3 Monitor and Manage Data

With the Monitor and Manage Data module in OpenClinica, you can oversee and validate data for a Study, allowing for increased productivity in clinical trials management. Access to the features in the module depends on your User Role: see Monitor and Manage Data - Permissions.

The module consists of the following features:

- **Source Data Verification:** When you review the conformity of data in CRFs and for Study Subjects, you can use Source Data Verification to track your evaluations, helping to ensure the Study is complete, accurate, and verifiable.
- **Study Audit Log:** You can view the change history for each Study Subject in log format and use it to facilitate the validation process of a Study.
- **Subject Matrix:** You can view information about each Subject in the Study or Site from the Subject matrix.
- **View Events:** You can view information about any Study Event.
- **Notes and Discrepancies:** Use Notes and Discrepancies for query and discrepancy management capabilities to help you verify the accuracy and completeness of data in a clinical trial.
- **Rules:** Use these tools to validate data entry for CRFs, test specific rule action, and perform cross-field and cross-form edit checks. Rules in OpenClinica are flexible and easy to define, run, and reuse. For details, see the Rules chapter.
- **Groups:** Use Subject Group Classes to categorize Subjects within a Study, such as for treatment options. There can be multiple Group Classes within a Study.
- **Manage CRFs:** View all case report forms (CRFs) for a Study, create new CRFs, or create new versions of existing CRFs.

3.1 Source Data Verification

When you review the conformity of data in CRFs, you can use the OpenClinica Source Data Verification (SDV) feature to track your evaluations, helping to ensure the Study is complete, accurate, and verifiable.

With the SDV feature, OpenClinica presents CRFs in a table format for you to verify. You can view the table either by Event CRF or by Subject, and filter the table to show only CRFs that match

criteria you specify. After you verify the data, you can mark CRFs as verified, either individually or as a group.

You can also use the Source Data Verification table to determine the CRFs that have been verified and those that have not.

When you add CRFs as part of creating the Study Event Definition, you specify if Source Data Verification is not applicable, not required, partially required, or 100% required for the CRF.

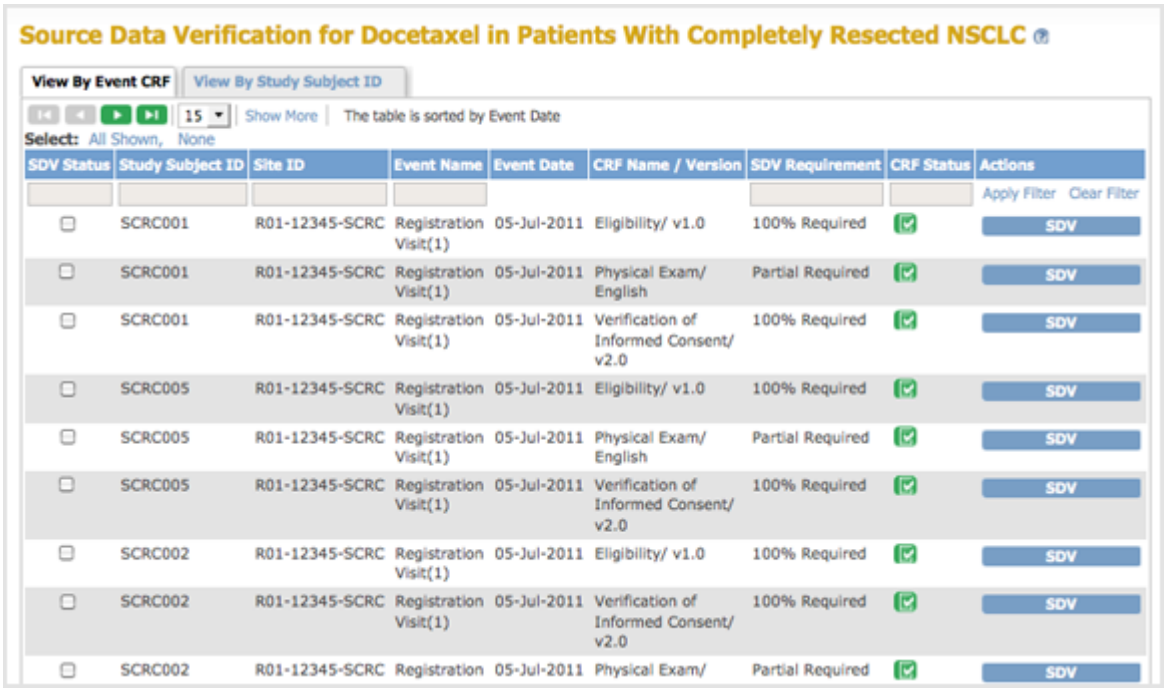
What does 'partially required' mean? Often there are CRFs which require 100% review, meaning every field on every CRF should be reviewed (such as for Adverse Events). Other CRFs, however, may only need to be partially reviewed. OpenClinica does not define what "partial" means, but it would be defined in your monitoring plan and you would instruct your team as to how to use this. Typically there are two ways that "partial" is used in organizations:

1. An organization may identify several fields in a CRF which are critical to the study. Monitors would be instructed to review only these fields in a CRF (rather than the whole CRF) for all of the subjects.
2. A monitor may review every field in the CRF but may only do this for a percentage of the subjects (instead of all subjects).

3.1.1 Verify Source Data

Users whose Roles have appropriate permission can verify source data in OpenClinica. To perform Source Data Verification, follow these steps:

1. Change the Current Study or Site to the one you want to perform Source Data Verification for.
2. Select Tasks > Source Data Verification.
   The Source Data Verification page for the current Study or Site opens.



3. Customize the view so the page shows only those CRFs or Subjects whose data you want to verify. By default, the view is By CRF, which lists only CRFs that are marked complete and therefore ready for Source Data Verification. The By Subject view lists all Subjects in the current Study or Site.
4. View details for the CRFs whose data you want to verify. How you access the CRF depends on how you set the view in the SDV page:
    - In the Event CRF view, for the CRF you want to view, click the icon in the CRF Status column.
    - In the Study Subject ID view, click the View icon in the Actions column for the Subject. The page shows all Event CRFs ready for verification for that Subject. Click the CRF Status icon for the CRF you want to view.

   The completed CRF opens in a new window.
5. Review the data in the CRF. You can add a Query type Discrepancy Note to record a question about any Item.
6. When you finish reviewing data in the CRF, click the Close button in the CRF window, which closes it. (Note that if you click Exit instead, the window remains open, showing Subject details.)
7. To mark the data as verified, in the Source Data Verification page click the SDV button for the CRF.

   In the SDV status column, the checkbox is replaced by an SDV Complete icon. In the Audit Log for the Subject, the Event CRF Source Data Verification Status is reported as true, and the date, time, and user are also recorded.
8. Continue viewing details and marking CRFs as verified, changing the view as needed. You can mark multiple CRFs as verified in any of these ways:
    - **All Eligible CRFs for a Subject:** In the Study Subject ID view, click the SDV button for the Subject to mark all eligible CRFs for that Subject as verified.
    - **Selected CRFs or Subjects:** In either the CRF or Subject view, select the checkbox in the SDV Status column for all CRFs or Subjects you want to mark as verified. You can deselect a row by clicking the checkbox again, or clear all selected rows by clicking the None link (located above the column headers). Then click the SDV All Checked button at the bottom of the page.
    - **All CRFs or Subjects Shown:** In either the CRF or Subject view, to select all CRFs or

Subjects on the page, click the All Shown link (located above the column headers), which selects all checkboxes in the SDV Status column on that page. You can deselect a row by clicking its checkbox, or clear all selected rows by clicking the None link (located above the column headers). Then click the SDV All Checked button at the bottom of the page.

