

<OpenClinica RDCIT Study Set up Guide>

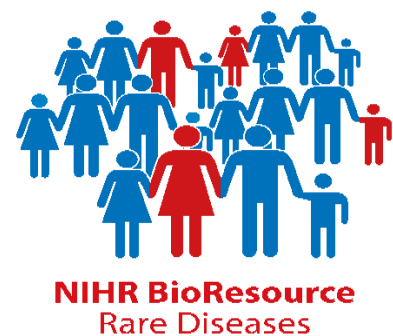
Purpose of this document: This document is a step-by-step guide on how to set up your study in a way that conforms to the RDCIT best practice standard. This document should be read in conjunction with the Best Practice Guide.

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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](#)

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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.

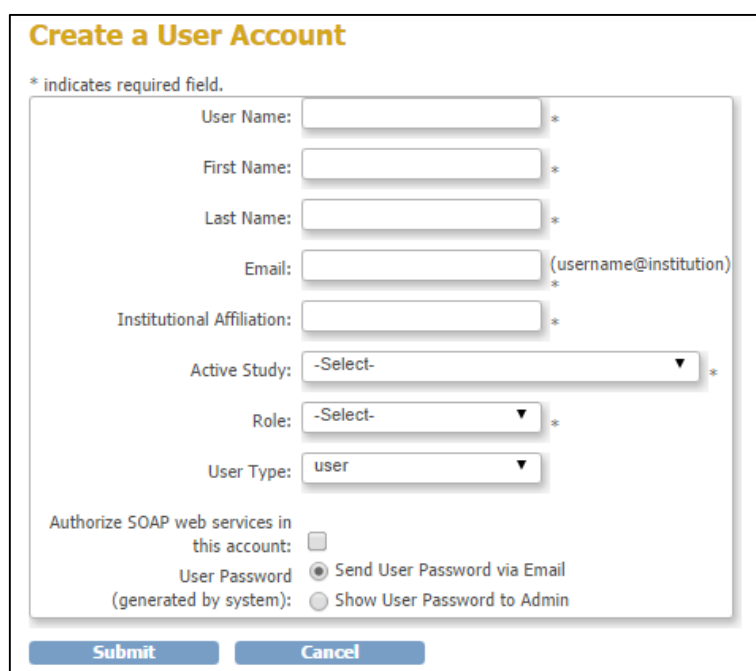
3 Before you get started

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 (alphanumeric, 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



The form is titled "Create a User Account" in orange. Below the title, a note states "* indicates required field." The form contains several input fields and dropdown menus, each followed by an asterisk to indicate it is required. The fields are: "User Name:" (text input), "First Name:" (text input), "Last Name:" (text input), "Email:" (text input with a placeholder "(username@institution)"), "Institutional Affiliation:" (text input), "Active Study:" (dropdown menu with "-Select-" selected), "Role:" (dropdown menu with "-Select-" selected), and "User Type:" (dropdown menu with "user" selected). At the bottom, there is a checkbox labeled "Authorize SOAP web services in this account:" which is currently unchecked. Below this checkbox are two radio buttons: "Send User Password via Email" (which is selected) and "Show User Password to Admin". At the very bottom of the form are two buttons: "Submit" and "Cancel".

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.

Reset password

Welcome to OpenClinica, Study Director. Your current password has been set by the system or has expired. In order to continue, you MUST change your password below.

* indicates required field.

Old Password: *

New Password: *

Confirm New Password: *

Password Challenge Question: *

Password Challenge Answer: *

[Change Password](#) [Exit](#)

If you have forgotten your password please follow the “[Forgot Password?](#)” link on the OC login page.

Login

User Name

Password

[Login](#) [Forgot Password?](#)

3.3 Login to OCplay

The URL for **OCplay** is:

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



OpenClinica
OCPlay: deleted regularly

OpenClinica recommends using Firefox 25 and Internet Explorer 11. While OpenClinica is designed to work on all standards-compliant browsers, we have not verified that the application functions correctly on other browsers or browser versions. If you do not have one of the above browsers installed you may need to contact your IT support group for assistance.

