



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Quick guide

## User Access Management

CTIS Training Programme – Module 03

Version 1.3 – April 2022

### Learning Objectives

- Remember how to log into CTIS and access the landing page.
- Understand the basic roles and permissions in CTIS.
- Understand how the user profile management functionality works.
- Understand how to search for an organisation and submit a request to create one in CTIS.

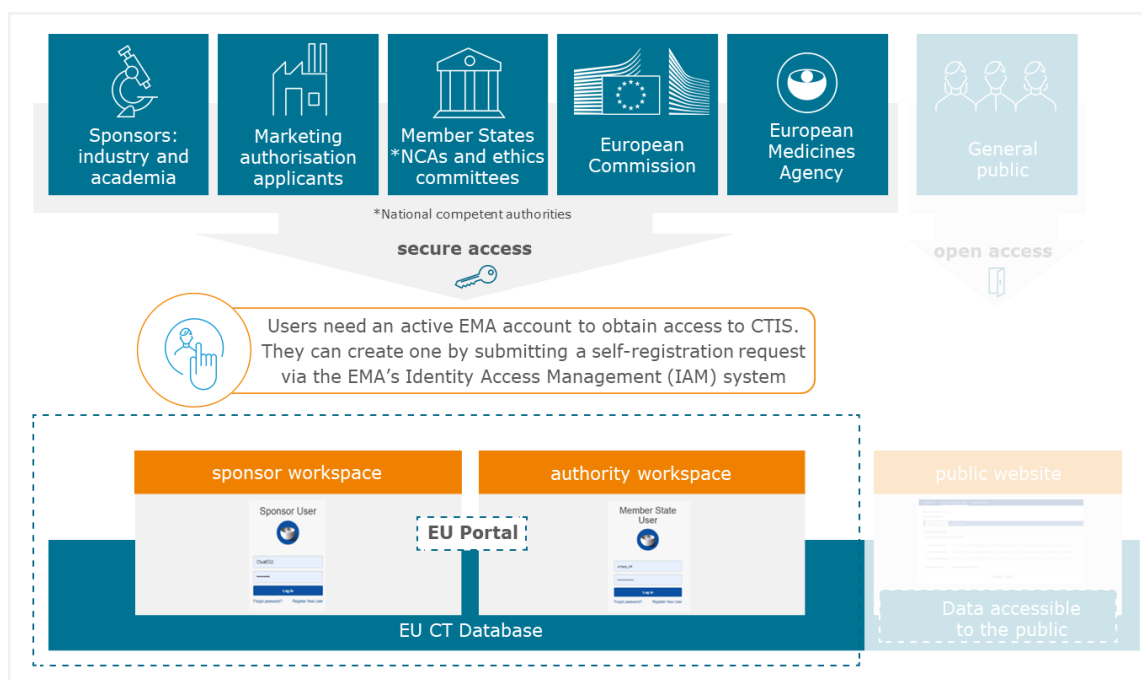
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# Introduction

CTIS is structured in two restricted and secured workspaces, **only accessible to registered users**, and a website openly accessible to the general public.<sup>1</sup>



To access CTIS restricted workspace, users need to have EMA Accounts. Users of other EMA applications (e.g. IRIS, EudraVigilance, SPOR) that have already created EMA accounts can use their credentials to access CTIS restricted workspaces. If an account is inactive for 6 months, it will be automatically deleted. If users need to recover their username or password, they can refer to the ['Recover your credentials and re-activate your account'](#) guide on the EMA Account Management website.

If users do not have EMA Accounts, they can refer to the ['How to create a new EMA account'](#) guide.

This quick guide outlines the steps that a user needs to follow in order to know:

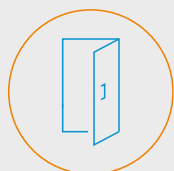
- How to log into the system and access the landing page.
- How to access and manage the user profile.
- The basic roles and permissions available in CTIS.<sup>2</sup>
- How to search for an organisation and submit a request to create organisations via CTIS.

<sup>1</sup> The website is not covered in this module. This module focuses on the user access management functionalities in the two restricted workspaces in CTIS.

<sup>2</sup> A dedicated module on the roles and permissions is foreseen as part of the CTIS Training Programme.

## Sections of this quick guide

This quick guide is structured in four sections:



### Log-in and landing page

This section outlines the steps that users need to follow to log into and logout from CTIS, in addition to provide an introduction to CTIS landing page.



### User profile

This section presents how users can access and manage their profile and view their roles.



