22R2 Customer Webinar For All

July 7, 2022

Veeva

CDMS Product Managers

Margaret Wehner

Product Manager

Data Entry, Review UI, Medical Assessments, Reports

Sharon Lin

Sr. Principal Product Manager

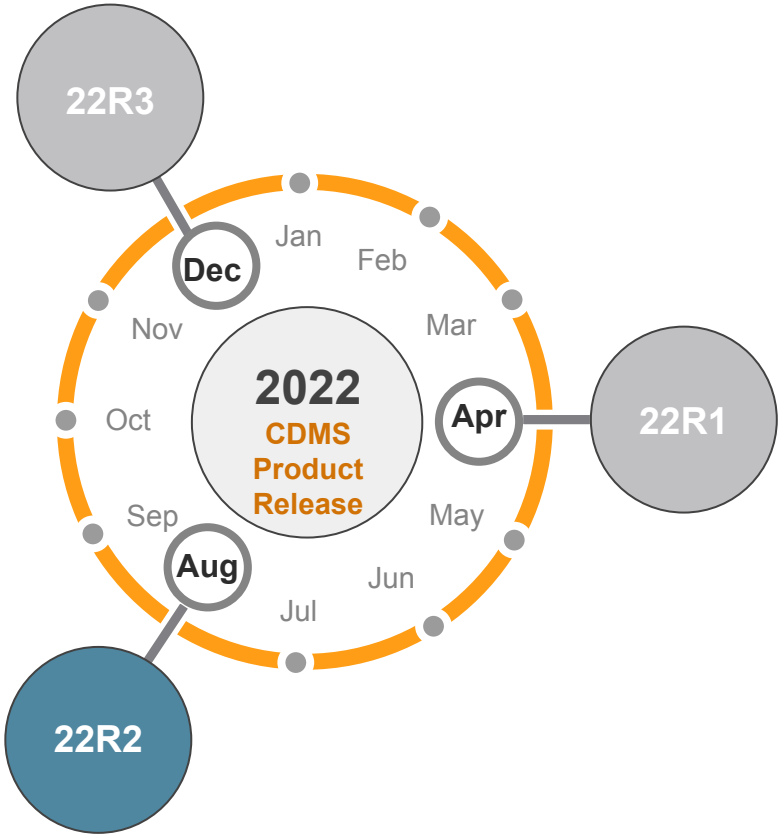
Local Labs, Randomization

John Roeckel (JB)

Product Manager

Data Entry, Query Handling

Veeva Vault Release Schedule



22R2 Release Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
JUL	04	05	06	07 **22R2 Release Webinar** 9 AM PT - All Customers 10 AM PT - Studio, Admin, Coder	08 **22R2 Pre-Release Upgrade**	09
10	11 Validation Docs	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
AUG	01	02	03	04	05 **22R2 General Release Upgrade**	23

Customer Validation

22R2 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 22R2 Release**

Validation Docs

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

22R2 Release

- All Customers Vaults upgraded to 22R2

Additional Validation Docs

- Validation Summary Report
- Executed OQ Scripts

Available Resources

https://cdmshelp.veeva.com/lr/rn/general-releases/22r2/

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

22R2 Feature Summary

Sites

- Data Entry updates
- Audit Trail Enhancements
- Assessment Enhancements
- Reassessments

Reports/Extracts

- Study Summary Metrics Report
- Event Progress Listing - Review Data
- Additive Review Listing
- Listings Enhancements
- SDE Enhancements
- Jobs Enhancements

Study Designer

- Property Panel Enhancements
- Object Usage Report
- Codelist Max Length
- General Rules Enhancements

Other

- CTMS Restricted Data Support
- CTMS Arms & Cohorts Support
- CDMS APIs

Admin

- Copy Study Data
- EDC Tools Study Settings
- Study Role Enhancements
- User Management Enhancements
- Learning Management Enhancements
- My Training Tab
- Vault Level Deployment to Template Vaults

Local Labs

- Global Versionless Labs
- Lab Header updates

Coding

- Dictionary Search Result Enhancement

Safety Link

- Mappable E2B ID E.i.9
- Follow-up vs Amendment

Local Labs

New Lab Architecture - Global Versionless Local Labs

BENEFIT

NO copying of Lab Units/Codelists into Studio

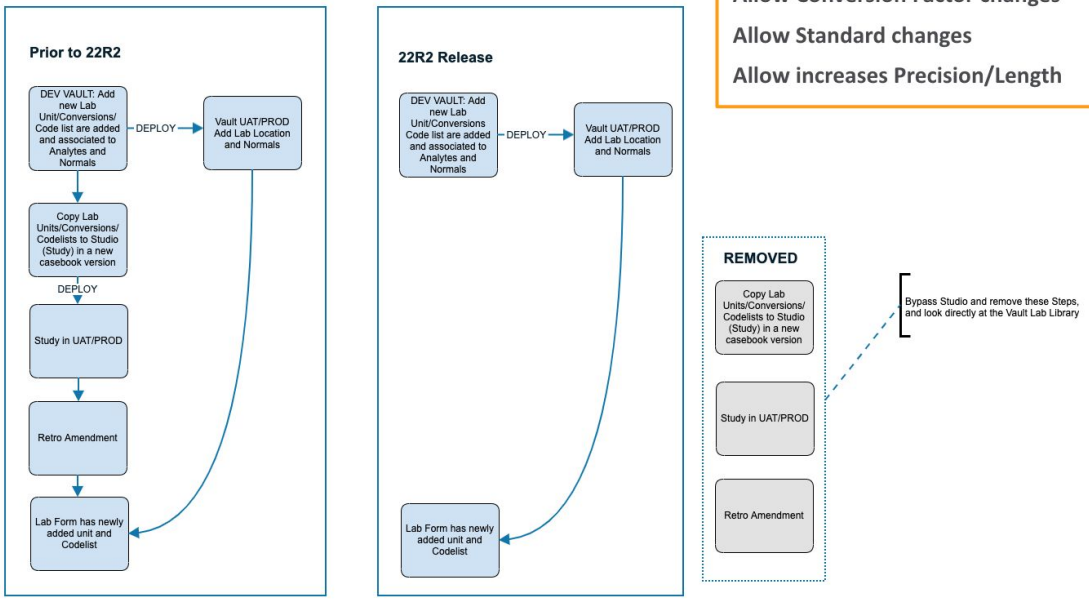
NO Deployments/Retro-amendments needed because a new Lab Unit is added

NO artificial increase in casebook versions

Allow Conversion Factor changes

Allow Standard changes

Allow increases Precision/Length



Global Versionless Labs

- Overview
  - The new Global Local Lab Architecture will directly consume Lab units, codelists, precision/length from Local Lab module and no longer from Studio for Lab eCRFs.
  - No more synching of the Lab Units/Codelists with Studio
  - No more increasing Casebook Versions, Studio Deployments, and Retro-amendments
  - Yes to Post Go Live changes to Unit Conversion Factors, Unit Standard changes, and increases to Precision and Length
  - Applicable to new studies created after 22R2, existing Studies will have to migrate. Migration will be performed by Veeva Services team.

- *Note: Global Labs is NOT supported in Utilities, but studies will be able to use listings that does not contain clinical lab data. The Study Data Extract (SDE) will support both Global and non-GLobal studies.*

- Use case

  Be able to add/update Lab Units and Codelists without creating a new casebook version, deploying, and performing a retro- amendment for each study.

