



Stack 18 Release:

Study Runner & Study Build System Changes

Scheduled Release: April 2023



Feature Enablement Detail

Auto-On Features

Turned on Day 1



Automatically available

Configurable Features

Turned off



Requires Configuration

Configurable Features

Turned off



*Requires Enablement,
Product Support
Request*

Feature Enablement Detail

Module Required

Modules require additional cost and may require support if not already enabled.

Insight
Participate
Randomize
Unite

Visible Roles

Study: Viewer
Data Manager
Data Specialist
Data Entry Person
Monitor

Site: Viewer
Data Manager
Investigator
Clinical Research Coordinator
Monitor



Data Managers

eConsent Module

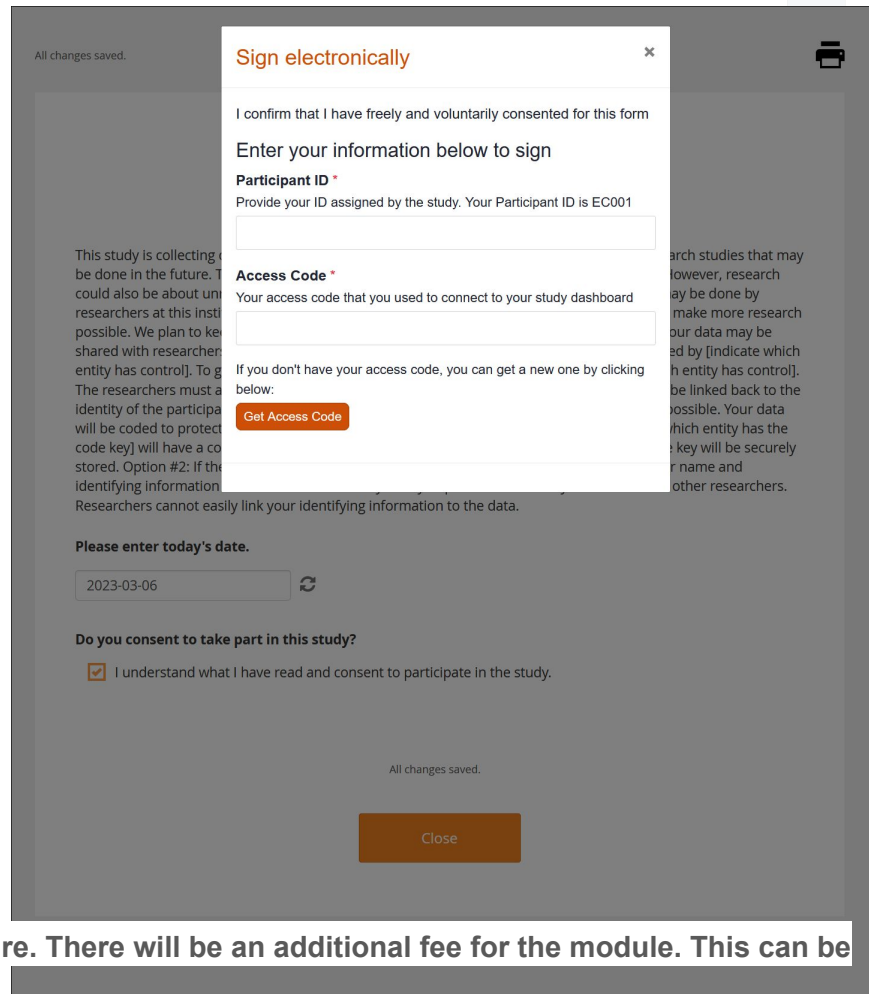
Overview

Allows Participants to sign Informed Consent forms electronically. Investigators and CRCs can add countersignatures from the Participant Details Page. Provides new tools for tracking the consent status of participants and an audit trail of all informed consent activity. PDF copies of signed eConsent forms can be downloaded by Participants as needed.

Business Value

This allows users to get 21 CFR Part 11-compliant signatures from participants and countersignatures from Investigators and CRCs through electronic means.

