SED-CARE

TEMP-CARE

MAP-CARE

The George Institute for Global Health Australia

Sedation Temperature and Pressure after Cardiac Arrest and Resuscitation

CONSENT, DATA ENTRY, eCRF & REMOTE MONITORING

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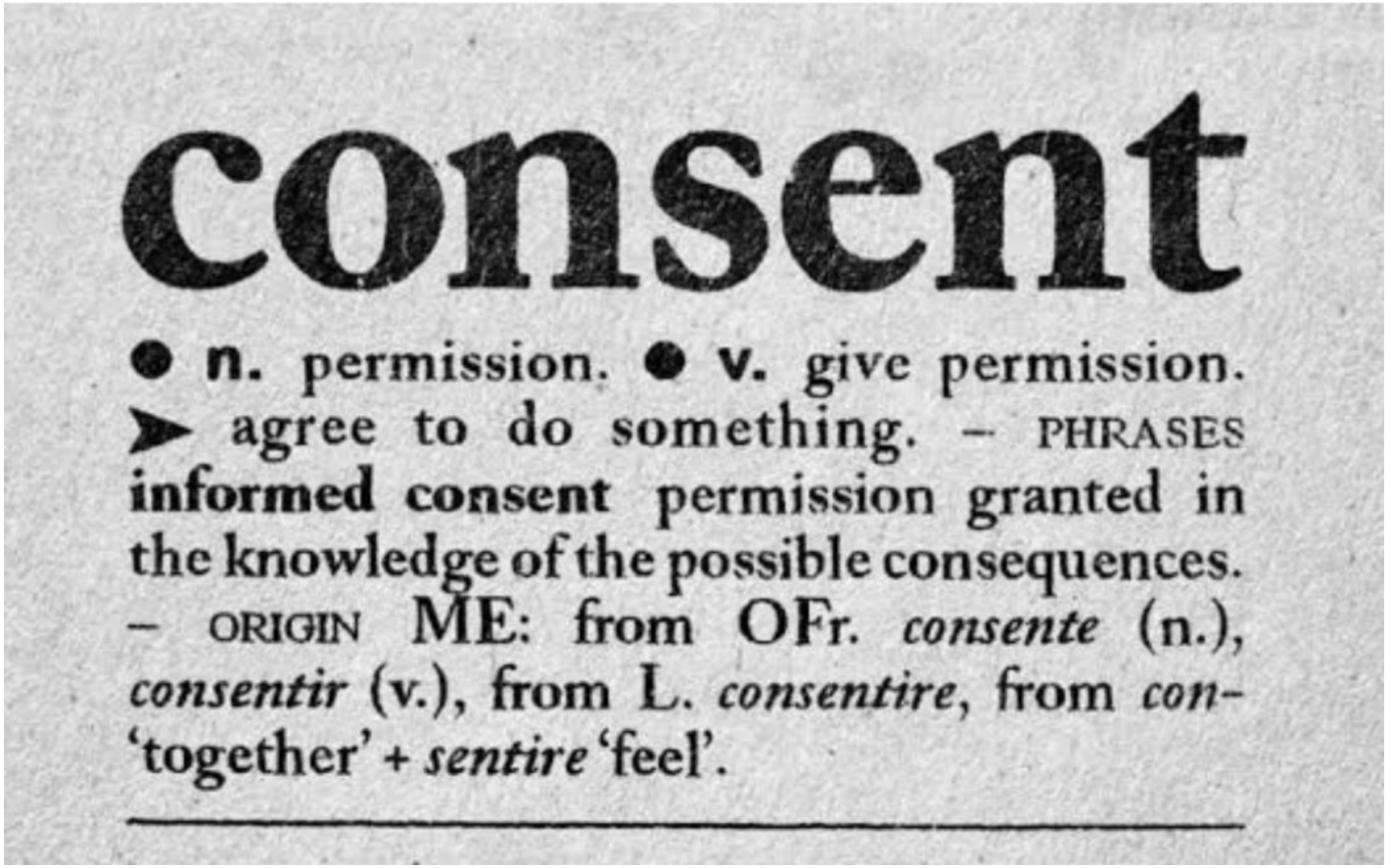
Dr Josef Dankiewicz: Cardiologist, Lund


consent
● n. permission. ● v. give permission.
➤ agree to do something. – PHRASES
informed consent permission granted in the knowledge of the possible consequences.
– ORIGIN ME: from OFr. consente (n.), consentir (v.), from L. consentire, from con- 'together' + sentire 'feel'.

Informed Consent Model

✗ **Consent from participant PRIOR to randomisation will NOT be possible**

✓ **Consent from Legally Authorised Representative (LAR), Person Responsible (PR)/ Substitute Decision Maker (SDM)/Medial Treatment Decision Maker (MTDM) PRIOR to randomisation**

- Whenever possible consent will be obtained from a LAR/PR/SDM/MTDM prior to randomisation

✓ **Inclusion without prior consent with option to continue or withdraw**

- Patients enrolled into the trial without prior consent, the participant or LAH/PR/SDM/MTDM informed about participation in study as soon as possible and given the option of consent to continue in the trial, or to withdraw from the trial

Who Obtains Consent?

- ICH-GCP: investigator's responsibility
- The investigator, or a person designated by the investigator, should fully inform the patient or LAR
- Investigator or designee (Co-PI, Sub-PI, RC.)
- Qualified, trained on the study protocol, consenting
- Comply with local ethical and regulatory requirement
- Any person obtaining consent throughout the study must be listed on the Site Signature & Delegation Log

How should consent be administered?

- Timing: before participation
- Environment: private, confidential dialogue can take place
- Fully inform all pertinent aspects of the trial
  - Orally and EC approved information sheet
- Non-technical and practical language
- Do no use language
  - to coerce or unduly influence to participate
  - that causes/appears to waive any legal rights or appear to release the investigator, institution, sponsor or their agents from liability for negligence
- Provide ample time and opportunity to inquire about the details of the trial and answer questions

What information should be provided to participants?

- Voluntary, can refuse, withdraw anytime
- Access to participant original medical records for verification, ensuring confidentiality, by monitors, auditor, ECs and reg. authorities
- Participants identify will be kept confidentiality
- If new information becomes available that is relevant to participation it will be provided in a timely manner
- Payments for participation, expenses to the participant

What information should be provided to participants?

- Contact details
  - for further information and the rights of the participant
  - event of trial-related injury
- Circumstances and/or reasons under which the subject's participation in the trial may be terminated
- Expected duration of participation in the trial
- Approximate number of participants involved in the trial

Consent Documentation

- The Participant or LAR/PR/SDM/MTDM and the person obtaining consent must sign and date the consent form
- All signed forms must be retained for 15 years
- Original signed consent form (and information sheet) is kept with the study file,
  - One full copy filed in patient's medical records
  - One full copy given to patient/PR/SDM/MTDM
- The consent process should be documented in the patient's medical record
- All consents will be reviewed at Site Monitoring Visits

Withdrawal of Consent

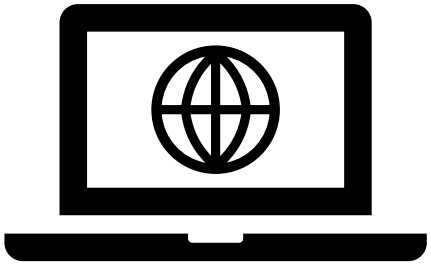
- The participant and/or their LAR/PR/SDM/MTDM may withdraw their consent to participate in the study at any time
- Please seek permission (with discretion) to
    - use all trial data
    - use trial data collected up to date of withdrawal
    - access medical record to obtain health information
    - contact participant at 30-days, 6 and 12-months to obtain health information
    - complete follow-up questionnaires by telephone or face-to-face visit to obtain health information
- Complete the “Participant Withdrawal of Participation” found on the last page of the Information Sheet and Consent Form
- Document in the patient’s medical records and study file


DATA
COLLECTION

Data Collection

- Data collected up to 12 months post-enrolment, or to death (whichever occurs first)
- eCRF built using Spinnaker
- Keep your login ID and password information confidential
- All data definitions and explanations are explained thoroughly within the database by selecting the information button
- There is not a separate data dictionary or study completion manual

Database & eCRF



https://stepcare.spinnakersoftware.com

Spinnaker

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CHANGES


Pe ct

Database Home Page

stepcare Participants Screening log Resources Manage Monitoring Reports Andromeda Infirm...

