Overview part II requirements in a CT application

Overview written and endorsed by MedEthicsEU

Latvian local requirements written and endorsed endorsed by Ethics Committee

Overview part II requirements Document history:	
Date of endorsement by MedEthicsEU	Written endorsement December 2024
Version, date	2.0, dd 6 December 2024
Supersedes version	1.0
Latvian local requirements	
Date of endorsement by Ethics Committee	February 2025
Version, date	2.0, 04 February 2025
Supersedes version	1.0

Important notice: This document should be read in combination with the Clinical Trials Regulation (EU) No 536/2014 (CTR). The information and views expressed in this document is not legally binding for the MS concerned nor for the sponsor of any clinical trial application. The overview is there to facilitate the submission of clinical trial applications in any of the MS concerned.

Additional supportive documents about the CTR can be retrieved on Eudralex 10: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en

INTRODUCTION

DISCLAIMER: The information has not been verified nor endorsed by COM , the document is a living document which will be updated on the basis of information received by Ethics Committees.

As of 31 January 2022, the clinical trial regulation EU no 2014/536 (CTR) is applicable in the EU/EEA. The CTR describes rules for the submission, assessment, start, conduct and closure of a clinical trial.

In CTR annex I section K to R the documentation of part II is described. For each of these section a placeholder is provided in CTIS where the sponsor can upload the required documentation. There is an additional placeholder in CTIS for compliance on rules biological samples (not mentioned in annex I CTR but in article 7.1h of the CTR). Templates for some of this documentation are published on Eudralex volume 10 (https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en):

- **Informed consent and patient recruitment procedure**: https://health.ec.europa.eu/document/download/dbe5bb25-dd62-4286-95b9-bd8d3ec8678d_en?filename=informedconsent_patientrecruitmentprocedure_en.pdf

- **Compensation for trial participants:** https://health.ec.europa.eu/document/download/0916045d-9dfe-4c74-9661-ba3a1406317f_en?filename=payment_compensation_template_en.pdf
- **Investigator Curriculum Vitae**: https://health.ec.europa.eu/document/download/58057fa9-ce4d-46ba-84b5-2099d4035b98_en?filename=investigator_cvtemplate_en.pdf
- **Declaration of interest (DoI):** https://health.ec.europa.eu/document/download/7721d624-6c00-494d-bf1c-e30577f0387a_en?filename=declaration_interest_template_en.pdf
- **Site suitability form:** https://health.ec.europa.eu/document/download/e8629b8b-bce1-4589-8433-511a88c974bb_en?filename=site_suitability_template_en.pdf
- **Compliance with applicable rules for biological samples:** https://health.ec.europa.eu/document/download/bd1f95f2-93a2-4877-8c20-45f150949aa4_en?filename=mp_compliance-app-rules-bio_en.pdf

The use of the templates published on Eudralex volume 10 can be mandatory depending on the MS's policy. Apart from these requirements, there can be additional requirements for the documentation per MS based on national legislation or guidelines.

Patient facing documents aimed on the assessment of endpoints as defined in the clinical trial protocol are part of the protocol and should be uploaded in the part I placeholder "protocol" (see also Q1.24 of Q&A CTR: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en . The language requirements for patient facing documents are presented in annex II of this Q&A.

It is recommended to use the naming conventions of the documents as published on the CTCG website: https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/CTCG/2023_04_CTCG_Best_practice_guide_naming_of_documents__version_2.0.pdf

This report provides an overview of the required part II documentation of 19 MS in EU/EEA. MedEthicsEU is still working to get the overview complete and to update the overview if there is a change in the MSC.

