MedEthicsEU

group of national representatives of Medical Research Ethics Committees in EU/EEA

Overview part II requirements in a CT application per MS

Overview written and endorsed by MedEthicsEU

Document history:	
Date of endorsement by MedEthicsEU	Written endorsement December 2024
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Supersedes version	1.0
Changes compared to superseded version	Update for Germany, Latvia, Spain and two MS added (Bulgaria and Romania)

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

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.

INTRODUCTION

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.

Any questions or remarks about the overview can be send to: *m.al@ccmo.nl*

TABLE OF CONTENT

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

AUSTRIA

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A A	Template Eudralex volume 10
Subject information and informed consent form				
	- SIS and ICF [description] - Site contact list - Other subject information material (e.g. information leaflet adults)	B,D C C	A A,C A	https://austrianethics.at/en/ctr/antragstellung?heading=Participant+Information+and+Consent+Form+%28ICF%29
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator - GCP certificate Principal Investigator	B B C	A A B,C	https://austrianethics.at/en/ctr/antragstellung?heading=Participant+Information+and+Consent+Form+%28ICF%29
Suitability of the facilities				
	- Site suitability form [CT site]	D	A,C	https://austrianethics.at/en/ctr/antragstellung?heading=Trial+Site+Suitability+Form+%28TSSF%29
Proof of insurance cover or indemnification				
	- Insurance policy - Insurance Confirmation/Certificate - Terms subject insurance - Terms Extended liability insurance for the investigator - Extended criminal law protection insurance for the investigator	C C C C C	A,B A,B A,B A,B A,B	https://austrianethics.at/en/ctr/antragstellung?heading=Insurance
Financial and other arrangements				
	- Compensation for trial participants	B.	A,C	
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	C	A	
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	C	A	

BULGARIA

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable): https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B B	A A	Template Eudralex volume 10, see also https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf
Subject information and informed consent form				
	- SIS and ICF [description] - Other subject information material (e.g. information leaflet adults)	C	A	https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B B	A A	Templates Eudralex volume 10, see also https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf
Suitability of the facilities				
	- Site suitability form [CT site]	D	C	https://www.bda.bg/bg/62-business-info/clinical-examinations-biz / Declaration
Proof of insurance cover or indemnification				
	- Proof of insurance	C	B	All insurance documents are according Art 90-92 of the Medicinal product in human medicinal act https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf
Financial and other arrangements				
	- Compensation for trial participants	B	A,B	Template Eudralex volume 10, see also https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	B	A	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A	A	Template Eudralex volume 10 https://www.bda.bg/images/stories/documents/clinical/20240112/CTIS_documents.pdf

CZECH REPUBLIC

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.sukl.eu/medicines/klh-ctis-01
Recruitment arrangements				
	- Template recruitment arrangements	C	A,B	https://www.sukl.eu/medicines/klh-ctis-01 (template no 1)
	- Recruitment material [description]	C	B,C	https://www.sukl.eu/medicines/klh-ctis-01 (section 3)
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, parents SIS and ICF 12-14 yr, 15-17 yr, pregnant trial participant and partner; ICF substudy)	B	A,B,C	https://www.sukl.eu/file/89189_1_2 https://www.sukl.eu/medicines/klh-ctis-01 (section 1)
	- Other subject information material (e.g. information leaflet adults)	C	A,B,C	
	- Other subject information material (e.g diaries, patient cards, questionnaires)		A.B.C	https://www.sukl.eu/medicines/klh-ctis-01 (section 2)
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	D B	A,B,C A	https://www.sukl.eu/medicines/klh-ctis-01 (section 4, template no 2) https://www.sukl.eu/medicines/klh-ctis-01 (template no 3)
Suitability of the facilities				
	- Trial Site Suitability [CT site]	B	A,B,C	https://www.sukl.eu/medicines/klh-ctis-01 (section 5, template no 4)
Proof of insurance cover or indemnification				
	- Insurance certificate - Insurance contract (including insurance terms and conditions in Czech language or bilingual)	C C	A,B A,B	https://www.sukl.eu/medicines/klh-ctis-01 (section 6)
Financial and other arrangements				
	- Trial subject remuneration and compensation	B.	A,C	https://www.sukl.eu/medicines/klh-ctis-01 (section 9, template no 6)
	- Description how CT will be financed	D	A,C	https://www.sukl.eu/medicines/klh-ctis-01 (section 10)
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	D	C	https://www.sukl.eu/medicines/klh-ctis-01 (section 8, template no 7)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A,D	A,C	https://www.sukl.eu/medicines/klh-ctis-01 (section 9, template no 6