Add participant

14 Participants randomised at 997 - Andromeda Infirmary

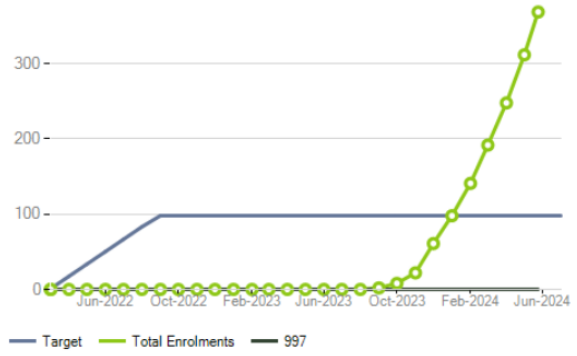
Participant Study Number | Find participant

Participant	Age	Sex	Initials	Day	Randomised
9970014	25	Male	TAB	45	11-Apr-2024
9970013	25	Male	ABCD	46	10-Apr-2024
9970012	58	Male	JTU	108	08-Feb-2024
9970011		Male		206	02-Nov-2023
9970010	36	Male	JUO	220	19-Oct-2023
9970009	44	Male	ATT	223	16-Oct-2023
9970008	56	Female	LOP	243	26-Sep-2023
9970007	47	Female	EEN	250	19-Sep-2023
9970006	39	Female		256	14-Sep-2023
9970005	39	Male	RRR	256	13-Sep-2023
9970004	59	Male	DGU	256	13-Sep-2023
9970003	23	Male	NNN	270	30-Aug-2023
9970002	19	Male	HJK	283	17-Aug-2023
9970001	34	Male	MOB	293	07-Aug-2023

Alerts at 997 - Andromeda Infirmary

369 enrolments in the STEPcare Trial

14 enrolments at 997 - Andromeda Infirmary



Randomising & Screening Patients

stepcare Participants Screening log Resources Manage Monitoring Reports Andromeda Infirm...

Add participant

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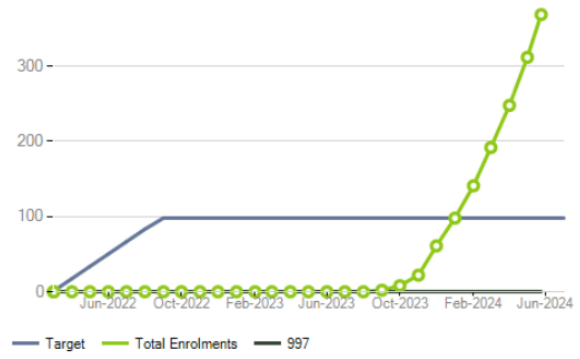

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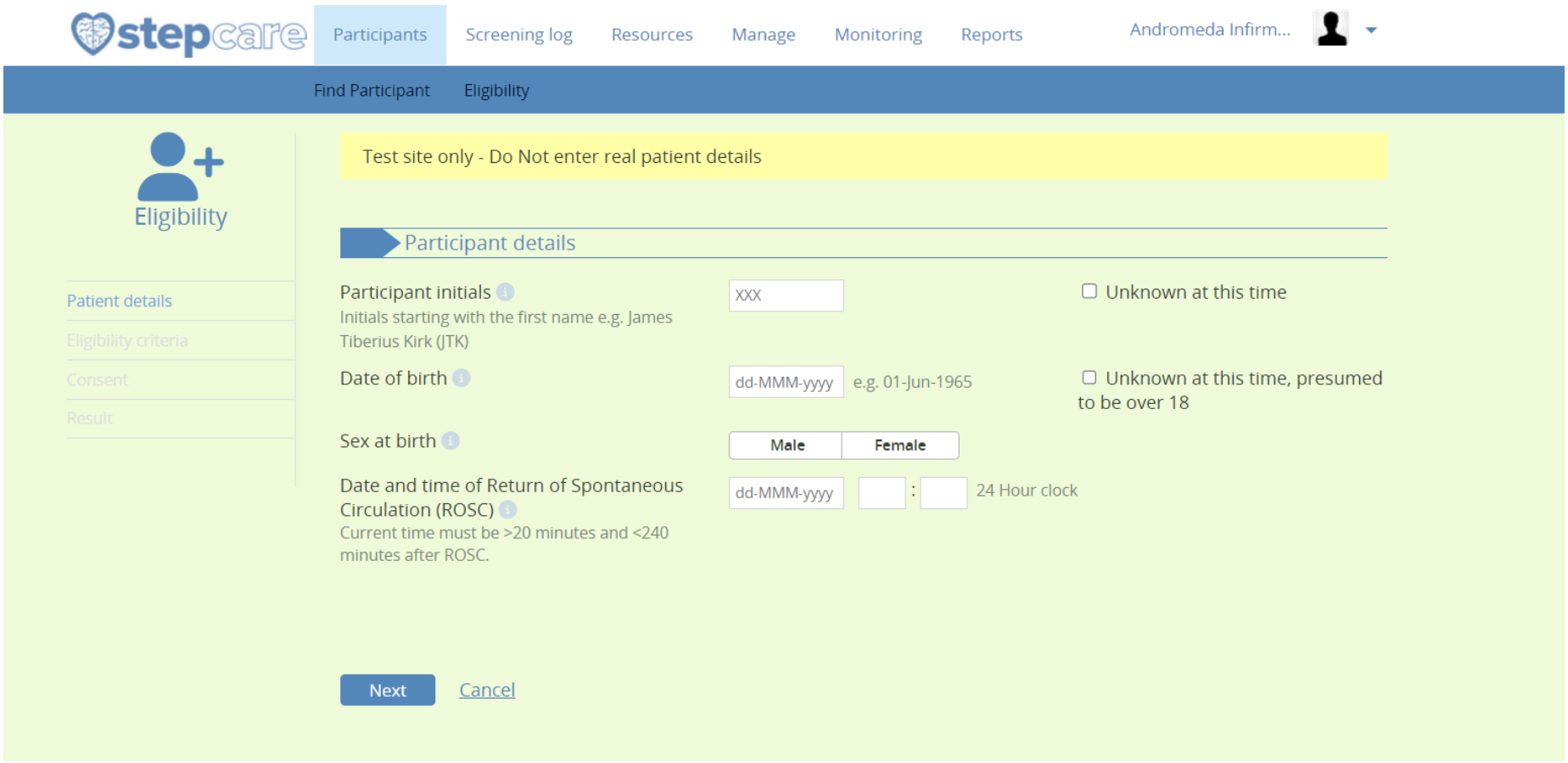
stepcare
Participants
Screening log
Resources
Manage
Monitoring
Reports
Andromeda Infirm...
Find Participant
Eligibility
Eligibility
Patient details
Eligibility criteria
Consent
Result
Test site only - Do Not enter real patient details
Participant details
Participant initials
Initials starting with the first name e.g. James Tiberius Kirk (JTK)
XXX
Unknown at this time
Date of birth
dd-MMM-yyyy
e.g. 01-Jun-1965
Unknown at this time, presumed to be over 18
Sex at birth
Male
Female
Date and time of Return of Spontaneous Circulation (ROSC)
Current time must be >20 minutes and <240 minutes after ROSC.
dd-MMM-yyyy
24 Hour clock
Next
Cancel

Eligibility
UBSLFS

- Patient details
- Eligibility criteria
- Best Interests
- Consent
- Result

Eligibility criteria

Arrest location

Out-of-hospital is defined as a patient not currently admitted in the hospital

In-hospital	Out-of-hospital

Arrest Cause

Please select the most probable cause of arrest as judged at the time of randomisation. If VT/VF and no other information choose arrhythmia not related to acute ischemia.