***The eConsent module is required for this feature. There will be an additional fee for the module. This can be used with or without the Participate Module.**



The screenshot displays a web interface for signing consent forms. A modal dialog box titled "Sign electronically" is open, containing the following text and fields:

- Confirmation text: "I confirm that I have freely and voluntarily consented for this form"
- Instruction: "Enter your information below to sign"
- Field: "Participant ID *" with a subtext "Provide your ID assigned by the study. Your Participant ID is EC001" and an input field.
- Field: "Access Code *" with a subtext "Your access code that you used to connect to your study dashboard" and an input field.
- Text: "If you don't have your access code, you can get a new one by clicking below:"
- Button: "Get Access Code" (orange)

The background shows a consent form with the following visible sections:

- Header: "All changes saved."
- Text: "This study is collecting... be done in the future. T... could also be about un... researchers at this inst... possible. We plan to ke... shared with research... entity has control]. To g... The researchers must a... identity of the partici... will be coded to protec... code key) will have a c... stored. Option #2: If th... identifying information... Researchers cannot easily link your identifying information to the data."
- Text: "Please enter today's date." with a date input field containing "2023-03-06" and a refresh icon.
- Text: "Do you consent to take part in this study?" with a checked checkbox and the text "I understand what I have read and consent to participate in the study."
- Footer: "All changes saved." and a "Close" button.



Configuration

Visible

All users



Automatic

Visible

Data Managers

Annotated Case Report Forms (CRFs)

Overview

Annotated CRFs will be available within Study Runner. A new Action button next to each Form version on the Manage Case Report Forms (CRFs) page will allow users to download the annotated CRF for that form version. There will also be an option to generate one Annotated Blank Casebook which contains annotated CRFs for all default forms within the study which would then be downloadable from the Bulk Actions log.

Business Value

Annotated CRFs are downloadable from Study Runner automatically without the need to manually add annotations in the Form Template in the Study Build System. This saves time for study designers and creates consistency for Annotated CRFs.



Study: S_RGB22(TEST) | Event: SE_SCREENINGVISIT | Form: F_VITALSIGNS-1

Vital Signs

<p>Were vital signs performed? [Name: VS_HORIZONTAL_VSPERF] [Type: select_one NY] [Item Group: VIT]</p> <p><i>Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.</i></p> <p><input type="radio"/> No [N] <input type="radio"/> Yes [Y]</p>	<p>Date [Name: VS_HORIZONTAL_VSDAT] [Type: date] [Item Group: VIT] [Show When: \$[VS_HORIZONTAL_VSPERF] = "Y"] [Constraint: . !t= today()] <i>Record date of measurements.</i></p>
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Results

[Name: VSDETAILS] [Type: group] [Show When: \$[VS_HORIZONTAL_VSPERF] = "Y"]

<p>Systolic Blood Pressure [Name: VS_HORIZONTAL_SYSBP_VSORRES] [Type: integer] [Item Group: VIT] <i>Record the vital sign results.</i></p>	<p>Systolic Blood Pressure Unit [Name: VS_HORIZONTAL_SYSBP_VSORRESU] [Type: text] [Item Group: VIT] [Required: yes] [Calculation: 'mmHg'] [Read-Only: yes] <i>Record or select the original unit in which these data were collected, if not preprinted on CRF.</i></p>
<p>Diastolic Blood Pressure [Name: VS_HORIZONTAL_DIABP_VSORRES] [Type: integer] [Item Group: VIT] <i>Record the vital sign results.</i></p>	<p>Diastolic Blood Pressure Unit [Name: VS_HORIZONTAL_DIABP_VSORRESU] [Type: text] [Item Group: VIT] [Required: yes] [Calculation: 'mmHg'] [Read-Only: yes] <i>Record or select the original unit in which these data were collected, if not preprinted on CRF.</i></p>
<p>Blood Pressure Position [Name: VS_HORIZONTAL_BP_VSPOS] [Type: select_one BPPPOS] [Item Group: VIT]</p> <p><i>Record the position of subject at time of test (e.g. SITTING).</i></p> <p><input type="radio"/> Prone [PRONE] <input type="radio"/> Semi-Reclumbent [SEMI-RECLUMBENT] <input type="radio"/> Sitting [SITTING] <input type="radio"/> Standing [STANDING] <input type="radio"/> Supine [SUPINE]</p>	<p>Blood Pressure Location [Name: VS_HORIZONTAL_BP_VSLOC] [Type: select_one BPLOC] [Item Group: VIT]</p> <p><i>Record or select location on body where measurement was performed, if not preprinted on CRF.</i></p> <p><input type="radio"/> Brachial Artery [BRACHIAL ARTERY] <input type="radio"/> Finger [FINGER] <input type="radio"/> Peripheral Artery [PERIPHERAL ARTERY] <input type="radio"/> Radial Artery [RADIAL ARTERY]</p>