Additional info Czech:

https://www.sukl.cz/leciva/klinicke-hodnoceni-leciv
https://www.sukl.cz/leciva/podklady-k-oblasti-klinickych-hodnoceni
https://www.sukl.eu/medicines/clinical-trial-on-pharmaceuticals

DENMARK

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements* - Recruitment material [description]	B C	A A	Template Eudralex volume 10 Actual video/audio files are submitted outside of CTIS (via e-mail to authorities) due to system limitations
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF minors) - Other subject information material (e.g. information leaflet adults)	C C	A,B A	https://researchethics.dk/information-for-researchers/interactive-application-guide https://videnskabsetik.dk/Media/637926929421871704/Dine%20rettigheder%20som%20fors%c3%b8gsperson%20i%20fors%c3%b8g%20med%20medicin.pdf (Pamphlet is not mandatory, however the information contained within is, if pamphlet is not submitted the information must be in subject information sheet)
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B B	A A	Template Eudralex volume 10 Template Eudralex volume 10
Suitability of the facilities				
	- Site suitability form [CT site]	B	A	Template Eudralex volume 10
Proof of insurance cover or indemnification				
	- Proof of coverage sponsor or investigator name sponsor/trial site [if not covered by trial participant insurance]	C	A,B	DK does not require the submission of stand-alone insurance policies if the trial sites in Denmark are covered by the public scheme Danish patient Compensation (In Danish: Patienterstatningen). In this case, the application material must state that the trial sites in Denmark are covered by the public scheme.
Financial and other arrangements				
	- Template compensation trial participants*	B	A	Template Eudralex volume 10.
Compliance with national requirements on data protection				
		B	A	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples*	B	A	Template Eudralex volume 10

**If EudraLex Volume 10 templates are not used, the information must be available elsewhere: For multinational trials: mandatory to submit separate part II document. For mononational trials: information must be in the protocol or separate part II document.*

FINLAND

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://tukija.fi/en/applications-under-regulation
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A A	Template Eudralex volume 10 (see instructions Finland: https://tukija.fi/en/applications-under-regulation)
Subject information and informed consent form				
	- SIS and ICF: SIS and ICF adults and children 15≥ and minors (15<) - Other subject information material (e.g. information leaflet adults)	D C	A,B,C A	https://tukija.fi/laaketutkimusasetuksen-mukaiset-hakemukset https://tukija.fi/en/applications-under-regulation
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B,C A	A A	Template Eudralex volume 10 Template Eudralex volume 10
Suitability of the facilities				
	- Site Suitability Statement [CT site]	B	A	Template Eudralex volume 10 https://tukija.fi/en/applications-under-regulation
Proof of insurance cover or indemnification				
	- Insurance certificate - Description of the insurance or other appropriate guarantee [name sponsor/trial site]	C C	A,B A,B	Official certificate of insurance or insurance statement required. A separate description of the insurance or other appropriate guarantee shall be submitted. https://tukija.fi/en/applications-under-regulation
Financial and other arrangements				
	- Description financing of the clinical trial - Template compensation trial participants	D B	A,C A,B,C	Instructions: https://tukija.fi/en/applications-under-regulation Tempate Eudralex volume 10
Compliance with national requirements on data protection				
		C	B	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A,B,C	Template Eudralex volume 10 Instructions: Interpretation of the application of national legislation when samples are collected for long-term storage or future research in connection with a clinical trial (14.1.2022) [available only in Finnish] https://tukija.fi/laaketutkimusasetuksen-mukaiset-hakemukset

