



OpenClinica Site Data Entry Guide

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1. Important Notes

1. The trial, events, CRFs and questions displayed in this document may not match the trial, events, CRFs and questions for your trial, but the same principles will apply.

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2. Training Database is always available and is an exact copy of the Live one. Contact the Trial team for access details. Use this to familiarise yourself with the database and to add practice subjects

3. Live Database - Please never add new patient by using 'Add New Patient' link on the Matrix table. Patients are added automatically to OpenClinica upon registration.

2. Accessing OpenClinica

Step 1 – To gain access to access to patient Case Report Forms (CRFs) in OpenClinica, a wet-signed completed staff contact responsibility sheet (SCRS) must be received by OCTO with the delegation option for 'completion of CRFs..' ticked. You will receive an email from OpenClinica detailing your individual user account name and password. The password will expire on 1st use and you will need to enter your own password.

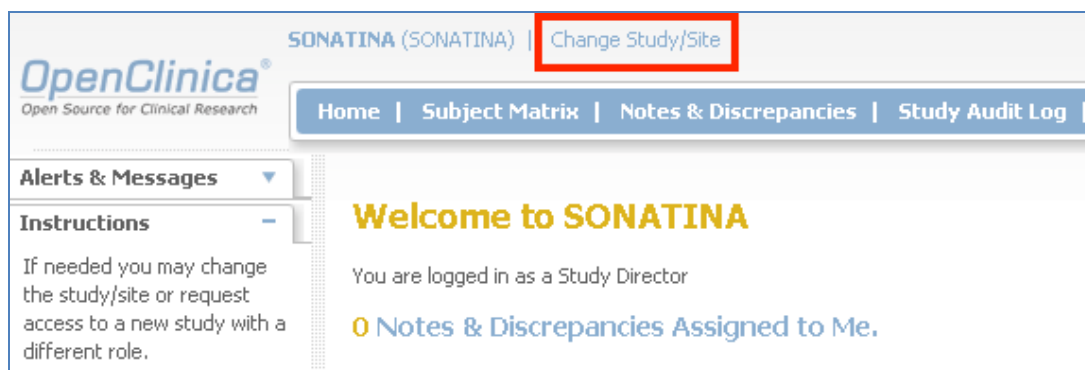
Step 2 - Open your web browser (Internet Explorer 11, Firefox 25 are supported, other browsers may work but are not guaranteed.)

Step 3 – Go to <https://octo-oc.oncology.ox.ac.uk/OpenClinica/> for the live website or https://octo-oc.oncology.ox.ac.uk/OpenClinica_test/ for the training website. N.B. the URLs are case sensitive. We recommend you add these sites to your website favourites for later use.

Step 4 – Log in to OpenClinica. The homepage for the trial you are working on will appear.

- Username structure: 1st initial from 1st name with full surname (all lowercase), i.e. Donald Duck username would be 'dduck'.
- Please note that user name and passwords fields are case sensitive.
- Note that there is a 'forgot password' facility on the log-on page. Trial staff at OCTO can also reset passwords and send username reminders should you need.

Step 5 – If required [only if you work on multiple OC trials] click the 'Change Study/Site' button (as below) to switch and access the correct trial.



The screenshot shows the OpenClinica user interface for the SONATINA trial. At the top, the text "SONATINA (SONATINA)" is displayed next to a button labeled "Change Study/Site", which is highlighted with a red rectangular box. Below this is a navigation bar with links for "Home", "Subject Matrix", "Notes & Discrepancies", and "Study Audit Log". On the left side, there is a sidebar with "Alerts & Messages" and "Instructions" sections. The main content area features a "Welcome to SONATINA" heading, a message "You are logged in as a Study Director", and a notification "0 Notes & Discrepancies Assigned to Me."

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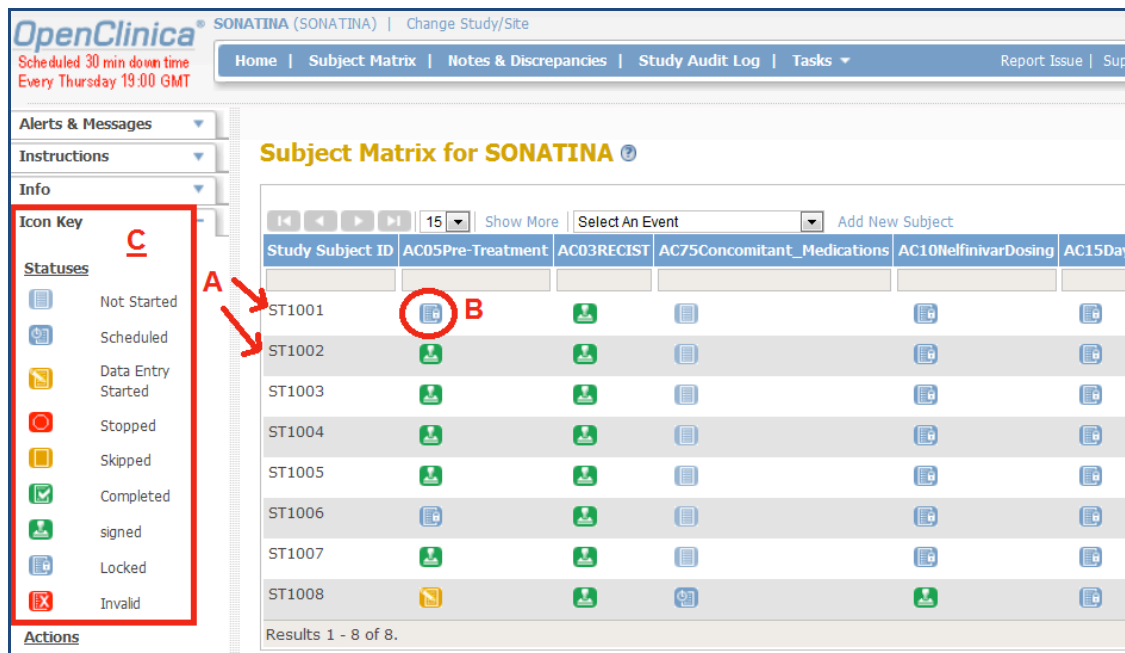
3. Entering Data

3.1 Subject Matrix Familiarisation

You should be initially presented with the subject matrix, if not click the 'Subject Matrix' option in the Header Tool Bar. The matrix gives you an overview of the trial. Across the top of the matrix table you have a row of different columns; each title represents a different time point in the trial where data is collected (each time point title will have several letters or numbers of coding prior to the event description e.g. 'AC05pre-treatment', the coding is unavoidable but is of no significance therefore please do not be concerned by it). In OpenClinica these time points are called and referred to as 'Events'. The events are in the order the patient will attend for their trial visit. i.e. the 1st column would be the event for pre-treatment or the screening visit. Then the next column, 1st treatment event, followed by the 1st scheduled trial assessment, etc. Any exceptions to this will be for events that are used in an ad-hoc manor, such as adverse events or trial withdrawal.

In the subject matrix:

- [See **A** in example below] There is a separate row for each patient registered to the trial by your site.
- [See **B** in example below] Event access point. Each event will contain a CRF or multiple CRFs which need to be completed for that patient time point i.e. the patient visit. The event icon will change as the data entry within progresses – see point [C] below.
- [See **C** in example below] Icon Key. The different icons indicate the status of data entry for each event.



OpenClinica SONATINA (SONATINA) | Change Study/Site

Scheduled 30 min down time Every Thursday 19:00 GMT

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Report Issue | Sup

Subject Matrix for SONATINA

Study Subject ID	AC05Pre-Treatment	AC03RECIST	AC75Concomitant_Medications	AC10NelfinavarDosing	AC15Da
ST1001					
ST1002					
ST1003					
ST1004					
ST1005					
ST1006					
ST1007					
ST1008					

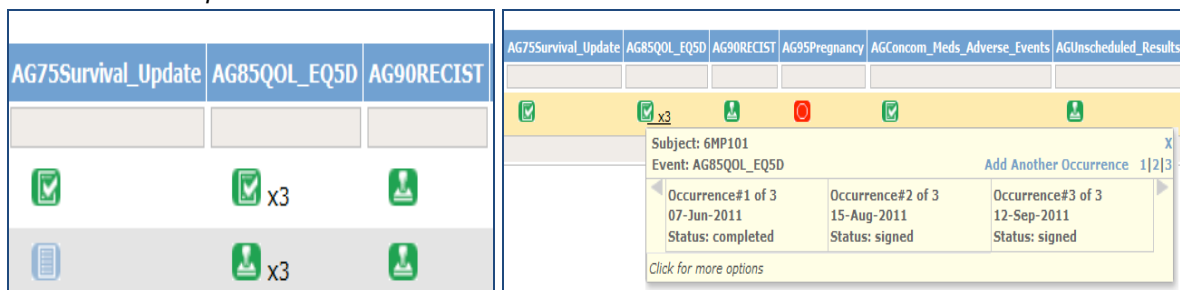
Results 1 - 8 of 8.

- Some events may be reoccurring, i.e. can occur more than once on the trial. Such events which have a times number next to the icon e.g. x2. These recurring events will become layered on top of each other (rather than a separate column for each). Where applicable,



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
click on a multiple icon to bring up the separate entry points to the individual event. See *example below*:

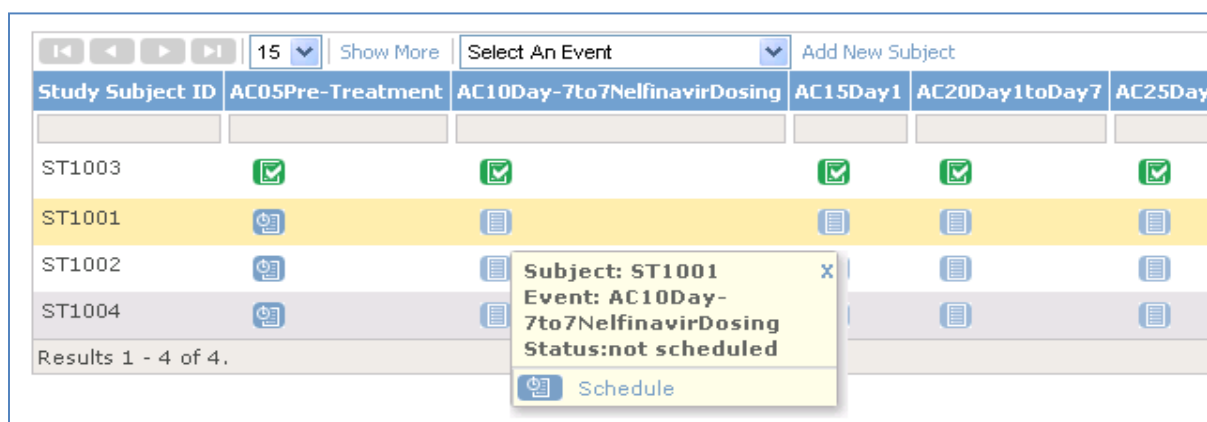


The screenshot shows a matrix table with columns for events: AG75Survival_Update, AG85QOL_EQ5D, and AG90RECIST. The AG85QOL_EQ5D column has a 'x3' icon. A sub-menu is open for the AG85QOL_EQ5D event, showing details for Subject: 6MP101 and three occurrences with their respective dates and statuses.