3.1.2 Customize the View in Source Data Verification

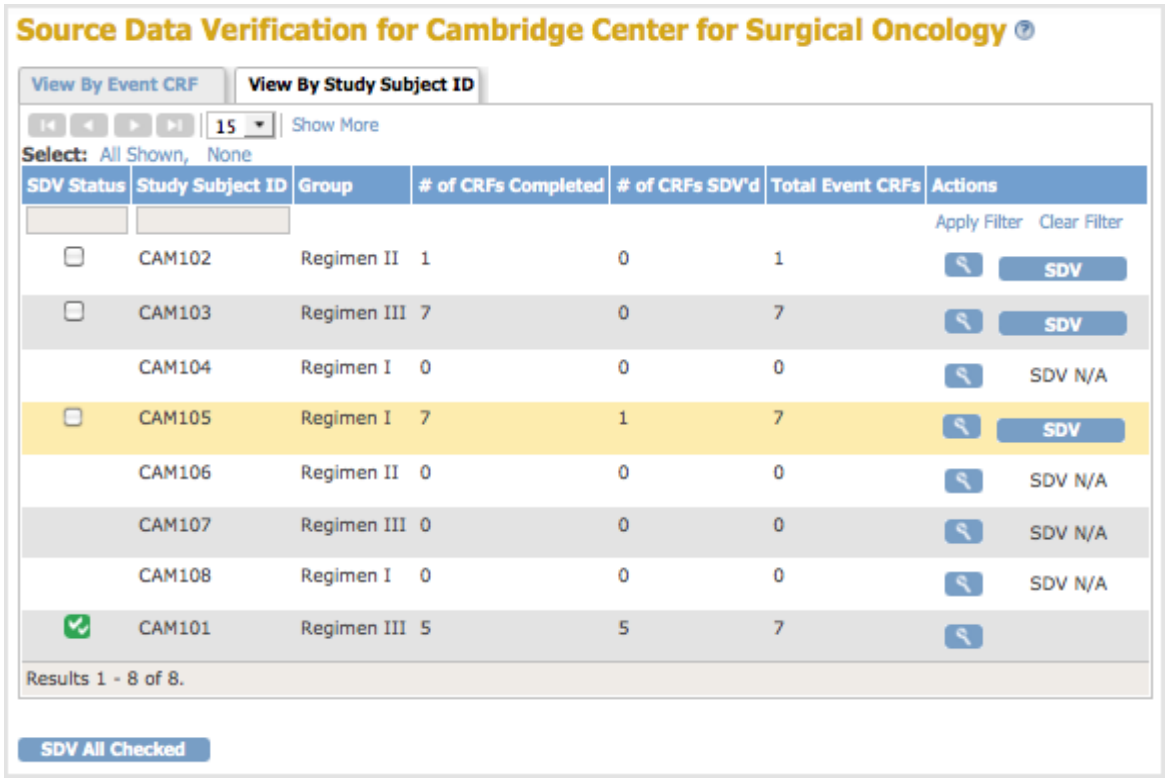
You can customize the view in the Source Data Verification page to adapt it for the workflow you use. For example, you can review all CRFs for a Subject to verify that Subject. Or if you use a sampling method, you can review a sample of CRFs for a Site, then mark all CRFs for that Site as verified. This section describes the ways you can customize the view.

3.1.2.1 View by CRF or by Subject

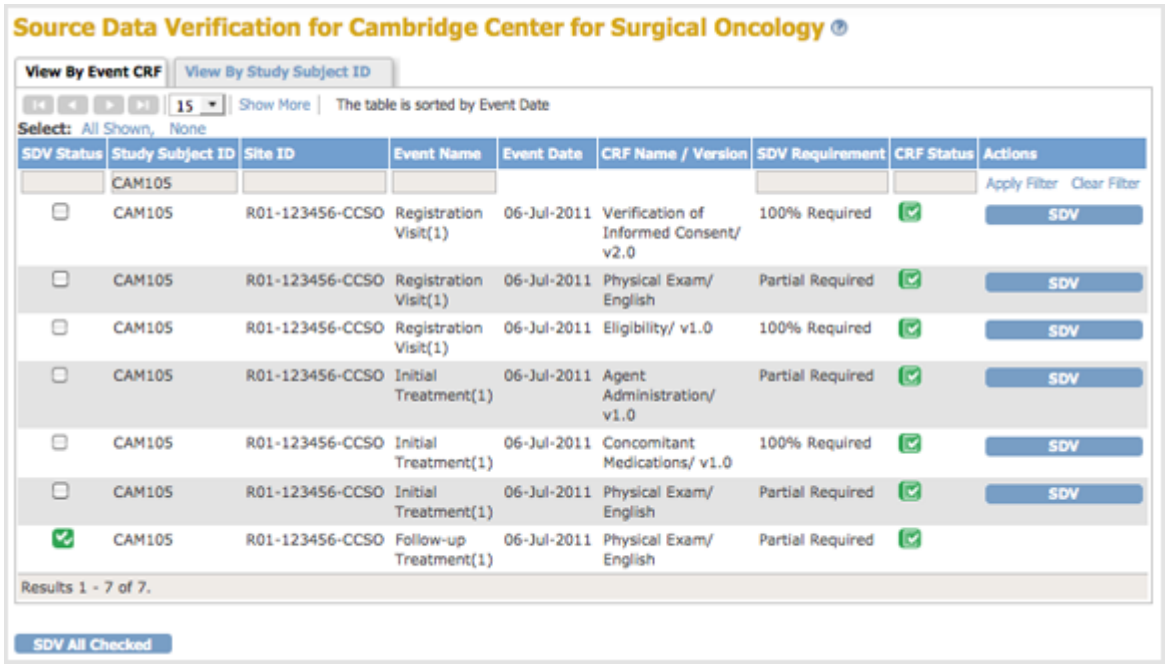
You can view Source Data Verification information by CRF or by Subject:

- **By CRF:** Click the View By Event CRF tab, and the table shows all CRFs in the current Study or Site that have been marked complete and therefore are eligible for Source Data Verification. CRFs are listed by Event Date, with the oldest at the top of the table. The CRF view also reports whether or not Source Data Verification is required for a CRF (shown in the SDV Requirement column, and specified in the CRF Event Definition). With this CRF view, you can mark one CRF or selected CRFs as verified.
- **By Subject:** Click the View By Study Subject ID tab, and the table shows all Subjects in the Study, reporting how many CRFs are eligible for verification and how many have already been verified for each Subject (shown in the # of CRFs Completed and the # of CRFs SDV'd columns). The view lists all Subjects, even those with no CRFs eligible for Source Data Verification (SDV N/A appears in the Actions column for Subjects who have no CRFs ready for Source Data Verification). With this Subject view, you can mark all CRFs for one or more Subjects as verified. You can also show the By CRF view for any Subject by clicking the View icon for that Subject, in order to access the Subject's CRF data.

Source Data Verification Page with the By Subject ID View for the Current Site; the Pointer is Hovering Over the Row for Subject CAM105, Temporarily Highlighting the Row in Yellow:



After Clicking the View Icon for Subject CAM105 in the By Subject ID View, the Page Shows CRFs Eligible for Source Data Verification for Subject CAM105. Below Column Headers, the Study Subject ID Field Indicates the Data is for CAM105:



3.1.2.2 Find and Organize SDV Data

In either the CRF or Subject view, you can:

- Navigate through the table pages and change the number of CRFs or Subjects shown per page
- Show more data for all rows, or hide it
- Filter the data in the table so it shows only the CRFs or Subjects you want to see

These features work the same way as in the Subject Matrix: for more information, see Find and Organize Data in the Subject Matrix.

3.1.3 View Source Data Verification Status

In the CRF view, icons in the SDV Status column indicate those CRFs that have had Source Data Verification completed (✅) and those that have not (☐). Use the filter for the SDV Status column to show only those CRFs with SDV complete, or only those CRFs that have not had SDV completed.

In the Subject view, icons in the SDV Status column indicate those Subjects that have had Source Data Verification completed (✅) and those that have not (☐). In addition, you can see how many CRFs have had SDV completed for each Subject (shown in the # of CRFs SDV'd column), along with the number of CRFs eligible for verification for that Subject (shown in the # of CRFs Completed column), which provides a summary of the SDV status by Subject.

3.1.4 Reset Source Data Verification Status

Source Data Verification status can be reset from verified to unverified either manually by user with appropriate permissions, or automatically by the OpenClinica software under certain conditions. Once marked as unverified, the CRF can be verified again at any time. The Study Audit Log tracks any change in Source Data Verification status for a CRF.