### Roles and permissions

This section introduces the types of roles and permissions that users can be assigned in CTIS.

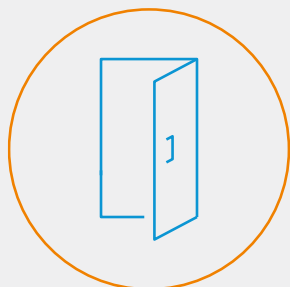


### Organisations

This section presents how users can search for an organisation and submit a request to create organisations via CTIS.

For simplicity purposes, this quick guide presents the user access management processes of both workspaces with screenshots taken mostly from the authority workspace. However, the same processes apply in the sponsor workspace with a slightly different look and feel.

## Log-in and landing page



The active tab by default in CTIS landing page allows users to search for CTs.

Users will be able to access also other tabs from the navigation pane on top of the page.



Users will see different tabs on the navigation pane depending on their roles and permissions.

### Log-in and landing page

In order to log into CTIS, users can access it through two workspaces:

- **Authority:** <https://euclinicaltrials.eu/ct-authority-services/login>
- **Sponsor:** <https://euclinicaltrials.eu/ct-sponsor-services/login>

Once they are in the corresponding workspace, they can enter the username provided in the **Self-service Registration Confirmation Form** by the EMA's Account Management Portal, and the password that they indicated in the **Self-service Registration Form**. After populating the username and password fields, users will click on '**Log in**'.

After clicking on the 'Log in' button, users will gain access to CTIS landing page, which will display the '**Clinical Trials**' tab by default. Depending on whether the user has accessed the sponsor or the authority workspace, different tabs will be displayed next to this one, as shown below:

All registered users via EMA's Account Management Portal receive a default role in CTIS that enables them to access the landing page. However, as a general rule, to navigate the system or access clinical trials data/documents, roles and permissions must be given to registered users by administrator users (see next section on *Roles and Permissions*).

At the bottom of the landing page, users can access relevant information such as the 'Help' page for resolving issues with CTIS; a 'Sitemap' containing the list of pages of their workspace in CTIS; a 'Contact' button to access relevant contact details; and a direct link to 'EMA's public website'.

[Help](#) · [Sitemap](#) · [Contact](#) · [EMA public website](#)

# User profile



This functionality allows users to **manage their profile information**, have visibility on their **roles and log out** from the system. It is accessible at all times on top of CTIS.

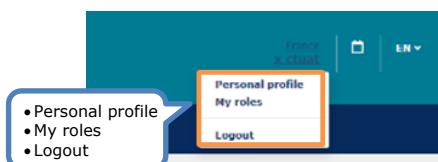
In the sponsors workspace, users can request a specific role from the 'My roles' sub-tab.

## #CTIS insights

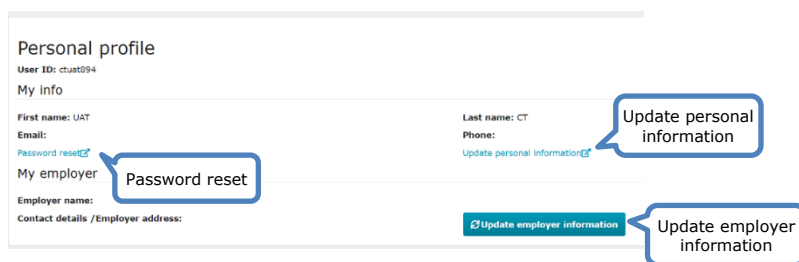
When clicking on the 'Password reset' link, the user will be redirected to the EMA Account Management Portal. The password must be at least 8 characters long and contain 4 different character types (e.g. P4\$\$w0rd, Americ@54, M3d!cines).

## User profile

CTIS allows users to manage their user profile information by **clicking their username button** at the top right corner of the CTIS interface. Users can manage their user profile information from the '**Personal profile**' sub-tab and have visibility of the roles assigned to them from the '**My roles**' sub-tab (and pro-actively request a role only in the case of sponsor users). Users can also log out from the system using the '**Logout**' sub-tab that drops down after clicking on the username button.

