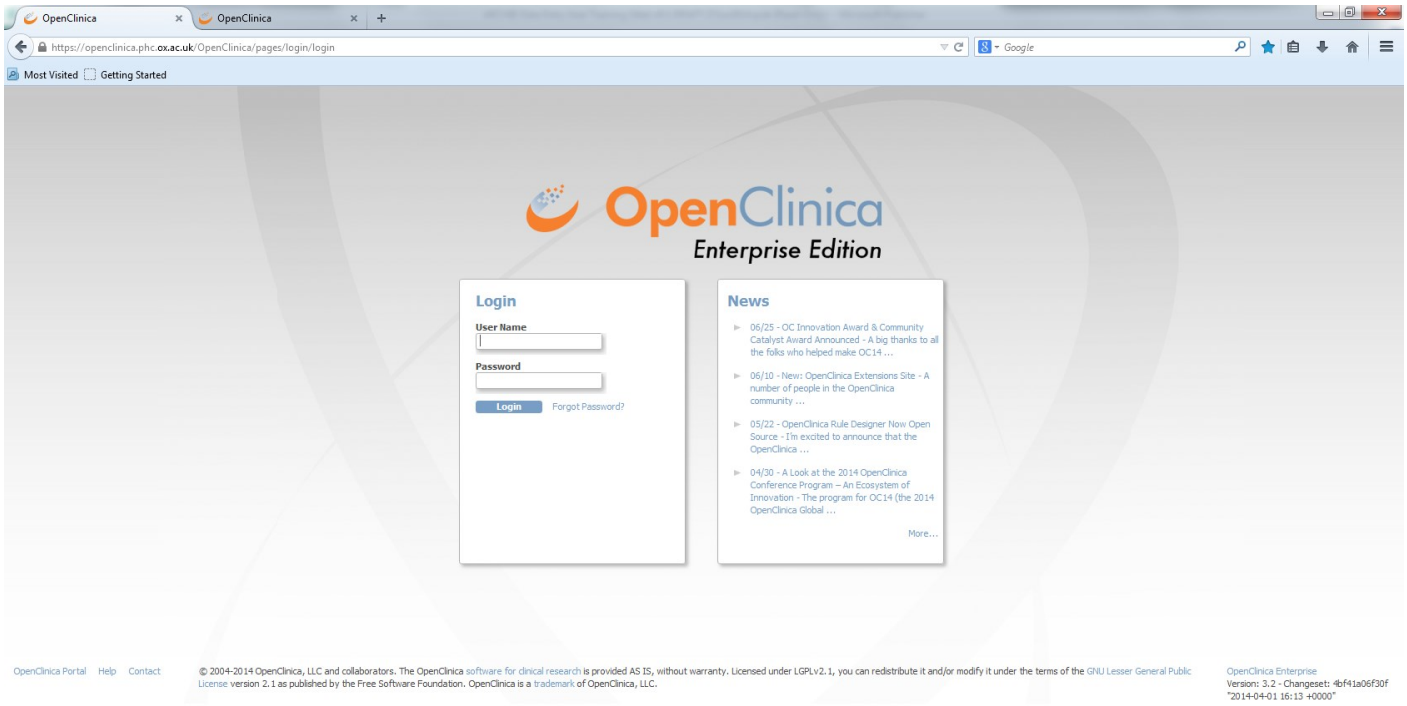
Data Entry User Guide



USER INFORMATION

User profiles will be created and maintained by the **System Administrator— sadie.kelly@phc.ox.ac.uk**

The system administrator will ensure appropriate access is given to the correct study and sites.

The system administrator will ensure that the correct account type and user role has been assigned.

PASSWORD

The system generates an initial, temporary password for a new user, which will be sent to your e-mail account (the system administrator will save your email address when creating your profile). You will then have the opportunity to change your password.

SYSTEM LOCKOUT

To enhance system security, OpenClinica is configured so that authorized users are only allowed 5 attempts to enter the correct password, and after that they are locked out and will be required to reset their password.

If you have any trouble accessing OpenClinica, or if you have been locked out, please contact the system administrator **(sadie.kelly@phc.ox.ac.uk)** who can re-set the account and send a new temporary password so you can successfully log in again.

Data Entry User Guide

Purpose of this guide

This data entry user guide explains how to use OpenClinica as a clinical database to record data collected in the ARCHIE study. It is organised by study visit so you can pick up the guide and follow instructions for the particular visit you are entering data. See the contents list below for the corresponding page number of the assessment or process you require.

Data Entry User Guide

Access to OpenClinica

You will initially have access to a test database where you can enter some dummy data by following through the steps described in this guide.

Once you have confirmed that you are happy using OpenClinica with the training provided, by signing off on your training log, you will gain access to the live database where data from ARCHIE participants will be collected. Your access to the test database will be revoked at this stage to prevent confusion.

The live OpenClinica database can be accessed from the link on the ARCHIE study website.

The link for the test database will be sent to you when your account is created.

To comply with Good Clinical Practice (GCP) guidelines, no personal identifiers (name of participant, parents, healthcare provider etc..) should be entered to OpenClinica, either in free text fields or in annotations and discrepancy notes. If reference to a person needs to be provided please enter as [participant], [parent], [doctor], [nurse] etc..

Definitions used in OpenClinica

Subject or Participant

A person who participates in a study. For ARCHIE, once a child is deemed to be eligible for the study (the child fulfils all inclusion criteria and has no exclusion criteria), they become a Subject/Participant whose data for the study will be recorded in OpenClinica. The terms Subject and Participant are used interchangeably throughout this guide.

Subject Identification (ID) number

Every participant will have their own unique ID number. In ARCHIE, the subject ID number will be comprised of a code specific to your surgery, hospital or recruiting site *(see below)* followed by a unique four digit number. The trial team will inform you of your site code which should be used for all participants recruited from your research site.

Site

A site is a set location (GP surgery, hospital or another place) where participant recruitment is taking place. Your OpenClinica user role will be assigned to a site or sites where you will only be able to view and enter data entered from your own site(s).

Definition used in OpenClinica *continued*

Study Event

A visit or encounter in the Study where data is collected from the participant. A Study Event involves completing one or more Case Report Forms (CRFs). In ARCHIE, study events are defined as assessments i.e. Baseline assessment, Week 1 and Week 2 follow up assessments and Notes Review are all separate study events that are expected to occur for each participant enrolled in the study. Additional study events are present for adverse and serious adverse events, study discontinuation and additional notes reviews where consent has been obtained for this.

Case Report Form (CRF)

A form that collects and contains Study Event data for a Study Subject.

Discrepancy Notes

OpenClinica has a feature which allows users to leave additional notes or annotations on a data field. OpenClinica can also automatically generate queries in response to entered data whose value, condition, level of detail, etc. are not as expected.

You may come across three different types of discrepancy note:

a) Annotations—these are comments or notes you can create when you need to provide extra information that will not fit into a data field, or where it would be helpful to explain the lack of data in a field. For example, an annotation could be provided to state 'Dosage varies' for a particular medication or 'Throat swab not done, child refused'. More information regarding annotations is given on page 27.

b) Failed Validation Checks—These will fire if data entered in a particular field does not comply with expected values (for example temperature higher or lower than usually expected), if there are missing data points where a value has not been entered that would usually be expected or if there are inconsistent data points that do not agree with data entered elsewhere on the same or another CRF. In these cases OpenClinica will automatically query the data field upon saving the form. FVCs will appear in red at the top of the data entry form. For more information please see page 28. A list of all Failed Validation Checks that apply to the ARCHIE study are given in the Appendix.

c) Reason for Change—if data in a field is changed after the CRF has already been saved to OpenClinica, for example if you have forgotten to add details of medication history and need to go back into the form to add them, then a 'Reason for Change' discrepancy note must be provided on that data point to explain why you have had to change the data. More details regarding how to edit entered data are given on page 26.

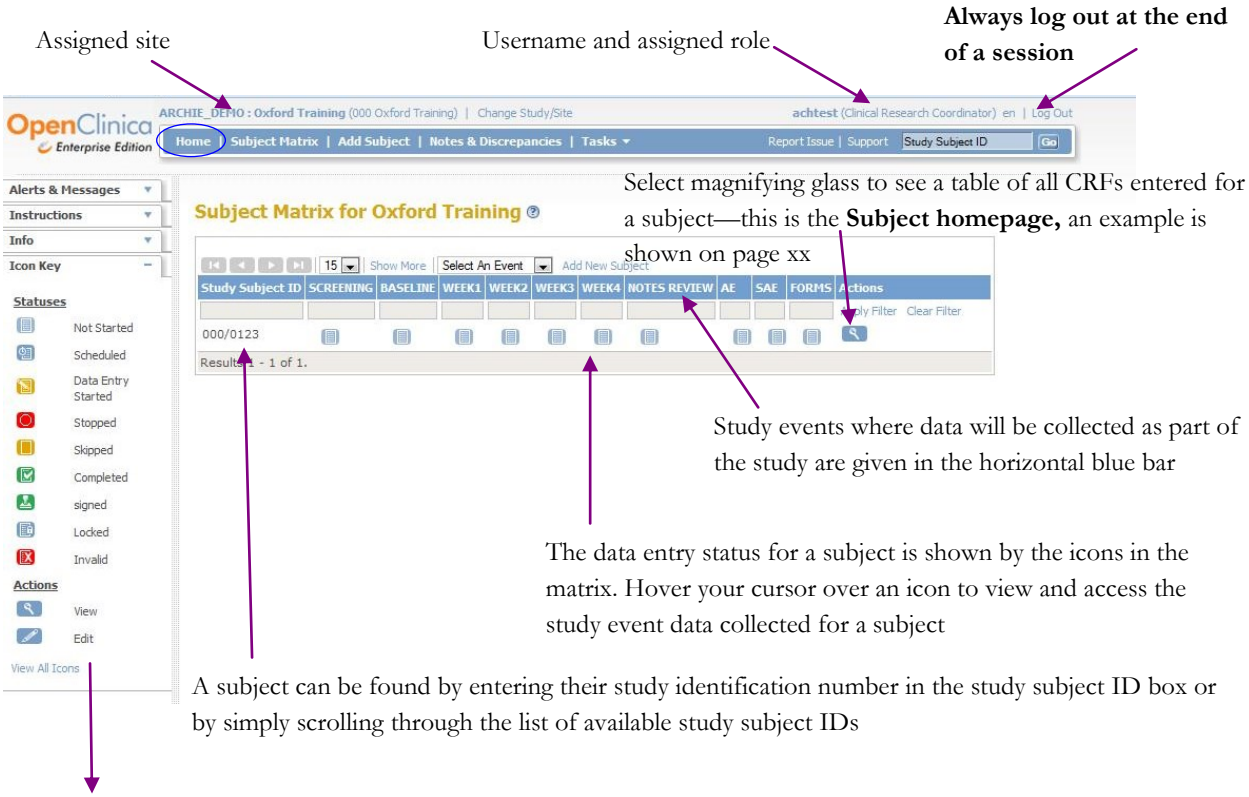
Data Entry User Guide

Study Homepage

Your assigned role in OpenClinica will be **Clinical Research Co-ordinator.** Using this role you will be able to:

- Add a new subject
- Add new study events
- View all subjects and their study events within your assigned site
- Enter CRF data
- Print entered data

The Subject Matrix lists all the subjects created at the site and the data entry status for all study events—this is your 'Overview' of all data entered for all subjects at your site. This is the page you will see whenever you first log in. Wherever you are in OpenClinica, if you select 'Home' from the blue task bar, this is the screen you will see.



COMMONLY USED ICON KEY DEFINITIONS

Scheduled A Study Event must be scheduled before data can be entered to any of the CRFs contained within that event. If an event is given as scheduled then no data has yet been collected for that event.

Data Entry Started Some data has been collected within the CRF but the CRF has not been 'Marked as complete'. Data within the CRF can be changed or added in the usual manner, without having to provide a 'Reason for Change' discrepancy note.

Completed Data has been collected within the CRF, the CRF has been 'Marked as complete' and the CRF submitted to the data-base. If any changes need to be made to any data points within the CRF then a 'Reason for Change' discrepancy note must be provided to give an explanation for the change.

Data to be collected

Data from the CRFs listed below will be **entered to the database by yourself using OpenClinica**. Each CRF can be entered only once, with the exception of Adverse Event and Serious Adverse Event Forms where multiple occurrences can be entered if required.

Study Event Name	CRF Name	Visit CRF	Repeating (can be entered for more than one occurrence)?
Baseline	Baseline	Baseline Assessment	No
Week 1	Week 1 Follow up	Week 1 Follow up	No
Week 2	Week 2 Follow up	Week 2 Follow up	No
Notes Review	Notes Review	Medical Notes Review	No
	Add Notes Review	Additional Medical Notes Review	No
AE	AE	Adverse Event Report Form	Yes
Forms	Discontinuation	Study Discontinuation Form	No

Other CRFs are listed within each study event, for example the Baseline Questionnaires within the Baseline event and Diary Day 1– Day 7 within the Week 1 follow up event. A full list is shown below. These will be completed on paper by the participant and should be **returned to the Clinical Trials Unit by post for entry to OpenClinica by data entry personnel.**

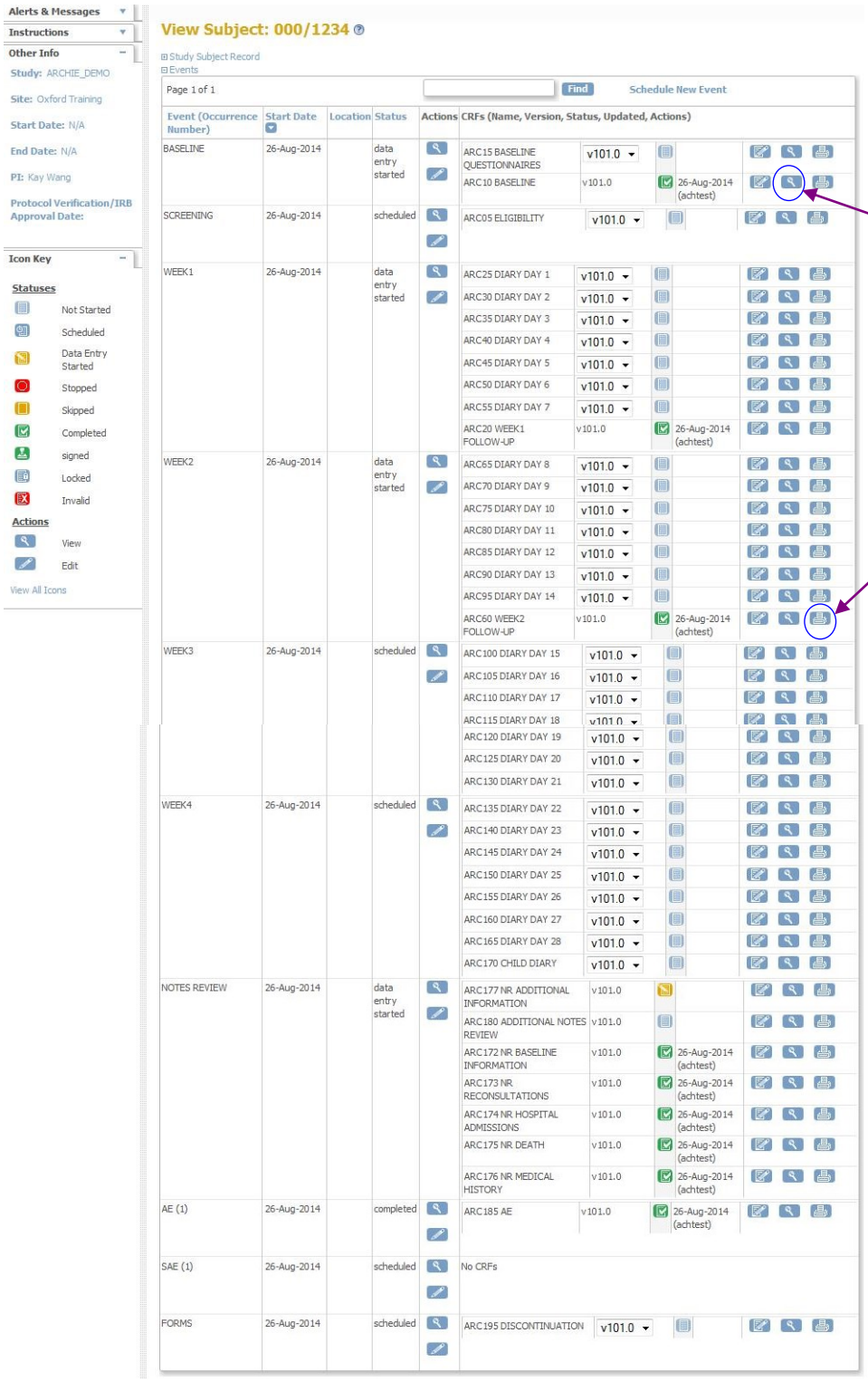
Study Event Name	CRF Name	Visit CRF	Data entered by
Eligibility	Eligibility assessment	Eligibility assessment	Completed online at site and uploaded to OpenClinica by CTU
Baseline	Baseline Questionnaires EQ-5D, CARIFS	Baseline Questionnaires	Paper CRF returned to CTU for data entry
Week 1	Diary days 1-7	Week 1 diary days 1-7	Paper CRF returned to CTU for data entry
Week 2	Diary days 8-14	Week 2 diary days 8-14	Paper CRF returned to CTU for data entry
Week 3	Diary days 15-21	Week 3 diary days 15-21	Paper CRF returned to CTU for data entry
Week 4	Diary days 22-28	Week 4 diary days 22-28	Paper CRF returned to CTU for data entry
	Child diary	Child diary	Paper CRF returned to CTU for data entry
Serious Adverse Event	Serious Adverse Event Report Form	Serious Adverse Event report form	Paper CRF returned to CTU for data entry

Data Entry User Guide

Subject homepage

The subject homepage is reached by selecting the magnifying glass next to a subject ID in the subject matrix. This is an overview of all data entered, or to be entered, for a subject in the study.

