Concomitant Medications

- Link multiple forms – AE to Con Meds to Medical History
- Link to same forms
- Search for texts in the form

- Business Value

Causality between records can now be defined by the site users.

Common Log Forms: **Concomitant medication** : Reference # 2 (2 of 2) ◀ ▶

FORM | [AE \(2\)](#)

Medication or Therapy?	What were the active ingredient(s)?	For what indication was the medication/ therapy taken?	What was the total daily dose of the medication/ therapy?
Tylenol	Acetaminophen	headache	500

[Edit Links](#) ⋮

Reference #	Event	AE Term	Start Date and Time	End Date and Time	Ongoing?
1	Common Log Forms	headache			
4	Common Log Forms	Migraine	04-Feb-2020 14:00	04-Feb-2020 16:00	No

Adverse Events

headache 🔍

Show: Current Event All Events 1-1 of 1

<input checked="" type="checkbox"/>	Reference #	Event	AE Term	Start Date and Time	End Date and Time	Ongoing?	Severity/Intensity	Toxicity Grade	Serious?
<input checked="" type="checkbox"/>	1	Common Log Forms	headache						

Show selected (1) Cancel Save





Copy Indication from Link

- Overview

Sites will have the option to copy Indication values from fields found on other forms

- Must be configured using form links
- Common use case: Indication may be copied from an AE or Medical History

- Business Value

This provides a quick and easy way to provide an accurate Indication value and so that the Form may be Coded correctly by the Coding team.

Con Meds: Concomitant Medications : Reference # 1 (1 of 1) Complete

FORM | AES (1) | MEDICAL HISTORY (0)

Medication or Therapy: Tylenol

Indication: Headache [Link and Copy](#)

Route: [Dropdown]

Link and Copy

Adverse Events | Medical History

1-13 of 13

Reference #	Event	Adverse Event	Start Date	Ongoing?	End Date	Relationship to ..	Serio
1	Adverse Event	Headache	01-Mar-2020	Yes		NOT RELATED	No
2	Adverse Event	Nausea	01-Mar-2020	Yes	06-Mar-2020	NOT RELATED	No
3	Adverse Event	Vomiting	01-Mar-2020	No	09-Mar-2020	NOT RELATED	No
4	Adverse Event	Back Pain	01-Mar-2020	Yes		NOT RELATED	No
5	Adverse Event	Rash	02-Mar-2020	No	11-Mar-2020	NOT RELATED	No
6	Adverse Event	Hair Loss	01-Mar-2020	Yes		NOT RELATED	No
7	Adverse Event	Eczema	10-Mar-2020	Yes		RELATED	No

Cancel Link and Copy





Coding

Automated Autocoding



Automatic

- Overview

Autocoding and Suggestions generation are now automated and run throughout the day.

- Adding a new record to a Synonym List, the system will update Autocoding and Suggestions on all Forms assigned to it.
- The **Autocoding jobs can no longer be scheduled** and any currently scheduled Autocoding jobs will be cancelled with this release. This **job can still be run ad-hoc basis**, if ever needed.

- Business Value

Automated autocoding and suggestions will keep data consistently updated across Studies without the Vault having to run unnecessary jobs.

Visible

CODER



Coding UI Enhancements



Automatic

- Overview

- New Refresh button to refresh the contents of the Coding table with updates from the Site and updates from Automated Autocoding.
- Removed Auto-Assign button
 - System is Autocoding in real-time and auto-assign button is not necessary

- Business Value

Updated Interface to match with the new automation that is happening in the background

The screenshot displays a web interface for managing coding requests. The main section is titled "All Bryce Pharma Mabrinone ConMed Requests" and includes a search bar, filters for "Coding Status" and "Query Status", a "Refresh" button, and pagination controls showing "1-20 of 51" items on page "1" of "3".

Verbatim	Indication	Route	Coding Status	Assigned Code
<input type="checkbox"/> ACETAMINOPHEN	Headache	Oral	AUTOCODED	N02BE ACETAMINOPHEN
<input checked="" type="checkbox"/> ACETAMINOPHEN	Headache	Oral	AUTOCODED	N02BE ACETAMINOPHEN
<input type="checkbox"/> ACETAMINOPHEN	Headache	Oral	AUTOCODED	N02BE ACETAMINOPHEN
<input type="checkbox"/> ACETAMINOPHEN	Headache	Oral	AUTOCODED	N02BE ACETAMINOPHEN

The right-hand panel provides a detailed view for the selected "ACETAMINOPHEN" entry, showing its "ASSIGNED CODE" with the following details:

Drug Name:	ACETAMINOPHEN	
Preferred Name:	PARACETAMOL	
ATC4:	N02BE	ANILIDES
ATC3:	N02B	OTHER ANALGESICS AND AN...
ATC2:	N02	ANALGESICS
ATC1:	N	NERVOUS SYSTEM

Visible

CODER





Site Demo



Thank you