OpenClinica Data Entry Guide

Effect of A Reduction in GFR after Nephrectomy on Arterial Stiffness (EARNEST)

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1.0 Introduction

OpenClinica (OC) is an open source clinical trial software used for capturing data. This document should be used as a guideline for data entry for the EARNEST study. Please note that the OC data base and manual are for both **CORE sites** (measurements include 24hr ABPM, aPWV and isotopic GFR) and **NON-CORE sites** (including 24 hr ABPM as the main measurement). It is expected that you complete data entry within **4 weeks** of the patient visit.

With this manual, you should be able to

1. Create new subjects
2. Enter data
3. View/resolve Discrepancy Notes /Failed Validation checks.
4. Monitor data

2.0 Icons used in OpenClinica

The following icons will be used in OpenClinica.

	Administrative editing		Enter data **CRF**		Schedule an event
	Archive		Export		SDV complete
	Calendar		Form contains changed /unsaved data		Set role
	Completed		Form has unchanged data		Sign
	Create new		Help		Skipped
	Delete		Initial data entry completed		Started
	Discrepancy Note: add		Invalid		Stopped
	Discrepancy Note: closed		Locked **CRF**		Un-archive
	Discrepancy Note: new		New version		View
	Discrepancy Note: not applicable		Not started **CRF**		
	Discrepancy Note: resolution proposed		Print **CRF**		
	Discrepancy Note: updated		Reassign		
	Double data entry		Remove		
	Download		Remove role		
	Edit		Restore		

3.0 Accessing OpenClinica

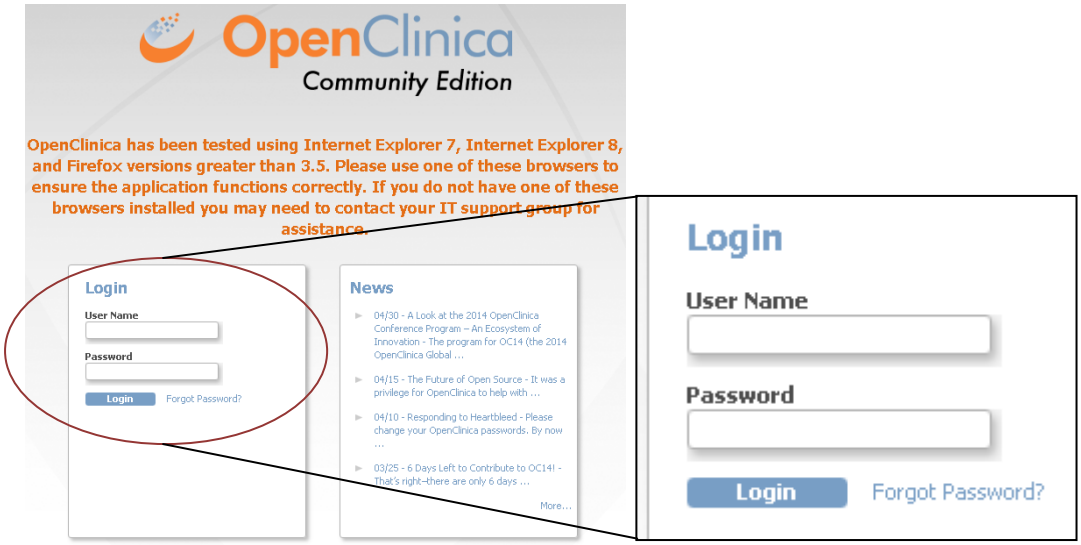
1. To access OpenClinica (OC) open your web browser and navigate to:

http://cctu.medschl.cam.ac.uk/OpenClinica/pages/login/login

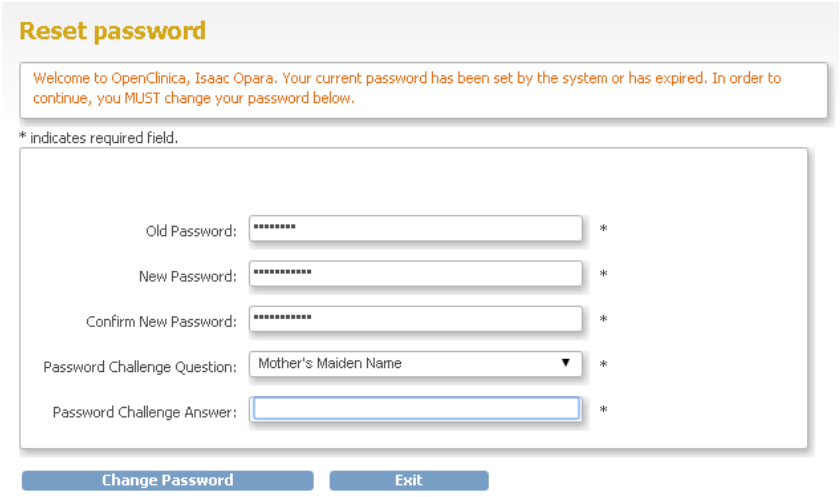
Tip 1: Add this page as a bookmark.

Note: Details of which browser works best with data entry are shown on the login page.

2. The login page will appear as below. Please use the Username/Password provided to you by the data manager to login. Both the Username and password are case sensitive.



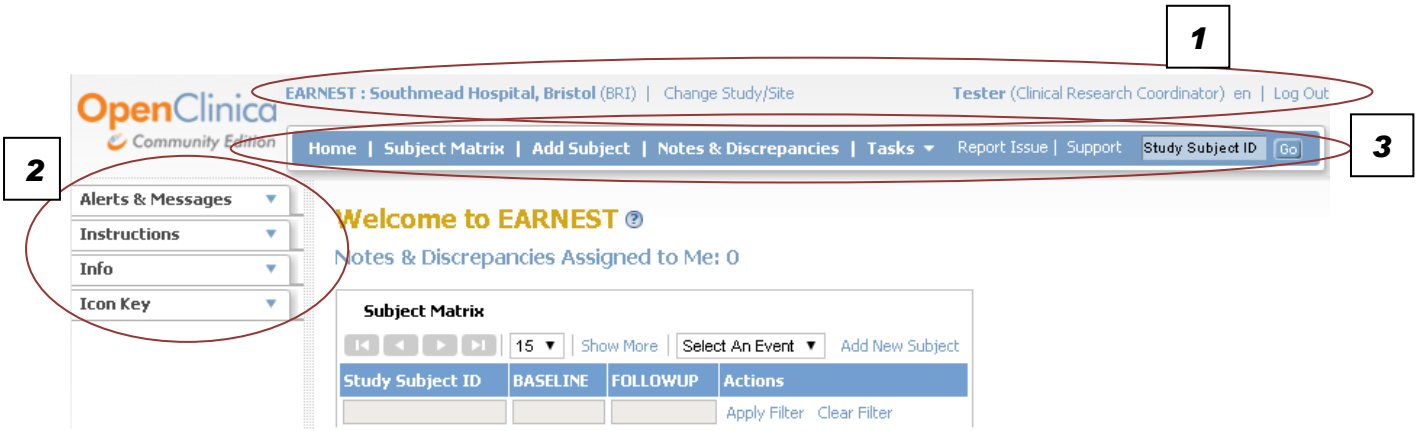
3. The first time you use your password it will expire. You will be prompted to enter your own password immediately after and select change password:



4. The 'Forgot Password?' function is not available in this version of OC, please email Sridevi.nagarajan@addenbrookes.nhs.uk for resetting your password.