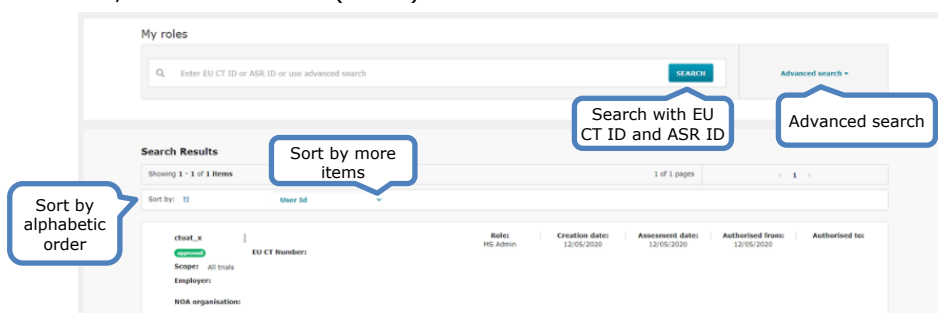


The '**Personal profile**' sub-tab allows users to access a page where they can find their personal information (first and last name, email address, and phone number), as well as information regarding their employer organisation (name and contact details).



In the '**Personal profile**' sub-tab, users can perform multiple actions concerning their profile information, such as resetting their password, updating their personal information (e.g. first name, last name, email, and phone), and also updating their employer's information (e.g. employer's name, contact details, or address), by using data from the Organisation Management Service (OMS).

The '**My roles**' sub-tab enables users to view the role(s) they have been assigned by a user with administrator permissions in order to perform specific actions in the system. Roles can be sorted by alphabetical order, user ID, email, employer, organisation name, organisation ID, role type, scope, EU CT number, creation date, assessment date, status, authorised from, or authorised to (dates).



## Roles and permissions



CTIS enables **administrator users to assign and revoke roles** with attached permissions to registered users to be able to perform different actions in the system.

### Roles and permissions

CTIS is a **role-based system** that enables users to perform different actions depending on the **permissions** attached to the **roles** assigned to them by a user from their organisation or Member State with administrator permissions. There are multiple **roles** in CTIS, which allow users to execute different actions in the system, in accordance with their respective responsibilities regarding a clinical trial.<sup>3</sup>

#### Permissions

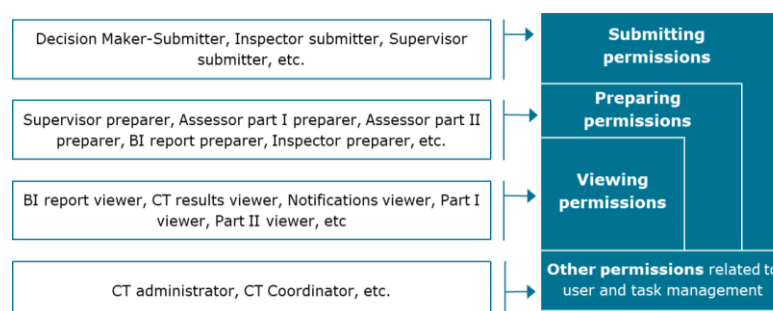
Predefined **levels of actions** that users can perform on data and documents stored in CTIS. These include:

- a) Business permissions** (e.g. Member States creating considerations, sponsors creating responses to RFIs).
- b) Access level permissions**, which are described as follows:
  - **View permissions**, which allow users to view and download structured data and documents in different formats.
  - **Prepare permissions** which, in addition to the viewing permissions, allow users to create, edit, save, upload, delete or cancel draft items. These permissions also enable users to copy data from an existing CTA to create a new one.
  - **Submit permissions** which, in addition to the former permissions, allow users to share, submit and withdraw data/documents from their respective workspace to the EU CT database, and to update submitted data/documents.
- c) Other permissions** related to user management and task management.

#### Roles

Predefined **group of actions** that users can perform in CTIS regarding a clinical trial application, or regarding data and documents submitted during the trial life cycle, in accordance with their responsibilities. **Two types of roles** can be distinguished:

- **Administrator roles**, which are able to assign roles to other users from their organisation or Member State, e.g. sponsor administrator, Member State administrator, National Organisation administrator, or CT administrator.
- **Business roles**, reflect the responsibilities of users during the life-cycle of a clinical trial. They are assigned by administrator users and are attached to the permissions described above.



## #CTIS insights

The permission levels are structured in a cascade system where the lowest level is viewing permissions, and the highest level is submitting permissions.

<sup>3</sup> Further details on the roles and permissions can be found in Module 7.

## Organisations



The higher number of the characters that is used in the search form, the more the scope is narrowed down, allowing users more accurate searches for organisations.



By using the 'City' and the 'Country' fields, users can refine even further your organisation search.

### Organisations

On various occasions (e.g. CTA creation, notifications submission, inspection records, employer information, etc.), CTIS users need to populate organisation details including information related to sponsors, CROs, third parties, clinical investigator sites captured in Part II of the CTA, inspected sites, etc. **This information is retrieved from the Organisation Management Service (OMS)**, using dedicated search functionalities.

