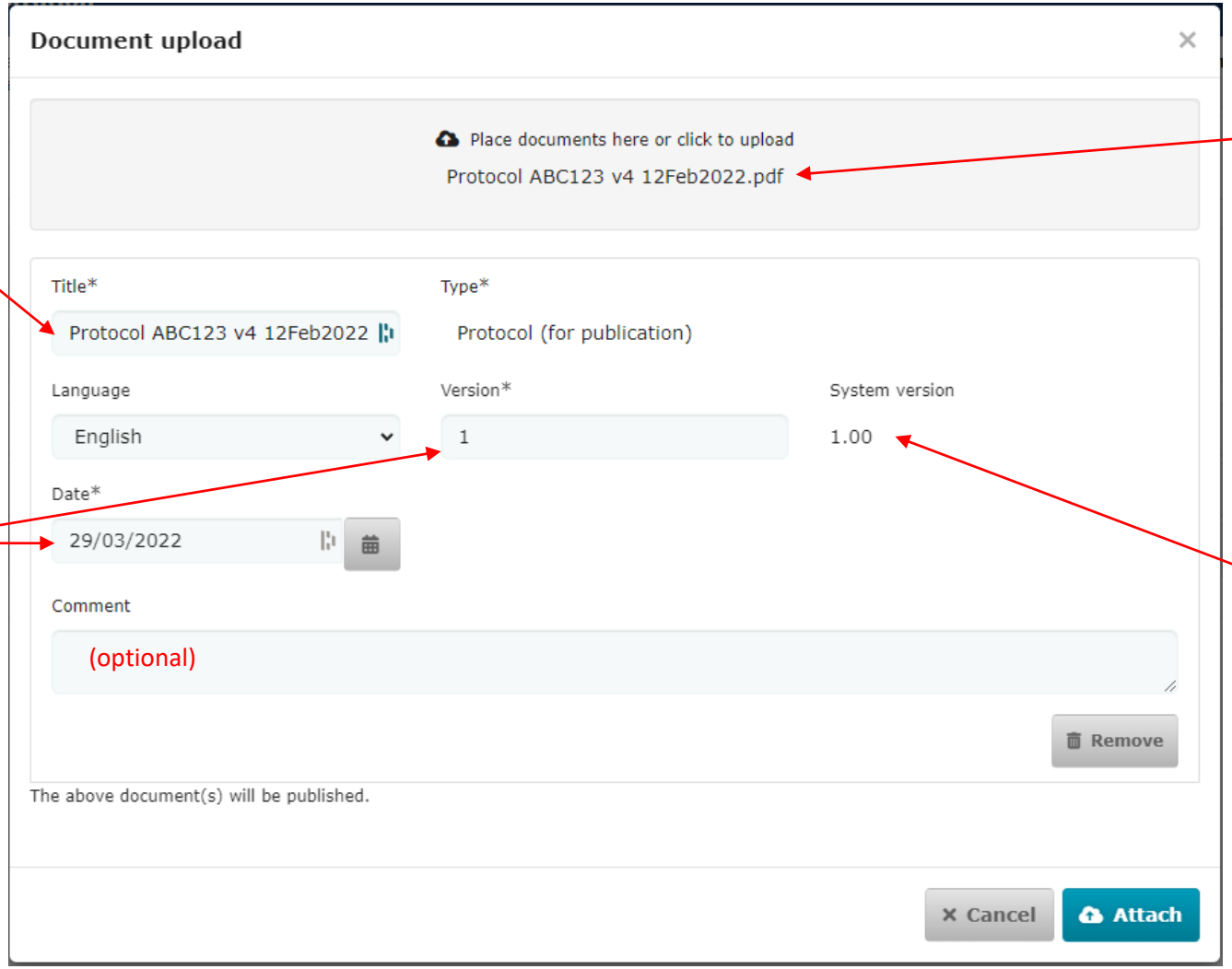
1. Uploading documents into CTIS: filename, CTIS title, version number and date

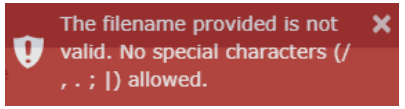
The **Title** of the document in CTIS. The filename as it was uploaded is pre-filled here, this should be changed to match the requirements for document coding and titles (see next slide). Always remove version and date from the Title, because the Title cannot be changed when uploading a newer version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

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.