Day 1 Impact to Clinical Teams

No

Visibility

Data Manager, Lead Data Manager, Lab Manager, Study Designers

Configuration

N/A

Dependencies

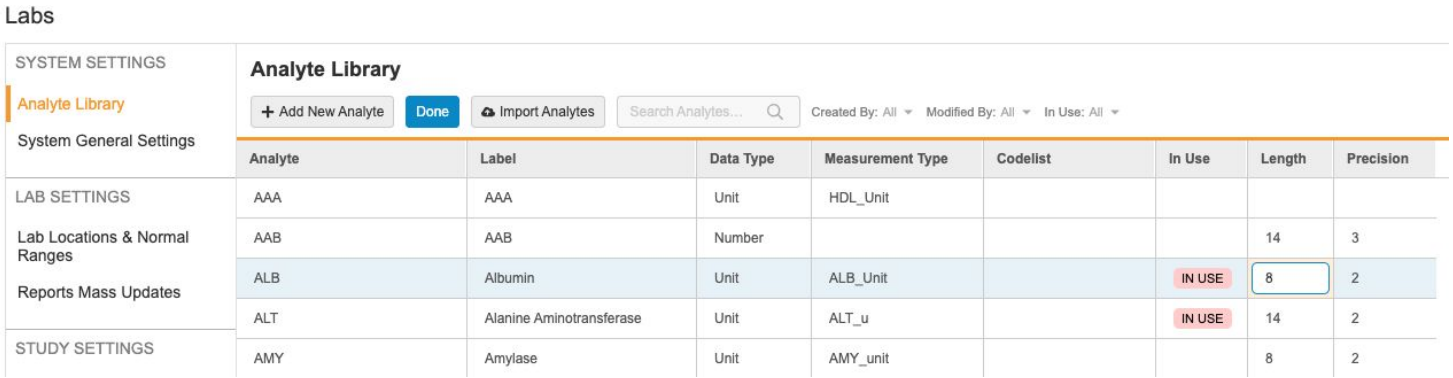
Labs Enabled New Studies Database Model 2

Increasing Precision and Length

- Overview
  - Precision and Length can be increased when analyte is marked “in use”
    - For new studies on the Global Labs, increasing precision and length is only done in the Lab Module
    - For existing studies, increases must be done in Local Labs and Studio to stay in sync
      - Studio will now allow increases to Precision and Length

- Use case

  Realizing that the Precision and Length was inaccurate after objects (eg. Lab Panels) were already associated to it, and still be allowed to update it.



Day 1 Impact to Clinical Teams

No

Visibility

Data Manager, Lead Data Manager, Lab Manager

Configuration

N/A

Dependencies

Labs Enabled
New Studies Database Model 2

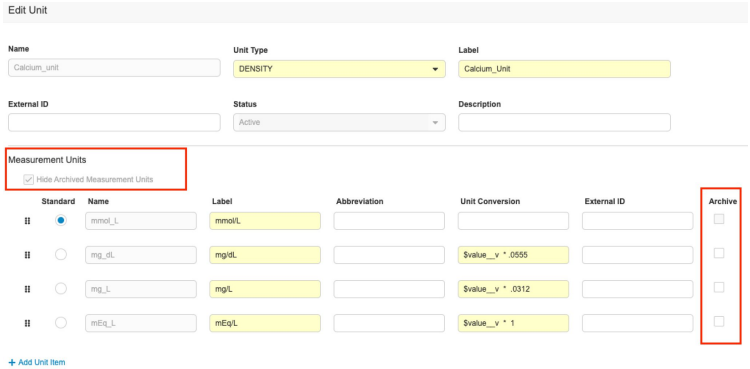
Archiving Lab Units/Codelists

- Overview
  - The Lab Units and Codelists will now be archived instead of deleted.
  - Lab Units and Codelists Name will be locked once saved. Labels, Unit Conversions, and Unit standards can be updated.
  - Once archived, Lab Normals will not be able to select the unit or codelist item (new and existing studies). Still preserved for previous Lab Normals, but once in edit mode, will not be able to select the archived item
  - Once archived, Labe eCRFS will not be able to select the unit or codelist item. Still preserved for existing Lab eCRFs, but once in edit mode, will not be able to select the archived item.
    - For the older architecture (Non - Global) existing studies, the Unit/Codelist item will still need to be hidden in Studio

- Use case

  Be able to archive a unit or codelist item

  that is no longer needed.



Day 1 Impact to Clinical Teams

No

Visibility

Data Manager, Lead Data Manager, Lab Manager

Configuration

N/A

Dependencies

Labs Enabled
New Studies
Database Model 2

Mass Update: Preview/Update Translated Value

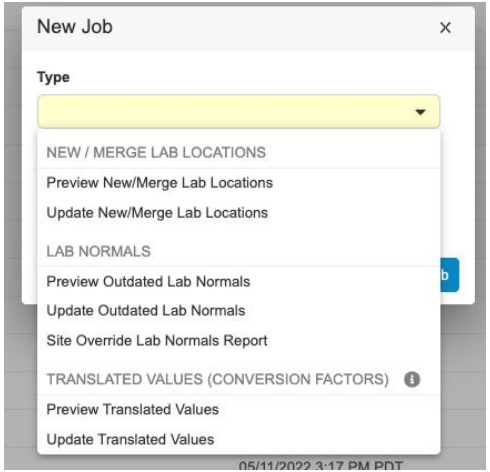
- Overview
  - With the allowance of Post Go Live updates to unit conversion factors and standards, existing forms who used the old unit conversion factors or different standards need to be updated to the new unit conversion factor or standards. A Mass update will need to be run on all the existing eCRFs to update to the new unit conversions/or standards.
  - Mass updates to Preview and Update Translated Values are *only available for Studies on Global Labs.*
  - Locked and Frozen items will not be updated with the mass update. If it needs to be updated, unlock or unfreeze and then run the mass update again.

Note - Change in the Report and Job Names for Mass Updates

- Use case

  Be able to easily update a unit conversion

  or unit standard Post Go Live



Day 1 Impact to Clinical Teams

No

Visibility

Data Manager, Lead Data Manager, Lab Manager

Configuration

N/A

Dependencies

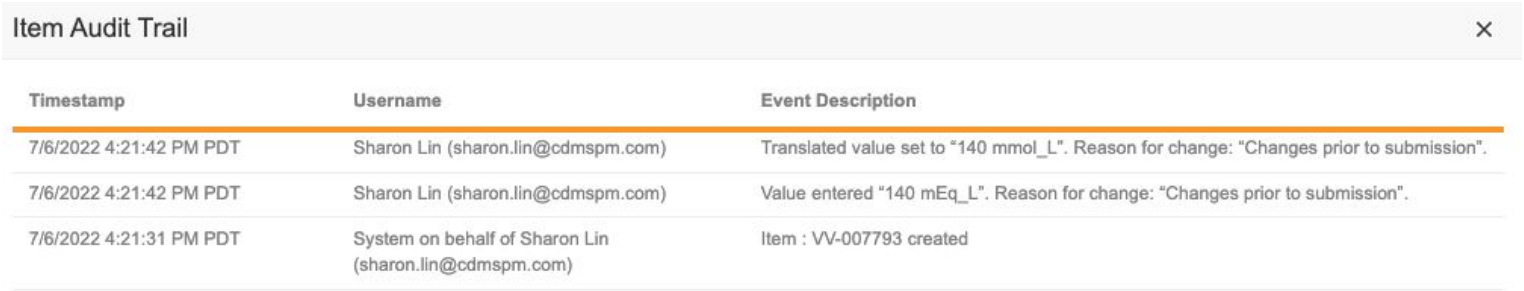
Labs Enabled
New Studies on Global Database Model 2

Audit Trail - Translated Values

- Overview
  - The Audit trail in the Data Entry now shows translated values if the item is a unit. This applies to Lab Forms and non - Lab Forms

- Use case

  Be able to see the translated value display in the Audit trail. Especially beneficial when a Mass Update - Update Translated Value job has been run on eCRFs.



Item Audit Trail

Timestamp	Username	Event Description
7/6/2022 4:21:42 PM PDT	Sharon Lin (sharon.lin@cdmspm.com)	Translated value set to "140 mmol_L". Reason for change: "Changes prior to submission".
7/6/2022 4:21:42 PM PDT	Sharon Lin (sharon.lin@cdmspm.com)	Value entered "140 mEq_L". Reason for change: "Changes prior to submission".
7/6/2022 4:21:31 PM PDT	System on behalf of Sharon Lin (sharon.lin@cdmspm.com)	Item : VV-007793 created

Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, Data Manager, Lead Data Manager