Cardiac	Non-cardiac	Trauma/Bleeding	Intracranial bleed

Unconscious Is the patient unconscious or intubated and sedated due to agitation	Yes	No
Is the patient eligible for intensive care without restrictions or limitations	Yes	No
Is the patient on ECMO	Yes	No
Is the patient pregnant	Yes	No
Previously randomised in the STEPCARE trial	Yes	No

Next Cancel

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Eligibility
UBSLFS

- Patient details
- Eligibility criteria
- Best Interests
- Consent
- Result

Consent

Are all local consent requirements met | Yes | No

Perceived prognosis - for research purposes

Does not impact randomisation and patient care

Do you (physician randomising or physician in-charge) think this patient will have a good neurological outcome in 6 months

- ○ Yes - I, the physician randomising or physician in-charge, think this patient will have a good neurological outcome in 6 months
- ○ No - I, the physician randomising or physician in-charge, **do not** think this patient will have a good neurological outcome in 6 months
- ○ I am not a physician and the physician in charge is not available to answer this question right now

Next Cancel

Eligibility
UBSLFS

- Patient details
- Eligibility criteria
- Best Interests
- Consent
- Result

This patient is eligible and will be randomised

Confirm | Edit Eligibility | No, add to screening log only

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Randomising a Patient

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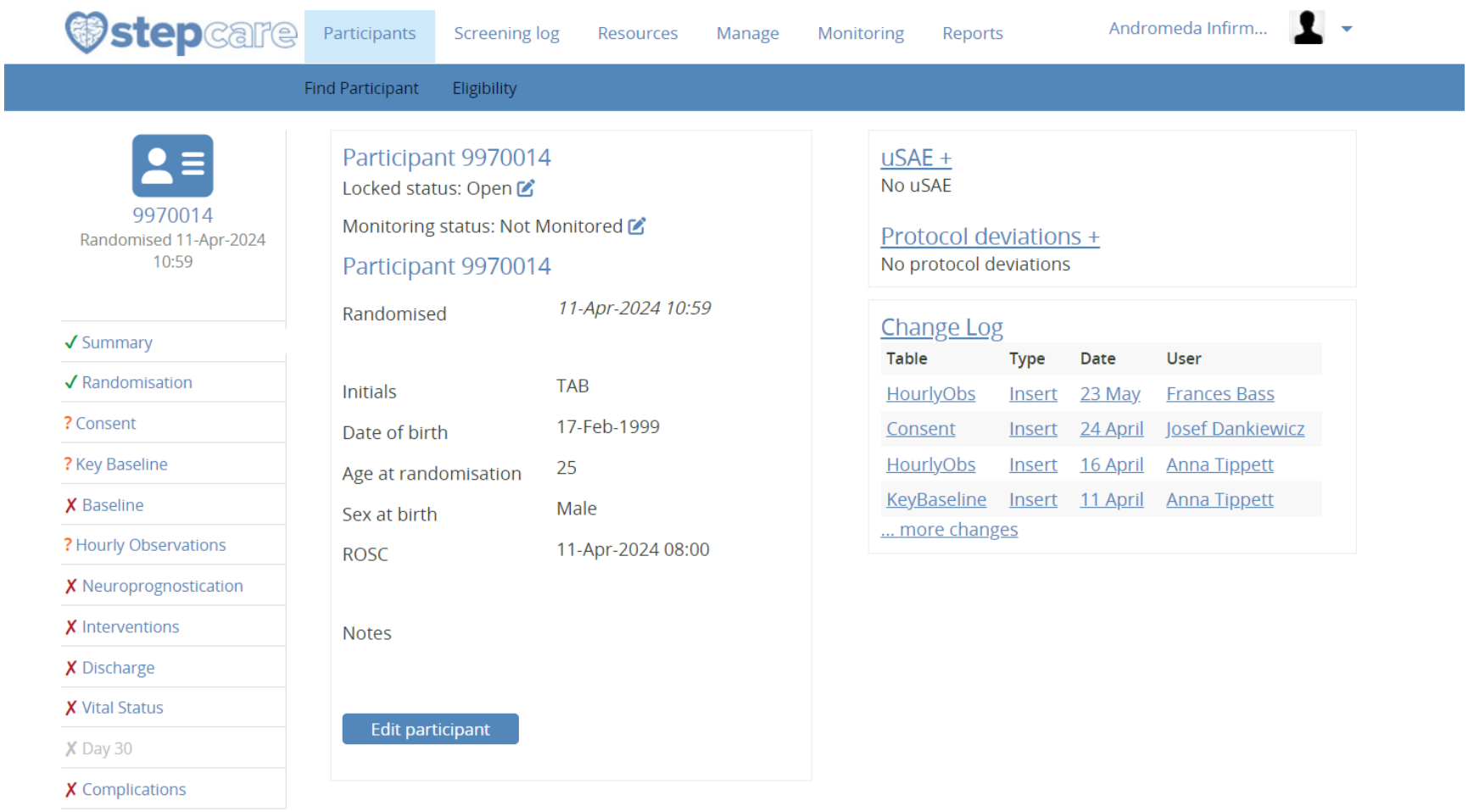
Patient Summary



