

# Introduction to OpenClinica

## A Genomics England Quick Guide

		Document Record ID Key	
<b>Work stream</b>		<b>Status</b>	
<b>Programme Director</b>		<b>Version</b>	V1.1
<b>Document Owner</b>	PG	<b>Version Date</b>	13/01/2017
<b>Document Author</b>	RS		

## Document History

The controlled copy of this document is maintained in the Genomics England internal document management system. Any copies of this document held outside of that system, in whatever format (for example, paper, email attachment), are considered to have passed out of control and should be checked for currency and validity. This document is uncontrolled when printed.

### 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
Ewen Rubython	QA and Test
Nuno Pestana	Sequencing and Samples
Helen Stevens	Sequencing and Samples
Caroline Moth	Service Management
Nathan Hicks	Development
Calum Boyd	Business Support

### 1.3 Approvers

This document must be approved by the following:

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

## 2 Contents

### Contents

1.1	Version History .....	1
1.2	Reviewers .....	1
1.3	Approvers .....	1
2	Contents .....	2
3	Introduction .....	2
4	What is OpenClinica .....	2
5	Getting Started.....	3
5.1	Log in .....	3
5.2	Click on the ‘Genomics England Portal’ folder .....	<b>Error! Bookmark not defined.</b>
5.3	GMC Portal Views.....	<b>Error! Bookmark not defined.</b>
6	Appendix .....	6
6.1	Browsers.....	8

## 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).

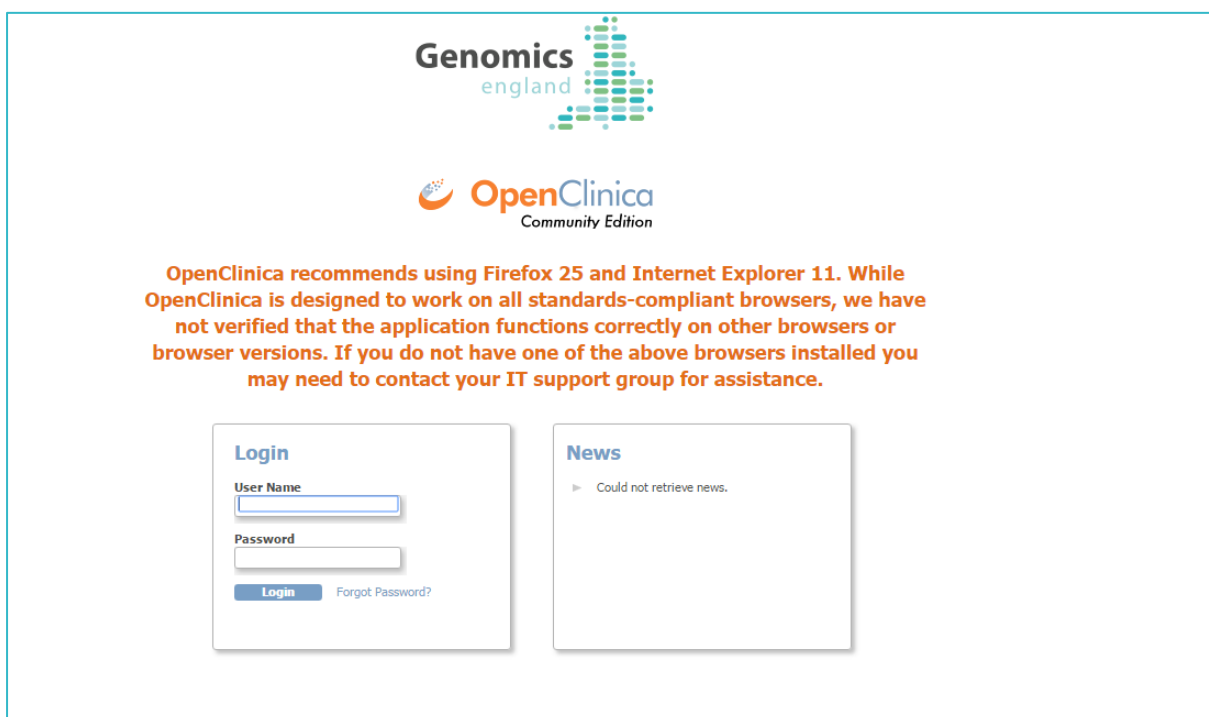
**IMPORTANT NOTE** – this means it is possible that data you have saved and is visible to you in OpenClinica has not been received by Genomics England.

