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: <u>https://openclinica.liv.ac.uk/UKMeningitisLive/</u>

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 <u>fmcgill@liv.ac.uk</u> 0151 795 9606

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



Finding a Subject Record

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

UKMenin	ngitis (UKMeningitis)	Change Study/Site			g	reggibson (Data Manao
Community Edition	e Subject Matrix	Notes & Discre	pancies Study Audit Log	Tasks 🕶	Report Issue 9	Support Study Subject II
rts & Messages – V elcome to OpenClinica, eg Gibson. You last Iged in on	Velcome to U otes & Discrepan	KMeningiti cies Assigned 1	5 🔊 to Me: 0			
-Mar-2015.	50	ubject Enrollment	By Site	Sub	ject Enrollment For S	tudy
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structions -				UKMeningitis 14	500	3%
eeded you may change		Study Progres	5		Subject Status Count	
tess to a new study with a	Event Status	# of Events	Percentage	Study Subject Status	# of Study Subjects	Percentage
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er Info –	data entry started	19	76%	signed	0	0%
udy: UKMeningitis	completed	4	16%	removed	0	0%
ut Date: 29-Jac-2015	signed	0	0%			
PC DUCE: 20-301-2013	locked	0	0%			
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Dr. Fiona McGil	stopped	0	0%			

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

Community Edition	lome Subject Matri	x Notes &	Discrepan	cies S	itudy Au	idit Log Tasks 🔻		Report Issue Suppo	ort Study Subj	ect ID
lerts & Messages	View Subject	: 1250 (3							
ther Info –	Study Subject Record Events									
tart Date: 28-Jan-2015	Page 1 of 1						Find	Schedule New Event		
nd Date: N/A	Event (Occurrence Number)	Start Date	Location 9	Status	Actions	CRFs (Name, Version	n, Status, Upo	ated, Actions)		
I: Dr. Fiona McGill rotocol Verification/IRB .pproval Date:	Enrolment	30-Mar -2015	c	completed	۹ ایک ا	enrolment_form_001	v1.0	30-Mar-2015 (greggibson)		₿ X

Creating a CRF

While in the subject's record click <u>'Schedule New Event'</u>

	UKMe	eningitis (UKMeningitis)	Change Stud	ly/Site					gregg	j ibson (Data	Manager)	en Log Out
UpenClinica Community Edition	Ho	ome Subject Matrix	(Notes &	Discrepa	ncies S	itudy Au	dit Log Tasks 🗸		Report Issue Suppo	rt Study S	ubject ID	Go
Alerts & Messages 🔹	וו							\mathbf{i}				
Instructions •	1	View Subject	: 1201 (9					\mathbf{N}			
Other Info -	1	Study Subject Record							\mathbf{X}			
Study: UKMeningitis		Bage 1 of 1						Find	Schadula Naw Evan	<u> </u>		
Start Date: 28-Jan-2015		Page 1011				_	1	Filld	Schedule New Even	>		_
End Date: N/A		Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Versio	n, Status, U	pdated, Actions)			
PI: Dr. Fiona McGill		Enrolment	30-Mar-2015		completed	٩	enrolment_form_001	v1.0	(gregoibson)	2		X
Protocol Verification/IRB	3					Ľ			(3 33			
Approvar bate:						X						
Icon Key –	1											
Statuses		 □ Group □ Global Subject Record 										
Not Started		Go Back to Subject List										

You can then select the type of event - in this case 'CRF (Repeating)'.

