

Event/Form Actions and Statuses:

[Overview video](#)

We are using a new status data model to provide more clarity on Event and Form statuses. In addition to the Workflow Statuses of **Not Scheduled**, **Scheduled**, **Data Entry Started**, **Stopped**, **Skipped**, and **Completed** Events can have the following independent statuses: **Locked**, **Signed**, **Removed**, and **Archived**. In addition to the Workflow Statuses of **Not Started**, **Initial Data Entry**, and **Complete**, Forms can have the following independent statuses: **Removed** and **Archived**.

The statuses can still be changed on the **Update Event** screen as before. In addition, buttons for **Lock**, **Unlock**, and **Sign** have been added directly to the **Participant Details** screen for eligible users. **Remove** is still available from many study screens, and **Archive** is still available from the Study Designer interface.

If an Event has a Workflow Status and other statuses, for example, **Completed**, **Locked**, and **Signed**. The **Status** column displays **Completed** with icons for the **Locked** and **Signed** underneath. If an Event is removed, then **Removed** will replace the Workflow Status.

Form statuses are similarly indicated by a Workflow Status and additional icons for other statuses. If a Form is currently using a Form Version that has been archived, an **Archived** icon is displayed next to the Form Version. This applies to the **Participant Matrix**, **Participant Details** screen, and **Enter or Validate Data** screen, which is used for viewing single Visit-Based Events.

Note: In the ODM schema, **OpenClinica:Status** for Events and Forms has been deprecated. It has been replaced by **OpenClinica:WorkflowStatus**, **OpenClinica:Archived**, **OpenClinica:Removed**, **OpenClinica:Signed**, and **OpenClinica:Locked**. For compatibility, the **OpenClinica:Status** ODM attribute will continue to be maintained for at least 3 months. Customers using integrations with OpenClinica or otherwise consuming the ODM data directly should make appropriate updates to stop using **OpenClinica:Status** during this time. All the same information is included in the new status model, but with more flexibility and precision.

Participant 003 003 Audit Log | Showing **Active Records**






















General Information

Edit

Participant ID	003	Status	Available
Study Name	Severe Headache Study	Site Name	BOSH

Visits

Page 1 of 1 **Find** **Add New**

Event (Occurrence Number)	Start Date	Status	Event Actions	CRFs															
Eligibility	20-Aug-2020	completed 	 	<table border="1"> <thead> <tr> <th>Name</th> <th>Version</th> <th>Status</th> <th>Update</th> <th>Actions</th> </tr> </thead> <tbody> <tr> <td>Consent</td> <td>1</td> <td> </td> <td>20-Aug-2020 (ktamminvadmin)</td> <td></td> </tr> <tr> <td>Eligibility</td> <td>1</td> <td> </td> <td>20-Aug-2020 (ktamminvadmin)</td> <td></td> </tr> </tbody> </table>	Name	Version	Status	Update	Actions	Consent	1	 	20-Aug-2020 (ktamminvadmin)		Eligibility	1	 	20-Aug-2020 (ktamminvadmin)	
Name	Version	Status	Update	Actions															
Consent	1	 	20-Aug-2020 (ktamminvadmin)																
Eligibility	1	 	20-Aug-2020 (ktamminvadmin)																

A new Form action, **Clear Form**, has replaced the **Delete** action. This clears all data in the Form, but audit history is retained. Once the icon is clicked, the Form status becomes **Not Started**.

