



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

How to respond to Requests for Information received during the evaluation of a Clinical Trial Application

CTIS Training Programme – Module 11

Version 1.3 – March 2022

What you will find

- Answers to questions regarding the evaluation process.
- Answers to questions regarding how users can receive, access and view a Request for Information.
- Answers to questions regarding how users can create a Request for Information response.
- Answers to questions regarding how users can submit a Request for Information response.

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FAQs

A photograph of laboratory glassware, including test tubes and a beaker, containing liquids of various colors (orange, green, blue). The background is blurred, showing a white lab coat and a blue object.

In this document, we list common questions regarding *Module 11: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application*. They are categorised into general questions regarding the Requests for Information (RFIs), the evaluation of a clinical trial application, how to receive and access an RFI, how to create an RFI, how to submit an RFI, and the roles and permissions related to RFIs. The specific learning objectives of this module are:

1. Remember the phases and associated timelines for the evaluation of a CTA.
2. Understand what RFIs are and the types of RFIs that can be raised by MSCs during the evaluation of a CTA.
3. Remember how to search and view RFIs raised during the evaluation of a CTA.
4. Understand how to create and submit an RFI response, including changes to an existing CTA.
5. Understand the roles and permissions involved in the management of a CTA RFI.

We encourage you to read these questions and answers carefully. If you have any questions that are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1. General questions

1.1. What is a Request for Information (RFI)?

An RFI is a request for additional information regarding an application dossier that a Member State may address to a sponsor in the context of the evaluation of a submitted Clinical Trial Application (CTA), as per Articles 5 (5) and 6 (8) of the CT Regulation¹.

Submitting an RFI is an optional action for a Member State Concerned (MSC). If the RFI is submitted as part of the evaluation of a CTA, the sponsor must respond to it by the deadline set by the MSC, within the maximum deadlines established by the CT Regulation. Failure to do so will lead to the full application lapse.

In CTIS, the RFI functionality is also used by MSC to raise requests for additional information to the sponsor in the context of ad hoc assessments, the assessment of Annual Safety Reports (ASR), and requests for opinions before applying a corrective measure.

1.2. What types of Request for Information are there?

There is not a fixed list of categories of RFI listed on the RFI tab in CTIS. But for training purposes, they can be classified into two main categories:

- **Clinical Trial Application RFIs** (CTA RFIs): RFIs that can be raised by the MSCs during the validation phase and the assessment phase of Part I and/or Part II when evaluating a CTA. These requests are established in the CT Regulation, and failure to respond to them by the established deadline leads to the application lapse.
- **Clinical Trial RFIs** (CT RFIs): Additional RFIs that can be raised by the MSCs to the sponsors after a CTA has been authorised, in the context of an Annual Safety Reports assessment, an ad hoc assessment, or to request the sponsor's opinion before applying a corrective measure. Although they are not established in the CT Regulation as RFI as such, they appear listed in the RFI functionality in CTIS.

¹ European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

2. Evaluation of a Clinical Trial Application

2.1. What are the phases and the timelines for evaluating an Initial Clinical Trial Application?

The evaluation process of an Initial CTA is divided into three main phases: Validation, Assessment, and Decision. The Assessment phase is divided into two parts (Part I and Part II), which may or may not run in parallel. Each phase has its own timelines and activities to be performed.

The Regulation (EU) No 536/2014 on Clinical Trials on medicinal products for human use (CT Regulation²) establishes an overall timeline of 60 days for the Member States to evaluate an Initial application. This deadline may be extended in case that RFIs are raised by the Reporting Member State (RMS) or by an MSC throughout the evaluation process. Timelines can be extended up to 15 days if the RFIs are raised in the Validation phase, and up to 31 days if the RFIs are raised in the Assessment phase. Additionally, if the evaluation requires consultation with experts, it can be extended by up to 50 days.

For a visual representation of these timelines, please refer to the [eLearning material](#) of this module.

2.2. What is the purpose of each phase in the evaluation of an Initial Clinical Trial Application?

Validation: To verify that the Clinical Trial falls under the scope of the CT Regulation and that the application dossier documentation is complete and in line with the requirements of Article 25 and Annex I of the CT Regulation³.

