KLH-CTIS-01

Version 3, dated 28 January 2026

Instruction of the SUKL Ethics Committee and Ethics Committees for Multicentre Clinical Trials

This instruction sets out the requirements for documents to be submitted with an application for approval of Part II of a clinical trial:

General Requirements:

- A list of the documentation under review, including versions and dates of the documents, must be submitted in a machine-readable format. *Note: The list does not need to be a separate document (List of Documents); it is sufficient to include it in the Cover Letter.*
- The use of templates is mandatory
- For **medical devices** and in **vitro diagnostic medical devices** (hereinafter referred to as "device/devices") used within the clinical trial of a medicinal product (hereinafter referred to as "CTMP"), the following must be submitted: EU certificate, EU Declaration of Conformity, Instructions for Use in the Czech language. The device may only be used in accordance with its intended purpose as stated in the Instructions for Use.
  If the device does not bear the CE mark but is approved for use by the FDA, justification must be provided as to why such a device must be used and why it cannot be replaced by another device certified in the EU. Documents confirming FDA approval of the device must be submitted together with the FDA-approved Instructions for Use. The device may only be used in accordance with its intended purpose as stated in the FDA-approved Instructions for Use. The CTMP sponsor must provide a declaration that such a device will be used exclusively within the CTMP and not for the provision of routine healthcare. These devices must be clearly marked with the statement: **"For clinical trial use only."** Additionally, the sponsor must submit Instructions for Use in Czech, clearly stating **"For clinical trial use only,"** and provide documentation on how training for device use will be ensured, how servicing will be arranged, and other conditions for handling the device as specified in the Instructions for Use. The CTMP sponsor is obliged to establish a system for recording and traceability of the device, which will form part of the CTMP documentation. After completion of the CTMP, the sponsor must withdraw such devices from research sites. In the event of a serious adverse event related to the device, the CTMP sponsor must immediately report it to the Institute. Sponsors are reminded of their obligation to ensure a contact point (e.g., helpdesk) for device malfunctions or other issues, and this contact must be able to communicate in Czech.
- If the device is the subject of a clinical investigation or a performance study intended to demonstrate or verify compliance with all requirements of Regulation (EU) 2017/745 on medical devices (hereinafter "MDR") or Regulation (EU) 2017/746 on in vitro diagnostic medical devices (hereinafter "IVDR"), approval for the clinical investigation or performance study must be requested if required by legislation. Further requirements are set out in MDR, IVDR, Act No. 375/2022 Coll., and other related documents and legislation. See also the following point.
- If the product falls under MDR or IVDR (see also detailed information in MDCG 2022-10, MDCG 2023-1, and MDCG 2025-5) and has not yet undergone conformity assessment or will be used

outside its intended purpose, a declaration must be submitted stating that the sponsor has applied (or will apply), if required by legislation, for approval of the clinical investigation or performance study at the relevant SUKL department (Medical Devices Regulation Section) and will not initiate the clinical investigation or performance study until all legislative requirements for devices have been met. See also the previous point.

- If devices are to be used within the clinical trial, the sponsor is obliged to indicate this in the application.

1. Patient Information / Informed Consent Forms (hereinafter referred to as PI/ICF)

(To be uploaded in CTIS under Part II – Subject Information and Informed Consent Form)

Requirements:

- Submission of Czech Version: The Czech version of the Patient Information/Informed Consent Form must be submitted, fully compliant with the requirements set out in Regulation (EU) No 536/2014, Chapter V, and ICH GCP Guideline E6 (R3), Section 2.8.
- English Version: The original English version shall not be submitted, as it will neither be reviewed nor approved. Bilingual versions are not permitted.
- Inclusion of Foreign Nationals: Where foreign nationals are enrolled, the PI/ICF must be provided in a language that the subject demonstrably understands (preferably their native language). A certified translation of the approved Czech version is required. This document shall be submitted via CTIS as a non-substantial amendment. In this case, a bilingual version is permitted.
- Inclusion of Minors: Written patient information must be provided for the following age groups: 12–14 years and 15–17 years. By signing this document, the minor confirms their free will to participate in the clinical trial. Younger minors may sign the same informed consent form together with their parents to express their willingness to participate. Signature of minors under 11 years of age is not mandatory.
- Mandatory Content for All PI/ICF Versions:
  - One copy shall be provided to the patient ("I have received a dated and signed copy of this informed consent form."), and one copy shall remain at the clinical trial site.
  - Consent for access to source documentation (medical records) by monitors, auditors, representatives of regulatory authorities/medicinal product agencies, ethics committee members, and study team members.
  - EU CT Number.
  - Statement that clinical trial results will be available on the EMA website (https://euclinicaltrials.eu) and not on the SUKL website or Clinical Trials Register.
  - For inquiries to the ethics committee, provide the following email address: eticka.komise@sukl.gov.cz or the email address of the specific ethics committee that reviewed, approved, and oversees the clinical trial. Telephone numbers must not be provided.
  - Full clinical trial titles must be stated in all PI/ICF versions to avoid unnecessary comments.
- When preparing patient information, it is recommended to follow Guideline KLH-22.
- Electronic Versions: Electronic versions of PI/ICF are permitted.

