

March Newsletter

18 Sites opened

211 Participants recruited

SeptiC

Sepsis Trials in Critical Care



Study site updates

This month we reached **200** participants recruited to SeptiC we would like to thank all of our sites for their incredibly hard work!

Top Recruiting Site in February:

Charing Cross Hospital

Well done to the following sites for hitting their monthly recruitment target:

- St Marys Hospital
- QA Portsmouth
- Bristol Royal Infirmary
- St Georges Hospital
- Russells Hall Hospital

In February we opened 3 new sites to SeptiC:

- Royal Stoke Hospital
- Belfast City Hospital
- Royal Victoria Belfast

Site Number	Site	February
102	Charing Cross Hospital	4
101	St Marys Hospital	2
106	QA Portsmouth	2
107	Bristol Royal Infirmary	2
109	St Georges Hospital	2
111	Russells Hall Hospital	2
103	Hammersmith Hospital	1
104	Kings Mill Hospital	1
105	Derriford Hospital	1
108	Kettering General Hospital	1
115	Kings College Hospital	1
118	Belfast City Hospital	1
119	Scunthorpe General Hospital	1
120	Royal Stoke Hospital	1
110	James Cook Hospital	0
113	Watford General Hospital	0
114	Sunderland Royal Hospital	0
117	Royal Victoria Belfast	0



Huge well done:

Shoutout to **Scunthorpe General Hospital, Royal Stoke Hospital** and **Belfast City Hospital** teams for recruiting their first participant to SeptiC!



SEPTIC REMINDERS

- Please check our FAQs on our website for any questions, we update this on a regular basis
- Openclinica should not be used to screen patients, we have a screening log/follow up calculator template for sites to use
- Use the follow up calculator to see when the Day 95 and Day 180 follow ups are due
- If there are any PI changes, please give as much notice as you can (if possible) as this will require contract and ethics amendments



Recent FAQ

Q. The de-resuscitation initially involves oral thiazide, what should we do if we come across patients who are in ileus (nil by mouth)?

If the patient is absolutely NBM, the thiazide can be omitted and this is not a protocol deviation. However, for a lot of patients who are NBM, there is no real risk associated with giving enteral medication (although absorption may be uncertain) and consideration should be given to administering the medication if there are no safety concerns.

GCP Corrections

ATTENTION PLEASE!

When correcting documents in clinical trials, it is essential to follow ICH-GCP guidelines to ensure data integrity and compliance. Here are the key steps:

- 1. Striking Through:** When making corrections, draw a single line through the incorrect entry. This ensures the original entry remains legible.
- 2. Dating and Initialing:** After striking through the incorrect entry, write the correct information nearby. Then, date and initial the correction. This provides a clear audit trail showing who made the correction and when it was made.
- 3. Avoiding Erasures:** Never use erasers, correction fluid, or any other means to obliterate the original entry. The goal is to maintain transparency and traceability of all changes.
- 4. Documenting Reasons for Changes:** If necessary, provide a brief explanation for the correction. This can be done in the margin or in a separate note linked to the correction.

Example

The example shows two scenarios for correcting a temperature entry on a notepad. The left side, labeled 'Invalid', shows the original entry 'Temperature = 39.8 deg.C' with the '39.8' crossed out and '41.2 deg.C' written below it. A green arrow points to the crossed-out text, and a label 'Original entry concealed' points to it. Below this, a bracket indicates that 'Who corrected', 'When corrected', and 'Reason for correction' are 'Not Available'. The right side, labeled 'Valid', shows the original entry 'Temperature = 39.8 deg.C' with a single line through it, and '41.2 deg.C' written next to it. A signature and date '21/07/2022' are written next to the correction. Below this, a bracket indicates that 'Who corrected', 'When corrected', and 'Reason for correction' are 'Attributable information Available'. A vertical line separates the two examples. A small logo 'LEARN ABOUT PHARMA' is visible between the two notepads.

Upcoming Webinar- Sharing best practices with the Kettering General Hospital SepTiC team

Our next webinar will include a presentation from the Kettering General SepTiC Team, they will share how they run the study at their site.

This will be an opportunity for all sites to discuss any obstacles that they may face at their site and share their best practices. The webinar will take place on Monday the 10th of March at 2pm. The link to join is below:

<https://imperial-ac-uk.zoom.us/j/93817767036?pwd=SzVFV0luZE8zaUp5dzFmZUd Tckhkdz09>

SEPTIC API FORUM CHANNEL

We have created a dedicated channel on MS teams for SepTiC APIs - this will be a place for APIs to communicate with each other.

We will monitor this channel but will leave it up to the APIs to lead any discussions and raise questions.

All APIs will be sent a link to join this- any new APIs that would like to join, please send an email to septic@imperial.ac.uk.