



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Step-by-step guide

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

CTIS Training Programme – Module 11  
Version 1.0 – September 2021

### 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.

The screenshot shows the 'RFI' tab selected in the top navigation bar. Below the navigation bar, there is a search bar with the placeholder text 'Enter EUCT, RFI, Ad hoc assessment, corrective measure IDs or use advanced SEARCH'. Below the search bar, there is a table of RFI items. The first item is highlighted with a callout box pointing to its RFI number: 'RFI-CT-2021-500177-16-00-IN-001 IN'. The table columns include MSC (Austria), Source type (Initial), Evaluation process (Assess part II), Submitted (21/01/2021), Responded, and Due (02/02/2021). The title is 'CTIS Training CT Testing' and the IMP1 is 'Paracetamol Tablets 500mg - PARACETAMOL'.

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.

The screenshot shows the 'CTIS Training CT Testing' page. The 'Evaluation' section is highlighted in the left sidebar. The main content area shows 'Assessment Part II' with a table of RFI items. The first item is 'RFI-CT-2021-500177-16-00-IN-001' with a due date of '02/02/2021' and a padlock icon next to it, indicating it can be edited.

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

The screenshot shows the RFI page for 'RFI-CT-2021-500134-26-00-IN-006' with a due date of '01/02/2021'. A 'Change application' button is highlighted in the bottom right corner.

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.

The screenshot shows the 'CTIS Training CT Testing - Change title' page. The 'Country specific details (Part II - DE)' section is visible, showing a table of trial sites. The first site is '2722 Universitätsklinikum ULM' with a 'First name' field containing 'Jason Javtokas'. A pencil icon is highlighted next to the 'First name' field, indicating it can be edited.

## View RFIs and modify a CTA

## View an RFI and modify an existing dossier of a CTA

- 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.

CTIS Training CT Testing - Change title 2021-500134-26-00  
/ Initial ID: IN Under evaluation New version draft RFI-CT-2021-500134-26-00-IN-008 View submitted application / RMS: Austria

Check Save Withdraw Copy

Country specific details (Part II - DE) Versions

Trial sites

Documents

Recruitment Arrangements

Recruitment arrangements \*:

2\_1\_Part2\_Recruitment\_Arrangement

English - Recruitment arrangements (for publication) - System version 1.00  
submission date 27/01/2021  
Version 1 - 12/01/2021

Add document

Button to upload new versions of documents

Subject information and informed consent form

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

CTIS Training CT Testing - Change title 2021-500134-26-00  
/ Initial ID: IN Under evaluation New version draft RFI-CT-2021-500134-26-00-IN-008 View submitted application / RMS: Austria

Check Save Withdraw Copy

Country specific details (Part II - DE) Versions

Trial sites

Documents

Recruitment Arrangements

Recruitment arrangements \*:

2\_1\_Part2\_Recruitment\_Arrangement

English - Recruitment arrangements (for publication) - System version 1.00  
submission date 27/01/2021  
Version 1 - 12/01/2021

Add document

- 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 Training CT Testing - Change title 2021-500134-26-00  
/ Initial ID: IN Under evaluation New version draft RFI-CT-2021-500134-26-00-IN-008 View submitted application / RMS: Austria

Check Save Withdraw Copy

Country specific details (Part II - DE) Versions

Trial sites

Documents

Recruitment Arrangements

Recruitment arrangements \*:

Add document

Evaluation

# Submit RFI responses

## How to respond to an RFI

- 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.

The screenshot shows the 'Form MSCs' interface for RFI-CT-2021-500134-26-00-IN-009. Under 'Part II', the checkbox 'Includes application changes' is checked. The 'Add document' button is highlighted with a red box.

- 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.

The screenshot shows the 'Response to consideration' form for RFI-CT-2021-500134-26-00-IN-006-01. The 'Response' text area is highlighted with a red box, and the 'Add document' button is also highlighted with a red box.

- Once the responses are included, sponsors can click on the **'Save response'** button. Finally, they can click on the **'Submit response'** button.

The screenshot shows the 'Response to consideration' form for RFI-CT-2021-500134-26-00-IN-006-01. The 'Save response' and 'Submit response' buttons are highlighted with red boxes.

- 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'**.

The screenshot shows the 'Submit response' confirmation dialog box. The 'Confirm' button is highlighted with a red box.

The screenshot shows the 'Assessment Part II' interface for RFI-CT-2021-500134-26-00-IN-005. The RFI status is shown as 'Responded: 18/01/2021'.

## 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 Training CT Testing - Change title 2021-500134-26-00 / Initial ID: in Under evaluation / RMS: Austria

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**Form**  
MSCs  
Part I  
Part II +  
- AT  
- DE  
Evaluation  
Timetable

Country specific details (Part II - DE) **Versions**

Trial sites	1   12/01/2021 2   RFI-CT-2021-500134-26-00-26-001   18/01/2021
Documents	3   RFI-CT-2021-500134-26-00-26-002   18/01/2021 4   RFI-CT-2021-500134-26-00-26-003   22/01/2021
Recruitment Arrangements	>
Subject information and informed consent form	>
Suitability of the investigator	>
Suitability of the facilities	>
Proof of insurance cover or indemnification	>
Financial and other arrangements	>
Compliance with national requirements on Data Protection	>
Compliance with use of Biological samples	>
All documents	>

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Clinical Trials Information System (CTIS)

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