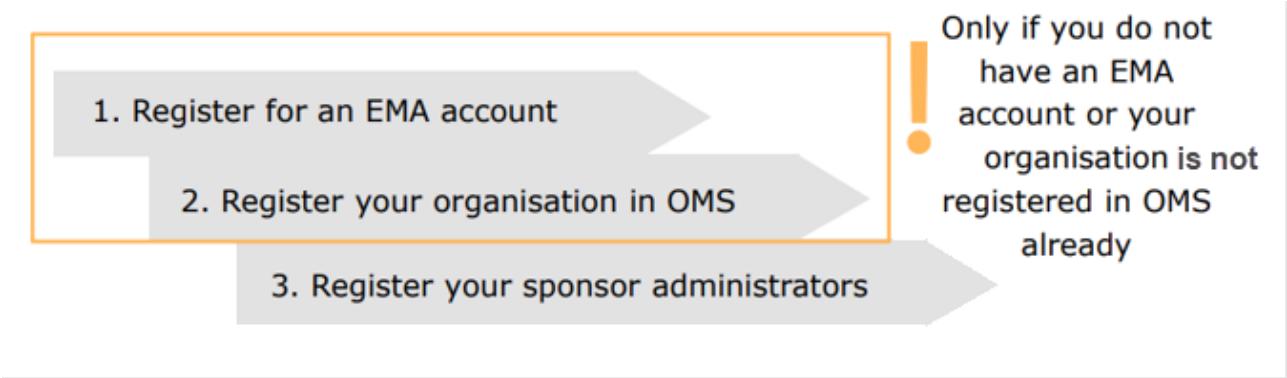
GCP| ENHEDERNE
God klinisk forskning

The Danish GCP Units guide – User access, roles and responsibilities in CTIS

Content

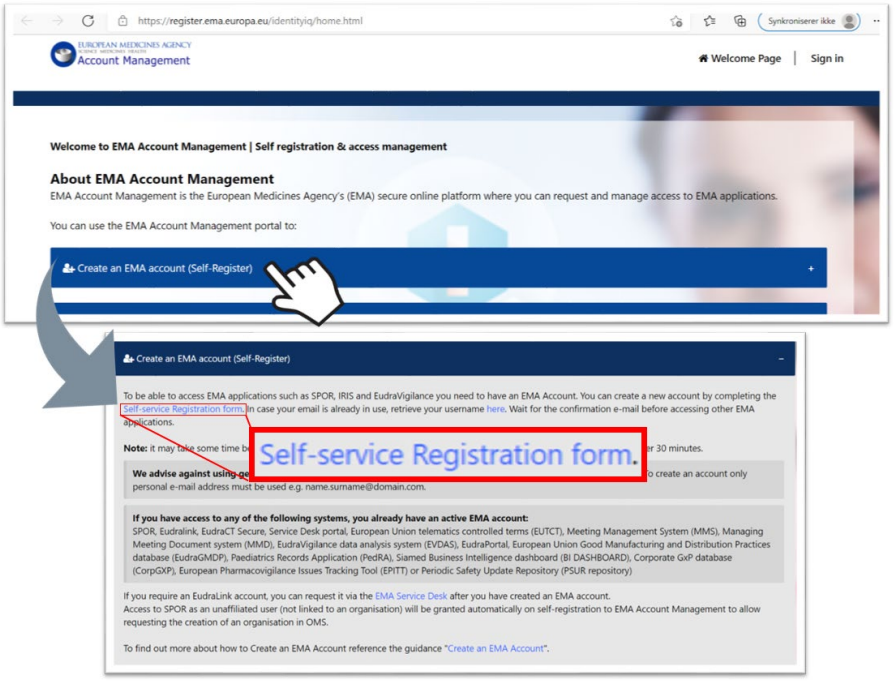
1 What is needed to work in CTIS? How to get started

In order to access the CTIS Sponsor workspace, a user will need to have an active EMA Account. If the user already uses other EMA applications (e.g. Eudralink, SPOR, IRIS, EudraVigilance, OMS or the EU Clinical Trials Database), the user already has an EMA Account and could access the CTIS Sponsor workspace using his/her existing EMA Account credentials. If the user does not have an active EMA Account, (s)he needs to create one, by self-registration. In addition, organisations must be registered in EMA's Organisation Management System (OMS).



