



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

User administration

CTIS Training Programme – Module 19
Version 1.0 – February 2022

Learning Objectives

- Understand the user administration's approach.
- Understand the assignment and request of roles in CTIS.

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User administration

After registering and accessing CTIS for the first time, users will receive a **default role** that will enable them to perform a limited number of activities, listed below:

- **View roles:** Users can view their own user profile and roles in CTIS, as well as their scope and status. Additionally, sponsor users can request a role to the admin user in their organisation.
- **Update personal profile:** All users can view, create and update their personal and employer information.
- **Create a Clinical Trial Application (CTA):** Sponsor users are able to create a CTA if the selected sponsor organisation does not have a sponsor administrator user.

If a user creates a new CTA for a sponsor organisation that does not have a registered sponsor administrator, that user will become the **CT admin** of that specific trial. However, if the sponsor organisation has a high-level administrator (sponsor administrator), then the user will need to be assigned first specific roles to be able to create a new CTA for this organisation. These two ways to create a CTA correspond to the two approaches of user administration available in CTIS: **CT-centric and Organisation-centric approaches**, respectively. This document provides details on the CT-centric administration approach. [For more information regarding the High-level Administrator registration, refer to the Step-by-Step guide \(High level CTIS administration\) of Module 07.](#)

This Step-by-step guide includes:



CT-Centric administration approach

This section outlines the steps that sponsor users should follow in order to adopt the CT-Centric approach for User administration.



Assign or request roles in CTIS

This section outlines the steps to assign and to request business roles in CTIS.

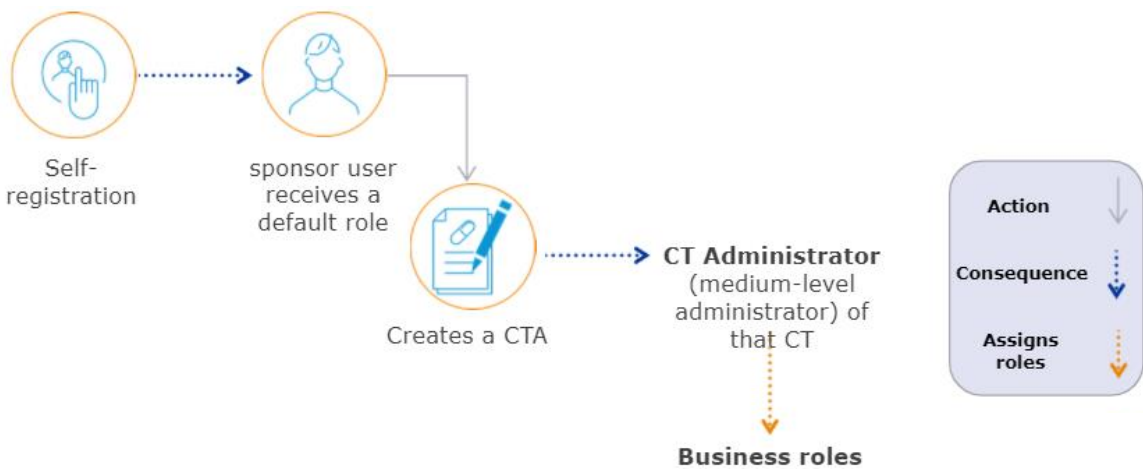
CT-Centric administration approach

CT-Centric Approach

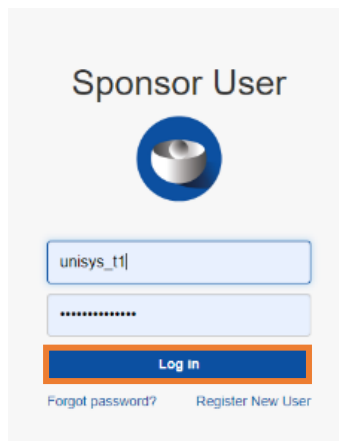
Before starting with the steps to be performed in the system, please note the following characteristics of the CT-Centric approach:

- No sponsor Admin validated by EMA is required.
- Users directly become the CT Admin of a CT by creating a CTA for an organisation without sponsor admin.
- Management of business roles to other users by the CT Admin is done at **trial level**.
- Intended to serve the needs of small organisations, and especially non-commercial sponsors, as it allows to manage a smaller number of users, CTAs and/or CTs.

In the graph below, the process that users need to follow in order to implement the CT-centric approach is defined:



1. Users can populate the credentials and then they can click on the **'Log in'** button.



CT-Centric administration approach

CT-Centric Approach

- Users can access the landing page and click on the '**Clinical trials**' tab.

Clinical trials

UAT CT

Clinical trials Notices & alerts RFI

- Then they can click on the '+ **New trial**' button.

Clinical Trials

Trial Advanced Search ▾

Application Advanced Search ▾

- Once they have the form, they can populate the **information of the new trial** (title, Organisation) and then they can click on the button '**Create**'.

Create new trial ×

Full title (English)*

Search organisation

Name ID City Country

ID	Name	Address	City	postCode	country	phone	email	actions
<div style="text-align: right;"> <input type="button" value="Cancel"/> <input type="button" value="Create"/> </div>								

Assign or request roles in CTIS

How to assign business role to users within the organisation

1. After the Administrator role (High-level or Medium level) is assigned, users can log in to CTIS and click on the '**User administration**' tab.

