



# **Sugar or Salt (SOS) Trial: Hyperosmolar therapy in traumatic brain injury**

## **Data Collection Guide V5.0 15 January 2025**



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# SOS Online Database

## Logging in

The link to the database is: <https://ctu.warwick.ac.uk/SOS/>

If laptop computers are to be used to log in to the trial database it is important to note that, as a security measure, the device will either need to be physically plugged into the network, or connected via VPN. Normal Wi-Fi connection is not sufficient, and you will not be able to again access.

The trial software is tested on Edge and Chrome but currently not Safari. If using a Mac, Chrome will need to be installed.

Enter your username and password (please email [SOStrial@warwick.ac.uk](mailto:SOStrial@warwick.ac.uk) with your name and public IP address to request a login. We require your public IP address as the WCTU database access is IP restricted for security reasons. To find out your public IP address, type “what’s my IP” into google from a computer in the hospital and your IP address will appear at the top).

You will only be able to log in to the database from a computer in the hospital (that is linked to your sites IP address).

Log in details will be provided following training on the SOS online database to allow trial data to be entered. On first log in, you will be required to change your password. Please do not share your password with anyone else and ensure you log out of the database when leaving the PC.

Please also note that this login page contains the SOS EudraCT number and details of the Chief Investigator and relevant contact details. As this is on the login page this information can be accessed by hospital staff without database access.

# SOS

Delivered by the WCTU Programming Team. Use our [online Help Desk](#) to ask a question or track your requests.

EudraCT Number: 2019-001688-66	Chief Investigator: Mr Angelos Kolias
Tel: 02476 151 738	Email: <a href="mailto:SOStrial@warwick.ac.uk">SOStrial@warwick.ac.uk</a>
Warwick Clinical Trials Unit, University of Warwick, Gibbet Hill Campus, Coventry CV4 7AL	

## Sign In

If you are a Warwick University staff member you can sign in using your University account.

Non Warwick University users must use the credentials assigned to them by the SOS Warwick CTU Trial Team.

Your account must be activated before you can sign in. Requests to activate an account can only be made by the System Owner.

User name:

Password:

Sign In

[Forgotten Password](#)

## SOS data collection – paper CRFs and online forms

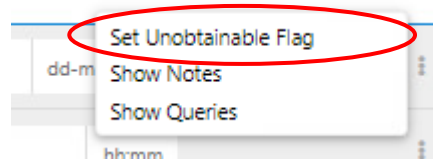
The table below lists trial forms required to be completed on the SOS online database.

Screening and Eligibility Form and End of Trial Form also need to be completed on paper forms and forwarded to the trial office for review of signatures. SAE forms are to be completed on paper forms and sent to the QA team.

Paper CRF number	Paper CRF name	Event type	Sub category	Database form name
CRF01	Screening and Eligibility Form	Scheduled	Pre Randomisation	Screening and Eligibility Form
CRF02	Participant Form	Scheduled	Randomisation	Informed Consent
CRF03	Randomisation Form	Scheduled	Randomisation	Randomisation Form
CRF04 (UK only)	Patient and Legal Representative Identifiers	Scheduled	Hospital stay	Patient and Legal Representative Identifiers
CRF05	Baseline	Scheduled	Hospital stay	Baseline Form
CRF06	Study Drug Administration	Scheduled	Hospital stay	Study Drug Administration
CRF07	ICP Monitoring	Scheduled	Hospital stay	ICP Monitoring
CRF08	Daily Data	Unscheduled	Daily Data	<a href="#">+ New Form</a>
CRF09	Concomitant Treatments	Scheduled	Hospital stay	Concomitant Treatments
CRF10	Critical Care Discharge Form	Scheduled	Hospital stay	Critical Care Discharge Form
CRF11	Hospital Discharge Form	Scheduled	Hospital stay	Hospital Discharge Form
CRF12	Follow up 3 months – 12 months	Scheduled	3 months	3 Month Follow-up form
CRF12	Follow up 3 months – 12 months	Scheduled	6 months	6 Month Follow-up form
CRF12	Follow up 3 months – 12 months	Scheduled	12 months	12 Month Follow-up form
CRF13	Protocol Non-compliances	Unscheduled	Protocol Non-compliance form	<a href="#">+ New Form</a>
CRF14	Withdrawal Form	Unscheduled	Withdrawal form	<a href="#">+ New Form</a>
CRF15	Death Notification Form	Unscheduled	Death Notification form	<a href="#">+ New Form</a>
CRF16	End of Trial Form	Scheduled	End of trial	End of Trial Form

