Quick guide

Overview of CTIS workspaces and common system functionalities

CTIS Training Programme – Module 2

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Learning Objectives

With this Quick guide you will:

- Understand what CTIS is and the two workspaces it is composed of
- Remember CTIS’ functionalities common to the main user groups

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Introduction

What is CTIS?

CTIS is the single entry point for submitting clinical trials information in the EU with the highest standards of safety for participants and increased transparency of clinical trial information. It supports the day-to-day business processes of authorities and sponsors throughout the life-cycle of a clinical trial through collaboration tools, workflow, and reporting and document management capabilities.

CTIS is structured in two restricted and secured workspaces, only accessible to registered users, and a website openly accessible to the general public:

- **The sponsor workspace**, accessible to commercial and non-commercial sponsors. It supports the preparation, compilation and submission of clinical trial data for its assessment by Member States.

- **The authority workspace**, accessible to national competent authorities, ethics committees, the European Commission, and the European Medicines Agency (EMA). It supports the activities of Member States and the European Commission in assessing and overseeing clinical trials.

- **The public website**, accessible to patients, healthcare professionals, scientists, clinical research associations, media, and members of the public. It supports the open access to clinical trials’ data in the European Union, in line with the transparency goal set out in Regulation (EU) No 536/2014 (Clinical Trials Regulation).
  - Access: [https://euclinicaltrials.eu/search-for-clinical-trials](https://euclinicaltrials.eu/search-for-clinical-trials)

- All the information mentioned above can be found on the Clinical trial page.
  - Additionally, this portal offers all public information related to clinical trials.
    - Access: [https://euclinicaltrials.eu/home](https://euclinicaltrials.eu/home)
Common functionalities

While each workspace has its specific functionalities that reflect the roles and responsibilities of the various actors involved in a clinical trial’s lifecycle, they also share a common set of functionalities.

Common system functionalities in both workspaces

<table>
<thead>
<tr>
<th>Clinical trials overview</th>
<th>Notices &amp; alerts</th>
</tr>
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<tbody>
<tr>
<td>Allows users to search, select and view a clinical trial, and to monitor the status and information of the clinical trials that are stored in the EU Clinical Trials’ Database.</td>
<td>Allows users to monitor the messages triggered by events that have occurred during the lifecycle of a clinical trial in which they are involved.</td>
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<tr>
<th>User administrator</th>
<th>Annual safety reporting</th>
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<tbody>
<tr>
<td>Allows users with administrator role to manage the roles and permissions of the registered users.</td>
<td>Allows sponsors to submit the annual reports on the safety status of their trials, and to have them assessed by Member States.</td>
</tr>
</tbody>
</table>

For simplicity purposes, this quick guide presents the common functionalities in both workspaces with screenshots taken mostly from the authority workspace. However, the same functionalities are found with a slightly different look and feel in the sponsor workspace.
In this tab users can retrieve information on clinical trials stored in the EU Clinical Trials Database. This is enabled through a search functionality that retrieves trial-relevant information for the user, such as the sponsor that submitted it, the Member State(s) concerned, the active substance, or the status of the trial (i.e. under evaluation, authorised, halted, withdrawn, etc.).

Users can look for trials using a basic search functionality with simple parameters or two advanced search functionalities, with a wider combination of parameters for a more targeted search:

- ‘Basic search’: Allows the user to look for a specific clinical trial by entering its EU CT number.
- ‘Advanced searches’:
  - ‘Trial Advanced search’: Allows the user to search for clinical trials that match a set of specified parameters.
  - ‘Application Advanced search’: Allows the user to retrieve clinical trials which contain application(s) that match the specified search parameters.

Once the search is run, the results are returned in a table and the clinical trial or application information details are accessible by clicking on the EU CT number. The details are visible on a summary page.