Login

User Name

Password

Login [Forgot Password?](#)

News

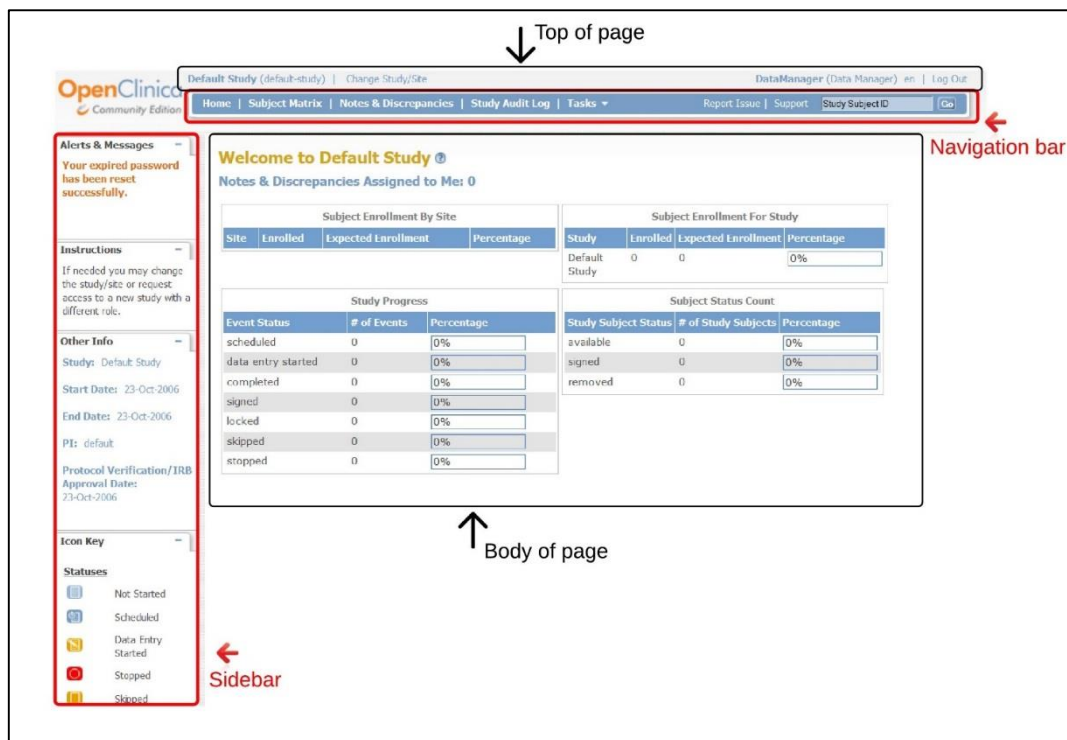
- ▶ 12/04 - 2015 Future of Open Source Survey Results - Open source software has emerged as the driving ...
- ▶ 09/24 - Reducing friction in patient engagement: an (unconventional) case study - Our quest for frictionless, electronic patient ...
- ▶ 08/17 - HTML Tips to Enhance Your eCRF - In some cases, the display of your OpenClinica ...
- ▶ 08/03 - Calculating ROI for ePRO - I recently delivered a webinar titled "Getting ...

[More...](#)

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.

Tasks ▾	Report Issue Support	Study Subject ID
Submit Data		
Subject Matrix	Schedule Event	
Add Subject	View Events	
Notes & Discrepancies	Import Data	
Monitor and Manage Data		
Source Data Verification	Groups	
Study Audit Log	CRFs	
Rules		
Extract Data		
View Datasets	Create Dataset	
Study Setup		
View Study	Users	
Build Study		
Administration		
Studies	Jobs	
Users	Subjects	
CRFs		
Other		
Update Profile	Log Out	

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.

