5 Study Setup

The Study Setup module in OpenClinica provides flexibility and control so you can design and set up clinical trials with minimal effort.

To use the Study Setup module, the Study must exist. You create a new Study using the Administration module, providing basic information about it. Once the Study has been created, you provide more details about it using the Study Setup module.

The Study Setup module has the following features:

- **View Study:** Presents the configuration of the current Study or Site, and an option to download the Study metadata.
- **Build Study:** Provides options to Edit a Study, Create CRFs, Create Event Definitions, Create Subject Group Classes, Create Rules, Create Sites, and Assign Users. A table presents the status of these tasks so you can see what's been completed and what tasks remain for the current Study.
- **Users:** Shows all users and their Roles in the current Study or Site. Also allows you to assign users to the current Study or Site, and change or remove roles for users assigned to the current Study or Site.

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5.1 View Study

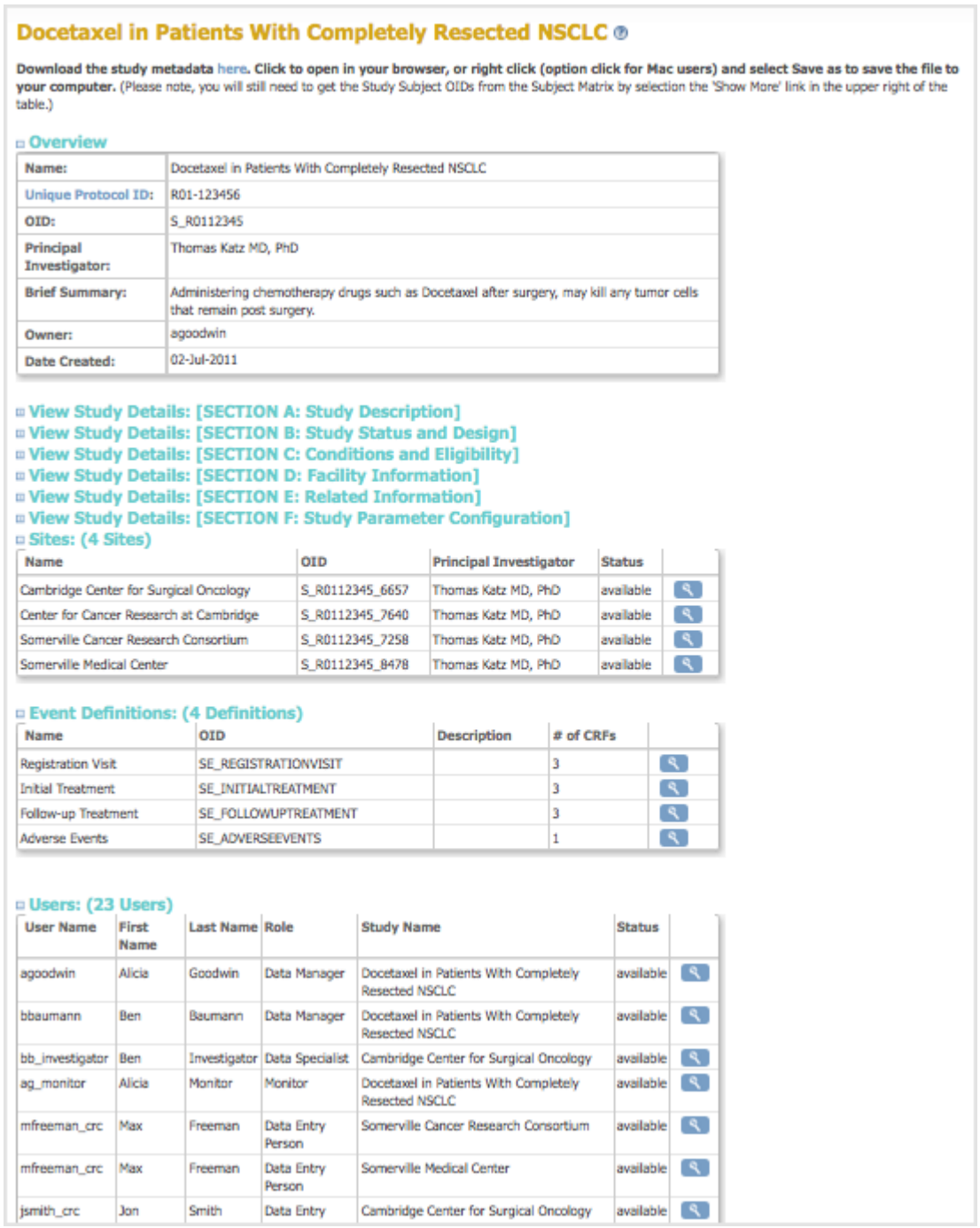
To see the configuration for the current Study or Site, and the users assigned to it, select Tasks > View Study. The page displays the configuration details for the Study or Site. Following are the tasks you can perform from the page, if your user Role has appropriate permission:

- **Download Study Metadata:** At the top of the page is a link to the Study metadata. Click the link to download the Object Identifiers (OIDs) for the Study. The OIDs are required for Data Import and for creating Rules in an XML-formatted file, and can be useful when extracting data to files that use certain formats.
- **View Definitions:** When viewing the tables on this page, click any of the links in the Name column to view the definition at the clinicaltrials.gov website.
- **Overview:** The Overview section presents information about the overall Study or Site.
- **View Study Details (Sections A to F):** Click the link for any section to view details for it.
- **Sites:** When the current Study or Site is set to the Study level, the Sites section shows all Sites in the Study. For details about a Site, click the View icon.
- **Event Definitions:** Lists the Event Definitions. Click the View icon for an Event to see all CRFs for it, and to access CRF details.
- **Users:** Lists the users assigned to the Study or Site. Click the View icon for a user to access

more information.

For more information any of the items on the View Study page or how to change them, see Build Study.

View Study Page. The Unique Protocol ID item is a link that displays a definition when you click it:



Docetaxel in Patients With Completely Resected NSCLC

Download the study metadata here. **Click to open in your browser, or right click (option click for Mac users) and select Save as to save the file to your computer.** (Please note, you will still need to get the Study Subject OIDs from the Subject Matrix by selection the 'Show More' link in the upper right of the table.)

Overview

Name:	Docetaxel in Patients With Completely Resected NSCLC
Unique Protocol ID:	R01-123456
OID:	S_R0112345
Principal Investigator:	Thomas Katz MD, PhD
Brief Summary:	Administering chemotherapy drugs such as Docetaxel after surgery, may kill any tumor cells that remain post surgery.
Owner:	agoodwin
Date Created:	02-Jul-2011

View Study Details: [SECTION A: Study Description]
View Study Details: [SECTION B: Study Status and Design]
View Study Details: [SECTION C: Conditions and Eligibility]
View Study Details: [SECTION D: Facility Information]
View Study Details: [SECTION E: Related Information]
View Study Details: [SECTION F: Study Parameter Configuration]

Sites: (4 Sites)

Name	OID	Principal Investigator	Status	
Cambridge Center for Surgical Oncology	S_R0112345_6657	Thomas Katz MD, PhD	available	
Center for Cancer Research at Cambridge	S_R0112345_7640	Thomas Katz MD, PhD	available	
Somerville Cancer Research Consortium	S_R0112345_7258	Thomas Katz MD, PhD	available	
Somerville Medical Center	S_R0112345_8478	Thomas Katz MD, PhD	available	

Event Definitions: (4 Definitions)

Name	OID	Description	# of CRFs	
Registration Visit	SE_REGISTRATIONVISIT		3	
Initial Treatment	SE_INITIALTREATMENT		3	
Follow-up Treatment	SE_FOLLOWUPTREATMENT		3	
Adverse Events	SE_ADVERSEEVENTS		1	

Users: (23 Users)

User Name	First Name	Last Name	Role	Study Name	Status	
agoodwin	Alicia	Goodwin	Data Manager	Docetaxel in Patients With Completely Resected NSCLC	available	
bbaumann	Ben	Baumann	Data Manager	Docetaxel in Patients With Completely Resected NSCLC	available	
bb_investigator	Ben	Investigator	Data Specialist	Cambridge Center for Surgical Oncology	available	
ag_monitor	Alicia	Monitor	Monitor	Docetaxel in Patients With Completely Resected NSCLC	available	
mfreeman_crc	Max	Freeman	Data Entry Person	Somerville Cancer Research Consortium	available	
mfreeman_crc	Max	Freeman	Data Entry Person	Somerville Medical Center	available	
jsmith_crc	Jon	Smith	Data Entry	Cambridge Center for Surgical Oncology	available	

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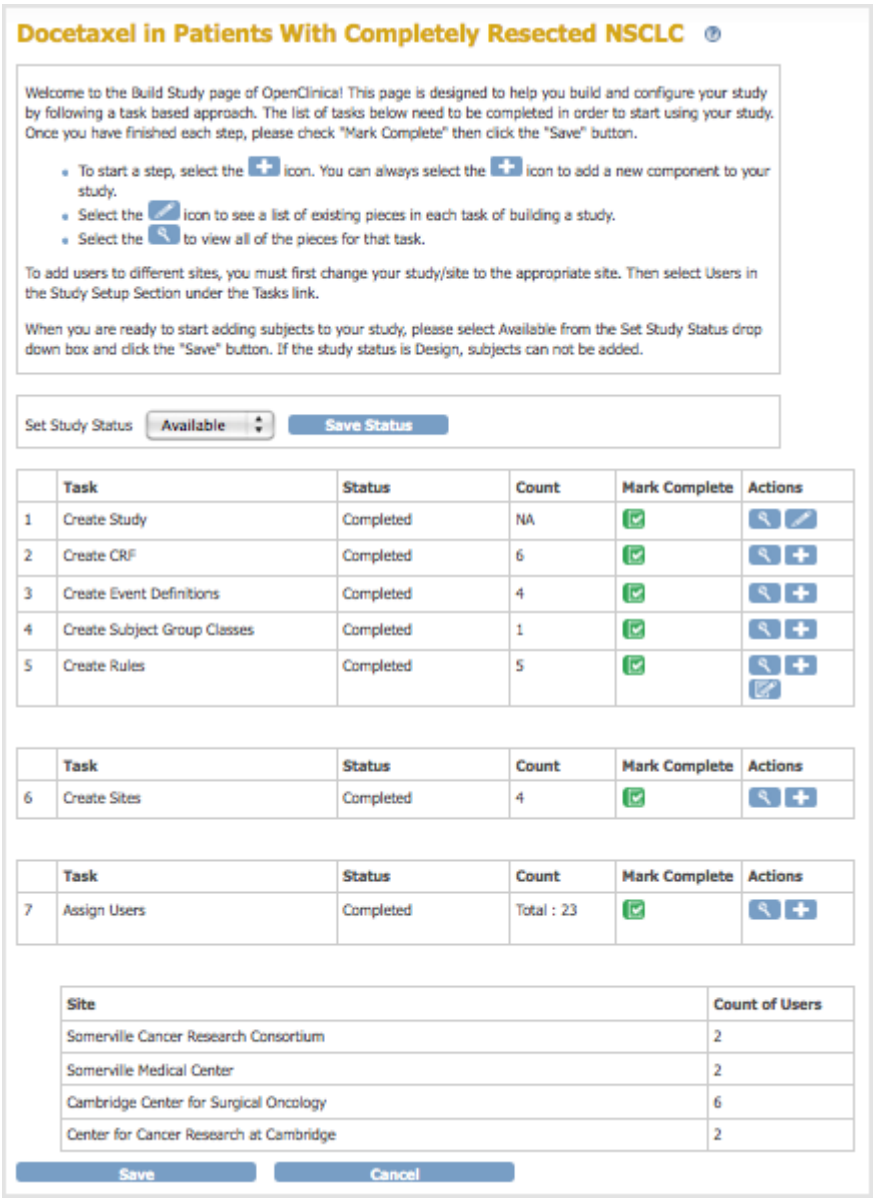
5.2 Build and Modify Study

Use the Build Study page to create or edit the Study Details, CRFs, Event Definitions, Subject Group Classes, Rules, Sites, and Users. Follow this basic workflow to design or edit a Study:

1. The Study must exist, having been created using the Administration module.
2. Change the current Study to the Study you want to work on. You must work at the Study level; the Build Study features are not available at the Site level.
3. Access the Build Study page by selecting Tasks > Build Study.
   The Build Study page opens for the current Study, presenting a table of the main Tasks, with status information for each, and options to view details, create new elements, and edit the existing configuration.
4. Set the Study Status, if needed:
   - When you are creating the Study, set the Status to Design, then click the Save Status button.
   - After you've created the Study and are making edits, set the Status to Available, then click the Save Status button.
     For more information, see Status of Study.
5. Add to or edit the Study configuration by clicking the appropriate icon for Tasks 1 to 5 in the table. For details, see the following sections:
   1. Create Study: Edit Details
   2. Create and Modify Case Report Forms (CRFs)
   3. Create and Modify Event Definitions
   4. Create and Modify Subject Group Classes
   5. Create and Modify Rules

   When you begin to work on a Task, the Task's Status changes from Not Started to In Progress.
6. When you have finished a Task, select the checkbox in the Mark Complete column, then click the Save button. The Task's Status changes from In Progress to Complete. Note that you can make changes to a Task, even when its Status is Complete.
7. After Tasks 1 to 5 are marked complete, add or modify Sites.
8. Add or modify Users.
9. If you haven't already done so, set the Study Status to Available, and click the Save Status button.
10. After the Status is Available, add Subjects to the Study and start collecting Study data.

Build Study Page After Completing Study Setup:



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5.2.1 Status of Study

Some actions update the Study status automatically, while some Status values are set by a user with appropriate permissions using the Set Study Status drop-down list on the Build Study page. These Status values also apply to Sites.

Status	Use to	Comments

Design (also displayed in OpenClinica as Pending)	Build a Study	• When you create a Study, the status is automatically set to Design. • Subjects cannot be enrolled in a Study if the status is Design (the Add Subject button is unavailable). • Once all the Build Study tasks are complete, for data entry to begin, the status must be changed to Available.
Available	Provide access to the Study to users (for Subject enrollment, data entry, editing, etc.) as the last step of building a Study.	• Subjects cannot be enrolled in a Study until the status is set to Available.
Frozen	Prevent Site users from signing, entering, and editing data, but allow Study level users to edit data as needed to close Notes and Discrepancies.	• Site users can view data but cannot enter or edit data. • Investigators cannot sign Events or Case Books. • Study-level users can view data and can close Discrepancies. Closing Discrepancies may involve editing data, which they *can* do via Notes and Discrepancies if they click the icon to View within record for CRFs having a status of Completed. It should be noted that this also allows users to change values for other items on the record that may not have an associated discrepancy. Your internal procedures should explicitly state what can/cannot be edited. • As always, all data changes are tracked in the Audit Log.
Locked	Prevent all users from entering or editing data.	• Neither Site nor Study level users can sign CRFs, enter or edit data, or create or edit Notes and Discrepancies. • Viewing, printing, and extracting data are permitted.
Removed	Make the study inaccessible to end users.	• This status is set automatically when a Study is Removed. • Only Administrators can remove a Study.

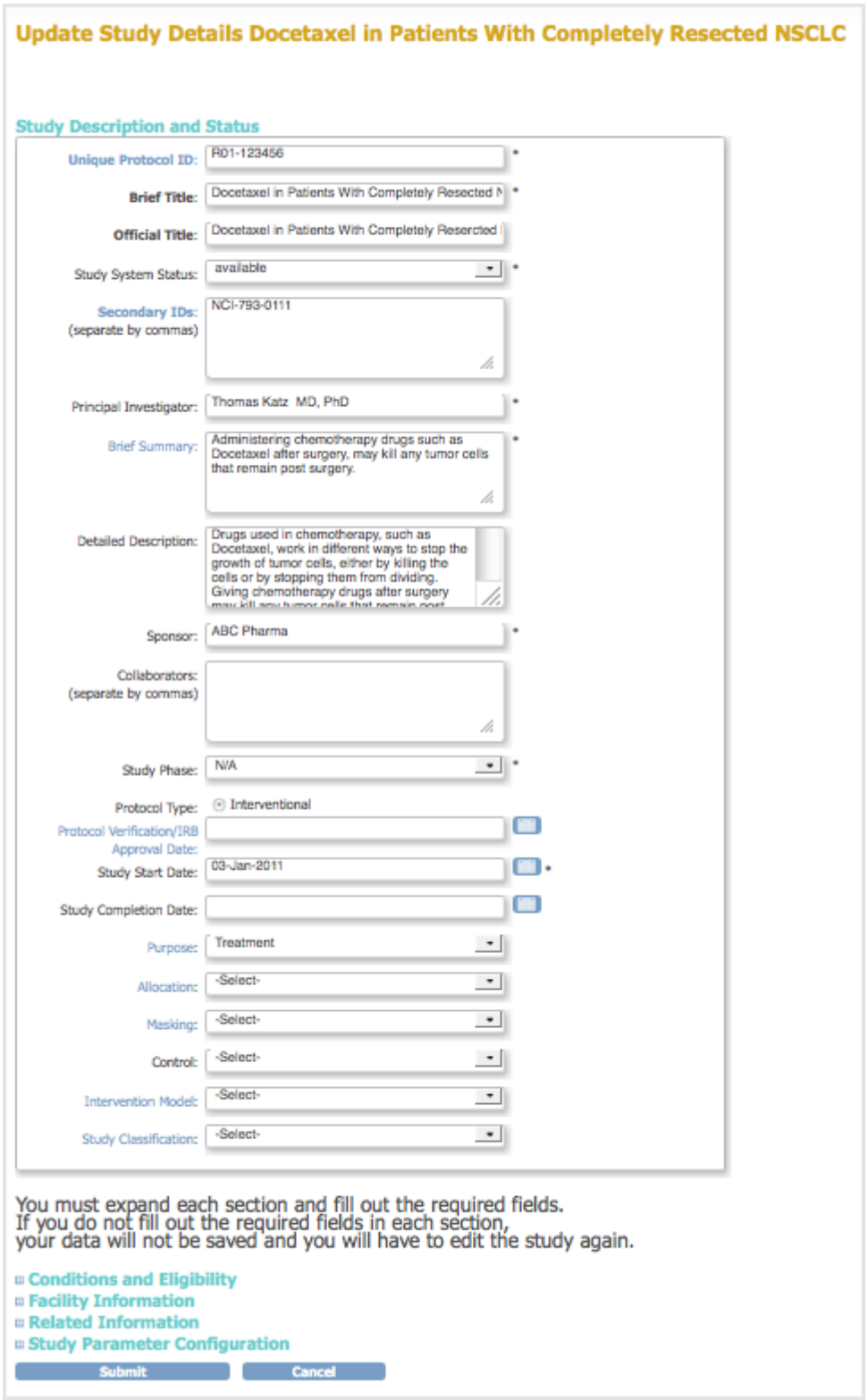
5.3 Create Study Edit Details

You can add or make changes to details for the current Study using the Study Setup module.

1. Access the Build Study page by selecting Tasks > Build Study.
2. In the Actions column of the table, for the Create Study task, click the Edit icon.
   The Update Study Details page opens. Values that were already supplied for the Study, either when it was created or in a previous editing session, are shown on the page.
3. Complete at least the required fields (marked with an asterisk *) for each section on the page; you need to expand each section to see the fields in it.

   Note: If a required field does not have a value, you cannot save any of the information you provide. If you cannot provide the value for a required field, enter a temporary value so that you can save all of the information you entered, then update the temporary value later. For more information about the fields, see About Study Details.

   Note: There are some OpenClinica configuration settings that impact every Study. See Configuring the OpenClinica Application.



4. After completing the fields, click the Submit button.
   The Build Study page displays.

Expanded Sections in the Update Study Details Page:

Conditions and Eligibility

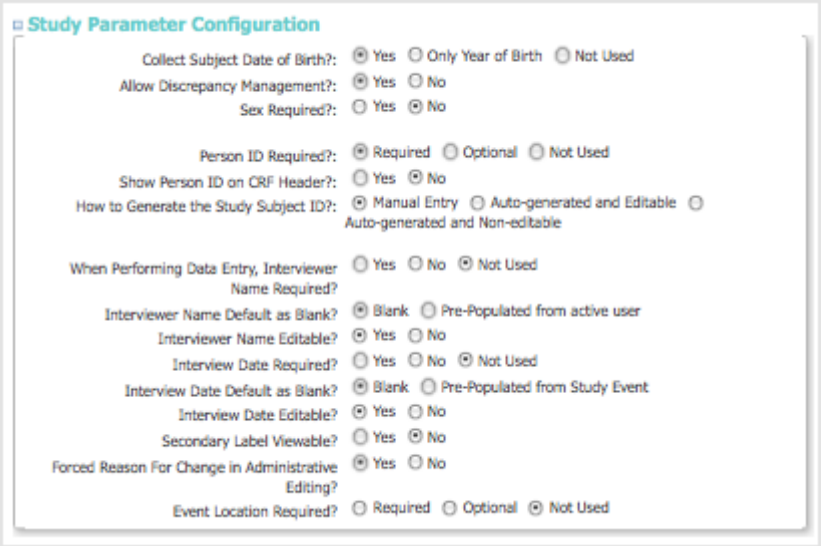
Conditions:	NSCLC
Keywords: (separate by commas)	Docetaxel, Non Small Cell Lung Cancer, NSLC
Eligibility Criteria:	
Sex:	Both
Minimum Age:	18
Maximum Age:	
Healthy Volunteers Accepted:	No
Expected total enrollment:	100 *

Facility Information

Facility Name:	OpenClinica Medical Facility
Facility City:	Waltham
Facility State/Province:	MA
Postal Code:	02451
Facility Country:	USA
Facility Contact Name:	Alicia Goodwin
Facility Contact Degree:	
Facility Contact Phone:	617-123-4567
Facility Contact Email:	agoodwin@example.com

Related Information

MEDLINE Identifier:	
Results Reference?:	No
URL Reference	
URL Description:	



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5.3.1 About Study Details

The following information can help you complete or edit values in the Update Study Details page.

All Sections

- When a field name is a link (blue text), you can click it to see the definition at the clinicaltrials.gov website.
- Information you provide in all sections except Study Parameter Configuration is for reporting and does not affect data collection. For example, if you specify a minimum age, OpenClinica does not use that information to verify the age of a Subject you add to the Study. The information you provide in Study Parameter Configuration does impact data collected in OpenClinica for the Study. For example, if you specify Yes for Collect Subject Date of Birth, then the full date of birth must be entered when adding a Subject to the Study.

Study Description and Status Section

- Unique Protocol ID is the user-defined number assigned to the Study when it was first created in OpenClinica.
- You cannot modify the Study System Status on the Update Study Details page. For more information, see Status of a Study.
- Principal Investigator is the person running the Study, and is responsible for the Study being completed and performed correctly.

Conditions and Eligibility Section

- This section can be used as a guideline for conditions and eligibility for the Study.
- Expected total enrollment is used for reporting statistics. It does not limit how many Subjects can be added to the Study, nor is it treated as a required minimum.

Facility Information Section

- Facility information can be for the sponsor, or a main location for the Study. There can be multiple facilities within a Study, where each is defined as a Site after the Study has been created.

Related Information Section

- The URL Reference and URL Description can be used to indicate where you publish your Study results.

Study Parameter Configuration Section

- If 'Collect Subject Date of Birth' parameter is set to 'Only Year of Birth', then the date of birth will be stored internally as January first of the year.
- If you specify No for Allow Discrepancy Management, you cannot create Notes and Discrepancies for CRF Data for the Study.
- If you edit the Sex Required field to change it from Yes to No, the item still appears in the CRF header but completing the field is not required.
- You can specify whether or not the Person ID is required in OpenClinica release 3.1 and higher. In releases prior to 3.1, you specify the parameter using show_unique_id for global ID in the datainfo.properties configuration file.
- When you specify Interviewer Name Required, and Interview Name Pre-Populated from active user, the active user is the user who scheduled the Event.
- When you specify Yes for Forced Reason For Change in Administrative Editing, a Discrepancy Note will be required to modify any Item in a CRF after that CRF has been marked complete.
- The 'Location' field can be used when scheduling or editing a study event. If set to 'Not Used' it will not appear in the user interface for the study.

5.4 Create and Modify Case Report Forms (CRFs)

This set of topics explains how you define (create) Case Report Forms (CRFs) and make changes to the defined forms. You define the form in an Excel spreadsheet file for use with Study Events in your OpenClinica system. OpenClinica presents the defined CRF in the web interface for users to collect Study Event data for a Subject.

To create and modify defined CRFs, your User Role or User Type requires appropriate permission.

Because defined CRFs are available for use across all Studies in OpenClinica, it does not matter what the current Study is when you create and modify them, but you must be at the Study level.

(If instead you want to enter or modify Event data for Subjects in CRFs, see View and Enter Event Data using the Subject Matrix.)