It should be noted that certain information relating to a clinical trial will not be displayed to users on the results page depending on the group they belong to. For instance:

- Sponsor users will not be able to see an ongoing assessment done by the Member State - they will only see the final outcome.
- Member State users will not be able to see draft clinical trial applications that are being completed by sponsors until they are submitted.
Users can **monitor the messages triggered by the system** following the occurrence of events during the lifecycle of the clinical trials they are monitoring (from the creation and submission to the reporting of results). In both workspaces, users will **only** receive messages for the clinical trials(s) **they are involved in**.

The first sub-tab on top of the page (‘New!’) allows users to quickly spot new messages received **since their last connection to the system**. The second sub-tab (‘All’) allows users to view all the messages they have received **since their role in a clinical trial started**.

The user can sort the messages by date, alphabetical older, type or title of the notice/alert, or EU CT number. The search functionality on top of the ‘Notices & Alerts’ page allows the user to browse the messages concerning a specific clinical trial either by introducing the EU CT number or the Annual Safety Reporting ID.

Moreover, the user can **search** for specific notices and/or alerts using the ‘Advanced Search’ functionality within this tab. This functionality allows the user to retrieve a particular notice/alert after populating one or several data fields such as the application type (e.g. initial, substantial modification, ASR, etc.), the date of reception, the sponsor, the responsible Member State(s), or the active substance.
The user administration functionality is common in both workspaces. However, it is only available to certain users who have an administration role. All other users who cannot assign roles are able to check the role(s) they have been assigned to by clicking on 'My roles' at the top-right of CTIS interface.

In the authority workspace, only users with an administrator role can operate this functionality. However, multiple administrators can be assigned for each authority. Administrator users can assign a role to a user, determine the scope of the role (for a specific clinical trial or for all clinical trials), and the duration of it.

It should be noted that administrators can assign multiple roles to a same user, amend the duration of their role, as well as revoke existing role(s) and permissions given to a specific user. Most role can be revoked except the high-level administrator roles. For more information, refer to Quick guide of Module 7.

Authority administrators can also delegate user management permissions to national organisation administrators (NOAs), which may be national competent authorities or ethics committees. NOAs will only be able to assign roles and permissions within their own organisation.
In the sponsor workspace, users can request a role for a specific clinical trial, or for all clinical trials from the organisation they belong to or act on behalf of. This can be done by clicking on 'My roles' at the top-right of CTIS interface. This is a key difference compared to the authority workspace.

Similarly to the authority workspace, in the sponsor workspace multiple administrator roles can be assigned within the same organisation. In the sponsor workspace, administrators can perform all the actions from the 'User administration' tab of the sponsor workspace. Incoming requests can be approved or rejected, and new roles can be assigned or revoked. **More than one role can be added at the same time**, either to the same user or to different users. This allows the sponsor administrator to establish the roles of the whole process of a clinical trial.

The sponsor administrator can also search for specific users within their organisation using the 'Basic search' functionality or the 'Advanced search' functionality in order to view their roles. Search parameters include the status of the request, organisation ID, or date of creation. This option is also available in the authority workspace.

When a user requests a role, the administrator will not receive any notification or alert. The request will appear in the User administration tab.
Overview of CTIS workspaces and common system functionalities

**Annual safety reporting**

In the 'Annual safety reporting' tab users of the sponsor workspace with the role of 'ASR submitter' are able to complete and submit new Annual Safety Reports (ASRs). Sponsor users can only view ASRs for the clinical trials they have a role in.

In the authority workspace, users with the roles of 'ASR assessor' and 'ASR decision maker-submitter' can assess and submit a decision regarding ASRs, respectively. Users can view ASRs for the clinical trials they have a role in.

Users can search ASRs by entering the EU CT number or ASR ID (only the number of the code without the 'ASR' or the 'CT' at the beginning, or use the 'Advanced search' with specific parameters. Once the specific ASR is retrieved, authority users can select it and view the ASR submission and the assessment data on CTIS or download the ASR submission and assessment documents.

CTIS does not include a save button for ASR. All the fields need to be populated in one go for submitting the ASR.
Clinical Trials Information System (CTIS).
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