



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# What is needed to work in CTIS: Organisation, Admin and User Registration

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July Info Event

Presented by Ana Rodriguez on 29<sup>th</sup> July 2021

An agency of the European Union





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1. Register for an EMA account

2. Register your organisation in OMS

3. Register your sponsor administrators



1. Register for an EMA account

2. Register your organisation in OMS

3. Register your sponsor administrators

Only if you do not have an EMA account or your organisation registered in OMS already




# 1. Register for an EMA account

- If you are already a user of EMA applications (e.g. (SPOR, IRIS, EudraVigilance), you can **access CTIS using your existing EMA account.**
- If you do not have an EMA account, go to [EMA Account Management](#) and click on **“Create a new EMA account”**.



EMA Account Management

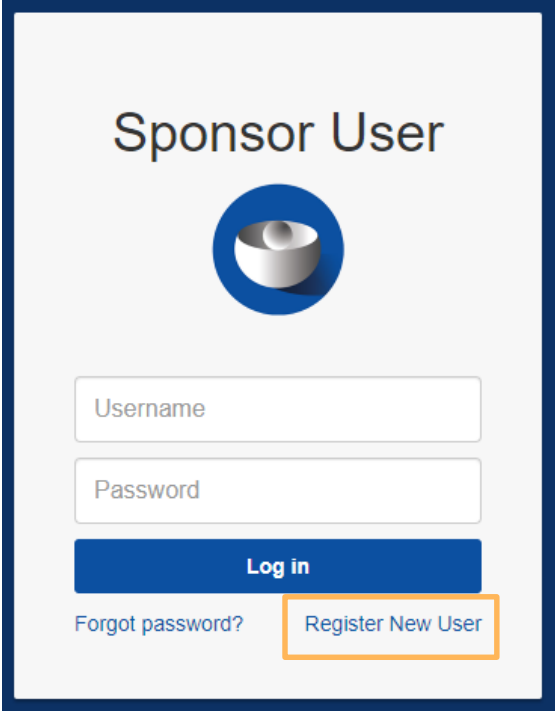


Username


Password

[Create a new EMA account](#) [Forgot Password?](#)  
[Not sure if you have an EMA account?](#) [Forgot Username?](#)

- Users can also register for an EMA account using the **'Register New User'** link on the CTIS Workspace login page.



Sponsor User



Username

Password

Log in

[Forgot password?](#) [Register New User](#)

- To create an account, fill in the **Self-service Registration Form** in EMA's Account Management Portal.

**EMA - Self-service Registration Form**

Submit the following form to register.

**First Name \***

This is used to create your username and to address you in email correspondence.

**Last Name \***

This is used to create your username and to address you in email correspondence.

**Email \***

We require a valid/active email address to create an EMA Account.

**Password \***

Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.