4.0 Home Page functions

All data entry users will see the **home page** below once logged-in.



The top panel **[1]** shows the study name, the site, username, role and the **'Log Out'** button.

The left hand tab **[2]** is for information (clicking on the blue arrow will show/hide information).

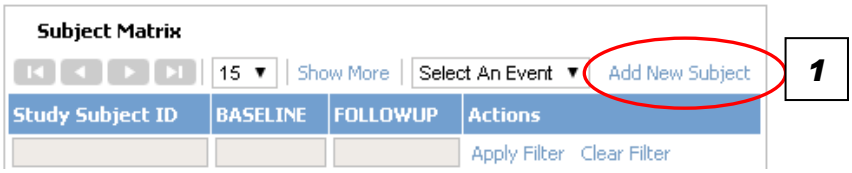
The blue panel **[3]** has several functions (Home and Subject Matrix are the main ones):

a. Home – returns you to the home page
b. Subject Matrix – shows you a table of subjects and events. The table will populate itself once you have added subjects. The matrix will also allow you to 'Add New Subject'.

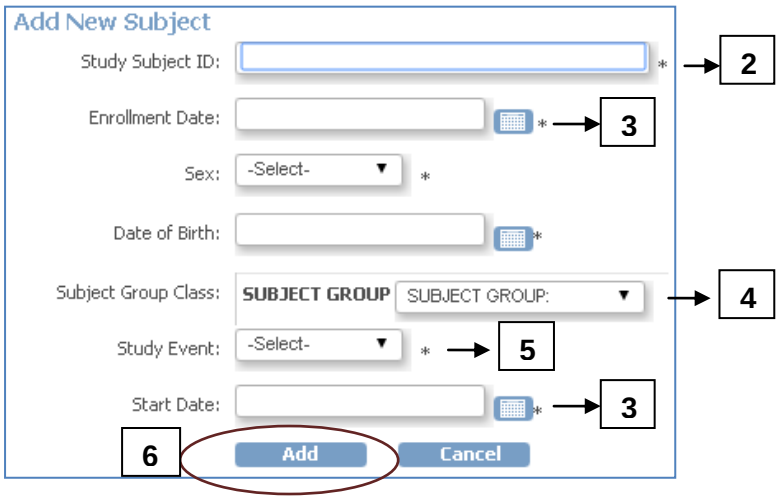
c. Add subject – an alternative way to create a subject
d. Notes and discrepancies – functions include collecting and viewing any missing data (explained further on in the manual in section 9.0)
e. Tasks – The tasks drop down menu will allow you to access a few more shortcuts including the ones in the blue tab Subject Matrix and Add Subject. You will **rarely** need to use this function.

5.0 Creating a subject and a baseline visit

Subjects can be created in a different ways (Subject matrix, Add Subject on the blue panel & Tasks dropdown menu). The **recommended** way is to use the **'Add New Subject'** in the **Subject Matrix [1].**



After clicking on 'Add New Subject' you will be presented with the screen below:



Further guidelines for completing Add New Subject

[2] Subject ID - Please use the table below to choose your Subject ID (e.g. Birmingham = BAM001, BAM002 etc). **Please ONLY use Capital letters for SUBJECT ID**. OpenClinica is case sensitive and therefore will register CAM001 or Cam001 or cam001 as different subjects.

Site Name	Study Subject ID (Range for recruitment)
Queen Elizabeth Hospital, Birmingham	BAM001 - BAM200
Belfast City Hospital, Belfast	BEL001 - BEL050
Southmead Hospital, Bristol	BRI001 - BRI050
Addenbrooke's Hospital Cambridge	CAM001 - CAM200

Site Name	Study Subject ID (Range for recruitment)
University Hospital Coventry	COV001 - COV050
Western Infirmary, Glasgow	GLA001 - GLA050
St.George's Hospital, London	GST001 - GST050
Northern General Hospital, Sheffield	SHE001 - SHE050
Central Manchester Hospital, Manchester	MAN001 - MAN050

[3] Enrolment & Start date – This is the date of **Consent**. You can manually type in the date or use the Calendar icon to navigate through the dates. The only accepted format for the date in OC is **DD-MMM-YYYY e.g. 06-MAY-2014**.

[4] Subject Group – Please choose if the subject is a **Donor or Control.**

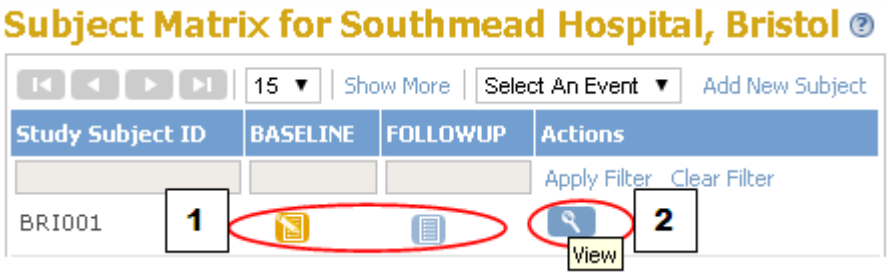
[5] Study Event - please select **BASELINE** ONLY at this stage.

[6] Add Subject: Click on '**Add**' to move onto the next screen/page (see section 6.0 [3]). Click the enter data icon to start data entry.

Note: The registration information will be displayed on the header of each CRF in OC. It is **mandatory** to have the **Subject ID, Date of Enrolment, Gender, DOB** and the **subject group** at the time of registration.