Refer to the Icon Key panel on the left side of the screen to provide information of the data entry status for all CRFs for a subject.



Once data has been entered into a CRF, you are able to **View** the data onscreen by selecting the magnifying glass icon

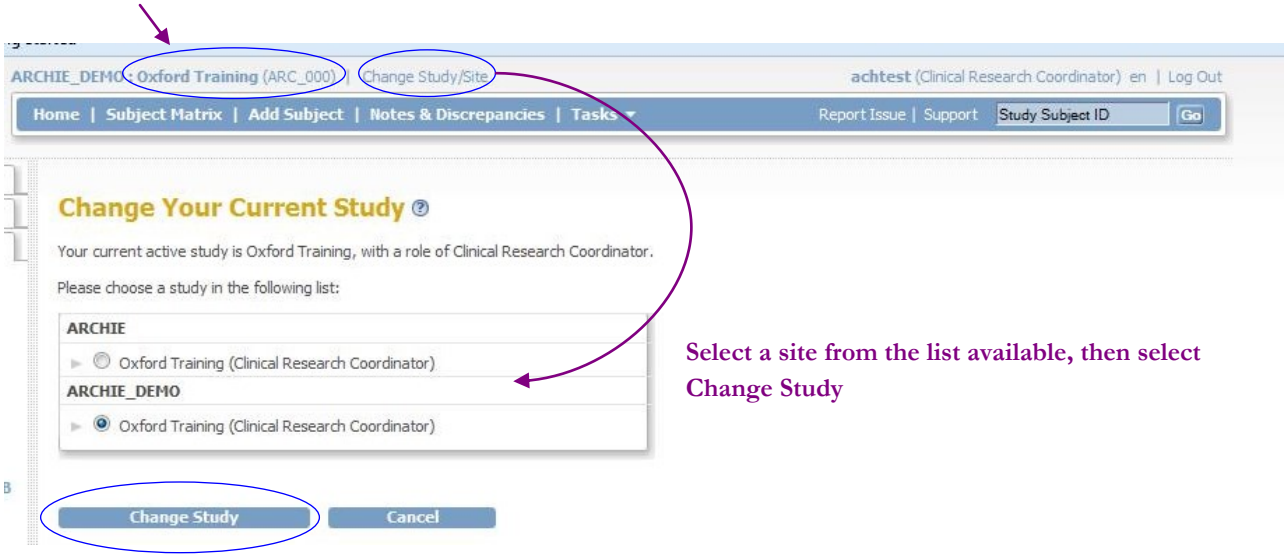
You are also able to produce a printable copy of the CRF by selecting the **Print** icon

Selecting the correct site on OpenClinica

If you will be recruiting participants from more than one location, then your user role will have access to more than one site on OpenClinica. Before adding any data, either for baseline or follow up assessments, ensure you are logged in to the correct site, as shown at the top of the screen. You will not be able to view data entered from another site that you have access to if you are not logged in to that site.

To change site, select **Change Study/Site** at the top of the screen. The window below then appears, with a list of all available sites to which you have access. Simply select the radio button next to the correct site then click **Change Study**. You will need to confirm your change on the next screen and then you will see the subject matrix for the site you selected.

Access provided to site shown



Select a site from the list available, then select Change Study

ARCHIE ID numbers

Subject ID numbers (or ARCHIE ID numbers as termed in your training videos) are always in the format

101/0012

101 refers to the code assigned to your site, and can be found in your study pack or in the site details shown at the top of the screen when you log into OpenClinica.

0012 is a unique number assigned to the participant from your site. No two participants will have the same ARCHIE ID number.

When entering a subject to OpenClinica (see page 9), the ID number should ALWAYS be added in this format, with a forward slash between the site code and the unique identifier and with no spaces.

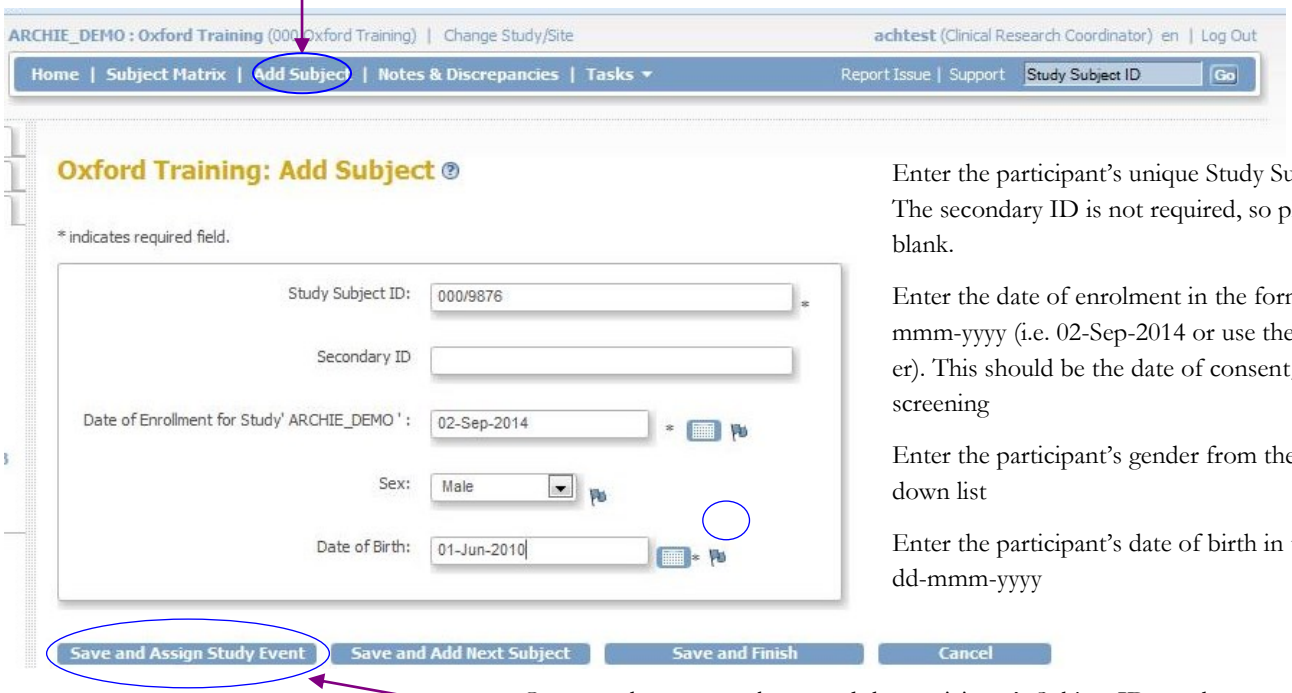
Adding a new subject

Once you have completed the online ARCHIE eligibility form to confirm the participant is eligible for inclusion in the study and you have assigned the participant an ARCHIE Subject ID number, the next step will be to add the participant to OpenClinica.

Participants are added using their unique ARCHIE Subject ID number which should always take the format of 111/1234 where the first three digits are specific to your research site and the last four digits are the participants unique identifier. Each Subject ID number can only be entered once in OpenClinica. The Subject ID number cannot be amended once it has been added, so it is **VERY IMPORTANT** that it is added correctly.

When you are ready to add a subject, select '**Add Subject**' from the blue bar at the top of the screen.

Select **Add Subject** from the blue bar to reach the 'Add subject' screen



Enter the participant's unique Study Subject ID. The secondary ID is not required, so please leave blank.

Enter the date of enrolment in the format dd-mmm-yyyy (i.e. 02-Sep-2014 or use the date picker). This should be the date of consent/eligibility screening

Enter the participant's gender from the drop down list

Enter the participant's date of birth in the format dd-mmm-yyyy

Once you have correctly entered the participant's Subject ID number and the basic details, select **'Save and Assign Study Event'** to proceed to enter data

If you wish to add another participant using their Subject ID before entering any data, select '**Save and Add Next Subject**' to clear the screen and add the next participant's details.

If you wish to finish before entering another participant or before entering data, select '**Save and Finish**' to enter data for this participant at a later stage.

If you have made any errors and wish to start again or complete the task later, select '**Cancel**'.

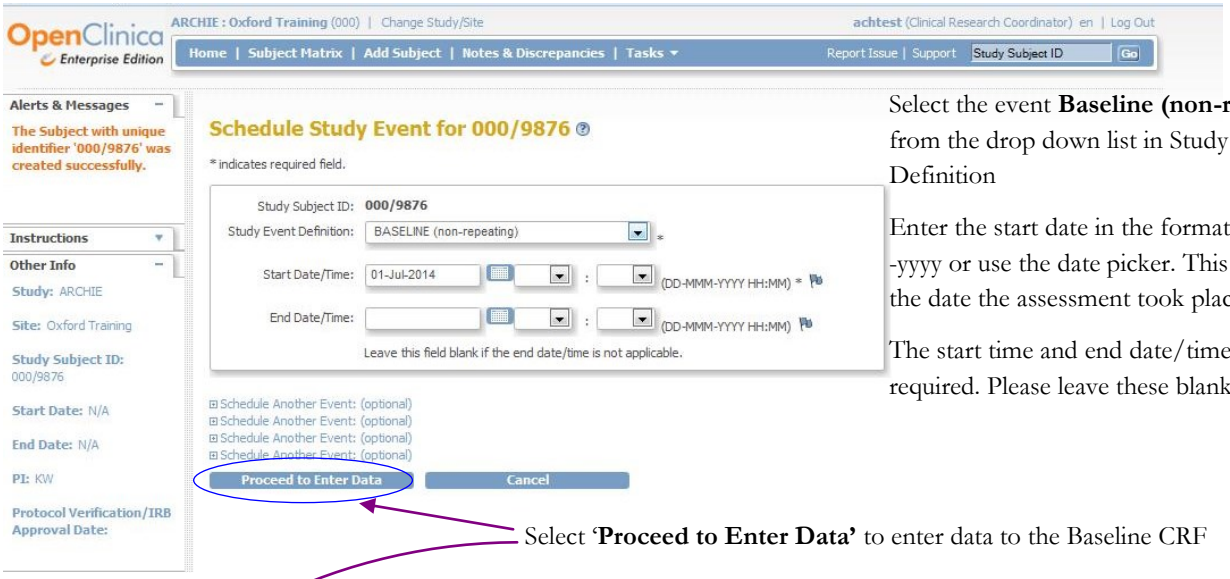
Data Entry User Guide

Scheduling Study Events

Study Events must be **Scheduled** in OpenClinica before any data relating to that visit can be entered.

The first event you will need to schedule once a participant has been added to OpenClinica is the Baseline event

Once data has been entered for the Baseline assessment, all other events are automatically scheduled for that participant, and are ready to collect data without the need for manually scheduling any further events.

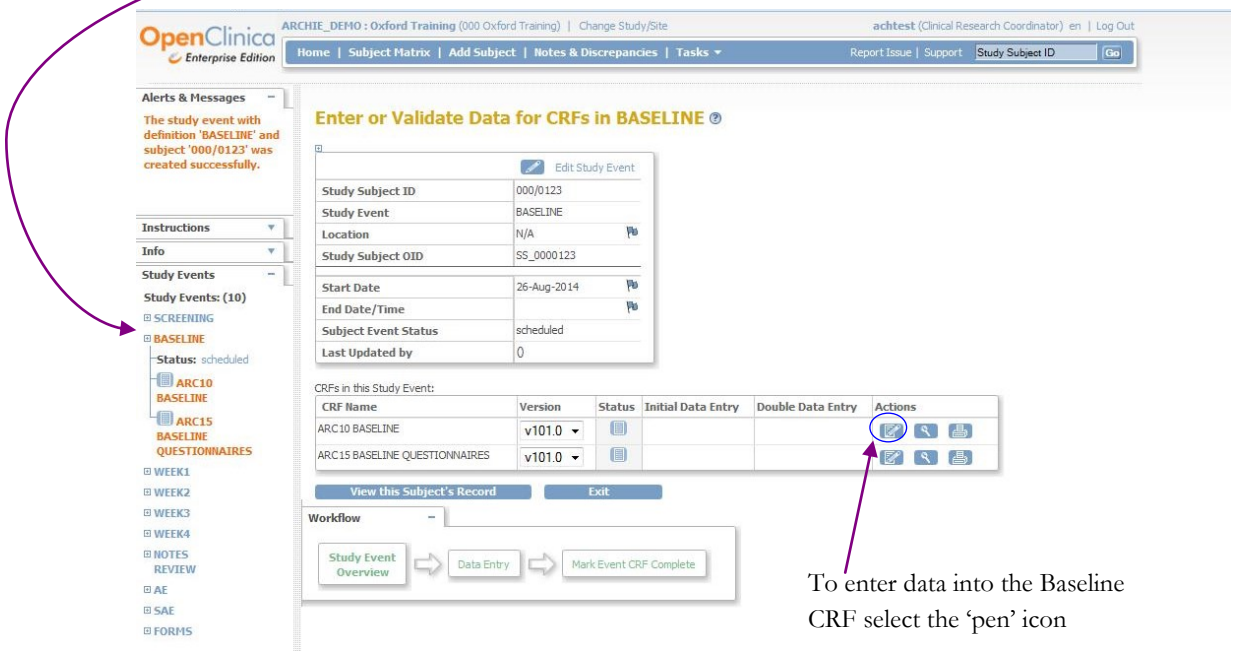


Select the event **Baseline (non-repeating)** from the drop down list in Study Event Definition

Enter the start date in the format dd-mmm -yyyy or use the date picker. This should be the date the assessment took place.

The start time and end date/time are not required. Please leave these blank.

