EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Support with workload management in the sponsor workspace

CTIS Training Programme – Module 04

Version 1.0 – September 2021

Learning Objectives

- Remember the main system functionalities enabling efficient workload management for the sponsor workspace.

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.

CTIS workload functionalities for the sponsor workspace

CTIS supports sponsor users in compiling, recording, and submitting data of clinical trials carried out in the EU. These activities are supported with three workload management functionalities.

- **Notices and alerts**: Enables users to monitor the messages triggered following the occurrence of events during the life cycle of a Clinical Trial (CT) (i.e. from creation and submission of an initial clinical trial application until the final reporting of a CT).
- **Request for Information (RFIs):** Enables users to access the requests from Member States Concerned (MSCs) about information that needs to be clarified in the context of the evaluation of a Clinical Trial Application (CTA), ad hoc assessments, corrective measures or annual safety reports.
- **Timetable:** Allows users to monitor the progress of the assessment of a particular CTA, by displaying the actual completion dates of each phase of the assessment and the expected completion date of the remaining ones.

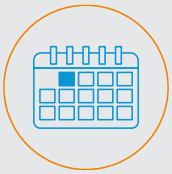
This Step-by-step guide includes:

Notices & alerts

This section outlines the steps that sponsor users should follow to use the Notices & alerts tab.

RFIs

This section outlines the steps that sponsor users should follow to access the RFI list tab to respond to RFIs.



Timetable

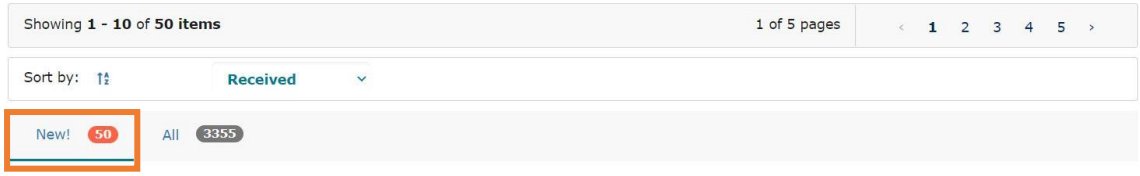
This section outlines the steps that sponsor users should follow to view the Timetable.

