



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

Overview of CTIS workspaces and common system functionalities

CTIS Training Programme – Module 2

Version 1.1 – November 2020

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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This training material describes and reflects preliminary versions of CTIS and will be revised in 2021 to match the Go-Live version and thereafter to match subsequent releases post Go-Live.

Therefore, this material is at this time to be considered DRAFT and is not to be further reproduced or distributed.

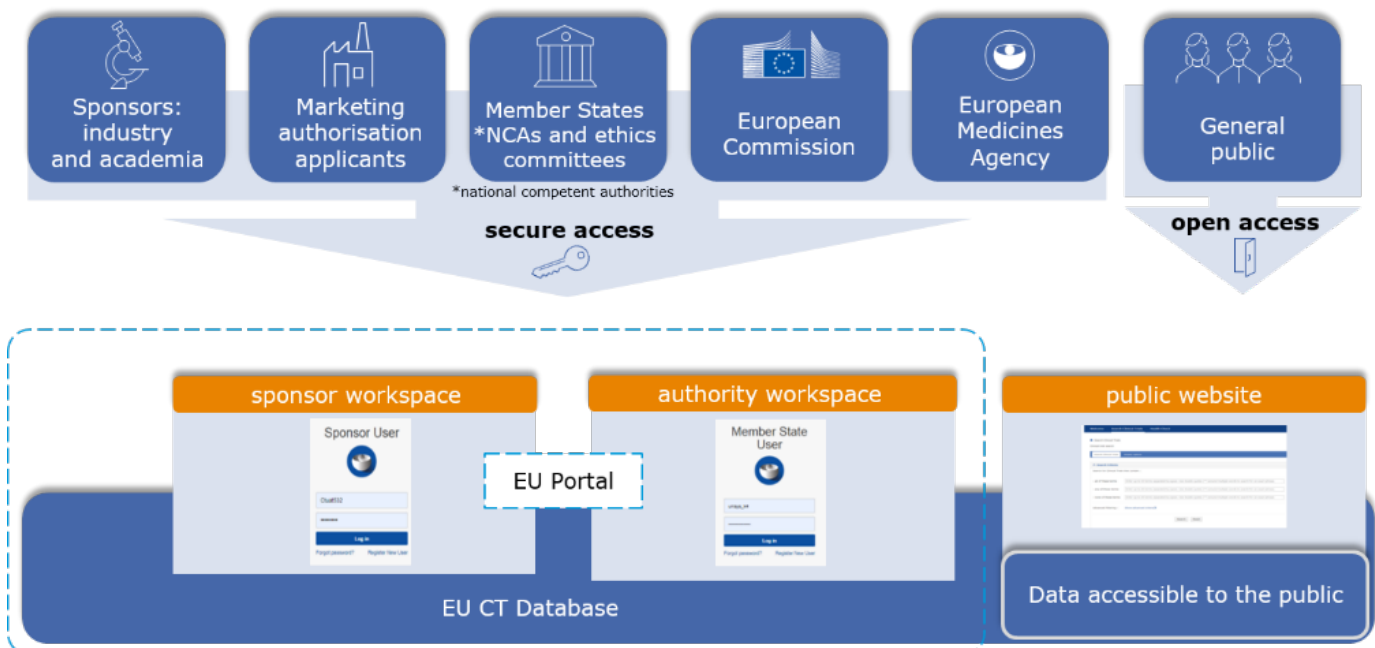
| Introduction

What is CTIS?

CTIS will become 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 will support 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).



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



Clinical trials overview

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.



Notices & alerts

Allows users to monitor the messages triggered by events that have occurred during the lifecycle of a clinical trial in which they are involved.



User administrator

Allows users with administrator role to manage the roles and permissions of the registered users that belong to their organisation or Member State.



Annual safety reporting

Allows sponsors to submit the annual reports on the safety status of their trials, and to have them assessed by Member States.

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.

Clinical trials overview



The 'Clinical trials' tab is the first tab on CTIS landing page. It allows users to see the clinical trials stored in the system.



The advanced searches allow users to narrow down the search using a variety of parameters, such as: the overall trial status, the Member State(s) concerned, the therapeutic area, or the active substance. Some parameters are available in both advanced searches, while others are specific.

