<OpenClinica RDCIT Study Set up Guide>

Purpose of this document: This document is a step-by-step guide on how to set up your study in a way that conforms to the RDCIT best practice standard. This document should be read in conjunction with the Best Practice Guide.

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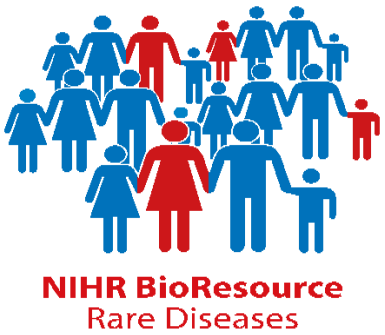
Authors: Ping Yu, Vera Matser

NIHR Rare Diseases Translational Research Collaboration
Department of Haematology, University of Cambridge
National Health Service Blood and Transplant Cambridge
Long Road, Cambridge
CB2 0PT



Document control

Version	Date	Author	Changes
1.0	03/10/2014	Vera Matser	First version
1.3	19/02/2015	Vera Matser	Changes to reflect Best Practice Guide v1.3 – incorporating the GeL minimum Standard. Skipped v1.1 and v1.2 to bring numbering in line with Best Practice Guide.
1.4	19/12/2015	Ping Yu	Changes to reflect Best Practice Guide v1.4 - Rewrite “Create Rules” and modify the Study Parameter Configuration.
1.5	22/01/2016	Ping Yu	Bring numbering in line with Best Practice Guide.
1.6	05/02/2016	Vera Matser	Bring numbering in line with Best Practice Guide. Changes to GMC number for clinicians.
1.7	11/03/2016	Vera Matser	Bring numbering in line with Best Practice Guide. Changes to Appendix section 5.1 Best Practice in one quick bite
1.8	09/08/2016	Ping Yu	Removed the Help desk. Bring numbering in line with Best Practice Guide.

Check if there is a later version of this document here

Contents

1 How to use this guide

In order for your study to comply with the RDCIT Best Practice Standard the set up will need to be completed in a specific way. This Study Set up Guide should be used in conjunction with the Best Practice Guide. The RDCIT will check your study complies with these guidelines before it is allowed to go into our secure OpenClinica environment (RDCIT Secure Data Service).

Items vital to the security of the systems will be highlighted in yellow and a star will appear next to the item(s).

This guide is not an exhaustive guide on the features of OpenClinica but will take you through the necessary steps of setting up your study. We recommend the OpenClinica user documentation and RDCIT OC "HOW TO" page if you require further information.

Common abbreviations:

RDCIT	Rare Diseases Clinical Infrastructure Team (supporting NIHR RD-TRC and Rare Diseases BioResource)
OC	OpenClinica
OCplay	OpenClinica play instance
CRF	Case Report Form

2 How to proceed with OpenClinica

We would recommend OpenClinica (OC) as the primary data collection software for deep-phenotyping but the Rare Diseases Clinical Infrastructure Team (RDCIT) will support projects in the transfer of data (primary data & metadata) from a third-party system; this strategy is referred to as "Good-neighbour policy".

If you decide to use OpenClinica as your primary collection software you will need to decide in which instance you want to set up your OpenClinica study. Please refer to the Best Practice Guide for more information on which choices are available.

This guide will use the **OCplay** instance provided by the RDCIT. You can request access to the **OCplay** instance by emailing the RDCIT (py234@medschl.cam.ac.uk)

Please note that you should ***NEVER*** store any patient data on **OCplay**. This OpenClinica instance is designed to give you an environment where you can get familiar with OpenClinica before you have access to your

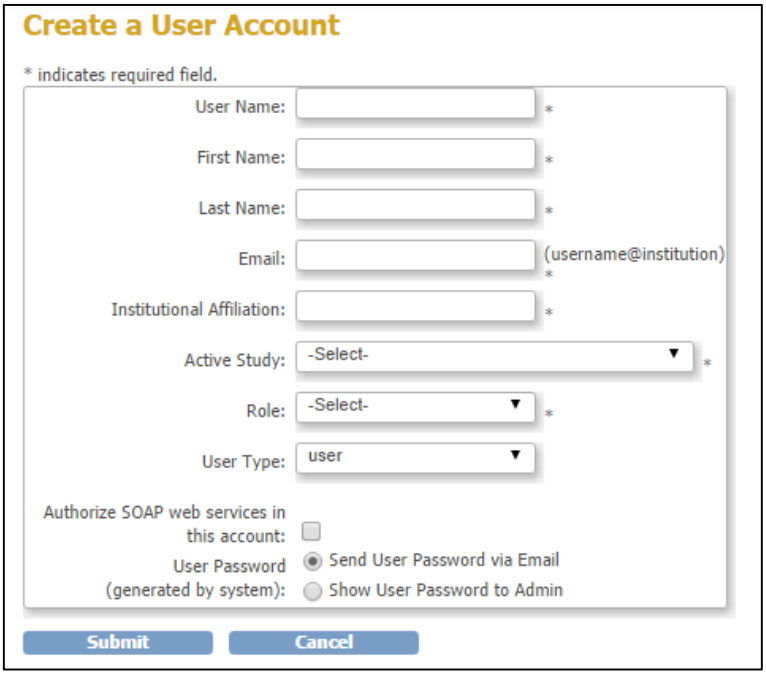
design instance (supported by RDCIT) or your own local instance. The **OCplay** instance will be wiped clean periodically.

3 Before you get started

3.1 Requesting a user account

To request access to the **OCplay** instance email the RDCIT.
You will need to provide the following information:

User Name	Please choose something memorable (alphanumerical, underscore allowed but no full stop)
First Name	
Last Name	
Email	Should be your main institutional email address
Institutional affiliation	Should be your main institution



Once your account had been setup you will receive an email with a temporary password from ch686@platgenbio.net. The first time you login to OC you will be asked to change your password. Please note that **OCplay** accounts will be setup as Business Administrators (high level system access) to allow you to explore all features of OpenClinica and have the ability to create other user accounts. If you are going to use the RDCIT hosted OpenClinica services your access will be more restricted (see the Best Practice Guide for further explanations).

3.2 Username and password conventions

Your OC user name will need to comply with the following rules:

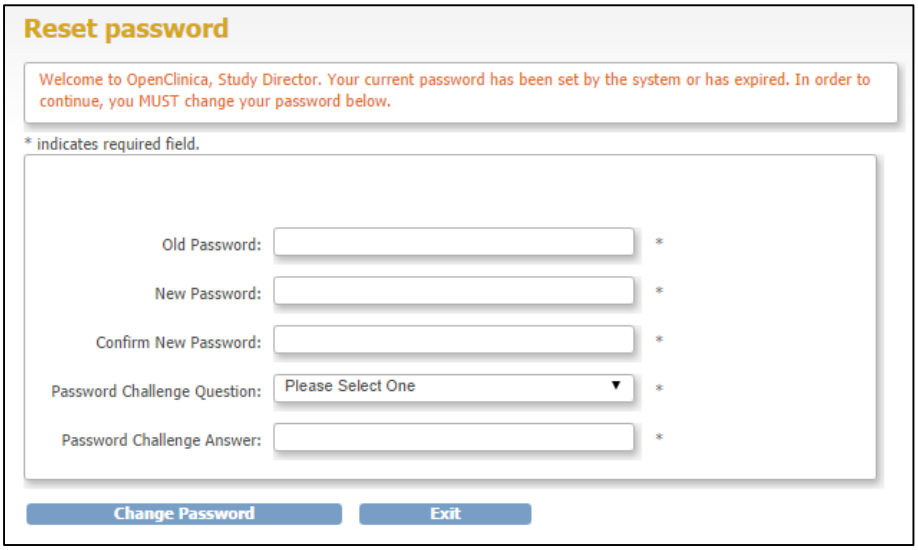
- Alphanumeric characters
- Minimum 5 characters
- Underscore allowed
- Full stop not allowed
- Your username should not be an email address

Please choose a user name that is easy to remember. If you forget your user name you will need to contact the **RDCIT** to ask for your user name.

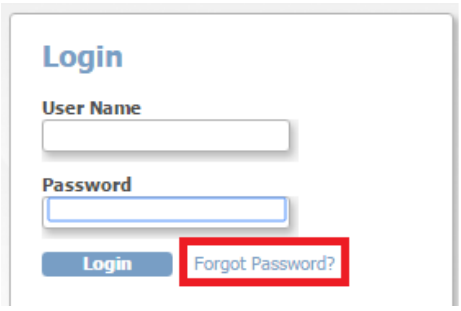
Your password will need to comply with the following rules:

- have a mixture of uppercase, lowercase, numbers and symbols
- not contain any dictionary words or your username
- be at least 8 characters long

Please note that your password will automatically expire after 6 months.



If you have forgotten your password please follow the "Forgot Password?" link on the OC login page.



3.3 Login to OCplay

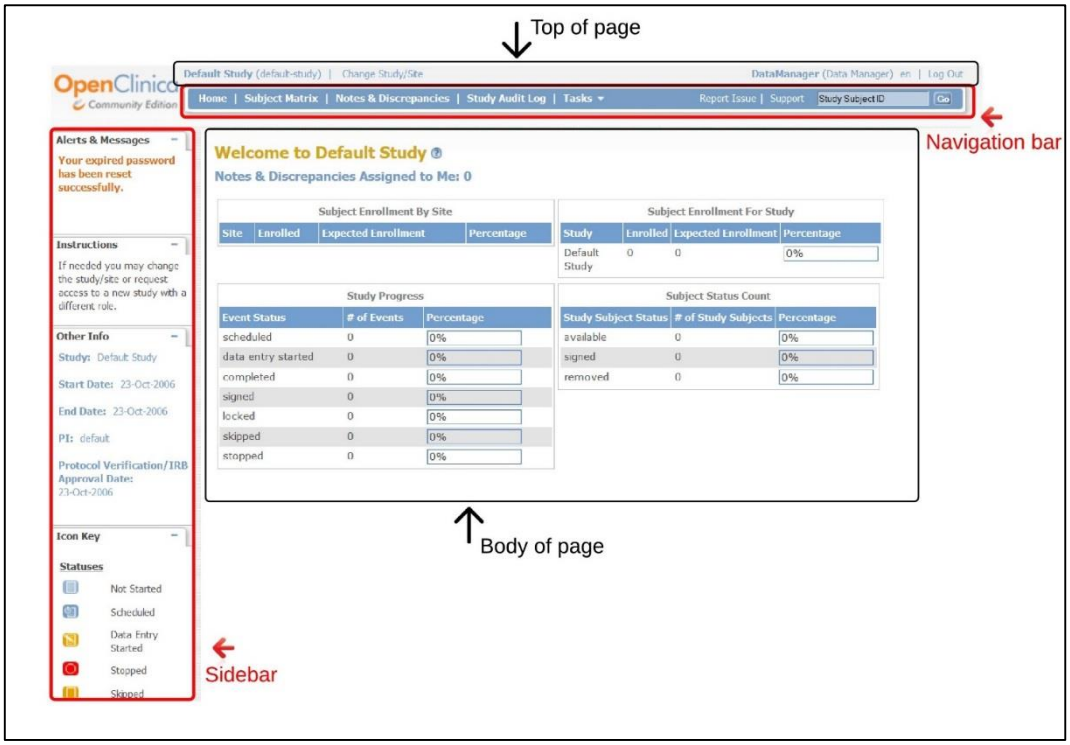
The URL for **OCplay** is:

http://openclinica-testing.medschl.cam.ac.uk/OCplay

Please note that the **OCplay** instance will be wiped clean periodically. We will attempt to warn all active users before the instance is re-installed.