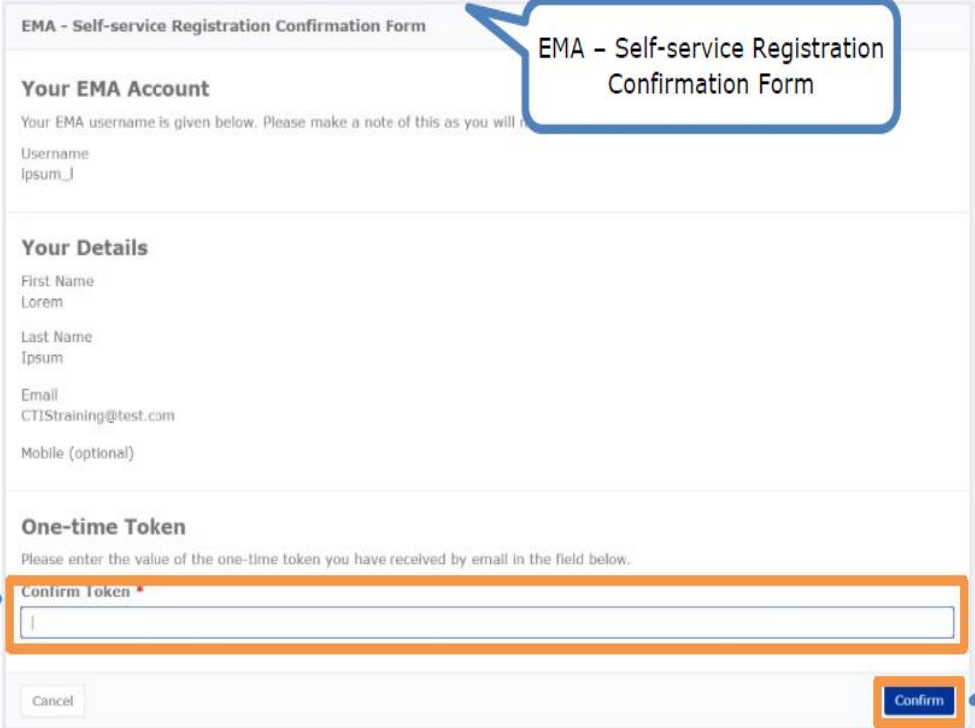
**Confirm Password \***

Country Code

Mobile (optional)



- Users will receive a **one-time token** by email, 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 to the system.  
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 Token \***

EMA - Self-service Registration Confirmation Form

Confirm one-time Token

'Confirm' button

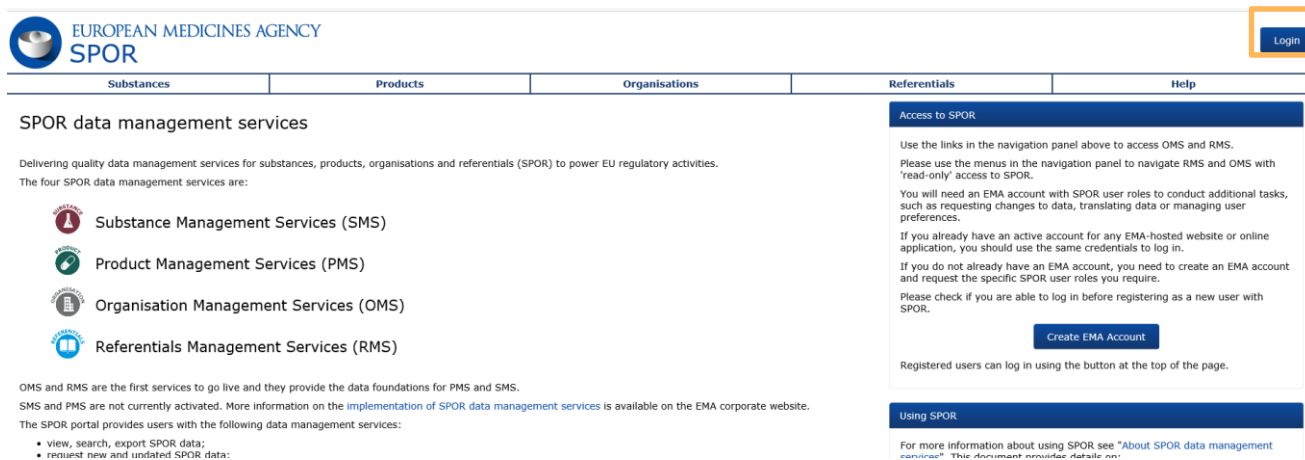


- After confirming the one-time token, users will see the **username** automatically generated by EMA's Account Management Portal, along with their personal information.
- This username and chosen **password**, will be needed to log into CTIS, so users are advised to **make a note of them**.
- Once the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