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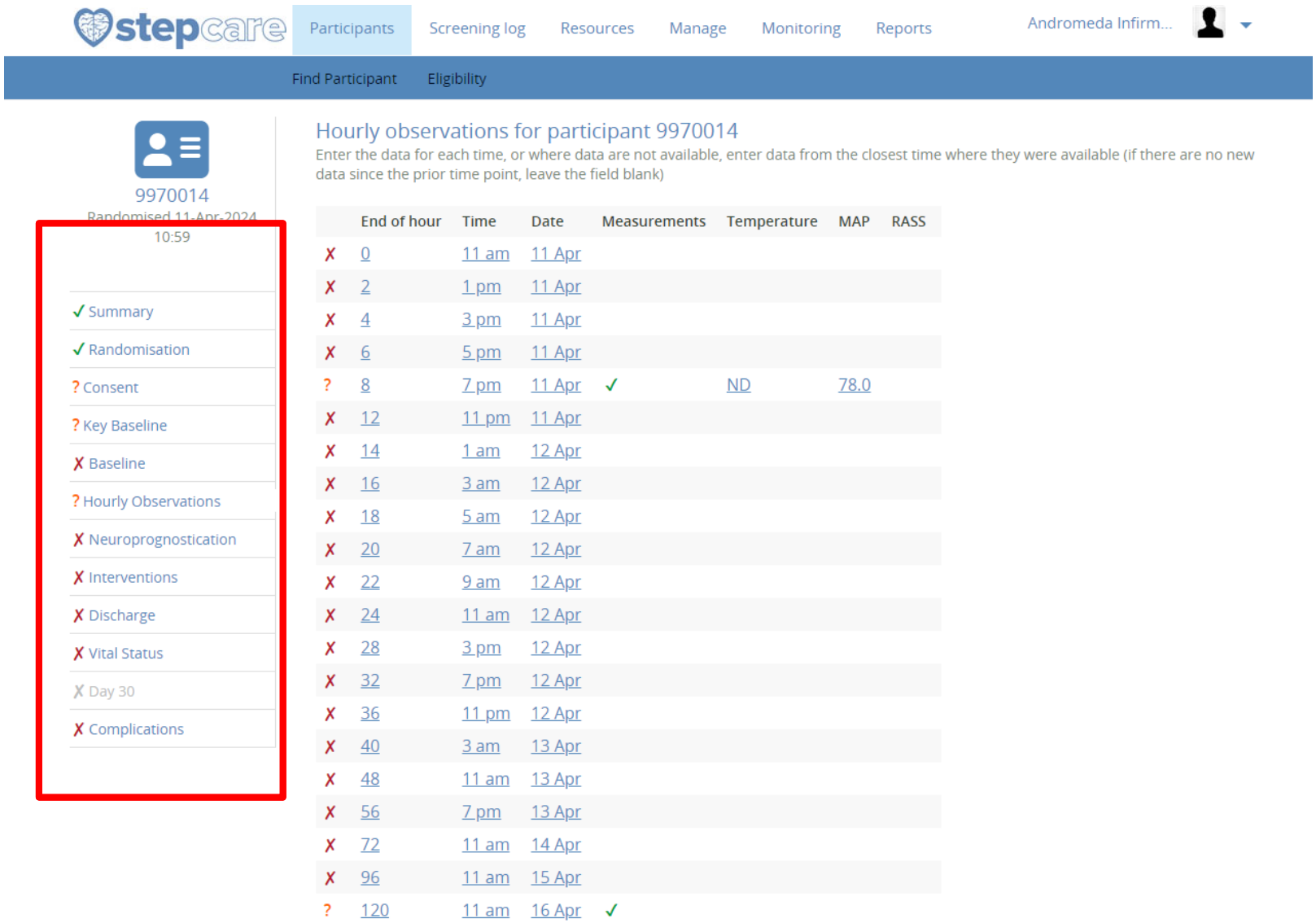
Hourly Observations

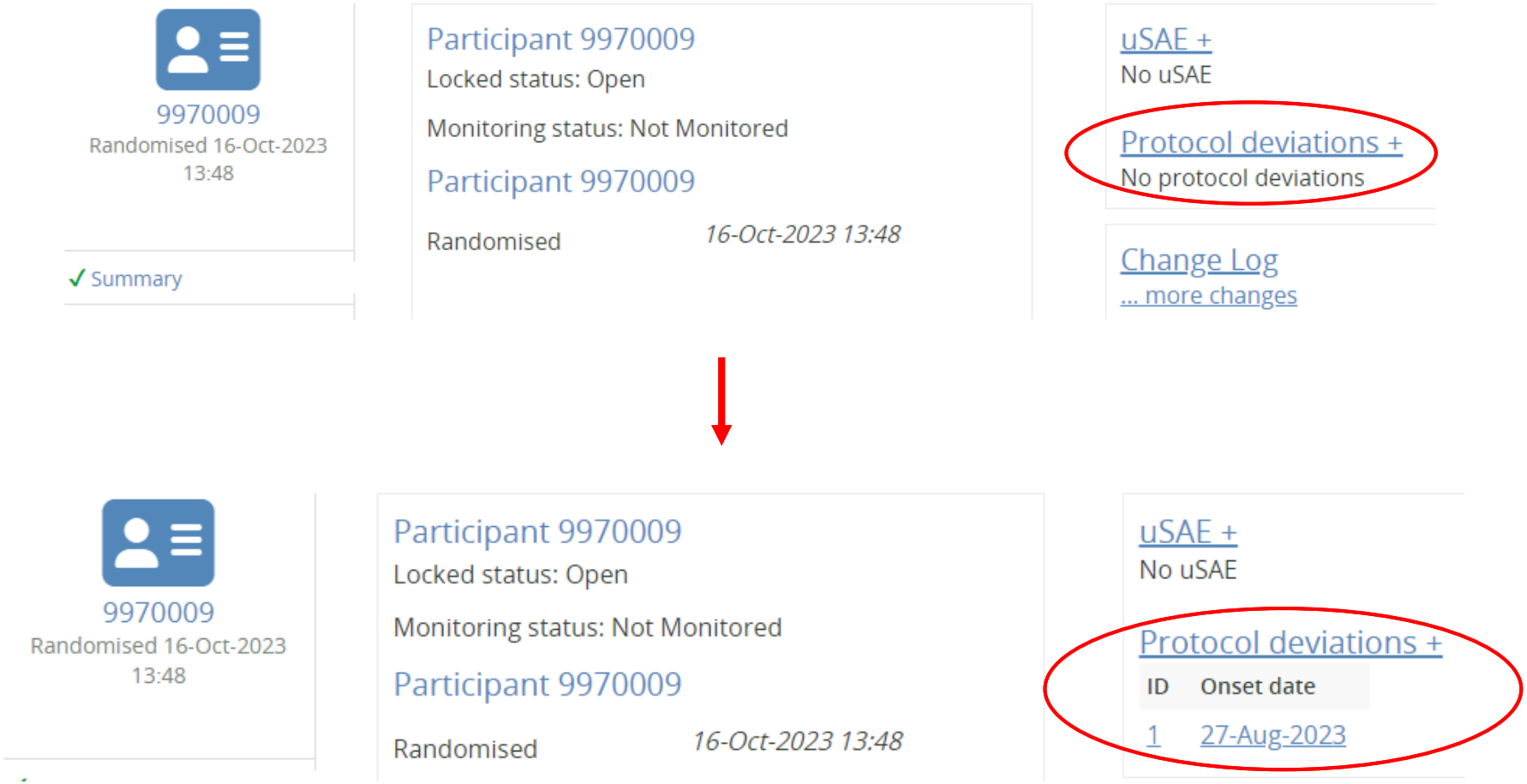


	End of hour	Time	Date	Measurements	Temperature	MAP	RASS
✗	0	11 am	11 Apr				
✗	2	1 pm	11 Apr				
✗	4	3 pm	11 Apr				
✗	6	5 pm	11 Apr				
?	8	7 pm	11 Apr	✓	ND	78.0	
✗	12	11 pm	11 Apr				
✗	14	1 am	12 Apr				
✗	16	3 am	12 Apr				
✗	18	5 am	12 Apr				
✗	20	7 am	12 Apr				
✗	22	9 am	12 Apr				
✗	24	11 am	12 Apr				
✗	28	3 pm	12 Apr				
✗	32	7 pm	12 Apr				
✗	36	11 pm	12 Apr				
✗	40	3 am	13 Apr				
✗	48	11 am	13 Apr				
✗	56	7 pm	13 Apr				
✗	72	11 am	14 Apr				
✗	96	11 am	15 Apr				
?	120	11 am	16 Apr	✓			

Protocol Deviations

- Tyes of Protocol Deviation's
  - Enrolment of ineligible patient
  - Failure to comply with allocated temperature management strategy
  - Failure to comply with allocated blood pressure management strategy
  - Failure to comply with allocated sedation management strategy
  - Other
- Document one Protocol Deviation per PD form
- Enter Protocol Deviation CRF onto the database ASAP
- Describe the deviation and corrective action taken

Protocol Deviations



Protocol Deviations

Protocol Deviation for participant 9970009

Nature of protocol deviation

Date and time of deviation dd-MMM-yyyy : 24 Hour clock

Type of deviation:

