

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

For clinical queries:
Fiona McGill
fmcgill@liv.ac.uk
0151 795 9606

For OpenClinica™ queries:
Greg Gibson
greg1@liv.ac.uk
0151 795 9670

Icon Key

Statuses

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

Actions

	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.

The screenshot shows the OpenClinica interface for the UKMeningitis study. The search box for 'Study Subject ID' is highlighted with a red circle. The page includes a navigation menu, a welcome message, and several data tables.

Site	Enrolled	Expected Enrollment	Percentage
UKMeningitis	14	500	3%

Study	Enrolled	Expected Enrollment	Percentage
UKMeningitis	14	500	3%

Event Status	# of Events	Percentage
scheduled	2	0%
data entry started	19	76%
completed	4	16%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Study Subject Status	# of Study Subjects	Percentage
available	14	100%
signed	0	0%
removed	0	0%

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

The screenshot shows the 'View Subject: 1250' page. The 'Schedule New Event' button is circled in red. The page displays a table of events for the subject.

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Enrolment	30-Mar-2015		completed	[Search] [Edit] [Delete]	enrolment_form_001 v1.0 [Check] 30-Mar-2015 (greggibson) [Search] [Print] [Close]

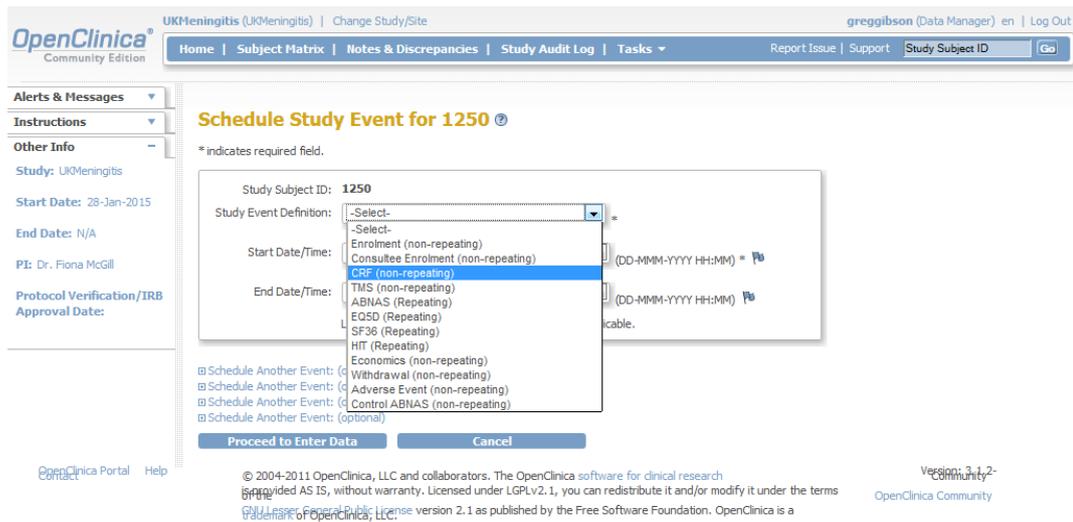
Creating a CRF

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

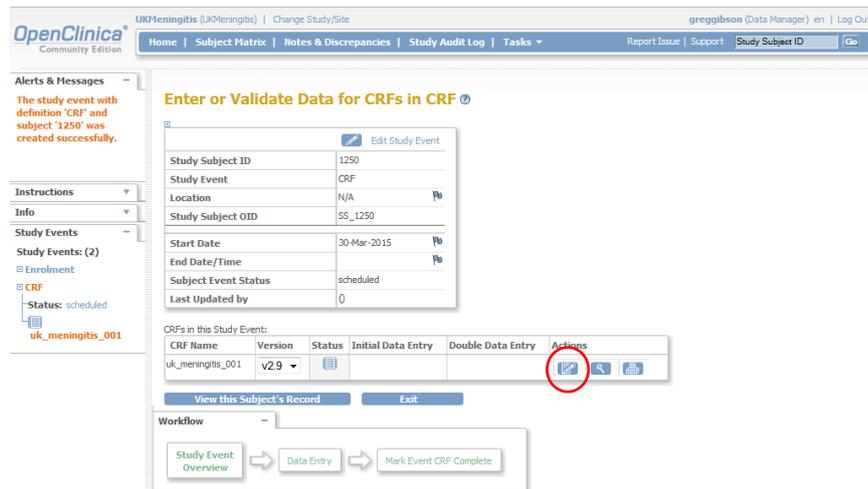
The screenshot shows the 'View Subject: 1201' page. The 'Schedule New Event' button is circled in red. The page displays a table of events for the subject.