## 2. Register your organisation in OMS

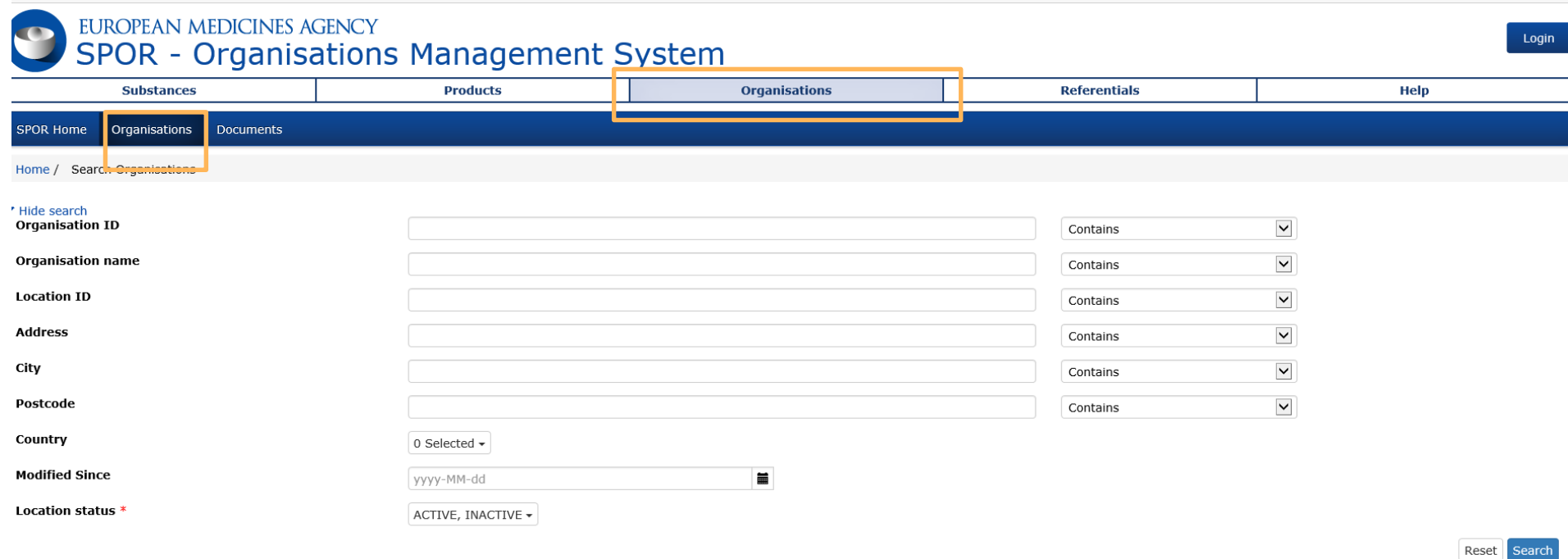
- If your organisation is already registered in OMS, **you do not need to complete this step.**
- If your **organisation is not registered in OMS** yet, go to the EMA's Substance, product, organisation and referential [\(SPOR\) portal](#) and log in with your EMA account.



The screenshot shows the SPOR portal interface. At the top left is the European Medicines Agency logo and the text 'EUROPEAN MEDICINES AGENCY SPOR'. A navigation menu includes 'Substances', 'Products', 'Organisations', 'Referentials', and 'Help'. A 'Login' button is highlighted with an orange box in the top right corner. The main content area is titled 'SPOR data management services' and includes a description of the services and a list of four services: Substance Management Services (SMS), Product Management Services (PMS), Organisation Management Services (OMS), and Referentials Management Services (RMS). A 'Create EMA Account' button is visible in the right-hand panel.

# Register your organization in OMS

- Before submitting a request to register an organisation via OMS, the **user must search the available records** for their organisation by clicking on the Organisations tab.