6.0 Data Entry Page

The recommended way for data entry (if you are not starting from 5.0) is from the Subject Matrix. When you have created a baseline event the subject matrix will appear as follows **[1]**:



[2] Click the 'View' icon which will take you onto the following page:

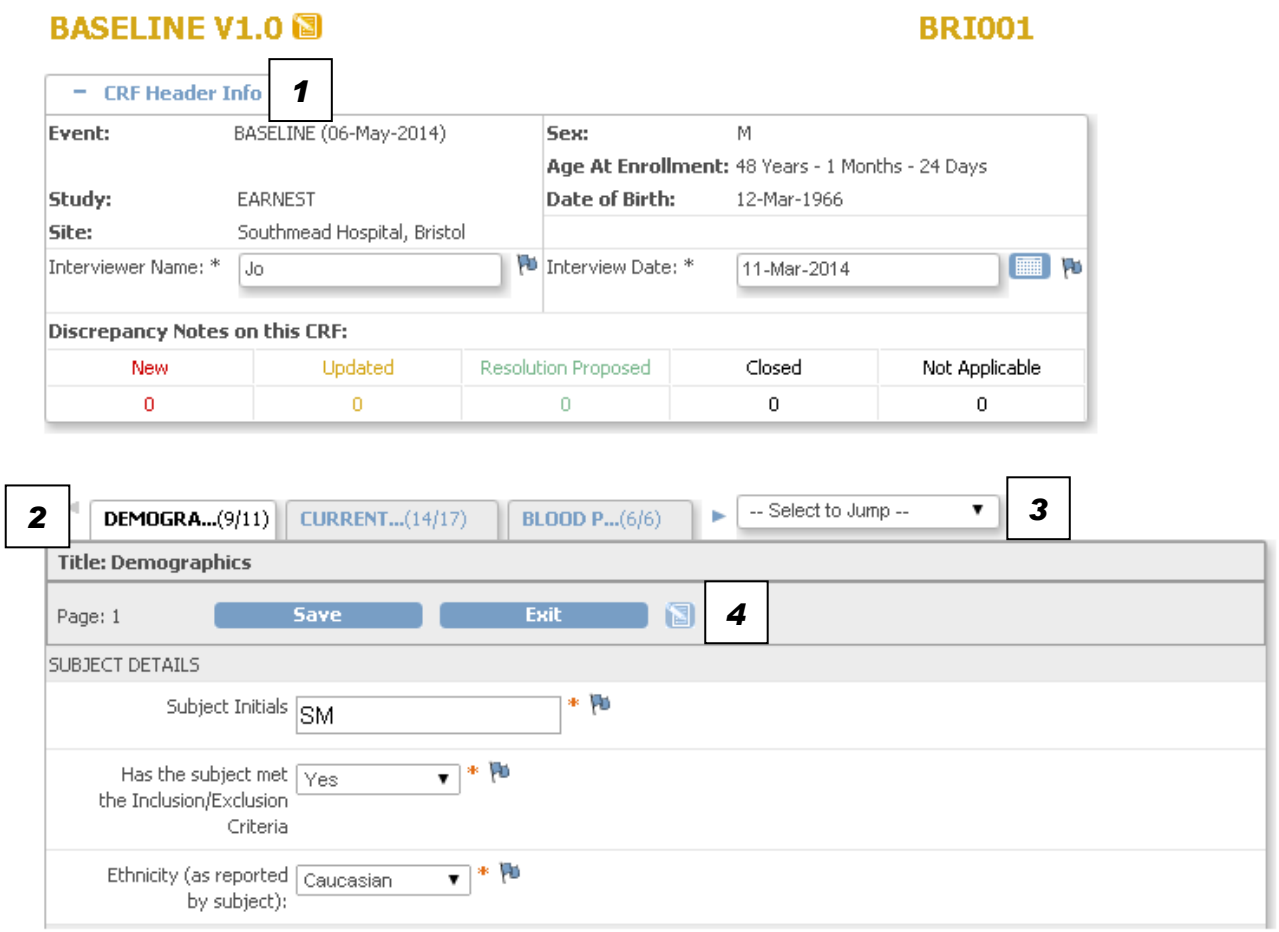
[3] Click the enter data icon to start data entry.

Note: If required you can edit the study event information by clicking on the edit icon in the first 'Actions' column.

[4] When you have 2 events scheduled (see section 8.0) you will see the Baseline and Follow-up data entry boxes in the subject record page as below:

7.0 Data Entry into the CRF

When you start to enter data you will be presented with the following page:



[1] CRF Header: Contains all the information entered in when adding the subject. The CRF header can be hidden by clicking the [-] sign next to 'CRF Header Info'.

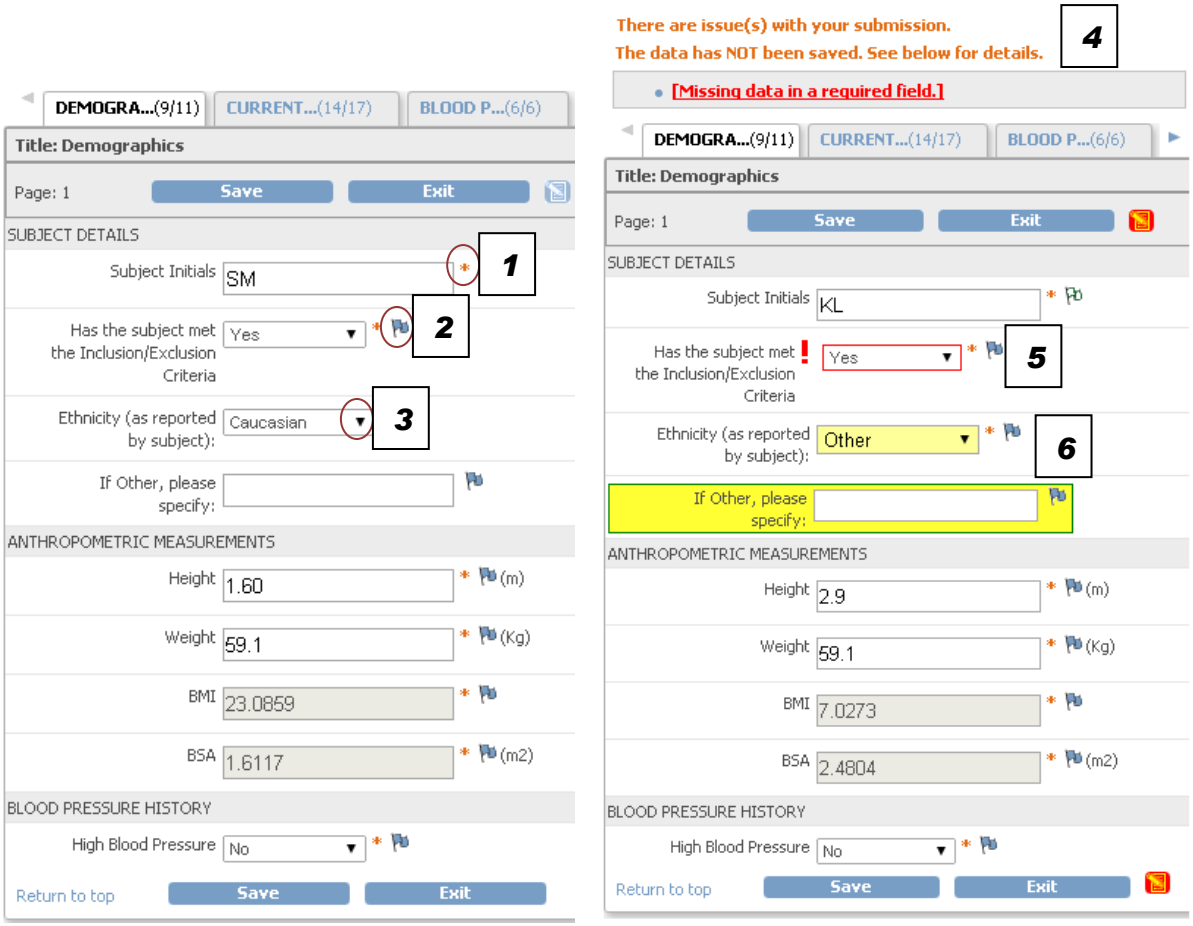
[2] CRF page tabs: You can use these tabs to go between CRF pages.