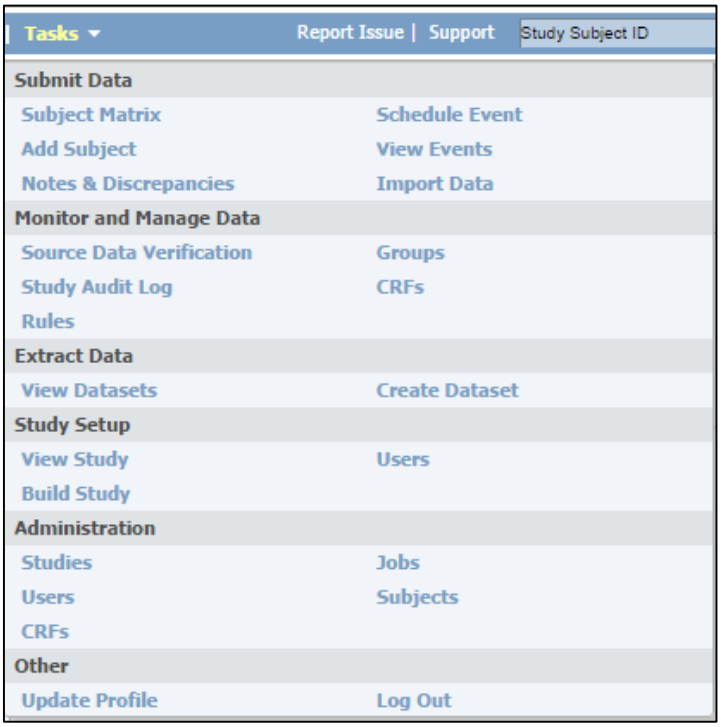
3.4 Navigating around OpenClinica

The OpenClinica home page contains the following sections:



Under *Tasks* on the navigation bar you will find the menu of actions that you can perform in OC.

Note that exactly what is displayed on the navigation bar and which actions are displayed under tasks depends on your user role in OpenClinica. See Best Practice Guide and OC user documentation for more detail on the different user roles.



You can explore the different OC user roles by creating a new user account in **OCplay** (Tasks < Administration < Users < New User). The following user roles are available in OC, we recommend you focus on the Data Manager (Study level) and the Clinical Research Coordinator/Data Entry at the Site level.

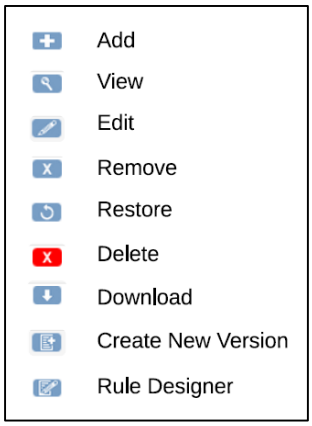
STUDY LEVEL

- Data Manager = Study Director
- Data Entry Person
- Monitor
- Data Specialist

SITE LEVEL

- Investigator
- Clinical Research Coordinator = Data Entry Person (Site level)
- Monitor

The following icons are routinely used in OpenClinica.

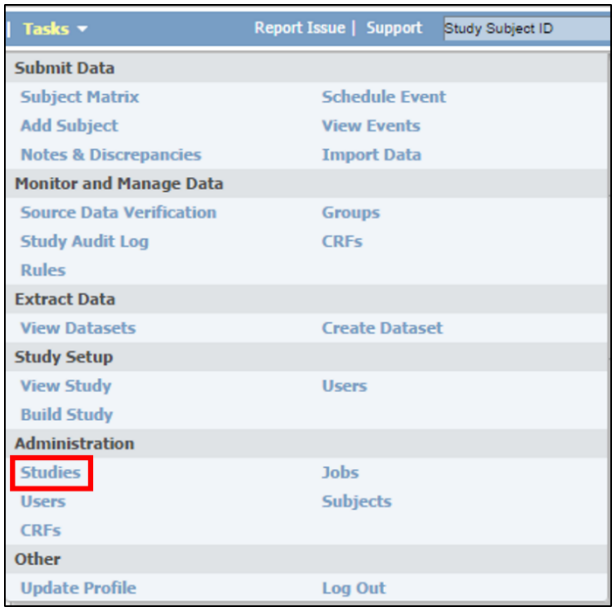


4 Setting up your study

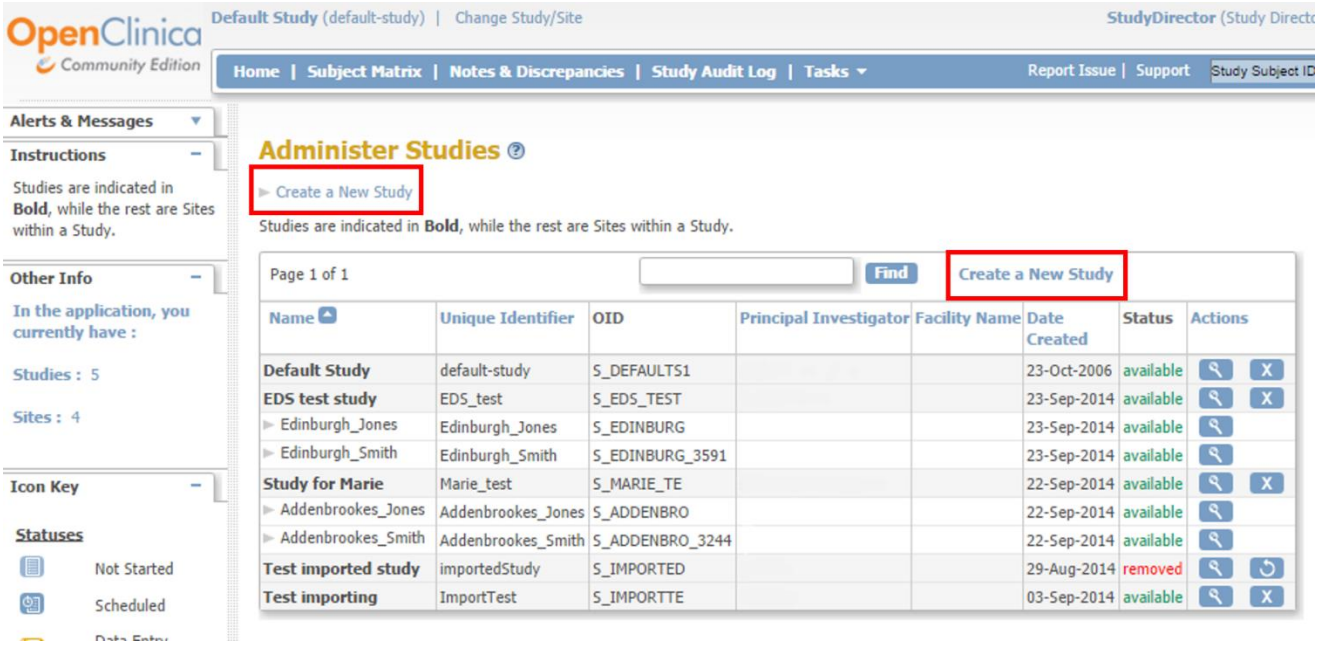
4.1 Create a new study

The initial step to create a new study in OpenClinica is similar to a stub or a placeholder.
The study itself will still need to be fully configured, this task can be assigned to a different user.

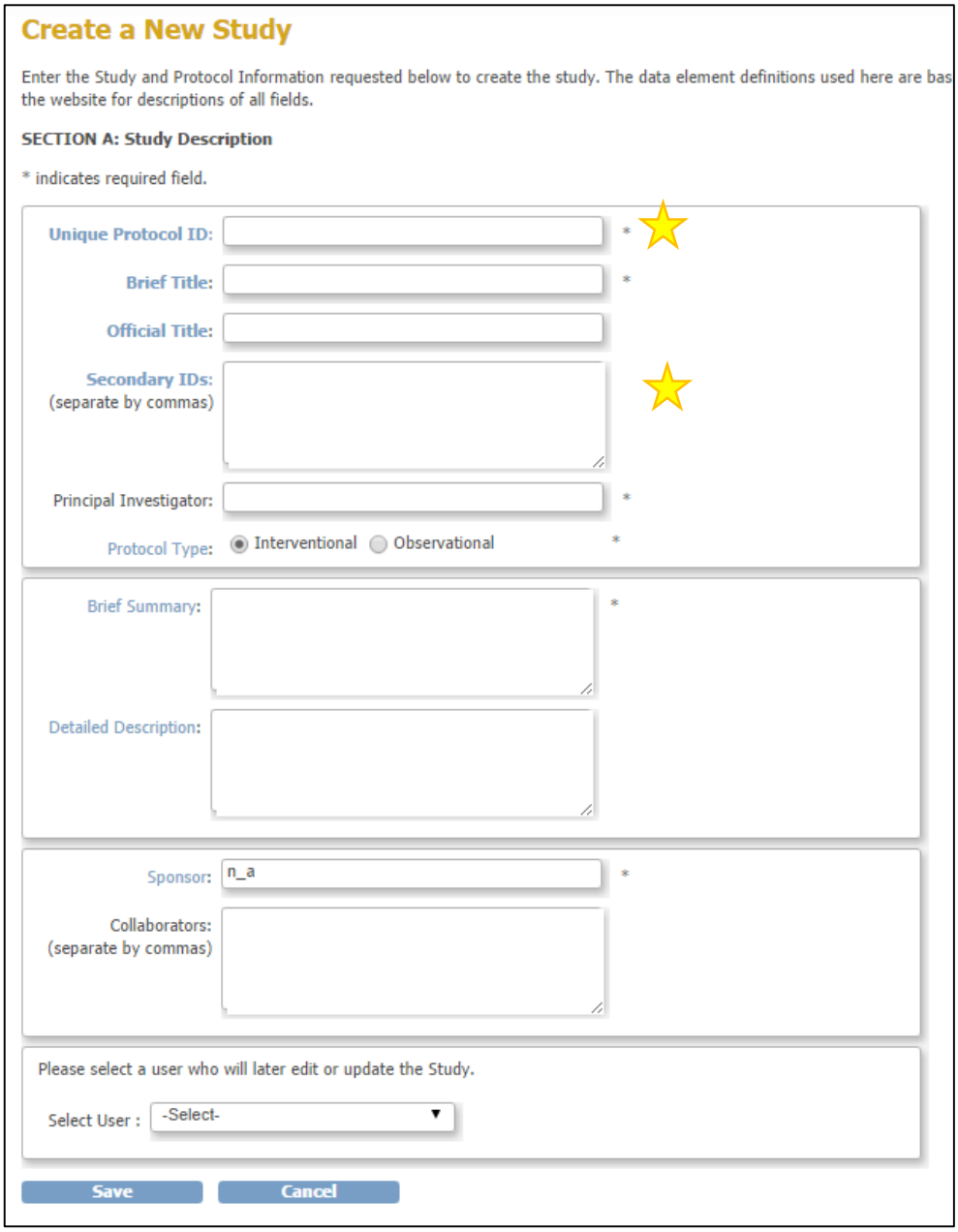
Tasks < Administration < Studies



On the "Administer Studies" page, click ‘Create a New Study’.



