SepTiC
Sepsis Trials in Critical Care

October Newsletter

Patients recruited: 410
Sites opened: 34

Issue 15

Top recruiting sites this month:

1. Bristol Royal Infirmary
2. St Georges Hospital
3. St Marys Hospital + Southend Hospital

This month we had a **total of 39** patients recruited - our highest recruiting month to date!

We are pleased to announce that the study has now surpassed **400 patients recruited,** marking a significant milestone in our collective efforts.

Big shout out to Charing Cross Hospital who recruited the studies 400th patient!

This achievement would not have been possible without the continued dedication and hard work of all participating sites. We extend our sincere thanks to each team for their invaluable contributions. Please take a moment to review and share this newsletter within your teams.

Recruiting sites this month

Site	September 25
Bristol Royal Infirmary	7
St George's Hospital	5
St Mary's Hospital	4
Southend University Hospital	4
Charing Cross Hospital	3
Royal Victoria Belfast	3
Kings Mill Hospital	2
Kettering General Hospital	1
Sunderland Royal Hospital	1
Kings College Hospital	1
Royal Glamorgan Hospital	1
Musgrove Park	1
Salford Royal Hospital	1
Queens Medical Centre	1
Royal Victoria Infirmary	1
Warrington Hospital	1
Huddersfield Royal Infirmary	1
John Radcliffe Hospital	1

New sites + First Recruits

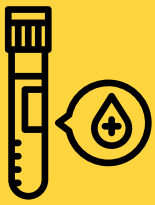
We would like to welcome Huddersfield Royal Infirmary, Calderdale Royal Hospital and John Radcliffe Hospital to the SepTiC team, the sites opened to the study earlier this month and have already recruited their first patient!

Congratulations to Royal Victoria Infirmary in Newcastle has also recruited their first patient this month!

PCR Diagnostic Arm: Procalcitonin (PCT) Testing Requirements

We would like to remind all sites of the specific protocol requirements for patients randomised to the PCR diagnostic arm of the study.
It is essential that PCT levels are measured at two key time points:

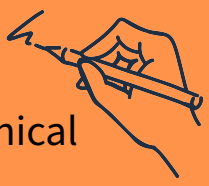
- On or before the day of randomisation (up to 48h before admission)
- On the day following randomisation (18-36h after the first test)



The novel intervention is the PCR diagnostic and we think it will work best coupled with PCT, so that is why we mandate PCT in the intervention arm. The control group should follow normal site procedure, which might include PCT.

If sites routinely conduct PCT tests, this can be entered in eCRF.
If PCT tests are not taken for patients randomised to the intervention, this would be a protocol deviation

GCP Guidance: Informed Consent Documentation



Please ensure the following practices are followed in line with Good Clinical Practice:

- Participants must **initial** each box on the consent form to confirm they have read and understood each statement.
- Ticks are not acceptable and do not meet regulatory requirements for documenting informed consent.
- If a participant is unable to initial due to physical weakness or other limitations:
- A proxy or impartial witness may initial on their behalf.
- The reason for proxy initials must be clearly documented in the trial records.
- The identity of the individual providing the initials should also be recorded.

SepTiC Webinars are back!

We're planning a set of SepTiC webinars later in the year which will be co-hosted by some of our top recruiting sites, this will be a great opportunity for sites to share their best practices - full details to be confirmed
We have scheduled a **December - Q&A with CI** and 2025 roundup with Trial Management Team on **Thursday 11th December 12:00-13:00.**