

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.

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.

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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:

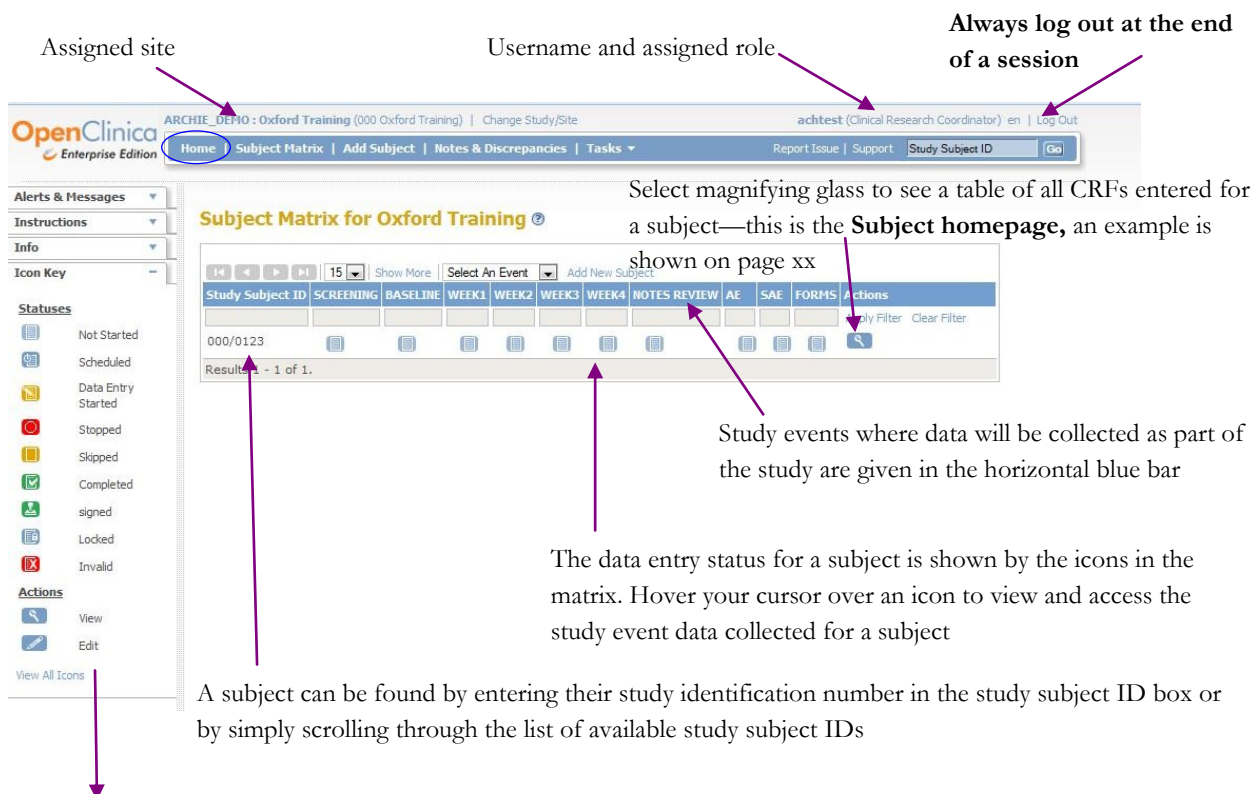
- a) Annotations—these are comments or notes you can create when you need to provide extra information that will not fit into a data field, or where it would be helpful to explain the lack of data in a field. For example, an annotation could be provided to state ‘Dosage varies’ for a particular medication 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.

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.



Assigned site

Username and assigned role

Always log out at the end of a session

Select magnifying glass to see a table of all CRFs entered for a subject—this is the **Subject homepage**, an example is shown on page xx

Study events where data will be collected as part of the study are given in the horizontal blue bar

The data entry status for a subject is shown by the icons in the matrix. Hover your cursor over an icon to view and access the study event data collected for a subject

A subject can be found by entering their study identification number in the study subject ID box or by simply scrolling through the list of available study subject IDs

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 database. 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

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.

Alerts & Messages

Instructions

Other Info

Study: ARCHIE_DEMO

Site: Oxford Training

Start Date: N/A

End Date: N/A

PI: Kay Wang

Protocol Verification/IRB Approval Date:

Icon Key

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

signed

Locked

Invalid

View

Edit

View All Icons

View Subject: 000/1234

Study Subject Record

Events

Page 1 of 1

Find

Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
BASELINE	26-Aug-2014		data entry started		<div>ARC15 BASELINE QUESTIONNAIRES v101.0 </div> <div>ARC10 BASELINE v101.0 26-Aug-2014 (achtest) </div>
SCREENING	26-Aug-2014		scheduled		ARC05 ELIGIBILITY v101.0
WEEK1	26-Aug-2014		data entry started		<div>ARC25 DIARY DAY 1 v101.0 </div> <div>ARC30 DIARY DAY 2 v101.0 </div> <div>ARC35 DIARY DAY 3 v101.0 </div> <div>ARC40 DIARY DAY 4 v101.0 </div> <div>ARC45 DIARY DAY 5 v101.0 </div> <div>ARC50 DIARY DAY 6 v101.0 </div> <div>ARC55 DIARY DAY 7 v101.0 </div> <div>ARC20 WEEK1 FOLLOW-UP v101.0 26-Aug-2014 (achtest) </div>
WEEK2	26-Aug-2014		data entry started		<div>ARC65 DIARY DAY 8 v101.0 </div> <div>ARC70 DIARY DAY 9 v101.0 </div> <div>ARC75 DIARY DAY 10 v101.0 </div> <div>ARC80 DIARY DAY 11 v101.0 </div> <div>ARC85 DIARY DAY 12 v101.0 </div> <div>ARC90 DIARY DAY 13 v101.0 </div> <div>ARC95 DIARY DAY 14 v101.0 </div> <div>ARC60 WEEK2 FOLLOW-UP v101.0 26-Aug-2014 (achtest) </div>
WEEK3	26-Aug-2014		scheduled		<div>ARC100 DIARY DAY 15 v101.0 </div> <div>ARC105 DIARY DAY 16 v101.0 </div> <div>ARC110 DIARY DAY 17 v101.0 </div> <div>ARC115 DIARY DAY 18 v101.0 </div> <div>ARC120 DIARY DAY 19 v101.0 </div> <div>ARC125 DIARY DAY 20 v101.0 </div> <div>ARC130 DIARY DAY 21 v101.0 </div>
WEEK4	26-Aug-2014		scheduled		<div>ARC135 DIARY DAY 22 v101.0 </div> <div>ARC140 DIARY DAY 23 v101.0 </div> <div>ARC145 DIARY DAY 24 v101.0 </div> <div>ARC150 DIARY DAY 25 v101.0 </div> <div>ARC155 DIARY DAY 26 v101.0 </div> <div>ARC160 DIARY DAY 27 v101.0 </div> <div>ARC165 DIARY DAY 28 v101.0 </div> <div>ARC170 CHILD DIARY v101.0 </div>
NOTES REVIEW	26-Aug-2014		data entry started		<div>ARC177 NR ADDITIONAL INFORMATION v101.0 </div> <div>ARC180 ADDITIONAL NOTES REVIEW v101.0 </div> <div>ARC172 NR BASELINE INFORMATION v101.0 26-Aug-2014 (achtest) </div> <div>ARC173 NR RECONSULTATIONS v101.0 26-Aug-2014 (achtest) </div> <div>ARC174 NR HOSPITAL ADMISSIONS v101.0 26-Aug-2014 (achtest) </div> <div>ARC175 NR DEATH v101.0 26-Aug-2014 (achtest) </div> <div>ARC176 NR MEDICAL HISTORY v101.0 26-Aug-2014 (achtest) </div>
AE (1)	26-Aug-2014		completed		ARC185 AE v101.0 26-Aug-2014 (achtest)
SAE (1)	26-Aug-2014		scheduled		No CRFs
FORMS	26-Aug-2014		scheduled		ARC195 DISCONTINUATION v101.0

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

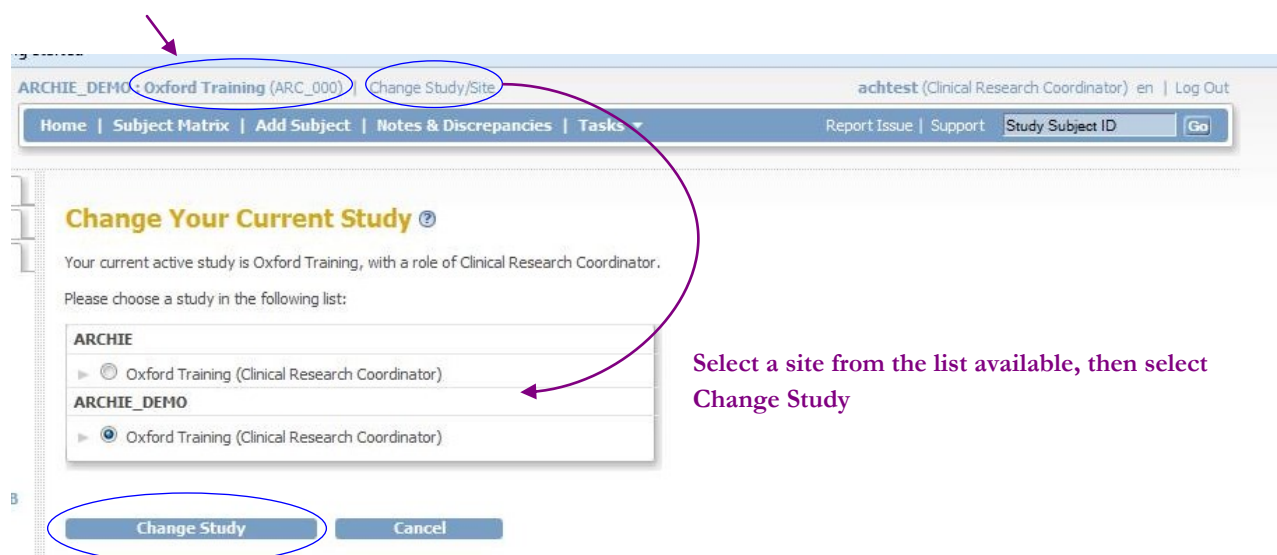
You are also able to produce a printable copy of the CRF by selecting the **Print** icon

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



ARCHIE DEMO Oxford Training (ARC_000) Change Study/Site achtest (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks Report Issue | Support Study Subject ID Go

Change Your Current Study ?

Your current active study is Oxford Training, with a role of Clinical Research Coordinator.

Please choose a study in the following list:

ARCHIE
▶ <input type="radio"/> Oxford Training (Clinical Research Coordinator)
ARCHIE DEMO
▶ <input checked="" type="radio"/> Oxford Training (Clinical Research Coordinator)

Change Study Cancel

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.

