EUROPEAN AND NATIONAL REQUIREMENTS FOR THE SLOVAK REPUBLIC - PART II – CLINICAL TRIAL APPLICATION (REGULATION (EU) NO 536/2014)

13.10.2023

Documents regarding Part II Regulation 536/2014 – Annex I	Document - Language requirements and a reference to applicable legislation or guidelines, EU recommendations and other information regarding the document
K. RECRUITMENT ARRANGEMENTS	**Documents regarding the recruitment of subjects (patient facing) - Slovak language** *(e.g. advertising materials intended for clinical trial participants, if used)* **Informed consent and patient recruitment procedure (general) - English language** *It is possible to use the template that can be found on the link in Chapter 1 (Chapter I) - „Recruitment and Informed consent procedure template„.*
L. SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE	**Informed Consent Forms (ICF) and other documents intended for trial participants prior to their inclusion in the clinical trial - Slovak language** *ICFs are prepared on the basis of Methodical guidance 131/2021 (State Institute for Drug´s Control)* **ICF with the use of samples for future research not related to the clinical trial - Slovak language** *either a separate document or a separate signature page included in the informed consent* Patient facing documents as part of the protocol (submitted with the protocol): Accepted in the following languages: **Slovak language* and English language** ***** *in Slovak only, only those documents intended for the clinical trial subjects (mono and multinational clinical trials)* *Local law 362/2011 - § 29a par. 9*

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	The EC will follow the requirements of the GCP when assessing the submitted documents.

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M. SUITABILITY OF THE INVESTIGATOR	**Curriculum vitae of the principal investigator- Slovak or English language** A CV uploaded to the CTIS (Clinical Trial Information System) portal will be accepted without a signature*, however it is the responsibility of the sponsor to ensure that an identical signed version is available for an inspection within the clinical trial site and is also available at sponsor´s trial master file. The use of this CV template is recommended, but all types of professional CVs are accepted. If the principal investigator does not have experience with the clinical trials in the required field, it is sufficient to include in the CV attestation or specialization within the required field. It is necessary to fulfill the national requirements regarding the qualification of the chief examiner - the necessity of certification in the field, resulting from Act no. 362/2011 on medicines and medical devices, § 29l "Requirements for the principal investigator, requirements for the examiner and requirements for the workplace where clinical trials of human medicines are carried out" and from Regulation of the Government of the Slovak Republic no. 296/2010 on professional competence for the performance of the health profession, the method of further education of health workers, the system of specialized fields and the system of certified work activities. Information about the completion of GCP - Good clinical practice.

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	Declaration of Interest (DoI) of the principal investigator - English language **DoI** uploaded to the CTIS (Clinical Trial Information System) portal will be accepted without a signature*, however it is the responsibility of the sponsor to ensure that an identical signed version is available for an inspection within the clinical trial site and is also available at sponsor´s trial master file. Template – (Chapter I EudraLex - Volume 10 - Clinical trials guidelines) **A list of the planned clinical trial sites, including the name and position of the principal investigators and the planned number of subjects at the sites or with the total planned subjects in Slovakia - Slovak or English language**

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N. SUITABILITY OF THE FACILITIES	**"Site suitability form"**– **Slovak language or English language** a written statement describing the suitability of the clinical trial sites, issued by a statutory representative of the healthcare facility. **Site suitability form** uploaded to the CTIS (Clinical Trial Information System) portal will be accepted without a signature*, however it is the responsibility of the sponsor to ensure that an identical signed version is available for an inspection within the clinical trial site and is also available at sponsor´s trial master file. Local bilingual version is available on https://www.health.gov.sk/?Eticka-komisia-pre-klinicke-skusanie The template is available in the downloads section -"dokumenty na stiahnutie" of the Ministry of Health website, Ethics Committee for Clinical Trials.
O. PROOF OF INSURANCE COVER OR INDEMNIFICATION	**Insurance certificate - Slovak language**
P. FINANCIAL AND OTHER ARRANGEMENTS	**Financial compensations paid to the subject are included either in the ICF or as a separate document - Slovak language**

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R. PROOF THAT DATA WILL BE PROCESSED IN COMPLIANCE WITH UNION LAW ON DATA PROTECTION	**A statement by the sponsor or sponsor´s representative** that data will be collected and processed in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council – Personal data protection - **English language** The statement will be uploaded in the CTIS when completing the clinical trial application form. Submission in part II is not needed.
General requirement for compliance with the good documentation practice - (page numbering, document date, document version)	

Links:

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en

*Electronic submission of the CTA to CTIS by the sponsor is regarded as equivalent to signing the document in accordance to Annex I.3. CTR is a regulation, which is directly applicable and ensures complete harmonisation of the sector, national laws should be set out to support its full implementation.