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REC Reference: 23/LO/0339

IRAS Reference: 1005848

Dear HRA, REC and MHRA

SepTiC Trial Substantial Amendment AM002

I am writing to you regarding the submission of substantial amendment for the SepTiC Trial.

We would like to submit the following changes:-

1. We have updated the IRAS (CWOW form) to clarify Victoria Pharmaceuticals (our labeller and distributor) as part of our manufacturing process and providing the finished IMPs to site. Tanner Pharma UK Limited are an importer site. The IMP is imported to Tanner UK, then to Victoria Pharmaceuticals for labelling and final release to sites.

2. Add a non-NHS site, Cleveland Clinic London, to the study

All information has been updated on the attached amendment tool

If you need any further information or documentation please let me know.

Yours sincerely

Janis Best-Lane

Clinical Trial Manager – SepTiC Trial