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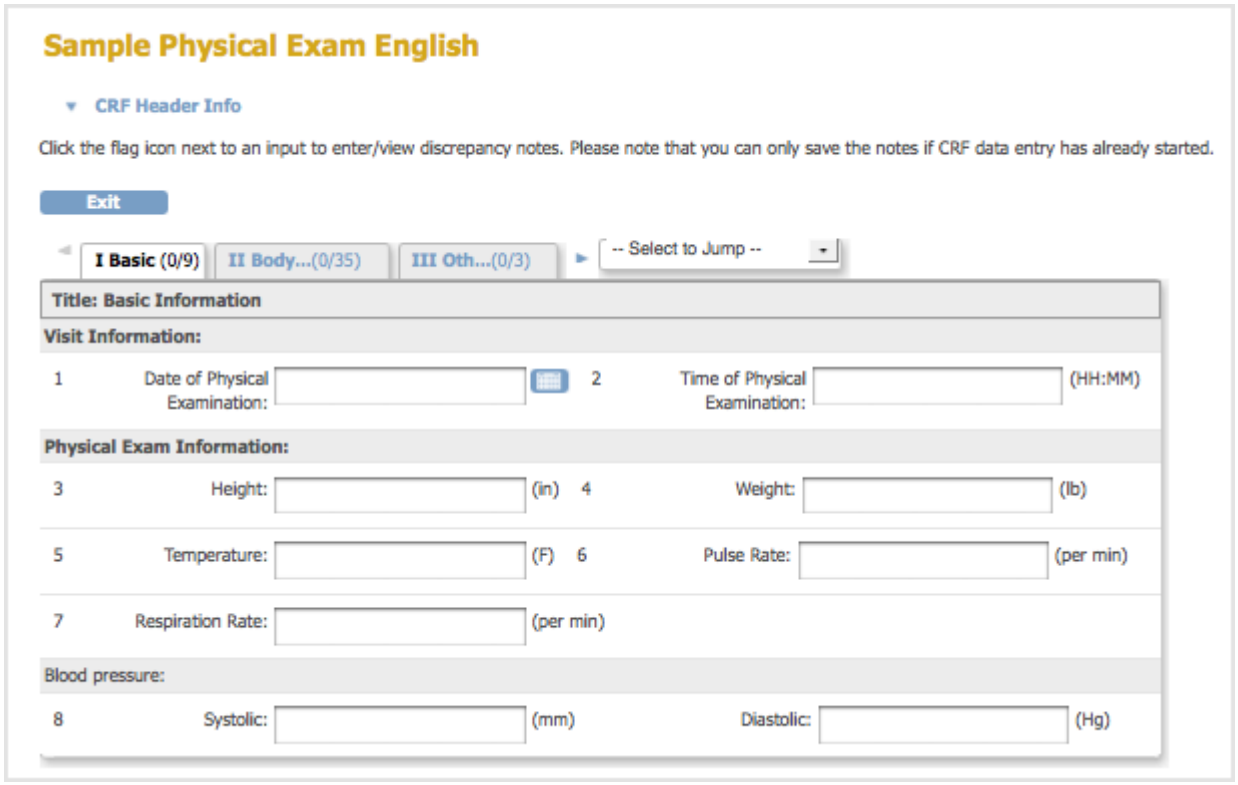
5.4.1 About CRFs in OpenClinica

A good way to familiarize yourself with a defined CRF is to look at its existing CRF .xls file and at the way OpenClinica presents it in the web interface:

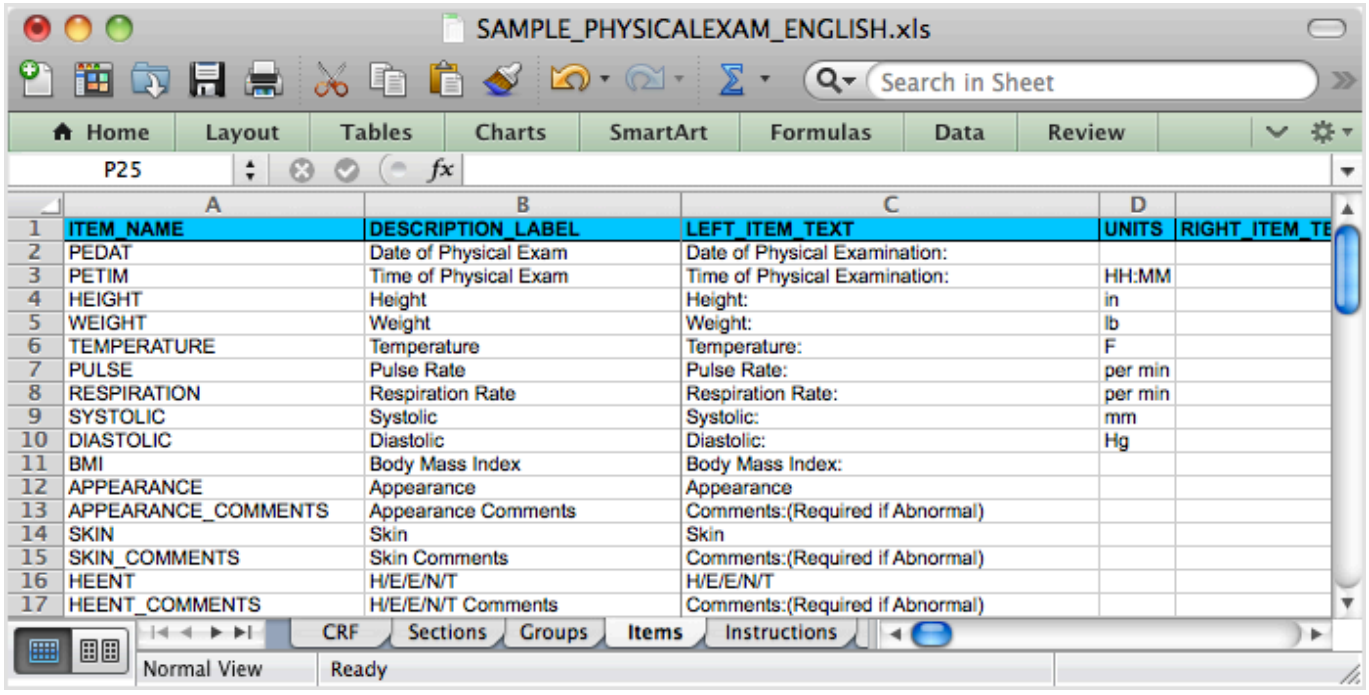
1. Click here to download a sample CRF defined for a Physical Examination, SAMPLE_PHYSICALEXAM_ENGLISH.xls. Save the file to your computer.
2. Upload the defined CRF to your OpenClinica system.
    1. Set the current Study to the Study level.
    2. From the Tasks menu, in the Monitor and Manage Data module, select CRFs.
       The Manage Case Report Forms page opens.
    3. Click Create a New CRF.
       The Create a New Case Report Form page opens.
    4. In the MS Excel File to Upload field, click Browse, then navigate to the file you downloaded in step 1, SAMPLE_PHYSICALEXAM_ENGLISH.xls. Select the file, then click Open.
       The path to the filename is shown in the MS Excel File to Upload field.
    5. Click Preview CRF Version.
       The Check CRF Version Data page opens, showing the CRF in the web interface format.
    6. Click Continue.
       The Create a New CRF Version - Data Committed Successfully page opens.
3. View the defined CRF in OpenClinica:
    1. From the Tasks menu, in the Monitor and Manage Data module, select CRFs.
       The Manage Case Report Forms page opens.
    2. For Sample Physical Exam - English Version, click the View icon.
       The defined CRF displays in the web interface format.
4. In Excel, open the CRF file you downloaded, SAMPLE_PHYSICALEXAM_ENGLISH.xls.
5. Compare the CRF when viewed in the web interface format to the defined CRF when opened in Excel.

A Sample Defined CRF when Viewed in the Web Interface:



Note that when the CRF is previewed after upload, or viewed through 'Manage CRFs', any hidden fields in the CRF are visible.

The Same CRF when Opened in Excel, Showing the Items Tab:



	A	B	C	D	
1	ITEM_NAME	DESCRIPTION_LABEL	LEFT_ITEM_TEXT	UNITS	RIGHT_ITEM_TE
2	PEDAT	Date of Physical Exam	Date of Physical Examination:		
3	PETIM	Time of Physical Exam	Time of Physical Examination:	HH:MM	
4	HEIGHT	Height	Height:	in	
5	WEIGHT	Weight	Weight:	lb	
6	TEMPERATURE	Temperature	Temperature:	F	
7	PULSE	Pulse Rate	Pulse Rate:	per min	
8	RESPIRATION	Respiration Rate	Respiration Rate:	per min	
9	SYSTOLIC	Systolic	Systolic:	mm	
10	DIASTOLIC	Diastolic	Diastolic:	Hg	
11	BMI	Body Mass Index	Body Mass Index:		
12	APPEARANCE	Appearance	Appearance		
13	APPEARANCE_COMMENTS	Appearance Comments	Comments:(Required if Abnormal)		
14	SKIN	Skin	Skin		
15	SKIN_COMMENTS	Skin Comments	Comments:(Required if Abnormal)		
16	HEENT	H/E/E/N/T	H/E/E/N/T		
17	HEENT_COMMENTS	H/E/E/N/T Comments	Comments:(Required if Abnormal)		

5.4.2 OpenClinica eCRF Specifications

OpenClinica provides a template to users for CRF design. This section explains each of the fields in the template and how those fields are either dependent or independent of each other. Best practices are provided as well as some examples of how the CRF Template can be used effectively.

Definitions and acronyms

- CRF Case Report Form, created in OpenClinica by uploading a CRF definition based on the CRF Template Excel file.
- Dynamics Skip Patterns/Skip Logic created using Rules and based on variables in the CRF template.
- Group - A mechanism for logically associating items within a CRF. Items within the same group may repeat together within a CRF.
- Item A variable within a CRF.
- OIDs Object Identifiers uniquely identify a study object such as a CRF, CRF Version, Item Group, or Item and are used to link objects to one another. OIDs for a given class of object are unique within an instance of OpenClinica, with the exception of Rule OIDs, which are only guaranteed to be unique within a study.
- Rules OpenClinicas mechanism to carry out cross form or cross field edit checks, skip logic and inserting data across CRFs. Rules are declared in XML and executed by the OpenClinica Rules Engine. Rules are declared external to the CRF Template but dependent on the variables defined in one or more CRFs.
- SCD Simple Conditional Display. A way of defining skip logic within the CRF Template, without the use of Rules.
- Section A mechanism for organizing items within a CRF for layout purposes. All items in a given section appear on the same page in a CRF. Multiple sections are displayed as tabs within the CRF.
- Tokens A means of displaying a Study Object value for use in a URL (e.g. in a parameterized link) or for use in other scripts (e.g. jquery). Tokens can also be used in Left Item Text, Right Item Text, Header, and/or Subheader to pass item values. The supported tokens are:

  ${studySubject} - Passes the current Subject ID

  ${studySubjectOID} - Passes the OID for the current Subject

  ${studyName} - Passes the current Study Name

  ${eventName} - Passes the current Event Name

  ${eventOrdinal} - For repeating Events, passes the Event repeat number (e.g., 2 for the second repeat)

  ${crfName} - Passes the CRF Name

  ${crfVersion} - Passes the CRF Version

  ${item[item_name]} - Passes the Item value

5.4.2.1 CRF Template - General Constraints

The OpenClinica CRF Template can only be edited and saved as a Microsoft Excel 2003.xls file. OpenOffice spreadsheets and later versions of Microsoft Excel can not be used reliably and may not be successful when uploaded to OpenClinica version 3.1.X.

The CRF Template is used to define the CRF on a client machine with MS Excel. Once the required information has been provided in the template, it must be uploaded to OpenClinica through the Add CRF page. Only certain privileged users are allowed access to this page.

During the upload process, a validation of the CRF design is performed. Errors that are caught at this stage will trigger messages to the user informing him of the error and changes necessary to fix the error.

5.4.2.2 Scope of CRFs and Items

A CRF (with its associated versions, groups, and items) is defined globally within an instance of OpenClinica and may be used in one or more studies. The groups and items defined within a particular CRF exist within the scope of the CRF only (though they will have globally unique OIDs). The CRF Physical Exam may have an item with ITEM_NAME blood_pressure and the CRF Vital Signs can have an item also named blood_pressure. OpenClinica treats these items as separate entities and they will have separate OIDs. Response sets also exist within the scope of the CRF only.

A CRF definition may be shared across OpenClinica instances by loading the CRF template spreadsheet into each instance. Each instance of OpenClinica generates OIDs at CRF upload time and those OIDs must be unique within that instance. Therefore the OIDs for the same CRF and items may be different across OpenClinica instances.

5.4.2.3 CRF Versioning

OpenClinica supports multiple CRF versions being in use at the same time. To create a new version, a user must keep the CRF_NAME field the same as the original, but update the CRF_VERSION field with a new value. This new version is uploaded by selecting the Create New CRF Version icon instead of adding a CRF through the Build Study module. The user does have the ability to overwrite a CRF Version if needed, however the CRF Version cannot have been assigned or used in any event definitions prior to the attempt to remove it.

When a new CRF Version is added, any item with the same ITEM_NAME as an item in a previous version of the CRF is treated as the same variable and will have the same OID, DESCRIPTION, and DATA_TYPE. The value of ITEM_NAME is case-sensitive, so items with ITEM_NAMEs 'ItemA' and 'itema' will be considered as different items by OpenClinica.

For Enterprise customers interested in using Datamart:

Please note that Datamart treats items in case-insensitive manner. Please make all ITEM_NAMES case-insensitive if you plan to use Datamart. Special characters and Postgres reserved words should not be used as item names.

New items that did not exist in prior CRF versions will be added and an appropriate OID generated.

Item metadata vs Item form metadata

Items in a CRF have two types of attributes. Item metadata attributes describe core intrinsic

properties of the item. These properties are independent of the CRF Version and cannot change across CRF Versions. These properties include:

ITEM_NAME

DESCRIPTION

DATA_TYPE

GROUP_LABEL

Response Sets (see discussion below)

The properties ITEM_NAME, DATA_TYPE, and RESPONSE_LABEL cannot be changed after the CRF is created.

Item form metadata attributes describe the items representation or behavior on a CRF and may have a different value in each version of a CRF. Most of the attributes in the Items Worksheet in the CRF Template fall into this category.

Response sets

The item properties beginning with RESPONSE_ on the Items worksheet together define a response set in a CRF. The response set is a coded list of allowable values for the item. The response set is given a name (RESPONSE_LABEL) that allows it to be re-used within the CRF if desired, and the set itself is made up of a list of coded values (RESPONSE_VALUES_OR_CALCULATIONS) with corresponding text labels (RESPONSE_OPTIONS_TEXT). Each item in the list of coded values should meet the constraints defined by the item DATA_TYPE and WIDTH_DECIMAL.

Response sets are intended for use in items that utilize a form input control (INPUT_TYPE) that allows the user to select from a constrained list.

* Note that the RESPONSE_VALUES_OR_CALCULATIONS attribute can also be used in a separate context to create calculated/derived items.

Versioning of response sets should not change the mapping RESPONSE_OPTIONS_TEXT - RESPONSE_VALUES_OR_CALCULATIONS, but it can delete or add new (_OPTIONS_TEXT - RESPONSE_VALUES_OR_CALCULATIONS) pair to existing set of values. 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 another version of CRF it is possible to drop or add several values, but you cannot redefine mapping by setting Absent to have value other than 1.

5.4.2.4 CRF Template Properties

The CRF Template contains five worksheets. Four of the worksheets are intended for input by the

user creating the CRF while the fifth worksheet provides instructions about each of the fields of the Template. When a user selects a cell in a column, a tooltip will popup explaining whether the field is Required or not, and other useful instructive text to help the user understand what the field is for.

In some cases HTML elements like Bold (<b>), Italics (<i>), Line Breaks (<br>), etc. can be used. In the cases where HTML elements are supported, they are designated as such in CRF Template Elements.

In OpenClinica 3.3, Tokens, were introduced. These are available for use in Left or Right Item Text, Header, or Subheader. They can be used to display the Study Object value for use in a URL (as in a Parameterized Link) or for use in other scripts (e.g., jquery). The supported tokens are:

${studySubject}

${studyName}

${eventName}

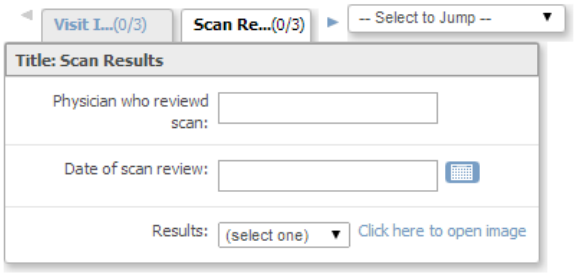
${eventOrdinal}

${crfName}

${crfVersion}

${item[item_name]}

Following is an example of a CRF that passes these tokens to a URL to bring up an image:



When the user clicks on the "Click here to open image" link, based on the following Right Item Text the CRF template, the imaging system (in this case www.example.com) is accessed and passes the values for studyName, eventName, crfName, and the SCAN_DATE item for the current Study, Event, and CRF.

Right Item Text:

Click here to open image

5.4.2.5 CRF Template Elements

Definitions, restrictions and when to use the OpenClinica CRF Template Elements

- CRF Worksheet
- Sections Worksheet
- Groups Worksheet
- Items Worksheet

OpenName.ini CMF Design Templates v1.5
Most recent CMF design template version is introductory, hyp, and dual person to help you better designs in OpenName.ini/Wiki.

Note:
Each CMF instance should be defined in its own Word file.

Replace what	Required	Word for replace and Why we'll use	Can't use for CMF instance	Word for Uses	When to Use	When after Values
CMF		This numbered should be in our first Uses list.				
		Define the characters a CMF can call by display at once OpenName. Define the characters a CMF can call by display at once OpenName. Max will be choosing this name. In the OpenName.ini/Wiki/CMF, will be choosing this name.		(Max) <word> Max<word> <word> <word> <word>		
CMF_NAME	Yes	Each Character, format, a way a many searches is a part of your CMF. Each Character, format, a way a many searches is a part of your CMF. Each character is a part CMF_NAME should be unique.	No	(Max) <word> Max<word> <word> <word> <word>	If the first in Mode, the CMF will be OpenCraft an upload class.	Text
VERSION	Yes	Define the version of the CMF as it works displayed on the OpenName.ini/Wiki/CMF. This doesn't store it contains relation for OpenName.ini/Wiki/CMF. This doesn't store it contains relation for this CMF. Max will be choosing this name. In the OpenName.ini/Wiki/CMF, this will be choosing this name.		(Max) <word> Max<word> <word> <word> <word>	If this is a new instance of a CMF that already exists, this CMF_NAME should match this. CMF_NAME of the pre-existing CMF for OpenCraft.	Text
				(Max) <word> Max<word> <word> <word> <word>	Max will be choosing this name. We'll be using this for a general changing, adding, or rotating any number from this to a new or changing a value of the parameter.	
VERSION_DESCRIPTION	Yes	This Word is used for short-hand and general purpose to many this list of what this CMF instance in the CMF is or created for.	Yes	(Max) <word> Max<word> <word> <word> <word>	This will/should be apparent as part of the CMF file/folder where this can't think on or Uses (original). This information is not displayed during data entry.	Text
				(Max) <word> Max<word> <word> <word> <word>	This will/should be apparent as part of the CMF file/folder where this can't think on or Uses (original). This information is not displayed during data entry.	
DESIGNER_SYSTEM	Yes	This Word is used to keep track of the Architects (or models) in this particular CMF	Yes	(Max) <word> Max<word> <word> <word> <word>	If this is the first version of the CMF, you can simply check this or a future you from. Using Microsoft, or OpenName.ini/Wiki/CMF, this will be choosing this name. In the OpenName.ini/Wiki/CMF, this will be choosing this name. If this is not a first version of a CMF, you should check this or a later in the OpenName.ini/Wiki/CMF, this will be choosing this name. Each version should use a unique design template.	Text
Surfaces						
		Word for surfaces in the our defined each module our spaces. This Word is used to define the surfaces in the our defined each module our spaces. This Word is used to define the surfaces in the our defined each module our spaces. This Word is used to define the surfaces in the our defined each module our spaces. This Word is used to define the surfaces in the our defined each module our spaces.				
SURFACE_LABEL	Yes	This Word is used to define the each of the CMF that we can use on the CMF Wireframe build.	No (Label) not (Label) not	(Max) <word> Max<word> <word> <word> <word>	This Word is used to define the each of the CMF that we can use on the CMF Wireframe build.	Alphanumeric text, no spaces
		This Word is used to define the each of the CMF that we can use on the CMF Wireframe build. This Word is used to define the each of the CMF that we can use on the CMF Wireframe build. This Word is used to define the each of the CMF that we can use on the CMF Wireframe build.				
SURFACE_TITLE	Yes	This Word is used to define the each of the CMF that we can use on the CMF Wireframe build.	No (Label) not (Label) not	(Max) <word> Max<word> <word> <word> <word>	This Word is used to define the each of the CMF that we can use on the CMF Wireframe build.	Text
		Long Surface Name (Max) (up to display) style.				
SURFACE	Yes	A surface (like a model). No Uses or Max.	No	(Max) <word> Max<word> <word> <word> <word>	Will be selected and suggested from the Uses.	Text
SURFACE_TYPE	Yes	Surface Name, at the top of the Surface (called the subtitle) that explains,	No	(Max) <word> Max<word> <word> <word> <word>	Will be selected and suggested from the Uses.	Text
		Surface Name, at the top of the Surface (called the subtitle) that explains,			

5.4.3 Overview of Creating and Modifying CRFs

Before defining the CRF, design it by identifying all the Items that will be on it, the parameters for each Item, and how they will be organized on the form. For guidelines, see Designing a CRF.

This is the overall process for defining a Case Report Form (CRF) for use in your OpenClinica system:

1. Download the CRF template or an existing, defined CRF. For detailed instructions, see Create a CRF.
2. Modify the Items and other content in the defined CRF using Microsoft Excel. See Providing Content for a Defined CRF.
3. Upload the defined CRF to your OpenClinica system, then identify and correct any errors.
4. Assign the defined CRF to an Event Definition in a Study as part of the Build Study process. Review the Event Definitions for the Sites in the Study, and if necessary, modify the parameters for the defined CRF at the Sites in the Study.

5.4.3.1 About CRF Versions

You can use a defined CRF in multiple Event Definitions and in multiple Studies in OpenClinica. You can also create different versions of the defined CRF. When you assign a CRF to a Study Event, you can specify which versions of the CRF are available to that Event and can specify the default version to be used. For example, you can create a defined CRF in English and create another version in Spanish; then, when a user completes the CRF for a Study Subject, the user can choose the version of the CRF based on the language they prefer to work with.

When you define a CRF, OpenClinica creates a parent record (called the "original"), and a version that can be used to collect data. When you create a new version of the CRF, it has the same name as the "original," but has a different version label assigned to it. When you make a change to a defined CRF, if there are other versions of the defined CRF that the change applies to, you will need to make the change to each version of the defined CRF.

5.4.4 Designing CRFs

When you design a CRF in OpenClinica, you can base it on an existing form you use (for example, a paper version), if you have one. But you will need to modify the form design so it works well in the OpenClinica web interface and takes advantage of OpenClinica's features. Whether or not you have an existing form, you can benefit from these guidelines for designing the form before you create the defined CRF:

1. List all the information (Items) you need to collect and record the parameters for each Item. For example, if you need to capture the Subjects temperature, the Item is Temperature, it is

required, and the parameters are any number between 95.0 and 103.9, with up to one decimal place, in degrees Fahrenheit. You specify the range so that when a user enters data into the form, OpenClinica flags a value outside the acceptable range for further action.

2. Determine if you will put all of the Items in one CRF or in multiple CRFs:
    - If a portion of the CRF can be used for other Events or other Studies, you might want to define a CRF for just that portion so you can reuse it, and define a different CRF for the rest of the Items.
    - If the information will be collected at different times during the Event, or at different physical locations (even within a Site), consider defining separate CRFs for each, or separate sections within the CRF for logistical convenience.
3. Determine the sections in the CRF and what Items to put in each section. When you enter data into a CRF, you save one section at a time, so fewer Items in a section minimizes the risk you will lose data if you accidentally close a CRF without first saving it. Fewer Items in a section also means the page opens quicker, makes it easier to locate an Item, and minimizes the need to scroll.

5.4.5 Create a CRF

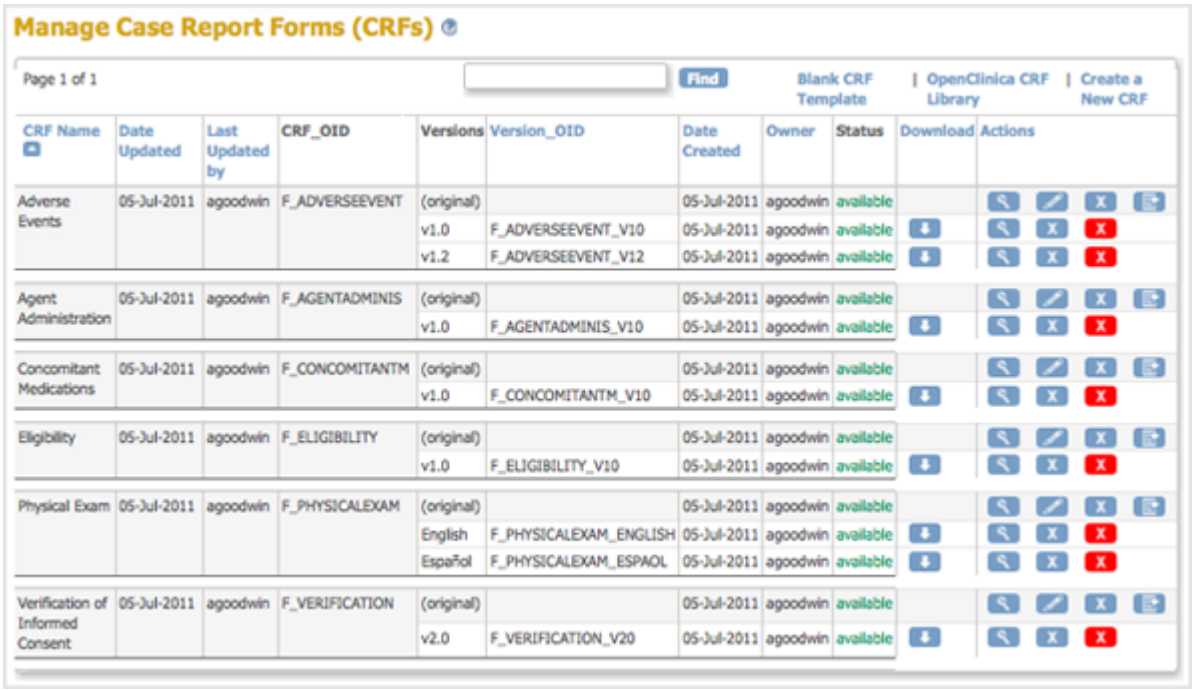
Before defining a CRF, you need to create the CRF you will use as a basis:

1. From the Tasks menu, in the Study Setup module, select Build Study.

   The Build Study page displays.

