



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

User Access Management

CTIS Training Programme – Module 3

Version 1.1 – November 2020

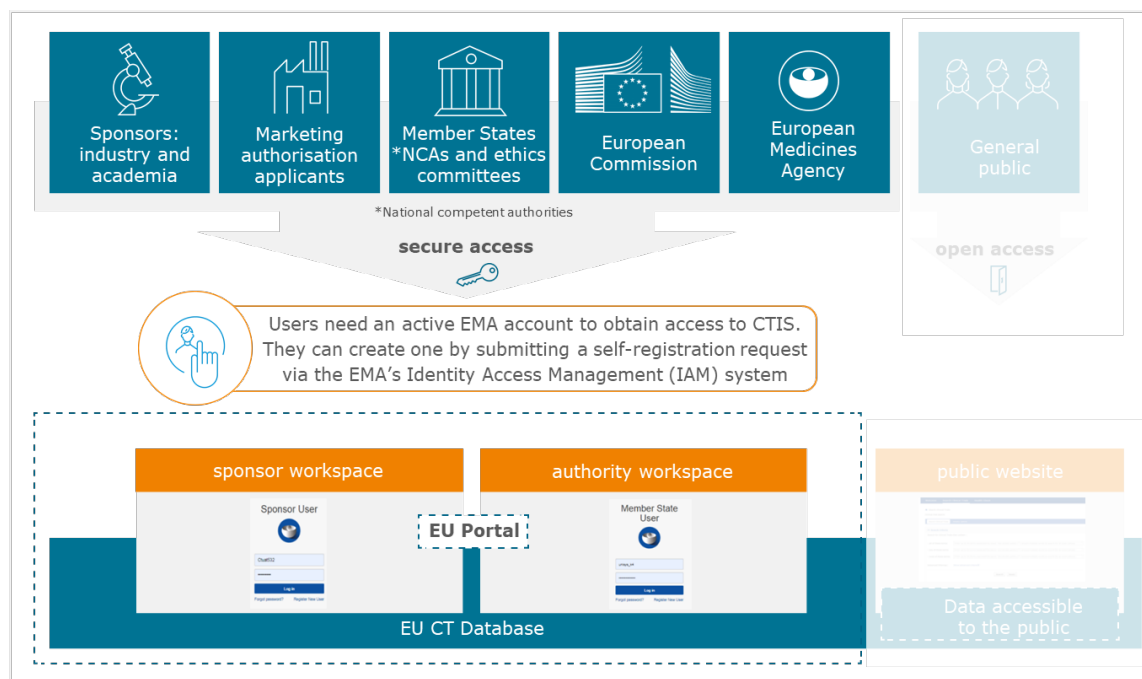
Learning Objectives

- Understand the process of self-registration in CTIS through EMA's Account Management Portal
- 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

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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

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



In order to access CTIS restricted workspaces, users will need to:

- Register in EMA's Account Management system.²
- Obtain user credentials via EMA Account Management Portal to be able to access CTIS.

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

- How to obtain user credentials to access CTIS
- 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.³

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

² The EMA Account Management system supports Identity and Access Management (IAM) for all EMA systems and applications, including CTIS.

³ A dedicated module on the roles and permissions is foreseen as part of the CTIS Training Programme.

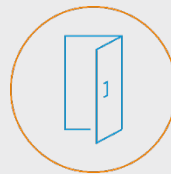
Sections of this quick guide

This quick guide is structured in four sections:



Self-registration

This section outlines the steps that users need to follow to register in EMA's Account Management Portal, in order to obtain user credentials to access CTIS.



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 providing an introduction to CTIS landing page.



Roles and permissions

This section provides an introduction to the types of roles and permissions that users can be assigned in CTIS.



User profile

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

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.

Self-registration



The self-registration of users in CTIS is performed via EMA's Account Management Portal, where users will need to fill in a **self-registration request**. They will receive an automatic confirmation to the email address provided.

#CTIS insights

EMA's Account Management system records user personal data (i.e. first name, last name, email address and phone), and provides user credentials to access CTIS.



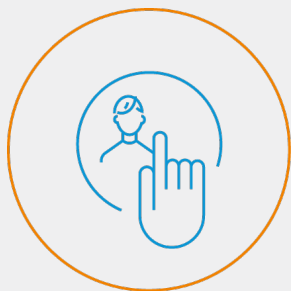
When accessing CTIS for the first time, users will need to select the link to their relevant workspace on CTIS welcome page. Each workspace has its own login window as displayed below. Users will need to click on '**Register New User**'.

Users will be re-directed to a **Self-service Registration Form** in EMA's Account Management Portal. Users will be asked to fill out the following mandatory fields: **First Name**, **Last Name**, **Email**, **Password** and **Confirm Password**. The fields **Country Code** and **Mobile** are optional.

After completing the Self-service Registration Form, the **EMA privacy statement** will be displayed.⁴ After reading it, users will click on the informed consent box at the end of the page and select '**I agree**'.

⁴ This privacy statement contains information regarding the personal data collected for the Identity and Access Management (IAM) process, the purposes of the data processing, the maximum data retention period, and the data subjects' rights.

Self-registration



Upon agreement to the EMA privacy statement, users will be asked to answer a set of **Security Questions** for password recovery purposes in case they forget it. Users will be asked to choose three different pre-defined questions and provide answers to each of them. After that, users will click on the **'Next'** button.

