KLH-CTIS-01

Version 1 of 20 January 2022

The Guideline Ethics Committee – SÚKL stipulates the requirements governing documents to be submitted with Part II of application for clinical trial authorisation:

1. Patient information sheet / informed consents *(to be entered into CTIS in Part II – Subject information and informed consent form)*

- The Czech version of the patient information sheet/informed consent meeting the requirements set forth by Regulation 536/2014, chapter V, and Directive GCP ICH E6 (R2), point 4.8.10, shall be submitted.
- The original English version shall not be submitted as it will not be assessed or approved. It is not permissible to submit bilingual versions.
- In case of inclusion of foreigners, where the text of the patient information sheet/informed consent must be in a language that the foreigner provably understands (ideally his/her native tongue), it is required that a certified translation of the Czech version of the document be safeguarded. This document shall be submitted via CTIS as a non-substantial amendment.
- In case minors are to be included, SÚKL requires that written patient information sheet for the age groups of 12-14 years and 15-17 years be submitted. By signing this document, the minor individual confirms his/her free will to participate in the clinical trial. Younger minors may sign the informed consent together with their parents, i.e., in the same document, to express their will to participate in the clinical trial. Signature of minors under the age of 11 years is not mandatory.
- In the preparation of subject information, it is advisable to observe guideline KLH-22 - here

2. Materials for trial subjects *(to be entered into CTIS in Part II – All documents)*

- The sponsor shall be obliged to submit materials intended for trial subjects in the Czech language:
- Diaries, cards with information about participation in the clinical trial, questionnaires, etc.
- Questionnaires may be submitted in the English language only if they are to be completed by the doctor together with the trial subject.
- Instructions for use of medicinal products, if applicable (e.g., in the case of product self-application by the trial subject, where subcutaneous, intramuscular, etc. administrations are concerned).
- Instructions for use of medical devices – if applicable. For medical devices, it is necessary to submit the CE mark, Declaration of Conformity, IFU in the Czech language, and information on how servicing etc. has been safeguarded.
  Where a medical device that has not been CE-marked by any European authority is concerned, but it has been approved for use for instance by FDA, it is necessary to evidence this information and provide other aforementioned documents (such as the IFU in the Czech language, information on how training in the use of the medical device and servicing will be safeguarded…).
  In case of medical devices without any registration, it is necessary to submit a declaration to the effect that the sponsor has applied or will apply for clinical investigation of the medical device with the concerned SÚKL unit (Medical Device Department).
- The sponsor is notified of their obligation to ensure contact for potential defect of or other problems with the medical device (e.g., a Helpdesk); this contact must be capable of communication in the Czech language.

3. Recruitment materials *(to be entered into CTIS in Part II – Recruitment Arrangements)*

- The sponsor shall submit completed **template.cz no. 1 Recruitment and Informed consent procedure**; if the sponsor does not use the template, the same information must be provided in another document and referenced appropriately.
- Furthermore, complete recruitment materials shall be submitted (advertisements, leaflets, other materials as appliable).
- In case other than printed recruitment materials (audio, video,...) are used, these formats must be submitted as well.

4. Investigator *(to be entered into CTIS in Part II – Suitability of the investigator)*

- The following documents must be submitted for the approval of the investigator or for principal investigator only where more doctors at the site will be involved in the clinical trial:
- Current CV – please use attached **template.cz no. 2 Investigator Curriculum Vitae** and **template.cz no. 3 Declaration of Investigator´s of Interest**, to be completed by the investigator or principal investigator in the Czech language, dated and signed thereby. If the investigator does not use template.cz no. 2 for the CV, the other CV format used must contain all of the data included in this template.cz.
- The sponsor shall not submit the list of co-investigators or other study team members or a proof of investigator´s or principal investigator´s training in good clinical practice principles – these documents must be available at the trial site for the purposes of monitoring, inspections, and audits.

5. Trial site *(to be entered into CTIS in Part II – Suitability of the facilities)*

- For trial site approval, please submit completed **template.cz no. 4 Site Suitability**.
- Non-state healthcare facilities shall be obliged to submit a document (scan) evidencing that the site is a healthcare facility (issued by the regional authority) and the scope of authorised operation (specialties– e.g., orthopaedics, internal medicine,…).
- In case some of the assessments or procedures specified by the protocol are not to be performed by the trial site itself, it is necessary to specify who they have been outsourced with (e.g., MRI, CT, eye examination, ECHO...).
- Sites conducting bioequivalence studies (BE), pharmacokinetic studies and First-in-Human (FIH) studies, who, pursuant to Section 54(3) of Act No 378/2007 Coll., on Pharmaceuticals, as amended by Act No 66/2017, must be holders of a good clinical practice certificate issued by SÚKL, shall submit this certificate (a scan thereof).

6. Insurance *(to be entered into CTIS in Part II – Proof of insurance cover or indemnification)*

- It is necessary to submit the complete insurance contract, including insurance terms and conditions (in the Czech language or as a bilingual document). The submission of insurance terms and conditions is absolutely necessary.
- Sponsor´s declaration on how injuries to health arising only after the completion of the clinical trial and after insurance contract termination are to be compensated if it is provably evidenced that the injury to health was caused by participation in the completed clinical trial.

7. Personal data processing *(to be entered into CTIS in Part II – Compliance with national requirements on Data Protection)*

- Submission of **Sponsor´s declaration on personal data processing in the concerned clinical trial - Form no. 5** signed by the sponsor.

8. Biological samples for future research *(to be entered into CTIS in Part II – Compliance with use of biological samples)*

- Subject's consent with the storage and use of biological samples obtained in the course of the clinical trial for future research may form part of the patient information sheet/informed consent form, where a separate signature of this consent will be required; or a separate document to be signed by the trial subject will be submitted.
- The information submitted for consent purposes should contain information on the duration of sample storage, whether the samples will remain pseudonymised or will be fully anonymised, and the primary purpose, where appropriate (e.g., for future research concerning the disease in question, the treatment of this disease, genetic testing, or only generally, without specification).

9. Trial subject remuneration and compensation *(to be entered into CTIS in Part II – Financial and other arrangements)*

- A description containing not only the amounts compensating trial subject´s expenses and possible trial subject remuneration, but also the form thereof.
- If the investigator does not use **template.cz no. 6 Compensation for Trial Participants**, the other format used must contain all of the data included in this template.cz no. 6

10. Financial coverage – how the CT will be financed *(to be entered into CTIS in Part II – Financial and other arrangements)*

- A description of how the clinical trial will be reimbursed.

11. Proof of fee payment *(to be entered into CTIS in Part II – All documents)*

- A proof of payment of the fee for the assessment of part II of the CT authorisation application dossier or substantial amendments to part II of an authorised clinical trial, specifying the variable number as per Guideline UST-29, codes K-023 to K-028.

Annexes to be completed in the Czech language – download here:
Template.cz no. 1 Recruitment and Informed consent procedure
Template.cz no. 2 Investigator Curriculum Vitae
Template.cz no. 3 Declaration of Investigator´s of Interest
Template.cz no. 4 Site Suitability
Form no. 5 Sponsor´s declaration on personal data processing in the concerned clinical trial
Template.cz no. 6 Compensation for Trial Participants
(*templates.cz in the English version will be added as soon as possible*)