In the case of Initial applications for multinational trials, the RMS selection occurs in parallel to the validation, as per Article 5 of the CT Regulation⁴. *For more information about the validation phase of a CTA and the RMS selection, please refer to the material targeted for Member States in Module 6: How to evaluate a CTA (types of applications, evaluation phases, RMS selection, and Validation).*

Assessment: To review the specific content provided by the sponsor in the application dossier. For Initial applications, the Assessment phase is divided into two parts: Part I and Part II. It is important to note that these phases can be performed in parallel or not, and they can only start after the submission of the validation decision by the RMS.

² European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

³ Idem.

⁴ Idem.

The Assessment phase concludes with an assessment report and the submission of the conclusion for both parts. The main objective of each part is:

- Part I: To review the scientific and medicinal product documentation, as defined in Article 6 of the CT Regulation⁵ (e.g. completeness and adequateness of the investigator's brochure, compliance with labelling requirements, protocol, etc.). This review is performed by the MSC and coordinated by the RMS.
- Part II: To evaluate the regulatory aspects of the CTA that are of a more national/local nature. In this case, the assessment is performed individually by the MSC for their own territory. The MSC reviews the requirements for informed consent, the arrangements for recruiting and compensating the patients, the data protection rules, etc., amongst other documents set out in Article 7 of the CT Regulation⁶ and the General Data Protection Regulation⁷.

Decision: To establish the outcome of the assessment of a CTA for the start of the Clinical Trial in an MSC territory. The Decision is made by each MSC and may result in the authorisation, authorisation subject to conditions, or rejection of the CT. *See Article 8 of the CT Regulation⁸ for more information.*

2.3. What are the evaluation phases of a Substantial Modification and an Additional of a Member State Concerned (MSC) application?

In general, all CTAs go through the evaluation phases described in question 2.2. However, there are some specificities to be noted:

- **Substantial Modification (SM) CTA:** Includes the whole process of evaluation: Validation, Assessment (Part I and/or Part II), and Decision. It should be noted that some Substantial Modification may concern only Part I, Part II, or both, depending on the scope of the modification.
- **Addition of an MSC application:** It includes an assessment of Part II and the Decision, since on Part I of the application a conclusion has already been reached. The additional MSC will have access to Part I of the application and will be able to document considerations, which will reach the RMS. However, the assessment made by the additional MSC on Part I, and its Decision on the evaluation of the whole

⁵ European Commission, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

⁶ Idem

⁷ Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

⁸ European Commission, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

application will have no bearing on the Decision issued by the RMS and the other MSC at the time of the evaluation of the initial application.

2.4. What can CTA RFIs cover?

RFIs raised during the evaluation of a CTA can include questions related to the aspects covered in both the validation and the assessment phases, but they can also refer to one specific part of the application. For training purposes, CTA RFIs can be classified into:

- **Validation RFIs**, which can contain questions for Part I -including Quality – Investigational Medicinal Product Dossier (Q-IMPDP)⁹ -, and for Part II. These RFIs are raised by the RMS in the case of multinational CTAs.
- **Assessment RFIs**, which can contain questions for Part I -including Q-IMPDP-, and questions for Part II. The RFIs concerning Part I are raised by the RMS, in the case of multinational CTAs, whereas the RFIs concerning Part II are raised individually by the MSCs.

2.5. What is the impact of Requests for Information being raised during the evaluation of an Initial Clinical Trial Application?

The RMS and MSCs can raise RFIs at any moment during the validation and assessment phases of a CTA. This action extends the overall timeline of 60 days for the evaluation of an Initial CTA established in the CT Regulation:

- If an RFI is submitted **during the validation phase**, it will add a **maximum of 15 days** to the deadline of the phase, including a maximum of 10 days for the sponsor to respond to the RFI, and 5 days for RMS and MSC to review the response.
- If an RFI is submitted **during the assessment phase**, it will add a **maximum of 31 days** to the deadline of the phase.
 - For part I: 12 days for the sponsor to respond, 12 days for MSCs to review the response, and 7 days for the RMS to consolidate the review.
 - For Part II: 12 days for the sponsor to respond and 19 days for MSCs to assess RFI response.
- Even if multiple RFIs are raised during any phase of the evaluation, the extension of the timelines will occur only once. Additionally, the timelines do not change if the

⁹ The Investigational Medicinal Product Dossier (IMPDP) is divided in Quality (IMPDP-Q) and Safety and Efficacy (IMPDP S and E). The IMPDP-Q includes the quality, manufacture and control of the investigational medicinal product. This document contains commercially confidential information.

sponsors respond to the RFIs earlier.

