



Wednesday 3 June 2020

To: National Principal Investigators of the Solidarity Trial
From: Executive Group Solidarity Trial

Subject: Follow-up to the letter of 24 May 2020 on emerging non-randomized evidence regarding use of hydroxychloroquine for the treatment of COVID-19 among hospitalised patients.

Dear Solidarity Trial Principal Investigator,

Following due diligence, all actions indicated in the aforementioned letter have been taken. The SOLIDARITY Data Safety Monitoring Committee (DSMC) members met today via video conference and the Executive Group of the Trial met immediately after.

On the basis of the available mortality data of SOLIDARITY, and also considering the letter of the DMC of the RECOVERY trial, the members of the SOLIDARITY DSMC unanimously agreed that there are no cogent reasons to recommend modifications of the protocol of the trial, and advised that the trial should be continued as planned.

For easy reference, here is content of the Recovery DMC letter. "The Committee reviewed the external evidence from the non-randomised observational study (Mehra et al. Lancet May 22nd 2020) and the evidence from the RECOVERY trial on the effects of hydroxychloroquine on mortality among patients admitted to hospital with COVID-19. We saw no cogent reason to suspend recruitment for safety reasons."

The Executive Group has decided, based on the DSMC advice, to resume the inclusion of patients in the hydroxychloroquine arm. Therefore, with immediate effect the randomization software will be reset to allocate newly randomized patients to hydroxychloroquine. Add-on trials such as the pan-European Discovery trial of Solidarity will likewise reset randomization to allocate to hydroxychloroquine. We thank all of the Solidarity principal investigators for your efforts to generate data on the potential effectiveness of all the drugs included. Should you have any questions please do not hesitate to contact one of the 3 co-leads of the WHO trial secretariat.

With best regards,

The Executive Group of the Steering Committee of the SOLIDARITY trial
John-Arne Røttingen (Chair), Quarraisha Abdool Karim, Marissa M. Alejandria,
César Hernández García, Marie-Paule Kieny, Reza Malekzadeh, Srinivas Murthy,
Srinath Reddy, Mirta Roses Periago, Richard Peto (observer from the DSMC)
and Soumya Swaminathan (on behalf of WHO)