IMPERIAL

Anaesthetics, Pain, Medicine and Intensive Care

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25.08.2026

IRAS Reference - 1005848
REC Reference – 23/LO/0339

SepTiC Trial Modification - AM013

Dear HRA, REC and MHRA,

We would like to submit a substantial modification for the SepTiC trial.

We would like to make the following changes:-

1. Protocol updates, please see main changes listed below:-
    - Change the sample size from 3758 for the diagnostic and fluid trials to 1300
    - Change the sample size from 1300 for the GM-CSF trial to 400
    - Update the statistical analysis and rationale for the sample size change detailed in section 9. Statistical Analysis.
    - Update to the archiving duration from 10 to 25 years.
2. We would like to update the end date to the trial to 31st August 2028.
3. We would like to make a change to our privacy notice regarding international transfer of data.

The below documents are included in this submission:

SepTiC_Protocol_V3.0_20260428_TC

SepTiC_Protocol_V3.0_20260428_Clean

SepTiC Privacy Notice v2.0 25.08.2026_TC

SepTiC Privacy Notice v2.0 25.08.2026_Clean

Please do not hesitate to contact us should you require further information.

Digitally signed by
Janis Best-Lane
Date: 2026.08.28
11:14:27 +01'00'

Kind regards,
Janis Best-Lane
Senior Trial Manager
Imperial College London