

9th April, 2021

Dear REMAP-CAP sites,

RE: Immune Modulation Domain Platform Conclusion

I am writing to inform you that on the 8th of April we received correspondence from the REMAP-CAP DSMB notifying us of Platform Conclusions arising from an adaptive analysis.

Previously, an adaptive analysis revealed that within the COVID-19 Immune Modulation Domain both [tocilizumab and sarilumab](#) had reached platform conclusions for efficacy when compared to the ‘no immune modulation’ intervention. As a result, the ‘no immune modulation’ intervention was closed, and the COVID-19 Immune Modulation Domain continued as a comparison between available active interventions (anakinra, interferon- β 1a, tocilizumab, and sarilumab). Since this time, more than 900 additional participants have been randomised to this domain.

The results of the most recent adaptive analysis, communicated to us by the DSMB, indicate that tocilizumab and sarilumab have now reached the statistical trigger for equivalence.

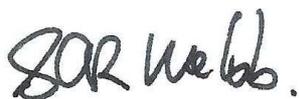
These results provide a clear indication that tocilizumab and sarilumab are equally effective for the treatment of patients with severe COVID-19, and are also the most effective interventions included in this domain. The REMAP-CAP ITSC have therefore decided to pause recruitment to this domain. A full analysis of all interventions included in this domain, including anakinra and interferon- β 1a, will be completed and the results made available as soon as possible.

Participants who have received an allocation to any intervention in the COVID-19 Immune Modulation Domain should continue to receive their allocated intervention, unless the treating clinician believes that doing so would not be in the best interests of the patient.

As part of this routine adaptive analysis the DSMB also reviewed the other domains included in the Pandemic Statistical Model (the Macrolide Duration Domain, Antiplatelet Domain, Vitamin C Domain, and Simvastatin Domain), as well as safety reports for all active domains. At this time the DSMB had no safety concerns and has recommended continuing enrolment to these domains.

I would like to thank the investigators, research coordinators, participants and their families, who continue to support REMAP-CAP for their contribution to these important findings.

Sincerely,



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