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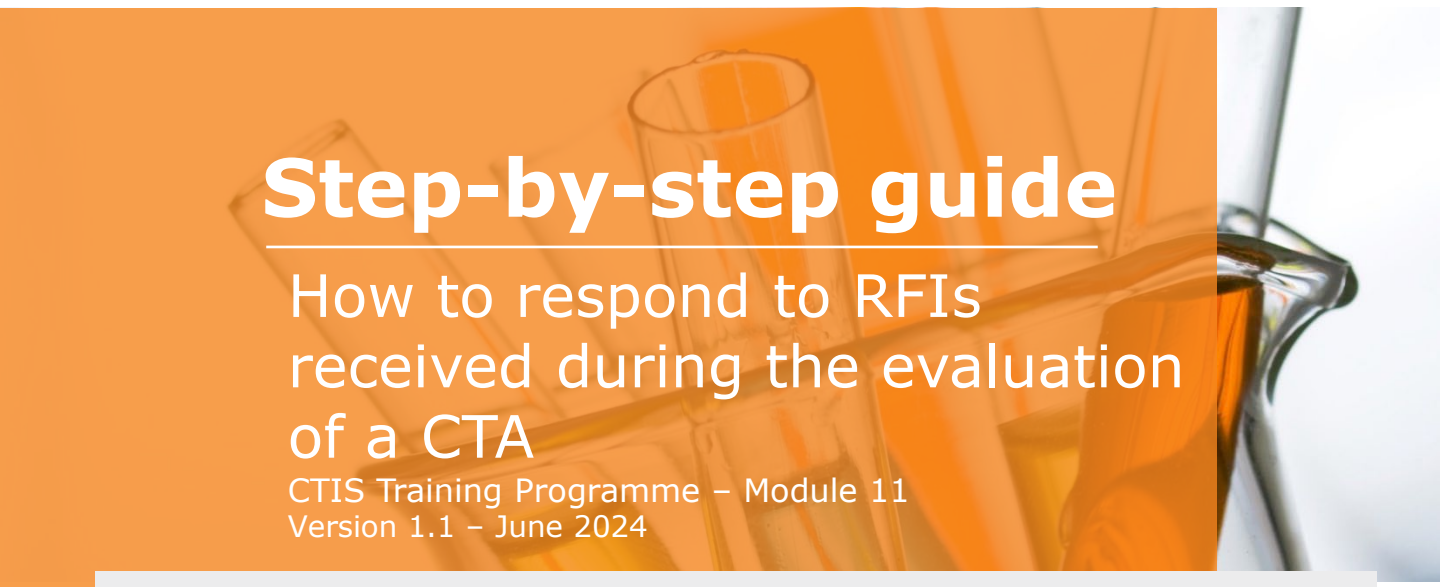

Step-by-step guide

How to respond to RFIs received during the evaluation of a CTA

CTIS Training Programme – Module 11
Version 1.1 – June 2024

Learning Objective

- Understand how to create and submit an RFI response, including changes to an existing application.

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How to create and submit an RFI response, including changes to an existing application

This Step-by-step guide focuses on how CTIS supports sponsor users to **view and access Request for Information (RFIs) raised by Member States Concerned (MSCs) during the validation and assessment phases of the evaluation of a Clinical Trial Application** (CTA), as well as on how to **create and submit the responses,** and how to **modify an existing CTA** as part of the response**.**

A CTA RFI is a request for information regarding an application dossier that a Member State Concerned (MSC) or a Reporting Member State (RMS) may address to a sponsor in the context of the evaluation of a submitted CTA.

The sponsor must respond to the RFIs by the deadline set by the MSCs/RMS. Failure to respond will lead to the full application lapse.

This Step-by-step guide includes:

View RFIs and modify a CTA

This section outlines the steps that sponsor users need to follow to search for an RFI and how to modify a CTA as part of the RFI response (if applicable).

Submit RFI responses

This section outlines the steps that sponsor users need to follow to save the changes and submit the RFI response.

