Introduction to OpenClinica

A Genomics England Quick Guide

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Document History

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1.1 Version History

Version	Date	Author	Description
V0.1	20/10/2016	PG	Draft Version
V1.0	1/12/16	PG/RS	Final Version
V1.1	13/1/17	CB	Removal of Draft Watermark

1.2 Reviewers

This document must be reviewed by the following:

Name	Area
Gavin Mulcahy	Product Owner
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1.3 Approvers

This document must be approved by the following:

Name	Responsibility	Date	Version
Gavin Mulcahy	Product Owner	1/12/16	1.0

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3 Introduction

This guide is intended to give users in NHS Genomic Medicine Centres (NHS GMC) an introduction to using the OpenClinica application.

This is not an exhaustive guide to OpenClinica functionality. Nor it is intended to provide a full list of data items expected to be submitted or to provide any guidance on the content of your submissions.

4 What is OpenClinica?

OpenClinica is one of the methods available to GMCs for entering and reviewing data to be submitted to Genomics England. This includes a user interface for data entry and a local database which holds data saved by you.

When you complete and submit data in OpenClinica, an XML file is generated and sent to be validated and accepted by the Genomics England central database (known as Mercury).

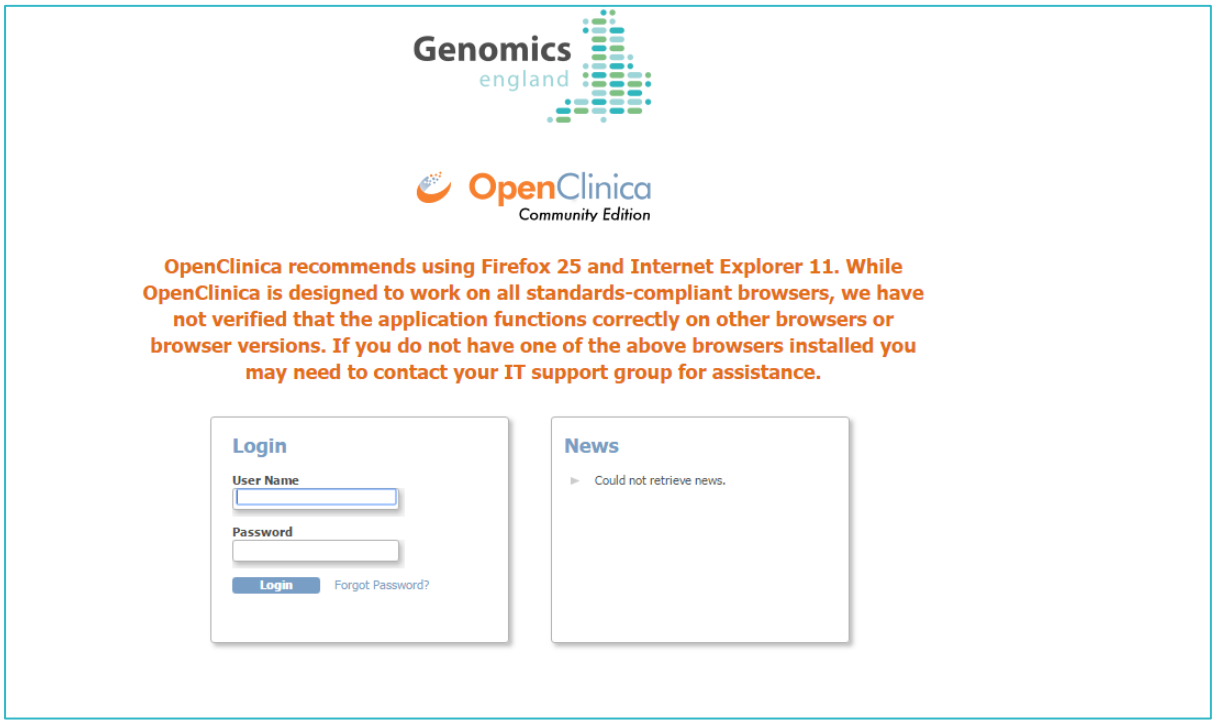
IMPORTANT NOTE – this means it is possible that data you have saved and is visible to you in OpenClinica has not been received by Genomics England.

If you wish to see data that has been submitted and received by Genomics England, you will require access to the data in Mercury, which is achieved through the viewing tool called LabKey.

