#### **Event/Form Actions and Statuses:**

#### Overview video

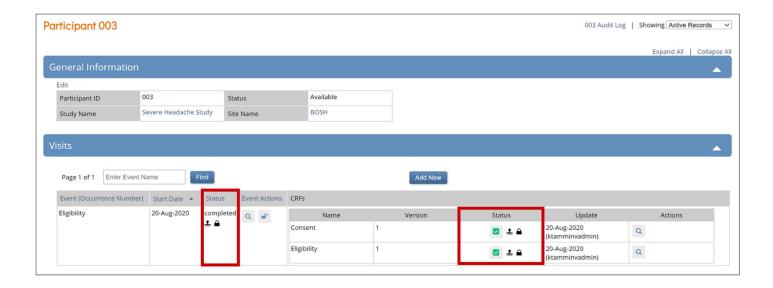
We are using a new status data model to provide more clarity on Event and Form statuses. In addition to the Workflow Statuses of Not Scheduled, Scheduled, Data Entry Started, Stopped, Skipped, and Completed Events can have the following independent statuses: Locked, Signed, Removed, and Archived. In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

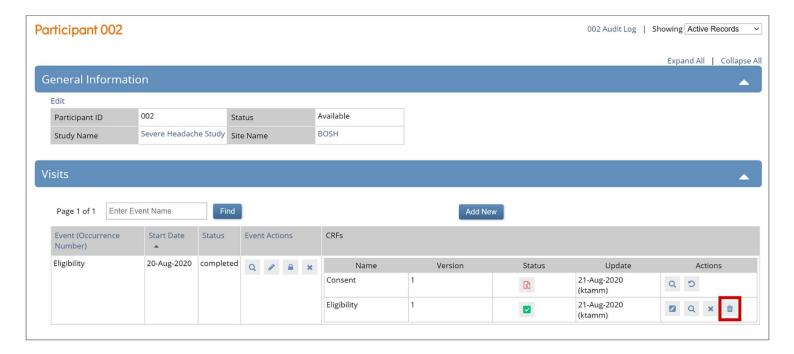
If an Event has a Workflow Status and other statuses, for example, **Completed**, **Locked**, and **Signed**. The **Status** column displays **Completed** with icons for the **Locked** and **Signed** underneath. If an Event is removed, then **Removed** will replace the Workflow Status.

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 If a Form is currently using a Form Version that has been archived, an **Archived** icon is displayed next to the Form Version.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 It has been replaced by **OpenClinica:WorkflowStatus**, **OpenClinica:Archived**, **OpenClinica:Removed**, **OpenClinica:Signed**, and **OpenClinica:Locked**.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.



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**.



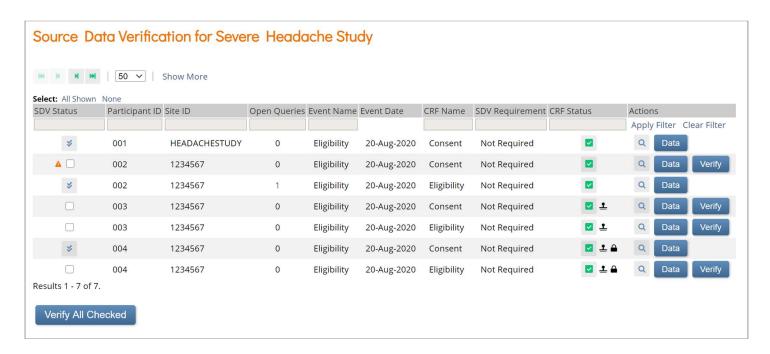
SDV with Item-Level Data, Additional Columns, Actions, and Statuses:

# 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.



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.



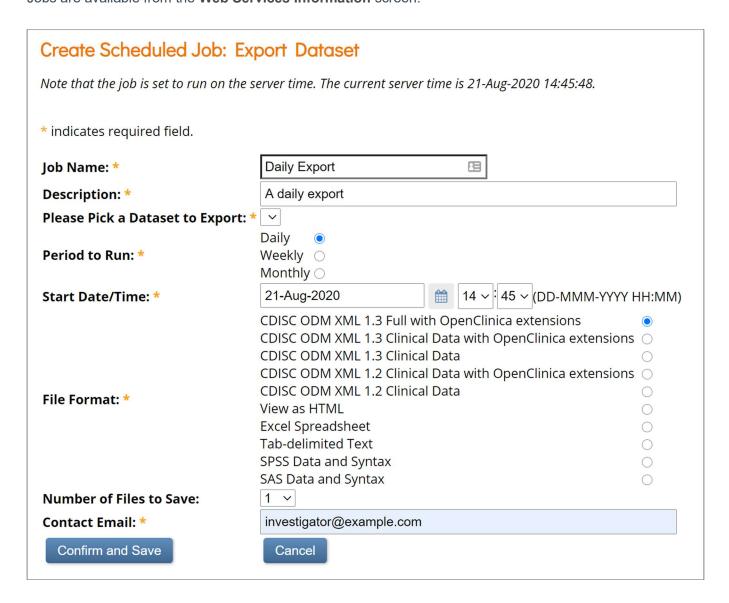
#### **Navigation for Data Managers and Administrators:**

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.



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 delimite | er 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 Time  Action                                  |                         |

## Insight:

## Overview video

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

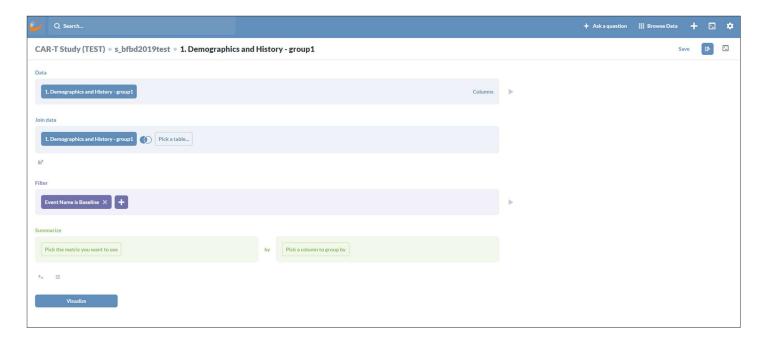
Note: In addition to other changes being made to columns in Insight data tables,

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.



#### **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.