EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

Support with workload management by workspace

CTIS Training Programme – Module 04
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What you will find

- Answers to questions regarding workload management functionalities common to both workspaces (section 1 & 2)
- Answers to questions related to specific workload management functionalities of each workspace: Tasks for authority workspace (section 3) and Request for Information for sponsor workspace (section 4).
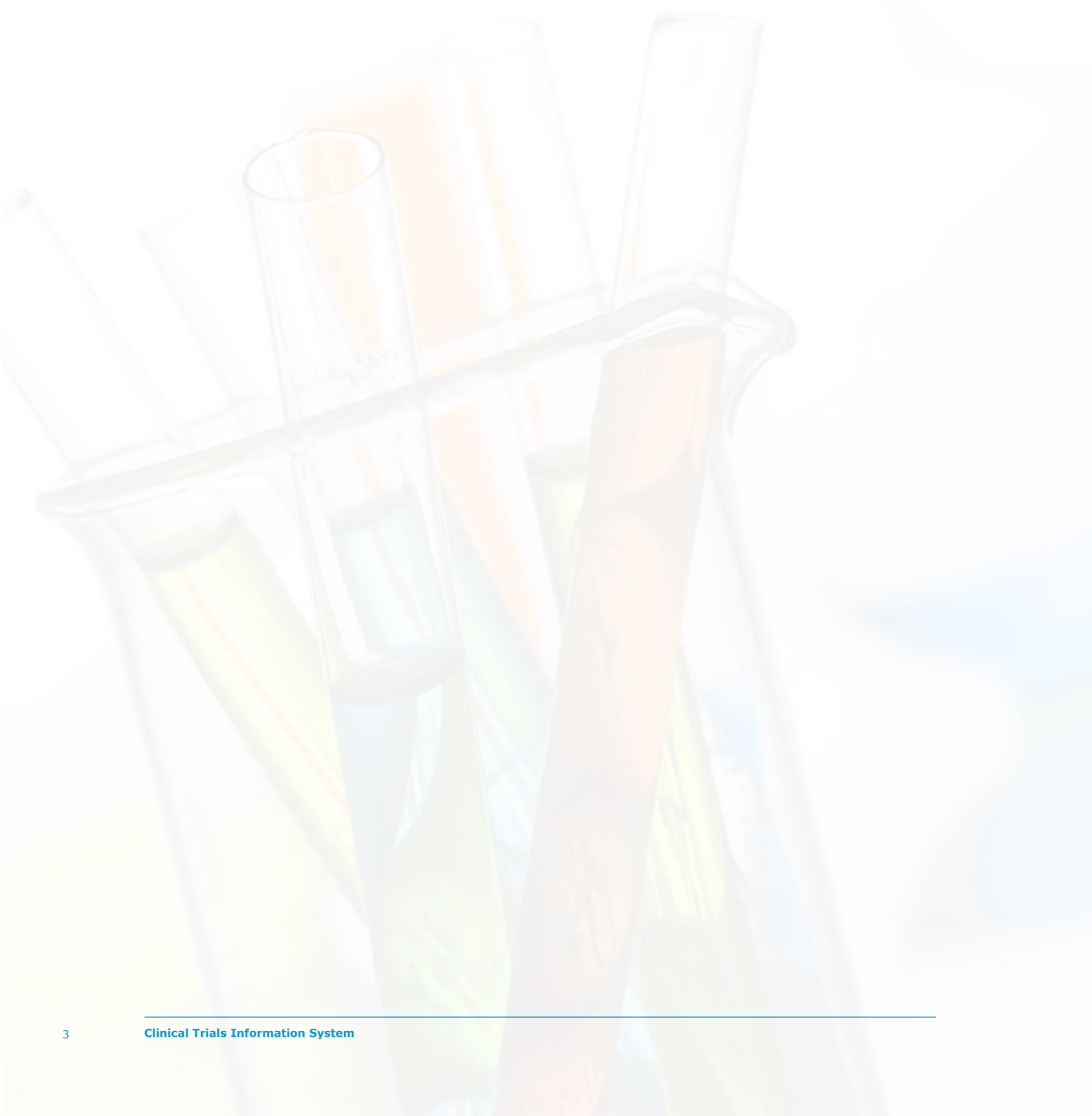
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FAQs

