



# Stack 18.1.1 Impact Analysis: Study Runner & Study Build System Changes

Release: June 22 2023





## Release Reason(s)

The purpose of **release 18.1.1** is to provide our clients with improved functionality through the process of resolving a set of reported bug issues.





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# Enablement Details

## Auto-On

Ready on Day 1



*Automatically available*

## Configurable

User Configurable



*Requires Configuration*

## Requestable

Request Assistance



*Requires Enablement,  
Product Support Request*

# Bug Fix Breakdown

Things YOU and your team need to know:

- [Data Transformation Module - \(OC-21140\)](#)
- [eConsent View Status - \(OC-20879\)](#)
- [eConsent Repeating Columns & Rows - \(OC-21075\)](#)
- [Audit Log \(Non-English Studies\) - \(OC-20899\)](#)
- [Data Transformation Module \(Non-English Studies\) - \(OC-20900\)](#)
- [Extracts & Scheduled Extract Jobs \(Non-English Studies\) - \(OC-20903\)](#)
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- [CRF Metadata - \(OC-20956\)](#)
- [View Events - \(OC-21065\)](#)
- [ODM - \(OC-21079\)](#)
- [Study Calendaring - \(OC-21124\)](#)
- [Source Data Verification Filtering - \(OC-20897\)](#)
- [Participate - \(OC-21194\)](#)
- [Reassigning Form Version\(s\) - \(OC-19330\)](#)



Click any of the hyperlinks to move through the slide deck.





## Fix By User Type:

- Data Manager
- Non-Data Manager
- Participant





# Data Manager





Fix is Automatic

# Reassigning Form Version(s)

## Overview:

Form migration is the ability to transfer data from one Form version to another. A Data Manager might choose to migrate Form data in order to update the Form to a new version.

## Release Fix Information (OC-19330):

Fixed a CRF version migration issue where the data incorrectly displayed on the "Confirm CRF Migration" page data mapping table.

## Expected Behavior:

When a user reassigns a form version from the Participant Details Page (PDP) and confirms the migration, the data displayed in the Current Version/Future Version data columns of the Data Mapping table will contain expected item values.

Enter Participant ID

Alerts & Messages **Confirm CRF Version Change**

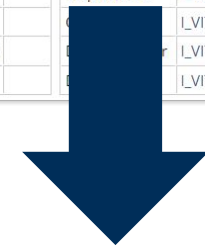
Participant ID: AP-2  
Event: Screening (25-Oct-2022)  
CRF Name: Vitals  
Current CRF Version: 1  
Selected CRF Version: 2

**Issue: values are unexpectedly displayed null.**

**Data Mapping**

The table below depicts the items, and their values, for the version of the CRF through which the data was collected.

Current CRF Version: '1'			Selected CRF Version: '2'		
Item Name	Item OID	Value	Item Name	Item OID	Value
systolic	I_VITAL_SYSTOLIC		systolic	I_VITAL_SYSTOLIC	
diastolic	I_VITAL_DIASTOLIC		diastolic	I_VITAL_DIASTOLIC	
beatspermin	I_VITAL_BEATSPERMIN		beatspermin	I_VITAL_BEATSPERMIN	
respirations	I_VITAL_RESPIRATIONS		respirations	I_VITAL_RESPIRATIONS	
O2Sat	I_VITAL_O2SAT		O2Sat	I_VITAL_O2SAT	
DisplayGender	I_VITAL_DISPLAYGENDER		DisplayGender	I_VITAL_DISPLAYGENDER	
DisplayAge	I_VITAL_DISPLAYAGE		DisplayAge	I_VITAL_DISPLAYAGE	



Fix

**Confirm CRF Version Change**

Participant ID: 8  
Event: Screening (14-Nov-2022)  
CRF Name: Eligibility  
Current CRF Version: 1  
Selected CRF Version: 2

**Data Mapping**  
The table below depicts the items, and their values, for the version of the CRF through which the data was collected. On the right is the information on how the data will be moved to the

Current CRF Version: '1'			Selected CRF Version: '2'		
Item Name	Item OID	Value	Item Name	Item OID	Value
ttest	I_ELIG_TTEST		ttest	I_ELIG_TTEST	
GENINCL_POS (1)	I_ELIG_GENINCL_POS	1	GENINCL_POS (1)	I_ELIG_GENINCL_POS	1
GENINCL_POS (2)	I_ELIG_GENINCL_POS	2	GENINCL_POS (2)	I_ELIG_GENINCL_POS	2
GENINCL_POS (3)	I_ELIG_GENINCL_POS	3	GENINCL_POS (3)	I_ELIG_GENINCL_POS	3

Green boxes highlight the 'Value' columns in both tables, and a green double-headed arrow connects them, indicating that the data is correctly transferred.

Visible

Data Managers



# Calendaring

## Overview:

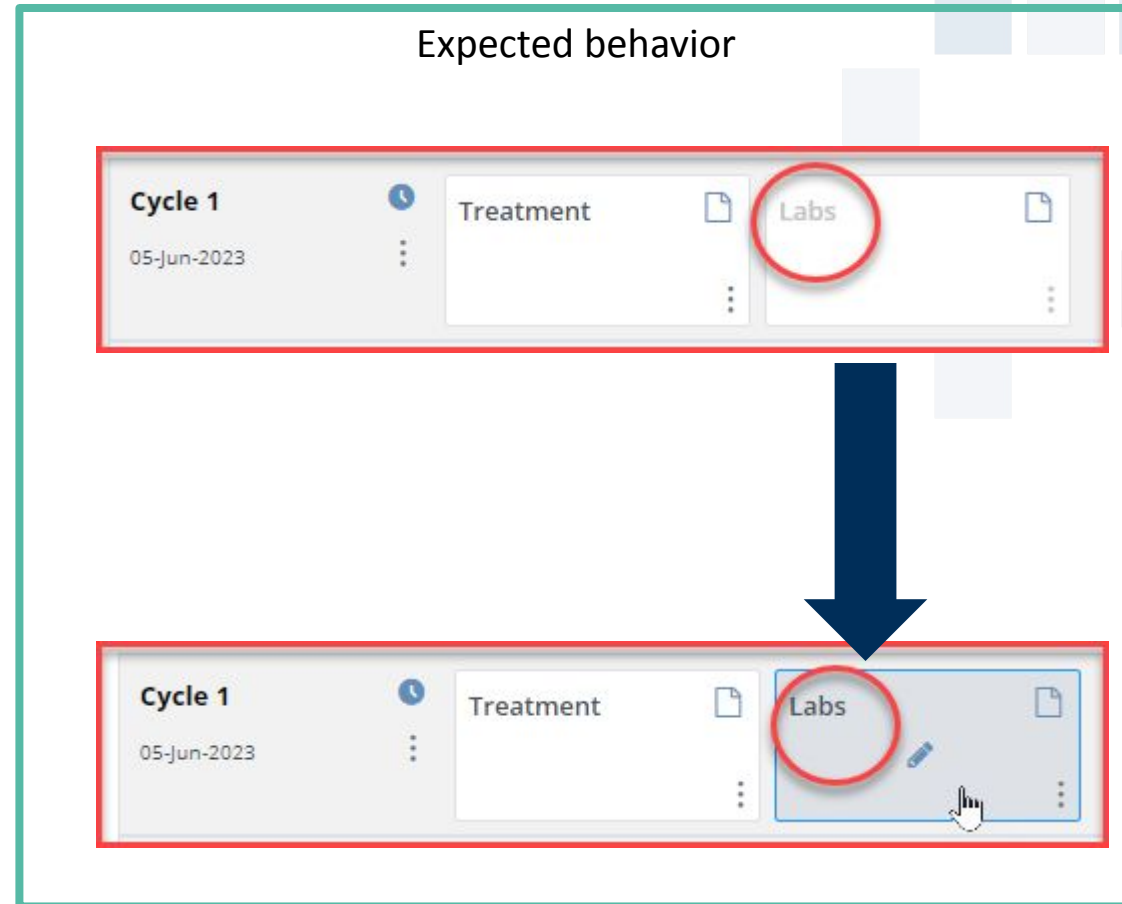
For currently enabled clients, Calendaring will evaluate rules to true or false based on user-specified conditions. When a rule expression evaluates to a specified result, a configured follow-up action executes