- Note that you will never need to use 'Add New Patient' link on the Matrix table. Patients are added automatically to OpenClinica upon registration.

3.2 Scheduling an Event

- Depending on the trial you are working on, the first event for the subject may already be scheduled. A scheduled event is indicated by this  icon. If the event is not scheduled then this  icon is displayed. Apart from the first event (if applicable to your trial), all subsequent events are required to be scheduled manually *If the event is not scheduled you need to complete the following step 'b & c', otherwise jump to 'Navigating to the CRF' below Section 2.3*
- Select the patient you want to enter data for and identify the event you want to schedule. Hover the mouse over the icon and click on it. Click 'schedule' on the sub-menu that is displayed.



The screenshot shows a matrix table with columns for events: AC05Pre-Treatment, AC10Day-7to7NelfinavirDosing, AC15Day1, AC20Day1toDay7, and AC25Day. The AC10Day-7to7NelfinavirDosing column has a document icon. A sub-menu is open for the AC10Day-7to7NelfinavirDosing event, showing details for Subject: ST1001 and its status as 'not scheduled'. A 'Schedule' button is visible at the bottom of the sub-menu.

- Enter the appropriate information. The start date should be the date the patient attends for the visit, or the first relevant date. (This start date is not used in the data analysis but is required in OpenClinica). If the event covers a period of time then you can enter the end date of the event, although this is not compulsory. 'Location' is also not compulsory. When you have finished, click the 'Proceed to enter data' button at the bottom of the screen.



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Schedule Study Event for RV1006 ?

* indicates required field.

Study Subject ID: **RV1006**

Study Event Definition: AJDay8_Treatment (non-repeating) *

Start Date/Time: 12-Mar-2013 : (DD-MMM-YYYY HH:MM) *

End Date/Time: : (DD-MMM-YYYY HH:MM)

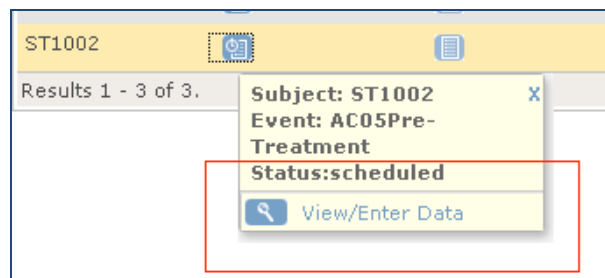
Leave this field blank if the end date/time is not applicable.

Location:

The event is now scheduled and you can start to enter the data.

3.3 Accessing and Navigating CRFs

- a. Hover your mouse over the icon  and click the icon. The following sub-menu will appear



Click the View/Enter Data option.

























USEFUL TIP: OpenClinica allows multiple pages to be open simultaneously, therefore you can right click and use ‘open page in new tab/new window’ – system permissions may vary. This is useful e.g. should you wish to refer between data entered in different CRFs/Events at the same time.

- b. You are now presented with a list of all the CRFs which make up this particular event. To enter data for a CRF click the Pencil icon as indicated by the red box in the next example.



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CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
AC05_medical_checks	v0.2				  
AC10_biopsy	v0.2				  
AC15_optional_biopsy	v0.2				  
AC20_bloods	v0.2				  
AC25_MRI_CT	v0.2				  
AC30_perf_dce_mri	v0.2				  

View this Subject's Record Exit

Note: Next to the pencil icon is the magnifying glass icon, which if you hover the mouse over, will tell you is 'view mode'. View mode allows you to view the data without being able to change the data. This feature is not relevant for data entry and it is advisable to not use the view icon at all. This is because - once in - view mode and edit mode are not easily distinguishable and situations where data entry persons have been in view, entered data, then found there data has not saved have occurred. Please therefore be aware of this.

Other things to note:

- The version number box will automatically be set to the correct version.
- The printer icon allows you to print your CRF out and print to PDF.
- You will see an option at the bottom of each event to 'view this subject's record'. This will bring up a page listing all CRFs from all events in one place in the order that the CRF was last amended.
- 'Exit button'. Click exit to go back to the Subject Matrix. Or if you have been opening separate tabs just close the tab.

3.4 CRF General Familiarisation

- After click on the pencil icon in on the Event CRF list. A blank CRF will be displayed ready for data entry. Some CRFs may be spread across more than one page. A CRF with more than one section will be indicated by the number of tabs shown at the top of the page [see box **A** in following example]. You can move between tabs freely, but once you have begun entering data on one of the tab (tabs can be completed in any order) you must save before moving onto the next tab. A warning will be shown if you attempt to change tabs without saving newly entered data on a page. Navigate between the tabs by clicking on the appropriate tab or by selecting the section from the drop down box [see box **B** in following example].

Note: Some CRFs may only have a total of 1 page; therefore only 1 tab will be visible.



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AA010_Screening v1.0 CP1005

▼ CRF Header Info

Demogra...(1/1) **A** Past Me...(4/4) B-CLL A...(14/14) **B** -- Select to Jump --

Title: Past Medical History

Instructions: Please obtain a relevant past medical history. For each element of the history, list every relevant past and present disease the participant has had.

Page: Save Exit

Past Medical History

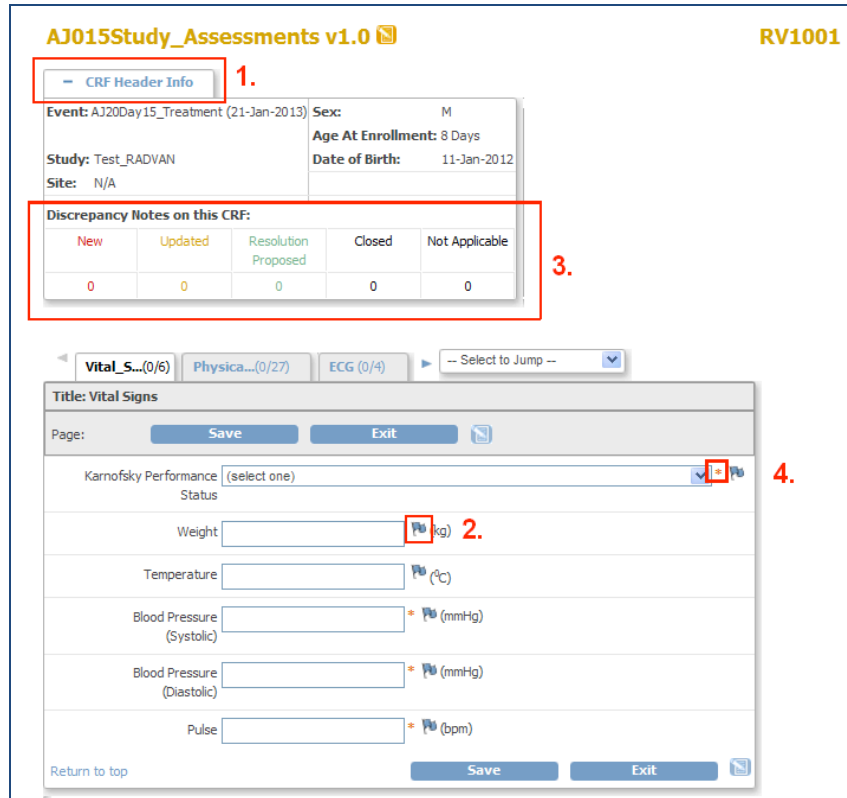
Medical History Date	History Event
May-2011 <input type="text"/> <input type="button" value="Calendar"/> <input type="button" value="Print"/>	Facelift <input type="button" value="Print"/>
Aug-2004 <input type="text"/> <input type="button" value="Calendar"/> <input type="button" value="Print"/>	tummy tuck <input type="button" value="Print"/>

Return to top Save Exit

Please take note of any instructions that are included below the CRF title, and any comments on the screen in between fields which will help to clarify the exact requirements. The units for your reply are usually indicated to the right of the field, please follow all of these specifications.

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3.5 CRF general familiarisation continued....



The screenshot shows the OpenClinica interface for 'AJ015Study_Assessments v1.0' (RV1001). It includes a 'CRF Header Info' section (1) with patient details like 'Event: AJ20Day15_Treatment (21-Jan-2013)', 'Sex: M', 'Age At Enrollment: 8 Days', 'Date of Birth: 11-Jan-2012', 'Study: Test_RADVAN', and 'Site: N/A'. Below it is a 'Discrepancy Notes on this CRF:' table (3) with columns for New, Updated, Resolution Proposed, Closed, and Not Applicable, all showing 0. The 'Vital Signs' section (4) contains fields for Karnofsky Performance Status, Weight (kg) (2), Temperature (°C), Blood Pressure (Systolic) (mmHg), Blood Pressure (Diastolic) (mmHg), and Pulse (bpm). Each field has a flag icon to its right.





3.5.1 CRF Header Info

BOX 1 in example above. Click on 'CRF Header Info' to open further details about the CRF page. The box that appears provides details about the trial patient and also confirms the Event the CRF is part of.

3.5.2 Discrepancy Flags



BOX 2 in example above. Discrepancy Flags - Each field will have an adjacent flag icon that upon clicking will cause a pop-up box to appear, which you can use to leave a comment/s (referred to as 'annotations' in OpenClinica) about the field. Also, if OCTO have a query about the data entered in the field, the flag will be used to raise a query See the 'Discrepancy Processing' section for further details.

The flag will change colour depending on the status:

 Blue Flag	Blank: Flag un-used.
 White Flag	Annotation: A comment has been made about this field.
 Red Flag:	Query: A query has been raised and requires attention.
 Green Flag	Resolution Proposed: A response/resolution to the query (Red Flag) has been provided with the expectation that the issue can now be resolved i.e. Closed.



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	<i>N.B. Only OCTO can close a query.</i>
 Orange Flag	Updated: a flag can turn orange if 'update' is selected, instead of 'Resolution proposed' when responding to a query (a Red Flag). An 'Update' can be used for any correspondence regarding the query that is not proposing a resolution. i.e. requesting clarification on the query raised, or explaining that you are waiting on information and will answer the query when possible.
 Black Flag	Closed: once a resolution has been proposed and accepted by OCTO the query will be closed and the flag will turn black.

Hint: if you have entered data in the flag box and the flag icon has not changed colour, try refreshing the page.