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

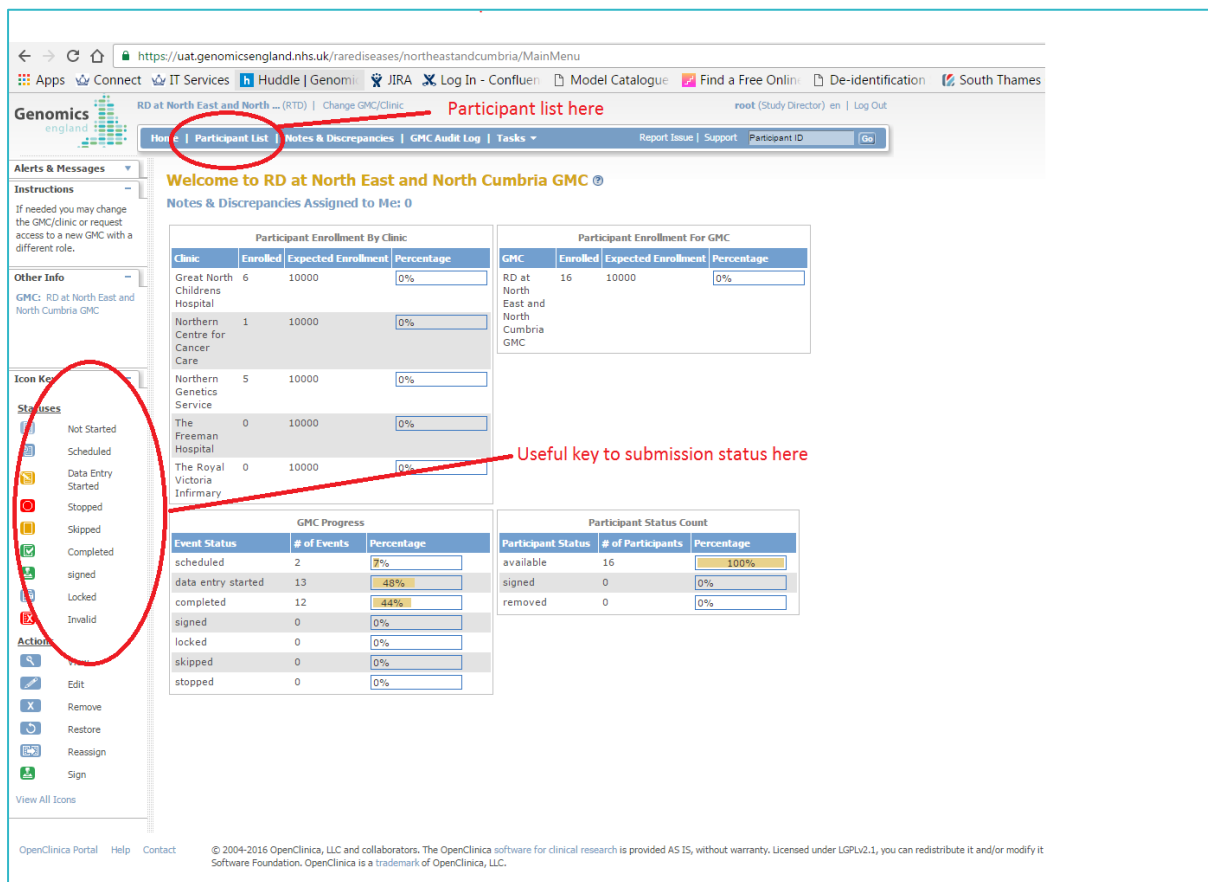
### 5.1 Log in

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](mailto:ssd.genomics@hscic.gov.uk).