- [ ] Enrolment of ineligible patient
- [ ] Failure to comply with allocated temperature management strategy for reasons not permitted in the protocol
- [ ] Failure to comply with allocated blood pressure management strategy for reasons not permitted in the protocol
- [ ] Failure to comply with allocated sedation management strategy for reasons not permitted in the protocol
- [ ] Other

Please describe the deviation:

Please describe any corrective actions that were taken in reaction to the protocol deviation:

Add Protocol deviation or Cancel

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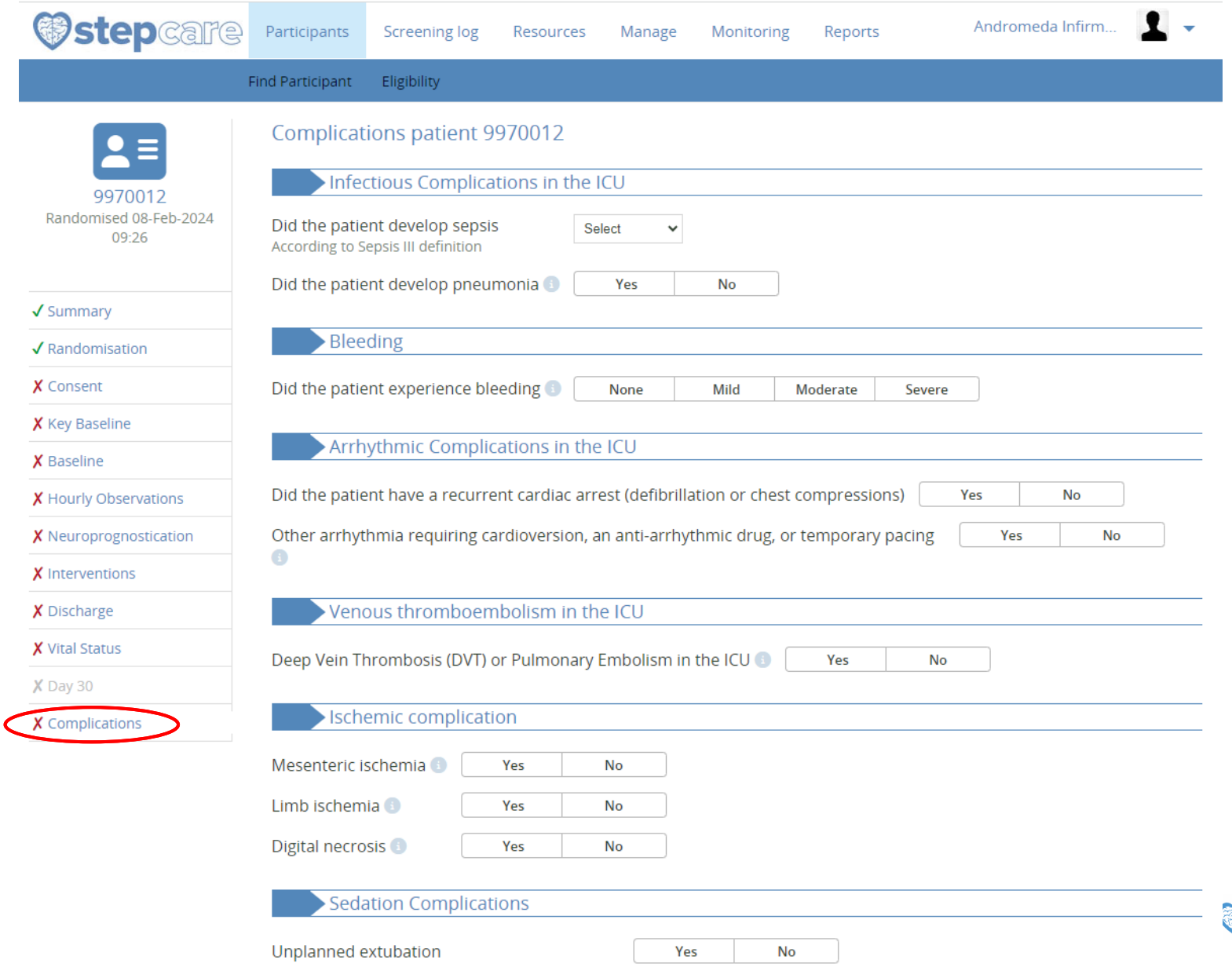
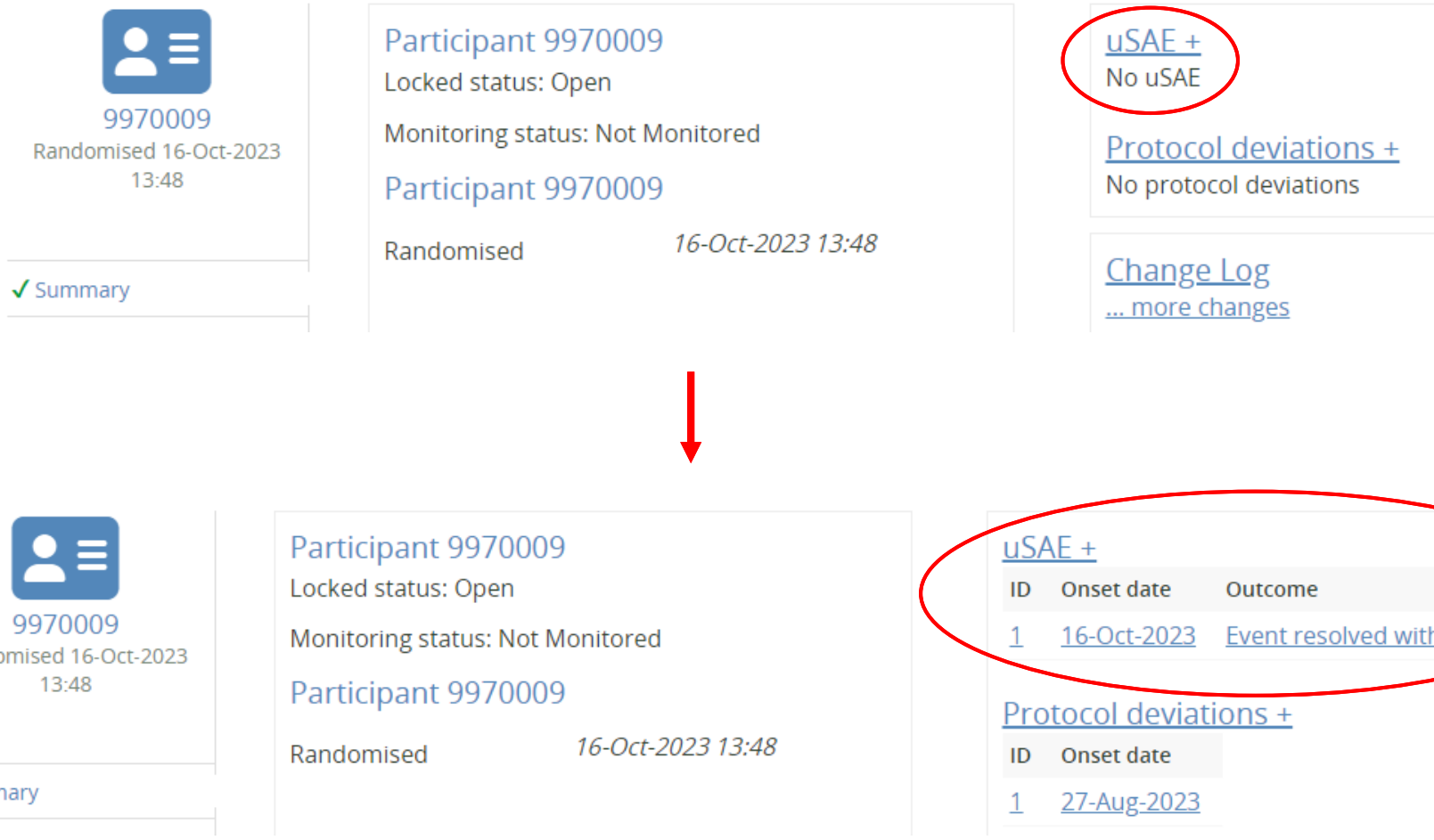
Complications – Safety Events