- **Manually:** To manually change the Source Data Verification status for any CRF, in the Source Data Verification page, click the SDV Complete icon in the SDV Status column:
  - In the Source Data Verification By Event View, you click the icon for a CRF. After you click the icon, it becomes a checkbox, and the CRF is no longer reported as verfied.
  - In the By Subject View, you click the icon for a Subject to reset the SDV Status for all CRFs for that Subject. After you click the icon, it becomes a checkbox, and all CRFs for that Subject are no longer reported as verfied.
- **Automatically:** The OpenClinica software automatically resets the Source Data Verification status for a CRF from verified to unverified in these cases:
  - When the CRF data changes
  - When an Annotation Discrepancy Note is added to the CRF

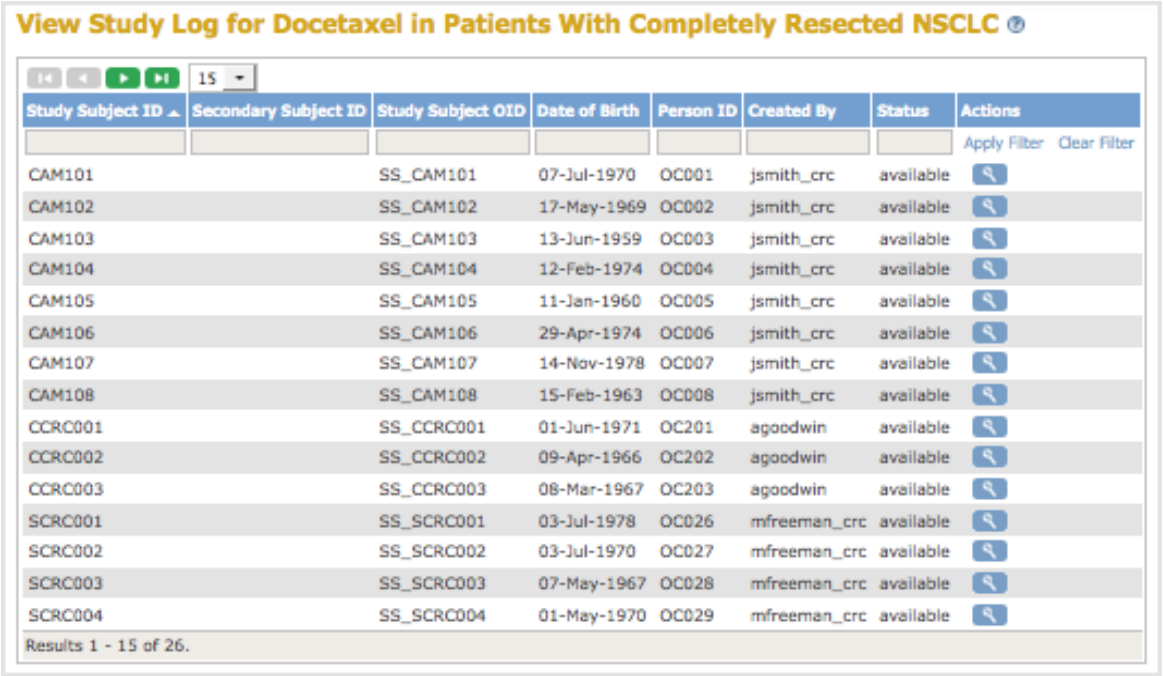
3.2 Study Audit Log

Use the Study Audit Log to view a history of actions on Subjects in the current Study. Only certain user Roles can access the log.

To access the Study Audit Log, click the Study Audit Log link in the navigation bar. The View Study Log page opens for the current Study, presenting a table with each Study Subject in its own row.

You can change the number of Subjects shown per page, change the sort order, and filter the table to show only the Subjects you want to see. These features work the same way as in the Subject Matrix: for more information, see Find and Organize Data in the Subject Matrix.

The View Study Log Page, Sorted by Subject ID:


View Study Log for Docetaxel in Patients With Completely Resected NSCLC

15

Study Subject ID	Secondary Subject ID	Study Subject OID	Date of Birth	Person ID	Created By	Status	Actions
							Apply Filter Clear Filter
CAM101		SS_CAM101	07-Jul-1970	OC001	jsmith_crc	available	
CAM102		SS_CAM102	17-May-1969	OC002	jsmith_crc	available	
CAM103		SS_CAM103	13-Jun-1959	OC003	jsmith_crc	available	
CAM104		SS_CAM104	12-Feb-1974	OC004	jsmith_crc	available	
CAM105		SS_CAM105	11-Jan-1960	OC005	jsmith_crc	available	
CAM106		SS_CAM106	29-Apr-1974	OC006	jsmith_crc	available	
CAM107		SS_CAM107	14-Nov-1978	OC007	jsmith_crc	available	
CAM108		SS_CAM108	15-Feb-1963	OC008	jsmith_crc	available	
CCRC001		SS_CCRC001	01-Jun-1971	OC201	agoodwin	available	
CCRC002		SS_CCRC002	09-Apr-1966	OC202	agoodwin	available	
CCRC003		SS_CCRC003	08-Mar-1967	OC203	agoodwin	available	
SCRC001		SS_SCRC001	03-Jul-1978	OC026	mfreeman_crc	available	
SCRC002		SS_SCRC002	03-Jul-1970	OC027	mfreeman_crc	available	
SCRC003		SS_SCRC003	07-May-1967	OC028	mfreeman_crc	available	
SCRC004		SS_SCRC004	01-May-1970	OC029	mfreeman_crc	available	

Results 1 - 15 of 26.

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3.2.1 Audit Logs Page for a Subject

To view the Audit Logs of Events for a Subject, click the View icon in the Actions column of the View Study Log page. The Audit Logs page opens for the Subject, providing a detailed history for all Events for the Subject.

You can also access the Audit Logs for a Subject from the Subject Matrix. Click the View icon in the Actions column of the Subject Matrix, and then on the View Subject page, expand the Study Subject Record section and select the Audit Logs link (located at the top of the section). The Subject's Audit Logs page opens.

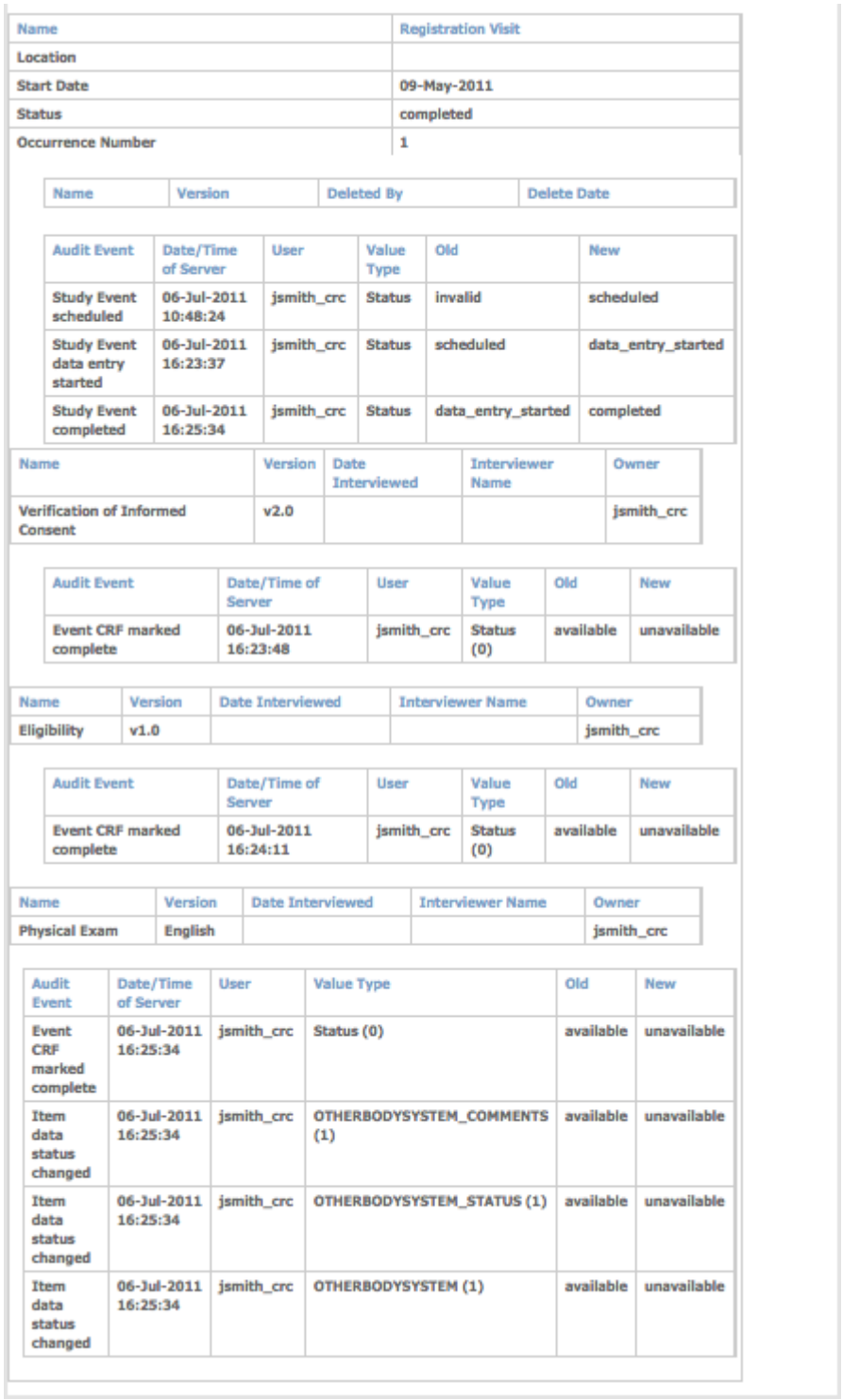
Excerpt from Audit Logs Page for a Subject (CAM103):