3.5.3 Discrepancy notes

BOX 3 in example on previous page. Discrepancy notes (See section 'Discrepancy Processing') - This will give you an overview of the notes and discrepancies status i.e. a count of the each flag attached to the CRF (this includes all pages/tabs of the CRF).

Red * (Compulsory Fields)

BOX 4 in example on previous page. Red * (Compulsory Fields) - All fields marked with a * must be answered. If you leave any of these fields empty, upon saving the CRF page an error message will appear requesting data to be entered in the highlighted fields, or a comment made in the related empty field flag to explain why the information is missing. Some fields may have further automatic checks programmed i.e. expected indices for Full Blood Count. If a field fails these checks, a 'Failed Validation' message will occur and red flag will appear next to the queried fields. If the data needs correcting, correct the field and press save. If data in this field is correct, click on the flag and enter a comment to state the data is correct, then save the CRF page again.

4. Entering Data into the CRF

4.1 Enter data into the appropriate fields.

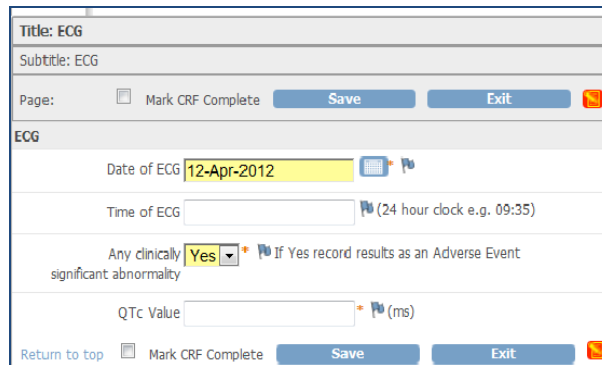
If something is unknown, or you need to provide further information, enter a comment into the flag. Even for non-compulsory fields, please use the annotation notes (where appropriate) to explain if something is unknown or e.g. the test was not done. A short, concise note is adequate. This will clarify to the trial office upon review that this field is purposely left empty, thus avoid a query being raised.

Example 1: non * fields (Non-compulsory fields)

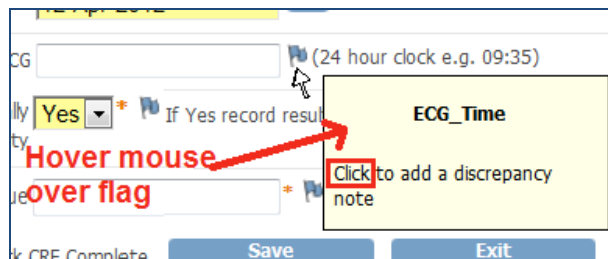


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- In this example 'Time of ECG' was not recorded in raw data in error, thus not rectifiable.



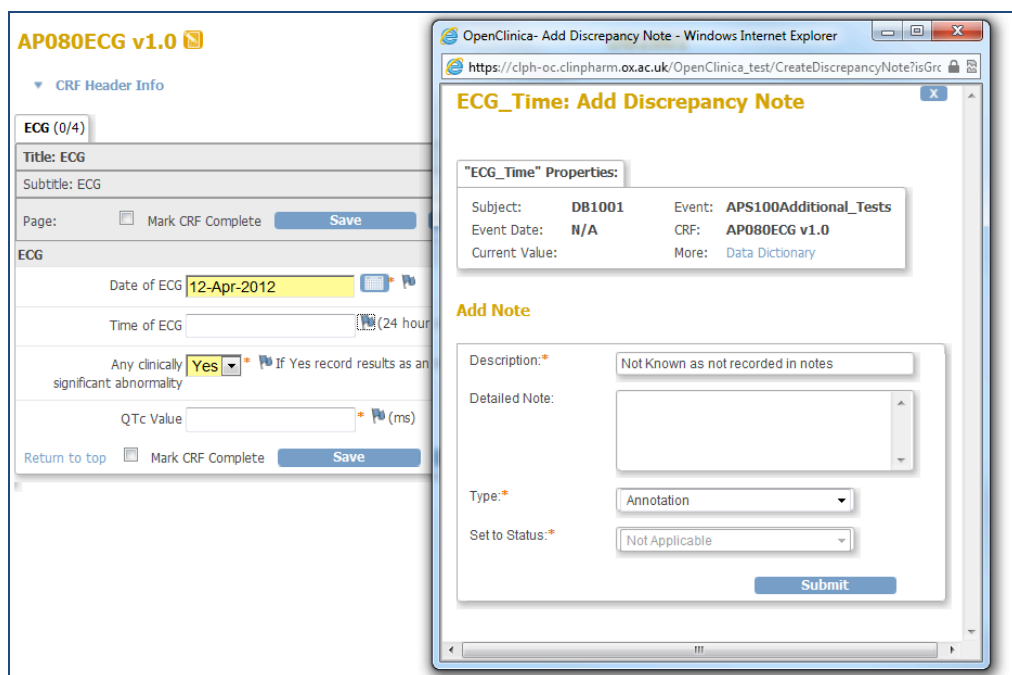
As this field will be left blank, an explanation should be given to confirm that this field is purposefully left empty. Following the example below, hover your mouse over the flag and click on link to 'add a discrepancy note' – ignore the term 'discrepancy note', you will be able to select the correct term 'annotation note' in the next stage. After clicking, wait for the flag's discrepancy note pop-up box to appear. Ensure pop-up boxes are enabled if it does not appear.





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- When the pop-up box has appeared, enter an explanation in the 'Description box'. (Detailed Note is optional).e.g. the field is purposefully left blank as. 'not known as not recorded in notes. The 'type' of discrepancy should default to 'annotation' but you can choose from the drop down list if necessary. (See example on next page). Upon saving, the box will close automatically – please be patient and only click submit once to avoid duplicating annotations being entered - and upon refreshing the CRF page the flag will become white to indicate an annotation note has been made on the field.

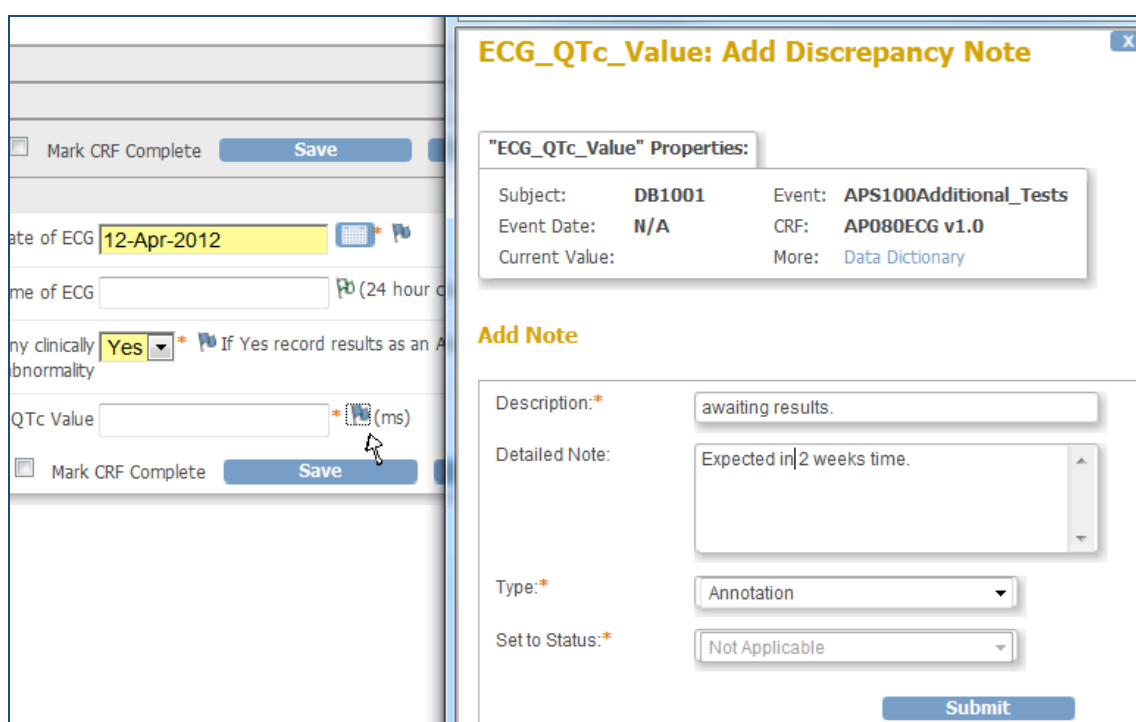




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Example 2: * fields (compulsory field)

- For * fields, you will not be able to save the page unless an annotation note has been added. In the next scenario, data has been entered but the result will not be known for the 'QTc Value' for 2 weeks, so to avoid having to postpone all data entry for this CRF, the rest of the data can be entered and an annotation note made for the field upon which you are waiting for data. Upon saving this annotation, even with a *field empty, the CRF page will now save successfully.

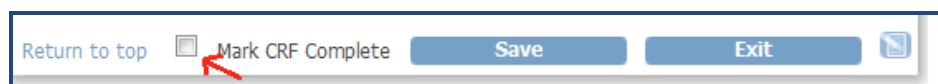


The screenshot shows a data entry form for an ECG test. A dialog box titled "ECG_QTc_Value: Add Discrepancy Note" is open. The dialog contains the following information:



- "ECG_QTc_Value" Properties:**
 - Subject: DB1001
 - Event: APS100Additional_Tests
 - Event Date: N/A
 - CRF: AP080ECG v1.0
 - Current Value: (empty)
 - More: [Data Dictionary](#)
- Add Note:**
 - Description: awaiting results.
 - Detailed Note: Expected in 2 weeks time.
 - Type: Annotation
 - Set to Status: Not Applicable

Buttons for "Save" and "Submit" are visible in the interface.

- Once all fields (or all that you can with annotation notes added for those you can't) are completed you must click **'Save'** to save the data you have entered. You will be taken automatically to the next tab (is applicable) of the CRF. Repeat this process until you come to the last tab (i.e. the last page) of the CRF.
- On the last tab page there is an additional tick box called 'Mark CRF Complete'.



A close-up of the bottom of the data entry form. It shows a "Return to top" link, an unchecked checkbox labeled "Mark CRF Complete", a "Save" button, and an "Exit" button. A red arrow points to the checkbox.