In this document, we list common questions regarding Module 4: Support with workload management by workspace. They are categorised into questions of a general nature and questions related to each of the main system functionalities enabling efficient workload management in CTIS, including the Tasks, the Requests for information (RFI), the Notices & Alerts, and the Timetable:

1. Remember the main system functionalities enabling efficient workload management.

2. Remember the use of the Notices & Alerts functionality

3. Understand the use of the Tasks functionality

4. Understand the use of the Request for Information functionality

5. Understand the use of the Timetable

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1. Notices & alerts

1.1. What are notices and alerts? What are they used for?

Notices and alerts are messages automatically triggered by the system that enable users to monitor the events that occurred during the lifecycle of a clinical trial, either with an informative purpose or with an actionable purpose. Notices and alerts inform the user of the events occurring during the clinical trial application and the clinical trial itself (including notifications, corrective measures, ad hoc assessment, etc.). Notices and alerts can be distinguished as follows:

- Notices are messages that aim to inform the user of an event. Examples: task completed by an MS, Part I and Part II or Part I (only) or Part II (only) submitted, etc.

- Alerts are messages indicating an action that needs to be performed by the user. Examples: serious breach submitted by the sponsor, consideration has been shared, etc. CTIS includes a sub-type of alerts ('alert reminders') which are specifically aimed at reminding sponsor and authority users of actions or tasks, respectively, which are about to expire.

1.2. What is the difference between 'Tasks' and 'Notices & alerts'?

The Notices & alerts functionality offers an overview of any activity happening during the whole life-cycle of a clinical trial. These include the events or actions happening during the assessment of the CTAs, ASR, and the events or actions happening once the CT is already authorised. As opposed to this, the Tasks functionality offers users an overview of the actions to be performed for the assessment and authorisation of clinical trial applications and the ASRs.

In other words, the Tasks functionality is a specific workload management functionality; it differs from Notices & alerts as it concerns only the assessment of CTAs and ASRs. It should be however noted that when a task is assigned or completed, a notice is sent in parallel to the user assigned.

1.3. How can users quickly view the notices and/or alerts they are interested in?

There are two sub-tabs on top of the page ('New!' and 'All'). 'New!' allows users to quickly spot new messages that they have received since their last connection to the system. 'All'

allows users to view all the messages that they have received since the start of his/her role in a clinical trial.

Moreover, the Notices & alerts tab includes sorting, filtering, and searching capabilities to identify specific notices and/or alerts.

- **Sorting options:** Users can sort the notices and alerts displayed in the Notices & alerts tab according to type (notice or alert), reference number, the title of the notice or alert, or received (all). All these sorting options can be ordered in a descendant (i.e. A-Z, 1-10) and an ascendant manner (i.e. Z-A, 10-1).

- **Filtering options:** Users can filter the notices and alerts displayed in the Notices & alerts tab. The default filtering is 'All', which shows all the notices and alerts relevant to their role in the system. Other filtering options include 'prioritised' which displays the notices and alerts that the system establishes as of an important nature (such notices and alerts regarding ASRs), and 'regular'.

Search options: Users can search for specific notices and alerts through the 'Basic search' and the 'Advanced search' capabilities.

- The **Basic search functionality** on top of the Notices & alerts tab allows users to search the tasks concerning a specific clinical trial either by introducing the EU CT number or the Annual Safety Reporting ID.

- The **Advanced search functionality** allows users to retrieve particular Notices & alerts populating one or several data fields such as the application type, date of reception, the sponsor who submitted it, the responsible Member State(s), or the active substance, among others.

1.4. What are the default settings for notices and alerts?

By default, the 'Notices & alerts' tab displays the messages received since the last connection to the system on the subtab ('New!') ordered by reception date (from most recent to less recent).

