EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide 2

CTIS workload functionalities for the sponsor workspace

CTIS Training Programme – Module 19
Version 1.0 – July 2021

Learning Objectives

- Remember CTIS main functionalities 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 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 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 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

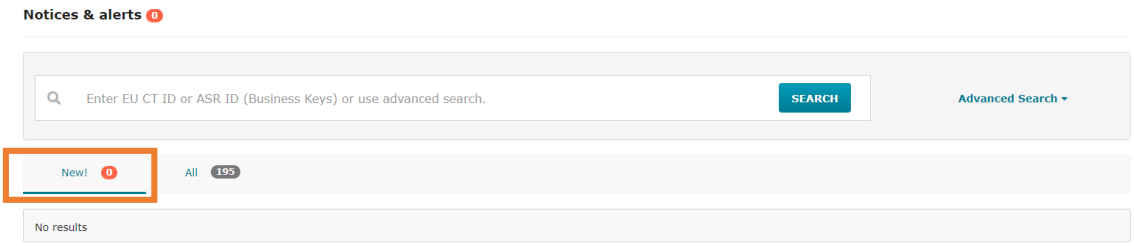
This section outlines the steps that sponsor users should follow to view the Timetable.

Notices & alerts

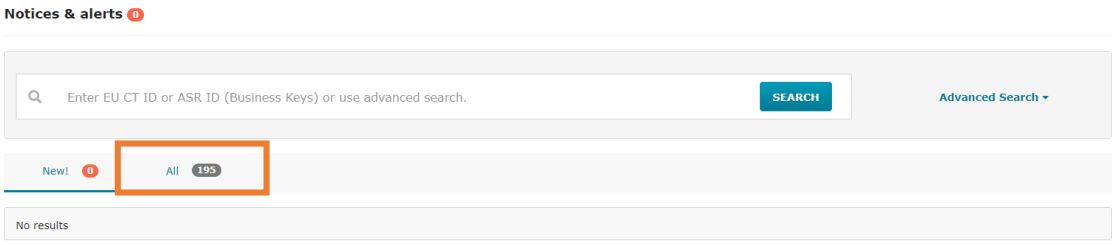
How to use the Notices & alerts tab.

1. Log in to CTIS and select the **Notices & alerts** tab.

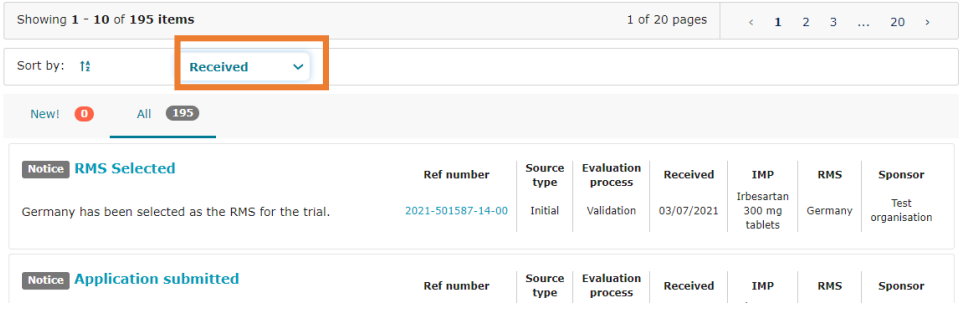
2. Click on the **'New!'** tab to view the new notices and alerts received since the **last connection** of the user to CTIS.



3. Click on the **'All'** tab to view all the notices and alerts received.



4. Sponsors can **sort** the notices and alerts by type, reference number, title of the notice, date, source type or evaluation process. Otherwise, they can **search** for a specific notice or alert by using the Basic or Advanced searches (*refer to Step-by-step guide 3: Search, view, and download a CT and a CTA in the sponsor workspace for more information*).



#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.