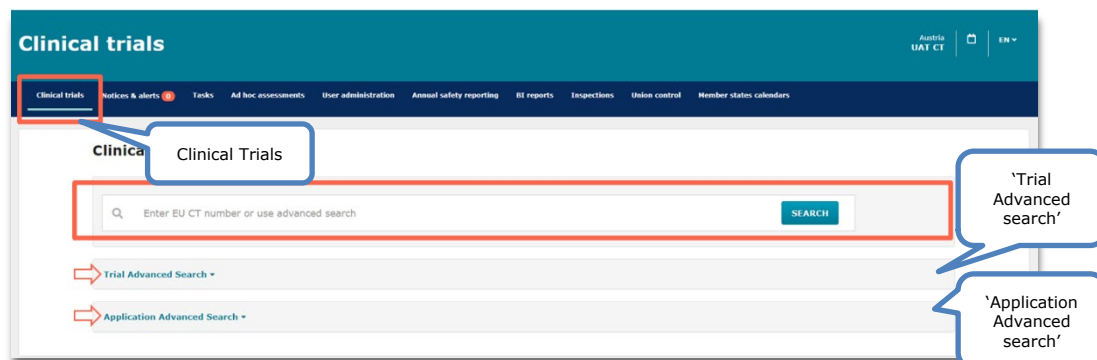
In this tab users can retrieve information on clinical trials stored in the EU Clinical Trials Database. This is enabled through a search functionality that retrieves trial-relevant information for the user, such as the sponsor that submitted it, the Member State(s) concerned, the active substance, or the status of the trial (i.e. under evaluation, authorised, halted, withdrawn, etc.).

Clinical trials

Clinical trials Notices & alerts 0 Tasks Ad hoc assessments User administration Annual safety reporting

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.

Notices & alerts



The 'Notices & Alerts' tab displays:

Notices: messages aiming to inform the user of an event related to a clinical trial.

Alerts: messages informing the user of an action to be performed.

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.

The screenshot shows the 'Clinical trials' workspace with the 'Notices & alerts' tab selected. The interface includes a search bar, a 'New!' sub-tab, an 'All' sub-tab, and an 'Advanced Search' button. A table of notices is displayed below.

Ref number	Evaluation process	Received	IRP	RMS	Sponsor
2020-000489-20-01	Received	02/04/2020	IRP	RMS	Sponsor
2020-000489-20-01	Received	02/04/2020	IRP	RMS	Sponsor
2020-000489-20-01	Received	02/04/2020	IRP	RMS	Sponsor
2020-000489-20-01	Received	02/04/2020	IRP	RMS	Sponsor



Every time a user accesses the system, any new messages since the last connection to the system appear on the 'New!' sub-tab. In the next login, these will have been automatically moved to the 'All' sub-tab (even if the user did not click on them to read them).

User administration

Authority workspace

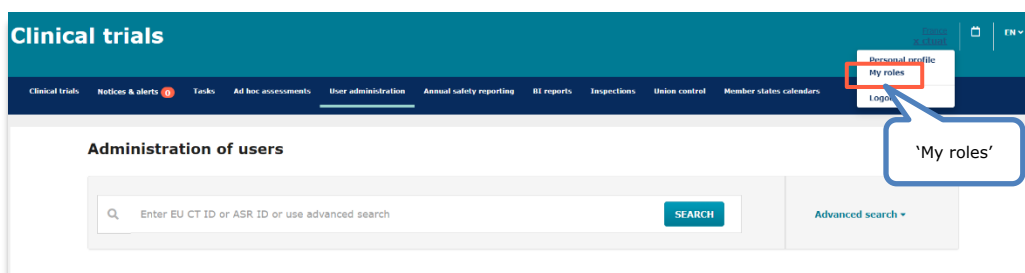


The 'User Administration' tab allows users with an administrator role to assign roles and permissions to users registered in the system who belong to their organisation or Member State.