A screenshot of the OpenClinica login page. At the top, the Genomics England logo is displayed on the left, and the OpenClinica Community Edition logo is on the right. Below the logos, a message in orange text states: "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." Below this message are two panels. The left panel is titled "Login" and contains two input fields: "User Name" and "Password". Below the fields is a blue "Login" button and a link for "Forgot Password?". The right panel is titled "News" and contains a message: "Could not retrieve news." with a small right-pointing arrow.

### 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.



Participant list here

Useful key to submission status here

Participant Enrollment By Clinic			
Clinic	Enrolled	Expected Enrollment	Percentage
Great North Childrens Hospital	6	10000	0%
Northern Centre for Cancer Care	1	10000	0%
Northern Genetics Service	5	10000	0%
The Freeman Hospital	0	10000	0%
The Royal Victoria Infirmary	0	10000	0%

Participant Enrollment For GMC			
GMC	Enrolled	Expected Enrollment	Percentage
RD at North East and North Cumbria GMC	16	10000	0%

GMC Progress		
Event Status	# of Events	Percentage
scheduled	2	7%
data entry started	13	48%
completed	12	44%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Participant Status Count		
Participant Status	# of Participants	Percentage
available	16	100%
signed	0	0%
removed	0	0%

### 5.3 The participant list

When you click on the link to the participant list, it will take you to a full list of participants 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.

Participant List for RareDisease at Demonstration

type in these boxes to search in any of these fields

The status of each participant's CRF is shown here

Things you can do

Participant ID	Family ID	Surname	Forenames	Date of Birth	HMS Number	Gender	Clinic ID	Registration	Consent Date	CRF Status	Physical Tests	Antibodies	Withdrawal	Death	Actions
100000015	1234567890	Smith	Davis	04/09/2016	2222222222	f	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000014	1245A000	Ola	Oladotun	13/09/2004	2222222222	f	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000013							DEMO	Y							View, Edit, Remove, Reassign, Sign
100000012							DEMO	Y							View, Edit, Remove, Reassign, Sign
100000011							DEMO	Y							View, Edit, Remove, Reassign, Sign
100000010	asdfsdf	Scott	Richard	10/07/2016	2222222222	m	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000009	1111111111	1	1	25/07/2016	1111111111	f	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000008	1111111111	111	11	25/07/2016	1111111111	f	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000007	1	111	111	04/07/2016	1111111111	m	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000006	1111111111	1	1	25/07/2016	1111111111	f	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000005							DEMO	Y							View, Edit, Remove, Reassign, Sign
100000004							DEMO	Y							View, Edit, Remove, Reassign, Sign
100000003							DEMO	Y							View, Edit, Remove, Reassign, Sign
100000002	100000002	Mohd	caroline	13/06/2016	2222222222	f	DEMO	Y							View, Edit, Remove, Reassign, Sign
100000001							DEMO	Y							View, Edit, Remove, Reassign, Sign

### 5.4 Adding a new participant

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

Participant List for RareDisease at Demonstration

15 Show More Select An Event Add New Participant

Participant ID	Family ID	Surname	Forenames	Date of Birth	HMS Number	Health Care Number
----------------	-----------	---------	-----------	---------------	------------	--------------------

