



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.

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# 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.

#### Clinical trials



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.

**Notices & alerts** 50

Enter EU CT ID or ASR ID (Business Keys) or use advanced search. SEARCH Advanced Search

☐ Notices ☐ Alerts ☒ Both

Title of the Notice/Alert  
 Add Title

Message of the Notice/Alert  
 Add Message

Received  
 From  To

Sponsor:

Source type  
 Add Source type

Active Substance:

Product Name:

ATC Code:

saMS:  
 Add Member states

RMS:  
 Add Member states

Assessing MS:  
 Add Member states

CLEAR SEARCH

Showing 1 - 10 of 3355 items 1 of 336 pages

Sort by:  Received

New! 50 All 3355

# 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**.

### Clinical trials

UAT 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.

RFI

 A screenshot of the RFI search interface. It features a search bar with a magnifying glass icon and placeholder text 'Enter EUCT, RFI, Ad hoc assessment, corrective measure IDs or use advanced se'. To the right of the search bar is a blue 'SEARCH' button and a link to 'Advanced Search'. Below the search bar, it says 'Showing 1 - 7 of 7 items' and '1 of 1 pages'. At the bottom, there is a 'Sort by:' dropdown menu currently set to 'No sorting', which is highlighted with an orange box.

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

RFI

 A screenshot of the RFI list table. The table has columns: 'MSC', 'Source type', 'Evaluation process', 'Submitted', 'Responded', and 'Due'. The first row is highlighted with an orange box and contains the text 'RFI-CT-2021-500139-38-00-IN-002 IN' and 'Pending CT-2021-500139-38-00'. The table also includes a search bar at the top and a 'Sort by:' dropdown menu.

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.

 A screenshot of the RFI details page. On the left, there is a sidebar with navigation links: 'Form', 'MSCs', 'Part I', 'Part II', and 'Evaluation'. The main content area is titled 'Assessment Part I' and shows a list of RFIs. The first RFI is highlighted with an orange box and contains a padlock icon. Below this, there is a section for 'Response to consideration' with another padlock icon highlighted by an orange box. At the bottom, there is a 'Consideration number' and 'Application section parts'.


#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.

### CT for training test

Pending 2021-501399-27-00 Proposed RMS: Austria

Summary

Full Trial Information

Notifications

Trial results

Corrective measures

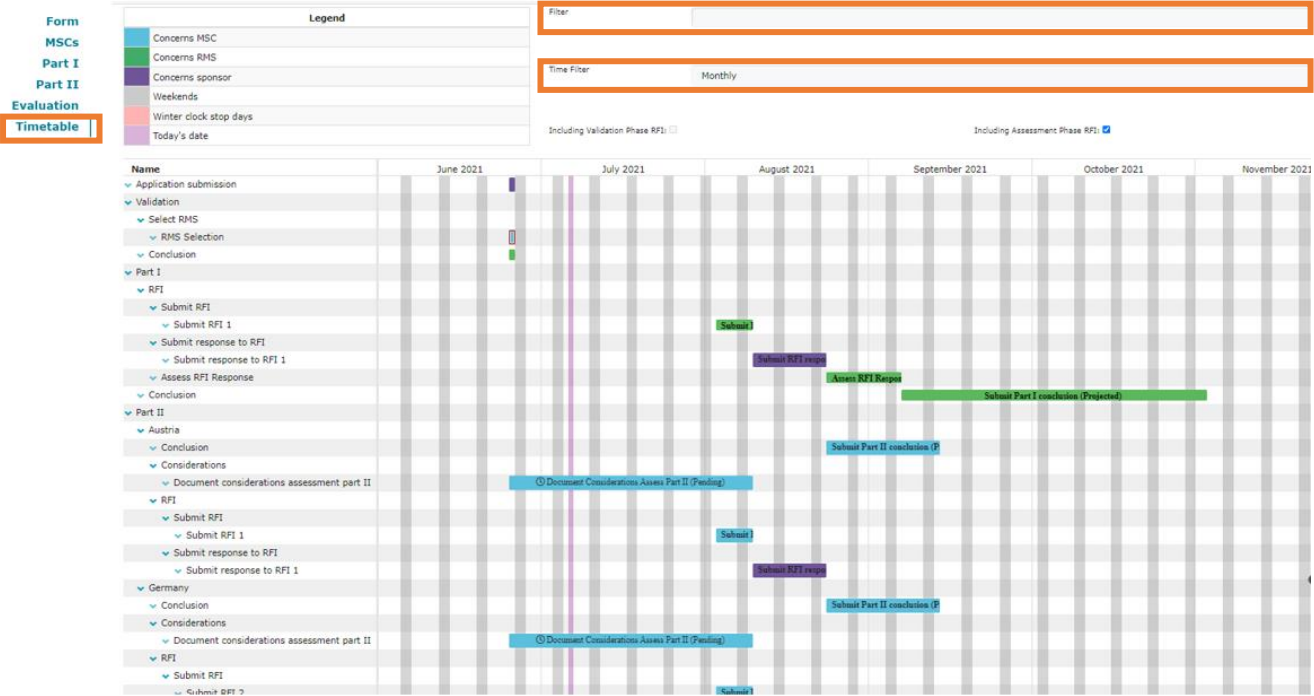
Ad Hoc assessments

Users

#### APPLICATION AND NON-SUBSTANTIAL MODIFICATION

Type	ID	Parts	MSCs	Submission date	Decision date
Initial	<a href="#">IN</a>	Part I Part I	AT(Draft) DE(Draft)		

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.*



**European Medicines Agency**

Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands

**Telephone** +31 (0)88 781 6000

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[www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Clinical Trials Information System (CTIS)

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