## Tips for completing forms

- ✓ Always remember to click 'save' when entering a new form or making any changes to the online forms.
- ✓ Date format should be 01-JAN-1980
- ✓ Time should be recorded in 24 hour clock
- ✓ Except for those forms which are required on paper (Screening and Eligibility, End of Trial, SAE forms and where a non-compliance does not relate to a specific participant), all data should be entered directly into the online database. Paper forms can be used as a back-up if there is a problem with accessing the database, and the data should then be entered into the database as soon as possible. Please retain all paper copies of forms if used.
- ✓ Source data (the first place data is recorded) should be retained in order to conduct source data verification (checking data in the database against the source e.g. medical records).
- ✓ When completing paper CRFs, if any mistakes are made they should be crossed out with a single line, and the correction added close to the original data. The correction should be initialled and dated by the person making the correction. This is a GCP requirement to ensure the integrity of data.
- ✓ If the data on the online database is amended, please ensure any paper CRFs are also updated. There should be a clear audit trail so trial data could be re-created from source data.
- ✓ If any data is unobtainable (or in some cases not applicable) you can mark it as such in the database by clicking on the three dots to the right of the field/form, then 'set unobtainable flag'.



## CRF COMPLETION NOTES

### CRF01 - Screening and Eligibility Form

Screening data will be reviewed throughout the trial. This will be vital information for the assessment of whether there are barriers to recruitment that could be addressed by amendments to the protocol.

You will need to keep track internally of patients who have been screened using the Screening and Enrolment Log. This log should **NOT** be sent to WCTU as it will contain personal identifiable data (PID) for non-consented patients which Warwick CTU do not have permission to hold. **Receipt of this PID is a breach of GDPR and will be a protocol non-compliance.** Screening data should be added to the SOS database using the Screening/Randomisation wizard.

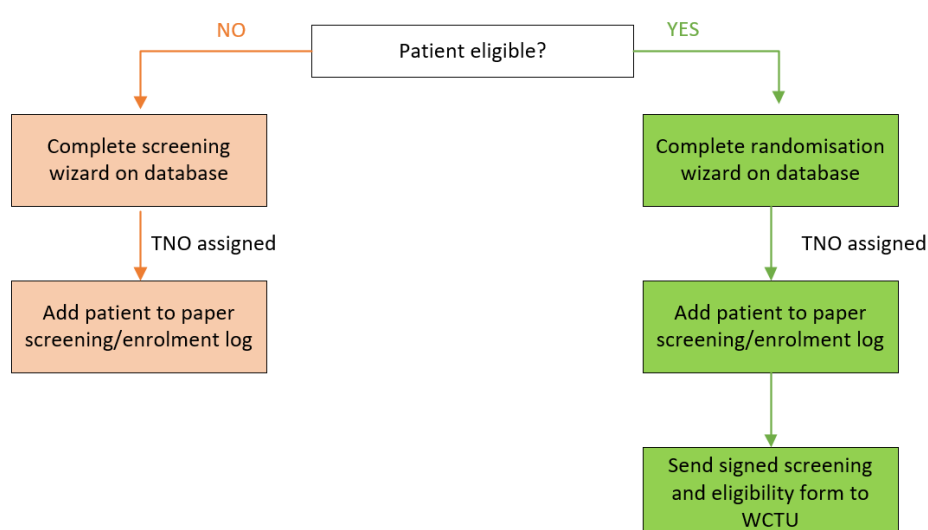
**All patients** admitted to ICU with severe TBI should be screened as soon as possible following admission.

Of the screened patients, only patients with an ICP bolt can be confirmed as being eligible for SOS, therefore we **only require screening data for patients who have had their ICP monitored with a bolt within the 10-day eligibility window.**

If a patient with a bolt is not eligible, with no chance of becoming eligible, for the trial this information can be entered into the Screening/randomisation wizard on the SOS database at this point. Screening data should only be entered onto the database once for each patient.