Select '**Proceed to Enter Data'** to enter data to the Baseline CRF



To enter data into the Baseline CRF select the 'pen' icon

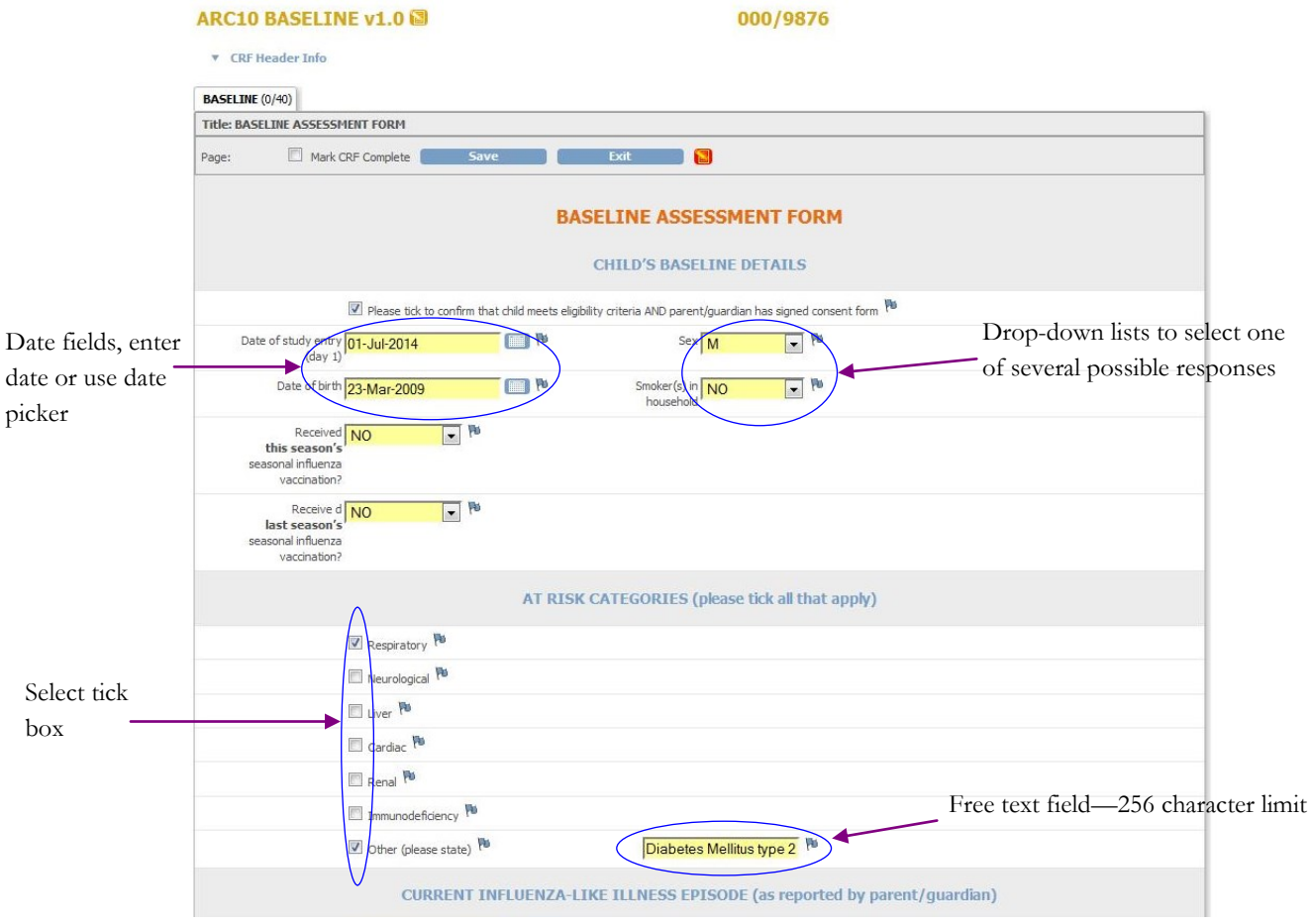
The BASELINE QUESTIONNAIRES CRF is completed by the participant on paper and will be returned to the Clinical Trials Unit by post for entry to OpenClinica by data entry personnel.

Entering data—Baseline Assessment

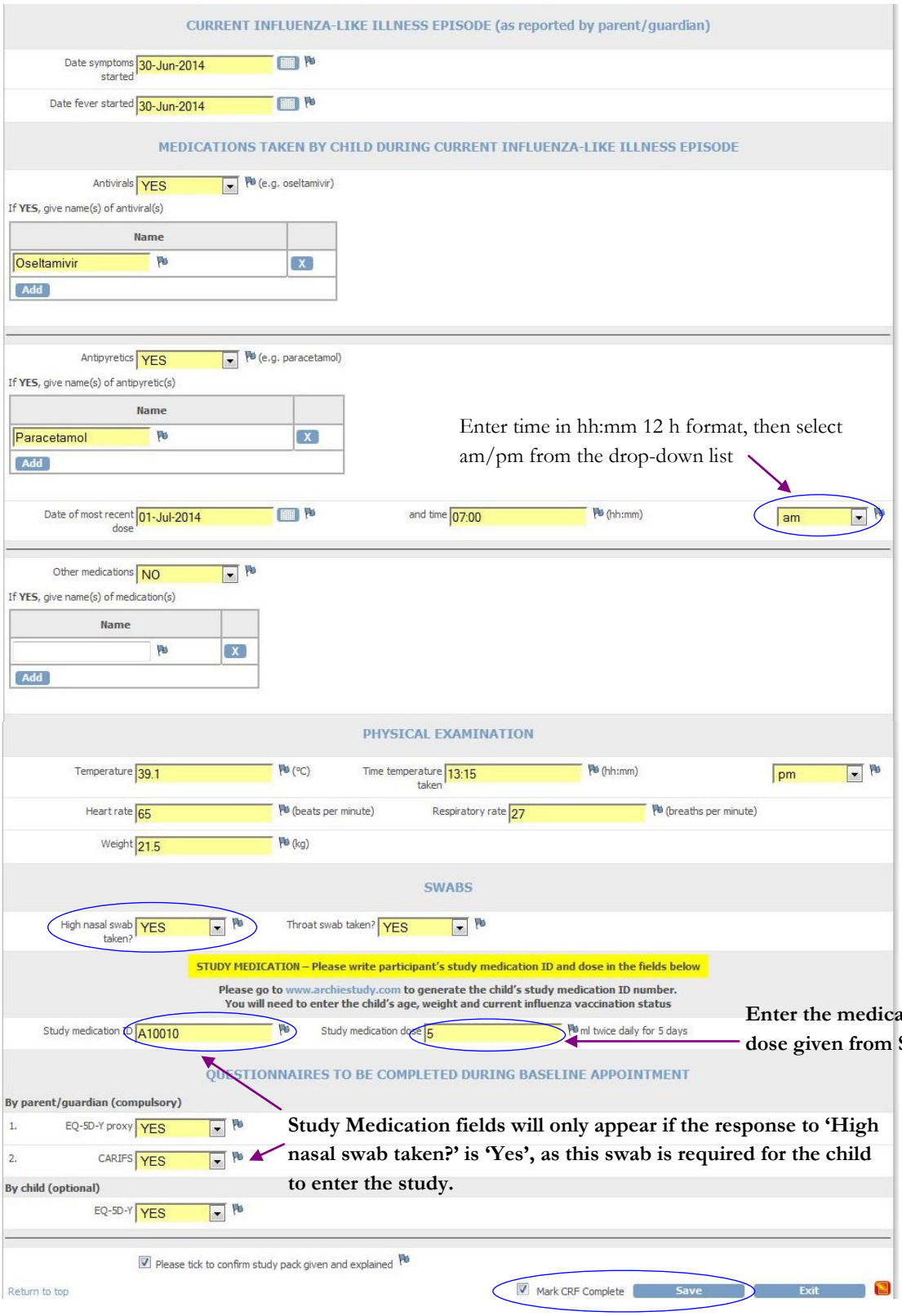
The name of the CRF and the Study subject ID is always displayed at the top of the data entry screen.

Data is collected in several different formats in OpenClinica:

- Tick boxes—select these to confirm a positive response to the question
- Date fields—dates should be entered in the format dd-mmm-yyyy i.e. 12-May-2014, or use the date picker to select the correct date. A date entered in any other format will result in an error message requesting re-entry in the correct format.
- Drop-down lists—select the arrow next to the response box and a list of the available responses is shown; select the correct response and it will appear in the response option
- Free text—these feature where further details are required or a description of an event such as an Adverse Event is required that cannot be covered by drop-down lists. Free text fields are limited to 256 characters. If you require more space to provide information this can be given in an annotation relating to the specific data-point. Please see page 27 for instructions on how to add an annotation.



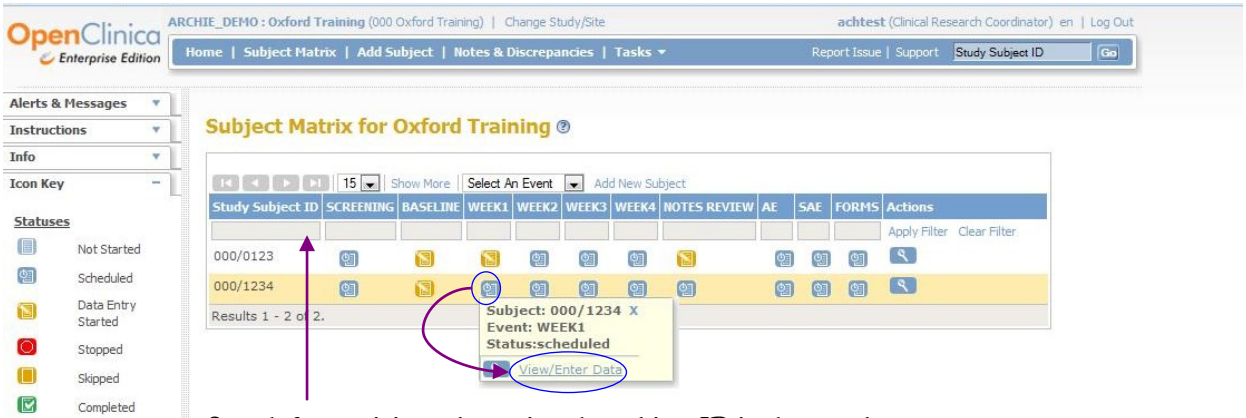
Entering Data—Baseline Assessment *continued*



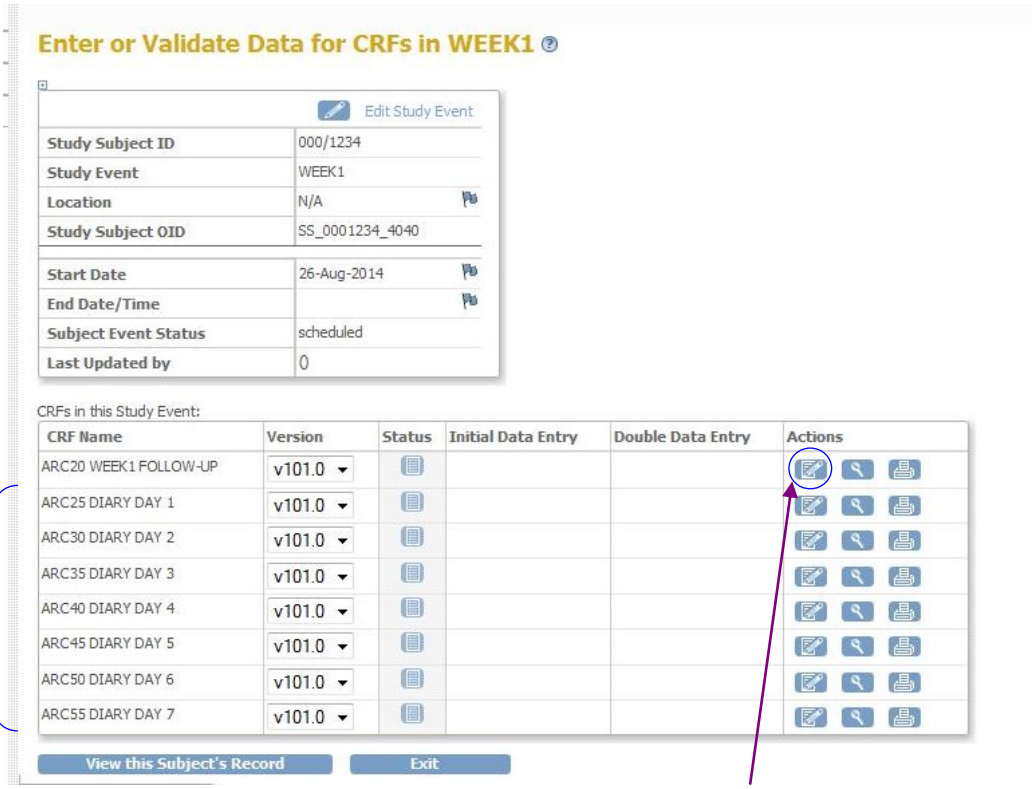
When you have finished entering baseline data, whether or not study medication details have been recorded, select the tick box '**Mark CRF complete'**, click OK when the pop up message appears, then select **Save** to save the data to the database. If you wish to complete data entry at a later stage, do not 'Mark CRF complete', select **Save** and you can finish entering data at another time.

Entering data for follow-up assessments—Week 1 follow up

When a participant returns for a follow up assessment and you are ready to enter data for that assessment you should log in to OpenClinica and reach the subject matrix screen. You can then locate the participant's Study ID number by either scrolling through to view the list or by typing the ID number in the grey box at the top of the Study Subject ID list. As the follow up assessments are automatically scheduled and ready to collect data, you simply need to select the event **Week 1** for the participant then **View/Enter Data** as shown below.



Search for participant by typing the subject ID in the grey box

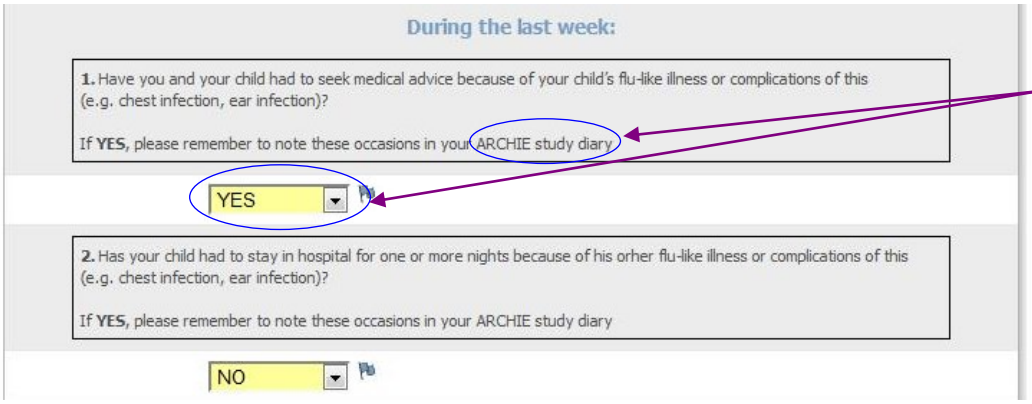


Select the 'Pen icon' in the Week 1 Follow up row to enter data for the Week 1 Follow up assessment

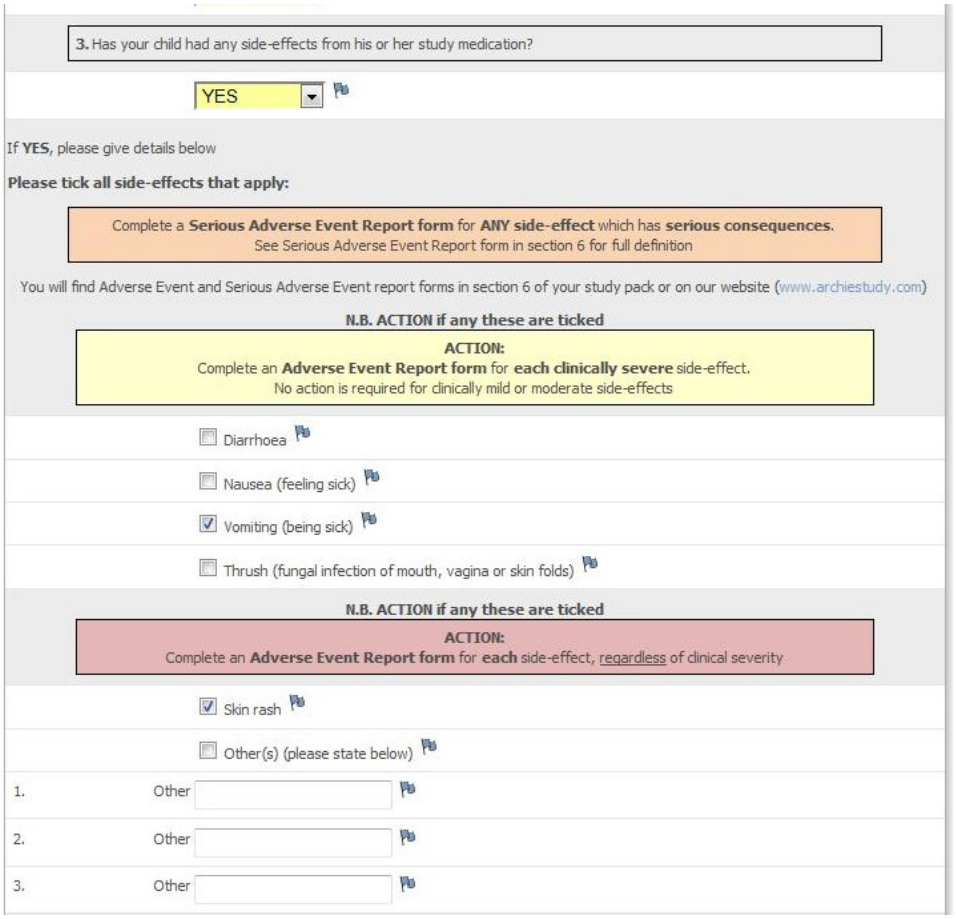
Please note: DIARY DAY 1-7 CRFs are completed by the participant on paper and will be returned to the Clinical Trials Unit by post for entry to OpenClinica by data entry personnel.