5 Getting Started

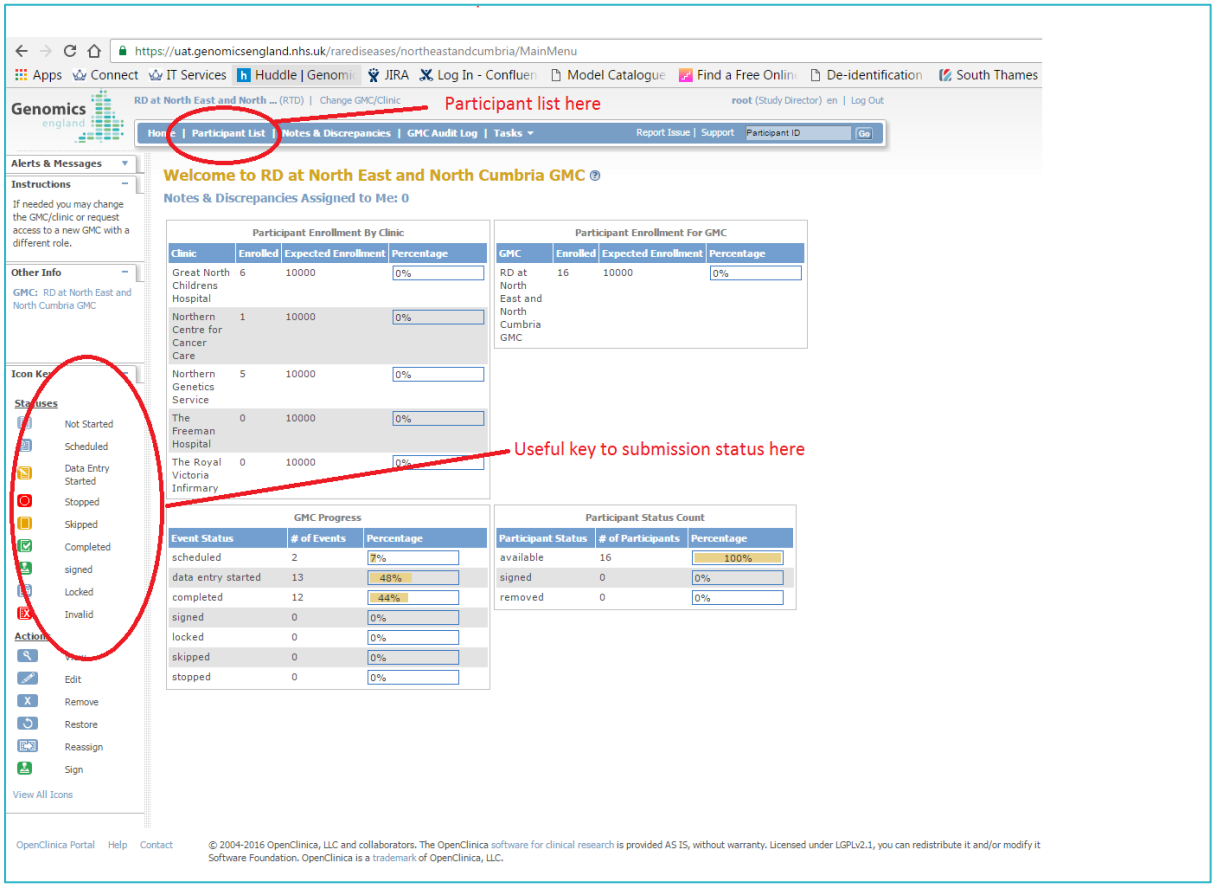
5.1 Log in

Enter your username and password details in the fields provided. If you do not have a username and password and require one, please contact ServiceDesk at ssd.genomics@hscic.gov.uk.



5.2 Home Page

The home page in OpenClinica presents a summary of your activity and submissions. Generally speaking, you will go from here to the participant list.

