

9th January, 2023

Dear REMAP-CAP sites,

RE: REMAP-CAP Simvastatin Domain

We are writing to inform you of a decision that has been made by the REMAP-CAP International Trial Steering Committee (ITSC) to close recruitment to the Simvastatin Domain of REMAP-CAP.

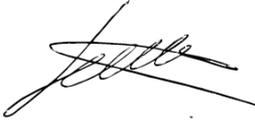
To date, over 2,900 participants have been randomized to the Simvastatin Domain, without having reached a pre-defined statistical trigger. On the basis of simulations conducted by the REMAP-CAP statisticians at Berry Consultants, it has been concluded that this domain is likely to be sitting at an indeterminate point between statistical triggers for superiority and futility, and that the likelihood of meeting a statistical trigger for futility or superiority of simvastatin is low despite ongoing recruitment to this domain.

In light of these simulations and the low likelihood of reaching a statistical trigger with continued recruitment to this domain, it is therefore considered that continuation of enrollment to this domain is operationally futile. In the interests of making data regarding the optimal treatment for COVID-19 available to the public while it still has relevance for clinical care, the REMAP-CAP ITSC has made the decision to close recruitment and report the results of this domain. This decision has the support of the REMAP-CAP DSMB.

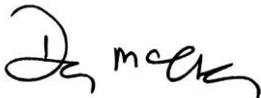
We recommend that for participants who have been allocated to the simvastatin intervention within this domain, administration of simvastatin should continue as per the Simvastatin Domain-Specific Appendix.

Updates will be forthcoming when available. We thank you sincerely for your participation in the Simvastatin Domain, and REMAP-CAP overall, as we continue to evaluate optimal treatment for CAP and COVID-19. We look forward to sharing the results of this domain with you, and the public, as soon as they are available.

Sincerely,



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