## Release Fix Information (OC-21124):

Resolved an issue where calendaring rules were not firing due to a lock on the participant's calendar.

## Expected Behavior:

Calendaring rules accurately executing when conditions are met.



Fix is Automatic



Feature is Requestable for a select user group at this time.

Visible

Data Managers



Fix is Automatic

Visible

Data Managers

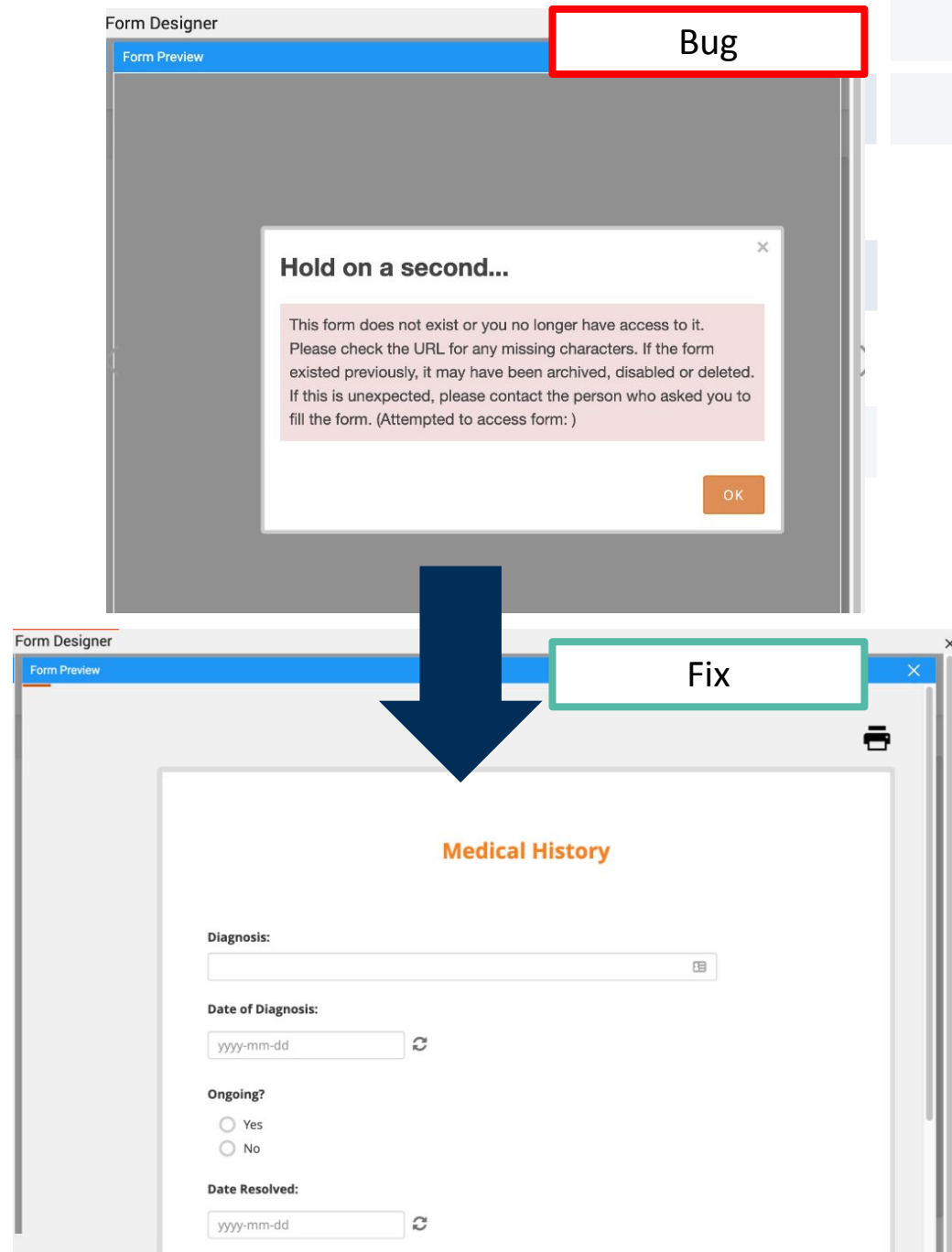
# Form Designer

## Release Fix Information (OC-20919):

Fixed an issue where users experienced an error message when previewing forms in designer.

## Expected Behavior:

In Form Designer, the ability to preview any successfully uploaded form definition or Form Designer-built form.





Fix is Automatic

Visible

Data Managers

# CRF Metadata

## Release Fix Information (OC-20956):

Fixed an issue where certain item group names for forms were missing from the study metadata page in Study Runner.

## Expected Behavior:

Metadata contains all item groups.