CAM103 Audit Logs

Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
CAM103		13-Jun-1959	OC003	jsmith_crc	available

Audit Event	Date/Time of Server	User	Value Type	Old	New
Study Subject Created	06-Jul-2011 10:47:25	jsmith_crc			
Subject Created	06-Jul-2011 10:47:25	jsmith_crc			
Subject Group Assignment	06-Jul-2011 10:47:25	jsmith_crc	Status		Regimen III

Study Events	Location	Date	Occurrence Number
Registration Visit		09-May-2011	1
Initial Treatment		16-May-2011	1
Follow-up Treatment		16-May-2011	1
Follow-up Treatment		30-May-2011	2
Follow-up Treatment		06-Jun-2011	3



Name	Registration Visit
Location	
Start Date	09-May-2011
Status	completed
Occurrence Number	1

Name	Version	Deleted By	Delete Date

Audit Event	Date/Time of Server	User	Value Type	Old	New
Study Event scheduled	06-Jul-2011 10:48:24	jsmith_crc	Status	invalid	scheduled
Study Event data entry started	06-Jul-2011 16:23:37	jsmith_crc	Status	scheduled	data_entry_started
Study Event completed	06-Jul-2011 16:25:34	jsmith_crc	Status	data_entry_started	completed

Name	Version	Date Interviewed	Interviewer Name	Owner
Verification of Informed Consent	v2.0			jsmith_crc

Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	06-Jul-2011 16:23:48	jsmith_crc	Status (0)	available	unavailable

Name	Version	Date Interviewed	Interviewer Name	Owner
Eligibility	v1.0			jsmith_crc

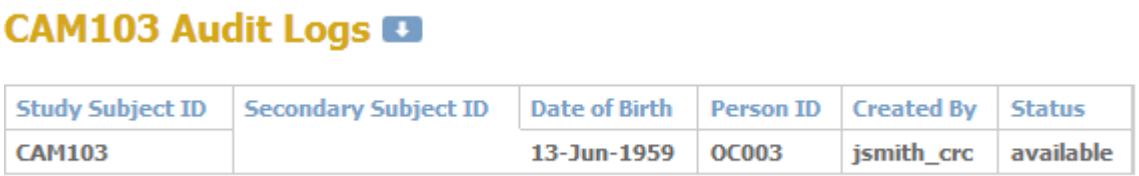
Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	06-Jul-2011 16:24:11	jsmith_crc	Status (0)	available	unavailable

Name	Version	Date Interviewed	Interviewer Name	Owner
Physical Exam	English			jsmith_crc

Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	06-Jul-2011 16:25:34	jsmith_crc	Status (0)	available	unavailable
Item data status changed	06-Jul-2011 16:25:34	jsmith_crc	OTHERBODYSYSTEM_COMMENTS (1)	available	unavailable
Item data status changed	06-Jul-2011 16:25:34	jsmith_crc	OTHERBODYSYSTEM_STATUS (1)	available	unavailable
Item data status changed	06-Jul-2011 16:25:34	jsmith_crc	OTHERBODYSYSTEM (1)	available	unavailable

Download the Audit Log to Excel

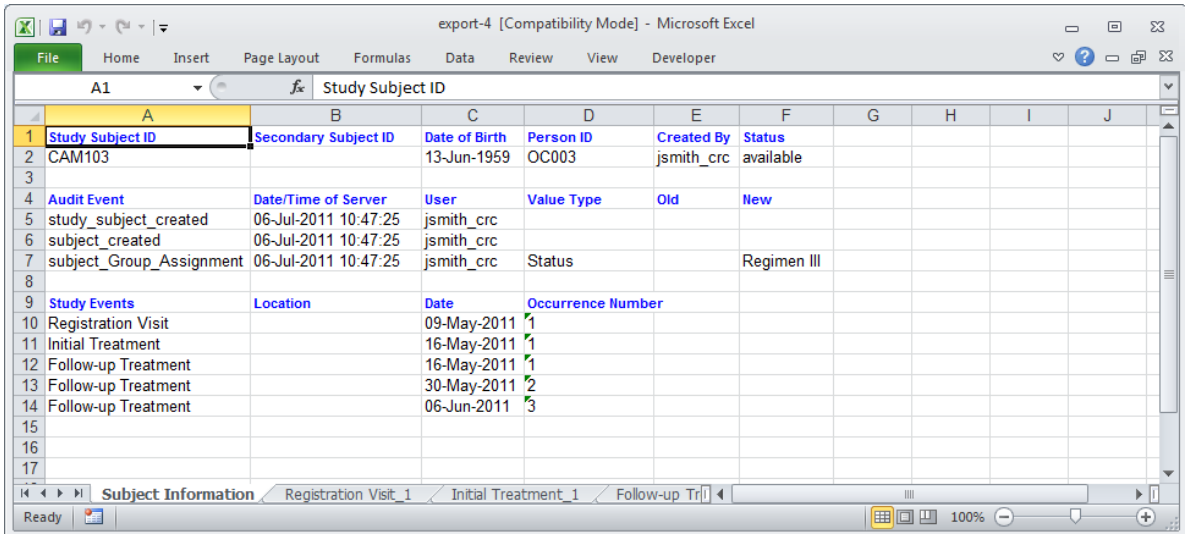
To download the Audit Log to Excel, click the blue download button to the right of the Audit Log header.



CAM103 Audit Logs

Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
CAM103		13-Jun-1959	OC003	jsmith_crc	available

Then, to open the Audit Log in Excel, click OK.



	A	B	C	D	E	F
1	Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
2	CAM103		13-Jun-1959	OC003	jsmith_crc	available
3						
4	Audit Event	Date/Time of Server	User	Value Type	Old	New
5	study_subject_created	06-Jul-2011 10:47:25	jsmith_crc			
6	subject_created	06-Jul-2011 10:47:25	jsmith_crc			
7	subject_Group_Assignment	06-Jul-2011 10:47:25	jsmith_crc	Status		Regimen III
8						
9	Study Events	Location	Date	Occurrence Number		
10	Registration Visit		09-May-2011	1		
11	Initial Treatment		16-May-2011	1		
12	Follow-up Treatment		16-May-2011	1		
13	Follow-up Treatment		30-May-2011	2		
14	Follow-up Treatment		06-Jun-2011	3		
15						
16						
17						

The Subject information is displayed on the first worksheet, and the audit information for each Event is displayed on a separate worksheet.