Unexpected Serious Adverse Events



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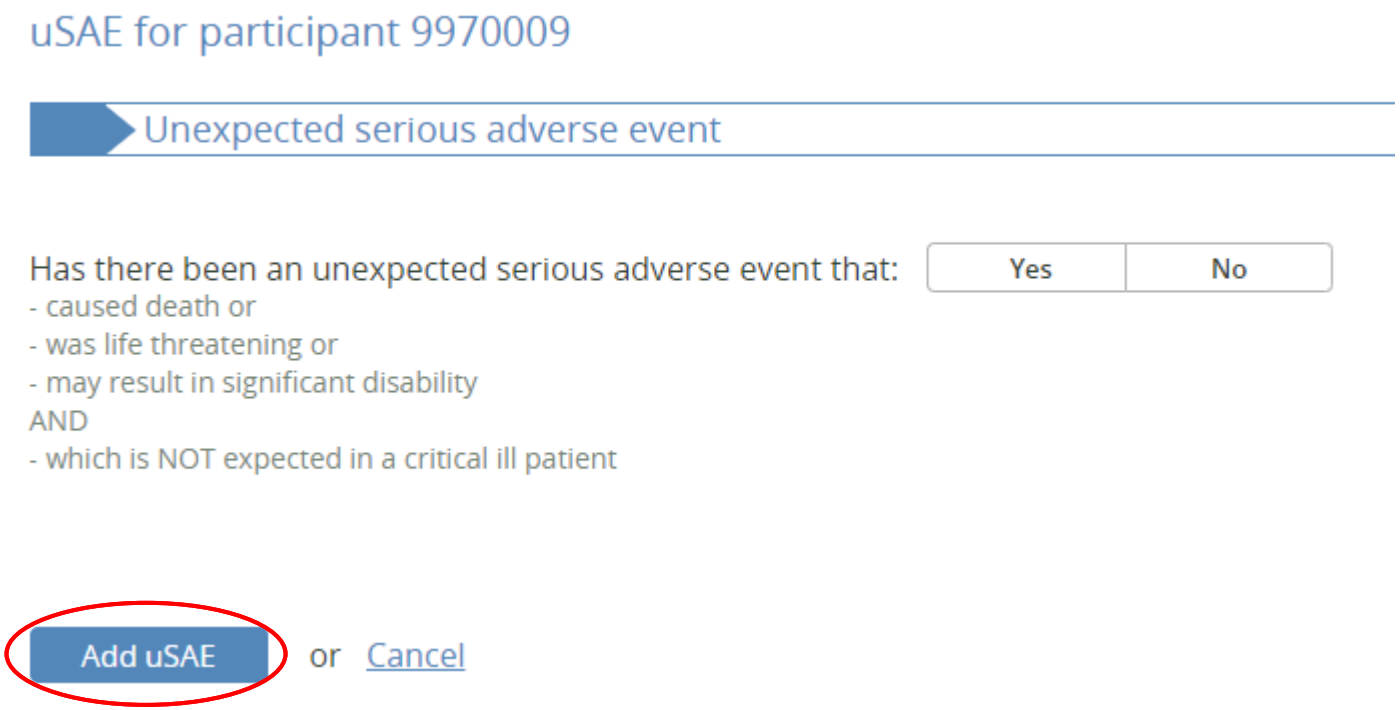

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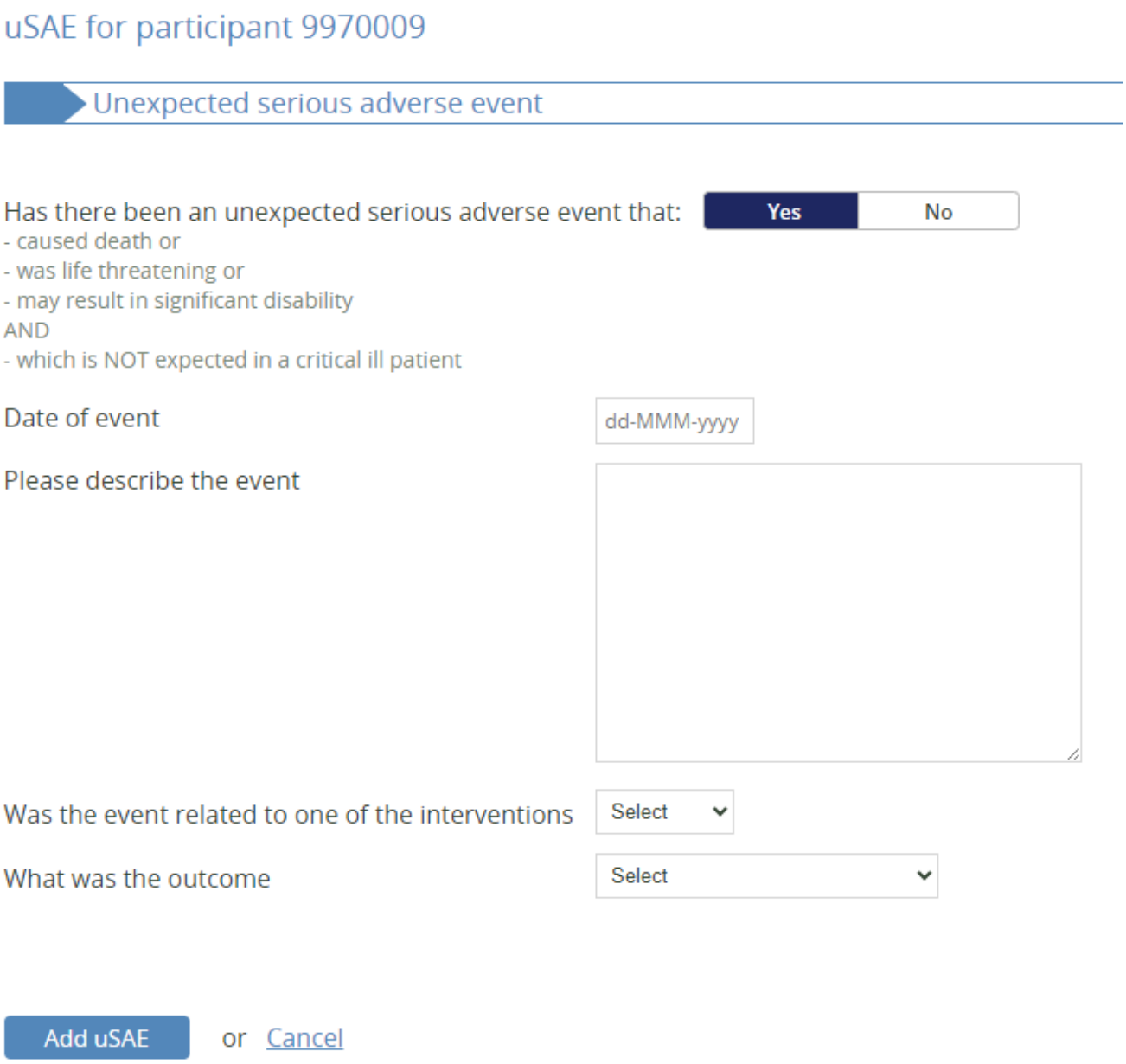


eCRF test accounts

Test site: https://stepcare-stage.spinnakersoftware.com/

Password: cardiacarrest

User name: Choose the location below corresponding to your time zone.