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Automatic

Open Queries and SDV Status Icons on Participant Details Page

Overview

A Query bubble icon was added to form cards on the Participant Details Page for forms that have any items with open queries. The Source Data Verification (SDV) status is also visible on the form cards.

Business Value

This allows users to easily identify if they need to respond to any queries or complete SDV at a quick glance while on the Participant Details Page.

The screenshot displays the 'Visits' section of the Participant Details Page. It features a list of form cards for a 'Screening Visit' on 01-Feb-2023. Each card includes a 'Sort by Date' dropdown, a 'Vital Signs' card with a green checkmark, and a 'Demographics' card with a green checkmark. A red speech bubble icon is present on the 'Demographics' card, indicating an open query. A magnifying glass icon is also visible on the 'Vital Signs' card, indicating SDV status. The status is shown as 'Not Verified' in the top-left view and 'Verified' in the bottom-right view. The 'Vital Signs' card also has a magnifying glass icon and a status indicator.



Automatic

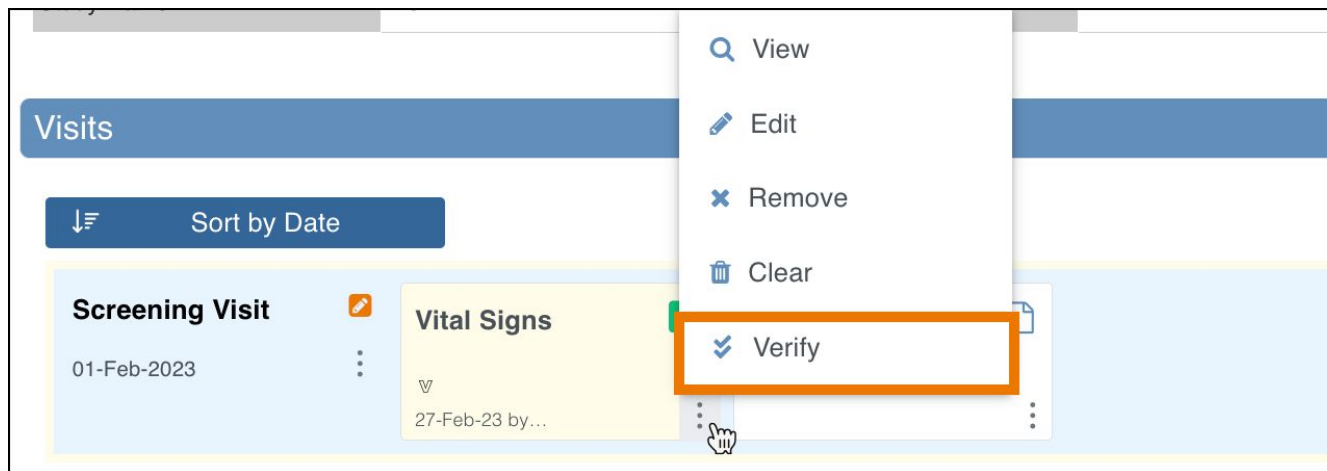
Verify on the Participant Details Page

Overview

The SDV Verify action was added to the Form card action menu on the Participant Details page to allow Data Managers and Monitors to more easily verify forms.

Business Value

This allows Data Managers and Monitors to Verify the form while on the Participant Details Page without the need to navigate back to the SDV page to perform the action.



Visible

Data
Managers,
Monitors



Automatic

Download Data Review Tables

Overview

A Download button was added to the Data Review Tables to allow users to download the table to review in another setting.