For a visual representation of these timelines, please refer to the [eLearning material](#) of this module.

3. Receive and access a Request for Information

3.1. How are users notified of a CTA RFI?

Sponsor users receive an alert on the 'Notices & alerts' tab stating that an RFI has been sent by the RMS and/or MSC in the context of evaluation of a CTA. By clicking on the alert, the RFI is displayed in the evaluation section of the relevant CTA page.

Users will only receive the alert of the submitted RFI if they have the appropriate role for the CTA part that is affected by the RFI (e.g. Part I preparers will receive alerts regarding RFIs concerning Part I).

3.2. How can users access a CTA RFI?

Sponsor users have three ways of accessing the RFIs: through the RFI tab, the Notices & alerts tab, and the CTA page of a specific Clinical Trial.

- **RFI tab:** specific tab where all RFIs received by the sponsor are listed. This tab includes RFIs raised during the evaluation of a CTA, as well as other types of RFIs referred to in question 1.2.
- **Notices & alerts tab:** general tab where the sponsor receives a wider list of messages related to events occurring during the trial life cycle, including alerts related to the RFIs raised by the MSCs during the evaluation of a CTA.
- **CTA page:** the last two options lead users to the CTA page after they click on the relevant RFI. Alternatively, they can also access it directly from the summary sub-tab of a Clinical Trial if they know the EU CT number or the RFI number to be able to run a basic search. At the bottom of the 'Summary' sub-tab of the 'Clinical Trial' page, users will find all the related CTAs, which they can open by clicking on the ID reference. Once inside the application, users can go to the evaluation section to search for the relevant RFI.

3.3. How can users search for a Request for Information in the RFI tab?

Within the RFI tab, there are sorting and searching capabilities to facilitate the search for an RFI:

- **Sorting options:** Sponsors can sort the RFIs that will be displayed in the RFI list. The default sorting displays all the RFIs that the sponsor has received from more recent to less recent (it should be noted that those RFIs received less recently will have a closer deadline) with no parameters applied. Sorting options include: the evaluation process, the application type, the MSC, the status (pending, responded, expired or cancelled), the due date, the response date (i.e. when the response was submitted), and the submission date (i.e. when the RFI was raised by the MSC). All these sorting options can be ordered in a descendant (i.e. A-Z, 1-10) and an ascendant manner (i.e. Z-A, 10-1).
- **Searching options:** Users can search for specific RFIs by using the basic search or the advanced search functionalities:
 - The Basic search functionality allows users to search for the RFI concerning a specific Clinical Trial either by introducing the EU CT number or the RFI number.
 - The Advanced search functionality allows users to retrieve a particular RFI after populating one or several data fields, such as the source type (e.g. initial CTA, substantial modification CTA); the MSC; the status (pending, responded, expired, and cancelled); the interval of the due date (i.e. between which dates the RFI must be responded), the interval of the response date (i.e. between which dates the response was given), and the submission date (i.e. between which dates the RFI was raised by the MSC).

3.4. How can users search for a Request for Information in the Notices & alerts tab?

Within the Notices & alerts tab, there are sorting and searching capabilities to facilitate the search for an RFI:

- **Sorting options:** The default sorting displays all the Notices & alerts that the sponsor has received, from more recent to less recent. Sorting options include: type (i.e. alert), reference number, title of the notice/alert, received date, source type (i.e. type of application such as Initial, Substantial Modification, etc.) or evaluation process part (e.g. Assessment of Part I). All these sorting options can be ordered in a descendant (i.e. A-Z, 1-10) and an ascendant manner (i.e. Z-A, 10-1).
- **Searching options:** Users can search for specific RFIs by using the basic search or the advanced search functionalities:

- The Basic search functionality allows users to search for an alert related to a particular RFI concerning a specific Clinical Trial either by introducing the EU CT number or ASR ID (to search for a CTA RFI, users need to introduce the first option).
- The Advanced search functionality allows users to retrieve a particular RFI after populating one or several data fields, such as the title of the alert (e.g. RFI sent to sponsor), the MSC, source type (e.g. initial CTA, substantial modification CTA), the interval of the due date (i.e. between which dates the RFI must be responded), the interval of the response date (i.e. between which dates the response was given), and the submission date (i.e. between which dates the RFI was raised by the MSC).