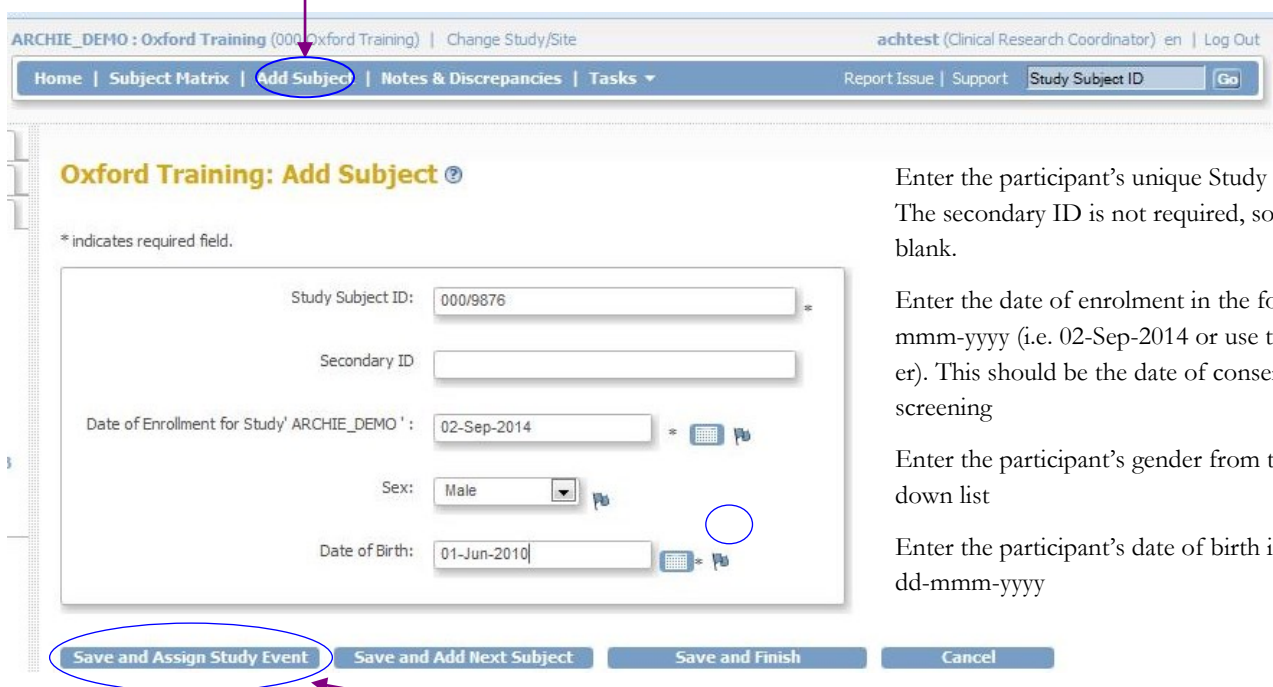
Adding a new subject

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.

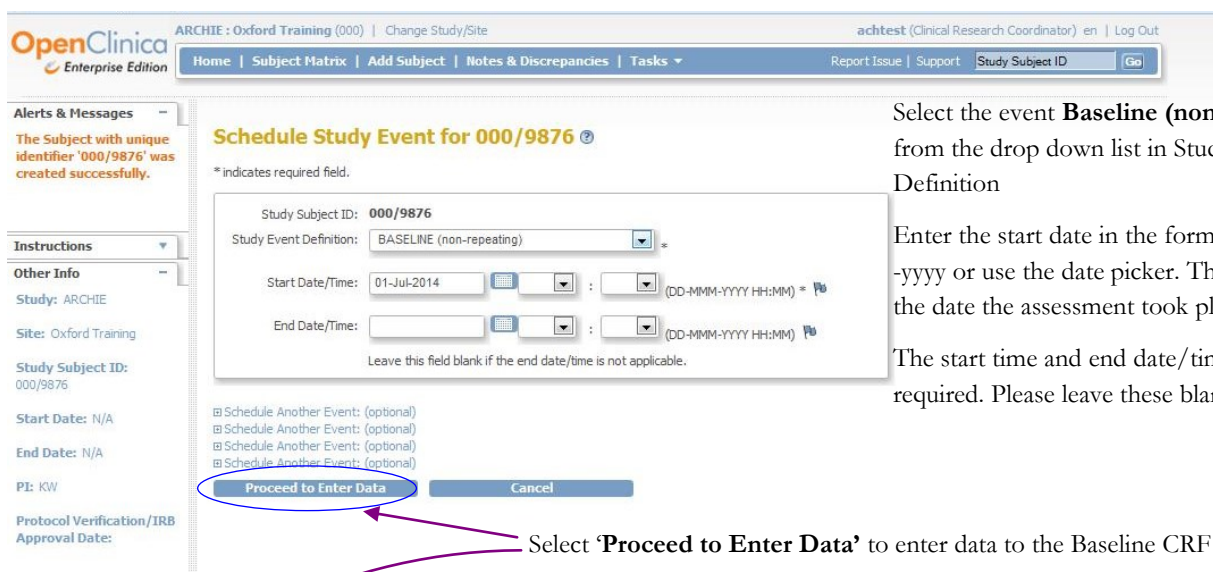
If you have made any errors and wish to start again or complete the task later, select '**Cancel**'.

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.



OpenClinica ARCHIE : Oxford Training (000) | Change Study/Site achtest (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Alerts & Messages
The Subject with unique identifier '000/9876' was created successfully.

Instructions
Other Info
Study: ARCHIE
Site: Oxford Training
Study Subject ID: 000/9876
Start Date: N/A
End Date: N/A
PI: KW
Protocol Verification/IRB Approval Date:

Schedule Study Event for 000/9876

* indicates required field.

Study Subject ID: 000/9876
Study Event Definition: BASELINE (non-repeating)
Start Date/Time: 01-Jul-2014 : (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.

☐ Schedule Another Event: (optional)
☐ Schedule Another Event: (optional)
☐ Schedule Another Event: (optional)
☐ Schedule Another Event: (optional)

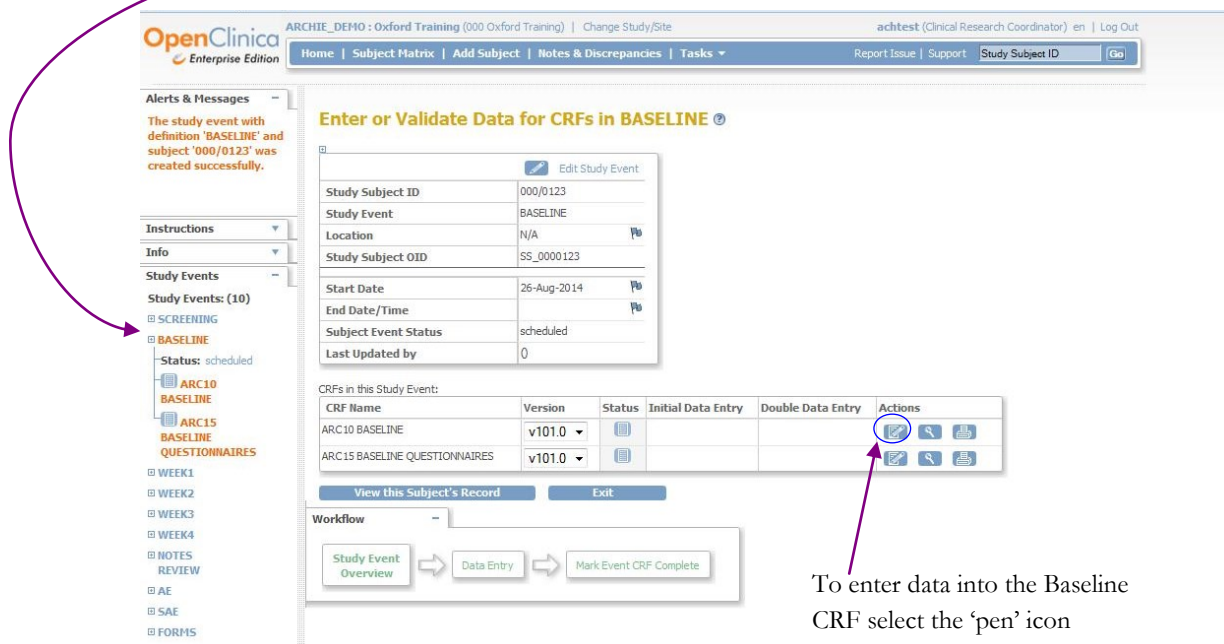
Proceed to Enter Data **Cancel**

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



OpenClinica ARCHIE_DEFO : Oxford Training (000 Oxford Training) | Change Study/Site achtest (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Alerts & Messages
The study event with definition 'BASELINE' and subject '000/0123' was created successfully.

Instructions
Info
Study Events
Study Events: (10)
SCREENING
BASELINE
Status: scheduled
ARC10 BASELINE
ARC15 BASELINE QUESTIONNAIRES
WEEK1
WEEK2
WEEK3
WEEK4
NOTES REVIEW
AE
SAE
FORMS

Enter or Validate Data for CRFs in BASELINE

Study Event
Study Subject ID: 000/0123
Study Event: BASELINE
Location: N/A
Study Subject OID: SS_0000123
Start Date: 26-Aug-2014
End Date/Time:
Subject Event Status: scheduled
Last Updated by: 0

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
ARC10 BASELINE	v101.0				
ARC15 BASELINE QUESTIONNAIRES	v101.0				

Workflow
Study Event Overview → Data Entry → Mark Event CRF Complete

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

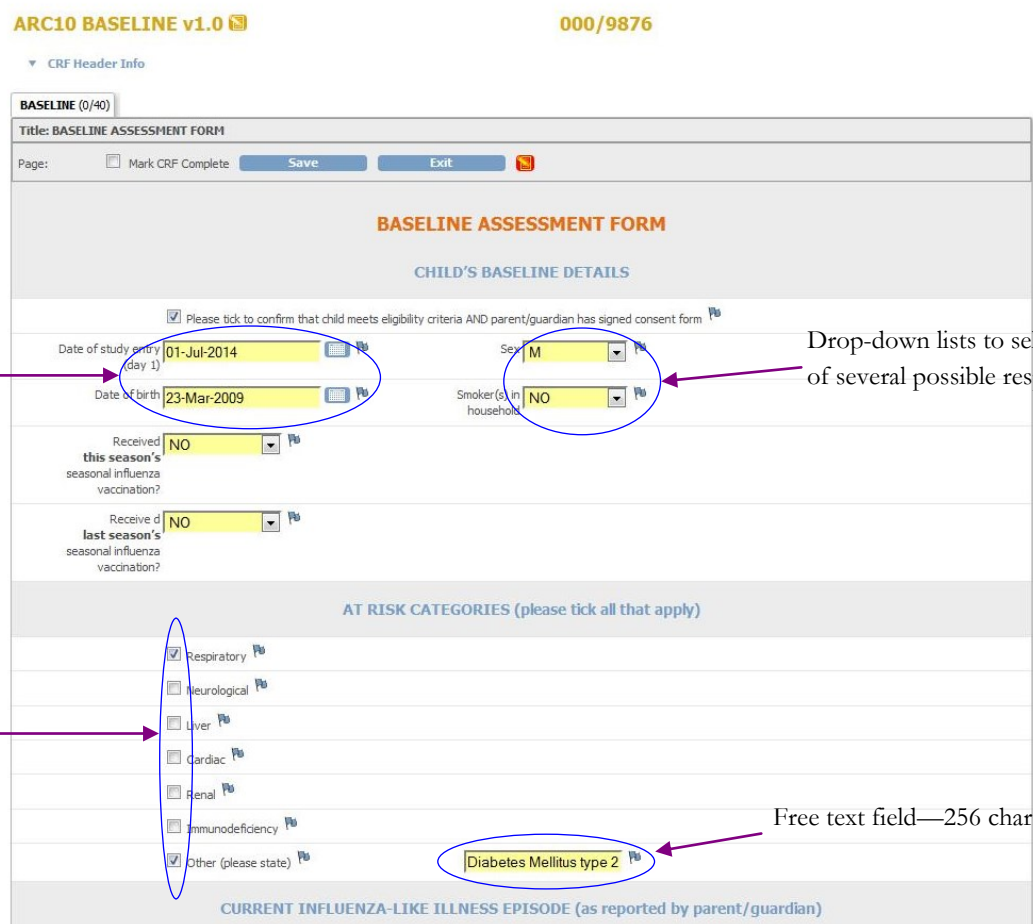
The BASELINE QUESTIONNAIRES CRF is completed by the participant on paper and will be returned to the Clinical Trials Unit by post for entry to OpenClinica by data entry personnel.

