EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Management of roles and permissions

High-level Administrator registration

CTIS Training Programme – Module 07
Version 1.3 – October 2022

Learning Objectives

- Understand how to request the High-level Administrator role for CTIS.

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

Record of updated versions

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1.3	Updating the training material to include the IAM process changes	October 2022
1.2	Inclusion of the table for High-level Admin Organisation (appendix).	February 2022
1.1	Training material version published at CTIS go-live.	January 2022

Introduction

The CTIS High-level Administrators (Sponsor, Member State, and European Commission Administrator) are roles that are requested and managed outside CTIS and need to be validated by EMA based on specific documentation to be provided by the user requesting this type of role (in case there are no other High-level Administrators or External Organisation Administrator[1] in an organisation).

High-level Administrators are assigned in the EMA's Account Management portal through a request via the Identity Access Management (IAM) process. Once approved, the CTIS High-level Administrators are able to manage all users within their organisation (Business roles and Medium-level Administrators in CTIS; and additional CTIS High-level Administrator roles in the EMA Account Management portal). Refer to the eLearning of Module 7: Management of roles and permissions for more information.

The Sponsor Administrators are the High-level Administrators in the sponsor workspace; while the Member State Administrators and the European Commission Administrators are the High-level Administrators in the authority workspace.

This step-by-step guide explains the steps to request High-level Administrator roles via the IAM process.

Request a High-level Admin role

This section outlines the steps that users need to follow to request the following High-level Administrator roles: Sponsor Administrator, MS Administrator and European Commission Administrator.

Approve / reject a High-level Admin role

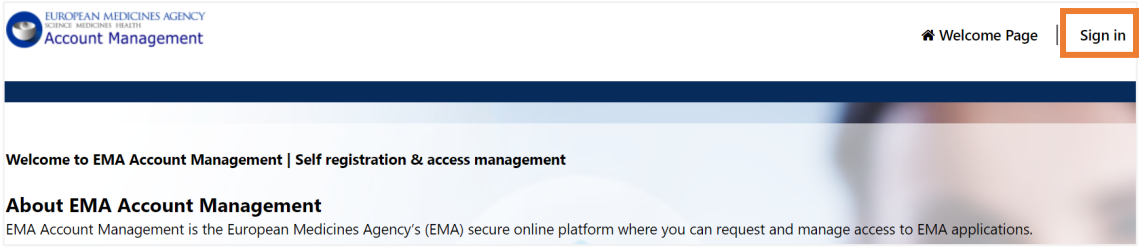
This section outlines the steps that the already assigned CTIS High-level Administrator users need to follow to approve or reject a High-level Administrator role request.

[1] https://register.ema.europa.eu/identityiq/help/useradmin.html#OrganisationAdmin - "External Organisation Administrator" section

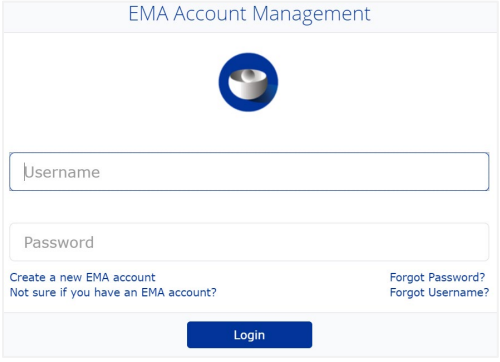
Request a High-level Admin role

EMA Account Management portal

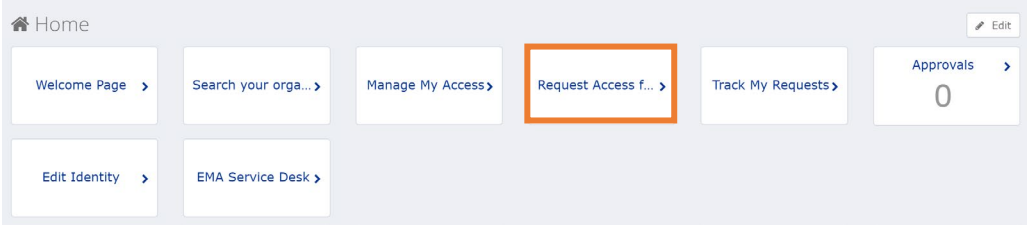
1. Once the users are registered and have credentials, they can open the EMA Account Management Homepage and **sign in using the EMA credentials**.



