



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Step-by-step guide

## Support with workload management in the authority workspace

CTIS Training Programme – Module 04

Version 1.1 – June 2026

### Learning Objectives

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

© European Medicines Agency, 2026

Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.



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.

## Record of updated versions

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1.1	Notices and alerts: Activation of email notifications in CTIS. – slide 5 Adding the 'Record of updated versions' – slide 2	June 2026
1.0	Training material version published at CTIS go-live.	September 2021

# CTIS workload functionalities for the authority workspace

CTIS supports authority users in assessing, issuing a decision and overseeing clinical trials carried out in the EU. These activities are supported by 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).
- **Tasks:** Enables users to view the actions to be performed regarding the evaluation of clinical trial applications and Annual Safety Reports, and to complete them by a certain date.
- **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 authority users should follow to use the Notices & alerts tab.



## Tasks

This section outlines the steps that authority users should follow to use the Tasks tab.



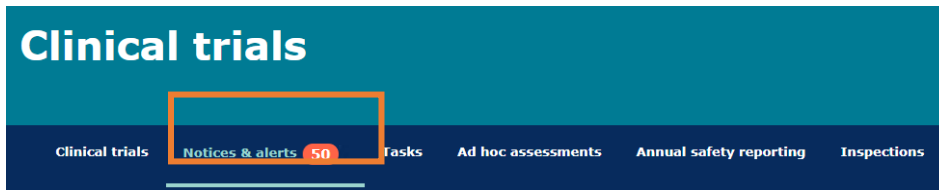
## Timetable

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

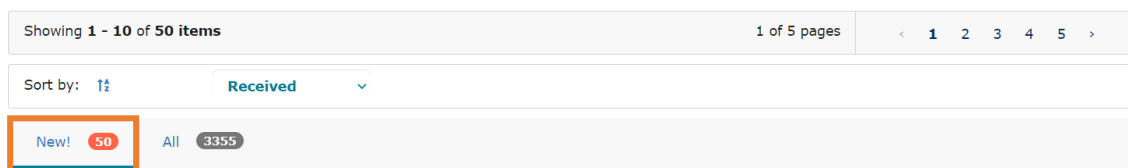
## Notices & alerts

### How to use the Notices & alerts tab.

1. Users 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. Users 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** by regular or prioritised notices and alerts on the drop-down on upper-right of the results list, or **sort** alphabetically by type, reference number, title, etc.

#### Notices & alerts 50



#CTIS  
insights

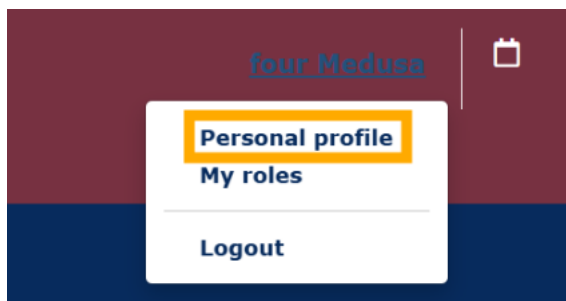
By default, the 'Notices & alerts' tab displays the messages received since the **last log-in** to the system ('New!') from most recent to less recent.

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

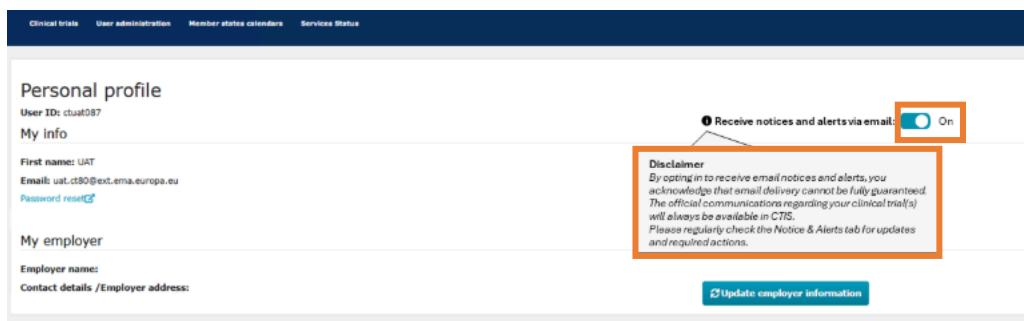
## Notices & alerts

### How to activate email notifications for notices and alerts

1. Log in to CTIS and click on your username and select 'Personal profile'



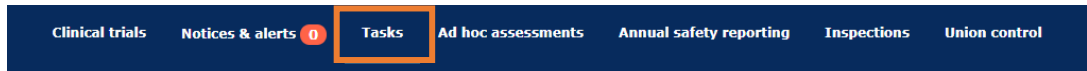
2. In the 'Personal profile' screen, click the radio button on the right-hand side to opt in to the email notifications



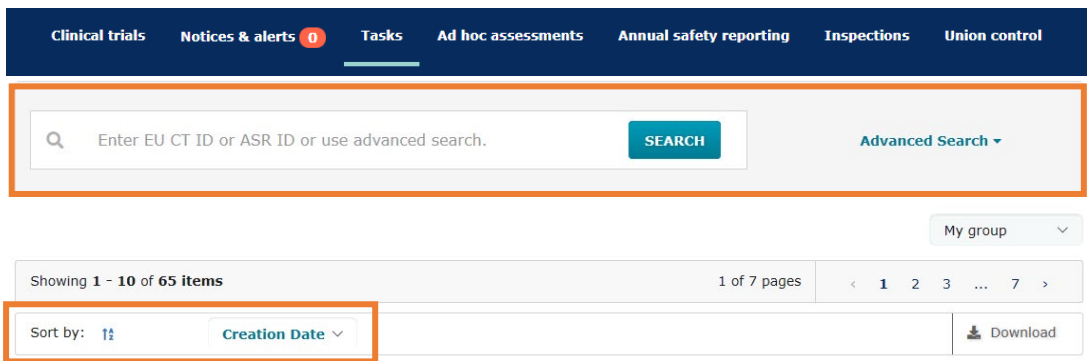
# Tasks

## How to use the Tasks tab


1. Users can log in to CTIS and then they can select the 'Tasks' tab.




2. Authority users can **search** for a task by populating specific information in the basic search (e.g. EU CT Number, ASR number, etc.), or by populating additional fields in the advance search (e.g. name of the task, application type, due date, active substance, etc.). Users can **sort** the tasks displayed in the 'Tasks' tab.