2. For the Create CRF task, click the View icon.

   The Manage Case Report Forms (CRFs) page opens.



3. From the Manage Case Report Forms page, download the CRF you will use as a basis for defining the CRF.
   Note that when you save the Excel file in this process, the Excel filename (the name that precedes .xls) is not used by OpenClinica in any way.

Choose one of the following options to download the CRF you will use as a basis:

- **Download an Existing Defined CRF:** When you want to define a CRF to be similar to one already in your OpenClinica system, download the existing defined CRF to use as a basis.

  1. From the Manage Case Report Forms page, click the Download icon in the Actions column for the version of the CRF you want to download.

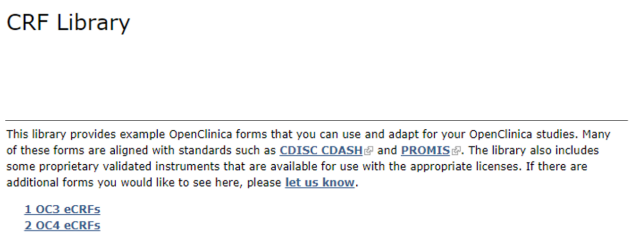
  2. Save the file to your computer using a unique, descriptive name.

  (Note that this is not the same as Creating a New Version of an Existing CRF)

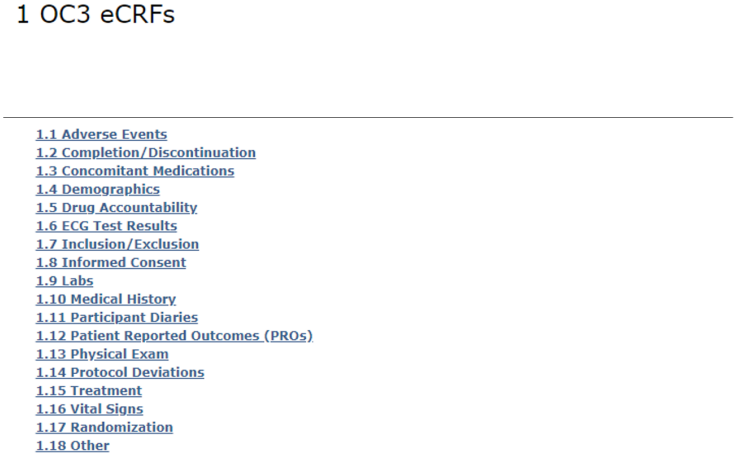
- **Download a Defined CRF from the CRF Library:** You can use a defined CRF from the OpenClinica library as a basis for the CRF you are defining. The library includes CRFs for common types of clinical forms that were defined by OpenClinica experts and are aligned with CDISC Clinical Data Acquisition Standards Harmonization (CDASH) standards, as well as CRFs defined by the OpenClinica community.

  1. Go to the CRF Library page of the OpenClinica documentation site.

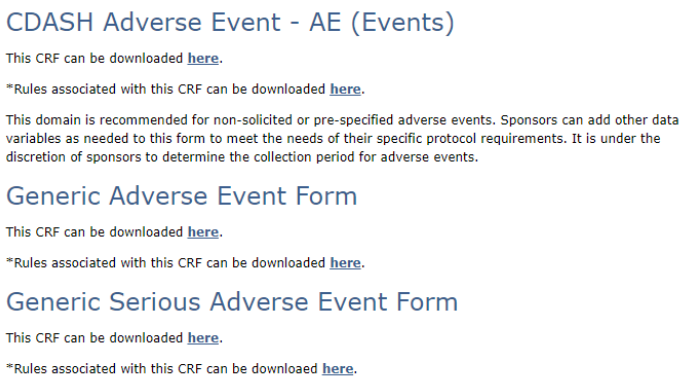
  2. Click Login, then log in using your OpenClinica username and password.
  The CRF Library page displays.



  3. Select the link for the version of OpenClinica that you are using.
  The list of available eCRFs displays:



  4. Click the link for the domain you are interested in. For example, Adverse Events.
  The domain page displays and may include multiple versions of forms.



5. Select the link for the form that best meets your needs.
   If applicable, Rules associated with the form are available and should be downloaded in addition to downloading the form.

6. Save the CRF and associated Rules to your computer using unique, descriptive names.

- **Download a Blank CRF Template:** If you have experience defining CRFs or there are no existing CRFs that are similar to what you need, use a blank template:

  1. From the Manage Case Report Forms page, click Blank CRF Template.

  2. Save the template to your computer using a unique, descriptive name.

After creating the CRF, provide content for it using Excel, then upload the defined CRF to OpenClinica.

5.4.6 Providing Content for a Defined CRF

When you define a CRF for use in OpenClinica, you use Excel (1997 to 2003 version) to provide the content in these four tabs (sheets) of the CRF .xls file:

- CRF
- Sections
- Groups
- Items

Each tab contains column headers that specify what belongs in that column; do not modify the column headers.

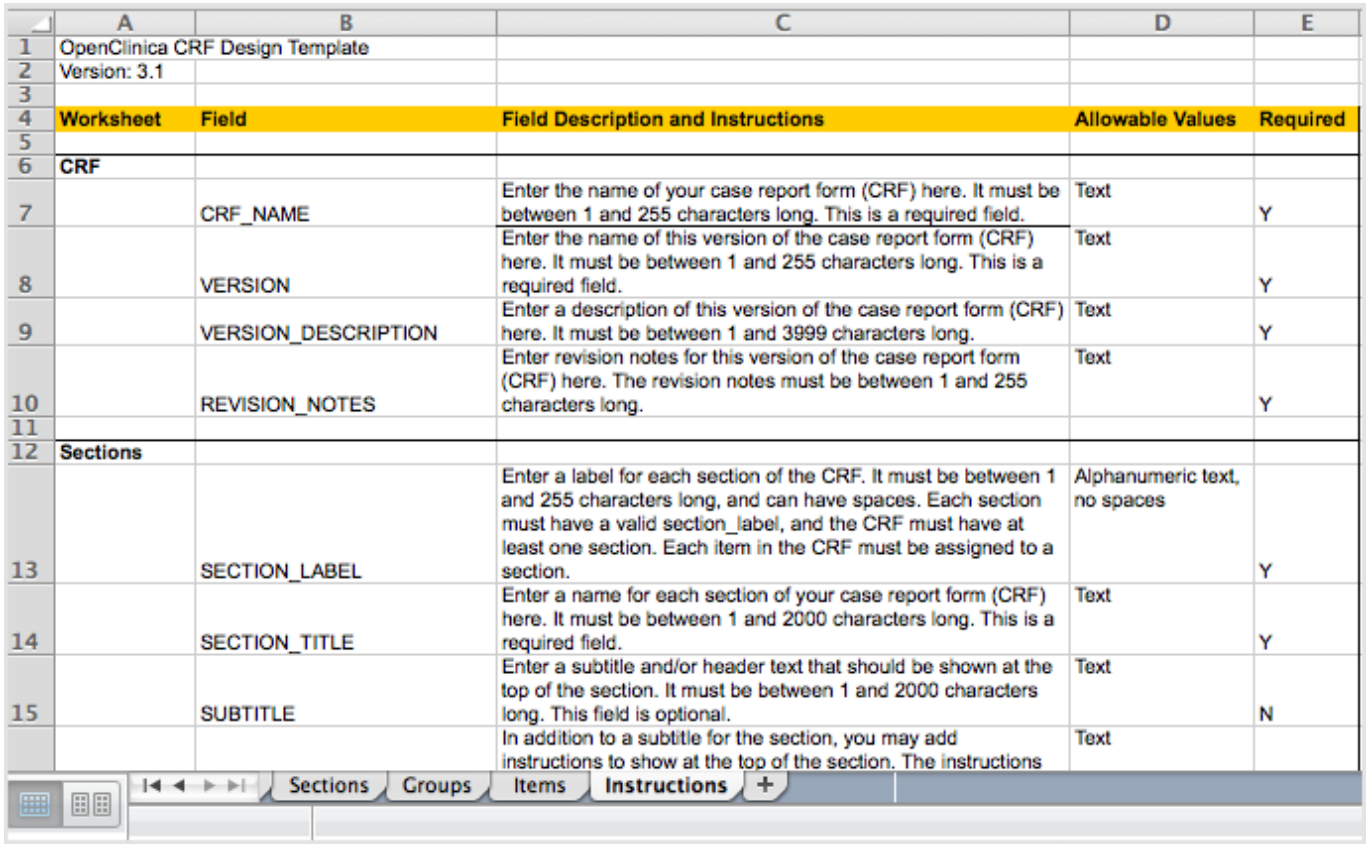
The fifth tab contains complete instructions for providing content for the CRF. You can also access instructions when you are providing content in the other tabs: click a column header and detailed instructions for that column display in a pop-up window.

To familiarize yourself with how the defined CRF in Excel relates to the presentation of that CRF in the OpenClinica web interface, see About CRFs in OpenClinica.

When you are first learning to provide content for defined CRFs for OpenClinica, work on only one or two Items at a time.

For more information, see OpenClinica eCRF Specifications in the OpenClinica Technical Documentation.

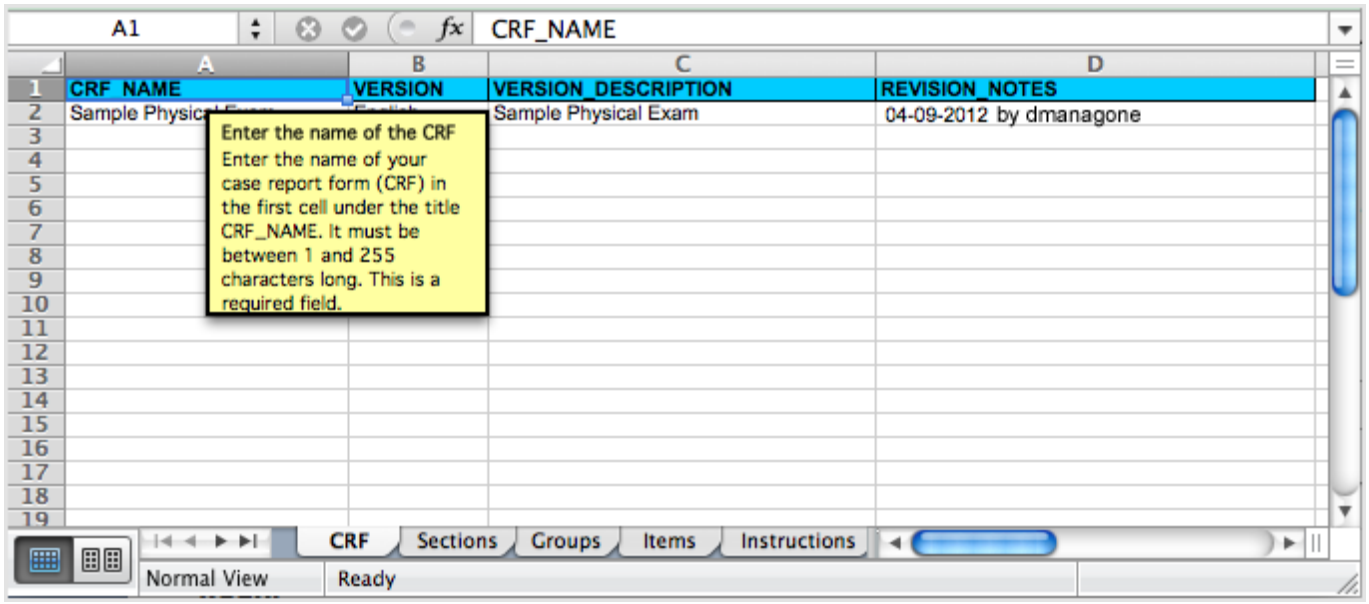
Instructions Tab in the Defined CRF:



	A	B	C	D	E
1	OpenClinica CRF Design Template				
2	Version: 3.1				
3					
4	**Worksheet**	**Field**	**Field Description and Instructions**	**Allowable Values**	**Required**
5					
6	**CRF**				
7		CRF_NAME	Enter the name of your case report form (CRF) here. It must be between 1 and 255 characters long. This is a required field.	Text	Y
8		VERSION	Enter the name of this version of the case report form (CRF) here. It must be between 1 and 255 characters long. This is a required field.	Text	Y
9		VERSION_DESCRIPTION	Enter a description of this version of the case report form (CRF) here. It must be between 1 and 3999 characters long.	Text	Y
10		REVISION_NOTES	Enter revision notes for this version of the case report form (CRF) here. The revision notes must be between 1 and 255 characters long.	Text	Y
11					
12	**Sections**				
13		SECTION_LABEL	Enter a label for each section of the CRF. It must be between 1 and 255 characters long, and can have spaces. Each section must have a valid section_label, and the CRF must have at least one section. Each item in the CRF must be assigned to a section.	Alphanumeric text, no spaces	Y
14		SECTION_TITLE	Enter a name for each section of your case report form (CRF) here. It must be between 1 and 2000 characters long. This is a required field.	Text	Y
15		SUBTITLE	Enter a subtitle and/or header text that should be shown at the top of the section. It must be between 1 and 2000 characters long. This field is optional.	Text	N
			In addition to a subtitle for the section, you may add instructions to show at the top of the section. The instructions	Text	

Sections | Groups | Items | Instructions

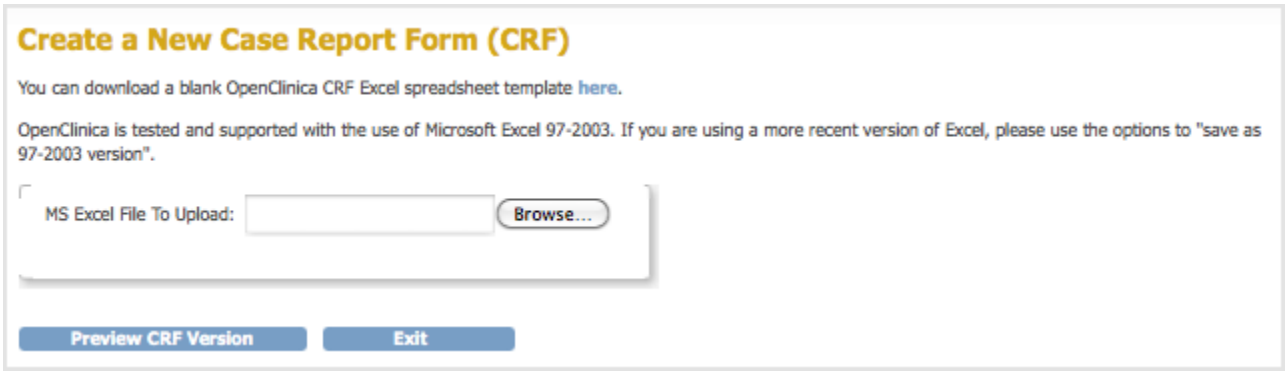
Clicking a Column Header in the Defined CRF Displays Instructions for that Column in a Pop-Up Window:



5.4.7 Upload a Defined CRF

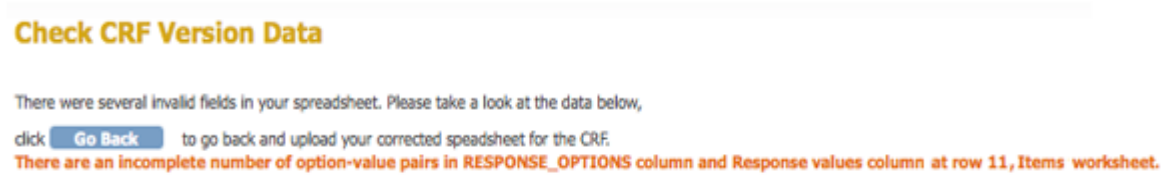
After using Excel to provide content for a defined CRF, upload the CRF to OpenClinca:

1. From the Tasks menu, in the Study Setup module, select Build Study.
   The Build Study page opens.
2. For the Create CRF task, click the View icon.
   The Manage Case Report Forms page opens.
3. Click Create a New CRF.
   The Create a New Case Report Form page opens.

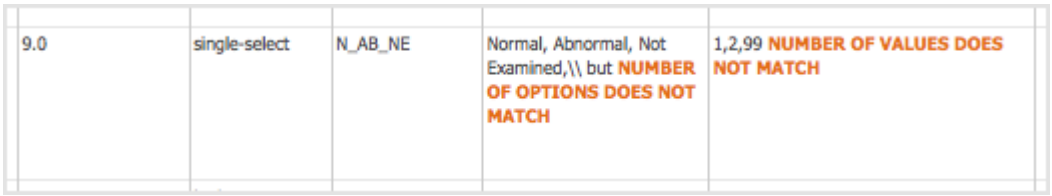


4. Click Browse, then navigate to the defined CRF you want to upload. Select the file and click Open.
5. In the Create a New Case Report Form page, click Preview CRF Version.
   The Check CRF Version Data page opens.
6. If there are any errors, OpenClinica reports them at the top of the page and provides details for the cells containing the errors below that. Click Go Back, correct the errors in the defined CRF using Excel, and repeat steps 4 through 6.

   Example of an Error Message for a Defined CRF:



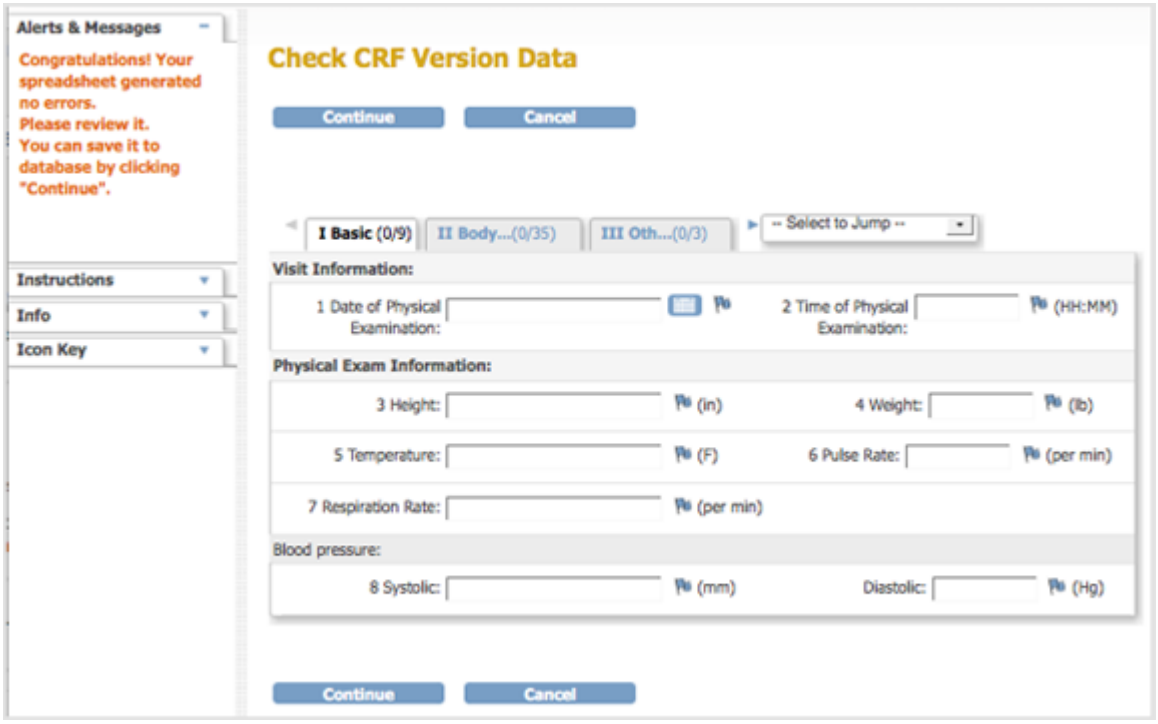
   Example Showing Details for the Errors that are in the Defined CRF:



7. When the defined CRF you uploaded is free of errors, OpenClinica displays a preview of the web interface for the CRF, and the Alerts & Messages sidebar panel displays a success message. Review each section of the CRF in the web interface preview (click the tab for a section to show it), viewing drop-down lists, checking wording and arrangement of Items, and so on. Make notes of anything you want to change. To make changes, click Cancel, make

changes using Excel and save the file, then repeat steps 4 through 6. (Note: do not click Continue while you are still changing the content of the defined CRF. If you do click Continue but still want to make changes, you will need to replace the existing CRF or create a new version of it.)

Preview a CRF:



8. After previewing the defined CRF and completing any changes, click Continue.

   The Create a New CRF - Data Committed Successfully page opens.

9. Review the defined CRF:
   1. Click Go back to the CRF List.
      The Manage CRFs page opens.
   2. For the CRF you want to review, click the View icon in the Actions column for the version you defined (do not click the View icon in the row that is marked "original" version).
   3. Review each section of the defined CRF (click the tab for a section to show it), viewing drop-down lists, checking wording and arrangement of Items, and so on. Make notes of anything you want to change. If you need to make changes to the name or description, see Edit a Defined CRF. If you want to, you can instead, Replace the Defined CRF.

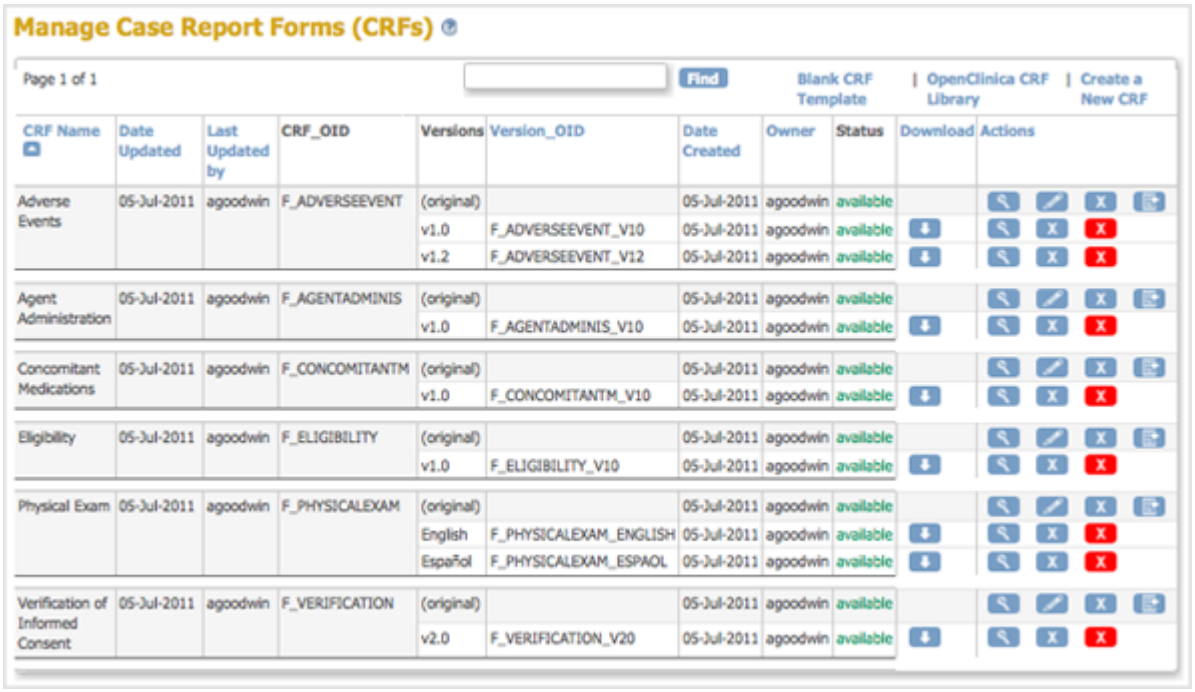
After completing all changes to a defined CRF, assign the CRF to an Event Definition for any of your

Studies.

5.4.8 Table of CRFs

The table of CRFs lists all versions of all defined CRFs in your OpenClinica system and provides access to features for managing the defined CRFs. The available features in the table depend on your User Role and User Type. To access the table of CRFs:

1. From the Tasks menu, in the Study Setup module, select Build Study.
   The Build Study page opens.
2. For the Create CRF task, click the View icon.
   The Manage Case Report Forms page opens.



