

LOGS TO UPDATE

The logs listed below must be kept up to date in the electronic Investigator Site File (eISF) at all times. This is a legal requirement as they will be required for monitoring.

To avoid the use of paper, where possible, **all logs should be completed electronically using the trial tablet provided**. Please review the training material 'How to access and maintain the eISF' for guidance on how to edit, upload, sign and save documents to the eISF.

TRIAL TEAM MEMBERS LOG

The Principal Investigator should list the names and contact details of all staff members who have trial related responsibilities. A blank log can be found in eISF 1, section 7 'Blank Forms and Logs', subsection 7vi 'Training team members Log'. The completed log should be filed in the eISF 2, section 11 'Site Information, responsibilities & training', subsection 11vii 'Completed Trial Team Members Logs'.

Remember to add new team members throughout the course of the trial.



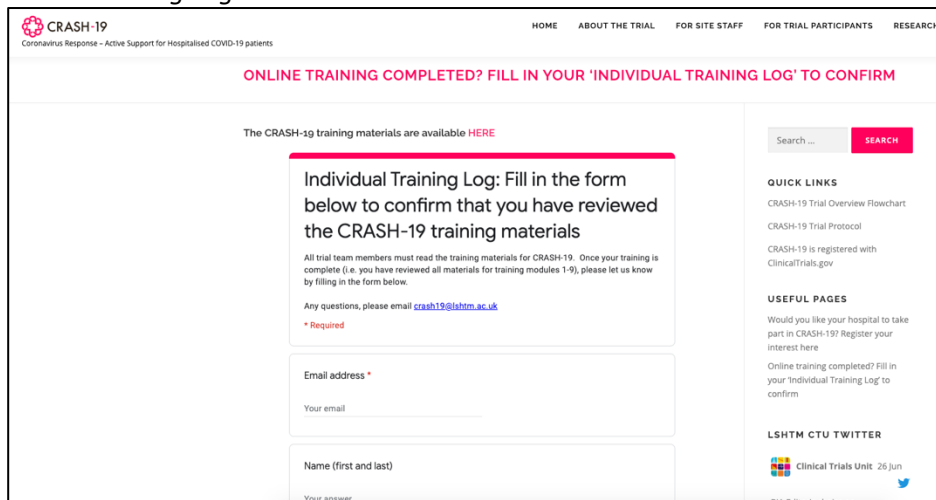
TRIAL TEAM MEMBERS LOG

HOSPITAL ID NUMBER	001	HOSPITAL NAME	Crash 19 Hospital
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NAME	JOB TITLE	EMAIL ADDRESS	PHONE NUMBER
PROF FIONA FERGUSSON	CONSULTANT	FIONAFERGUSSON@EMAIL.COM	0123 234 1234
DR KEVIN AL AKASH	REGISTRAR	DR.KEVINALAKASH@HSM.NET	0123 567 6789
ANTHONY MCKULCKIN	RESEARCH NURSE	AMCKULCKIN@YOOHA.CO.UK	0123 789 7890 / 0456 123 4321
ANDRES SIMPACO	RESEARCH NURSE	DRES.SIMPA@GEMAIL.CA	0789 234 3456
LINDA LU	PHARMACIST	LINDA.LU@MAILHOT.COM	0765 345 4567/ EXT 123


INDIVIDUAL TRAINING LOG

Appropriate training must be completed before staff can undertake trial related responsibilities. Once training has been completed, each trial team member must complete the online 'Individual Training Log' which is available on the trial [website](#). The LSHTM-CTU will save a copy of your completed log to eISF 2, section 11vi 'Completed individual Training Logs'.



The screenshot shows the 'Individual Training Log' form on the CRASH-19 website. The form is titled 'Individual Training Log: Fill in the form below to confirm that you have reviewed the CRASH-19 training materials'. It includes a search bar, a 'QUICK LINKS' section with links to the trial overview flowchart, protocol, and registration, and a 'USEFUL PAGES' section with links to the trial website and the LSHTM CTU Twitter account. The form also has a section for 'Email address' and 'Name (first and last)' with input fields and a 'Required' label.

If you are not able to complete the training log online, a blank form of the same document is available in the eISF 1, section 7 'Blank Forms and Logs', subsection 7iv 'Individual Training Log'. The completed log should be filed in eISF 2, section 11 'Site Information, responsibilities & training', subsection 11vi 'Completed individual Training Logs.'