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]

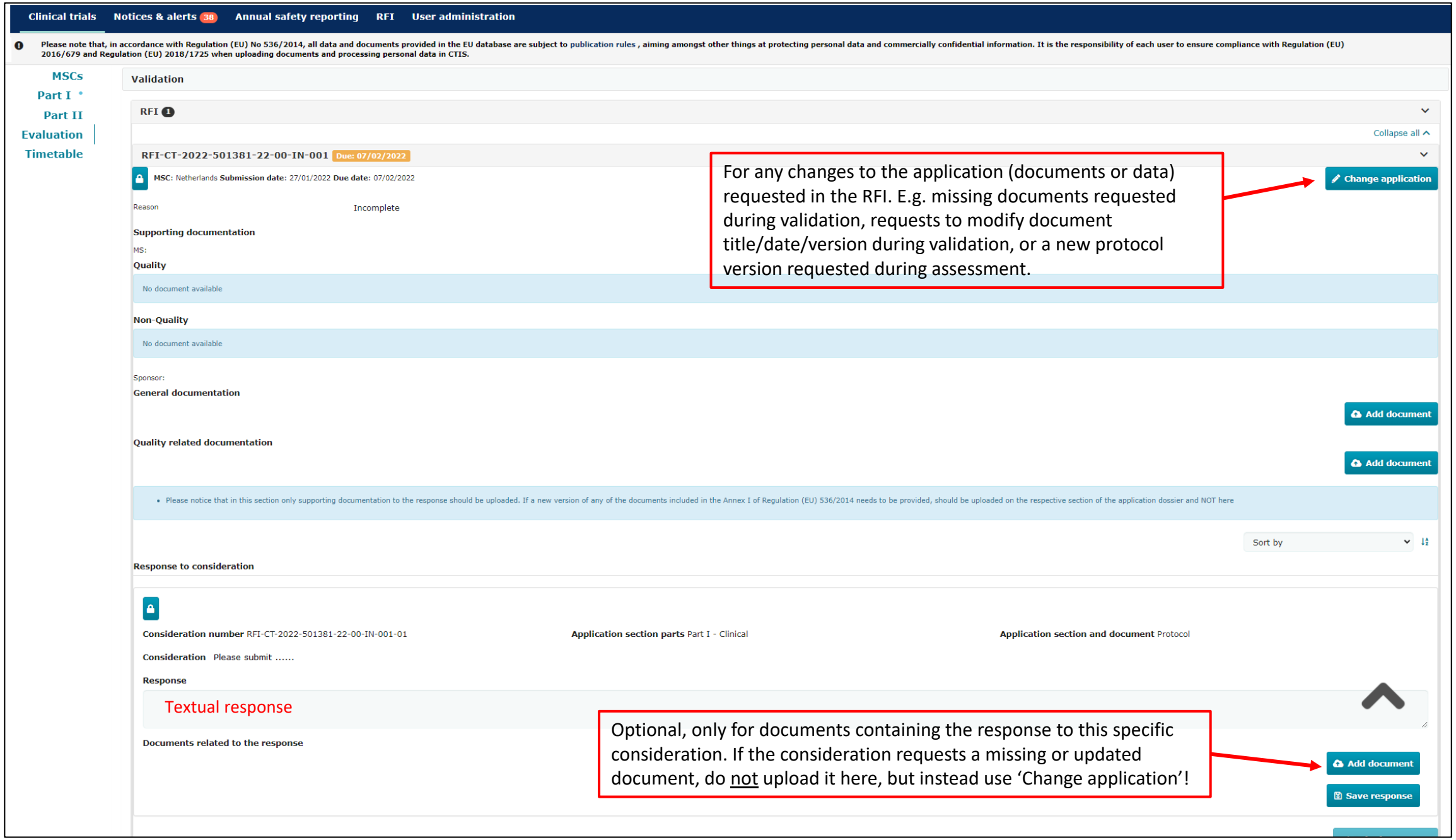
O. Proof of Insurance or idemnification
O1. WMO trial participant insurance certificate
O2. Proof of coverage sponsor or investigator [name sponsor/trial site] (*if not included on VGO*)

