

# 20R3 Customer Webinar

Sites, CRAs, Data Managers

November 12, 2020



# CDMS Product Team



**Sharon Lin**  
Principal Product Manager,  
Vault CDMS



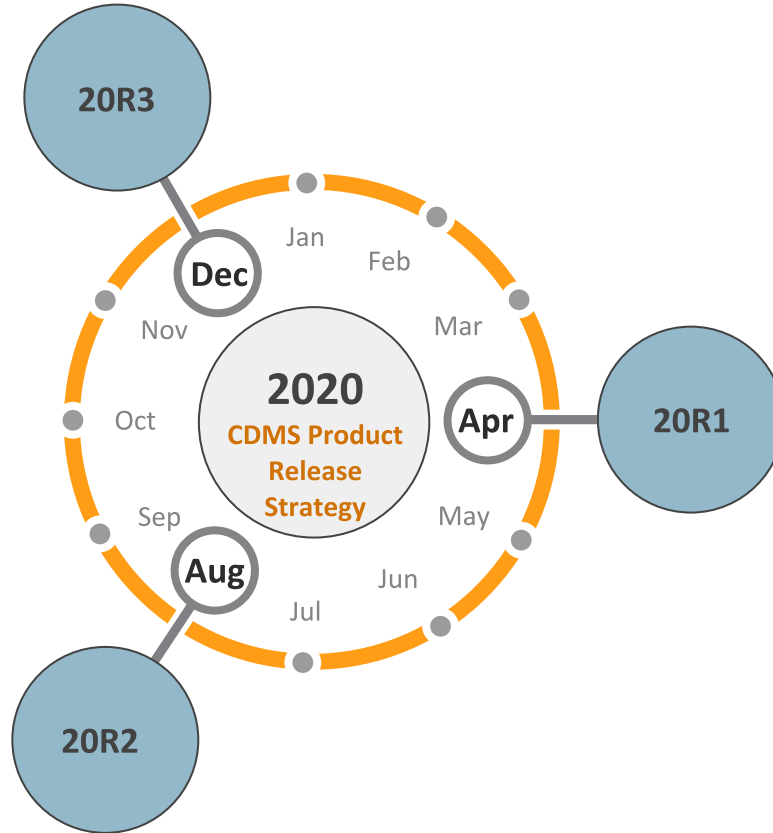
**Quentin Paresys**  
Product Manager,  
Vault CDMS



**Cory Etzcorn**  
Product Manager,  
Vault CDMS



# Veeva Vault Release Schedule



## 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, Coder 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



# Pre-Release Environment

<https://login.veevavault.com>

- Clone of UAT
  - Special Request for Dev
- Users
  - Contact Veeva Post Implementation Manager or Customer Success Manager to add users
- Available up to 4 weeks after the 20R3 upgrade

**NOV**

**Monday  
16th**



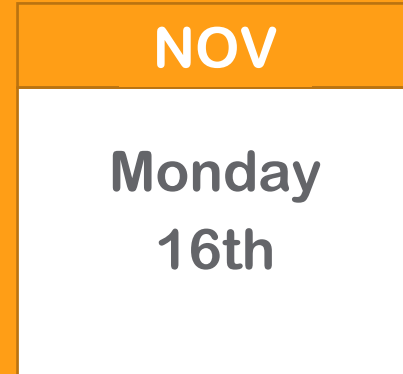
# Validation Documents

On Monday, Nov 16

- Validation Project Plan
- IOQ Protocol
- Business Requirements Documents
- Validation Impact Assessment
- System Release Memo
- Traceability Matrix

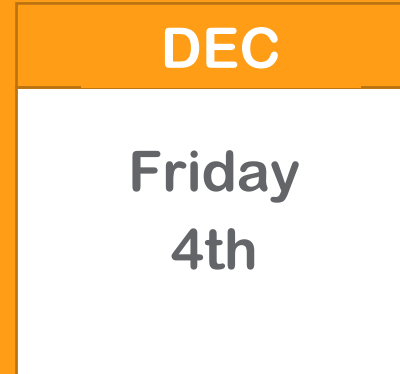
On Friday, Dec 04

- Validation Summary Report
- Executed OQ Scripts  
(unexecuted in Word format available upon request)



## 20R3 Go Live

- ALL customer vaults upgraded to 20R3
- EU starts at 2:00pm PT
- APAC & US starts at 5:00 PM PT
- May take up to 6 hours



## 20R3 General Release Resources

- **Resources Available**
- <https://cdmshelp.veeva.com/lr/rn/general-releases/20r3/>
  - Important Dates
  - Notifications Opt-In
  - Feature information
  - Pre- Release Information
  - Release Information
  - Release Impact Assessment (RIA)





