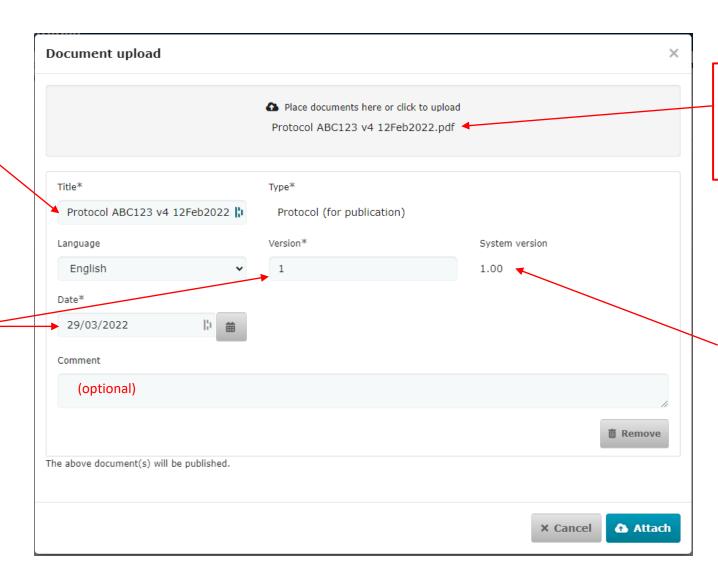
## 1. Uploading documents into CTIS: filename, CTIS title, version number and date

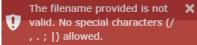
The **Title** of the document in CTIS. The filename as it was uploaded is pre-filled here, this should be changed to match the requirements for document coding and titles (see next slide). Always remove version and date from the Title, because the Title cannot be changed when uploading a newer version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

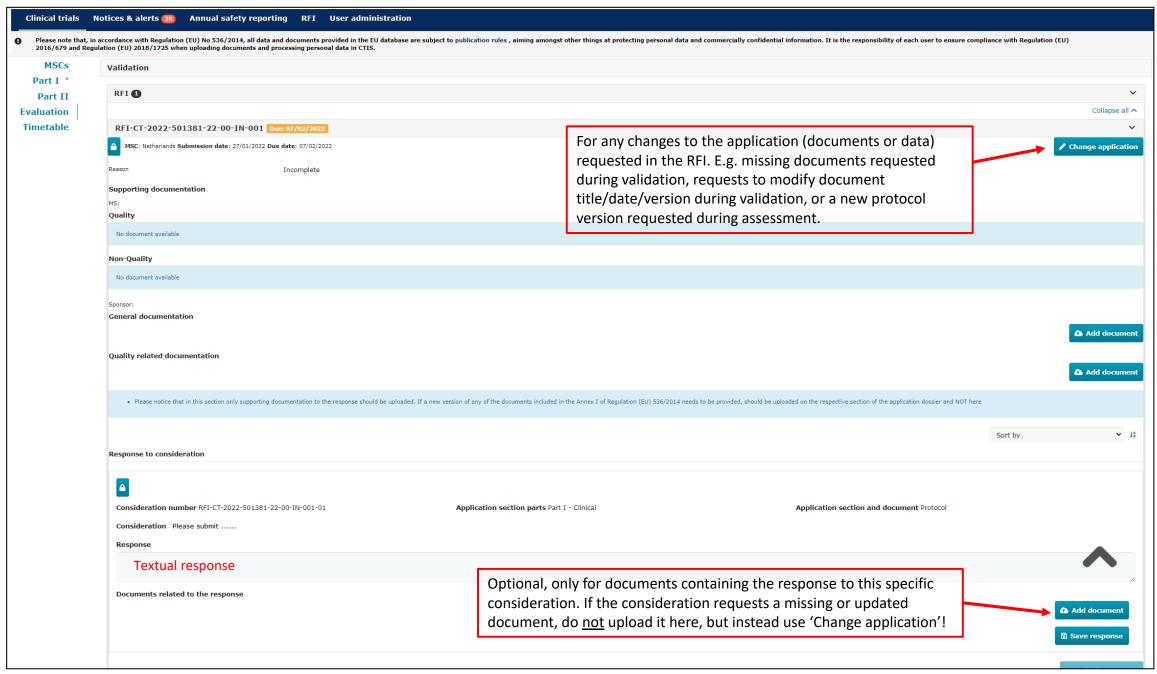


The **filename** of the uploaded file. The uploaded files can have any name, except for some forbidden characters:

