

# ŠÚKL GUIDANCE FOR THE CLINICAL TRIALS IN SLOVAKIA DURING THE EXCEPTIONAL COVID-19 SITUATION

Version 1 (2.4. 2020)

In connection with the increasing number of questions regarding limitations on ongoing clinical trials in Slovakia during the COVID-19 emergency situation, ŠÚKL issues the following recommendations, which will be continuously updated:

## **1. Provision/securing of health care to participants in the clinical trial (hereinafter referred to as “KS”)**

- we recommend, if possible, in agreement with the sponsor of the clinical trial, the postponement of the participant's personal visit to the centre of the clinical trial for telephone control due to their safety, closure of the medical facility or recommendations of restricted movement of natural persons issued by the government. The telephone contact should be properly documented in the medical records, including the reason for contact, epidemiological facts (e.g. a participant of the KS is in quarantine) and consent to a new procedure (e.g. telephone visits, sending the test product by courier). We recommend confirming the participant's consent to the new procedure by e-mail if possible. Later, when the situation stabilizes and it is possible to visit the centre of the KS, it is necessary that the participant of the KS confirms their consent to any changes during epidemiological constraints by signing a new version of the Informed consent;  
In the case that a follow-up visit to the centre of the KS is postponed or completely omitted with a view to ensuring the safety of participants of the KS, it is necessary to document and subsequently assess the impact on the validity and quality of clinical trial data;
- If a visit to the centre of the KS is necessary and the medical facility allows it, it is necessary to take as many sanitary precautions as possible to avoid accumulation of patients (e.g. telephone ordering, time reserved for follow-up visits outside normal patients) and provide protective equipment for both participants of the KS and medical staff. Protective equipment is to be provided by the sponsor of the KS (Section 43 (h), point 1 of Act no. 362/2011 Coll.

## **2. Provision of the investigational medicinal product (hereinafter referred to as “IMP”) to participants of the KS**

- One option may be to provide IMP and non-IMP for a longer period of time than originally planned;
- In order to minimize visits to healthcare facilities, we recommend, if possible (e.g. the pharmaceutical form is suitable for home administration and storage), to use an

authorized carrier who will arrange the transport of an IMP from the centre of the KS to the participant of the KS to their place of residence. Delivery of the IMP to the participant of the KS directly from the sponsor of the KS is not allowed in Slovakia. It is the principal investigator who is responsible for the transport of the IMP to the participant of the KS, the costs of which are borne by the sponsor of the KS (contractual arrangement). The sponsor of the KS will also ensure that the personal data of the participant of the KS is protected (contractual conditions), i.e. unauthorized persons, including the sponsor of the KS, will not access the personal data of the participant of the KS (name and address). GMDP and GCP requirements for IMP transport and storage should be maintained (e.g. transport temperature control). The transporter/carrier will be ordered by the principal investigator and then the principal investigator will confirm the receipt of the IMP with the participant by telephone, which he/she will record in the source documentation of the participant of the KS. The participant of the KS must be trained to administer and store the IMP. IMP transport should be documented in accordance with GCP requirements. Records from the IMP transport, containing the personal data of the participant of the KS, should be kept at the centre of the KS for traceability. If it is necessary to keep copies of the records of transport of the IMP on the part of the sponsor of the KS in TMF e.g. documentation of protocol deviation, pseudonymized copies will be provided that do not allow identification of the participant of the KS. In case the transport of the IMP from the centre of the KS directly to the participants of the KS represents an enormous burden on the centre of the KS, it is possible to entrust this activity to other health care workers, while the responsibility remains with the principal investigator (GCP 4.2.5, 4.2.6);

- if the participant of the KS is to bring the rest of the unused IMP during the planned visit, it can be instructed not to use the remaining packages and put them as long as they can come to the principal investigator, if applicable;
- another possibility is for relatives of the participant of the KS to collect the IMP after telephone verification of such an option by the principal investigator of the centre of the KS with the specific participant of the KS. Subsequent acceptance of the IMP with the participant of the KS will be verified by telephone by the principal investigator and recorded in the source documentation together with information on the previous issue of the IMP to a relative;
- for each, the sponsor will ensure study detailed written instructions for the principal investigator concerning the distribution of the IMP to the participants of the KS and will send them to ŠÚKL for information;
- if the assistance of a physician/doctor or other health care professional is necessary for the administration of the IMP and the participant must visit the centre, we recommend that the personal visit of the participant at the centre be postponed for as long as possible. If it is not possible to postpone the administration of the IMP at the centre of the KS, or it has already been postponed for the maximum possible time, the administration of the IMP at the centre of the KS should be carried out in

compliance with the safety hygiene (mentioned above in the provision of health care).

### 3. Monitoring of the KS

In accordance with the EMA guideline for management of the KS during the COVID-19 pandemic, we are aware of the significant impact on the performance of the supervisory of the sponsor by a designated person called monitoring. The monitors will not be able to carry out personal monitoring visits to centres of the KS according to the monitoring plans. The sponsor must therefore find alternative options in order to preserve the security of participants of the KS and preserve data integrity and quality.

In line with the EMA Guideline, we recommend and complement the local legislative framework as follows:

- cancellation or postponement of personal monitoring visits to centres of the KS for the period after the COVID-19 pandemic (when the situation stabilizes) and/or extension of intervals between visits to centres of the KS;
- implementation of telephone or video calls, if this does not represent an increased burden on the centre of the KS and at the same time the rights of participants of the KS in terms of their physical integrity and mental integrity, the right to privacy and the protection of personal data are guaranteed (§30 c) of Act no. 362/2011 Coll.);
- updating monitoring plans based on new risk assessments, including additional or increased centralized monitoring where possible and meaningful (e.g. centrally generated electronic documents such as pseudonymized ECG, drug laboratory safety results called „drug accountability sheets“);
- remote control of data sources (remote source data verification, hereinafter referred to as “SDV”) kept by the healthcare provider in writing, whether in the form of identifying the participant of the KS or in a pseudonymized copy of the medical documentation, is not allowed in Slovakia. According to §2 par. 1) and par. 12) Act no. 576/2004 Coll. health care includes, inter alia, biomedical research, which includes clinical trials on a human medicine. In addition, the Act stipulates, in §25, to whom and how the disclosure of the data from the medical records necessary for the SDV are provided. The data is provided in the form of consultation/insight, whom it is given to. Section 2 of that paragraph refers to the possibility of making copies or extracts, but only at the site. Further, in accordance with GCP requirements, the monitor cannot be sure that it has been provided with the participant's medical documentation for the remote SDV of pseudonymized source data, whether there was no accidental confusion between the participants of the KS, furthermore, whether he/she has been provided with the complete documentation of the relevant participant of the KS, or whether there was no accidental or deliberate failure to provide all necessary data. Last but not least, remote SDV by means of pseudonymized source data in PDF format would represent an increased burden on the centre of the KS;

- During this emergency situation, remote selection visits of the centre of the KS and training activities of the centre of the KS are allowed, if necessary, providing they do not increase the burden on the centre.