

# 1. Uploading documents into CTIS: filename, CTIS title, version number and date

The **Title** of the document in CTIS. The filename as it was uploaded is pre-filled here, this should be changed to match the requirements for document coding and titles (see next slide). Always remove version and date from the Title, because the Title cannot be changed when uploading a newer version later.

Change the default version (1) and default date (today) to the actual date and version of the document (in this example: version 4, date 12/02/2022).

Please note: the version field is free text: e.g. a zero of N/A can be filled in for documents that do not have a version number.

**Document upload**

Place documents here or click to upload  
Protocol ABC123 v4 12Feb2022.pdf

Title\* Protocol ABC123 v4 12Feb2022  
Type\* Protocol (for publication)

Language English  
Version\* 1  
System version 1.00

Date\* 29/03/2022

Comment (optional)

The above document(s) will be published.

Cancel Attach

The **filename** of the uploaded file. The uploaded files can have any name, except for some forbidden characters:

The filename provided is not valid. No special characters (/ , . ; |) allowed.

The CTIS System version of a document, always starting at 1.00 for the first version of a document uploaded into CTIS, and increasing when using the Update functionality. Cannot be edited. System Version therefore does not necessarily match the true version.

## Document codes and titles in CTIS

Please adhere to the structure of CTR Annex I for document codes and titles when uploading files in CTIS, as shown below. Please fill in the requested information in the marked [grey fields]. Make sure that all documents have unique titles. Please note that the files uploaded into CTIS can have any filename; 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 here, 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.

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### 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]

D2. Protocol\_modification nr [number] [EU CT number]

D3. DSMB Charter [EU CT number]

D4. Patient facing documents [questionnaire, diary] (if applicable)

### E. Investigator's Brochure

E1. IB [product name]

### F. Documents GMP compliance (if applicable)

F1. GMP declaration

F2. QP declaration

F3. Other statements/licences (e.g. import license)

### 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]

J1. Label IMP\_ENG [product name]

J2. Label AxMP\_NL [product name]

J2. Label AxMP\_ENG [product name]

### K. Recruitment arrangement

K1. Template recruitment arrangements NL

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]

M2. DoI Investigator [name investigator]

### N. Suitability facilities

N1. VGO [name investigational site]

### O. Proof of Insurance or idemnification

O1. WMO trial participant insurance certificate

O2. Proof of coverage sponsor or investigator [name sponsor/trial site] (if not included on VGO)

### P. Financial and other arrangements

P1. Template compensation trial participants, investigator, funding and other arrangements

### R. Compliance GDPR

R1. Template on the collection and use personal data NL

### S. Biological samples

S1. Template on the collection, use and storage of biological samples NL

## 2. Uploading documents into CTIS in response to an RFI: change application

Clinical trials Notices & alerts 38 Annual safety reporting RFI User administration

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

MSCs  
Part I \*  
Part II  
Evaluation  
Timetable

Validation

RFI 1

RFI-CT-2022-501381-22-00-IN-001 Due: 07/02/2022

MSC: Netherlands Submission date: 27/01/2022 Due date: 07/02/2022

Reason Incomplete

Supporting documentation

MS:  
Quality

No document available

Non-Quality

No document available

Sponsor:

General documentation [Add document](#)

Quality related documentation [Add document](#)

Please notice that in this section only supporting documentation to the response should be uploaded. If a new version of any of the documents included in the Annex I of Regulation (EU) 536/2014 needs to be provided, should be uploaded on the respective section of the application dossier and NOT here

Sort by

Response to consideration

Consideration number RFI-CT-2022-501381-22-00-IN-001-01 Application section parts Part I - Clinical Application section and document Protocol

Consideration Please submit .....

Response

Textual response

Documents related to the response

[Add document](#)  
[Save response](#)

Change application

For any changes to the application (documents or data) requested in the RFI. E.g. missing documents requested during validation, requests to modify document title/date/version during validation, or a new protocol version requested during assessment.

Optional, only for documents containing the response to this specific consideration. If the consideration requests a missing or updated document, do not upload it here, but instead use 'Change application'!

Clicking 'Change application' and confirming it, leads you back to the dossier, where documents can be added similarly to the initial submission. Click the lock and navigate to the location of the dossier where the change should be made.

The screenshot shows a web interface for managing a clinical trial dossier. At the top right, there are three buttons: 'Check', 'Save', and 'Withdraw'. Below this is a section titled 'Trial specific information (Part I)'. Underneath, there are several expandable sections: 'Trial details', 'Trial identifiers', 'Trial information', and 'Protocol information'. The 'Protocol information' section is expanded to show 'Clinical trial protocol' and 'Protocol \*'. A document titled 'Protocol' is listed with a 'System version 1.00' and a 'submission date 27/01/2022'. To the right of the document title are icons for edit, update, delete, and add. A red circle highlights the lock icon in the top right corner of the 'Trial details' section. Another red circle highlights the 'Add document' button. A red box with an arrow points to the 'Update' icon, and another red box with an arrow points to the 'Edit' icon.

**Update:** for uploading a new version of an existing document, e.g. protocol v2 with changes requested by the MS. You are asked to enter the version number and date, but the document title in CTIS cannot be changed!

**Edit:** for changing the title, version or date of an existing document. If by mistake an uploaded document contained a version or date in its title, or the indicated version and/or date do not match the documents, then you will likely be asked to correct this in the Validation RFI.

**Add document:** for adding fully new documents, e.g. missing documents requested by the MS during validation. The System version will be 1.00. Please use document codes and titles as explained earlier.

Uploading a new version of an existing document using the **Update**-button, creates System Version 2.00

The screenshot shows a document management interface with the following elements:

- Trial Identifiers** (collapsible)
- Trial information** (collapsible)
- Protocol information** (collapsible)
- Clinical trial protocol** (collapsible)
- Protocol \*** (document title)
- CTIS system version, does not necessarily match own version number** (red box annotation pointing to the document title)
- Newest version is shown on the left, previous versions are shown here.** (red box annotation pointing to the document title)
- Add document** (blue button)
- Previous versions 1** (link with up arrow)
- Protocol** (document icon)
- English · Protocol (for publication) · System version 2.00** (document details)
- submission date 27/01/2022** (document details)
- Version 2 · 27/01/2022** (document details)
- Own version number and date, as entered during the upload.** (red box annotation pointing to the submission date)
- Comment v2 uploaded in response to RFI** (document details)

When finished adding new/changed documents to the application, navigate back to the RFI response.

The screenshot shows an RFI response interface with the following elements:

- Form** (link)
- MSCs** (link)
- Part I** (link)
- Part II** (link)
- Evaluation** (link)
- Timetable** (link)
- Evaluation** (tab)
- Validation** (tab)
- RFI 1** (RFI title)
- RFI-CT-2022-501381-22-00-IN-001** (RFI ID)
- Due: 07/02/2022** (due date)
- MSC: Netherlands** (MSC name)
- Submission date: 27/01/2022** (submission date)
- Due date: 07/02/2022** (due date)
- Discard changes** (blue button)
- Reason** (label)
- Incomplete** (reason)
- Includes application changes** (checkbox)
- Changes to the application \*** (label)
- No document has been uploaded.** (message)
- Add document** (blue button)

It is now indicated that changes to the application were made, and it is mandatory to upload a list of changes.