22R1 Customer Webinar For All

March 24, 2022

Veeva

CDMS Product Managers

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Product Manager

Data Entry, Review UI, Clinical Assessments, Reports

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Rules

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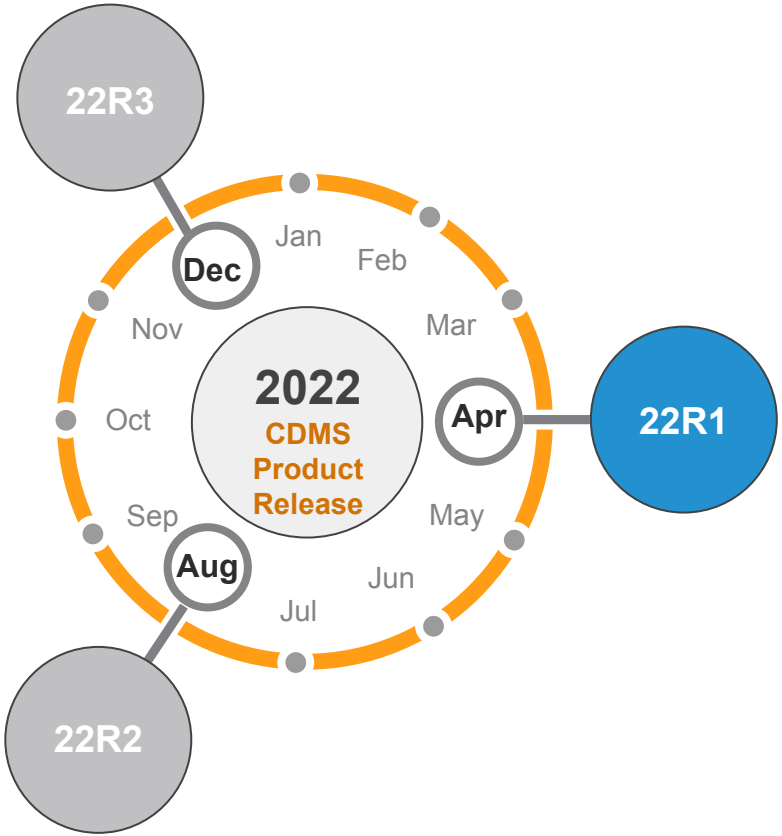
Local Labs, Randomization

Veeva Vault Release Schedule



22R1 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
MAR	21	22	23	24 **22R1 Release webinar** 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	25 **22R1 Pre-Release Upgrade**	26
27	28 Validation Docs	29	30	31	01 APR	02
03	04	05	06	07	08	09
10	11	12	13	14	15	16
17	18	19	20	21	22 **22R1 General Release Upgrade**	23

Customer Validation

22R1 Release Dates

Pre – Release

- **Clone of UAT**
- Special Request for DEV
- **Users**
- Added by Project Managers or Customers Success Managers
- **Available up to 6 weeks after 22R1 Release**

Validation Docs

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

22R1 Release

- All Customers Vaults upgraded to 22R1

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts

Available Resources

https://cdmshelp.veeva.com/lr/rn/general-releases/21r2/

- Important Dates
- Notifications Opt-In
- Feature information
- Pre- Release Information
- Release Information
- Release Impact Assessment (RIA)

22R1 Feature Summary

Sites

- Item to Form Linking
- Form Linking UI Improvements
- Additive Review
- Study Listings in Review Tab
- General EDC Enhancements

Reports/Extracts

- SDE Enhancements
- Unique Terms Report

Study Designer

- Library Classifications
- Event Window Enhancements
- Item to Form linking config
- General Library and Studio Enhancements
- Rules Enhancements
  - Comparison Rules
  - Standardized Dates in Emails
  - Query Scoping Repeating Objects
  - New Attributes
  - Updated Form Requirements

Other

- External FTP Connection
- CDMS APis

Admin

- Study Environment Deletion
- Vault Config Report
- Study Role Updates
- Performance Enhancements

Local Labs

- Study/Site Initiated the Lab
- Update to Outdated Normals Report
- Audit Trail update