-	UKMeningitis (UKMeningitis)	Change Study/Site			greggibs	son (Data Manager) er	n Log Out
Community Edition	Home Subject Matrix	Notes & Discrepancies	Study Audit Log	Tasks 🔻	Report Issue Support	Study Subject ID	Go
Alerts & Messages Instructions Other Info Study: Manipulie	Schedule Stud * indicates required field.	y Event for 1250	0				
Start Date: 28-Jan-2015 End Date: N/A PI: Dr. Fiona McGill	Study Subject ID: Study Event Definition: Start Date/Time:	1250 -SelectSelect- Enrolment (non-repeating) Consultee Enrolment (non-receasing) COE (non-sense tion)	epeating)	* (DD-MMM-YYYY HH:MM) * 阳			
Protocol Verification/IRE Approval Date:	B End Date/Time:	TMS (non-repeating) ABNAS (Repeating) EQ5D (Repeating) SF36 (Repeating) HIT (Repeating) Economics (non-repeating) (2 Withdrawal (non-repeating)	j	(DD-MMM-YYYY HH:MM) 🍋 cable.			
Opp<u>CI</u>nica Portal Hel	Schedule Another Event: Schedule Another Event: Schedule Another Event: Proceed to Enter I Proceed to Enter I @ 2004-2011 Ope grampided ASIS, GNULeser Event	(C Adverse Event (non-repeat (C Control ABNAS (non-repeat (optional) Data Car nClinica, LLC and collaborators. abuilto License unco abuilto License version 2, 1 as	ing) ing) Incel The OpenClinica softwa der LGPLv2. 1, you can ro published hus the Free S	are for dinical research edistribute it and/or modify it u	nder the terms Ope	Veesiกการสำนัง2- nClinica Community	

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

	UKMeningitis (UKMeningitis) Change Stu	dy/Site			greggib	ion (Data Manager) e	n Log C
Community Edition	Home Subject Matrix Notes &	Discrepancies Stu	dy Audit Log Tasks 🔻	 Report Issu 	e Support	Study Subject ID	Go
Alerts & Messages - The study event with definition 'CRF' and subject '1250' was	Enter or Validate Dat	ta for CRFs in	CRF @				
created successfully.		📝 🛛 Edit Study Ev	ent				
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Instructions •	Location	N/A	Po				
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CRF	Subject Event Status	scheduled	_				
Status: scheduled	Last Updated by	0					
uk_meningitis_001	CRFs in this Study Event:	atus Initial Data Entr	v Double Data Entry	Actions			
	uk_meningitis_001 v2.9 -						
	View this Subject's Record	Exit		\smile			
	Study Event Overview	try 🕞 Mark Ever	t CRF Complete				

Editing CRFs

To edit a CRF follow the steps for Finding a Record and click the edit button next to the CRF.

o o:	JKMeningitis (UKMeningitis)	Change Stud	dy/Site				greggil	oson (Data Manag	er) en Log Out
Community Edition	Home Subject Matri	x Notes &	Discrepancies 1	Study Audit Lo) Tasks 🔻		Report Issue Support	Study Subject II	D G0
Alerts & Messages 🔹 🔻									
Instructions Instructions 	View Subject	t: 1250 @	9						
Other Info -	Study Subject Record Events								
Start Date: 28-Jan-2015	Page 1 of 1					Find	Schedule New Event		
End Date: N/A	Event (Occurrence Number)	Start Date	Location Status	Actions CRFs	(Name, Versio	n, Status, Upda	ated, Actions)		
PI: Dr. Fiona McGill	Enrolment	30-Mar-2015	completed	enrol	nent_form_001	v1.0	30-Mar-2015 (greggibson)	Ø 9 4	
Protocol Verification/IRB Approval Date:				X					
Icon Key -		30-Mar-2015	data entry started	S uk_m	aningitis_001	v2.9		8	4
<u>Statuses</u>				X					
Not Started		1							

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.



Further History

History (26/34)	Further(6/16)	Examina(7/8) 🕨 Sele	ct to Jump	•
Title: Further History					
Page:	Save	Exit			
Has the patient receive	ed any of the follow	ing vaccinations	5?		
Vac	cination		If yes w	hen	
(please select)	- V	۵		🔑 (year)	
Add					
Travel History					
Has the patient travelled to	o any of the following (places in the last 1	2 months?		
Inc	lia 🔘 yes 🔹 🏴				

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.

