INFORMATION ABOUT CONDITIONAL POSITION STATEMENTS ISSUED DURING THE HEALTHCARE EMERGENCY CREATED BY THE COVID-19 PANDEMIC[1]

1) According to European and Hungarian recommendations[1] , the MRC ECCP issues its professional/ethical position statements on the execution of ongoing studies, patient recruitment, the start-up of new study sites, the enrolment of new patients and, in particular, the initiation of new studies, first and foremost with the interests of the patients in mind.
2) The Committee conducts risk analysis for studies continued or started. Constant risks include the increased risk of infection associated with undergoing tests required for inclusion in the study and completing study visits during the present extraordinary situation created by the coronavirus epidemic.
3) Bearing all this in mind, an otherwise satisfactory protocol will only be endorsed *unconditionally* by the Committee if the study offers a cure or a relief to a patient population suffering from a severe, life-threatening and progressive disease with no proper therapy, such as oncological, severe cardiovascular, certain autoimmune and some rare genetic conditions.
4) In all other cases, the Committee *will set the following prerequisite* for starting studies: "Studies in Hungary may only be commenced following the official announcement of the end of the coronavirus epidemic."
5) Similarly, the Committee will apply the same prerequisite for the inclusion of new patients - if the Applicant proposes an amendment to increase the number of patients - or the inclusion of new, otherwise suitable study sites in an already started study.

All these changes will be reflected by the position statements issued by the Committee after 23 March 2020 and will remain in effect until the official end of the epidemic.

6) At the same time, the Committee will also implement some simplifications and concessions for the evaluation of the original protocols and their substantial modifications.
7) They include the following:

- Clinical drug trials involving COVID-19 will be given priority and will be evaluated as a matter of urgency, given priority over others (though naturally, they will still need to fully comply with the principle of scientific soundness as well as ethical principles). The GCP certifications of Principal Investigators will be accepted even after their expiry until 31 December 2020, provided that they attach their application for the next (even online) Hungarian GCP course.
- During ongoing studies, in the context of substantial modifications, we would like to draw the attention of the Sponsors and Applicants to CTEG[1] recommendations and information provided by the NIPN[1] with regard to remote monitoring, dispensation of the investigational product, reports, visits and communication issues.

All other issues will be subject to individual assessment.

Budapest, 3 April 2020

Prof. Dr. Zsuzsanna Fürst
University Professor
Chairman of the MRC ECCP

1.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, subject to coordination by the EMA, formulated recommendations under the title "Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic" for measures to be taken in the current epidemiological situation. The MRC ECCP makes its decision based on the document "Information on the continuity of clinical trials during the COVID-19 (coronavirus) pandemic - 24/03/2020" available on NIPN's website, taking the recommendations into account.