Notices & alerts

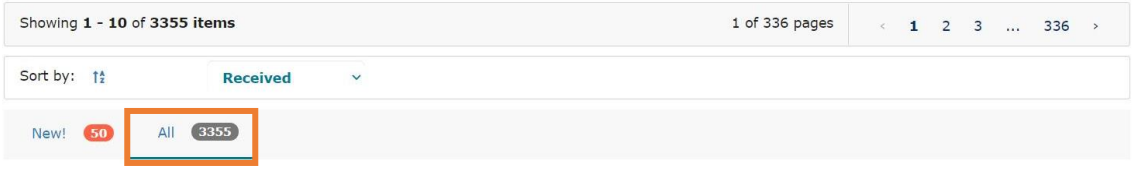
How to use the Notices & alerts tab

1. Sponsors can log in to CTIS and they can select the **'Notices & alerts'** tab.

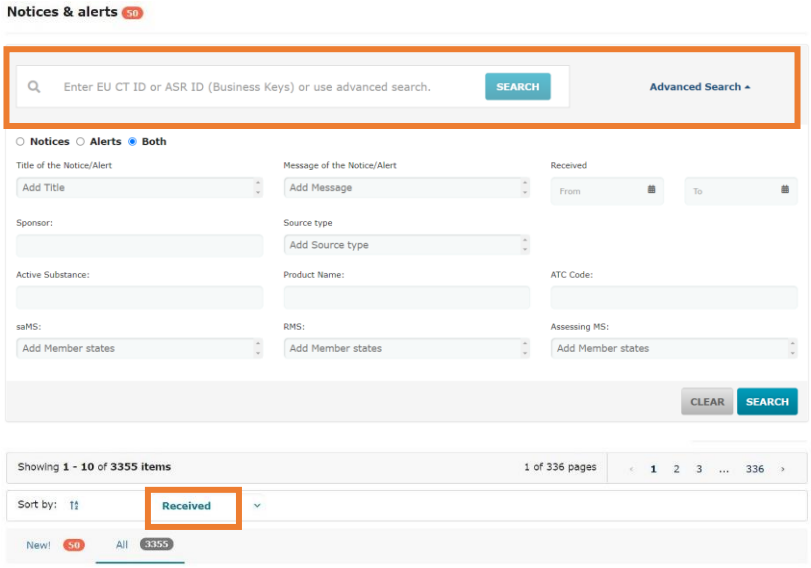
2. Then, they can click on the **'New!'** tab to view the new notices and alerts received according to the role they have since the **last connection** of the user to CTIS.



3. If the users want to view all the notices and alerts received, they can click on the **'All'** tab. Users that are assigned a new role will see here the "old" notices and alerts of such a role.



4. Sponsors can **search** the notices and alerts by using the basic search or advanced search to use criteria such as type, title of the notice, dates received, source type, etc. In addition, they can **sort** the results alphabetically by type, reference number, title, etc.



#CTIS insights

By default, the 'Notices & alerts' tab displays the messages received since the **last log-in** to the system ('New!') from most recent to less recent.

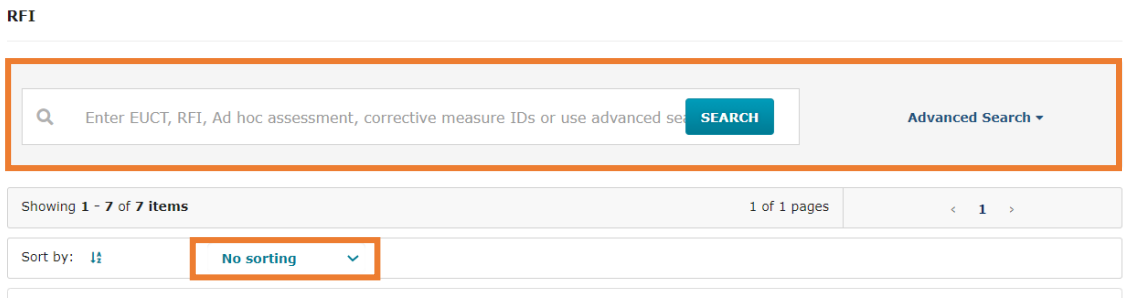
Users will receive notices and alerts regarding the clinical trial applications and clinical trials data for which they have a role.

Request for Information (RFI)

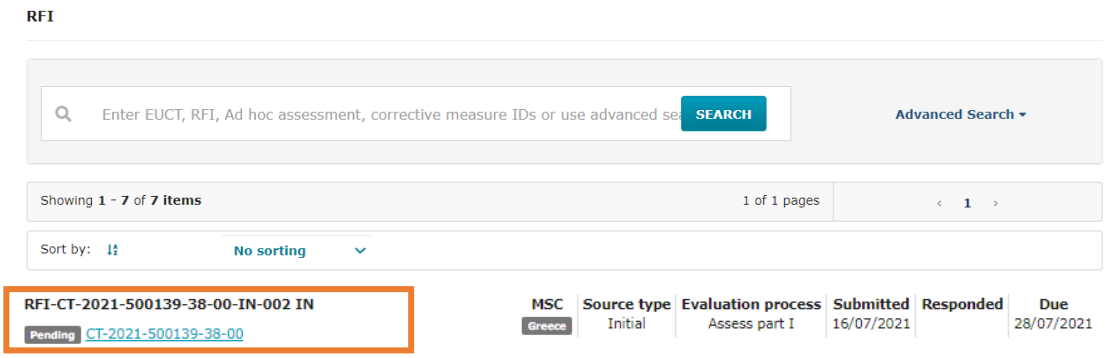
How to use the RFI list tab to respond to RFIs