Coding

- Inactivate Coding Forms
- Reconstitute Code Request Job Enhancement

Safety Link

- Codelist Mapper
- Suspect ConMeds

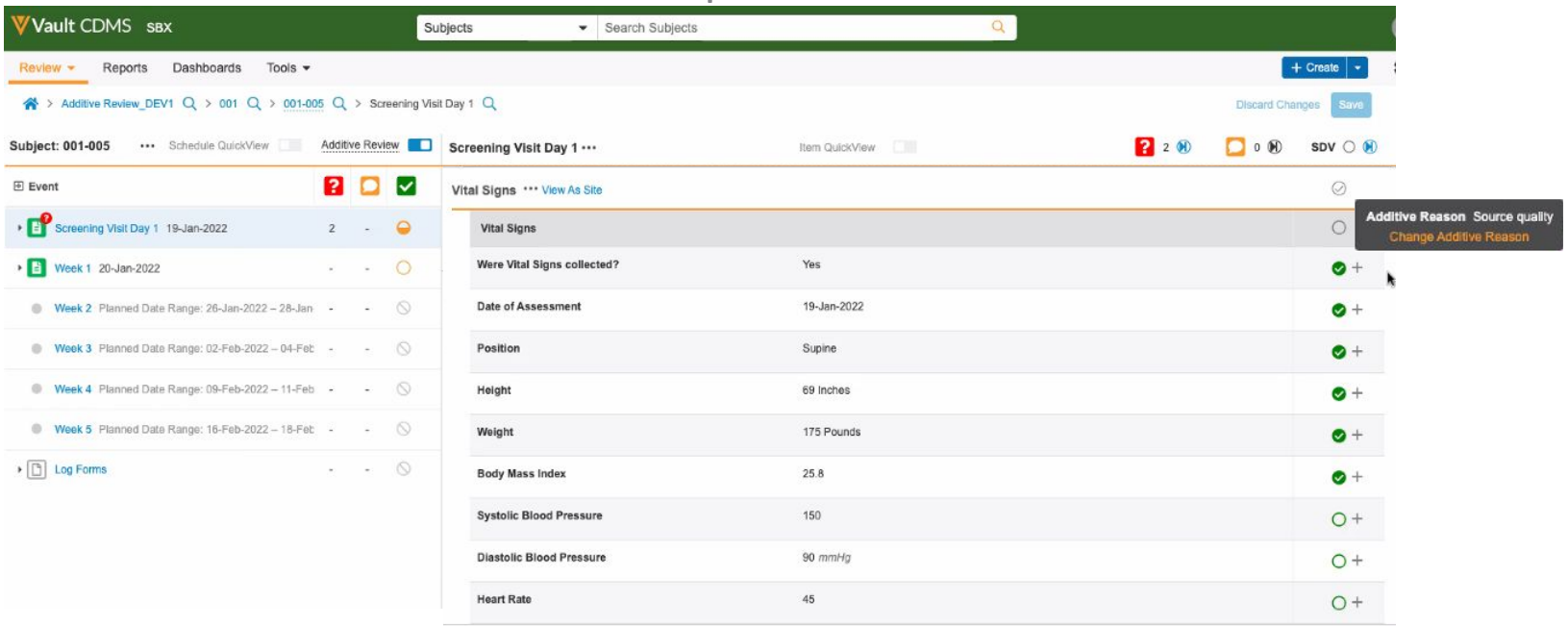
Randomization

- Option to Require Login Credential to Reveal Treatment

Additive SDV

Notice something questionable? Concerned about data quality?

CRAs can now SDV *more* than what was specified by the targeted review plan.



Sites / CRAs / Data Managers

Item Form Linking

- Overview

  With this feature, study designers can add a new form link item type and set up Display Items in Studio.

  In EDC, users will be able to link an individual item to a form, and data from the linked form will be visible in the Display Items within the form link item.

  Form links items and the linked data will be available in clinical dataset.

- Use case

  Allows for more specificity when linking, providing downstream teams with more context as to why data is linked.