Business Value

This allows users to keep a log of the Data Review Tables because it is a dynamic list and will change based on the content at the time it is opened.

☰ Active Records

Medical History

<input type="checkbox"/>	Participant ID	Event Start Date	Form Status	Event Name	Event Status	Form Last ModifiedBy	Form Last Modified Date	Age	DM_AGEALC	Age Unit	Birth Date	Ethnicity	Race
	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾	↑↓ ▾
<input type="checkbox"/>	001	01-Feb-2023	data entry complete ↻	Screening Visit	completed	rbianchi@openclinica.com	27-Feb-2023	23	23	YEARS	03-Jan-2000	Not Hispanic or Latino (NOT HISPANIC OR LATINO)	Asian (ASIAN), Native Hawaiian or Other Pacific Islander (NATIVE_HAWAIIAN_OTHER_PACIFIC_ISLANDER)
<input type="checkbox"/>	002	01-Feb-2023	data entry complete	Screening Visit	completed	rbianchi@openclinica.com	27-Feb-2023	23	23	YEARS	02-Feb-2000	Not Reported (NOT REPORTED)	Not Reported (NOT_REPORTED)

Showing 1 to 2 of 2 entries << < 1 > >> 20 ▾ [Download current view](#)

Visible

All Users



Automatic

Data Dictionary Updates

Overview

The Data Dictionary was updated to show columns for Form Properties, Participate Properties (if Participate is configured for the study), and Calendaring (if Study Calendaring is configured for the study).

Business Value

This allows critical information to be found easily in one consistent place.

Data Dictionary					
<input type="checkbox"/> Include items in no versions		Participate Properties <input type="checkbox"/> Participate Form <input checked="" type="checkbox"/> Public URL <input type="checkbox"/> Offline Capable		Form Properties <input type="checkbox"/> Hide from site users <input type="checkbox"/> Required SDV: Not Applicable	
				Versions <input type="radio"/> v33-acrf <input type="radio"/> v33-acrf-1	
Item Label	Item Brief Description	Item Group Name	Item Group OID	Item Type	
	Weight	Group1	IG_ANNOT_GROUP1	calculate	v33-acrf,v33-acrf-ajp,v33-acrf-1,v33-acrf_slash,ann_core,demo_new_4
	bp_dia_count	Group2	IG_ANNOT_GROUP2	calculate	v33-acrf,v33-acrf-1,v33-acrf_slash,demo_new_colors,v33

Visible

Data
Managers



Automatic

Default Values Populate on Previously Cleared Forms when Edited

Overview

Updated previously cleared forms to populate the defaults the first time a form is edited after being cleared.

Business Value

This allows users to have a fresh start on a form by clearing it, including with the default values being populated again to avoid tedious repopulation of fields.

Visible

All Users



Automatic

Bulk Actions Visibility for Data Managers

Overview

The visibility of jobs in the Bulk Actions Log was updated for Data Managers to be able to see all jobs that do not display clinical data in their results regardless of who ran them.

Business Value

This allows Data Managers to better access the information they need to do their job.

(AJP Common Event Study) **Test Environment** | Change | Design | Share | Settings rbianchi@openclinica.com (Data Manager) ▾

View Home Participant Matrix Queries Study Audit Log Tasks ▾

Bulk Actions Log

Bulk actions log displays logfiles that are generated by executing the bulk APIs. [Click here](#) to access API documentation. Reload this page to update job statuses. Search:

Source	Job Type	Site Name	Job Status	Start Time	Submitted By	Completion Time	Actions
Bulk_Upload.csv	BULK_ADD_PARTICIPANTS	S_BETA(TEST)	COMPLETED	01-Nov-2022 09:33	apotischman@openclinica.com	01-Nov-2022 09:33	🔍 📄 🗑️