2 How to create a new EMA account

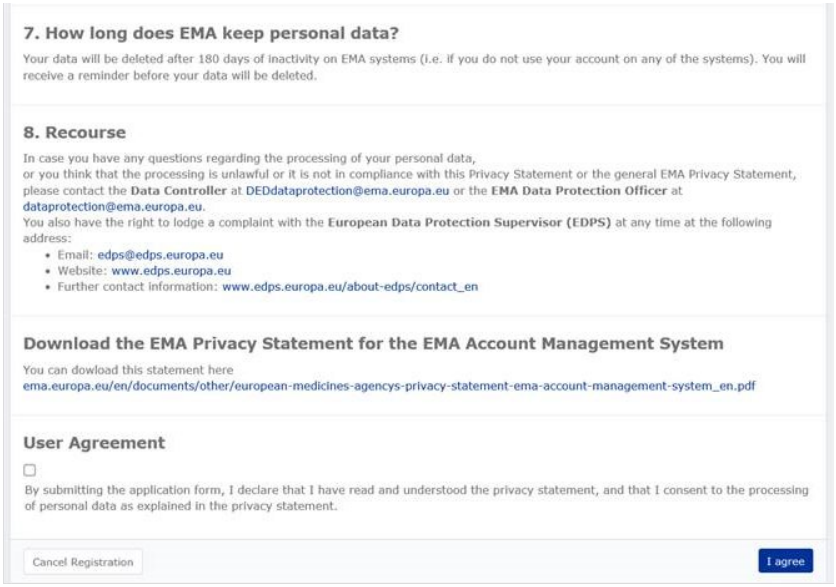
Go to EMA's Account Management portal: **Home · EMA Account Management (europa.eu)**



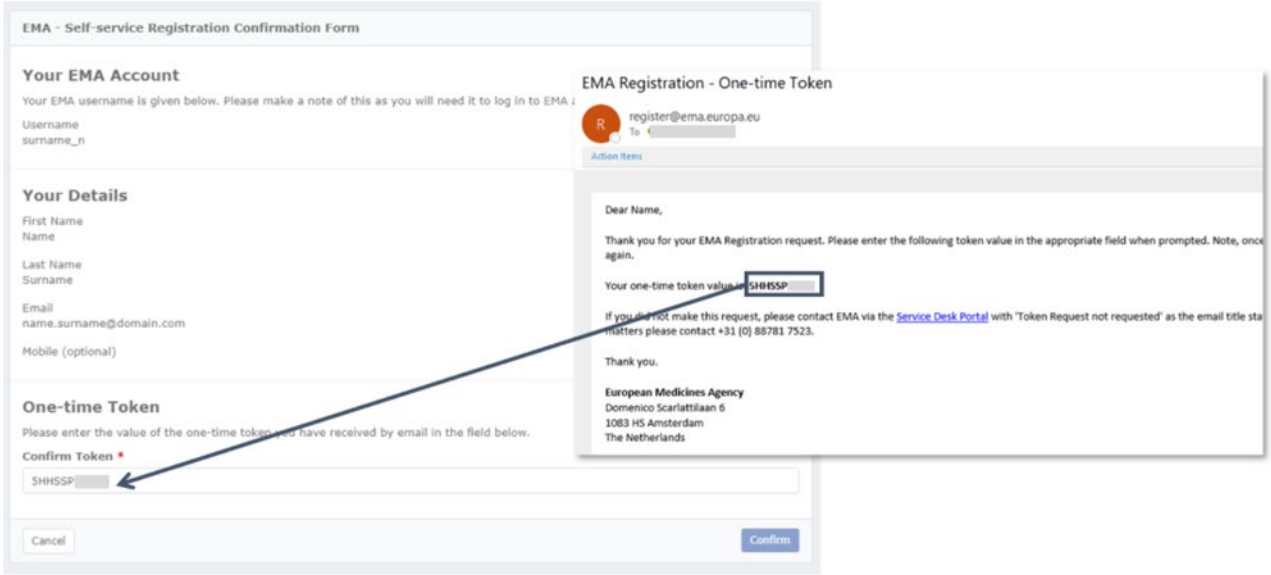
Click on "Create an EMA account (Self Register)" and open the "Self-service Registration form".

Complete the "Self-service Registration Form" with the relevant information. Fields marked with red asterisks (*) are mandatory. Password is case sensitive and must be at least 8 characters long and contain 4 different character types. Now you can download and read the EMA Privacy Statement.