Note: Though the Audit Log may be easier to read in Excel, this cannot be considered a compliant Audit Log since it can be edited. This functionality is solely provided for ease of viewing the audit information. The Audit Log that is viewed in OpenClinica, however, is fully compliant and cannot be edited.

3.2.2 What the Study Audit Log Tracks

The Audit Log tracks the following for Events:

- Date and time
- Location
- Status
- Date started

This table lists the actions the Audit Log tracks:

What	Actions
CRF	Initial data entry complete
CRF	Initial data entry completed with password
CRF	Double data entry complete
CRF	Double data entry completed with password
CRF	Marked complete
CRF	Completed with password
CRF	Properties changed
CRF	Source data verification status changed
Item on CRF	Data value updated (see Note, below the table)
Item on CRF	Data status changed
Item on CRF	Data deleted
Item on CRF	Data inserted for repeating row
Event	Scheduled
Event	Data entry started

Event	Completed
Event	Stopped
Event	Skipped
Event	Locked
Event	Removed
Event	Start date changed
Event	End date changed
Event	Location changed
Event	Signed
Study Subject	Created
Study Subject	Status changed
Study Subject	Value changed
Subject	Created
Subject	Status changed
Subject	Value changed
Subject	Global value changed
Subject	Site assignment made
Subject	Group assignment made
Subject	Group changed

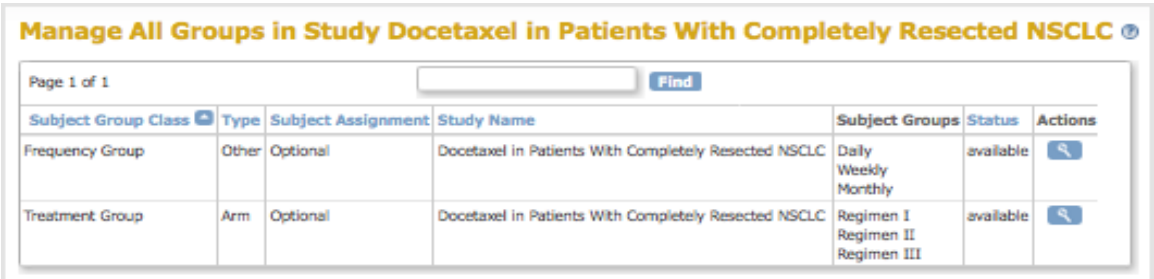
Note: Starting with the OpenClinica 3.1.2 release, initial values for CRF Items provided during data entry are tracked in the Audit Logs, and reported as "Item data value updated." This is only tracked when a value is provided; empty or non-existent values are not tracked. Prior to the OpenClinica 3.1.2 release, initial values for CRF items were not tracked.

The Audit Log does not track Discrepancy Notes, but you can view or download the full thread for any Discrepancy Notes you want to see. Discrepancy Notes cannot be removed, so they are all always available.

3.3 Manage Groups

Subject Group Classes are specified as part of Study setup, and then Subjects are assigned to Groups within Group Classes either when they are added to a Study or later by editing their Subject record.

To view data for Subject Group Classes and Groups, use the Manage All Groups page. Your user Role must have permission to access the page. To open the page, select Tasks > Groups. The Manage All Groups page opens.



The table lists one Group Class per row. These are some actions you can perform:

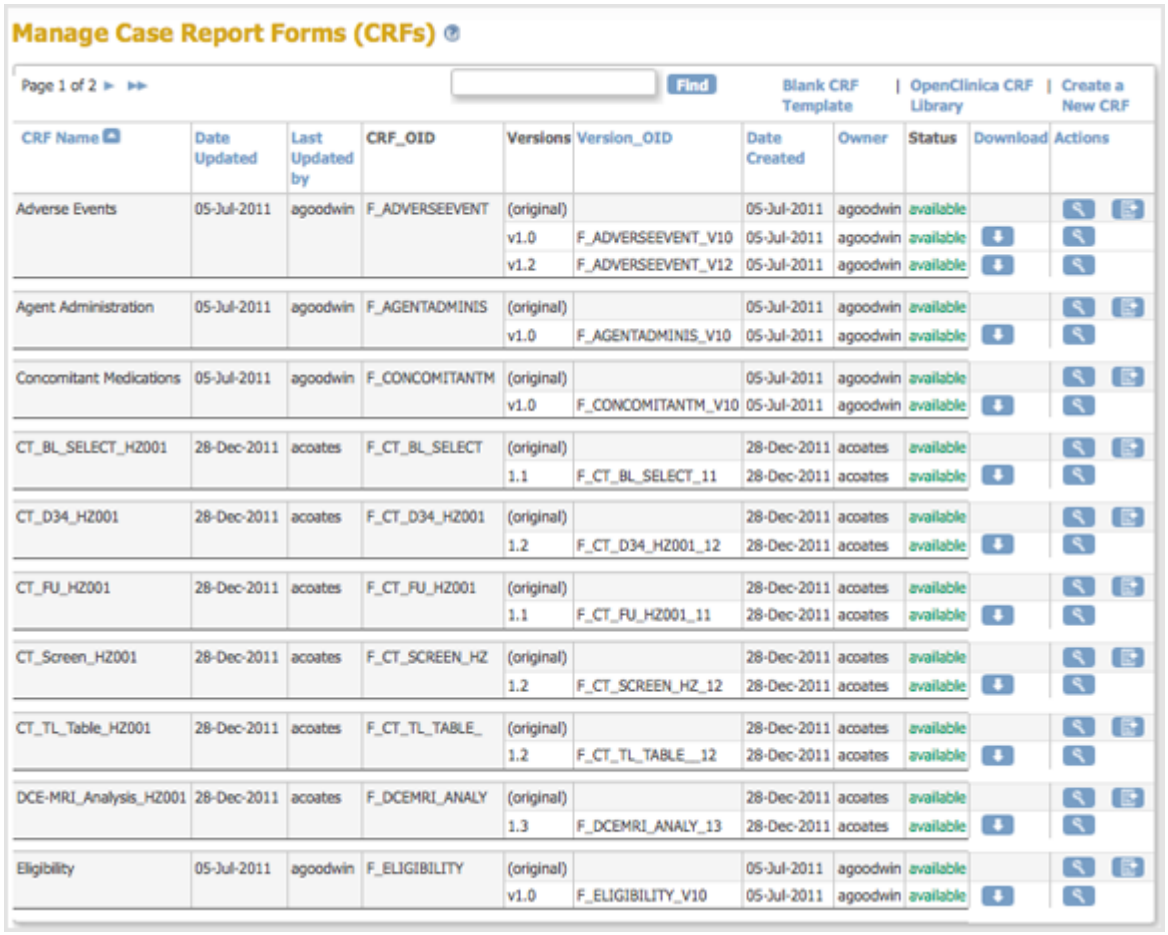
- To change the sort order for the table, click on any column header that is a link. To reverse the sort order in a column, click the column header again.
- To find a Subject Group Class, enter a string in the Find text field and click the Find button (located above the column headers). The table then shows only the Subject Group Classes whose name, Type, or Subject Assignment include that string.
- To see the Subjects assigned to each Group within the Group Class, click the View icon in the Actions column for the Group Class.

For information about assigning a Subject to a Group, see Add Subject. Also see, Create and Modify Subject Group Classes for information about creating, editing, removing, and restoring Subject Group Classes.

3.4 Manage CRFs

If your User Role or Type has appropriate permission, you can access a table of all defined CRFs in your OpenClinica system. To do so, in the Tasks menu, under the Monitor and Manage Data module, select CRFs. The Manage Case Report Forms page opens, presenting the table. Use this page to view information about defined CRFs and to find and organize the CRFs.

You can also use this page to create defined CRFs and modify them. Certain User Roles and Types can perform additional actions: see Remove, Restore, and Delete Defined CRFs.



If you want to view and manage CRFs that contain Subject data for Study Events, see View Event Details in Subject Matrix.

