EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Support with workload management in the authority workspace

CTIS Training Programme – Module 04

Version 1.0 – September 2021

Learning Objectives

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

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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.

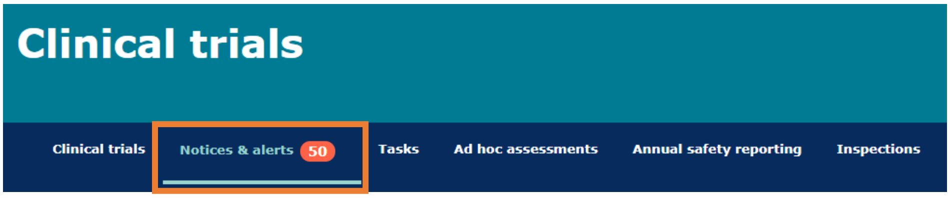
Timetable

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

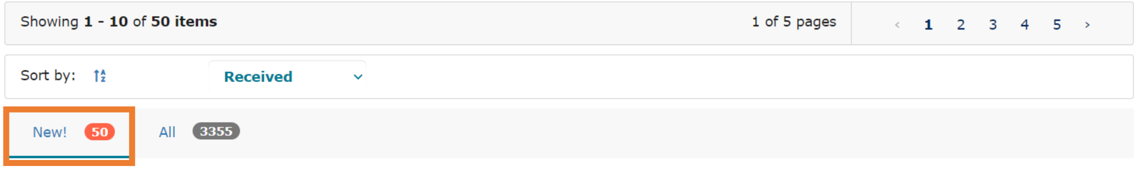
Notices & alerts

How to use the Notices & alerts tab.

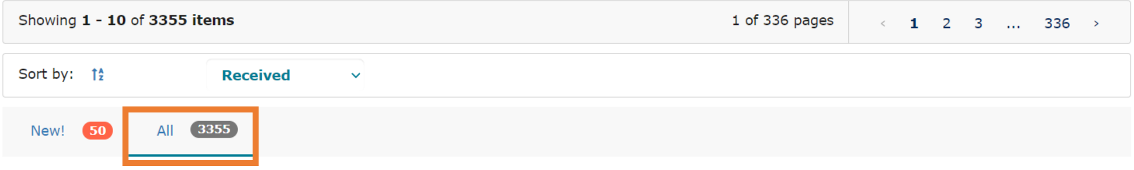
1. Users can log in to CTIS and they can select the '**Notices & alerts'** tab.



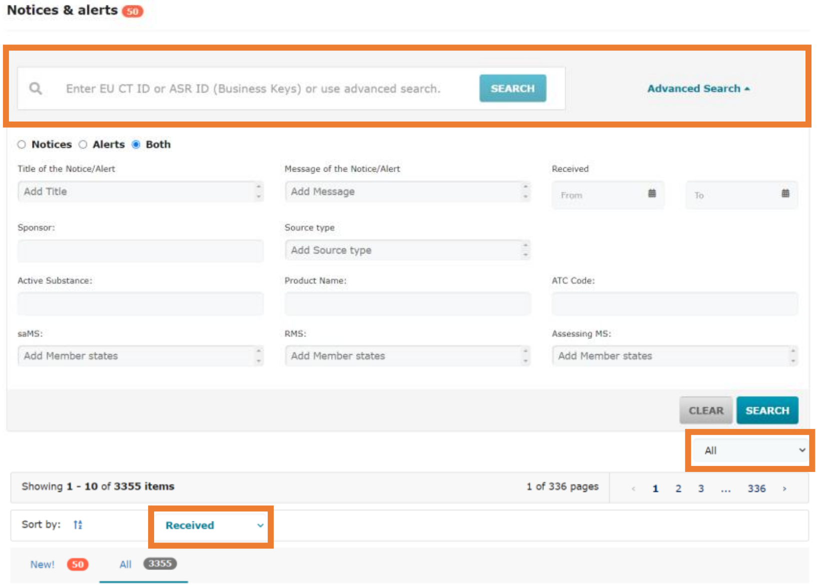
2. Then, they can click on the **'New!'** tab to view the new notices and alerts received according to the role they have since the **last connection** of the user to CTIS.



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.



#CTIS insights

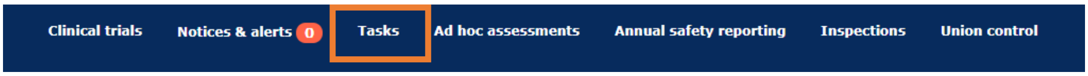
By default, the 'Notices & alerts' tab displays the messages received since the **last log-in** to the system ('New!') from most recent to less recent.