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.



The screenshot shows the 'ARC10 BASELINE v1.0' form for study subject '000/9876'. The form is titled 'BASELINE ASSESSMENT FORM' and includes a 'CHILD'S BASELINE DETAILS' section. Annotations point to various input fields:

- Date fields:** 'Date of study entry (day 1)' and 'Date of birth' are highlighted with blue circles. A purple arrow points to the 'Date of study entry' field with the text 'Date fields, enter date or use date picker'.
- Drop-down lists:** 'Sex' (M) and 'Smoker(s) in household' (NO) are highlighted with blue circles. A purple arrow points to the 'Smoker(s) in household' field with the text 'Drop-down lists to select one of several possible responses'.
- Select tick box:** The 'Respiratory' tick box is highlighted with a blue circle. A purple arrow points to it with the text 'Select tick box'.
- Free text field:** The 'Diabetes Mellitus type 2' text field is highlighted with a blue circle. A purple arrow points to it with the text 'Free text field—256 character limit'.

The form also includes sections for 'AT RISK CATEGORIES (please tick all that apply)' and 'CURRENT INFLUENZA-LIKE ILLNESS EPISODE (as reported by parent/guardian)'.

Entering Data—Baseline Assessment *continued*

CURRENT INFLUENZA-LIKE ILLNESS EPISODE (as reported by parent/guardian)

Date symptoms started: 30-Jun-2014

Date fever started: 30-Jun-2014

MEDICATIONS TAKEN BY CHILD DURING CURRENT INFLUENZA-LIKE ILLNESS EPISODE

Antivirals: YES (e.g. oseltamivir)

If YES, give name(s) of antiviral(s)

Name	
Oseltamivir	X

Add

Antipyretics: YES (e.g. paracetamol)

If YES, give name(s) of antipyretic(s)

Name	
Paracetamol	X

Add

Date of most recent dose: 01-Jul-2014 and time: 07:00 (hh:mm) **am**

Other medications: NO

If YES, give name(s) of medication(s)

Name	
	X

Add

PHYSICAL EXAMINATION

Temperature: 39.1 (°C) Time temperature taken: 13:15 (hh:mm) **pm**

Heart rate: 65 (beats per minute) Respiratory rate: 27 (breaths per minute)

Weight: 21.5 (kg)

SWABS

High nasal swab taken? YES Throat swab taken? YES

STUDY MEDICATION – Please write participant's study medication ID and dose in the fields below

Please go to www.archiestudy.com to generate the child's study medication ID number. You will need to enter the child's age, weight and current influenza vaccination status

Study medication ID: A10010 Study medication dose: 5 ml twice daily for 5 days

QUESTIONNAIRES TO BE COMPLETED DURING BASELINE APPOINTMENT

By parent/guardian (compulsory)

1. EQ-5D-Y proxy: YES

2. CARIFS: YES

By child (optional)

EQ-5D-Y: YES

Please tick to confirm study pack given and explained

Return to top

Mark CRF Complete Save Exit

Enter time in hh:mm 12 h format, then select am/pm from the drop-down list

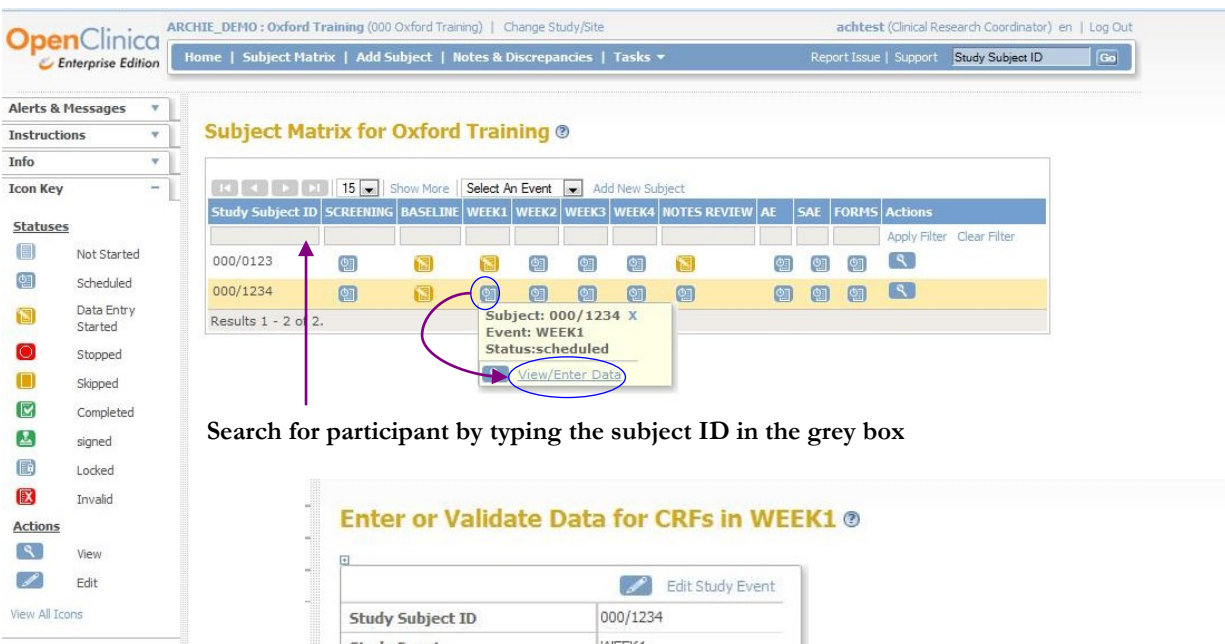
Enter the medication ID and dose given from Sortition

Study Medication fields will only appear if the response to 'High nasal swab taken?' is 'Yes', as this swab is required for the child to enter the study.

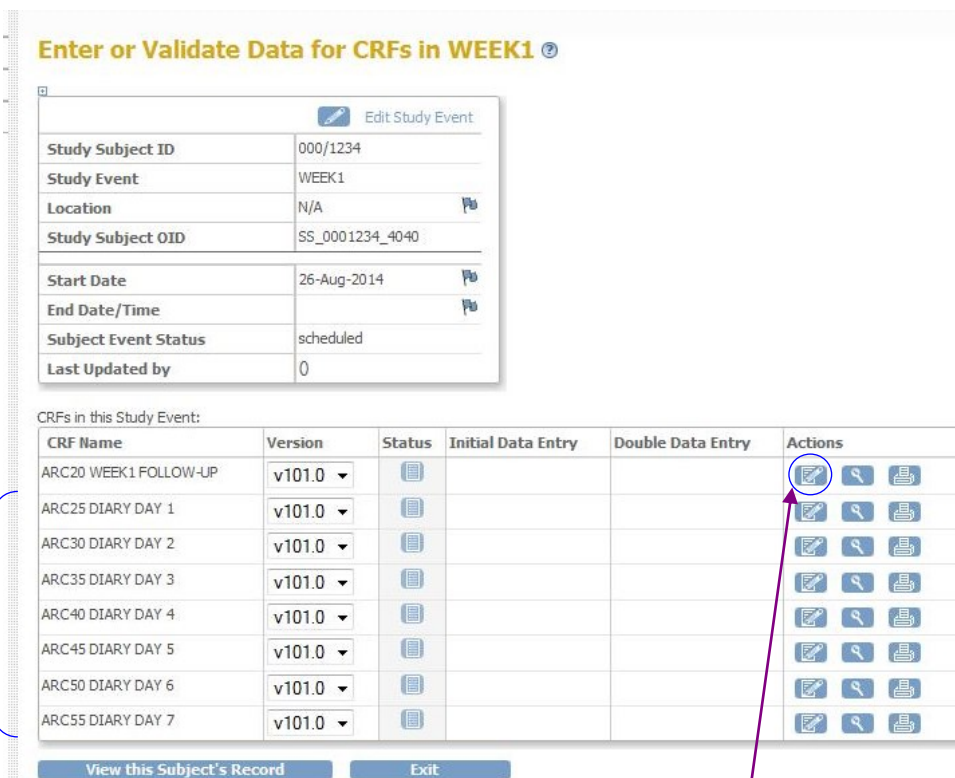
When you have finished entering baseline data, whether or not study medication details have been recorded, select the tick box 'Mark CRF complete', click OK when the pop up message appears, then select **Save** to save the data to the database. If you wish to complete data entry at a later stage, do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

During the last week:

1. Have you and your child had to seek medical advice because of your child's flu-like illness or complications of this (e.g. chest infection, ear infection)?

If YES, please remember to note these occasions in your ARCHIE study diary

☐ YES ☐ NO

2. Has your child had to stay in hospital for one or more nights because of his/her flu-like illness or complications of this (e.g. chest infection, ear infection)?

If YES, please remember to note these occasions in your ARCHIE study diary

☐ YES ☐ NO

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.