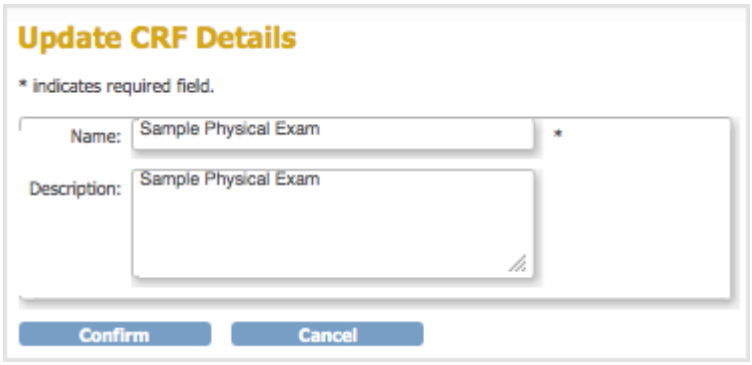
The CRFs table is the same table you can access from the Monitor and Manage Data module. In addition to using this table to create, modify, and remove defined CRFs as described in other topics on this page, you can use this table to:

- View information about an original CRF and the details for each version
- Find and organize CRFs

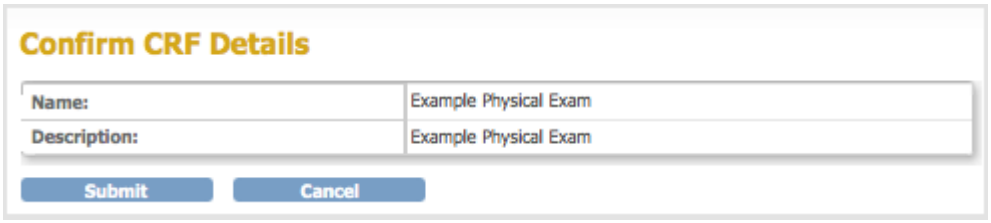
5.4.9 Edit the Defined CRF Name and Description

After adding a defined CRF to OpenClinica, you can change the Name and Description shown in OpenClinica for that CRF:

1. Access the Table of CRFs.
2. For the CRF whose Name and/or Description you want to change, click the Edit icon in the Actions column.
   The Update CRF Details page opens.



3. Change the Name and Description, then click Confirm.
   The Confirm CRF Details page opens.



4. Click Submit.
   The Table of CRFs page opens and shows the updated name for the CRF.

5.4.10 Create a New Version of a Defined CRF

You can make changes to a defined CRF that is already in your OpenClinica system.

Start by downloading the existing defined CRF from OpenClinica: see Download an Existing Defined CRF in Create a CRF. Then make changes to defined CRF using Excel: see Providing Content for a Defined CRF. Finally, upload the new version to OpenClinica. When you upload it, you can either:

- Replace the existing version (under certain conditions), or
- Add the modified CRF as a new version

5.4.10.1 Replace a Defined CRF

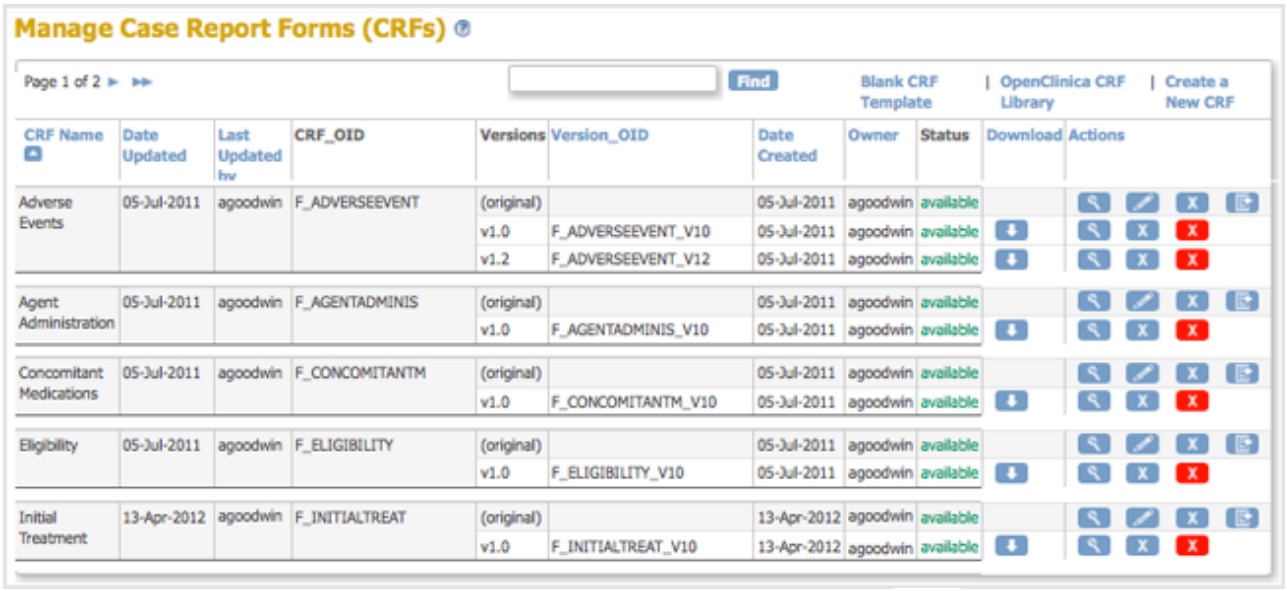
You can replace an existing version of a defined CRF under the following conditions:

- You must be the CRF's Owner, as listed in the Table of CRFs. The Owner is the user who uploaded the CRF you are replacing.
- The CRF cannot be assigned to any Event Definitions in any Studies.
- The values for CRF_NAME and VERSION for the CRF already in OpenClinica and the CRF you are replacing it with must match exactly.

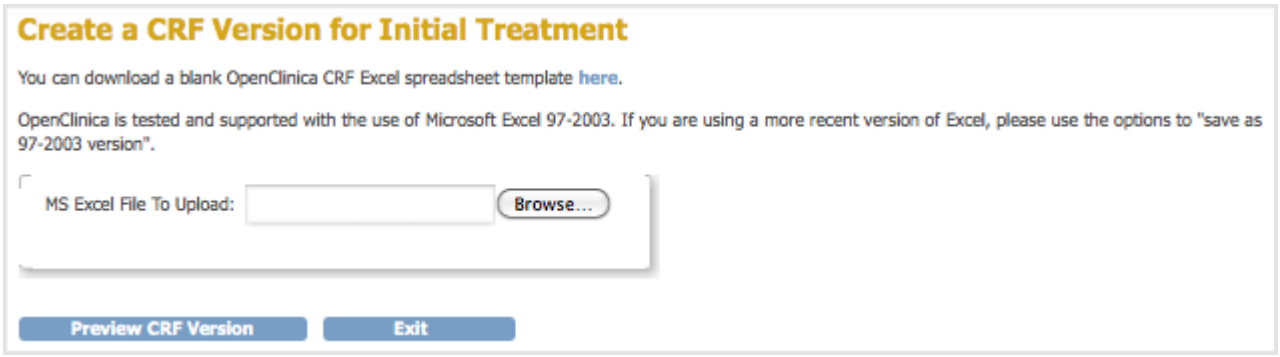
If these conditions are not met, OpenClinica prevents you from replacing the CRF, but you can instead Add it as a New Version of the CRF.

To replace a CRF:

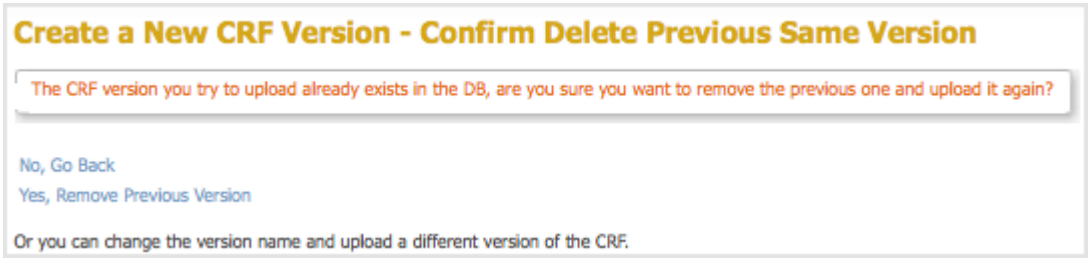
1. Access the Table of CRFs.



2. For the CRF you are replacing, click the Create New Version icon .
   The Create a CRF Version for ... page opens. In the example shown here, the CRF being replaced is Initial Treatment.

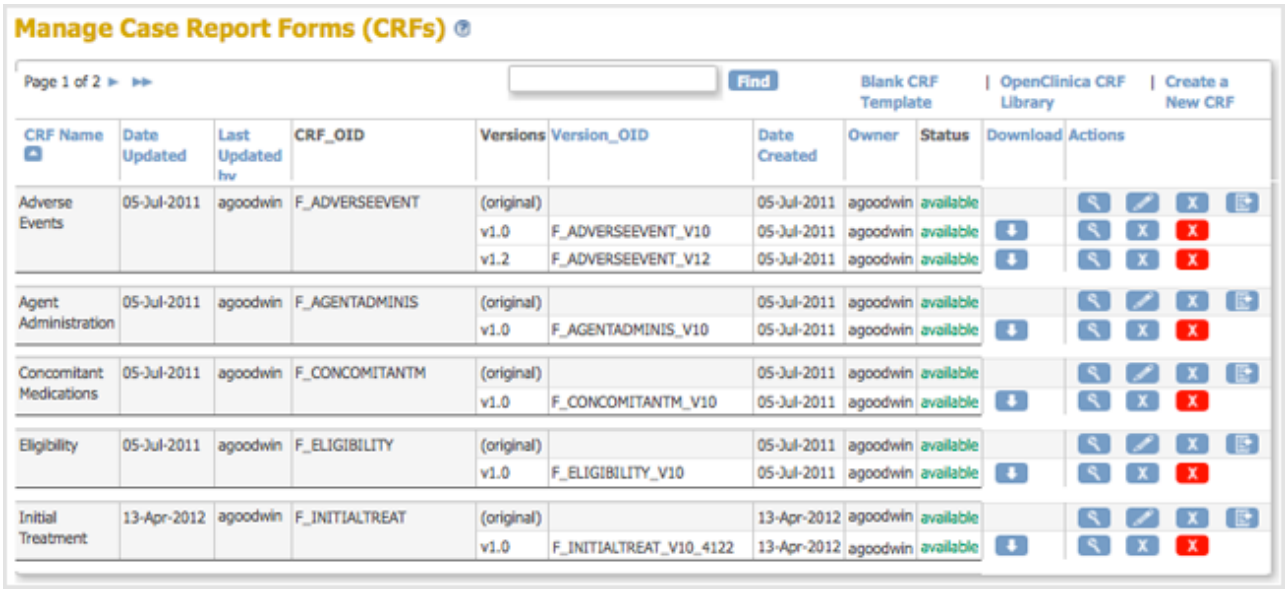


3. Click Browse, then navigate to the CRF you want to upload. Select the file and click Open.
4. Click Preview CRF Version.
   The Create a New CRF Version - Confirm Delete Previous Same Version page opens.
   In the example, the v1.0 version of the Initial Treatment CRF is being replaced: the CRF you are uploading has the value v1.0 for VERSION, and Initial Treatment for CRF_NAME.



5. Click Yes, Remove Previous Version.
   The Check CRF Version Data page opens, presenting a preview of the CRF in the OpenClinica web interface.
6. Correct any errors as described in Upload a Defined CRF (step 6).
7. After previewing the CRF and completing any changes, click Continue.
   The Create a New CRF Version - Data Committed Successfully page opens.
8. Click Go back to the CRF List.
   The Manage CRFs page opens.

- There will be a new value for Date Updated if you the version you replaced was last uploaded on a previous date.
- There is a new Version_OID for the CRF you replaced. This is not the same as the value you specified for VERSION for the CRF, but is an internal identifier that OpenClinica uses to manage CRF versions.



5.4.10.2 Add a New Version of a Defined CRF

For background information, see About CRF Versions.

You can add a new version of a CRF to OpenClinica under the following conditions:

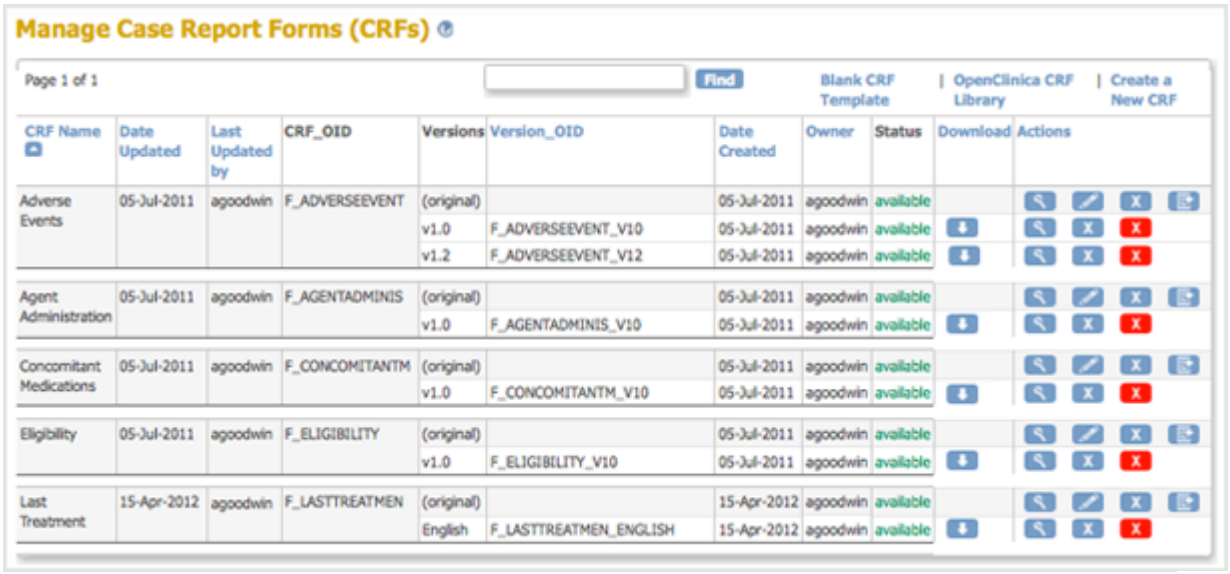
- The CRF_NAME in the new version of the defined CRF must match the CRF Name already in OpenClinica, but the value for VERSION must be different.
- For each ITEM_NAME, the DESCRIPTION, GROUP LABEL, and DATA_TYPE must exactly match the DESCRIPTION, GROUP LABEL, and DATA_TYPE already in OpenClinica. Changes to response sets are limited.

For more information, see CRF Versioning in the OpenClinica Technical Documentation.

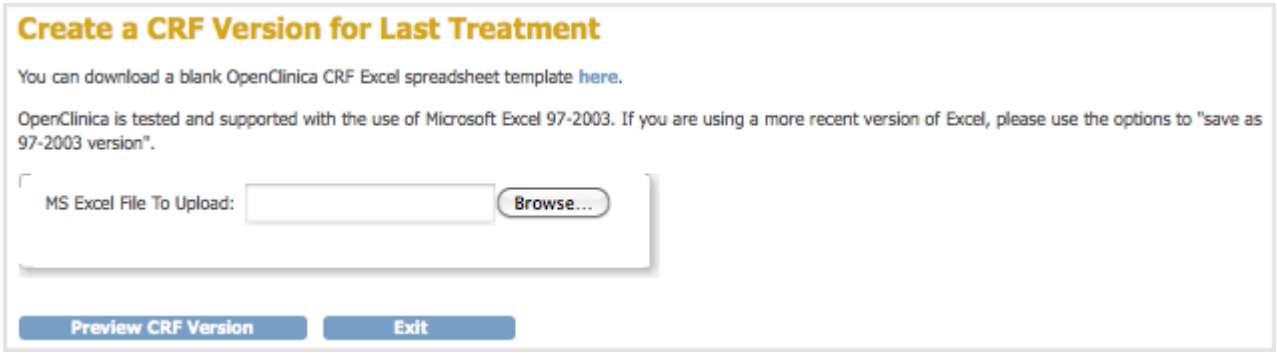
When you add a new version of a CRF, the version already in OpenClinica remains. If you want to, you can remove the previous version from OpenClinica after adding the new version, or you can keep the previous version if you want users to be able to complete either versions going forward.

To add a new version:

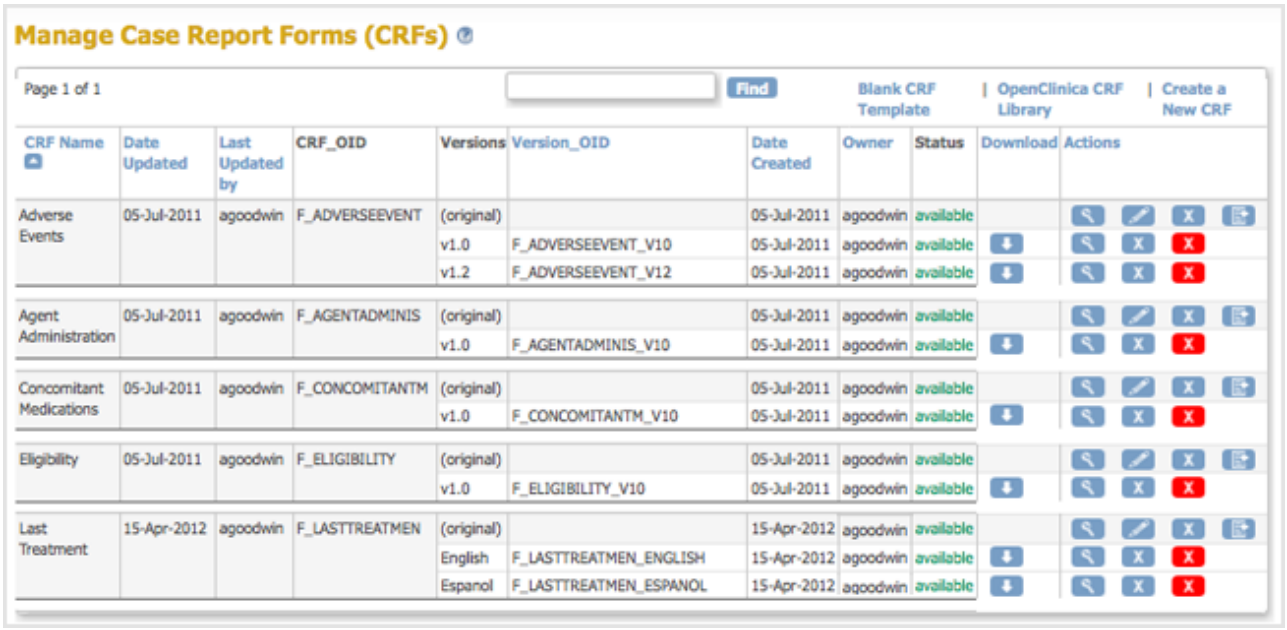
1. Access the Table of CRFs.



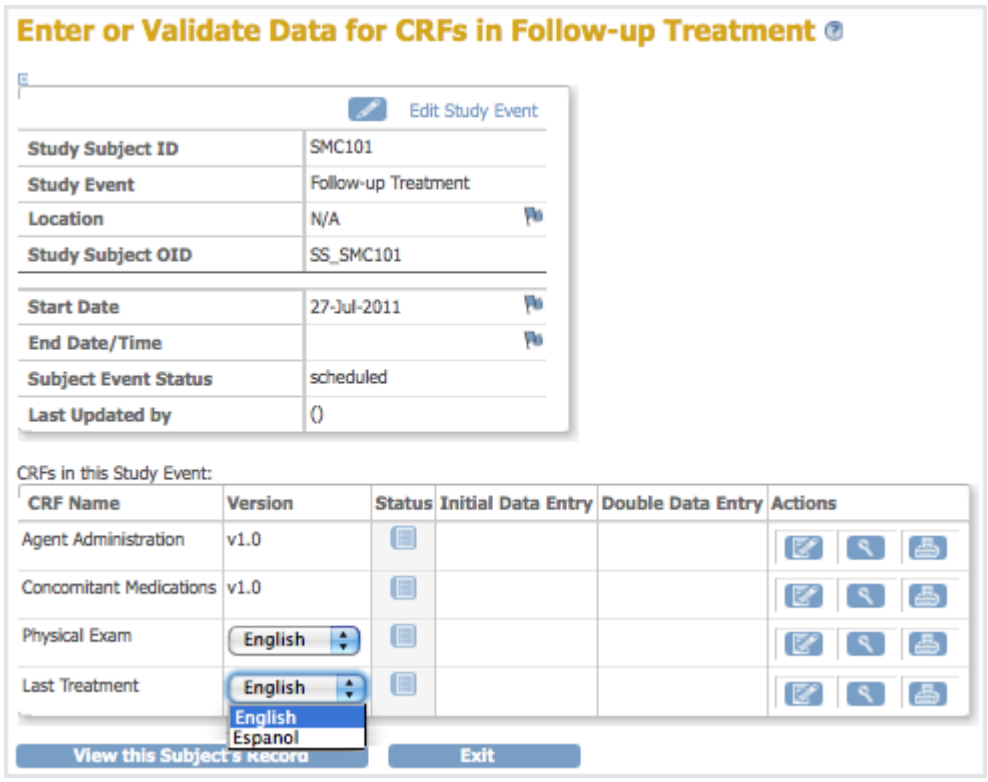
2. For the CRF to which you are adding a new version, click the Create New Version icon . The Create a CRF Version for ... page opens. In the example shown here, a new version (Espanol) is being added for the Last Treatment CRF.



3. Click Browse, then navigate to the CRF you want to upload. Select the file and click Open.
4. Click Preview CRF Version.
   The Check CRF Version Data page opens, presenting a preview of the defined CRF in the OpenClinica web interface.
5. Correct any errors as described in Upload a Defined CRF (step 6).
6. After previewing the CRF and making changes, click Continue.
   The Create a New CRF Version - Data Committed Successfully page opens.
7. Click Go back to the CRF List.
   The Manage CRFs page opens. The version of the CRF you added is listed in the table.



Now, when a user enters Event Data for a Subject, they can choose which version of the defined CRF to use. For the example, Last Treatment, the user can choose the English or Espanol version.



5.4.11 Remove, Restore, and Delete Defined CRFs

If your User Type has appropriate permission, you can perform the following actions on defined CRFs or versions you no longer want to use:

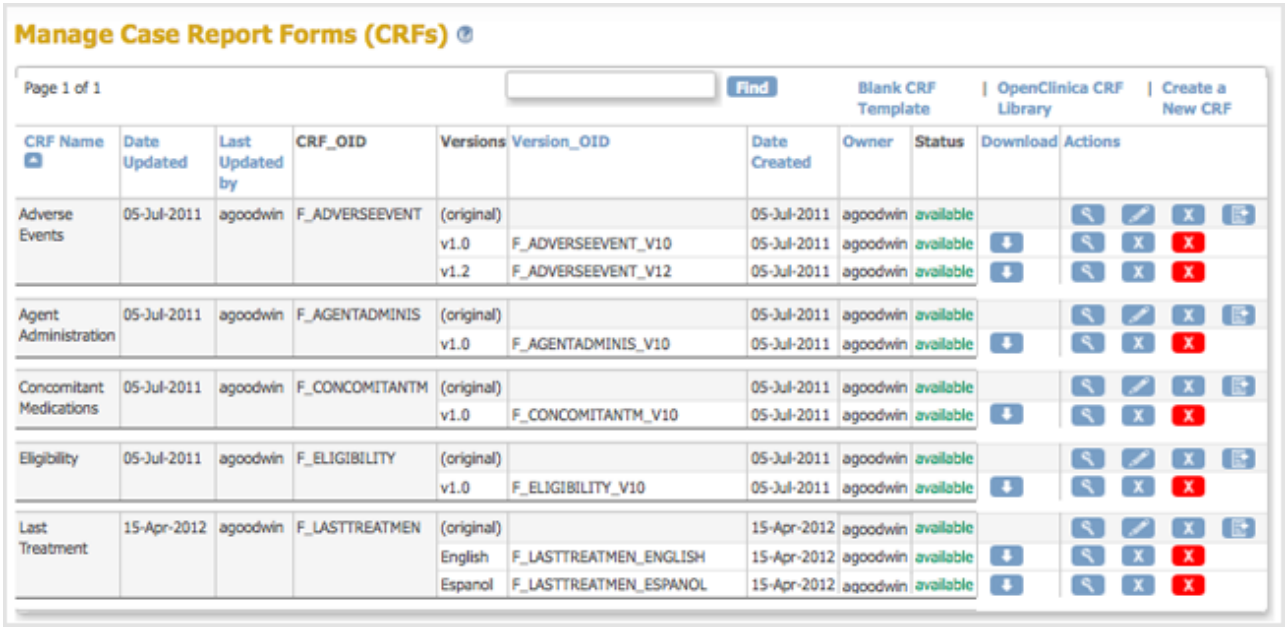
- Delete a version of a CRF if it has not been used for data entry for any Subjects and you no longer want the CRF in your OpenClinica system for potential use in any Studies. You cannot recover the CRF after its been deleted.

- Remove a version of the CRF if it has been used for data entry for Subjects, to prevent its use going forward. Data captured using this version of the CRF is not included in data extracts whose definition specifies that CRF. You can restore a version of the CRF that's been removed.
- Restore a version of the CRF that has previously been removed, which allows it to again be used for data entry for Subjects.
- Remove the "original" (parent) CRF to prevent any versions of that CRF to be used going forward, and to prevent the CRF from being assigned to any more Event Definitions. You can restore the parent CRF, and all versions, after it has been removed. Data captured using any versions of the CRF is not included in data extracts whose definition specifies that CRF.
- Restore an "original" CRF that has previously been removed, which allows any versions of that CRF to be used going forward, and allows the CRF to be assigned to Event Definitions.
- Archive a version of the CRF to prevent it from being added to any more Event Definitions. Data previously captured using that version of the CRF is included in data extracts whose definition specifies that CRF. Instructions to archive a CRF are in Administer CRFs.