3.5. How can users view all the submitted Requests for Information responses?

Users can view all the RFIs responses submitted for a CTA in the evaluation section of the CTA page. Their status will show as 'responded', and it will be displayed next to the date of the submission. The rest of the RFI raised for the same part of the CTA will also be displayed. *See image below.*

The screenshot shows a section titled "Assessment Part II" with a dropdown menu for "AT". Below it, there is a section for "RFI" with a count of 3. A "Collapse all" link is visible. The list contains three RFI entries:

- RFI-CT-2021-500134-26-00-IN-005: Responded: 18/01/2021
- RFI-CT-2021-500134-26-00-IN-006: Due: 01/02/2021 (locked)
- RFI-CT-2021-500134-26-00-IN-007: Due: 01/02/2021 (locked)

A "Conclusion" section is also visible at the bottom of the list.

Users can also see all the responses submitted for all CTAs from the RFI Tab.

RFI-CT-2021-500057-13-00-IN-003	MSC	Source type	Evaluation process	Submitted	Responded	Due
IN	Austria	Initial	Assess part I	04/02/2021		16/02/2021
Pending CT-2021-500057-13-00 Title: CTIS Training Programme test CT for Demo						

4. Create a Request for Information response

4.1. How can users create a Request for Information response?

In order to reply to an RFI, users can click on the **RFI number** from the RFI listed in the RFI tab (if they click on the EU CT number they will be directed to the relevant CT page), or on the **RFI alert** from the 'Notices & alerts' tab. The RFI is then displayed in the evaluation section of the relevant CTA page. Users can easily identify the RFI to be addressed by the RFI number and click on the padlock button to edit it. Once the RFI is shown, users can view the change application button, the supporting documentation (if any) that the MSCs may have attached, and the considerations raised as part of the RFI. To respond to each of them, the user needs to click on the padlock button, enter a response, and add a supporting document (if applicable). *For more information, refer to the [eLearning material](#) of this module.*

4.2. How must users respond to a Request for Information?

How to respond to an RFI depends on the content of the request raised by the RMS/MS and the consequent action expected from the sponsor. Two scenarios can be envisaged:

1. No changes to the CTA are needed (e.g. when simple clarifications are requested to the sponsor).
2. Changes are expected to be made to the CTA: users may need to modify the structured data and/or documents displayed in the application dossier. If users need to upload new versions of CTA dossier documents, they can submit a clean version of the updated document in the same placeholder of the CTA dossier, as well as the original document with track changes to facilitate the assessment. Users shall not use the 'Add document' placeholder below the written response to consideration to upload updated CTA dossier documents.

Different processes are required depending on the content of the request raised. *For more information refer to the [eLearning material](#) of this module.*

Irrespective of whether changes are or not expected to be made in the existing CTA, users will always need to provide a written response to the considerations raised by the MSC. Additionally, users can upload a document to support their response by clicking on the 'Add document' field. This field is not used for updating documents that are included in a CTA (e.g. Protocol, Recruitment arrangement, etc.).


Response to consideration

 Consideration number RFI-CT-2022-502474-16-00-SM01-002-Application section parts Part I - Non-clinical Application section and document Cover letter 01

Consideration can | change cover letter while responding to SM Part I RFI (not initial CTA)

Response

Documents related to the response

 Add document

 Save response

4.3. Can users modify the Cover letter as part of a Request for Information?

No. Users cannot change the cover letter as part of an RFI response.

4.4. Can users modify Deferrals as part of a Request for Information?

Yes. Users can change a deferral as part of an RFI response related to an initial CTA evaluation. However, deferrals cannot be changed as part of a related RFI response during the evaluation of an Additional MSC or Substantial modification CTA. Users should note that the deferrals cannot also be changed by submitting an Additional MSC or Substantial modification CTA.