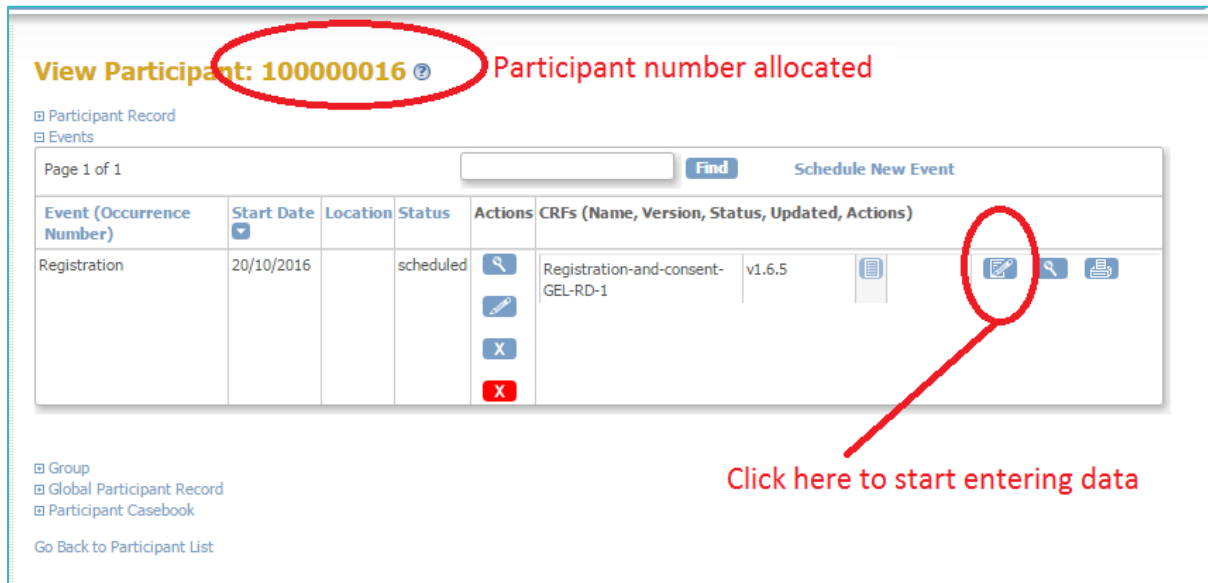
This will generate a pop-up window. If you are certain you wish to add a participant, click 'Add'. Doing this will generate the participant ID for your participant.

Add New Participant

Participant ID: ID will be generated on Save or Add \*

Add Cancel

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



**View Participant: 10000016** Participant number allocated

Participant Record  
Events

Page 1 of 1  **Find** [Schedule New Event](#)

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Registration	20/10/2016		scheduled	<a href="#">View</a> <a href="#">Edit</a> <a href="#">Delete</a> <a href="#">Cancel</a>	Registration-and-consent-GEL-RD-1 v1.6.5 <a href="#">View</a> <a href="#">Edit</a> <a href="#">Print</a>