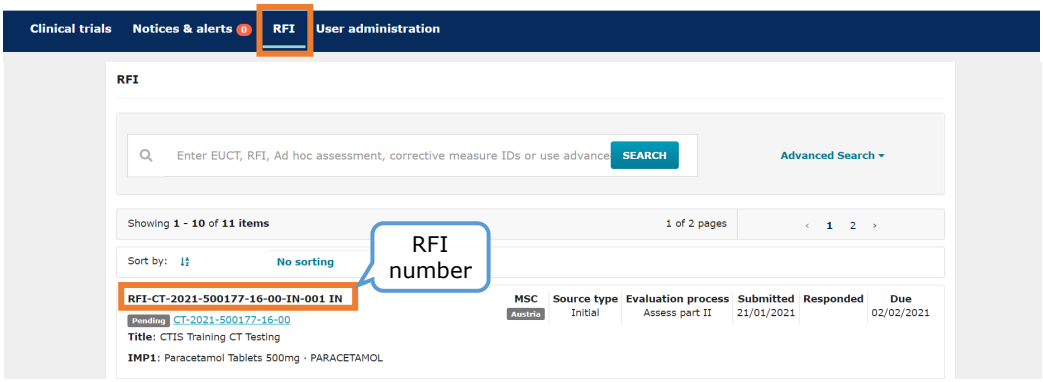
View submitted versions

This section outlines the steps that sponsor users need to follow to know how the new version of a CTA is displayed.

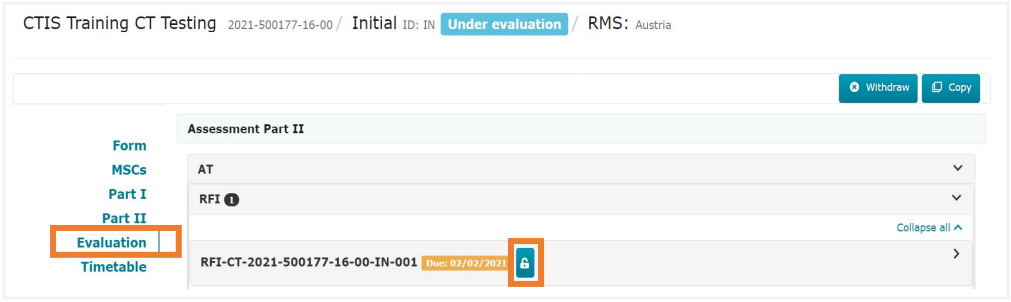
View RFIs and modify a CTA

View an RFI and modify an existing dossier of a CTA

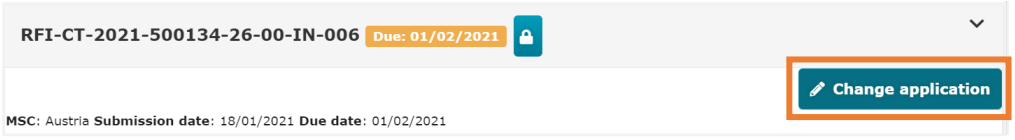
1. In the **'RFI' tab**, users can click on the **RFI number** to access the RFI.



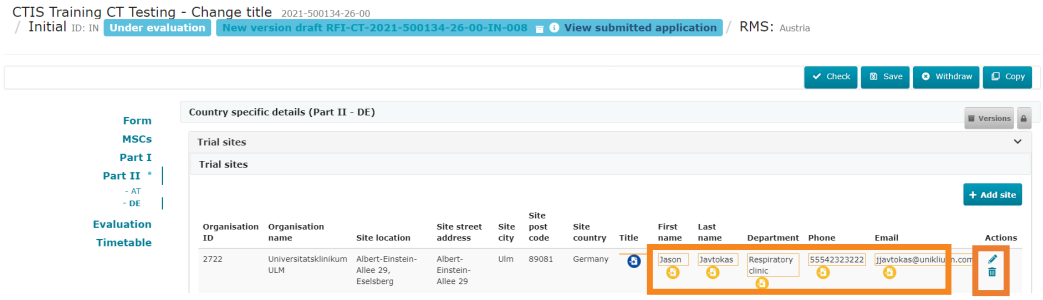
2. RFIs are listed in the **evaluation section of the CTA page**. The sponsors can identify the relevant RFI and click on the **padlock** button to edit it.



3. Once in the RFI, the sponsors can review the comments from the RMS/MSC. If a CTA requires changes, they can click on the **'Change application'** button, and a draft CTA version will be created.