 **CRASH-19**

INDIVIDUAL TRAINING LOG (Each person on the team must complete and maintain their own log)

All trial team members must complete the training modules relevant to their role(s) in the trial. Training materials are available in your eISF 1, folder number 6 and on the [trial website](#).

Where possible, please complete the online training confirmation log via the [CRASH-19 Training Google Form](#).

Alternatively, each team member should **make a copy** of this document and complete the form below. Please ensure that all individual training logs are saved in eISF 2, folder number 10vi. Any questions, please email crash19@lshtm.ac.uk.


Name	John Smith	Email	john.smith@internetprovider.com	
Hospital name	Crash 19 Hospital	Country	UK	

TYPE OF TRAINING RECEIVED / COMPLETED ONLINE	DATE OF TRAINING	SIGNATURE
TRIAL OVERVIEW PRESENTATION (REQUIRED FOR ALL TRIAL STAFF)	19/AUG/2020	Jamith
SITE SET-UP PRESENTATION (REQUIRED FOR ALL TRIAL STAFF)	19/AUG/2020	Jamith
MINIMISING INFECTION RISK FROM THE TRIAL MATERIALS (REQUIRED FOR ALL TRIAL STAFF)	21/AUG/2020	Jamith
HOW TO ASSESS ELIGIBILITY *	21/AUG/2020	Jamith
HOW TO OBTAIN CONSENT *	22/AUG/2020	Jamith
HOW TO RECORD CONSENT AND COLLECT DATA USING THE ONLINE ELECTRONIC SYSTEM *	24/AUG/2020	Jamith
HOW TO COLLECT BASELINE DATA AND RANDOMISE PATIENTS *	24/AUG/2020	Jamith
HOW TO COMPLETE THE OUTCOME FORM *	24/AUG/2020	Jamith
ADVERSE EVENT AND SAFETY REPORTING (REQUIRED FOR ALL TRIAL STAFF)	25/AUG/2020	Jamith
GCP TRAINING (OPTIONAL)	25/AUG/2020	Jamith

*Please complete this training if you will be responsible for this trial procedure
CRASH 19 Individual Training log

GROUP TRAINING LOG

If a group training session has been carried out, a Group Training Log should be completed and signed by all attendees. A blank form can be found in the eISF 1, folder 7 'Blank Forms and Logs', subsection 7v 'Group Training Log'. Completed Group Training logs should be filed in the eISF 2, section 11 'Site Information, responsibilities & training', subsection 11v 'Completed Group Training Logs'.

 **CRASH-19**

GROUP TRAINING LOG

Hospital ID: 001 Hospital name: CRASH 19 Hospital

- PLEASE DOCUMENT ALL TRIAL RELATED TRAINING INCLUDING TEAM MEETINGS
- USE ONE FORM PER SESSION

TYPE OF TRAINING e.g. consent procedure; trial procedures; implementation of protocol amendment; etc.	Trial Procedures
DETAILS OF TRAINING (what was covered)	uploading documents with the trail tablet
NAME OF PERSON GIVING THE TRAINING	R. Rudolph
DATE OF TRAINING SESSION	30/06/2020
CURRENT PROTOCOL VERSION	V1.0


Name of attendee	Job Title	Role in the trial	Signature of attendee
Sara Jane Smith	Dr	Research Fellow	SJS
Tom Jones	Dr	Research Fellow	TJ
Rudolph Claus	Prof	PI	RC

SITE PHARMACY DISPENSING LOG

With each batch of trial drugs sent to site, printed copies of *Site Pharmacy Dispensing Logs* will be sent for each of the trial drugs (aspirin, losartan, simvastatin). Each time drugs are dispensed for the trial, and when unused trial drugs are destroyed, the corresponding dispensing log should be updated.

To enable monitoring of drug stock at site, pictures of the logs should be sent to the NCC and LSHTM-CTU **weekly** via WhatsApp or email. The NCC will save these in your site eISF 2, folder 12 'Trial Drug Information'.

SITE PHARMACY DISPENSING LOG: ASPIRIN



The dispensing log must be updated each time ASPIRIN is dispensed for the trial.

If a patient is discharged or dies before all the dispensed trial treatment has been used; the unused drugs should be returned to the pharmacy, should be destroyed (as per local hospital policy for drug destruction) and recorded in the dispensing log.