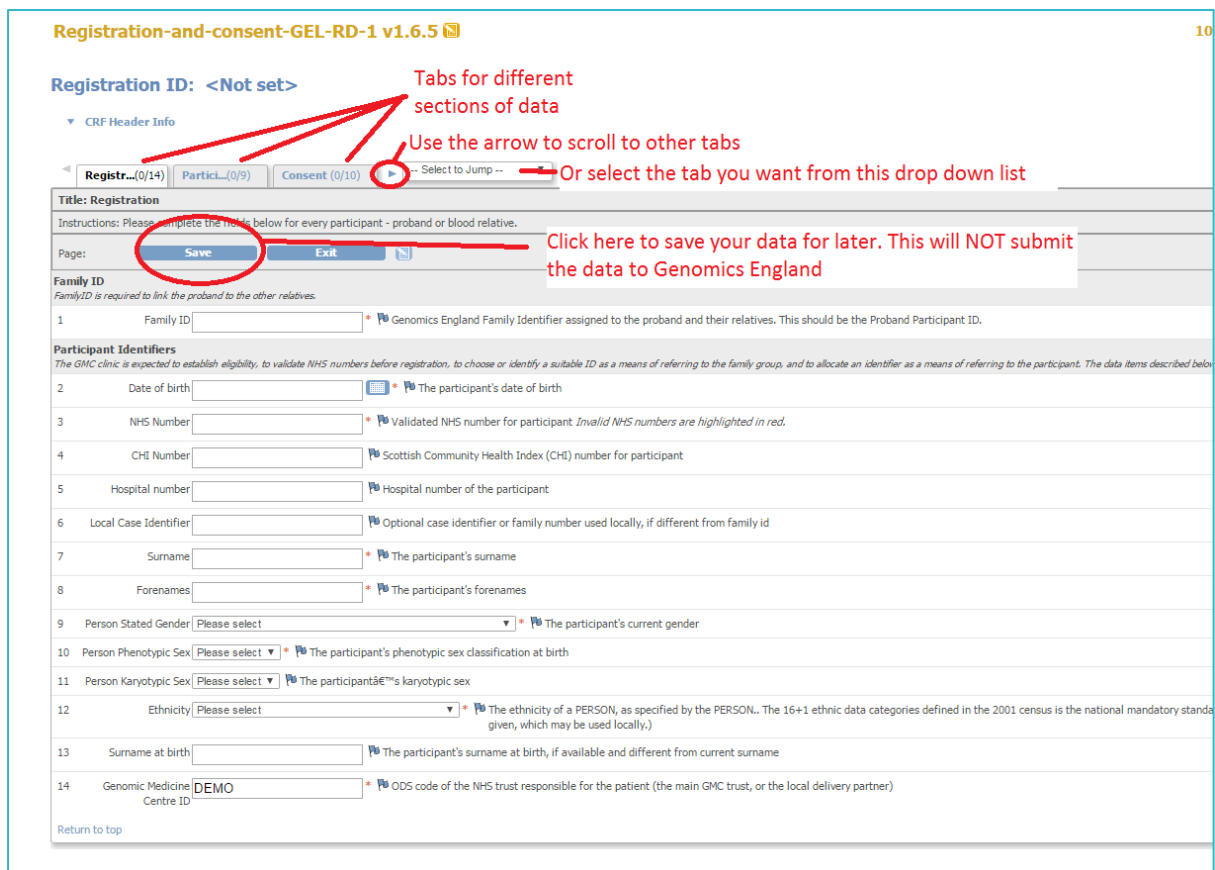
Group  
Global Participant Record  
Participant Casebook

[Go Back to Participant List](#)

**Click here to start entering data**

## 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.



**Registration-and-consent-GEL-RD-1 v1.6.5** 10

Registration ID: <Not set>

CRF Header Info

[Registr...\(0/14\)](#)
[Partici...\(0/9\)](#)
[Consent \(0/10\)](#)
Select to Jump --

Title: Registration

Instructions: Please complete the fields below for every participant - proband or blood relative.

Page: **Save** [Exit](#)

Family ID  
FamilyID is required to link the proband to the other relatives.

1 Family ID  \* Genomics England Family Identifier assigned to the proband and their relatives. This should be the Proband Participant ID.

Participant Identifiers  
The GMC clinic is expected to establish eligibility, to validate NHS numbers before registration, to choose or identify a suitable ID as a means of referring to the family group, and to allocate an identifier as a means of referring to the participant. The data items described below

2 Date of birth  \* The participant's date of birth

3 NHS Number  \* Validated NHS number for participant. Invalid NHS numbers are highlighted in red.

4 CHI Number  Scottish Community Health Index (CHI) number for participant

5 Hospital number  Hospital number of the participant

6 Local Case Identifier  Optional case identifier or family number used locally, if different from family id

7 Surname  \* The participant's surname

8 Forenames  \* The participant's forenames

9 Person Stated Gender  \* The participant's current gender

10 Person Phenotypic Sex  \* The participant's phenotypic sex classification at birth

11 Person Karyotypic Sex  \* The participant's karyotypic sex

12 Ethnicity  \* The ethnicity of a PERSON, as specified by the PERSON. The 16+1 ethnic data categories defined in the 2001 census is the national mandatory standard given, which may be used locally.)