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

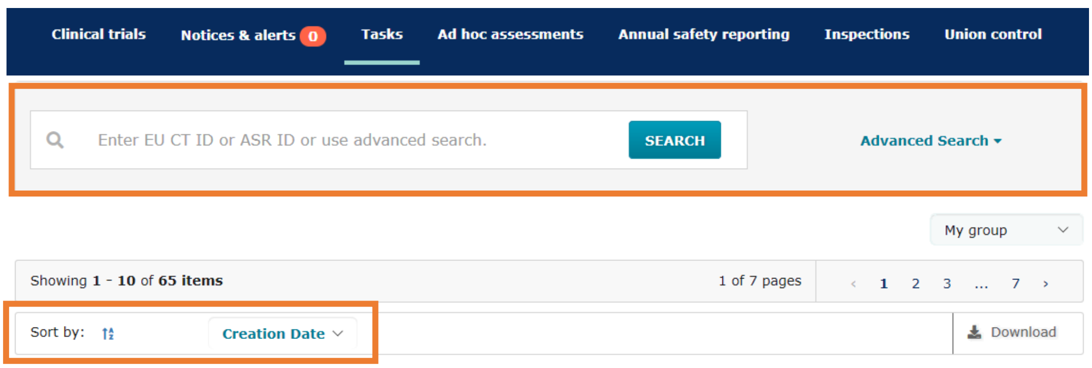
Tasks

How to use the Tasks tab

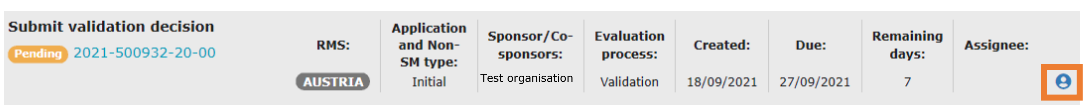
1. Users can log in to CTIS and then they can select the '**Tasks'** tab.



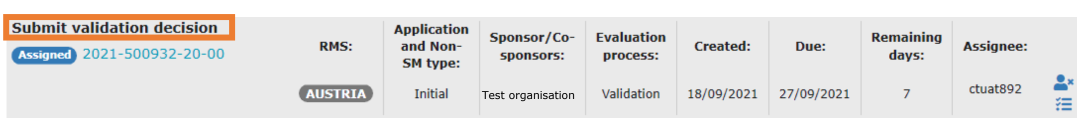
2. Authority users can **search** for a task by populating specific information in the basic search (e.g. EU CT Number, ASR number, etc.), or by populating additional fields in the advance search (e.g. name of the task, application type, due date, active substance, etc.). Users can **sort** the tasks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



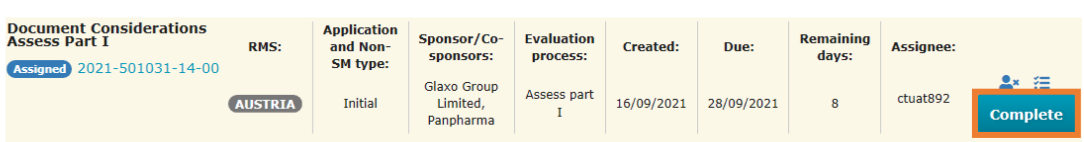
3. Once users have found the task, they can click on the **assignation button** on the right side of the task. *In the example below, the user has the appropriate role to select the '**Assign to me**' button (refer to the slide 'Overview of the task assignation' of the eLearning of this module to view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