Screening should be a continuous process and, in some situations, patients who are not initially eligible may become eligible at a later date if their ICP rises. Once a patient is deemed eligible, please complete the online Screening/Randomisation wizard at the time they become eligible and ensure the paper Screening and Eligibility form is completed and signed by the doctor who assessed eligibility as soon as practicably possible. For UK recruits, this is to be emailed to [SOSTrial@warwick.ac.uk](mailto:SOSTrial@warwick.ac.uk) within 3 days of the randomisation.

If you are monitoring a patient's ICP over the course of the 10-day eligibility period but it does not rise enough for them to become eligible, please complete the screening/randomisation wizard on the database at the end of the 9 days from TBI when they can no longer be enrolled in the study.



Eligibility must be assessed and confirmed by a medically qualified doctor or an Advanced Clinical Practitioner (ACCP) only, prior to the patient being enrolled. The paper Screening and Eligibility form (CRF01) should be signed by the doctor or advanced clinical practitioner who confirmed eligibility.

The justification for the patient meeting all of the eligibility criteria must be clearly documented in the patient's medical notes for monitoring purposes. This must include recording the patients ICP and serum sodium readings at the point of confirming eligibility.

### Completing the paper Screening and Eligibility form (CRF01)

This form should be completed at the time eligibility is confirmed or as soon as is practically possible after the patient has been randomised and the initial emergency has passed.

This form only needs to be completed for patients that are eligible to be enrolled in the SOS trial. You do not need to complete this form for patients who are not going to be randomised.

The doctor or advanced clinical practitioner confirming eligibility must sign the form and record the date and time that eligibility was confirmed. This should match the time and date that is entered in the randomisation wizard in the database.


If an advanced clinical practitioner confirms eligibility, make sure a TBI diagnosis is documented in the patient's medical notes/CT scan report and the relevant field ticked Yes on the screening and eligibility form.

Once you have randomised the patient on the online database or using the IVR phone line, the patient will be assigned a TNO. Please use this TNO on the paper CRF.

If the IVR phone line is used to randomise the patient, please ensure the name of the person who completed the randomisation is recorded on the paper CRF. This should also be documented in the medical notes.

Please email a signed copy of the completed form to [sostrial@warwick.ac.uk](mailto:sostrial@warwick.ac.uk) **within 3 days** of the patient being enrolled (UK only).

The SOS trial team will cross check the signature of the doctor or advanced clinical practitioner person who confirmed eligibility and the name of the person who randomised the patient against the training log to ensure they have completed the appropriate trial training.

TNO: <input type="text"/>		<b>Screening and Eligibility Form</b>
Site: <input type="text"/>		
THIS CRF SHOULD BE COMPLETED FOR ALL PATIENTS ADMITTED TO ICU WITH TRAUMATIC BRAIN INJURY WHERE AN ICP BOLT HAS BEEN INSERTED		
<b>INCLUSION CRITERIA</b>		
Participants will be excluded if <b>ANY</b> of the following are No:		
1 Adult aged 16 years or above	YES <input type="checkbox"/>	NO <input type="checkbox"/>
2 Admission to ICU following traumatic brain injury	<input type="checkbox"/>	<input type="checkbox"/>
3 ICP > 20mmHg for more than 5 minutes despite stage 1 procedures	<input type="checkbox"/>	<input type="checkbox"/>
4 < 10 days from initial primary head injury	<input type="checkbox"/>	<input type="checkbox"/>
5 Abnormal CT scan consistent with TBI	<input type="checkbox"/>	<input type="checkbox"/>
<b>EXCLUSION CRITERIA</b>		
Participants will be excluded if <b>ANY</b> of the following are Yes:		
1. Devastating brain injury with withdrawal of treatment anticipated in the next 24 hours	YES <input type="checkbox"/>	NO <input type="checkbox"/>
2. Pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
3. Severe hyponatraemia (serum sodium > 155 mmol/L)	<input type="checkbox"/>	<input type="checkbox"/>
4. 2 or more prior doses of hyperosmolar therapy given on ICU	<input type="checkbox"/>	<input type="checkbox"/>
If yes, record the name of the medically qualified doctor or advanced clinical practitioner who has confirmed the patient is eligible to be enrolled in the SOS trial, and the date and time confirmed. This should also be reflected in the medical notes.		
Has a medically qualified doctor or advanced clinical practitioner* assessed and confirmed that the patient is eligible?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
*If an advanced clinical practitioner has confirmed eligibility, please confirm that the diagnosis of TBI has been documented	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Name of doctor/advanced clinical practitioner	<input style="width: 100%;" type="text"/>	
Signature of doctor/advanced clinical practitioner	<input style="width: 100%;" type="text"/>	
Date and time confirmed	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	DD/MM/YYYY      HH:MM	
If the patient is not enrolled, please give the reason for non-enrolment (tick the primary reason only):		
Patient enrolled in the SOS trial?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
If IVR phone line used to enrol, name of person who completed randomisation	<input style="width: 100%;" type="text"/>	
<b>REASON FOR NON-ENROLMENT</b>		
Eligible but consent declined by personal legal representative	<input type="checkbox"/>	
Eligible but consent declined by professional legal representative	<input type="checkbox"/>	
Not eligible	<input type="checkbox"/>	