Clinical trials

UAT CT | 📅 | EN ▾



2. Then they can click on the '**Assign new role**' button.

Administration of users

The screenshot shows a search bar with the placeholder text 'Enter EU CT ID or ASR ID or use advanced search'. To the right of the search bar is a blue 'SEARCH' button and a link for 'Advanced search'.

Search Results

The screenshot shows a table with one row of search results. The table has columns for 'Showing 1 - 1 of 1 items', '1 of 1 pages', and a pagination control showing '< 1 >'. Below the table, there are several action buttons: 'Sort by: 1?', 'Creation Dat' (with a dropdown arrow), 'Approve', 'Reject', 'Revoke', and 'ASSIGN NEW ROLE' (highlighted with an orange box).

3. Once they have accessed the form, Administrators can populate the details of the user and the role and click on the '**Assign**' button.

The screenshot shows a form titled 'Assign role(s)' with a close button (X) in the top right corner. The form contains several input fields:

- User Id:** A text input field with the placeholder 'Type User Id'.
- EU CT number:** A text input field with a dashed line placeholder.
- Organisation name:** A dropdown menu with 'Test organisation' selected.
- Organisation Id:** A text input field with the value 'ORG-100013346'.
- Role:** A dropdown menu with 'Select from list' selected.
- Scope:** A dropdown menu with 'Select from list' selected.
- Authorised date:** Two date input fields with the placeholder 'dd/mm/yyyy' and a calendar icon.

 At the bottom of the form, there is a blue '+ ADD ROLE' button and a grey 'CANCEL' button. The 'ASSIGN' button is highlighted with an orange box.

Assign or request roles in CTIS

How to request a role – Sponsors users

1. Users can log in to CTIS and click on the **username button at the top-right corner** of the CTIS landing page.

Clinical trials

UAT CT

Clinical trials Notices & alerts RFI User administration

2. Then they can click on **'My roles'** button.

Personal profile

My roles

Logout

3. Once they are in 'My roles' page, they can click on the **'Request role'** button.

My roles

Advanced search ▾

Search Results

Showing 1 - 1 of 1 items 1 of 1 pages < 1 >

Sort by: 1 Creation Dat ▾

4. Finally, they can populate the fields of the pop-up window and click the **'Request'** button.

Request roles

✕

Assign or request roles in CTIS

How to request a role – Sponsors users

- Once users request a role, the **Administrator** user can click the **checkbox** next to the role and then clicks on the **'Approve'** or **'Reject'** buttons.

Administration of users

The screenshot displays the 'Administration of users' interface. At the top, there is a search bar with the placeholder text 'Enter EU CT ID or ASR ID or use advanced search' and a 'SEARCH' button. To the right of the search bar is an 'Advanced search' dropdown menu. Below the search bar, the 'Search Results' section is visible, showing 'Showing 1 - 2 of 2 items' and '1 of 1 pages'. The results are sorted by 'Creation Date'. A table lists the search results, with the first row highlighted. The table has columns for 'Role', 'Creation date', and 'Assesment date'. The first row shows a role named 'unisys_k4' with a 'Creation date' of '19/07/2021'. The role is marked as 'requested' and has a checkbox checked. The 'Approve' and 'Reject' buttons are highlighted with an orange box, and a blue callout bubble points to them with the text: 'Approve' and 'Reject' buttons. Other buttons visible include 'Revoke' and 'ASSIGN NEW ROLE'.

Role	Creation date	Assesment date
unisys_k4 ASR Submitter	19/07/2021	

Reference table

Module	Material	Source
Module 07: Management of registered users and role matrix	eLearning course	EMA corporate website
Module 07: Management of registered users and role matrix	Step-by-step guide (high-level CTIS administration)	EMA corporate website
Module 07: Management of registered users and role matrix	Frequently Asked Questions	EMA corporate website
Module 07: Management of registered users and role matrix	Video - Creating a clinical trial: Clinical trial centric approach vs organisation centric approach	EMA YouTube channel
Module 07: Management of registered users and role matrix	Video - How to request roles and how to assign roles to registered users in CTIS	EMA YouTube channel
Module 07: Management of registered users and role matrix	Video - How to amend and revoke roles of registered users in CTIS	EMA YouTube channel
Module 07: Management of registered users and role matrix	Video - How to request the CTIS high level Administrator role via IAM	EMA YouTube channel
Module 07: Management of registered users and role matrix	Video - How to approve requests for CTIS Administrator role and how to remove CTIS Admin role	EMA YouTube channel
Module 07: Management of registered users and role matrix	Roles and permissions matrix summary - Authority Workspace	EMA corporate website
Module 07: Management of registered users and role matrix	Roles and permissions matrix summary - Sponsors Workspace	EMA corporate website
Module 07: Management of registered users and role matrix	Member States Business Processes and Roles	EMA corporate website
Module 07: Management of registered users and role matrix	Sponsors Business Processes and Roles	EMA corporate website
Module 07: Management of registered users and role matrix	Notices and alerts per role	EMA corporate website
IAM	User Administration Guide	EMA Account management homepage
IAM	Frequently Asked Questions	EMA Account management homepage

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Clinical Trials Information System (CTIS)

Module 19: CTIS for SMEs and Academia

Step-by-step guide: User administration

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