Configuration

N/A

Dependencies

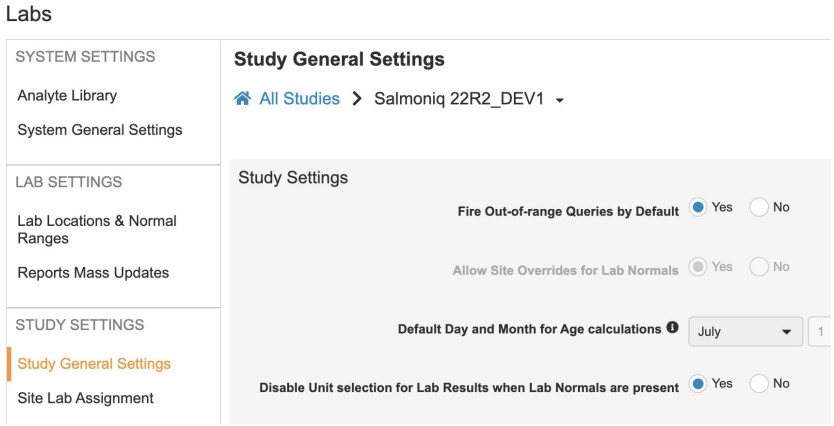
Labs Enabled
Database Model 2

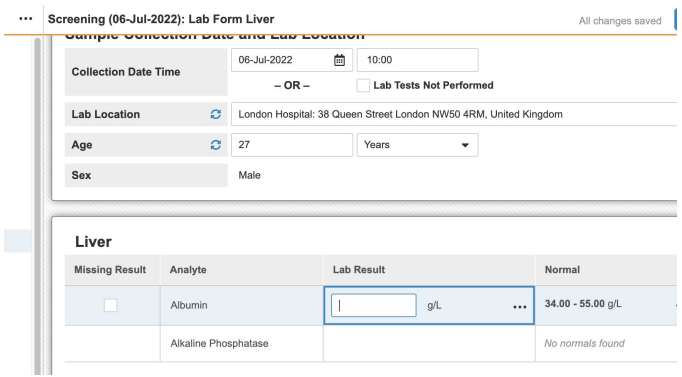
Disable Unit Selection for Lab Results when Lab Normals are Present

- Overview
  - Configure Lab eCRFs so a Site can not update the Lab Result unit. The Lab result unit will be the approved Lab Normal Unit.

- Use case

  Some sponsors do not want the Site to update the Lab Result unit. If the Lab Result unit is incorrect, the Site can add an Override Lab Normal unit (if configured).





Day 1 Impact to Clinical Teams

Yes

Visibility

Data Manager, Lead Data Manager

Configuration

Yes

Dependencies

Labs Enabled

Studio Updates

- Overview
  - Global Labs - New Items being Added when Labs is enabled
    - Age (LBAGE), Sex (LBSEX), and Female Cycle (LBFEMALECYCLE)
      - New item LBSEX, use that in the eCRF, and add that to your casebook variable
      - No longer have to add the Lab_sex codelist to a Sex item. The Sex item is automatically created for you (LBSEX), but you still need to add it in the casebook variable.
  - New Study created after 22R2 will be in the new Global Labs
    - Warning: Copying a study with the older Labs architecture model, it will create a new study with the old labs model. Migration to the new Labs Global Versionless Model will be necessary.
  - Lab units and Lab codelists will no longer be created in Studio when the Lab panel is saved, since the Lab eCRFs will look directly to the Lab Module.

- Use case

  The Lab Sex item will be created automatically, so users don't have to create it. And the new Global model will no longer have to sync to Studio, therefore creation of Lab Units and Codelists is not necessary.

Day 1 Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

Studio

Dependencies

Labs Enabled
New Studies
Database Model 2

Summary

Feature	Global Versionless (new model)	Study Level Version (old model)
Increasing Precision and Length	Config only in Labs	Config in Labs. Must be increased in Studio in New Casebook Version, Deployment, Retro-amendment
Lab Units	Config only in Labs	Config in Labs. Must be synched to Studio in New Casebook Version, Deployment, Retro-amendment
Lab Codelists	Config only in Labs	Config in Labs. Must be synched to Studio in New Casebook Version, Deployment, Retro-amendment
Lab Unit/Codelist Archive (hide)	Config only in Labs	Config in Labs. Must be hidden in Studio in New Casebook Version, Deployment, Retro-amendment
Lab Unit Conversions change post go live	Update conversion in Labs. Run Mass update - Update Translated Values	Config in Labs - Create a new lab unit item with the new lab unit conversion. Must be synched to Studio in New Casebook Version, Label the old unit item do not use. Deployment, Retro-amendment.
Lab Unit Standard change post go live	Update Standard in Labs. Run Mass update - Update Translated Values	Config in Labs - Create a new lab unit with the new lab unit standard. Must be synched to Studio in New Casebook Version, Label the old unit item do not use. Deployment, Retro-amendment.
Disable Unit selection for Lab Results when Lab Normals are Present	Same	Same
Audit Trail for Translated Values	Same	Same

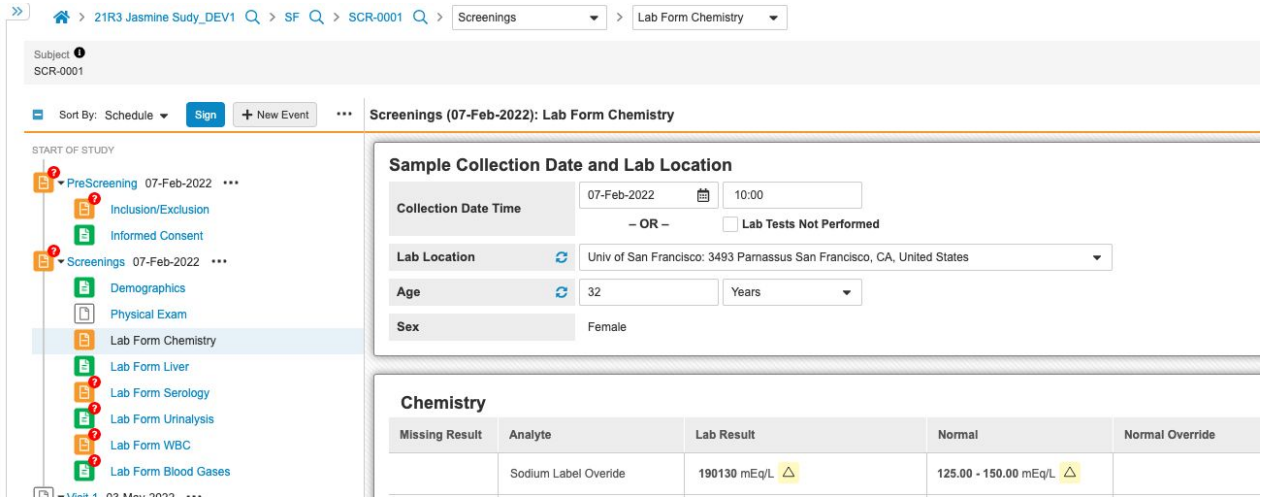
Lab Header Updates

- Overview

  For easier and streamlined data entry, the lab header has been updated to a new look and feel.

- Use case

  When entering data on a lab form, the collection date, lab location, age and sex will be left aligned, making it easier to enter data on smaller screens.



Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users

Configuration

N/A

Dependencies

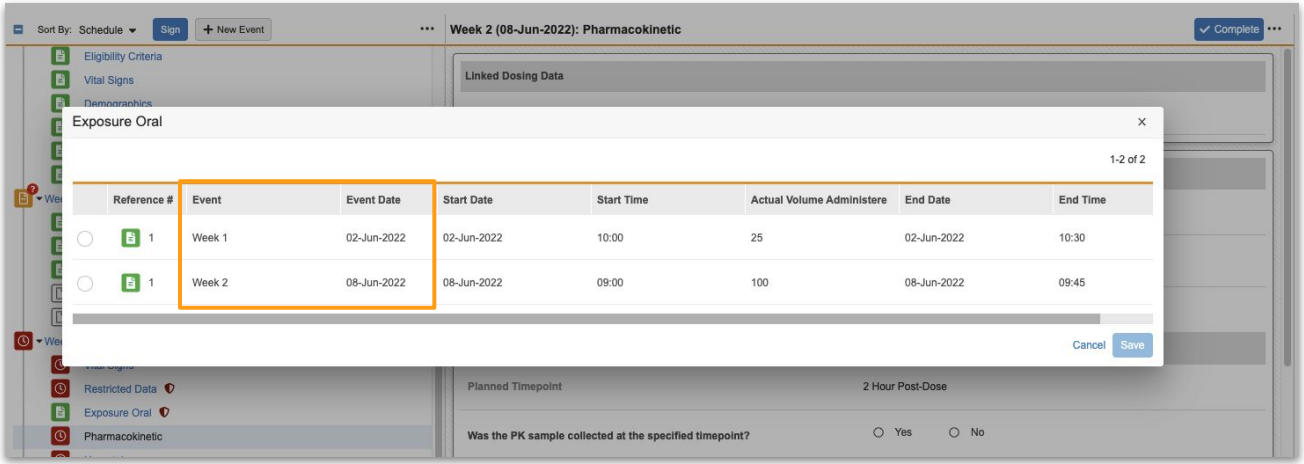
Labs enabled

Data Entry

Data Entry Updates

- Overview
  - Event & Event Date in Item form Linking Dialog
  - New icon for ILB
  - Hint Labels in Detail & Closeout PDFs

