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 assignation 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**

- **Assign or request roles in CTIS**
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.

The **CT-centric approach** allows a faster process when submitting a first initial application. This approach is not suitable if the sponsor organisation manages multiple trials.
2. Users can access the landing page and click on the ‘Clinical trials’ tab.

3. Then they can click on the ‘+ New trial’ button.

4. 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’.

For security and data accuracy reasons, if an organisation has a Sponsor Administrator assigned and a user without the appropriate roles tries to create a CTA, the system will block this action and display an error message.
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.

2. Then they can click on the ‘Assign new role’ button.

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

Sponsor administrators can manage roles from the ‘User administration’ tab in CTIS. This tab allows them to assign, approve or revoke roles to users registered in the system.

When sponsor administrators click on ‘Assign new role’, a pop-up window appears where they need to populate different fields: User ID, organisation name, role, scope and authorised date.
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.

2. Then they can click on `My roles` button.

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

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

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**Clinical trials**

![Clinical trials interface](image)

**Search Results**

![Search Results interface](image)

**Request roles**

![Request roles interface](image)

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When a role is assigned, users must **log out and log in again** in order to have the role assigned to them in the system.

To request a role, sponsor users must populate the organisation name, ID, the scope of the role they are requesting, the EU CT number and the role. **All the fields are mandatory.**
5. 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.

Role requests will appear in the **User administration** tab. **No notice or alert** will be generated. Therefore, Administrators users are encouraged to **check** the User administration tab **regularly**.
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