Tick the "**User Agreement**" checkbox and then click on the "I agree" button.



Set up "**Security Questions**", answer the captcha (Completely Automated Public Turing test to tell Computers and Humans Apart) question and click the "Next" button. A "**Self-service Registration Confirmation Form**" will appear:



Complete the one-time Token received by mail and click Confirm. An automatic notification will be sent to the email address that you provided to confirm your account registration. It is recommended to save this confirmation-email.

It may take up to 30 minutes before the access is granted.

A **multi-factor (MFA) authentication** strategy for user login to CTIS is launched in June 2023. This strategy will effectively reinforce the security of user accounts.

This MFA second factor can be:

- a token received in Microsoft Authenticator mobile app
- an automated phone call or a text to mobile phone
- a call to office phone.

Users may choose their preferred second factor method and amend their choice at any time. For more information go to: Sign In · EMA Account Management (europa.eu)

3 User access, roles and responsibilities in CTIS – Trial-centric approach

There are two general approaches to user management in CTIS: The organisation-centric approach and the trial-centric approach.

The focus of this guide is the trial-centric approach.

In Denmark only Odense University Hospital has, as an academic sponsor chosen to use the organisation-centric approach for submission of an EU Clinical Trial Application (CTA). Researchers from OUH must contact the GCP unit at Odense University Hospital, for initiation of a new CTA (with OUH as sponsor) and assignment of roles.

Trial-centric approach - Is intended to serve the needs of small organisations and specifically academic sponsors, which may initiate trials on an ad hoc basis. It allows for the management of a smaller number of users and one or very limited numbers of clinical trials. This approach allows a faster process (no need for registration of a high-level sponsor administrator) when submitting a first initial, and subsequent application. Further allocation of other CT Administrator (CT Admin) roles or business roles is assigned to users at the clinical trial level. The CT Admin can manage users only for the particular trial(s) of his/her concern and can perform all sponsor business activities in CTIS related only to the particular trial.

3.1 How to check for registration of the sponsor organisation in OMS

You can search The Organisation Management System (OMS) without an EMA account.

Please go to **"Documents"** and refer to document E – OMS change request if you need to make changes or add new location or organisations. You need a SPOR user affiliation role in order to make changes in OMS.

Each organisation (University Hospital, Hospital or University) has **one** Organisation ID, but can have several location ID's. Be sure you choose the right address for the specific organisation.

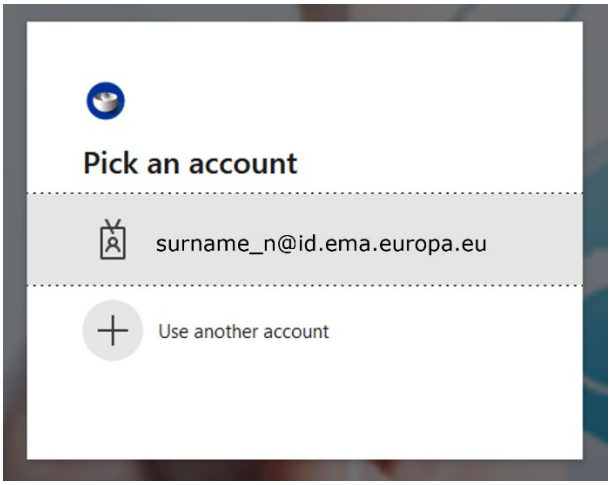
The sponsor details from OMS must first be added when you have logged into the CTIS database, please refer to section 2.2 in "The Danish GCP-units guide to CTIS".

