



University of
Nottingham

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DATA CORRECTION GUIDANCE

Stroke Trials Unit, Nottingham

Final v1.0 07.03.2023



Data corrections

The coordinating centre may raise data queries if there is missing data or if something is not quite right. Please log into the respective trial website

- TICH-3: <http://tich-3.ac.uk/live/>
- RECAST-3: <http://recast-3.ac.uk/live/>
- ENOS-2: <https://stroke.nottingham.ac.uk/enos-2/live/>

You will see an alert for any outstanding data queries when you click on participant list, click on this and it will show open queries for actioning.

[There is one active data query](#)

Please click on the CRF where the data query is located i.e. in this example Day 7. You can also they can also click on the issue ID (glint+seesaw) to go directly to the specific query/questions

Open queries for C001 NOTTINGHAM, Nottingham DEMO Hospital, UK

Participant ID	CRF	Question IDs/query details	Date/time/ data query ID	Assigned to
C001-0002-0NK	Day 7	<input type="checkbox"/> A2c 'Test' isn't a valid reason.	6 Oct 2022 12:50 glint+seesaw	Haywood, Lee centre 1

Found one matching data query



Data corrections

The data query will show above the question where the data is to entered/amended. Please click on the link for 'data correction request'

A2b	Date/time of first dose <i>(dd-mmm-yyyy hh:mm 24hr)</i>	<i>(No data) (No data)</i>	Not known ▼
Query raised on 6 Oct 2022 Data query ID: glint+seesaw		See A2c 'Test' isn't a valid reason. Assigned to: Haywood, Lee centre 1 (ljhaywood_c1) <ul style="list-style-type: none">Please submit a data correction request (see the button at the top of this page)You may need to update the CRF comments, or contact us about this data query	
A2c	Explanation if treatment not received or data missing	Test	

You will then complete a participant identity check.

Data correction request – participant identity check

It is essential that the data collected are entered against the correct trial participant.

Please complete the following identity questions to continue to the data correction request CRF.

Trial number 2

Initials

Sex Male Female

Date of birth - Day - ▼ - Month - ▼ - Year - ▼



The data correction request form **does not** support draft records. The form **must** be submitted completely, otherwise the data will be lost.



Data corrections

A5: Question ID and label is the number and title of question and the data originally entered

A6: Enter question ID of where the new data is to be entered, and the values that should appear once the CRF record has been amended

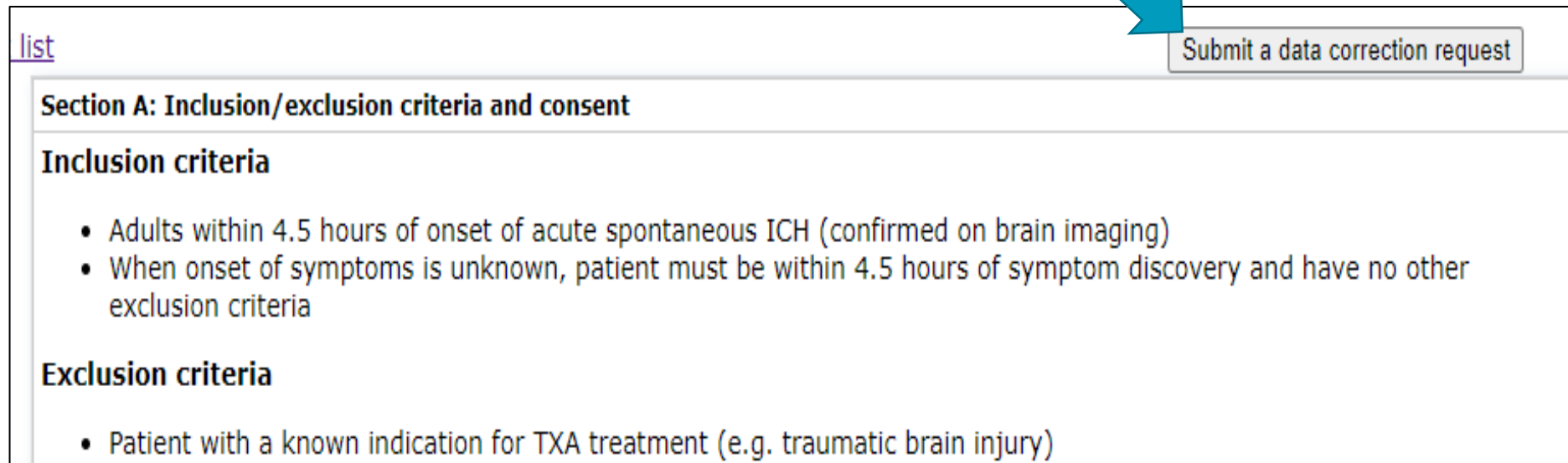
A7: Please enter the reason for the change

A5	Existing data Please list each: <i>Question ID</i> <i>Question label</i> <i>Data shown on report</i>	A2c: Explanation if treatment not received or data missing - "Test". Explanation for missing data: "Transferred before day 7".
A6	New data Please list each: <i>Question ID</i> <i>New value(s)</i>	A2c: "Participant transferred for surgery before full dose given." Explanation for missing data: "Transferred on first day for surgery".
A7	Reason for change	Required full explanation had not been given.



Data corrections

You can submit a data correction request without a data query being raised by the coordinating centre e.g. if you put a comment that the EQ-5D-5L was not done at the time and would update the data later. When the data is available click on the 'submit a data correction request' button at the top of the eCRF.



The screenshot shows a web interface for an eCRF. At the top right, there is a button labeled "Submit a data correction request" with a blue arrow pointing to it from the text above. Below the button, the form content is visible, starting with a "list" link on the left. The main section is titled "Section A: Inclusion/exclusion criteria and consent". Underneath, there are two sub-sections: "Inclusion criteria" and "Exclusion criteria".

[list](#)

Section A: Inclusion/exclusion criteria and consent

Inclusion criteria

- Adults within 4.5 hours of onset of acute spontaneous ICH (confirmed on brain imaging)
- When onset of symptoms is unknown, patient must be within 4.5 hours of symptom discovery and have no other exclusion criteria

Exclusion criteria

- Patient with a known indication for TXA treatment (e.g. traumatic brain injury)

As before, you will need to complete the participant identity check to access the data correction request form. If applicable, please also give existing/new text for the full explanation for missing data (state 'n/a' for 'New data' if text to be removed).



Common issues

- Update data for all affected questions in a single request, when possible - especially related questions
- Use one line per question
- Make sure that existing data are always given, stating "Not done" and "Not known" where previously missing
- Do not list questions whose values have not changed