								-
Page: S	ave	Ex	it 関					
Were blood cultures	O Yes	Po						
taken?	No							
	unknown							
Data Bathland			COLUMN TWO	These first bland		104		
cultures taken			1	cultures taken		(u		
		-						
Was blood culture	Yes	10						
positive	🔍 No							
	unknown							
Gram film result	Not done		Pb .					
	No Orozoia	me Caso						
	Gram Posit	ive Corri Zeto	20					
	Gram Posit	ive cocci ?star	ah					
	Gram Neos	tive cocci						
	Gram Posit	tve Bacili						
	Gram Nega	itive Bacili						
	Yeast							
	Other (exp	and)						
	unknown							
Other plants control					Vo			
Other prease expans					1-			
Culture result								
Blood culture result	No growth		Po					
	Streptococ	cus poeumoni	ae^					
	Neisseria n	eningitids^						
	Listeria mo	nocytogenes	~					
	Haemophile	us influenzae						
	Cryptococi	cus neoformat	15					
	Staphyloco	ccus aureus						
	Escherichia	coli						
	C Other (ples	ase state)						
	🔲 unknown							
If other please state			Po					
^ Please record			Po					
serotype/serogroup								
Blood PCR								
Meningococcal PCR	Pos	Po	Date		09 III	Time		
	Neg							
	Not Done							
	🔍 unknown							
Dianan marc - data			No.					
serotype if positive			1-					
		No.						
Pneumococcal PCR	Pos	10	Date		iiii ko	Time		
	Neg							
	Not Done							
	🔍 unknown							
Any other PCR on	O Pag	Po	Please state which				Po	
blood	POS Nec		(including 16s and					
	Not Done		result)					
	- 1010016							
	C unknown							
	🔍 unknown							
	C unknown							

If the LP was *not* done please complete the following:

'	d blood C(0112) CSF res(0)27 CSF PCR(05) + - Select to Jump - •
	Title: CSF results
	Page: Save Lot S
Did the method there are LDO No.	Dd the patient have O Yes * 14
Did the patient have an LP? No	en Dr © Ne ⊙ uninown
	1f no -please give 🔄 unsuccessful attempts 阳 Other please expand
	discil contraindication petent refused
Please give reason	deemed dirically not indicated after enrolment office (please expand)
8	Caste of Lunbar 10 Time of Lunbar 10
	Puncture Pun
Tick Not Done for Opening Pressure	Unitation **
5	White cells <pre>cs P* OR P* (per nm3 or 10^6)()</pre>
	red cels 📰 < 1 🍽 OR 👎 (mn.1)
Enter UNK for white & red blood cells	Untroun
	Neutrophig/Hutymorphi Pte (%)
	Protein * N (gl.)
Enter UNK for Protein	Glucose 👘 (mmol/L)
	Concurrent blood (% (mol)) Date (% Time (% Tim
	glucose (must be within 4
	Gran film result 📰 Not done 🍽
	No Organism Seen Gram Positive Cocci httpp
	Gram Positive cocci httpph Gram Hegative cocci
	Gran Positive Bacili
	Cither (expand)
	ELI urinnen Other please expand
	Hicroscopy for AFBs
	Autonine () Positive (O Nepative
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	Zteh Nelsen () Positive (*
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Select unknown for CSF culture result	CSF culture result 🔄 No growth 🔹 🍽
	Streptococus preumoniae^^ Nesseria meningitida ^
	Listeria monocytogenes* Heenophius influenze*
	Crystosoccus neefinans
If the LP was completed, please enter as	conservous of BPUS Excelential Defending
normal	urizown
normai.	Other please state
	erotypy/bengroup
	Other (please state)
	Return to top Save Exit

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**.

 Outcome. 	(4/4)	Substud(3/2	4) Approval (0)/1) ► S	elect to Jump	•
Title: Substudi	es					
Page:	Sa	ve	Exit			
Substudies 6.9.	3, 6.9.4 and	6.9.5.				
Has the patient co	nsented to h	aving extra sam	ple of blood/CSF ta	aken for research		
C	ionsented? ((Yes * No unknown	(b)			

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.

 Ot 	utcome(0/4)	Substud(0/24)	Approval (0/1)		Select to Jun	np 💌
Title: A	pproval					
Page:	Mark	CRF Complete	Save		Exit	
Electror	ic CRFs should (ONLY be marked co	mplete by member	s of E	Brain Infection	s UK Staff
	This CRF has bee completed b	n (please actest)	* 10			
Return t	o top	ark CRF Complete	Save		Exit	

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.