Delete a CRF Version

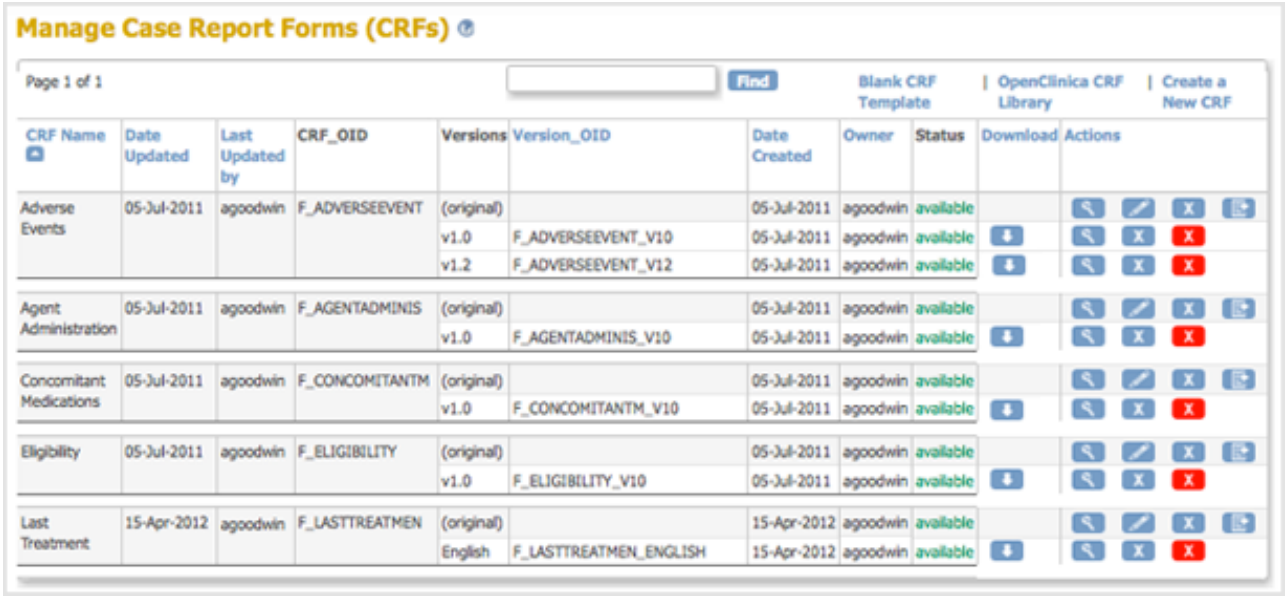
Delete a version of a defined CRF if it has not been used for data entry for any Subjects. A deleted version of a CRF cannot be restored. To delete a version of a CRF:

1. Access the Table of CRFs.

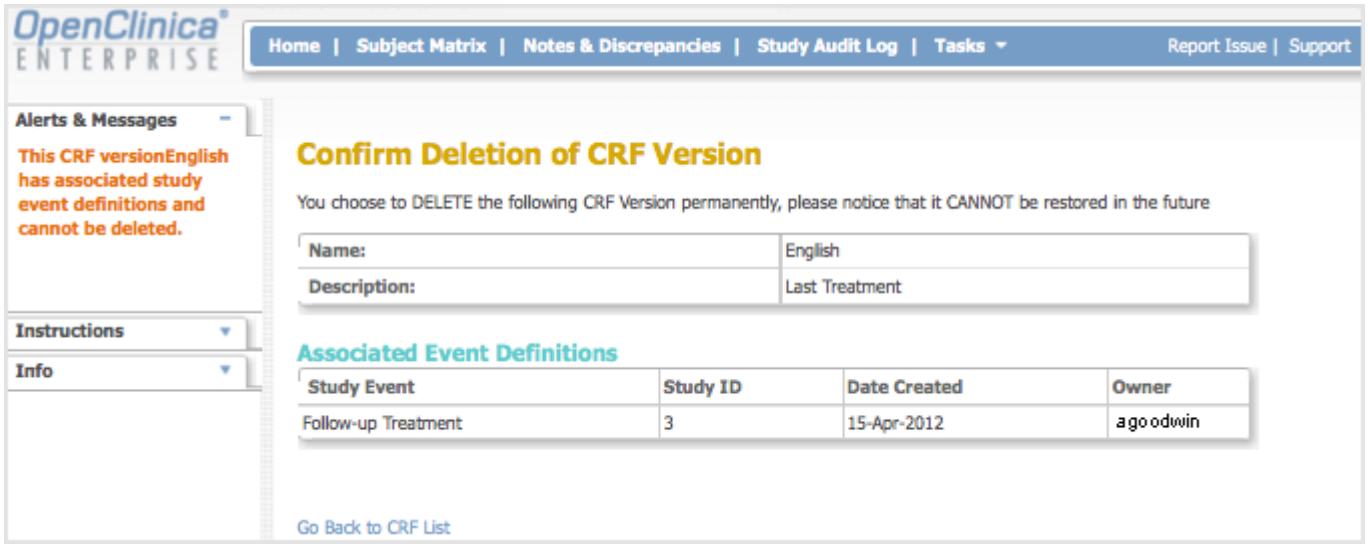


2. For the version of the CRF you want to delete, click the Delete icon X. For the example, the Espanol version of the Last Treatment CRF is being deleted.
The Confirm Deletion of CRF Version page opens.

3. Click Delete CRF Version, then click OK in the confirmation dialog box.
   The Manage CRFs page opens. The version of the CRF you deleted no longer appears in the table.



If you try to delete a version of a CRF that has already been used to enter Subject data, OpenClinica prevents you and displays the following:

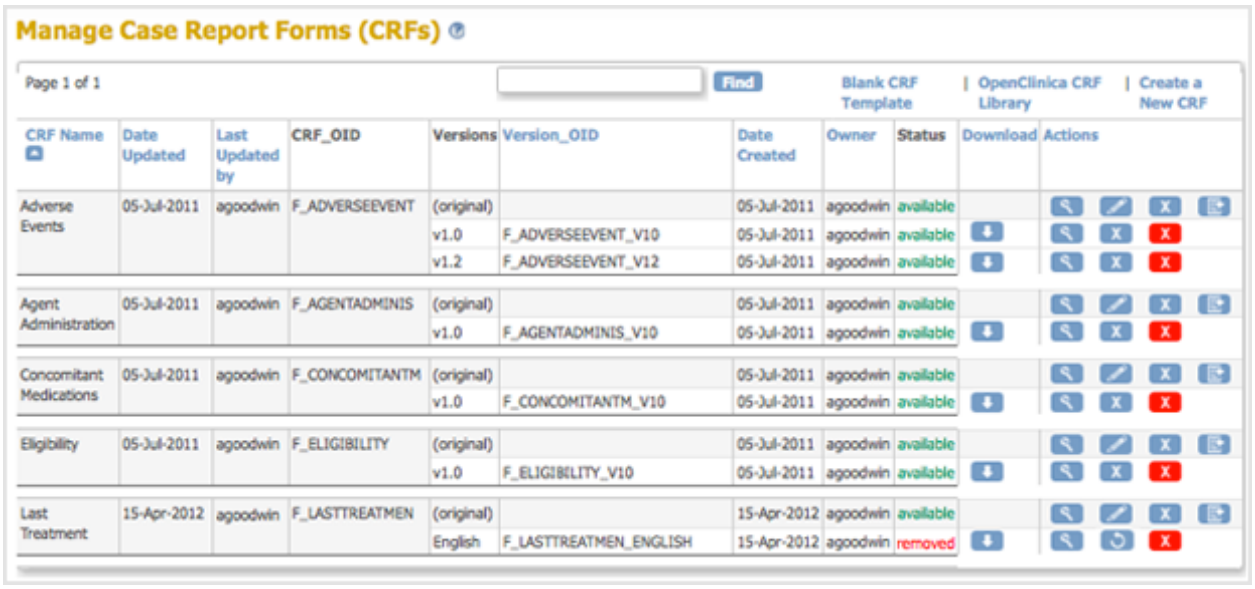


Remove a CRF Version

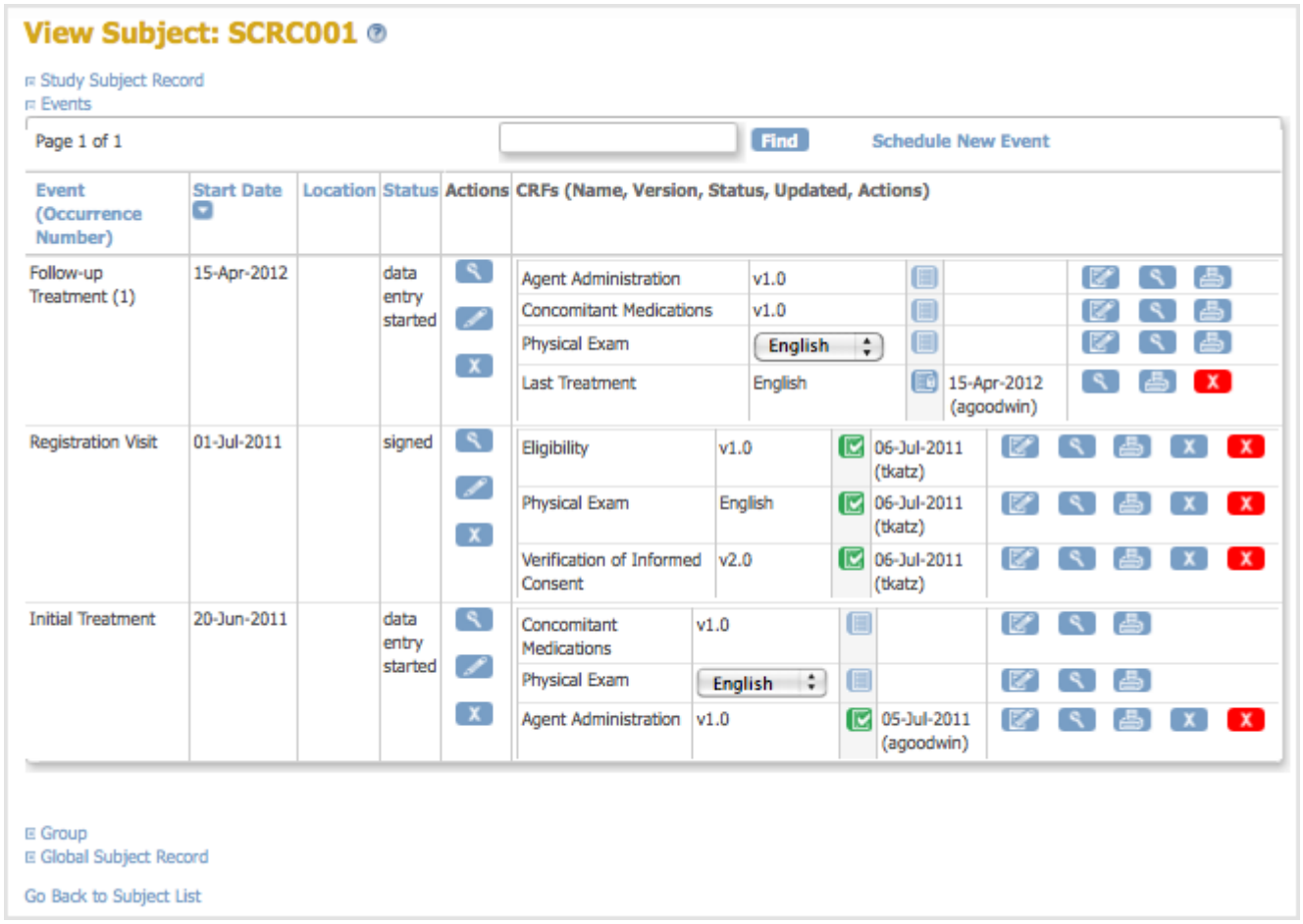
If a version of a defined CRF has been used for data entry for Subjects, you can prevent its use going forward by removing it. A version of a CRF that has been removed can be restored. To remove a version of the CRF:

1. Access the Table of CRFs.
2. For the version of the CRF you want to remove, click the Remove icon X. For the example shown here, the Last Treatment CRF, English version, is being removed.
   The Confirm Removal of CRF Version page opens. It lists the Event CRFs and Subjects who have had data entered using that version of the CRF.

3. Click Remove CRF Version, and then click OK in the confirmation dialog box.
   The Manage CRFs page opens. The version of the CRF you removed is listed, but with a Restore icon instead of a Remove icon in the Actions column and a Status of "removed".



After removing the version of the CRF, you can still view the CRF and can still view Subject data for that version of the CRF, as shown below, however you cannot change any of the data. The status of the CRF for the Subject is "locked":



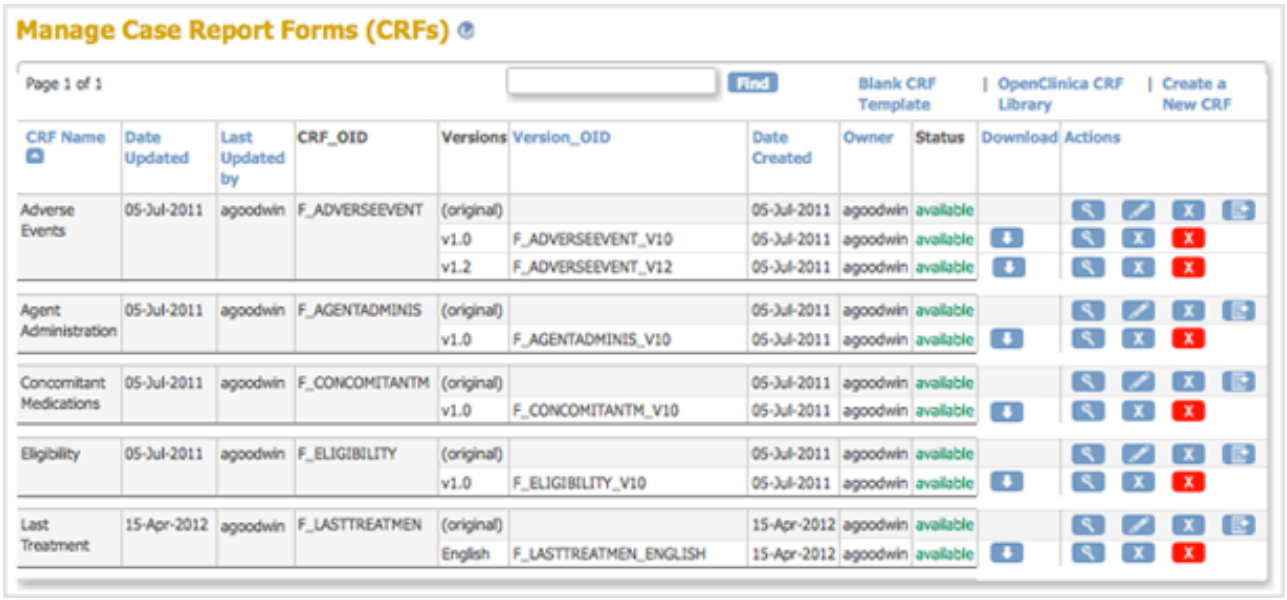
After removing a version of the CRF, it is no longer available for you to choose from when you enter data for any other Subjects for that CRF.

Restore a CRF Version

After removing a version of a defined CRF, you can restore it to make it available for use for entering Subject data. To restore a version of the CRF:

1. Access the Table of CRFs.
2. For the version of the CRF you want to restore, click the Restore icon . For the example shown here, the Last Treatment CRF, English version, is being restored.
   The Confirm Restore of CRF Version page opens. It lists the Event CRFs and Subjects who have had data entered using that version of the CRF.

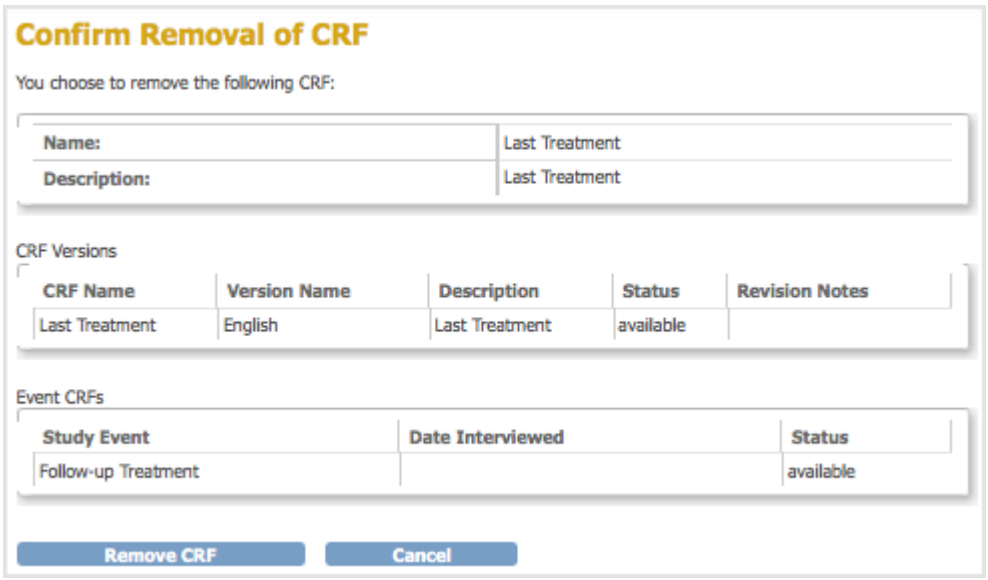
3. Click Restore CRF Version, then click OK in the confirmation dialog box.
   The Manage CRFs page opens. The CRF you restored is listed with a status of "available."



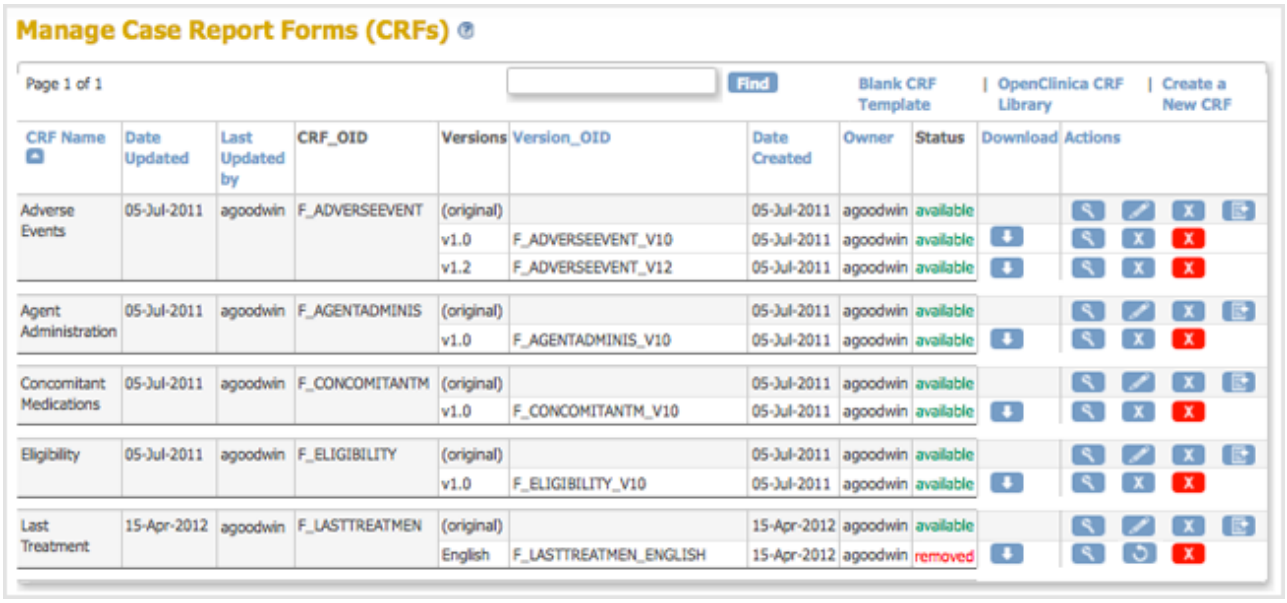
Remove the Original Version of a CRF

You can remove the original (parent) version of a defined CRF, which automatically removes all versions of the CRF. To remove the original version of a CRF:

1. Access the Table of CRFs.
2. For the CRF you want to remove, click the Remove icon in the row for the version "original". For the example shown, the Last Treatment CRF is being removed.
   The Confirm Removal of CRF page opens. It lists all versions of that CRF and all Event Definitions to which the CRF has been assigned.



3. Click Remove CRF, then click OK in the confirmation dialog box.
   The Manage CRFs page opens. The CRF you removed is listed, but with a Restore icon instead of a Remove icon in the Actions column and a Status of "removed." All versions of the CRF are listed, but with a status of "auto-removed."



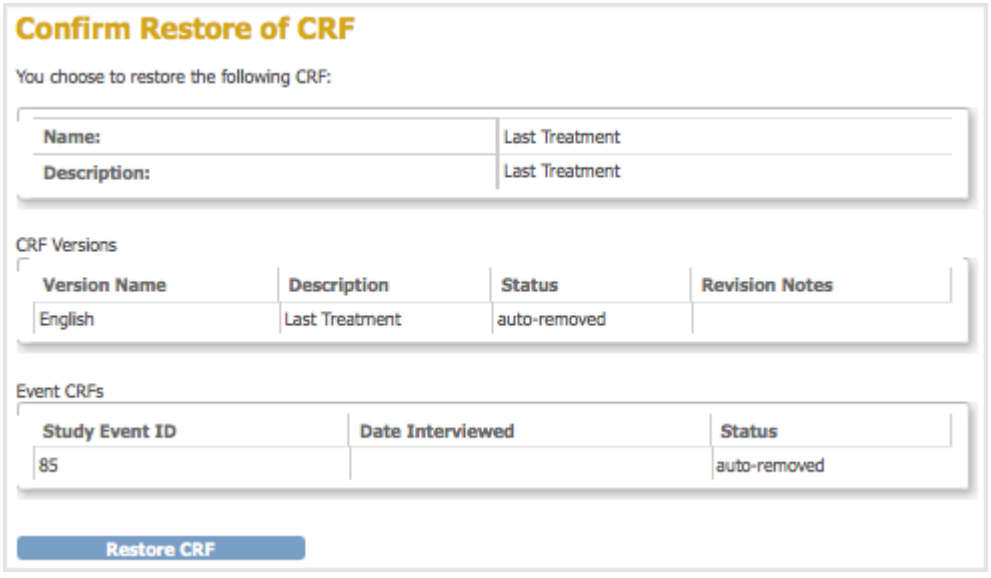
After removing the original version of a defined CRF, any Event Definitions to which the CRF was assigned list the CRF, but show the status as auto-removed. When you are adding CRFs to Event Definitions, the removed CRF is not listed for you to choose from.

Note: you cannot delete the original version of a defined CRF.

Restore the Original Version of a CRF

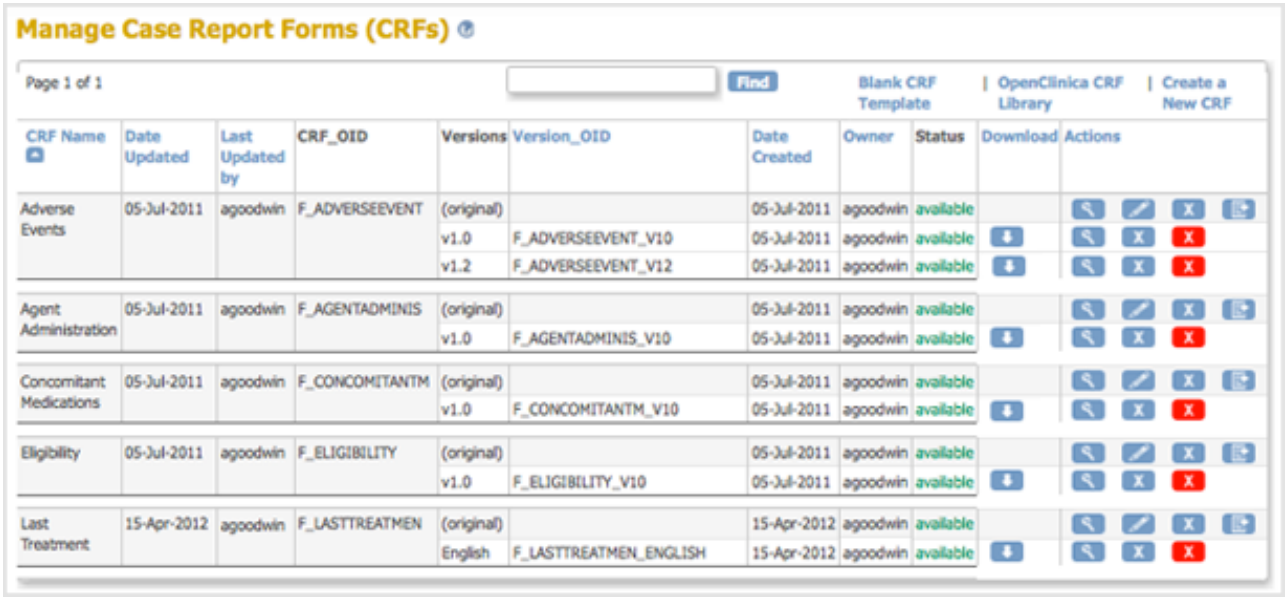
After removing the original version of a CRF, you can restore it. Restoring the original CRF restores all versions of it to all Event Definitions in all Studies to which the CRF was assigned. To restore the original version of a CRF:

1. Access the Table of CRFs.
2. For the CRF you want to restore, click the Restore icon in the row for the version "original." For the example shown, the Last Treatment CRF is being restored.
   The Confirm Restore of CRF page opens. It lists CRF versions for that CRF and all Event Definitions to which the CRF has been assigned.