FRANCE

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/article/la-commission-nationale-des-recherches-impliquant-la-personne-humaine
Recruitment arrangements				
	- Template recruitment arrangements - Document additionnel pour la soumission des essais cliniques régis par le règlement EU 536/2014 en France - Recruitment material and communication [description]	A D C	A C A,B	Template Eudralex volume 10 https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/article/la-commission-nationale-des-recherches-impliquant-la-personne-humaine Material/communication on website, sponsor must share access to website or sreenshot of the communication
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults) - Inform and consent document for genetic testing (constitutional) - Other subject information material (e.g. information leaflet adults)	C C	A,B,C B A	Instructions on how to complete France: https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/article/la-commission-nationale-des-recherches-impliquant-la-personne-humaine
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator - List principal investigators - Investigator information on national considerations of the clinical trial	A A C D	A A C C	Template Eudralex volume 10 Template Eudralex volume 10 Complete the following document : https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/article/la-commission-nationale-des-recherches-impliquant-la-personne-humaine
Suitability of the facilities				
	- Site Suitability Statement [CT site] - Site autorisation - List clinical trial sites	A D C	A B C	Template Eudralex volume 10 Each health institute receives an autorisation for a specific period. This autorisation is mandatory and delivered by ARS (Regional Health Agency). List clinical trial sites can be combined in list PIs (see above)
Proof of insurance cover or indemnification				
	- Proof of insurance	C	A,B	
Financial and other arrangements				
	- Template compensation trial participants - Document additionnel pour la soumission des essais cliniques régis par le règlement EU 536/2014 en France	A D	A,B A,C	Template Eudralex volume 10 Instructions France: sante.gouv.fr/systeme-de-sante/innovation-et-recherche/article/la-commission-nationale-des-recherches-impliquant-la-personne-humaine

Compliance with national requirements on data protection				
	- The receipt of compliance GDPR issued by the CNIL	D	A,B	CNIL (National concil for information and liberty) has identified 4 references methodologies.Sponsors should prouve the compliance xith one of them. Then, CNIL deliver them a receipt (généralement MR001)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A	A,B	Template Eudralex volume 10

GERMANY

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B B	A A	Template Eudralex volume 10 Instructions Germany: https://www.akek.de/wp-content/uploads/RichtlinienfuerRekrutierungsanzeigenVersion10112012.pdf
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-17 yr) - Other subject information material (e.g. information leaflet adults)	B C	A,B A	https://www.akek.de/arzneimittelgesetz-amg/ and https://www.akek.de/etic-2/
Suitability of the investigator				
	- CV Principal Investigator - Certificates on Regulatory Training - DoI Principal Investigator	B B B	A A A	Template Eudralex volume 10 https://www.akek.de/curriculare-fortbildungen/ Template Eudralex volume 10
Suitability of the facilities				
	- Site Suitability Statement [CT site] - List of Trial Sites	B C	A,B,C A,C	https://www.akek.de/wp-content/uploads/Site-Suitability-Template_Germany_v2-04.docx
Proof of insurance cover or indemnification				
	- Insurance certificate - Insurance terms and conditions	C C	A,B A,B	
Financial and other arrangements				
	- Template compensation trial participants - Draft of the contract between the sponsor and the trial site	B C	A A	Template Eudralex volume 10
Compliance with national requirements on data protection				
		B	A,B	The GDPR statement according to the Eudralex volume 10 template should be submitted including a statement that the National requirements on data protection to be observed will be respected, where GDPR opening clauses apply. If the latter aspect is not included in the GDPR statement, a separate part II document should be submitted.
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A	Template Eudralex volume 10

IRELAND

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.nrecoffice.ie/submit-under-the-clinical-trial-regulation/
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	A or D C	A A	Aligned with Eudralex volume 10 template
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-16 yr) - Other subject information material (e.g. information leaflet adults)	C C	A A	
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	A or D A or D	A A	Aligned with Eudralex volume 10 template Aligned with Eudralex volume 10 template
Suitability of the facilities				
	- Site Suitability Form [CT site]	D	A,B	https://www.nrecoffice.ie/wp-content/uploads/NREC-CT-Site-Suitability-Template-V2.docx
Proof of insurance cover or indemnification				
	- Insurance certificate	C	A,C	SIG-10-03-Indemnity-and-Insurance-Arrangements-for-Clinical-Trials-Health-Research-Interactive.pdf (stateclaims.ie)
Financial and other arrangements				
	- Template compensation trial participants	A or D	A	Aligned with Eudralex volume 10 template
Compliance with national requirements on data protection				
	- Template statement of data compliance	D	A,B	https://www.nrecoffice.ie/wp-content/uploads/R1_NREC_CT_Statement_of_Compliance_V1.docx Guidance: https://www.nrecoffice.ie/wp-content/uploads/Guidance_Statement-of-Compliance.pdf
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A or D	A	Aligned with Eudralex volume 10 template