MS overview footnotes:

#:A. Eudralex volume 10 template is mandatory, B. Eudralex volume 10 template/national template is recommended, C. No mandatory templates, D. National template is mandatory.
$: A. CTR, B. National legislation, C. National guidelines, D. Other

LATVIA

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info and Latvian local requirements
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	A C	A A	Template Eudralex volume 10 ✓ A description of the recruitment activities and all materials, including those intended for doctors, must be submitted ✓ Materials intended for participants and doctors must be submitted in Latvian Before developing recruitment activities and materials, we encourage a thorough assessment of their relevance, usefulness, and compliance with local customs, societal norms, and resource consumption, ensuring environmental sustainability
Subject information and informed consent form				
	- SIS and ICF (e.g. SIS and ICF adults, SIS and ICF 0-14 yr , 14-18 yr) - Other subject information material (e.g. information leaflet adults)	B C	A; B A	✓ Compliance of content and format with the requirements of the local regulations, and GCP guidelines. ✓ Take into account the study participant population and the specific features of the study protocol when designing the informed consent. ✓ Make the document as concise and reader-friendly as possible, avoiding text repetition and unnecessary wording. ✓ The document must include: •The name and address of the study center •The data controller, • The State Agency of Medicines (ZVA), •The Ethics Committee (ĒK), • The Data State Inspectorate (DVI), with contact details (fields/placeholders for this information should be included in the consent forms). ✓ For the participation of minors, in addition to the legal representative's consent, the child's own consent is mandatory from the age of 14 and recommended for younger children, depending on their maturity. **Formal requirements:** ✓ Date/version/clinical trial identification protocol number, including both the sponsor-assigned number and the CTIS study number.

				✓ The choice of document language must be based on GCP requirements regarding the comprehensibility of informed consent for study participants, considering the expected study population's age, while respecting that the national language is Latvian.
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B A	A,C A	Template Eudralex volume 10 Template Eudralex volume 10 **Requirements for the Investigator's Qualification Description (CV):** ✓ It is recommended to submit the CV using the Eudralex Volume 10 form ✓ The investigator's (physician's) specialty, workplace, and position must be specified ✓ The medical practitioner's certificate number and its validity period must be indicated ✓ The date of GCP (Good Clinical Practice) training, the GCP version, and the specific edition completed must be provided ✓ GCP training certificate does not need to be submitted ✓ Only the qualification (CV) of the principal investigator is to be submitted and assessed
Suitability of the facilities				
	- Site Suitability Statement	A	A	Template Eudralex volume 10 The study site suitability description must be submitted using the Eudralex Volume 10 Site Suitability Template, following these conditions: • The document must clearly identify the study protocol title and the sponsor's protocol number • The document must be signed by an authorized representative of the healthcare institution or another appropriately authorized person in charge • The date of signing must be indicated in the document

				• If any of the study procedures (e.g., radiological or other types of diagnostics) are planned to be performed at another place not at the site, the name and address of the healthcare institution where these procedures will be conducted must be specified (this does not apply to laboratories and centrally provided services).
Proof of insurance cover or indemnification				
	- Insurance certificate - Insurance terms and conditions (in case if terms and conditions not included in certificate)	C	A,B	National legislation: https://likumi.lv/ta/id/350827-cilvekiem-paredzeto-zalu-klinisko-petijumu-noteikumi ✓ The submitted insurance documents must clearly identify • the specific study, • the number of insured study participants, if the format of the policy or insurance certificate allows • and, if the format of the policy or insurance certificate allows, the names and addresses of the study sites. ✓ The proof of insurance must comply with local regulatory requirements
Financial and other arrangements				
	- (1) Template compensation trial participants - (2) Other agreements: - - Description of trial's financial and other arrangements or draft agreement with budget for each investigator/site	A (1) C (2)	A A,B	Template Eudralex volume 10 https://likumi.lv/ta/id/350827-cilvekiem-paredzeto-zalu-klinisko-petijumu-noteikumi ✓ A draft contract with the investigator and/or trial site. ✓ A draft trial budget, specifying the allocation for each investigator and/or trial site.
Compliance with national requirements on data protection				
		B	A,B	Template Eudralex volume 10

				✓ A sponsor's statement must be submitted confirming that data will be collected and processed in accordance with Regulation (EU) 2016/679 (GDPR) and local legislation ✓ The Eudralex Volume 10 form may be used
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A	Template Eudralex volume 10 ✓ It is recommended to use the Eudralex Volume 10 form "Compliance with Applicable Rules for Biological Samples".