	Add
	View
	Edit
	Remove
	Restore
	Delete
	Download
	Create New Version
	Rule Designer

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

Tasks ▾	Report Issue Support	Study Subject ID
Submit Data		
Subject Matrix	Schedule Event	
Add Subject	View Events	
Notes & Discrepancies	Import Data	
Monitor and Manage Data		
Source Data Verification	Groups	
Study Audit Log	CRFs	
Rules		
Extract Data		
View Datasets	Create Dataset	
Study Setup		
View Study	Users	
Build Study		
Administration		
Studies	Jobs	
Users	Subjects	
CRFs		
Other		
Update Profile	Log Out	

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

Default Study (default-study) | Change Study/Site

StudyDirector (Study Director)

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Report Issue | Support | Study Subject ID

Alerts & Messages
Instructions
Other Info
Icon Key

Studies are indicated in **Bold**, while the rest are Sites within a Study.

In the application, you currently have :

Studies : 5

Sites : 4

Statuses

Not Started

Scheduled

Administer Studies

» Create a New Study

Studies are indicated in **Bold**, while the rest are Sites within a Study.

Page 1 of 1
Find
Create a New Study

Name	Unique Identifier	OID	Principal Investigator	Facility Name	Date Created	Status	Actions
Default Study	default-study	S_DEFAULTS1			23-Oct-2006	available	
EDS test study	EDS_test	S_EDS_TEST			23-Sep-2014	available	
» Edinburgh_Jones	Edinburgh_Jones	S_EDINBURG			23-Sep-2014	available	
» Edinburgh_Smith	Edinburgh_Smith	S_EDINBURG_3591			23-Sep-2014	available	
Study for Marie	Marie_test	S_MARIE_TE			22-Sep-2014	available	
» Addenbrookes_Jones	Addenbrookes_Jones	S_ADDENBRO			22-Sep-2014	available	
» Addenbrookes_Smith	Addenbrookes_Smith	S_ADDENBRO_3244			22-Sep-2014	available	
Test imported study	importedStudy	S_IMPORTED			29-Aug-2014	removed	
Test importing	ImportTest	S_IMPORTTE			03-Sep-2014	available	

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

Create a New Study

Enter the Study and Protocol Information requested below to create the study. The data element definitions used here are based on the website for descriptions of all fields.

SECTION A: Study Description

* indicates required field.

Unique Protocol ID: *

Brief Title: *

Official Title:

Secondary IDs: *

(separate by commas)

Principal Investigator: *

Protocol Type: ☒ Interventional ☐ Observational *

Brief Summary: *

Detailed Description:

Sponsor: *

Collaborators:

(separate by commas)

Please select a user who will later edit or update the Study.

Select User :



- 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

The screenshot shows the OpenClinica Community Edition interface. At the top, there's a navigation bar with 'OC Training (Training_study)' and a highlighted 'Change Study/Site' link. Below this is a menu with 'Home', 'Subject Matrix', 'Notes & Discrepancies', 'Study Audit Log', and 'Tasks'. On the left, a sidebar contains 'Alerts & Messages', 'Instructions', and 'Other Info'. The 'Other Info' section shows details for the current study: 'Study: OC Training', 'Start Date: 01-Sep-2015', 'End Date: N/A', 'PI: Ping', and 'Protocol Verification/IRB Approval Date:'. The main content area is titled 'Change Your Current Study' and contains the text: 'Your current active study is OC Training, with a role of Study Director. Please choose a study in the following list:'. Below this is a list of studies with radio buttons. The studies are: 'Car Chasing (Study Director)', 'Cambridge (Study Director)', 'Ely (Study Director)', 'Chickenpox (Data Manager)', 'Laptop1 (Data Manager)', 'Laptop2 (Data Manager)', 'Final Exam (Data Manager)', 'Ely (Data Manager)', 'Littleport (Data Manager)', 'GBCs test study (Data Manager)', 'SiteA (Data Manager)', 'SiteB (Data Manager)', 'SiteC (Data Manager)', 'Java Script and Rule Design (Data Manager)', 'Scott Java Study (Data Manager)', 'Scott Java Study site 2 (Data Manager)', 'New Study (Data Manager)', 'Addenbrooke's site (Data Manager)', 'Newcastle site (Data Manager)', 'OC Training (Study Director)' (which is selected), and 'ODIN test (Study Director)'. At the bottom of the dialog are two buttons: 'Change Study' and 'Cancel'.

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.