Day 1
Impact to Clinical Teams

No

Visibility

Study Designers

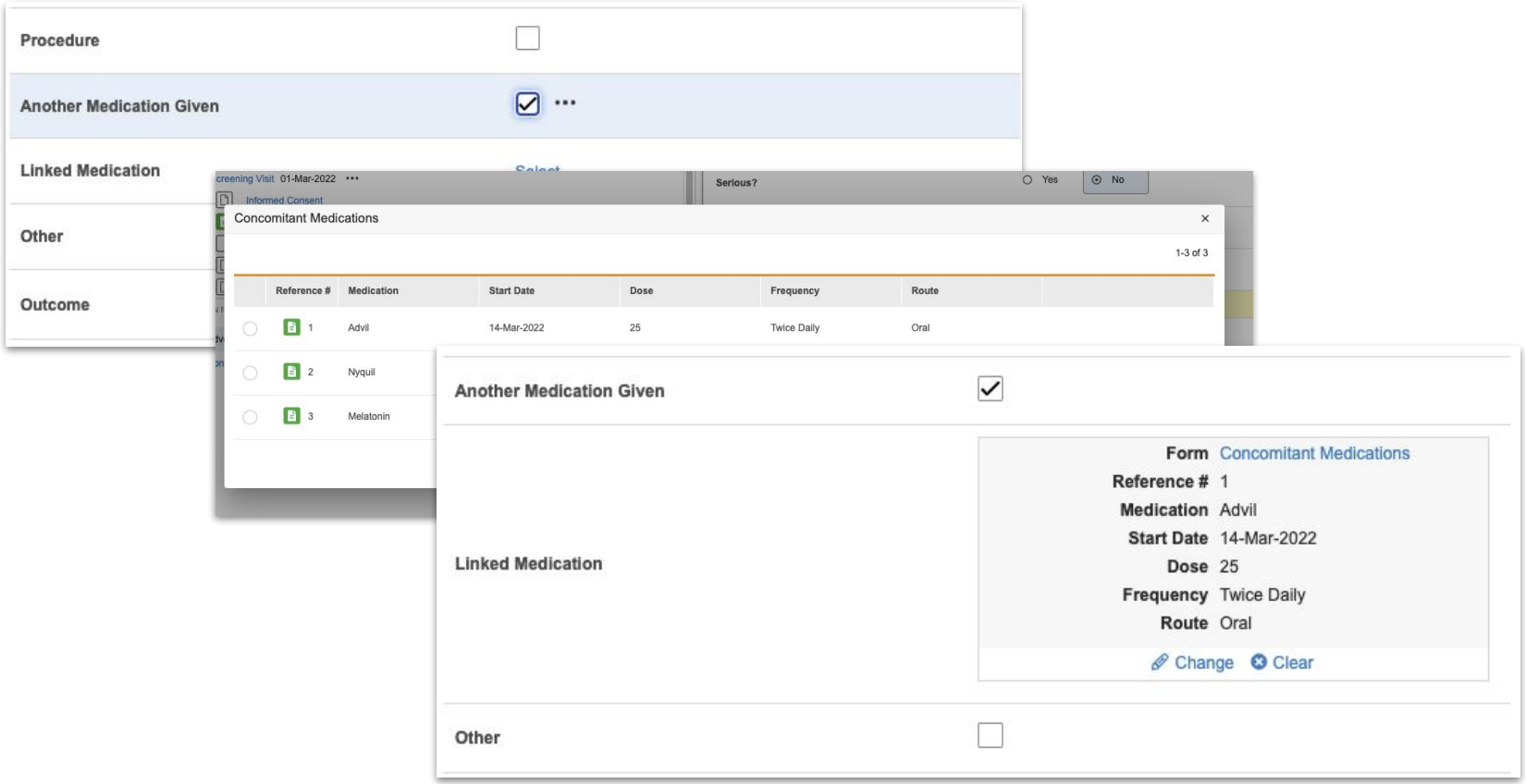
Configuration

Studio

Dependencies

Data Model 2

Item Form Linking



Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration Studio

Dependencies

Data Model 2

Form Linking V2

- Overview

  For studies using Form Linking V2, form links will appear in a new section at the bottom of the data entry form.

  Users can add, edit and view links on the same page as the form data.

  Users can quickly navigate to the link section using jump links at the top of the page.

- Use case

  Site users were missing or forgetting to link forms when linking was performed in a separate tab at the top of the page. This allows linking to be done on the same page as data entry.

