




CRASH-19

Aspirin, losartan & simvastatin in hospitalised COVID-19 patients: a multinational randomised open-label factorial trial

How to use the trial database:

reporting serious adverse reactions, queries and database reports

Reporting a Serious Adverse Reaction








CRASH-19 Development Mode

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

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Data Collection Instrument	Form Status. Click on the radio buttons below to view/ add a form
Consent Complete this form first -->	<input checked="" type="radio"/> + 
Entry	<input checked="" type="radio"/> 
Randomisation	<input checked="" type="radio"/> 
Outcome	<input type="radio"/> 
Serious Adverse Reaction	<input type="radio"/> 
Query	<input type="radio"/>


If you need to report a SAR, click on a patient's randomisation number to navigate to the patient's record home page,

Then click on the radio button next to 'Serious Adverse Reaction'

Reporting a Serious Adverse Reaction

You must only report Serious Adverse Reactions for CRASH-19.

If you enter any data that indicates that the event being reported is **NOT** a Serious Adverse Reaction, an alert will appear and you must leave the form without saving.

Serious Adverse Reaction form  **CRASH-19**

Use this form to reports any SARs. If you do not have any SARs to report, leave this form without saving.

Please ensure the event you are about to report is:
SERIOUS, and
SUSPECTED TO BE RELATED TO THE TRIAL TREATMENT

If the event is not serious or not suspected to be related to the trial treatment, **DO NOT** report.

Hospital Name _____
Country Pakistan
Patient randomisation number 53

Report type Initial Follow up reset

1. Age 0 characters remaining
* must provide value
years

2. Serious adverse reaction in Medical Terms
(diagnosis needed - avoid signs and symptoms if possible)
* must provide value

3. Is the event due to progression of underlying illness? Yes No reset
* must provide value

4. Onset of first signs/symptoms of SAR
* must provide value

5. Seriousness criteria
(tick all appropriate to the event)
* must provide value

- None of the following
- Patient died
- Involved or prolonged in patient hospitalisation
- Results in persistent or significant disability
- Life threatening
- Other medically important

IF NONE, this is NOT a Serious Adverse Reaction. Please exit this form without saving.

Reporting a Serious Adverse Reaction

Serious Adverse Reaction form



Use this form to reports any SARs. If you do not have any SARs to report, leave this form without saving.

Please ensure the event you are about to report is:

SERIOUS, and

SUSPECTED TO BE RELATED TO THE TRIAL TREATMENT

If the event is not serious or not suspected to be related to the trial treatment, DO NOT report.

Hospital Name

Country

Patient randomisation number

Report type
* must provide value

1. Age

2. Serious adverse reaction in Medical Terms
(diagnosis needed - avoid signs and symptoms if possible)
* must provide value

3. Is the event due to progression of underlying illness?

16. Concomitant treatment
Was the patient taking/receiving any concomitant medications and/or therapies at the time of the Serious Adverse Reaction? Yes No reset

17. Comments

Details of person reporting the SAR

18a. Name of person reporting
* must provide value





18b. Telephone number

19. Date reported
* must provide value

Form Status

Complete all fields on the Serious Adverse reaction form and 'Save & Exit'

Reporting multiple Serious Adverse Reaction

Data Collection Instrument	Form Status. Click on the radio buttons below to view/ add a form
Consent Complete this form first -->	<input checked="" type="radio"/> + 
Entry	<input checked="" type="radio"/> 
Randomisation	<input checked="" type="radio"/> 
Outcome	<input type="radio"/>
Serious Adverse Reaction	<input checked="" type="radio"/> + 
Query	<input type="radio"/>

If you need to report multiple Serious Adverse Reactions per patient, click the '+' button next to the coloured radio button

After data entry

Once data has been saved:

- The CTU will review and acknowledge by email all data forms entered
- You can view Entry, Randomisation, Outcome and Serious Adverse Reaction data can be viewed once submitted, but cannot be edited
- If a data amendment is required to an Entry or Outcome Form, a written request must be sent to the CTU data team

Data queries

CTU staff may raise **data queries** to resolve any questions about the data entered in the trial database. If a query is raised, all users at site with database access will receive an email notification of this.

CRASH-19 Trial - Query 'Date of admission?' has been created for Patient '33-9' - Brentwood Hospital, Pakistan Inbox x

crash19@lshtm.ac.uk 8:21 AM (0 minutes ago)
to Madeleine.Cargill, me ▾

A new query 'Date of admission?' (Query ID 33-9-1) has just been created by Madeleine Cargill

The query message is:
Please could you confirm the date of admission? Many thanks.