Participant 002 002 Audit Log | Showing **Active Records**





























General Information

Edit

Participant ID	002	Status	Available
Study Name	Severe Headache Study	Site Name	BOSH

Visits

Page 1 of 1 **Find** **Add New**

Event (Occurrence Number)	Start Date	Status	Event Actions	CRFs															
Eligibility	20-Aug-2020	completed	   	<table border="1"> <thead> <tr> <th>Name</th> <th>Version</th> <th>Status</th> <th>Update</th> <th>Actions</th> </tr> </thead> <tbody> <tr> <td>Consent</td> <td>1</td> <td></td> <td>21-Aug-2020 (ktamm)</td> <td> </td> </tr> <tr> <td>Eligibility</td> <td>1</td> <td></td> <td>21-Aug-2020 (ktamm)</td> <td>   </td> </tr> </tbody> </table>	Name	Version	Status	Update	Actions	Consent	1		21-Aug-2020 (ktamm)	 	Eligibility	1		21-Aug-2020 (ktamm)	   
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Consent	1		21-Aug-2020 (ktamm)	 															
Eligibility	1		21-Aug-2020 (ktamm)	   															

SDV with Item-Level Data, Additional Columns, Actions, and Statuses:

[Overview video](#)

When a Form that was verified has any data changed, it will automatically update to Changed since Verified status. Status filters in the SDV column have changed to **Verified**, **Ready to Verify**, **Changed since Verified**, and **Ready to Verify + Changed since Verified**.

The new column, **Open Queries**, displays the number of open queries for the corresponding Form. You can go to the **Queries** screen by clicking the number of open queries.

The existing **CRF Status** column displays icons according to the new status model described above.

Source Data Verification for Severe Headache Study

| 50 | 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
	001	HEADACHESTUDY	0	Eligibility	20-Aug-2020	Consent	Not Required		Data
	002	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required		Data Verify
	002	1234567	1	Eligibility	20-Aug-2020	Eligibility	Not Required		Data
	003	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required		Data Verify
	003	1234567	0	Eligibility	20-Aug-2020	Eligibility	Not Required		Data Verify
	004	1234567	0	Eligibility	20-Aug-2020	Consent	Not Required		Data
	004	1234567	0	Eligibility	20-Aug-2020	Eligibility	Not Required		Data Verify

Results 1 - 7 of 7.

[Verify All Checked](#)

You can now click the **Data** button to view item-level data for any Form in the **SDV** table. This view includes the following for each item on the Form: current value, number of open queries, last modified date, last verified date, and a link to open the Form directly to the item. This view automatically defaults to showing only items that have been changed since the Form was last verified.

Participant ID: 002

Site ID: 1234567

Form Name: Eligibility

Form Status: data entry complete

Event Name: Eligibility

Event Start Date: 20-Aug-2020 12:00

SDV Requirement: Not Required

SDV Status: Changed since verified

[Clear Filter](#) ☐ Show all items ☒ Show only changed since last Verified

Brief Description (Item Name)	Value	Last Verified (UTC)	Open Queries	Last Modified (UTC)	Modified By	Actions
Participant suffers from severe headaches (participant_suffers_from)	no	20-Aug-2020 13:50	0	21-Aug-2020 19:05	Kerry Tamm	

[Verify](#)

Navigation for Data Managers and Administrators:

Data Managers and Administrators can now navigate from the current study in Runtime to the Study Build System for the same study by clicking links at the top of the screen.


Scheduled Extract Jobs:

Users with a **User Type** of **Admin** can configure extract jobs to run daily, weekly, or monthly. The resulting datasets can be downloaded via the Datasets screen as well as via API. The new APIs for working with Scheduled Extract Jobs are available from the **Web Services Information** screen.

Create Scheduled Job: Export Dataset

Note that the job is set to run on the server time. The current server time is 21-Aug-2020 14:45:48.

* indicates required field.