3.2 Access to CTIS

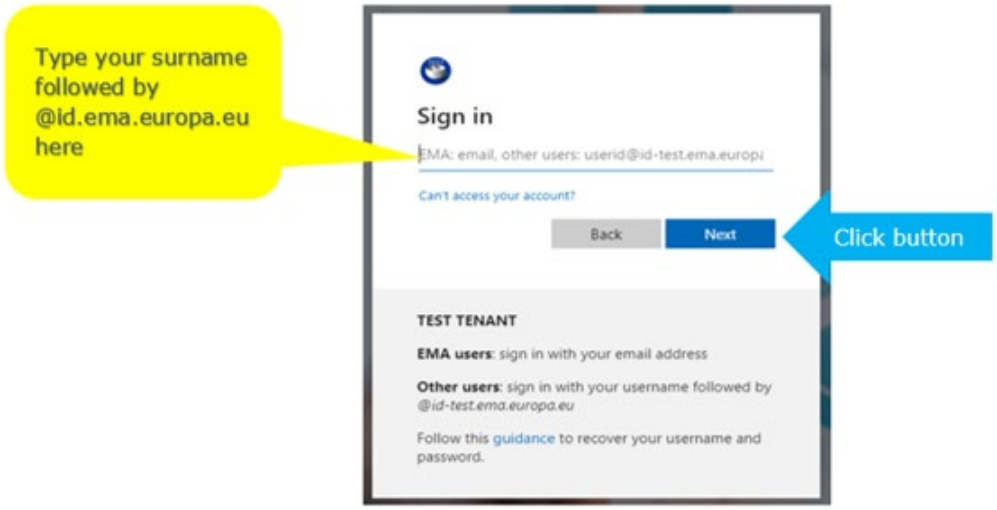
First Time Log-in:

1. After you have received notification that your user access role has been granted, it can take up to 30 minutes to gain access to the system.
2. Go to the CTIS.

3. Click the Login button for sponsor workspace
4. Select an EMA account from the Pick an account window (see below)

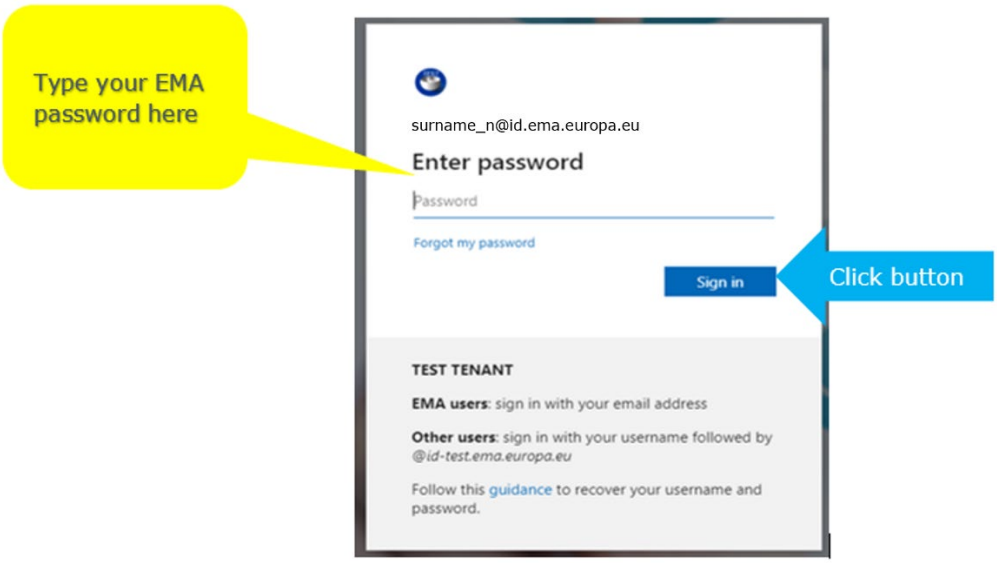


5. Click on the appropriate account name if it appears in the Pick an account list (see above).
6. If the account name does not appear, click on **Use another account** and in the **Sign in** window (see below) type in your **EMA username** followed by **@id.ema.europa.eu**, for example, if your EMA username is “surname_a”, type in **surname_a@id.ema.europa.eu.**



After adding your username and **@id.ema.europa.eu** click **Next** button.

Enter your EMA password and click the Sign In button.



When logging into the clinical trial information system (CTIS) to create a new CTA, the system will automatically check if a high-level sponsor administrator has been appointed for the sponsor organisation selected.

If that is not the case, the user will be able to proceed becoming the clinical trial administrator (CT Admin) for that particular trial and can then assign other roles in the particular trial to other users also holding an EMA account.

Video on this topic in EMA training module 7:

How to request roles and how to assign roles to register users in CTIS

3.3 Considerations of which roles to assign to users within the organisation

For consideration of which roles to assign in CTIS the document CTIS User Personas can be used. Please refer to page 6-8 in this guide.