- Acceptable electronic signatures: Qualified electronic signature, recognized or guaranteed electronic signature, dynamic biometric signature (fingerprint, facial recognition, ID identity).
- Unacceptable electronic signatures: Any sponsor-created signature type that does not meet the above criteria.

2. Materials Intended for Study Participants

(To be uploaded in CTIS under Part II – All Documents)

- The sponsor should submit materials intended for study participants in the Czech language, such as diaries, cards with information about participation in the clinical trial, questionnaires, etc.
- Questionnaires may be submitted in English only if they will be completed together with the study participant by the investigator. However, they will not be listed in the approved documentation in the Decision.
- If questionnaires are in electronic form, screenshots must be provided.
- The sponsor is obliged to submit:
  - Instructions for use of medicinal products, if applicable (e.g., in cases where the study participant administers the product, such as subcutaneous or intramuscular administration).
  - Instructions for use of medical devices, if applicable (e.g., glucometer, etc.).

3. Recruitment Materials

(To be uploaded in CTIS under Part II – Recruitment Arrangements)

- The sponsor shall submit the completed Template No. 1 **"Recruitment and Informed consent procedure template**." The template is attached to this document, bilingual, and based on the EMA template. It may be completed in Czech or English.
- Additionally, all recruitment materials (advertisements, leaflets, and any other materials) must be submitted.
- For recruitment materials in non-print formats (audio, video, etc.), these formats should also be submitted, if possible, in CTIS.

4. Investigators

(*To be uploaded in CTIS under Part II – Suitability of the Investigator*)

For approval of the investigator, or only the principal investigator, if multiple physicians will participate at the site, the following documents must be submitted:

- Current CV – use the attached **Template No. 2 'Investigator Curriculum Vitae'** and **Template No. 3 'Declaration of Investigator's Interest**,' which must be completed in Czech, dated, and signed by the physician.
- A list of trial sites and principal investigators in Czech, including diacritics (which is very important) and all academic titles of the physician, in a machine-readable format.
- If the investigator does not submit a GCP certificate and instead states completion of training in the CV, the month and year and the company providing the training must be indicated. The

GCP certificate must not be older than 3 years. In view of the revision of ICH E6 (R3), it is necessary to state which version of ICH E6 the training covered.

- Signature Requirements: The CV and the declaration of conflict of interest may be signed either by hand or electronically. Acceptable electronic signatures: Recognized, qualified electronic signature; guaranteed electronic signature; dynamic biometric signature (fingerprint, facial recognition, ID identity). Unacceptable electronic signatures: DocuSign or any sponsor-created signature type that does not meet the above criteria.
- Additional Notes: The sponsor does not submit a list of sub-investigators or other study team members, nor proof of their GCP training – these documents must be available at the site for monitoring, inspections, and audits.

5. Clinical Trial Site

(To be uploaded in CTIS under Part II – Suitability of the Facilities)

- For approval of the clinical trial site, the completed **Template No. 4 "Sitze Suitability"** must be submitted.
- For non-state healthcare facilities, it is mandatory to provide a document (scan) confirming that the site is a healthcare facility (issued by the Regional Authority) and the scope of permitted activities (specializations – e.g., orthopaedics, internal medicine, etc.). This requirement also applies to all healthcare facilities established by entities other than the Ministry of Health of the Czech Republic, such as regional authorities.
- If certain examinations or procedures required by the protocol will not be performed directly at the trial site, it must be specified who will provide them (e.g., MRI, CT, ophthalmologic examination, echocardiography, etc.).
- For trial sites conducting bioequivalence (BE) studies, pharmacokinetic studies, and First-in-Human (FIH) studies, which in accordance with Section 54(3) of Act No. 378/2007 Coll., on Pharmaceuticals, as amended by Act No. 66/2017, must hold a Good Clinical Practice certificate issued by SUKL, this certificate must be submitted (scan of the certificate).
- The Site Suitability form should be signed by the head of the site (department head or clinic director) or the principal investigator. The form must include the name and address of the trial site.
- The form may be signed by hand or electronically using a recognized, qualified electronic signature, guaranteed electronic signature, or dynamic biometric signature (fingerprint, facial recognition, ID identity). Unacceptable electronic signatures: DocuSign or any sponsor-created signature type that does not meet the above criteria.
- If parts of the clinical trial will be conducted at another facility (sub-trial site), this facility must be listed in Template No. 4 along with the activities to be performed there and the personnel assigned to these activities. It must be a healthcare facility; therefore, a document (scan) confirming its status as a healthcare facility (issued by the Regional Authority) and the scope of permitted activities (specializations – e.g., orthopaedics, internal medicine, etc.) must be submitted.
- A list of trial sites and principal investigators in Czech, including diacritics (which is very important) and all academic titles of the physician, must be submitted in a machine-readable format.