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

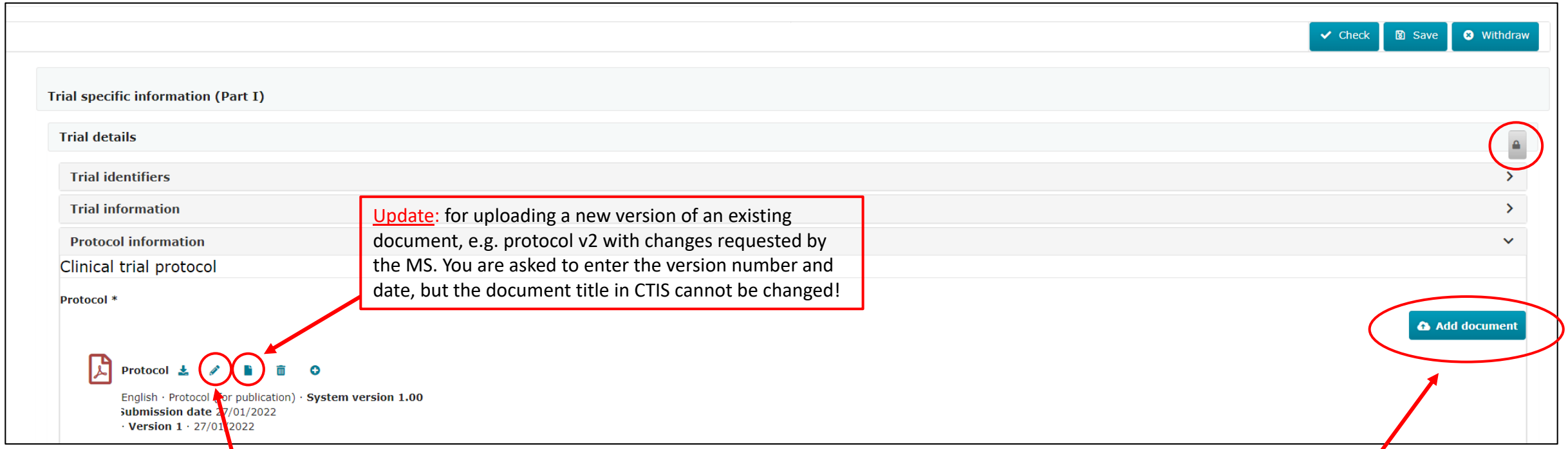
R. Compliance GDPR
R1. Template on the collection and use personal data NL

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



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.

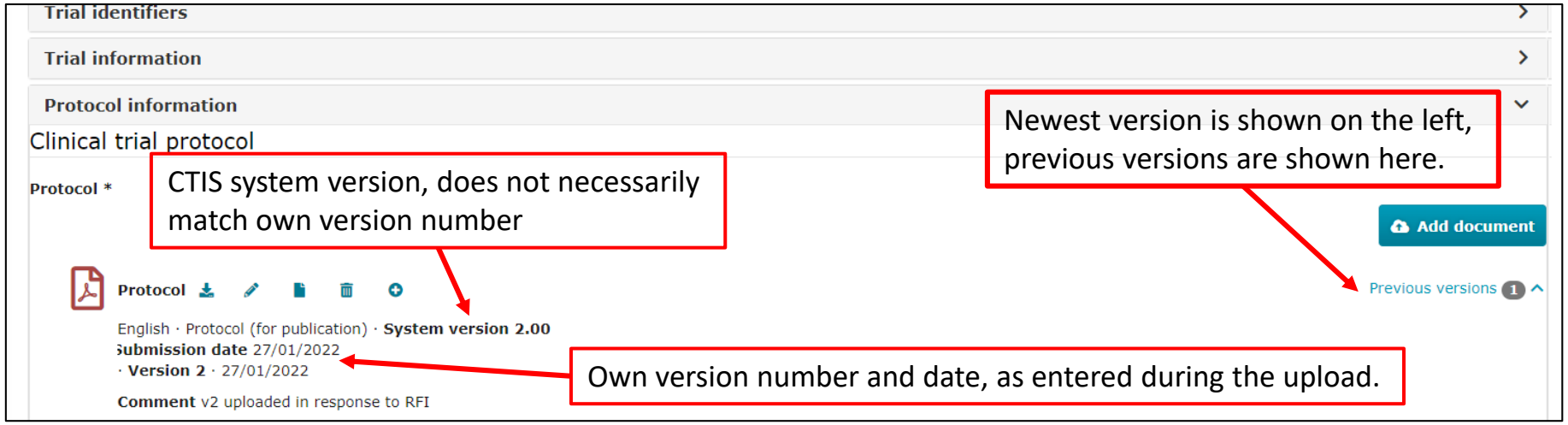


Update: for uploading a new version of an existing document, e.g. protocol v2 with changes requested by the MS. You are asked to enter the version number and date, but the document title in CTIS cannot be changed!

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



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