3. Click Restore CRF, then click OK in the confirmation dialog box.
   The Manage CRFs page opens. It lists the CRF you restored and all versions of it with a status

of "available."



5.5 Create and Modify Event Definitions

As part of building a Study, you define the Study's Events. A Study Event is a visit or encounter in the Study where data is captured or created. Creating a Study Event Definition means specifying the case report forms (CRFs) for the Event as well as the Event parameters. Users then complete the CRFs for each Subject for the Study Event.

Once created, you can view, modify, remove, restore, and add new Event Definitions.

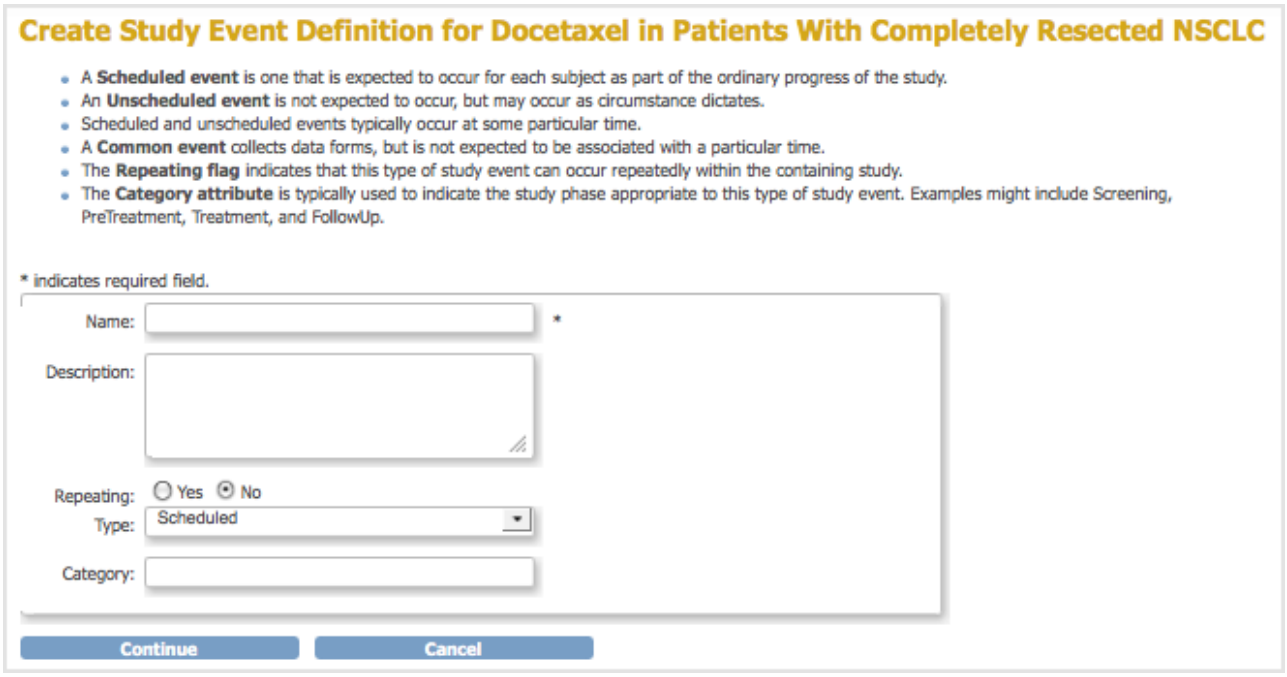
Approved for publication by Ben Baumann. Signed on 2014-03-24 8:39AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

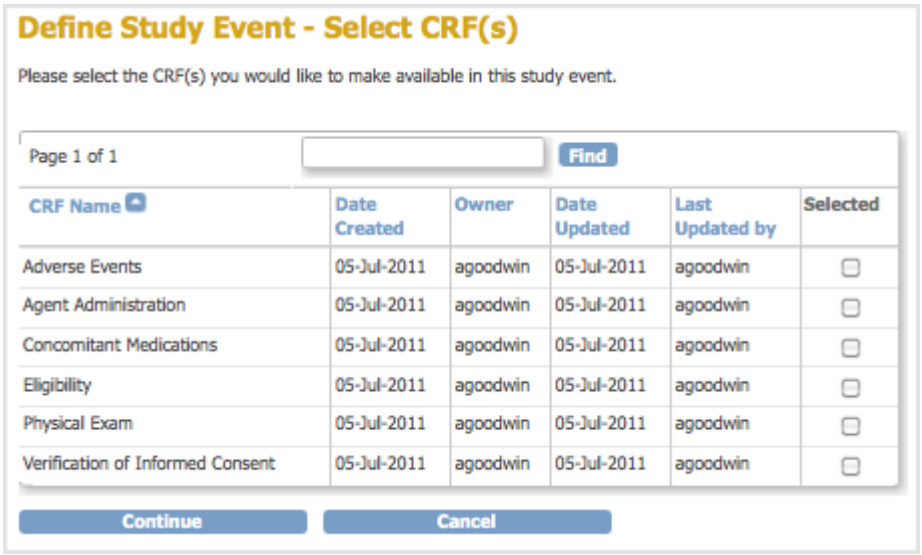
5.5.1 Create Event Definitions

When you create an Event Definition, you specify its parameters and select the CRFs for it. You do not have to specify CRFs for the Event Definition when you first create it, but can select the CRFs later. To create an Event Definition for the current Study:

1. Access the Build Study page by selecting **Tasks > Build Study**.
2. In the Actions column of the table, for the **Create Event Definitions** task, click the Add icon .
   The Create Study Event Definition page opens.

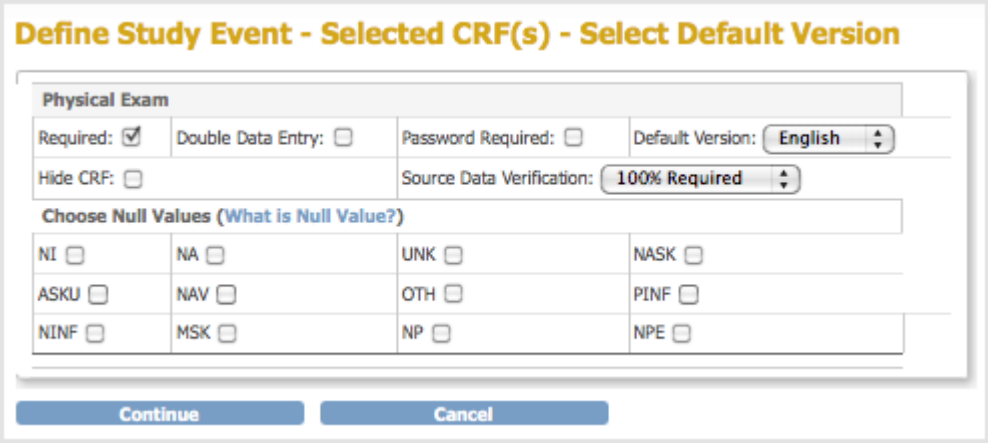


3. Complete the dialog box, referring to the field descriptions included in the dialog box. For example:
   - **Name** (of Event Definition): Follow Up Visit
   - **Description:** Each scheduled session to administer the treatment.
   - **Repeating:** Yes (because a Subject will complete the Event multiple times in the Study; each time, the user completes a new set of forms for the Subject for that occurrence of the Event).
   - **Type:** Scheduled (because the Event will be scheduled for specific dates and times). Note that an Event whose Type is Unscheduled might or might not occur (like an Adverse Event), while an Event whose Type is Common is expected to occur but at an unknown time.
   - **Category:** Treatment.
4. Click **Continue**.
   The Define Study Event - Select CRF(s) page opens. It lists all CRFs created in your OpenClinica system.

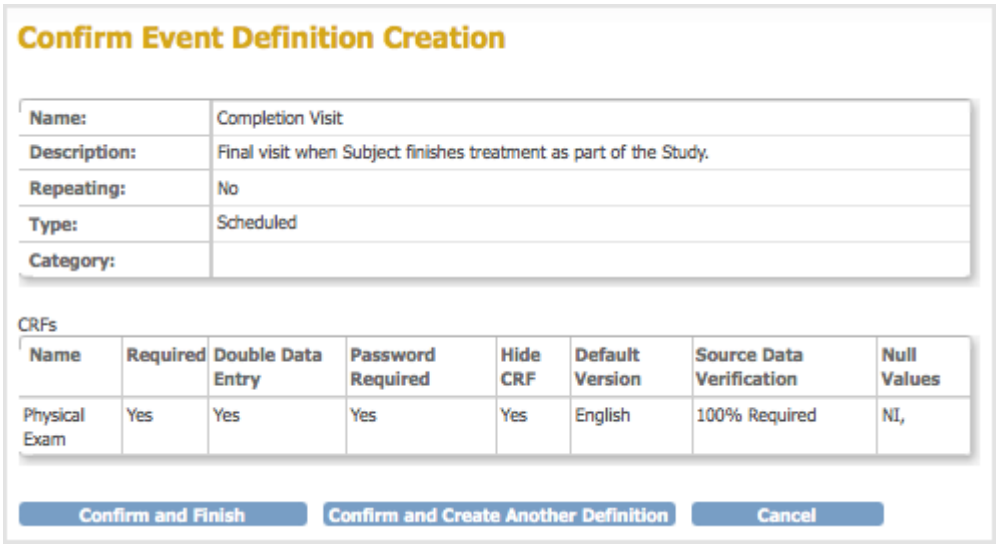


5. In this step, you select the CRFs for the Event Definition. To help locate CRFs to include, click a column header to sort by that column, or use the Find field. You do not have to select CRFs

at this point--you can complete the Event Definition without them, then add the CRFs later if you like. If you want to select the CRFs now, click the checkbox in the Selected column for each CRF you want to include in the Event Definition, then click Continue. For example, select the Physical Exam CRF, which will be completed for each Followup Visit Event in the Study.
The Define Study Event - Selected CRF(s) - Select Default Version page opens. It lists configuration options for each CRF you selected.



6. Specify the configuration parameters for each CRF you selected, referring to the following information as needed. Note that you can specify different parameters for the CRFs at different sites; for more information, see Create and Modify Sites.
    - **Required:** Select if the CRF must be completed for the Event, or do not select if the CRF is optional for the Event.
    - **Double Data Entry:** Select if the data for the CRF must be entered twice. For more information on how this works, see Double Data Entry.
    - **Password Required:** Select if a user must supply their OpenClinica password when marking a CRF complete at the end of data entry.
    - **Default Version:** If more than one version of the CRF exists, such as for multiple languages, select the default version for the Event. You can limit the available versions for a Site when you create or modify the Site as part of building the Study.
    - **Hide CRF:** Select to make the CRF viewable only at the Study level, meaning Sites cannot access the CRF. Typically, you hide a CRF when the data is not entered using the OpenClinica web interface but rather is imported from files.
    - **Source Data Verification:** Select one of the values from the drop-down list. Select 100% Required, Partially Required, or Not Required to help you organize CRFs in the Source Data Verification table. When you specify Not Applicable, the CRFs are not included in Source Data Verification table. For more information, see Source Data Verification.
    - **Choose Null Values:** ***Please Do Not Use This Feature***. This functionality will be removed in future versions of OpenClinica. If you need to specify selections to define null values (for example "Not Done" or "Unknown," add those selections to the Response Options Text and Response Values columns of the CRF template.
7. Click **Continue**.
   The Confirm Event Definition page opens.
8. Verify the Event Definition information, then click **Confirm and Finish** to complete this Event Definition.

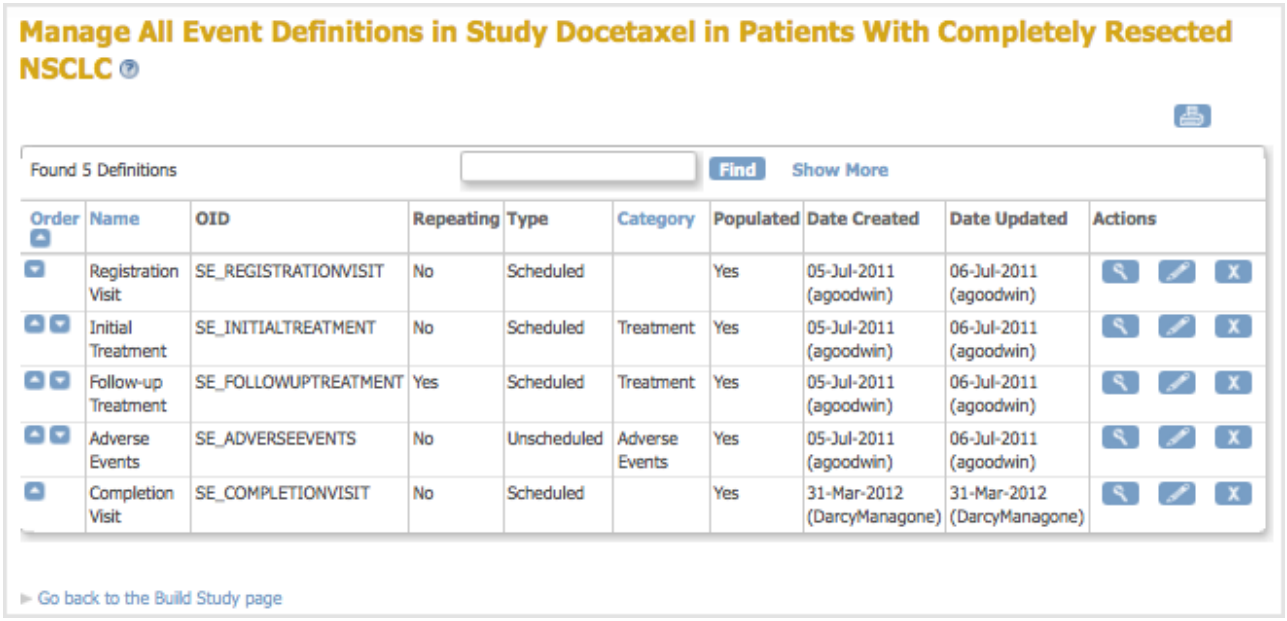


The Build Study page opens. The Alerts and Messages sidebar panel displays a message that the Event Definition was successfully added. In the Create Event Definitions row, the Count has increased by 1, reflecting the Event Definition you just completed.

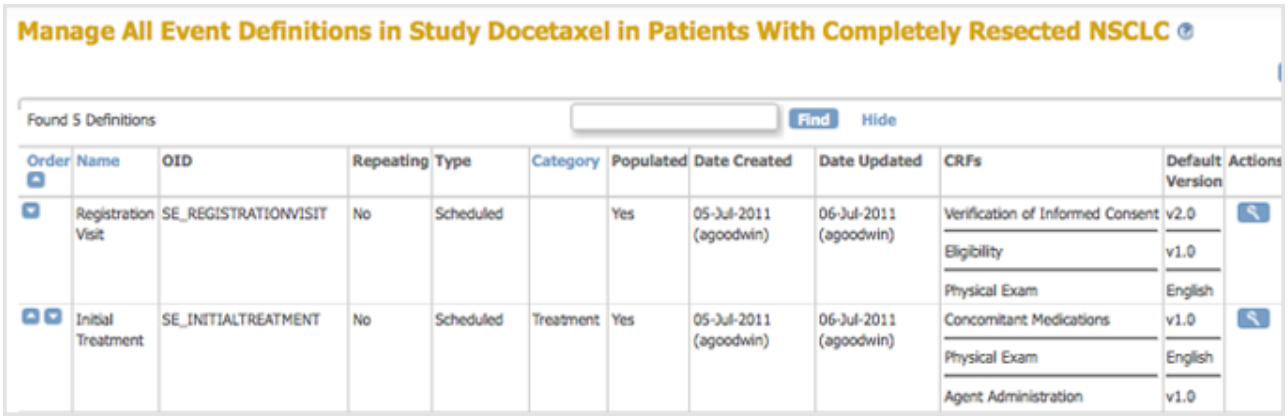
5.5.2 View Event Definitions

To view the Event Definitions for the current Study:

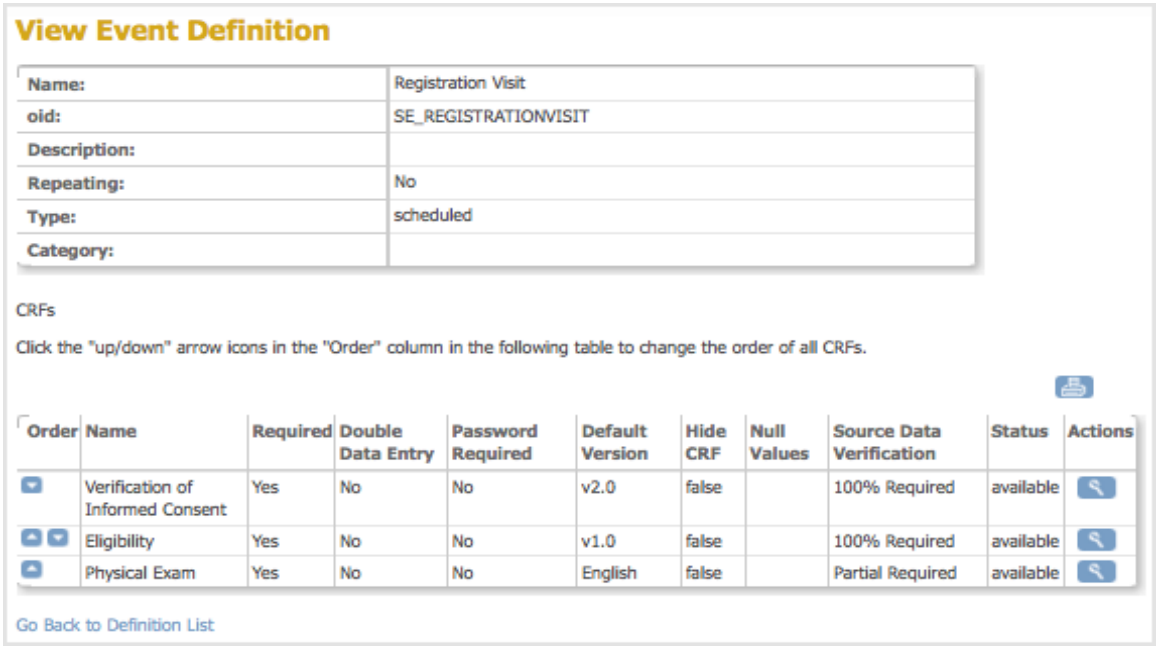
1. Access the Build Study page by selecting Tasks > Build Study.
2. For the Create Event Definitions row, click the View icon in the Actions column.
   The Manage All Event Definitions page opens, listing all Event Definitions created for the current Study. The Populated column indicates if any data has been entered for any of the CRFs for the Event.



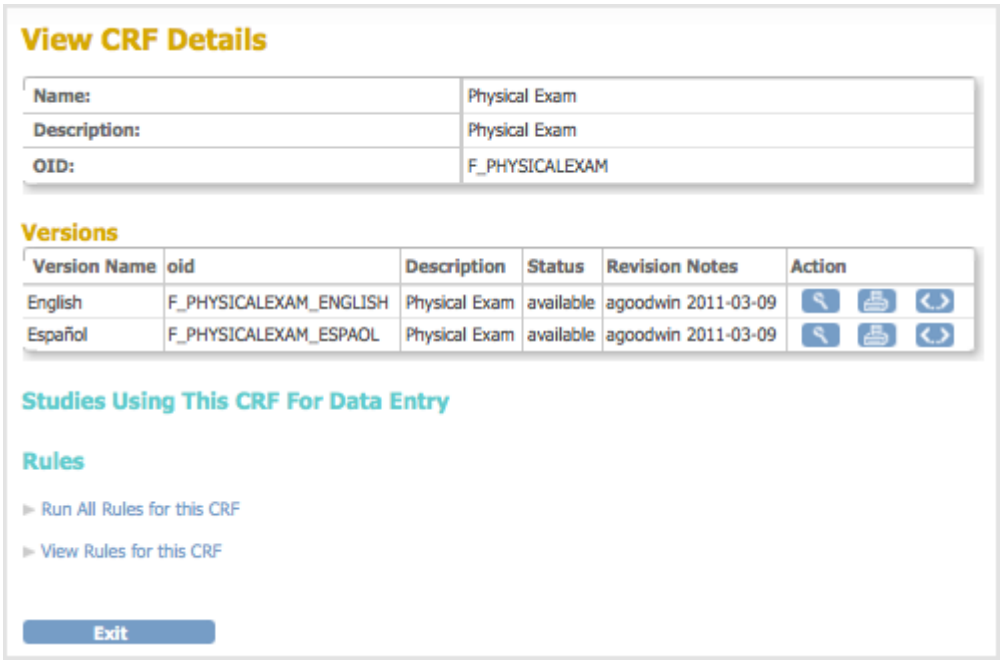
3. To help you find an Event Definition, you can type text in the Find field.
4. To view the CRFs and versions assigned to each Event, click Show More at the top of the table. The following example is a partial view of the page with Show More selected.



5. To view details for an Event Definition, in the Actions column, click the View icon for that Event.
   The View Event Definition page opens.



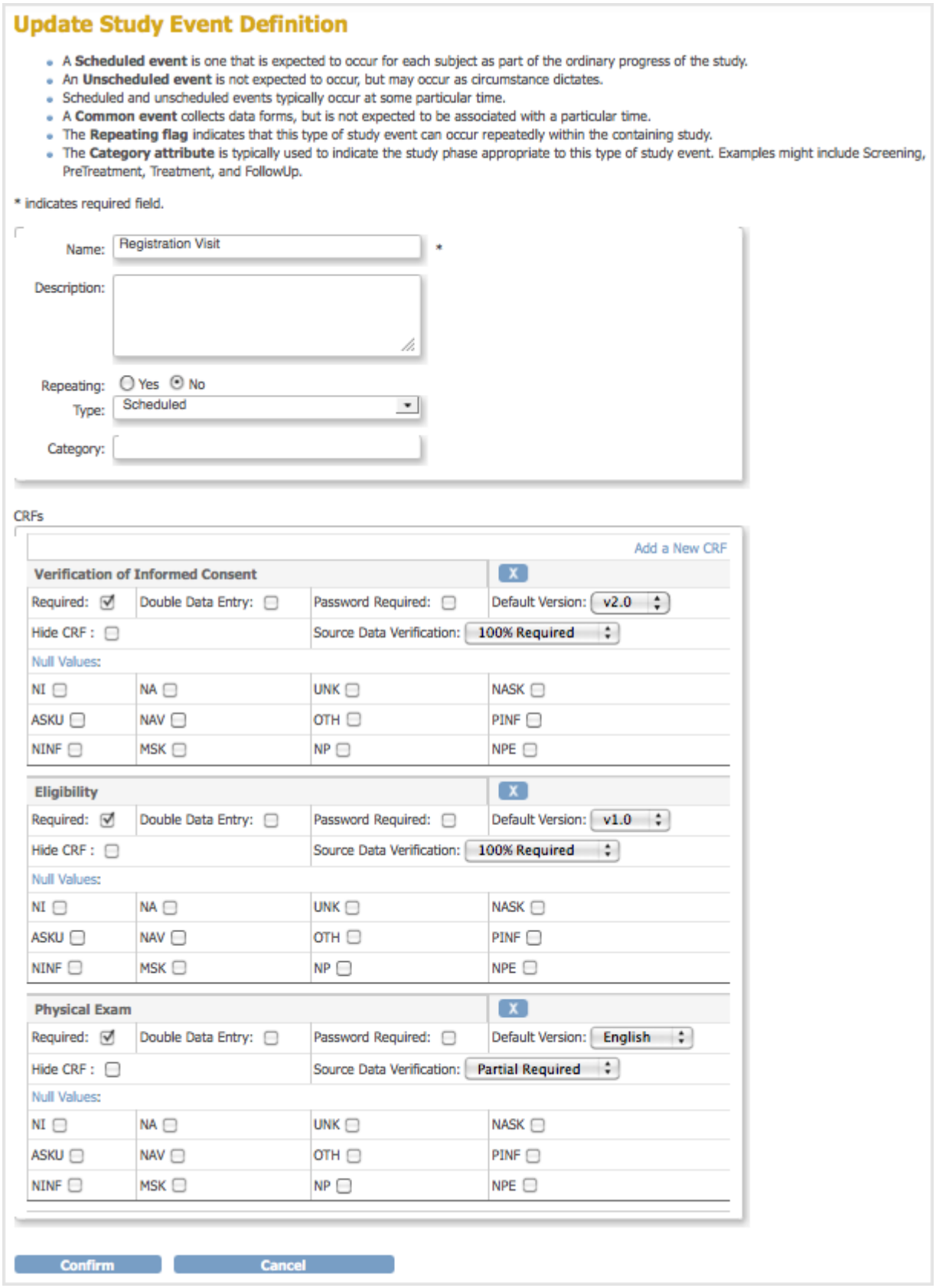
6. To view details for any of the CRFs shown on the View Event Definition page, for that CRF, click the View icon in the Actions column. The View CRF Details page opens, listing the CRF versions for that CRF. To view details for any of the versions, click the View icon for that version from the Action column.