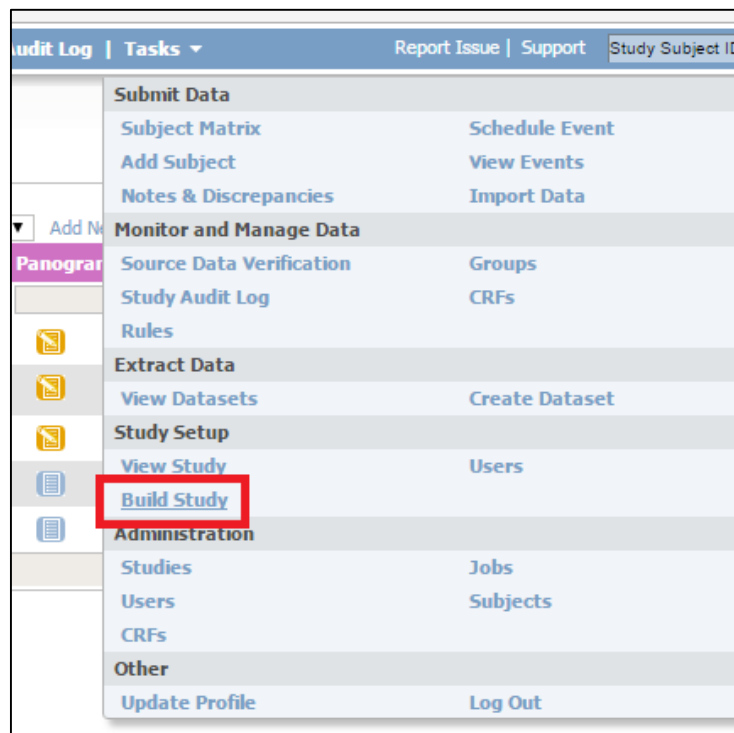
Your study has been created but will need to be fully configured.

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.

HowtoGuide 

Welcome to the Build Study page of OpenClinical! This page is designed to help you build and configure your Study by following a task-based approach. The tasks listed below need to be completed in order to start using your Study. Once you have finished each task, check "Mark Complete" then click the "Save" button.

- To start a task, select the  icon. You can always select the  icon to add a new component to your Study.
- Select the  icon to edit the values for a task.
- Select the  to view the specified values for that task.

To add users to different Sites, you must first change your Study/Site to the appropriate Site. Then, in the Tasks menu, from the Study Setup module, select Users.

When you are ready to start adding Subjects to your Study, select Available from the Set Study Status drop-down list and click the "Save" button. If the Study status is Design, Subjects cannot be added.

Set Study Status: Design Save Status

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

	Task	Status	Count	Mark Complete	Actions
6	Create Sites	Not Started	0	☐	

	Task	Status	Count	Mark Complete	Actions
7	Assign Users	In Progress	Total : 1	☐	 

Save Cancel

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.

Set Study Status: Available Save Status

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

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

	Task	Status	Count	Mark Complete	Actions
1	Create Study	In Progress	NA	☐	 

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.

Manage Case Report Forms (CRFs)											
Page 1 of 1						Find		Blank CRF Template		OpenClinica CRF Library	
CRF Name		Date Updated	Last Updated by	CRF_OID	Version(s)	Version_OID	Date Created	Owner	Status	Download	Actions
CRF Design Examples		22-Sep-2014	vmatser	F_CRFDESIGNEXA	(original)		22-Sep-2014	vmatser	available		
					v2.0	F_CRFDESIGNEXA_V20	22-Sep-2014	vmatser	available		

4.2.2.1 Upload a new CRF

Action: + (add) to upload a new CRF

	Task	Status	Count	Mark Complete	Actions
1	Create Study	In Progress	NA	☐	
2	Create CRF	Not Started	0	☐	
3	Create Event Definitions	Not Started	0	☐	

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

Create a New Case Report Form (CRF)

You can download a blank OpenClinica CRF Excel spreadsheet template [here](#).

OpenClinica is tested and supported with the use of Microsoft Excel 97-2003. If you 2003 version".

MS Excel File To Upload:

Choose File
No file chosen

Preview CRF Version

Exit

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.