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





Local Labs

# Local Lab Solution

## Master List (Library)

Lab Normals and Units are centrally managed

- Analytes
- Lab Locations and Lab Normals
- Units
- Codelists

## Minimizes Data Entry

Sites enter the Collection Date & Time, and Select Lab Location

- Normals are auto - populated
- Units are auto - populated

## Maximizes Data Quality

Lab Normals and Units are entered one time

- Available for Studies immediately
- Minimizes studies using outdated or information

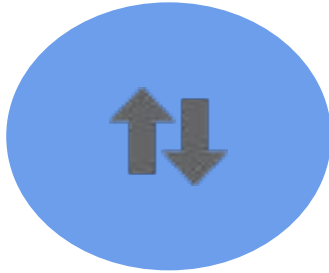


# 5 Key Differentiators



## Modern UI

A simple, intuitive UI for Sites. Select lab location, the Units and Normals get auto-populated.



## Visual Indicator

Lab Results that are outside Normal Ranges will have visual indicators so Site can determine Clinical Significance.



## LOINC Codes

Comply with FDA guidance to report LOINC codes with Lab Results by adding the LOINC Code to your Master Analyte Library.



## Outdated Normal Report

Identify which Sites are using outdated Lab Normals and Run the job to update the Form.



## Standard Units

Standard Units are maintained in the system so they can be easily extracted as part of the data.

# Features: Site

Clean, intuitive user interface	The modern UI is easy to navigate and use with little training needed. The local lab data is fully unified with Vault EDC administration, workflows, and case report forms.
Visual Indicators when out of Normal Ranges	Visual icons indicate when results are outside of reference ranges. Sites can easily see which results need review for clinical significance
Data Driven Normals Selection	Vault uses the patient demographic information such as age, sex, and collection date to auto-populate the appropriate normal range data for that specific patient, laboratory, and analyte.
Manual Override of Auto-populated Normals	If authorized, sites may override the auto-populated range values for a particular analyte. Both sets of values are displayed.
Pre-Defined Units	Vault automatically loads the appropriate-units once sites designate which lab was used. No more selecting units from a dropdown list.
Downloadable Reference Range Template to easily share Normal updates available in Help	Sites can download a template from the User Help section and fill out lab normals, email to Data Manager to import into the centralized Lab Locations and Normals





# Local Labs Demo



Sites / CRAs / Data  
Managers





# Query Teams

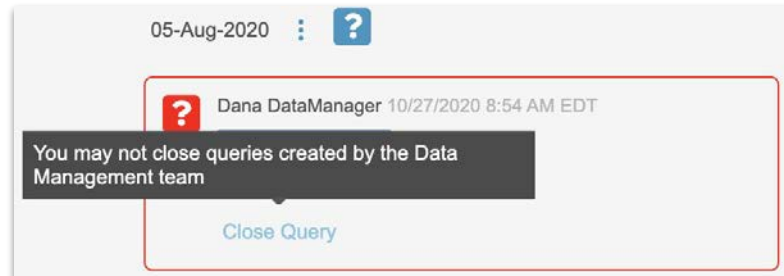
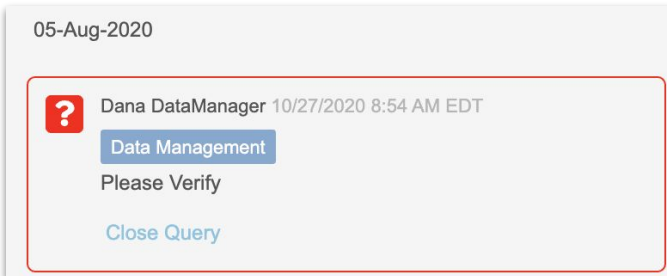
- Overview

Sponsors can utilize Query Teams to enforce restrictions within a study on who can close a manual query. By default, all Standard roles are placed into their corresponding team. Sponsors can choose to place any custom roles within their corresponding Query Team. When enabled for a study, only users within the same team as the user who created the manual query will be able to close it. Users outside of the team will still be able to view and comment on the query, but the “Close Query” button will be disabled. System queries are not assigned a team and can be closed by any user with the “Close Query” permission.

Any role with the “Close all Queries” permission will be able to override the Query Team concept and close any open queries, regardless of their team. By default, only the CDMS Lead Data Manager role will have this permission.

- Business Value

Provides Sponsors with the ability to enforce restrictions around which roles can close queries created by another role within a study.





# Sites & CRAs / Data Managers Demo



Questions

# Dedicated DEMO

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





Thank you