Tick this box if you have fully completed the CRF and have no further data to enter. This will change the CRF status to 'Data Entry Completed' and the icon will change to , otherwise the CRF remains with a status of 'Initial Data Entry' with an icon of . You can still edit the CRF after marking it as complete but you will be prompted to enter a discrepancy note to explain why you are making the changes (see section 'Adding or



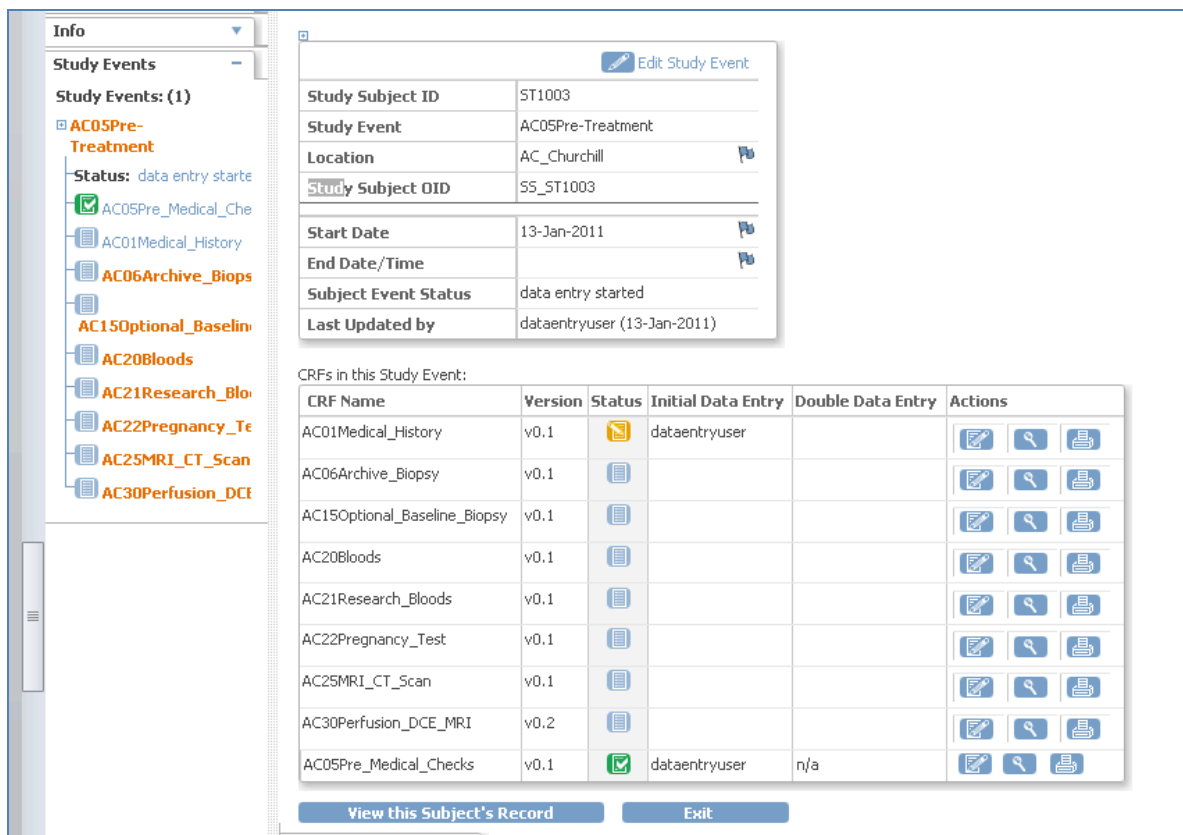
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amending data in a CRF marked as ‘Completed’ in this guide) . Marking a CRF Complete, will start the data review process by OCTO.

As a general rule, it is not advisable to mark the CRF complete until you know you have completed all data input (i.e. in the example above with a delayed QTc value, do not mark as complete yet; if it is not complete you will know that there is something outstanding, so on review will be reminded to chase the delayed data item)

*Important Note: For CRFs with multiple tabs you will not be able to mark the CRF as complete until all compulsory fields (red * field) across all tabs have been completed or an annotation note has been completed to explain the missing data. If you have a large number of compulsory fields to complete which are not applicable and you therefore are unable to mark the CRF as complete, please contact the trial office who have the ability to force the CRF to be marked as complete. The trial office can do this quickly and are happy to help, therefore please do not hesitate to make this request.*

After marking a CRF as complete, the status will change in the Event CRF screen. The example below shows once CRF has been completed (green) and the other (yellow) is in ‘data entry started’ phase.



The screenshot displays the 'Edit Study Event' window for Study Subject ID ST1003. The event is 'AC05Pre-Treatment' at location 'AC_Churchill' on '13-Jan-2011'. The 'Subject Event Status' is 'data entry started'. Below this, a table lists CRFs in this study event.

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
AC01Medical_History	v0.1	Yellow	dataentryuser		[Edit] [Search] [Print]
AC06Archive_Biopsy	v0.1	Blue			[Edit] [Search] [Print]
AC15Optional_Baseline_Biopsy	v0.1	Blue			[Edit] [Search] [Print]
AC20Bloods	v0.1	Blue			[Edit] [Search] [Print]
AC21Research_Bloods	v0.1	Blue			[Edit] [Search] [Print]
AC22Pregnancy_Test	v0.1	Blue			[Edit] [Search] [Print]
AC25MRI_CT_Scan	v0.1	Blue			[Edit] [Search] [Print]
AC30Perfusion_DCE_MRI	v0.2	Blue			[Edit] [Search] [Print]
AC05Pre_Medical_Checks	v0.1	Green	dataentryuser	n/a	[Edit] [Search] [Print]

Buttons at the bottom: 'View this Subject's Record' and 'Exit'.


- d) When you have entered all the available data, click the ‘Exit’ button. The ‘Subject Event Status’ will remain as ‘Data Entry Started’ until all CRFs are marked as ‘Complete’.

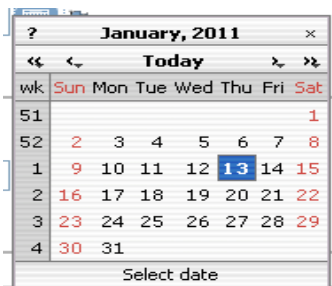
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Note: Once all CRFs have been entered and completed the 'Subject Event Status' will automatically change to 'Completed'. The Icon on the subject matrix will also automatically update to represent the 'Subject Event Status' indicated.

- e) Continue entering data for the remaining CRFs when the data becomes available

4.2 Entering Dates

All date fields have date widget attached to them . When this is clicked a calendar is displayed:



You can change the year by clicking on the >> << signs; click and hold down to display a list of years, select the year you want. Change months by clicking the < > signs. Again clicking and holding will display the list of months. Click the date to populate the field on the CRF and close the widget.

You can type the dates in by hand but the following format must be followed: DD-MMM-YYYY e.g. 23-Jan-2010. The month is not case sensitive but it must be entered as a word and not a number. Also a hyphen must be used e.g. 23-jan-2010. The following is not accepted 23/Jan/2010.

4.3 Entering Partial Dates

Some fields will accept partial dates, usually indicated on the CRF, for example for previous medical history details. The format of partial dates must be as follows: MMM-YYYY e.g Feb-2010 or Apr-2010. Again, the month is not case sensitive but a hyphen must be used. If only the year is known then enter YYYY e.g 1996.

4.4 Tests Not Done

When data cannot be entered because a test has not been done, please provide as much information as possible as to why it was not done (otherwise this would have to be requested any in a discrepancy note anyway, in order for OCTO to have oversight of possible deviations, or logistical problems with complying with the protocol etc)



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4.5 Adding Extra Rows

You may come across an 'Add' button at the bottom of a table of rows in a CRF. This allows for unlimited duplicate blank rows to be added, should you need more space.

Physical Examination (To view CTCAE Definitions click [here](#))

Type of exam:	Evaluation	If abnormal please describe	If abnormal provide a CTCAE evaluation Fill out AE or SAE as appropriate
(select one) ▾	(select one) ▾		
Add			

4.6 Mark CRF Complete

You should only select 'Mark CRF Complete' checkbox once all the data has been completed for that CRF.

It is very crucial for Conmed and Adverse Event CRFs not to mark complete while patient is on study. These should only be marked complete once all the data has been entered, after either patient has stopped treatment, completed all the relevant follow up visits or has died.

Has the patient any * If yes, specify below
SAE occurring as a
result of the research
scan sessions?

Serious Adverse Events as per CTCAE4.0, dates dd-Mmm-yyyy

Serious Adverse Event name	Start date	End date	CTCAE grade (maximum)	Imaging causality	Outcome	SAE continuing at end of study?
Vomiting	04-Oct-2016	05-Oct-2017	3	Probably related	Resolved	No

Add

[Return to top](#)

Mark CRF Complete

Save

Exit

4.7 Schedule multiple occurrences of a repeated Event

Go to the subject matrix view and click on repeating event and select 'Add Another Occurrence' to schedule a new event. A screen appears as usual as you would have scheduled any other event.



OpenClinica Site Data Entry Guide

BA166 Stop Treatment	BA170 End_Of Trtment	BA175 28Days Post_Dose	BA180 Post_Trial Care	BA185 Additional Test	BA190 Death Notification	BA195 Survival Status	Consent Withdrawal	BA200 Monitoring	Actions
									Apply Filter Clear Filter
								x2	
								x2	

Subject: M10002 X

Event: BA200
Monitoring

Occurrence#1 of 1
19-Oct-2015
Status : data entry started

Add Another Occurrence

View/Enter Data

Edit

Remove

4.8 View/Enter Data within a repeated Event

Click on a repeated event and select 'View/Enter Data' option for the visit you are interested in as in the image below. The choice of tasks displays for each of the existing occurrences. You will be able to view or enter data in any CRF for the selected visit.

BA175 28Days Post_Dose	BA180 Post_Trial Care	BA185 Additional Test	BA190 Death Notification	BA195 Survival Status	Consent Withdrawal	BA200 Monitoring	Actions
							Apply Filter Clear Filter
						x2	

Subject: M1004 X

Event: BA200
Monitoring

[Add Another Occurrence](#) 1|2

<p>Occurrence#1 of 2 08-Nov-2017 Status: data entry started</p> <p>View/Enter Data</p> <p> Edit</p> <p> Remove</p>	<p>Occurrence#2 of 2 08-Nov-2017 Status: scheduled</p> <p>View/Enter Data</p> <p> Edit</p> <p> Remove</p>
--	---

OpenClinica Site Data Entry Guide

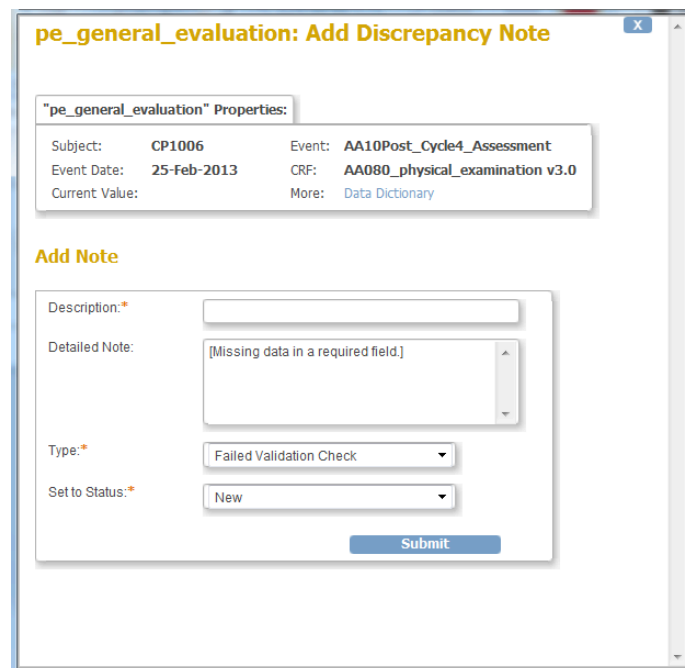
5. Dealing with Data Queries raised in Discrepancy Note (Flags):

5.1 Failed Validation Test - Discrepancy Note

Why you may get a 'Failed Validation Test': Some fields will only accept certain values, e.g. strict date format (see section 'Entering Date'), or have rules i.e. an expected range on a blood test, or only accept number values. Or as mentioned earlier on in this guide, if a * compulsory field is left blank upon saving.