Day 1 Impact to Clinical Teams

No

Visibility

Study Designer

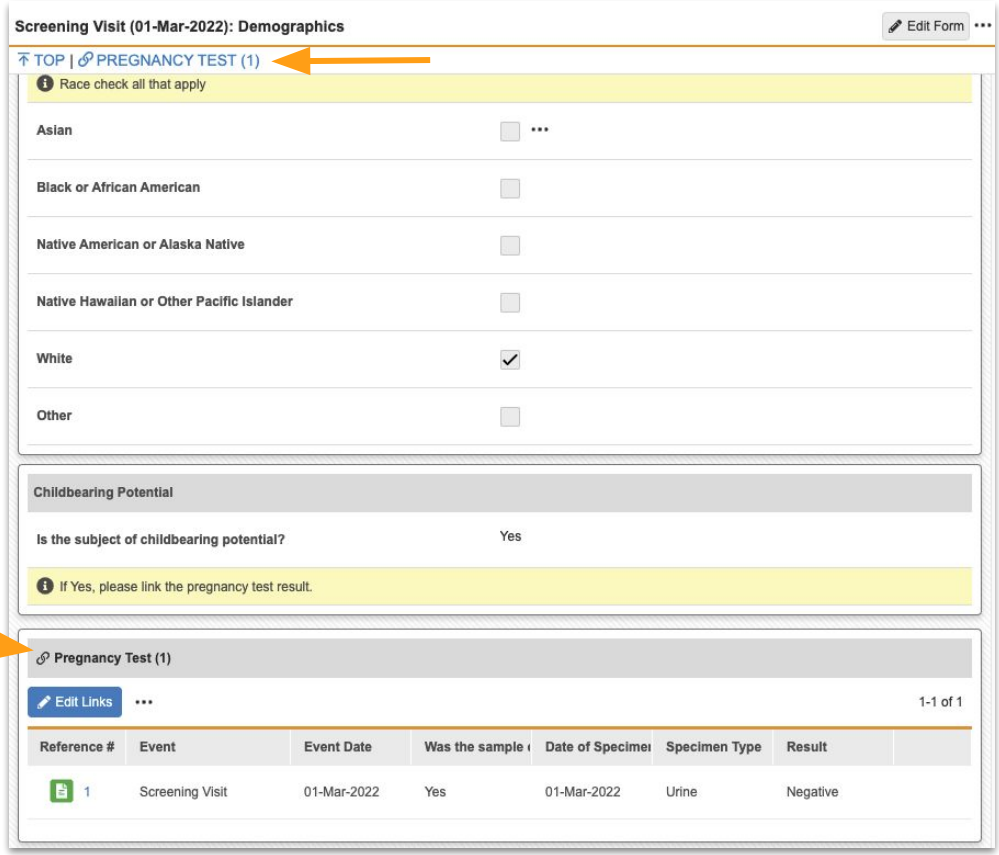
Configuration

Studio - New Studies
Vault Owner in Business Admin for existing studies

Dependencies

Form Linking must be enabled

Form Linking V2



Day 1 Impact to Clinical Teams

No

Visibility

Vault Owners

Configuration

Studio - New Studies
Vault Owner in Business Admin for existing studies

Dependencies

Form Linking must be enabled

Additive Review

- Overview

  CRAs and Data Managers can SDV or DMR items that are not required by the patient's review plan.

  When enabled, they will choose a reason why they're additively reviewing data, which will be applied to any items additively reviewed.

- Use case

  CRAs and Data Managers can now record and track their additional SDV and DMR work within CDMS.

Day 1 Impact to Clinical Teams

No

Visibility

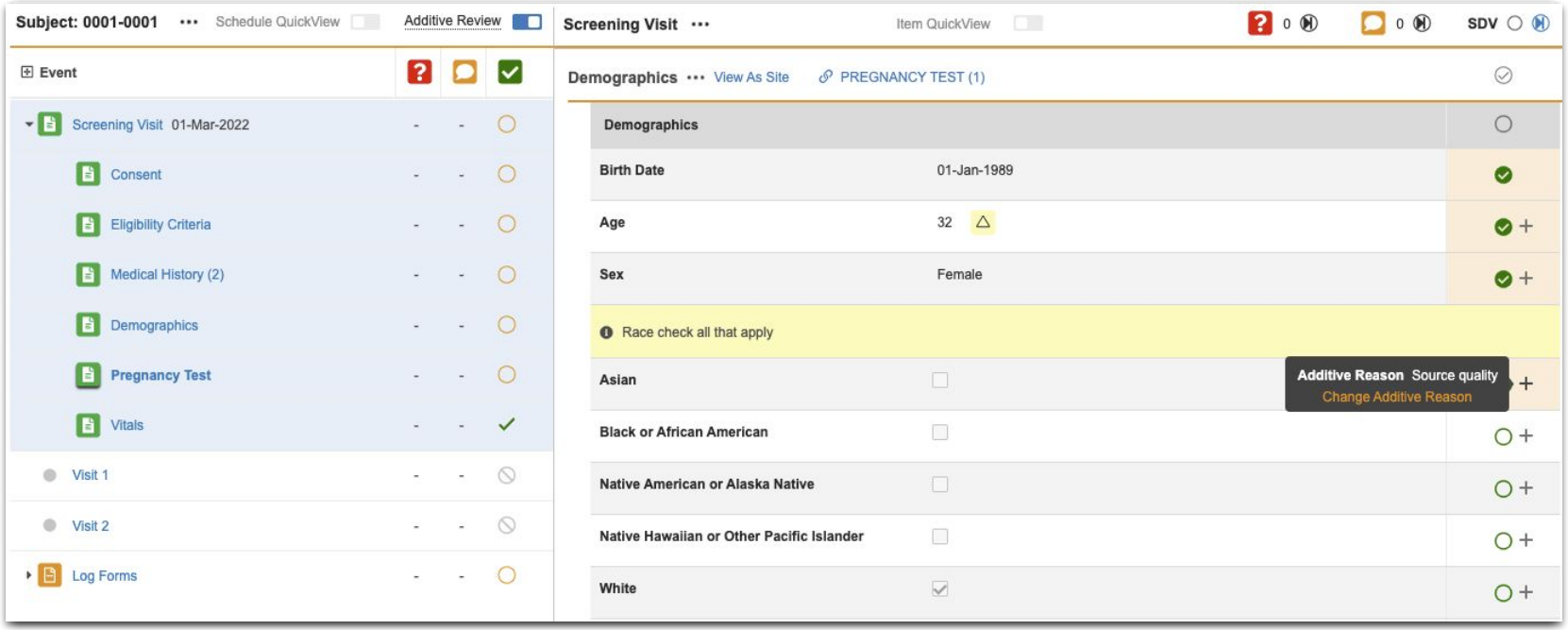
Study Designer

Configuration Studio

Dependencies

Review Rollup V2

Additive Review



Day 1 Impact to Clinical Teams

No

Visibility

Study Designer

Configuration Studio

Dependencies

Review Rollup V2

Study Listings in Review

- Overview

  CRAs and Data Managers are now able to run and schedule the below study listings from the Review Tab:

  1. Event Progress Listing
  2. Form Progress Listing
  3. Query Details Listing
  4. Subject Progress Listing

  Users can filter by study country or site.