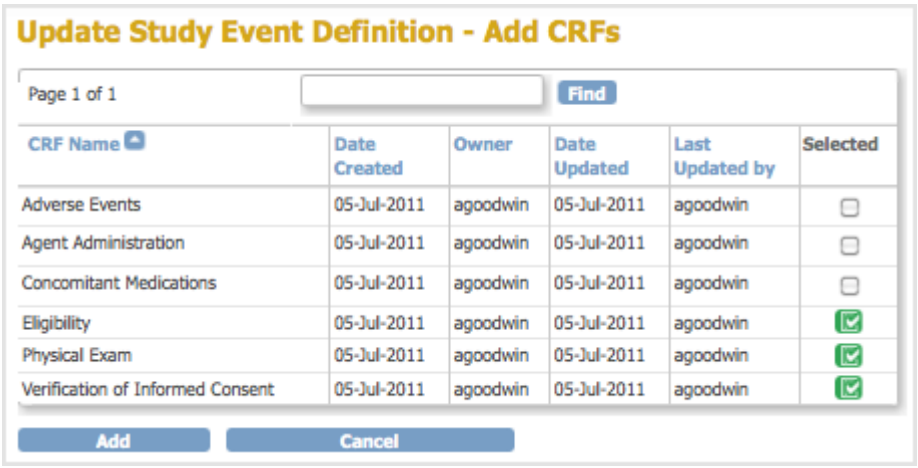
5.5.3 Edit Event Definitions

You can change parameters for an Event Definition, add or remove CRFs in the Event Definition, and change the order in which CRFs and Events appear.

1. Access the Build Study page by selecting Tasks > Build Study.
2. Access the Manage All Event Definitions page by clicking the View icon in the Actions column for the Create Event Defintions row.
3. If you want to change the order in which the Events appear (as in the Subject Matrix, for example), use the arrow buttons in the Order column. For example, click a down arrow once to move that Event down in the order by one position.
4. If you want to change the order in which CRFs appear for an Event:
    1. Click the View icon for that Event.
    2. In the View Event Definition page, use the arrow buttons in the Order column. For example, click a down arrow once to move that CRF down in the order by one position.
    3. Click the Go Back to Definition list link to return to the Manage All Event Definitions page.
5. If you want to edit the Event Defintion, from the Actions column of the Manage All Event Definitions page, click the Edit icon for that Event.
   The Update Study Event Definition page opens.

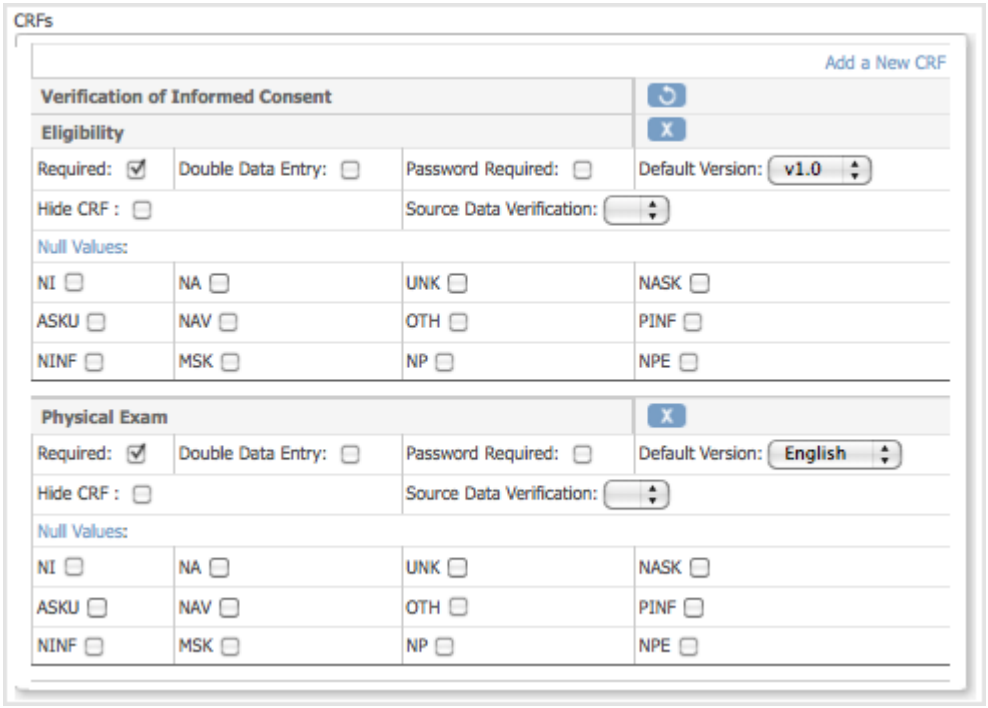


6. If you want to add a new CRF to the Event Definition:
    1. Click the Add a New CRF link (at the top of the CRFs section).
    The Update Study Event Definition - Add CRFs page opens. The Selected column shows the CRFs that are already included in the Event.

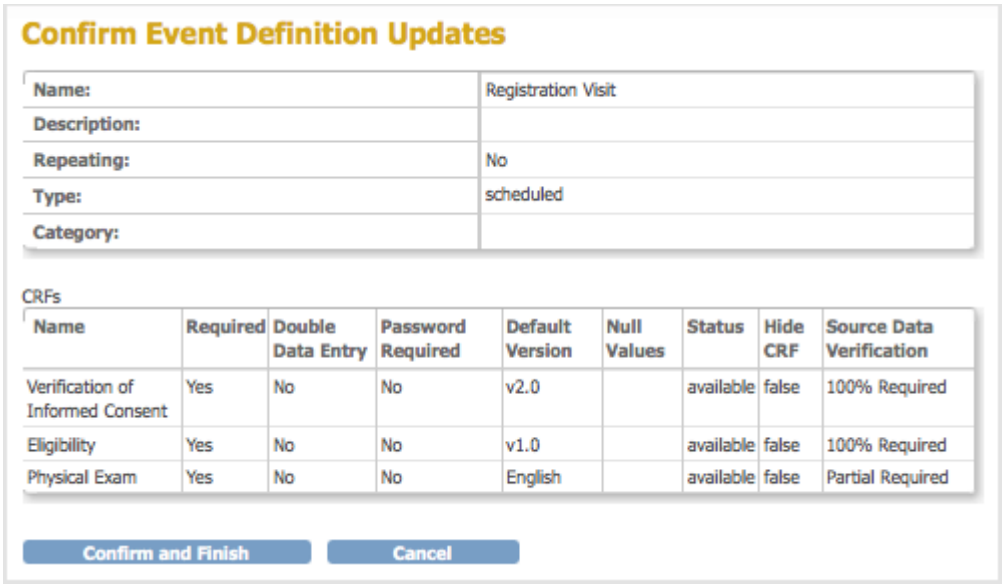


2. Click the checkbox in the Selected column for the CRFs you want to add to the Event.
3. Click Add.
   The Update Study Event Definition page opens and now includes the CRFs you added to the Event.

7. If you want to remove a CRF from an Event, click the Remove icon for that Event.
   The Update Study Event Definition page now shows only the name of the CRF you removed, along with a Restore icon. You can later restore the CRF to the Event by clicking the Restore icon. The partial view of the example page here shows that the Verification of Informed Consent CRF was removed:



8. You can change the Name and other values for the Event Definition, and can change parameters for any of the CRFs, such as the default version or Null Values. For more information, see Create Event Definitions.
9. When you finish making changes to the Event Definition, click Confirm.
   The Confirm Event Definition Updates page opens.



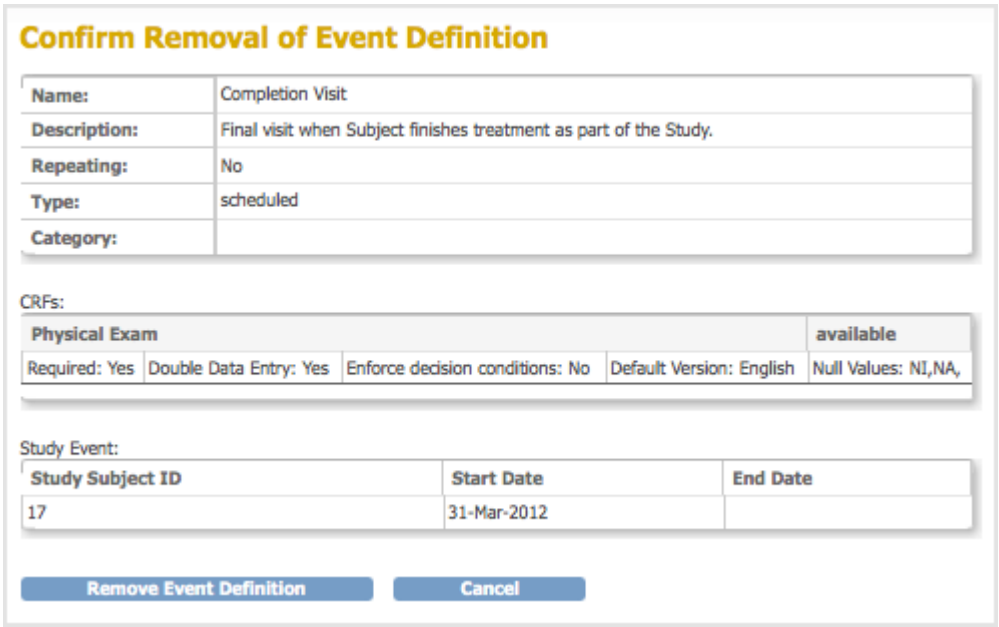
10. Verify the changes you made, then click Confirm and Finish.
    The Manage All Event Definitions page opens, reflecting the changes you made.

5.5.4 Remove and Restore Event Definitions

Remove Event Definition from Study

You can remove a Study Event Definition from the Study.

1. Access the Build Study page by selecting Tasks > Build Study.
2. Access the Manage All Event Definitions page by clicking the View icon in the Actions column for the Create Event Definitions task.
3. For the Event Definition you want to remove, click the Remove icon in the Actions column.
   The Confirm Removal of Event Definition page opens. It lists all Subjects whose status for the Study Event is other than "not scheduled."



4. Verify the information, then click Remove Event Definition.
5. Click OK in the confirmation dialog box.

The Manage All Event Definitions page opens, and reflects the Event Definition you just removed.

After removing the Event Definition, any Subject data already collected for that Event is maintained in the system, and you can view the data. However, you cannot enter new data for the Event for any Subjects. When you view a Subject record where data had already been captured for the Event, the status of CRFs for the Event is reported as "invalid." Similarly, when you create datasets, you cannot include the removed Event.

Restore Event Definition to Study

To restore an Event you removed from the Study:

1. Access the Build Study page by selecting Tasks > Build Study.
2. Access the Manage All Event Definitions page by clicking the View icon in the Actions column for the Create Event Definitions row.
3. For the Event Definition you want to restore, click the Restore icon in the Actions column. The Confirm Restore of Event Definition page opens. It lists all Subjects whose status for the Study Event is other than "not scheduled."
4. Verify the information, then click Restore Event Definition.
5. Click OK in the confirmation dialog box.
   The Manage All Event Definitions page opens, and reflects the Event Definition you just restored. All Subject data for that Event is restored and can be modified if needed. Subjects can again be scheduled and data can be collected for that Event.

5.6 Create and Modify Subject Group Classes

If your user Role has appropriate permission, you can create, edit, remove, and restore Subject Group Classes for the current Study using the Study Setup module, as described in the topics on this page.

If instead you want to view Subjects assigned to existing Subject Group Classes, use the Manage Groups feature in the Monitor and Manage Data module.

Or, if you instead want to assign a Subject to a Group within a Group Class, you can do so when you add the Subject to the Study, or by editing a Subject's record.

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5.6.1 About Subject Group Classes

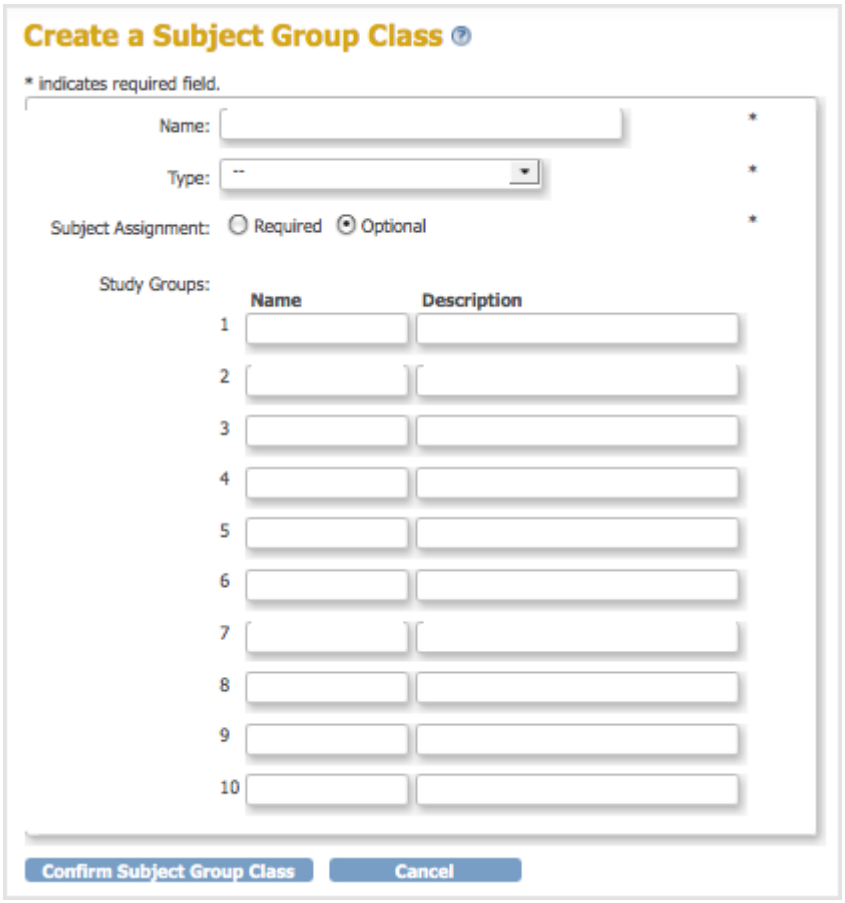
Use Subject Group Classes in OpenClinica to categorize Subjects within a Study, such as for treatment options. For example, you might create a Subject Group Class called Treatment Group that contains three Subject Groups within the Class: Regimen I, Regimen II, and Regimen III. There can be multiple Group Classes within a Study. For example, you can also have a Group Class for age

with these Groups: Adolescent, Adult, and Elderly. You can specify that a Study Subject be required to be assigned to a Group, or allow assignment to Groups as optional. A Study Subject can be assigned to more than one Group Class, but can be assigned to only one Group within a Group Class.

5.6.2 Create Subject Group Class

To create Subject Group Classes and Groups within a Class:

1. Select Tasks > Build Study.
   The Build Study page opens for the current Study.
2. You can see the number of existing Group Classes for the current Study in the Count column for Create Subject Group Class. To see more information, click the View icon in the Actions column.
3. On the Build Study page, click the Add icon in the Actions column for the Create Subject Group Class task.
   The Create a Subject Group Class page opens.



4. Complete the fields on the page. This information is primarily used for reporting and affects workflow and data collection in OpenClinica only when a Subject Assignment to a Group Class is required.
   1. Provide a name for the Group Class. For example, Age Group.
   2. Select the type of Group Class. For example, Demographic.
   3. Specify if assignment to the Group Class is required or optional.
   4. Enter a name and description for each Group within that Group Class. For example:
      - Adolescent: Subjects under 18 years old.
      - Adult: Subjects between 18 and 65 years old.

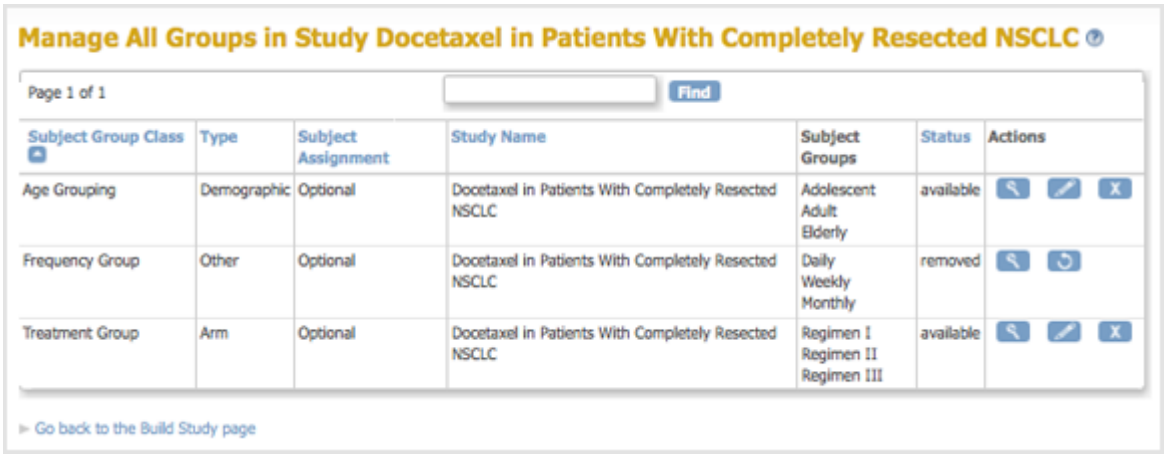
- Elderly: Subjects over 65 years old.

5. Click Confirm Subject Group Class.
   The Confirm Subject Group Class page displays, showing you the information you just entered.
6. Click Submit Subject Group Class.
   The Build Study page displays. The Count for Create Subject Group Class has increased by 1, a reflection of the Group Class you just added.

5.6.3 Edit Subject Group Class

After creating a Subject Group Class, you can modify the information for it:

1. Select Tasks > Build Study.
   The Build Study page opens for the current Study.
2. Click the View icon in the Actions column for the Create Subject Group Class task.
   The Manage All Groups page opens, listing information about all Subject Group Classes for the current Study.



3. You can click any column header that is in blue (a link) to sort by that column. You can also enter a string in the Find field to filter the list to show only those Group Classes whose name, Type, or Subject Assignment includes that string.
4. In the Actions column, click the Edit icon for the Group Class you want to modify.
   The Update a Subject Group Class page opens for the Group Class you selected.
5. Make changes to the Group Class and Group information.
6. Click Confirm Subject Group Class.
   The Confirm a Subject Group Class page displays, showing you the information you just entered.
7. Click Submit Subject Group Class.
   The Manage All Groups page displays, reflecting the changes you made.

5.6.4 Remove or Restore Subject Group Class

You can remove a Subject Group Class. After removing a Group Class, no additional users can be assigned to the Group Class, however the records for any Subjects already assigned to that Group Class will still reflect the assignment. To remove a Subject Group Class:

1. Select Tasks > Build Study.
   The Build Study page opens for the current Study.

2. Click the View icon in the Actions column for the Create Subject Group Class task.
   The Manage All Groups page opens, listing all Subject Group Classes for the current Study.
3. In the Actions column, click the Remove icon for the Group Class you want to remove.
   The Confirm to Remove a Subject Group Class page opens for the Group Class you selected.
4. Click Remove Subject Group Class.
5. In the confirmation popup window, click OK.
   The Manage All Groups page displays. The Group Class you removed is listed in the table, but the Restore icon is in the Actions column, having replaced the View and Edit icons.

You can restore a removed Subject Group Class, which means that Subjects can again be added to it. To do so:

1. Select Tasks > Build Study.
   The Build Study page opens for the current Study.
2. Click the View icon in the Actions column for the Create Subject Group Class task.
   The Manage All Groups page opens, listing all Subject Group Classes for the current Study.
3. In the Actions column, click the Restore icon for the Group Class you want to restore.
   The Confirm to Restore a Subject Group Class page opens for the Group Class you selected.
4. Click Restore Subject Group Class.
5. In the confirmation popup window, click OK.
   The Manage All Groups page displays. The Group Class you restored now has View and Edit icons in the Actions column instead of the Restore icon.

5.7 Create Rules

You can create Rules to perform advanced validation for Study data within OpenClinica. For details, see Rules.

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5.8 Create and Modify Sites

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5.8.1 About Sites

In OpenClinica, a Site is typically a location to which Subjects are assigned, although it can be a different organization to which Subjects are assigned. A Study can have more than one Site, where each Site might be in a different city or at a different institution. Event Definitions for the Study are

assigned to Sites in the Study. Subjects are added to a Site and scheduled for Events at the Site. OpenClinica users are assigned permission to access information at one or more Sites, and can also be assigned to access data at the overall Study level.

Even if there is only one location for a Study when you create it, it is strongly recommended that you create a Site for it, and add Subjects to the Site rather than only add them at the Study level. By doing this, there are more options available for user permissions, and you will be able to easily add Sites in the future, should the Study expand.

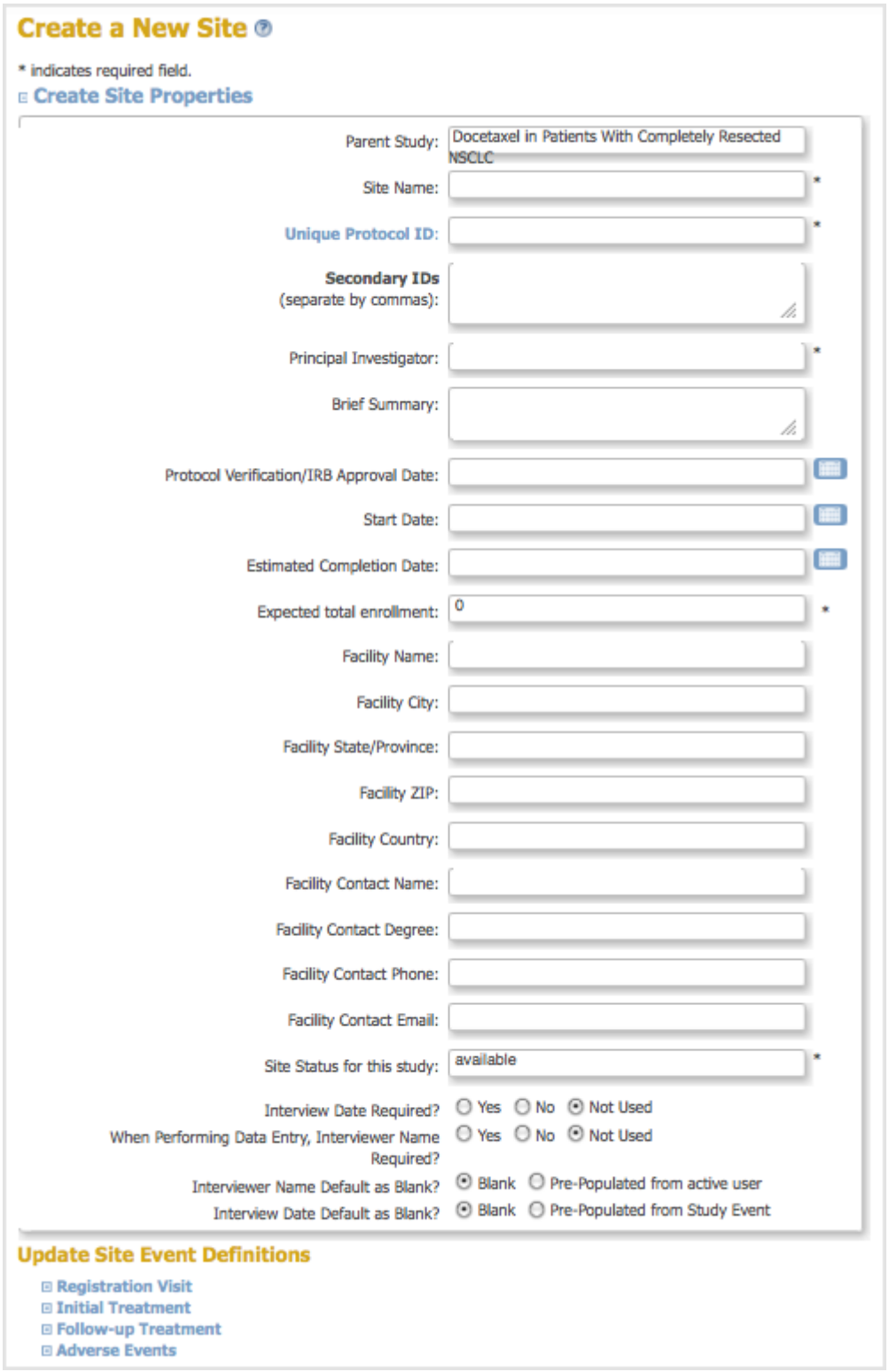
5.8.2 Create Site

A user whose Role has appropriate permission can create a new Site. When you create a new Site, it inherits some information from its parent Study, but you can make changes to it.

You can create Sites for a Study at any time after you have completed the first five steps in the Build Study process.

To create a Site:

1. Change the current Study to the Study you want to create a Site for.
2. Select Tasks > Build Study.
   The Build Study page for the current Study opens.
3. In the table, for Create Sites (Task 6), click the Add icon .
   The Create a New Site page opens.



