EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS) Bitesize talk

Requests for Information (RFIs)

Presented by Noémie Manent and Laura Pioppo on 28 April 2022
European Medicines Agency

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CTIS Bitesize talk: Requests for Information (RFIs)

14:00 - 14:05 **Introduction**

14:05 – 15:25 **CTIS Demonstration Sessions followed by live Q&A Sessions**

15:25 - 15:30 **Closing remarks**

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A few housekeeping rules

For your questions,
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QR code:

Tips for optimal screen viewing

- Make use of the instructions under the embedded video in the event page and connect directly to the **IBM channel** *for the full-screen experience*
- Increase the *video quality* from the **HD button** on the right bottom of the screen setting it to 720p or 1080p.

Main Session: CTIS Demo with Q&A

Requests for Information (RFIs)

- CTA and CT RFIs
- What is a CTA RFI?
- CTA evaluation and RFIs timelines
- CTA RFIs classifications
- How to search and view an RFI during the evaluation of a CTA
- Sponsors' responses to RFI and CTA changes
- Sponsor user roles and permissions on RFI management

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Noémie Manent
Scientific Officer in CTIS programme

EUROPEAN MEDICINES AGENCY
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Laura Pioppo
Scientific Officer in CTIS programme

Requests for Information

CTA and CT RFIs

CTIS supports RFIs to be raised during the evaluation of a CTA, as well as in the context of ad hoc assessments, corrective measures and Annual Safety Reporting.

Clinical Trial Application (CTA) RFIs

- Evaluation

Clinical Trial (CT) RFIs

- Ad hoc assessment
- Corrective measures
- Annual Safety Reporting

What is a CTA RFI?

Clinical Trial Application (CTA) RFIs

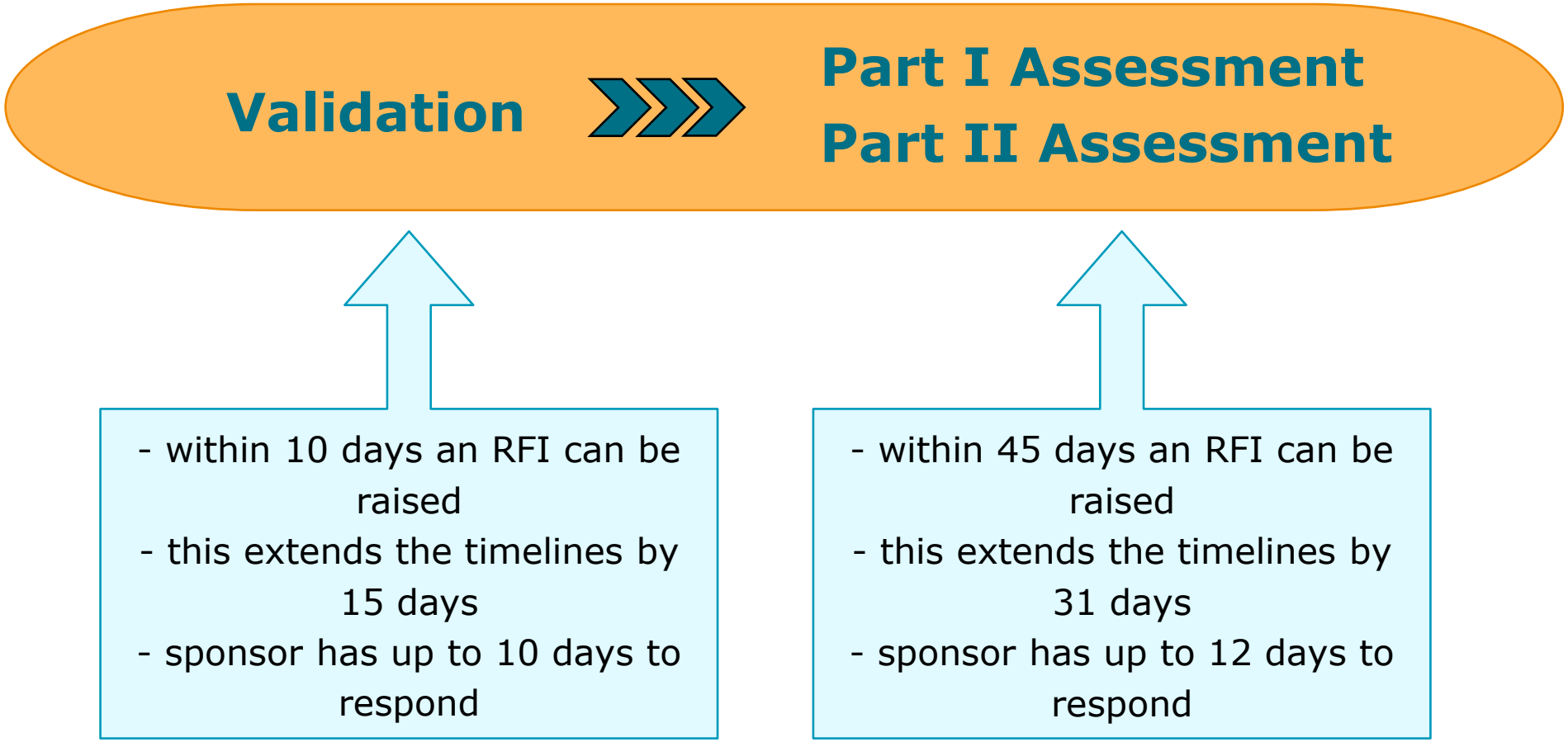
A CTA RFI is a request for additional information raised optionally by the RMS/MSC during the evaluation of an application