Week 1 Follow up assessment CRF *continued*

Complete the Week 1 Follow up assessment CRF as for Baseline. Instructions are included to remind you of the study schedule, to remind the parent/guardian to return the Week 1 diaries and to prompt you to complete an adverse event form if necessary.



Remind the parent/ guardian to record any occurrences of medical advice or hospital admissions in their study diary before returning the diary to the Clinical Trials Unit by post.

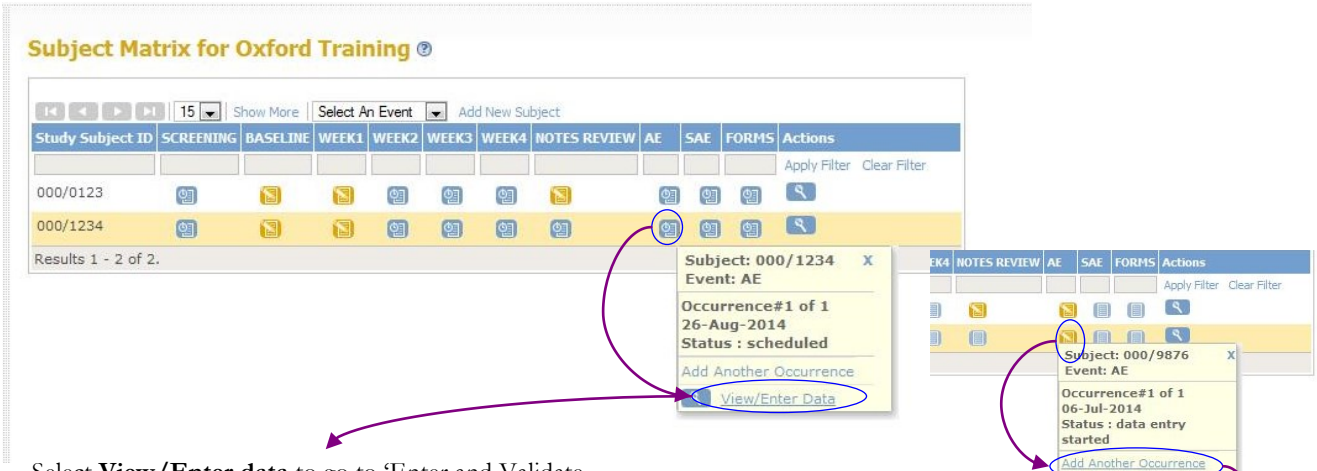


If the participant has experienced any adverse events that should be reported, as stated in the onscreen instructions, a message will appear to remind you to complete an adverse event report form on OpenClinica. Instructions on how to complete an adverse event form are given on page 15.

Select '**Mark CRF complete'**, acknowledge the pop-up message and click '**Save'** to save the completed CRF to the database.

Adverse Event (AE) Report Form

Adverse Event (AE) Report Forms can be entered as many times as necessary to record multiple adverse events for a participant involved in the study. The first occurrence is automatically scheduled once the baseline assessment has been completed. Any further occurrences need to be scheduled manually after selecting '**Add another occurrence'** as shown below.



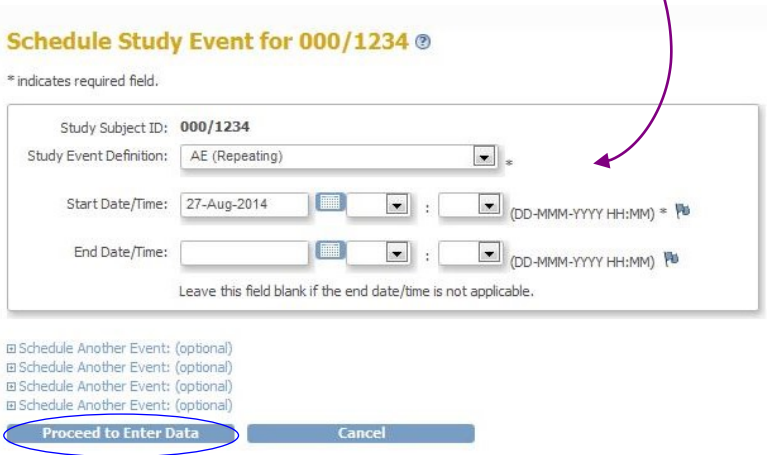
Select **View/Enter data** to go to 'Enter and Validate Data for CRFS in AE' screen below

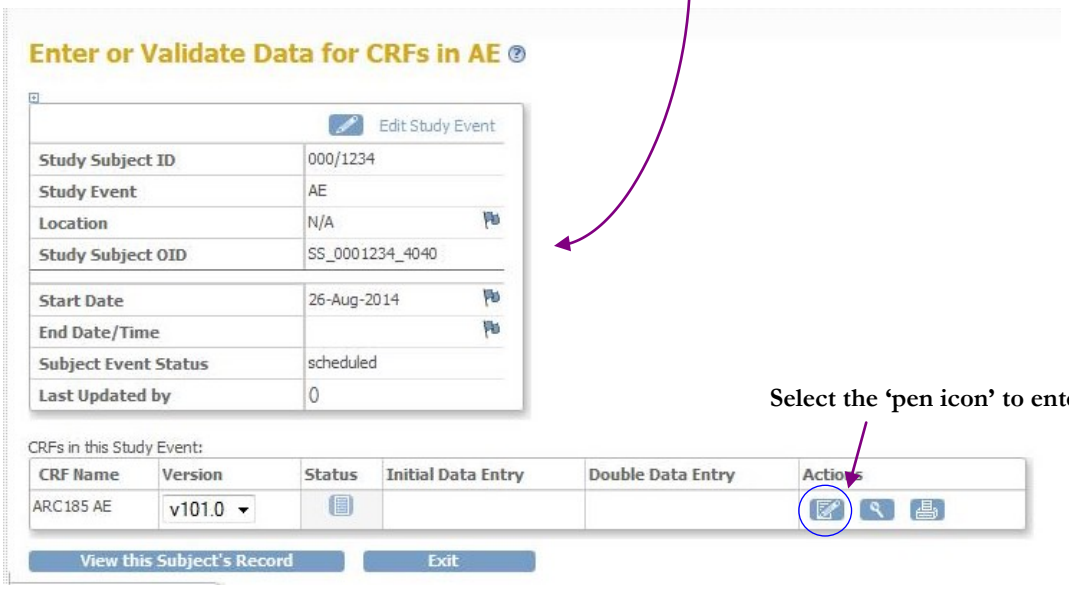
Study Event Definition states '**AE (Repeating)**'

Enter the start date; this should be the start date of the adverse event for which you are entering data

Start time and end date/time are not required so please leave blank

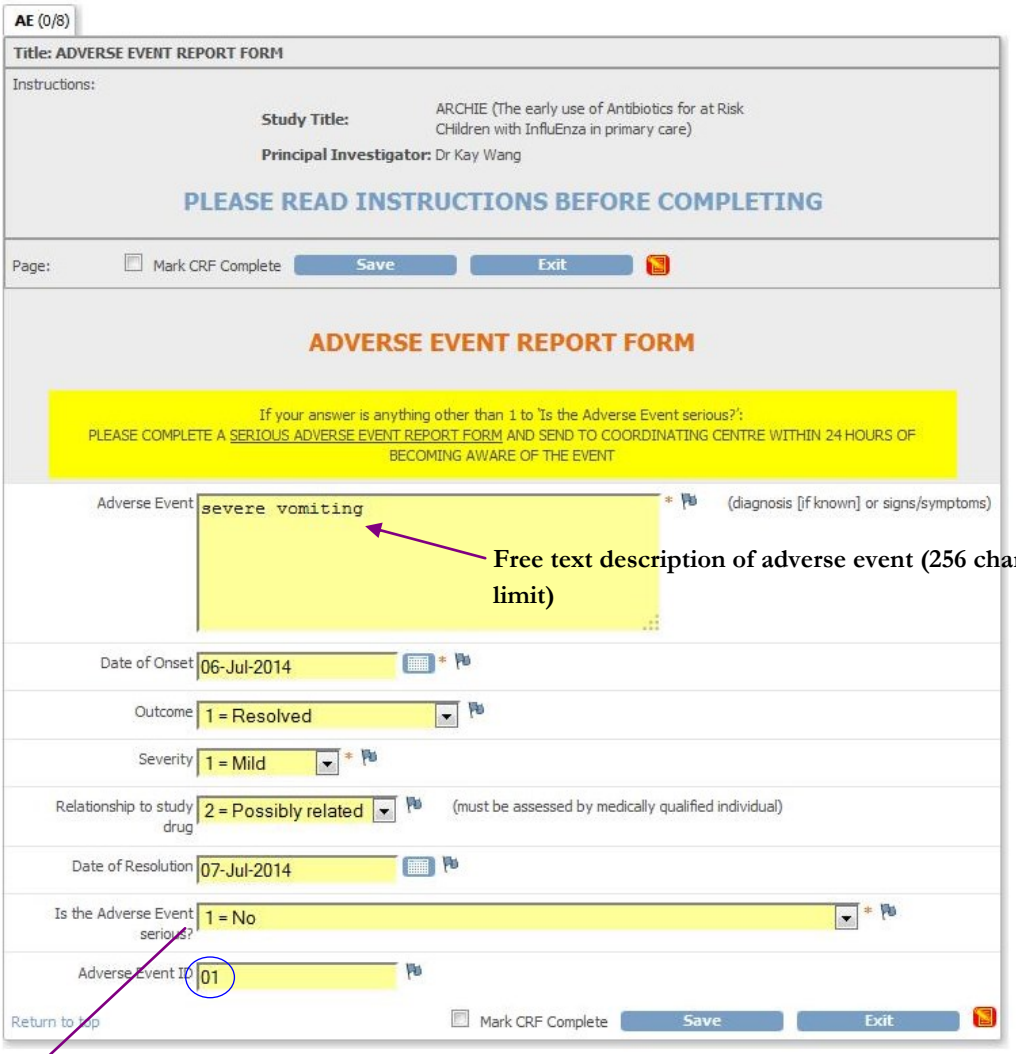
Select **Proceed to Enter Data** to continue





Select the 'pen icon' to enter Adverse Event Data

Completing the Adverse Event Report Form



The **Adverse Event ID** is pre-printed on the Adverse event report log. Please enter the corresponding ID given on the log for the Adverse event you are entering to the database.

1 = No

2 = Results in death

3 = Is life=threatening

4 = Requires inpatient hospitalisation or prolongation of existing hospitalisation

5 = Results in persistent or significant disability / incapacity

6 = Is a congenital anomaly / birth defect

7 = Jeopardised the participant (or unborn child) and required or may require medical or surgical intervention to prevent any of the outcomes listed in 2-5

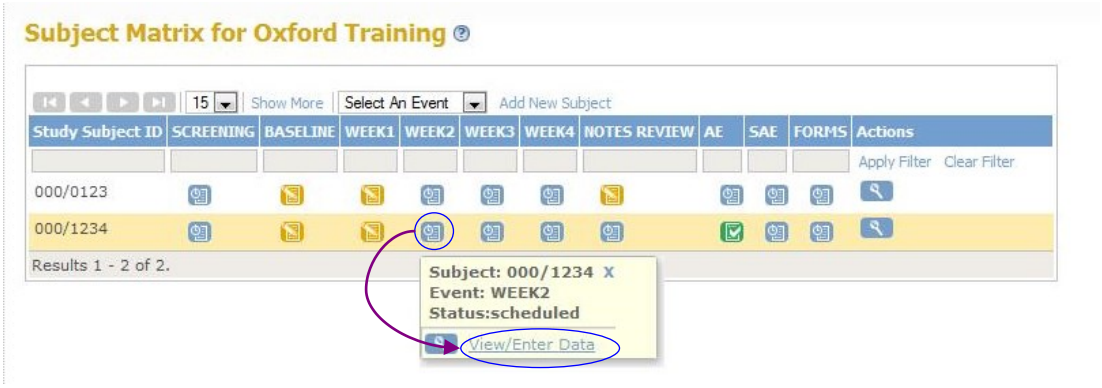
The Adverse event description, date of onset, severity and seriousness are **required fields,** indicated by a red asterisk next to the data field. This means that a response must be provided for these questions otherwise the form will not save. An error message will appear if you try to save the form with a blank response to any of these fields, directing you to complete entry for the required data point.

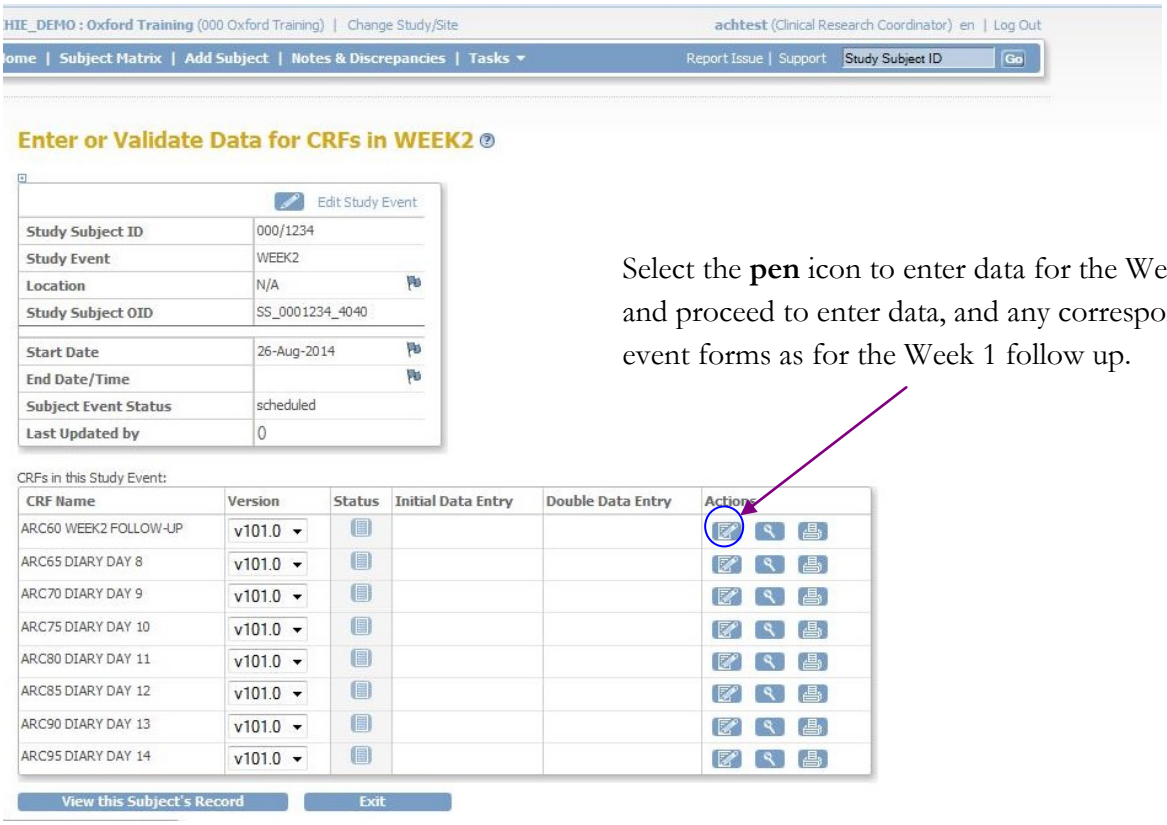
If your response to **Is the Adverse Event serious?** is any of the response options from 2-7 the study team will be notified immediately once your data entry has been saved. You will be required to complete a Serious Adverse Event Report Form. A member of the study team will be able to advise you.

As for all other CRFs, once you have completed data entry for the Adverse event form, select **Mark CRF complete** then select **Save** to submit your entry to the database.

Week 2 Follow up Assessment

Data for the Week 2 Follow up assessment is entered in much the same way as the Week 1 Follow up assessment. If the participant or the parent has reported any adverse events in the week since the Week 1 Follow up that require reporting, please complete an Adverse Event form as described for the Week 1 assessment (see page 15).





Select the **pen** icon to enter data for the Week 2 follow up and proceed to enter data, and any corresponding adverse event forms as for the Week 1 follow up.