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3.4.1 Find and Organize CRFs

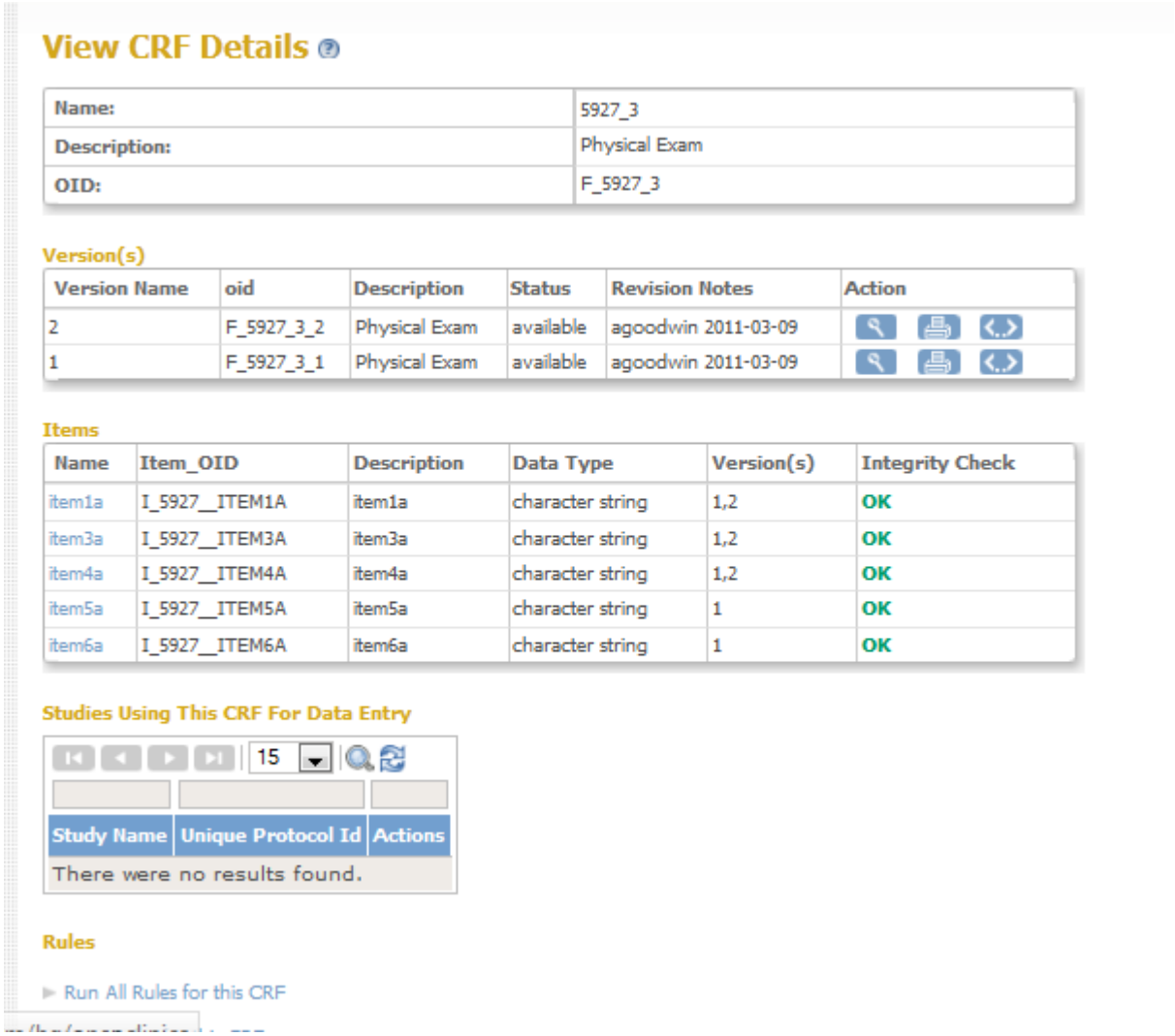
By default, defined CRFs in the Manage CRFs table are listed in alphabetical order by CRF Name. If there are more CRFs than can be viewed on the page, access other pages using the arrows at the top of the table.

You can sort the data by another column if that column header is a link: click the column header. To reverse the sort order in the column, click the column header again. An arrow next to the column header indicates the current sort order: up for ascending and down for descending.

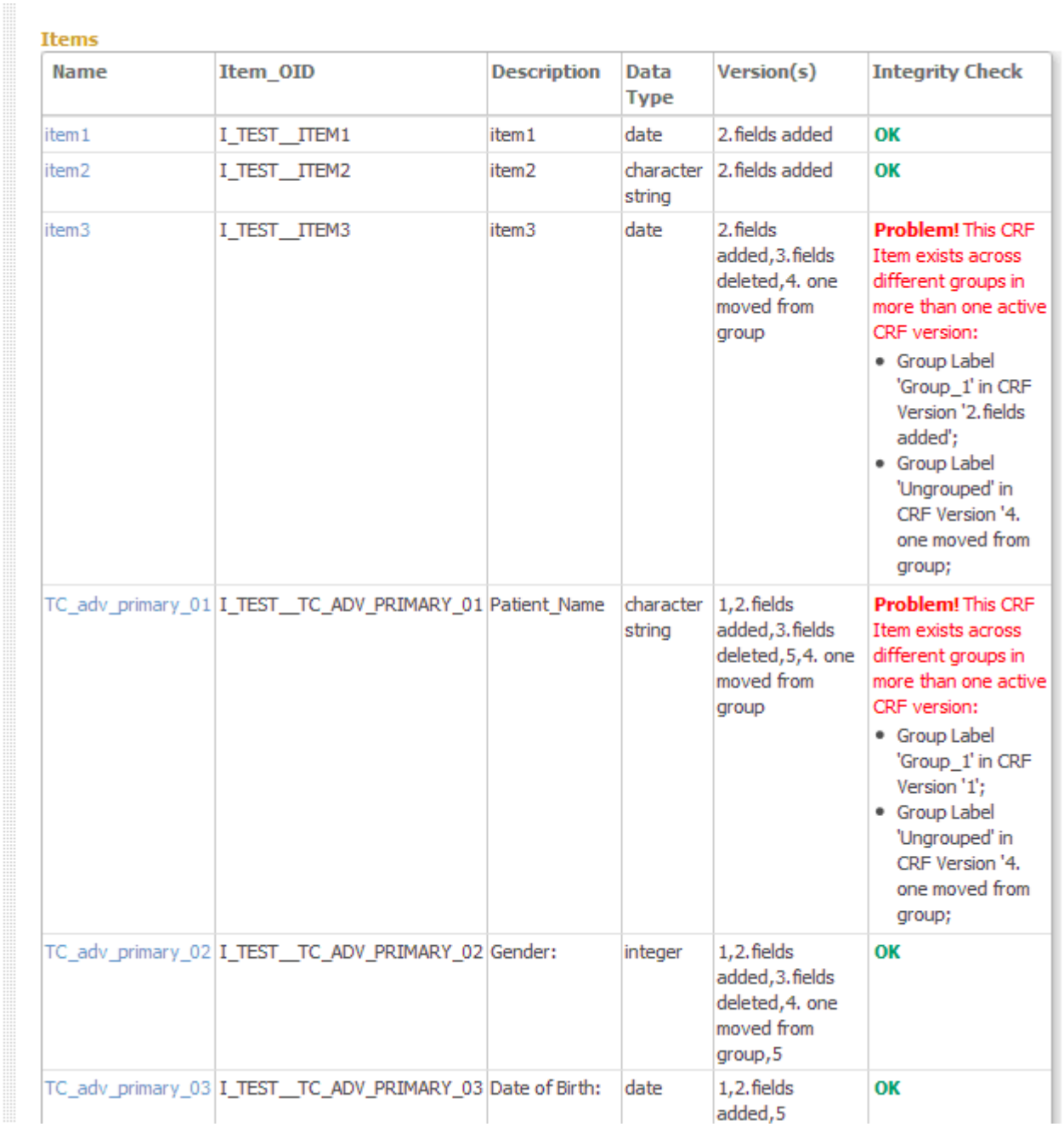
To find a defined CRF that includes a string you specify, enter the string in the Find field, then click the Find button. The table shows only those CRFs whose name includes the string you entered. For example, type CT to find all defined CRFs whose name includes CT.