Create a New CRF Version - Data Committed Successfully

The new CRF version was committed into the database successfully.

- [Go back to the CRF List](#)
- [View CRF Version Data Entry](#)
- [Go back to the Build Study page](#)
- [CRF Version Metadata](#)

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.

Check CRF Version Data

There were several invalid fields in your spreadsheet. Please take a look at the data below, click [Go Back](#) to go back and upload your corrected spreadsheet for the CRF.

The SECTION_LABEL column is not a valid section at row 2, Items sheet. Check the Sections worksheet to see that there is a valid LABEL for this SECTION_LABEL.
 The SECTION_LABEL column is not a valid section at row 2, Items sheet. Check the Sections worksheet to see that there is a valid LABEL for this SECTION_LABEL.
 The RESPONSE_TYPE column was blank at row 4, Items sheet.
 Error found at row "5" in items worksheet. ResponseLabel "text" for ResponseType "" has been used for another ResponseType.
 Items of one repeating group spread over several sections. Check items in Group 'ListOfMeasurements'.

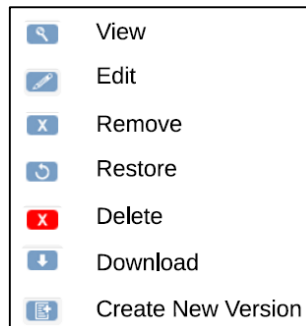
CRF														
CRF_NAME					VERSION					VERSION_DESCRIPTION				
SampleCRF					v.1.0					latest version				
Sections														
SECTION_LABEL					SECTION_TITLE					SUBTITLE			INSTRUCTIONS	
Exerc.					Exercise test									
Groups														
GROUP_LABEL					GROUP_LAYOUT					GROUP_HEADER			GROUP_REPEAT_NUMBER	
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							radio	YesNo
TestType	Type of test	Type			Exerc.	ListOfMeasurements							single-select	TestType
VO2Max	VO2 Max	VO2			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.

Update CRF Details

* indicates required field.

Name: Vera_design *

Description:

CRF with examples of field layouts, calculations, groupings, javascript library functions, dynamic logic, conditional displays and html formatting. (for OpenClinica v3.3)

Confirm

Cancel

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.

Vera_design	01-Oct-2014	StudyDirector	F_VERA_DESIGN	(original)		25-Sep-2014	StudyDirector	available					
				v2.1	F_VERA_DESIGN_V21	01-Oct-2014	StudyDirector	available					
				v2.0	F_VERA_DESIGN_V20	25-Sep-2014	StudyDirector	available					

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

Vera_design	01-Oct-2014	StudyDirector	F_VERA_DESIGN	(original)		25-Sep-2014	StudyDirector	available					
				v2.1	F_VERA_DESIGN_V21	01-Oct-2014	StudyDirector	removed					
				v2.0	F_VERA_DESIGN_V20	25-Sep-2014	StudyDirector	available					

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](#).

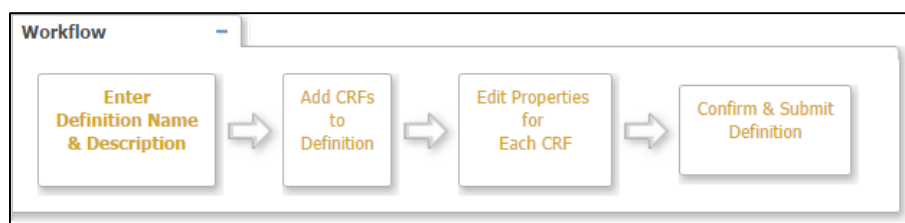
Vera_design	01-Oct-2014	StudyDirector	F_VERA_DESIGN	(original)		25-Sep-2014	StudyDirector	available					
				v2.1	F_VERA_DESIGN_V21	01-Oct-2014	StudyDirector	available					
				v2.0	F_VERA_DESIGN_V20	25-Sep-2014	StudyDirector	available					

4.2.3 Create event

Action: to add an event

	Task	Status	Count	Mark Complete	Actions
1	Create Study	Completed	NA		
2	Create CRF	In Progress	1	☐	
3	Create Event Definitions	Not Started	0	☐	

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.