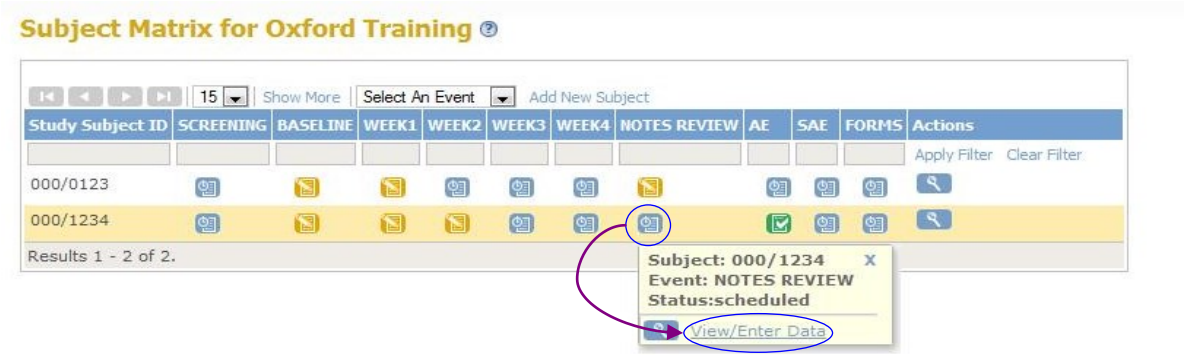
Diary day 8-14 CRFs will be completed by the participant on paper and returned to the Clinical Trials Unit by post for entry by data entry personnel.

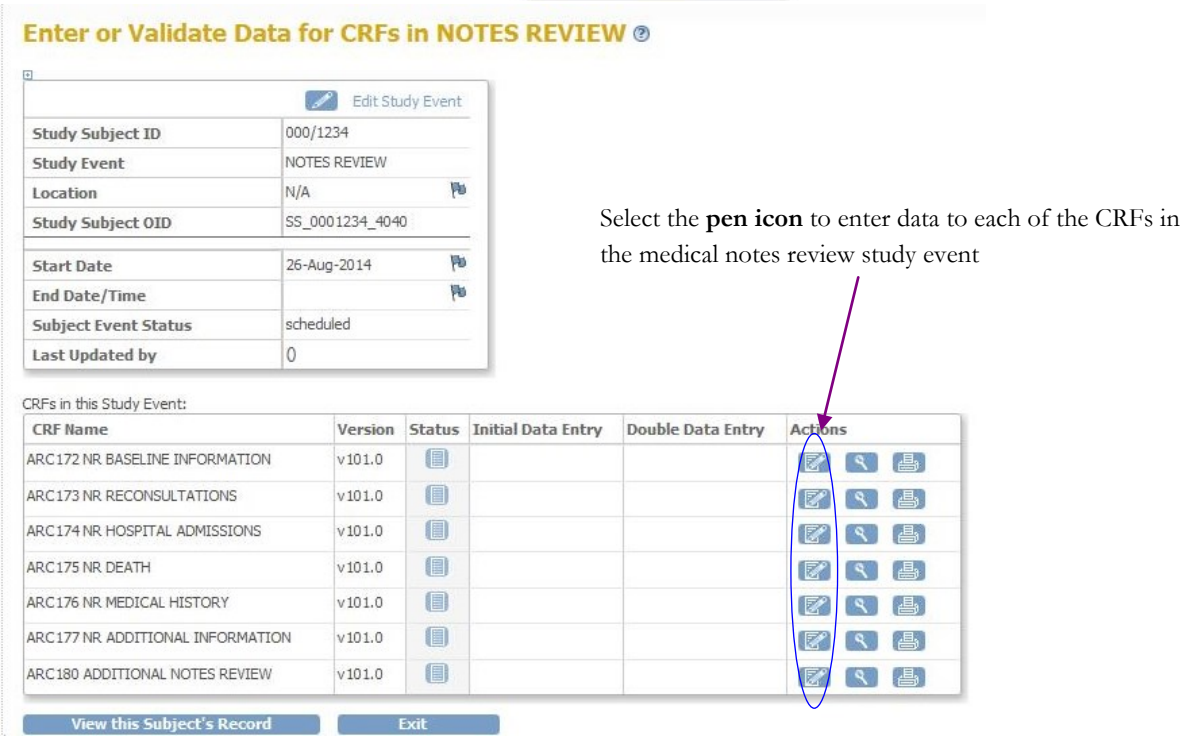
Data collected in Weeks 3 and 4 comprise the participant-completed symptom diaries and questionnaires which are returned to the Clinical Trials Unit by post for entry to the database.

Medical Notes Review

The trial team will send you a reminder when the medical notes reviews for the participants recruited from your site should be completed. This reminder will also detail the date range for which we would like information collected regarding re-consultations and hospital admissions for each participant so please refer to this when completing the review. The entry screens provide details of date ranges for other records of medical history so please read the onscreen instructions carefully. Any dates that are submitted on the notes review CRF that are outside of the specified range will result in a query sent to you in order to confirm if the correct data has been entered.

The Notes Review study event is automatically scheduled for entry once the participant has completed the Baseline assessment. To enter data select the scheduled icon for the correct participant in the Notes Review column and then select **View/Enter Data.**



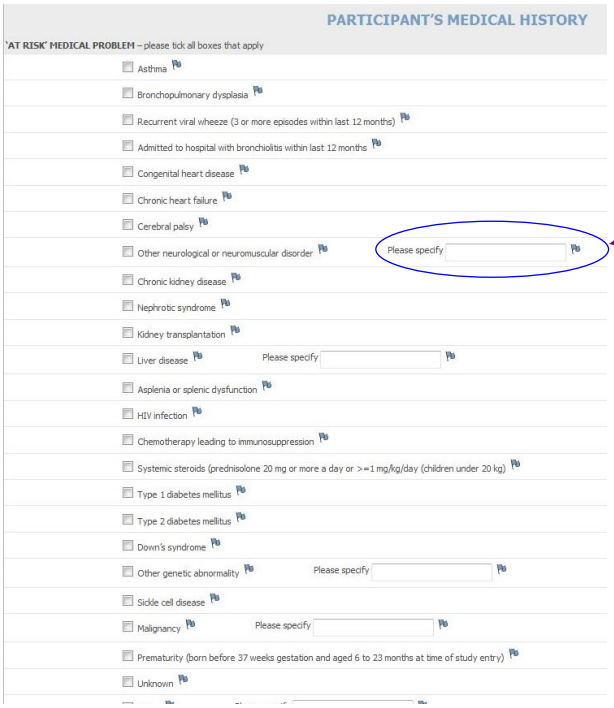


Select the **pen icon** to enter data to each of the CRFs in the medical notes review study event

The Notes Review to be completed by all participants is split into 6 separate CRFs (ARC172 to ARC177, as shown above). ARC180 Additional Notes Review only needs to be completed by those participants who have given consent to provide follow up throat swabs. Please enter data to each CRF, even if you think there is nothing to record for a participant, as a simple 'Yes/No' question will be present as the first data point to confirm if there were any occurrences in the requested timeframe. The Clinical Data Manager will then know that there is no data to record and will not raise a query for what appears to be missing data.

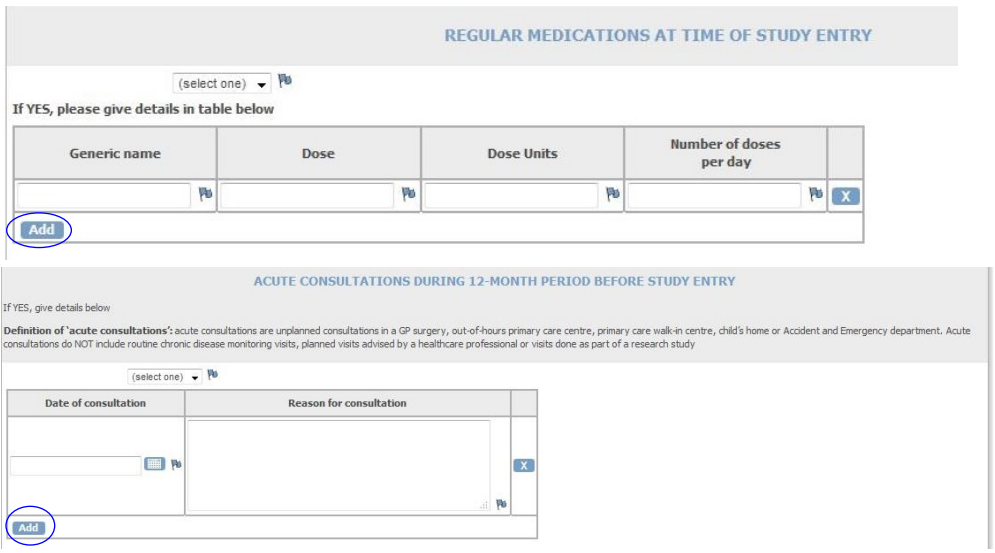
Medical Notes Review: Medical History

The medical history CRF can be completed at the Baseline assessment, if you wish, or along with the rest of the notes review after day 28. This CRF asks you to provide some details of the participant's medical history, including details of their 'at risk' medical problem, regular medications, dates of vaccinations, details of acute consultations in the 12 months prior to study entry and antibiotics prescribed in the three months prior to study entry. Partial dates, for example, month and year or year only are permissible in this CRF for dates of vaccinations, acute consultations and antibiotic prescriptions. So if a full date is not available for any of these fields please enter as much information as possible in mmm-yyyy or yyyy format. Please try to provide as much information as possible regarding dosage and duration of any medications recorded. If any detail is unknown you can add an annotation to the field to state 'Information not known' or similar. Please see page 27 on how to create and save annotations.



Free text field to specify details where required

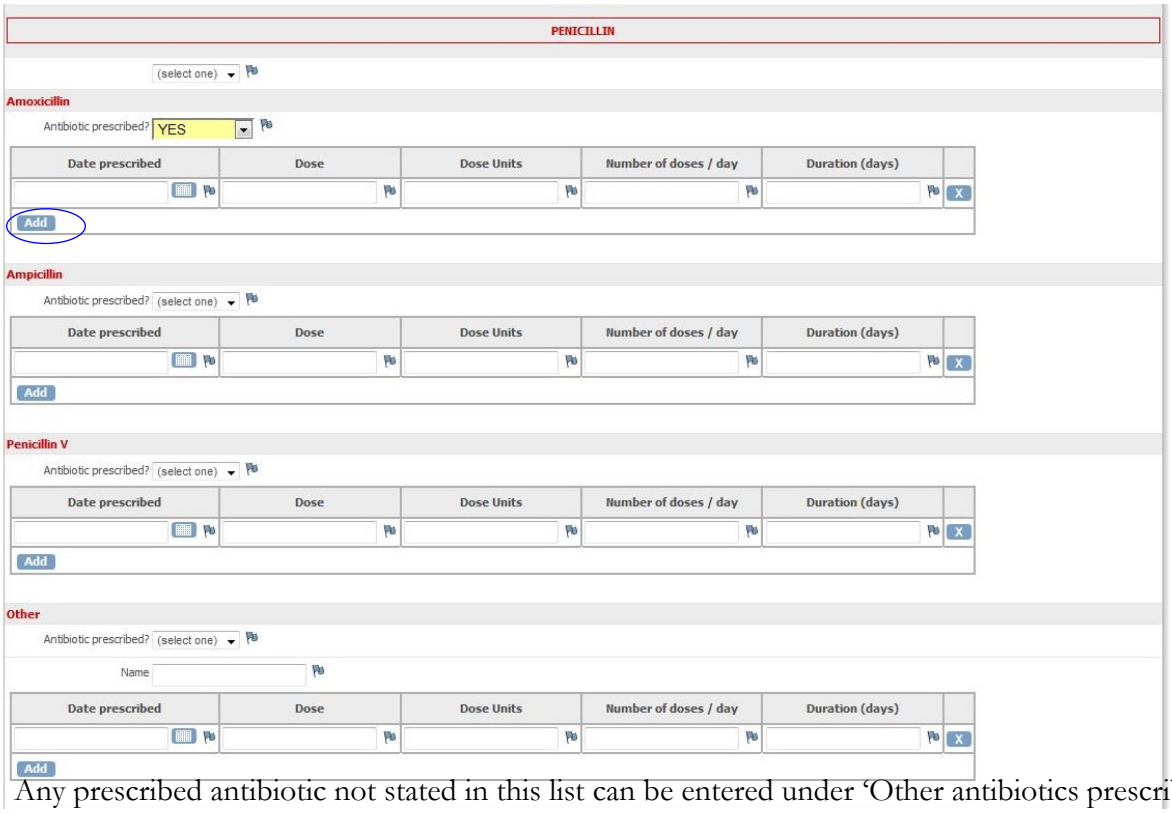
You can add as many rows of Regular medications and Acute consultations as required by clicking the **'Add'** button after each entry, as shown below.



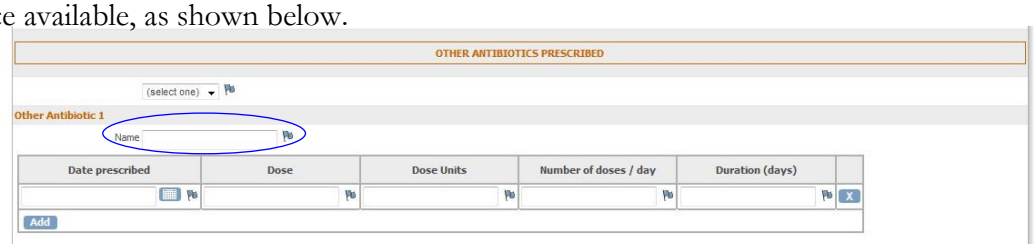
Data Entry User Guide

Medical Notes Review: Medical history of prescribed antibiotics

The final section of the medical history CRF asks for details of antibiotics prescribed in the 3 months prior to study entry. The trial team can inform you of the specific date ranges required for each participant recruited from your research site. Antibiotics are split into their types and then further into generic names, see example for penicillin group of antibiotics below. You can enter as many records of prescription for each antibiotic type as necessary by selecting **'Add'** for each record, as shown below.



Any prescribed antibiotic not stated in this list can be entered under 'Other antibiotics prescribed', providing the generic name in the space available, as shown below.



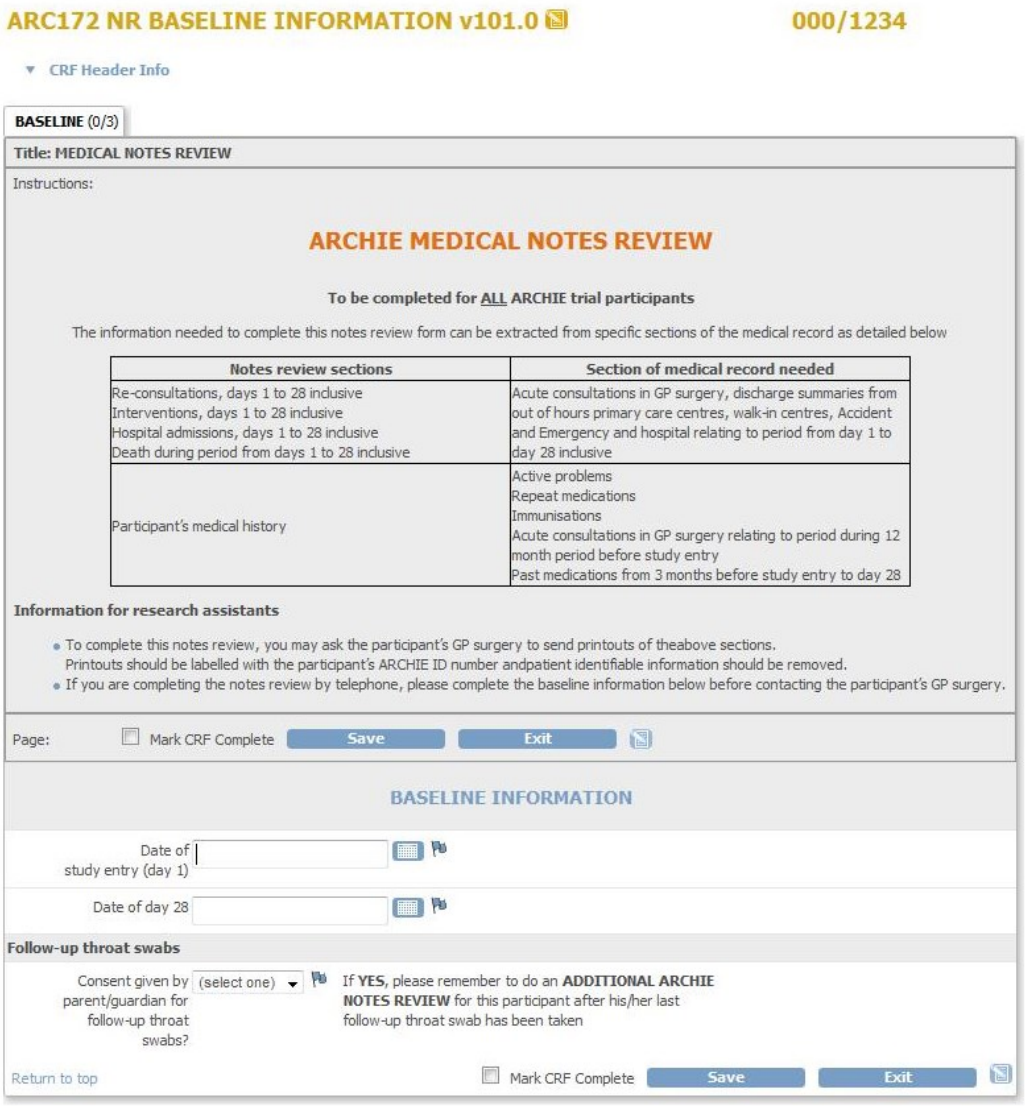
The generic names of antibiotics and their associated type for which detail of prescriptions are requested are given in the table below.