To view the query follow the link below, and check the box '**Add query**' to respond to the query:
[View query here](#)

Thank you

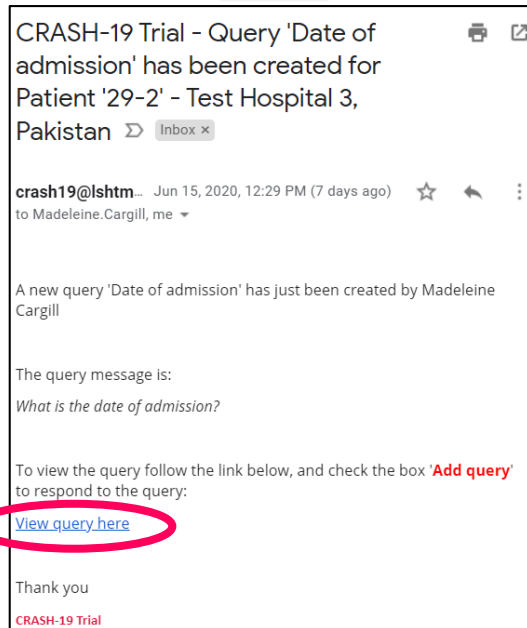
CRASH-19 Trial
Clinical Trials Unit, LSHTM | Keppel Street, London WC1E 7HT
Tel +44(0)20 7299 4684 | Fax +44(0)20 7299 4663
CRASH19@LSHTM.ac.uk

Please respond to all queries
as soon as possible

Responding to data queries

1. Notification of a new query received by email

2. Click the link in the email



3. Prompted to log in to database

4. Automatically direct you to the query to view

Hospital Name: Test Hospital 3
Country: Pakistan
Patient randomisation number: 29-4

Query details

Related CRF: Entry

Query title: Date of admission

Query ID 29-4-1

Query message: Please confirm the date of admission. Many thanks.

Add message

5. Check the box above 'Add message.'

6. Add ONE response and click 'Save & Exit form'

Add message

Query message

The date of admission is 22/06/2020.

Add message

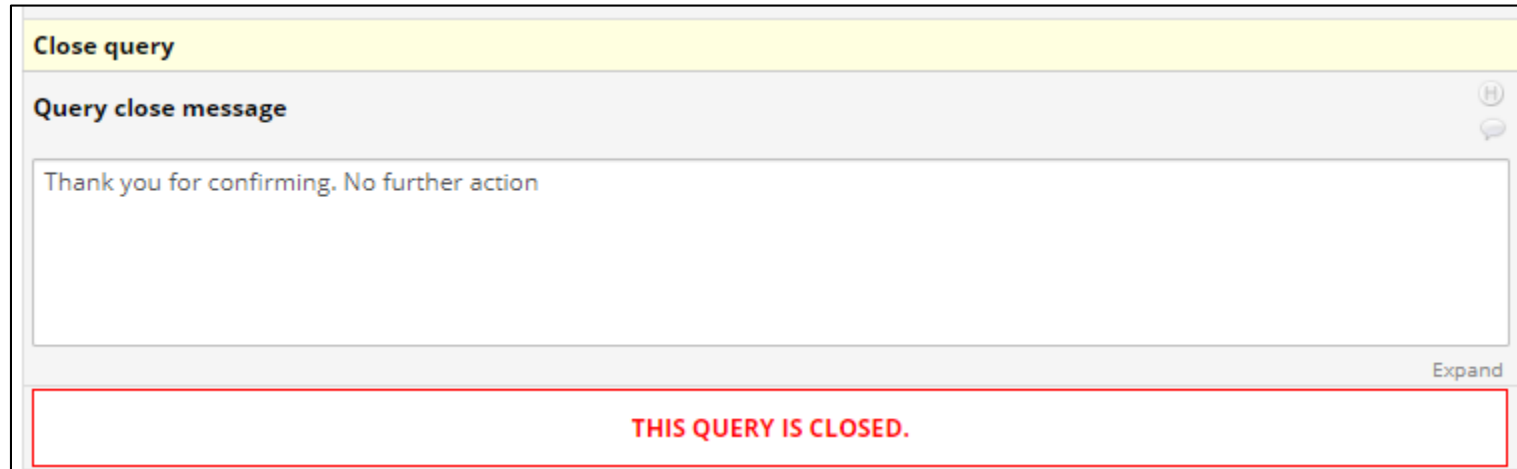
Form Status

Save & Exit Form Save & Stay

-- Cancel --

Management of data queries

- CTU staff will review responses. Further clarification may be required and more query messages may be sent.
- CTU will close the query once resolved.
- Once closed, you cannot add another query message.