4. If **changes** are required to the **structured data of the CTA**, the sponsors can click on the **pencil icon** to edit the fields. Such changes can be related to the sections Form, Part I and Part II, depending on the information provided in the RFI.



#CTIS insights

Users can **access RFIs through**: CTA page, Notices & alert tab and RFI tab.

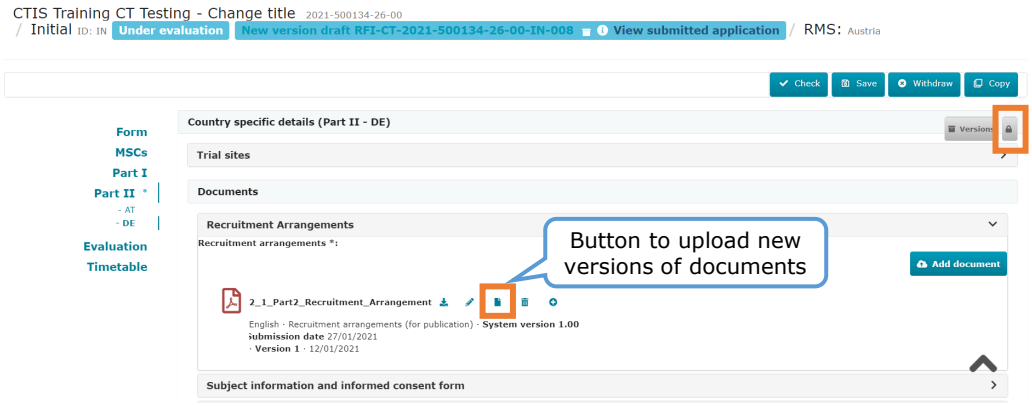
The 'RFI' tab lists **all the RFIs received** during the entire life cycle of a CT, including CTA RFIs and other types of RFIs.

An existing CTA can be modified to respond to an RFI if this is required based on the information provided by the RMS/MSC.

View RFIs and modify a CTA

View an RFI and modify an existing dossier of a CTA

5. As part of a CTA RFI, users can also **upload new versions of documents** previously submitted in an existing CTA. For this purpose, they can click on the **padlock** button and then on the **sheet icon** in the relevant document section.



6. Additionally, a new document of the same type can also be attached by clicking on the **'Add document'** button.

7. After the required changes are included, users can save the draft by clicking on the **'Save'** button. Then, they can click on the **'Evaluation' section** to go back to the RFI working area to progress with the submission of the updated application dossier and RFI responses.

#CTIS insights

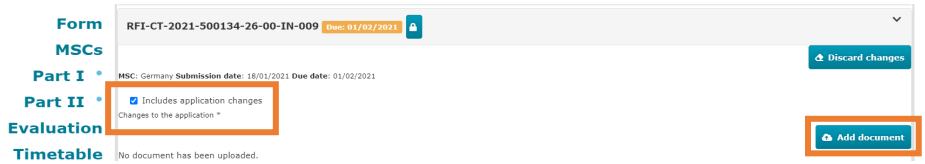
When responding to an RFI, **only a subsequent version of the document can be uploaded** (in the dossier).

Sponsors will **not receive an email** when an RFI is received.