Upon saving, OpenClinica will automatically check the data and trigger 'Failed Validation Check' notification if any issues are found. If this happens, an error message will appear warning you that you have failed one or more validation tests. The field/s with error/s will be visible by a red flag icon and an exclamation mark. The error will also be listed underneath the CRF header.

You will need to resolve the issue by correcting the field and pressing save **or** by clicking on the flag icon and using the pop-up box to provide an explanation for either the missing, incorrect or outlaying data – see the example below.



Enter a brief reason in the 'Description' box to state why the item failed the validation check and if required any further details in the 'Detailed Note' section and click submit (*Note: Please be patient and do not click more than once. The submit button is sensitive and repetitive responses may be entered if you press more the submit button more than once*) A confirmation screen will appear which will close automatically. This must be repeated for all



OpenClinica Site Data Entry Guide

fields that have failed the validation check. When you have finished dealing with the 'Failed Validations Checks' you must press save again on the CRF.

WARNING: If you press exit, the page will not be saved.

5.2 Queries raised by the Trial Office

When a CRF is marked as complete, OCTO will review the CRF and if they have any questions will raise 'Query' type discrepancy notes. Queries will be assigned to a specific user at the site, usually the person who entered the data.

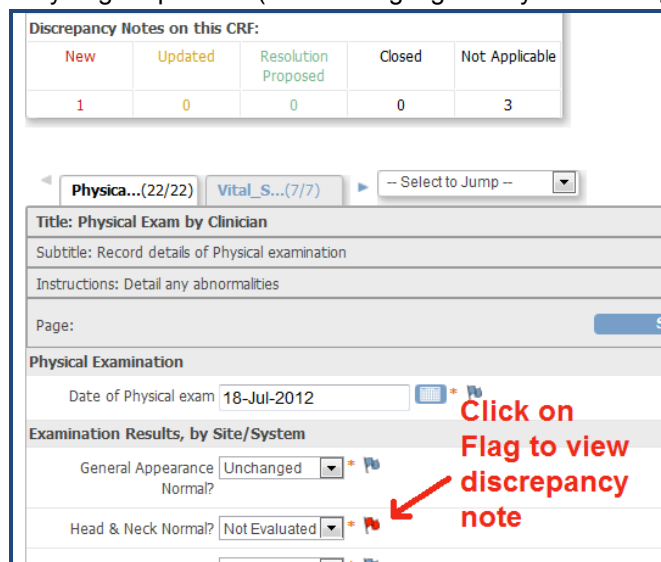
There are a number of ways of knowing that you have queries to be answered:

5.3 Notification Emails

When OCTO reviews a CRF, for the first query raised on the reviewed CRF, an email notification will be sent to you. For subsequent queries on that CRF raised at the same time, an email will not be sent. This is to prevent swamping your inbox with emails informing you have a query has been raised in OpenClinica. When you access your CRF to respond to the initial email notification, please check the 'Notes and discrepancies' counts in the CRF Header (See also 'Notes and Discrepancy assigned to me' section below), as you will also be able to see the additional red flags which indicates that further queries have been raised after the initial email. Please respond to all the queries as and when data become available.

To respond to the queries:

1. Click the discrepancy flag in question (it will be highlighted by the red flag)



New	Updated	Resolution Proposed	Closed	Not Applicable
1	0	0	0	3

Physica...(22/22) Vital_S...(7/7) -- Select to Jump --

Title: Physical Exam by Clinician
 Subtitle: Record details of Physical examination
 Instructions: Detail any abnormalities

Page: [] S:

Physical Examination
 Date of Physical exam: 18-Jul-2012

Examination Results, by Site/System

General Appearance: Unchanged [*]
 Normal?

Head & Neck Normal?: Not Evaluated [*]

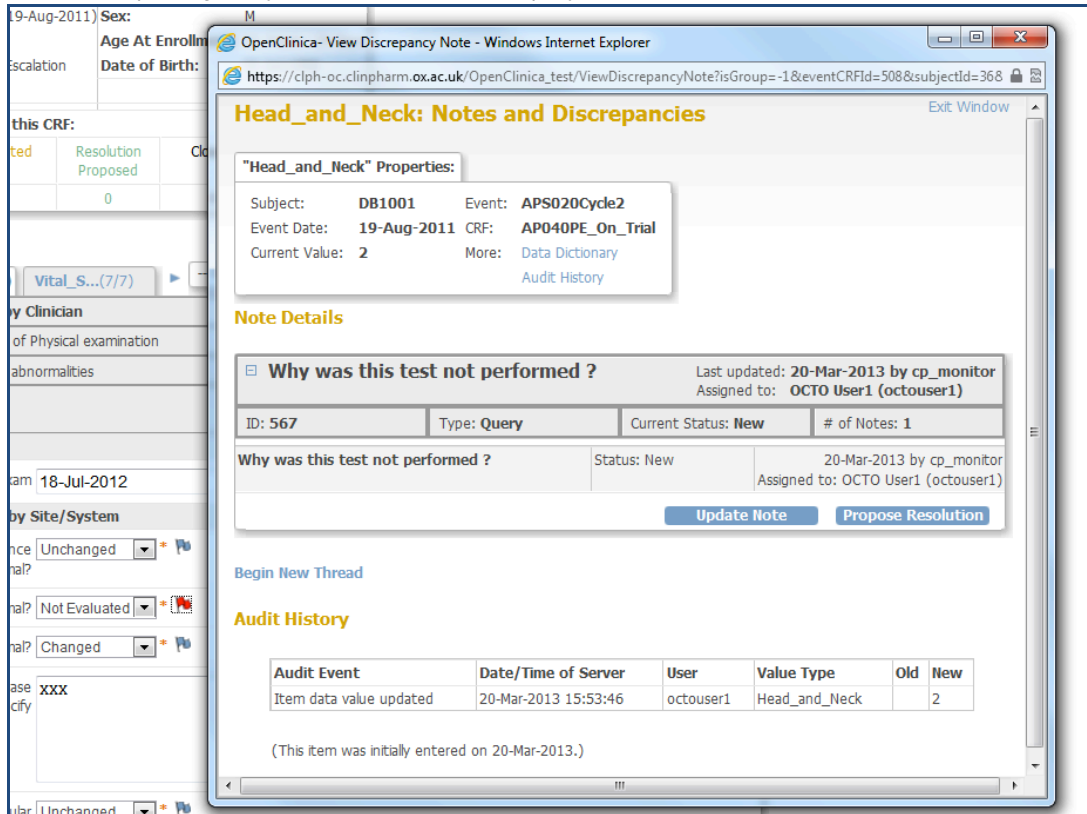
Click on Flag to view discrepancy note

2. View the query
3. If applicable, update by overwriting, the field in the CRF with the resolution. The field background will become yellow to highlight the field you have adjusted. Or, you can continue with the actions below and make the changes to the field after you have closed the pop-up query box.
4. On the pop-up query box, click 'propose resolution' or 'update' as appropriate:



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- 'Propose resolution' would be used when you have solved the query, i.e. by providing an explanation for the data queried or by correcting the field in the CRF.
- 'Update' would be used if you are unable to answer the query and what to inform that e.g. this information is pending, or if you are unsure of what the query means.



The screenshot shows a web browser window titled "OpenClinica- View Discrepancy Note - Windows Internet Explorer". The URL is https://clph-oc.clinpharm.ox.ac.uk/OpenClinica_test/ViewDiscrepancyNote?isGroup=-1&eventCRFId=508&subjectId=368. The page title is "Head_and_Neck: Notes and Discrepancies".

"Head_and_Neck" Properties:

Subject:	DB1001	Event:	APS020Cycle2
Event Date:	19-Aug-2011	CRF:	AP040PE_On_Trial
Current Value:	2	More:	Data Dictionary Audit History

Note Details

Why was this test not performed ? Last updated: 20-Mar-2013 by cp_monitor
Assigned to: OCTO User1 (octouser1)

ID: 567	Type: Query	Current Status: New	# of Notes: 1
---------	-------------	---------------------	---------------

Why was this test not performed ? Status: New 20-Mar-2013 by cp_monitor
Assigned to: OCTO User1 (octouser1)

Update Note **Propose Resolution**

Audit History

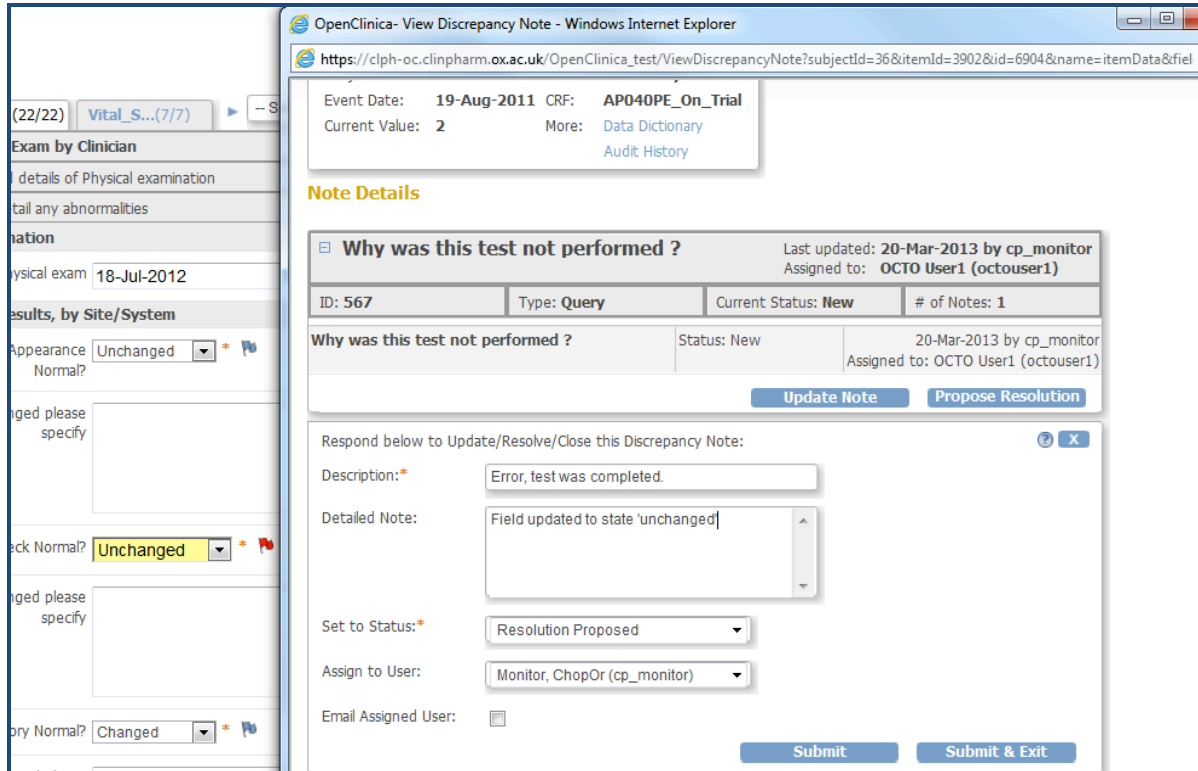
Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	20-Mar-2013 15:53:46	octouser1	Head_and_Neck		2

(This item was initially entered on 20-Mar-2013.)