ITALY

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.aifa.gov.it/en/centro-coordinamento-comitati-etici https://www.aifa.gov.it/en/regolamento-europeo-sperimentazioni-cliniche
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	A C	A,C A	Template Eudralex volume 10 Guidance: "Linee di indirizzo per la raccolta del consenso informato alla partecipazione a sperimentazioni cliniche" https://www.aifa.gov.it/centro-coordinamento-comitati-etici
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-17 yr) - Other subject information material (e.g. information leaflet adults)	B C	A A	https://www.aifa.gov.it/centro-coordinamento-comitati-etici
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	A D	A A	Template Eudralex volume 10 or national template Guidance: "GUIDA ALLA VALUTAZIONE DI CUI ALL'ART 7 DEL REGOLAMENTO (UE) n. 536/2014, DA PARTE DEI COMITATI ETICI TERRITORIALI" https://www.aifa.gov.it/centro-coordinamento-comitati-etici
Suitability of the facilities				
	- Site suitability form [CT site]	A	A,C	Template Eudralex volume 10 Guidance: "GUIDA ALLA VALUTAZIONE DI CUI ALL'ART 7 DEL REGOLAMENTO (UE) n. 536/2014, DA PARTE DEI COMITATI ETICI TERRITORIALI" https://www.aifa.gov.it/centro-coordinamento-comitati-etici
Proof of insurance cover or indemnification				
	- Insurance certificate	C	B	https://www.aifa.gov.it/documents/20142/0/Decreto_Ministeriale_14luglio2009.pdf
Financial and other arrangements				
	- Template reimbursement and allowances for trial participant - Clinical Trial Agreement	D D	A,C A,B	Guidance: "GUIDA ALLA VALUTAZIONE DI CUI ALL'ART 7 DEL REGOLAMENTO (UE) n. 536/2014, DA PARTE DEI COMITATI ETICI TERRITORIALI" https://www.aifa.gov.it/centro-coordinamento-comitati-etici The minimum contents of the "Contract for the conduct of clinical trials on medicinal products" have been identified by the CNCCE and the model, which is binding, is available on the website: https://www.aifa.gov.it/centro-coordinamento-comitati-etici
Compliance with national requirements on data protection				
		C	A	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)

Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A,D	A	Template Eudralex volume 10

LATVIA

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	A C	A A	Template Eudralex volume 10 https://www.zva.gov.lv/sites/default/files/inline-files/II%20dalas%20prasibas%20EN%2002_05_2023.pdf
Subject information and informed consent form				
	- SIS and ICF [description] (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	National legislation: https://likumi.lv/ta/en/en/id/203008-law-on-the-rights-of-patients https://likumi.lv/ta/id/350827-cilvekiem-paredzeto-zalu-klinisko-petijumu-noteikumi (no official English translation available yet) https://www.zva.gov.lv/sites/default/files/inline-files/II%20dalas%20prasibas%20EN%2002_05_2023.pdf ICFs for minors according to Patient Right Law and CT Regulations
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B A	A,C A	Template Eudralex volume 10 Template Eudralex volume 10 https://www.zva.gov.lv/sites/default/files/inline-files/II%20dalas%20prasibas%20EN%2002_05_2023.pdf
Suitability of the facilities				
	- Site Suitability Statement [CT site]	A	A	Template Eudralex volume 10 https://www.zva.gov.lv/sites/default/files/inline-files/II%20dalas%20prasibas%20EN%2002_05_2023.pdf
Proof of insurance cover or indemnification				
	- Insurance certificate - Insurance terms and conditions (in case if terms and conditions to be assessed not included in certificate)	C	A,B	National legislation: https://likumi.lv/ta/id/350827-cilvekiem-paredzeto-zalu-klinisko-petijumu-noteikumi (no official English translation available yet)
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 (1) https://www.zva.gov.lv/sites/default/files/inline-files/II%20dalas%20prasibas%20EN%2002_05_2023.pdf https://likumi.lv/ta/id/350827-cilvekiem-paredzeto-zalu-klinisko-petijumu-noteikumi
Compliance with national requirements on data protection				
		B	A,B	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)

Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A	Template Eudralex volume 10