Results 1-1 of 1 Show per page < >



Automatic

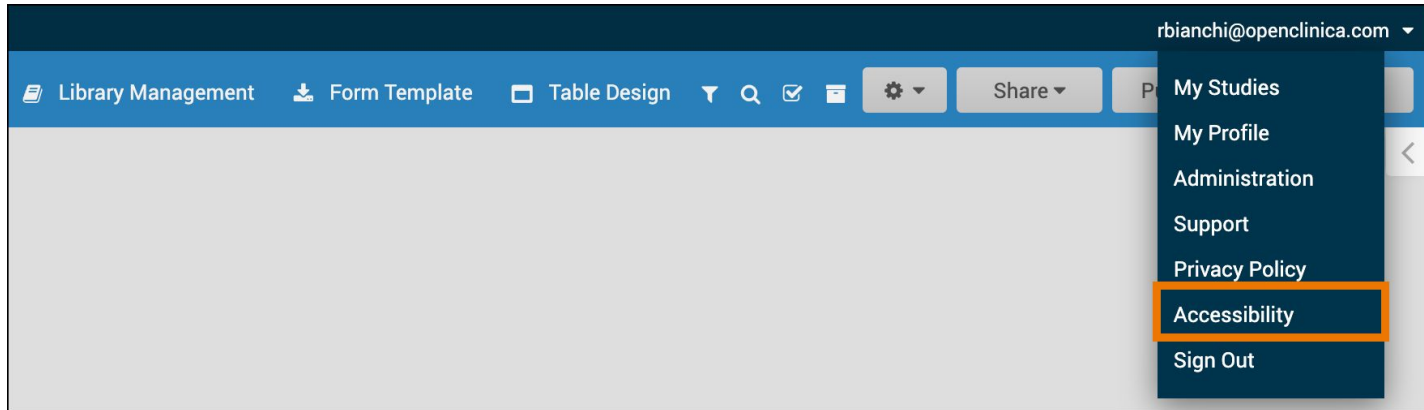
Accessibility Statement Links Added

Overview

Added Accessibility Statement links to Study Manager, Study Designer, and the Participate dashboard. Also added Privacy Policy link to the Participate dashboard.

Business Value

This allows users to easily find the Accessibility Statement and Privacy Policy documents from anywhere in the system.



Visible

All Users



Automatic

Data Transformation Module Updates

Overview

Added description of files at upload, and bulk log download to the Data Transformation Module.





Added the ability to download the Data Transformation Queue table and Restore/Reject files in bulk from the Data Transformation Module.


Business Value

This allows users to more easily use the Data Transformation Module.

Data Transformation Queue

+ Add a new file

<input type="checkbox"/>	Actions	Site	File Name	Status	Uploaded On (UTC)
					
<input checked="" type="checkbox"/>		1 Manual Import Validation	data_file_visit.txt	Unprocessed	26-Sep-2022 20:17
<input checked="" type="checkbox"/>		2 Manual Import Validation	data_file_visit.txt	Unprocessed	11-Jul-2022 20:00
<input checked="" type="checkbox"/>		1 Manual Import Validation	data_file_common.txt	Unprocessed	11-Jul-2022 19:25

Navigation: << < 1 > >> 50 

Direct Access to Specific Events on the Participant Details Page



Automatic

Overview

The “Enter or Validate Data For Event” page in Sudy Runner was retired. Now, when a user clicks View for an event on the Participant Matrix, it will take the user to the corresponding event on the Participant Details Page.

Business Value

This retires older functionality and creates more consistency for users. Now, when a user clicks View for an Event, it will open the Participant’s record to that Event on the on the Participant Details Page.

The screenshot shows the OpenClinica interface for a participant's details. The main content area is titled "Enter or Validate Data for CRFs in Eligibility and Randomization". A large red 'X' is overlaid on this area, indicating that this functionality is retired. The interface includes a sidebar with navigation options like "Alerts & Messages", "Quick Access", "Instructions", "Info", and "Study Events". The "Study Events" section is expanded to show "Eligibility and Randomization" with a status of "data entry started". Below this, there is a table for "CRFs in this Study Event:".

CRF Name	Version	Last Modified by:	Actions
ePRO Delivery Preference	1.1		
Arm Exclusion - Retrospective	2.1		
Health History	4.7e	nanwar	



Automatic

Automatic Queries for Soft Edit Checks

Overview

Updated the form engine to prompt data entry users on whether they would like to add automatic queries for standard soft required and constraint errors when marking a form as Complete.