  Available for users with access to the Review tab and Manage Jobs permission.

- Use Case

  CRAs and Data Managers can now access the study listings without needing access to EDC Tools.

Day 1 Impact to Clinical Teams

No

Visibility

CRAs and Data Managers

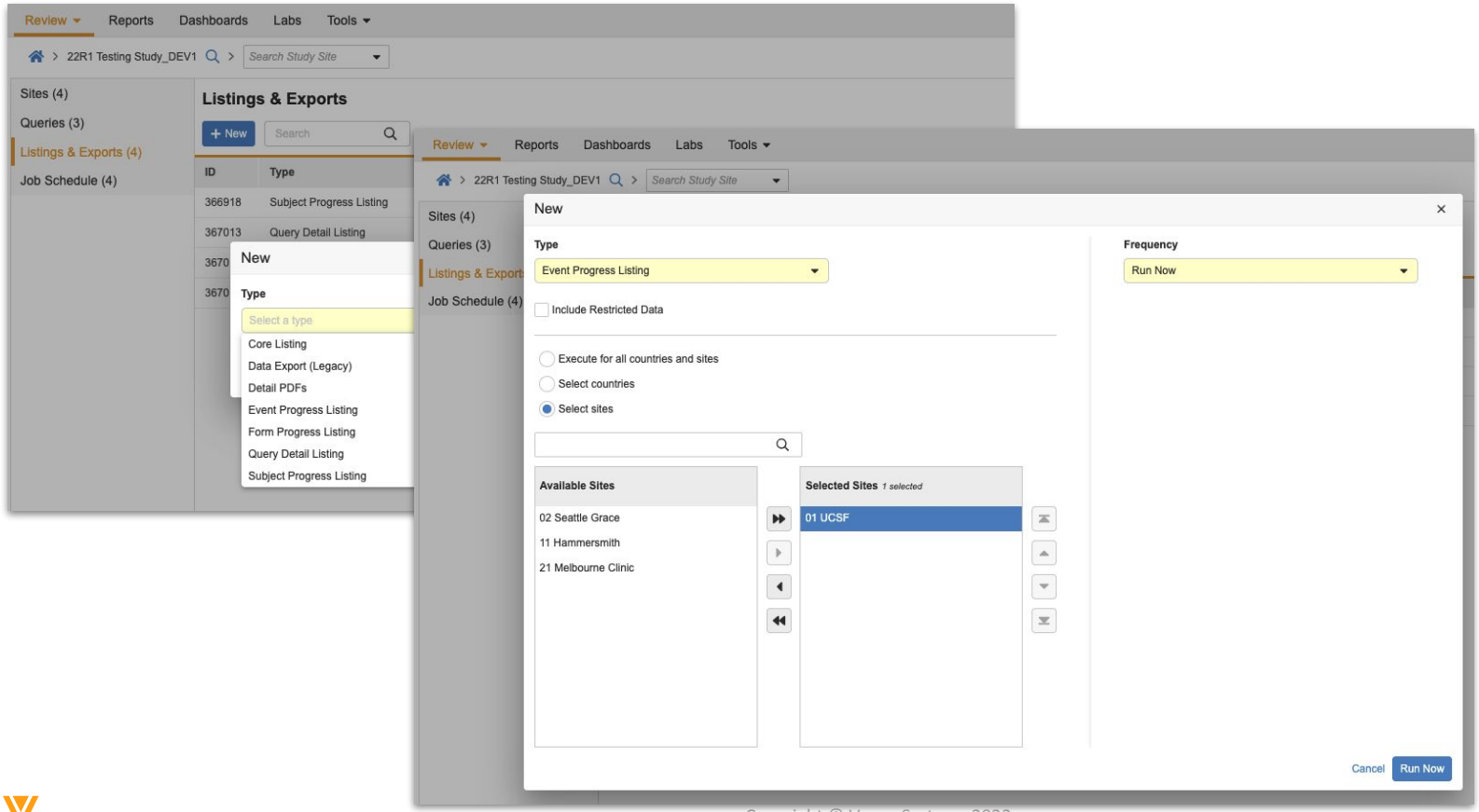
Configuration

Manage Jobs permission

Dependencies

N/A

Study Listings in Review



Day 1 Impact to Clinical Teams

No

Visibility

CRAs and Data Managers

Configuration

Manage Jobs permission

Dependencies

N/A

Study Listings in Review

Study	Country	Site	Subject	Subject Status	Most recent visit	Date of most recent visit	Next Event	Entry Complete	SDV Plan	SDV Complete	DMR Plan	DMR Complete	Frozen	Locked	Signed
22R1 Testing Study_DEV1	United States	1	0001-0001	Enrolled	Screening Visit	2022-03-01	Visit 1	No	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0002	Screen Failure	Screening Visit	2022-03-02		No	Full SDV	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0003	Enrolled	Visit 2	2022-03-10		Yes	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0004	Enrolled	Screening Visit	2022-03-02	Visit 1	No	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0005	Enrolled	Screening Visit	2022-03-01	Visit 1	Yes	Target SDV Plan	No	Data Manager Review	No	No	No	No
22R1 Testing Study_DEV1	United States	1	0001-0006	Enrolled	Screening Visit	2022-03-18	Visit 1	No	Full SDV	No	Data Manager Review	No	No	No	No

Day 1 Impact to Clinical Teams

No

Visibility

CRAs and Data Managers

Configuration

Manage Jobs permission

Dependencies

N/A

General EDC Enhancements

- Removed redundant information in repeating form headers

21R3

22R1

Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, Data Managers

Configuration

N/A

Dependencies

N/A

General EDC Enhancements

- Review users can now jump to the previous/next instance of a repeating form in Review