1.5. Is it possible to delete old alerts?

No, for traceability purposes alerts cannot be deleted. Old notices and alerts will be moved down as new messages come in. Users are encouraged to use the different sorting and filtering options available to see the most recent notices & alerts. It should also be noted that the same rule applies for the task (even when completed) they cannot be deleted.

1.6. Are the notices and alerts displayed dependent on the user's roles in the same way that tasks are?

Yes, users only receive the notices and alerts related to the clinical trial/s of their Member State, to which they have been given access and a specific role in CTIS.

2. Timetable

2.1. What is the timetable used for?

The timetable gives users an overview of the status and progress of the tasks or actions related to the assessment of a specific clinical trial application, by offering a visual representation of the phases completed and the projected dates by which the remaining activities should be completed (latest).

The timetable functionality is present in both workspaces in CTIS, but the visibility of activities in the authority workspace is broader than in the sponsor workspace.

- Member State users can view the timetable for those clinical trial applications for which they are an MSC. They will be able to see the hard and soft tasks in each of the phases of the assessment of a clinical trial application.

- In the case of the sponsors, the users with relevant roles will be able to see the timetable of the clinical trial applications that they are involved in.

MSC and sponsors users will have slightly different visibility of the tasks displayed in the Timetable.

2.2. Where is the timetable located in CTIS?

The timetable can be accessed from the Summary page of a clinical trial.

- The user will need to scroll down to the 'application and non-substantial modification' section of the summary page and click on the application ID of the application for which they want to view the Timetable.

- Once inside the application page, the user will have to click on the Timetable header on the navigation panel on the left-hand side of the clinical trial application page to view the Timetable.

2.3. What are authority users able to see on the timetable?

Authority users can see the timings related to the main phases of the clinical trial application (Submission, validation, Part I, Part II, and Decision) and all the tasks (hard and soft) performed in each of the phases of the assessment. Authority users can view the timetable for those clinical trial applications for which they are an MSC, and for those in which they are not MSC, regardless of their roles. European Commission users also have full viewing permissions regarding the timetable.

2.4. What are sponsor users able to see on the Timetable?

Sponsor workspace users can see the phases and the main tasks (hard tasks) performed in each of the phases of the assessment of a clinical trial application. They will only be able to see the information on the clinical trial applications they are involved in. *(For more information, refer to question 2.1).*

2.5. Can users download the timetable?

Users can also download the timetable as a CSV file, which will display the dates of the completed tasks and the dates foreseen for the remaining ones.

2.6. How are due dates calculated?

The Timetable displays a projection of the due dates for each assessment phase based on the deadlines set out in the Clinical Trials Regulation[1] (CT Regulation). Once, each phase has been completed, the Timetable is automatically adjusted, maintaining the maximum days established in the CT Regulation for the evaluation of each phase.

For calculating the final due dates, the system applies a set of rules stemming from Regulation 1182/71[2], which defines how timelines should be calculated for legally defined delays. These rules are:

- The reference time zone is Central European Time.

- Start of a task: A task will start on the day after it has been created.

- End of the task:

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[1] https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31971R1182&from=EN

o   The task due date cannot fall on a weekend or bank holidays. It will automatically be moved to the following calendar (working) day.

o   At least a period of two consecutive working days shall be foreseen for completing a task.

- The tasks timer will be paused during the period from the 23rd December until the 7th January.

2.7. Can users apply filtering options and/or perform advanced searches in the timetable?

Users can filter the visibility of the timetable according to the different phases of the assessment process (submit an application, submit validation conclusion, submit Part I conclusion, submit Part II conclusion, submit decision, express willingness/unwillingness, etc.).

Users can also adjust the visibility of the Timetable according to the time they are interested in (daily, monthly, or yearly).

Moreover, users can include RFIs that have been requested in each of the phases of the assessment, which will result in an extension of the standard deadlines for assessment. *(For more information, refer to question 4.8).*

3.   Tasks

3.1. What are tasks? What are they used for?

Tasks are activities automatically created by the system that support the assessment and decision regarding clinical trial applications and the assessment of Annual Safety Reports (ASRs) by Member State users. These provide an overview to the user of what needs to be done and by when. They can be found in the authority workspace and can only be seen and performed by Member State users.

