EUCROF
European CRO Federation

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Attn Dr Fergus Sweeney
Head of Inspections, Human Medicines Pharmacovigilance & Committees Division

13 March 2020

RE: CORONAVIRUS and Clinical Trials

Dear Dr Sweeney,

With the Coronavirus pandemic and the emergency situations across Europe, there are challenges arising that affect the proper conduct of clinical trials as per the current GCP regulations and guidelines.

In the last days, we have seen advices from a few national authorities such as the MHRA in the UK *(https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/)* and AIFA in Italy *(https://www.aifa.gov.it/web/guest/-/gestione-degli-studi-clinici-in-italia-in-corso-di-emergenza-covid-19-coronavirus-disease-19-)*.

For the performance of multinational clinical trials, a harmonised approach for handling the critical situation would be beneficial.
Is the EMA going to issue some advice as to how best behave so that clinical trials are not endangered to be considered as GCP non-compliant?
The emergency situation requires a different approach to guarantee the safety of the patients, the trial sites and the sponsor/CRO trial personnel and at the same time ensure the trial is GCP compliant.

We are looking forward to your response and wish to thank you very much in advance.

Yours Sincerely,

Dr Martine Dehlinger-Kremer
EUCROF President

Mob.: +49 15256772444
president@eucrof.eu