### View CRF Version Details: Medical History'

#### Groups

Group Name	Group OID	Group Type
RG1	IG_MEDIC_RG1	Repeating

No Item group names on the CRF Details Page

Bug

#### Items

Item Name	Item OID	Group OID	Description	Group Name	Item Data Type	Label	Response Options	Response Values	Required
diagnosis	I_MEDIC_DIAGNOSIS	IG_MEDIC_RG1			character string	Diagnosis:	text	text	No
date_diagnosis	I_MEDIC_DATE_DIAGNOSIS	IG_MEDIC_RG1			date	Date of Diagnosis:	text	text	No
ongoing	I_MEDIC_ONGOING	IG_MEDIC_RG1			character string	Ongoing?	Yes, No	1, 2	No
date_resolved	I_MEDIC_DATE_RESOLVED	IG_MEDIC_RG1			date	Date Resolved:	text	text	No
add_comm	I_MEDIC_ADD_COMM	IG_MEDIC_RG1			character string	Additional Comments:	text	text	No

### View CRF Version Details: Medical History'

#### Groups

Group Name	Group OID	Group Type
RG1	IG_MEDIC_RG1	Repeating

Item group names on the CRF Details Page

Fix

#### Items

Item Name	Item OID	Group OID	Description	Group Name	Item Data Type	Label	Response Options	Response Values	Required
diagnosis	I_MEDIC_DIAGNOSIS	IG_MEDIC_RG1		RG1	character string	Diagnosis:	text	text	No
date_diagnosis	I_MEDIC_DATE_DIAGNOSIS	IG_MEDIC_RG1		RG1	date	Date of Diagnosis:	text	text	No
ongoing	I_MEDIC_ONGOING	IG_MEDIC_RG1		RG1	character string	Ongoing?	Yes, No	1, 2	No
date_resolved	I_MEDIC_DATE_RESOLVED	IG_MEDIC_RG1		RG1	date	Date Resolved:	text	text	No
add_comm	I_MEDIC_ADD_COMM	IG_MEDIC_RG1		RG1	character string	Additional Comments:	text	text	No



# Audit Log (Non-English Studies)

## Overview:

Study Runner and Forms opened from Study Runner can be displayed in different languages based on study configuration and a user's browser locale settings. Initially, English (en) and German (de) are the supported languages.

## Release Fix Information (OC-20899):

Fixed an issue with the Study Audit Log Page where the view button hover text always displayed as "View" rather than using the user's OpenClinica study language.

## Expected Behavior:

Hover text for the "View" button display is translated into the user's OpenClinica study language.

**\*\*Screenshots on next slide\*\***



Fix is  
Automatic

Visible

Data  
Managers

# Audit Log (Non-English Studies)

Fix

The screenshot shows the OpenClinica interface for an English study. The header includes the OpenClinica logo, the study name "Study 1023: Import Validati... (23dtm1)", and navigation links for "Change", "Design", "Share", and "Settings". Below the header is a search bar with "Enter Participant ID" and a "View" button. The main content area is titled "Audit Log for Study 1023: Import Validation Test-dtm1" and features a table with columns for "Participant ID", "Created By", "Status", and "Actions". The table contains four rows of data. A red box highlights the "View" button in the "Actions" column for the first row. A red arrow points from this button to a larger, magnified view of the button on the right.

Participant ID	Created By	Status	Actions
test	dm007	Available	View
test1	dm007	Available	View
Q01-23q-1-Sub	dm007	Available	View
Q12-23q-e-Sub	dm007	Available	View

A magnified view of the "View" button, which is a small icon with a magnifying glass and the text "View" below it. A red box surrounds the button, and a red arrow points from the button in the table above to this magnified view.

Translation

The screenshot shows the OpenClinica interface for a German study. The header includes the OpenClinica logo, the study name "Studie 1023: Importvalidierung... (23dtm1)", and navigation links for "Ändern", "Design", "Teilen", and "Einstellungen". Below the header is a search bar with "Geben Sie die Teilnehmer-ID" and a "Sicht" button. The main content area is titled "Audit-Protokoll für Studie 1023: Importvalidierungstest-dtm1" and features a table with columns for "Teilnehmer-ID", "Erstellt von", "Status", and "Aktionen". The table contains four rows of data. A red box highlights the "Sicht" button in the "Aktionen" column for the first row. A red arrow points from this button to a larger, magnified view of the button on the right.

Teilnehmer-ID	Erstellt von	Status	Aktionen
prüfen	dm007	Verfügbar	Sicht
test1	dm007	Verfügbar	Sicht
Q01-23q-1-Sub	dm007	Verfügbar	Sicht
Q12-23q-e-Sub	dm007	Verfügbar	Sicht

A magnified view of the "Sicht" button, which is a small icon with a magnifying glass and the text "Sicht" below it. A red box surrounds the button, and a red arrow points from the button in the table above to this magnified view.



Fix is Automatic

Visible Data Managers

# Updates For Data Managers & Non-Data Managers

## Things YOU and your team need to know:

- [Data Transformation Module - \(OC-21140\)](#)
- [eConsent View Status - \(OC-20879\)](#)
- [eConsent Repeating Columns & Rows - \(OC-21075\)](#)
- [Data Transformation Module \(Non-English Studies\) - \(OC-20900\)](#)
- [Extracts & Scheduled Extract Jobs \(Non-English Studies\) - \(OC-20903\)](#)
- [Data Review Table Hover Text \(Non-English Studies\) - \(OC-20904\)](#)
- [Data Review Table Extract Column Headers \(Non-English Studies\) - \(OC-20905\)](#)
- [View Events - \(OC-21065\)](#)
- [ODM - \(OC-21079\)](#)
- [Source Data Verification Filtering - \(OC-20897\)](#)
- [Participate - \(OC-21194\)](#)



Click any of the hyperlinks to move through the slide deck.





# Non-Data Manager

15



Fix is Automatic



Feature is Requestable

Visible

Data Managers, Data Entry Person, Data Specialist

# Data Transformation Module

## Overview:

This feature affects a subset of clients. Data can be imported and transformed within OpenClinica's Data Transformation Module interface.

## Release Fix Information (OC-21140):

Fixed an issue where files uploaded to the Data Transformation Module that contained multiple periods had the site name appended to the filename in the wrong place when downloaded.

## Expected Behavior:

When a user downloads a file from the Data Transformation Module, the original file extension will be preserved in the download with the site name appearing before the last period in the filename.



OpenClinica Study 1023: Import Validati... (23dtrm1) | Change | Design | Share | Settings

Enter Participant ID  View

Alerts & Messages ▾

Quick Access ▾

My Queries

Instructions ▾

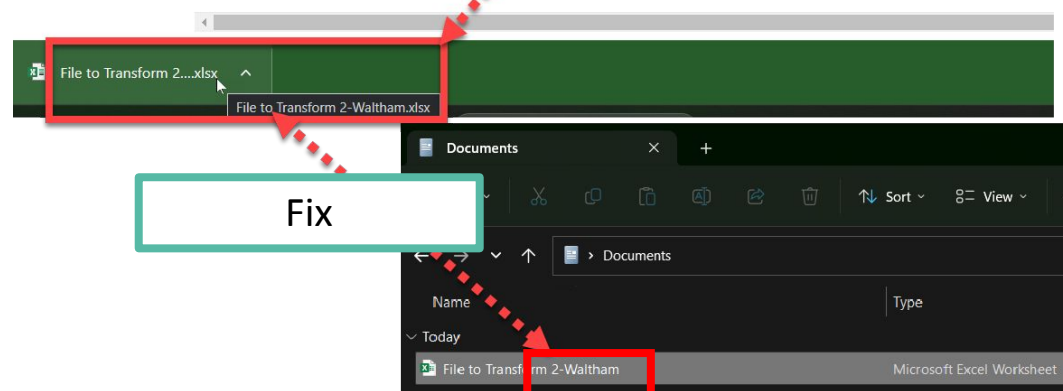
Upload files to the Data Transformation Queue to transform them with a custom pipeline, and optionally import the results. Contact your administrator with questions about customizing a pipeline.

