

Top recruiting sites this month:



1. Bristol Royal Infirmary
2. Southmead Hospital
3. Southend Hospital

This month we had a **total of 29** patients recruited.

We would like to welcome Warrington Hospital to the SepTiC team, the site opened to the study earlier this month and have already recruited their first patient

Welcome to the September edition of the SepTiC newsletter. As we head into autumn, we have several important updates, reminders, and exciting announcements to share. Please take a few minutes to read through and circulate this newsletter within your teams.

Reminder: Do not add screening patients to the eCRF



We've seen a few cases of patients being added at the screening stage. Just a reminder that patients should **only** be added once they are **eligible** and have **provided consent**.

If a patient has been added incorrectly, **only the PI** can request their removal from the database.

September Site responsibilities



1. Yellow-Top SST Tubes – Valid Until End of September

Sites may continue using yellow-top SST tubes until 30th September 2025. We will be sending out replacement tubes to all sites shortly to ensure continuity. Please check your stock and let us know if you're running low on any other consumables and we will make sure to replenish this stock too.

2. Data Entry Deadline – 18th September

To prepare for the upcoming data extract, we kindly ask all sites to: Enter any outstanding data into OpenClinica and respond to all open queries. This is crucial to ensure the completeness and accuracy of the dataset.

New and updated documents

We're circulating two important documents with this newsletter:



1. Updated Insurance Certificate

The latest version of the SepTiC trial insurance certificate is now available. Please ensure this is filed appropriately in your site file and shared with your R&D department if required.

2. Eligibility Form – Version 2.0 (28-Aug-2025)

A new version of the Eligibility Form has been released. This updated form should be used going forward for all new participants.

Consent Annotations – GCP Guidance



As part of Good Clinical Practice, it's essential that consent annotations in the medical notes are **clear, complete, and accurately reflect the consent process**. This helps ensure **transparency and supports regulatory compliance**.

When documenting consent in the medical notes, please ensure the following details are included:

1. **Confirmation** that **informed consent** was **obtained** e.g. "Informed consent obtained for participation in the SepTiC trial."
2. **Date of consent**: This should match the date on the signed consent form.
3. **Name of the person** who obtained consent: Include their role (e.g. Research Nurse, PI).
4. **Version number** and **date** of the Patient Information Sheet and Consent Form used: This ensures the correct documents were used.
5. **Confirmation** that the patient had **capacity** at the time of consent: If retrospective consent was obtained, this should be clearly stated.
6. **Any relevant discussion points** or questions raised by the patient: this is very helpful for context.

Meet Us at UKCCRG in Manchester !



We're excited to be attending the UKCCRG Conference in Manchester next week. We will be hosting a SepTiC session on Tuesday the 9th at 6pm in the conference room. Come visit us—there will be refreshments, drinks, and goodies available!

Please note: Due to the conference, no kits will be dispatched between 8th–12th September.