3. Has your child had any side-effects from his or her study medication?

☐ YES ☐ NO

If YES, please give details below

Please tick all side-effects that apply:

Complete a **Serious Adverse Event Report form** for **ANY side-effect** which has **serious consequences**.
See Serious Adverse Event Report form in section 6 for full definition

You will find Adverse Event and Serious Adverse Event report forms in section 6 of your study pack or on our website (www.archiestudy.com)

N.B. ACTION if any these are ticked

ACTION:
Complete an **Adverse Event Report form** for **each clinically severe** side-effect.
No action is required for clinically mild or moderate side-effects

☐ Diarrhoea ☐ Nausea (feeling sick) ☒ Vomiting (being sick) ☐ Thrush (fungal infection of mouth, vagina or skin folds)

N.B. ACTION if any these are ticked

ACTION:
Complete an **Adverse Event Report form** for **each side-effect, regardless of clinical severity**

☒ Skin rash ☐ Other(s) (please state below)

1. Other

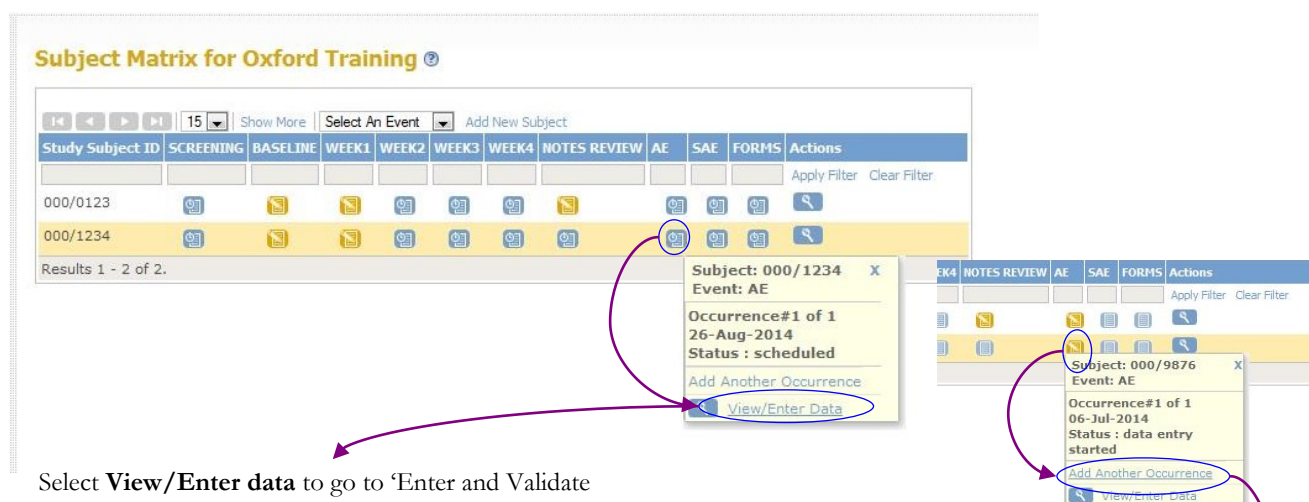
2. Other

3. Other

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.



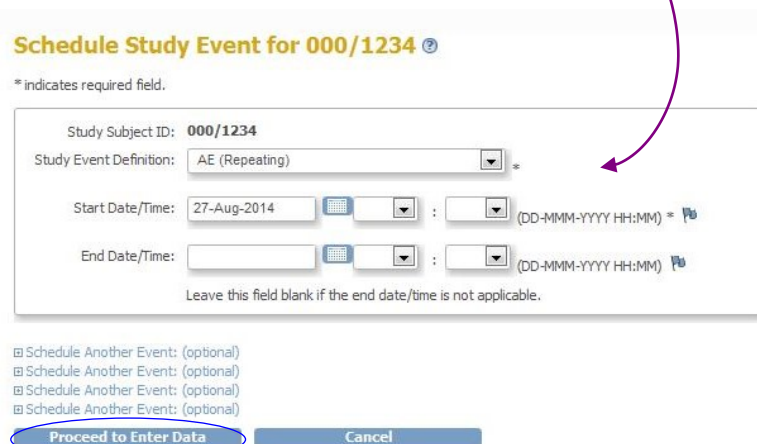
Select **View/Enter data** to go to 'Enter and Validate Data for CRFs in AE' screen below

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



* indicates required field.

Study Subject ID: 000/1234

Study Event Definition: AE (Repeating) *

Start Date/Time: 27-Aug-2014 : (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.

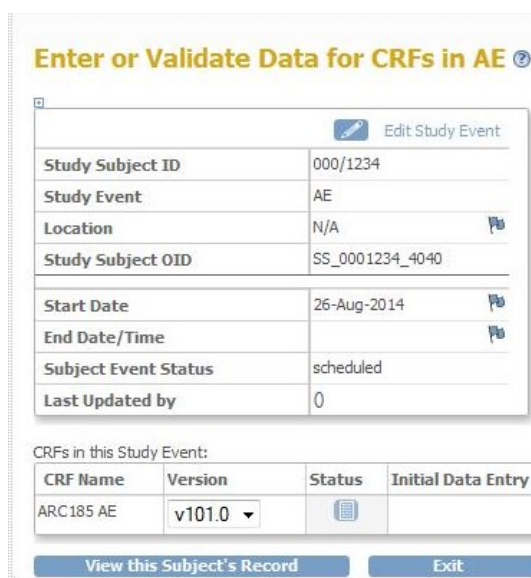
☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

Proceed to Enter Data Cancel



Enter or Validate Data for CRFs in AE

Edit Study Event

Study Subject ID: 000/1234

Study Event: AE

Location: N/A

Study Subject OID: SS_0001234_4040




Start Date: 26-Aug-2014

End Date/Time:

Subject Event Status: scheduled

Last Updated by: 0

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
ARC185 AE	v101.0				  

View this Subject's Record **Exit**

Select the 'pen icon' to enter Adverse Event Data

Completing the Adverse Event Report Form

AE (0/8)

Title: ADVERSE EVENT REPORT FORM

Instructions:

Study Title: ARCHIE (The early use of Antibiotics for at Risk Children with Influenza in primary care)

Principal Investigator: Dr Kay Wang

PLEASE READ INSTRUCTIONS BEFORE COMPLETING

Page: ☐ Mark CRF Complete **Save** **Exit**

ADVERSE EVENT REPORT FORM

If your answer is anything other than 1 to 'Is the Adverse Event serious?':
PLEASE COMPLETE A SERIOUS ADVERSE EVENT REPORT FORM AND SEND TO COORDINATING CENTRE WITHIN 24 HOURS OF BECOMING AWARE OF THE EVENT

Adverse Event **severe vomiting** * (diagnosis [if known] or signs/symptoms)

Date of Onset **06-Jul-2014** *

Outcome **1 = Resolved**

Severity **1 = Mild** *

Relationship to study drug **2 = Possibly related** (must be assessed by medically qualified individual)

Date of Resolution **07-Jul-2014**

Is the Adverse Event serious? **1 = No** *

Adverse Event ID **01**

Free text description of adverse event (256 character limit)

Return to top ☐ Mark CRF Complete **Save** **Exit**

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).

Subject Matrix for Oxford Training

15 Show More Select An Event Add New Subject

Study Subject ID	SCREENING	BASELINE	WEEK1	WEEK2	WEEK3	WEEK4	NOTES REVIEW	AE	SAE	FORMS	Actions
000/0123											Apply Filter Clear Filter
000/1234											

Results 1 - 2 of 2.

Subject: 000/1234 X
Event: WEEK2
Status:scheduled
View/Enter Data

HIE_DEMO : Oxford Training (000 Oxford Training) | Change Study/Site | achtest (Clinical Research Coordinator) en | Log Out

Home | Subject Matrix | Add Subject | Notes & Discrepancies | Tasks | Report Issue | Support | Study Subject ID | Go

Enter or Validate Data for CRFs in WEEK2

Edit Study Event

Study Subject ID	000/1234
Study Event	WEEK2
Location	N/A
Study Subject OID	SS_0001234_4040
Start Date	26-Aug-2014
End Date/Time	
Subject Event Status	scheduled
Last Updated by	0

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.

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
ARC60 WEEK2 FOLLOW-UP	v101.0				
ARC65 DIARY DAY 8	v101.0				
ARC70 DIARY DAY 9	v101.0				
ARC75 DIARY DAY 10	v101.0				
ARC80 DIARY DAY 11	v101.0				
ARC85 DIARY DAY 12	v101.0				
ARC90 DIARY DAY 13	v101.0				
ARC95 DIARY DAY 14	v101.0				

View this Subject's Record Exit

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**.

Subject Matrix for Oxford Training

Study Subject ID	SCREENING	BASELINE	WEEK1	WEEK2	WEEK3	WEEK4	NOTES REVIEW	AE	SAE	FORMS	Actions
000/0123											
000/1234											

Results 1 - 2 of 2.

Subject: 000/1234
Event: NOTES REVIEW
Status: scheduled
View/Enter Data

Enter or Validate Data for CRFs in NOTES REVIEW

Study Subject ID: 000/1234
Study Event: NOTES REVIEW
Location: N/A
Study Subject OID: SS_0001234_4040
Start Date: 26-Aug-2014
End Date/Time:
Subject Event Status: scheduled
Last Updated by: 0

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
ARC172 NR BASELINE INFORMATION	v101.0				
ARC173 NR RECONSULTATIONS	v101.0				
ARC174 NR HOSPITAL ADMISSIONS	v101.0				
ARC175 NR DEATH	v101.0				
ARC176 NR MEDICAL HISTORY	v101.0				
ARC177 NR ADDITIONAL INFORMATION	v101.0				
ARC180 ADDITIONAL NOTES REVIEW	v101.0				

View this Subject's Record Exit

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.

PARTICIPANT'S MEDICAL HISTORY

'AT RISK' MEDICAL PROBLEM – please tick all boxes that apply

<input type="checkbox"/> Asthma	<input type="text"/>
<input type="checkbox"/> Bronchopulmonary dysplasia	<input type="text"/>
<input type="checkbox"/> Recurrent viral wheeze (3 or more episodes within last 12 months)	<input type="text"/>
<input type="checkbox"/> Admitted to hospital with bronchiolitis within last 12 months	<input type="text"/>
<input type="checkbox"/> Congenital heart disease	<input type="text"/>
<input type="checkbox"/> Chronic heart failure	<input type="text"/>
<input type="checkbox"/> Cerebral palsy	<input type="text"/>
<input type="checkbox"/> Other neurological or neuromuscular disorder	<input type="text"/>
<input type="checkbox"/> Chronic kidney disease	<input type="text"/>
<input type="checkbox"/> Nephrotic syndrome	<input type="text"/>
<input type="checkbox"/> Kidney transplantation	<input type="text"/>
<input type="checkbox"/> Liver disease	<input type="text"/>
<input type="checkbox"/> Asplenia or splenic dysfunction	<input type="text"/>
<input type="checkbox"/> HIV infection	<input type="text"/>
<input type="checkbox"/> Chemotherapy leading to immunosuppression	<input type="text"/>
<input type="checkbox"/> Systemic steroids (prednisolone 20 mg or more a day or >=1 mg/kg/day (children under 20 kg))	<input type="text"/>
<input type="checkbox"/> Type 1 diabetes mellitus	<input type="text"/>
<input type="checkbox"/> Type 2 diabetes mellitus	<input type="text"/>
<input type="checkbox"/> Down's syndrome	<input type="text"/>
<input type="checkbox"/> Other genetic abnormality	<input type="text"/>
<input type="checkbox"/> Sickle cell disease	<input type="text"/>
<input type="checkbox"/> Malignancy	<input type="text"/>
<input type="checkbox"/> Prematurity (born before 37 weeks gestation and aged 6 to 23 months at time of study entry)	<input type="text"/>
<input type="checkbox"/> Unknown	<input type="text"/>

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.