[3] Select to jump menu: This is a dropdown menu that allows you to select the CRF page directly.

[4] Save/Exit: Important: All the mandatory fields must contain data before a page can be saved. Therefore, it is important to have all the data for the CRF before you start entering data.

CRF page guidelines

Below is a general guide to some of the function on the CRF pages.



[1] * = Red stars are mandatory fields which must be completed before a CRF can be saved.

[2] = Clicking on the flag will bring up a pop-box that will allow you to enter a comment (annotation). Explained in detail in section 9.0.

[3] The arrow is a prompt to bring up a dropdown menu for you to choose the correct value.

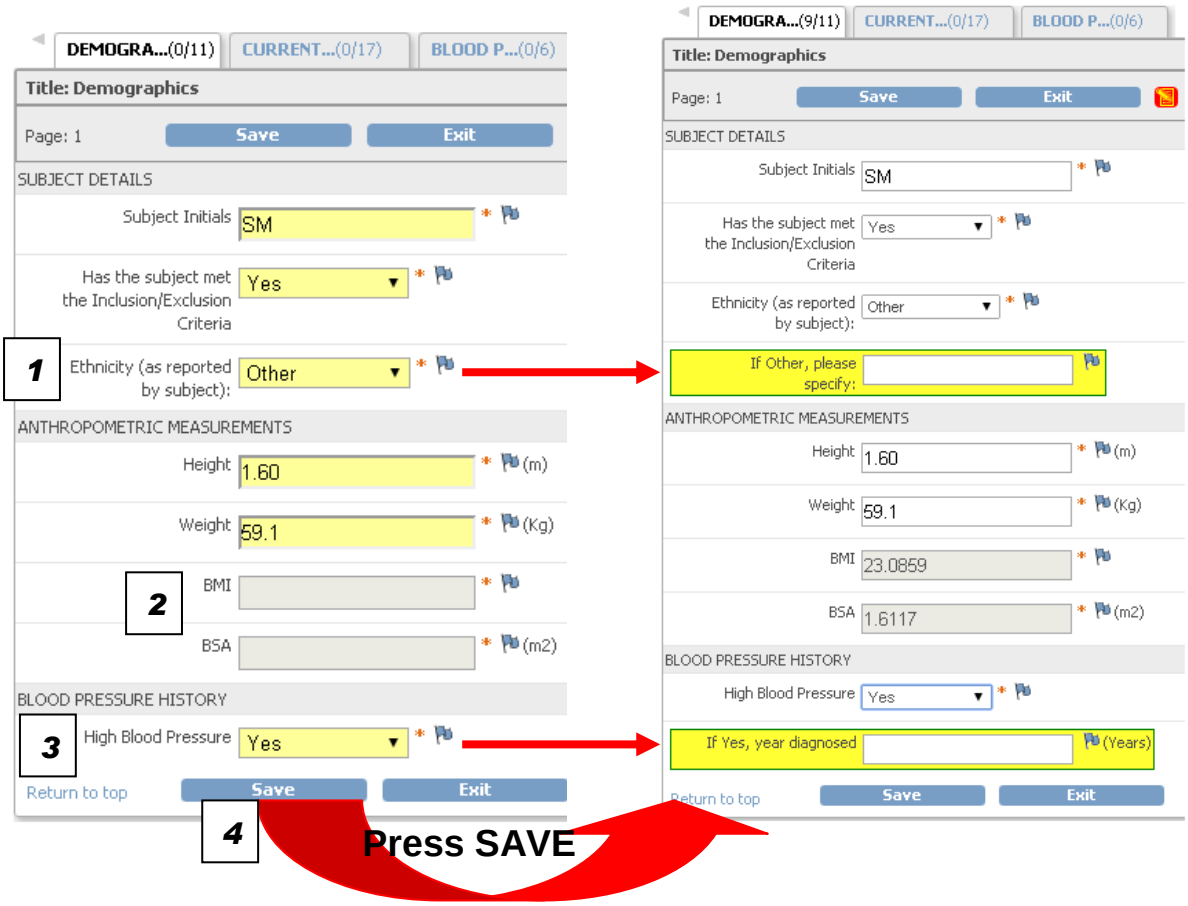
[4] A validation message may appear if for example a field that has been missed on the page

[5] A red exclaimation mark will appear when there is missing mandatory information after you press save.

[6] A yellow highlighted field alerts the user that information has been entered into a field or after pressing save there is extra information that is required to be filled.

Demographics CRF

The demographics page will appear as below on the left:



Most fields are self explanatory like the subject initials and subject inc/excl criteria.

Guidelines for highlighted fields above:

[1] Ethnicity – If you select 'Other' than an additional field will appear – see [4] below.

[2] BMI/BSA – The BMI and BSA are calculated automatically from the height and weight. Grey blanked out fields represent calculated/derived fields. No data can be entered into them.

[3] High Blood Pressure – If you select 'YES' to this field then an additional box will appear – see [4] below.

[4] The additional boxes will appear after you press **'SAVE'. Remember** you must answer all the questions on the CRF before pressing **SAVE** (i.e. there is no need to press save after each question.)

Important note: Once you select 'YES' to a question that reveals an additional box you will not be able to close those boxes if you change your answer to 'NO' later on. Therefore, it is important to make sure that you enter in the correct information from the onset.

Note: This will apply to all CRF pages where additional information is required.

Current Drug Therapy CRF

The Current Drug Therapy page will appear as below on the left:

[1] To enter prescribed medication you need to answer 'Yes' to this question.

