CTCG best practice guide naming of documents, version 2.0[1], 9 March 2023

CTCG has set up a best practice for the naming of documents in CTIS. The purpose of this naming convention is to provide a harmonised structured overview of the documents in the clinical trial application dossier, in alignment with the document types referred to in the sections of CTR annex I and II. Please note that this naming convention refers to the document title in CTIS, and that the documents as uploaded into CTIS may have any desired filename, except for the special characters ()/,.;|[]. Each document uploaded in CTIS, especially multiple documents of the same document type, must have a CTIS title that is unique, self-explanatory including relevant identification when applicable, short and concise (not exceeding 100 characters).

The document title in CTIS may be according to sponsor document management system, including the sequence of relevant details, as long it fulfills the following principles:

- Starts with designated **letter code prefix** of the section the document belongs to (B-S)
- **Self-explanatory** name of document type (abbreviation possible), e.g. protocol, IB, manufacturer authorisation or MIA, questionnaire, recruitment material, ICF etc.
- **Relevant details** as appropriate
    - Details of document sub-type, e.g. ICF type (e.g. adult, 12-16 yr), advertisement type, “addendum”, ICH Common Technical Document module number, etc.
    - Country identification (e.g. ISO country code) for country-specific documents
    - Trial site identification (site name, site number) for site-specific documents
    - **Language** (e.g. ISO language code) as needed to differentiate language translations
    - **Product name** as needed to differentiate product-related documents
    - **Organisation name** (abbreviated name) as needed to differentiate organisation-related documents, e.g. manufacturer, authority name giving scientific advice, other sponsor reference etc.
    - **Person name** should be included in the file name only where compliant with the public disclosure rules in CTIS, i.e. person with legal role under EU CTR (for site-specific documentation permitted only for investigator-related suitability documents, e.g. CV or Declaration of Interest, since the name of the principal investigator will be made public)
- Circumstantial attributes as needed
    - **“Number”** where document to be uploaded exceeds CTIS file size limits (50 MB) and is to be split into multiple parts
    - **“Public”** or “**redacted”** in the document version “for publication” where a second document version “not for publication” is uploaded in addition to the version “for publication”
    - “**Tracked changes**” or “tc” where a tracked changes document version is uploaded in addition to a clean version of the document
    - “Summary of changes” or “extract” where a document extract is uploaded using this CTIS document sub-type for substantial or non-substantial modifications (ref. EU CTR Annex II, D5 (a)
- **Note**: Version number and date should not be included in the document title. The version number and date should only be entered in the corresponding CTIS document metadata fields in the document upload window.

EU-trial number within document

The re-submission process in CTIS changes the last two digits of the CT number from 00 to 01. In order to simplify the re-submission process, CTCG accepts that the CT numbers within the documents uploaded into the system do not include the last 2 digits, so that they do not need to be changed for re-submission. 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.

[1] Changes compared to the previous version concerns the instruction for use

Example of structure CTA dossier

<section code><Type><Sub-type plus additional details such as organisation, name etc.><Country><language><circumstantial details>

At each section, between brackets the **placeholder in CTIS** is indicated where the document must be uploaded. **Note**: this is not the full list of documents to be uploaded in CTIS. At some places in CTIS, additional documents should be uploaded but for these documents the structure below is not applicable (e.g. in the Forms section 'Proof of payment of fee' and 'Statement of compliance with Regulation (EU) 2016/679 (GDPR)' or in the Associated Trial Section 'Agreement from other sponsor' (if applicable).

FORM

B. Cover letter *(placeholder cover letter in CTIS)*
B1_Cover letter EU CT number
B1_Cover letter SM EU CT number (including a description of the changes)

PART I

D. Protocol (*placeholder protocol information in CTIS*)
D1_Protocol EU CT number
D1_Protocol synopsis MS EU CT number (*include MS language code in title)*
D1_Master protocol EU CT number and name and sub-protocol name and specific number/ID *(only for CCT)*
D2_Protocol modification nr number EU CT number *(in case of SM as separate doc.*)
D3_DSMB Charter EU CT number
D4_Patient facing documents e.g. questionnaire or diary *(if applicable*)

E. Investigator's Brochure (*placeholder product information in CTIS*)
E1_IB product name
E2_SmPC product name

F. Documents GMP compliance (if applicable) (*placeholder product information in CTIS*)
F1_ Marketing/importing authorization MIA product name abbreviated name manufacturer/importer
F2_QP GMP declaration product name abbreviated name manufacturer/importer
F3_ Other statements/licences *(e.g. import license*) product name abbreviated name manufacturer/importer

G. Investigational Medicinal Product Dossier (*placeholder product information in CTIS*)
G1_IMPD_Q product name
G1_IMPD_E-S product name
G1_Simplified IMPD_Q product name
G1_Simplified IMPD E-S product name

H. Auxiliary Medicinal Product Dossier (*placeholder product information in CTIS*)
H1_AxMPD product name

I. Scientific advice and pediatric investigational plan (PIP) (*same placeholder in CTIS*)
I1_Scientific advice summary name organisation
I1_Scienfitic advice Quality name organisation
I2_PedCo opinion
I3_EMA PIP decision name agency

J. Labeling (*placeholder product information in CTIS*)
J1_Label IMP_MS product name (*include MS language code in title)*
J2_Label AxMP_NL product name (*include MS language code in title*)

PART II

K. Recruitment arrangement (*same placeholder in CTIS*)
K1_Recruitment arrangements
K2_Recruitment material description

L. Subject information sheet, informed consent form, other subject information material (*same placeholder in CTIS*)
L1_SIS and ICF description (*e.g. SIS and ICF adults, SIS and ICF 12-16 yr)*
L2_Other subject information material description (*e.g. information leaflet adults)*

M. Suitability investigator (*same placeholder in CTIS*)
M1_CV Investigator name investigator and clinical trial site *(use abbreviations)*
M2_DoI Investigator name investigator and clinical trial site *(use abbreviations)*

N. Suitability facilities (*same placeholder in CTIS*)
N1_Site suitability form name clinical trial site

O. Proof of Insurance or indemnification (*same placeholder in CTIS*)
O1_Trial participant insurance certificate
O2_Proof of coverage sponsor or investigator name sponsor/trial site *(if not covered by O1*)

P. Financial and other arrangements (*same placeholder in CTIS*)
P1_Compensation trial participants, investigator, funding and other arrangements

R. Compliance GDPR (*same placeholder in CTIS*)
R1_Compliance on the collection and use of personal data

S. Biological samples (*same placeholder in CTIS*)
S1_Compliance on the collection, use and storage of biological samples