EUROPEAN MEDICINES AGENCY  
SPOR - Organisations Management System

Substances Products **Organisations** Referentials Help

SPOR Home **Organisations** Documents

Home / Search **Organisations**

\* Hide search

**Organisation ID**  Contains

**Organisation name**  Contains

**Location ID**  Contains

**Address**  Contains

**City**  Contains

**Postcode**  Contains

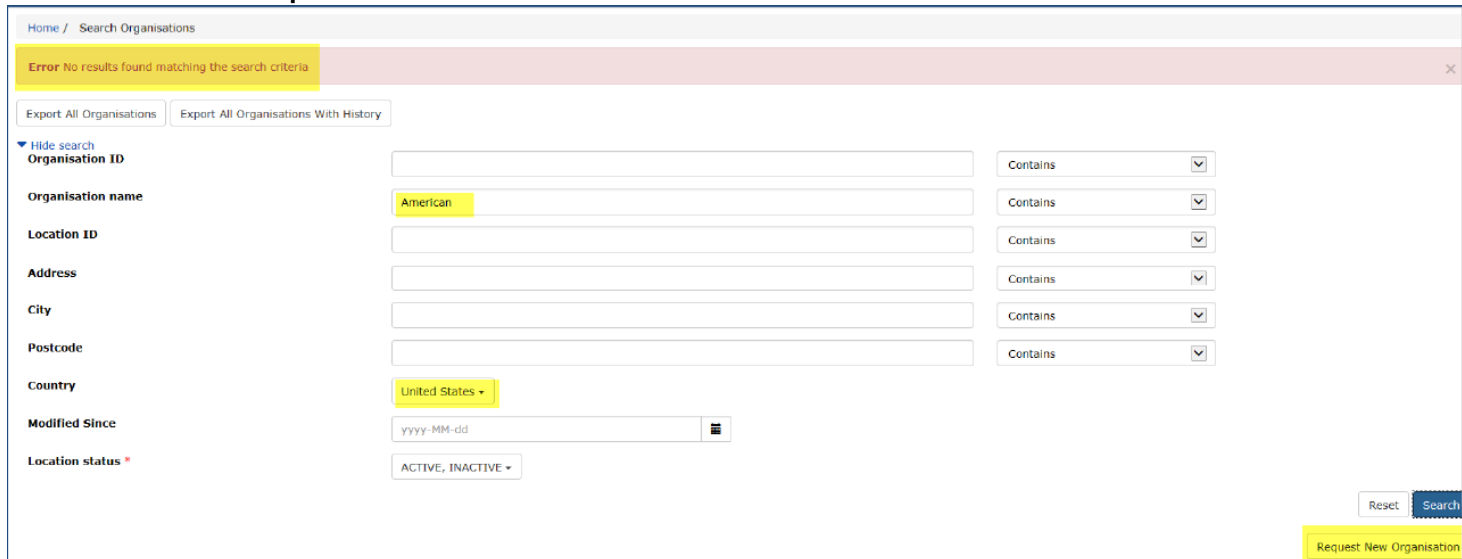
**Country** 0 Selected

**Modified Since** yyyy-MM-dd

**Location status \*** ACTIVE, INACTIVE

Reset Search

- If the user cannot find their organisation by name and country, they can **request creation of a new organisation** from the search page or from the View Organisation/Location Details page.
- **Supporting documents** must be submitted which allow the EMA Data Stewards to validate the request.



The screenshot shows the 'Search Organisations' page in the OMS system. At the top, there is a breadcrumb 'Home / Search Organisations' and a red error message: 'Error No results found matching the search criteria'. Below the error, there are two buttons: 'Export All Organisations' and 'Export All Organisations With History'. The search criteria section is expanded, showing the following fields and values:

Field	Value	Filter
Organisation ID		Contains
Organisation name	American	Contains
Location ID		Contains
Address		Contains
City		Contains
Postcode		Contains
Country	United States	Contains
Modified Since	yyyy-MM-dd	
Location status	ACTIVE, INACTIVE	

At the bottom right of the search criteria section, there are 'Reset' and 'Search' buttons. A yellow button labeled 'Request New Organisation' is visible at the bottom right of the page.

What is needed to work in CTIS

- **Additional details** on the OMS registration process can be found in the **OMS Web User Manual** in the [Documents section](#) of OMS.



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SPOR - Organisations Management System

Login

Substances	Products	Organisations	Referentials	Help
SPOR Home	Organisations	<b>Documents</b>		