2. Users can introduce their **Username and password**.



3. Then they can click on the **Request Access for Organisations**' tile in the Account Management Portal dashboard.



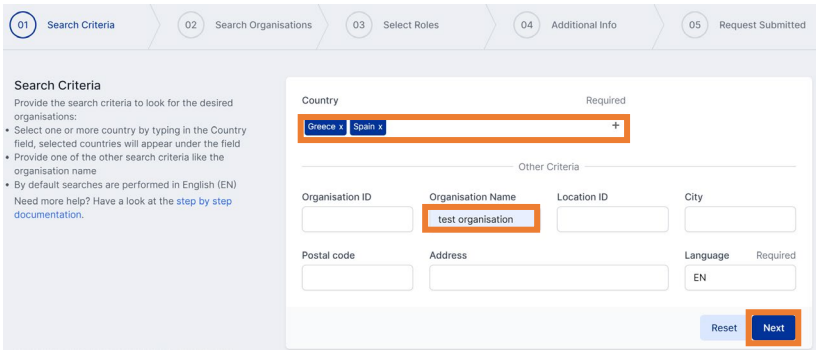
#CTIS insights

If users are not registered in the EMA Account management portal, a new EMA account will need to be created (*refer to the Quick guide of Module 3: User Access Management).*

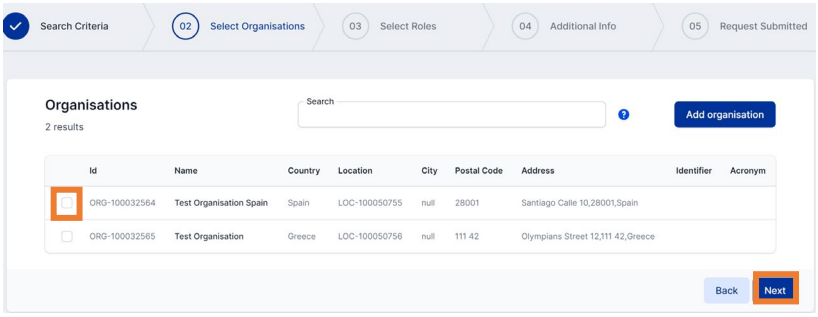
Users will receive a token to verify the account and a confirmation email of the registration.

Request a High-level Admin role

4. Once they are in the Request Access for Organisations page, they will add at least two search criteria: 'Country' (required) and organisation ID or Organisation name, etc. and then click '**Next**'

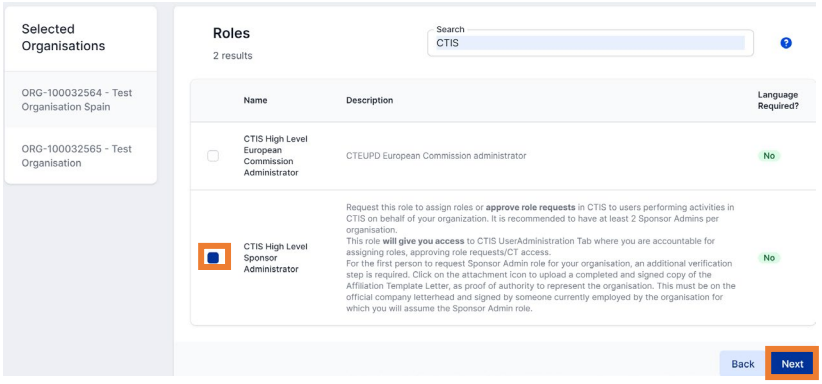


5. Once the criteria have been added, on the next page, they can select the organisation or organisations they want to request the role for.



Request the role

6. Once the organisation(s) has been selected, on the next page, they can search the key word '**CTIS**'. Users can select the **High-level Administrator** role to be requested and then they can click on the '**Next**' button.



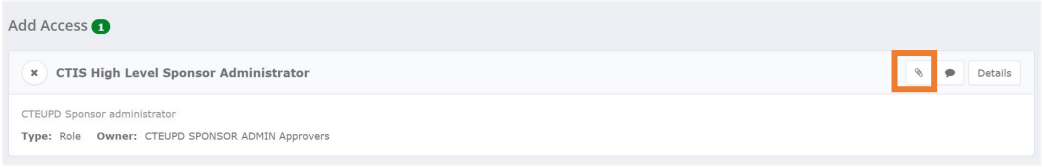
#CTIS insights

When the registration opens, users will be able to download a template of a letter of affiliation at https://register.ema.europa.eu/identityiq/help/affiliationtemplate.docx.