Info ▾

### Data Transformation Queue

+ Add a new file

<input type="checkbox"/>	Actions	Site	File Name	File Type
<input type="checkbox"/>	⋮	↑↓ ▾	↑↓ ▾	↑↓ ▾
<input type="checkbox"/>	⋮	Waltham	File to Transform 3.xlsx	xlsx
<input type="checkbox"/>	⋮	Waltham	File to Transform 2.xlsx	xlsx
<input type="checkbox"/>	⋮	Waltham	File to Transform.xlsx	xlsx
<input type="checkbox"/>	⋮	1 Manual Import Validation	SAMPLE_PHYSICALEXAM_ENGLISH.xls	xls
<input type="checkbox"/>	⋮	1 Manual Import Validation	SAMPLE_PHYSICALEXAM_ENGLISH.xls	xls



# eConsent View Status

## Overview:

OpenClinica eConsent allows users to get 21 CFR Part 11-compliant signatures from participants. It also provides tools for tracking the consent status of participants.

## Release Fix Information (OC-20879):

Fixed an issue preventing certain user roles from seeing eConsent statuses on the Participant Matrix when an eConsent form contained participant contact data.

## Expected Behavior:

Show status of consent forms on the Participant Matrix for all roles regardless of the presence of contact data on the form.

Participant Matrix for a

50 Show More Select An Event Add New Participant

Participant ID	eConsent	Screening Visit	Daily Form	Visit	Consent	Actions
001	Requires Reconsent	<input checked="" type="checkbox"/>				
002	Consent Countersigned	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	
003	Consent Signed				<input checked="" type="checkbox"/>	
004	Consent Not Signed					

Results 1 - 4 of 4.

Fix

Participant Matrix for a

50 Show More Select An Event

Participant ID	eConsent	Screening Vi
001	Requires Reconsent	<input checked="" type="checkbox"/>
002	Consent Countersigned	<input checked="" type="checkbox"/>
003	Consent Signed	
004	Consent Not Signed	

Results 1 - 4 of 4.



Fix is Automatic



Feature is Configurable

Visible

All Users





Fix is Automatic



Feature is Configurable

Visible

All Users

# eConsent Repeating Columns & Rows

## Overview:

OpenClinica eConsent allows users to get 21 CFR Part 11-compliant signatures from participants. It also provides tools for tracking the consent status of participants.

## Release Fix Information (OC-21075):

Fixed an issue where duplicate eConsent Status columns were added to the Participant Matrix.

Fixed an issue where duplicate eConsent Status rows were added to the Participant Details Page. This occurred after a Data Manager saved any site configurations.

## Expected Behavior:

Per eConsent Form, only one column and one row will exist on the Participant Matrix and Participant Details Page.



Fix

General Information

Edit

Participant ID	001	Status
Study Name	RGB22	Site Name
eConsent Status	Consent Signed	

Visits

↓
Sort by Date

<b>Consent</b> <span style="float: right; color: green;">✓</span>	<b>eConsent</b> <span style="float: right; color: green;">✓</span>
30-Mar-2023	<div style="border: 1px solid orange; padding: 2px; display: inline-block;"> </div> 30-Mar-23 by...



Fix is  
Automatic

Visible

Data  
Managers,  
Data Entry  
Person, Data  
Specialist

# Data Transformation Module (Non-English Studies)

## Overview:

Study Runner and Forms opened from Study Runner can be displayed in different languages based on study configuration and a user's browser locale settings. Initially, English (en) and German (de) are the supported languages.

## Release Fix Information (OC-20900):

Fixed an issue with Data Transformation Module download button hover text always displaying as "Download" rather than using the user's OpenClinica study language.

## Expected Behavior:

Hover text for the "Download" button display is translated into the user's OpenClinica study language.

**\*\*Screenshots on next slide\*\***

# Data Transformation Module (Non-English Studies)

Fix

OpenClinica Study 1023: Import Validati... (23dtm1) | Change | Design | Share | Settings | eprager@openclinica.com (Data Manager)

Enter Participant ID  View

Home Participant Matrix Queries Study Audit Log Tasks

Alerts & Messages Data Transformation Queue

Quick Access + Add a new file

Instructions Upload files to the Data Transformation Queue to transform them with a custom pipeline, and optionally import the results. Contact your administrator with questions about customizing a pipeline.

<input type="checkbox"/>	Actions	Site	File Name	File Type	File Size (B)	Status	Uploaded On (UTC)	Uploaded By	Transformed On (UTC)
<input type="checkbox"/>		Waltham	Examination.1.2.3.xls	xls	125440	Unprocessed	05-Jun-2023 19:02	mjackson	
<input type="checkbox"/>		Waltham	Examination.test.xls	xls	125440	Unprocessed	05-Jun-2023 18:57	mjackson	
<input type="checkbox"/>		2 Manual Import Validation	data_file_visit-test1	None	160	Transformed	02-May-2023 13:47	root	02-May-2023 14:22
<input type="checkbox"/>		2 Manual Import Validation	data_file_visit-test1.txt	txt	160	Transformed	02-May-2023 13:45	root	02-May-2023 13:50
<input type="checkbox"/>		2 Manual Import Validation	data_file_dtm-1-1_Manual_Import_Validation-2_Manual_Import_Validation.txt	txt	139	Transformed	28-Mar-2023 19:59	mjackson	28-Mar-2023 20:00
<input type="checkbox"/>		2 Manual Import Validation	data_file_dtm-1-1_Manual_Import_Validation-2_Manual_Import_Validation.txt	txt	139	Imported	28-Mar-2023 14:02	mjackson	28-Mar-2023 14:02
<input type="checkbox"/>		1 Manual Import Validation	data_file_dtm-1_Manual_Import_Validation.txt	txt	166	Transformed	05-Mar-2023 00:06	mjackson	14-Mar-2023 09:20

Download

OpenClinica Studie 1023: Importvalidierung... (23dtm1) | Ändern | Design | Teilen | Einstellungen | eprager@openclinica.com (Datenmanager)