The CT Administrator role is as mentioned assigned automatically to the person that initiates a new CTA, but it is recommended that at least one back up CT Admin is assigned as well. Users can also be given one of the business roles; Viewer, Preparer or Submitter.

Viewer role:

- Allows user to view structured data, documents, and includes download of document.

Preparer role (the Preparers also have Viewers permissions):

- Create permission: allows the user to edit, upload documents, save, update saved drafts. It also allows users to copy from an existing CTA to create a new one.
- Delete permission: delete refers only to eliminate/cancel draft items.

Submitter role (the Submitters also have the Viewers and Preparers permissions):

- Submit permission: allows the user to submit data/documents from their respective workspace to CTIS
- Update permission: allows updating submitted information
- Withdraw permission: refers to the withdrawal of submitted items

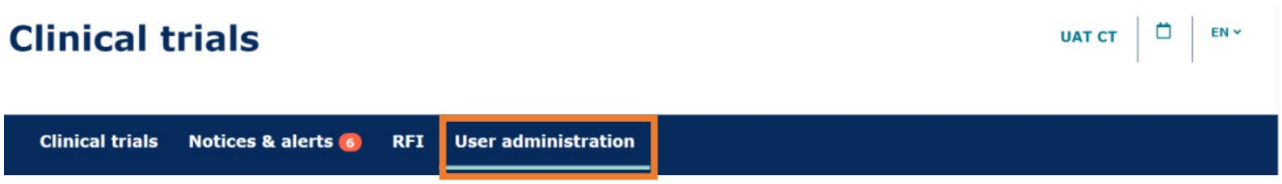
3.4 How to assign business role to users within the organisation

After a new CTA is created (See section 2.1), the CT Admin can assign business roles for that specific trial

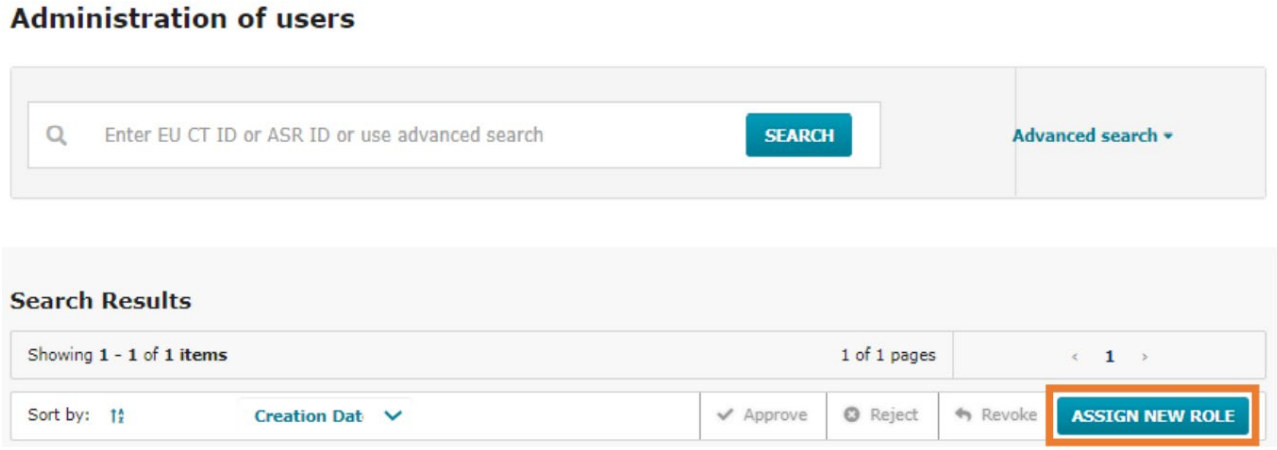
1. After the CT Admin is approved, users can log in to CTIS and click the User administration tab.