3.2. What is the difference between hard tasks and soft tasks?

The Tasks functionality allows users to perform two kinds of tasks: hard tasks and soft tasks.

- **Hard Tasks**: Mandatory actions expected to be performed by the user in the context of the evaluation and decision of a clinical trial application, and ASRs. If the user does not act by a given deadline, the system will automatically apply a decision,

which will have a direct impact on the assessment status (e.g. submit validation decision or submit the decision on the clinical trial application). Hard tasks can only be performed by the users that have been assigned those tasks, and their status changes automatically as soon as they have been completed by the assignee user.

- **Soft Tasks:** Non-mandatory actions which "guide" the user, but do not have direct effects on the assessment result itself (e.g. document considerations for validation or circulate draft assessment report). If the user does not perform them, the system will not perform any automatic decision and it will not have an impact on the process. Soft tasks do not need to be assigned to a user. If they are assigned, they can be executed by other users than the assignee. Yet, once it has been performed, only the assignee can indicate that the task has been completed for the status of the task to be updated.

3.3. Do all tasks need to be assigned?

Hard tasks always need to be assigned to users who can perform them according to their roles to be performed. Soft tasks do not need to be assigned for users to perform them. In the latter case, any user with the appropriate role can proceed and perform them, even if the task has not been assigned or has been assigned to another user. However, if assigned to one user only that user can "complete" the soft task.

3.4. Who can assign tasks and how?

Users with the CT Coordinator role can assign tasks to other users. Moreover, users with submitter permissions can assign specific tasks to themselves, provided that their role corresponds to the process of the assessment or the decision of a clinical trial application. Users can assign or self-assign tasks using the relevant buttons displayed on the right-hand side of the overview results table on the tasks tab (e.g. 'Assign', 'Assign to me', 'Release').

3.5. What do users have to do when they are assigned a task?

If an authority user is assigned a task, he/she can click on the task and will be redirected to the area where this task can be performed in the system. Authority users will receive a notice as soon as the task is assigned to them by a CT Coordinator. There is no difference concerning the notice they received regardless of whether it is a hard or soft task.

3.6. What do users have to do when they complete/finish a task?

In the case of hard tasks, once the task has been performed by the user, the system will automatically deem the task as 'complete'. In the case of soft tasks, after the user has finished the task he/she needs to click on 'Complete' to finalise the task. When a task is completed the system will trigger a notice or an alert for those involved in that particular task and/or clinical trial application.

3.7. How can users quickly view the tasks they are interested in?

The Tasks tab includes sorting, filtering, and searching functionalities to identify specific tasks. By default, the tasks are displayed ordered by due date (from more urgent to less urgent).

- **Sorting options:** Users can sort the tasks displayed in the tasks tab according to status (e.g. pending or assigned), CT number, application type, due date, creation date, and the user the task is assigned to. All these sorting options can be ordered in a descendant (i.e. A-Z, 1-10) and an ascendant manner (i.e. Z-A, 10-1).

- **Filtering options:** Users can filter the tasks to be displayed in the tasks tab. The default filtering is 'My group', which shows all the tasks of the users of the Member State Concerned with the same profile. Other filtering options include 'My tasks', which display the tasks that the user has been assigned; 'My subtasks', which displays the subtasks that the user has been assigned; and 'Coordinator' (only visible for the CT Coordinator role) which displays the tasks to be yet assigned by the CT coordinator.

Search options: Users can search for specific tasks the 'Basic search' functionality and the 'Advanced search' functionality.

- The **Basic search functionality** on top of the Tasks page allows users to browse the tasks concerning a specific clinical trial either by introducing the EU CT number or the Annual Safety Reporting ID.

- The **Advanced search functionality** allows users to retrieve a particular task after populating one or several data fields such as the name of the task, the application type, due date, the sponsor who submitted it, the evaluation process, or the active substance, among others.

3.8. When a subtask is completed, is the CT Coordinator informed?

When a user completes a subtask, a notice is generated to inform the user who initially created it who could be the CT coordinator or any other user with the right permission to view and assign to him/herself the initial task.

