



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 1.1 – 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.

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 blue box and a callout bubble labeled 'RFI number'. The item details are: RFI-CT-2021-500177-16-00-IN-001 IN, MSC: Austria, Source type: Initial, Evaluation process: Assess part II, Submitted: 21/01/2021, Responded: 02/02/2021, Title: CTIS Training CT Testing, IMP1: 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 'Evaluation' section of the CTA page. The 'Evaluation' tab is highlighted in the left sidebar. The main content area shows 'Assessment Part II' with a table of RFI items. The first item is highlighted with a blue box and a callout bubble labeled 'RFI number'. The item details are: RFI-CT-2021-500177-16-00-IN-001, Due: 02/02/2021. A blue padlock icon is visible next to the item.

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 with the 'Change application' button highlighted with a blue box. The button is located at the bottom right of the RFI details section.

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 'Change title' section of the CTA page. The 'Change title' section is highlighted with a blue box. The 'Change application' button is also highlighted with a blue box. The 'Change title' section shows the current title 'CTIS Training CT Testing - Change title' and a new version draft 'RFI-CT-2021-500134-26-00-IN-008'. Below the 'Change title' section, there is a table of trial sites. The first row is highlighted with a blue box and a callout bubble labeled 'Change application'. The table columns are: Organisation ID, Organisation name, Site location, Site street address, Site city, Site post code, Site country, Title, First name, Last name, Department, Phone, Email, and Actions.

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

Subject information and informed consent form

Button to upload new versions of documents

- 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

Subject information and informed consent form

- 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.

Form RFI-CT-2021-500134-26-00-IN-009 (Date: 01/02/2021) [Lock icon]

MSCs [Discard changes]

Part I MSC: Germany Submission date: 18/01/2021 Due date: 01/02/2021

Part II Includes application changes
Changes to the application *

Evaluation [Add document]

Timetable No document has been uploaded.

- 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.

Response to consideration

Consideration number RFI-CT-2021-500134-26-00-IN-006-01 Application section parts Part II Application section and document Recruitment arrangements

Consideration Assessment Part II - Austria - consideration nr8

Response

Documents related to the response [Add document]

[Save response]

[Submit response]

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

Response to consideration

Consideration number RFI-CT-2021-500134-26-00-IN-006-01 Application section parts Part II Application section and document Recruitment arrangements

Consideration Assessment Part II - Austria - consideration nr8

Response

Documents related to the response [Add document]

[Save response]

[Submit response]

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).

- 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'**.

Submit response

I, on behalf of the Sponsor, confirm that the:

- Information provided is complete
- Attached documents contain an accurate account of the information available
- Clinical trial is to be conducted in accordance with the protocol
- Clinical trial is to be conducted in accordance with the Regulation (EU) No. 536/2014
- Data will be collected and processed in accordance with Directive 95/46/EEC

Confirm submission of the response to request for information RFI-CT-2021-500134-26-00-IN-008, Initial and APPLICATION EVALUATION EVALUATION_PROCESS.ASSESS_PART_II to Germany?

Upon confirmation, the response will be sent to the EU Member State(s) as per Regulation (EU) No. 536/2014. Documents and data will be published for public view according to rules and timelines stipulated in Regulation (EU) No. 536/2014, and the appendix on disclosure rules EMA/228383/2015.

Please note that you may only withdraw a clinical trial application between submission of the application dossier and notification date of the decision on trial.

[Cancel] [Confirm]

Assessment Part II

AT

RFI 3

RFI-CT-2021-500134-26-00-IN-005 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

Withdraw Copy

Form	Country specific details (Part II - DE)	Versions
MSCs	Trial sites	1 12/01/2021
Part I		2 RFI-CT-2021-500134-26-00-2N-001 18/01/2021
Part II	Documents	3 RFI-CT-2021-500134-26-00-2N-002 18/01/2021
- AT		4 RFI-CT-2021-500134-26-00-2N-003 22/01/2021
- DE		
Evaluation	Recruitment Arrangements	>
Timetable	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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