4.5. When are changes to the Clinical Trial Application expected as part of a Request for Information response?

It is appropriate to modify an existing CTA to respond to an RFI when it is required based on the information provided by the RMS/MS in the relevant RFI. For, example, if the information on the CTA dossier is incorrect or if there is missing information. Such changes may be related to any of the sections in the application dossier (i.e. Form, Part I, and Part II).

4.6. Are Part I RFIs allowed in an Additional MSC CTA evaluation?

Yes, as part of 'Additional MSC CTA', Member States can raise considerations. The RMS will then consolidate them and submit an RFI, even though Part I has already been concluded.

4.7. What happens if more than one Request for Information is received?

Users can respond simultaneously to more than one RFI if no changes to the CTA dossier are required. But if more than one change is needed in the same part of the application, corresponding to two or more RFIs the system only allows to have one application draft opened at a time. This is so to ensure traceability of the changes made to an application. For this type of RFIs, if there is a draft CTA opened, the 'change application' button will not be visible until that draft CTA is submitted or discarded.

The only exception to this rule is in case RFIs are simultaneously raised for Part I and Part II of the assessment phase. In that case, users may work on two simultaneous drafts of the application to address the changes needed as they concern different parts of the application and therefore the traceability of changes is assured. In Part II the system allows to have more than one RFI, one for each MS.

4.8. Can users save a draft version of the Clinical Trial Application before submitting it as part of a Request for Information response?

Yes. Users can save a draft version of the CTA they are working on as part of a response to an RFI by clicking on the save button. Users will see a blue ribbon at the top of the CTA page when they are in draft mode. Next to the blue ribbon, there is a version icon and by clicking on it, a drop-down list of draft CTA versions being edited simultaneously will be displayed. Next to it, another button allows users to view the originally submitted CTA. *See image below.*



5. Submit a Request for Information response

5.1. How can users submit a Request for Information response?

Once users have made the necessary modifications to the CTA as part of an RFI response, by using the 'change application' button, they should follow these steps:

- Go to the evaluation section of the CTA.
- Locate the RFI to be responded.

- Enter a response for the considerations of the RFI.
- Save the responses to the considerations of the RFI.
- Submit the RFI response.

If the RFI does not require any change to the CTA dossier, users need only to submit a written response to the consideration of the RFI. Whether an RFI response will require or not a change to the application, will depend on the nature of the RFI raised by the RMS/MSC (see question 4.5).

Additionally, users can upload a document to support their response by clicking on the 'add document' field. This document is different to the documents attached in a CTA (e.g. update the Protocol in the CTA not in the RFI response). Users can click on 'Save response' button to capture the response.

5.2. How much time do sponsors have to respond to a CTA RFI?

The maximum deadlines for responding to a CTA RFI depend on the evaluation phase in which a CTA RFI has been raised:

- For validation RFIs, MSCs can establish a maximum of 10 days for sponsors to respond.
- For assessment of Part I and/or Part II RFIs, MSCs can establish a maximum of 12 days for sponsors to respond.

The above deadlines are a maximum number of days; however, the RMS/MSCs can specify a shorter period available for sponsors to respond to the RFIs when they create the RFI. Sponsors need to take into account the actual deadlines given by the RMS/MSC to respond to an RFI.



5.3. Where can users check the due date to respond to a Request for Information?

Users can view the due date of each RFI in the RFI Tab. See image below.

RFI-CT-2021-500057-13-00-IN-003	MSC	Source type	Evaluation process	Submitted	Responded	Due
IN	Austria	Initial	Assess part I	04/02/2021		16/02/2021
Pending CT-2021-500057-13-00 Title: CTIS Training Programme test CT for Demo						

They can also check the due date for the RFIs of a specific CTA in the evaluation section of the CTA in question. To display the information, users need to click on the arrow of the RIF

tile. See image below.

Assessment Part II	
AT	▼
RFI 3	▼
Collapse all ▲	
RFI-CT-2021-500134-26-00-IN-005	Responded: 18/01/2021 >
RFI-CT-2021-500134-26-00-IN-006	Due: 01/02/2021  >
RFI-CT-2021-500134-26-00-IN-007	Due: 01/02/2021  >
Conclusion	>

5.4. Can MSCs determine shorter deadlines for sponsors to submit Request for Information responses than the ones established in the CT Regulation?