1. Sponsors can log in to CTIS and then they can select the **'RFI' tab**. *The RFI tab lists all the information requested by Member States during the **evaluation of a CTA** or when **supervising an authorised CT**.*

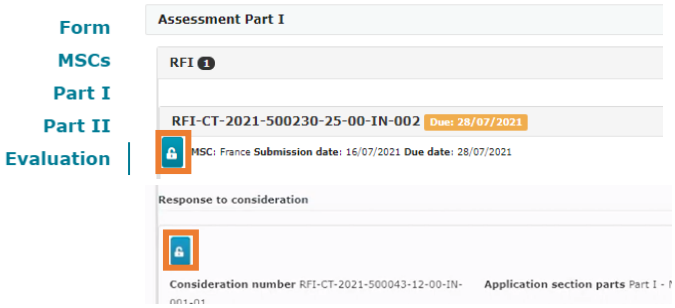
2. Sponsors can **search** RFIs by using a specific the basic or advanced search. In addition, they can **sort** the results alphabetically by source type, evaluation process, EU CT number, MSC, submission date, due date, etc.



3. Then, sponsors can click on the RFI to access it **from the CTA page.**



4. To respond to the RFI, users can click on the **padlock button** to be able to work on the RFI to for example change the application, add documentation, etc. Users will have another **padlock button** below to be able to work on the responses to each RFI consideration.



#CTIS insights

In case users do not respond within the period set to the RFI raised during CTA evaluation, the **CTA will lapse**.

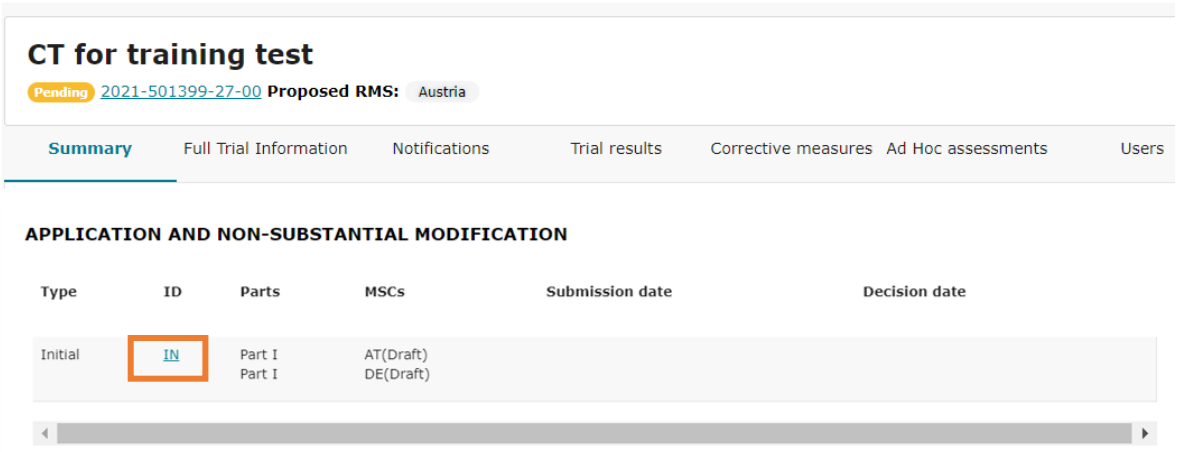
The type of response to an RFI depends on the **action expected from the sponsor** (responding to the considerations is mandatory):

1. No changes to the CTA are needed.
2. Modification of the structured data and/or documents of the application dossier are expected.