For investigators and nurses

United Kingdom, Ireland (UTC +00.00)
User name: STEPCAREtest_UK

Sweden, Belgium, Italy, Luxembourg, Norway, Switzerland (UTC +01.00)
User name: STEPCAREtest_SE

Finland, Czech Republic (UTC +02.00)
User name: STEPCAREtest_FI

Saudia Arabia, Kuwait (UTC +03.00)
User name: STEPCAREtest_SA

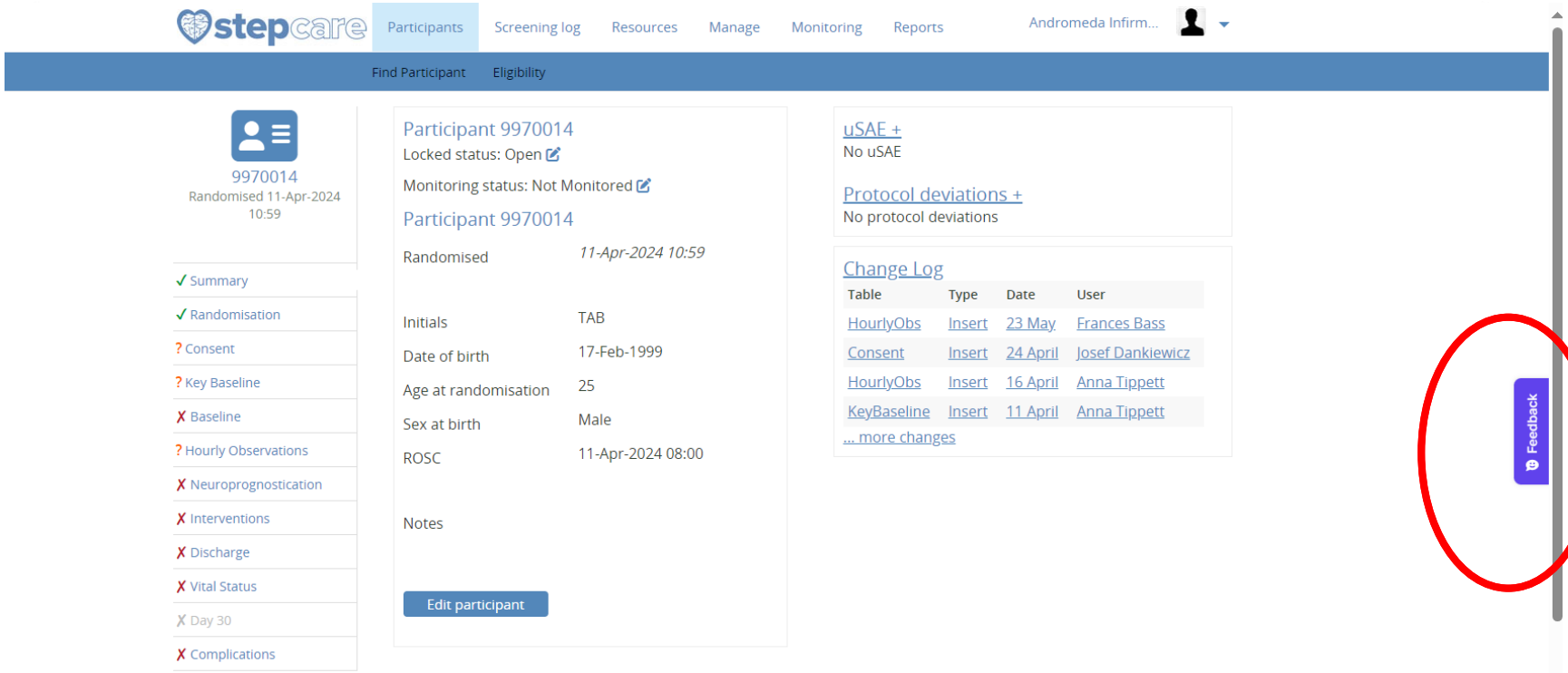
Singapore (UTC +08.00)
User name: STEPCAREtest_SG

Australia (UTC +10.00)
User name: STEPCAREtest_AU

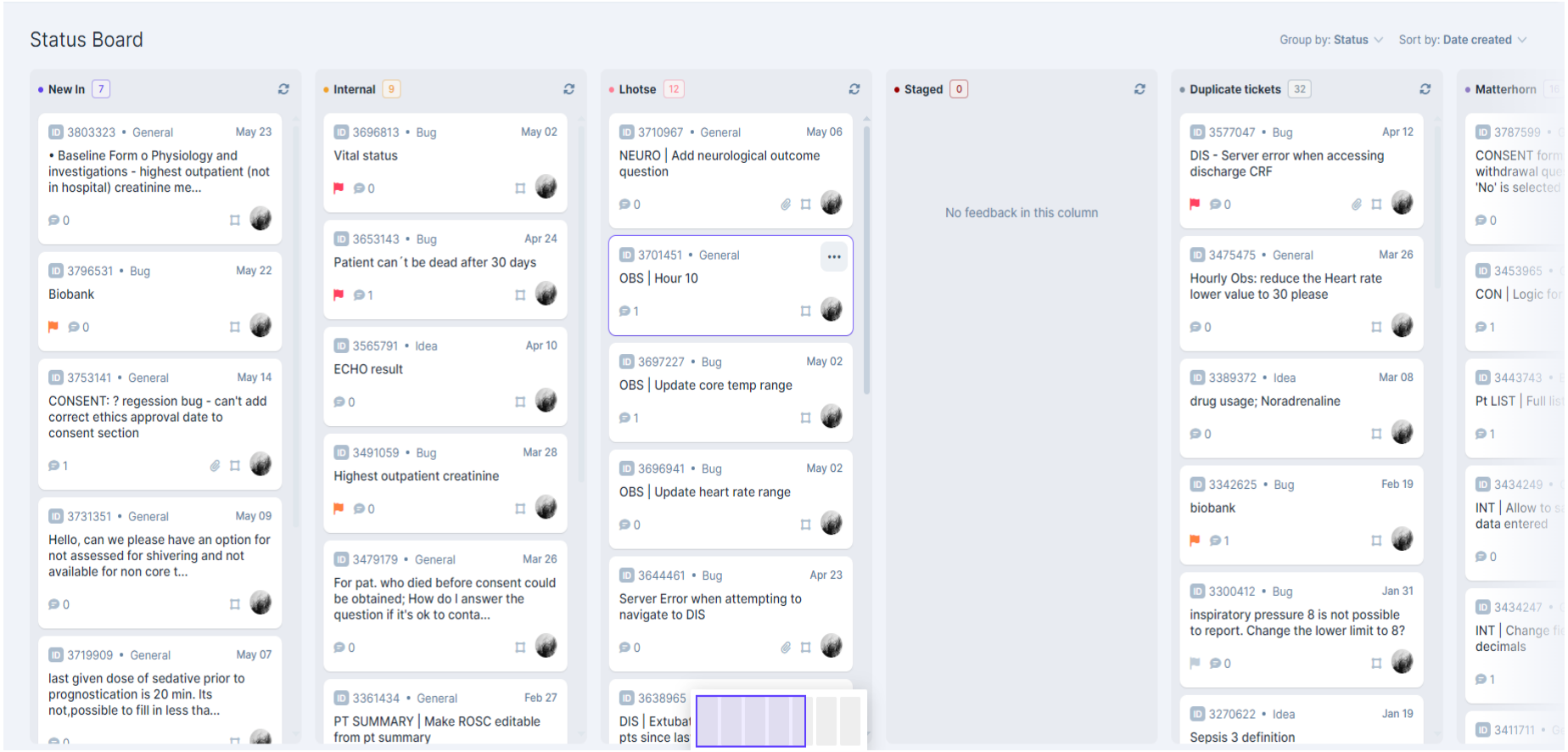
Safety reporting

- Safety events will be reported during the intensive care unit stay only
- Safety events should be reported within 24 hours from awareness of the event
- The specific safety events will be reported whether they are considered related to the intervention or not
- The relatedness between the trial interventions and the unexpected serious complications should be determined by the local investigator