3.4.2 View Original CRF and CRF Versions

From the table of CRFs, you can view information about the parent record (termed "original version") for a CRF and the versions for it. To view the parent record, click the View icon in the row where the version is "original". The View CRF Details page opens. The Studies to which the defined CRF is assigned are listed under Studies Using This CRF for Data Entry (the current Study is not listed).



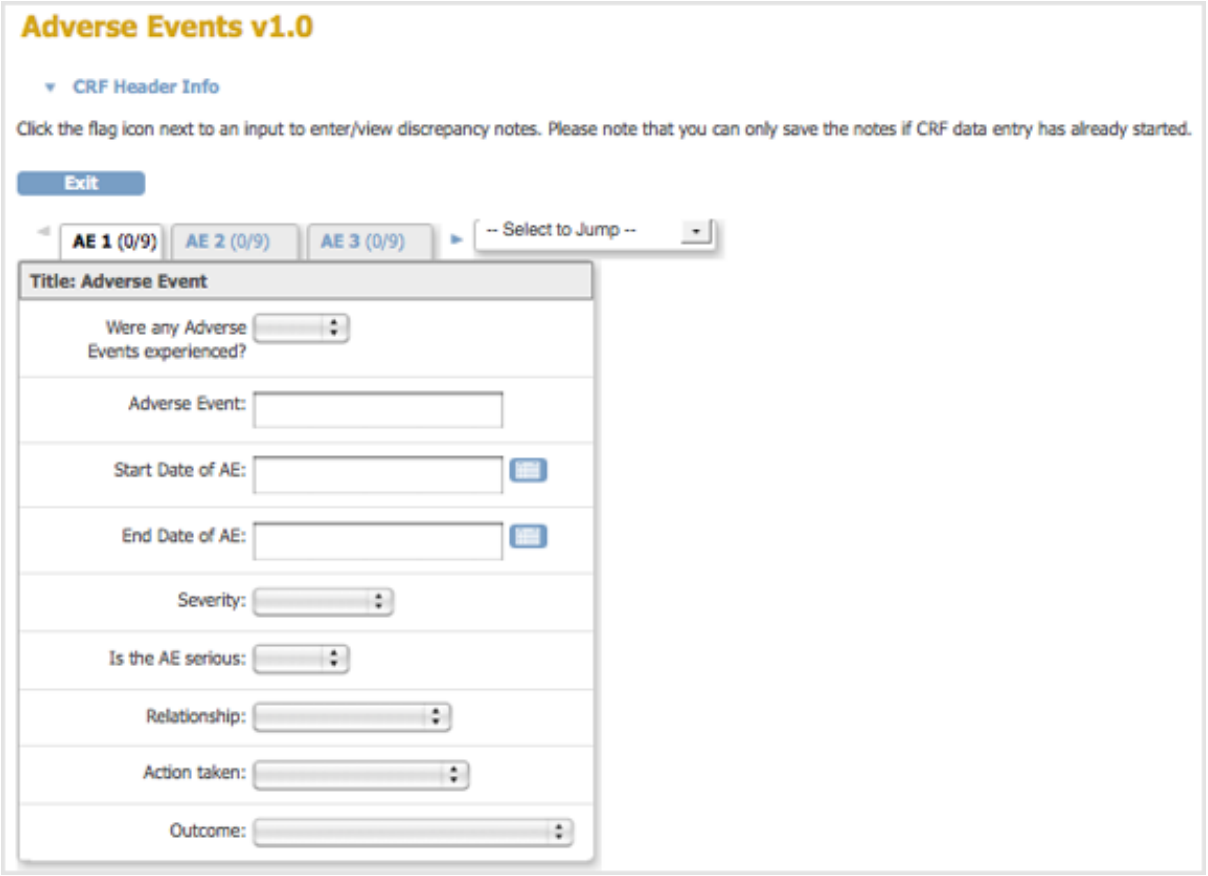
The Items table has been introduced in OpenClinica version 3.1.3 to allow viewing which items are part of which CRF versions and provide a check on CRF integrity. OpenClinica 3.1.2 and earlier versions allowed items to be moved from one group to another in different CRF Versions. At the same time OpenClinica ODM does not support this type of structure change between different CRF versions, meaning data extracts can be broken for items that changed their group from one CRF version to another. If CRF has items moved from one group to another the Items table will show error message for the such items.



Items

Name	Item_OID	Description	Data Type	Version(s)	Integrity Check
item1	I_TEST__ITEM1	item1	date	2.fields added	OK
item2	I_TEST__ITEM2	item2	character string	2.fields added	OK
item3	I_TEST__ITEM3	item3	date	2.fields added,3.fields deleted,4. one moved from group	**Problem!** This CRF Item exists across different groups in more than one active CRF version: • Group Label 'Group_1' in CRF Version '2.fields added'; • Group Label 'Ungrouped' in CRF Version '4. one moved from group;
TC_adv_primary_01	I_TEST__TC_ADV_PRIMARY_01	Patient_Name	character string	1,2.fields added,3.fields deleted,5,4. one moved from group	**Problem!** This CRF Item exists across different groups in more than one active CRF version: • Group Label 'Group_1' in CRF Version '1'; • Group Label 'Ungrouped' in CRF Version '4. one moved from group;
TC_adv_primary_02	I_TEST__TC_ADV_PRIMARY_02	Gender:	integer	1,2.fields added,3.fields deleted,4. one moved from group,5	OK
TC_adv_primary_03	I_TEST__TC_ADV_PRIMARY_03	Date of Birth:	date	1,2.fields added,5	OK

From the View CRF Details page or from the Manage CRFs table, you can view a CRF version as it appears in the OpenClinica web interface. To view it, click the View icon for the version you want to view. The form opens, showing the first section. To see another section, click the tab for it. Note that when the CRF is viewed in this manner all hidden fields in the CRF are displayed.



3.5 CRF Version Migration

CRF Version Migration was first introduced in OpenClinica 3.1.3 and supports the ability to migrate data entered for a particular version of CRF for a subject to a different available version of the CRF. This is done on a subject-by-subject, event-by-event basis. Starting with OpenClinia 3.12, there is also the option for Batch CRF Version Migration, which allows you to migrate from one version of a CRF to another for all Events and all Subjects in a Study. The subject-by-subject migration and batch migration steps are outlined below.

Regardless of which means of migration you use, no data entered for the subject is deleted from the database as a result of CRF version migration. However, data that had previously been entered may not display on eCRFs or in extracts if previous versions of a CRF had more items than the new CRF to which data was migrated. Details of various migration examples are provided below.

CRF Version Migration: Subject-by-Subject

The CRF Migration feature is accessed from **View Study Subject** and **Enter Data for Study Event** pages for users with appropriate privileges.

Conditions for event CRF Version Migration feature:

- Data Entry status: event CRF has been started (user started data entry or only opened CRF and exit it without any data saved);
- Study status: Available;
- User Role: Study Director or Data Manager;
- Subject Status: Subject should be active;
- Event Status: event should be active (not removed, locked or skipped);

- CRF Status: Active (not removed)
- CRF Version: only active (not removed) CRF versions will appear in drop down as possible migration targets;
- CRF version migration is only available if CRF Version used for data entry is an active CRF version.

If the above conditions are met for the event CRF the user will see the reassign ( ) icon for the CRF.

To migrate data for an Event for a Subject:

- Click the **Reassign CRF to a New Version** icon.
  This opens the Reassign CRF to a New Version page.
- To cancel and return to the View Study Subject page, click **Cancel**.
- To migrate the Subject's Event CRF to a new version:
  - Review the list of available versions and select the version to which you want the data migrated.
  - Click **Continue**.
    The Confirm CRF Version Change page displays.
  - Verify the migration details and click **Submit**.

CRF Migration Examples:

- Scenario A:More items in original CRF than resulting CRF
  - Before Migration:
    - CRF Version A has an item named meditem2.
    - CRF Version B does not have the 'meditem2' item.
    - Both CRF versions have an item named item_1.
    - The EventCRF has been migrated from Version A to Version B.
  - After Migration:
    - Data for item item_1 are migrated.