When the "Create a New Study" page opens, complete at least the required fields (marked with an asterisk*).

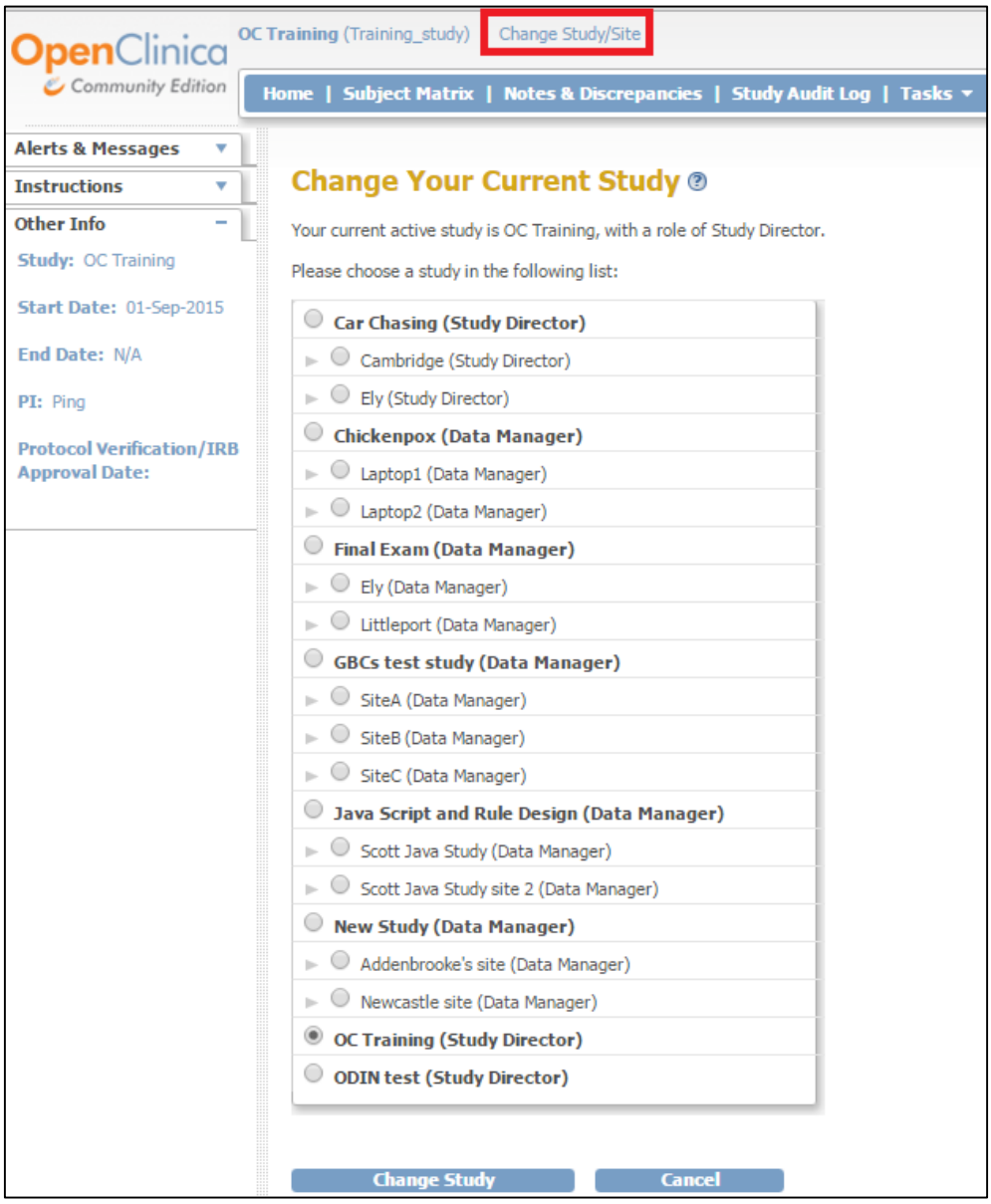


- The Unique Protocol ID needs to be your 3 character project code (BRIDGE project code).
- The Secondary ID identifies different projects streams; choose from BRIDGE (NIHR RD BioResource), RD-TRC, GMC or Other.

If you have successfully created your new study the following message will appear in the sidebar:

The new Study has been created successfully. Change the current Study to the one you just created. Then go to the Build Study page to continue configuring the Study or notify the user responsible for configuring the Study that it is ready for them

You can change to a different study at the top of the page by following the Change Study/Site link



4.2 Building a study

Note: If an administrator (e.g. RDCIT or RD-TRC Data Coordinator) has completed the initial study creation for you, the previous steps may have been done for you.

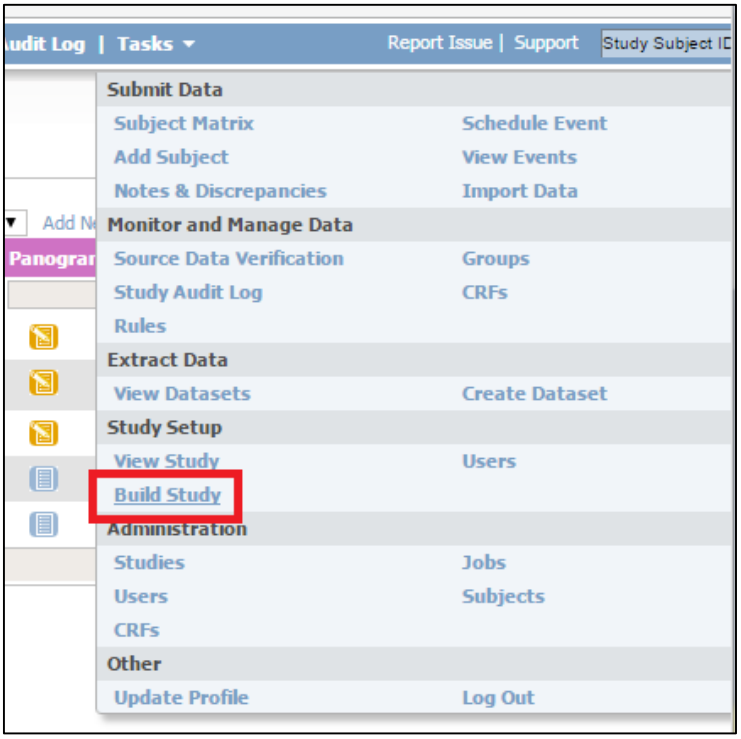
Your study has been created but will need to be fully configured.

Configuring or building a study consists of 7 steps:

1. Create Study
2. Create CRF
3. Create Event Definitions

4. Create Subject Group Classes
5. Create Rules
6. Create Sites
7. Assign Users

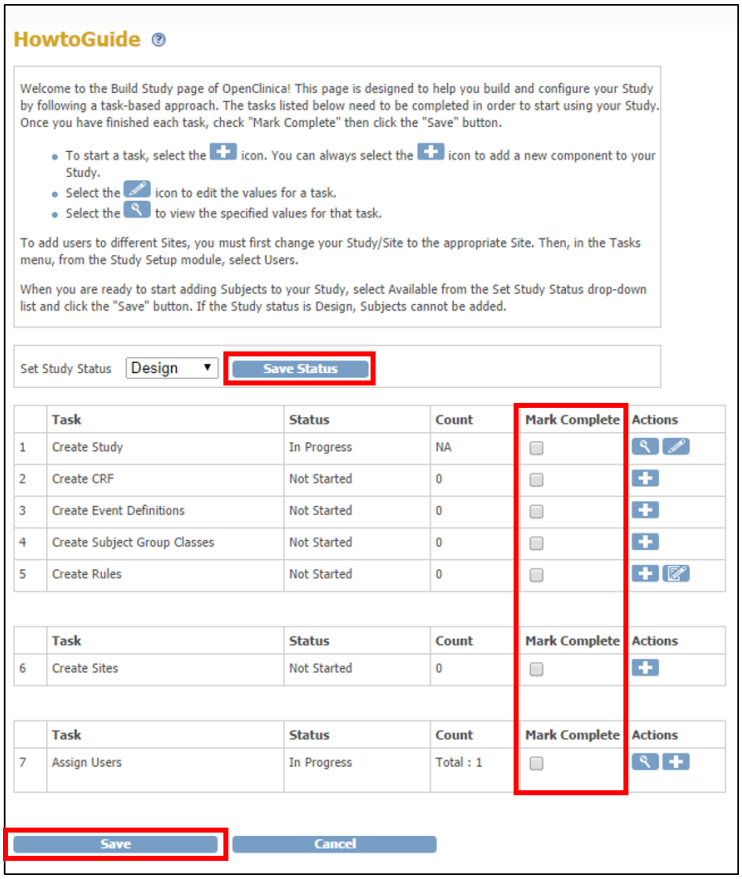
The OC page that displays the progress on these steps is called ***Build Study*** page.
It can be found under Tasks < Study Setup < Build Study



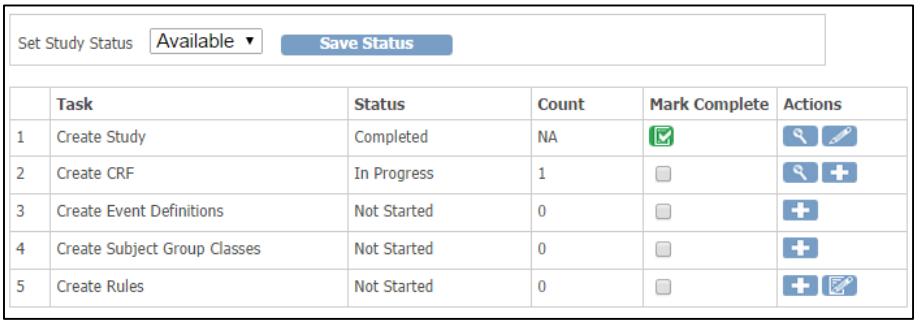
Note: There is no strict order or timeframe in which you need to complete the 7 steps to build a study (e.g. CRFs, sites, users, rules etc.). It is an iterative and refining process, until you are ready to test. You can save your progress and continue the Build Study process later.

