Document codes and titles in CTIS (version 1.4, dd 7 September 2022)

Please adhere to the structure of CTR Annex I for document codes and titles when uploading files in CTIS, as shown below (Part I: section B-J; Part II: section K-S). Please fill in the requested information in the marked grey fields. Make sure that all documents have self-explanatory titles including relevant identification when applicable as mentioned below and include "redacted" in the file name in case a separate document for publication is uploaded. Please note that the files uploaded into CTIS can have any filename, but do not include special characters ()/,.;|[]. The coding and naming applies to the document name in CTIS (the field 'Title' in the upload window). The original filename is pre-filled in the field 'Title' but can be adapted. Version number and date should not be in the document title, instead indicate the correct version number and date in the corresponding fields in the upload window.

B. Cover letter

B1_ Cover letter EU CT number

D. Protocol

D1_ Protocol EU CT number
D1_ Protocol synopsis_ENG EU CT number
D1_ Protocol synopsis_NL EU CT number (*include MS in title, example is for NL)*
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*)
D5_ Master protocol EU CT number and name and sub-protocol name and specific number/ID *(applicable for complex CT)*

E. Investigator's Brochure

E1_ IB product name

F. Documents GMP compliance (if applicable)

F1_ GMP declaration abbreviated name manufacturer/importer
F2_ QP declaration abbreviated name manufacturer/importer
F3_ Other statements/licences *(e.g. import license*) abbreviated name manufacturer/importer

G. Investigational Medicinal Product Dossier

G1_ IMPD_Q product name
G1_ IMPD_E-S product name
G2_ SmPC product name

H. Auxiliary Medicinal Product Dossier

H1_ AxMPD product name

I. Scientific advice and pediatric investigational plan (PIP)

I1_ Scientific advice name organization
I2_ PedCo opinion
I3_ PIP decision name agency

J. Labeling

J1_ Label IMP_NL product name (*include MS in title, example is for NL)*
J1_ Label IMP_ENG product name
J2_ Label AxMP_NL product name (*include MS in title, example is for NL*)
J2_ Label AxMP_ENG product name

K. Recruitment arrangement

K1_ Recruitment arrangements
K2_ Recruitment material description

L. Subject information sheet, informed consent form, other subject information material

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

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

N1_ Site suitability form name clinical trial site

O. Proof of Insurance or indemnification

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

P1_ Compensation trial participants, investigator, funding and other arrangements

R. Compliance GDPR

R1_ Compliance on the collection and use of personal data

S. Biological samples

S1_ Compliance on the collection, use and storage of biological samples