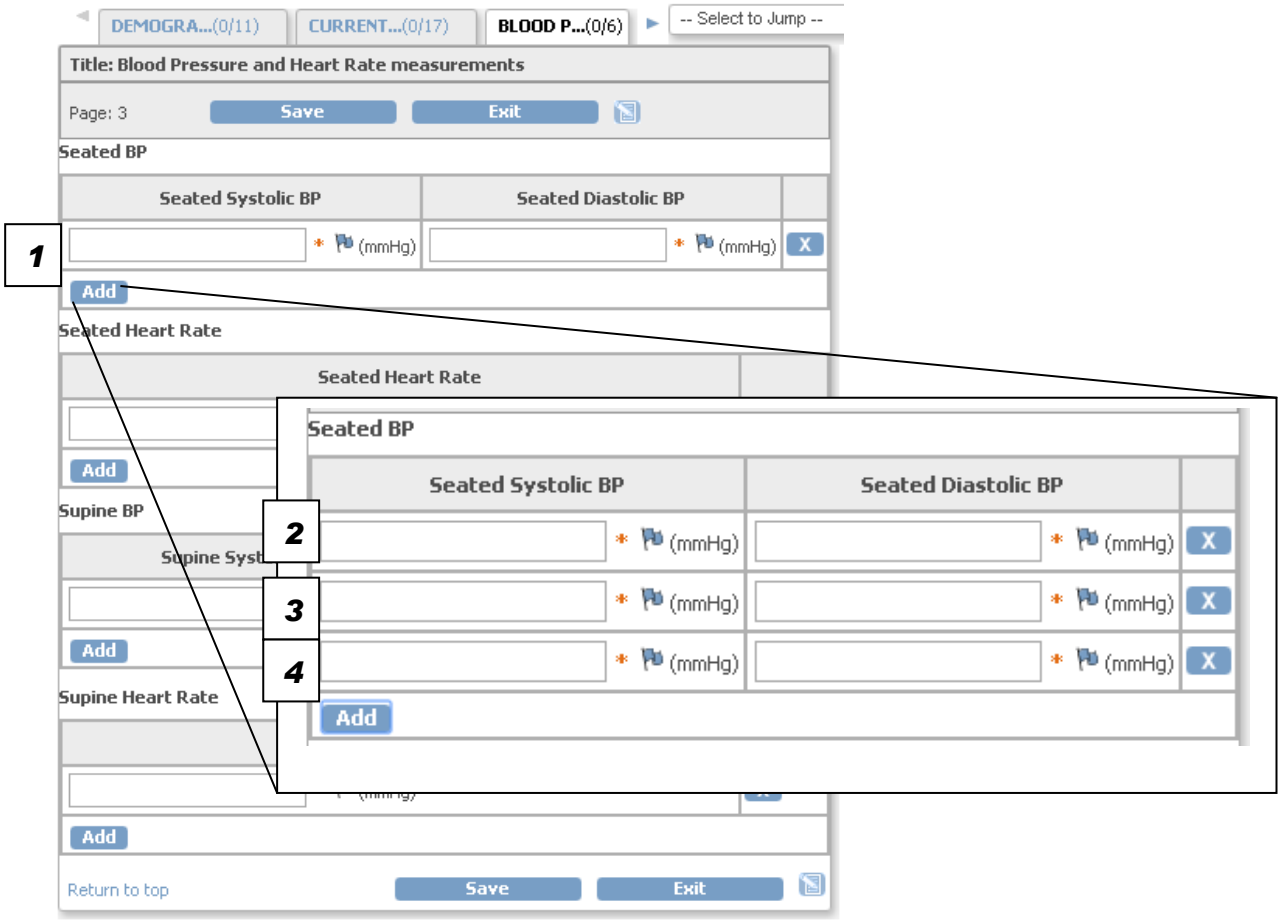
[2] You can ONLY complete this box if you select 'Yes' to [1] and only after pressing **save** (at the end) but you have to complete the whole form first.

[3] If you answer 'YES' to medication for blood pressure then when you press **save** (at the end) a selection of options will appear**.** Select the correct options from the list of drugs.

[4] If you select 'Current or EX SMOKER' then you will see further info boxes. The Total Pack Years will be calculated automatically from the 2 boxes above.

Blood Pressure and Heart Rate measurement CRF

The BP/HR page will appear as below:



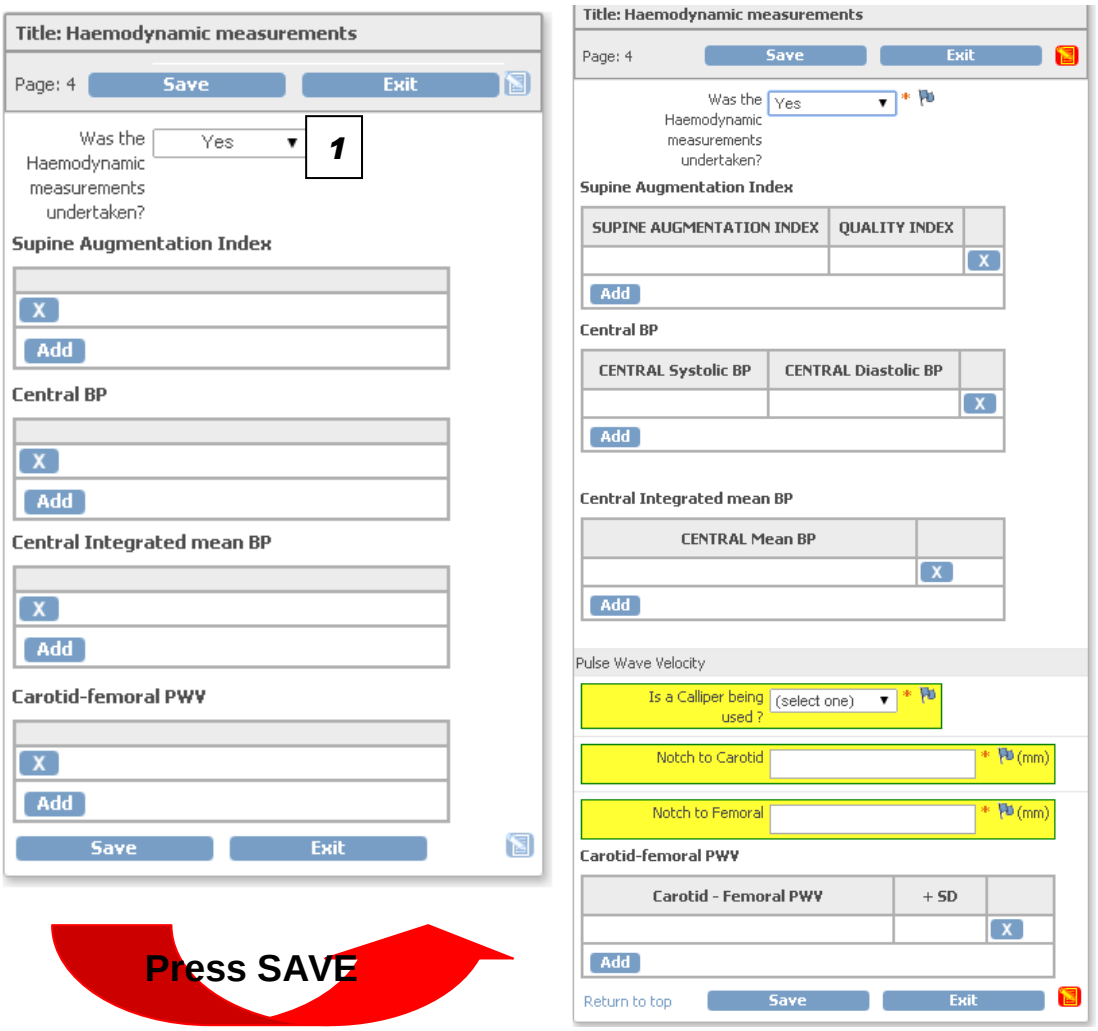
Use the 'Add' button add lines for each individual blood pressure/Heart rate result that you have used to calculate the average and then put the manually calculated average result in the last row. E.g. **[1]**=reading 1, **[2]**=reading 2, **[3]**=reading 3 and **[4]**=average reading. You should aim to replicate the paper CRF/source data.

