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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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

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 do not have EMA Accounts, it is necessary to:

- Register in EMA’s Account Management system.
- Obtain user credentials via EMA Account Management Portal to be able to access CTIS secure domains.

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.²
- How to search for an organisation and submit request to create organisations via CTIS.

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 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 five 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.

- **Organisations**
  This section presents how users can search for an organisation and submit 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.
Self-registration

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. If users do not have an EMA account, they 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. After reading it, users will click on the informed consent box at the end of the page and select ‘I agree’.

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.
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.

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.

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

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

- **Authority**: [https://euclinicaltrials.eu/ct-authority-services/login](https://euclinicaltrials.eu/ct-authority-services/login)
- **Sponsor**: [https://euclinicaltrials.eu/ct-sponsor-services/login](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’.

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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.

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#CTIS insights

Users will see different tabs on the navigation pane depending on their roles and permissions.
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.4

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.

Further details on the roles and permissions can be found in Module 7.

4 Further details on the roles and permissions can be found in Module 7.
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 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), 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).

#CTIS insights

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

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.

#CTIS insights

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

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 organisation registration form.

Populating invalid data or documentation on the form might result in rejection of the user request.
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 OMS team, the user will receive an email acknowledgement with the outcome:

- **Approved Change request**: acknowledgement that will contain the outcome and the correspondent 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.
Clinical Trials Information System (CTIS).

Quick guide: How to search, view and download a CT and a CTA (Authority).