4. Complete at least the required fields in the Create Site Properties section, referring to these guidelines as needed:
    - The Protocol ID for the Site must be unique.
    - The Expected total enrollment is for reporting statistics only; it does not limit the number of Subjects you can add to the Site, nor is it used to enforce any minimum required enrollment.
    - You can view but cannot change the Site Status at this point; its Status is "available" when you first create it. You can also complete the other fields and can make changes to the Site Event Definitions.
5. You can update Site Event Definitions. The Events for all Sites in a Study must be the same,

but you can use different CRF versions and different CRF parameters at different Sites. For example, you might use an English version of a CRF at one Site, and a French version of the same CRF at a different Site, or you might require double data entry for a CRF for one Site but not for another Site. The default values are specified for the Study as part of the Event Defiinition; for more information, see Create and Modify Event Definitions.

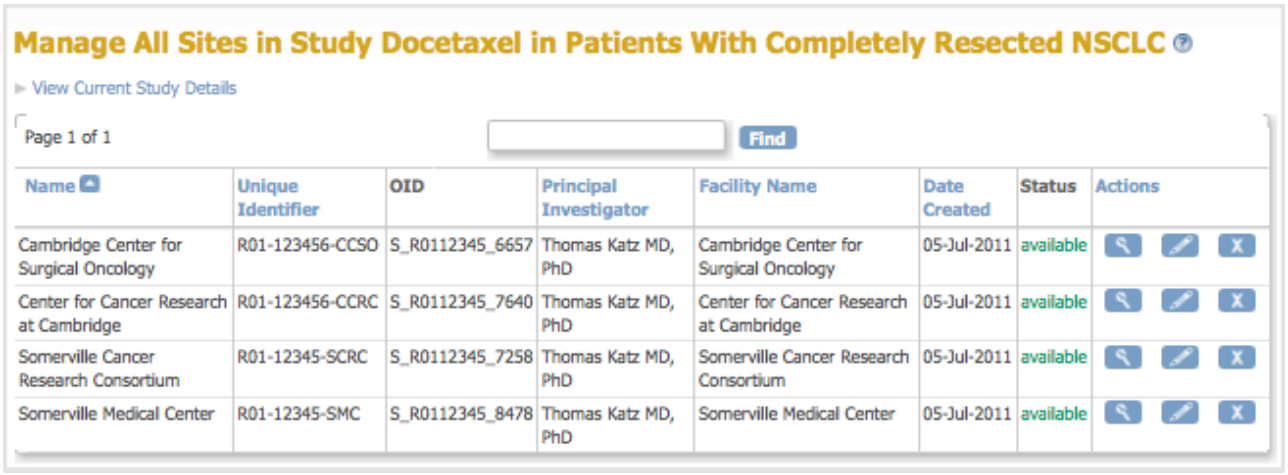
6. Click Confirm Site.
   The Confirm Site page opens.
7. Verify that the information is correct, then click Submit Site.
   The Build Study page opens. The Count for the Create Sites task increased by one to reflect the Site you just added.
8. Continue adding Sites by repeating steps 3 through 6 now, or at another time. When you have completed adding Sites, select the Mark Complete checkbox for the Create Sites task, then click Save. Note that even though the task Status is Complete, you can add more Sites later.

5.8.3 View Site Information

To view information about the current Site, click the Site name link in the Other Info sidebar panel or at the top of the page. The view Study Metadata page opens, showing information for the current Site.

To view all Sites assigned to the current Study and access information for each Site:

1. Change the current Study to the Study whose Site information you want to access.
2. Select Tasks > Build Study.
   The Build Study page for the current Study opens.
3. In the table, for Create Sites (Task 6), click the View icon.
   The Manage All Sites page for the current Study opens, listing a summary of information for each Site in the Study.



Name	Unique Identifier	OID	Principal Investigator	Facility Name	Date Created	Status	Actions
Cambridge Center for Surgical Oncology	R01-123456-CCSO	S_R0112345_6657	Thomas Katz MD, PhD	Cambridge Center for Surgical Oncology	05-Jul-2011	available	
Center for Cancer Research at Cambridge	R01-123456-CCRC	S_R0112345_7640	Thomas Katz MD, PhD	Center for Cancer Research at Cambridge	05-Jul-2011	available	
Somerville Cancer Research Consortium	R01-12345-SCRC	S_R0112345_7258	Thomas Katz MD, PhD	Somerville Cancer Research Consortium	05-Jul-2011	available	
Somerville Medical Center	R01-12345-SMC	S_R0112345_8478	Thomas Katz MD, PhD	Somerville Medical Center	05-Jul-2011	available	

4. To view information about a Site, click the View icon in the Actions column for that Site.
   The View Site Details page opens for that Site.
5. The View Site Details page displays information for the site. From the page, you can print all CRFs for each Event by clicking the Print icon in the Event section.
6. Click Exit to return to the Manage All Sites page, from which you can make changes to Site details or the Site status.

5.8.4 Edit Site Information

After creating a Site, you can edit the information for it, including its status:

1. Change the current Study to the Study whose Site information you want to access.
2. Select Tasks > Build Study.
   The Build Study page for the current Study opens.
3. In the table, for Create Sites (Task 6), click the View icon.
   The Manage All Sites page for the current Study opens, listing a summary of information for each Site in the Study.
4. Click the Edit icon in the Actions column for the Site whose information you want to edit.
   The Update Site Details page opens, showing current values for the Site details.
5. Make changes to values in the Update Site Properties section, including changing the Status for the Site. The Status values you can select for a Site are: available, pending, locked, and frozen. For more about the meaning of each Status value, see Status of a Study; the meanings described in that topic apply, but they are for the Site, not the Study.
6. Make changes to information for any of the Event Definitions for the Site. For example, you might use an English version of a CRF at one Site, and a French version of the same CRF at a different Site, or you might require double data entry for a CRF for one Site but not for another Site.
7. Click Submit Site.
   The Manage All Sites page opens.

5.8.5 Remove or Restore Site

Remove a Site

You can remove a Site to make it unavailable. This removes all Events, Users, and Subjects for the Site, but does not delete any data. After removing a Site, you can restore it, if needed. To remove a Site:

1. Change the current Study to the Study whose Site you want to remove.
2. Select Tasks > Build Study.
   The Build Study page for the current Study opens.
3. In Actions column for the Create Sites task, click the View icon.
   The Manage All Sites in Study page opens, listing all Sites in the current Study.
4. In the table, click the Remove icon for the Site you want to remove.
   The Confirm Removal of Site page opens.
5. Click Remove Site.
6. In the confirmation dialog box, click OK.
   The Manage All Sites page opens. The status for the Site is reported as "removed."

Restore a Site

After removing a Site, you can restore it if you want to access it again. The relationships of Subjects to the Site and the Site to the Study are preserved. To restore a Site:

1. Change the current Study to the Study whose Site you want to restore.
2. Select Tasks > Build Study.
   The Build Study page for the current Study opens.

3. In Actions column for the Create Sites task, click the View icon.
   The Manage All Sites in Study page opens, listing all Sites in the current Study.
4. In the table, click the Restore icon for the Site you want to restore.
   The Confirm Restore of Site page opens.
5. Click Restore Site.
6. In the confirmation dialog box, click OK.
   The Manage All Sites page opens, and the Site status is no longer "removed."

5.9 Users and Roles at Current Study or Site

When you set up a Study, you assign OpenClinica users to it so they can work with the system and access Studies and Sites in it. You also specify their user Roles at the Study level and for Sites in the Study. As part of the Study Setup module, you can also view all users, make changes to user assignments, assign additional users, remove users, and change user Roles at the current Study or Site.

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5.9.1 View Users and Roles at Current Study or Site

You can view summary information for all users at the current Study or Site, and you can view additional information for each user. For descriptions of the terms that apply to user accounts, see About User Information in the Study Setup Module.

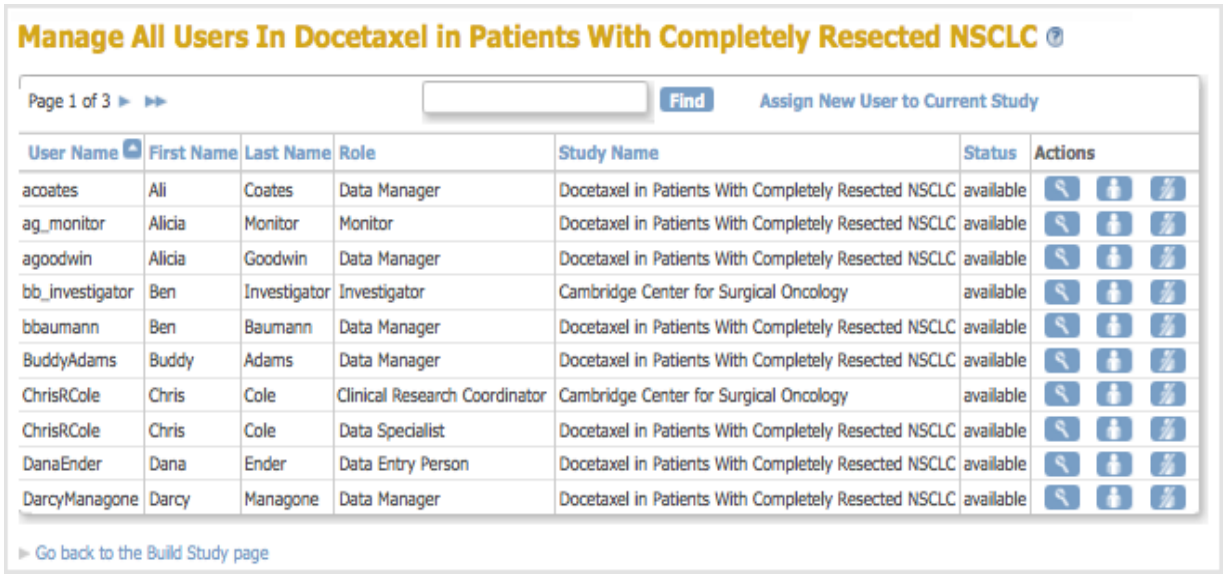
View Information for All Users at Current Study or Site

To view users already assigned to the current Study or Site, select the Tasks menu, and in the Study Setup module, select Users.

The Manage All Users page opens for the current Study or Site, with all users listed in a table.

- When the current Study is at the Study level, the table includes a row for the user at the Study level, as well as a row for each Site the user is assigned to in the current Study.
- When the current Study is at the Site level, the table includes one row for each user assigned to the Site.

Manage All Users for the Current Study:

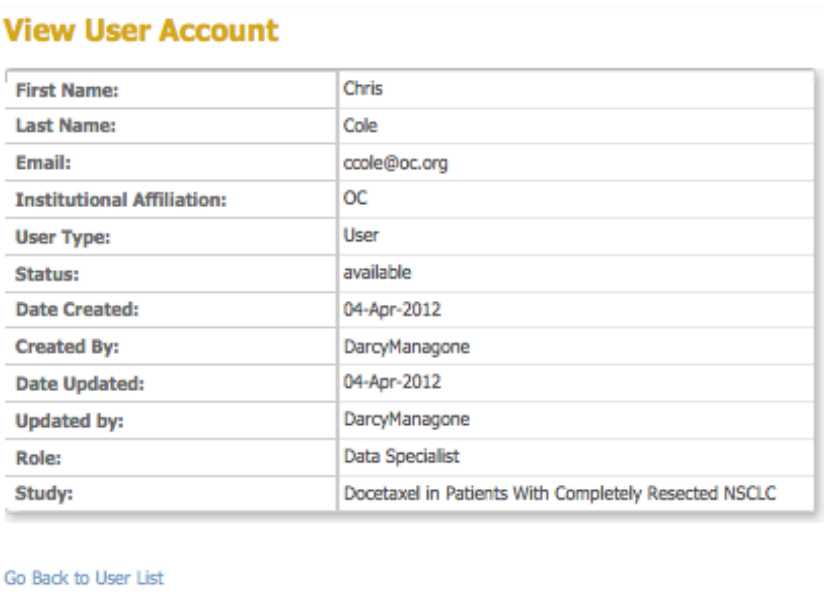


Manage All Users for the Current Site:

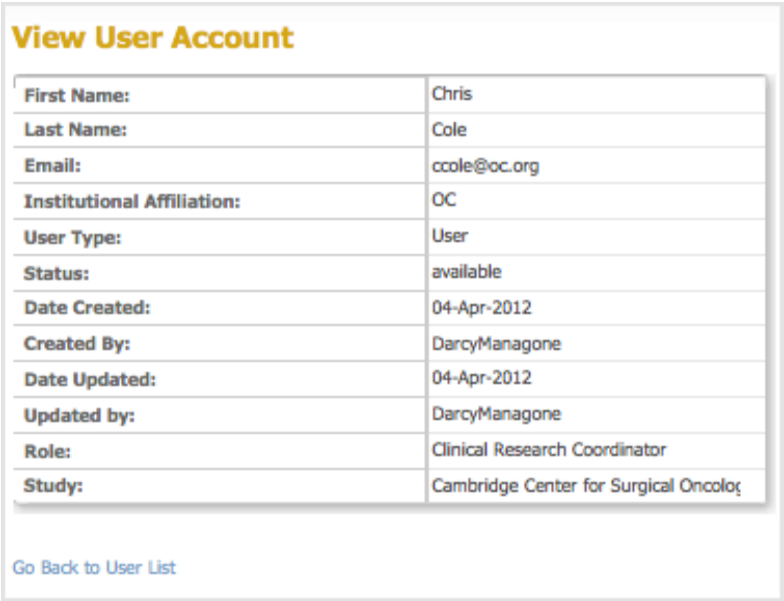
View Information for A User at Current Study or Site

From the Manage All Users page, you can view more information about a user by clicking the View icon. The View User Account page opens.

View User Account for User at the Current Study:



View User Account for User at the Current Site:



5.9.1.1 About User Information in the Study Setup Module

The following information is helpful when you work with user accounts in the Study Setup module:

- **User Name:** Is not the same as any other user name in the OpenClinica system.
- **Email:** Address for the user. Used for messages that the OpenClinica system sends, such as notification when a job completes, or a temporary password if the user requests a new password.
- **User Type:** The User Type was specified in the Administration module. For more information, see About User Roles and Types.
- **Status:** Not relevant to user information accessed from the Study Setup module.
- **Role:** Roles for the Active Study, which you assign when you create the user, and all other Roles in the current Study or in the system, depending on how you view the user information. Available Roles depend on whether the current Study is at the Site or Study level. After creating the user, you can change or remove the Role for each Study or Site the user is assigned to. For more information, see About User Roles and Types.
- **Study:** A user can be assigned to the Study level and/or to Sites within the Study. When the current Study is set to the Study level, the Study field reports the name and the Study and all Sites within the Study to which the user is assigned. When the current Study is set to the Site level, the Study field reports only the current Site name.

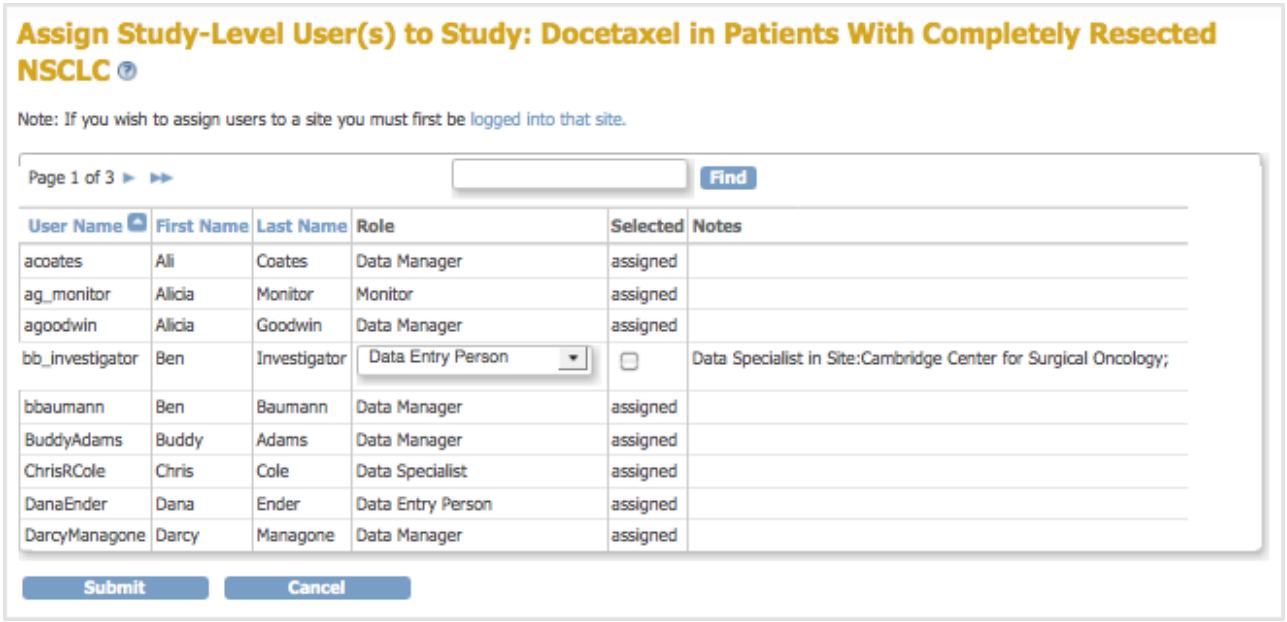
5.9.2 Assign Users to Current Study or Site

Before you can assign a user to a Study or Site, they must exist in the OpenClinica system, having been added to the system with the Administration module. The following steps describe how to assign a user to the current Study or Site from the Study Setup module. In the Study Setup module, you can only assign users in the current Study or Site. If you want to assign users across multiple Studies and Site, you will need to repeat the steps for each Study and Site, or use the user account features in the Administration module that allow you to assign multiple users at one time.

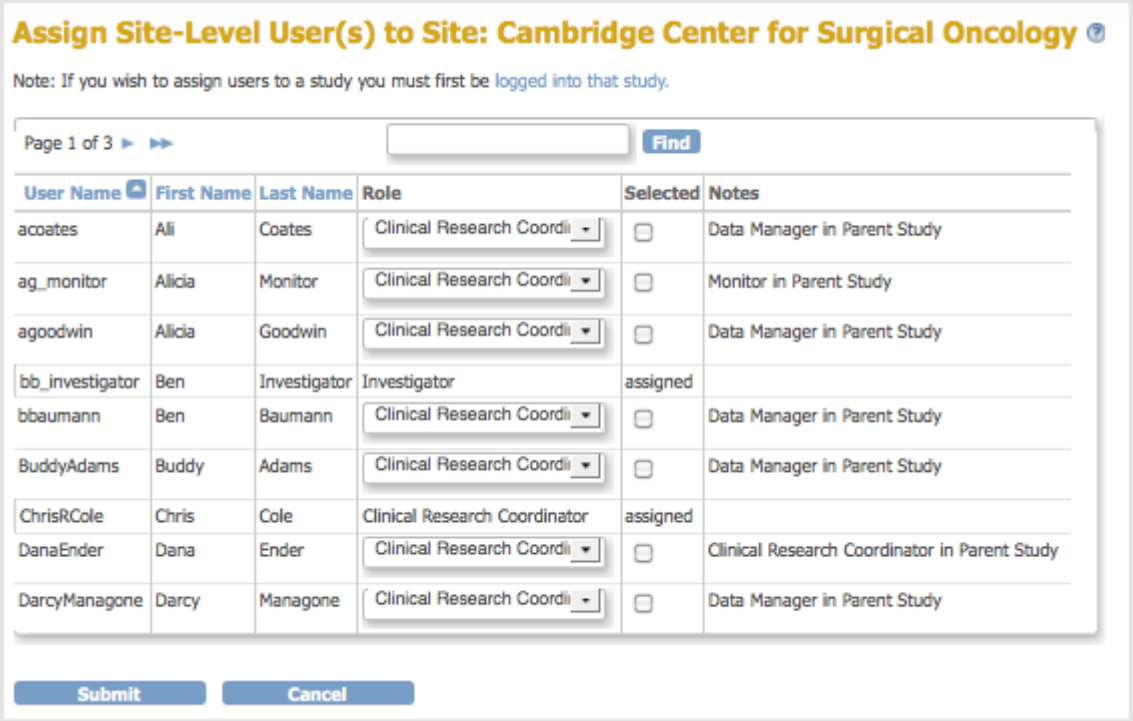
To assign users to the current Study or Site, using the Study Setup module:

1. Change the current Study or Site to the one you want to assign users to.
2. In the Tasks menu, under the Study Setup module, select Users.
   The Manage All Users page opens.
3. Click the link Assign New User to Current Study.
   The Assign Users page opens and includes the following:
   - **The page heading:** Indicates whether you are assigning to the Study level or Site level.
   - **The table:** Lists all users in your OpenClinica system, on one or more pages.
   - **The Selected column:** Includes a checkbox if the user is not assigned to the current Study or Site. If the user is already assigned, the column displays "assigned" instead of a checkbox.
   - **The Role column:** Provides a drop-down list if the user is not assigned to the current Study or Site, where the Roles in the list differ if the current Study is at the Study level or the Site level. If the user is already assigned to the current Study or Site, it reports their Role there. If the Role is "invalid," the user has been removed from the current Study or Site.
   - **The Notes column:** Reports other assignments for the user. If you are at the Site level, the Notes column reports the user's Role at the parent Study level, if any. If you are at the Study level, the Notes column reports the user's Roles at Sites in the current Study, if any.

Assign Users to Study Level:



Assign Users to Site Level:



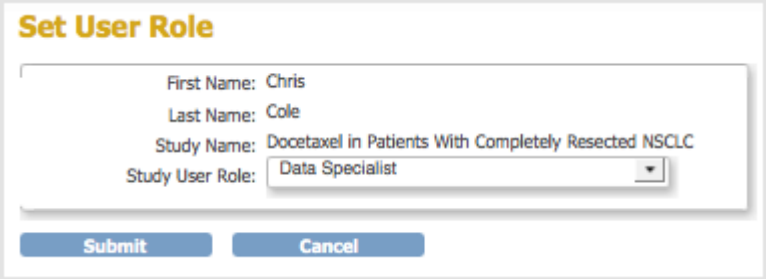
4. Locate the users you want to assign. If you want to limit the users shown to only those that match criteria you specify, use the Find filter, or sort on a column by clicking the column header.
5. For the user you want to assign to the current Study or Site:
    1. Select the checkbox in the Selected column.
    2. Select the Role you want to assign to the user from the drop-down list in the Role column.
6. Repeat for other users on the same page who you want to assign, then click Submit.
   The Alerts and Messages sidebar panel reports the assignments you just made.
   The Manage All Users page opens for the current Study or Site, and lists the users you just assigned; use it if you need to change users' Roles at the Study or Site.
7. To add more users, such as those listed on other pages of the Assign Users page, repeat this process, starting at step 1.

5.9.3 Change User Role at Current Study or Site

To change a user's role at the current Site, or at the current Study and Sites within the Study:

1. From the Tasks menu, in the Study Setup module, select Users.
   The Manage All Users page opens for the current Study or Site. For more information about the page, see View Users and Roles at Current Study or Site.
2. Click the Set Role icon for the user whose Role you want to change. If you are at the Site level, you can only change Roles at the Site. If you are at the Study level, you can change Roles at the Study level or at Sites within the Study:
    - To change the user Role at the Study level, use the icon in that row.
    - To change the user Role at a Site within the current Study, use the icon in the row for that Site.

   The Set User Role page opens for the user at that Study or Site.



3. Select the new Role for the user from the drop-down list, then click Submit.
   The Manage All Users page opens for the current Study or Site and reflects the Role change you just made.

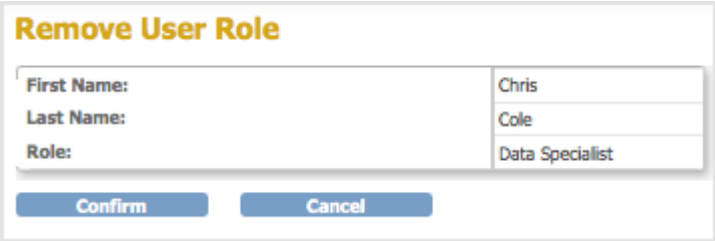
5.9.4 Remove User from Current Study or Site

When you remove a user from the current Study or Site, the user can still log in to OpenClinica, but can no longer access the Study or Site that they were removed from, and they cannot use the Change Current Study or Site feature to select that Study or Site. Removing a user from the current Study removes them from access at the Study level; it does not remove the user from any Sites they are assigned to within that Study. To remove a user from the Study level and from all Sites within the Study to which they are assigned, separately remove the user from Study and from each Site.

To remove a user from the current Study or Site:

1. From the Tasks menu, in the Study Setup module, select Users.
   The Manage All Users page opens for the current Study or Site. For more about the page, see View Users and Roles at Current Study or Site.
2. Click the Remove Role icon for the user you want to remove:
   - If you are at the Site level, you can only remove users from that Site.
   - If you are at the Study level and you want to remove the user from the Study level, use the icon in the row for the Study.
   - If you are at the Study level and you want to remove the user from a Site in the current Study, use the icon in the row for that Site.

   The Remove User Role page opens for the user at that Study or Site.



3. Verify the information, then click Confirm.
   The Manage All Users page opens for the current Study or Site. The user you just removed is no longer listed in the table for that Site or Study.
4. Repeat steps 2 and 3 if you want to remove the user at other Sites or the Study, or to remove additional users.

After removing a user from a Site or Study, you cannot restore them using the Study Setup module.

Instead, use the Restore User feature in the Administration module.

You can remove a user from the OpenClinica system so that they cannot log in, and therefore, cannot access any Studies or Sites: use the Remove User feature in the Administration module.