Info box:
For more detailed information please refer to Module19 - Step-by-step guide - User access management and user administration (europa.eu)

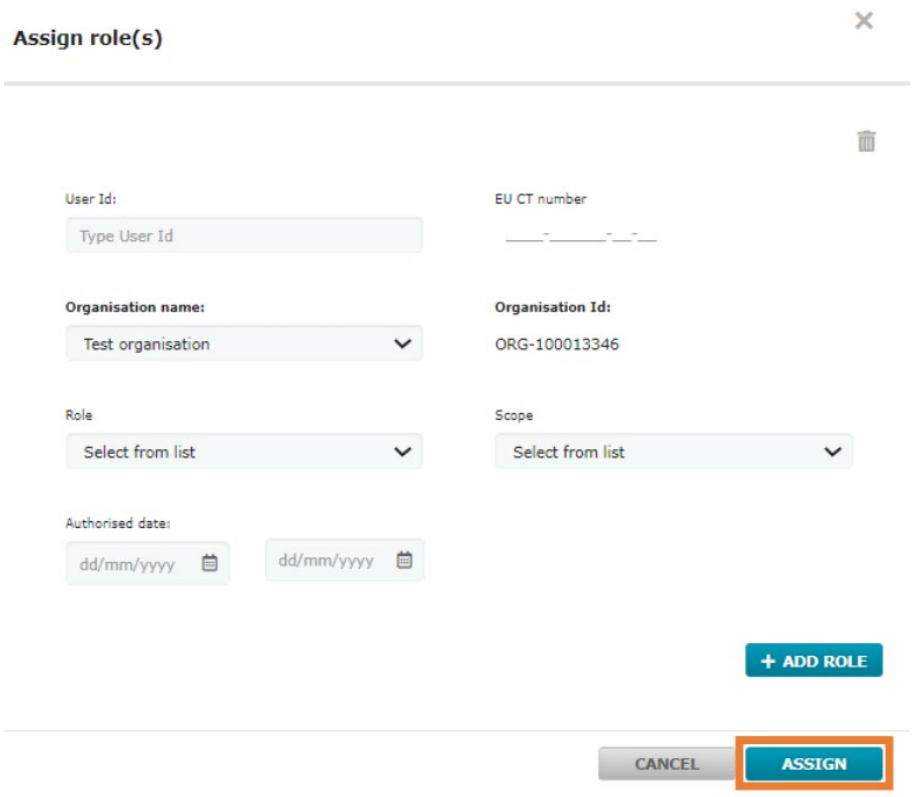
Refer and "Roles and permissions matrix summary Sponsors Workspace CTIS Training Programme – Module 7" Sponsor workspace - Roles and permissions summary (europa.eu)



2. Click on the 'Assign new role' button.



3. Fill in the information about the business role to be assigned to users within the organisation and click on the 'Assign' button.