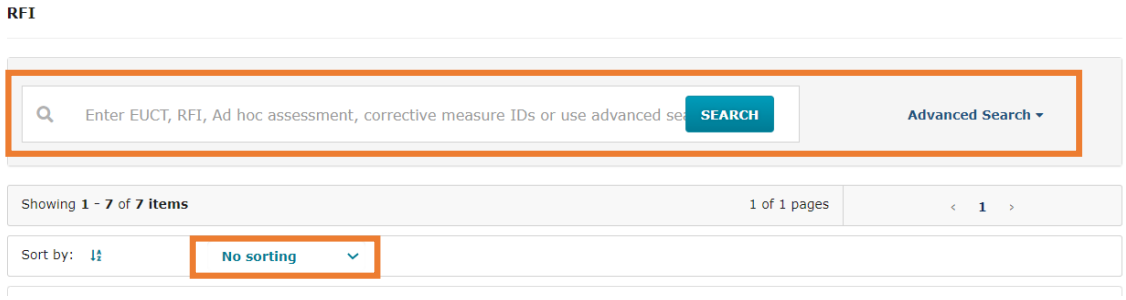
Users will receive notices and alerts regarding the clinical trial applications and clinical trials data that **they have access to**.

Request for Information (RFI)

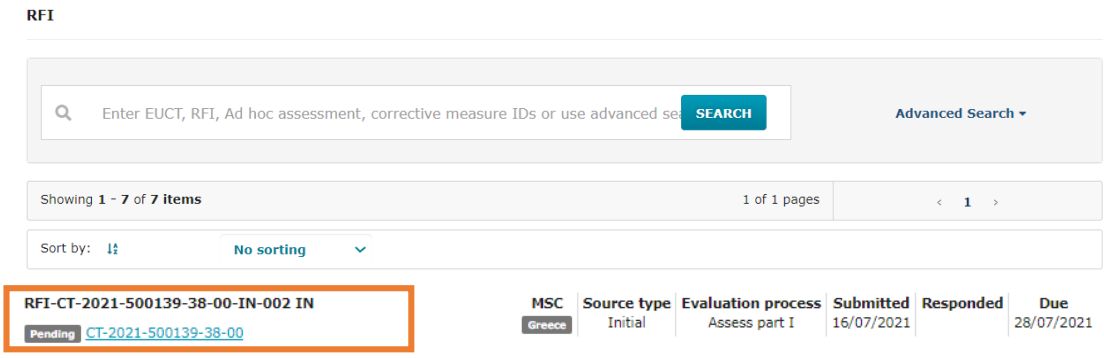
How to use the RFI list tab to respond to RFIs.

1. Log in to CTIS and 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 **sort** the RFIs by source type, evaluation process, EUCT number, MSC, submission date, due date, response date or status. Otherwise, they can **search** for a specific RFI by using the Basic or Advanced searches (*refer to Step-by-step guide 3: Search, view, and download a CT and a CTA in the sponsor workspace for more information*).



3. Click on the RFI to access it **from the CTA page.**



4. To respond to the RFI, users click on the **padlock** button and edit the response to each consideration of the RFI.

#CTIS insights

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

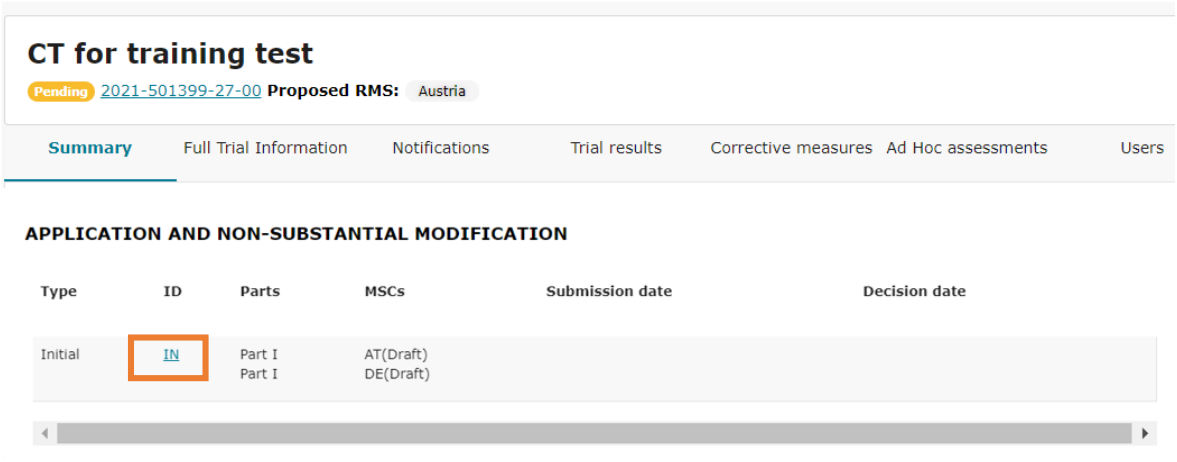
The type of response to an RFI depends on the **action expected from the sponsor** (responding to the considerations is mandatory):