REGULAR MEDICATIONS AT TIME OF STUDY ENTRY

(select one)

If YES, please give details in table below

Generic name	Dose	Dose Units	Number of doses per day
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="button" value="Add"/>			

ACUTE CONSULTATIONS DURING 12-MONTH PERIOD BEFORE STUDY ENTRY

If YES, give details below

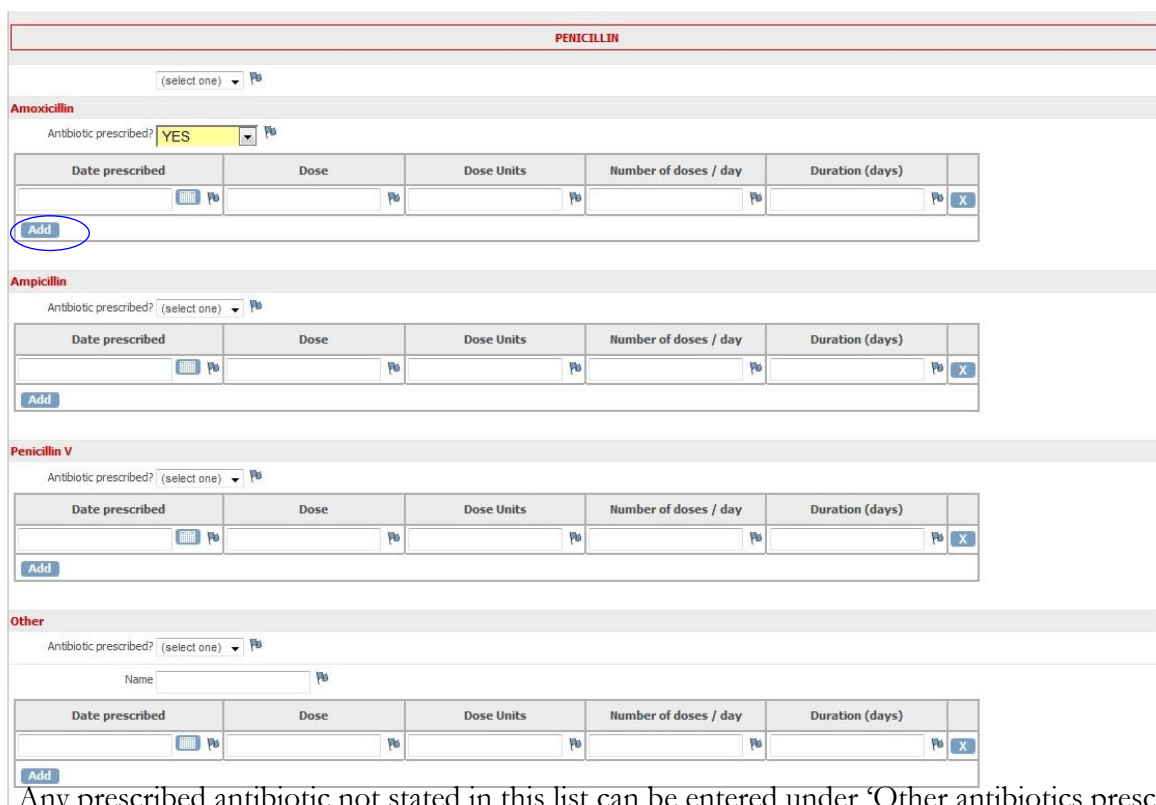
Definition of 'acute consultations': acute consultations are unplanned consultations in a GP surgery, out-of-hours primary care centre, primary care walk-in centre, child's home or Accident and Emergency department. Acute consultations do NOT include routine chronic disease monitoring visits, planned visits advised by a healthcare professional or visits done as part of a research study

(select one)

Date of consultation	Reason for consultation
<input type="text"/>	<input type="text"/>
<input type="button" value="Add"/>	

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.



PENICILLIN

(select one) ▾

Amoxicillin

Antibiotic prescribed? **YES** ▾

Date prescribed	Dose	Dose Units	Number of doses / day	Duration (days)

Add

Ampicillin

Antibiotic prescribed? (select one) ▾

Date prescribed	Dose	Dose Units	Number of doses / day	Duration (days)

Add

Penicillin V

Antibiotic prescribed? (select one) ▾

Date prescribed	Dose	Dose Units	Number of doses / day	Duration (days)

Add

Other

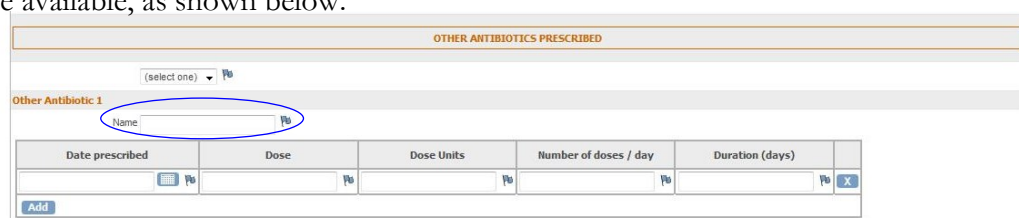
Antibiotic prescribed? (select one) ▾

Name

Date prescribed	Dose	Dose Units	Number of doses / day	Duration (days)

Add

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.



OTHER ANTIBIOTICS PRESCRIBED

(select one) ▾

Other Antibiotic 1

Name

Date prescribed	Dose	Dose Units	Number of doses / day	Duration (days)

Add

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 antibiotics 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.

ARC172 NR BASELINE INFORMATION v101.0 000/1234

▼ CRF Header Info

BASELINE (0/3)

Title: MEDICAL NOTES REVIEW

Instructions:

ARCHIE MEDICAL NOTES REVIEW


To be completed for ALL ARCHIE trial participants

The information needed to complete this notes review form can be extracted from specific sections of the medical record as detailed below



Notes review sections	Section of medical record needed
Re-consultations, days 1 to 28 inclusive Interventions, days 1 to 28 inclusive Hospital admissions, days 1 to 28 inclusive Death during period from days 1 to 28 inclusive	Acute consultations in GP surgery, discharge summaries from out of hours primary care centres, walk-in centres, Accident and Emergency and hospital relating to period from day 1 to day 28 inclusive
Participant's medical history	Active problems Repeat medications Immunisations Acute consultations in GP surgery relating to period during 12 month period before study entry Past medications from 3 months before study entry to day 28



Information for research assistants

- To complete this notes review, you may ask the participant's GP surgery to send printouts of the above sections. Printouts should be labelled with the participant's ARCHIE ID number and patient identifiable information should be removed.
- If you are completing the notes review by telephone, please complete the baseline information below before contacting the participant's GP surgery.



Page: ☐ Mark CRF Complete 


BASELINE INFORMATION

Date of study entry (day 1)  

Date of day 28  

Follow-up throat swabs

Consent given by (select one)   If **YES**, please remember to do an **ADDITIONAL ARCHIE NOTES REVIEW** for this participant after his/her last follow-up throat swab has been taken

Return to top ☐ Mark CRF Complete 

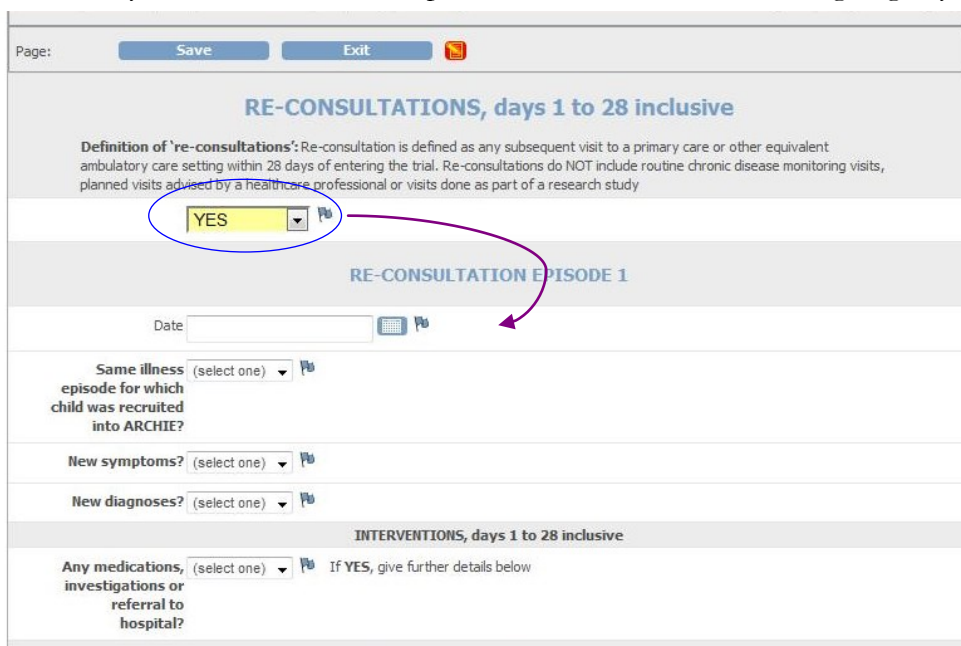
Instructions are present at the top of each CRF within the notes review study event to help you complete each form.


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 re-requested by a data query later on. If the participant had no re-consultations 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.