 [Please give dura 	tion of diarrohe	a in hours]		
History (0/34) Fu	arther(0/16)	Examina(0/8)	Select to Jump -	
itle: History				
age:	Save	Exit 🔡		
Date of onset of symptome	f 27-Mar-2015	- Ha		
Route of admission	A and E GP Other unknown	No Other		99 1
Date of admission to hospita	29-Mar-2015	- <i>h</i> e	Time of admission to 17:00 hospital	* 76 (HH:MM
Fever or history of fever	f Yes ONo Ounknown	Duration (hours)	!	lie (hours)
Headache	 Yes No unknown 	Duration (hours)		🍽 (hours)
Neck stiffness	 Yes No unknown 	Duration (hours)		Pe (hours)
Photophobia	 Yes No unknown 	Duration (hours)		Pe (hours)
Diarrohea	 Yes No unknown 	Duration (hours)	!	Pe (hours)

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.

• [GCS must be bety	veen 3 and 15]		
History (18/34)	Further(0/16)	Examina(0/8)	Select to Jump
tle: Examination			
structions: Please record f	findings of admission	examination (If something is no	t recorded please tick Not Do
ige: S	ave	Exit 🔁	
Ethnicity	White British	• Pa	
Photophobia	 Yes No unknown 		
Neck stiffness	 ○ Yes ♥ No ○ unknown 		
Rash	● Yes * № ◎ No ◎ unknown		
Any focal neurology	© Yes * № No © unknown		
If focal neurology was present please expand			4
What was the patient's GCS on admission? (lowest value recorded in the first 24 hours)	21	- 10	
What was the patient's temperature on admission? (highest value in first 24 hours)	37.6	* 198 (oC)	
de una das dasse		Faure	E-sta

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

Examina(7/8)	Blood R(10/12) Blood	C(0/18) Select to Jump	
Title: Blood Results			
Page: S	ave Exi		
WCC	UNK	+ <i>h</i> e	
Neuts	1.2	= We wcc	
Lymphs	1.1	 No Click to add a discrepancy note 	
Platelets	123	- <i>1</i> 0	
Hb	0.1	* 🏁 (g/dL)	
	☑ CRP < 10mg/L 🏴 □ unknown	OR CRP (mg/L)	
Procalcitonin	6.1	• 🎁 (ng/ml)	
Sodium	45	• 🎋 (mmol/L)	
PT	1.4	🔁 (seconds) OR INR	p
APTT	4.6	• 🏁 (seconds)	
Return to top		Save Exit	6

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



Annotation

> Not Applicable

Submit

Type:*

Set to Status.

•

Responding to Data Queries

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

UKMe	ningitis (UKMeningitis)	Change Study/Site					gr	eggibson (Data Manag	jer) en Log Out
Community Edition	me Subject Matrix	Notes & Discre	pancies	Study Audit Lo	g Tasks 🔻		Report Issue Su	pport Study Subject	D Go
Alerts & Messages 🔻	<u> </u>								
Instructions -	Welcome to I	IKMeningiti	5 🕐	-					
If needed you may change	Notes & Discrepa	ncies Assigned	to Mei 1						
access to a new study with a	9	Subject Enrollment	By Site			Subj	ect Enrollment For Stu	ıdy	
different role.	Site Enrolled E	Expected Enrollmer	ıt	Percentage	Study	Enrolled	Expected Enrollment	Percentage	
Other Info -					UKMeningitis	16	500	₿%	5
Study: UKMeningitis		Study Progres	55			Su	ıbject Status Count		
Start Date: 28-Jan-2015	Event Status	# of Events	Percen	tage	Study Subjec	t Status	# of Study Subjects	Percentage	
End Date: N/A	scheduled	2	7%		available		16	100%	
PI: Dr. Fiona McGill	data entry started	20	71	%	signed		0	0%	
	completed	6	21%		removed		0	0%	
Protocol Verification/IRB Approval Date:	signed	0	0%						
	locked	0	0%						
Icon Key	skipped	0	0%						
1000 MC 7	stopped	0	0%						
Statuses									