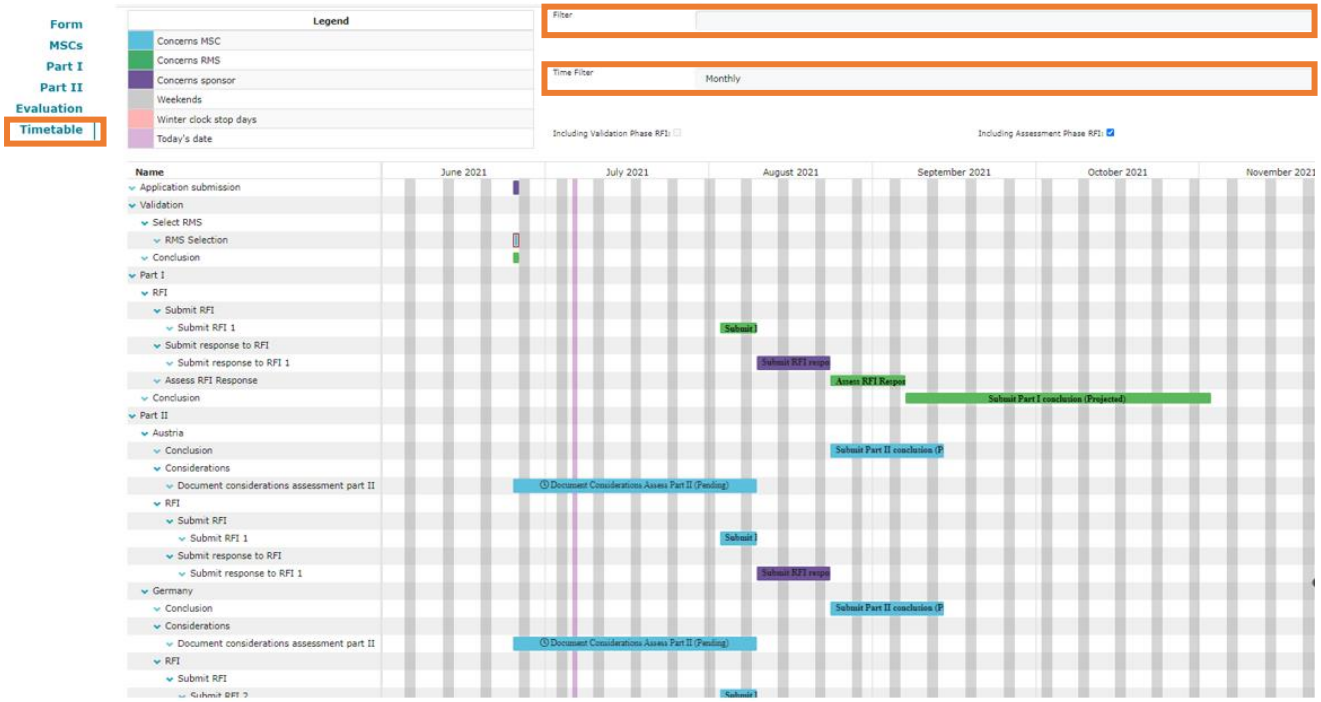
Timetable

How to view the Timetable

1. To view the timetable, sponsors can **search** a clinical trial application, and under the **'Summary' sub-tab**, scroll down to the '**Application and non-substantial modification'** section. Then, they can select the link under the 'ID' column.



2. Sponsors can click on the '**Timetable' sub-section** on the left of the screen and filter the visibility of the Timetable according to the different phases of the evaluation process. *The system includes a dynamic workflow by which, if a soft task from the MSCs is completed before its deadline, the corresponding deadlines for the following soft tasks are recalculated, but the maximum timeframes of the hard tasks are not modified by an earlier completion of the intermediate soft tasks.*



#CTIS insights

The Timetable displays a **projection of dates** for each evaluation phase based on the deadlines set out in the CT Regulation.

Users can also filter the visibility of the Timetable according to the **time scale** they are interested in (daily, monthly or yearly). It is also possible to filter to include or not the timelines of RFIs raised during the assessment.

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