Job Name: *	<input type="text" value="Daily Export"/>
Description: *	<input type="text" value="A daily export"/>
Please Pick a Dataset to Export: *	<input type="text" value="v"/>
Period to Run: *	Daily <input checked="" type="radio"/> Weekly <input type="radio"/> Monthly <input type="radio"/>
Start Date/Time: *	<input type="text" value="21-Aug-2020"/>  <input type="text" value="14"/> : <input type="text" value="45"/> (DD-MMM-YYYY HH:MM)
File Format: *	<div><div>CDISC ODM XML 1.3 Full with OpenClinica extensions <input checked="" type="radio"/></div><div>CDISC ODM XML 1.3 Clinical Data with OpenClinica extensions <input type="radio"/></div><div>CDISC ODM XML 1.3 Clinical Data <input type="radio"/></div><div>CDISC ODM XML 1.2 Clinical Data with OpenClinica extensions <input type="radio"/></div><div>CDISC ODM XML 1.2 Clinical Data <input type="radio"/></div><div>View as HTML <input type="radio"/></div><div>Excel Spreadsheet <input type="radio"/></div><div>Tab-delimited Text <input type="radio"/></div><div>SPSS Data and Syntax <input type="radio"/></div><div>SAS Data and Syntax <input type="radio"/></div></div>
Number of Files to Save:	<input type="text" value="1"/> v
Contact Email: *	<input type="text" value="investigator@example.com"/>
<div><div>Confirm and Save</div><div>Cancel</div></div>	

Import Tabular Files (Excel, CSV, Pipe-Delimited, SAS):

The **Import Data** link on the **Tasks** menu now goes to a screen that includes a link to import Tabular files in addition to a link to import XML files.

For Tabular files, the type of delimiter (for example, pipe, comma, or tab) can be set in the Data Mapping Template along with other import configurations and the mapping between the Data file and the items on your Forms. After a Tabular import job is completed, a log of the results is accessible from the same page.

Import CRF Data

Import XML Data

Import CRF data from XML files. This matches the CDISC ODM XML extract format.

Import Tabular Data

Import CRF data from flat, tabular files. Supported formats include Excel, Text, CSV, and SAS.

Import Tabular CRF Data

Upload one data file and one mapping file. Supported file formats: .xlsx, .txt, .csv, and .sas7bdat. For .txt files, configure the delimiter in the mapping file.

Choose Files No file chosen

Submit

Cancel

[Download mapping template](#) (open in a text editor after downloading)

Log File Name	File Size	Updated Time	Action
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Insight:

[Overview video](#)

Insight has a new UI and new Report Builder with the ability to join tables without using SQL.

Note: In addition to other changes being made to columns in Insight data tables, the **study_event_status_label** column for Event statuses and **event_crf_status_label** for Forms statuses have been deprecated. They have been replaced by columns named **label** in their respective status tables, and **archived**, **removed**, **signed**, and **locked** in the Events/Forms tables.

Likewise, the **sdv_status** column will be replaced by the column **label** in the **event_crf_sdv_status** table. For compatibility, the **study_event_status_label** column, **event_crf_status_label** column, **sdv_status** column, and other deprecated status columns, will continue to be maintained for at least 3 months.

Customers using the **study_event_status_label** or **event_crf_status_label** column in reports should make appropriate updates to stop using this column during this time. All the same information is included in the new status model, but with more flexibility and precision.

Since these columns may be widely used to monitor progress, they may be among the most impactful, but there are other columns that will also be affected. A full list of the changes being made to Insight table structures and guidance on how to update your existing Questions to prepare for the deprecations will be provided with the upgrade.

The screenshot shows a web application interface for a study named "CAR-T Study (TEST)". The breadcrumb trail indicates the current view is "s_bfbd2019test" > "1. Demographics and History - group1". The interface includes a search bar at the top left and navigation links like "Ask a question", "Browse Data", and "Save" at the top right. The main query builder area is divided into several sections: "Data" with a selected table "1. Demographics and History - group1"; "Join data" with a "Pick a table..." button; "Filter" with a filter "Event Name is Baseline" and a "+" button to add more; and "Summarize" with a "Pick the metric you want to see" button and a "Pick a column to group by" button. A "Visualize" button is located at the bottom left of the query builder area.

Performance Improvements and Bug Fixes:

- Form loading improvements for existing Forms that already contain data
- Loading improvements for the **Participant Matrix**
- Loading improvements for the **Enter or Validate Data** screen
- PDF Casebook improvements, such as formatting and including the site name in the header
- Administrators can find users more easily from the **Administration** screen
- Updates query workflow so that only Data Managers and Monitors can reopen closed queries
- And many more enhancements and fixes too numerous to list.