Page: Save Exit 


RE-CONSULTATIONS, days 1 to 28 inclusive


Definition of 're-consultations': Re-consultation is defined as any subsequent visit to a primary care or other equivalent ambulatory care setting within 28 days of entering the trial. Re-consultations do NOT include routine chronic disease monitoring visits, planned visits advised by a healthcare professional or visits done as part of a research study


YES 

RE-CONSULTATION EPISODE 1


Date  

Same illness episode for which child was recruited into ARCHIE? (select one) 

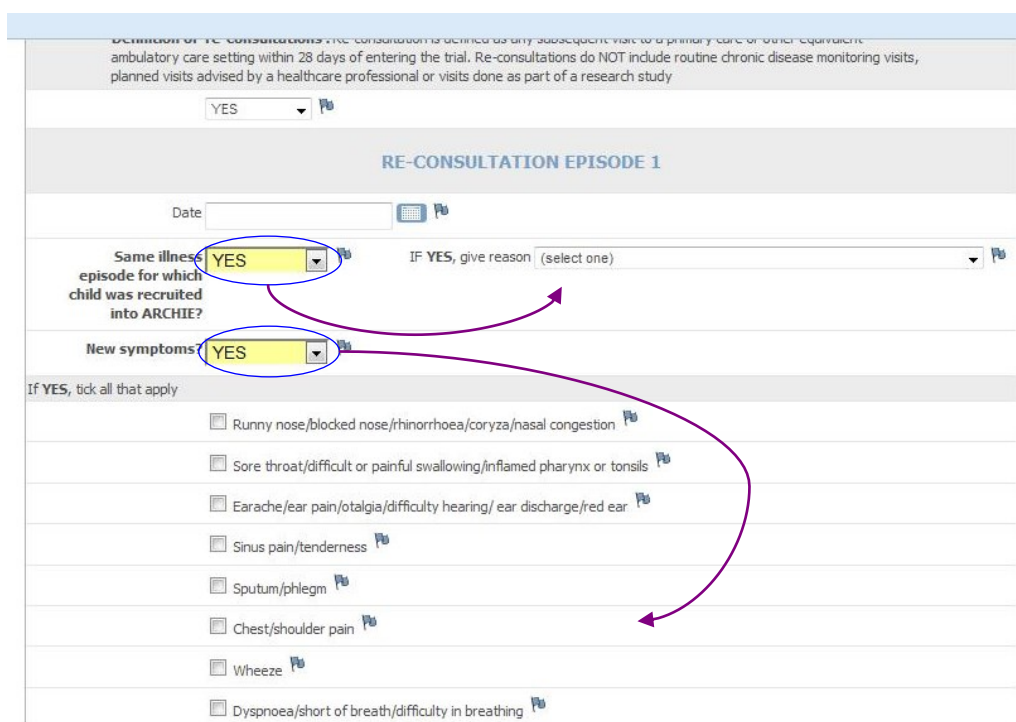
New symptoms? (select one) 

New diagnoses? (select one) 


INTERVENTIONS, days 1 to 28 inclusive

Any medications, investigations or referral to hospital? (select one)  If YES, give further details below



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






Definition of 're-consultations': Re-consultation is defined as any subsequent visit to a primary care or other equivalent ambulatory care setting within 28 days of entering the trial. Re-consultations do NOT include routine chronic disease monitoring visits, planned visits advised by a healthcare professional or visits done as part of a research study

YES 









RE-CONSULTATION EPISODE 1

Date  

Same illness episode for which child was recruited into ARCHIE? **YES**  IF YES, give reason (select one) 

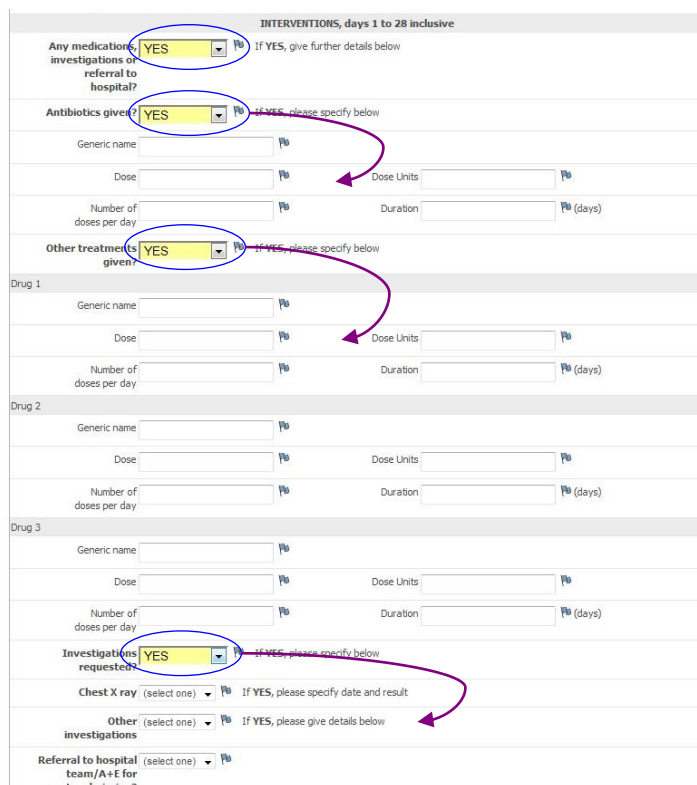
New symptoms? **YES** 

If YES, tick all that apply

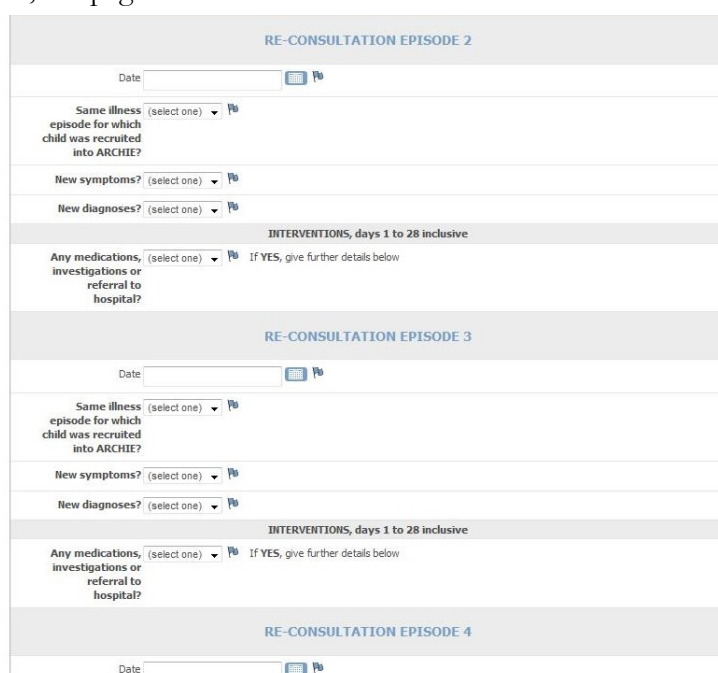
- ☐ Runny nose/blocked nose/rhinorrhoea/coryza/nasal congestion 
- ☐ Sore throat/difficult or painful swallowing/inflamed pharynx or tonsils 
- ☐ Earache/ear pain/otalgia/difficulty hearing/ ear discharge/red ear 
- ☐ Sinus pain/tenderness 
- ☐ Sputum/phlegm 
- ☐ Chest/shoulder pain 
- ☐ Wheeze 
- ☐ Dyspnoea/short of breath/difficulty in breathing 

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.



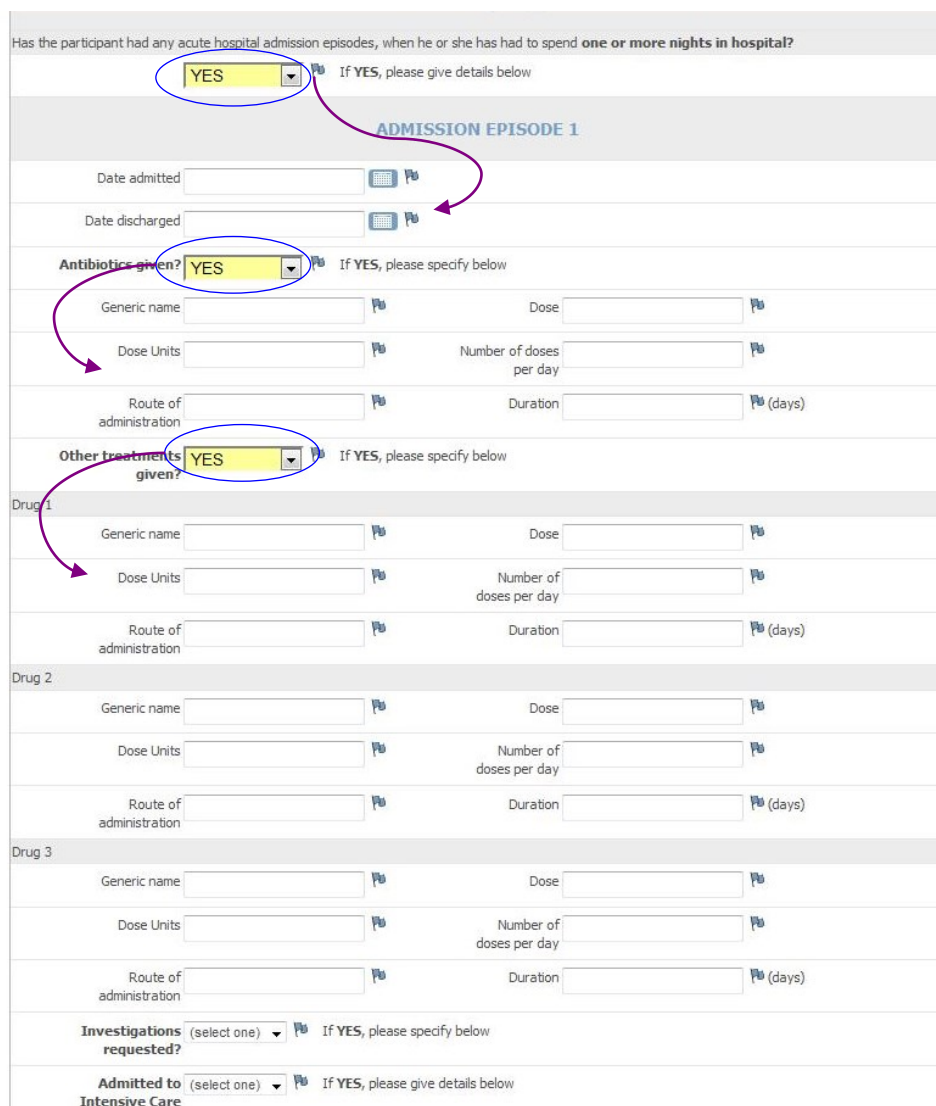
Up to four re-consultation episodes can be entered on this CRF of the medical notes review. If you need to record details of any additional re-consultation episodes then please use the Additional information CRF within the notes review study event, see page 25 for details.



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.



Has the participant had any acute hospital admission episodes, when he or she has had to spend **one or more nights in hospital**?