## Screening/Randomisation Wizard

### How to add screening data to the database

To enter screening information on the online database for patients who are not being randomised:

1. Click on 'Recruitment' tab
2. Click 'Go' on the Screening/Randomisation wizard

3. Click 'New'

Follow the instructions within the Wizard and select 'Next' to move to the next page.

4. To select the randomising site, start typing the name of your site, a drop-down list will appear
  - Click on your site
  - Click 'Next'

Please keep a record of the patient's information on your internal screening and enrolment log.



Participant Information RECRUITMENT DASHBOARD

Randomising site

5. Enter the eligibility data.
  6. Select 'no' for 'Will the patient be randomised?'.
  7. Record the primary reason why the patient is not being randomised in the 'reason for non-enrolment' field.
- Once a patient has been registered, a trial number will be allocated and will appear on the next screen. This should be added to your screening and enrolment log.

PARTICIPANT TRIAL NUMBER RECRUITMENT DASHBOARD

Participant Trial Number

### How to randomise eligible patients

1. Follow steps 1-5 as above for entering screening data.
2. Select 'yes' for 'will the patient be randomised?'. All **inclusion criteria** must be '**Yes**' and all **exclusion criteria** must be '**No**' for the patient to be eligible.
3. If the patient **is eligible** and will be randomised, the question 'Has a medically qualified doctor or advanced clinical practitioner assessed and confirmed that the patient is eligible?' must be '**Yes**'. Please ensure the name of doctor, and the date and time eligibility was confirmed is recorded. This date and time should match that recorded on the paper Screening and Eligibility CRF.
4. Please ensure **all** fields are completed on the 'Randomisation' page. The person completing randomisation must be suitably trial-trained and should select their name from the drop-down list.
5. Check all the information entered is correct then click 'randomise' on the randomisation confirmation page.

The patient’s trial number (TNO) and treatment allocation will appear on the next screen. Confirmation emails will be sent to your site and to the SOS trial team, to alert of a randomisation or a screened patient.

PARTICIPANT TRIAL NUMBER

RECRUITMENT DASHBOARD

Participant Trial Number

0004

Allocated Trial Arm

Hypertonic saline

Date and time of randomisation

03-Dec-2024 17:19

6. Please print/save the email confirmation and store in your site file.

Accessing participant forms on the database

To access the CRFs in the database for each participant once they have been randomised:

- 1. Click ‘Data Management’
- 2. Click ‘Participant Manager’.

SOS

Admin

Recruitment

Data Management

Participant Manager

Form Manager

Query Manager

RECRUITMENT DASHBOARD

Recruitment Wizards

Welcome to the SOS recruitment dashboard. Click on a wizard's GO button to start the recruitment process.

Here you can see a summary of how many forms are outstanding for each participant:

SOS

Admin

Recruitment

Data Management

Search by TNO

Select Participant Status

Apply Filters

	TNO	Enrolled Date	Enrolled Site	Completed Forms	Incomplete Forms	Overdue Forms
<div>View Forms</div>	0001	03-Dec-2024	John Radcliffe Hospital	0	30	7
<div>View Forms</div>	0002	03-Dec-2024	University Of São Paulo Medical School	0	26	5
<div>View Forms</div>	0003	03-Dec-2024	John Radcliffe Hospital	0	1	1
<div>View Forms</div>	0004	03-Dec-2024	John Radcliffe Hospital	0	24	2

➤ Select ‘View forms’ for the relevant participant.

