UK Meningitis Study
Improving the diagnosis of meningitis

CRF v2.0 Standard Operating Procedures

Please note that from 1st May 2015 the UK Meningitis Study will be using CRF v2.0 for newly enrolled patients.

The online CRF can be accessed through OpenClinica™ at:
https://openclinica.liv.ac.uk/UKMeningitisLive/

If you do not have a login for OpenClinica™ please contact the UK Meningitis Team.

- Please complete the CRF within 28 days of enrolment.

- If you have more than two CRFs incomplete for longer than 28 days we may consider pausing recruitment for your site to allow you to complete CRFs.

- Please do NOT mark the CRF as complete on the final page, instead please email greg1@liv.ac.uk to notify us a CRF has been entered.

- Dates should be entered as DD-MMM-YYYY. Times should be entered as HH:MM in the 24 hour clock format.

- If a value is not available in patient records please enter UNK. Please use only when absolutely necessary. NA is no longer compatible with the CRF.

Contacts

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Icon Key

Statuses

Icon	Status
	Not Started
	Scheduled
	Data Entry Started
	Stopped
	Skipped
	Completed
	signed
	Locked
	Invalid

Actions

Icon	Action
	View
	Edit
	Remove
	Restore
	Reassign
	Sign

Finding a Subject Record

From the home page, click into the Study Subject ID search box and enter the Subject ID number you have been given.

You will be taken directly to the subject's record.

Creating a CRF

While in the subject's record click 'Schedule New Event'

You can then select the type of event – in this case 'CRF (Repeating)'.
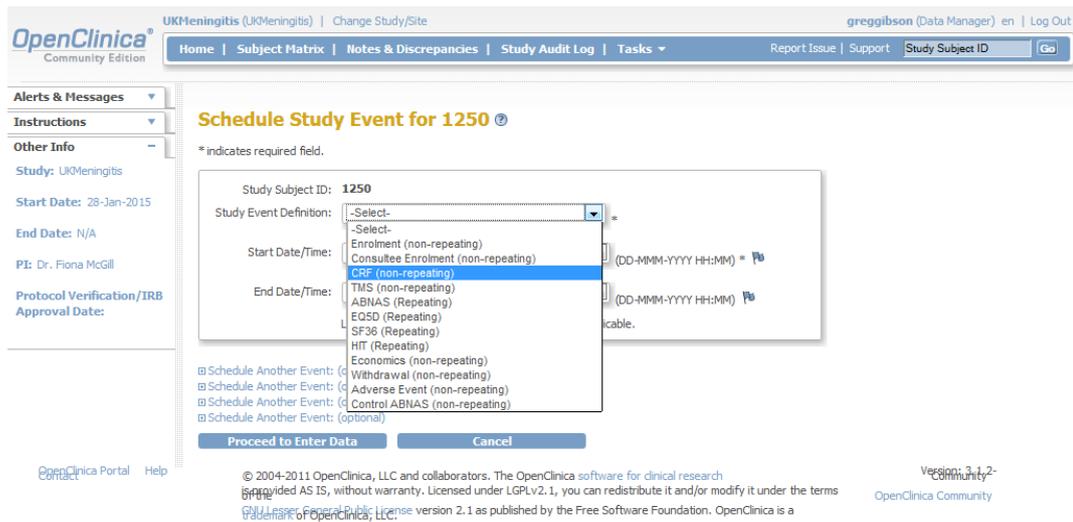
Then click the pencil (edit button) to start entering data
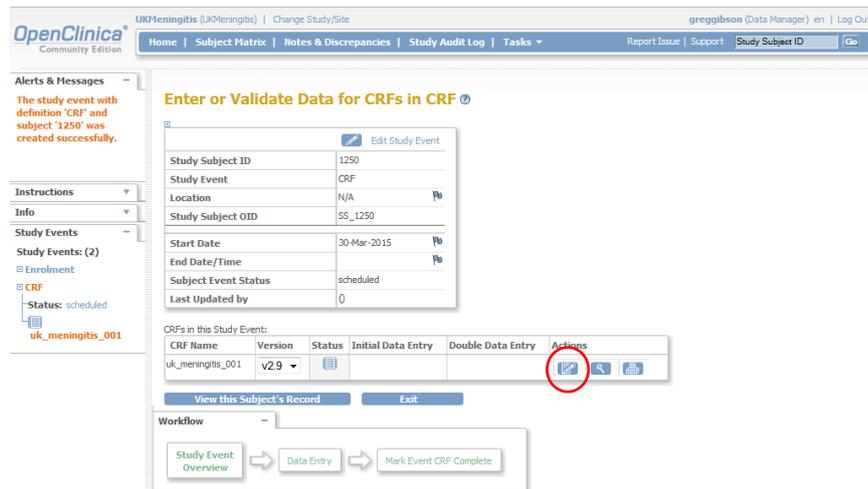
<u>Editing CRFs</u>