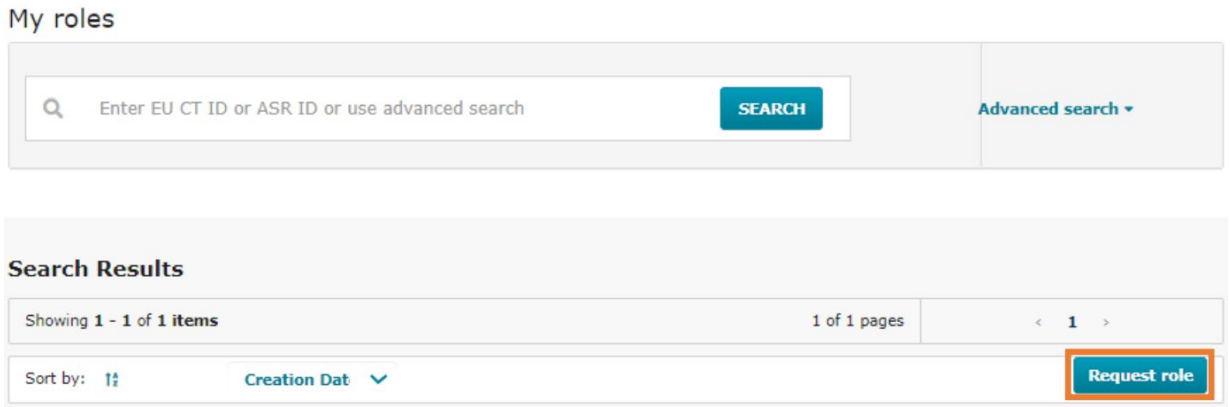


3.5 How to request a role

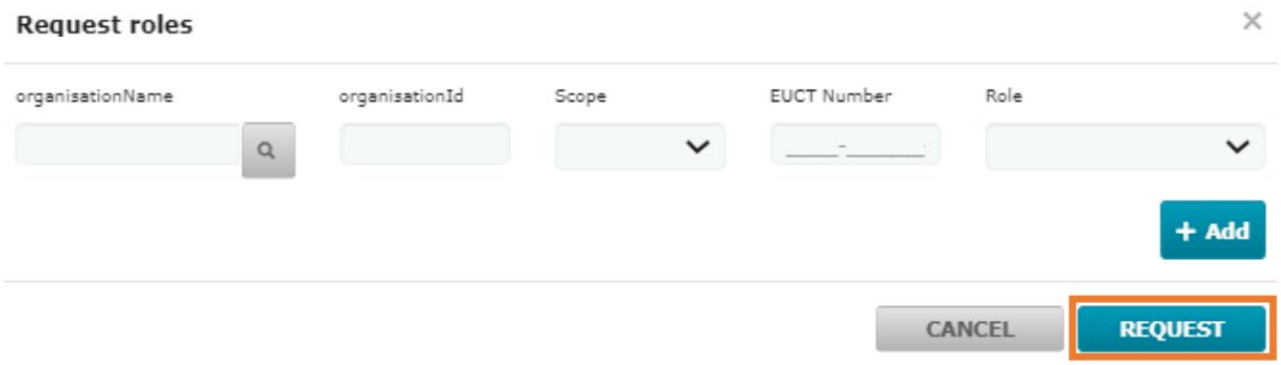
1. Users can instead choose to request a role this is done by log in to CTIS and click the username button at the top-right corner of the CTIS start page.

2. Click on the 'My roles' button.

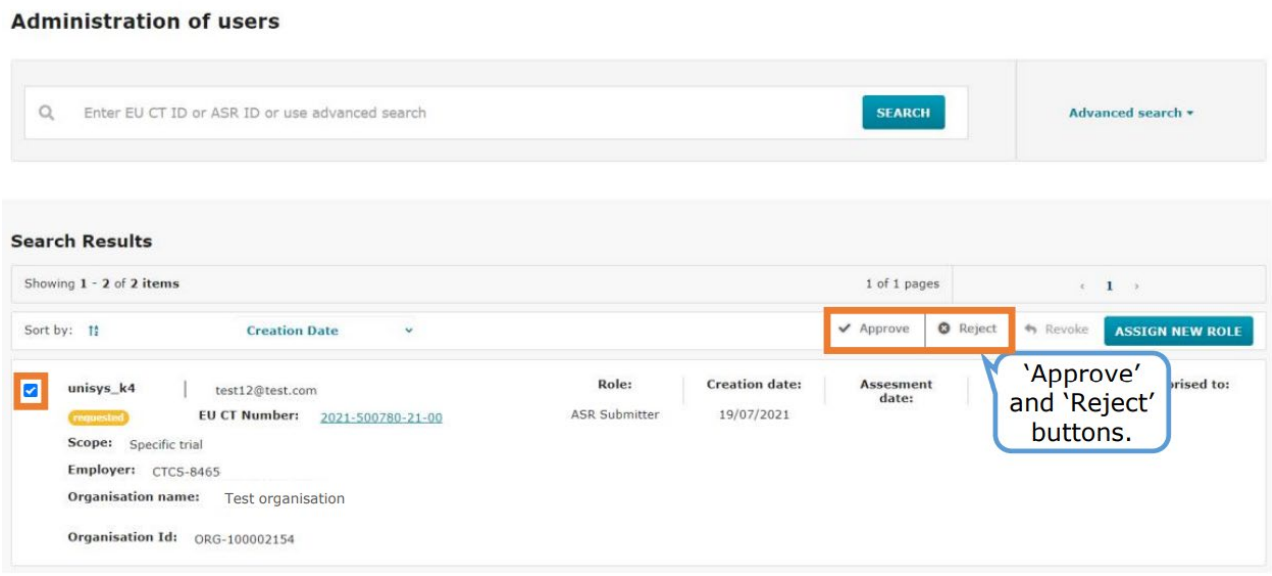
3. Click on the 'Request role' button.



4. Populate the information from the pop-up window and click the 'Request' button.



5. Once users request a role, the CT admin clicks the checkbox next to the role and clicks on the 'Approve' or 'Reject' buttons. Role requests will appear in the User administration tab. No notice or alert will be generated. Therefore, CT administrators are encouraged to check the User administration tab regularly.



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.

4 Changes log

Version 1.0

Version 1.1 Updated with information on multi-factor (MFA) authentication strategy for user logins to CTIS

Version 1.2 Further explanation about log in to CTIS