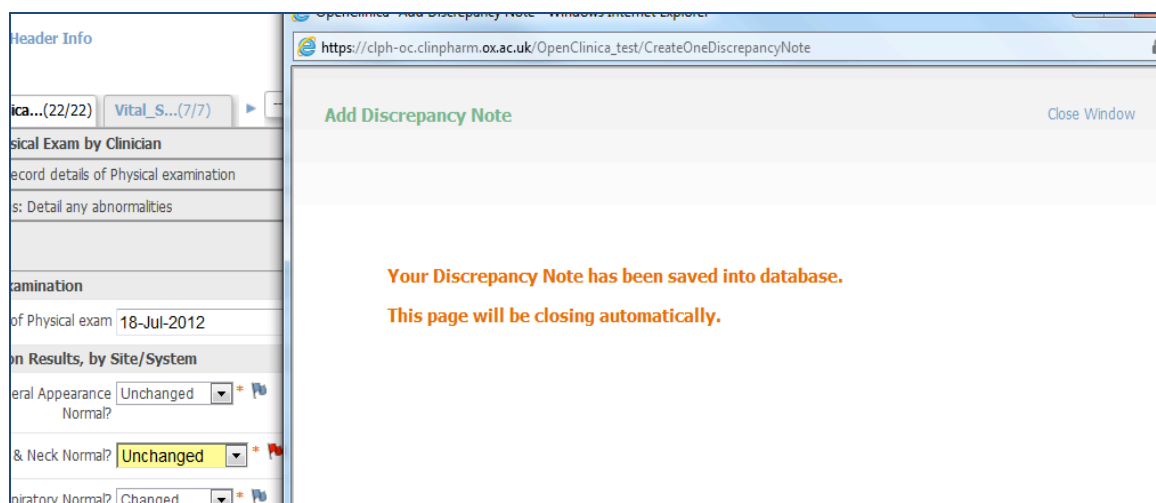
5. Enter a description. *The detailed note is optional.*



OpenClinica Site Data Entry Guide



6. Assign your response to the trial office member who raised the query (usually this will be the default selection)
7. Tick the email flag. *Optional – however please use if the query was urgent.*
8. Click submit. (Please be patient and do not click more than once. The submit button is sensitive and repetitive responses may be entered if you press the submit button more than once).
9. Click close or wait for Pop up box to close automatically








10. If there are any other queries on the CRF, repeat the above process.



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11. As well as responding to the query, you will need to update the data fields in the CRF itself as required
12. **Ensure you Save the CRF** if you have made changes to fields.
13. Note that any changes made in the flag pop-up box will be saved automatically, however the flag colour on the CRF may not update until the page has been refreshed.

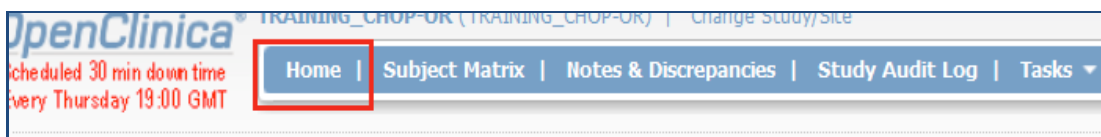
This example shows the flag has become green after the CRF page was saved i.e. refreshed:

Title: Physical Exam by Clinician	
Subtitle: Record details of Physical examination	
Instructions: Detail any abnormalities	
Page:	<input type="button" value="Save"/> <input type="button" value="Exit"/>
Physical Examination	
Date of Physical exam	18-Jul-2012  * 
Examination Results, by Site/System	
General Appearance Normal?	Unchanged <input type="button" value="*"/> 
Head & Neck Normal?	Unchanged <input type="button" value="*"/> 
Respiratory Normal?	Changed <input type="button" value="*"/> 

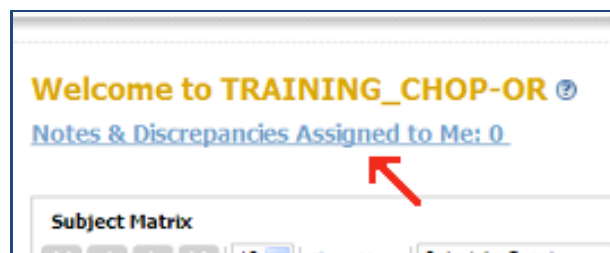
5.4 'Notes and Discrepancies Assigned to Me'

There are also other ways to deal with the queries:

- On the 'Home' screen...




...click on 'Notes and Discrepancies Assigned to Me' in the toolbar at the top of the page.





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Please Note: Due to a reported bug on the system, the count next to this link displayed on the home screen is not always accurate; therefore you should always click on the actual link to be taken to the Notes and discrepancies page for the accurate count. The notes and discrepancies page will default to show how many New Queries/queries not yet addressed, are assigned to you.





Notes and Discrepancies 

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	8	--	--	--	8
Updated	1	--	--	--	1
Resolution Proposed	--	--	--	--	--
Closed	--	--	--	--	--
Not Applicable	--	--	--	2	2
Total	9	--	--	2	11

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF
CP1001	Query	New	AA_TRAINING_SITE_1	0	233	AA355Serious_Adverse_Event	AA120_serious_a
CP1008	Query	New	AA_TRAINING_SITE_1	0	0	AA07Cycle1_Extra_LFTs	AA140_Liver_fun
CP1001	Query	Updated	AA_TRAINING_SITE_1	0	233	AA355Serious_Adverse_Event	AA120_serious_a
CP1001	Annotation	Not Applicable	AA_TRAINING_SITE_1			AA15Post_Cycle6_Assessment	AA070_scan_resu
CP1001	Query	New	AA_TRAINING_SITE_1	0	233	AA355Serious_Adverse_Event	AA120_serious_a
CP1001	Query	New	AA_TRAINING_SITE_1	0	233	AA355Serious_Adverse_Event	AA120_serious_a
CP1001	Query	New	AA_TRAINING_SITE_1	0	233	AA355Serious_Adverse_Event	AA120_serious_a
CP1008	Query	New	AA_TRAINING_SITE_1	0	0	AA07Cycle1_Extra_LFTs	AA140_Liver_fun

- Each row is a separate query. N.B. There may be multiple queries on 1 CRF but each will be shown as a separate query.
- To view and answer the query within the CRF;
 - i. Scroll to the last column 'Actions' at the far right hand side of the page **[A]** of the query you want to deal with. If your browser allows, right click on 'View in Record' and select from the sub-menu 'open in a new window' or 'open in new tab' – this will allow you to come back to the Notes and discrepancies table easily. Or just left click.

Entity Name	Entity Value	Description	Assigned User	Actions
				Apply Filter Clear Filter
ct_scan_bulk_lymph_node_over_5_cm		nd	()	  A
ct_scan_staging_dlbccl_criteria		nd	()	 

B points to the first row of the table.

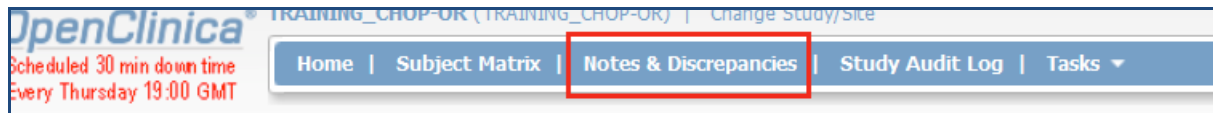


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- ii. The CRF page will open and the query pop-up box will appear. Complete the query as normal ensuring you save the CRF page. Should the save option not appear on the CRF page, please phone OCTO for advice.
- iii. Alternatively you could open the CRF itself by starting with the subject matrix (go to task Subject matrix, right click to open it in a new tab which keeps the discrepancy tab still open, and drilling down through the event to the CRF of interest.

*Note: You can then use the filters (the grey box under the column titles **[B]**) to narrow the table down e.g. by patient number, CRF, or resolution status, e.g. to select new and updated queries only).*

- o To see all 'notes and discrepancies' that are assigned to all users at your site, click on 'Notes and Discrepancies' on the toolbar of the home screen.



This will open the Notes and discrepancies page displaying, as default, all flags; queries, failed validation checks, updates, resolution proposed, closed and annotations, for all patients' CRFs at your Site.

Again, you can then use the filters to narrow the table down e.g. by patient number, CRF, or Type (flag icon).

5.5 Adding or amending data in a CRF marked as 'Completed'

If you have additional data to enter or you wish to amend data already entered on a CRF marked as Complete, you can do this but OpenClinica will make you provide a reason for change.

