KLH-CTIS-01

Version 2 of 15 May 2023

The Guideline SÚKL´s Ethics Committee and Multicentric Ethics Committees stipulates the requirements governing documents to be submitted with Part II of application for clinical trial authorisation:

1. Patient information sheet / informed consent form (hereinafter referred to as PIS/ICF) *(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.

- Any PIS/ICF version should include the following information:
  - One copy shall be kept at the trial site
  - Agreement with viewing of the source documentation (medical documentation) - not only for monitors, auditors, representatives of regulatory authorities/medicine agencies, ethics committee members, but also for study team members
  - EU CT number
  - Information that the results of clinical trials may be found at EMA´s website (https://euclinicaltrials.eu), and not on SÚKL´s website or not in Clinical Trials Register
  - For questions addressed to the ethics committee, the following address is to be specified: eticka.komise@sukl.cz; telephone numbers are not to be provided

- 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.
- Where questionnaires are going to be used in electronic format, print screens be submitted.
- 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 provide justification why such medical device should be used and why it cannot be replaced with another, EU certified device, and information that it will be used only for scientific/research purposes, and not for the provision of therapeutic care.
  Furthermore, it is necessary to submit 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.
- Where the clinical trial will include also the use of medical devices, the sponsor must mention this fact in the application.

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 Conflict 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.

- Where the sponsor´s CV format is used and filled in in the English language, a list of trial sites and principal investigators, incl. all medical degree titles, in the Czech language must be submitted – it is very important to maintain all diacritic marks.
- If the investigator does not submit a Good Clinical Practice Certificate and claims completion of the training in their CV, it is necessary to specify the month and year of the training as well as the company that provided the training. The Good Clinical Practice Certificate cannot be older than 3 years.
- The CV and the Conflict-of-Interest Declaration should be signed in hand or electronically. If signed electronically, it is necessary to use acknowledged or qualified signature.
- 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).
- The site suitability form should be signed by the site manager (department head doctor or clinic chief doctor) or by the principal investigator. The form should also specify the trial site´s name and address.
- The form should be signed in hand or electronically, using an acknowledged or qualified signature.

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.
- Where a third-country sponsor is concerned, the form should be signed by this sponsor rather than a representative of the company or CRO established within the territory of the EU.
- The sponsor may replace this document with a declaration entered into PART I, section Forms, providing the same document is entered into Part II – "Compliance with national requirements on Data Protection".

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).
- The sponsor must also submit completed Template no. 7, which should contain not only information on samples for future research, but also on sampling within the scope of the clinical trial. This document must be completed in full.

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.
- In case compensation for lost income is to be paid, it is necessary to specify for whose lost income and how it is going to be calculated.
- Where payment cards will be used, the following conditions must be met:
    - The trial subject will not incur any costs associated with the use of the card (fees for withdrawals or for non-use of the card…).
    - Communication associated with the use of the card or problems therewith must be secured in the Czech language, there must not be any reference to foreign phone numbers, where the call would be paid by the trial subject.
    - It is advisable to provide also another option for the payment of compensation rather than the payment card alone.
    - For the use of payment cards, the trial subject's health condition must be always taken into account to ensure they are able to use the payment card, i.e., it is not possible for trial subjects in acute conditions, unconscious subjects, subjects with limited mental capacity (Alzheimer, dementia…)
- 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)***

- With regard to the involvement of other ethics committees in the assessment of applications for clinical trial authorisation submitted via CTIS, sponsors are kindly requested to wait with the payment of the fee until it is determined which ethics committee is to assess their clinical trial.
- In respect of documentation Part II assessment, sponsors are kindly requested to provide invoicing data and e-mail address where the invoice for the payment of the fee is to be sent, if their application is to be assessed by one of the multicentric ethics committees.
- If SÚKL´s ethics committee is appointed, the sponsor shall proceed in compliance with guideline UST-29 - 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.
- Annex 8 specifies the amount of fees for Part II documentation assessment – the fee amount ex. VAT (payments to SÚKL´s ethics committee) and the fee amount incl. VAT (payments to multicentric ethics committees).

Template no. 1 – Trial subject recruitment and obtaining of informed consent
Template no. 2 – Investigator´s CV
Template no. 3 – Investigator´s Conflict of Interest Declaration
Template no. 4 – Trial site suitability
Form no. 5 – Sponsor´s declaration on personal data processing in the concerned clinical trial
Template no. 6 – Compensation for study participants
Template no. 7 – Compliance with effective rules of the Member State for sampling, storage and future use of human biological samples (Art. 7(1)(h))
Annex 8 – Table of fees for the assessment of applications for clinical trial authorisation for documentation Part II