Penicillin	Penicillin/beta-lactamase inhibitor	Cephalosporin	Macrolide	Quinolone	Other antibiotics
Amoxicillin	Co-amoxiclav	Cefalexin	Erythromycin	Moxifloxacin	Space to provide up to four further records of prescribed anitbiotics not covered elsewhere, or for additional records
Ampicillin	Other (please state generic name)	Cefradine	Clarithromycin	Ciprofloxacin	
Penicillin V		Other (please state generic name)	Other (please state generic name)	Other (please state generic name)	
Other (please state generic name)					

Medical Notes Review—Baseline Information

The first CRF of the Medical notes review to be completed after day 28 is simply to collect the dates of study entry, the date of day 28 of the study schedule and whether consent has been given for follow up throat swabs.

We would like to know of any re-consultations and hospital admissions that have occurred between study entry and day 28 so please use these dates as a reference for the re-consultations and hospital admissions CRFs.



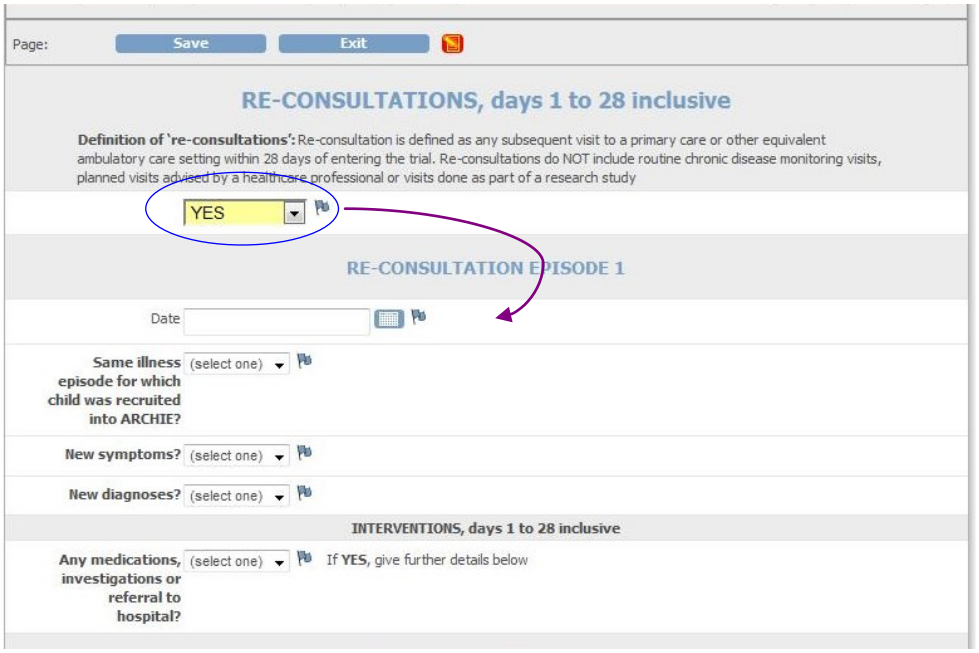
Instructions are present at the top of each CRF within the notes review study event to help you complete each form.

Once you have finished entering data for the Baseline Information CRF, select **Mark CRF Complete** then **Save** to submit your entry to the database.

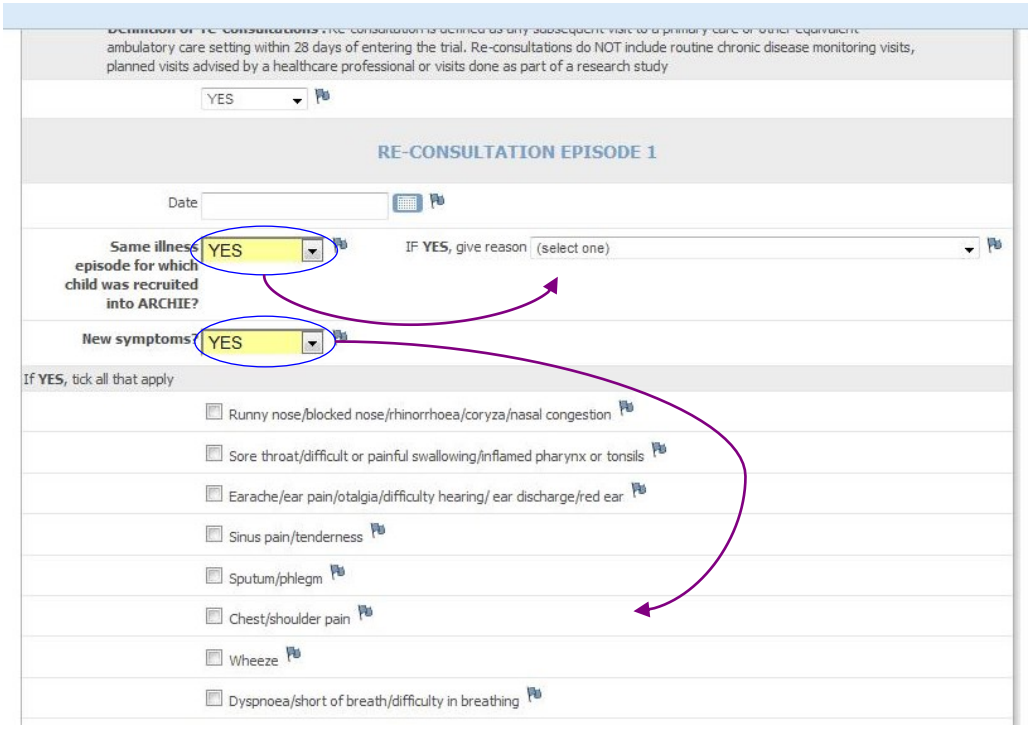
Please then proceed to complete the Re-consultations CRF of the Notes Review.

Medical Notes Review: Re-consultations

The medical notes review CRFs are quite extensive and detailed. The entry screens are designed so that more questions about the re-consultation become visible only if a positive **'Yes'** response is given. The screens are therefore much easier to follow and by the questions appearing dynamically in this way should prompt you to provide as much information as possible with less chance of missing important details which would be requested by a data query later on. If the participant had no re-consulatations then just select **'No'** and the dynamic fields will not be visible and you can Mark CRF complete and Save the form without going any further.

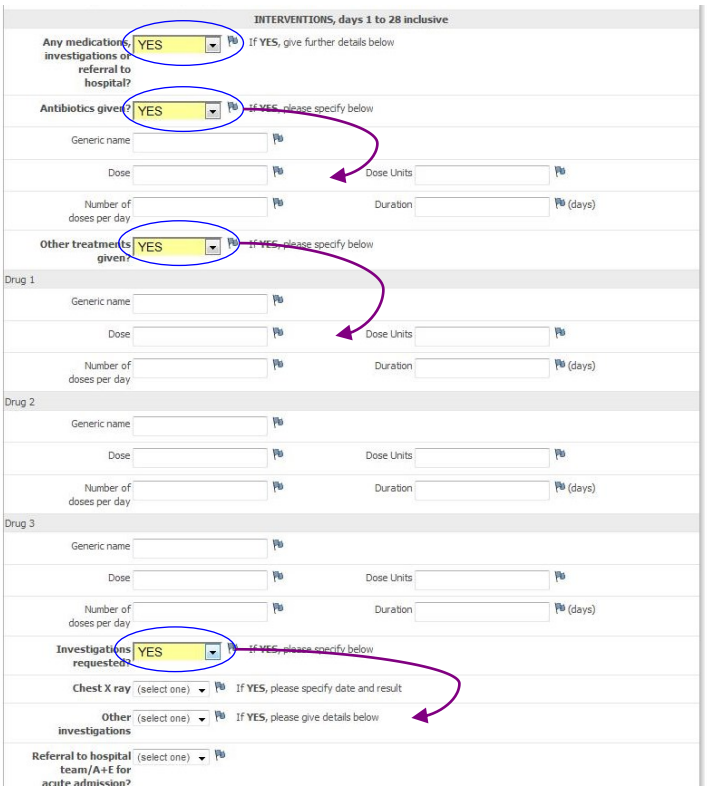


Work through the questions regarding each re-consultation, providing as much information as possible.

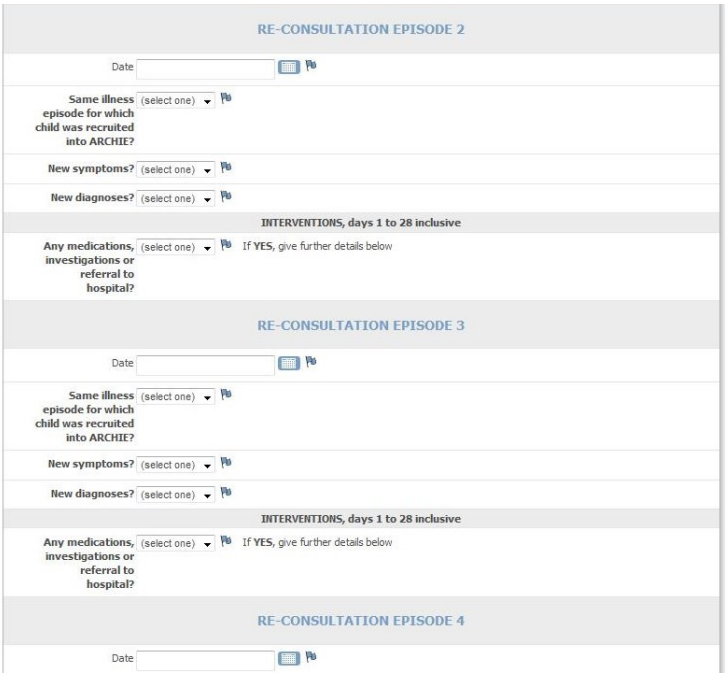


Medical Notes Review: Re-consultations *continued*

In addition to the questions concerning new symptoms and diagnoses you will also be asked for details of any medications, investigations or referrals to hospital.



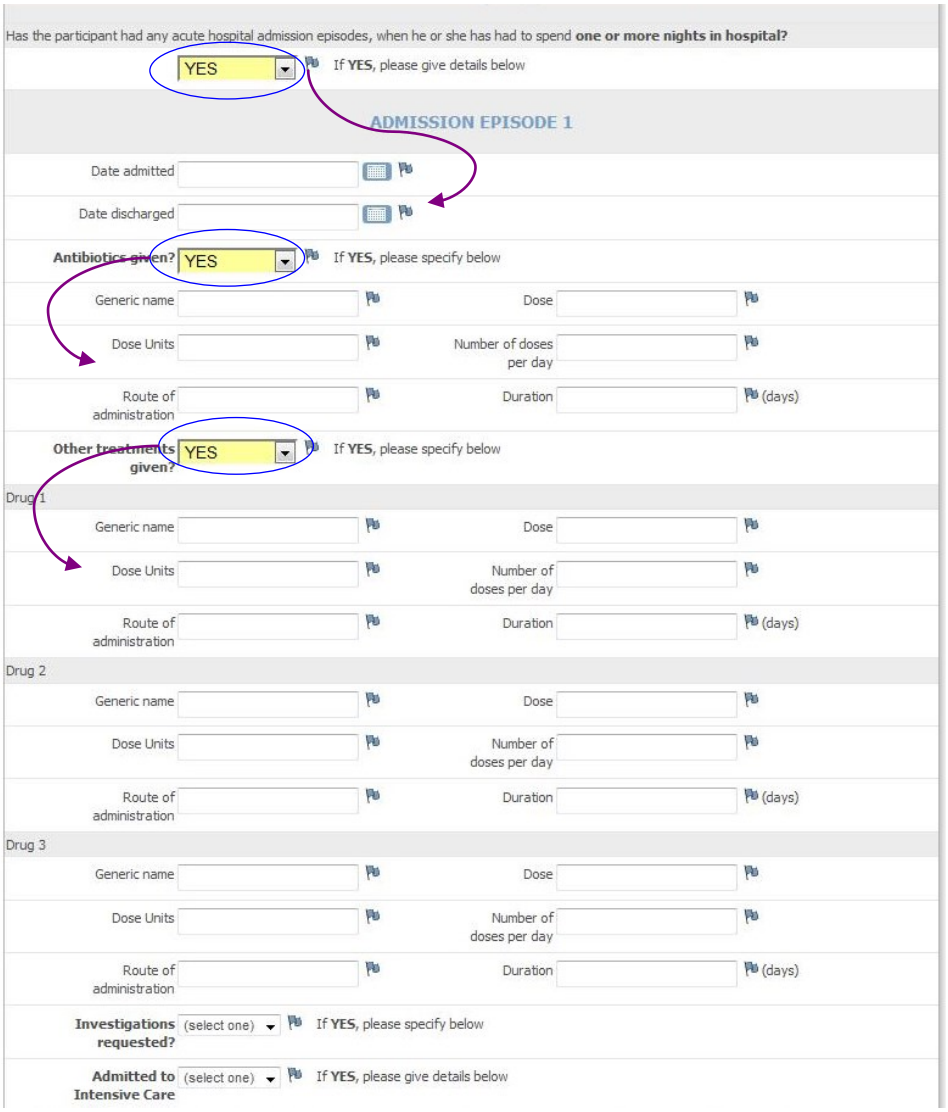
Up to four re-consultation episodes can be entered on this CRF of the medical notes review. If you need to record details of any additional re-consultation episodes then please use the Additional information CRF within the notes review study event, see page 25 for details.



Once you have entered all data for re-consultations select **'Mark CRF complete'** then **'Save'** to submit your entry to the database.

Medical Notes Review: Hospital Admissions

The Hospital Admissions CRF works in much the same way as the Re-consultations CRF. More questions will be asked if a **'Yes'** response is provided, prompting you to provide as much detail as possible. As for re-consultations, details for up to four hospital admissions can be provided. You will be asked to provide detail of medications, investigations and admission to intensive care, if applicable. If the participant has not been admitted to hospital select **'No'** then simply Mark CRF complete and Save.

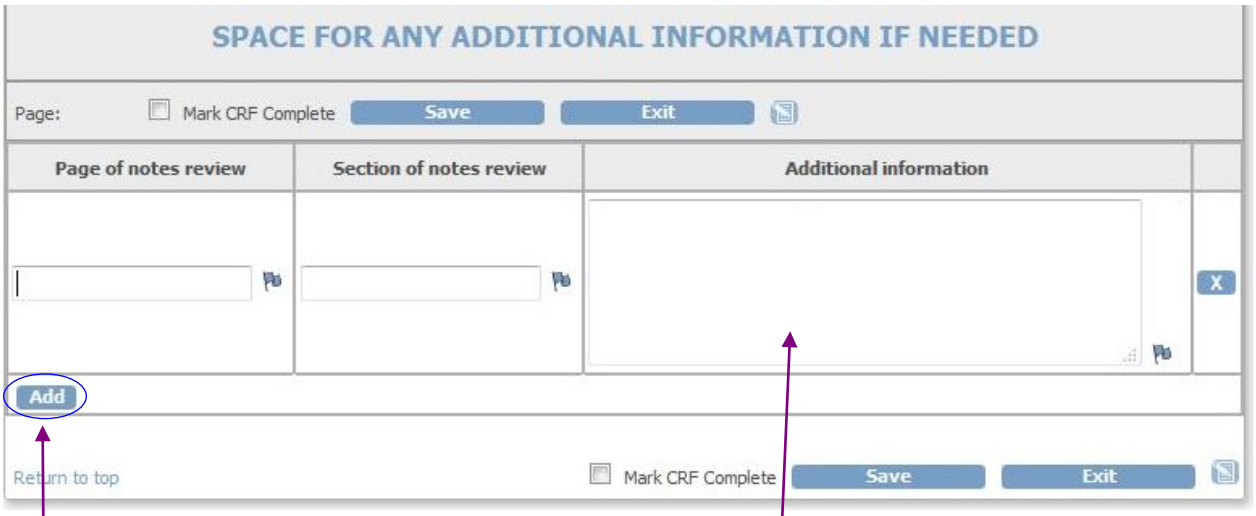


Once you have entered all hospital admission data select **'Mark CRF complete'** and **'Save'** at the bottom of the screen.

