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

Collapse all

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

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

Change application

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

Documents related to the response

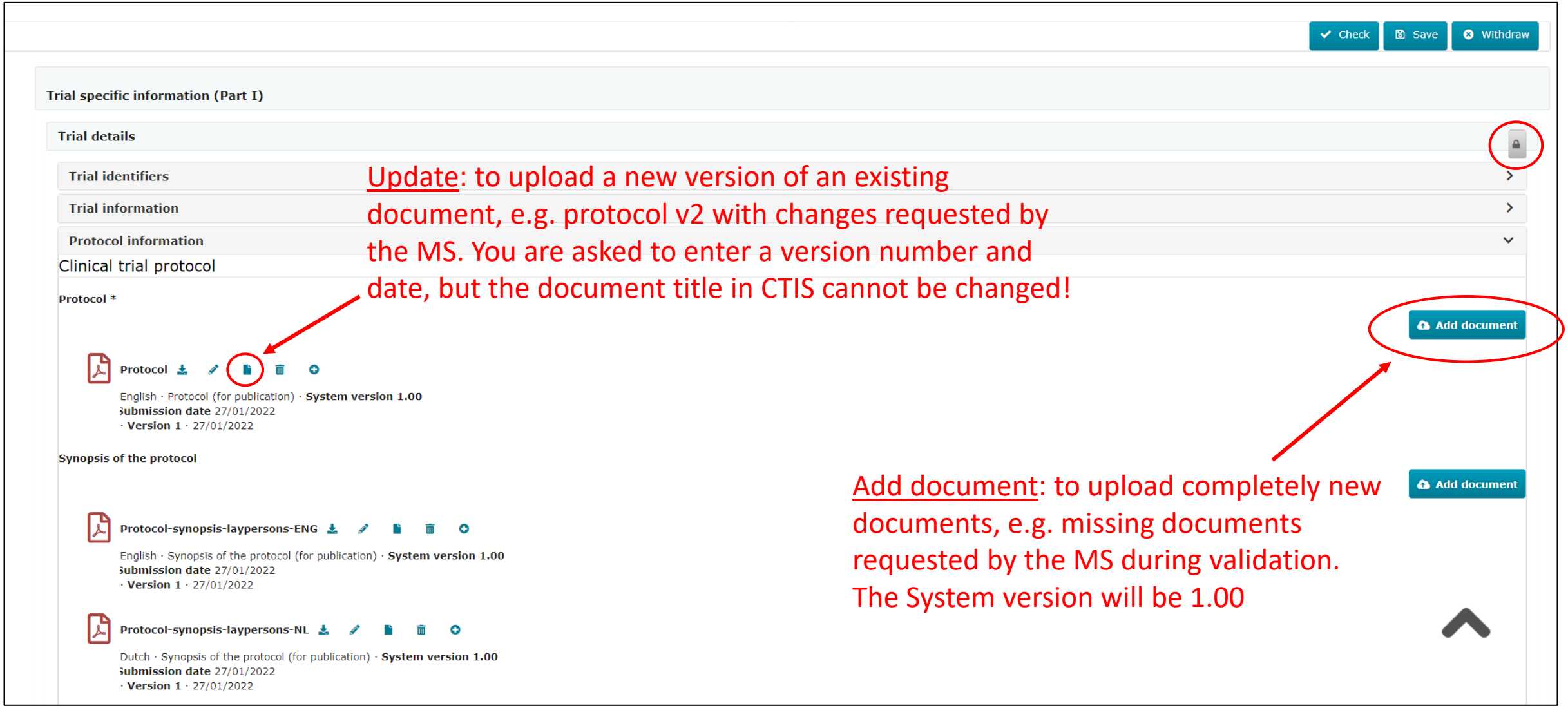
Add document

Save response

For all documents to be added to the dossier. E.g. missing documents requested during validation, or a new protocol version requested during assessment.