Business Value

This makes it easier for users because they do not need to add queries to all of the items manually. Previously, automatic queries could be added for items with constraint errors only when closing a form (not changing it to Complete status) and automatic queries could not be added for missing required items prior to marking a form as Complete.



Automatic

User Role Caching For Improved Study Runner Performance and Consistency

Overview

When a user is in Study Runner, the user's study roles will be refreshed every 5 minutes or when the user uses the Change Study page or the Go button from the Study Build System.

Business Value

This reduces system load and improves performance in Study Runner. It also allows users to have a role change while logged into Study Runner and ensure that the change will take effect without the user needing to log out and log back in.

Visible

All Users



All Roles

18

eConsent Module

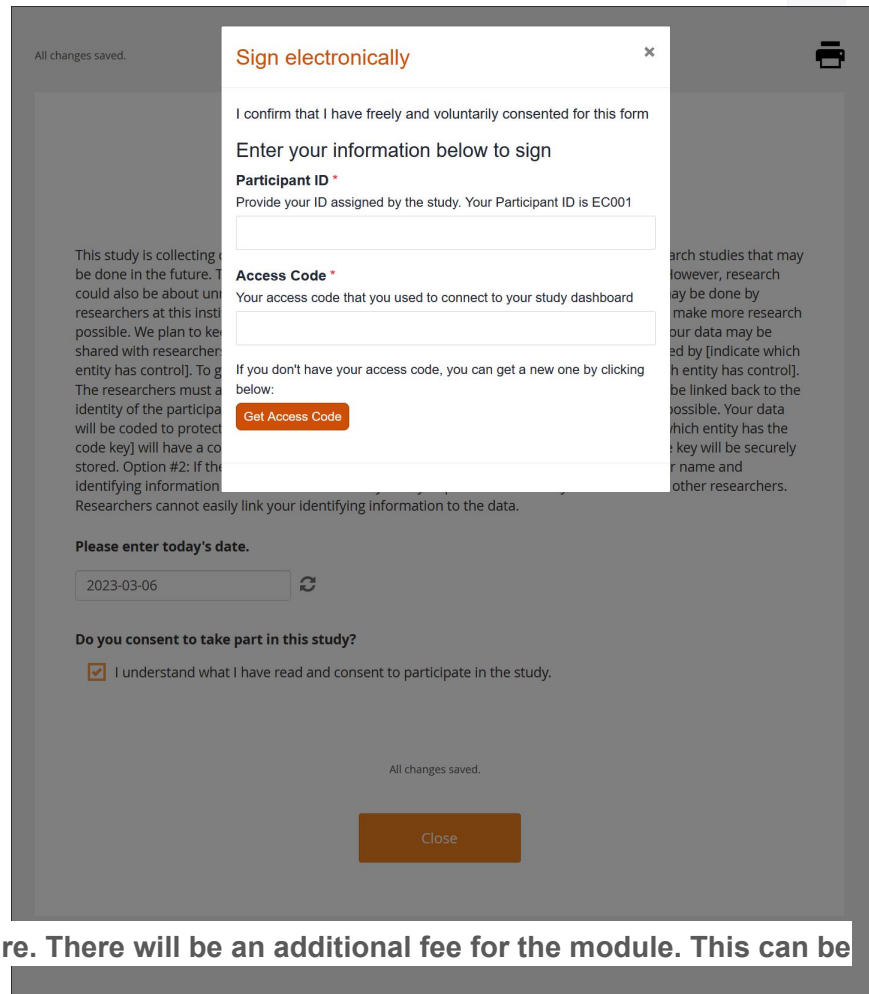
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Business Value

This allows users to get 21 CFR Part 11-compliant signatures from participants and countersignatures from Investigators and CRCs through electronic means.

***The eConsent module is required for this feature. There will be an additional fee for the module. This can be used with or without the Participate Module.**



The screenshot displays a web interface for signing consent forms. A modal dialog box titled "Sign electronically" is open, containing the following elements:

- A confirmation statement: "I confirm that I have freely and voluntarily consented for this form".
- A heading: "Enter your information below to sign".
- A field for "Participant ID *", with a note: "Provide your ID assigned by the study. Your Participant ID is EC001".
- A field for "Access Code *", with a note: "Your access code that you used to connect to your study dashboard".
- A button labeled "Get Access Code" with the text: "If you don't have your access code, you can get a new one by clicking below:".
- A "Close" button at the bottom of the dialog.