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Enrolment	30-Mar-2015		completed	[Search] [Edit] [Delete]	enrolment_form_001 v1.0 [Check] 30-Mar-2015 (greggibson) [Search] [Print] [Close]

You can then select the type of event – in this case ‘CRF (Repeating)’.

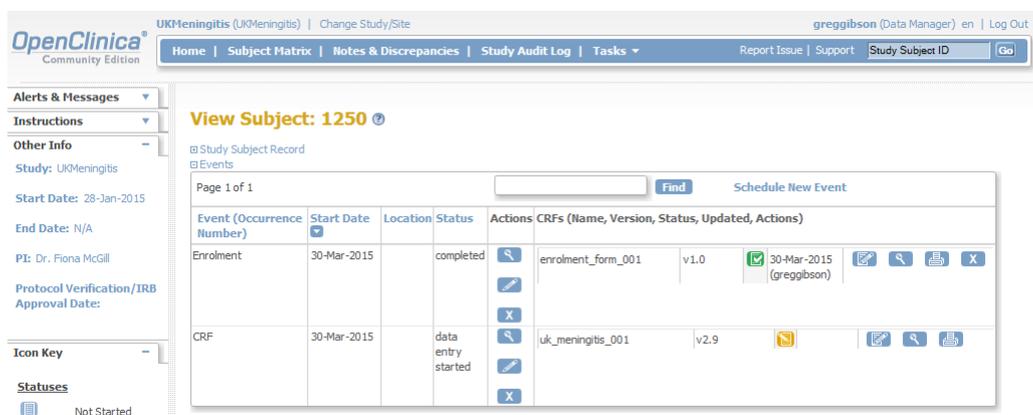


Then click the pencil (edit button) to start entering data



Editing CRFs

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.

uk_meningitis_001 v2.9 1250
 CRF Header Info

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.**

The screenshot shows the 'Substudies' section of a CRF form. At the top, there are navigation tabs: 'Outcome... (4/4)', 'Substud... (3/24)', and 'Approval (0/1)'. Below the tabs, the title is 'Substudies'. There are 'Save' and 'Exit' buttons. The text reads 'Substudies 6.9.3, 6.9.4 and 6.9.5.' followed by the question 'Has the patient consented to having extra sample of blood/CSF taken for research'. The 'Consented?' field has three radio button options: 'Yes' (selected), 'No', and 'unknown'.

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.

The screenshot shows the 'Approval' section of a CRF form. At the top, there are navigation tabs: 'Outcome... (0/4)', 'Substud... (0/24)', and 'Approval (0/1)'. Below the tabs, the title is 'Approval'. There are 'Save' and 'Exit' buttons. The text reads 'Electronic CRFs should ONLY be marked complete by members of Brain Infections UK Staff'. Below this, there is a dropdown menu with '(please select)' and a 'Mark CRF Complete' checkbox. The 'Return to top' link also has a 'Mark CRF Complete' checkbox. Red X marks are placed over the 'Mark CRF Complete' checkboxes and the dropdown menu.

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.

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

The screenshot shows a form titled "CSF PCR Results". At the top, there is a red error message: "[Missing data in a required field.]". Below this, there are navigation tabs for "CSF res...(10/27)", "CSF PCR...(0/9)", and "Other L...(0/7)". The form contains several sections for PCR results, each with radio buttons for "Positive", "Negative", "Not Done", and "unknown". An orange asterisk is next to the "Positive" option in each section, indicating a validation error. The sections are: Meningococcal, Pneumococcal, HSV-1, HSV-2, and Enterovirus.