13 Surname at birth  The participant's surname at birth, if available and different from current surname

14 Genomic Medicine Centre ID  \* ODS code of the NHS trust responsible for the patient (the main GMC trust, or the local delivery partner)

[Return to top](#)

**Click here to save your data for later. This will NOT submit the data to Genomics England**

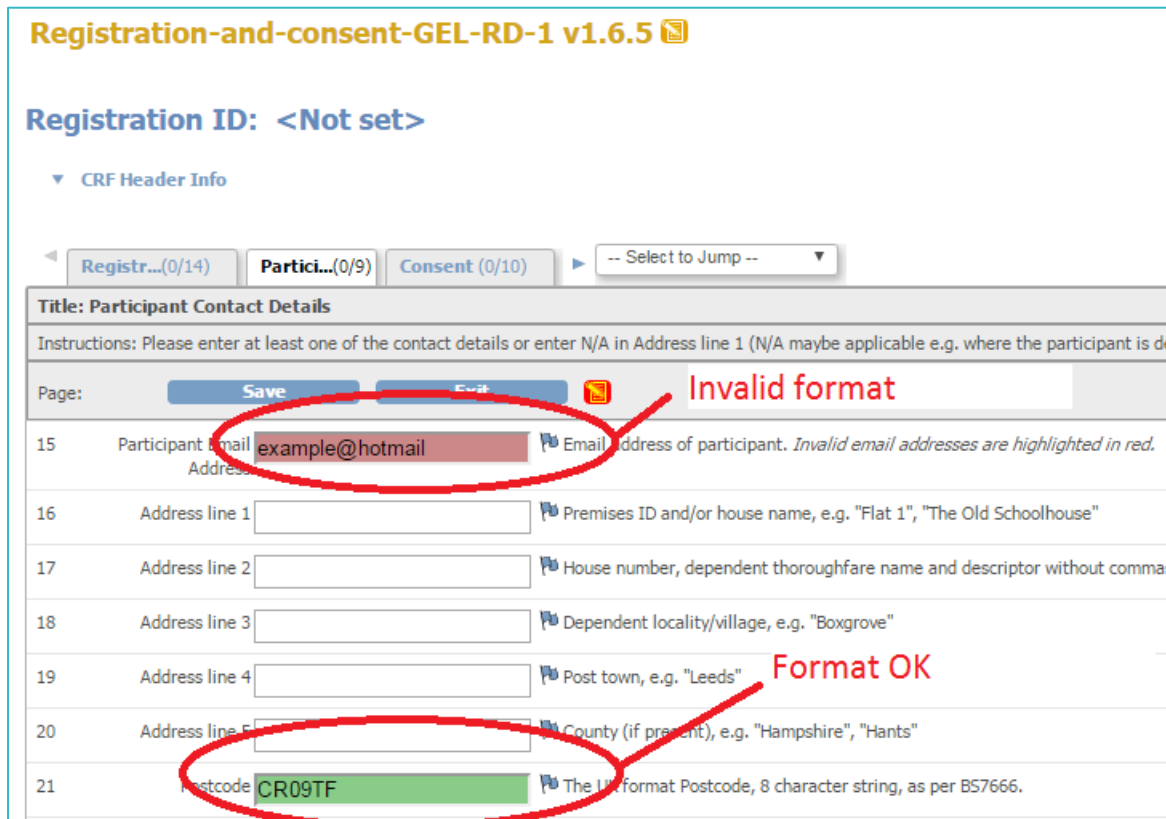
**Use the arrow to scroll to other tabs**

**Or select the tab you want from this drop down list**

For Distribution to GMCs

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.



**Registration and consent-GEL-RD-1 v1.6.5**

Registration ID: <Not set>

CRF Header Info

Registr...(0/14) | Partici...(0/9) | Consent (0/10) | -- Select to Jump --

**Title: Participant Contact Details**

Instructions: Please enter at least one of the contact details or enter N/A in Address line 1 (N/A maybe applicable e.g. where the participant is deceased)