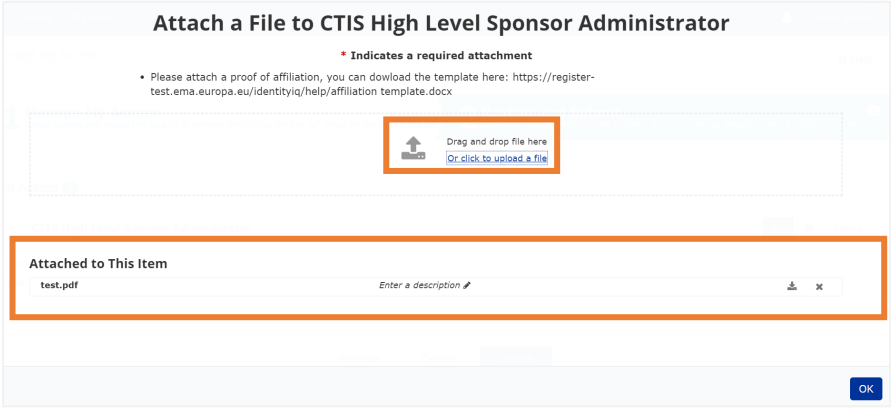
Users can add a description of the document by selecting the 'Pencil' icon next to the document.

Request a High-level Admin role

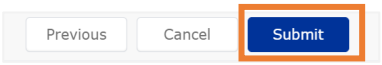
7. Users can click on the 'Attach' button (paper clip icon).



8. Then they can attach the *Affiliation Letter* and select the 'Ok' button. *This step is mandatory only if no other High-level Administrator or External Organisation Administrator exist for that organisation. If there is a High-level Admin, the necessity of this step is defined internally by the organisation's internal procedures.*



9. Finally, they can click on the 'Submit' button.



#CTIS insights

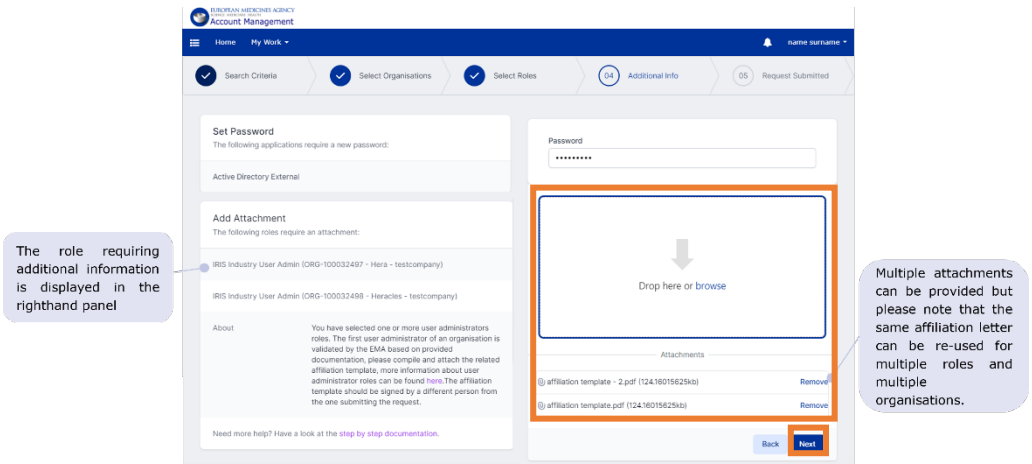
To request the MS Admin role, the user needs to populate the name of the organisation -or National Organisation- that has the responsibility to assign the roles of the MS Admin to authority users. *(Refer to appendix)*

When a request is approved, the user will receive a confirmation email.