Yes. The RMS/MSCs can determine a shorter period available for sponsors to respond to the RFIs (i.e. maximum 10 days for validation RFIs and maximum of 12 days for assessment RFIs). However, a minimum of one working day must be given for sponsors to respond.

5.5. What are the consequences of not responding to CTA RFIs?

In case sponsors do not respond to an RFI raised during the evaluation of a CTA within the period established by the RMS/MSCs, the CTA lapses and can no longer be considered for evaluation.

5.6. How much time do MSCs have to assess a Request for Information response?

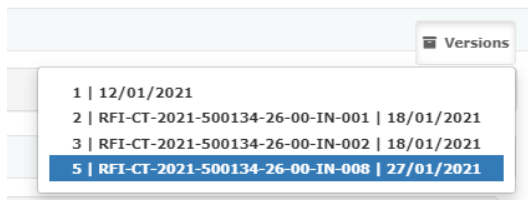
The applicable deadlines depend on the phase of the evaluation:

- For Validation RFIs, the RMS and MSCs have a maximum of 5 days after receiving the RFI response from the sponsor to assess it.
- For Part I RFIs, the RMS and MSCs have a maximum of 12 days after receiving the RFI response to assess the response provided by the sponsor. In case of multinational trials, the RMS has 7 additional days to consolidate the assessment of the RFI response.
- For Part II RFIs, MSCs have a maximum of 19 days to assess the RFI response

provided by the sponsor.

5.7. How can users view all the Clinical Trial Application versions submitted?

Users can view all the versions of an application submitted in response to a CTA RFI by clicking on the 'versions' button displayed on the Clinical Trial page. All versions will be listed, and users can consult them by clicking on them. *See image below.*



5.8. How can users view the changes applied to the Clinical Trial Application dossier data?

Changes made to the data in the application dossier will be highlighted in yellow after the users click on the 'Padlock' button. *For more information, refer to the [eLearning material](#) of this module.*

5.9. What happens to the previous versions of a document when a new document is submitted?

When responding to an RFI, the system only allows the user to upload a subsequent version of the existing documents. It is not possible to delete previously submitted version(s) of the documents in the system. Additionally, the name of the document cannot be replaced with the new document updated, only the number/coding of the version.

5.10. How can users view the previous versions of a document after submitting a new version?

Users will be able to access the previous versions of documents by clicking on the 'previous versions' button located in the 'All documents' in each section of a CTA version. *See image below. For more information, refer to the [eLearning material](#) of this module.*

5.11. Can users update a Request for Information response?

No. RFI responses cannot be edited after they have been submitted for the RMS/MSC to review.

5.12. What happens if an MSC deems a Request for Information response as incomplete?

If an MSC deems that the RFI response provided by the sponsor is incomplete, the MSC shall submit another RFI.

5.13. Is it possible to withdraw a Request for Information response?

No. A submitted RFI cannot be withdrawn.

6. Roles and permissions

6.1. What roles and permissions are involved in managing a Request for Information response?

Only the CT admin and the application submitter can submit an RFI response. Five roles may be involved in the creation/preparation of RFI responses depending on the CTA section to which the RFI refers to (*see examples below*). Eight roles can view RFIs.

- **Submit an RFI response:** CT admin and Application submitter.
- **Create an RFI response:** CT Admin, Part I Preparer (exc Q-IMPD), Part II Preparer, Q-IMPD Preparer, and Application Submitter. These users can create RFI responses as long as the RFI corresponds to the section of the application dossier in which they have a role (e.g. Part II Preparer can create an RFI response if the RFI corresponds to Part II; Q-IMPD Preparer can create an RFI response if the RFI corresponds to Part I Quality, etc).

- **View an RFI:** CT Admin, Part I Viewer (exc Q-IMPD), Part I Preparer (exc Q-IMPD), Part II Viewer, Part II Preparer, Q-IMPD Viewer, Q-IMPD Preparer, and Application Submitter. These users may see the sections and/or considerations in the RFI form as long as the RFI corresponds to the section of the application dossier in which they have a role (i.e. Part II viewer will only see the RFI related to Part II).

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).

FAQs: How to respond to RFIs received during the evaluation of a Clinical Trial Application.

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