The next CRF in the notes review event is to record details of a death. This short section is self-explanatory and completed in the same manner as the other CRFs.

Medical Notes Review: Additional information

The final CRF comprising the Medical Notes Review study event provides space for you to record any additional relevant information that could not be captured elsewhere in the medical notes review CRFs. Please provide information to state which section of the notes review the information you are giving relates to, then state the information in the 'Additional information' field. As many rows as necessary can be added by selecting the **'Add'** button after each record.



Select to add as many rows as required

All sections here are free text with 256 character limit. Longer narratives can be split over as many rows as necessary to provide as much information as possible

Additional Medical Notes review

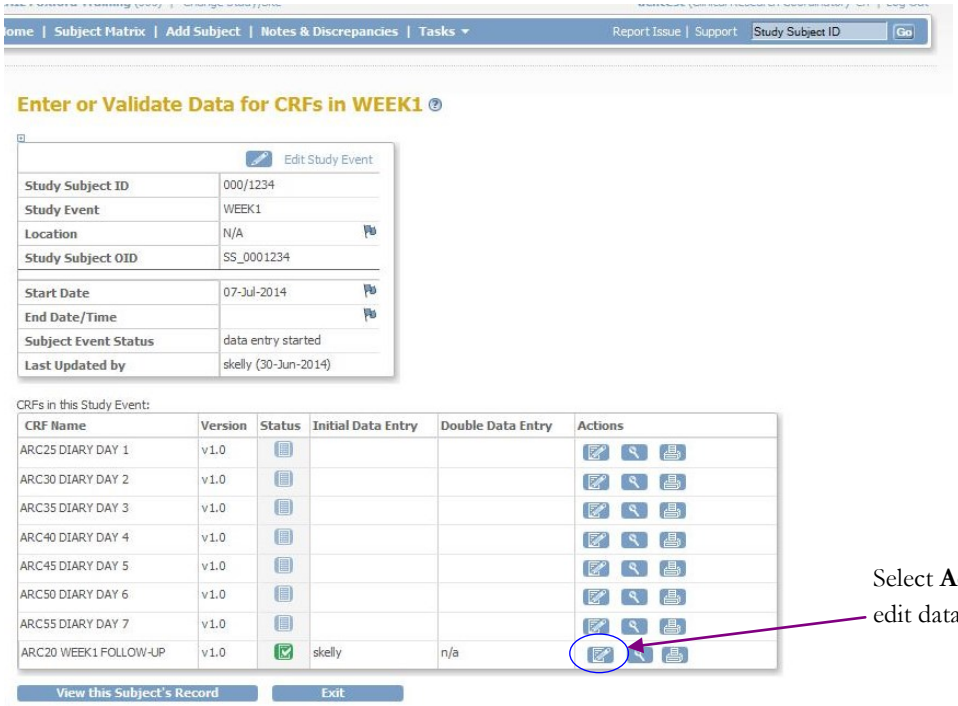
If the participant consented to providing follow up swabs at 3 months, 6 months and 12 months the Additional Notes review will also need to be conducted 12 months after study entry. This form captures details of the antibiotics prescribed in the 12 months since study entry. The trial team will contact you when this review is due with the requested time frame provided for each participant recruited at your research site.

The additional notes review online entry form takes the same format as the Medical history—Antibiotics section of the medical notes review form and data should be entered in the same manner, as described on page 20.

Editing entered data— 'Reason for change' discrepancy notes

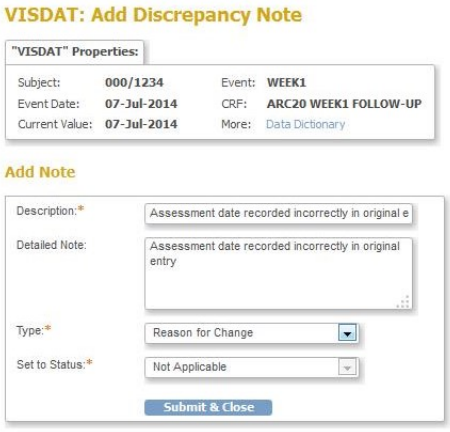
It is possible to change data that has already been entered (by yourself or someone else) if, for example, you realise after submitting the data that an error was made. Once a CRF is 'Marked complete' you will need to follow this process to raise a 'Reason for Change' note to edit any previously entered data.

To edit previously entered data, go to the Subject Homepage, select the event for the CRF you wish to edit, and then select the 'Administrative editing' icon next to the CRF you wish to edit.



Select **Administrative Editing** to view and edit data already entered for this CRF

Enter the correct data in the data field. The field area will change to a yellow colour if data has been changed. To save the edited data you will need to provide a **Reason for change** note. To do this, select the flag icon next to the edited data.

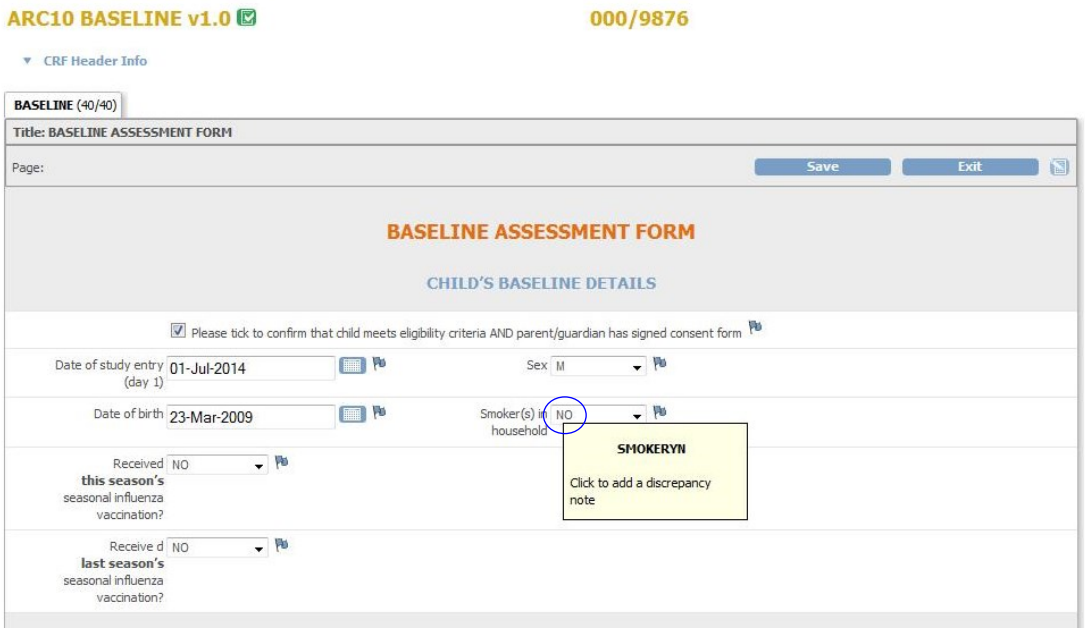


In the discrepancy note window, provide a brief explanation of why the data point was edited. Set type to 'Reason for Change' and Status to 'Not Applicable'. Click **Submit and Close** to submit the discrepancy note to the database.

To save the edited CRF select **Save** on the CRF entry screen.

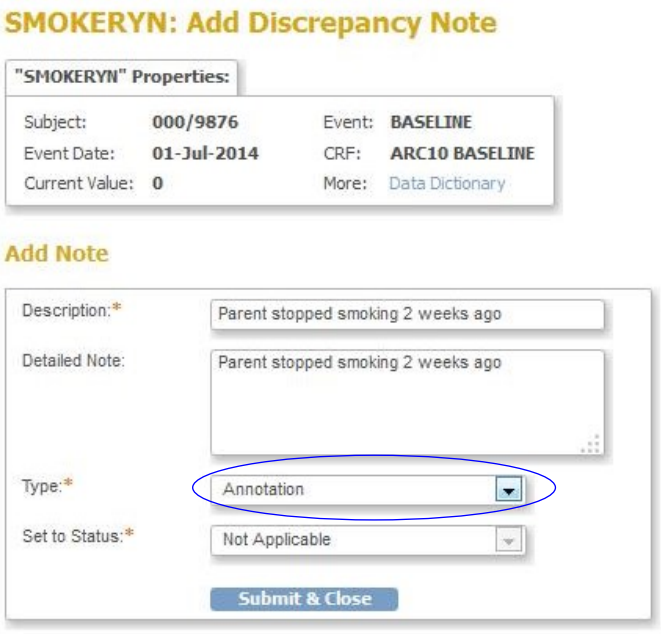
Discrepancy Notes: Annotations

An **Annotation** can be added to any data field where you think relevant additional information exists but there is no space to record this on the CRF entry screen. They can also be used as a method of communication between yourself and the data manager, to inform them, for example, that the requested data is unavailable for the participant by giving a brief explanation to detail why e.g 'Child refused' or 'Dosage not known'. Adding an annotation in this way will prevent the data manager issuing data queries to you for information that is not available. Annotations can be added at any time during initial entry or whilst editing entered data in the Administrative editing mode.



To add an annotation (any additional information) to any data point, select the flag icon next to the relevant data point.

A **Discrepancy note** window will open where you can enter the relevant information.



Enter the additional information in the Description and Detailed Notes text fields then select type as **Annotation**

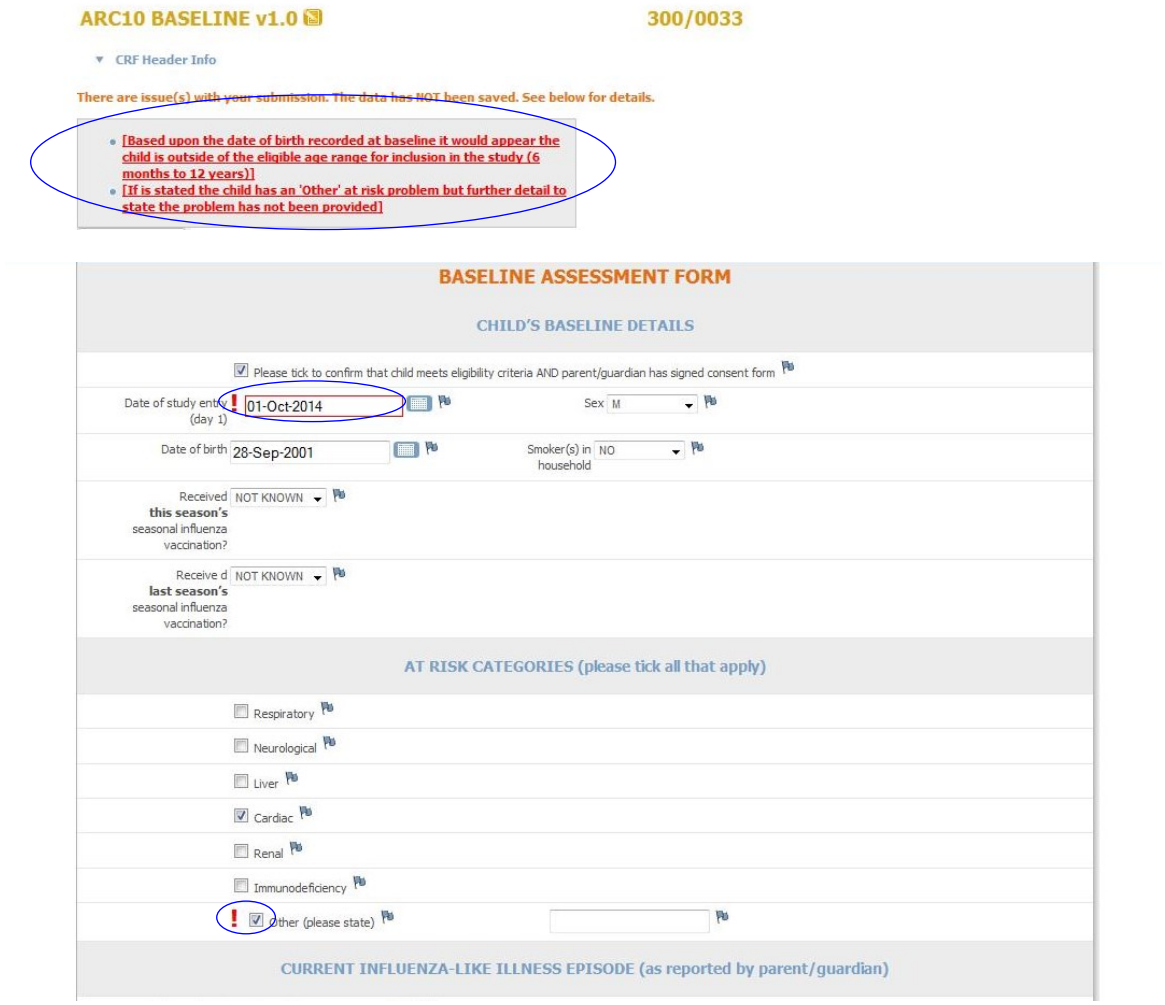
To save the annotation select **Submit and Close,** to return to the main CRF entry screen.

If adding an annotation after initial entry (during administrative editing) you do not need to save the CRF again after adding an annotation; the annotation is saved once **Submit and Close** is selected in the discrepancy note screen.

If an annotation has been added to a data field, the flag next to the data field will turn white.

Discrepancy notes and Failed Validation Checks

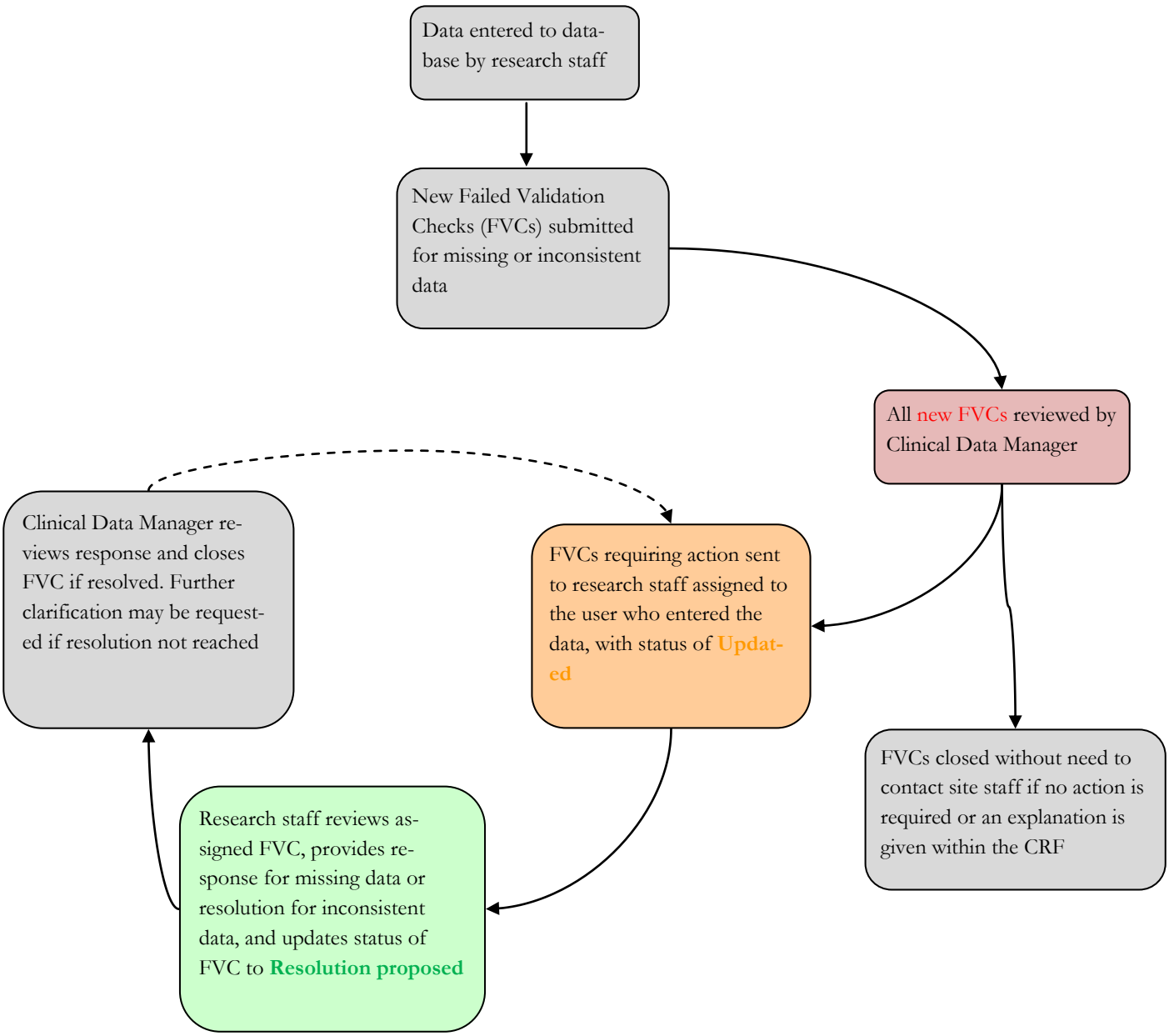
After marking a CRF complete and saving the form in OpenClinica, rules (validations) will check that there are no missing or inconsistent data points recorded. If a validation check picks up a data point which appears to not conform to a rule, a message will appear at the top of the entry screen detailing the issue. In addition, the discrepant data point will be highlighted in red to guide you. You are able to amend the entry at this stage if a mistake was made during data entry. Select **Save** again to save the CRF after you have corrected an entry error. In this case the failed validation check will not be saved to the system.



