Recommendations for conducting clinical trials in a COVID-19 (coronavirus infection) pandemic

2020-03-18, updated 23/03/2020

With regard to the 14th Resolution No. 207 of the Government of the Republic of Lithuania on the "Quarantine Announcement of the Republic of Lithuania" and in response to inquiries from biomedical research, including clinical trials (hereafter "clinical trials"), sponsors, client representatives, and research centers on clinical trials for COVID-19 (coronavirus infection) in the event of a pandemic, the Lithuanian Bioethics Committee makes the following recommendations.
Please note that these guidelines will be supplemented or amended on an ongoing basis in the light of changing circumstances, incoming inquiries and decisions by the competent authorities.

• In the light of the 2020 March 14 Government of the Republic of Lithuania 207 "On the announcement of quarantine in the Republic of Lithuania", the work of the Lithuanian Bioethics Committee shall be organized and the applicants shall be provided remotely, except when it is necessary to perform the relevant functions in the workplace. Therefore, we request that documents related to biomedical research be submitted through the Electronic Government Gate or by email to lbek@bioetika.sam.lt. Clinical trial counseling is available by tel. 8 5 261 0632.

• Clarify that the Lithuanian Committee on Bioethics will prioritize the evaluation of new applications related to COVID-19 and ongoing clinical trial modifications required by COVID-19. With this in mind, please note in the accompanying letter that the application relates to COVID-19 when submitting new clinical trial applications, major clinical trial amendments, or changes to biomedical studies. This will help prioritize their evaluation.

• Due to limited visits to research centers and the increased workload of investigators (health care professionals), the subjects may be subject to self-isolation, study visits, and study drug use according to the study protocol. The safety of subjects is a top priority, and investigators and investigators should re-evaluate the risks of COVID-19 infection responsibly against the benefits to the subject and to the community before embarking on new studies, continuing patient involvement, and deciding on further study participation).
• When initiating a new clinical trial or continuing to enroll patients in an ongoing clinical trial, it is advisable to evaluate the feasibility of conducting clinical trial visits during the quarantine period and to consider temporarily suspending enrollment and initiation of new trials / trial centers, possible.

• The initiation of a clinical trial involving at-risk subjects, immunosuppressed patients> 60 years of age and / or sufferers of chronic diseases (this list is not exhaustive and is subject to evaluation by a physician). It is also important to consider whether treatment with the study does not increase the risk of COVID-19 in the subjects.

• It is recommended to postpone, as far as possible, study visit visits to the study center in accordance with the protocol, and to replace them by telephone or other telecommunication to detect adverse events and ensure continuity of medical care. If necessary, the sponsor may, in exceptional cases, consider moving the subject to another study center to ensure the patient's continued participation in the clinical trial.

Organize patient and patient streams in necessary clinical trial visits and services that would result in the need or significant deterioration of the subject's medical care to avoid accidental direct patient-staff contact, and use the necessary safeguards during the visit.

• If repeated consent is needed from subjects already enrolled in the clinical trial, situations in which subjects should only come to the trial center to sign an updated informed consent form should be avoided.

• If subject consent is required to implement new urgent security measures (possibly due to changes related to COVID-19), alternatives to obtaining consent during the quarantine period should be

considered, for example, by contacting the subject via telephone, video call or other remote communication, and with their verbal consent, which should then be confirmed by email. Such consent should be documented and confirmed as part of the normal consent procedure as soon as possible and subject to further visit to study centers.

• As a reminder, in the case of critical illnesses or other medical conditions requiring emergency medical assistance, the individual and any other person who may have consented to the trial may be informed and consent to the trial may be obtained after inclusion in the biomedical trial, provided that all the conditions laid down in Article 7 (6) of the Biomedical Research Ethics Act.

• Where possible, alternative ways of delivering investigational medicinal products to the subject should be considered, such as delivering the investigational medicinal product from the study center to the patient's home, ensuring proper storage and use of the investigational medicinal products infection control conditions and subject confidentiality.

• Given the limitations of clinical trial monitoring and auditing in research centers, it is advisable to consider alternative options, such as central monitoring.

• We understand that protocol deviations may increase. They must be properly documented in the research center (ICH GCP Rules E6 clause 4.5.3).
• Reminder that when the sponsor and / or investigator is required to take urgent safety measures to protect subjects from the immediate danger associated with conducting a clinical trial, the sponsor and investigator may take appropriate emergency precautions without notifying the Lithuanian Bioethics Committee. to inform the Lithuanian Committee on Bioethics, measures taken and further action plan.

• If the changes affect the safety and well-being of the subjects and / or the scientific value of the study but do not require immediate action by the sponsor and the investigator, they should be submitted as a substantial amendment to the clinical trial. Description of Procedures for Conduct and Control of Investigations approved by Minister of Health of the Republic of Lithuania May 31 Order no. V-435 on the Approval of the Description of the Procedures for the Approval of Clinical Trials and Authorization of Clinical Trials, Conduct of Trials and Controls, in accordance with Chapter IV. • It should be noted that any changes to the conduct of clinical trials should not place an unreasonable additional burden on the research center or investigators (personal health care professionals).