When you have finished a task you can mark it as *complete* and save it at the bottom left of the page. To start data entry on your study you will need to change the study status from *Design* to *Available* and save the status.

Note that there are separate buttons to save the Status and your Build Study progress.



Until you change your study status to available, your study sites will have the status *pending* and you will be unable to assign users or add subjects.

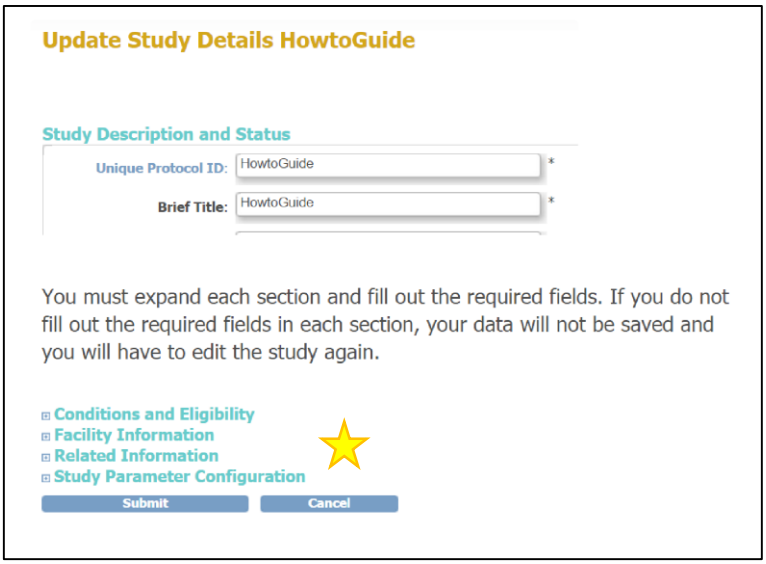


4.2.1 Create Study

This may be counter intuitive because section 4.1 outlined how to create a new study. The following steps are about configuring the parameters of your study. The Best Practice Guide will give you full explanations about why certain setting have been chosen and which conventions should be followed.

1. Create study -> click Edit

You can now update the study details. There are 5 sections, though only a limited number of fields are required and some will be prefilled (from information filled in during *Create a New Study*).



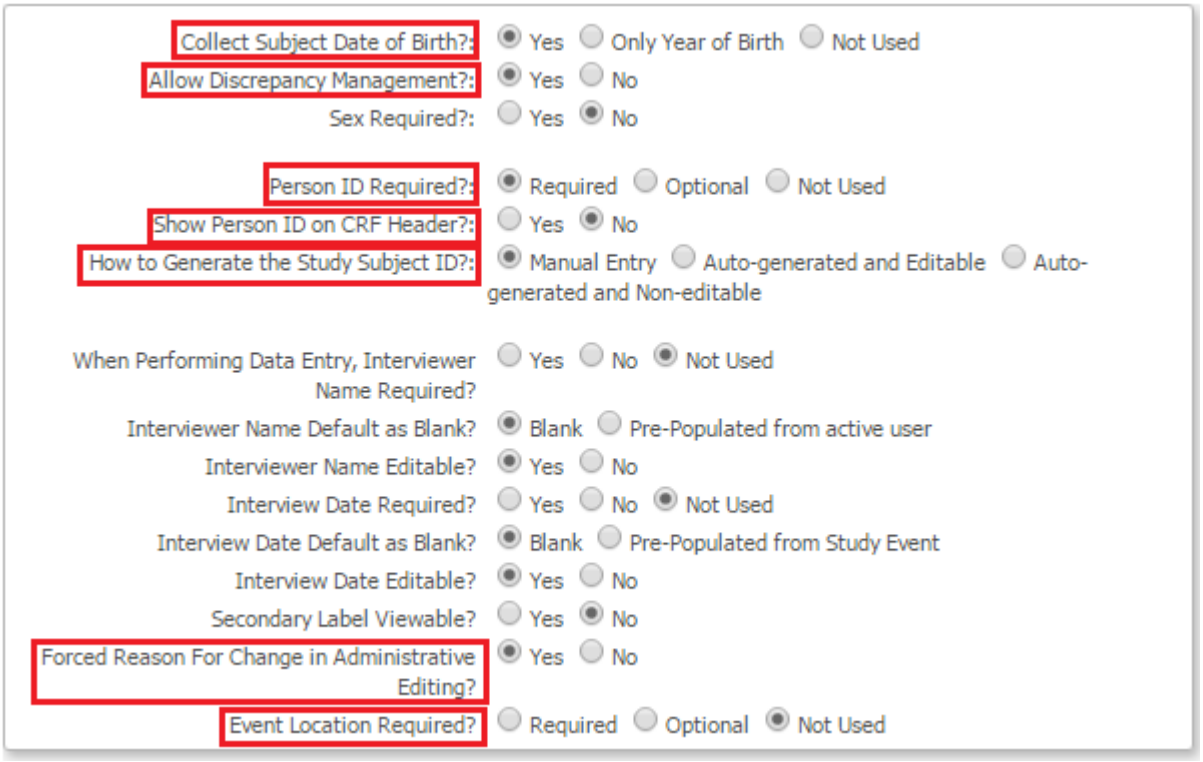
The following field will need to be filled in:

- Study description and Status
  OC Required – Study start date
- Conditions and Eligibility
  OC Required - Expected total enrolment

Note: Your expected total study enrolment will need to correspond to the sum of your expected site enrolments.

- Facility Information
  Required by RDCIT; these should be the PI's contact details
- Related Information
  No required fields
- Study Parameter Configuration
  OC & RDCIT Required – See required parameter configuration below

- Collect subject Date of Birth
- Allow Discrepancy Management
- Person ID **optional** (NHS number in OClive or OCimport)
- Not show person ID on CRF header
- Manual Entry for generating the Study Subject ID
- Forced reason for change (Required for full audit trail)
- Event location not used



Note: The following fields are the decision of the study

- Sex required
- Interviewer name default as blank
- Interviewer name editable
- Interview date default as blank
- Interview date editable
- Secondary label viewable

For "*When performing data entry interviewer name required?* " the RDCIT Best Practice Guide recommends to only use if interviewer is different from OpenClinica User, if the same this is unnecessary as the User Name is logged.

Please contact the RDCIT if you are unsure which settings best suit your study. We can discuss the available options with you.

4.2.2 Create CRF

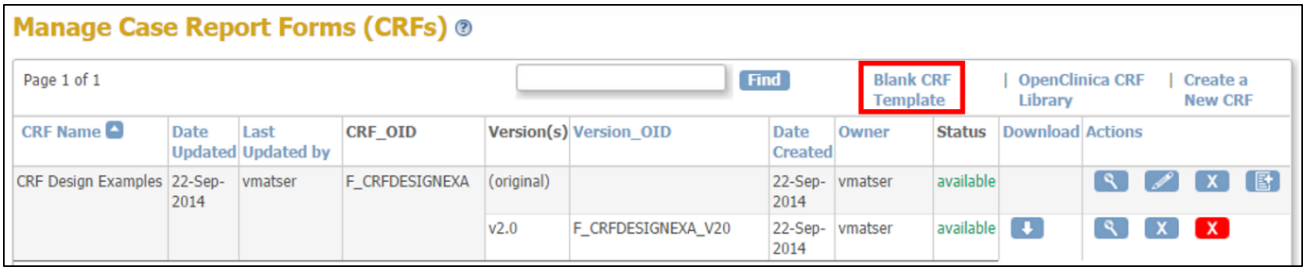
For advice on how to create a CRFs see our CRF Design Guide

Your CRF name needs to be prefixed by your 3 character project code (Unique protocol ID)

A full list of CRFs can be found under Task < Monitor and Manage Data < CRFs

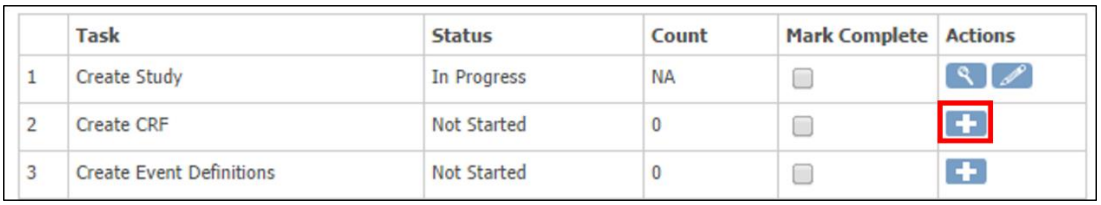
Whether you can see the CRF list and which actions you can perform depends on what role you have been assigned. The CRF list will show the original CRF, the different versions and whether or not they are active.

The CRF template can be downloaded at the top of the CRF list. We recommend you download the template each time you need it rather than store a local copy.

