INFORMATION REGARDING THE MRC-ECCP'S SPECIAL MEASURES DURING THE SITUATION OF EPIDEMIOLOGICAL PREPAREDNESS INTRODUCED DUE TO THE COVID-19 PANDEMIC

In formulating its professional and ethical position statements related to the implementation of trials in progress, patient recruitment, the opening of new trial sites, the enrolment of new patients and in particular the launch of new trials, the MRC-ECCP (Medical Research Council – Ethics Committee for Clinical Pharmacology; in Hungarian: "*Egészségügyi Tudományos Tanács – Klinikai Farmakológiai Etikai Bizottság*") primarily takes into account the interests and protection of rights of the patients and healthy people participating in the trials.

Our Committee deems it important to ensure that clinical trials in Hungary that comply with the professional rules and the law also continue during the period of the epidemiological preparedness.

1) Risk assessment

The Committee performs risk assessment in the scope of the procedure for authorising trials. It is, however, the responsibility of the sponsor and the principal investigator to conduct a new risk/benefit analysis before starting/restarting a trial or enrolling new patients (please refer to Guidance[1]). In the current pandemic situation, the increased risk of infection due to the virus outbreak is a constant risk during trials and visits involving patient selection. The severity and extent of this risk may vary per trial site and trial.

2) Facilitation

Prioritised evaluation: The Committee will evaluate clinical trials submitted in connection with SARS-COV-2 infections as a matter of urgency, out of its normal order of business (naturally the requirement of professional well-foundedness and the ethical principles must still be met);

GCP acceptance: Until 31 December 2020, the Committee will accept the GCP certificates of principal investigators even if they have expired/are invalid, provided that the persons concerned attach their application to the next accredited GCP course organised (whether online or not) by a university in Hungary. A copy of the GCP certificate must be submitted until 31 December 2020.

3) Patient Information Sheets and Informed Consent Forms

- The text of these documents must be supplemented to include the safety measures taken during the period of the situation of epidemiological preparedness.

- If the patient is unable to visit the site for the consenting procedure and to sign the Patient Information Sheet and Informed Consent Form, the investigator/principal investigator may provide the documents to the patient either via regular post or electronically or via a courier service so as the patient can review them. The patient

may ask his/her questions to the principal investigator or the principal investigator's representative by a phone or video call. After all questions have been answered and if the patient decides to participate in the trial, he or she will sign the documents in the (concurrent) presence of two witnesses. The document must also be signed (including name and address) by two witnesses who do not participate and have no vested interest in the trial, who certify that the patient has signed the documents in their presence or has recognised the earlier signature as his/her own in their presence.

The documents must then be returned to the trial site with the help of the sponsor by one of the above specified way.

- Detailed information must be provided regarding any alternative visits (phone or video call) to be conducted in the patient's home, the home delivery of the trial medicinal products and any other assets, the use of courier services (the name and address provided to them and the means of keeping in contact), etc. The Informed Consent Form must, similarly to those described above, contain the patient's consent thereto.

The Committee considers it possible during the period of the situation of epidemiological preparedness to join the Supplemental Patient Information Sheet and Informed Consent Form – compliant with the foregoing – into one document. Please note that in addition to the Patient Information Sheet, the Informed Consent Form must also include all items to which the patient consented in detail.

4) Supplemental changes

If a supplemantal change takes place in the course of a trial in progress, the attention of the sponsors and applicants must be drawn to the CTEG[1] recommendations and the above information in relation to remote monitoring, the issue/distribution of the trial product, as well as other matters related to reports, visits and communication.

Budapest, 3 November 2020

The Clinical Trials Expert Group (CTEG), the Clinical Trials Facilitation and Coordination Group (CTFG), the Heads of Medicines Agencies (HMA) and the GCP Inspectors' Working Group – under the coordination of the EMA – formulated recommendations regarding the measures to be taken in the present pandemic situation with the title "Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic". This document is available on the website of the Hungarian National Institute of Pharmacy and Nutrition (in Hungarian: "*Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet"*) based on the document titled "Information regarding the continuity of clinical trials during the COVID-19 (Coronavirus) situation, 05.05.2020". The MRC-ECCP will make its decisions having regard to these recommendations.