EMA - Self Registration Security Questions

Security Question 1
What is your mother's maiden name?

Answer 1 *

Security Question 2
What is your favorite color?

Answer 2 *

Security Question 3
What is the name of the first street you lived on?

Answer 3 *

Captcha Question *
What is the value of 38 + 31

Captcha Answer *

Cancel

EMA - Self Registration Security Questions

'Next' button

The final step of the self-registration process consists in entering the **one-time token** in the **Self-service Registration Confirmation Form**. Users will receive this one-time token in the email account indicated in the Registration Form, which they will need to enter in the field highlighted below and click on the 'Confirm' button.

EMA - Self-service Registration Confirmation Form

Your EMA Account
Your EMA username is given below. Please make a note of this as you will need it to log in.

Username
Ipsum_1

Your Details
First Name
Lorem
Last Name
Ipsum
Email
CTIStraining@test.com
Mobile (optional)

One-time Token
Please enter the value of the one-time token you have received by email in the field below.

Confirm one-time Token

Confirm Token *

Cancel

EMA - Self-service Registration Confirmation Form

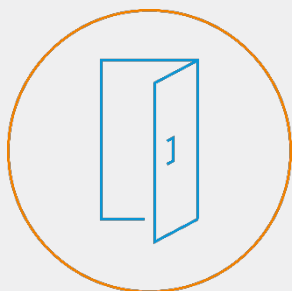
'Confirm' button



The one-time token is valid for 24 hours. Users are advised to check the spam folder if they do not receive the one-time token.

After confirming the one-time token, users will see the username automatically generated by the EMA's Account Management Portal, along with their personal information. This username will be requested, together with the chosen password, in order to log into CTIS, so users are advised to make a note of it. Once the self-registration request is submitted, an automatic confirmation email will be sent to the email address provided by users to confirm the account registration.

Log-in and landing page

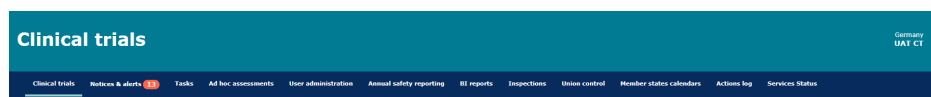


The active tab by default in CTIS landing page allows users to search for CTs.

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

In order to log into CTIS, users will have to 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:



Clinical trials tab

Landing page of the authority workspace

Clinical trials

UAT CT



Clinical trials tab

Landing page of the sponsor workspace

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*). Users can also access their user profile (see section *User profile* of this quick guide), and change the preferred language of the CTIS interface from the top-right corner of the landing page.



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



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

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.

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.⁵

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.

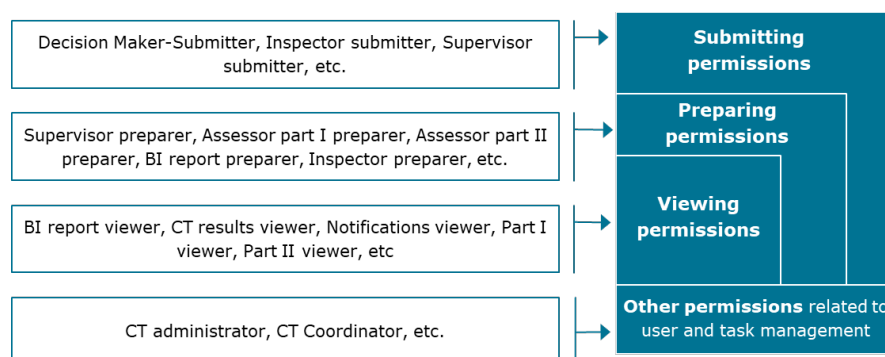
Roles: Predefined **group of actions** that users are able to perform in CTIS regarding a clinical trial application, or regarding data and documents submitted during the trial life cycle, in accordance with their responsibilities.

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**, reflecting 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.



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



Matching of roles and permissions in CTIS

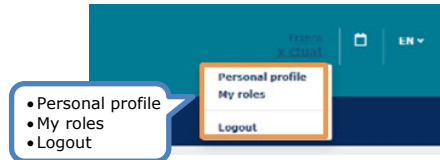
⁵ Further details on the roles and permissions will be presented in a future module.

User profile

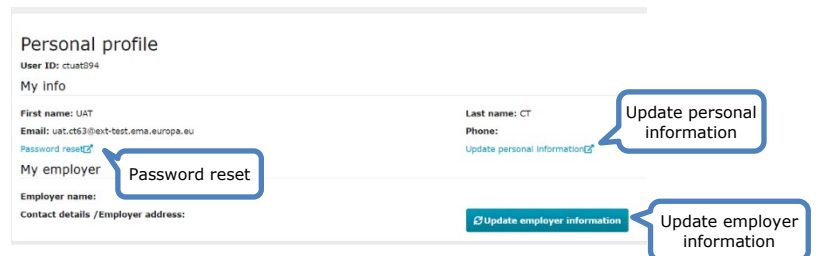


This functionality allows users to **manage** their **profile information**, have visibility on their **roles** and **log out** from the system. It is accessible at all times on top of CTIS.

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 the 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).



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

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).