LITHUANIA

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://bioetika.lrv.lt/en/biomedical-research/authorisation-of-clinical-trials-on-medicinal-products-according-to-the-requirements-of-the-regulation-eu-no-5362014/
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A A	Template (Word) (10.1.) Recommendations: https://bioetika.lrv.lt/media/viesa/saugykla/2024/1/wRHxo9yqzTU.pdf
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-16 yr) - Other subject information material (e.g. information leaflet adults)	C,D C	A A	Template (Word) (11.1.) Recommendations (Word) (11.1)
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator - List of sites (name sites, principal investigator and number of subjects) - Investigators suitability [name investigator and cliical trial site	B,C B C B	A A C A	Template (Word) (12.3) Template (Word) (12.4) Template (Word) (12.2)
Suitability of the facilities				
	- Site suitability form [CT site]	B	A	Template (Word) (13.)
Proof of insurance cover or indemnification				
	- Insurance certificate	C	A,B	Legal terms for insurance
Financial and other arrangements				
	- Template compensation trial participants - Financial agreements	B. C	A A	Template (Word) (15.1)
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	B	A	
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A	Template (Word) (18.)

LUXEMBOURG

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A,C A	Template Eudralex volume 10 https://legilux.public.lu/eli/etat/leg/rgd/2005/05/30/n5/jo
Subject information and informed consent form				
	- SIS and ICF [description] (adults, parents, assent for minors) - SIS and ICF for secondary use (adults, parents)	B C	A,B A,B	https://legilux.public.lu/eli/etat/leg/rgd/2005/05/30/n5/jo national recommendations for expected content in SIS and ICF, and ICF for secondary use : https://cner.gouvernement.lu/en/publications.html
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	C B	A,B A	https://legilux.public.lu/eli/etat/leg/rgd/2005/05/30/n5/jo Template Eudralex volume 10
Suitability of the facilities				
	- Site suitability form [CT site]	B	A	Template Eudralex volume 10
Proof of insurance cover or indemnification				
	- Insurance certificate	C	A,B	https://legilux.public.lu/eli/etat/leg/rgd/2005/05/30/n5/jo
Financial and other arrangements				
	- Compensation trial participants - Description on how clinical trial will be reimbursed	B C	A,B A.B	Template Eudralex volume 10.
Compliance with national requirements on data protection				
	- Statement of compliance with Regulation (EU) 2016/679 (GDPR)	B	A	
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A	Template Eudralex volume 10

NETHERLANDS

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A A	https://english.ccmo.nl/investigators/publications/publications/2021/11/11/template-recruitment-procedure-nl
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-16 yr) - Other subject information material (e.g. information leaflet adults)	D C	A A	https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/subject-information-informed-consent-and-informed-consent-procedure
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B,C A	A A	Aligned with Eudralex volume 10 templates https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/suitability-of-the-investigator
Suitability of the facilities				
	- VGO [clinical trial site]	D	A,B	https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/suitability-of-the-facilities
Proof of insurance cover or indemnification				
	- WMO trial participant insurance certificate - Proof of coverage sponsor or investigator (if not included on VGO)	C C	A,B A,B	https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/proof-of-insurance-cover-or-indemnification
Financial and other arrangements				
	- Template compensation trial participants, investigator, funding and other arrangements	D.	A,C	https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/financial-and-other-arrangements
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	D	A	https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/compliance-with-national-requirements-on-data-protection
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A,D	A	Aligned with Eudralex volume 10 template https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/preparation-ctr/research-dossier-part-ii/compliance-with-use-of-biological-samples

NORWAY

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable)
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B,C C	A A	Template Eudralex volume 10*
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-16 yr) - Other subject information material (e.g. information leaflet adults)	B,C C	A A	https://rekportalen.no/#hjem/informasjonsskriv*
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B,C B,C	A A	Template Eudralex volume 10* Template Eudralex volume 10*
Suitability of the facilities				
	- Site suitability form [CT site]	B,C	A	Template Eudralex volume 10*
Proof of insurance cover or indemnification				
	- Proof of coverage sponsor or investigator	D	A,B	No template, but must in the application include a valid insurance certificate issued by the Norwegian Medicines Liability Association
Financial and other arrangements				
	- Template compensation trial participants - Description of trial's financial and other arrangements	B,C C	A A	Template Eudralex volume 10*
Compliance with national requirements on data protection				
	- Compliance on the collection and use personal data	C	A	Same document on compliance GDPR submitted under Form is acceptable, if this statement also refers to national legislation
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B,C	A	Template Eudralex volume 10*

**If the recommended template is not used, then it is expected that corresponding information is provided in an alternative document.*