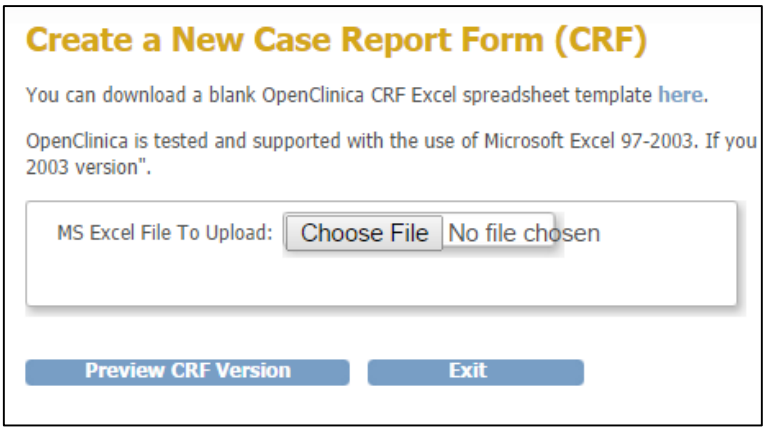


4.2.2.1 Upload a new CRF

Action: + (add) to upload a new CRF

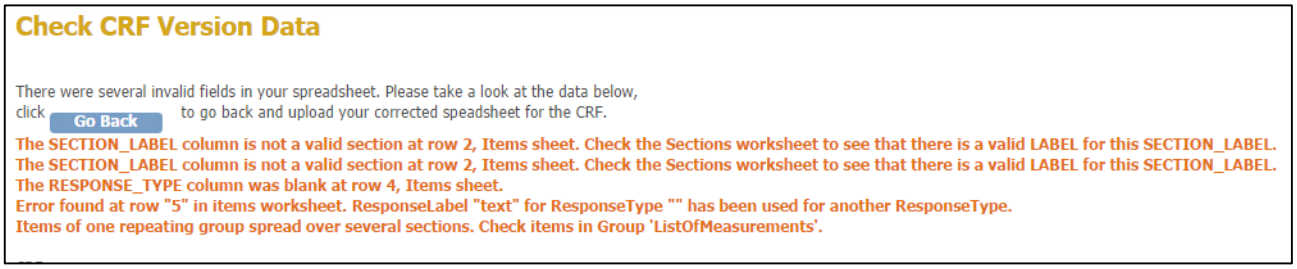


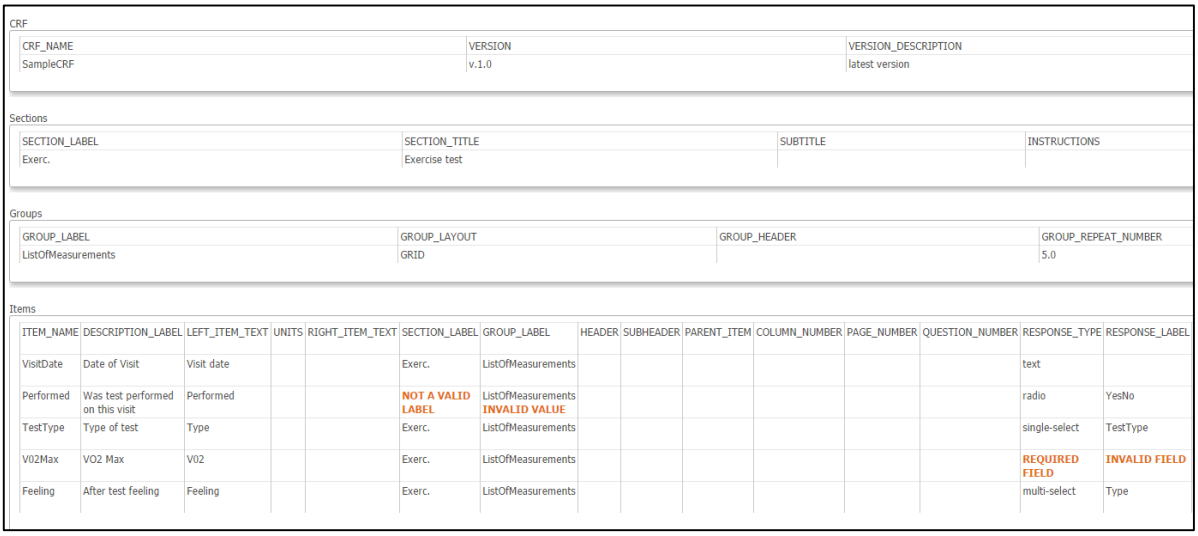
Choose File to browse your directory for your CRFs < Preview CRF version



If your CRF generated no errors a message of congratulations will be displayed in the sidebar. You need to click *continue* to save the CRF to the database. Your CRF is now available in the CRF List and can be attached to an event.

If your CRF generated errors you will see variations of the following messages. The error messages in OC are reasonably clear and will point you at the sheet and row in your excel sheet where it detected the error.





CRF

CRF_NAME	VERSION	VERSION_DESCRIPTION
SampleCRF	v.1.0	latest version

Sections

SECTION_LABEL	SECTION_TITLE	SUBTITLE	INSTRUCTIONS
Exerc.	Exercise test		

Groups

GROUP_LABEL	GROUP_LAYOUT	GROUP_HEADER	GROUP_REPEAT_NUMBER
ListOfMeasurements	GRID		5.0

Items

ITEM_NAME	DESCRIPTION_LABEL	LEFT_ITEM_TEXT	UNITS	RIGHT_ITEM_TEXT	SECTION_LABEL	GROUP_LABEL	HEADER	SUBHEADER	PARENT_ITEM	COLUMN_NUMBER	PAGE_NUMBER	QUESTION_NUMBER	RESPONSE_TYPE	RESPONSE_LABEL
VisitDate	Date of Visit	Visit date			Exerc.	ListOfMeasurements							text	
Performed	Was test performed on this visit	Performed			NOT A VALID LABEL	ListOfMeasurements INVALID VALUE							radio	YesNo
TestType	Type of test	Type			Exerc.	ListOfMeasurements							single-select	TestType
V02Max	VO2 Max	V02			Exerc.	ListOfMeasurements							REQUIRED FIELD	INVALID FIELD
Feeling	After test feeling	Feeling			Exerc.	ListOfMeasurements							multi-select	Type

Once the errors are fixed you can preview the CRF again and save to the database if no further errors occur.

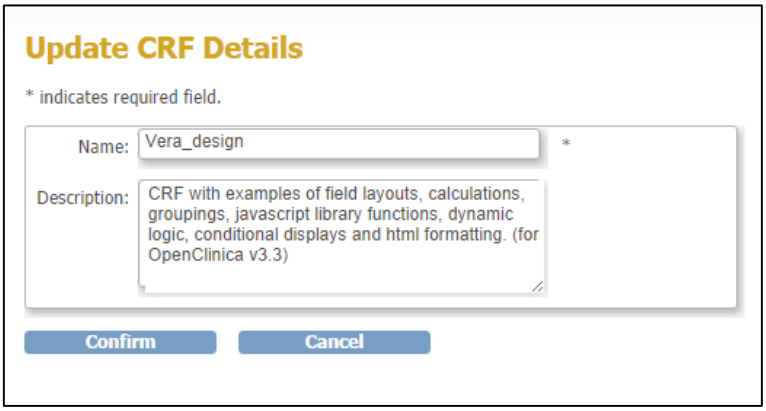
4.2.2.2 Manage CRFs

The full list of CRFs can be found under Task < Monitor and Manage Data < CRFs

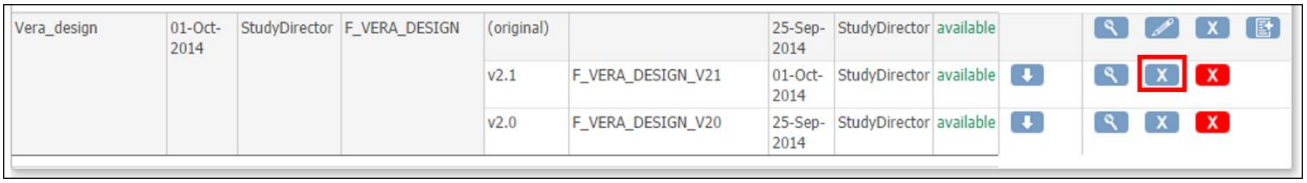
The following actions can be performed on each of the CRFs. Whether you can see the CRF list and which actions you can perform depends on what role you have been assigned.

View: This view is only of limited value as the structure and advanced features (rules, conditional displays) are not visible. It will allow you to double check quickly if the CRF content is of interest to you.

Edit: You will only be able to edit the name and the description of the CRF. For more substantial changes you need to download the CRF, edit the excel sheet and either upload a new version or upload a new CRF.



Remove: You can remove a CRF from the list. The CRF has not been deleted but it will be removed from all events definitions and studies. Data cannot be entered, modified or extracted but can be viewed. Removing a CRF prevents the creation of a new version.



Restore: A CRF that has been removed can be restored using the restore icon.

Download: You can download any of your CRF versions from this list.

Create New Version: Versioning your CRF is similar to creating a new CRF. You might create a new version of your CRF to correct small mistakes, layout changes or add additional items. Whether you can create a new

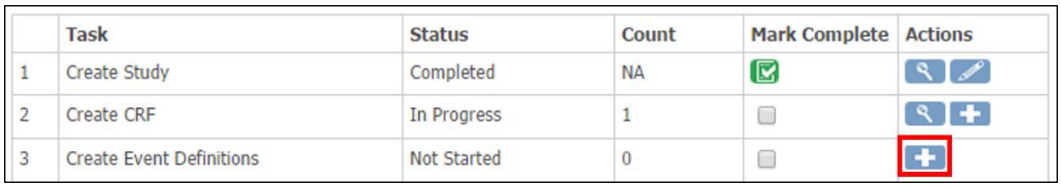
version or need to create a new CRF depends on whether the CRF is assigned to any events, any data has been entered, and the items you are trying to change.

Delete: 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.

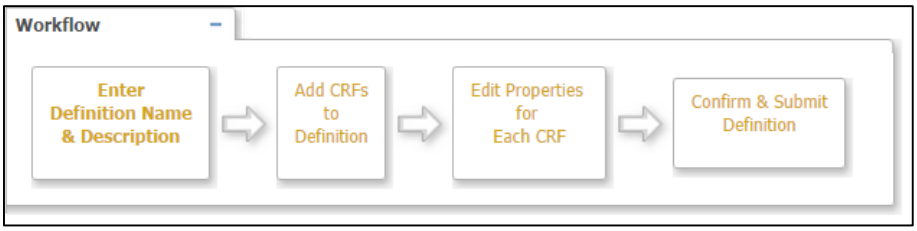
Note: Versioning CRFs is complicated and can get messy quite quickly, and in general is best avoided whenever possible. For more details on CRF versioning and tips on how to avoid the need for new versions look at the CRF Version Migration.

4.2.3 Create event

Action: to add an event

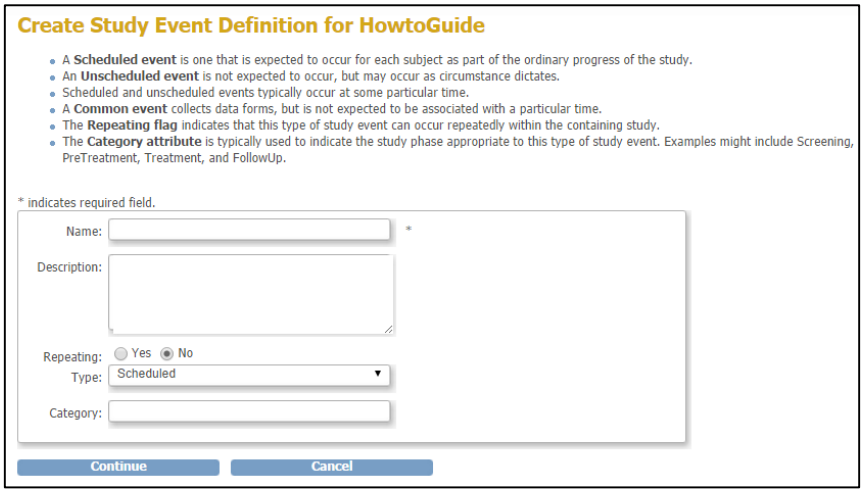


The steps to submit an event are to create event definition (Name and Description), add one or multiple CRFs, and edit CRF properties. Your project structure (or data collection strategy) will determine if it is preferable to add one CRF per event or add multiple CRFs to an event. You don't have to specify CRFs for the Event Definition when you first create it, but can select the CRFs later.