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



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



#CTIS insights

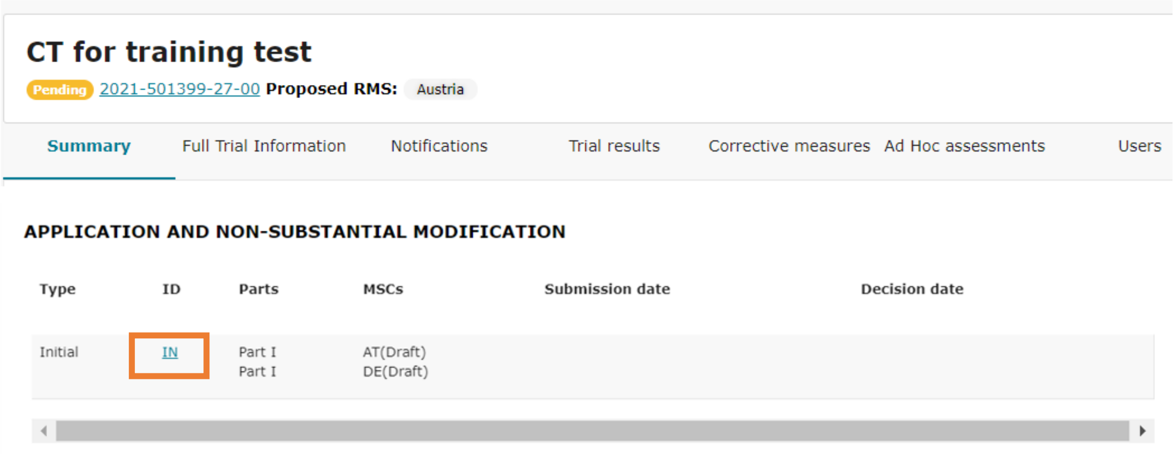
Once a task is assigned, assignees can also release the task by using the '**Release**' button.

For hard tasks, the system **automatically deems them as completed** as soon as they are executed. For soft tasks, the task assignee must click on 'complete' to finalise them.

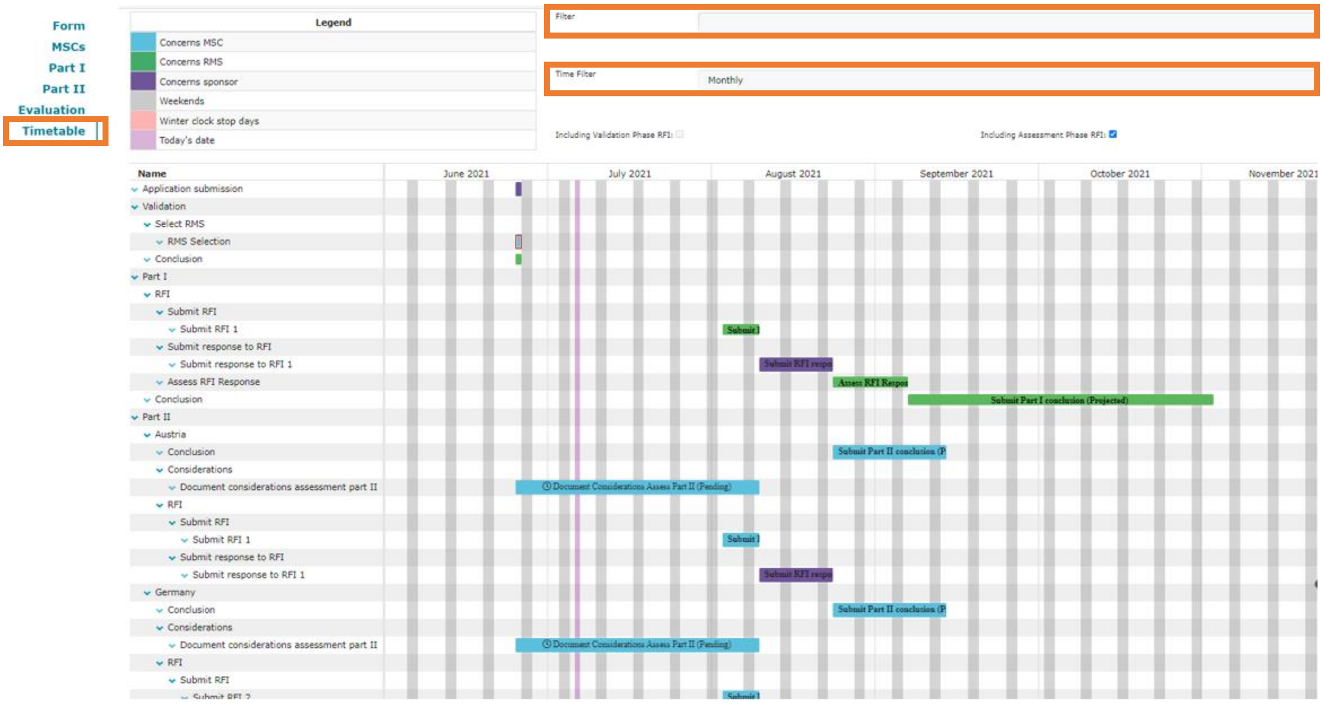
Timetable

How to view the Timetable

1. 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.



2. 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 RFIs raised during the assessment.

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Clinical Trials Information System (CTIS)
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