Create Study Event Definition for HowtoGuide

- A **Scheduled event** is one that is expected to occur for each subject as part of the ordinary progress of the study.
- An **Unscheduled event** is not expected to occur, but may occur as circumstance dictates.
- Scheduled and unscheduled events typically occur at some particular time.
- A **Common event** collects data forms, but is not expected to be associated with a particular time.
- The **Repeating flag** indicates that this type of study event can occur repeatedly within the containing study.
- The **Category attribute** is typically used to indicate the study phase appropriate to this type of study event. Examples might include Screening, PreTreatment, Treatment, and FollowUp.

* indicates required field.

Name: *

Description:

Repeating: ☐ Yes ☒ No

Type:

Category:

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.

Define Study Event - Select CRF(s)

Please select the CRF(s) you would like to make available in this study event.

Page 1 of 1

CRF Name	Date Created	Owner	Date Updated	Last Updated by	Selected
CRF Design Examples	22-Sep-2014	vmatser	22-Sep-2014	vmatser	☐
Design_Vera	25-Sep-2014	StudyDirector	01-Oct-2014	StudyDirector	☐
easyFill Testing	03-Sep-2014	ch686	03-Sep-2014	ch686	☐
EDS	23-Sep-2014	vmatser	23-Sep-2014	vmatser	☐
ICD10 Link	03-Sep-2014	ch686	03-Sep-2014	ch686	☐
SampleCRF	02-Oct-2014	StudyDirector	02-Oct-2014	StudyDirector	☒
SPD_DEMOGRAPHICS	22-Sep-2014	me363	22-Sep-2014	me363	☐
SPD_Phenotypes	26-Sep-2014	me363	30-Sep-2014	me363	☐
TDS: repeating items group	22-Sep-2014	vmatser	22-Sep-2014	vmatser	☐
TDS_EOS	22-Sep-2014	vmatser	22-Sep-2014	vmatser	☐

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.

Define Study Event - Selected CRF(s) - Select Default Version

SampleCRF

Required: ☒ Double Data Entry: ☐ Password Required: ☐ Default Version: v1.0 ▼

Hide CRF: ☐ Source Data Verification: Not Required ▼

Choose Null Values (What is Null Value?)

NI ☐	NA ☐	UNK ☐	NASK ☐
ASKU ☐	NAV ☐	OTH ☐	PINF ☐
NINF ☐	MSK ☐	NP ☐	NPE ☐

Continue Cancel

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

4.2.3.4 Step 4: Confirm & Submit Definition

Confirm Event Definition Creation

Name:	InitialVisit
Description:	Initial assessment and paperwork
Repeating:	No
Type:	Scheduled
Category:	

CRFs

Name	Required	Double Data Entry	Password Required	Hide CRF	Default Version	Source Data Verification	Null Values
SampleCRF	Yes	No	No	No	v1.0	Not Required	

Confirm and Finish Confirm and Create Another Definition Cancel

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.

Create a Subject Group Class ?

* indicates required field.

Name: *

Type: *

Subject Assignment: ☐ Required ☒ Optional *

Study Groups:

	Name	Description
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

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

	Task	Status	Count	Mark Complete	Actions
6	Create Sites	Not Started	0	☐	

Create a New Site

* indicates required field.

 Create Site Properties




Parent Study:

Site Name:

Unique Protocol ID:

Secondary IDs
(separate by commas):

Principal Investigator:

Brief Summary:

HowtoGuide



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

Site Status for this study:

When Performing Data Entry, Interviewer Name Required? ☐ Yes ☐ No ☒ Not Used

Interviewer Name Default as Blank? ☒ Blank ☐ Pre-Populated from active user

Interview Date Required? ☐ Yes ☐ No ☒ Not Used

Interview Date Default as Blank? ☒ Blank ☐ Pre-Populated from Study Event

Update Site Event Definitions

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.