Evaluation

- Validation
- Part I
- Part II

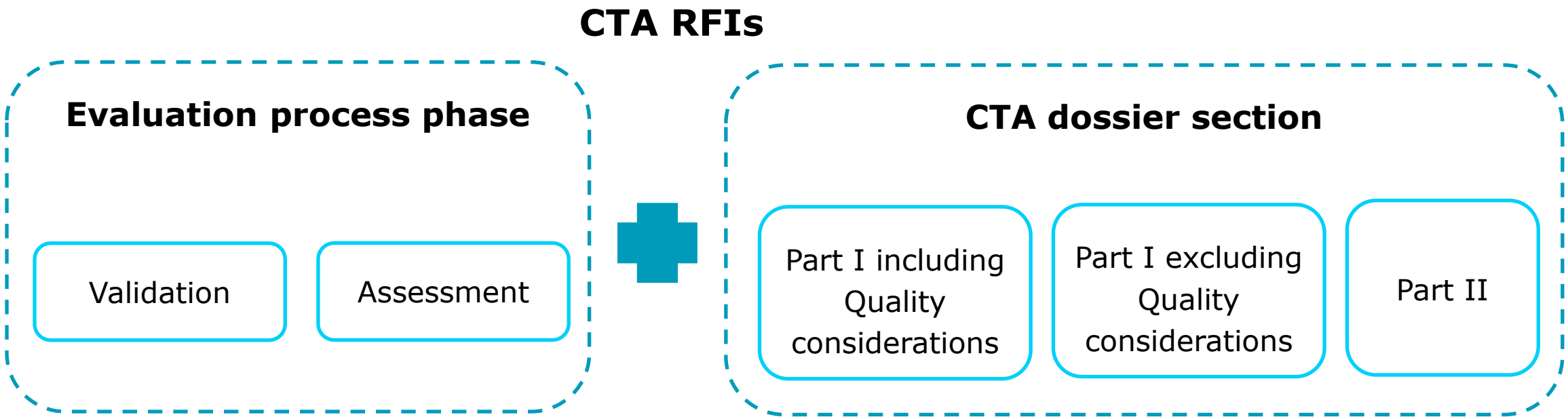
Sponsors must respond to CTA RFIs in order for the assessment of the CTAs to move forward. In case the sponsor does not respond to the individual RFI within the period set for it, **the CTA will lapse**, i.e. it will come to an end and no decision will be provided

CTA evaluation and RFIs timelines



CTA RFI classifications

A CTA RFI may be classified based on the evaluation phase it is raised in, and the specific CTA section it refers to.



How to search and view an RFI

Users can access RFIs in three different ways: through a CTA page, Notices & Alerts tab or RFI tab.

View RFIs by accessing the evaluation section of a CTA.