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

	KMeningitis (UKMeningitis)	Chang	e Study/S	lite					greggit	oson (Data	Manager) en	Log Out				
Community Edition	Home Subject Matri	x No	tes & Dis	crepancies Study Au	udit Log Ta	isks 🔻				Study S	ubject ID					
Alerts & Messages 🔹																
nstructions -	Notes and Di	screp	pancie	es @									\backslash			
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or a given study/site and by			Query	Failed Validation Chec	k Reason	for Change	Annotation	Total								
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sing the column headers. To	Opdated Resolution Propose	ery Me b														
ew or update the note, ease select the "View" or	Closed	i i												\backslash		
iew within record" action	Not Applicable	Po				-	-							\mathbf{A}		
ther Info -	Total		1					1	1							
tudy: LIKMeningitis																
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tart Date: 28-Jan-2015	Study Subject ID 1	ype R	esolutio	n Status Site ID	Days Open L	ays Since Up	pdated Event	Name	CRF		Entity Name	Entity Value	e Description	Assigned	Usev	Actions
nd Date: N/A														greggibso	on	Coar Filter
1: Dr. Fiona McGill	1234 0	Query	New	UKMeningitis	0 0		CRF		uk_mening	jitis_001	WCC	14.0	Why is WCC	Greg Gib (greggibs	son son)	
Protocol Verification/IRB Approval Date:	Results 1 - 1 of 1.												14.0?			
	Workflow	- 1														
		_														
	Manage Study		otes and	Discrepancies												
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To respo	ond click up	odat	te n	ote 🔨												
					\mathbf{i}		hy is WCC	: 14.0)?			Last Assi	t updated: 30- igned to: Gre	-Mar-2015 eg Gibson (i by gı (grege	reggibson gibson)
						ID: 41			Type: Que	ery	Cu	rrent Status:	New	# of Notes	: 1	
						Why is	WCC 14.0?				Status: Ne	ew	Assigned	30-Mar-2 d to: Greg G	015 by ibson ((greggibson) (greggibson)
									0	Upda	te Note	Propose	e Resolution) [cl	ose N	ote
						Begin N	lew Thread									
						Audit	History									
						A	udit Event		Da	ite/Time	of Server	User	Value	туре	Old	New
						Ite	em data value	updated	30	-Mar - 2015	12:22:00	greggibs	son wcc			14.0
						(Thi	is item was init	ally ent	ered on 26-F	eb-2015.)						

Version 3.1 28/04/2015

	iu Discrepancies		
"wcc" Properties:			You can answer the query here
Subject: 1234 Event Date: 26-Fo Current Value: 14.0	Event: CRF eb-2015 CRF: uk_menir More: Data Diction Audit Histor	igitis_001 ναγγ γ	
Note Details			
Use Why is WCC	14.0?	Last updated: 30-Mar-2015 Assigned to: Greg Gibson (g	y greggibson reggibson)
ID: 41	Type: Query	Current Status: New # of Notes:	1
Why is WCC 14.0?	lladate	Status: New 30-Mar-20 Assigned to: Greg Gib	15 by greggitson son (c eggibson)
Respond below to Upd	ate/Resolve/Close this Discrepa	incy Note:	Set status as updated
Description:*	See below		
Detailed Note:	This is my answer		Assign the note to the person who raised the query
Detailed Note: Set to Status:*	This is my answer	.::	Assign the note to the person who raised the query
Detailed Note: Set to Status:* Assign to User:	This is my answer	.::	Assign the note to the person who raised the query Submit & Exit when done.
Detailed Note: Set to Status:* Assign to User: Email Assigned User:	This is my answer	.::	Assign the note to the person who raised the query Submit & Exit when done.



For clinical queries: Fiona McGill <u>fmcgill@liv.ac.uk</u> 0151 795 9606 For OpenClinica[™] queries: Greg Gibson <u>greg1@liv.ac.uk</u> 0151 795 9670