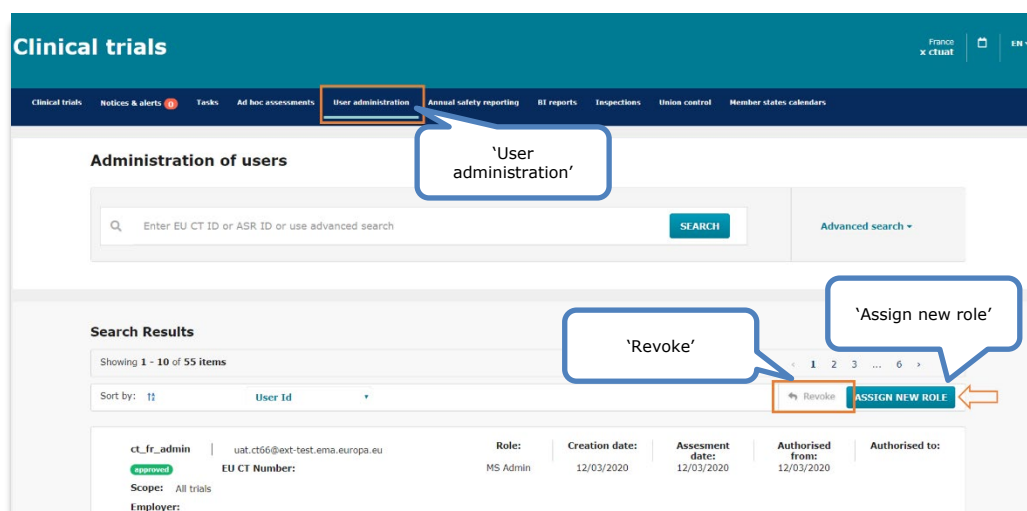
'Amend' only allows to change the authorised dates. To revoke the role of a user click on the tick box on the left side of the user and press 'revoke on top of the search result.

While this functionality is common in both workspaces, it is **only available to certain users who have an administration role** that enables them to manage users within their respective organisations or Member States. 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. Any role can be revoked except for the administrator roles, which are managed externally.



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.

User administration

Sponsor workspace

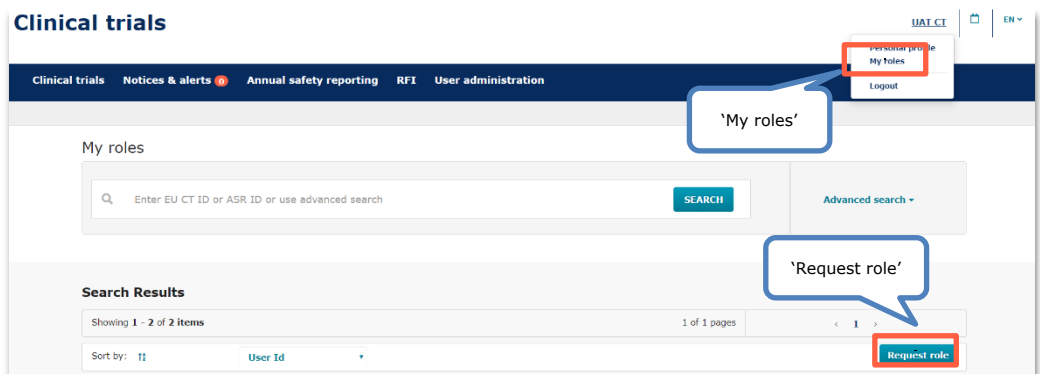


The 'User Administration' tab allows users with an administrator role to assign roles and permissions to users registered in the system.



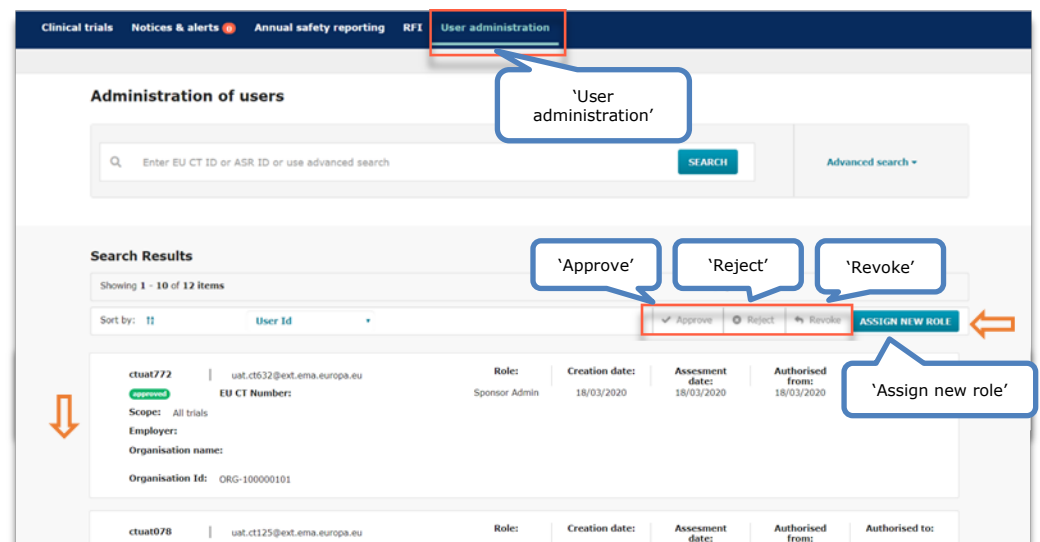
When a user requests a role, the sponsor administrator will not receive any notification or alert. The request will appear in the User administration tab.

