Set of European and national requirements for the Slovak Republic for Part II dossier to an application for an authorisation of a clinical trial

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)** **Informed consent and patient recruitment procedure (general) can be in english language**	**Slovak language** **It is possible to use the template that can be found on the link n Chapter 1 (Chapter I) - „Recruitment and Informed consent procedure template„**
L. SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE	**Informed Consent Forms** **ICF with the use of sample for future research not related to the clinical trial** – either a separate document or a separate signature page included in the informed consent Patient diaries, Questionnaires, screenshots from electronic diaries (patient facing), if used	**Slovak language** ICFs are prepared on the basis of Methodical guidance 131/2021 (State Institute for Drug´s Control) Slovak language **Slovak language**
M. SUITABILITY OF THE INVESTIGATOR	**Curriculum vitae of the principal investigator**	**Slovak or English language** CV with the original signature or advanced electronic signature of the principal investigator The use of this CV template is recommended but all types of professional CVs are accepted.

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
		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. **<u>Recommendation: With regards to the Good Documentation Practice it is essential to use page numbering and version of the document in a footer.</u>** **<u>English language</u>** DoI with the original signature or advanced electronic signature of the principal investigator
	Declaration of Interest of the principal investigator	

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
	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	**Recommendation: Regarding to Good Documentation Practice it is essential to use page numbering and add document versioning** Template – (Chapter I EudraLex - Volume 10 - Clinical trials guidelines) **Slovak or English language**
N. SUITABILITY OF THE FACILITIES	**"Site suitability form"**– a written statement describing the suitability of the clinical trial sites, issued by a statutory representative of the healthcare facility	**Slovak language** Site suitability form with the original or advanced electronic signature of the statutory representative of the healthcare facility Bilingual version 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 a separate document**	**Slovak language**

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
R. PROOF THAT DATA WILL BE PROCESSED IN COMPLIANCE WITH UNION LAW ON DATA PROTECTION	**A statement by the sponsor or his or her 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 by completing the clinical trial application form.
General requirement for compliance with the good documentation practice - (page numbering, document date, document version)		