- Use case
  - Consistency with data entry UI and UI/UX patterns



Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users

Configuration

N/A

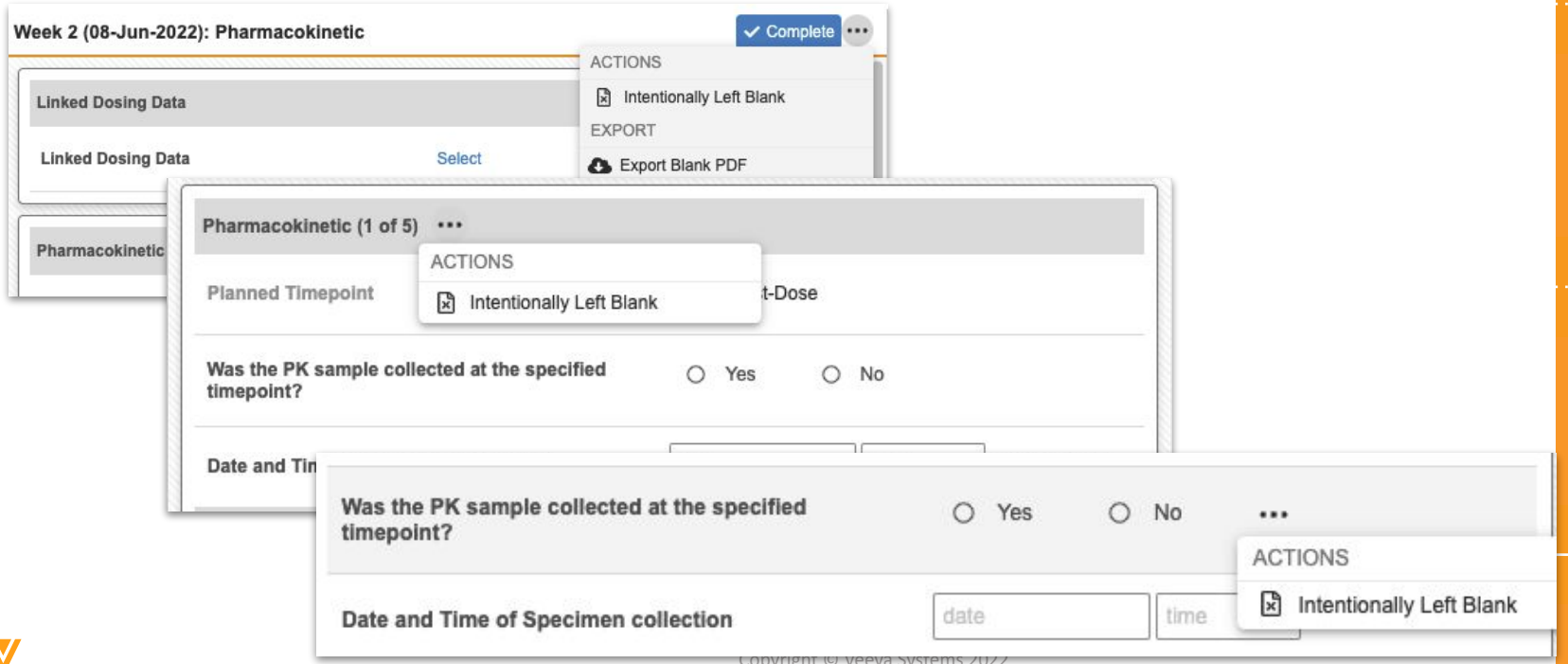
Dependencies

N/A

Data Entry Updates

New icon for ILB

- Form
- Item Group
- Item



Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users

Configuration

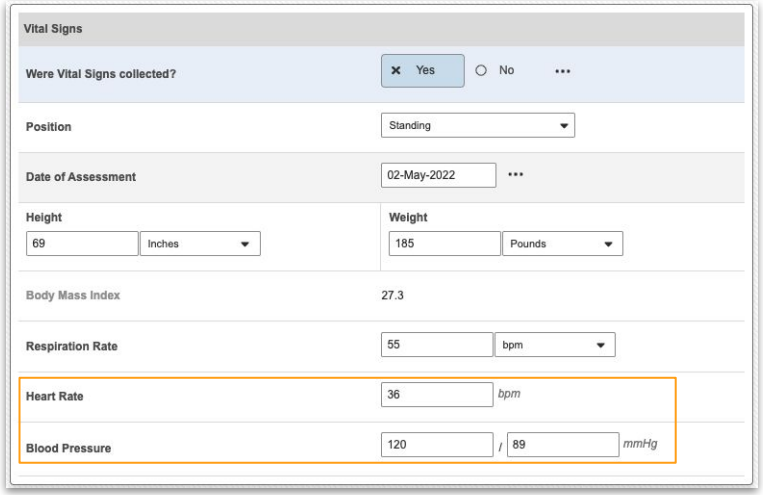
N/A

Dependencies

N/A

Data Entry Updates

Hint Labels in Detail & Closeout PDFs



Form in EDC

Event: Screening Visit Day 1
Event Date: 02-May-2022
Form: Vital Signs
Version: 1

Item	Value
Vital Signs	
Were Vital Signs collected?	Yes
Position	Standing
Date of Assessment	02-May-2022
Height	69 Inches
Weight	185 Pounds
Body Mass Index	27.3
Respiration Rate	55 bpm
Heart Rate	36 [bpm]
Systolic Blood Pressure	120
Diastolic Blood Pressure	89 [mmHg]

Form in Detailed PDF

Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users

Configuration

N/A

Dependencies

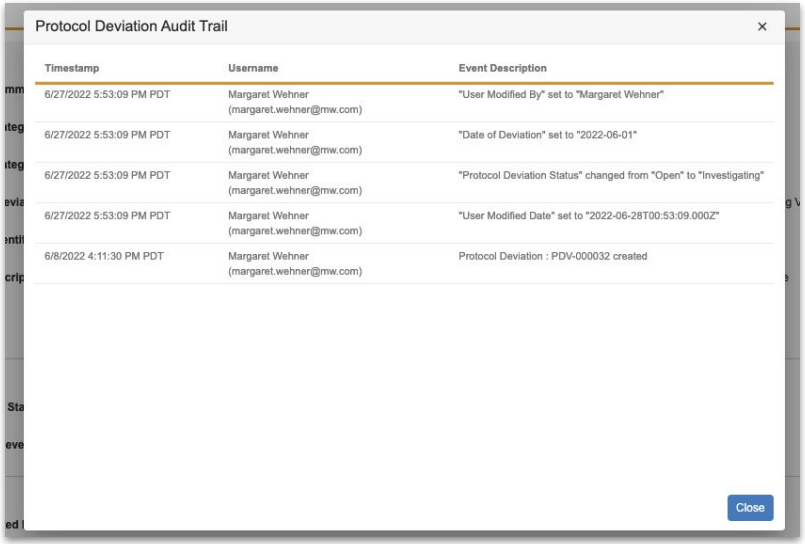
N/A

Audit Trail Enhancements

- Overview
  - Form Link Audit Trail is available in Review
  - PDs and Assessments in Audit Trail Export
  - Updated look & feel for PD Audit Trail
  - Event Audit Trail to include:
    - Event Date
    - Planned Date
    - Overdue Date
  - Form Audit Trail to include:
    - Site
    - Country
  - Entry in Form Audit if legal statement changes

- Use case

  Gives users more access to their audit data.



Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, DMs

Configuration

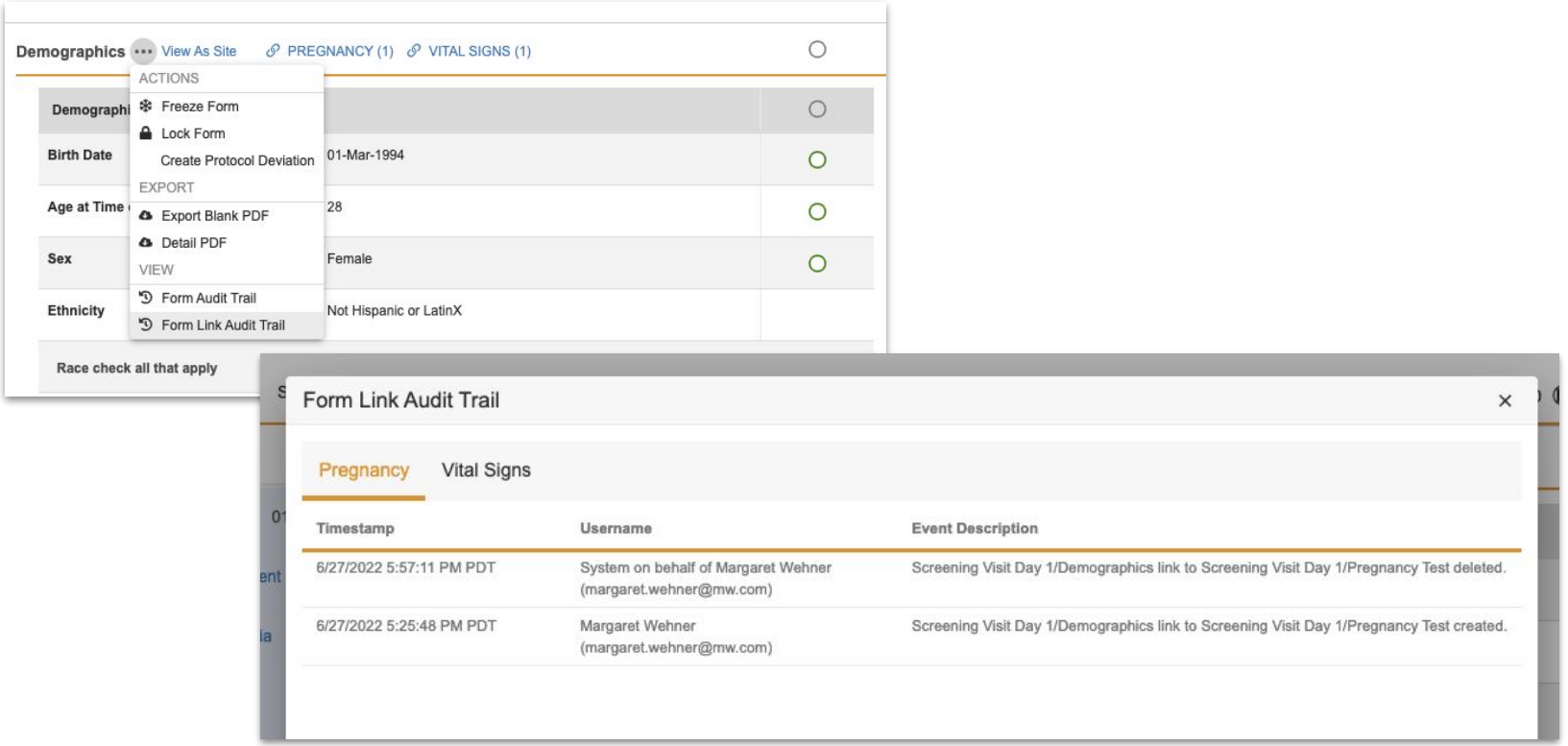
N/A

Dependencies

N/A

Audit Trail Enhancements

Form Link Audit Trail in Review



Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, DMs

Configuration

N/A

Dependencies

N/A

Audit Trail Enhancements

PDs and Assessments in Audit Trail Export

Audit Timestamp	Audit User	Assessment	Object	Record ID	Record Name	Audit Description
14-May-2022 01:18:36 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000023	Pregnant Patient	Protocol Deviation : PDV-000023 created
14-May-2022 01:18:53 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	Protocol Deviation : PDV-000024 created
20-May-2022 00:18:42 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000023	Pregnant Patient	"Description" set to "Patient was positive on first test, but negative on second test"
20-May-2022 00:18:42 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000023	Pregnant Patient	"User Modified Date" set to "2022-05-20T00:18:42.000Z"
20-May-2022 00:18:42 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000023	Pregnant Patient	"Protocol Deviation Status" changed from "Open" to "Investigating"
20-May-2022 00:18:42 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000023	Pregnant Patient	"Date of Deviation" set to "2022-05-02"
20-May-2022 00:18:42 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000023	Pregnant Patient	"User Modified By" set to "Margaret Wehner"
20-May-2022 00:19:22 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"User Modified Date" set to "2022-05-20T00:19:22.000Z"
20-May-2022 00:19:22 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"Protocol Deviation Status" changed from "Open" to "Investigating"
20-May-2022 00:19:22 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"Date of Deviation" set to "2022-05-02"
20-May-2022 00:19:22 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"User Modified By" set to "Margaret Wehner"
20-May-2022 00:26:01 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"Resolution" set to "Data entry error - Informed consent was signed at the screening visit."
20-May-2022 00:26:01 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"User Modified Date" changed from "2022-05-20T00:19:22.000Z" to "2022-05-20T00:26:01.000Z"
20-May-2022 00:26:01 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"Protocol Deviation Status" changed from "Investigating" to "Inactive"
20-May-2022 00:26:01 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"Last Inactivated Date" set to "2022-05-20T00:26:01.000Z"
20-May-2022 00:26:01 UTC	Margaret Wehner (margaret.wehner@mw.com)		Protocol Deviation	PDV-000024	Date of Informed Consent	"Inactivated By System" set to "false"
09-Jun-2022 03:27:46 UTC	System	serious_adverse_event	Assessment	VV-000019	serious_adverse_event	Assessment : VV-000019 created
09-Jun-2022 03:27:48 UTC	System	serious_adverse_event	Assessment Response	VV-000028	Comment	Assessment Response : VV-000028 created
09-Jun-2022 03:27:48 UTC	System	serious_adverse_event	Assessment Response	VV-000029	SAE_Number	Assessment Response : VV-000029 created
28-Jun-2022 00:08:05 UTC	Margaret Wehner (margaret.wehner@mw.com)	serious_adverse_event	Assessment Response	VV-000028	Comment	"Answer" set to "Yes, this is a serious adverse event. Please reconcile with pharmacovigilance database."
28-Jun-2022 00:08:05 UTC	Margaret Wehner (margaret.wehner@mw.com)	serious_adverse_event	Assessment Response	VV-000029	SAE_Number	"Answer" set to "123"

Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, DMs

Configuration

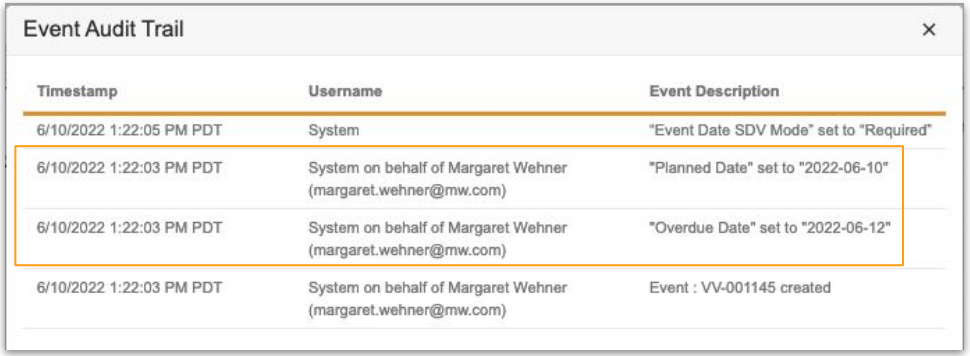
N/A

Dependencies

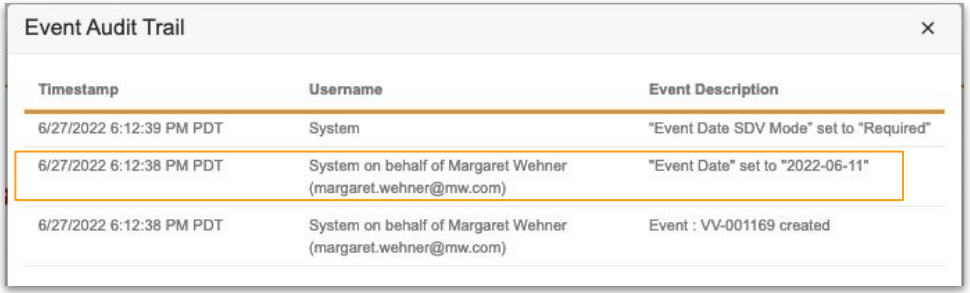
N/A

Audit Trail Enhancements

Event Audit Trail Updates



Scheduled Offset Events



Unscheduled Events

Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, DMs

Configuration

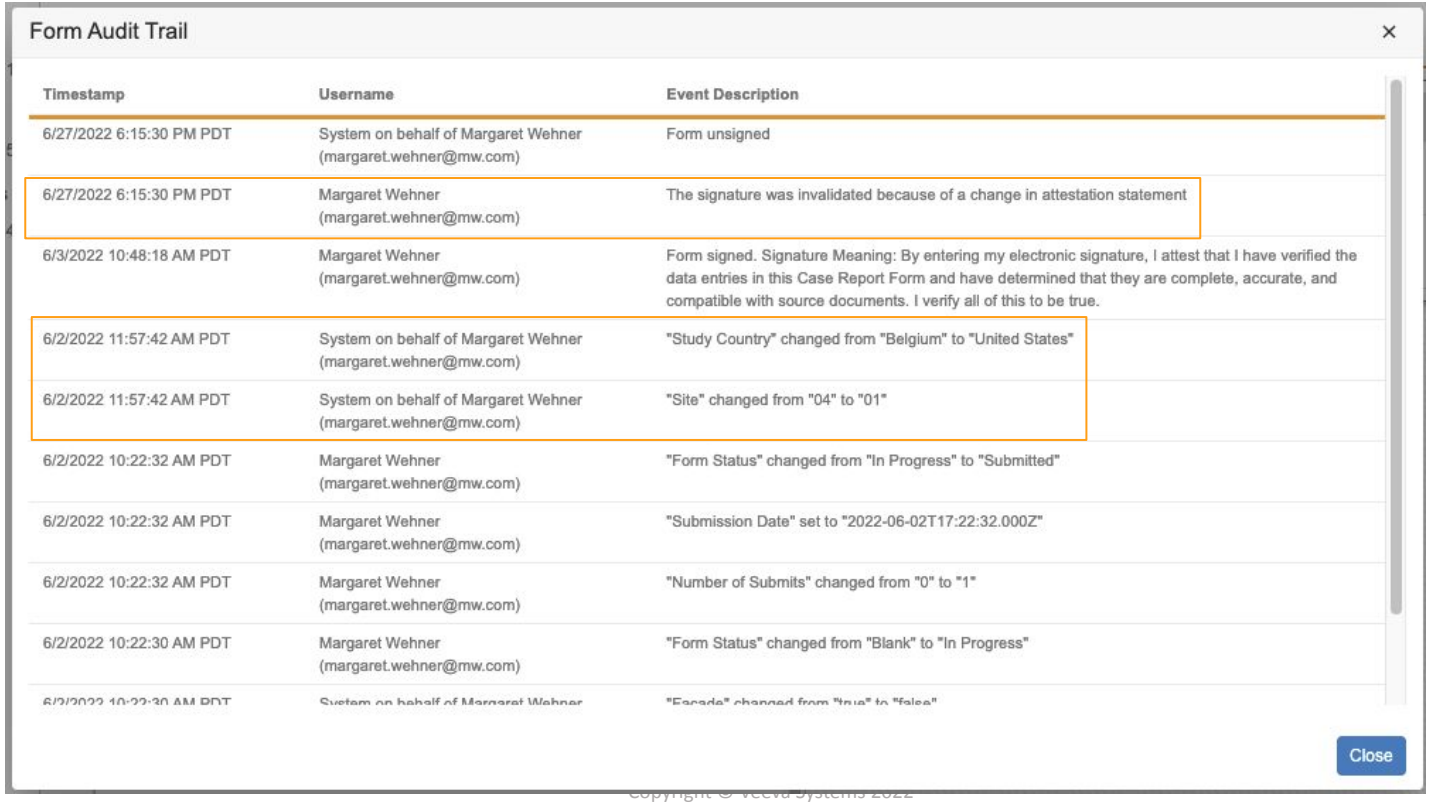
N/A

Dependencies

N/A

Audit Trail Enhancements

Form Audit Trail Updates



Day 1 Impact to Clinical Teams

Yes

Visibility

Site Users, CRAs, DMs

Configuration

N/A

Dependencies

N/A

Reassessment

Reassessment

- Overview
  - New Reassessment tab in the assessment definition in Studio that allows the user to choose which visible items should trigger a reassessment when data changes
  - Reassessment only opens when the previous assessment is completed
  - Previous assessment is made obsolete and new assessment is opened and marked as a reassessment

- Use case

  When data changes since the last assessment, a new assessment will open allowing an assessor to make an assessment on the latest data.

Day 1
Impact to Clinical Teams

No

Visibility

Study Designers

Configuration

Studio

Dependencies

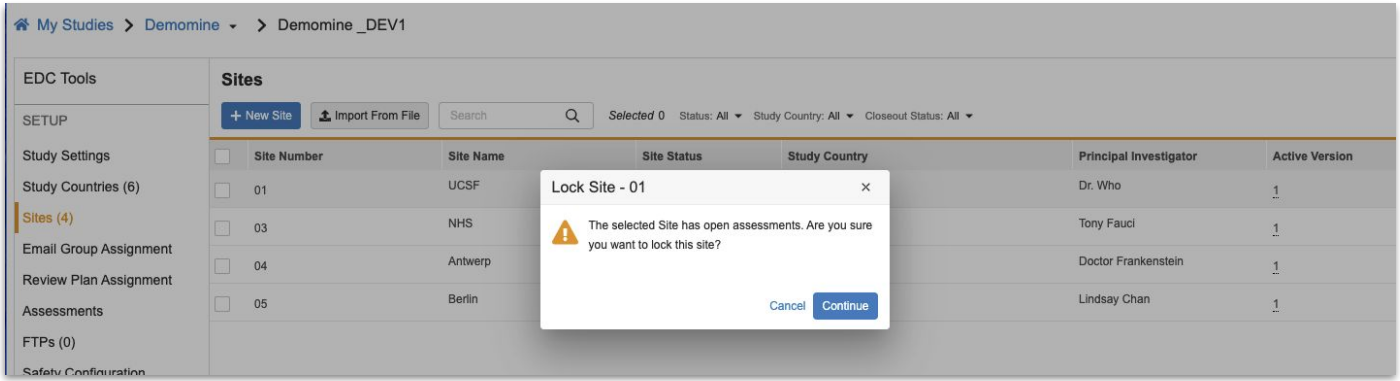
Data Model 2

Assessment Enhancements

- Overview
  - Can’t complete or edit assessments when study/site is locked
  - Warning when locking a site with open assessments

- Use case

  When a study or site is locked, users are no longer able to change assessment data.