The background interface shows a form with a date field set to "2023-03-06" and a consent checkbox that is checked, with the text "I understand what I have read and consent to participate in the study.".



Configuration

Visible

All users



Automatic

Open Queries and SDV Status Icons on Participant Details Page

Overview

A Query bubble icon was added to form cards on the Participant Details Page for forms that have any items with open queries. The Source Data Verification (SDV) status is also visible on the form cards.

Business Value

This allows users to easily identify if they need to respond to any queries or complete SDV at a quick glance while on the Participant Details Page.

The image displays three screenshots of the OpenClinica interface, illustrating the changes to form cards on the Participant Details Page. Each screenshot shows a 'Visits' section with a 'Sort by Date' dropdown and a list of form cards.

- Top Left Screenshot:** Shows a 'Screening Visit' card for '01-Feb-2023'. The 'Vital Signs' card has a red speech bubble icon (query) and a green checkmark (SDV). A tooltip for the 'Vital Signs' card is visible, showing 'Not Verified'.
- Top Right Screenshot:** Shows a 'Screening Visit' card for '01-Mar-2023'. The 'Vital Signs' card has a red speech bubble icon (query) and a green checkmark (SDV). The 'Demographics' card has a green checkmark (SDV).
- Bottom Screenshot:** Shows a 'Screening Visit' card for '01-Feb-2023'. The 'Vital Signs' card has a red speech bubble icon (query) and a green checkmark (SDV). A tooltip for the 'Vital Signs' card is visible, showing 'Verified'.



Automatic

Visible

Data
Managers,
Monitors

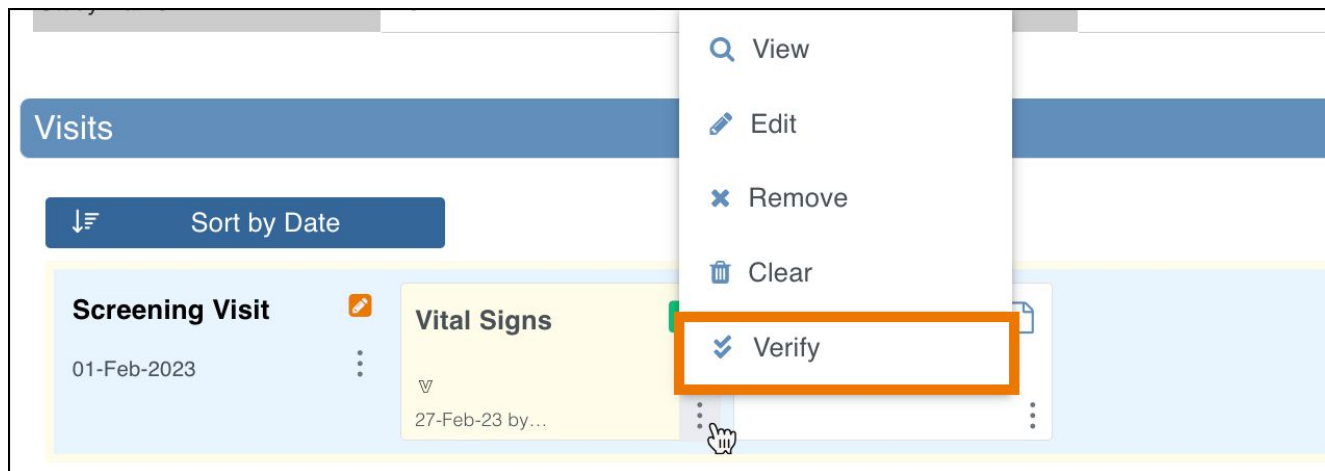
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Automatic

Download Data Review Tables

Overview

A Download button was added to the Data Review Tables to allow users to download the table to review in another setting.