        - Data for item meditem2 are not migrated.
        - When the EventCRF record is viewed, the user will not see meditem2, because it does not belong to the current CRF version.
        - Data for this item will not be included in extracts (see below for extract rules). However, data for the item is not removed or altered in the database, so if the EventCRF is migrated back to the original version of the CRF, the data for the item will be displayed in the EventCRF and in the extract.

- Scenario B:More Response Options in original CRF than in resulting CRF
    - Before Migration:
        - Both CRF Version A and B have an item called item_1.
        - Version A has response options X, Y and Z.
        - Version B has response options of X and Y only.
        - User selected option Z during data entry in Version A.
        - The EventCRF was then migrated from Version A to Version B.
    - After Migration:
        - The data for item_1 is migrated, however, because the active version of CRF does not have option Z, the user wont see the selection and the field appears as if no data has been entered.
        - For single select response types (single-select and radio button), new data, if entered, will overwrite the existing value.
        - For multi-select response-types (multi-select and checkbox), new choices will be added.
            - For example, if item_1 has a checkbox response-type, after migrating to Version B, the user wont see that the field has a value of Z as an option and selects option Y. Though the user only sees option Y selected, the item has both Y and Z options stored in database.

- Scenario C:Group Repeat Max in original CRF is greater than the Group Repeat Max setting in the resulting CRF
    - Before Migration
        - Both CRF Version A and B have a repeating group Group1.
        - The parameter for GROUP_REPEAT_MAX for Group1 in Version A is 5.
        - The parameter for GROUP_REPEAT_MAX for Group1 in Version B is 3.
        - Data was entered into Version A with 5 repeats in Group1.
        - The EventCRF was migrated from Version A to Version B.
    - After Migration:
        - All 5 rows entered for the eventCRF display, despite the fact that Version B allows fewer rows to be entered.
        - No new row can be added.

Notes:

Only One CRF Version
The Reassign CRF Version icon will be shown even if CRF has only one version.

Audit Log
CRF version migration events are reflected in the audit log with information about the original CRF version and target CRF version.

Data Validation
Data validations are run based on the rules associated with active (new) CRF version after CRF

version migration.

E-signature status
If the subject casebook or an EventCRF has been e-signed before CRF version migration, the migration process removes the electronic signature for the EventCRF that had been migrated.

SDV status
The SDV status for migrated CRFs will be reset to need source data verification after CRF version migration.

Extracts
Values for items not present in active CRF version definition do not show up in the extracts. For example, data is entered into CRF Version A for ITEM_X. Then that eventCRF is migrated to Version B, which does not have ITEM_X. The value for ITEM_X will not be present in extract for the migrated CRF.

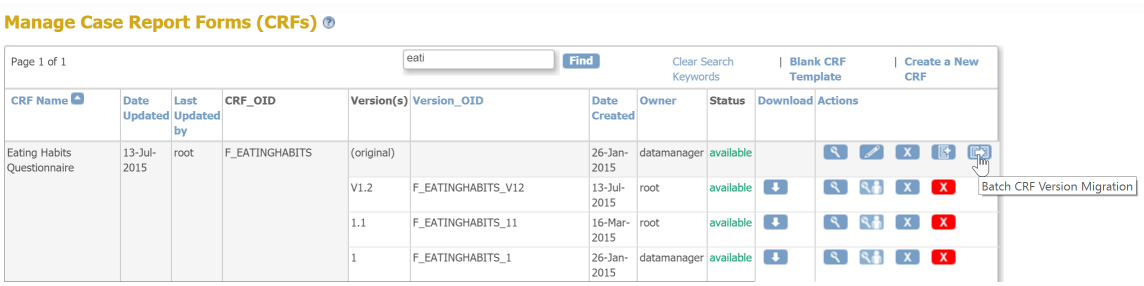
Response Sets
Please note that OpenClinica 3.1.3 does not impose restrictions on the Versioning of response sets. If you assume that individual event CRF will have to be migrated from one CRF Version to another, response sets for the same item MUST have unique values across all CRF versions. For example, an item is a single-select and its RESPONSE_OPTIONS_TEXT defined as *Absent, Mild, Moderate, Severe, Life-threatening* while RESPONSE_VALUES_OR_CALCULATIONS defined as *1,2,3,4,5* in one version. You can to drop or add several values in another version of CRF, but you cannot redefine mapping by setting Absent to have value other than 1 (OpenClinica 3.1.3 and early does not check for consistency of mapping)

Batch CRF Version Migration

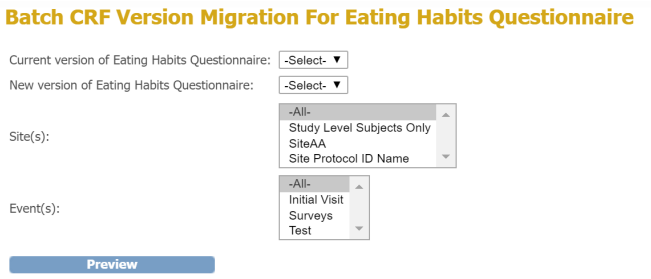
Batch CRF version migration was introduced in OpenClinica 3.12. This allows you to migrate from one version of a CRF to another for a group of subjects and/or events.

To perform Batch CRF Version Migration:

1. From the menu bar, select **Tasks > Monitor and Manage Data > CRFs**.
   The Manage Case Report Forms (CRFs) page displays.
2. On the Manage CRFs page, for the CRF that you want to migrate, click the Batch CRF Version Migration icon:



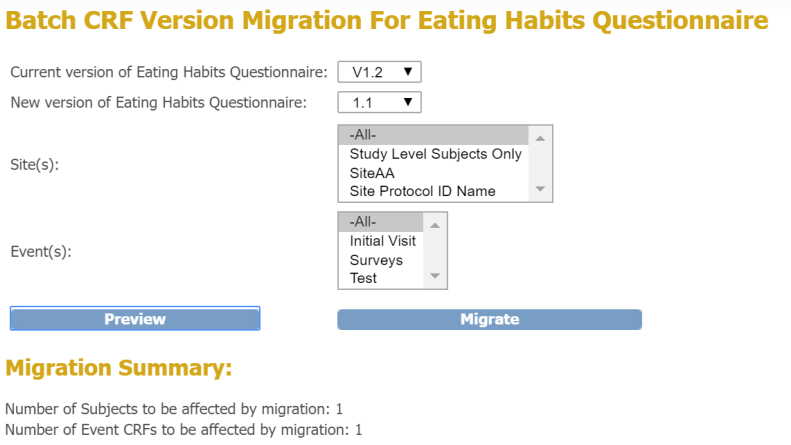
The following screen displays (note that the screen name will vary based on the selected CRF):



3. Select the current version of the form.
4. Select the version to which you want to migrate the form data.
5. Select migration options as follows:

    - In the Site(s) selection box:
        - To migrate the selected CRF for a specific site, select the site for which you want to migrate forms
        - To migrate the selected CRF for multiple sites, hold down **CTRL** (CMD on Mac) and click the sites for which you want to migrate forms
        - To migrate the selected CRF for subjects entered at the study level, select **Study Level Subjects Only**
        - To migrate all study and site-level subjects, select **-All-**
    - In the Event(s) selection box:
        - To migrate the selected CRF for a specific event, select the event for which you want to migrate forms
        - To migrate the selected CRF for multiple sites, hold down **CTRL** (CMD on Mac) and click the Events for which you want to migrate forms
        - To migrate the selected CRF for all sites, select **-All-**

6. Click **Preview**.
   A count of the number of subjects and event CRFs displays. If both counts are 0, migration is not possible.



7. If the number of records meets your expectations, to complete the migration, click **Migrate**.
   You return to the Manage CRFs page and the following displays in the Alerts & Messages section:
   Batch CRF version migration is running. You will receive an email once the process is complete

   You will receive an email notification indicating that the migration is complete. The email will

contain a link to a report of the migration, which will provide a list of all migrated Subjects and Event CRFs.

Functional approval by Jessica MacMinn. Signed on 2016-09-14 11:03AM

Approved for publication by Laura Keita. Signed on 2016-09-23 5:52PM

3.5.1 CRF Version Migration Screencast