REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

7th January, 2021

Dear REMAP-CAP sites,

RE: Immunoglobulin Domain in Severe State

I am writing to inform you of decisions that have been made by the REMAP-CAP international trial steering committee (ITSC) in response to communication from the Data Safety Monitoring Board (DSMB).

After reviewing the results of interim analyses and safety reports, the REMAP-CAP DSMB have notified the ITSC that the COVID-19 convalescent plasma intervention has reached a prespecified threshold for futility for patients in the Severe State as a whole (admitted to an Intensive Care Unit and receiving one or more qualifying organ failure supports). There were no concerns regarding the overall safety of convalescent plasma for COVID-19 patients in the Severe State. The unanimous recommendation of the DSMB was that this domain be closed for patients in the Severe State. This is occurring as a 'pause' pending additional analyses and completion of follow-up of already enrolled participants, which are being undertaken urgently.

This recommendation has been accepted by the ITSC. This has been implemented within the REMAP-CAP eligibility system at all sites recruiting patients in the Severe State.

For current participants who are enrolled in the immunoglobulin domain in the Severe State and have been assigned convalescent plasma, the recommendation of the ITSC is for the treating clinician to complete the convalescent plasma treatment.

The DSMB recommended that patients in the Moderate State (hospitalised patients not requiring organ failure support in an intensive care unit) continue to be enrolled and randomised in the immunoglobulin domain. This recommendation has also been accepted by the ITSC and the domain remains available for randomisation of patients in the Moderate State. The DSMB have made no recommendation to modify the protocol and, at this time, patients enrolled in Moderate State should continue their treatment assignment as specified in the trial protocol.

Whilst we work to complete follow-up, analyse and report these findings as soon as possible, we request that sites and blood services make this information available only to relevant staff prior to a public statement, which should be issued shortly.

On behalf of the REMAP-CAP ITSC I would like to thank the DSMB and the Statistical Advisory Committee for their vital work in ensuring the safety of participants enrolled in REMAP-CAP. I would also like to sincerely thank all investigators, research coordinators, blood services, clinical and laboratory staff, donors, participants and their families who continue to support REMAP-CAP and the generation of evidence for the treatment of COVID-19.

If you have any questions about any of the above, please don't hesitate to contact me.

Sincerely,

Professor Steve Webb
Chair,
REMAP-CAP International Trial Steering Committee

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