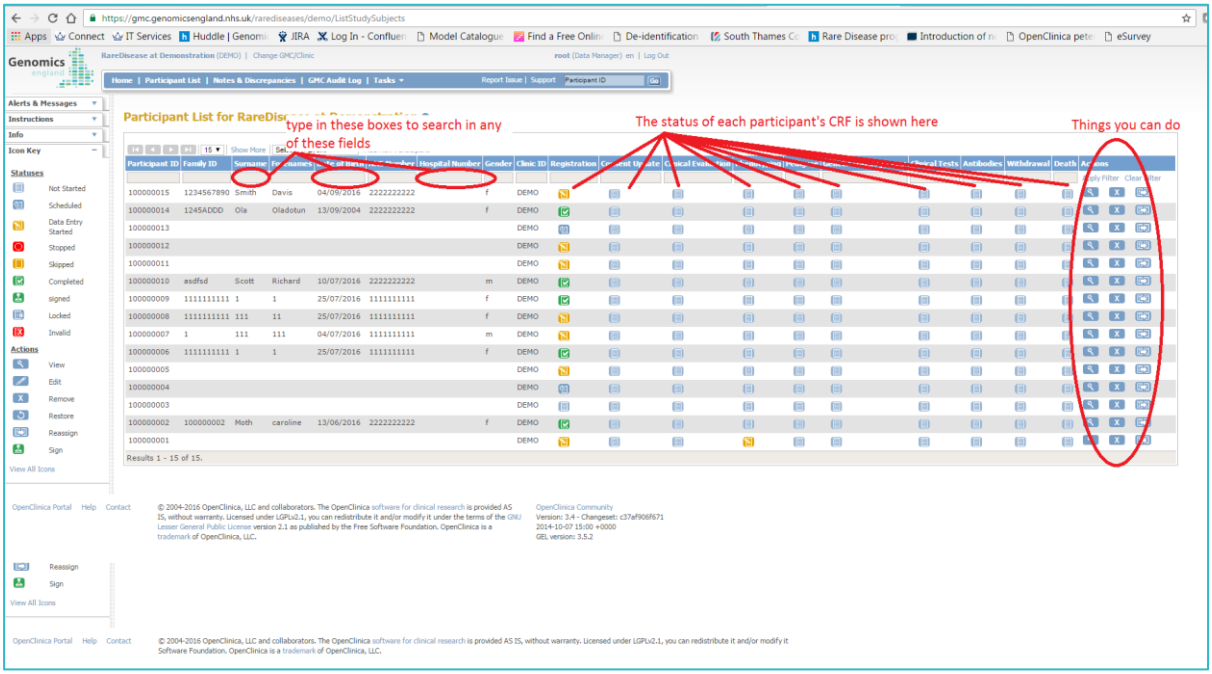


5.3 The participant list

When you click on the link to the participant list, it will take you to a full list of particpants you have previously submitted. This includes participants submitted to Genomics England and those unfinished participants where you have saved the data locally but not yet submitted.

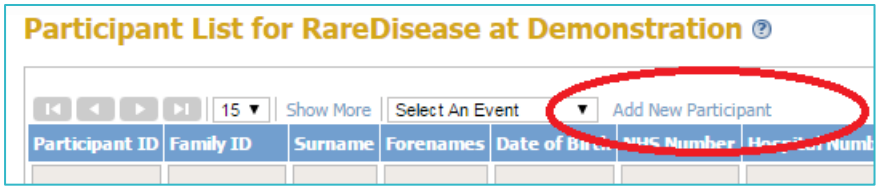
Each participant is shown on their own row, with some identifying information and an icon showing the status for each of the different Clinical Record Forms that you have started or completed working on.

You can search for a participant by participant number, or by typing the information you are looking for into the empty field at the top of any of the columns.

