



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.

© European Medicines Agency, 2024

Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.



The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

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/MS. 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.

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)

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

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)

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

Subject information and informed consent form

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)

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

Subject information and informed consent form

Add document

Evaluation



#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.

Form MSCs

Part I

Part II

Evaluation

Timetable

RFI-CT-2021-500134-26-00-IN-009 (Due: 01/02/2021)

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

☒ Includes application changes
(Changes to the application *)

No document has been uploaded.

Discard changes

Add document

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.

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

3. 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).

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'**.

Submit response

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

1. Information provided is complete
2. Attached documents contain an accurate account of the information available
3. Clinical trial is to be conducted in accordance with the protocol
4. Clinical trial is to be conducted in accordance with the Regulation (EU) No. 536/2014
5. 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
MSCs
Part I
Part II *
- AT
- DE
Evaluation
Timetable

Country specific details (Part II - DE)

Trial sites

Documents

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

Versions

1 | 12/01/2021
2 | RFI-CT-2021-500134-26-00-IN-001 | 18/01/2021
3 | RFI-CT-2021-500134-26-00-IN-002 | 18/01/2021
4 | RFI-CT-2021-500134-26-00-IN-003 | 12/01/2021



#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.

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000

Send a question

www.ema.europa.eu/contact

Clinical Trials Information System (CTIS)

Module 11: How to respond to RFIs received during the evaluation of a CTA

© European Medicines Agency, 2024.

Reproduction is authorised provided the source is acknowledged.