Page: Save Edit

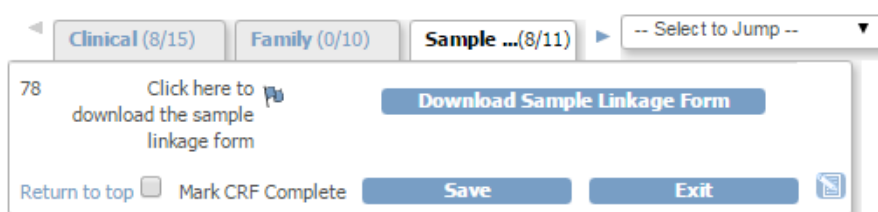
15	Participant Email Address	example@hotmail	Email address of participant. <i>Invalid email addresses are highlighted in red.</i>
16	Address line 1		Premises ID and/or house name, e.g. "Flat 1", "The Old Schoolhouse"
17	Address line 2		House number, dependent thoroughfare name and descriptor without commas
18	Address line 3		Dependent locality/village, e.g. "Boxgrove"
19	Address line 4		Post town, e.g. "Leeds"
20	Address line 5		County (if present), e.g. "Hampshire", "Hants"
21	Postcode	CR09TF	The UK format Postcode, 8 character string, as per BS7666.

## 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:



Clinical (8/15) | Family (0/10) | Sample ... (8/11) | -- Select to Jump --

78 Click here to download the sample linkage form

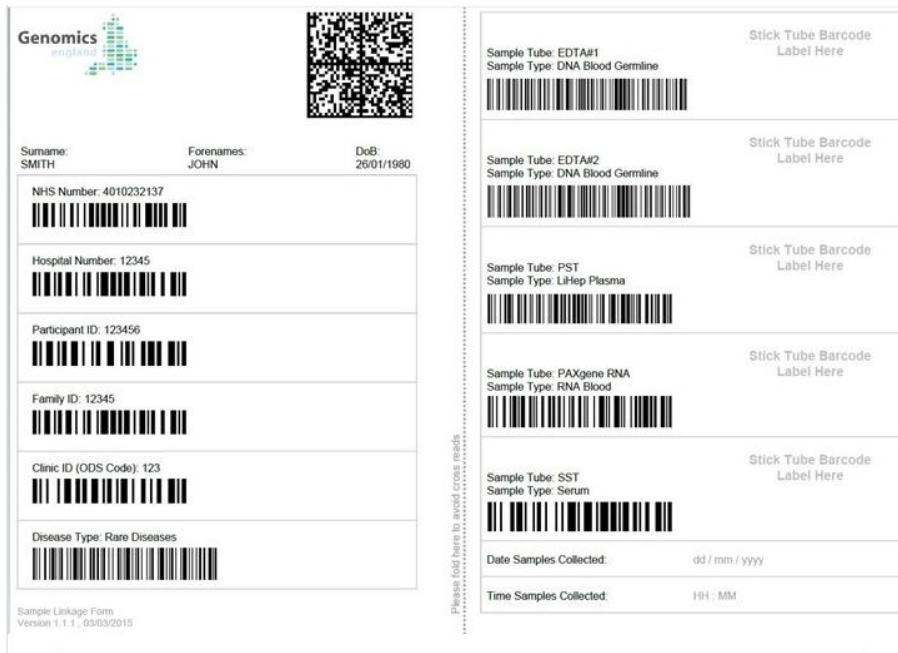
**Download Sample Linkage Form**

Return to top  Mark CRF Complete Save Exit

For Distribution to GMCs



The downloaded, printable form will look like this:



Genomics  
england

QR Code

Surname: SMITH Forenames: JOHN DoB: 26/01/1980

NHS Number: 4010232137

Hospital Number: 12345

Participant ID: 123456

Family ID: 12345

Clinic ID (ODS Code): 123

Disease Type: Rare Diseases

Sample Tube: EDTA#1  
Sample Type: DNA Blood Germline

Stick Tube Barcode Label Here

Sample Tube: EDTA#2  
Sample Type: DNA Blood Germline

Stick Tube Barcode Label Here

Sample Tube: PST  
Sample Type: LiHep Plasma

Stick Tube Barcode Label Here

Sample Tube: PAXgene RNA  
Sample Type: RNA Blood

Stick Tube Barcode Label Here

Sample Tube: SST  
Sample Type: Serum

Stick Tube Barcode Label Here

Date Samples Collected: dd / mm / yyyy

Time Samples Collected: HH : MM

Please fold here to avoid cross reads.