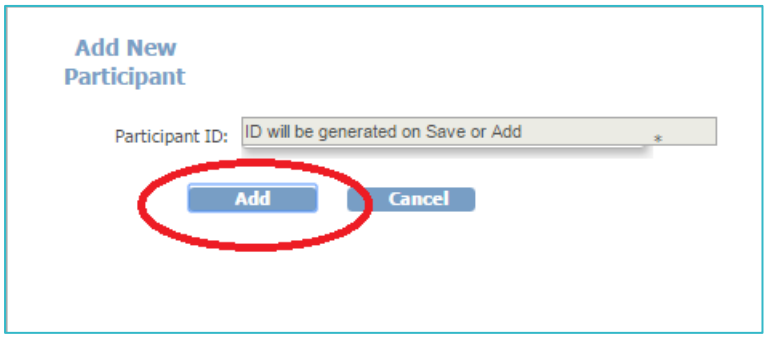


5.4 Adding a new participant

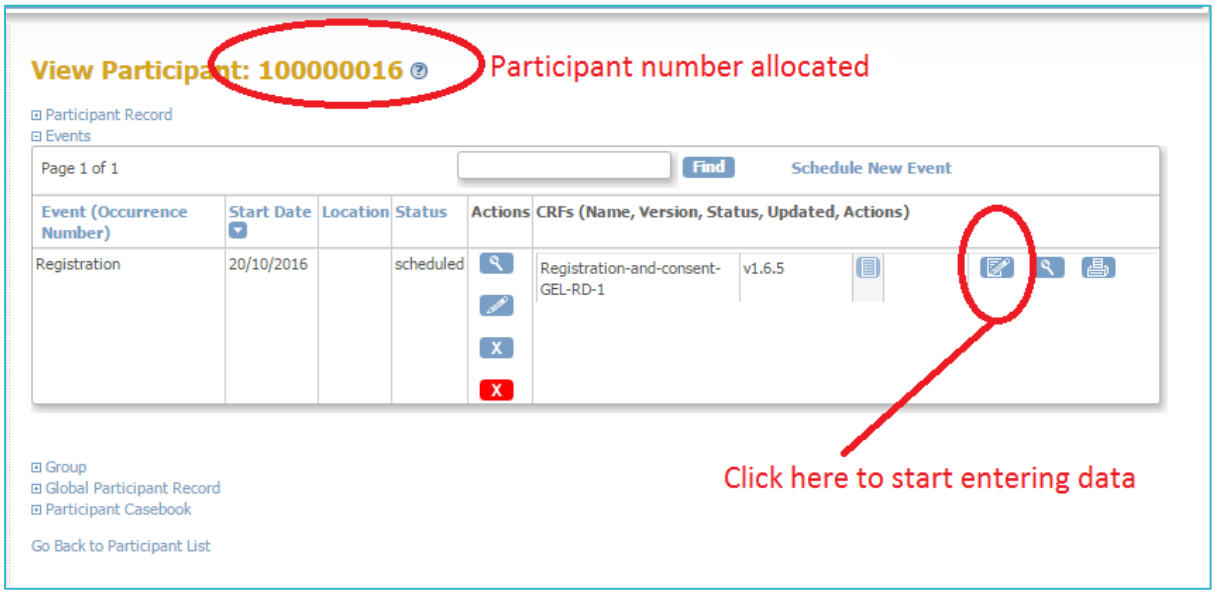
From the participant list, you can add a new participant by clicking on the link shown.



This will generate a pop-up window. If you are certain you wish to add a participant, click 'Add'. Doing this will generate the participant ID for your participant.

