**PART I**

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| **File/Document** | **CTR Annex I**  | **References** |
| B. Cover letter | B | * According to CTR annex I of CTR
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| D. Protocol | D 24 | * According to annex I of CTR
* See also ICH E6 GCP
* The protocol shall be accompanied by a synopsis of the protocol, provided as a separate document in Dutch, French and German.
* DSMB charter (if applicable)
* Patient facing documents\* (same language requirements as for ICF. See annex II of the CTR Q&A on [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014))
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| E. Investigator’s brochure | E | * According to annex I of CTR
* See also ICH E6 GCP
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| F. Documentation relating to GMP for the IMP* Copy of the manufacturing authorisation
* Certification by the Qualified Person
 | F | * GMP certificates not accepted, only GMP manufacturing authorisations
* EU template strongly recommended for QP declaration
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| G. IMPD dossier | G | * See also [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014) chapter III for content and Common Technical Document (CTD) format
* GLP statement has to be part of the IMPD (see: point 44 of annex I of the CTR and <http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/QAs_document_on_GLP_-_2017.pdf>
 |
| G. Simplified IMPD | G  | See CTR (annex I points 50 to 53) to see cases when a simplified IMPD is accepted |
| G. SMPC | G  | If applicable.  |
| H. AXMP dossier  | H | AXMPD or SPC if applicable |
| I. Copy of the summary of scientific advice | I 56 | If applicable.The outcome of the scientific advice should be reflected : the summary of the scientific advice should include both the questions and the answers provided by the European Agency, or any Member State or third country otherwise the “advice” would be missing. A text limited to the questions does not summarise the scientific advice. |
| I. Copy on the agreement on the PIP | I 57 | If applicable |
| J. Content of the labelling | J | Example of the planned label in accordance with Law of 7 May 2017:- 3 national languages- but specific label for the trial not mandatory if registered products- and allowed in 1 language (English included) if administered at site and patients do not deal with the product |

\*See question 1.24 of the CTR Q&A in [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014) for a description of what are patient facing documents.

**PART II**

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| **File/Document** | **CTR Annex I**  | **References** |
| K. Recruitment arrangements, unless described in the protocol | K 59 | Stand-alone document or reference to the applicable section of the protocol has to be providedA [template](https://health.ec.europa.eu/document/download/a3833031-a6d5-4eb2-a6ab-2e0f581c91e0_en?filename=informedconsent_patientrecruitmentprocedure_en.docx) developed by the EU Commission is available in [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014) |
| K. Advertising material | K 60 | If applicable |
| L. Subject (and legally designated representative) information and informed consentICF and recruitment material | L 61&63 | * Use of the existing template is strongly recommended.
* **A new version of the ICF template for interventional trials in adults and dated 28-06-2019 has been published on** [http://www.ct-college.be](http://www.ct-college.be/)
* ICF(s) to be submitted at least in the official national language(s) of the region(s) where the trial is conducted
* Sponsor is responsible for appropriate translations. The EC only reviews the ICFs in one language
* Recruitment material\* (to be submitted at least in the official national language(s) of the region(s) where the trial is conducted)

\* See question 1.24 of CTR Q&A in [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014) for an explanation on the difference between recruitment material and patient facing documents |
| L. Informed consent Procedure | L 62 | A stand-alone document or a reference to the applicable section of the protocol has to be providedA [template](https://health.ec.europa.eu/document/download/a3833031-a6d5-4eb2-a6ab-2e0f581c91e0_en?filename=informedconsent_patientrecruitmentprocedure_en.docx) developed by the EU Commission is available in [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014) |
| M. List of the planned sites, name and position of PI and planned number of subjects at the sites | M 64 | Has to be provided if more than one site in Belgium |
| M. CV and declaration of interest of the principal investigator of each site | M 65&66 | * [BE specific CV template](https://www.famhp.be/sites/default/files/This%20template%20may%20be%20used%20by%20Sponsors%20of%20clinical%20trials%20as%20part%20of%20the%20application%20dossier_1.docx) strongly recommended.

