Explanation

Codes and document titles for digital submission

We request you adhere to the format of the standard research file when naming your documents (see the CCMO website). Below you will find examples of the correct coding and document titles for your documents. You are requested to fill in the necessary data in the marked grey fields of the document title. The *italic text* between brackets serves as an explanation. The documents must have **unique document titles** – please do not use identical titles. If you are using a file transfer system, such as Eudralink, please file all documents in one single folder.

Codes and filenames documents

A. Correspondence

A1: Covering letter submitting party dd dd-mm-yy (see model letter)

A2: Authorisation letter from the sponsor dd dd-mm-yy (if the submitting party is not the sponsor)

A3: Confirmation e-mail EudraCT number dd dd-mm-yy

B. Forms

B1: ABR form version … dd dd-mm-yy (see ToetsingOnline)

B2: Local addendum to the ABR form (if applicable)

B3: EudraCT application form dd dd-mm-yy

B4: Gene therapy/GMO form dd dd-mm-yy (if applicable)

B5: EudraCT form notification of amendment dd dd-mm-yy

B5: Notification of the addition of a centre [name centre] dd dd-mm-yy

B7: EudraCT end of trial form dd dd-mm-yy

C. Protocol and amendments

C1: Research protocol NLxxxxx.xxx.xx, version … dd dd-mm-yy

C2: Amendment version … dd dd-mm-yy

D. Product information

D1: IB [*name product*] version … dd dd-mm-yy

D1. Survey list of SUSARs dd dd-mm-yy (only concerning SUSARs after the IB date)

D2: IMPD [*name product*] version … dd dd-mm-yy

D2: IMDD [*name product*] version … dd dd-mm-yy (if applicable)

D2: List of relevant trials dd dd-mm-yy

D3: Example lables in Dutch version … dd dd-mm-yy

D4: GMP-declaration dd dd-mm-yy (if applicable)

D5: Product information hospital pharmacist (if applicable)

D6: Digital nucleotide sequence of the vector [*name vector*] if applicable)

D6. Additional product data (type of document)

E. Information for the research subjects

E1/E2: Research subject/representative information leaflet including the consent form(s) version … dd dd-mm-yy

E3: Advertising texts or other recruitment material version … dd dd-mm-yy (if applicable, type of document)

E4: Information materials version … dd dd-mm-yy (if applicable, type of document)

F. Questionnaires, patient diaries, patient cards, etc. (if applicable)

F1: [*Type of questionnaire*] version … dd dd-mm-yy

F2: Patient diary version … dd dd-mm-yy

F3: Patient card version … dd dd-mm-yy

F4: Other documents (type of document) dd dd-mm-yy

G. Insurance information

G1: Insurance certificate for WMO research with human subject insurance dd dd-mm-yy

G1. Declaration of human subjects insurance dd dd-mm-yy (if applicable)

G2: Proof of coverage of investigator or sponsor, for example liability insurance [*name sponsor/centre*] dd dd-mm-yy

H. CVs

H1: CV independent expert [*name centre*], [name expert] dd dd-mm-yy

H2: CV coordinating investigator [*name investigator*] dd dd-mm-yy

I. Information per participating centre in the Netherlands

I1: List of participating centres and principal investigators per centre dd dd-mm-yy

I2: Research declaration from the head of department/healthcare group manager (or equivalent) [*name centre*] dd dd-mm-yy

I3: CV of the principal investigator [*name centre*], [*name investigator*] dd dd-mm-yy

I4: Other information per participating centre (if applicable)

J. Additional information regarding financial compensation

J1: Information on compensation for research subjects dd dd-mm-yy

J2: Information on compensation for investigators and centres dd dd-mm-yy

K. Other relevant documents

K1: Copy of reviews by other institutions [*name institutions*], dd dd-mm-yy (e.g. grant giving body or recommendations by EMA, FDA etc.)

K2: Overview foreign competent authorities together with copy of reviews by foreign MRECs/ECs or authorised authorities dd dd-mm-yy (including VHP)

K3: Clinical trial agreement from sponsor or funder and the investigator and/or institution [*name centre*], dd dd-mm-yy

K4: Scientific publications [*author, year, journal, volume, pages*] dd dd-mm-yy

K5: Data Safety Monitoring Board (DSMB) [*composition, charter, advise*] version … dd-mm-yy (if applicable)

K6: Other documents (if applicable, type of document)

L. Safety information

L1: SUSARs ……. dd dd-mm-yy

L2: Periodic line listings SUSARs [name product] dd [from dd-mm-yy to dd-mm-yy]

L3: Development Safety Update Reports [name product] dd dd-mm-yy

L4: SAEs ……. dd dd-mm-yy

L2: Periodic line listings SAEs [name product] dd [from dd-mm-yy to dd-mm-yy]

L6: Other relevant safety information [type document] dd dd-mm-yy

M. Progress reports and research results

M1: Progress report dd dd-mm-yy

M2: Summary of research results/scientific publications dd dd-mm-yy

M3: Clinical trial report dd dd-mm-yy