PARTICIPANT RANDOMISATION NUMBER	DISPENSING DETAILS							UNUSED TRIAL TREATMENT		
	DISPENSE DATE	DRUG NAME	BATCH NUMBER	EXPIRY DATE	DAILY DOSE	QUANTITY DISPENSED (number of days)	DISPENSED BY SIGNATURE	QUANTITY UNUSED	DATE UNUSED DRUG(S) DESTROYED	DESTROYED BY SIGNATURE
1234	16/06/2020	Aspirin	1001	16/06/2021	150 mg	7 days	CF	3 days	27/06/2020	CF
		Aspirin			150 mg					
		Aspirin			150 mg					
		Aspirin			150 mg					
		Aspirin			150 mg					
		Aspirin			150 mg					
		Aspirin			150 mg					

RANDOMISATION LOG

The randomisation log will be automatically generated by the trial database and should be downloaded periodically and saved in eISF 2, section 10 'Completed Forms and Logs', subsection 10v 'Randomisation Log'. For guidance on how to download the randomisation log, see the 'Data and Data Collection' training materials



Logged in as charlotte.fleming@lshtm.ac.uk
Log out

REDCap Messenger

Project Home and Design

Project Home

Project status: Development

Data Collection

Record Status Dashboard
View data collection status of all records

Add / Edit Records
Create new records or edit/view existing ones

Show data collection instruments

Applications

Data Exports, Reports, and Stats

Field Comment Log

REDCap Mobile App

Reports

Site reports


1) Randomisation log



2) Queries

External Modules

Custom Report Builder

Help & Information



CRASH-19 Development Mode

Coronavirus Response - Active Support for Hospitalised COVID-19 patients.

Data Exports, Reports, and Stats

VIDEO: How to use Data Exports, Reports, and Stats

My Reports & Exports Other Export Options View Report: Randomisation log

Number of results returned: 2
Total number of records queried: 30

Export Data Print Page


Randomisation log

1. Country country	2. Hospital name	3. Patient randomisation number patient	4. Name of participant patientname_rand	5. Date of randomisation randdate	6. Time of randomisation(24-hour clock) randtime	7. Name of person randomising (Full name) personrandomising
Nigeria (2)	Hospital 1	27-25		24-06-2020	15:10	Me
Nigeria (2)	Hospital 1	27-26		01-07-2020	12:48	CF

Where patients provide paper consent, the randomisation log on the trial database will not show the name of the participant. In this case, sites should either:

- i) Print the randomisation log from the trial database, manually write the patients name in the blank field, take a picture of the log and upload it to eISF 2, section 10 'Completed Forms and Logs', subsection 10v 'Randomisation Log'; OR
- ii) A blank copy of the log has been provided eISF1, section 7 *Blank Forms and Logs*, subsection 7iii *Randomisation Log*; add the participant's details to this log and save in eISF 2, section 10 'Completed Forms and Logs', subsection 10v 'Randomisation Log'.

RANDOMISATION LOG


CRASH-19

Hospital ID

Hospital name

Country


PLEASE RECORD DETAILS OF ALL PATIENTS RANDOMISED TO THE CRASH 19 TRIAL

FULL NAME OF THE PARTICIPANT	RANDOMISATION NUMBER	DATE OF RANDOMISATION	TIME OF RANDOMISATION (24-HOUR CLOCK)	NAME OF PERSON RANDOMISING (FULL NAME)
John Smith	12345	23/Aug/2020	19:35	Dr A Phillips
Anthony Potterton	12346	24/Aug/2020	07:40	Louise Stevenson
Maria Anderson	12347	24/Aug/2020	13:30	Dr P Lee

SITE VISIT LOG

The Site Visit Log should be completed each time there is a trial related visit at your site. A blank form can be found in eISF 1, section 7 '*Blank Forms and Logs*', subsection 7vii '*Site visit Log*'. The completed log should be filed in the eISF 2, section 10 '*Site Information, responsibilities & training*', subsection 10viii '*Completed Site Visit Log(s)*'.

SITE VISIT LOG


CRASH-19

To be completed by all personnel conducting site visits (including, but not limited to, National Coordinators, National Coordinating Centre Staff, Monitors and CTU staff)

DATE	VISIT DONE BY (Name and affiliation)	REASON FOR VISIT
26/SEPT/2020	PROF SMITH (CHIEF INVESTIGATOR-LSHTM) ROSE OLABIDE (TRAIL MANAGER- LSHTM)	SITE INITIATION TRAINING