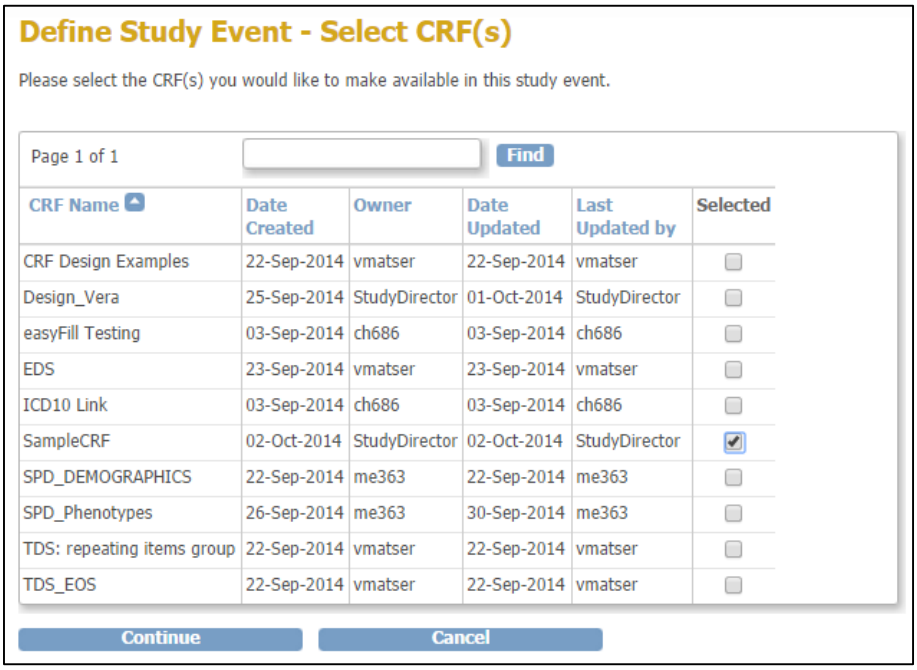
4.2.3.1 Step 1: Enter Definition Name & Description:

Schedule an event by adding the relevant data to the above form. *Type* (e.g. scheduled) is a useful parameter to think about. We currently do not use *Category* (e.g. screening), though you are free to use this parameter if useful to you in your study.



4.2.3.2 Step 2: Add CRFs to Definition

Select the CRF(s) you would like to add to your event. If you have a new CRF you need to upload the CRF to the database before you can attach it to your event.



Note: You do not have to select CRF now, but can complete the Event Definition without adding CRFs, then add the CRFs later.

4.2.3.3 Step 3: Edit Properties for each CRF

For each CRF you add to your event you have a number of properties that you can configure. Please note that if multiple versions of your CRF exist at the same time you need to set the default version. All active versions of the CRF are available from the drop down.

Specify parameters for each CRF you selected:

Required: Select if the CRF must be completed for the Event.

Double Data Entry: Select if the data for the CRF must be entered twice.

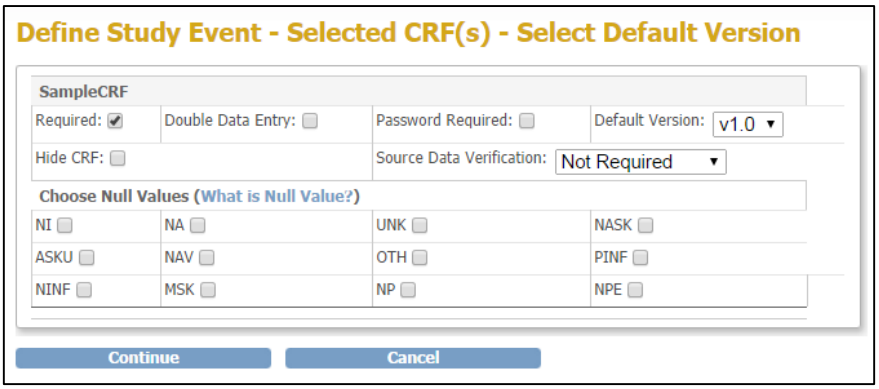
Password Required: Select if a user must supply their OpenClinica password when marking a CRF complete at the end of data entry.

Default Version: 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.

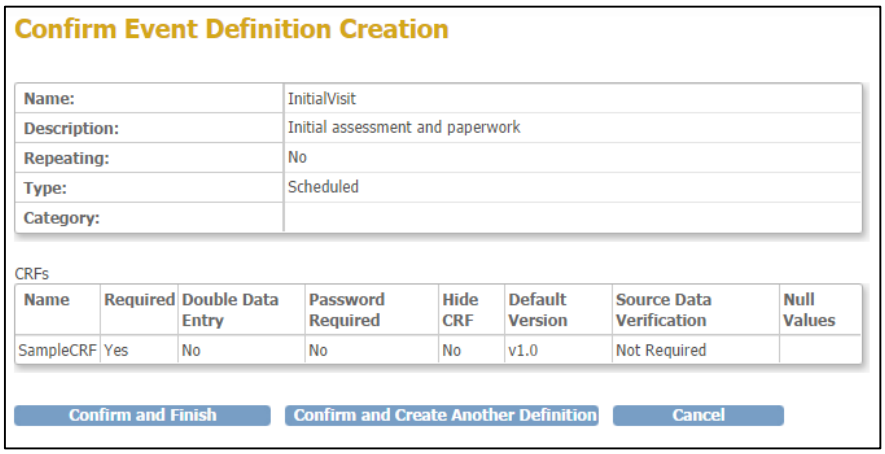
Source Data Verification: Select one of the values from the drop-down list. Select 100% Required, Partially Required, or Not Required to help you organize CRFs in the Source Data Verification table.

Null Values: In the CRF, for each Item that allows a user to choose from a drop-down list, the name of the null values you select here will be included as options in the drop-down list when the user enters data into the CRF.



Note: You can specify different parameters for the CRFs at different sites.

4.2.3.4 Step 4: Confirm & Submit Definition



If your event was created the message "*The new Event Definition has been created successfully"* will be displayed in the sidebar.

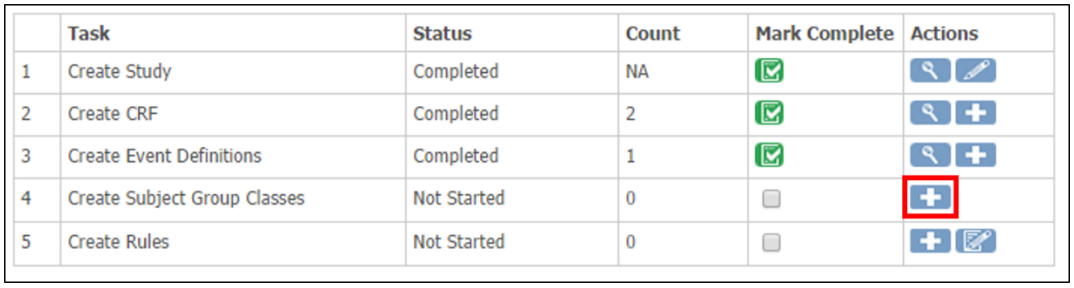
You can create multiple events, one after another, or if you want to add an additional event at a later date go to the *build study* page and repeat the steps under *create event*.

You can now mark this task as complete.

4.2.4 Create Subject Group Classes

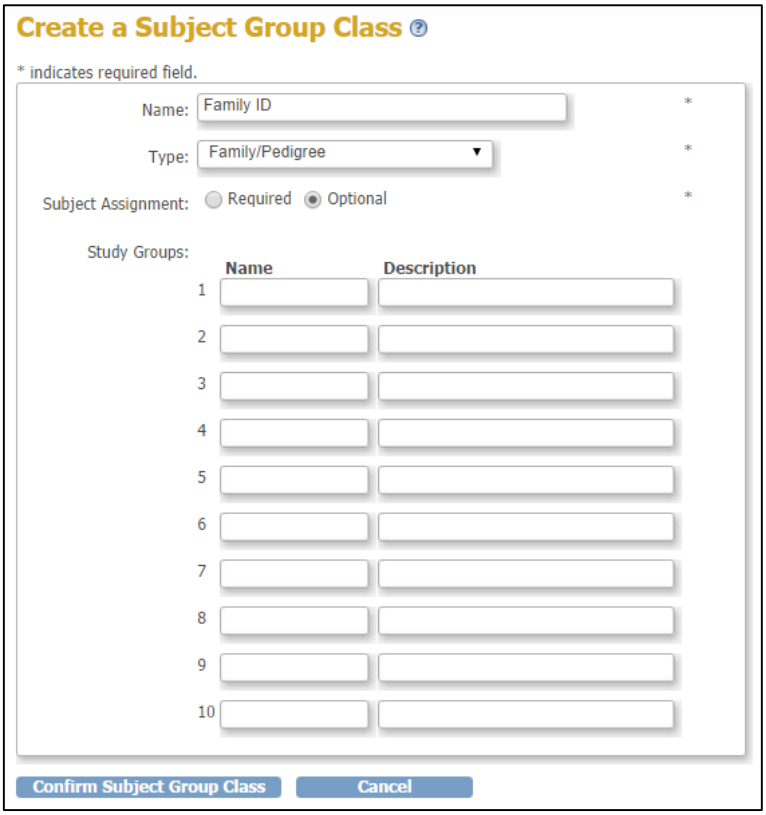
Use Subject Group Classes in OpenClinica to categorize Subjects within a Study, such as for treatment options. A Study Subject can be assigned to more than one Group Class, but can be assigned to only one Group within a Group Class.

Action:  to add a Subject Group Class



	Task	Status	Count	Mark Complete	Actions
1	Create Study	Completed	NA	☑	
2	Create CRF	Completed	2	☑	
3	Create Event Definitions	Completed	1	☑	
4	Create Subject Group Classes	Not Started	0	☐	
5	Create Rules	Not Started	0	☐	

Give your Subject Group Class a name, choose the types and decide if the subject assignment is required or not.



If your Subject Group Class was created the following message will appear in the sidebar "*The Subject Group Class was created successfully"* and you will return to the *build study* page. You can now mark this task as complete.