21R3

22R1

Day 1 Impact to Clinical Teams

Yes

Visibility

CRAs, Data Managers

Configuration

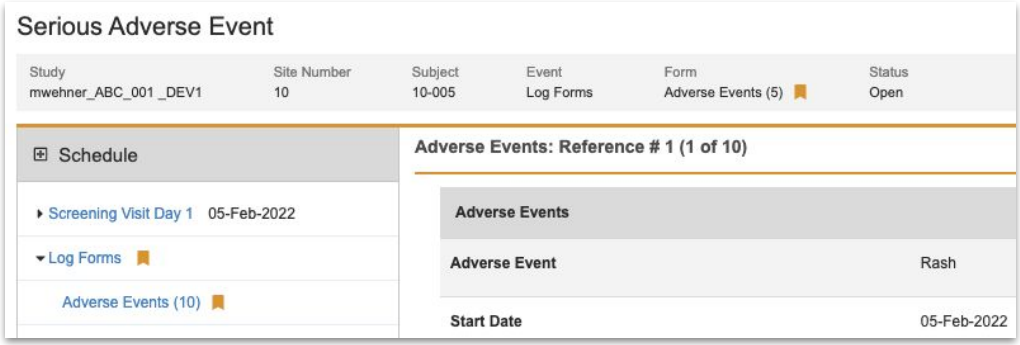
N/A

Dependencies

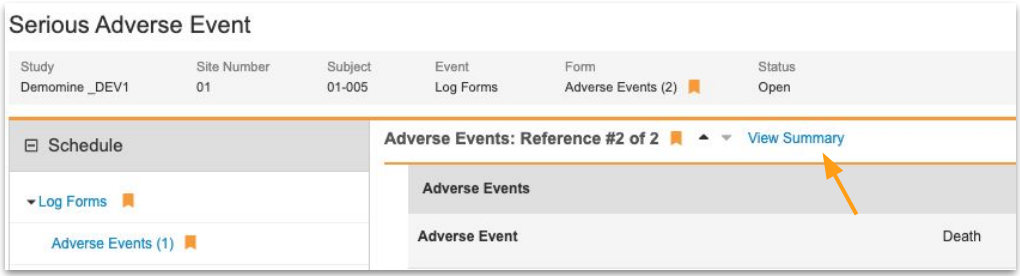
N/A

General EDC Enhancements

- Assessors can View Summary for repeating forms in Assessments



21R3



22R1

Day 1 Impact to Clinical Teams

Yes

Visibility

Assessors

Configuration

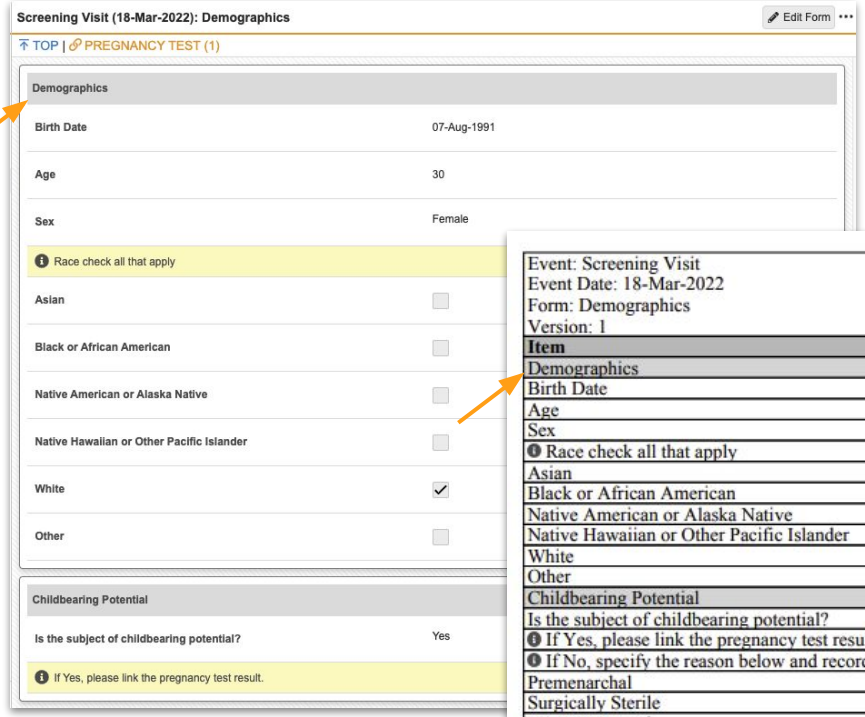
N/A

Dependencies

N/A

General EDC Enhancements

- Visible non-repeating Item Group headers will now display in the Detail PDF



Event: Screening Visit
Event Date: 18-Mar-2022
Form: Demographics
Version: 1

Item	Value
Demographics	
Birth Date	07-Aug-1991
Age	30
Sex	Female
Race check all that apply	
Asian	
Black or African American	
Native American or Alaska Native	