In the sponsor workspace, users without administrator roles 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. The sponsor administrator 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.

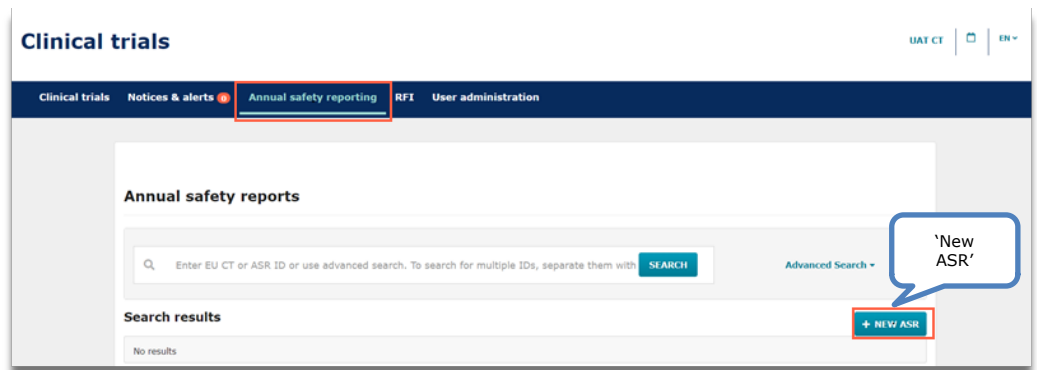


Annual safety reporting

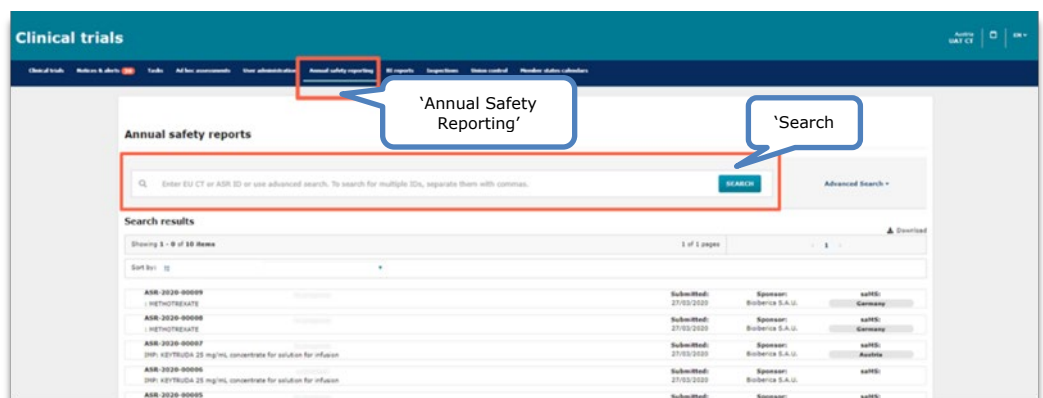


The 'Annual Safety Reporting' tab allows sponsors to submit the annual reports on the safety status of investigational medicinal product used in a trial, and Member States to assess the content of the ASR and adequately monitor the safety profile of the investigational drug.

In the 'Annual safety reporting' (ASR) 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.



CTIS does not include a save button for ASR. All the fields need to be populated in one go for submitting the ASR.

Users can **search** ASRs by entering the EU CT number or ASR ID, 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.

