

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

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

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



Change application

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



Add document

Save response

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.

The screenshot displays the 'Trial specific information (Part I)' section of a CTIS dossier. At the top right, there are buttons for 'Check', 'Save', and 'Withdraw'. Below this, the 'Trial details' section is visible, including 'Trial identifiers', 'Trial information', and 'Protocol information'. The 'Protocol information' section is expanded to show 'Clinical trial protocol' details. Under 'Protocol \*', there is a document titled 'Protocol' with a submission date of 27/01/2022 and System version 1.00. Below this, the 'Synopsis of the protocol' section shows two documents: 'Protocol-synopsis-laypersons-ENG' and 'Protocol-synopsis-laypersons-NL', both with submission dates of 27/01/2022 and System version 1.00. A red circle highlights a lock icon in the top right corner of the 'Trial details' section. A red circle highlights the 'Add document' button in the top right corner of the 'Protocol \*' section. A red circle highlights the 'Add document' button in the top right corner of the 'Synopsis of the protocol' section. A red arrow points from the 'Add document' button in the 'Synopsis of the protocol' section to the 'Protocol' document. A red arrow points from the 'Add document' button in the 'Synopsis of the protocol' section to the 'Add document' button in the 'Protocol \*' section. A red arrow points from the 'Add document' button in the 'Synopsis of the protocol' section to the 'Add document' button in the 'Synopsis of the protocol' section.

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

**Add document:** to upload completely new documents, e.g. missing documents requested by the MS during validation. The System version will be 1.00

→ 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

The screenshot displays a document management interface with several sections: "Trial identifiers", "Trial information", "Protocol information", "Clinical trial protocol", "Synopsis of the protocol", and "Data safety monitoring committee charter". Each section contains document entries with icons for download, edit, delete, and add. The "Protocol" document is highlighted, showing its details: "English · Protocol (for publication) · System version 2.00", "submission date 27/01/2022", and "Version 2 · 27/01/2022". A comment below reads "v2 uploaded in response to RFI". The "Synopsis of the protocol" section shows two documents: "Protocol-synopsis-laypersons-ENG" and "Protocol-synopsis-laypersons-NL", both with "System version 1.00" and "Version 1" dated "27/01/2022". Red annotations with arrows point to the "System version 2.00" and "Version 2" fields, the comment, and the "Previous versions" link. The "Previous versions" link is labeled "Previous versions 1 ^".

**CTIS system version, does not necessarily match own version number**

**Own version number, date and comment, as entered during the upload**

**Newest version is shown on the left, previous versions are shown here.**

Previous versions 1 ^

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

The screenshot shows a web interface for an RFI application. On the left is a navigation menu with links for 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation', and 'Timetable'. The main content area is titled 'Evaluation' and contains a 'Validation' section. Under 'Validation', there is an 'RFI 1' section with a 'Collapse all' link. Below this is a specific RFI entry: 'RFI-CT-2022-501381-22-00-IN-001' with a 'Due: 07/02/2022' tag. The entry details include 'MSC: Netherlands', 'Submission date: 27/01/2022', and 'Due date: 07/02/2022'. A 'Discard changes' button is located to the right of these details. Below the details, the 'Reason' is listed as 'Incomplete'. A checkbox labeled 'Includes application changes' is checked. The text 'Changes to the application \*' is followed by 'No document has been uploaded'. Below this is a section for 'Supporting documentation' with sub-sections for 'MS:' and 'Quality'. An 'Add document' button is located to the right of the 'No document has been uploaded' text. Two red arrows point from the text below to the 'Changes to the application \*' label and the 'Add document' button.

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