Day 1 Impact to Clinical Teams

Yes

Visibility

Assessment Editors, Admins

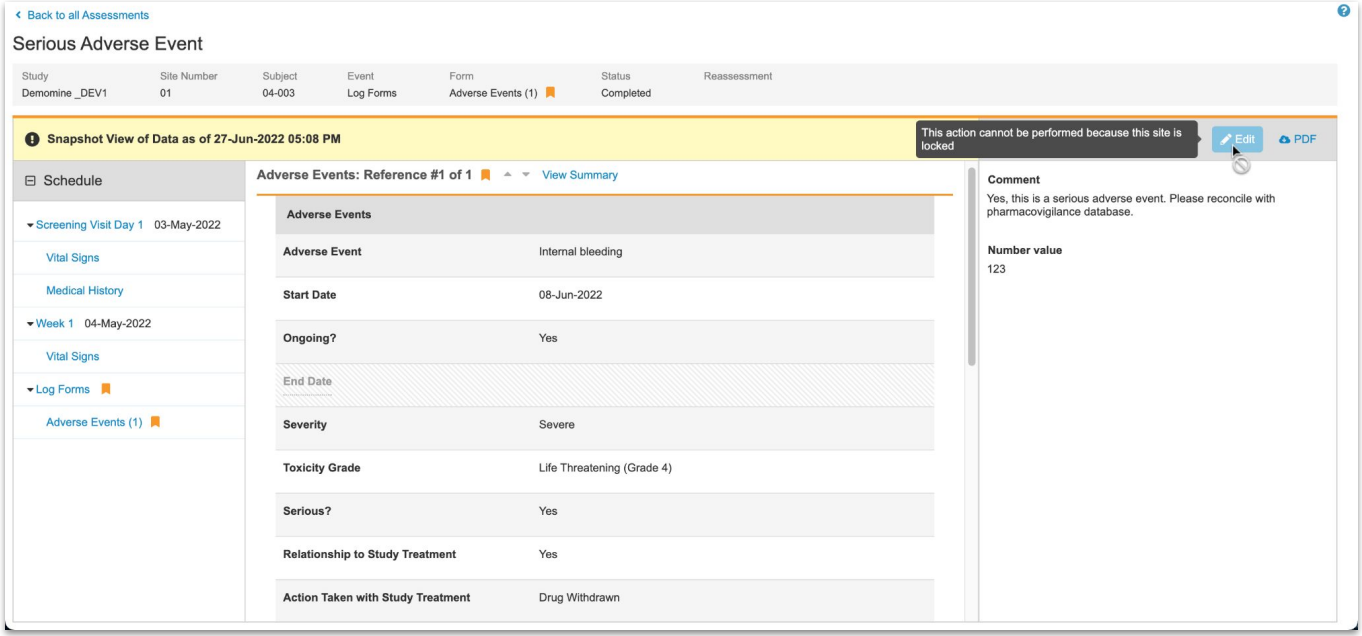
Configuration

N/A

Dependencies

Assessments

Assessment Enhancements



Day 1 Impact to Clinical Teams

Yes

Visibility

Assessment Editors, Admins

Configuration

N/A

Dependencies

Assessments

Reports

Study Summary Metrics Report

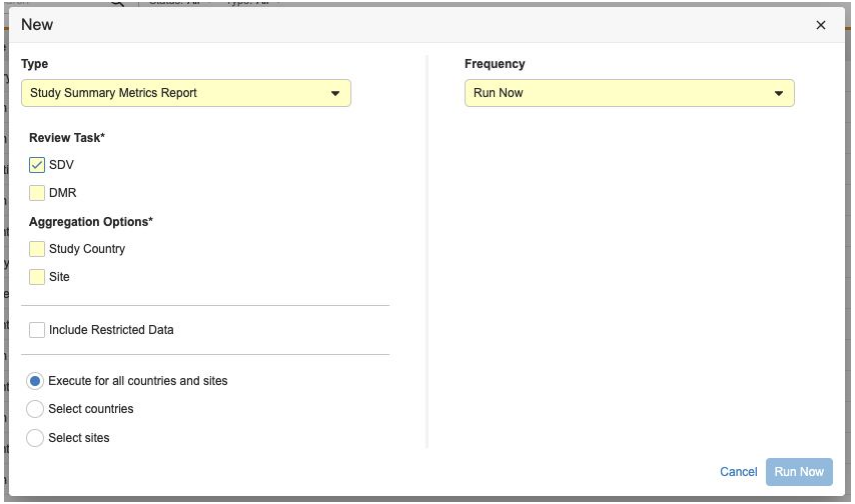
- Overview

  The Study Summary Metrics Report will summarize how much SDV and DMR has occurred in the study at the site and country levels.

  It will include the number of sites, subjects, events and forms that are reviewed and calculate the percentage of review completed.

- Use case

  This report summarizes how much SDV and DMR has been completed in the study and how much work is still remaining.



Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

N/A

Dependencies

Review Rollup V2

Study Summary Metrics Report

Study Country Aggregates

Study	Study Country	Total Sites SDV Required	Sites SDV Complete	Sites SDV %	Total Subjects SDV Required	Subjects SDV Complete	Subjects SDV %	Total Events SDV Required	Events SDV Complete	Events SDV %	Total Forms SDV Required	Forms SDV Complete	Forms SDV %	Last Run of Listing
Demomine _DEV1	Belgium	1	0	0	5	1	20	8	2	25	21	8	38	6/28/22 1:20
Demomine _DEV1	Germany	1	0	0	1	0	0	2	1	50	7	6	85	6/28/22 1:20
Demomine _DEV1	United States	2	0	0	10	0	0	25	5	20	69	24	34	6/28/22 1:20

Study Country Aggregates

Study	Study Country	Study Site	Total Subjects SDV Required	Subjects SDV Complete	Subjects SDV %	Total Events SDV Required	Events SDV Complete	Events SDV %	Total Forms SDV Required	Forms SDV Complete	Forms SDV %	Last Run of Listing
Demomine _DEV1	United States	UCSF	7	0	0	19	2	10	55	13	23	6/28/22 1:20
Demomine _DEV1	United States	NHS	3	0	0	6	3	50	14	11	78	6/28/22 1:20
Demomine _DEV1	Belgium	Antwerp	5	1	20	8	2	25	21	8	38	6/28/22 1:20
Demomine _DEV1	Germany	Berlin	1	0	0	2	1	50	7	6	85	6/28/22 1:20

Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

N/A

Dependencies

Review Rollup V2

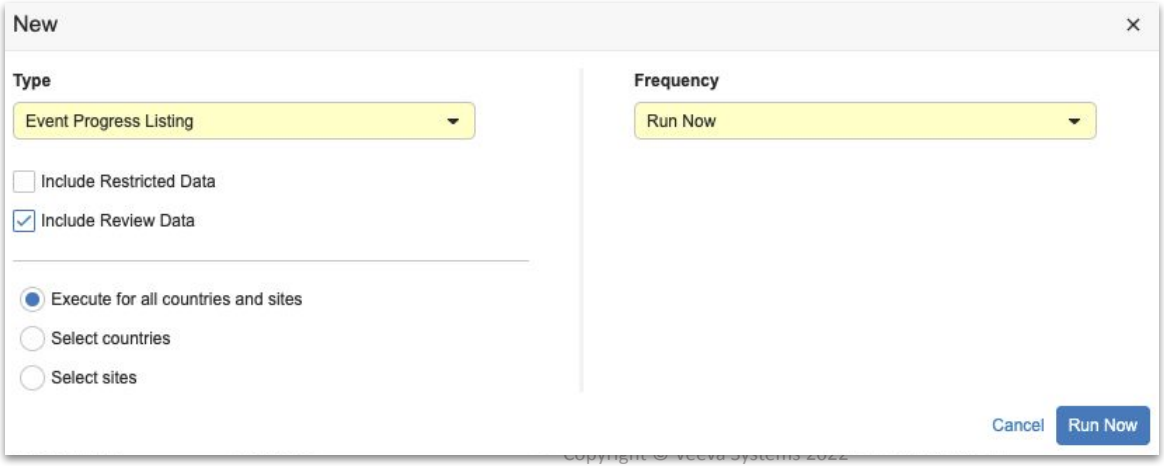
Event Progress Listing - Review Data

- Overview

  The Study Summary Metrics Report will summarize how much SDV and DMR has occurred in the study at the site and country levels. It will include the number of sites, subjects, events and forms that are reviewed and calculate the percentage of review completed.

- Use case

  The Event Progress Listing will now provide a high level summary of how events are progressing throughout the study, with additional information about how much SDV and DMR has been completed.



Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

N/A

Dependencies

Review Rollup V2

Event Progress Listing - Review Data

D	E	F	G	S	T	U	V	W	X	Y	Z
Subject	Subject Status	Event Group Label	Event Label	SDV Plan	Event Date SDV	Event Date SDV Required	Event Date SDV Date	Total Forms SDV Complete	Total Forms - SDV Required	% Forms SDV	SDV Completion Date
03-001	Enrolled	Screening Visit	Screening Visit Day 1	Treatment SDV Plan	Y	Required	5/20/22 22:56	4	4	100	5/20/22 22:56
03-001	Enrolled	Log Form Prompts	Log Forms	Treatment SDV Plan				0	1	0	
03-001	Enrolled	Treatment	Week 1	Treatment SDV Plan	N	Required		0	0		
03-001	Enrolled	Treatment	Week 2	Treatment SDV Plan	N	Required		0	0		
03-001	Enrolled	Treatment	Week 3	Treatment SDV Plan	N	Required		0	0		
03-001	Enrolled	Treatment	Week 4	Treatment SDV Plan	N	Required		0	0		
03-001	Enrolled	Treatment	Week 5	Treatment SDV Plan	N	Required		0	0		
03-002	In Screening	Screening Visit	Screening Visit Day 1	Treatment SDV Plan	N	Required		4	4	100	6/3/22 18:05
03-002	In Screening	Log Form Prompts	Log Forms	Treatment SDV Plan				2	3	66	
03-002	In Screening	Treatment	Week 1	Treatment SDV Plan	N	Required		1	1	100	6/3/22 18:05
03-002	In Screening	Treatment	Week 2	Treatment SDV Plan	N	Required		0	0		
03-002	In Screening	Treatment	Week 3	Treatment SDV Plan	N	Required		0	0		
03-002	In Screening	Treatment	Week 4	Treatment SDV Plan	N	Required		0	0		
03-002	In Screening	Treatment	Week 5	Treatment SDV Plan	N	Required		0	0		
01-002	Enrolled	Screening Visit	Screening Visit Day 1	Full SDV Plan	Y	Required	5/24/22 22:50	4	7	57	
01-002	Enrolled	Treatment	Week 1	Full SDV Plan	Y	Required	5/17/22 22:49	3	3	100	5/24/22 22:49
01-003	Screen Failure	Screening Visit	Screening Visit Day 1	Treatment SDV Plan	Y	Required	5/20/22 22:49	4	5	80	
01-002	Enrolled	Treatment	Week 2	Full SDV Plan	N	Required		0	1	0	
01-002	Enrolled	Treatment	Week 3	Full SDV Plan	N	Required		0	0		
01-002	Enrolled	Treatment	Week 4	Full SDV Plan	N	Required		0	0		
01-002	Enrolled	Treatment	Week 5	Full SDV Plan	N	Required		0	0		
01-002	Enrolled	Log Form Prompts	Log Forms	Full SDV Plan				0	4	0	
01-004	In Screening	Screening Visit	Screening Visit Day 1	Treatment SDV Plan	Y	Required	5/17/22 22:49	1	1	100	5/17/22 22:49
01-004	In Screening	Log Form Prompts	Log Forms	Treatment SDV Plan				0	2	0	

Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

N/A

Dependencies

Review Rollup V2

Study Progress Listing Enhancements

- Form Progress Listing

  SDV and DMR columns are renamed to **SDV Complete** and **DMR Complete**

- Use case

  This will help clarify if SDV or DMR was completed for a form.

T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE
SDV Plan	SDV Override Plan	**SDV Complete**	SDV Required	Items SDV Required Completed	Items SDV Required	SDV %	SDV Age	SDV Date	DMR Plan	DMR Override Plan	**DMR Complete**
Treatment SDV Plan		Yes	Yes	2	2	100		5/20/22 22:56			No
Treatment SDV Plan		Yes	Yes	1	1	100		5/20/22 22:56			No
Treatment SDV Plan		Yes	Yes	3	3	100		5/20/22 22:56			No
Treatment SDV Plan		No	No	0	0						No
Treatment SDV Plan		Yes	Yes	4	4	100		5/20/22 22:56			No
Treatment SDV Plan		No	No	0	0						No
Treatment SDV Plan		No	No	0	0						No

Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

N/A

Dependencies

N/A

Additive Review Listing

- Overview

  With the Additive Review Listing, users can report on how much additive review was performed in the study during a specific time period.

  In the listing, there will be a summary of the items and event dates reviewed. Additionally, there will be a detailed report of the additively reviewed items and dates, answering who performed the review, when and the reason why.

- Use case

  This listing will summarize how much additive review was performed in a study during a specific time period and why. It will allow users to identify sites with high and low amounts of review or CRAs and Data Managers performing review outside of their required duties.

Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

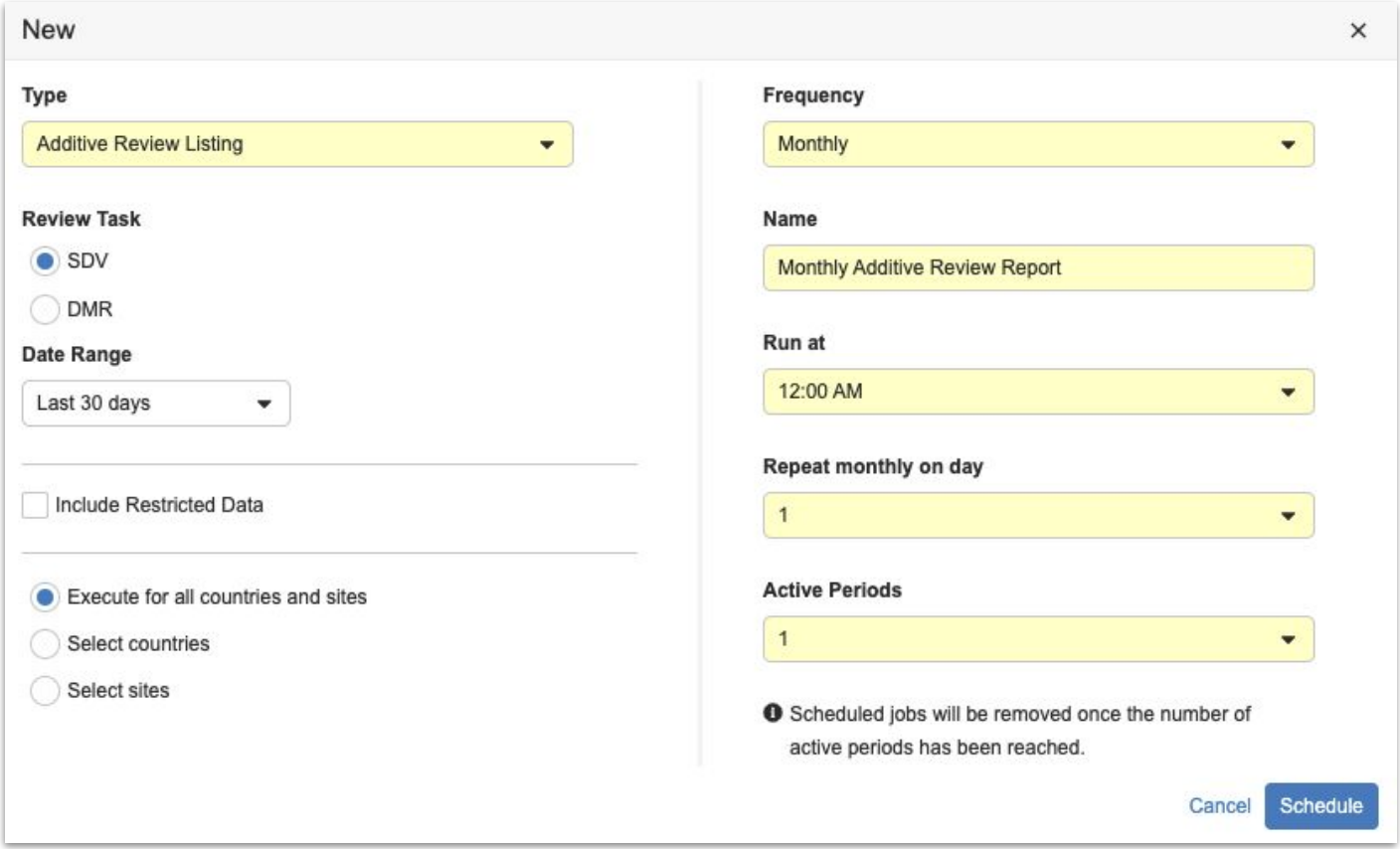
Configuration

Studio

Dependencies

Additive Review enabled

Additive Review Listing



Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

Studio

Dependencies

Additive Review enabled

Additive Review Listing

Additive Review Summary

Country		Number of Items Additively SDV
Belgium		73
Germany		14
United States		37
Country	Site	Number of Items Additively SDV
Belgium	4	73
Germany	5	14
United State	1	14
United State	3	23

Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration Studio

Dependencies

Additive Review enabled

Additive Review Listing

Additive Review Summary

Item Label	Review Plan Type	Last Reviewed By	Last Reviewed Date	Additive Reason	Last Run of Listing
Is the subject of childbearing potential?	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Other	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Postmenopausal	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Premenarchal	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Specify Other Reason for Non-childbearing Potential	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Surgically Sterile	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Black or African American	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Asian	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Ethnicity	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Native American or Alaska Native	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Native Hawaiian or Other Pacific Islander	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Other	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
White	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Were Vital Signs collected?	SDV	Cathy CRA	2022-05-20T22:49Z	Evidence of transcription errors	6/28/22 1:32
Is the subject of childbearing potential?	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Other	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Postmenopausal	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Premenarchal	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Specify Other Reason for Non-childbearing Potential	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Surgically Sterile	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Black or African American	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Age at Time of Informed Consent	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Asian	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Birth Date	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Ethnicity	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Native American or Alaska Native	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Native Hawaiian or Other Pacific Islander	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Other	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32
Sex	SDV	Margaret Wehner	2022-05-20T22:56Z	Source quality	6/28/22 1:32

Day 1 Impact to Clinical Teams

No

Visibility

CRA, DM, Lead Data Manager

Configuration

Studio

Dependencies

Additive Review enabled

Dedicated DEMO

For a dedicated demo of any these features,

please contact your

Account Executive OR

Customer Success Manager

Thank you