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

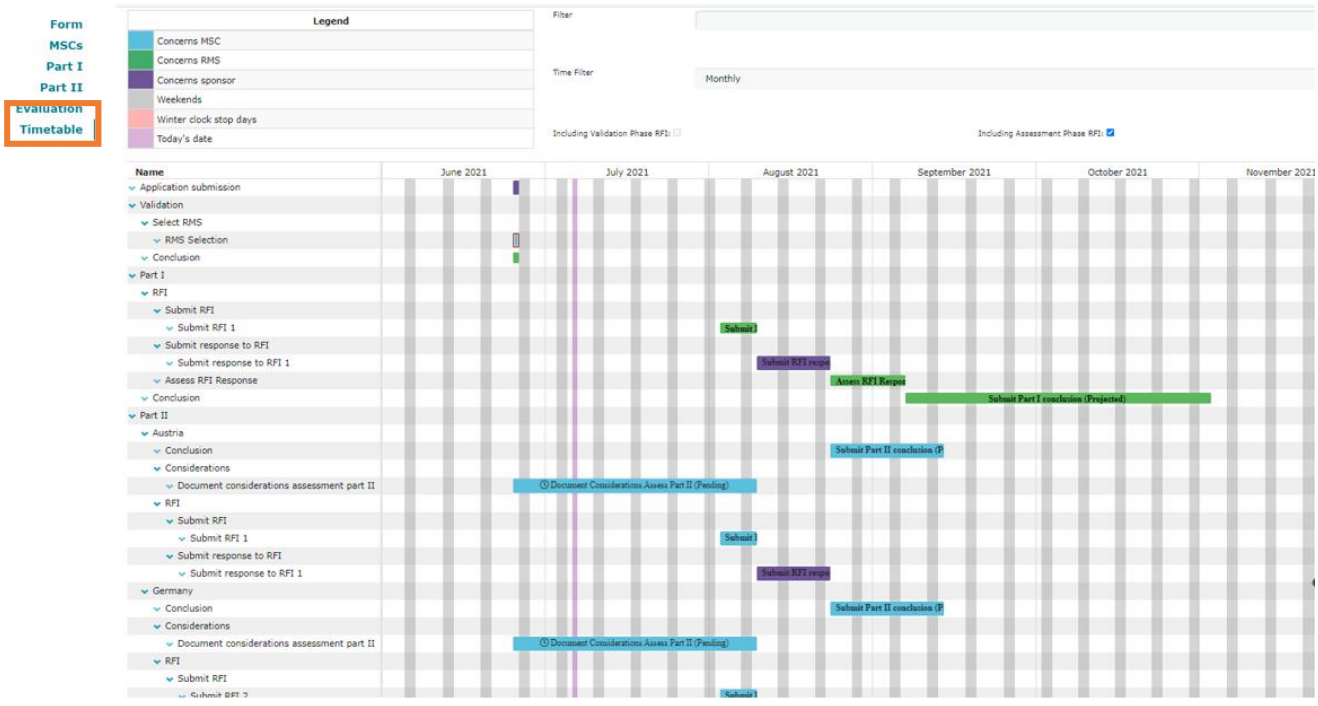
Timetable

How to view the Timetable

1. To view the timetable, **search** a clinical trial application (*refer to Step-by-step guide 3: Search, view, and download a CT and a CTA in the sponsor workspace for more information*), and under the **'Summary' sub-tab**, scroll down to the '**Application and non-substantial modification'** section and select the link under the 'ID' column.



2. 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 (submit application, submit validation conclusion, submit Part I conclusion, submit Part II conclusion, submit decision, express willingness/unwillingness, etc.). *The system includes a dynamic workflow by which, if a task is completed before its deadline, the corresponding deadlines for the following tasks are recalculated, but the maximum timeframes are still respected.*



#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 in the timelines of RFIs raised during the assessment.

Reference table

Find below relevant links with further information on this topic:

Module	Material	Source
Module 04: Support with workload management	eLearning course	EMA corporate website
Module 04: Support with workload management	Frequently Asked Questions	EMA corporate website
Module 04: Support with workload management	Video - How to manage the workload in CTIS - RFI tab (sponsor workspace)	EMA YouTube channel
Module 04: Support with workload management	Video - How to manage the workload in CTIS - Timetable	EMA YouTube channel

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