If the data entered is correct as recorded then the Failed Validation Check will be submitted to the system when you click **Save**. A data field with a failed validation check saved to it will have a red flag next to it. All failed validation checks will be reviewed by the Clinical Data Manager who may contact you to help resolve the issue. Further details of the query resolution process are given on page 29 onwards. A list of all validations are given in the Appendix. These cover range checks, which require a value entered to lie within a specified range, missing information where it is indicated the data is available, and checks for inconsistency.

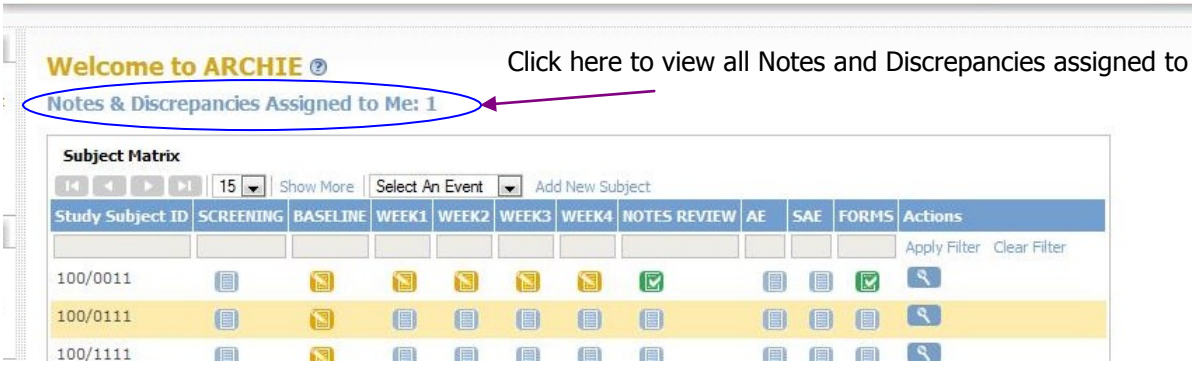
Resolution of Failed Validation Checks (FVCs) - Data queries

The Clinical Data Manager will review all Failed Validation Checks (queries) that have fired during data entry. The Clinical Data Manager may close the query if no further action is required, or they may respond to the research site to request, for example, a response to a missing data point or inconsistent data which may be resolved. An overview of the query resolution process is shown below.

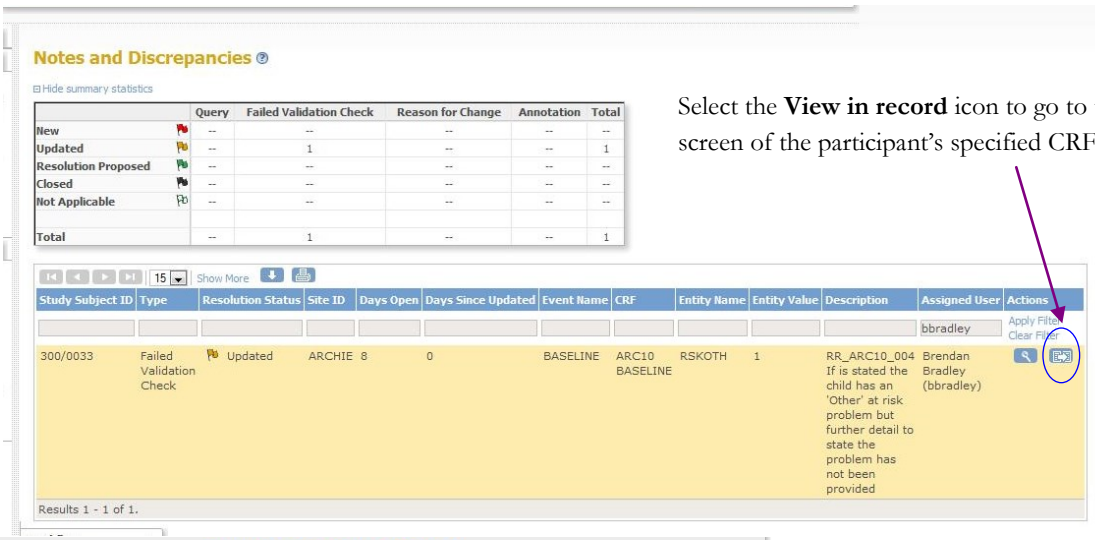


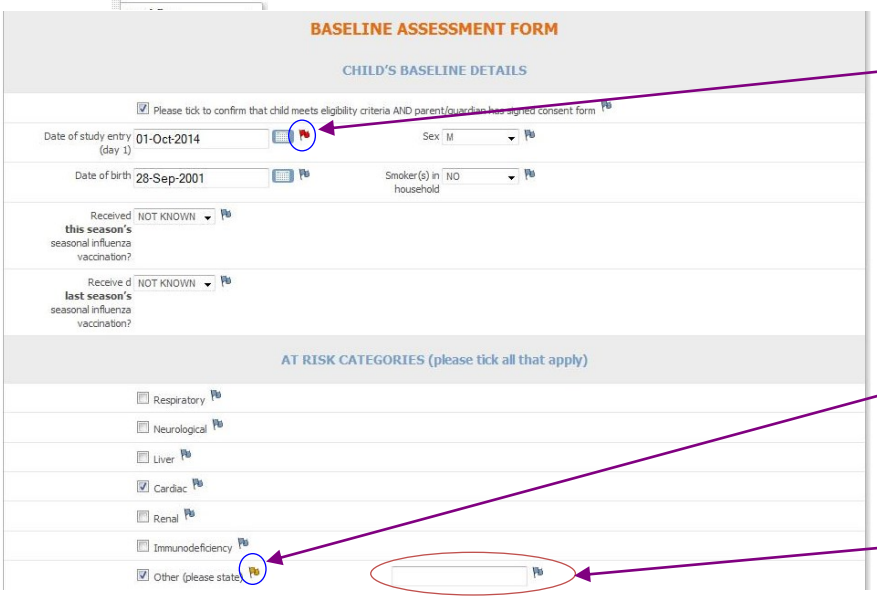
Query Resolution

If the Clinical Data Manager has decided that any FVCs raised during data entry require action or clarification, these will be seen in **'Notes and Discrepancies Assigned to Me'** from the subject matrix home screen visible when you log in to OpenClinica.



Details of all assigned FVCs will be displayed in a list, with the Subject ID number, form name, variable name and description of the query given.





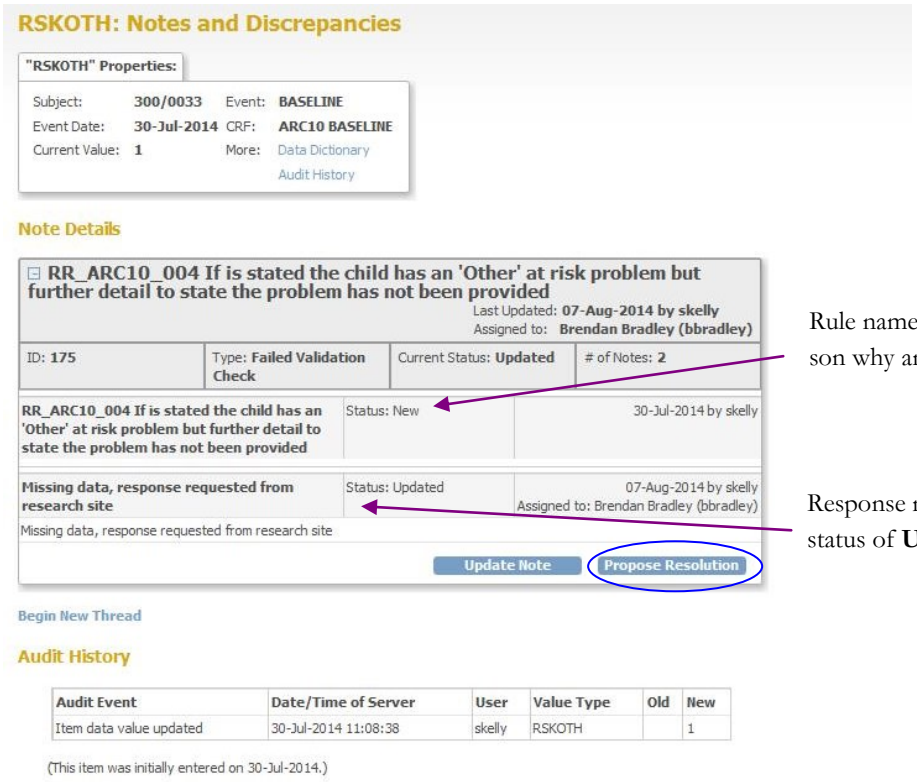
New FVCs are shown with a red flag next to the data point. Leave these for review by the Clinical Data Manager.

FVCs that have been reviewed by the Data Manager and require action are shown by an orange flag.

Response requested for missing data

Query resolution *continued*

Click on the orange flag next to the discrepant data point to open up the discrepancy note window, as shown below. This opens in a new window so the CRF data entry screen is still visible. The discrepancy note window details the validation message that caused the rule to fire, and the updated response message from the Clinical Data Manager.



Rule name and validation message detailing the reason why an FVC was raised, status **New**

Response message from clinical data manager with status of **Updated**

Review the validation message (data query) from the data manager and the data entered, and then enter a response for any missing data or update any current data points on the CRF entry screen.

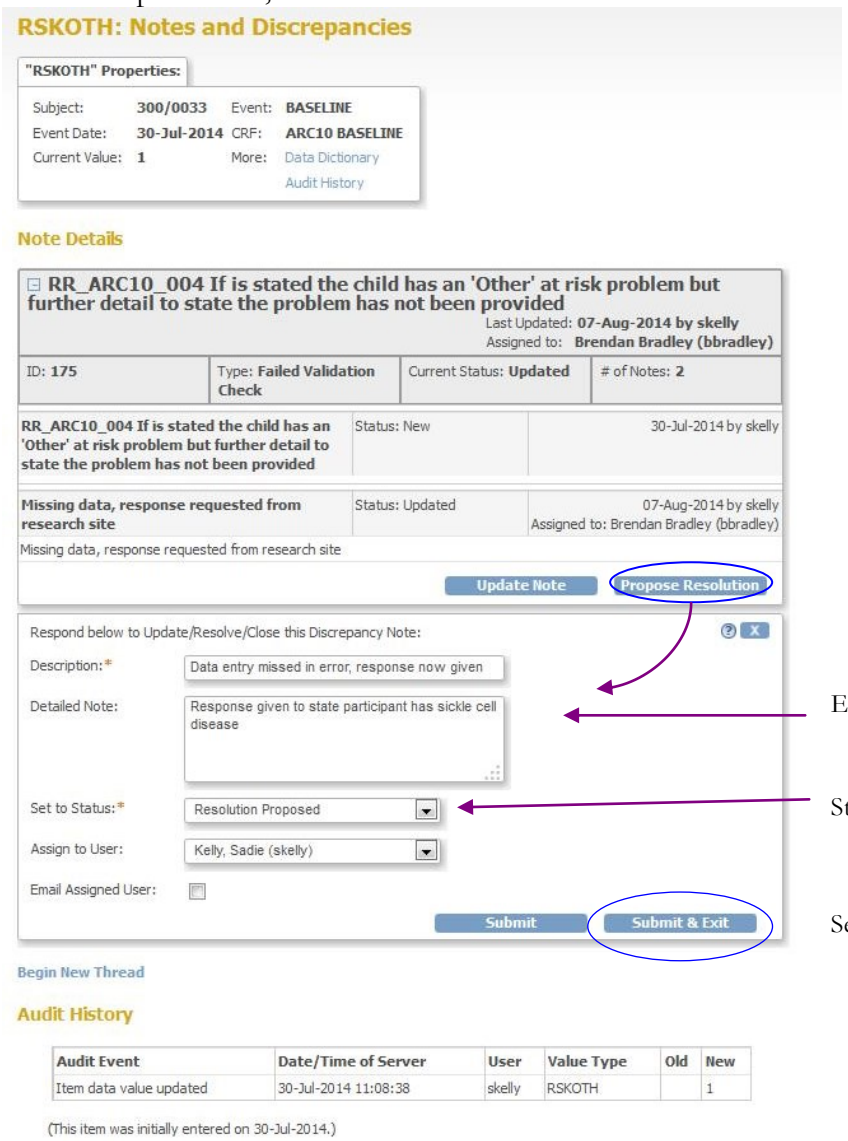
If your response requires you to update a data point other than the one for which the validation fired, i.e. a data point other than the one with the orange flag, you will need to provide a **Reason for Change** discrepancy note; see page 26 describing how to edit previously entered data.

If you only need to update the data point associated with the orange flag, an additional Reason for change note is not needed. Once you have entered your updated data, select **Propose Resolution** in the discrepancy note window.

If you do not need to amend any data entered as you confirm the data is recorded correctly, then please provide clarification of this when you **Propose Resolution** in the discrepancy note window. This will prevent the data manager issuing a re-query if an explanation for missing or inconsistent data is provided.

Query resolution *continued*

When **Propose Resolution** is selected, a further section of the discrepancy note window opens where you can provide a brief explanation of the update made, or clarification to explain that the original data is correct as recorded and no update needs to be made. Please note, while a maximum of 256 characters can be entered in the Description field, the number of characters is not limited in the Detailed Note field.

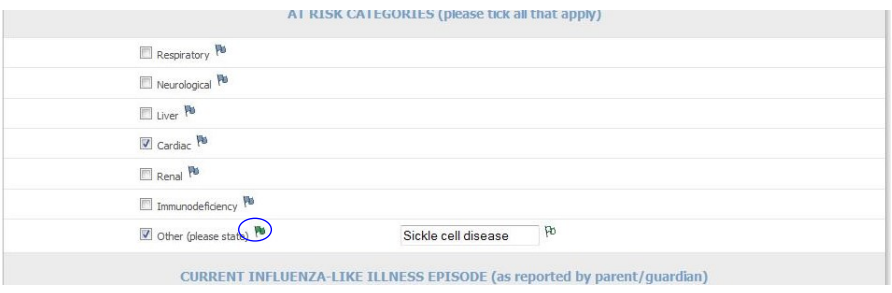


Enter details of the update with a brief explanation.

Status should be set to **Resolution Proposed**

Select **Submit and Exit** when complete

The main CRF entry screen will still be visible once you have closed the Discrepancy Note window. Once all updates have been made, including any further Reason for Change notes if you have updated any other data points, select **Save** on the CRF to save your changes to the database.



Once saved, a green flag now appears to reflect the change in status to **Resolution Proposed.** The clinical data manager will review the response and close down the query. In some cases a re-query may be necessary. The same procedure would be followed to resolve these.