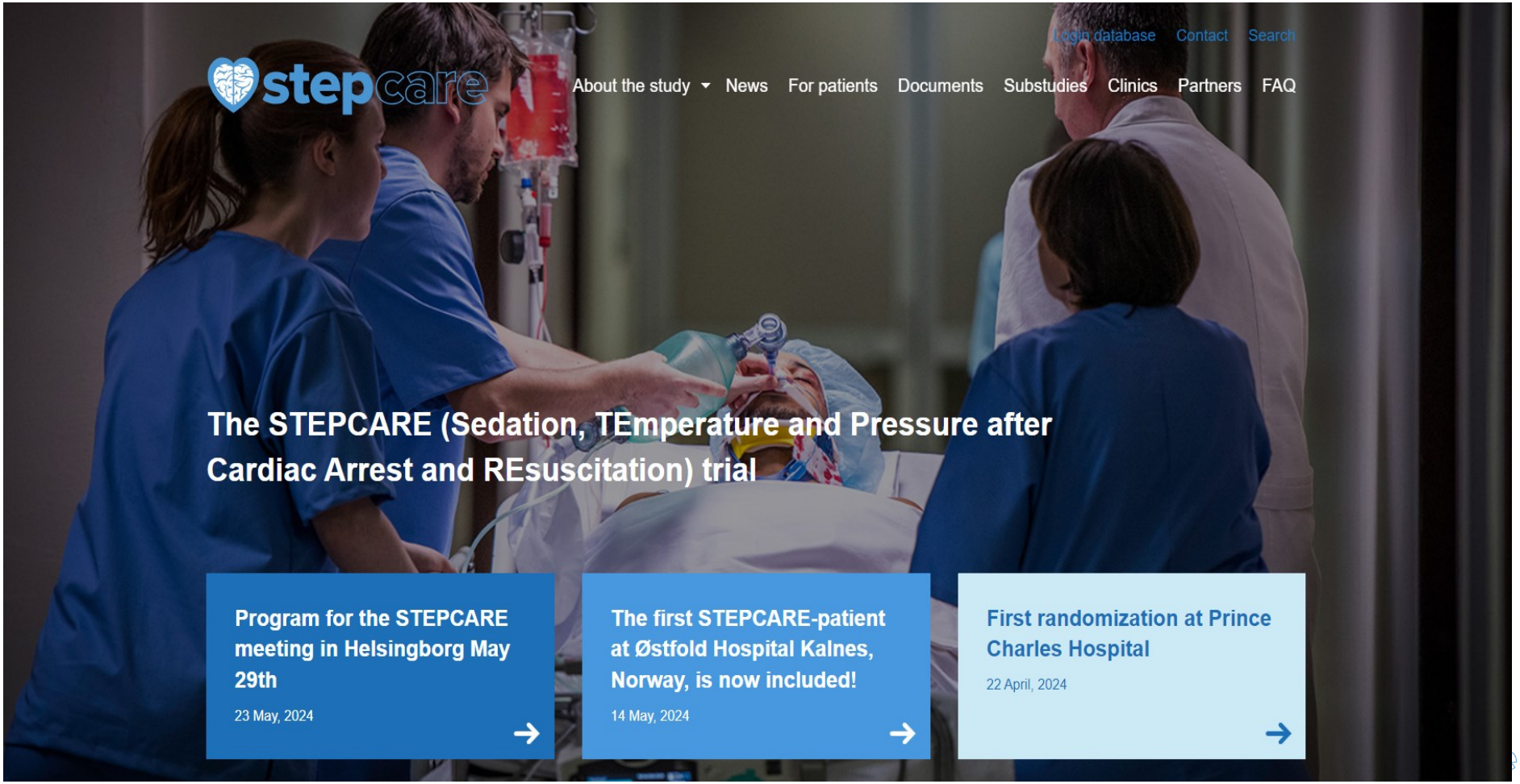
eCRF feedback



fbass@georgeinstitute.org.au


Status Board
Group by: Status
Sort by: Date created
New In 7
3803323 • General May 23
• Baseline Form o Physiology and investigations - highest outpatient (not in hospital) creatinine me...
3796531 • Bug May 22
Biobank
3753141 • General May 14
CONSENT: ? regession bug - can't add correct ethics approval date to consent section
3731351 • General May 09
Hello, can we please have an option for not assessed for shivering and not available for non core t...
3719909 • General May 07
last given dose of sedative prior to prognostication is 20 min. Its not,possible to fill in less tha...
Internal 9
3696813 • Bug May 02
Vital status
3653143 • Bug Apr 24
Patient can´t be dead after 30 days
3565791 • Idea Apr 10
ECHO result
3491059 • Bug Mar 28
Highest outpatient creatinine
3479179 • General Mar 26
For pat. who died before consent could be obtained; How do I answer the question if it's ok to conta...
3361434 • General Feb 27
PT SUMMARY | Make ROSC editable from pt summary
Lhotse 12
3710967 • General May 06
NEURO | Add neurological outcome question
3701451 • General
OBS | Hour 10
3697227 • Bug May 02
OBS | Update core temp range
3696941 • Bug May 02
OBS | Update heart rate range
3644461 • Bug Apr 23
Server Error when attempting to navigate to DIS
3638965
DIS | Extubat
pts since las
Staged 0
No feedback in this column
Duplicate tickets 32
3577047 • Bug Apr 12
DIS - Server error when accessing discharge CRF
3475475 • General Mar 26
Hourly Obs: reduce the Heart rate lower value to 30 please
3389372 • Idea Mar 08
drug usage; Noradrenaline
3342625 • Bug Feb 19
biobank
3300412 • Bug Jan 31
inspiratory pressure 8 is not possible to report. Change the lower limit to 8?
3270622 • Idea Jan 19
Sepsis 3 definition
Matterhorn
3787599
CONSENT form withdrawal que 'No' is selected
3453965
CON | Logic for
3443743
Pt LIST | Full list
3434249
INT | Allow to s data entered
3434247
INT | Change fi decimals
3411711

https://stepcare.org/



Documents

PROTOCOL

CRF

MANUALS

SCREENING AND RANDOMISATION

INTERVENTIONS

NEUROLOGY

BIOMARKERS

FOLLOW UP

PRESENTATIONS

START UP

ETHICS

INVESTIGATOR STUDY FILE

Monitoring

- The purpose of monitoring is to ensure that the clinical trial is conducted in accordance with the study protocol, GCP and any local regulatory requirements
- Early visits conducted to pick-up any consistent errors and to discuss issues (if any)

Remote Monitoring

Josef to discuss

Source Data Verification

- The purpose of SDV is to document the existence of the patient and substantiate integrity of the study data collected
- A source document is the first place something is recorded i.e. original documents, data and records
- Data collected should be from a source document which can be verified by a study monitor or local/national regulatory authorities.
- Examples of source documents include medical notes (electronic or paper), laboratory results, ambulance chart, ED charts, ward charts, OT charts and other hospital records
- A paper case report form is not a source document