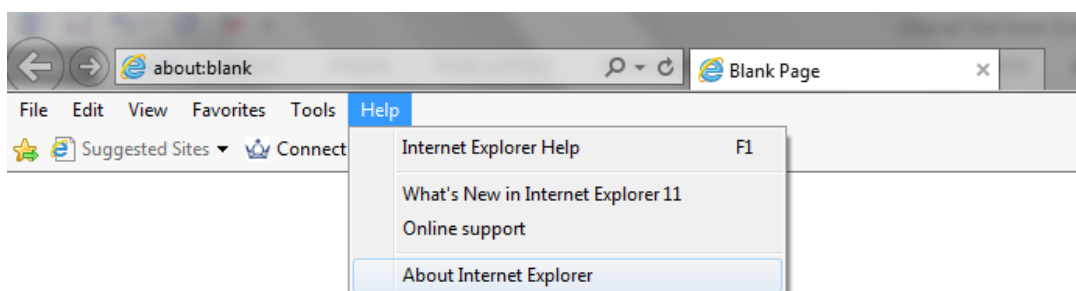
Sample Linkage Form  
Version 1.1.1, 03/03/2015

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.

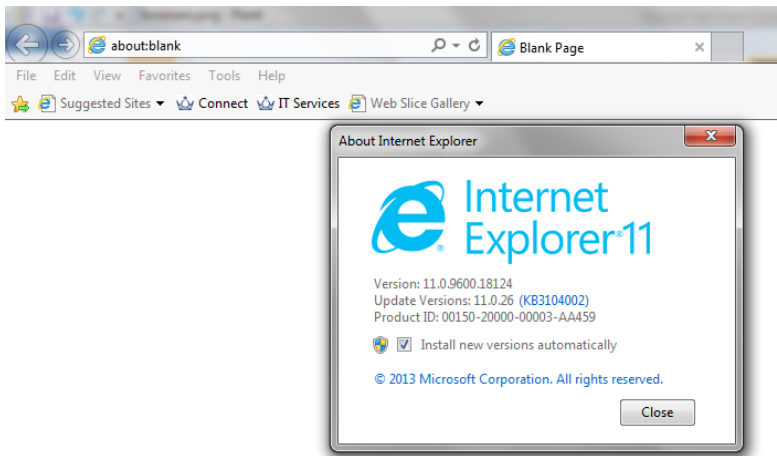
## Appendix

### 5.7 A note on Browsers

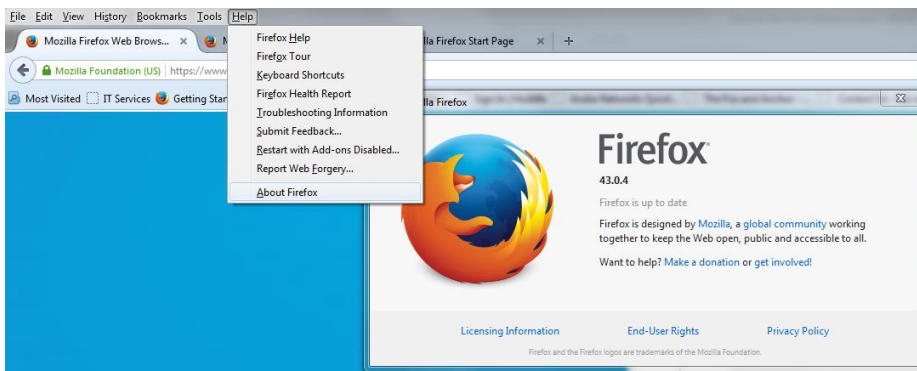
Genomics England is mandated to use specific versions of internet browsers to allow the use of CRF forms within the EDCT, which is an Openclinica based application. Openclinica recommends using Firefox version 25 and Internet Explorer 11. Genomics England cannot guarantee the functionality of the application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