6. Insurance

(To be uploaded in CTIS under Part II – Proof of Insurance Cover or Indemnification)

- The insurance certificate, the full insurance policy including terms and conditions (in Czech or bilingual version) must be submitted. Submission of the insurance terms and conditions is mandatory.
- The insurance certificate does not need to include the number of enrolled subjects. If the number of planned subjects is indicated in this document and increases during the clinical trial, an updated insurance certificate must be submitted as a non-substantial modification (non-SM).
- A statement from the sponsor describing how compensation will be ensured for health damage that manifests after the clinical trial and after the insurance policy has expired, provided the damage is demonstrably caused by participation in the completed clinical trial.

7. Processing of Personal Data

(To be uploaded in CTIS under Part II – Compliance with National Requirements on Data Protection)

- Submission of the sponsor-signed "**Sponsor´s declaration on personal data processing in the concerned clinical trial" – Template No. 5.**
- For sponsors from third countries, the form must be signed by the sponsor, not by a representative of the company or CRO established in the EU.
- The sponsor may replace this document with the declaration uploaded in Part I under Forms by submitting the same document in Part II – "Compliance with National Requirements on Data Protection."

8. Biological Samples for Future Research

(To be uploaded in CTIS under Part II – Compliance with Use of Biological Samples)

- Consent of the study participant to the storage and use of biological samples obtained during the clinical trial for future research may be included in the Patient Information/Informed Consent Form, requiring a separate signature for this consent, or submitted as a separate document to be signed by the participant.
- The statement accompanying the consent should include information on how long the samples will be stored, whether they will remain pseudonymized or fully anonymized, and the main purpose (e.g., future research related to the disease, treatment of the disease, genetic testing, or general research without specification).
- The sponsor must also submit the completed **Template No. 7 Compliance with Member State applicable rules for the collection, storage and future use of human biological samples (Article 7.1h)**, providing information not only on samples for future research but also on samples collected during the clinical trial. This document must be completed in full.

9. Compensation and Reimbursement for Study Subjects

(To be uploaded in CTIS under Part II – Financial and Other Arrangements)

- It is recommended to standardize patient compensation payments as a lump sum. The description must include not only the amount of expense reimbursement, compensation, and any remuneration for participation in the clinical trial but also the form of payment.

- When using payment cards, the following conditions must be met:
  The study participant must not incur any costs related to the use of the card (fees for withdrawals or non-use of the card, etc.).
  - Communication regarding card use or issues must be available in Czech; references to foreign phone numbers where the participant would pay for the call are not permitted.
  - There must be an option for reimbursement by a method other than payment card.
  - The health condition of the study subjects must be considered to ensure they can use the payment card. Payment cards are not suitable for participants in acute conditions, unconscious, or with limited mental capacity (e.g., Alzheimer's disease, dementia).
- **Template No. 6 "Compensation for Study Participants"**; if the sponsor does not use the attached template, references to where all information contained in the template can be found must be provided.

10. Financial Coverage – How the Clinical Trial Will Be Funded

(To be uploaded in CTIS under Part II – Financial and Other Arrangements)

- Description of how the clinical trial will be financed.

11. Proof of Payment of Fee

(To be uploaded in CTIS under Part II – All Documents)

- Due to the involvement of additional ethics committees in the assessment of applications for clinical trial approval submitted via CTIS, sponsors are requested to wait with payment of the fee until it is determined which ethics committee will assess their clinical trial.
- Sponsors are requested to provide billing details and an email address for sending the invoice for payment of the fee if their application will be assessed by one of the ethics committees for multicentre clinical trials.
- If the SUKL Ethics Committee is assigned, the sponsor shall proceed according to Guideline UST-29 – Proof of Payment of Fee for Assessment of Part II Documentation of the Application for Clinical Trial Approval or Significant Amendment to Part II of an Approved Clinical Trial, including the variable symbol according to Guideline UST-29, codes K-023 to K-028.
- Annex No. 8 specifies the amount of fees for assessment of Part II documentation – fee amounts excluding VAT (payments to SUKL Ethics Committee) and fee amounts including VAT (payments to ethics committees for multicentre clinical trials).

Template No. 1 - Recruitment and Informed consent procedure
Template No. 2 - Investigator Curriculum Vitae
Template No. 3 - Declaration of Investigator´s Interests
Template No 4 - Site Suitability
Form No. 5 - Sponsor´s declaration on personal data processing in the concerned clinical trial
Template No. 6 - Compensation for trial participants
Template No. 7 - Compliance with Member State applicable rules for the collection, storage and future use of human biological samples (Article 7.1h)
Appendix No. 8 – The fees for the assessment of Part II of the CT documentation excluding VAT (EK-SÚKL) and including Vat (Multicentric Ethics Committee)