Hemodynamic Measurements CRF

The Hemodynamic Measurements page will appear as below on the left.

Core Sites

This measurement is for CORE sites only and therefore CORE sites should always select '**YES**' unless none were recorded. In this case you will need to click on the blue flag and select 'Annotation' and supply a reason for not completing (see section 9.0).



[1] As before once you select 'YES', press save to reveal the information boxes.

Non-Core Sites

Please select **'NO'** for this CRF.

Blood and Urine results CRF

The blood results CRF (below) contains all the measurements for both CORE and NON-CORE sites and also the additional Fasting Glucose test which is optional.

Core Sites

[1] Please complete all the fields on the whole page so that they are all highlighted yellow.

[2] Please remember to put units into the Units field.

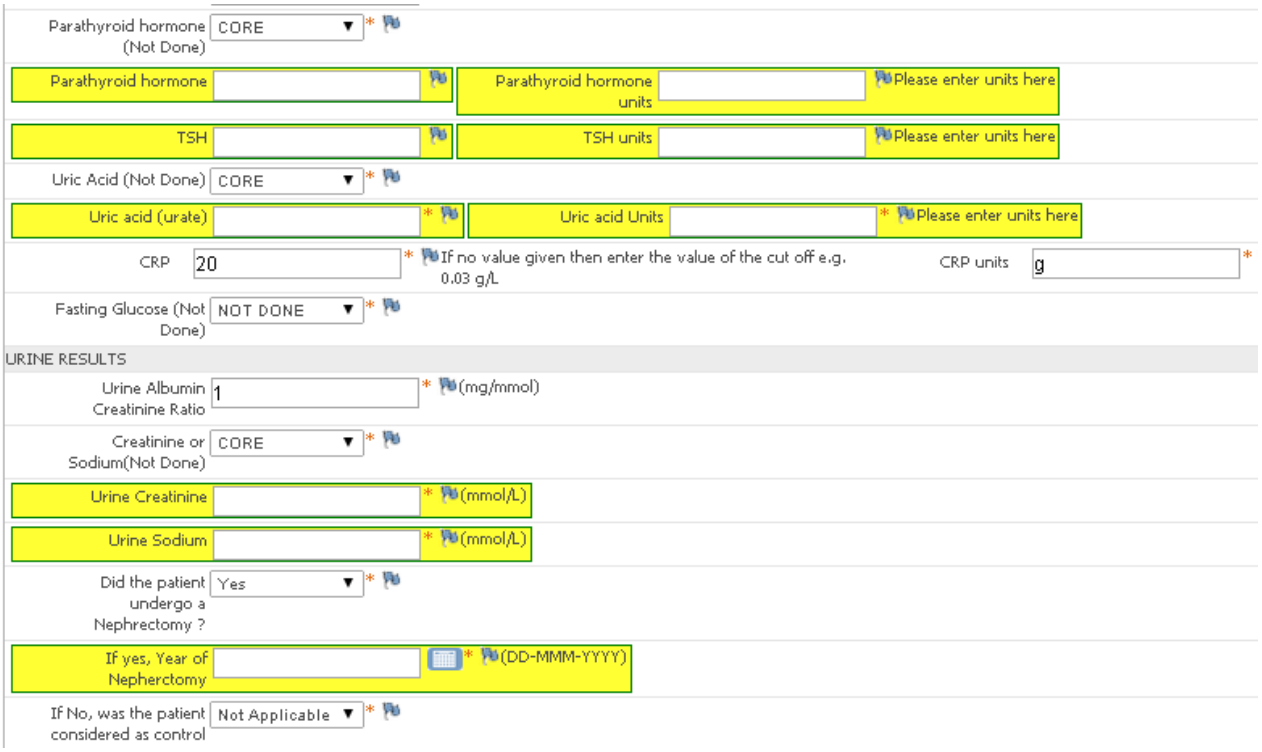
[3] Select '**CORE SITE'** or '**Non CORE**' in **[3]** and **[6]. DO NOT SELECT ANY OTHER OPTION.**

[4] If you have a fasting glucose result for the patient then select '**CORE Site'** otherwise enter **'NOT DONE'**

[5] As before select 'CORE SITE' or 'Non-CORE Site'.

[6] Complete details for nephrectomy here. If 'YES' then put 'N/A' in the next box as above.

After pressing 'SAVE' you should see the additional information boxes to complete as below.