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.

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

The screenshot shows a form titled "History". At the top, there are two red error messages: "[Please give duration of fever in hours]" and "[Please give duration of diarrhoea in hours]". Below these, there are navigation tabs for "History (0/36)", "Further...(0/36)", and "Examina...(0/8)". The form contains several sections for symptom history, each with radio buttons for "Yes", "No", and "unknown", and a "Duration (hours)" field. The sections are: "Fever or history of fever", "Headache", "Neck stiffness", "Photophobia", and "Diarrhoea". The "Duration (hours)" fields for "Fever or history of fever" and "Diarrhoea" are highlighted in red, indicating validation errors.

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 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.

wcc: Add Discrepancy Note

Add Note

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.

The screenshot shows the OpenClinica interface for the UKMeningitis study. A red arrow points to the link "Notes & Discrepancies Assigned to Me: 1" which is circled in red. The page also displays various enrollment and progress statistics.

Site	Enrolled	Expected Enrollment	Percentage
UKMeningitis	16	500	3%

Event Status	# of Events	Percentage
scheduled	2	7%
data entry started	20	71%
completed	6	21%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Study Subject Status	# of Study Subjects	Percentage
available	16	100%
signed	0	0%
removed	0	0%

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

The screenshot shows the "Notes and Discrepancies" page. A table lists queries with columns for Query, Failed Validation Check, Reason for Change, Annotation, and Total. Below the table is a detailed view of a query for Subject ID 1234. A red arrow points to a magnifying glass icon in the "Actions" column of the query table.

Query	Failed Validation Check	Reason for Change	Annotation	Total
New	1	--	--	1
Updated	--	--	--	--
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
1234	Query	New	UKMeningitis	0	0	CRF	uk_meningitis_001	wcc	14.0	Why is WCC 14.0?	Greg Gibson (greggibson)	

The query will appear here

To respond click update note

The screenshot shows the detailed view of a query. It includes "wcc" Properties, Note Details, and an Audit History table. A red arrow points to the "Update Note" button, which is circled in red.

wcc: Notes and Discrepancies

"wcc" Properties:

- Subject: 1234
- Event: CRF
- Event Date: 26-Feb-2015
- CRF: uk_meningitis_001
- Current Value: 14.0
- More: Data Dictionary, Audit History

Note Details

Why is WCC 14.0? (Last updated: 30-Mar-2015 by greggibson)

ID: 41 | Type: Query | Current Status: New | # of Notes: 1

Why is WCC 14.0? | Status: New | 30-Mar-2015 by greggibson | Assigned to: Greg Gibson (greggibson)

Update Note | Propose Resolution | Close Note

Audit History

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	30-Mar-2015 12:22:00	greggibson	wcc		14.0

(This item was initially entered on 26-Feb-2015.)

wcc: Notes and Discrepancies

"wcc" Properties:

Subject:	1234	Event:	CRF
Event Date:	26-Feb-2015	CRF:	uk_meningitis_001
Current Value:	14.0	More:	Data Dictionary
			Audit History

Note Details

Why is WCC 14.0? Last updated: 30-Mar-2015 by greggibson
Assigned to: Greg Gibson (greggibson)

ID: 41	Type: Query	Current Status: New	# of Notes: 1
--------	-------------	---------------------	---------------

Why is WCC 14.0? Status: New 30-Mar-2015 by greggibson
Assigned to: Greg Gibson (greggibson)

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

Description: *

Detailed Note:

Set to Status: *

Assign to User:

Email Assigned User:

[Begin New Thread](#)

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.

For clinical queries:
 Fiona McGill
fmcgill@liv.ac.uk
 0151 795 9606

For OpenClinica™ queries:
 Greg Gibson
greg1@liv.ac.uk
 0151 795 9670