Home / View Documents

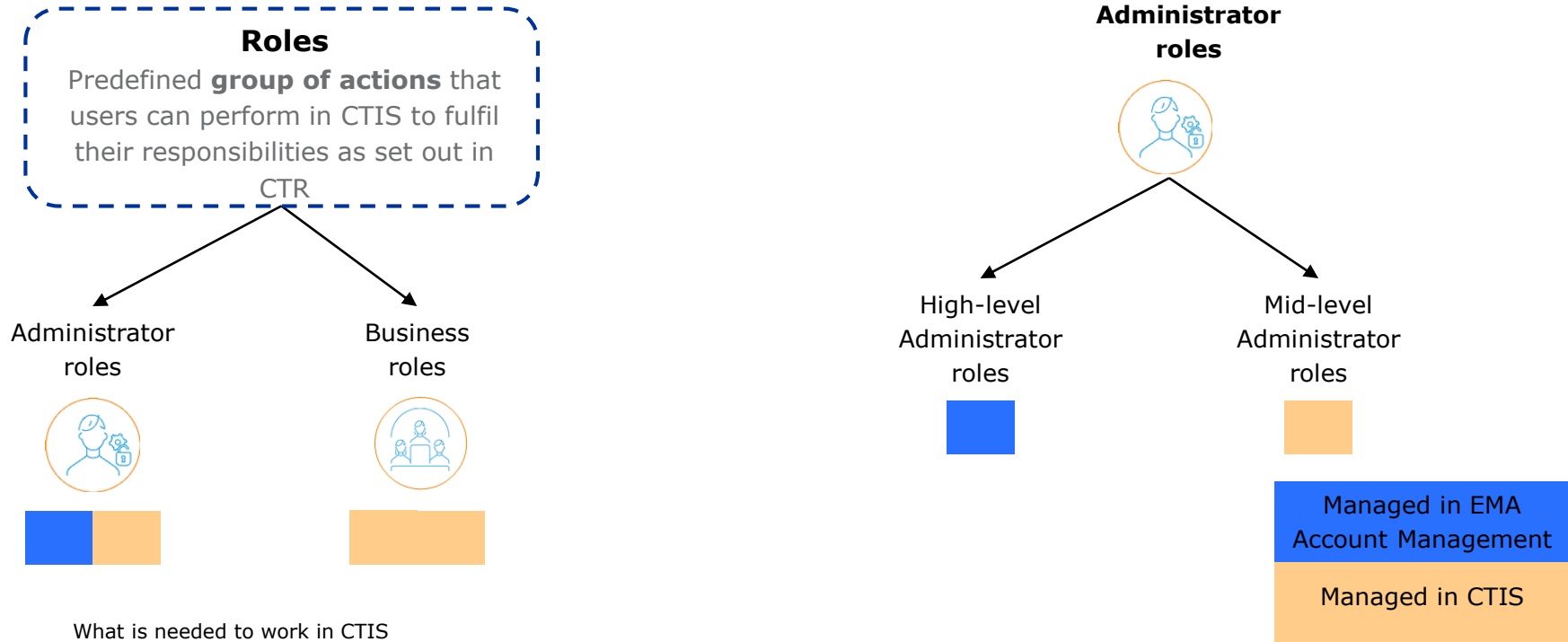
Document Name ▲	Document Description †	Published Date ‡	Actions
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.	2017-06-26	
A1 - OMS Introduction - Webinar 3 February 2021	Webinar - OMS Key principles, services and activities - 3 February 2021	2021-02-04	
B - OMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.	2018-05-25	
C - OMS Data Quality standards	Guidance - Data quality standards applied in OMS	2017-06-16	
C1 - OMS DQ - Webinar 25 September 2018	Webinar - Key principles and rules covered in OMS Data Quality standards - 25 September 2018	2018-11-19	
C2 - OMS DQ - Webinar 26 February 2019	Webinar - OMS Data Quality Issues - 26 February 2019	2019-08-16	
C3 - OMS Guidance on Assessing Organisation Names and Location Data	Guidance - When minor differences between organisation names and location data are acceptable	2021-02-16	
C4 - OMS Mapping Guidance	Guidance - Process for mapping and when to create an OMS change request	2021-06-02	
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS	2017-06-16	
E - OMS Change Requests	Guidance - Rules and Supporting documentation required for change requests	2018-05-16	
F - OMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in OMS web Portal.	2018-04-17	

What is needed to work in CTIS

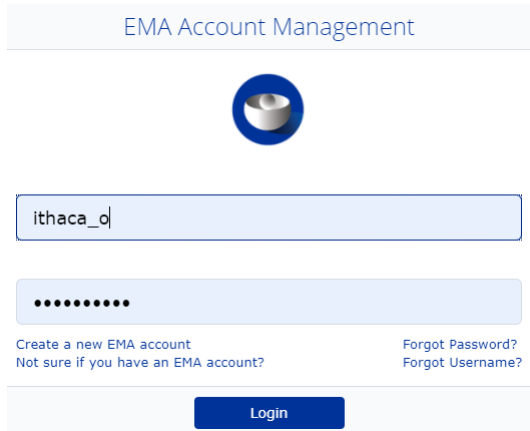
## 3. Register your sponsor administrators




High-level administrator CTIS roles (e.g. Sponsor Admin) must be requested via EMA Account Management. This can be done from **September 2021**.