Geben Sie die Teilnehmer-ID  Sicht

Heim Teilnehmermatrix Abfragen Studien-Audit-Protokoll Aufgaben

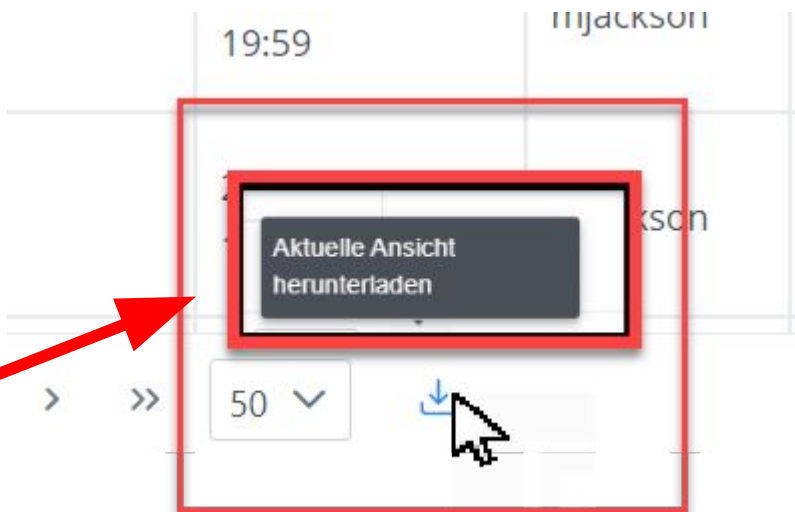
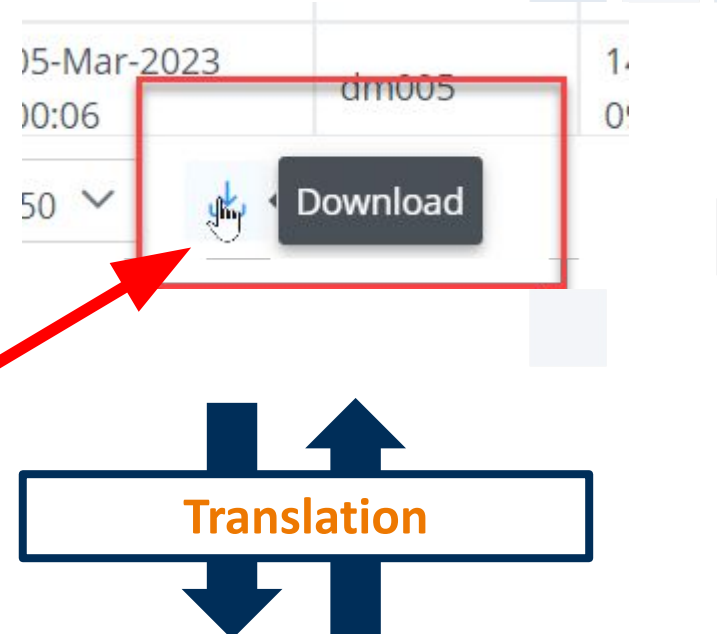
Warnungen und Nachrichten Transformationswarteschlange

Schneller Zugang Sie eine neue Datei hinzu

Anweisungen Laden Sie Dateien in die Datentransformationswarteschlange hoch, um sie mit einer benutzerdefinierten Pipeline umzuwandeln, und importieren Sie optional die Ergebnisse. Wenden Sie sich bei Fragen zum Anpassen einer Pipeline an Ihren Administrator.

<input type="checkbox"/>	Aktionen	Grundstück	Dateinamen	Dateityp	Dateigröße (B)	Status	Hochgeladen am (UTC)	Hochgeladen von	Transformiert am (UTC)
<input type="checkbox"/>		Waltham	Prüfung.1.2.3.xls	xls	125440	Unbearbeitet	05.06.2023 19:02	mjackson	
<input type="checkbox"/>		Waltham	Prüfung.test.xls	xls	125440	Unbearbeitet	05.06.2023 18:57	mjackson	
<input type="checkbox"/>		2 Manuelle Importvalidierung	data_file_visit-test1	Keiner	160	Transformiert	02. Mai 2023 13:47	Wurzel	02. Mai 2023 14:22
<input type="checkbox"/>		2 Manuelle Importvalidierung	data_file_visit-test1.txt	txt	160	Transformiert	02. Mai 2023 13:45	Wurzel	02. Mai 2023 13:50
<input type="checkbox"/>		2 Manuelle Importvalidierung	data_file_dtm-1-1_Manual_Import_Validation-2_Manual_Import_Validation.txt	txt	139	Transformiert	28.03.2023 19:59	mjackson	28.03.2023 20:00
<input type="checkbox"/>		2 Manuelle Importvalidierung	data_file_dtm-1-1_Manual_Import_Validation-2_Manual_Import_Validation.txt	txt	139	Importiert	28.03.2023 14:02	mjackson	28.03.2023 14:02

Aktuelle Ansicht herunterladen



Fix is Automatic

Visible

Data Managers, Data Entry Person, Data Specialist



Fix is Automatic

Visible

Data Managers,  
Data Specialist,  
Investigator,  
Site/Study Viewer,  
Monitor

# Extracts & Scheduled Extract Jobs (Non-English Studies)

## Overview:

Study Runner and Forms opened from Study Runner can be displayed in different languages based on study configuration and a user's browser locale settings. Currently, English (en) and German (de) are the supported languages.

## Release Fix Information (OC-20903):

Fixed an issue where an extract job or extract dataset result table always displays "Status" information in English rather than using the user's OpenClinica study language.

## Expected Behavior:

Result statuses of ""In Progress", "Completed", "Failed", "Deleted", "In Queue", "Not Executed", and "Completed with errors" are translated into the user's current browser language.

**\*\*Screenshots on next slide\*\***



# Extracts & Scheduled Extract Jobs (Non-English Studies)

Fix

Create Dataset: Select Format

Dataset name:	Extract1
Dataset description:	Extract1
Item status:	Data from all available CRFs

**Note:** Large extracts may take some time to run. Once complete, you will receive an email notification and you can download your extract in the table below.

- CDISC ODM XML 1.3 Full with OpenClinica extensions Run Now
- CDISC ODM XML 1.3 Clinical Data with OpenClinica extensions Run Now
- CDISC ODM XML 1.3 Clinical Data Run Now
- CDISC ODM XML 1.2 Clinical Data with OpenClinica extensions Run Now
- CDISC ODM XML 1.2 Clinical Data Run Now
- View as HTML Run Now
- Excel Spreadsheet Run Now
- Excel Spreadsheet (no headers) Run Now
- Tab-delimited Text Run Now
- Tab-delimited Text (no headers) Run Now
- SPSS Data and Syntax Run Now
- SAS Data and Syntax Run Now

Previously exported datasets:

Page 1 of 1

Dataset Format	File Name	Run Time (s)	File Size	Created Date	Created By	Status	Job Type	Action
ODM XML 1.2 with OC extensions		0.0	0	07-Jul-2023 03:46:53	epragen@openclinica.com	IN_PROGRESS	Manual	
Excel		0.0	0	07-Jul-2023 03:46:51	epragen@openclinica.com	IN_QUEUE	Manual	
ODM XML 1.3 with OC extensions	odm1_3_clinical_ext_Extract1_2023-07-07-034647199.xml.zip	2.0	11877	07-Jul-2023 03:46:51	epragen@openclinica.com	COMPLETED	Manual	
ODM XML 1.3 Full with OC extensions	odm1_3_full_Extract1_2023-07-07-034644564.xml.zip	3.0	23424	07-Jul-2023 03:46:47	epragen@openclinica.com	COMPLETED	Manual	

Datensatz erstellen: Wählen Sie Format aus

Datensatzname:	Extrahieren1
Beschreibung des Datensatzes:	Extrahieren1
Artikelstatus:	Daten aus allen verfügbaren CRFs

**Hinweis:** Die Ausführung großer Extrakte kann einige Zeit dauern. Sobald Sie fertig sind, erhalten Sie eine E-Mail-Benachrichtigung und können Ihren Auszug in der Tabelle unten herunterladen.