- You can then navigate through the forms on the left-hand column for each participant.

SOS Admin Recruitment Data Management

TNO: 0004 | Enrolled Date: 03-Dec-2024 | Site: John Radcliffe Hospital

Participant Search

Scheduled Events

- Pre Randomisation
- Randomisation
- Hospital stay
- 3 months
- 6 months
- 12 months
- End of trial

Unscheduled Events

- Daily Data
- Protocol Non-compliance form
- Withdrawal form
- Death Notification form
- Serious Adverse Event form

Pre Randomisation - Expected: 03-Dec-2024

Screening and Eligibility Form

Data Summary

Data entry status: 1 Missing field (95.83%)

Form status: N/A

User Notes

Open Queries

Audit Summary

Created date: 03-Dec-2024 17:18 (UTC+0)

Created by: u2072240

Last modified date: 03-Dec-2024 17:18 (UTC+0)

Last modified by: u2072240

Form Options

View Form

Click 'View form' to open forms.

## CRF02 – Participant form / Informed consent

This form should be completed on the online database **within 3 days** of randomisation.

- For each participant, you must select the type of consent prior to enrolment i.e. written consent from a personal or professional legal representative, or deferred consent.

SOS Admin Recruitment Data Management

TNO: 0004 - Informed Consent

Back Form Notes Form Queries

INFORMED CONSENT PRIOR TO ENROLMENT

Type of initial consent prior to enrolment:

Date of Informed Consent :

Consent to receive trial intervention:

Consent to complete questionnaire:

Consent to remote data collection:

If declined, please give reason:

- Please then complete the relevant section for each participant i.e. informed consent prior to enrolment, informed consent from professional legal representative after enrolment and/or informed consent from a personal legal representative after enrolment.
- If the 'if declined, please give reason' field is not applicable, please enter N/A here to avoid this appearing as missing data.
- If the patient regains capacity and provides consent at a later date, please remember to go back in to update the 'informed consent from the patient' section.
- Click **Save** before exiting the form.

SOS Admin Recruitment Data Management

TNO: 0004 - Informed Consent

Back Form Notes Form Queries

INFORMED CONSENT PRIOR TO ENROLMENT

Type of initial consent prior to enrolment: Informed consent from professional LR

Date of Informed Consent : 03-dec-2024

Consent to receive trial intervention:

Consent to complete questionnaire:

Save

## CRF04 - Patient and Legal Representative Identifiers (UK only)

Consent will need to be in place and the relevant section of the Informed Consent form completed before the Patient and Legal Representative Identifiers form appears.

Please **do not** complete this form for patients that have died before consent could be obtained.

- Complete the patient details and relevant legal representative details if applicable.
- This form can be completed if professional legal representative consent, personal legal representative consent and/or patient consent is in place
- If there are any changes to contact details, please update them accordingly.
- Click **Save** before exiting the form.

## CRF05 Baseline

Please use the data dictionary to guide you in completing some of the fields on the form (found in ISF Section 11.4). Further information on how to complete some fields:

- Sex at birth – This is the patient's sex at birth
- Weight – If patient's actual weight is not known, please use **ideal body weight** to estimate. The weight recorded here should be used to calculate the dose of Mannitol/HTS using the dosing table provided. Please record if the weight used was estimated or actual.
- ICP prior to randomisation - This should be the last ICP reading immediately prior to randomisation.
- Date and Time of CT Scan, CT scan appearance - This relates to the initial routine CT scan at the first hospital that the patient was admitted to.
- Co-enrolment to other trials – if you discover after randomisation that a patient has been co-enrolled to a non-CTIMP trial or participated in another CTIMP within the preceding 90 days and no prior agreement was in place, please inform the WCTU immediately by phone or email.
- Pregnancy – if a patient has been enrolled and it is later discovered they are pregnant, discontinue trial interventions and inform the WCTU immediately. A non-compliance form and withdrawal form will also need to be completed. Pregnancy is not a contraindication to hyperosmolar therapy, however, for regulatory reasons, pregnant patients are required to be excluded from the trial.