Update Site Event Definitions

☒ InitialVisit

Name: InitialVisit

Description: Initial assessment and paperwork

CRFs

SampleCRF

Required: ☒ Double Data Entry: ☐ Password Required: ☐ Default Version: v1.0

Available Versions (Default version will be included.):

v1.0

Hide CRF: ☐ Source Data Verification: Not Required

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.

Task	Status	Count	Mark Complete	Actions
6 Create Sites	Completed	1	☒	Search Add
7 Assign Users	In Progress	Total : 3	☐	Search Add

Site	Count of Users
Addenbrookes_Smith	0

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](#)

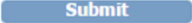
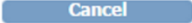
Assign Study-Level User(s) to Study: HowtoGuide 

Note: If you wish to assign users to a site you must first be **logged into that site.**

Page 1 of 2  



User Name 	First Name	Last Name	Role	Selected	Notes
			Data Entry Person 	☐	
			Data Entry Person 	☐	
			Data Entry Person 	☐	
			Data Entry Person 	☐	
			Data Entry Person 	☐	
			invalid	assigned	
			Data Entry Person 	☐	
			Data Entry Person 	☐	
			Data Entry Person 	☐	
			Data Entry Person 	☐	

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

Change Your Current Study ?

Your current active study is HowtoGuide, with a role of Data Manager.

Please choose a study in the following list:

☐

Default Study (Study Director)

☐

HowtoGuide (Data Manager)

☒

Addenbrookes_Smith (Data Manager)

☐

Study for Marie (Monitor)

☐

Addenbrookes_Jones (Monitor)

☐

Addenbrookes_Smith (Monitor)

Change Study

Cancel

Confirm Changing Study

You are choosing to switch to the study: Addenbrookes_Smith with a role of Data Manager. The study/site status is available

Confirm

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

OpenClinica
Community Edition

HowtoGuide : Addenbrookes_Smith (HTG) | Change Study/Site

StudyDirector (0

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Report Issue | Support | Stu

Alerts & Messages

Your current active study has been changed successfully.

Instructions

If needed you may change the study/site or request access to a new study with a different role.

Other Info

Study: HowtoGuide

Site: Addenbrookes_Smith

Start Date: N/A

End Date: N/A

PI: Vera Matser

Welcome to HowtoGuide ?

Notes & Discrepancies Assigned to Me: 0

Subject Enrollment By Site

Site	Enrolled	Expected Enrollment	Percentage
Addenbrookes_Smith	0	50	0%

Study Progress

Event Status	# of Events	Percentage
scheduled	0	0%
data entry started	0	0%
completed	0	0%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Submit Data

Subject Matrix

Add Subject

Notes & Discrepancies

Schedule Event

View Events

Import Data

Monitor and Manage Data

Source Data Verification

Study Audit Log

Extract Data

View Datasets

Create Dataset

Study Setup

View Study

Users

Administration

Studies

CRFs

Jobs

Subjects

Other

Update Profile

Log Out

Manage All Users In Addenbrookes_Smith ?

No Pages [Find](#) [Assign New User to Current Study](#)

User Name	First Name	Last Name	Role	Study Name	Status	Actions
There are no rows to display.						

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).

Assign Site-Level User(s) to Site: Addenbrookes_Smith ?

Note: If you wish to assign users to a study you must first be [logged into that study](#).

Page 1 of 2 [Find](#)

User Name	First Name	Last Name	Role	Selected	Notes
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	
			Clinical Research Coordii	☐	

[Submit](#) [Cancel](#)

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.

Manage All Users In Addenbrookes_Smith ?

Page 1 of 1 [Find](#) [Clear Search Keywords](#) | [Assign New User to Current Study](#)

User Name	First Name	Last Name	Role	Study Name	Status	Actions
DataManager	Data	Manager	Clinical Research Coordinator	Addenbrookes_Smith	available	Search User Add

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

Set Study Status
Available ▼
Save Status

	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	Completed	1	☒	
5	Create Rules	Completed	0	☒	

	Task	Status	Count	Mark Complete	Actions
6	Create Sites	Completed	1	☒	

	Task	Status	Count	Mark Complete	Actions
7	Assign Users	Completed	Total : 3	☒	

Site	Count of Users
Addenbrookes_Smith	1

Save
Cancel

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).