1. Within the CRF enter or edit the data



OpenClinica Site Data Entry Guide

ECG (4/4)

Title: ECG
Subtitle: ECG

Page:

ECG

Date of ECG: 29-Jul-2011 *

Time of ECG: 10:00 (24 hour clock e.g. 09:35)

Any clinically significant abnormality: No * If Yes record results as an Adverse Event

QTc Value: 400 (ms)

ECG (4/4)

Title: ECG
Subtitle: ECG

Page:

ECG

Date of ECG: 01-Aug-2011| *

Time of ECG: 10:00 (24 hour clock e.g. 09:35)

Any clinically significant abnormality: No * If Yes record results as an Adverse Event

QTc Value: 400 (ms)

Make change by overwriting previous entry

↓

2. Click on the corresponding flag for each field amended. A pop-up box will appear.

ECG (4/4)

Title: ECG
Subtitle: ECG

Page:

ECG

Date of ECG: 01-Aug-2011 *

Time of ECG: 10:00 (24 hour clock e.g. 09:35)

Any clinically significant abnormality: No * If Yes record results as an Adverse Event

QTc Value: 400 (ms)

OpenClinica- Add Discrepancy Note - Windows Inter...
https://clph-oc.clinpharm.ox.ac.uk/OpenClinica_test/CreateDiscrep

ECG_Date: Add Discrepancy Note

"ECG_Date" Properties:

Subject:	DB1001	Event:	AP5015Cycle1
Event Date:	29-Jul-2011	CRF:	AP080ECG
Current Value:	29-Jul-2011	More:	Data Dictionary

Add Note

Description:*

Detailed Note:

Type:*

Set to Status:*

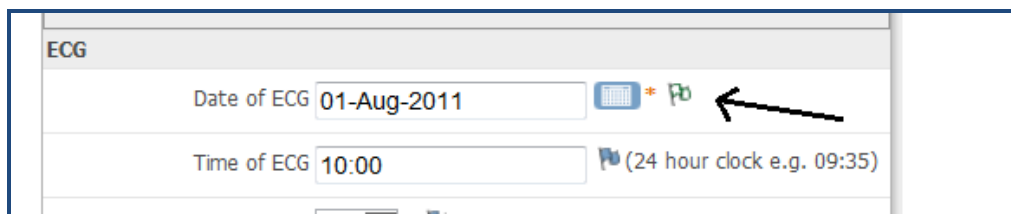


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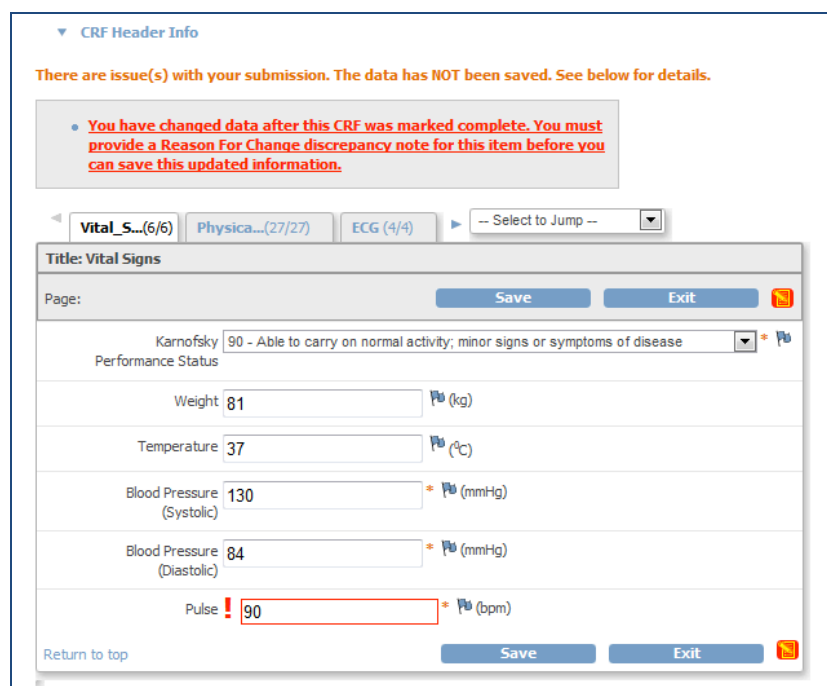
1. Select 'Reason for change', if it has not defaulted to it.
2. Enter Description. E.g. correction made, new information, etc.
3. Click submit (Please be patient and do not click more than once. The submit button is sensitive and repetitive responses may be entered if you press the submit button more than once)
4. Click close or wait for Pop up box to close automatically
5. Repeat process for all fields where a change has been made.

N.B. If you have a large amount of data in a CRF to change/add, please contact OCTO who can manually change the status of the CRF back to 'Data Entry Started' thus allowing you to make changes to the CRF without having to complete 'Reason For Change'. N.B. You will need to re-mark the CRF as 'Completed' once you have finished making changes.

6. Flags will turn white when a 'reason for change' i.e. an annotation, has been left.



The CRF can now be saved with the new data. If you have forgotten to add a 'Reason for change' discrepancy note for any questions, you will be prompted to add one when saving the CRF. See example of prompt in example below. The field in question will be highlighted red and marked with an exclamation, and an error message will be displayed at the top of the page:





OpenClinica Site Data Entry Guide

In this example: the pulse field was changed and on a CRF marked as complete. Upon saving, the prompts to provide a 'reason for change' explanation are demonstrated.

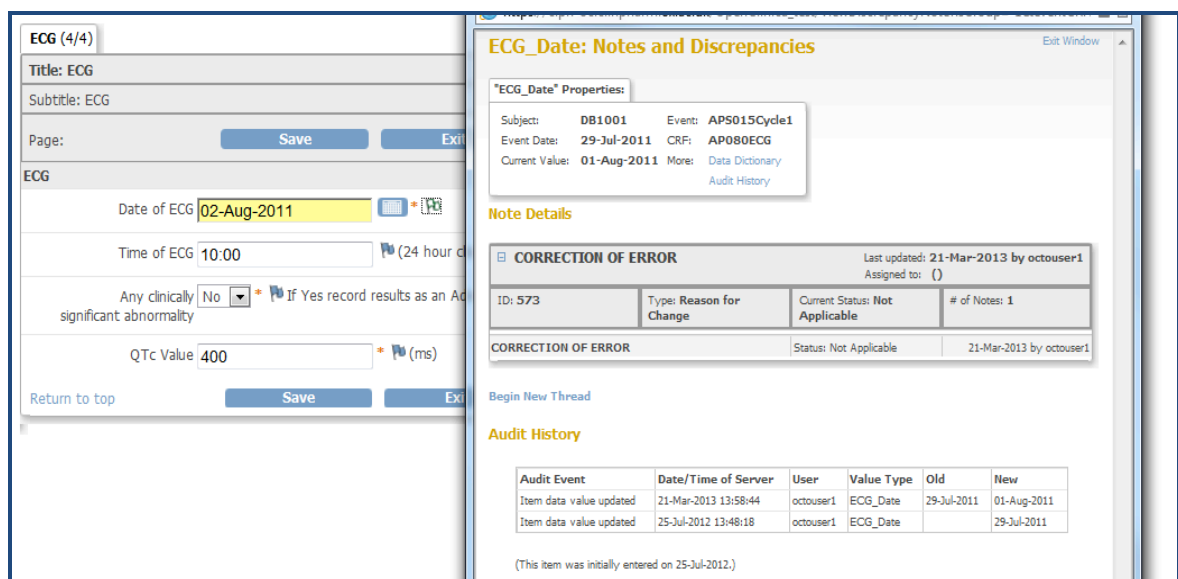
If you cannot change the discrepancy type to 'reason for change' please contact the trial office.

If you need to do several amendments each with their 'reason for change' explanations within one previously completed CRF, contact the OCTO office who may be able to set the CRF status back from completed to 'data entry started', thus avoiding all the reasons for change requirements

5.6 Using a flag multiple times.

Flags can be used more than once. For example, if you need to make another change to a field where you have already completed a 'reason for change', thus the flag is white, this is not a problem. To make another change to the field where the flag has been previously used:

Simply make the change required and select on the flag as normal:



The screenshot displays the OpenClinica data entry interface. On the left, a form titled 'ECG (4/4)' is shown with fields for 'Date of ECG' (02-Aug-2011), 'Time of ECG' (10:00), and 'QTC Value' (400). On the right, a 'Notes and Discrepancies' window is open, showing a 'CORRECTION OF ERROR' note with ID 573, Type 'Reason for Change', and an audit history table.

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	21-Mar-2013 13:58:44	octouser1	ECG_Date	29-Jul-2011	01-Aug-2011
Item data value updated	25-Jul-2012 13:48:18	octouser1	ECG_Date		29-Jul-2011

1. Select 'Begin New Thread'. A new box will open. Select reason for change and complete as normal. See example below. Note that the audit history displays the previous version of the field.



OpenClinica Site Data Entry Guide

Save Exit

ECG 02-Aug-2011

ECG 10:00 (24 hour c

ically No * If Yes record results as an Ad
ality

alue 400 (ms)

Save Exit

CORRECTION OF ERROR Last updated: 21-Mar-2013 by octouser1
Assigned to: ()

ID: 573	Type: Reason for Change	Current Status: Not Applicable	# of Notes: 1
---------	-------------------------	--------------------------------	---------------

CORRECTION OF ERROR Status: Not Applicable 21-Mar-2013 by octouser1

Begin New Thread

Description: *

Detailed Note:

Type: *

Annotation
Failed Validation Check
Annotation
Reason for Change

Set to Status: *

Submit Submit & Exit

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	21-Mar-2013 13:58:44	octouser1	ECG_Date	29-Jul-2011	01-Aug-2011
Item data value updated	25-Jul-2012 13:48:18	octouser1	ECG_Date		29-Jul-2011


Note that only one colour can be displayed on the flag. If a flag has a query and annotation note, the colour shown would be a RED, as the query has a higher priority.

Additional notes about queries

- OCTO will review your responses to the queries in a timely manner.
- Only OCTO have the ability to close queries i.e. making the flag colour turn to black indicating the query has been closed.
- Annotations (white flags) are the exception. These flags will remain white as it is not applicable for these notes to be closed.

6.0 Locked events to confirm data is clean

Note: the use of the lock feature was introduced in OCTO for new trials being developed after November 2017, so this may not be relevant to older trials

Once OCTO have reviewed an entire event and all CRFs are completed and any queries closed, OCTO will mark the event as Locked . You can still view the data under this status, but will not be able to edit unless the event is unlocked. If you subsequently need to amend a CRF within a locked



OpenClinica Site Data Entry Guide

Event , contact OCTO office by calling or via email to request the unlocking, giving your reason. The Event will be unlocked at request and amended data will be reviewed and will be locked again.


7.0 Signing patient data

During SIV the use of the OpenClinica signing feature will be decided, this varies depending on the trial.

7.1 Sign-off by Site at the end of study

At the end of the trial, once the data has been cleaned, all the queries have been closed, OCTO is satisfied with the data, patient data must be signed in Open Clinica by the Principal Investigator for each site (or their named delegate on the delegation log) . OCTO office will request PI signature once the trial is closed.

Principal Investigator/ delegate will be given Open Clinica access with the OpenClinica role of Investigator. Password and username will be sent by emails.