4.2.5 Create Rules

You can build and test rules in OpenClinica by using Rule Designer. The Rule Designer provides an interface that allows you to drag-and-drop OpenClinica objects to build your rule, and OpenClinica writes your XML code for you behind the scenes.

Rule Designer utilizes OIDs (Object Identifiers). OIDs are identifiers used in OpenClinica to uniquely identify various entities. These identifiers are generated by OpenClinica and made available to users on multiple screens. Each Rule has a unique Rule OID and it is how your rule will be referred in the database.

If your Study uses Rules, we recommend you to prefix your Rule OID with your 3-character project code (Unique Protocol ID).

Action: to create a new rule using Rule Designer

5	Create Rules	Completed	10		

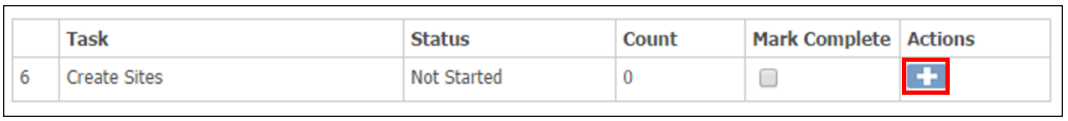
Please refer to the RDCIT "HOW TO" for more about building a new rule using Rule Designer.

4.2.6 Create Sites

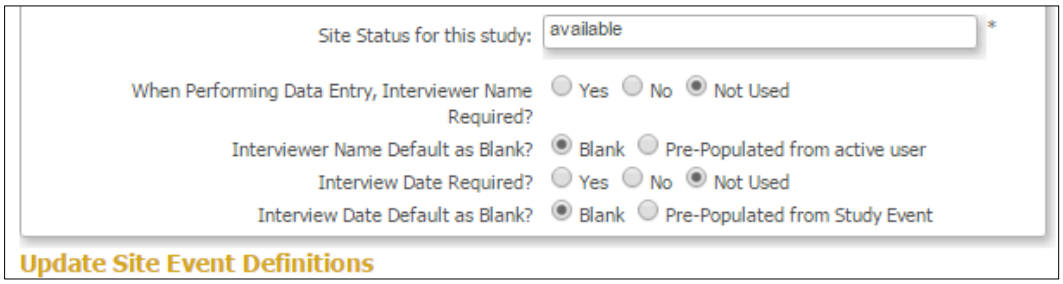
Creating sites is imperative to the security model of the RDCIT Best Practice standards.

- Create a site per each location which patients are assigned to a study.
- You will need to create a site per consultant if a hospital has multiple clinical leads within a study and who do not share patients.
- The site Unique Protocol ID should be related to your study Unique Protocol ID (3 character project code) e.g. TRN_ADD for Addenbrooke's site on Training (TRN) study
- Principal Investigator should be the lead clinician on the site.
- Enrolment at sites needs to add up to enrolment in study
- Site name: Hospital_Consultant e.g. Addenbrookes_Smith

Action:  to create a new site

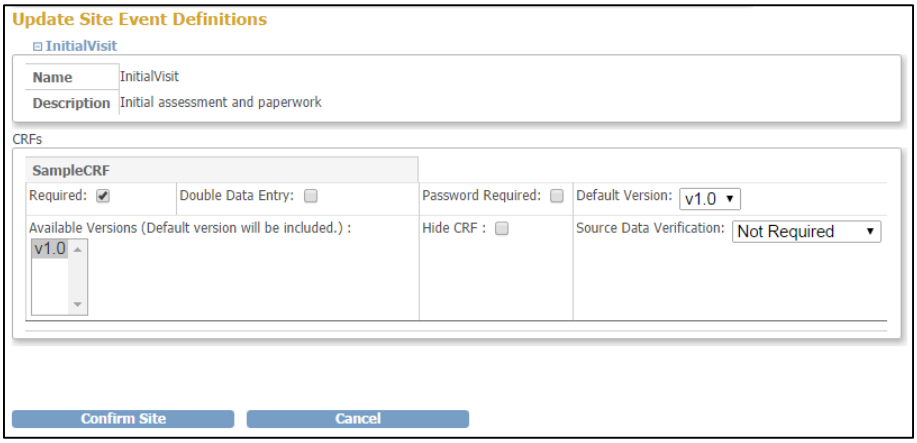


Per default the Site Parameters match the Study Parameters, these parameters are the decision of the study.



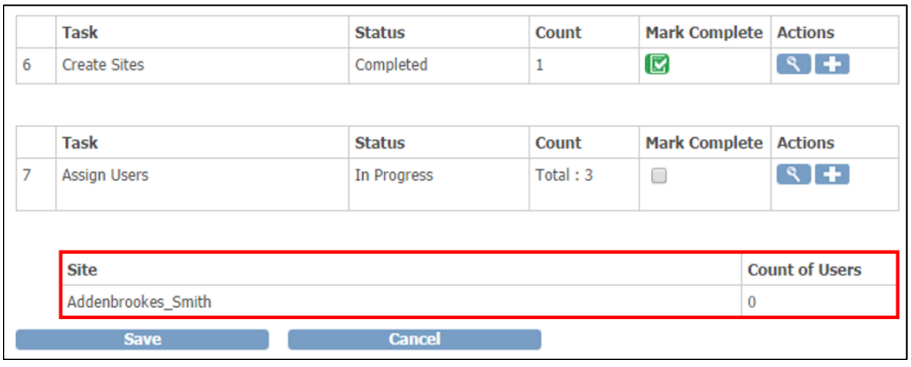
As with the study parameters we recommend choosing "Not Used" for these parameters as the audit trail logs the username and date.

During the configuration of your sites you are given the opportunity to modify the event definitions based on the site.



OpenClinica will show you a summary of the data you entered for your site and ask you to confirm the site.

If your site was added the following message will appear in the sidebar "*The new Site has been created successfully*" and you will return to the *build study* page. Your site will now be visible on the *build study* page.



Repeat the steps under *Create a Site* until you have your full list of Sites. Note that you need to create a site for each consultant. You can now mark this task as complete.

4.2.7 Assign users

For the integrity of the RDCIT OpenClinica security model it is essential that users are assigned at a site level **not** at study level.

- To assign a user to a site you need to login to that site.
- Users will need to have a user account before they can be assigned to a study. Depending on how you use OpenClinica you may need to ask the RDCIT to create the user accounts for you.

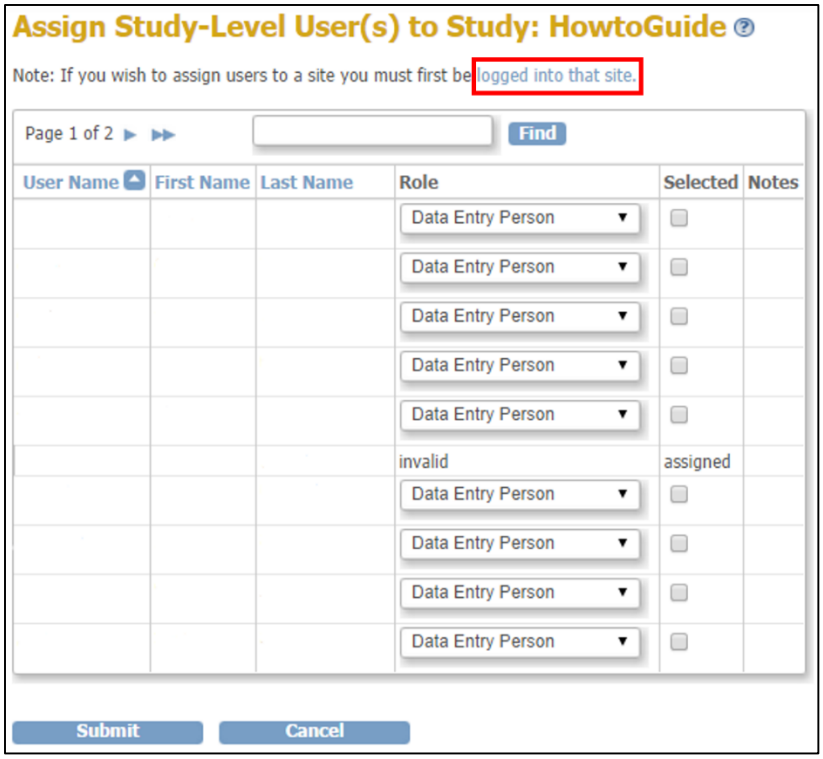
Note: Your study needs to be set to *Available* if you want to assign users to your study.

You can view which users are currently assigned to your study by clicking on the view icon.

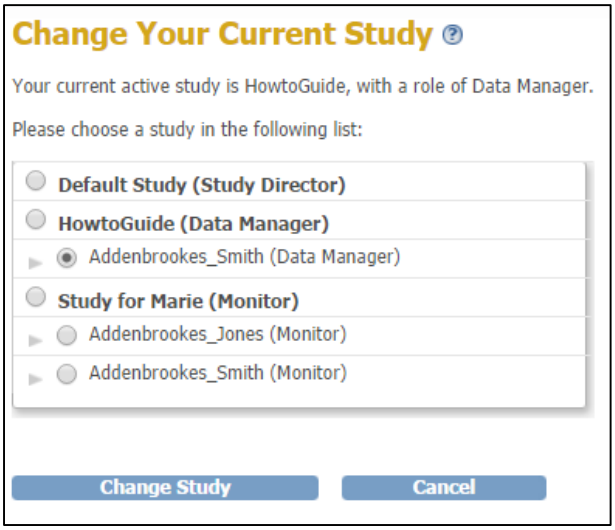
Actions:  to add a new user

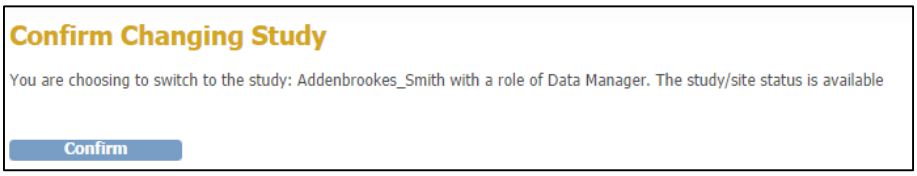
	Task	Status	Count	Mark Complete	Actions
7	Assign Users	In Progress	Total : 3		

Follow the link logged into that site, or alternatively you can log into a site at the top of the page Change Study/Site



Note: user names and details on this image have been deleted for privacy reasons.