- CDISC ODM XML 1.3 Vollständig mit OpenClinica-Erweiterungen Jetzt ausführen
- CDISC ODM XML 1.3 Klinische Daten mit OpenClinica-Erweiterungen werden jetzt ausgeführt
- Klinische Daten von CDISC ODM XML 1.3 werden jetzt ausgeführt
- CDISC ODM XML 1.2 Klinische Daten mit OpenClinica-Erweiterungen werden jetzt ausgeführt
- Klinische Daten von CDISC ODM XML 1.2 werden jetzt ausgeführt
- Als HTML anzeigen Jetzt ausführen
- Excel-Tabelle jetzt ausführen
- Excel-Tabelle (ohne Kopfzeilen) Jetzt ausführen
- Tabulatorgetrennter Text wird jetzt ausgeführt
- Durch Tabulatoren getrennter Text (keine Kopfzeilen) Jetzt ausführen
- SPSS-Daten und -Syntax werden jetzt ausgeführt
- SAS-Daten und Syntax werden jetzt ausgeführt

Zuvor exportierte Datensätze:

Seite 1 von 1

Datensatzformat	Datensatznamen	Laufzeit (s)	Datengröße	Erstellungsdatum	Erstellt von	Status	Auftragstyp	Aktion
ODM XML 1.2 mit OC-Erweiterungen		0,0	0	07.07.2023 03:46:53	epragen@openclinica.com	IM GANGE	handbuch	
Excel		0,0	0	07.07.2023 03:46:51	epragen@openclinica.com	IN DER WARTESCHLANGE	handbuch	
ODM XML 1.3 mit OC-Erweiterungen	odm1_3_clinical_ext_Extract1_2023-07-07-034647199.xml.zip	2,0	11877	07.07.2023 03:46:51	epragen@openclinica.com	VOLLENDET	handbuch	
ODM XML 1.3 Vollständig mit OC-Erweiterungen	odm1_3_full_Extract1_2023-07-07-034644564.xml.zip	3,0	23424	07.07.2023 03:46:47	epragen@openclinica.com	VOLLENDET	handbuch	

Status	Job T
IN_PROGRESS	Man
IN_QUEUE	Man
COMPLETED	Man
COMPLETED	Man



Status	Auftr
IM GANGE	Hand
IN DER WARTESCHLANGE	Hand
VOLLENDET	Hand
VOLLENDET	Hand



Fix is Automatic

Visible

Data Managers,  
Data Specialist,  
Investigator,  
Site/Study Viewer,  
Monitor



Fix is  
Automatic

Visible

Study Users

# Data Review Table Hover Text (Non-English Studies)

## Overview:

Study Runner and Forms opened from Study Runner can be displayed in different languages based on study configuration and a user's browser locale settings. Currently, English (en) and German (de) are the supported languages.

## Release Fix Information ([OC-20904](#)):

Fixed an issue with Data Review Table download button hover text always displaying as "Download current view" rather than using the user's OpenClinica study language.

## Expected Behavior:

Hover text for the download button translates to the user's OpenClinica study language.

**\*\*Screenshots on next slide\*\***

# Data Review Table Hover Text (Non-English Studies)

Fix



Fix is Automatic

## Multi-Level\_CRF

<input type="checkbox"/>	Participant ID	Site	Event Start Date	Form Status	Occurrence	Event Name	Event Status	Form Last ModifiedBy	Form Last Modified Date
<input type="checkbox"/>	Q07-23x-o-Sub	1 Manual Import Validation	29-Mar-2022	data entry complete	1	23_Repeating_Event1	data entry started	dm007	29-Mar-2022
<input type="checkbox"/>	Q07-23x-m-Sub	1 Manual Import Validation	01-Jan-2020	data entry complete	1	23_Repeating_Event1	data entry started	dm007	29-Mar-2022
<input type="checkbox"/>	Q07-23x-e-Sub	1 Manual Import Validation	13-Dec-2020	data entry complete	1	23_Repeating_Event1	data entry started	dm007	29-Mar-2022
<input type="checkbox"/>	Q07-23x-b-Sub	1 Manual Import Validation	13-Dec-2020	data entry complete	1	23_Repeating_Event1	data entry started	dm007	29-Mar-2022
<input type="checkbox"/>	Q07-23x-f-Sub	1 Manual Import Validation	13-Dec-2020	data entry complete	1	23_Repeating_Event1	data entry started	dm007	29-Mar-2022

Showing 1 to 20 of 34 entries << < 1 2 > >> 20

Download current view

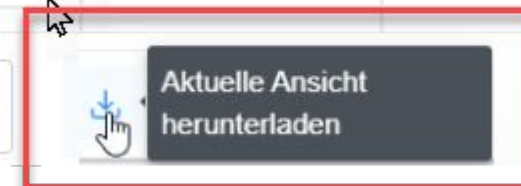


## Multi-Level\_CRF

<input type="checkbox"/>	Teilnehmer-ID	Grundstück	Startdatum der Veranstaltung	Formularstatus	Auftreten	Veranstaltungsname	Ereignisstatus	Formular zuletzt geändert von	Datum der letzten Änderung des Formulars
<input type="checkbox"/>	Q07-23x-o-Sub	1 Manuelle Importvalidierung	29. März 2022	Dateneingabe abgeschlossen	1	23_Wiederholendes_Ereignis1	Dateneingabe gestartet	dm007	29. März 2022
<input type="checkbox"/>	Q07-23x-m-Sub	1 Manuelle Importvalidierung	01.01.2020	Dateneingabe abgeschlossen	1	23_Wiederholendes_Ereignis1	Dateneingabe gestartet	dm007	29. März 2022
<input type="checkbox"/>	Q07-23x-e-Sub	1 Manuelle Importvalidierung	13. Dezember 2020	Dateneingabe abgeschlossen	1	23_Wiederholendes_Ereignis1	Dateneingabe gestartet	dm007	29. März 2022

Zeigt 1 bis 20 von 34 Einträgen << < 1 2 > >> 20

Aktuelle Ansicht herunterladen



Visible

Study Users



Fix is Automatic

Visible

Study Users

# Data Review Table Extract Column Headers (Non-English Studies)

## Overview:

Study Runner and Forms opened from Study Runner can be displayed in different languages based on study configuration and a user's browser locale settings. Currently, English (en) and German (de) are the supported languages.