PORTUGAL

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.ceic.pt/documents/20727/0/Lista+REC_24+fev/ce031816-44e2-4bd3-86e8-094dab5b4b00
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	C C	A A,C	Template Eudralex volume 10 or same information in another document
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS / ICF 16-18 yr) - Other subject information material.	C C	A,B,C A,C	* PT is preparing the publication of national Templates (yet not mandatory) All materials must be submitted such as patient´s cards, information leaflet, guides, brochures, visit appointment information, instructions in accordance with the CT specificities
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator - GCP certificate or information in CV	B,C A C	A A A	Template Eudralex volume 10 Template Eudralex volume 10
Suitability of the facilities				
	- Site suitability form including pharmaceutical declarations and medical products circuit [CT site]	C	A,B	Template Eudralex volume 10 plus: https://www.ceic.pt/documents/20727/0/Lista+REC_24+fev/ce031816-44e2-4bd3-86e8-094dab5b4b00
Proof of insurance cover or indemnification				
	- Insurance certificate	C	A	
Financial and other arrangements				
	- Template compensation trial participants - Description of financial and other arrangements	C	A,C C,D (soft law)	Template Eudralex volume 10 https://www.ceic.pt/documents/20727/57520/Esclarecimentos+CEIC+sobre+procedimentos+relativos+a+Disposi%C3%A7%C3%B5es+Financeiras+-+Contrato+com+os+Centros+de+Ensaio+%C2%BF+Pasta+P.+Regulamento+de+Ensaios+Cl%C3%ADnicos+%C2%BF+Submiss%C3%A3o+CTIS/8cd44084-0a8b-48cb-b351-e9ac2099d565
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	A	A	Same document on compliance GDPR submitted under Form is acceptable
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	A	A	Template Eudralex volume 10

ROMANIA

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable): https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	D C	A,B A	RO_ Procedure for recruitment and obtaining informed consent*_V1_May 2022 (Annex no. 3), https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf
Subject information and informed consent form				
	- SIS and ICF [description] - Other subject information material (e.g. information leaflet adults)	C C	A,B A,B	https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	D D	A,B A,B	RO_Formular CV_Investigator_V1_May 2022 (Annex no. 4) RO_Formular_Declaration of interests of the principal investigator_ V1_ May 2022 (Annex no. 5) https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf
Suitability of the facilities				
	- Site suitability forms	D D D	A,B B B	RO-Form regarding the description of the facilities of the investigation center for participation in the study _ V1_May 2022 (Annex no. 6) RO_Application form for the authorization of health facilities for the conduct of clinical studies of_phase I or of bioequivalence_ V1_May 2022 (Annex no. 8) RO_Description of the infrastructure of the emergency service of the operating centers clinical phase I and bioequivalence studies _ V1_ May 2022 (Annex no. 9) https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf
Proof of insurance cover or indemnification				
	- Trial participant insurance certificate - Proof of coverage sponsor or investigator	C C	A,B A,B	https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf
Financial and other arrangements				
	- Compensation for trial participants	D	A,B	RO_Formular_ Financial compensation for clinical study participants_V1_mai 2022 (Annex no. 7) https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf

Compliance with national requirements on data protection				
	- Template on the collection and use personal data	C	A	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	D	A,B	Form regarding compliance with national legislation on collection, storage and further use of human biological samples Version RO 1.0 (Annex no. 10) https://www.anm.ro/_/ORDINE/Ordin%203390-2022.pdfrdin 3390-2022.pdf

SLOVAK REPUBLIC

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.health.gov.sk/?Eticka-komisia-pre-klinicke-skusanie https://www.health.gov.sk/Zdroje?/Sources/komisie/Eticka-komisia-pre-klinicke-skusanie/Requirements-SR-clinical-trial-application.pdf
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B,C C	A A	Template Eudralex volume 10
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-18 yr) - Other subject information material (e.g. information leaflet adults)	C C	A A	ICFs are prepared on the basis of Methodical guidance 131/2021 (State Institute for Drug´s Control): https://www.sukl.sk/buxus/docs/Bezpecnost_liekov/Pokyny/MP_131-2021...NICKEHO_SKUSANIA%E2%80%9C.pdf
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator - 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	B,C B,C ?	A A ?	Template Eudralex volume 10 or similar document Template Eudralex volume 10 or similar document https://www.health.gov.sk/Zdroje?/Sources/komisie/Eticka-komisia-pre-klinicke-skusanie/Requirements-SR-clinical-trial-application.pdf
Suitability of the facilities				
	- Site Suitability Form [CT site]	D	A,B	https://www.health.gov.sk/Zdroje?/Sources/komisie/Eticka-komisia-pre-klinicke-skusanie/site_suitability_form_ENG_SVK.docx
Proof of insurance cover or indemnification				
	- Insurance certificate	C	A,B	
Financial and other arrangements				
	- Template compensation trial participants	C	A,C	Template Eudralex volume 10 (if not provided in the subject information letter)
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	C	A	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	C	A	Template Eudralex volume 10