## CRF06 Study Drug Administration

- Hyperosmolar therapy doses given pre-randomisation should not be entered onto this form.
- Record all doses of the study drug **in the order** they were administered on this form.
- Click on the '+' symbol to add a new dose.
- Keep clicking the '+' to add additional doses.
- If the patient was randomised but did not end up receiving any IMP, please select 'other' for drug given and explain what happened in the free text box. Record the 'dose administered'

as 0ml. If a dose of IMP is then later given e.g. the patients ICP spikes again, please create a new record for that dose – do not overwrite the 0ml.

The screenshot shows the 'STUDY DRUG ADMINISTRATION' form in the SOS system. The form is titled 'STUDY DRUG ADMINISTRATION' and includes fields for 'DOSE', 'Date of dose:', 'Time of dose:', 'Drug given:', 'If other, please specify:', and 'Dose administered:'. A red circle highlights the 'Add' button (a plus sign in a circle) at the bottom of the form.

## CRF07 ICP Monitoring

Please record the ICP monitoring details on this form. Remember to go in and update this form if there are any problems experienced during ICP monitoring, and once ICP monitoring has been stopped.

## CRF08 Daily Data

This form should be completed daily for all participants during their stay on critical care:

- Day 0 = day of randomisation.
- Select the number of calendar days since the patient was randomised.
- Start collecting data on Day 0 from the time of randomisation i.e. the first observations carried out following randomisation.
- Intracranial pressure (ICP), mean arterial pressure (MAP) and serum sodium should be collected **hourly** on a daily basis **whilst ICP is being monitored** i.e. until bolt removed.
- If readings for ICP, MAP or serum sodium are not taken on the hour, please report the highest value for that hour.
- If ICP/MAP/serum sodium are not routinely recorded for that hour, enter 'NR' into relevant fields – you do not need to take any additional readings.
- Organ support needs to be recorded on a **daily basis** for the **duration of the patient's stay on critical care**. The data dictionary can be used to help complete this section.

## CRF09 Concomitant Treatments

This form should be updated as required but should be completed before the patient is discharged from critical care.

Please record if the patient has had each treatment listed – 'yes' or 'no'.

## CRF10 Critical Care Discharge Form & CRF11 Hospital Discharge Form

These forms should be completed for ALL participants on discharge from critical care and the hospital, including for those who have died.

### Critical Care Discharge Form:

- If the patient has died before discharge from ICU, please still complete all fields on the form.
  - In these cases, record the date and time of death as the date and time of discharge.

### Hospital Discharge Form

- This data should be collected **as close as possible** to the time of discharge by a **team member who is blinded to the patient's treatment allocation**, if possible. You will need to regularly check in on patients that have been discharged from ICU so that you are aware when they are likely to be discharged.
- If the patient has not regained capacity to complete the EQ-5D questions themselves, then you can ask their next of kin/personal legal representative to respond. If there is not a suitable next of kin available, a healthcare professional involved in the patient's care can complete the questions on behalf of the patient.
- If the trial hospital is the same as the final hospital on discharge, please only complete the sections for the trial hospital. The final hospital sections will be blanked out following completion of the trial hospital section, unless discharge to 'other hospital' is selected.
- If the patient is discharged to another hospital, please continue to follow up the patient with the hospital as much as is practically possible to enable collection of data on discharge from final hospital.
- If the patient dies before they are discharged from hospital, please complete all fields in the following sections:
  - Hospital discharge information – use date and time of death for date and time of discharge.
  - Follow up information
  - Modified Oxford Handicap Scale.
- You do not need to complete the EQ-5D information for patients that have died before discharge. These can be marked as unobtainable.

If the patient has died, please also complete the **Death Notification Form** and **End of Trial Form**.

## CRF14 – Withdrawal Form

If a patient or legal representative expresses the wish to withdraw from the study, please complete the withdrawal form. If the patient/legal representative is willing to give a reason for wanting to withdraw, please give details on the form.

If a treating clinician withdraws a patient, they are only able to withdraw them from the trial treatment only.

The **End of Trial Form** should also be completed when a patient has withdrawn completely from the trial, i.e. Withdrawn from remote data collection.

