The documents mentioned in the annex I of the Clinical Trial Regulation (536/2014) and other relevant documents regarding the assessment of the part II of the application dossier

Unless otherwise stated, the documents can be submitted in English. A signature is not required in the documents. Please submit the documents in a PDF or PDF/A form.

SECTION OF THE ANNEX I	NATIONAL REQUIREMENTS
K. RECRUITMENT ARRANGEMENTS (INFORMATION PER MEMBER STATE CONCERNED)	
59. Unless described in the protocol, a separate document shall describe in detail the procedures for inclusion of subjects and shall provide a clear indication of what the first act of recruitment is.	The published template *Recruitment and Informed consent procedure* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en The template can be used for description mentioned in the section K 59. In addition to that, the following should be noticed: - Section 6 of the template cannot be filled since the simplified consent (art. 30) is not applicable in Finland. - The requirements of the Finnish Act on Clinical Trials on Medicinal Products (983/2021, sections 13-15) must be followed when applicable.
60. Where the recruitment of subjects is done through advertisement, copies of the advertising material shall be submitted, including any printed materials, and audio or visual recordings. The procedures proposed for handling responses to the advertisement shall be	The documents shall be written in Finnish and/or Swedish.

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outlined. This includes copies of communications used to invite subjects to participate in the clinical trial and arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial.	
L. SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE (INFORMATION PER MEMBER STATE CONCERNED)	The published template *Recruitment and Informed consent procedure* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en When using mentioned template for Annex I section L, it shall be fulfilled in Finnish and/or Swedish.
61. All information given to the subjects (or, where applicable, to their legally designated representatives) before their decision to participate or abstain from participation shall be submitted together with the form for written informed consent, or other alternative means according to Article 29(1) for recording informed consent.	Tukija has published a subject information sheet and informed consent template: *Malli tutkittavalle annettavasta tiedotteesta ja suostumusasiakirjasta* (17.2.2023, available in Finnish and Swedish): https://tukija.fi/en/applications-under-regulation The subject information sheet and informed consent shall be written in Finnish and/or Swedish. The Swedish version of the subject information sheet does not need to be submitted to the CTIS after the Finnish version has been approved. The material of this section must include the information according to the General Data Protection Regulation (art. 12-14). It can be for example a separate document or an annex to the subject information sheet.
62. A description of procedures relating to informed consent for all subjects, and in particular: (a) in clinical trials with minors or incapacitated subjects, the procedures to obtain informed consent from	The documents shall be written in Finnish and/or in Swedish.

the legally designated representatives, and the involvement of the minor or incapacitated subject shall be described; (b) if a procedure with consent witnessed by an impartial witness is to be used, relevant information on the reason for using an impartial witness, on the selection of the impartial witness and on the procedure for obtaining informed consent shall be provided; (c) in the case of clinical trials in emergency situations as referred to in Article 35, the procedure for obtaining the informed consent of the subject or the legally designated representative to continue the clinical trial shall be described; (d) in the case of clinical trials in emergency situations as referred to in Article 35, the description of the procedures followed to identify the urgency of the situation and to document it; (e) in the case of clinical trials where their methodology requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products, as referred to in	

Article 30, and where, as a consequence, simplified means for obtaining informed consent will be used, the simplified means shall be described.	The article 30 is not applicable in Finland.
63. In the cases set out in paragraph 62, the information given to the subject and to his or her legally designated representative shall be submitted.	The document shall be written in Finnish and/or in Swedish.
M. SUITABILITY OF THE INVESTIGATOR (INFORMATION PER MEMBER STATE CONCERNED)	
64. A list of the planned clinical trial sites, the name and position of the principal investigators and the planned number of subjects at the sites shall be submitted.	- *No extra requirements*-
65. Description of the qualification of the investigators in a current curriculum vitae and other relevant documents shall be submitted. Any previous training in the principles of good clinical practice or experience obtained from work with clinical trials and patient care shall be described.	The published template *Investigator Curriculum Vitae* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en
66. Any conditions, such as economic interests and institutional affiliations, that might influence the impartiality of the investigators shall be presented.	The published template *Declaration of interest* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en

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N. SUITABILITY OF THE FACILITIES (INFORMATION PER MEMBER STATE CONCERNED)	
67. A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted.	The published template *Site Suitability Template* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en The statement of the suitability of the facilities can be done separately for all clinical trial sites, or in one document in which the clinical trials sites are clearly separated may be employed. The statement can also be done by the contact person of the sponsor or someone else who is representing the sponsor.
O. PROOF OF INSURANCE COVER OR INDEMNIFICATION (INFORMATION PER MEMBER STATE CONCERNED)	
68. Proof of insurance, a guarantee, or a similar arrangement shall be submitted, if applicable.	Act on Clinical Trials on Medicinal Products (983/2021), section 5: The sponsor shall ensure that insurance or other appropriate guarantee to compensate for damage suffered by subjects is in place that covers the sponsor's and investigator's liability. A separate description of the insurance or other appropriate guarantee shall be submitted.
P. FINANCIAL AND OTHER ARRANGEMENTS (INFORMATION PER MEMBER STATE CONCERNED)	
69. A brief description of the financing of the clinical trial.	The description must be done according to the instructions of Tukija,

	Instructions on reporting financial matters related to clinical trials (25.10.2022) https://tukija.fi/en/applications-under-regulation
70. Information on financial transactions and compensation paid to subjects and investigator/site for participating in the clinical trial shall be submitted.	The Finnish Act on Clinical Trials on Medicinal Products (983/2021), section 22: The costs for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol are free of charge to the subject unless there is a justified reason for charging for them. The published *Compensation for trial participants* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en If there is a possibility that there might be some costs for the research subject, the reason of that shall be explained. Also, the section 23 of the Finnish Act on Clinical Trials on Medicinal Products shall be followed. All equipment or products shall be identified on section "other".
71. Description of any other agreement between the sponsor and the site shall be submitted.	- *No extra requirements*-
Q. PROOF OF PAYMENT OF FEE (INFORMATION PER MEMBER STATE CONCERNED)	
72. Proof of payment shall be submitted, if applicable	See Fimea's instructions: https://www.fimea.fi/web/en/supervision/clinical_drug_trials/trials-under-the-eu-regulation/trial-application-and-modifications
R. PROOF THAT DATA WILL BE PROCESSED IN COMPLIANCE WITH UNION LAW ON DATA PROTECTION	
73. A statement by the sponsor or his or her representative that data will be collected and processed in	- *No extra requirements*-

accordance with Directive 95/46/EEC shall be provided.	
Compliance with the applicable rules for the collection, storage and future use of biological samples of the subject set out in the article 7.1.h of the CTR.	The published template *Compliance with applicable rules for biological samples* is requested to be used, a Word version is available at: https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en Memorandum of TUKIJA and Fimea (14.1.2022) shall be taken into account: https://tukija.fi/en/applications-under-regulation (available only in Finnish).

The European Commission has published harmonization guidance on the documents regarding part II: https://ec.europa.eu/health/system/files/2020-11/harmonisation_guidance_en_0.pdf

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