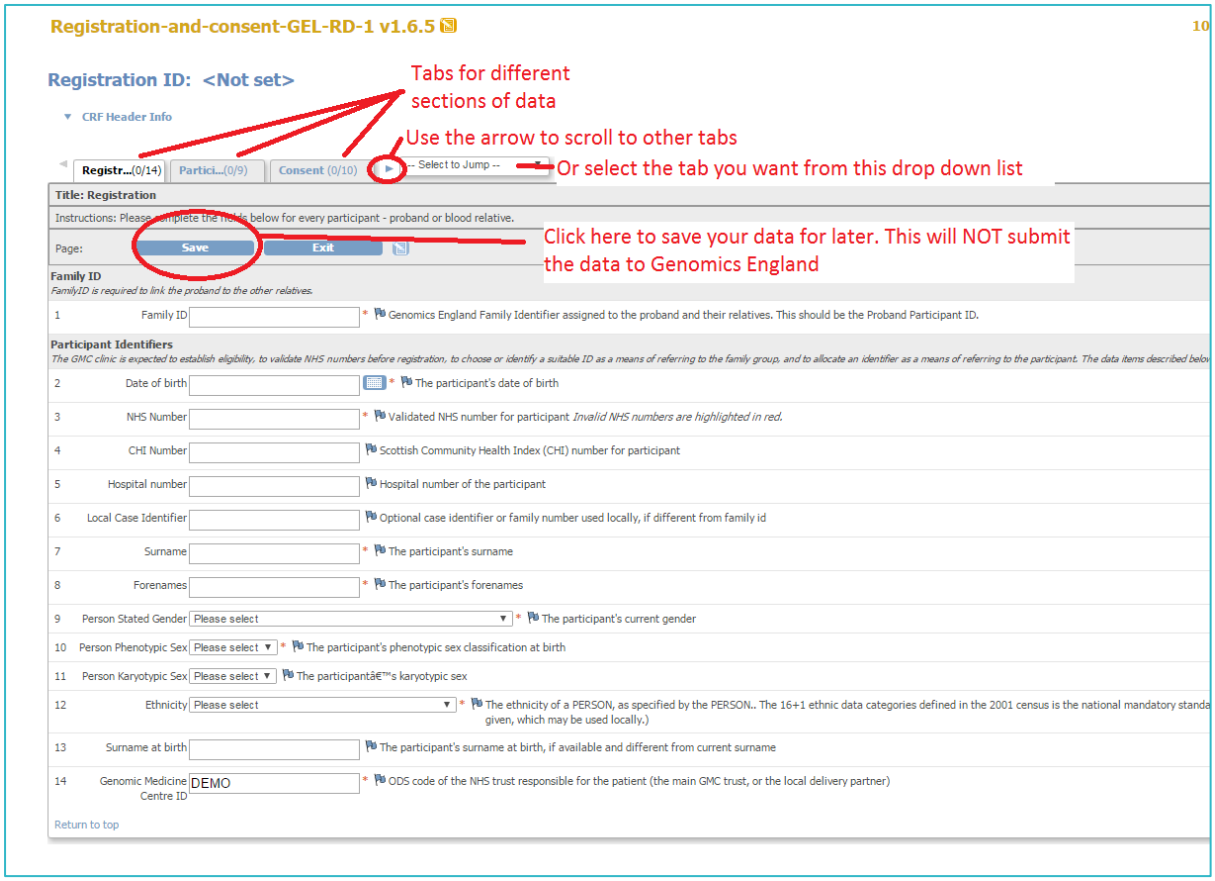


You will then be presented with a screen showing your partipant's allocated number. In order to start entering data by clicking on the icon shown below.



