SepTiC

Sepsis Trials in Critical Care

August Newsletter

Issue 13

As we move into the second half of the year, we want to thank all our site teams for their continued dedication and hard work on the SepTiC study.

Patients recruited: 342
Sites opened: 30

Top recruiting sites this month:

1. Royal Victoria Belfast
2. Charing Cross Hospital
3. Bristol Royal Infirmary

This month we had a total of 26 patients recruited.
Well done to Countess of Chester, Queens Medical Centre and Southmead Hospital for recruiting their first patients into the trial!

This month's issue focuses on **key reminders** and recent findings from our review of site documentation. We've highlighted important updates around **consent**, **randomisation**, **sample collection,** and the **GM-CSF** intervention to support compliance and ensure smooth trial delivery.

Implementation of AM008 – Effective 1st August 2025

We would like to remind all sites that if we have not heard from you by **Friday 1st August 2025,** we will assume your organisation can implement **Amendment 8.** Please ensure your site has saved the amendment documents in your ISF / eISF.

You can implement the updated Telephone Agreement (v2.0, 14-Mar-2025), once you have localised the form and sent it to the SepTiC inbox for approval.

GM-CSF Intervention – Site Responsibilities

Sites participating in the GM-CSF intervention must ensure the following:

- **Stock Management**: Maintain sufficient stock of GM-CSF on ICU. Ensure accountability logs are up to date and reflect current inventory.
- **Temperature Monitoring**: Temperature deviations must be reported as soon as they occur. Logs should be reviewed regularly and kept current.
- **Trained Staff Only**: The IMP must only be administered by staff who have received appropriate training.
- **Follow the IMP Handling Manual**: Administration must be in accordance with the IMP Handling Manual. Please ensure all staff are familiar with the procedures outlined.

Consent Forms – Common Issues & Best Practice

We have also identified several recurring issues related to consent. Please ensure the following points are reviewed and that this newsletter is shared with your teams, and filed in your ISF/e-ISF for future reference.

- **Use the most recent consent form versions only**. Superseded versions must be removed from circulation and clearly superseded in the ISF.
- **Check consent forms for completion and accuracy** at the time of consent, in line with Good Clinical Practice (GCP) requirements.
- The NIHR have many training modules on taking consent and the regulatory requirements for those who wish to have further information:
  - NIHR Informed Consent Training
  - Taking Consent from Adults Lacking Capacity
- If a patient **lacks capacity,** a **Personal Legal Representative (PerLR)** or **Professional Legal Representative (ProLR)** must be sought **as soon as possible**.
- **Consent annotations** (including **version and date**) must be clearly documented in the **patient's medical records**.
- **The Telephone Agreement** wording has been updated in AM008 to clarify that the witness **must be** independent from the trial team.
- Eligibility Forms must be completed **before randomisation** by a delegated, trained assessor listed on the delegation log.

Randomisation & Data Entry – Best Practices

- All **OpenClinica users** should verify their access before **randomising** their first patient.
- Remember: OpenClinica is a **LIVE system** – treat it accordingly.
- Only **eligible patients** who will be randomised should be entered into the database.
- Please remember to complete the **microbiology form** for **all patients.**
- **Randomisation guidance** is available in multiple formats:
  - SepTiC Randomisation and Troubleshooting Guide v1.0 23.04.2025
  - Quick Reference Crib Sheets
  - Training Video
- Still unsure? Contact the SepTiC team via **phone or email** – we're happy to help!
- Don't forget to check the FAQs on our website: link to FAQs

Sample Collection & Avoiding Report Delays

- **All sample shipping forms** must include the **patient ID and partial DOB** and any missing information may delay the PCR report being issued to your site.
- PCR reports are only sent to **email addresses listed on the shipping form** therefore you must ensure these details are correct**. No text messages** are issued.
- **Do not send patient identifiable information** to the SepTiC inbox or to the central lab.
- Collect samples **only as per the Sample Manual**. Any additional samples taken that were not required will be logged as a **protocol deviation.** You can also watch our Sample Collection Video for guidance on which samples to take.
- Before sample collection, always check that the **sample tubes are in date** and notify the SepTiC team **immediately** if any are expired.