Any other template (e.g. TransCelerate) can be accepted but should at least contain the same information* GCP training should be documented (in the CV or by a GCP certificate), mentioning the name of the certifying organisation **and should not be older than three years**
* [Declaration of interest](https://health.ec.europa.eu/document/download/7dbff6f3-5e32-4c59-81c4-8b2582f971ed_en?filename=declaration_interest_template_en.docx): template developed by the EU Commission available on [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014)

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| N. Statement on the suitability of the sites | N | Most recent version of the written statement issued by the site. **Please mention the name of the institution and not the campus.*** [Template available](https://www.famhp.be/sites/default/files/EU%20regulation%20536_1.docx) : this template is **mandatory for Belgium**
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| O. Proof of insurance cover or indemnification | O | Certificate with specification of the amount insured and reference to the Belgian law of 7 May 2017 Art. 12. § 1er (no fault insurance) |
| P. Brief description of the financing of the CT | P 69 | If applicable |
| P. Information on financial transactions and compensation paid to subjects and investigator/site | P 70 | * Draft version of the contract with (draft) amounts is currently accepted
* It is advised to contact the CTCs of the concerned sites as soon as possible in order to gain time in the evaluation of the financial agreements
* A template has been developed by EU Clinical Trials Expert Group for “[Compensation for trial participants](https://health.ec.europa.eu/document/download/f982c9a5-a841-4199-b4fd-0d4049e64e5d_en?filename=payment_compensation_template_en.docx)” and is available on [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014)
 |
| P. Description of any other agreement | P 71 | Clinical trial agreements and others related to the trial if applicable |
| R. Statement that data will be collected and processed in accordance with the GDPR | R | We currently still accept that only a general document is provided in the FORM section of CTIS.No specific document for Belgium currently requested.**This document should at least contain**:“[name of sponsor] confirms that collection and processing during clinical trials is done in full compliance with the European Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR)” |
| S. “Collection, storage and future use of human biological samples” |  | A [template](https://health.ec.europa.eu/document/download/29ba64b6-8057-4e39-b09b-8ad356a8f5ca_en?filename=mp_compliance-app-rules-bio_en.docx) has been developed by EMA and is available on [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014). This template is currently not mandatory for Belgium if the information is properly available in the dossier. |

For any question on the content of the dossier to be submitted for Belgium in CTIS or on the clarification of a consideration in the RFI list on Part I (when Belgium is RMS) or on Part II, please contact : CTR@fagg-afmps.be

Transitioning trials:

Please consult the last version of the CTR Q&A as available on [Eudralex volume 10](https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014) (Section 11. Arrangements for the transitional period). Questions related to transitioning trials have been clarified.

Fee for Belgium:

No payment will be requested at the moment of the submission of the dossier. Therefore no proof of payment must be provided for Belgium in the CTIS submission dossier.

However the fee related to the safety assessment of these dossiers (1109, 43 euros for initials and 476, 09 for substantial modifications as stated in the “Loi de financement” from February 2022) will be requested by the mean of an invoice that will be provided at regular basis to sponsors (contact details will be taken from contact details as provided in CTIS for the sponsor). This invoice will be related to all CTA applications submitted in CTIS for Belgium during this period. A fee will also be requested by the mean of an invoice at regular basis to sponsors for GCP inspections (also stated in the “Loi de financement” from February 2022). We refer you to slide n°15 of [this presentation](https://www.afmps.be/sites/default/files/Loi%20de%20financement%20AFMPS%202022%20-%20session%20d%27info%2023.02.2022.pptx) where the annual fee related to the GCP inspections is indicated as “Authorisation”.

Naming of the documents:

Please precede the name of the document with CTR annex I corresponding letter. This will allow the member states to have a structured list of documents after download of each Part of the dossier from CTIS. Version number and dates should not be part of the name of the document and have to be directly entered as structured data in CTIS.

See also the [Best Practice guide for Sponsors of document naming in CTIS](https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/CTCG/2022_09_CTCG_Instruction_naming_documents_CTIS_EU_v1.4.pdf) on the website of the [CLINICAL TRIALS COORDINATION GROUP](https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html) (CTCG).

In order to simplify the re-submission process to CTIS, CTCG accepts that the CT numbers within the documents uploaded into the system are shortened concerning the last 2 digits which only show how often the sponsor created previous submissions and re-submitted the applications.

In case of a decision letter the full number including the last 2 digits will be reflected.

If the full number is reflected in the documents and a re-submission takes place, there is no expectation that these numbers are immediately corrected within the documents during the ongoing procedure. This can be done at a later stage when the documentation is updated during a SM procedure.