Please note when PI /delegate signs patient data using signed  icon all the events get signed including the hidden events for which PI is not responsible.(Hidden events are for OCTO use. They could include information on monitoring, imported reference data for value ranges, imported registration information etc)

OCTO requests a whole subject sign-off for the convenience of the PI or delegate, rather than requesting signing off of dozens of individual Events. OCTO uses this whole subject signing feature in OpenClinica with the understanding that the PI/delegate is not responsible for the data that is hidden

7.2 By OCTO – signing patient data to confirm data is clean


For some trials, particularly trials running before November 2017, OCTO uses the sign-off feature to indicate that the CRFs in that event/case record are clean. In this situation the Site personnel do not use this feature

7.3 Signing Patient data:

Once you log in to the database as Investigator the following screen appears.



































OpenClinica Site Data Entry Guide

Browse through the patient record as required to ensure that you are satisfied that the patient data is complete and accurate. Click on  icon in order to sign all the events (patient data) for a selected patient.

Welcome to TEST_PIONIR

Notes & Discrepancies Assigned to Me: 0

Subject Matrix					
   		15 	Show More	Select An Event 	Add New Subject
Study Subject ID	Baseline	Operation	AEs	Actions	
				Apply Filter Clear Filter	
Test 4				 	
Test 5				 	
Test1				 	
Test2				  	
Test3				 	

Results 1 - 5 of 5.



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Enter your User name and password again and select submit in the following screen

Sign Subject Test2

Enter your user name and password below to signify agreement with the following statement:

"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

User Full Name: Kulwinder Kaur

Date/Time: 03-Nov-2017

(The exact date and time will be recorded by the system upon submission of the signature form.)

Role: Data Specialist

User Name :	<input type="text"/>
Password	<input type="password"/>

[Group](#) [Global Subject Record](#) [Audit Logs](#)

Subject Record for Test2

Study Subject ID	Test2
Secondary ID	
OID	SS_TEST2
Person ID	
Date of Birth	28-Jan-2001


























Study Name	TEST_PIONIR
Unique Protocol ID	AR_PIONIR
Site Name	
Date Record Created	28-Jan-2013
Created By	mtaylor



OpenClinica Site Data Entry Guide

After submitting, all the events, for the selected patient are signed..

Subject Matrix for TEST_PIONIR

Study Subject ID	Baseline	Operation	AEs	Actions	
				Apply Filter	Clear Filter
Test 4					
Test 5					
Test1					
Test2					
Test3					

Results 1 - 5 of 5.

7.4 Re-signing altered patient data in an Event after initial PI sign

OCTO office and Site require the PI signature once the data is clean and no further amendments are required; a request will be sent from OCTO.

If in the unlikely circumstance that data alteration is required, the 'signed' icon is automatically removed from each of the Events that have been changed. Therefore after data cleaning there will be a further request from OCTO to re-sign the amended event(s).

The names of the Events appear as column headings. OCTO will provide the name of the subject identifiers and Events to be re-signed

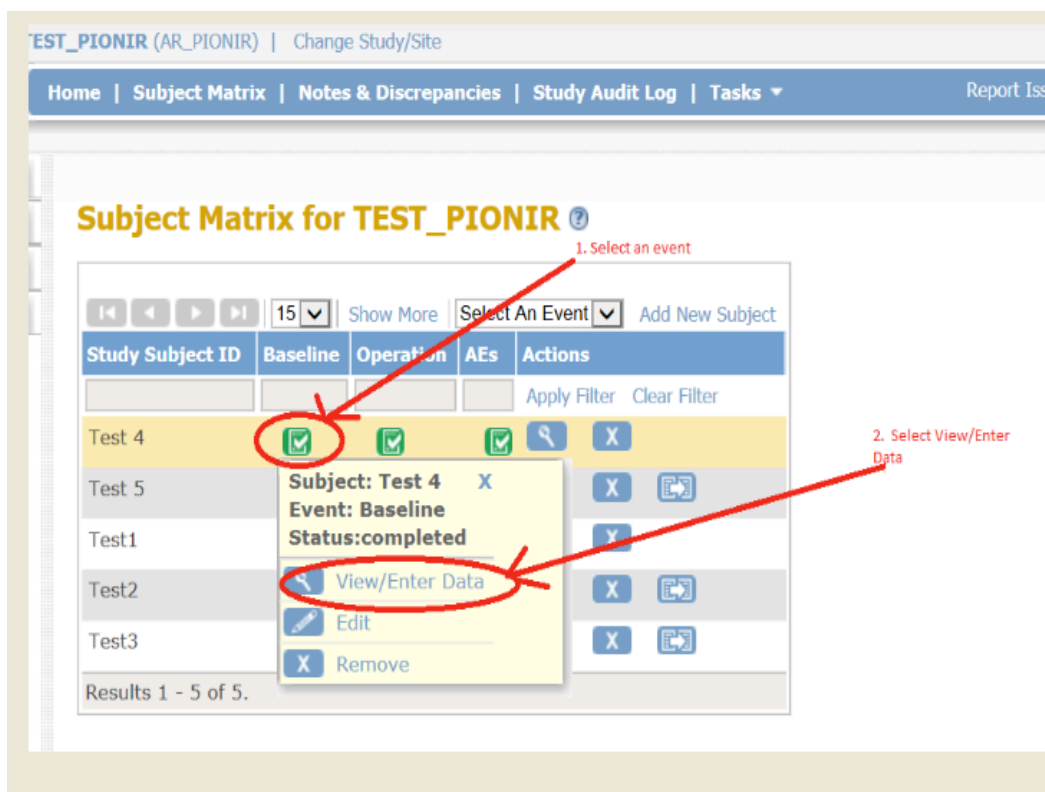
Browse the CRFs in those Events as required to ensure that you accept the updated data.

OpenClinica Site Data Entry Guide

7.5 Signing an individual event

Note: If for any reason sign off icon doesn't appear at the end of all the events (under clear filter) an individual event can to be signed. To do this:

- a. Select event in question and then select View/Enter data option from the drop down menu.



The screenshot shows the 'Subject Matrix for TEST_PIONIR' interface. At the top, there are navigation links: Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Report Issue. Below this is a table with columns: Study Subject ID, Baseline, Operation, AEs, and Actions. The table contains rows for Test 4, Test 5, Test1, Test2, and Test3. A dropdown menu is open for Test 4, showing options: View/Enter Data, Edit, and Remove. Red arrows and text annotations indicate the steps: '1. Select an event' points to the 'View/Enter Data' option in the dropdown, and '2. Select View/Enter Data' points to the 'View/Enter Data' option in the dropdown.





Study Subject ID	Baseline	Operation	AEs	Actions
Test 4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Test 5				<input type="checkbox"/> <input type="checkbox"/>
Test1				<input type="checkbox"/> <input type="checkbox"/>
Test2				<input type="checkbox"/> <input type="checkbox"/>
Test3				<input type="checkbox"/> <input type="checkbox"/>
























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b. The following screen displays. 'Select Edit Study Event'

Enter or Validate Data for CRFs in Baseline ⓘ

 Edit Study Event	
Study Subject ID	Test 4
Study Event	Baseline
Location	N/A 
Study Subject OID	SS_TEST4
Start Date	28-Mar-2013 
End Date/Time	28-Mar-2013 
Subject Event Status	completed
Last Updated by	kkaur (01-Nov-2017)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
AR010_InformedConsent	1.0		medoncuser	n/a	     
AR030_MEDICALHIST	1.0		medoncuser	n/a	     
AR020_DEMOGRAPHICS	1.0		medoncuser	n/a	     

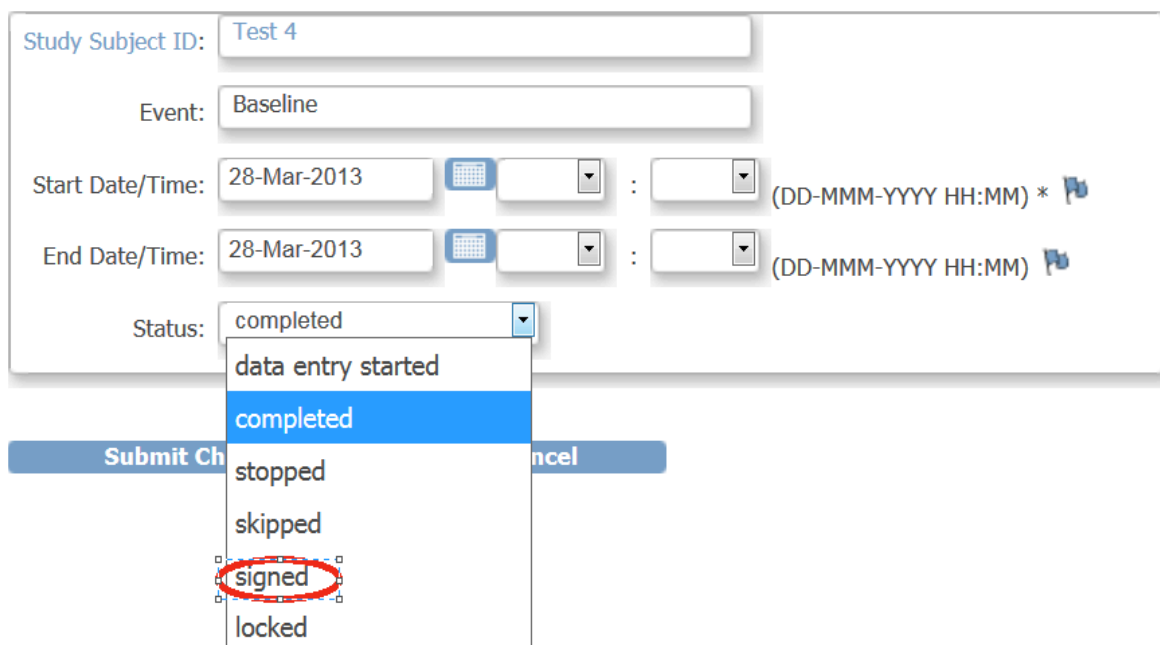
[View this Subject's Record](#) [Exit](#)



OpenClinica Site Data Entry Guide

c. For 'Status' field select 'signed' option and submit changes.

Update Study Event



Study Subject ID: Test 4

Event: Baseline

Start Date/Time: 28-Mar-2013 : (DD-MMM-YYYY HH:MM) *

End Date/Time: 28-Mar-2013 : (DD-MMM-YYYY HH:MM)

Status: completed



- data entry started
- completed
- stopped
- skipped
- signed**
- locked

Submit Changes Cancel


























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d. Go to the subject matrix and the selected Event must be replaced from  to  icon

Subject Matrix for TEST_PIONIR

Study Subject ID	Baseline	Operation	AEs	Actions
				Apply Filter Clear Filter
Test 4				 
Test 5				 
Test1				 
Test2				 
Test3				 

Results 1 - 5 of 5.

This is the end of the user guide. Should you have any questions on OpenClinica please contact the Trial team at OCTO who will be happy to assist.

Final Page