Recommendations for conducting clinical trials in the context of COVID-19 (coronavirus infection) pandemic

3/18/2018

With regard to the Government of the Republic of Lithuania 14th Resolution No. 207 on the "Quarantine Announcement of the Republic of Lithuania" and in response to inquiries from biomedical research, including clinical trials (hereafter "clinical trials"), sponsors, 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 constantly updated or modified to take account of ever changing situations, incoming inquiries and decisions by the competent authorities (GCP IWG, Clinical Trial Promotion Group and CTFG). recommendations for conducting clinical trials during the COVID-19 pandemic in the EU and the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania, which are expected to be published in the near future).

• 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, please submit documents related to biomedical research through the Electronic Government Gate or by email to lbek@bioetika.sam.lt. Clinical trial counseling is available by tel. 8 5 261 0632.

• We clarify that the Lithuanian Committee on Bioethics will prioritize the evaluation of new applications related to COVID-19 (coronovirus infection) and ongoing clinical trial corrections required by COVID-19 (coronovirus infection). In this regard, please note in the application for new clinical trial applications, major changes to clinical trials, or changes to biomedical studies that the application relates to COVID-19. This will help prioritize their evaluation.

• Please note that urgent safety action may be taken in accordance with the Good Clinical Practice Statement.

• We understand that protocol deviations may increase. They must be properly documented in the research center (ICH GCP Rules E6 4.5.3).

• 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 assess the feasibility of conducting clinical trial visits during the quarantine period and to consider suspending enrollment in ongoing clinical trials and initiating new trials, if appropriate. 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 that the immunosuppressive regimen used in the study may increase the risk of COVID-19 in subjects.

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

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

• 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 infections