What is needed to work in CTIS



EMA Account Management



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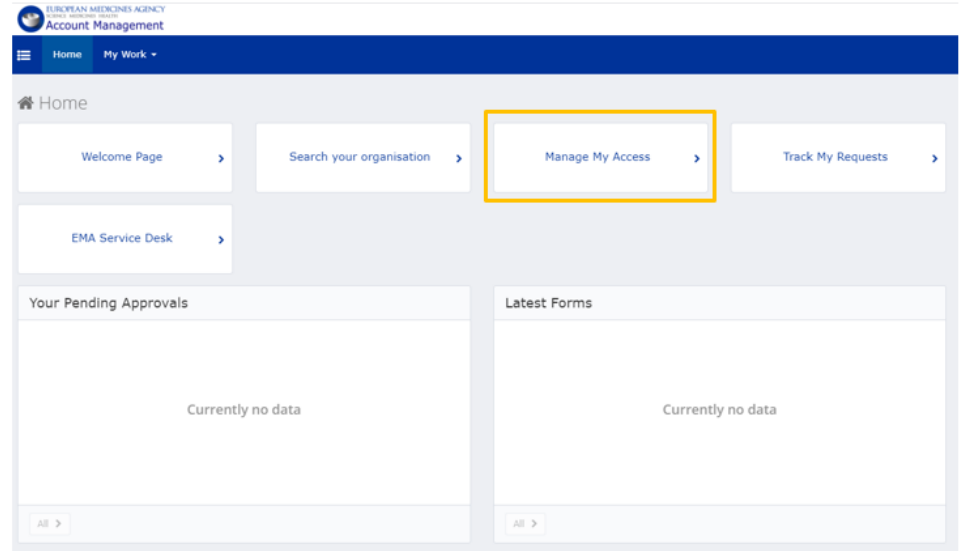
.....

Create a new EMA account  
Not sure if you have an EMA account?

Forgot Password?  
Forgot Username?

Login

Log in to EMA Account Management



EUROPEAN MEDICINES AGENCY  
Account Management

Home My Work

Home

Welcome Page Search your organisation Manage My Access Track My Requests

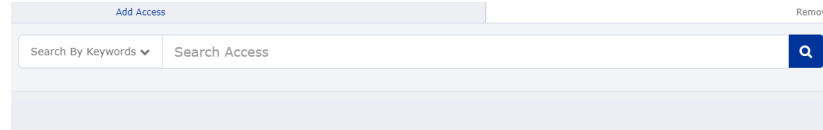
EMA Service Desk

Your Pending Approvals  
Currently no data

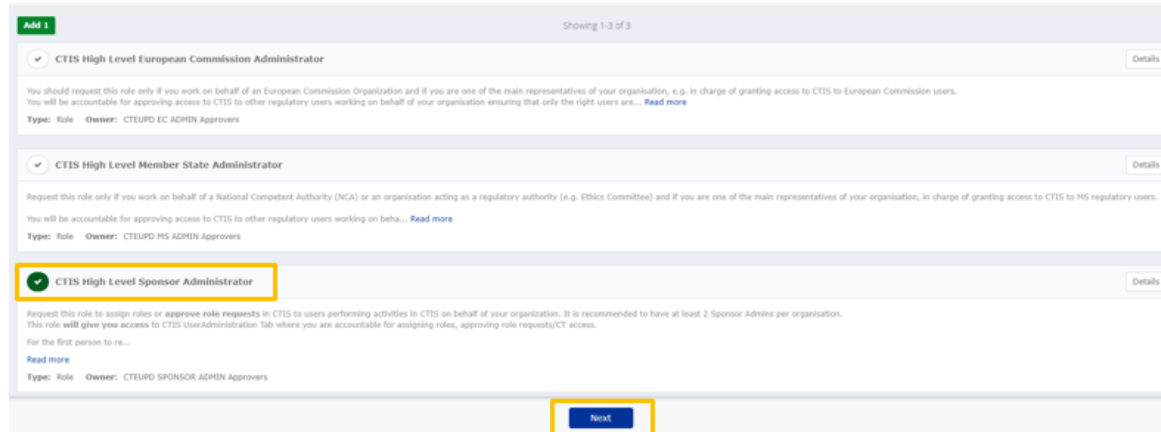
Latest Forms  
Currently no data

All All

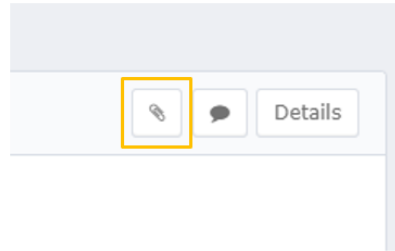
Click on "Manage My Access"