## Release Fix Information (OC-20905):

Fixed an issue where downloaded Data Review Table files contained column headers in English rather than using the user's OpenClinica study language.

## Expected Behavior:

Extract Column Header text translates to the user's OpenClinica study language.

Multi-Level\_CRF

Fix

Teilnehmer-ID	Startdatum des Ereignisses	Formularstatus	Vorkommen	Ereignisname	Ereignisstatus
TOC13555S001		Dateneingabe abgeschlossen	3	Repeat_Common1	abgeschlossen

AutoSave Off DataReviewTable\_drt\_repeat\_common\_event\_2023-06-28-012121000

File Home Insert Draw Page Layout Formulas Data Review View Automate

Calibri 11 A A

B I U Font Alignment

F1 Formular zuletzt geändert von

Teilnehmer-ID	Startdatum des Ereignisses	Formularstatus	Ereignisname	Ereignisstatus
TOC13555S001		Dateneingabe abgeschlossen	Repeat_Common1	abgeschlossen
TOC13555S001		erste Dateneingabe	Repeat_Common1	Dateneingabe begonnen
TOC13555S001		Dateneingabe abgeschlossen	Repeat_Common1	abgeschlossen
OC13555TestSite001		Dateneingabe abgeschlossen	Repeat_Common1	abgeschlossen
OC13555TestSite001		Dateneingabe abgeschlossen	Repeat_Common1	abgeschlossen
OC13555TestSite001		Dateneingabe abgeschlossen	Repeat_Common1	abgeschlossen





Fix is Automatic

# View Events

## Overview:

You can use this page to filter Study Events. The default view shows Study Events that apply to the current month. Participants for whom Events were scheduled but have not had data recorded as of the expected Event date will appear highlighted in yellow.

## Release Fix Information (OC-21065):

Resolved an issue where participant IDs were not shown on the View Events page.

## Expected Behavior:

Participant IDs shown on the View Events page.

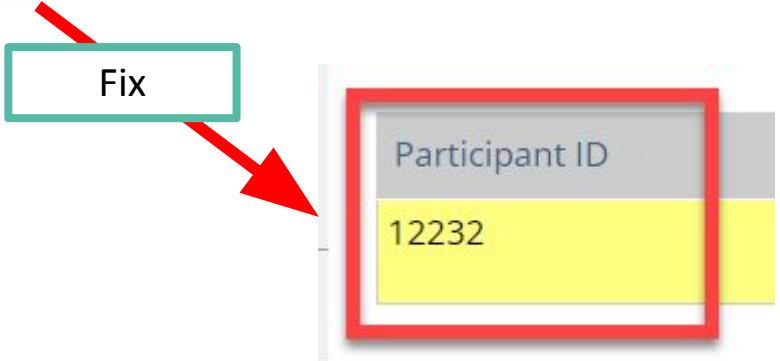
View All Events in Study 1023

Filter events by:  
Study Event Definition: --All--  
Status: --All--  
Date Started: 02-April-2023  
Date Ended: 07-Jul-2023  
Apply Filter

Event Name: Repeating\_Event  
Event Type: Unscheduled, Repeating Category: N/A  
Participants Scheduled: 1 (start date of first Event: 02-May-2023 ) Completed: 0 (completion date of last Event: N/A ) Discontinued: 0

Page 1 of 1

Participant ID	Event Start Date	Event Status	Actions
12232	02-May-2023	scheduled	



Visible

All Users



Fix is Automatic

Visible

Data Managers, Data Specialist, Investigator, Site Viewer, Study Monitor, Study Viewer

# ODM

## Overview:

OpenClinica provides and/or consumes CDISC ODM XML representations in its Extract Data and Import Data modules and other parts of the software.

## Release Fix Information (OC-21079):

Fixed a data extract formatting issue with OpenClinica Extension ODM nodes, specifically OpenClinica:StudyDetails XML node.

## Expected Behavior:

Extracting data in an ODM XML format contains OpenClinica:StudyDetails XML node information as XML tag attributes rather than as values outside of the XML tag.

```

</FormRef>
</StudyEventDef>
<FormDef OID="F_CONTACTDATAF" Name="Contact Data Form" Repeating="No">
  <ItemGroupRef ItemGroupOID="IG_CONTA_RG1" Mandatory="No"/>
  <OpenClinica:FormLayoutDef OID="1" OpenClinica:Status="AVAILABLE">
    <OpenClinica:URL/>
  </OpenClinica:FormLayoutDef>
  <OpenClinica:FormDetails>
  </OpenClinica:FormDetails>
</FormDef>
<ItemGroupDef OID="IG_CONTA_RG1" Name="RG1" Repeating="No" SASDatasetName="RG1">
  <ItemRef ItemOID="I_CONTA_DIAGNOSIS" OrderNumber="1" Mandatory="No"/>
</ItemGroupDef>
<ItemDef OID="I_CONTA_DIAGNOSIS" Name="diagnosis" DataType="text" Length="4000"
  SASFieldName="diagnosis" OpenClinica:FormOID="F_CONTACTDATAF">
  <Question>
    <TranslatedText>
      Diagnosis
    </TranslatedText>
  </Question>
</ItemDef>
<OpenClinica:StudyDetails StudyOID="S_DLILT(PROD)">
  DateCreated="2023-05-19" StartDate="2020-06-29"
  StudyCompletionDate="2023-12-31"
  <OpenClinica:StudySystemStatus>AVAILABLE</OpenClinica:StudySystemStatus>
  <OpenClinica:PrincipalInvestigator>null</OpenClinica:PrincipalInvestigator>
  <OpenClinica:StudyPhase>PHASEIV</OpenClinica:StudyPhase>
  <OpenClinica:ProtocolType>interventional</OpenClinica:ProtocolType>
  <OpenClinica:ExpectedTotalEnrollment>200</OpenClinica:ExpectedTotalEnrollment>