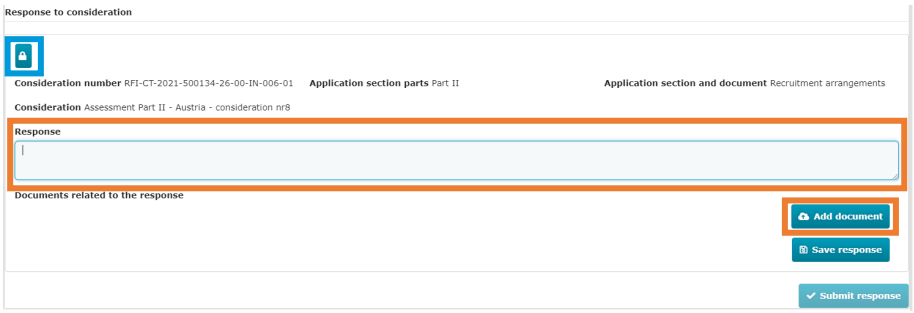
Submit RFI responses

How to respond to an RFI

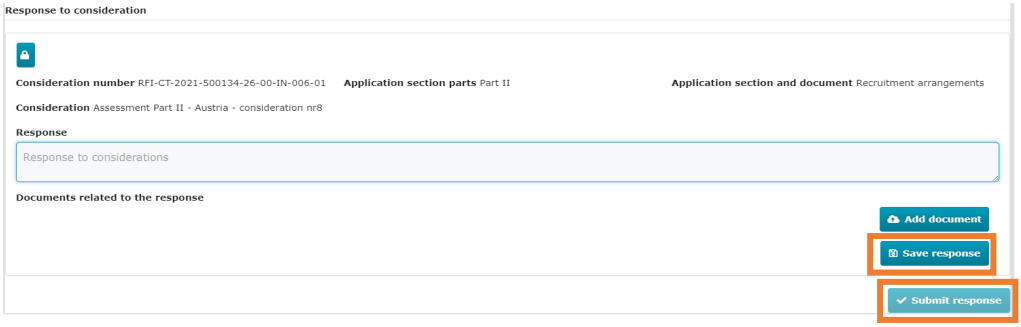
1. To conclude the process, within the **'Evaluation' section**, in case users have included **changes in the dossier**, they can click on the **tick box** ('Includes application changes') and then on **the 'Add documents'** button to describe the changes in the application.



2. Sponsors can respond in writing to the considerations raised by the MSCs. Additionally, supporting documents can be uploaded by clicking on the **'Add document'** button.

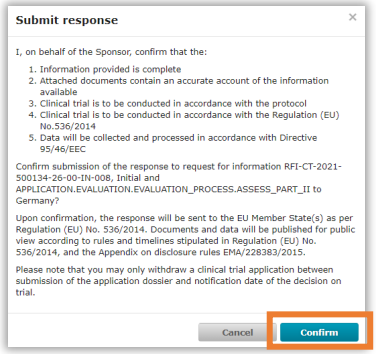


3. [1] Once the responses are included, sponsors can click on the **'Save response'** button. Finally, they can click on the **'Submit response'** button.



[1] Button 'Submit response' is not visible if user has not locked the padlock found above the considerations, as can be seen in step 2 (button highlighted in blue).

4. After clicking on the '**Submit response**' button, a **confirmation text** will be displayed. Once the submission is confirmed, the status of the **RFI will change to 'responded'.**



#CTIS insights

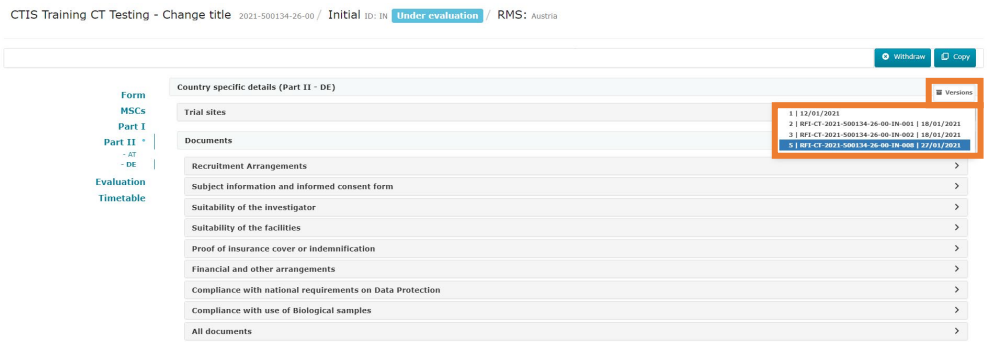
Users can **discard the changes** applied to the CTA **before the submission**. In this case, only the responses to the RFI considerations will be submitted.

Responses to the considerations **are mandatory** even if no changes to the CTA are required.

View submitted versions

How to view the CTA versions

1. After submitting an RFI that required changes to a CTA, all the CTA versions are displayed by clicking on the **'Versions'** button.



#CTIS insights

Sponsors can go to the '**Notice & alerts**' tab to **check the notice that the response** was sent to MSCs.

All communications between Member States and sponsors will take place **in CTIS** and **no emails** will be pushed by the system.

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Clinical Trials Information System (CTIS)
Module 11: How to respond to RFIs received during the evaluation of a CTA

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