## CRF15 Death Notification form

This form should be completed for patients who have died. In addition to recording the date and time of death, please select the primary reason for death and give some brief details.

The **End of Trial Form** also needs to be completed.

## CRF16 End of trial form

This form should be completed for all patients.

Select if the patient has completed the trial. If you become aware that a patient has not completed the trial i.e. dies, withdraws from trial completely, etc. then select 'no'; then below, the primary reason for discontinuation.

This form should also be completed on paper. The PI will need to sign and date the bottom of the form before sending a copy to the WCTU via email.

## Completing survival checks

Survival checks need completing at 3 months, 6 months and 12 months following randomisation. If the patient is still in hospital at any of these time points, the survival check will need completing.

- Select the forms for the relevant follow up time point.
- Select the 3/6/12 month follow up form.
- Enter the date of assessment and the patient's mortality status.

The screenshot displays the SOS Data Management interface for a patient (TNO: 0004, Site: John Radcliffe Hospital). The 'Scheduled Events' sidebar on the left lists various events, with '3 months' highlighted. The main content area shows the '3 Month Follow-up form' selected, with fields for 'Data entry status', 'Form status', 'User Notes', and 'Open Queries'. A red circle highlights the '3 months' event in the sidebar, and a blue arrow points to the '3 Month Questionnaire: Resource Use' form, which is noted as 'Resource use for UK only'.

## Completing 3, 6 and 12 month follow-up (Brazil only)

Follow-up data obtained from participant/legal representative completed questionnaires is to be entered onto the database forms which have been split into 3 sections:

- Completion information
  - This is who completed the questionnaire
- Extended Glasgow Outcome Scale
  - GOS-E score questions (not applicable for the 3 month timepoint)
- Quality of Life  
EQ-5D-5L data

## Non-compliance reporting

All non-compliances with the SOS protocol or GCP should be reported to the WCTU **within 24 hours** of becoming aware of the event. Please give as much detail as possible.

If your non-compliance is **not** related to an individual participant, but is a more general site issue, please complete the CAPA form on paper (electronic or by hand) and email it to [sostrial@warwick.ac.uk](mailto:sostrial@warwick.ac.uk). To report a new, participant specific, protocol non-compliance on the SOS database select the following:

- Data Management
- Participant Manager
- 'View forms' for participant TNO that the non-compliance is related to
- Protocol non-compliance form
- + New Form

The screenshot displays the SOS Data Management interface. At the top, there are tabs for 'Admin', 'Recruitment', and 'Data Management'. Below these, a header bar shows 'TNO: 0004 | Enrolled Date: 03-Dec-2024 | Site: John Radcliffe Hospital'. A 'Participant Search' link is visible. The main content area is divided into two panels. The left panel, titled 'Scheduled Events', lists various events: Pre Randomisation, Randomisation, Hospital stay, 3 months, 6 months, 12 months, End of trial, and a section for 'Unscheduled Events' including Daily Data, Protocol Non-compliance form (highlighted with a red circle), and Withdrawal form. The right panel, titled 'Protocol Non-compliance form', contains the text 'No forms have been entered for this event.' and a '+ New Form' button (highlighted with a red circle).



To be able to enter information in the form, select yes for 'Are there any non-compliances to report?'

Complete all fields in the following sections, providing as much detail as possible:

- Event details
- Category of Event
- Corrective actions
- Preventative actions
- Form details

You do not need to complete the sections under **WCTU use only**.

### Providing follow up information for a non-compliance

If you have not yet gathered all the details regarding the non-compliance, you must still inform the WCTU immediately with as much information as possible. The initial report can be updated at a later date once you have gathered more information.

To update an existing non-compliance form, select 'view form' on the relevant non-compliance form that you want to update, then 'edit' in the top right-hand corner.

Please add the date and your initials before entering the updated information on the form. When you have finished, click 'save'. Please record your reason for amending the form in the pop up that appears.

We will receive regular reports listing new non-compliances that have been entered, but if you come across a non-compliance that you believe is serious or requires urgent attention, please call a member of the SOS trial team or email [sostrial@warwick.ac.uk](mailto:sostrial@warwick.ac.uk).

## Data queries

Data queries (e.g. missing data) will be sent on a monthly basis via a spreadsheet. Any updates or additional information should be added to the database rather than sent by email.