```

Bug

StudyCompletionDate="2023-12-31";>

```

</FormRef>
</StudyEventDef>
<FormDef OID="F_CONTACTDATAF" Name="Contact Data Form" Repeating="No">
  <ItemGroupRef ItemGroupOID="IG_CONTA_RG1" Mandatory="No"/>
  <OpenClinica:FormLayoutDef OID="1" OpenClinica:Status="AVAILABLE">
    <OpenClinica:URL/>
  </OpenClinica:FormLayoutDef>
  <OpenClinica:FormDetails>
  </OpenClinica:FormDetails>
</FormDef>
<ItemGroupDef OID="IG_CONTA_R
  <ItemRef ItemOID="I_CONTA
</ItemGroupDef>
<ItemDef OID="I_CONTA_DIAGNOS
  SASFieldName="diagnosis" OpenClinica:FormOID="F_CONTACTDATAF">
  <Question>
    <TranslatedText>
      Diagnosis
    </TranslatedText>
  </Question>
</ItemDef>
<OpenClinica:StudyDetails StudyOID="S_DLILT(PROD)"
  DateCreated="2023-06-10" StartDate="2016-01-01" StudyCompletionDate="2021-12-31"
  <OpenClinica:StudySystemStatus>AVAILABLE</OpenClinica:StudySystemStatus>
  <OpenClinica:PrincipalInvestigator>null</OpenClinica:PrincipalInvestigator>
  <OpenClinica:StudyPhase>PHASEIV</OpenClinica:StudyPhase>
  <OpenClinica:ProtocolType>interventional</OpenClinica:ProtocolType>
  <OpenClinica:ExpectedTotalEnrollment>200</OpenClinica:ExpectedTotalEnrollment>

```

Fix

StudyCompletionDate="2021-12-31">





Fix is Automatic

# Source Data Verification (SDV) Filtering

## Overview:

Source Data Verification (SDV) is the process of reviewing and verifying data against source records to ensure accuracy. The SDV table only displays completed forms with an SDV requirement other than Not Applicable. You can filter a column by clicking the gray box below the column header.

## Release Fix Information (OC-20897):

Fixed an issue where users experienced incorrect total CRF result counts on the SDV table due to sites with forms marked as hidden.

Fixed an issue where filtering on the SDV table could show incorrect results if there was a form that appeared in multiple events with different SDV settings.

## Expected Behavior:

Correct SDV table results rows are displayed when using one or more column filters.

Fix

Source Data Verification

15 Show More

Select: All Shown None

SDV Status	Participant ID	Site ID	Open Queries	Event Name	Event Date	CRF Name	SDV Requirement	CRF Status	Actions
Ready to verify + ...						Treatment			Apply Filter Clear Filter
<input type="checkbox"/>	007	HOSP-A	0	Cycle 1	14-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	012	HOSP-A	0	Cycle 1	21-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	004	HOSP-A	0	Cycle 1	21-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	006	HOSP-A	0	Cycle 1	21-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	015	HOSP-A	0	Cycle 1	22-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	004	HOSP-A	0	Cycle 2	22-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	014	HOSP-A	0	Cycle 1	24-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	006	HOSP-A	0	Cycle 2	28-Nov-2022	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	001	HOSP-A	0	Cycle 1	30-Jun-2023	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	003	HOSP-A	0	Cycle 1	30-Jun-2023	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	005	HOSP-A	0	Cycle 1	30-Jun-2023	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	001	HOSP-A	0	Cycle 2	06-Jul-2023	Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	003			06-Jul-2023		Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	005			06-Jul-2023		Treatment	Item Level	✓	Q Data Verify
<input type="checkbox"/>	007			06-Jul-2023		Treatment	Item Level	✓	Q Data Verify

Results 1 - 15 of 18.

Apply one or more filters

Correct total of filtered results





# Participant





Fix is Automatic



Feature is Configurable

Visible

Participant, Site Users

# Participate Dashboard Display

## Overview:

OpenClinica Participate allows you to design Forms for Participant data entry.

## Release Fix Information (OC-21194):

Fixed a Participate issue where the Dashboard would not show any forms when a Participant's next forms to complete were in a visit containing many forms.

## Expected Behavior:

Participate users can access events and forms via Participate when events contains a large number of forms. Example 90+ forms in 1 event.

CAR-T Study

Welcome, Bob. Ready to get started?

Event containing a large number of forms

QOL (Pre-Treatment)  
0 of 2 worked on. Complete by October 3

RAND SF-12 Form 1 Let's Go →

FACT-G (ePRO) Form 2 Let's Go →

⋮

SF-T-G (ePRO) Form x Let's Go →



# Index: Tickets, Info, & Links

# Release Log

- **Study Runner**

- CRF metadata

- ([OC-20956](#)) - Fixed an issue where certain item group names for forms were missing from the study metadata page in Study Runner.

- View events

- ([OC-21065](#)) - Resolved an issue where participant IDs were not shown on the View Events page.

- ODM

- ([OC-21079](#)) - Fixed a data extract formatting issue with OpenClinica Extension ODM nodes, specifically OpenClinica:StudyDetails XML node.

- Source Data Verification (SDV)

- ([OC-20897](#)) - Fixed an issue where filtering on the SDV table could show incorrect results if there was a form that appeared in multiple events with different SDV settings.

# Release Log Continued

- **Study Runner Continued**
  - **Data Transformation Module (DTM)**
    - ([OC-21140](#)) - Fixed an issue where files uploaded to the Data Transformation Module containing multiple periods were, when downloaded, having the site name appended to the filename in the wrong place.
  - **eConsent**
    - ([OC-20879](#)) - Fixed an issue preventing certain user roles from seeing eConsent statuses on the Participant Matrix when an eConsent form contained participant contact data.
    - ([OC-21075](#)) - Fixed an issue where duplicate eConsent Status columns were added to the Participant Matrix. Fixed an issue where duplicate eConsent Status rows were added to the Participant Details Page. This occurred after a Data Manager saved any site configurations.



# Release Log Continued

- **Non-English Studies**

- Audit Log

- ([OC-20899](#)) - Fixed an issue with the Study Audit Log Page where the view button hover text always displayed as "View" rather than using the user's OpenClinica study language.

- Data Transformation Module

- ([OC-20900](#)) - Fixed an issue with Data Transformation Module download button hover text always displayed as "Download" rather than using the user's OpenClinica study language.

- Extracts & Scheduled Extract Jobs

- ([OC-20903](#)) - Fixed an issue where an extract job or extract dataset result table always displayed "Status" information in English rather than using the user's OpenClinica study language.

- Data Review Table

- ([OC-20904](#)) - Fixed an issue with Data Review Table download button hover text always displayed as "Download current view" rather than using the user's OpenClinica study language.
    - ([OC-20905](#)) - Fixed an issue where downloaded Data Review Table files contained column headers in English rather than using the user's OpenClinica study language.

# Release Log Continued

- **Form Designer**

- ([OC-20919](#)) - Fixed an issue where users experienced an error message when previewing forms in Form Designer.

- **Calendaring**

- ([OC-21124](#)) - Resolved an issue where calendaring rules were not firing due to a lock on the participant's calendar.

- **Participate**

- ([OC-21194](#)) - Fixed a Participate issue where the Dashboard would not show any forms when a Participant's next forms to complete were in a visit containing many forms.

- **Security**

- Enhanced security

# Thank you