YES If YES, please give details below

ADMISSION EPISODE 1

Date admitted

Date discharged

Antibiotics given? **YES** If YES, please specify below

Generic name Dose

Dose Units Number of doses per day

Route of administration Duration (days)

Other treatments given? **YES** If YES, please specify below

Drug 1

Generic name Dose

Dose Units Number of doses per day

Route of administration Duration (days)

Drug 2

Generic name Dose

Dose Units Number of doses per day

Route of administration Duration (days)

Drug 3

Generic name Dose

Dose Units Number of doses per day

Route of administration Duration (days)

Investigations requested? (select one) If YES, please specify below

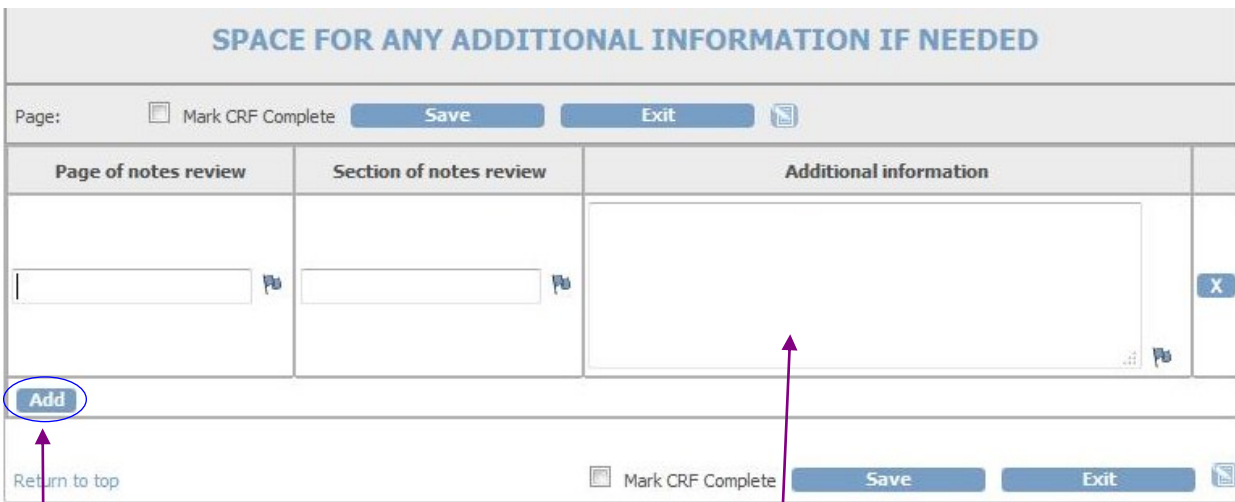
Admitted to Intensive Care (select one) If YES, please give details below

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

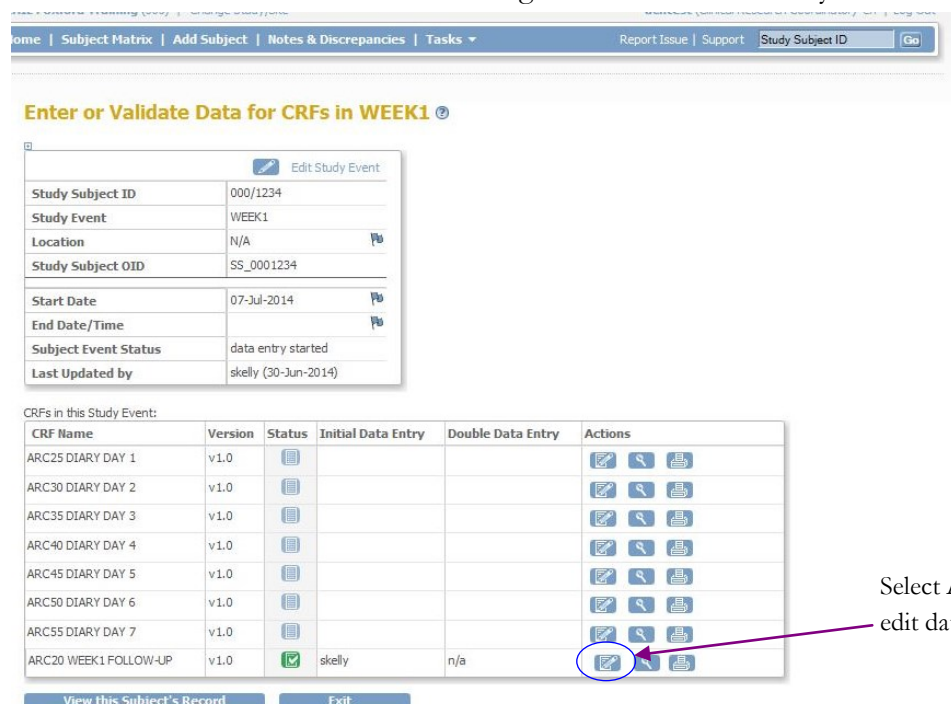
If the participant consented to providing follow up swabs at 3 months, 6 months and 12 months the Additional Notes review will also need to be conducted 12 months after study entry. This form captures details of the antibiotics prescribed in the 12 months since study entry. The trial team will contact 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.



Enter or Validate Data for CRFs in WEEK1

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
ARC25 DIARY DAY 1	v1.0				
ARC30 DIARY DAY 2	v1.0				
ARC35 DIARY DAY 3	v1.0				
ARC40 DIARY DAY 4	v1.0				
ARC45 DIARY DAY 5	v1.0				
ARC50 DIARY DAY 6	v1.0				
ARC55 DIARY DAY 7	v1.0				
ARC20 WEEK1 FOLLOW-UP	v1.0	skelly	n/a		

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.



ARC20 WEEK1 FOLLOW-UP v1.0

000/1234

WEEK1FU (15/15)

Title: WEEK 1 FOLLOW-UP

Page: Save Exit

WEEK 1 FOLLOW-UP

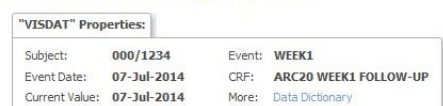
Questions for participant's parent/guardian - to be completed by healthcare professional or research assistant at week 1 telephone consultation (can be done from day 7 to day 10 inclusive)

Please remind parent/guardian to return completed week 1 study diary by e-mail (with ARCHIE ID in subject line) or post

Date of study entry (day 1) 30-Jun-2014

Date of week 1 follow-up 08-Jul-2014

VISDAT: Add Discrepancy Note



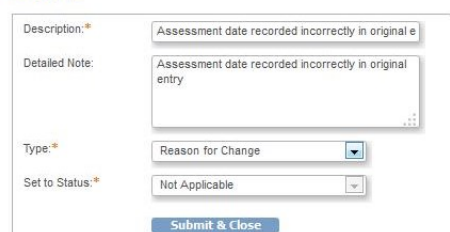
"VISDAT" Properties:

Subject: 000/1234 Event: WEEK1

Event Date: 07-Jul-2014 CRF: ARC20 WEEK1 FOLLOW-UP

Current Value: 07-Jul-2014 More: Data Dictionary

Add Note



Description: Assessment date recorded incorrectly in original e

Detailed Note: Assessment date recorded incorrectly in original entry

Type: Reason for Change

Set to Status: Not Applicable


Submit & Close

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.

ARC10 BASELINE v1.0  000/9876

▼ CRF Header Info


BASELINE (40/40)



Title: BASELINE ASSESSMENT FORM



Page: Save Exit


BASELINE ASSESSMENT FORM


CHILD'S BASELINE DETAILS

☒ Please tick to confirm that child meets eligibility criteria AND parent/guardian has signed consent form 

Date of study entry (day 1) 01-Jul-2014  Sex M 

Date of birth 23-Mar-2009  Smoker(s) in household NO 

Received this season's seasonal influenza vaccination? NO 

Received last season's seasonal influenza vaccination? NO 

SMOKERYN

Click to add a discrepancy note

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.

SMOKERYN: Add Discrepancy Note

"SMOKERYN" Properties:

Subject: 000/9876 Event: BASELINE

Event Date: 01-Jul-2014 CRF: ARC10 BASELINE

Current Value: 0 More: [Data Dictionary](#)

Add Note

Description:* Parent stopped smoking 2 weeks ago

Detailed Note: Parent stopped smoking 2 weeks ago

Type:* Annotation 

Set to Status:* Not Applicable

Submit & Close

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.

ARC10 BASELINE v1.0  **300/0033**

▼ CRF Header Info

There are issue(s) with your submission. The data has NOT been saved. See below for details.

- [Based upon the date of birth recorded at baseline it would appear the child is outside of the eligible age range for inclusion in the study (6 months to 12 years)]
- [If it is stated the child has an 'Other' at risk problem but further detail to state the problem has not been provided]


BASELINE ASSESSMENT FORM

CHILD'S BASELINE DETAILS

☒ Please tick to confirm that child meets eligibility criteria AND parent/guardian has signed consent form 

Date of study entry (day 1)  **01-Oct-2014**   Sex: M 

Date of birth **28-Sep-2001**   Smoker(s) in household NO 

Received **this season's** seasonal influenza vaccination? NOT KNOWN 

Received **last season's** seasonal influenza vaccination? NOT KNOWN 

AT RISK CATEGORIES (please tick all that apply)


☐ Respiratory 

☐ Neurological 

☐ Liver 

☒ Cardiac 

☐ Renal 

☐ Immunodeficiency 

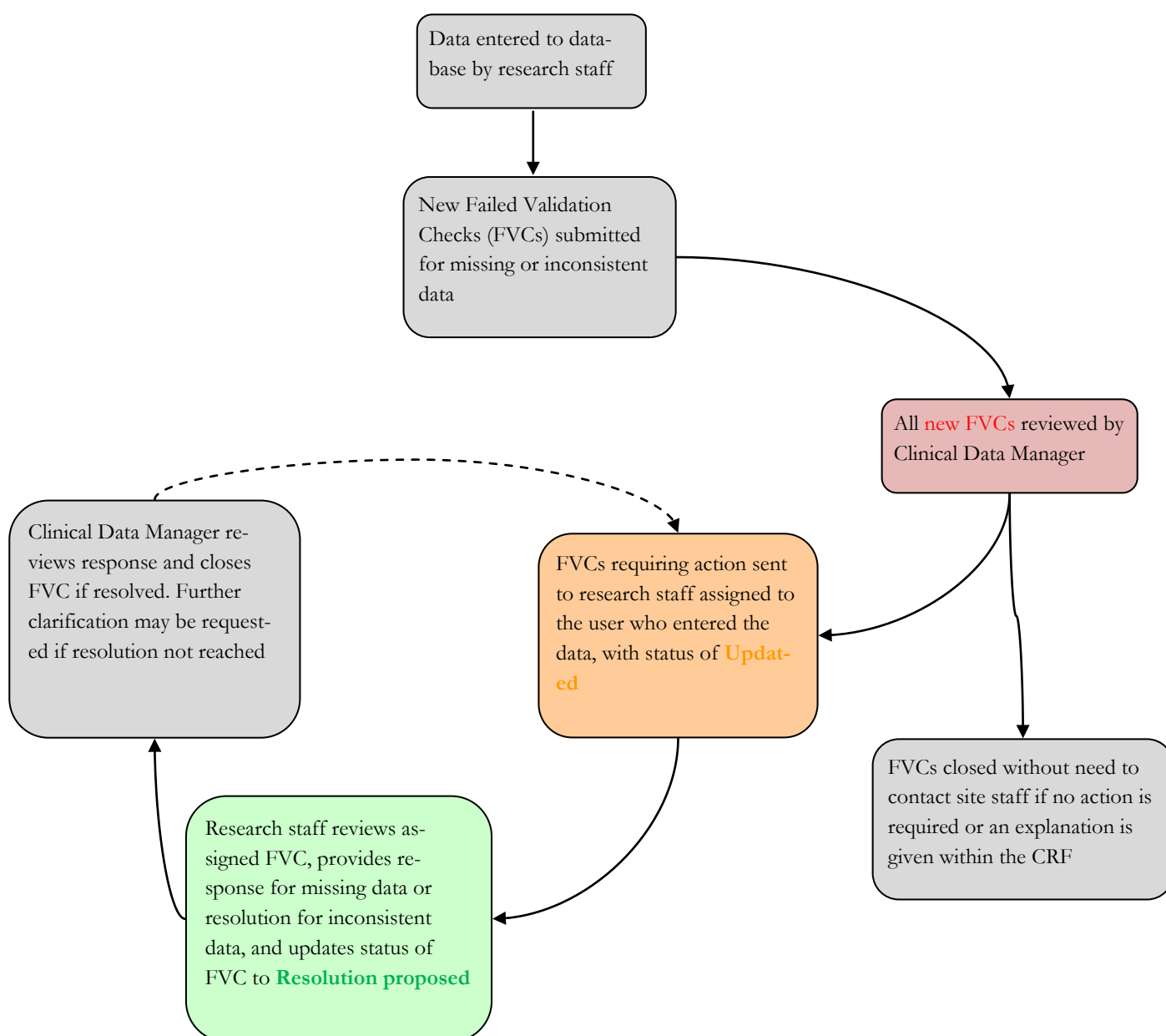
 ☒ Other (please state) 

CURRENT INFLUENZA-LIKE ILLNESS EPISODE (as reported by parent/guardian)

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.