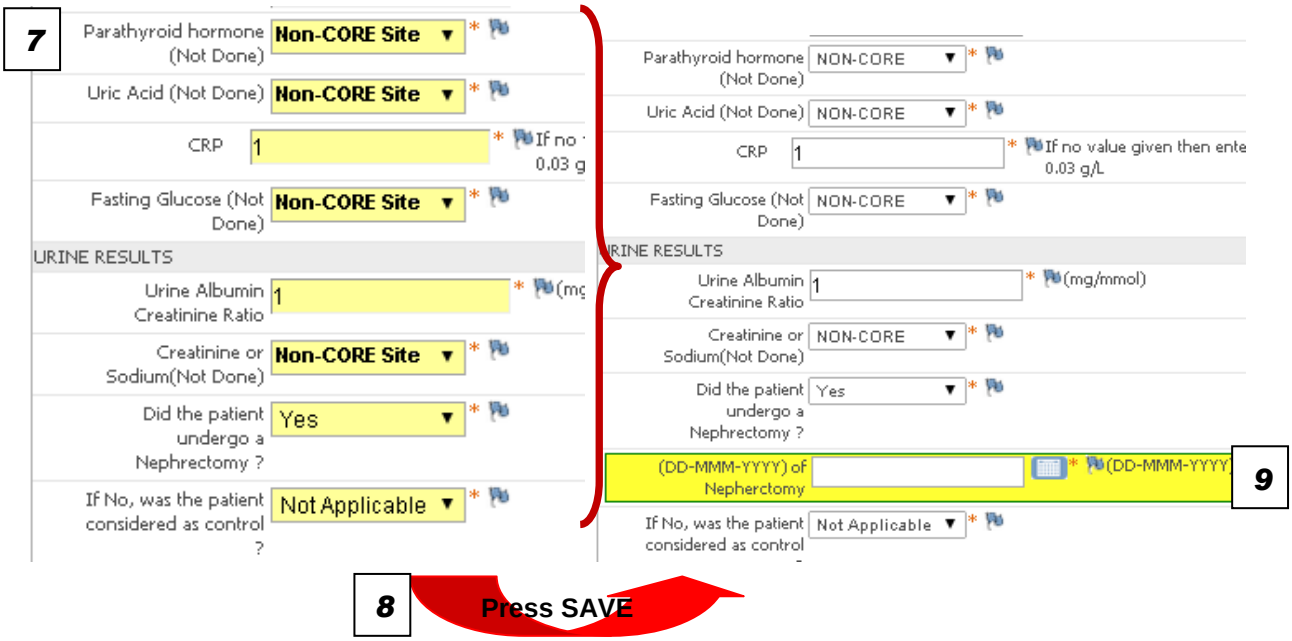


Non-Core Sites

[7] Non-CORE sites should populate as below. **DO NOT SELECT ANY OTHER OPTION.**

[8] Press save which will show you the screenshot on the right below.

[9] Please complete the date of the Nephrectomy.



8.0 Creating a Follow-up Visit from the Subject Matrix

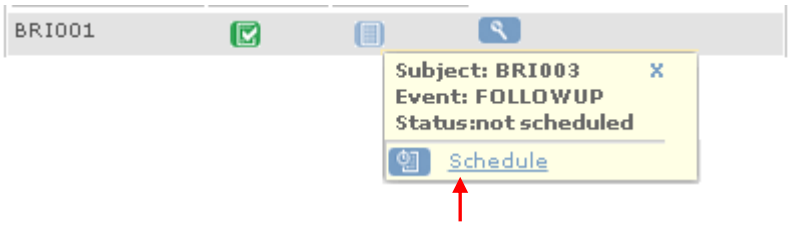
For EARNEST there are 2 visits for the patient (Baseline and Follow-up). When the patient arrives for Follow-up in 1 year you will need to create the follow-up visit.

Schedule a Follow-up visit

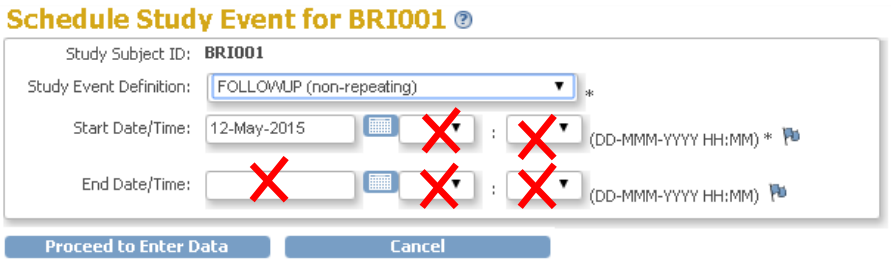
Click on the Subject Matrix. Your subject matrix **[1]** should be populated with a CRF icon that shows data entry is complete for the 'Baseline' column and a blank CRF icon in the 'Follow Up' column as below:

Add a follow-up visit

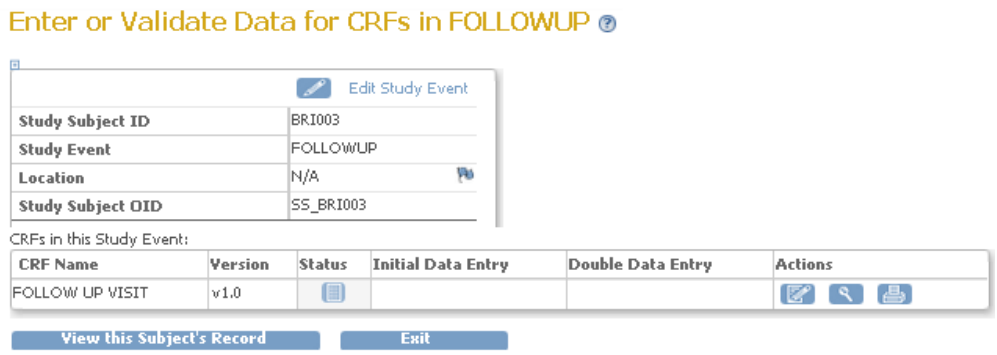
Click on the blank CRF icon



Next, click on the 'Schedule' dialogue button. You will be presented with the screen below which will require you to fill-in the follow-up visit details. There is no need to complete the time and end date details. Click 'proceed to enter data' when finished



Click on 'View this Subject's Record' to take you to the Subject Record page (section 6.0 [4]).



9.0 Notes and discrepancies

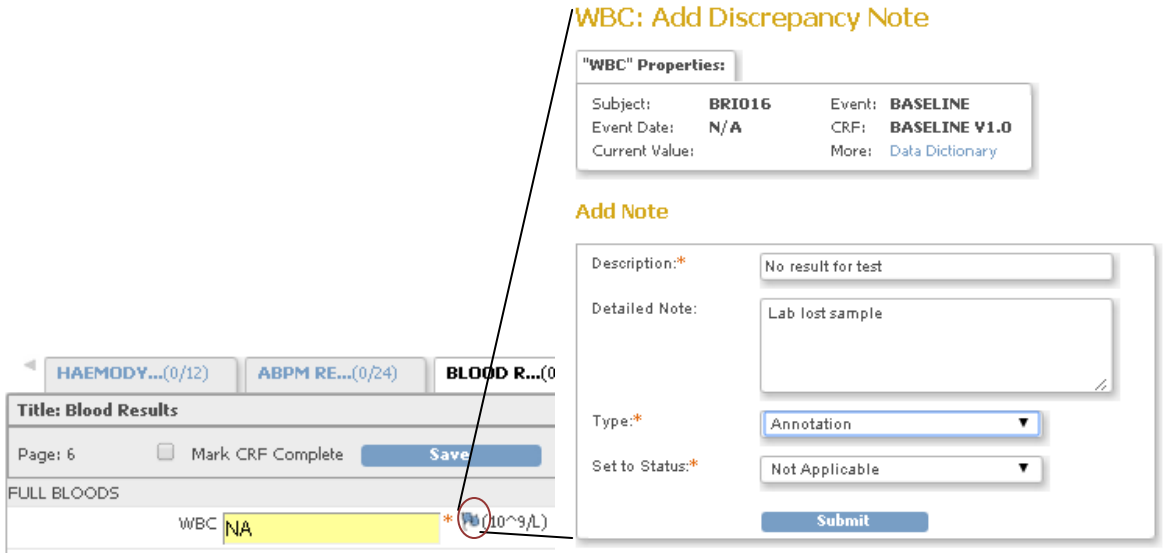
Missing values (Annotation/Explanation)

As explained previously OC does not allow you to save the CRF page until all the mandatory questions have been answered. In some case there will be information that cannot be entered because of a **Missing value** e.g. due to a technical issue.