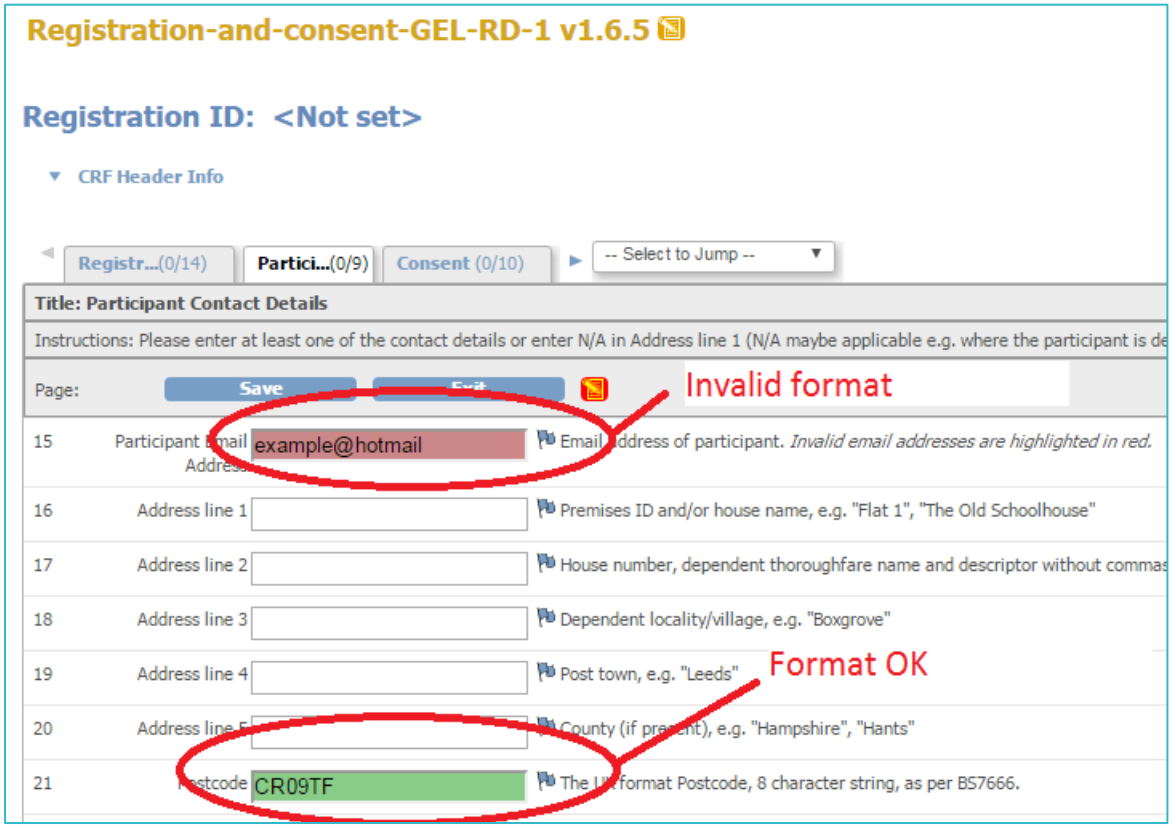
5.5 Starting entering data

Once your participant has been added, you will be presented with the first of the tabs you need to complete in order to submit your data and register your participant with Genomics England.



Clicking on 'save' when a tab is complete will move you to the next tab. Otherwise you can use the scroll arrows, or the drop down list to move to other tabs.

Mandatory fields are marked with an asterisk. Additionally, some fields will only accept data in specific formats e.g. NHS number. In these cases, fields will appear red when data is entered but not valid, and green when entered in a valid format as shown below.

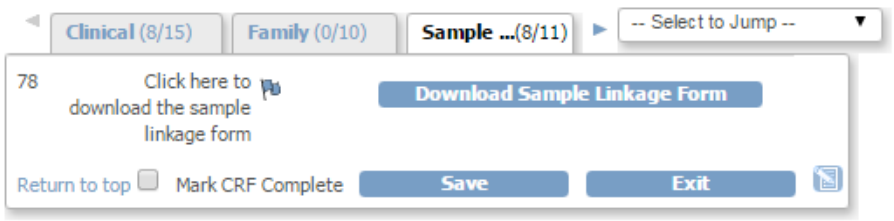


5.6 Download the Sample Linkage Form

The final tab of the registration form allows the user to download a **Sample Linkage Form** containing the NHS number, the Family identifier, and the Genomics England Participant identifier (amongst other information).

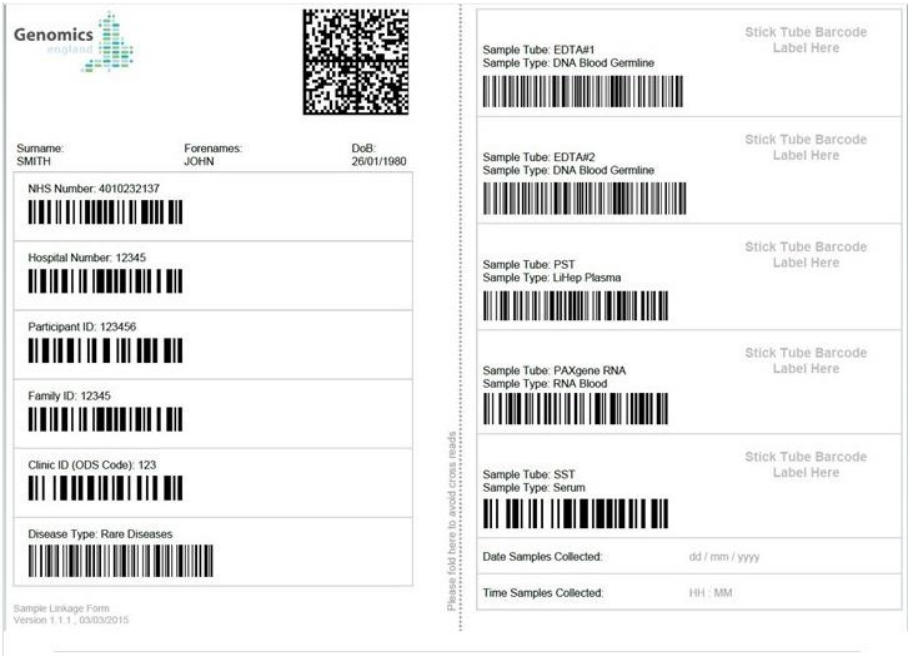
The purpose of this form is to facilitate the entry of data into the GMC laboratory information system (LIMS) used for reporting upon the processing of samples and the dispatch of the extracted products. It can be used instead of, or alongside, a local sample request form.