To edit a CRF follow the steps for Finding a Record and click the edit button next to the CRF.
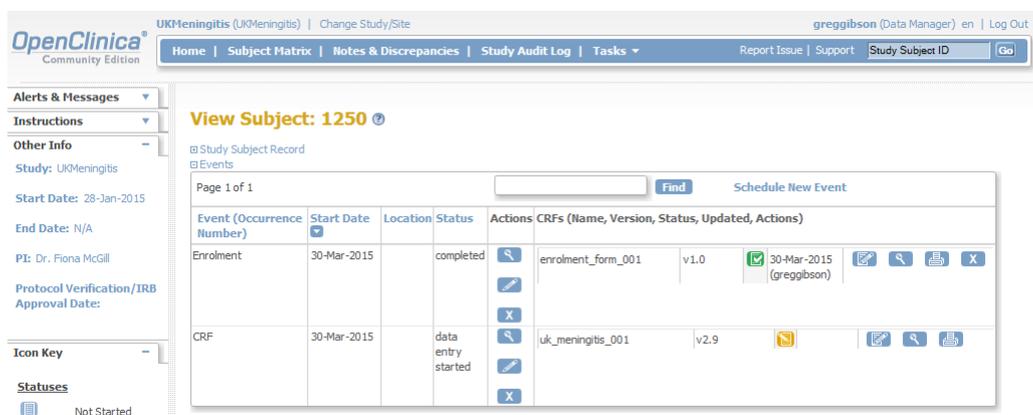
If a subject is readmitted to hospital and has an LP please create a second CRF. You can do this by repeating the steps for Creating a CRF above.

Entering data into the CRF

Please see below some common errors/notes to be aware of.

History

Date of onset of symptoms should be before or on the date of admission. If it is not recorded from the notes please use the longest duration as an indication e.g. if longest duration is 48 hours (2 days) and date of admission is 30th March 2015, please use 28th March 2015 as date of onset.

Date of admission should be earliest date recorded for admission – including time of entry to A&E if patient attended A&E before admission to hospital.

Please record duration for all present symptoms. Record as a whole number without the word hours, if not in notes please work out from date of onset/other symptoms.

Further History

If you are able to get vaccination history from the patient's GP/notes then please enter this here.

If there is no information available or the patient had no vaccinations leave the dropdown option as '(please select)' and move on to the next question (leave 'If yes when' box blank).

Blood Cultures

If blood cultures were not taken enter 'No' and skip to the Blood PCR section (enter 'Not Done' for each). Do NOT complete anything else or this will cause a Failed Validation Check.

If blood culture is negative please enter 'No' for 'Was blood culture positive' and skip down to the Blood PCR section.

Please **do not enter** anything into the blood culture positive box if the blood cultures were not taken.

If the LP was _not_ done please complete the following:

Did the patient have an LP? No

Please give reason

Tick Not Done for Opening Pressure

Enter UNK for white & red blood cells

Enter UNK for Protein

Select unknown for CSF culture result

If the LP _was_ completed, **please enter as normal.**

Treatment

If the patient was admitted via A&E and you have recorded this as their admission date and time, please record any treatment given to the patient in A&E as pre-admission antimicrobials on the treatment page and select A&E as the prescriber.

Other Treatment

Please note you will have to scroll across to complete all sections of the chart.

Substudies

Please make sure that the consented question at the top of the substudies matches the answer given to point 8 on the consent form, **regardless of whether samples were taken**.

If the patient was consented to the study after discharge please make a note that no extra samples were taken as patient was consented by post in the comments box at the bottom of the substudies section.

Completing a CRF

Once you reach the final page of the CRF please either save or exit.

Please do **not** select anything from the drop down list and do **not** tick the box 'Mark CRF Complete'.

Once you have done this please email a member of the UK Meningitis Study team to let them know the CRF has been completed for this subject.

Failed Validation Check

If incorrect or conflicting data is entered onto OpenClinica™ then the system will highlight the problem with a note in red at the top of the page and red exclamation marks at the side of the area that the problem has occurred, this is called a 'Failed Validation Check'.

If you correct the issue and save you can continue to enter data. If you don't correct the issue and save again a 'Failed Validation Check' will be created – which will then need to be resolved by the UK Meningitis team.

If you repeatedly have a problem with failed validation checks, please contact the study team ASAP.

If you cannot correct the issue due to missing data then you can enter UNK and create a discrepancy note (see later section) to explain why the data is missing.

Below are some examples of failed validation checks and how these can be corrected.

If you don't enter a question with an orange asterisk next to it * and go to save OpenClinica™ will flag the question. Please complete the question and save again.

Data has been missed from the durations of these symptoms.

In this case enter the number of hours (as a number only e.g. 24) for each present symptom and then save.

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

• [GCS must be between 3 and 15]

GCS can only be between 3 and 15 so the system has flagged a number that is too high. Correct the data and save.

Creating a Discrepancy Note

Click the flag next to the data box you are raising a query for and a new window will open

Please enter the reason why the discrepancy has been raised (in this case white cell count is unknown) in the description and give any further details in the detailed note.

Leave type as annotation

Set status to not applicable

When complete please click Submit. The window will close and you can continue entry as normal.

Responding to Data Queries

To access data queries that have been assigned to you, click on Notes & Discrepancies Assigned to Me on the front page.

You will be taken to a list of all queries. To respond click the view button (magnifying glass) next to the query.

The query will appear here

To respond click update note

You can answer the query here

Set status as updated

Assign the note to the person who raised the query

Submit & Exit when done.

Thank you for completing the CRF.

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