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Date: 27 May 2020

Full Title: multi-Arm Therapeutic study in pre-ICU patients admitted with Covid-19 – Experimental Drugs (TACTIC-E)
Short Title: TACTIC-E
EUDRACT Number: 2020-002229-27
IRAS Number: 283769

Dear Sir/Madam,

I am writing to submit the documentation listed below for **urgent review** in support of the application to the HRA to conduct the above-named trial.

TACTIC-E is a randomised, parallel arm, open-label, platform trial of potential disease modifying therapies in patients with late stage 1/stage 2 COVID-19-related disease, with a diagnosis based either on a positive assay or high suspicion of COVID-19 infection by clinical and radiological assessment.

TACTIC-E is part of the TACTIC programme of research that will look at repurposing drugs and experimental drugs in the management of COVID-19 related complications.

The aim TACTIC-E trial is to determine if a novel immunomodulatory intervention reduces the composite progression of patients with COVID-19-related disease to organ failure or death.

The trial will be solely sponsored by Cambridge University Hospitals NHS Foundation Trust.

Please find enclosed the following documentation in support of our application for review.

Document	Version	Date
Cover letter	n/a	27/05/2020
IRAS Clinical trial application form in PDF	n/a	27/05/2020
Application checklist	n/a	27/05/2020
Chief Investigator CV	n/a	07/04/2020
TACTIC-E Protocol	1.0	27/05/2020
TACTIC-E PIS & ICF	1.0	27/05/2020
TACTIC-E Short PIS	1.0	27/05/2020
TACTIC E Endothelial cells collection PIS	1.0	27/05/2020
TACTIC-E GP Letter Ambrisentan+Dapagliflozin	1.0	27/05/2020
TACTIC E GP letter EDP1815	1.0	27/05/2020
TACTIC-E GP Letter Standard of care	1.0	27/05/2020
TACTIC-E Patient ID Card	1.0	27/05/2020
Ambrisentan SmPC	n/a	12/11/2018
DapagliflozinSmPC	n/a	02/01/2020
EDP1815 Investigator's Brochure	2.1	28/01/2020
HRA OID	1.0	27/05/2020
modified Draft mNCA	1.0	27/05/2020
SoECAT	0.2	26/05/2020
Peer Reviews	n/a	n/a
Confirmation of Funding (Astrazeneca PLC)	n/a	18/05/2020
Confirmation of Funding (Evelo Biosciences)	n/a	22/05/2020
TACTIC-E Poster and social media wording	1.0	27/05/2020

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

I look forward to hearing from you in due course.

Many thanks.

Dr Joseph Cheriyan