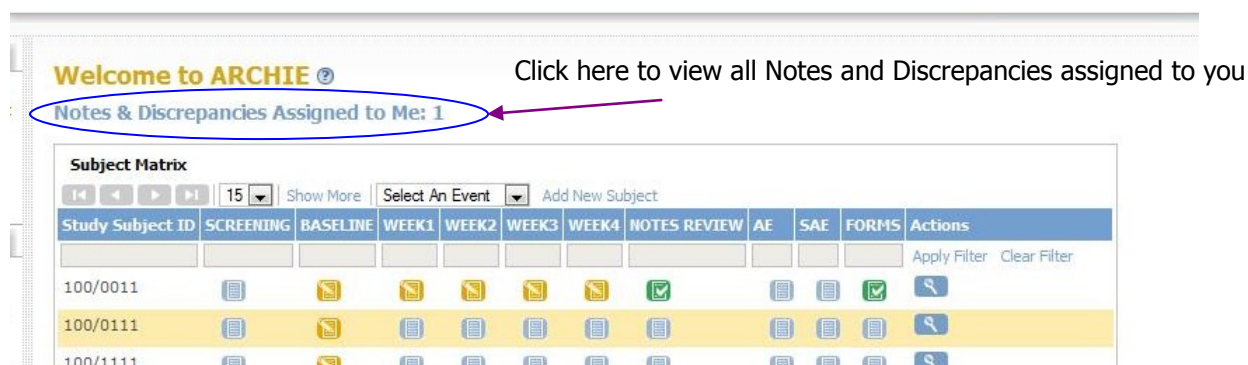
Resolution of Failed Validation Checks (FVCs) - Data queries

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.



Welcome to ARCHIE ?

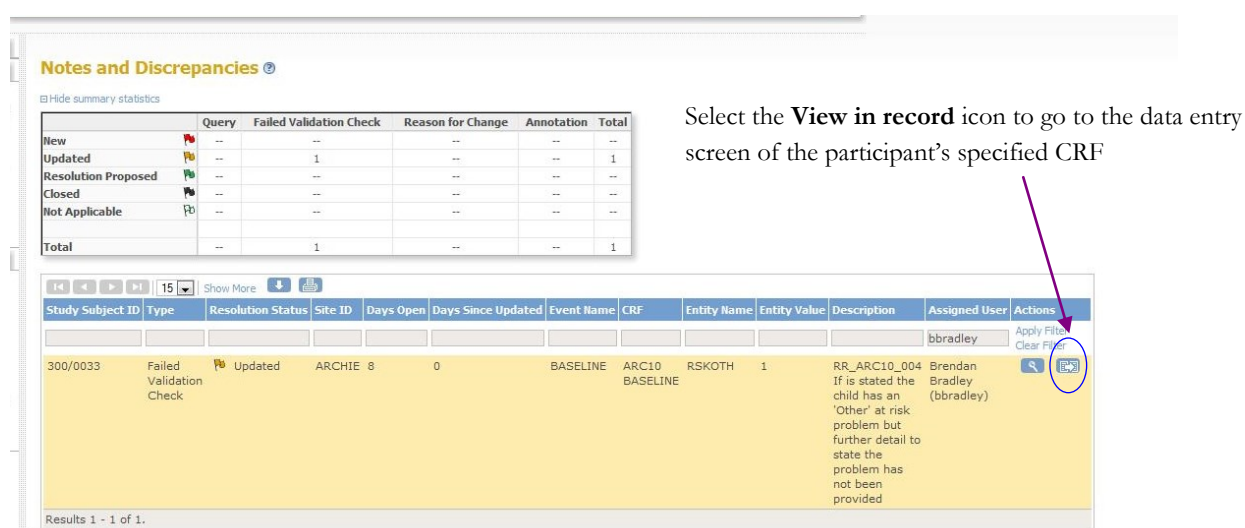
Click here to view all Notes and Discrepancies assigned to you

Notes & Discrepancies Assigned to Me: 1

Subject Matrix

Study Subject ID	SCREENING	BASELINE	WEEK1	WEEK2	WEEK3	WEEK4	NOTES REVIEW	AE	SAE	FORMS	Actions
100/0011											
100/0111											
100/1111											

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.



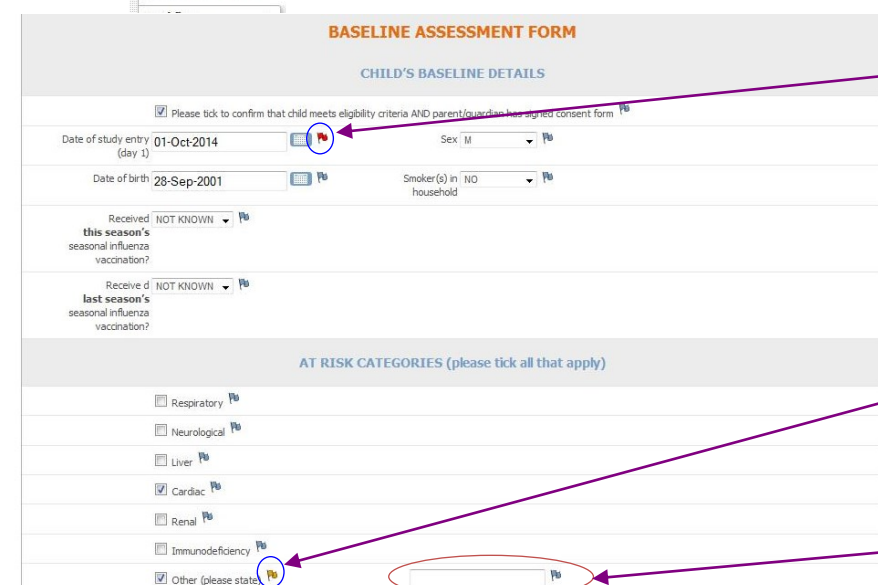
Notes and Discrepancies ?

Hide summary statistics

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

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
300/0033	Failed Validation Check	Updated	ARCHIE 8	0		BASELINE	ARC10 BASELINE	RSKOTH	1	RR_ARC10_004 If is stated the child has an 'Other' at risk problem but further detail to state the problem has not been provided	Brendan Bradley (bbradley)	

Results 1 - 1 of 1.



BASELINE ASSESSMENT FORM

CHILD'S BASELINE DETAILS

☒ Please tick to confirm that child meets eligibility criteria AND parent/guardian has signed consent form

Date of study entry (day 1) 01-Oct-2014

Sex M

Date of birth 28-Sep-2001

Smoker(s) in household NO

Received this season's seasonal influenza vaccination? NOT KNOWN

Received last season's seasonal influenza vaccination? NOT KNOWN

AT RISK CATEGORIES (please tick all that apply)

☐ Respiratory

☐ Neurological

☐ Liver

☒ Cardiac

☐ Renal

☐ Immunodeficiency

☒ Other (please state)

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.

RSKOTH: Notes and Discrepancies

"RSKOTH" Properties:

Subject: 300/0033 Event: BASELINE
 Event Date: 30-Jul-2014 CRF: ARC10 BASELINE
 Current Value: 1 More: [Data Dictionary](#)
[Audit History](#)

Note Details

☒ **RR_ARC10_004 If is stated the child has an 'Other' at risk problem but further detail to state the problem has not been provided**
 Last Updated: 07-Aug-2014 by skelly
 Assigned to: Brendan Bradley (bbradley)

ID: 175	Type: Failed Validation Check	Current Status: Updated	# of Notes: 2
RR_ARC10_004 If is stated the child has an 'Other' at risk problem but further detail to state the problem has not been provided		Status: New	30-Jul-2014 by skelly
Missing data, response requested from research site Missing data, response requested from research site		Status: Updated Assigned to: Brendan Bradley (bbradley)	07-Aug-2014 by skelly

[Update Note](#) [Propose Resolution](#)

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	30-Jul-2014 11:08:38	skelly	RSKOTH		1

(This item was initially entered on 30-Jul-2014.)

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.

RSKOTH: Notes and Discrepancies

"RSKOTH" Properties:

Subject: 300/0033	Event: BASELINE
Event Date: 30-Jul-2014	CRF: ARC10 BASELINE
Current Value: 1	More: Data Dictionary
	Audit History

Note Details

☐ RR_ARC10_004 If is stated the child has an 'Other' at risk problem but further detail to state the problem has not been provided
Last Updated: 07-Aug-2014 by skelly
Assigned to: Brendan Bradley (bbradley)

ID: 175	Type: Failed Validation Check	Current Status: Updated	# of Notes: 2
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RR_ARC10_004 If is stated the child has an 'Other' at risk problem but further detail to state the problem has not been provided	Status: New	30-Jul-2014 by skelly
Missing data, response requested from research site	Status: Updated	07-Aug-2014 by skelly Assigned to: Brendan Bradley (bbradley)

Missing data, response requested from research site

[Update Note](#) [Propose Resolution](#)

Respond below to Update/Resolve/Close this Discrepancy Note:

Description:*

Detailed Note:

Set to Status:*

Assign to User:

Email Assigned User: ☐

[Submit](#) [Submit & Exit](#)

Enter details of the update with a brief explanation.

Status should be set to **Resolution Proposed**

Select **Submit and Exit** when complete

[Begin New Thread](#)

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	30-Jul-2014 11:08:38	skelly	RSKOTH		1

(This item was initially entered on 30-Jul-2014.)

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.

AT RISK CATEGORIES (please tick all that apply)

<input type="checkbox"/> Respiratory	<input type="checkbox"/> Neurological	<input type="checkbox"/> Liver	<input checked="" type="checkbox"/> Cardiac	<input type="checkbox"/> Renal	<input type="checkbox"/> Immunodeficiency	<input checked="" type="checkbox"/> Other (please state)	<input type="text" value="Sickle cell disease"/>
--------------------------------------	---------------------------------------	--------------------------------	---	--------------------------------	---	--	--

CURRENT INFLUENZA-LIKE ILLNESS EPISODE (as reported by parent/guardian)

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.