3. Once users have found the task, they can click on the **assignment button** on the right side of the task. *In the example below, the user has the appropriate role to select the 'Assign to me' button (refer to the slide 'Overview of the task assignment' of the eLearning of this module to view the different assignment buttons available).*

Submit validation decision	RMS:	Application and Non-SM type:	Sponsor/Co-sponsors:	Evaluation process:	Created:	Due:	Remaining days:	Assignee:
<span>Pending</span> 2021-500932-20-00	AUSTRIA	Initial	Test organisation	Validation	18/09/2021	27/09/2021	7	

4. After the task has been assigned, users can access it by **selecting the name of the task**.

Submit validation decision	RMS:	Application and Non-SM type:	Sponsor/Co-sponsors:	Evaluation process:	Created:	Due:	Remaining days:	Assignee:
<span>Assigned</span> 2021-500932-20-00	AUSTRIA	Initial	Test organisation	Validation	18/09/2021	27/09/2021	7	ctuats92 

5. In the case of soft tasks, once the users deem the task as completed, they can click on the 'Complete' button.

Document Considerations Assess Part I	RMS:	Application and Non-SM type:	Sponsor/Co-sponsors:	Evaluation process:	Created:	Due:	Remaining days:	Assignee:
<span>Assigned</span> 2021-501031-14-00	AUSTRIA	Initial	Glaxo Group Limited, Panpharma	Assess part I	16/09/2021	28/09/2021	8	ctuats92 

# Timetable

## How to view the Timetable

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

### CT for training test

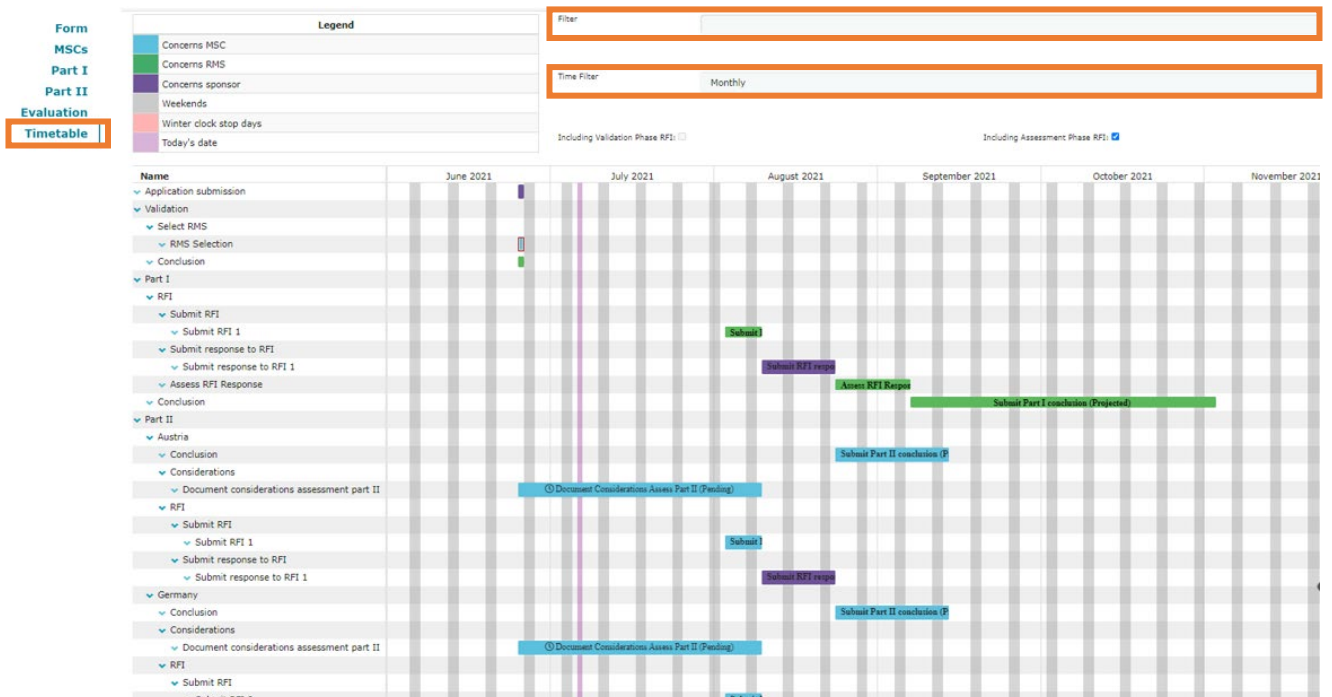
Pending [2021-501399-27-00](#) Proposed RMS: Austria

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)		

- Then, users 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 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 RFI's raised during the assessment.

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

Clinical Trials Information System (CTIS)

Step-by-step guide: Support with workload management in the authority workspace

© European Medicines Agency, 2026.

Reproduction is authorised provided the source is acknowledged.