3.9. Will there be an automated e-mail sent to the user when a task is assigned or an alert is received?

There are no e-mails sent to users to monitor the sequence of the events during the CT life cycle. Users are advised to monitor the system through the 'Tasks' or 'Notices & alerts' tabs that will keep them informed on the life cycle of the trials.

4. Request for Information

4.1. What is a Request for Information (RFI)?

An RFI is a question or additional information that a Member State can request to a sponsor during the evaluation of clinical trial applications they are reviewing. Requesting an RFI is an optional action by a Member State during the assessment of a clinical trial application. If the RFI is submitted as part of a clinical trial application, the sponsor must respond to it by the given deadline set by the MSC. Failure to do so will result in a lapse in the application.

4.2. What types of RFI there exist?

There is not a fixed list of categories or types of RFIs. However, the most common RFIs are those submitted during the validation and assessment of Parts I and II phases of clinical trial applications. Additionally, RFIs can be sent to sponsors in the context of an ASR assessment, an ad hoc assessment, or in the context of corrective measures after a clinical trial application has been authorised. The list of specific RFIs is outlined below:

Validation RFI

- RFIs containing questions for Part I, Part I IMPD-Q, but also any MSC Part II question raised by the Reporting Member State (RMS).

Assessment RFI

- RFI with questions to Part I and Part I IMPD-Q.

- RFI with questions to MSC Part II raised individually by the MSC.

Annual Safety Reporting

- RFIs with questions about ASR.

Ad hoc assessments

- RFIs with questions about the notification or event that is triggering the ad hoc assessments.

Corrective measures

- Authority users request the sponsor's opinion before applying a corrective measure.

4.3. How is an RFI requested by the authority user?

This will depend on the type of RFI. In general terms, an authority user leading the validation, Parts I and II, and ASR will gather the considerations from the rest of the users evaluating that phase, and the authority user leading the assessment will consolidate the considerations and chose to include those in the form of an RFI for sponsors to respond.

For ad hoc assessment and corrective measures RFIs, authority users in charge of the supervision of a clinical trial will describe the set of questions they have and submit the RFI for sponsors to respond in the dedicated sub-section in a clinical trial page (ad hoc assessment, corrective measures, etc.).

4.4. How is an RFI received by the sponsor user?

Sponsor users have two ways of monitoring the RFIs: Directly through the RFI tab, and also on the Notices & Alerts tab, where they receive messages about RFIs sent by a Member State. The notices that the sponsor users will receive will depend on the type of RFI and their role regarding the clinical trial for which the RFI is requested.

The RFI tab lists all the RFIs that are sent from the Member States to the sponsors during the assessment of a clinical trial application, as well as clarifications raised during the clinical trial as part of an ad hoc assessment or opinion request before applying a corrective measure.

4.5. How can users quickly view the RFIs they are interested in?

Within the RFI tab, there are sorting and searching capabilities to facilitate users' workload management:

- **Sorting options:** Users can sort the RFIs that will be displayed in the RFI list. The default filtering is 'No filtering', which displays all the RFIs of the sponsor concerned that they represent. Other filtering options include: the evaluation process, the application type, the MSC, the status (pending, responded, expired or cancelled, due date, response date, and submission date). All these sorting options can be ordered in a descendant (i.e. A-Z, 1-10) and an ascendant manner (i.e. Z-A, 10-1).

Searching options: Users can search for specific RFIs using Basic search and Advanced search capabilities.

- The **Basic search functionality** on top of the RFI tab page allows users to search the tasks concerning a specific clinical trial either by introducing the EU CT number, the RFI number, the Ad hoc assessment, or the corrective measure ID.

- The **Advanced search functionality** allows users to retrieve a particular task after populating one or several data fields such as the evaluation process (e.g. validation, assess part I, assess part II, assess ASR, decision); application type (e.g. initial, substantial modification, ASR); MSC; status (pending, responded, expired, cancelled); the range of due date, response date, and submission date.

Clinical Trials Information System (CTIS).

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