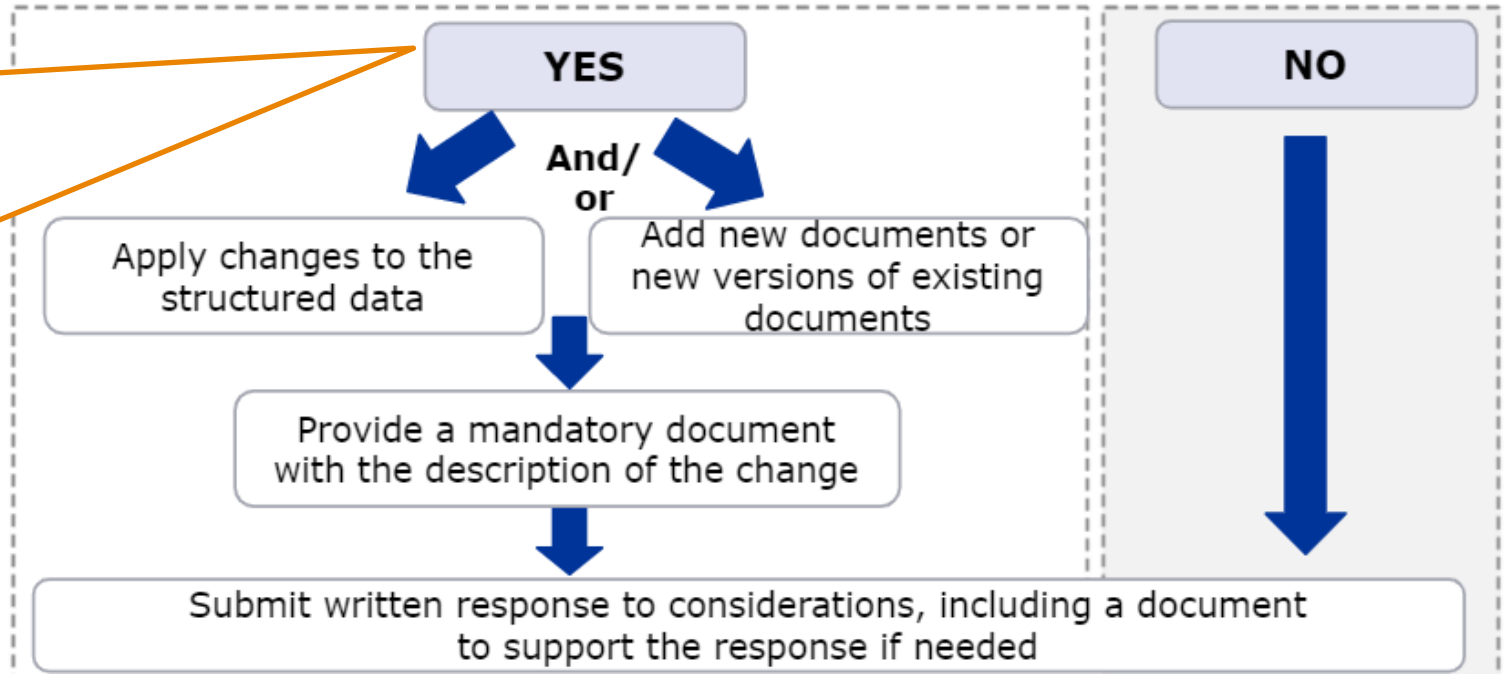
Receive alerts via the 'Notices & alerts' tab each time an RFI is sent to them.

Access to the full list of RFIs through the 'RFI' tab.

Sponsors' responses to RFI and CTA changes

The response to a CTA RFI involve the following actions: respond to the considerations in writing (mandatory); change the CTA structured data; and update or add documents.

Sponsor users **should not** place the updated CTA dossier documents in the placeholders found under considerations, but to use the respective placeholders found on **CTA dossier**, using the 'Update document' functionality.



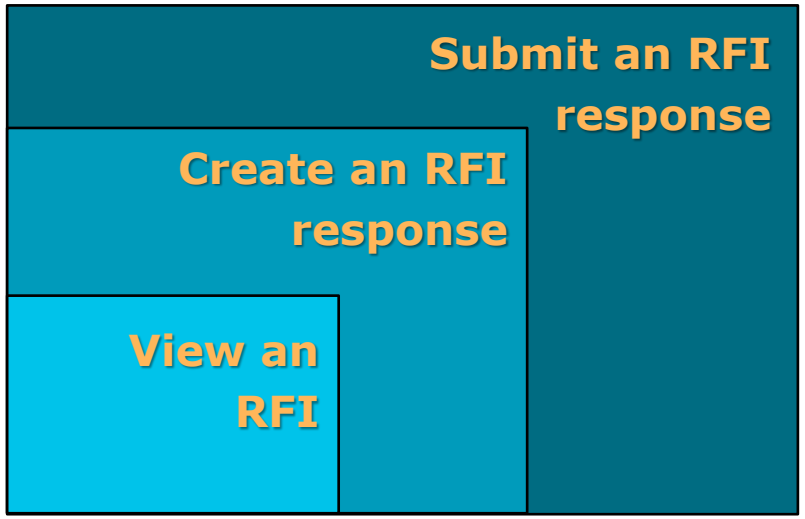
Sponsor users roles and permissions on RFI management

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, while eight roles can review RFIs, depending on the CTA section the RFI refers to.

CT Admin; Application submitter →

CT Admin; Application submitter; Part I Preparer (excl. Q-IMPD); Part II Preparer; Q-IMPD Preparer →

CT Admin; Application submitter; Part I Preparer (excl. Q-IMPD); Part II Preparer; Q-IMPD Preparer; Part I Viewer (excl. Q-IMPD); Part II Viewer; Q-IMPD Viewer →



Q-IMPD roles

Only users with Q-IMPD role have the ability to upload in the placeholder labelled Q-IMPD documents that may be of sensitive nature : e.g. the documents regarding quality, manufacture and control of the investigational medicinal product

Questions & Answers

For questions,

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We ask for your feedback on this event

A brief **poll is now open** in Slido

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For further comments please fill in our **EUsurvey**
(link available on EMA event page)

Thank you for attending today's event

Next CTIS bitesize talk on 31 May

Further information

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Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000

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