Native Hawaiian or Other Pacific Islander	
White	true
Other	
Childbearing Potential	
Is the subject of childbearing potential?	Yes
If Yes, please link the pregnancy test result.	
If No, specify the reason below and record any necessary information on the Medical History form. (select all that apply)	
Premenarchal	
Surgically Sterile	
Postmenopausal	
Other	

Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, Data Managers

Configuration

N/A

Dependencies

N/A

Local Labs

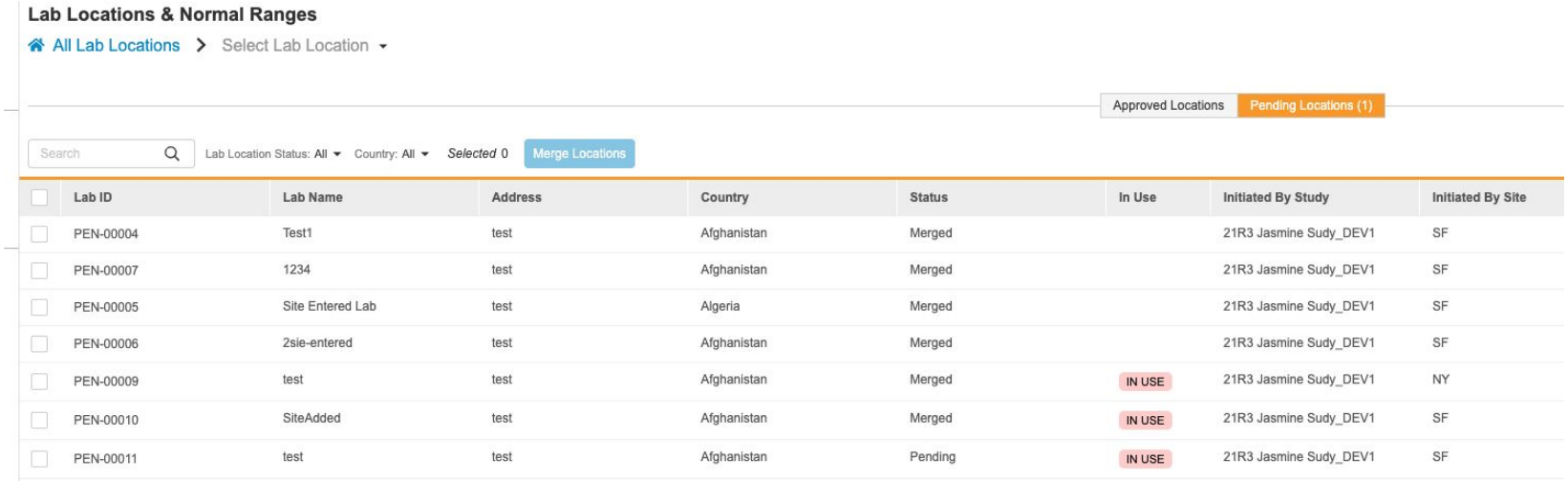
Lab Initiated by Study/Site

- Overview

  For studies with Local Labs and approvals enabled, there is a new column in Approved and Pending Locations that will indicate which Study/Site initiated the Lab

- Use case

  Allow managers to be able to search for Labs via the Study or Site that created it