To retrieve organisations from OMS, users need to populate either a minimum of three characters on the 'Name' field or at least one character on the 'Organisation-ID' field, to activate the 'Search organisation' button.

Search organisation

Name  starts with  ID  starts with  City  starts with  Country

ID	Name	Address	City	postCode	country	phone	email
<input type="radio"/> ORG-	Test Organisation	Olympians		:	Greece	02000000000	info@test
<input type="radio"/> ORG-	Test Organisation Spain	Santiago			Spain	0200110000	info@testspain.com

1 - 2 of 2

After performing the organisation search, users can select one of the organisations listed in the results, using the respective radio button on the left side of the results. If the organisation is not listed, users can submit a change request to create a new organisation in OMS. **This request can be submitted either via CTIS or via OMS** (for more information, refer to the [Quick Guide OMS](#)).

### CTIS

After an organisation search is performed, a '+ New organisation' button is activated on the organisation search functionality (see image above). By clicking on it, users can create and submit a change request to the OMS team to create a new organisation. A pop-up form opens and users need to fill in all the required fields and add the necessary supporting documentation before clicking on the 'Submit' button.

# Organisations



Users need to fill in the mandatory fields, indicated by an asterisk and use the document placeholder in the end of the form to attach the required documentation.

**Registration Request** X

---

**Requestor details**

Contact email \*  Contact phone \*

Comment

---

**Organisation details**

Organisation name\*

Acronym  Organisation type

---

**Organisation address**

Address line 1 \*  Address line 2

Address line 3  Address line 4

City  Post code

Country \*  Email\*

Location phone Intl.  Phone number \*  Ext.

DUNS ID  GS1 ID

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**Attachments**

[Add document](#)

---

[Cancel](#) [Submit](#)

Users may consult the [OMS portal](#) documentation (under 'Documents' sub-tab), and more specifically, document 'E - OMS Change Requests' to make sure that all fields and required documentation are populated correctly in the organisation registration form.



Populating invalid data or documentation on the form might result in rejection of the user request.

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**SPOR - Organisations Management System**

Substances	Products	Organisations	Referentials						
<p>SPOR Home   Organisations   <b>Documents</b></p> <p>Home / View Documents</p> <p>General   <b>Technical</b></p> <table border="1"> <thead> <tr> <th>Document Name ▲</th> <th>Document Description ↓</th> </tr> </thead> <tbody> <tr> <td>D - OMS Controlled Vocabularies</td> <td>Guidance - Controlled vocabularies used in OMS</td> </tr> <tr style="border: 2px solid orange;"> <td><b>E - OMS Change Requests</b></td> <td>Guidance - Rules and Supporting documentation required by change request type</td> </tr> </tbody> </table>				Document Name ▲	Document Description ↓	D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS	<b>E - OMS Change Requests</b>	Guidance - Rules and Supporting documentation required by change request type
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D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS								
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## Organisations



A 'ORQ' ID cannot be retrieved by the organisation search functionality. Once the request is approved by OMS, the new organisation can be retrieved by using either keywords of the organisation name, or even the resulting organisation ID (in the ID field).

Once users have submitted the request, **the validation process can take up to 10 days**. The ID provided by the system at this point is not the final Organisation ID. Any ID starting with ORQ refers to the change request ID. This change request ID can be used this time to allow users to submit the data they have prepared (CTA submission, notification submission, inspection record submission, etc.). But they cannot use it again in subsequent organisation searches.

Once the change request is validated and processed by the OMS team, the user will receive an email acknowledgement with the outcome:

- **Approved change request:** acknowledgement that will contain the outcome and the corresponding Organisation-ID.
- **Rejected change request:** acknowledgement that will contain the outcome, reason for rejection and, when applicable, guidance on necessary steps for a successfully approved change request.

### OMS

For more information on how to submit a change request in OMS, please refer to the [Quick Guide OMS](#) of [Module 03](#), to the documentation found on the 'Documents' sub-tab (see snapshot below) on the [OMS portal](#), or in [CTIS Handbook](#).

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**SPOR - Organisations Management System**

Substances	Products	Organisations	Referentials
SPOR Home	Organisations	<b>Documents</b>	

Home / View Documents

General Technical

Document Name ▲	Document Description ↓
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.
A1 - OMS Introduction - Webinar 21 October 2021	Webinar - OMS Key principles, services and activities - 21 October 2021

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Clinical Trials Information System (CTIS).

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