SPAIN

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/CTIS-Guidance-v2-june.pdf
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A A	Strongly recommended to use Template Eudralex volume 10
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults, SIS and ICF 12-18 yr) - Paragrah in ICF for biological samples - - Other subject information material (e.g. information leaflet adults)	B B B	A,B A,B A,B	Strongly recommended to use national template https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/Annex-8A-202311.pdf https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/annexVIIIb-Guia-HIP-CI_ingles.pdf
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B A	A A	Strongly recommended to use Template Eudralex volume 10 or similar document Strongly recommended to use Template Eudralex volume 10
Suitability of the facilities				
	- Site Suitability Form [CT site]	B	A,B	Template Eudralex volume 10 or Spanish template: https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/annex4-Ins-AEMPS-EC.pdf
Proof of insurance cover or indemnification				
	- Annex VA. Insurance certificate model - Annex VB. Additional responsibility commitment in relation to coverage clinical trial insurance - Annex VI in cases where the waiver to present the insurance within 30 days after the CT authorisaton applies, as per art. 9.3 of Royal Decree 1090/2015 - Annex VII. Certificate low intervention clinical trials	B B B b	A,B A,B A,B A,B	Strongly recommended to use national templates https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/annex5a-Ins-AEMPS-EC.pdf https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/annex5b-Ins-AEMPS-EC.pdf https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/annex6-Ins-AEMPS-EC.pdf https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/annex7-Ins-AEMPS-EC.pdf
Financial and other arrangements				
	- Template compensation trial participants - Financial budget	B C	A,C A,C	Strongly recommended to use Template Eudralex volume 10 Financial budget according to Spanish instructions. https://www.aemps.gob.es/annexes-to-instruction-document-of-the-spanish-agency-of-medicines-and-medical-devices-for-conducting-clinical-trials-in-spain/?lang=en

Compliance with national requirements on data protection				
	- Template on the collection and use personal data	C	A	There is no national requirement for a separate Part II document on data protection, provided that the relevant information is included in the Subject Information and Informed Consent Form (Annex VIIIA)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A	Strongly recommended national template: which is the EU template including a paragraph referent to Spanish legislation in section 5.1 https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/Annex-13-compliance.pdf

SWEDEN

CTIS placeholder	Documents per placeholder	Mandatory templates#	Legal basis$	Link to document or additional info (if applicable) https://www.lakemedelsverket.se/en/permission-approval-and-control/clinical-trials/medicinal-products-for-human-use/clinical-trials-regulation-eu-536-2014/apply-for-clinical-trial-permit-according-to-regulation-536-2014#AccordionBlock-26611 All documents have to be in Swedish
Recruitment arrangements				
	- Template recruitment arrangements - Recruitment material [description]	B C	A,B A,B	Template Eudralex volume 10 (in Swedish):
Subject information and informed consent form				
	- SIS and ICF [description] (e.g. SIS and ICF adults) - Other subject information material (e.g. information leaflet adults)	C C	A,B A,B	
Suitability of the investigator				
	- CV Principal Investigator - DoI Principal Investigator	B B	A,B A,B	Template Eudralex volume 10 (in Swedish) Template Eudralex volum e10 (in Swedish)
Suitability of the facilities				
	- Site Suitability Form [CT site]	B	A,B	Template Eudralex volume 10 (in Swedish)
Proof of insurance cover or indemnification				
	- Insurance certificate)	C	A,B	The insurance for the trial shall be described in Swedish but insurance documentation issued in English by the insurer could be submitted as an appendix.
Financial and other arrangements				
	- Template compensation trial participants - Brief description on finance clinical trial and other possible arrangements	B C	A,B A,B	Template Eudralex volume 10 (in Swedish)
Compliance with national requirements on data protection				
	- Template on the collection and use personal data	C	A,B	No national requirement of separate Part II document on data protection besides the Template Eudralex volume 10 on GDPR statement (submitted under Form)
Compliance with use of biological samples				
	- Template on the collection, use and storage of biological samples	B	A,B	Template Eudralex volume 10 (in Swedish)