The recommended way to deal with this issue is:

1. Fill the field in with - **NA** (Not available)
2. Use the blue flag to provide a reason for the missing value

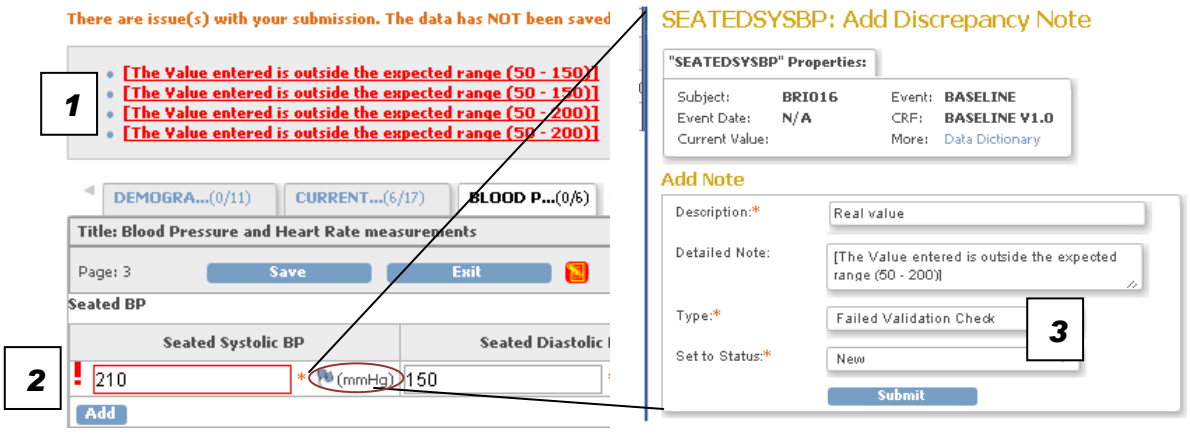
Please see the screenshot below which shows an example of how to populate the 'Note' pop-up page. Remember that a comment or clarification is '**ANNOTATION**' in OpenClinica.



Next click 'submit'. When you save the form the note will be saved and the flag turns Green/White.

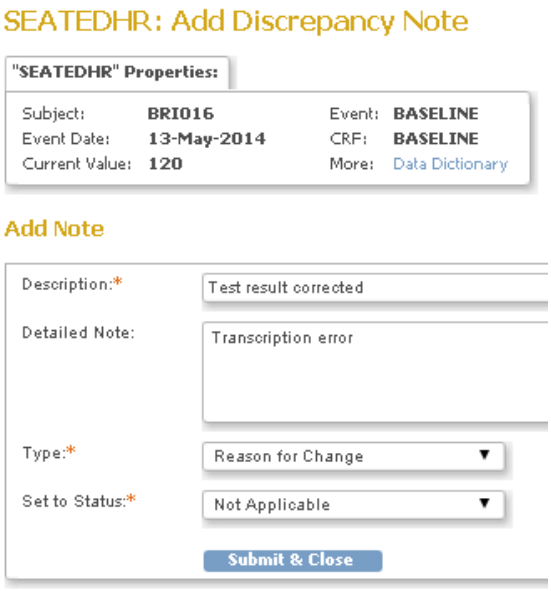
Failed Validation Check

In rare situations you may get a failed validation warning **[1]** even though the value may be correct **[2]**. This scenario will be rare but if this occurs then click the blue flag, enter a reason and select '**FAILED VALIDATION'** in the 'TYPE' dropdown menu **[3].** When you save the form the note will be saved and the flag turns Green/White.



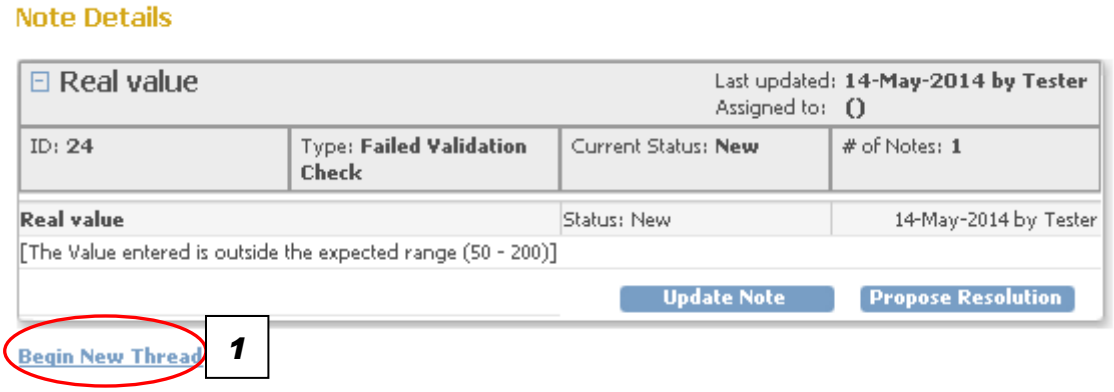
Reason for change

If you have saved a CRF and then want to go back and change a value due to a transcription error then it would be useful to put a comment by clicking the blue flag. Click on field and change the value, then click on the blue flag and provide an explanation and select 'Reason for Change', click submit and save the CRF. When you click back into the CRF the status of the flag will be green and white indicating a comment has been made.



Adding additional notes

If a flag is already Gren and White then you can still add an additional comment by clicking on the flag and selecting the option '**Begin New Thread' [1].**



Viewing Notes & Discrepancies

All Notes/discrepancies raised can be viewed by clicking on Notes & Discrepancies on the blue panel. All the flags will be displayed for that site including reasons for discrepancies. The study coordinator can raise queries with you remotely and change the status of the flag to 'RED' indicating a query. The coordinator may ask you to resolve some queries if required.

Clicking on in the 'Notes & Discrepancies' menu will be take you to that subject's CRF. Below are the various Flag that you may come across.

Blue Flag	Blank - unused flag.
White Flag	Comment – A comment has been made about this field.
Red Flag	Query - A query has been raised that has not been resolved.
Green Flag	Resolution proposed - A response to a red flag query has been provided.
Orange Flag	Update – an update has been added to a query. This query is still open.
Black Flag	Closed – a resolution to a query has been proposed and accepted.

10.0 Signed events

Once CCTU Data Management (DM) have reviewed an entire event and all CRFs are completed and queries are closed, DM can mark the event as SIGNED ( ).

You can still view the data under this status, but please do not change any data after you see a signed form.

11.0 Marking CRF as complete

Please seek the advice of the CCTU data manger.

This is the end of the user guide. Should you have any questions on OpenClinica please contact the Sridevi.Nagarajan@addenbrookes.nhs.uk who will be happy to assist.

END OF DOCUMENT.