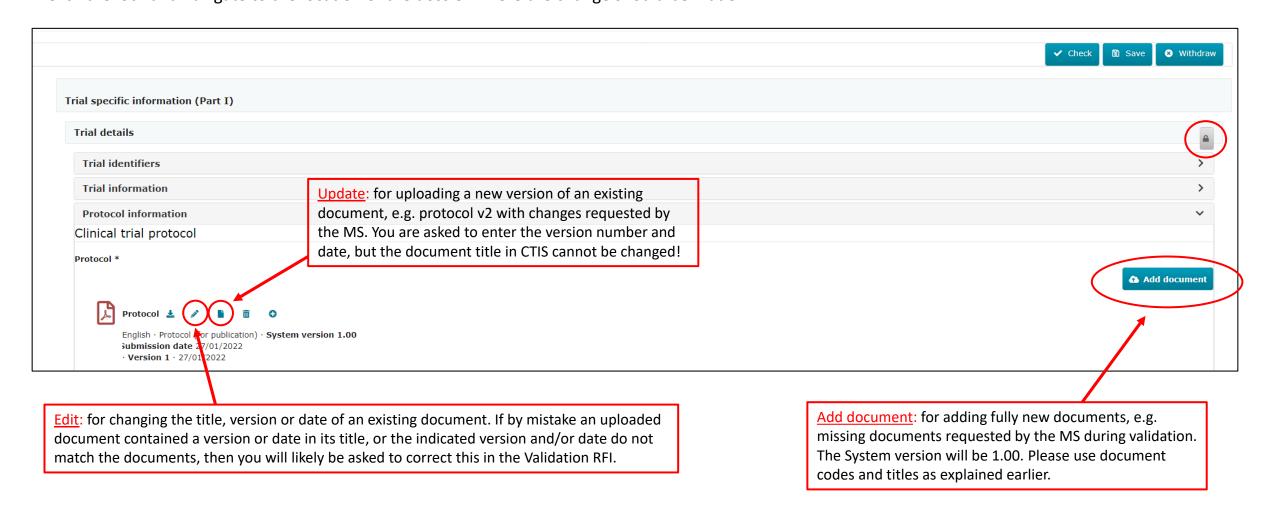


The CTIS System version of a document, always starting at 1.00 for the first version of a document uploaded into CTIS, and increasing when using the Update functionality. Cannot be edited. System Version therefore does not necessarily match the true version.

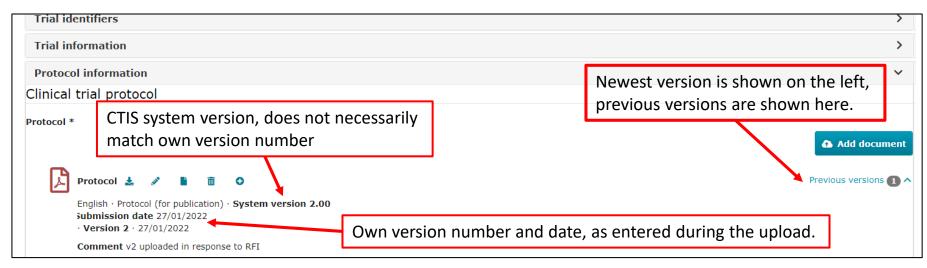
## 2. Uploading documents into CTIS in response to an RFI: change application



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.



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



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

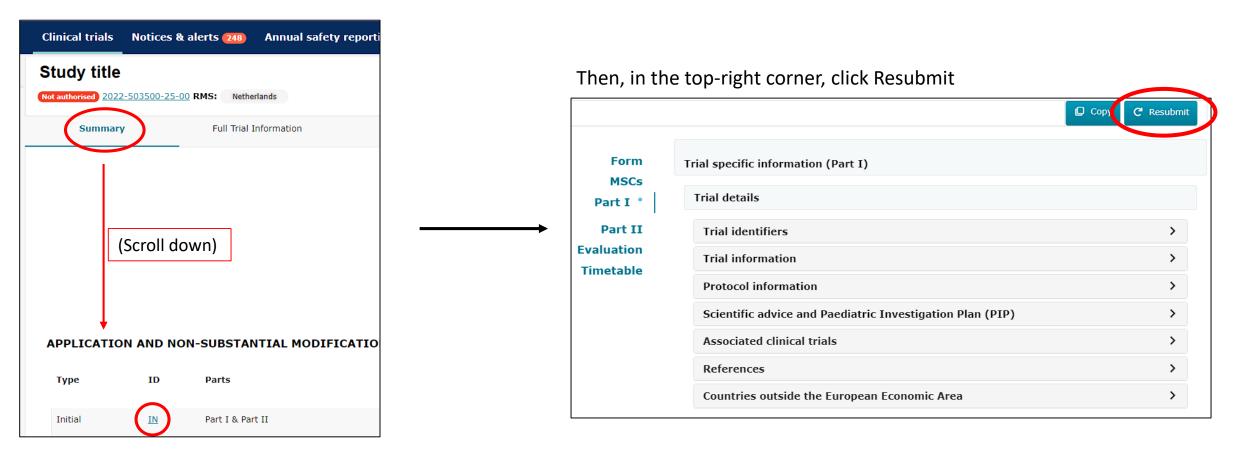


It is now indicated that changes to the application were made, and it is mandatory to upload a list of changes.

## Resubmission of a trial

CT applications can lapse (e.g. when the sponsor misses a response due date), be withdrawn by the sponsor, or rejected by the authorities. Lapsed, withdrawn and rejected CT applications can be <u>resubmitted</u>.

On the CT page, in the Summary tab, scroll down to the application section. Click the application you want to resubmit: IN = initial application.



The documents of the original submission will be copied to the resubmission. Documents can be replaced if necessary (e.g. cover letter). Please note: the version and date of all documents is reset to v1 and today, so click Edit (pencil icon) to enter the correct version and date for all documents. The resubmission will keep the original CT-number, but ending with -01.