Once the form has been completed, a paper sample linkage form can be generated:



For Distribution to GMCs

The downloaded, printable form will look like this:

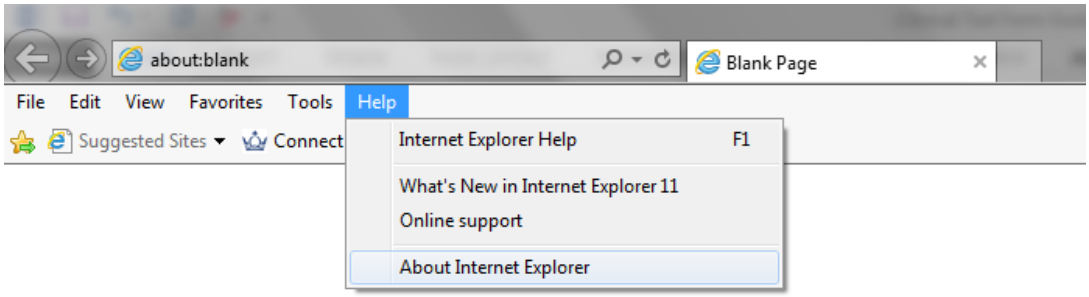


Finally, and most importantly, this last tab allows the user to mark the registration form as complete. This must be done in advance of the dispatch of extracted products to the Biorepository.

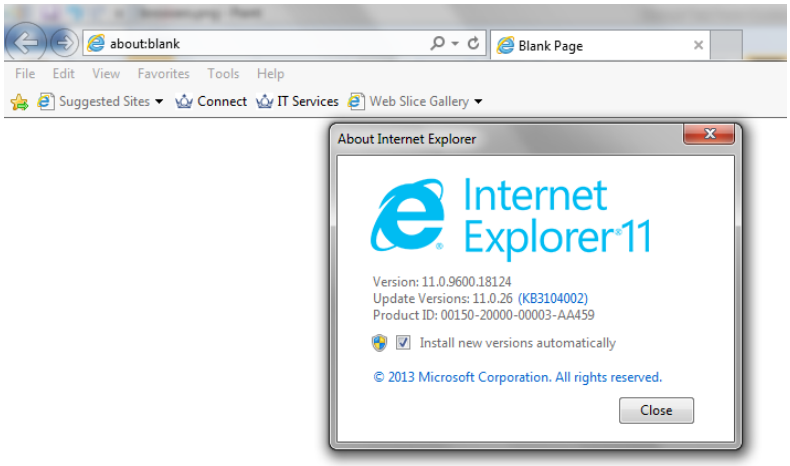
Appendix

5.7 A note on Browsers

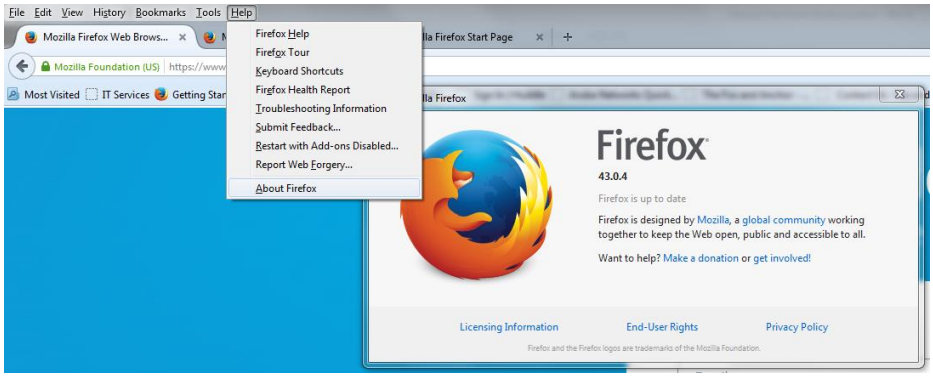
Genomics England is mandated to use specific versions of internet browsers to allow the use of CRF forms within the EDCT, which is an Openclinica based application. Openclinica recommends using Firefox version 25 and Internet Explorer 11. Genomics England cannot guarantee the functionality of the application when other browsers are used.



To check the name and version of your version of Internet Explorer select **About** from the Help heading on the main Menu bar.



Firefox is similar, **Main Menu** then **Help**, then **About.** Note you may need to add the Menu bar by right clicking at the top pf the screen.



Please consider alternatives to the Genomics England support desk when using browsers which have not been specified for use with this application.