Lab ID	Lab Name	Address	Country	Status	In Use	Initiated By Study	Initiated By Site
PEN-00004	Test1	test	Afghanistan	Merged		21R3 Jasmine Sudy_DEV1	SF
PEN-00007	1234	test	Afghanistan	Merged		21R3 Jasmine Sudy_DEV1	SF
PEN-00005	Site Entered Lab	test	Algeria	Merged		21R3 Jasmine Sudy_DEV1	SF
PEN-00006	2sie-entered	test	Afghanistan	Merged		21R3 Jasmine Sudy_DEV1	SF
PEN-00009	test	test	Afghanistan	Merged	IN USE	21R3 Jasmine Sudy_DEV1	NY
PEN-00010	SiteAdded	test	Afghanistan	Merged	IN USE	21R3 Jasmine Sudy_DEV1	SF
PEN-00011	test	test	Afghanistan	Pending	IN USE	21R3 Jasmine Sudy_DEV1	SF

Day 1 Impact to Clinical Teams

Yes

Visibility

Data Manager, Lab Manager

Configuration

N/A

Dependencies

Labs Enabled

Outdated Normals Report - New Columns

- Overview

  There are 2 new columns in the Outdated Normals Report - Lab Name (Title) and Lab ID

- Use case

  When the eCRFs have outdated normals, this report will show what Lab Name and ID was selected on the form that shows a different lab normal than what was selected on the eCRF

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Study	Study Site	Subject	Event Group Label	Event Group Sequence Number	Event Label	Form Label	Form Sequence Number	Lab ID	Lab Title	Lab Panel	Analyte Definition Label	Normal Low	Norm High
2	21R3 Jasmin	SF	SCR-0001	Screening	1	Screenings	Lab Form Blo	1	CopyUCSF	COPY Univ of San Francisco	Blood Gases	pH		
3	21R3 Jasmin	SF	SCR-0001	Screening	1	Screenings	Lab Form Se	1	UCSF	Univ of San Francisco	Serology	Hepatitis B		
4	21R3 Jasmin	SF	SCR-0003	Screening	1	Screenings	Lab Form Se	1	UCSF	Univ of San Francisco	Serology	Hepatitis B		
5														
6														

Day 1 Impact to Clinical Teams

Yes

Visibility

Data Manager, Lab Manager

Configuration

N/A

Dependencies

Labs Enabled

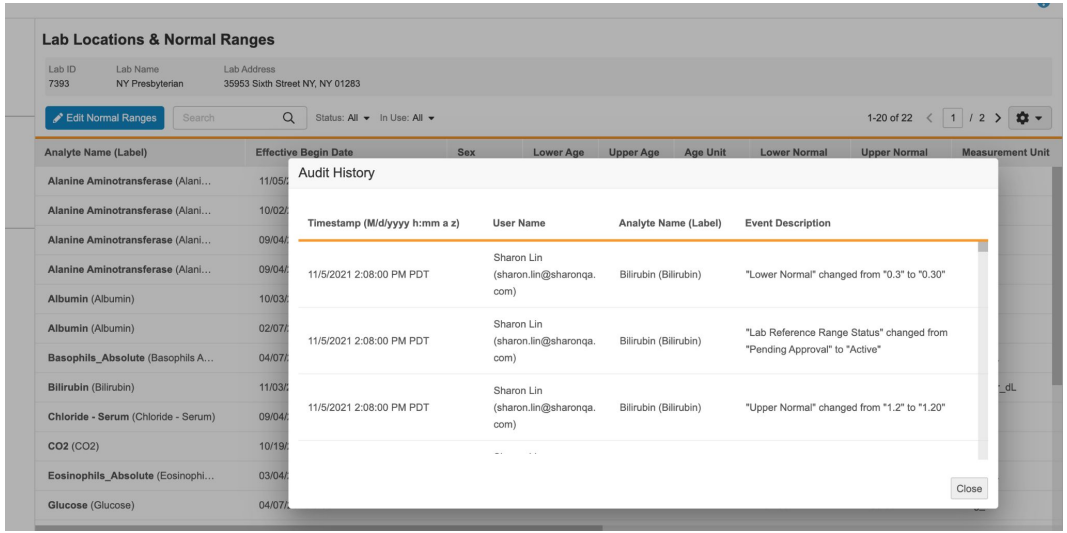
Audit Trail - added column

- Overview

  The Audit trail history in the Lab Normals has an added column - Analyte Name

- Use case

  This makes the consolidated audit trail more consumable showing which analyte the change referred to



Day 1 Impact to Clinical Teams

Yes

Visibility

Data Manager, Lab Manager

Configuration

N/A

Dependencies

Labs Enabled

Dedicated DEMO

For a dedicated demo of any these features,

please contact your

Account Executive OR

Customer Success Manager

Thank you