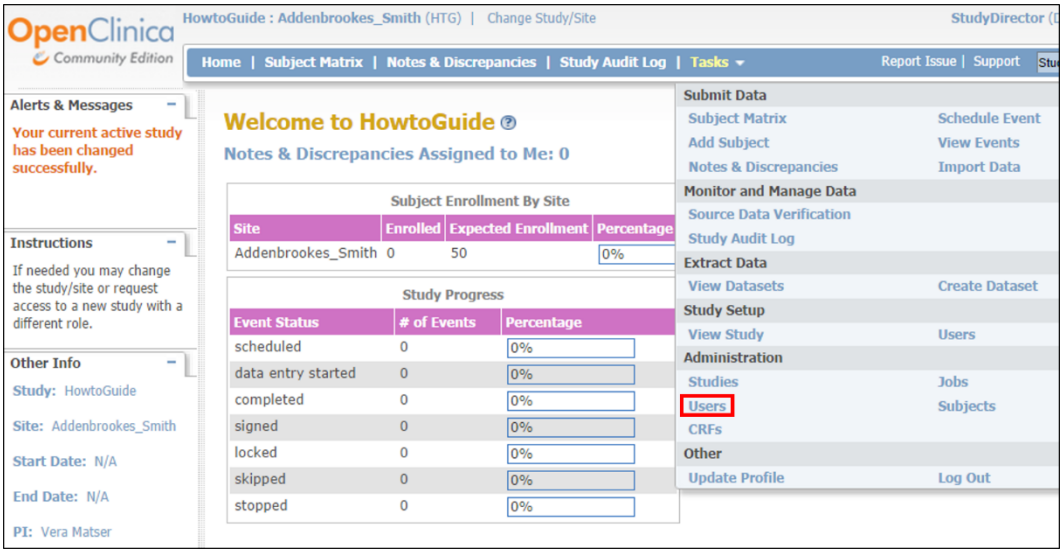


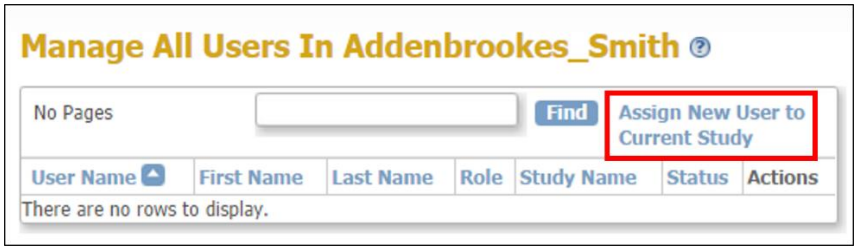
OpenClinica does not make a difference between changing studies or changing sites.

You will be directed to the homescreen of your site.

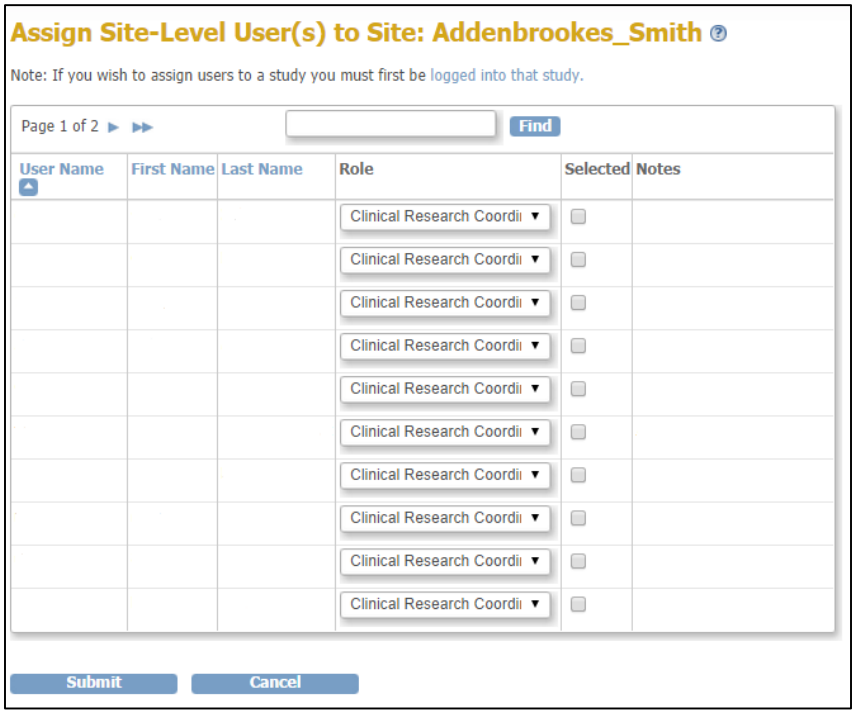
To add users to your site

Tasks < Study Setup < Users



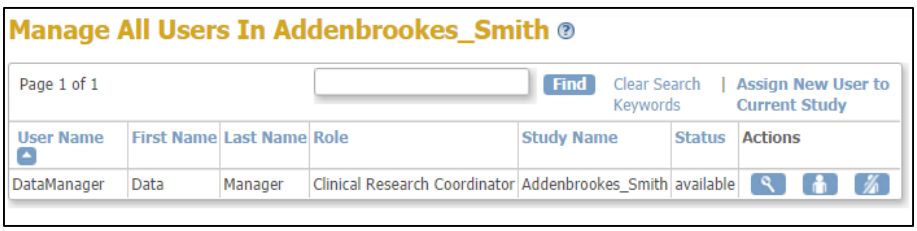


Follow the link Assign New User to Current Study. Select the user and their associated role (drop-down menu) you want to assign to your site and submit (note user names and details on this image have been deleted for privacy reasons).

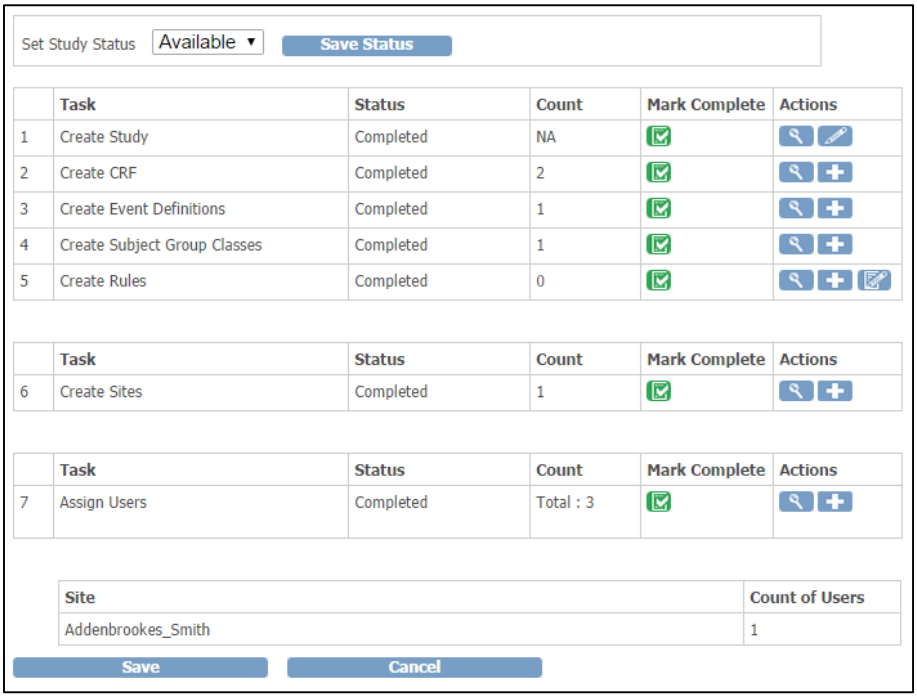


If the user was added to your site a variation of the following message "*Data Manager(user name: DataManager) has been assigned to the Site Addenbrookes_Smith under the Study HowtoGuide as "Clinical Research Coordinator*" will be displayed in the sidebar.

You will now see an overview of the users that are assigned to your site.



Repeat the steps listed under *assign users* until you have added all your users. You can now mark this task as complete.



Congratulations, you have completed your study setup. Make sure you have marked you Study Status as available. Subjects can now be added to your study/site and data entry started.

5 Appendix

5.1 Best Practice in one quick bite

The follow-on sections are an extract of the Best Practice Guide which provide detailed guidance for setting up your study in OpenClinica. This section provides a more easily digestible read of the key practices. Note that in using OpenClinica as it is designed, much of these points will be taken care of.

Patients (Subjects)

- The NHS number must be provided for all subjects.
- Use the Person ID field to store the NHS number.
- Use an identifier which is pseudonymised as the Study Subject ID. Note if your study is part of the Genomics England 100,000 Genomes Project, a unique participant ID will be provided by GEL.
- The project decides on the study parameter options (Person ID visibility, Secondary Label (Subject Secondary ID) visibility and use; Date of Birth options) unless pre-defined by the RDCIT.
- If applicable, Patient Identifiable Data (PID – e.g. contact data) should be preferentially stored in CiviCRM or in the standardised (RDCIT-owned) PID CRF in OpenClinica (Name: COZ_PID). This CRF should not be customised by any study.

Clinicians (Users)

- Everyone who is entering or accessing OpenClinica must have their own user account
- User accounts should be requested using the RDCIT User Authorisation form (6.2.1)

Pre-study setup

- A RDCIT approved data plan should be developed (see 4. Clinical Coding)
- Prior to the study going live the RDCIT Study Authorisation form will need to be completed by the PI

CRF Design

- In CRF design where possible use the standard conventions for naming items, values displayed and values stored. (see **Error! Reference source not found.**)
- Prefix CRF names with the Unique Protocol ID (e.g. 3 character project code or BRIDGE project code)
- Only load verified CRFs to the OpenClinica live environment.

Study setup

- Provide full contact details for the Principal Investigator (Lead Applicant) on the study.
- Unique Protocol ID: Use the unique three character project code (e.g. BRIDGE project code) as the studies Unique Protocol ID in the Study Description
- Secondary IDs: indicate whether your study is part of BRIDGE, RD-TRC, GMC, or Other (if not belonging to the previous three)

Sites

- The site Unique Protocol ID should be prefixed with the three character project code (which is the Study Unique Protocol ID)
- For each site provide full contact details of the clinician on that site responsible for patient care (in Facility Information section)
- If a hospital has multiple clinical leads within a study, who do not share patients, a study can set up separate sites e.g. Brompton: Smith and Brompton: Jones.
- Ensure all clinicians are assigned to a site (to restrict their access to patients they are responsible for)
- Ensure all patients are assigned to a site (corresponding to clinicians administering their records)
- The only users with access at study level should be the Principal Investigator and people responsible for configuring or monitoring the study (designate/ OpenClinica Data Manager).

Final Sign off Procedure

- RDCIT will provide a checklist for each study to review with the RDCIT team prior to launching their OpenClinica study (based on Data Plan).

- Study and User Authorisation form must be completed prior to the study going live
- Users who have access to data across multiple sites will need to complete a Research Passport/Letter of Access with Cambridge University Hospitals NHS Foundation Trust (CUH).