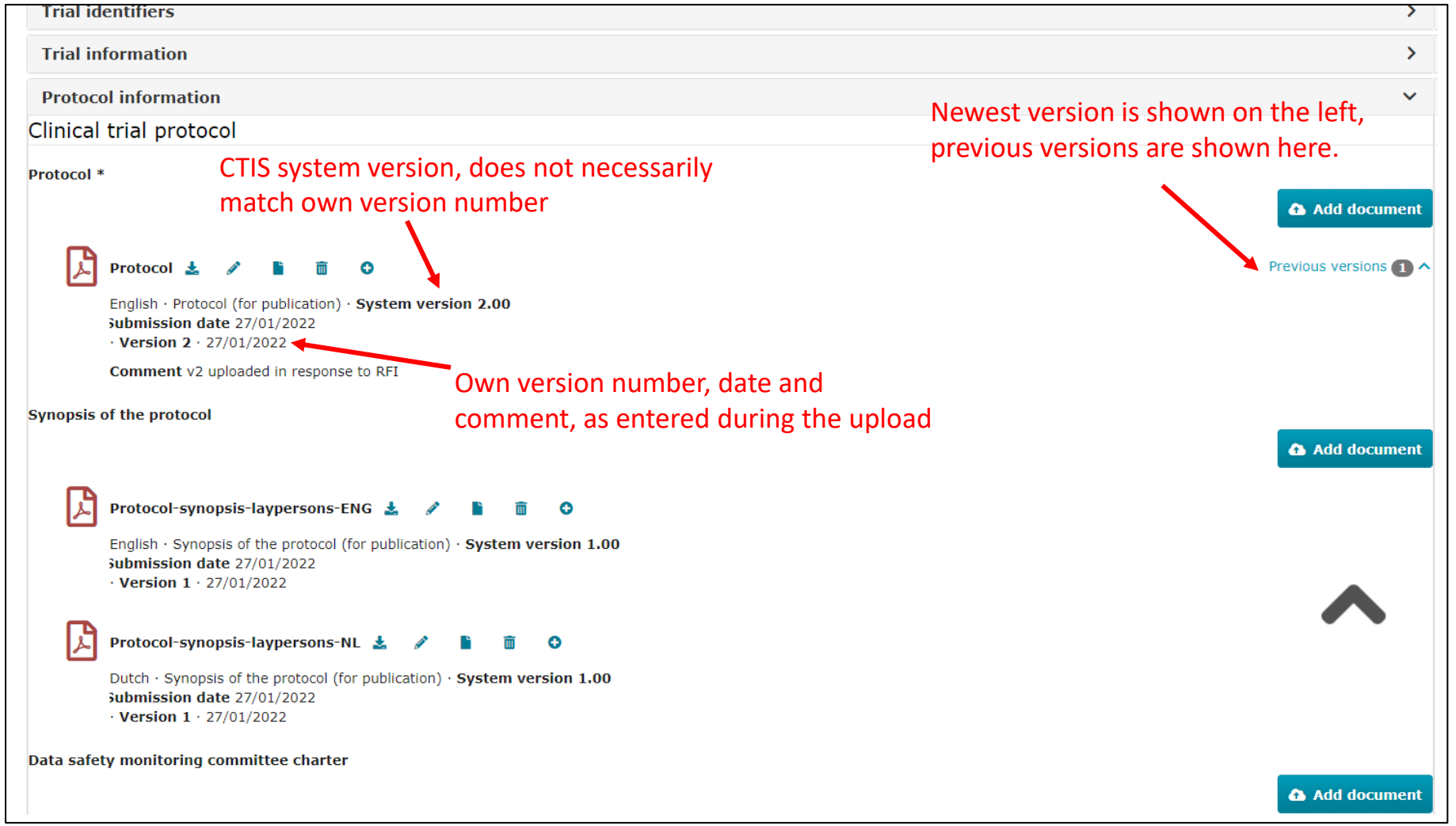
Optional, only for documents containing the response to this specific consideration

Clicking ‘Change application’ and confirming it, leads you back to the dossier, where documents can be added similar to the initial submission.
Click the lock and navigate to the right location.

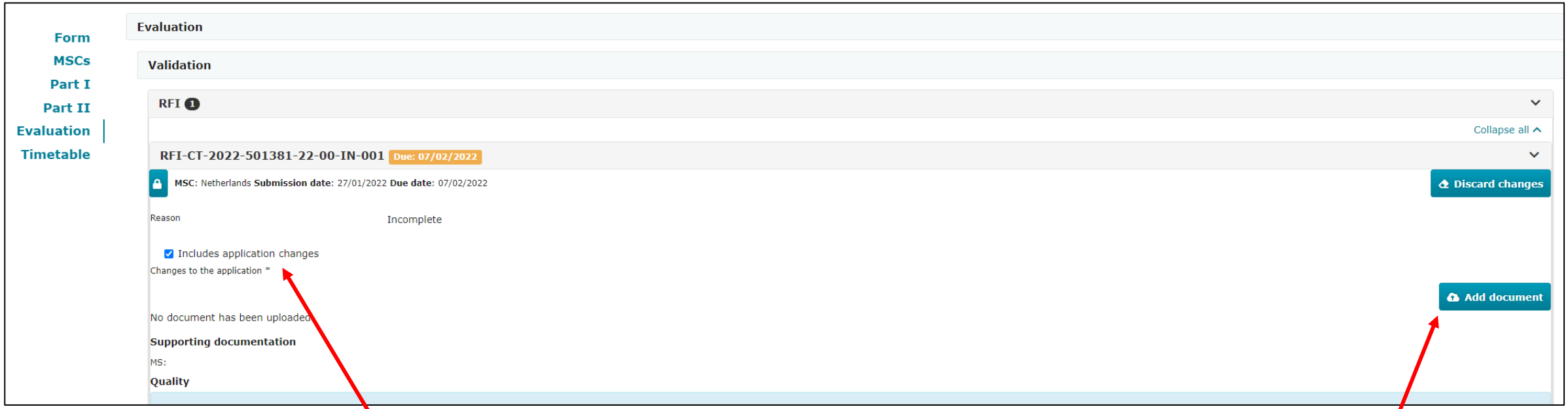


→ When uploading documents into CTIS, the PDF file itself can have any name, but remove the version number and date from the CTIS title field!

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.