The screenshot shows a dialog box titled "Close query" with a yellow header. Below the header is a section labeled "Query close message" containing a text input field with the placeholder text "Thank you for confirming. No further action". To the right of the input field are two small circular icons. At the bottom right of the dialog box is an "Expand" button. A red-bordered box at the bottom of the dialog contains the text "THIS QUERY IS CLOSED." in red capital letters.

To ensure there is an audit trail of all queries and corrections made on the database, all email correspondence or query chains must be saved in the electronic Investigator Site File.

Additional features: Reports

- The Randomisation log and a report of all queries can also be downloaded

REDCap®

Logged in as **madeleine.cargill92@gmail.com**
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

Field Comment Log
REDCap Mobile App

Reports

Site reports
1) Randomisation log
2) Queries

Help & Information

Contact REDCap administrator

CRASH-19 CLINICAL TRIALS UNIT LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

CRASH-19 Development Mode

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

Data Exports, Reports, and Stats [VIDEO: How to use Data Exports, R](#)

[My Reports & Exports](#) [Other Export Options](#) [View Report: Randomisation log](#)

Number of results returned: 15
Total number of records queried: 150

[Export Data](#) [Print Page](#)

Randomisation log

1. Country	2. Hospital name	Randomisation number	Repeat Instrument	Repeat Instance	Full name of participant	33. Date of randomisation	34. Time of randomisation(24-hour clock)	35. Name of per randomising (Fu
country	site	randomisation_id	redcap_repeat_instrument	redcap_repeat_instance	Sha'awar Shiga Bincike	randdate	randtime	personrandomisin
Pakistan (1)	Test Hospital 3	29-1			Orúko olùkopa Suna Mai شريك ما نام	12-06-2020	12:25	maddy

This will open an online view of the report.

To download the report, click the 'Export Data' button.

On the navigation panel, click the report you wish to download

Additional features: Reports

Exporting "Randomisation log"

Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and if you want to export the data to a specific statistical analysis package.

Choose export format

- CSV / Microsoft Excel (raw data)
- CSV / Microsoft Excel (labels)**
- SPSS Statistical Software
- SAS Statistical Software
- R Statistical Software
- Stata Statistical Software
- CDISC ODM (XML)

De-identification options (optional)

The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check a box to apply.

Known Identifiers:

- Remove all tagged Identifier fields (tagged in Data Dictionary)
- Hash the Record ID field (converts record name to an unrecognizable value)

Force all numbers

You may choose to force all numbers to have a specified decimal format. This will be applied to all calculations and number-validated text values in the export file.

Use fields' native decimal format (default)

NOTE: Your data formatting selections above will be remembered in the future and will be pre-selected upon your next export.

Free form text:

- Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)
- Remove Notes/Essay box fields

Date and datetime fields:

- Remove all date and datetime fields — OR —
- Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) [What is date shifting?](#)
- Also shift all survey completion timestamps by value between 0 and 364 days (shifted amount determined by algorithm for each record)

[Deselect all options](#)

Export Data Cancel

Another pop-up will appear. Click the Excel icon to download the file. Close the pop-up once the download is complete

✓ **Data export was successful!**

The data export was successful, and your data is now ready to be downloaded. Click the download icon(s) below on the right to download your data file. If exporting to a specific statistical analysis package, you will additionally need to download the syntax file that is provided for that stats package. For more details, follow the instructions in the box below.

Citation Notice

Please **cite the REDCap project when publishing manuscripts** (citation information and template methods language are [available here](#)).

CSV / Microsoft Excel (labels)

You may download the survey results in CSV (comma-separated) format, which can be opened in Excel. You have the choice of downloading the data either with the full headers and answer labels or just with the answer codes (i.e. raw data).

NOTE: If you are using a version of Microsoft Excel prior to Excel 2007, due to limitations the data will only be read to 255 columns when opened.

Click icon(s) to download:

EXCEL CSV Labels

[Send file?](#)

Close

The logo for CRASH-19 is a stylized pink flower-like shape composed of interlocking loops, resembling a cross with rounded ends.

CRASH-19

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