Use Search to find the “Sponsor Administrator” role  
Use “CTIS” as a keyword



Select the “Sponsor Administrator” role and click on  
“Next” button



Attach the affiliation letter and click “Submit”.

NOTE: the affiliation template letter will be made available at the following link prior:

<https://register.ema.europa.eu/identityiq/help/requestaccess.html>

The affiliation template letter will be made available for use when admin registration opens.

## More Info Needed

More information is needed to complete your request. Fill out the form to provide additional information.

**Identity:** Odysseus Ithaca

Later

Complete Form

Click on the “Complete Form” button

### Select your Organisation

#### Requested Roles

CTEUPD SPONSOR ADMIN

#### 1. Search Organisation

test organisation

Enter an organisation name or OMS ID to narrow down the results. Select the correct organisation from the menu below by clicking on the drop-down arrow on the right.

#### 2. Select your Organisation \*

ORG-100022987 - Test Organisation 1]

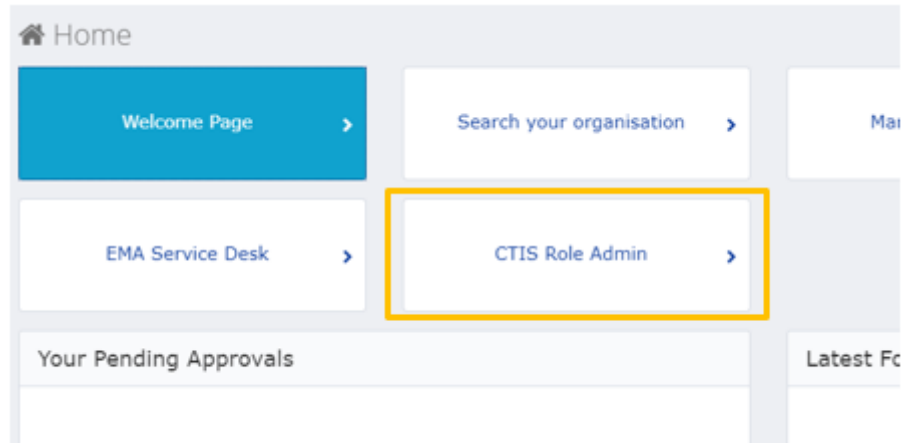
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI. In case you cannot find your organisation in the list, please verify that it has been registered correctly with OMS <http://spor-uat.ema.europa.eu/omswi/>

Save for later

Cancel Request

Submit Request

Use the Search functionality to find the sponsor organisation.  
Click on the “Submit Request” button



EMA validates the request to become a Sponsor Admin.

When the Sponsor Admin role has been assigned, you will see it in your EMA Account Management portal.

# Request Sponsor Admin role

The screenshot displays the EMA Account Management interface. The top navigation bar includes 'Home' and 'My Work'. A notification bell icon in the top right corner is highlighted with an orange box and shows a count of 1. Below the navigation bar, there are several quick action cards: 'Welcome Page', 'Search your organisation', 'Manage My Access', 'Track My Requests', 'Approvals' (highlighted with an orange box and showing a count of 1), and 'Edit Identity'. Below these cards, there are two main sections: 'Your Pending Approvals' (highlighted with an orange box) and 'Latest Forms'. The 'Your Pending Approvals' section contains a table with the following data:

Approval For Requester	Requested Item	Date	
Odysseus Ithaca Odysseus Ithaca	CTEUPD SPONSOR A...	03/06/2021 08:02	>

The 'Latest Forms' section currently displays 'Currently no data'. At the bottom of both sections, there is an 'All >' button.

You can now manage other users' requests to become Sponsor Admins of your organisation.

You will see the requests in the 3 highlighted areas.



# Any questions?

## Further information

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