Business Value

This allows users to keep a log of the Data Review Tables because it is a dynamic list and will change based on the content at the time it is opened.

Active Records

Medical History

<input type="checkbox"/>	Participant ID	Event Start Date	Form Status	Event Name	Event Status	Form Last ModifiedBy	Form Last Modified Date	Age	DM_AGEALC	Age Unit	Birth Date	Ethnicity	Race
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Showing 1 to 2 of 2 entries << < 1 > >> 20  Download current view

Visible

All Users



Automatic

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Visible

All Users



Automatic

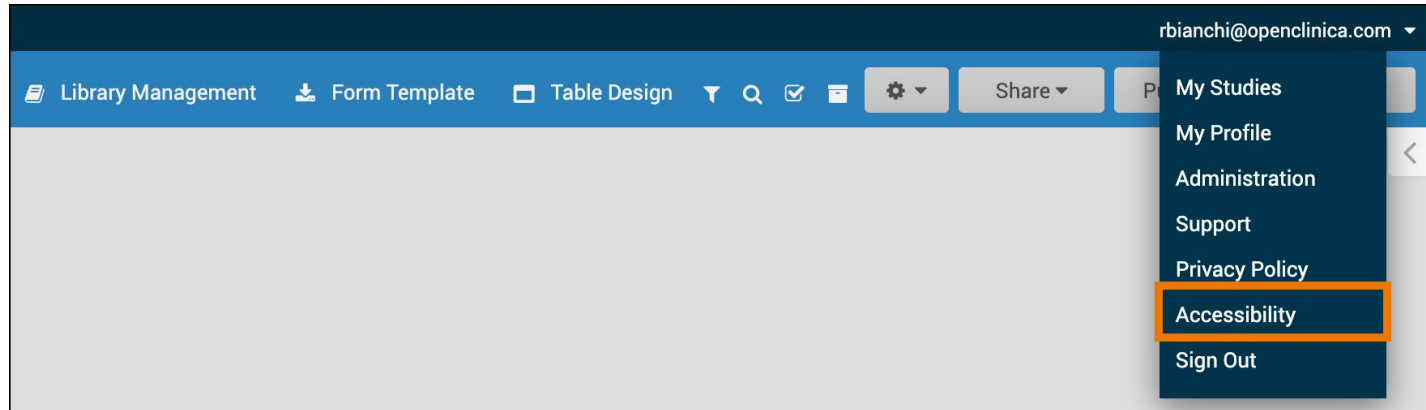
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<input type="checkbox"/>	Actions	Site	File Name	Status	Uploaded On (UTC)
					
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Navigation: << < 1 > >> 50 [Download icon]

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Business Value

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The screenshot shows the OpenClinica interface. At the top, there is a navigation bar with 'Home', 'Participant Matrix', 'Queries', 'Study Audit Log', and 'Tasks'. Below this, there is a search bar for 'Enter Participant ID' and a 'View' button. The main content area is titled 'Enter or Validate Data for CRFs in Eligibility and Randomization'. On the left, there is a sidebar with 'Alerts & Messages', 'Quick Access', 'My Queries', 'Recent 006299', 'Instructions', 'Info', and 'Study Events: (5)'. The 'Study Events' section is expanded to show 'Eligibility and Randomization' with a status of 'data entry started'. The main content area contains a form for 'Edit Study Event' with fields for 'Participant ID' (006299), 'Study Event' (Eligibility and Randomization), and 'Participant OID' (55_018638). Below this is a table for 'CRFs in this Study Event:' with columns for 'CRF Name', 'Version', 'Last Modified by', and 'Actions'. The table lists three CRFs: 'ePRO Delivery Preference' (Version 1.1), 'Arm Exclusion - Retrospective' (Version 2.1), and 'Health History' (Version 4.7e). A large red X is overlaid on the entire screenshot, indicating that this functionality is retired.

CRF Name	Version	Last Modified by	Actions
ePRO Delivery Preference	1.1		
Arm Exclusion - Retrospective	2.1		
Health History	4.7e	nanwar	



Automatic

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Visible

All Users

For additional information and a complete list of changes in the Stack 18 Release, please review the [Stack 18 Release Notes](#).

Thank you