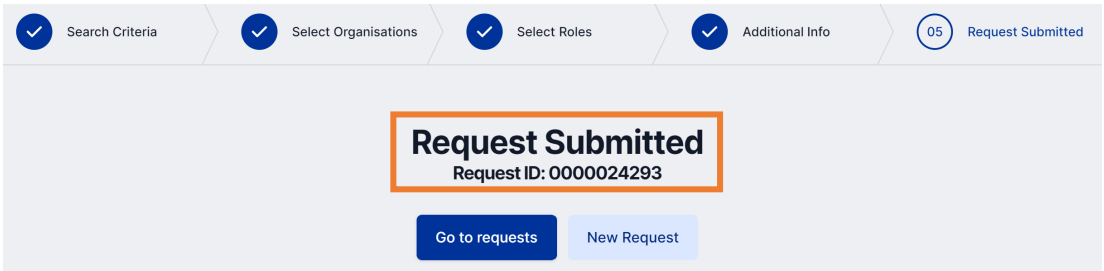
Request a High-level Admin role

Complete the form

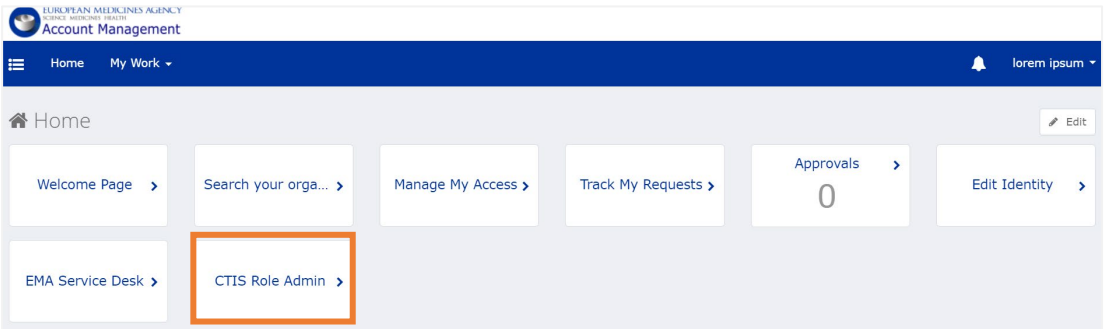
10. Once the users have attached the affiliation letter, they can click on '**Next**' button.
The **Additional Information** page is displayed only if the combination of selected organisations and roles requires it. If no additional information is required, your request will be submitted.



11. After the completion of the request, they will see that the request has been submitted and the Request ID.



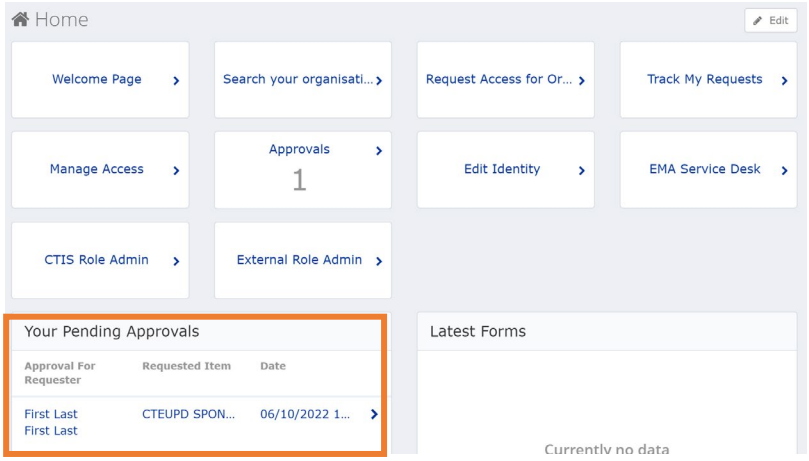
12. When the request is approved, a **new tile** will be displayed in the EMA Account Management portal **Home dashboard**: the CTIS Role Admin.



Approve /reject a High-level Admin role

Approve a request

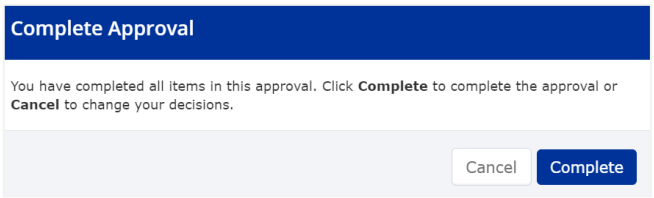
1. Users can view the request in the 'Your pending approvals' section EMA Account Management portal Home dashboard and click on the request.



2. They can review the request details.

3. Users can select the 'Approve' or 'Deny' button.

4. Finally, they can complete the approval by clicking on the 'Complete' button on the pop-up window.



#CTIS insights

CTIS High-level Administrator users will receive an email when a new request is submitted for approval. More information on the IAM process: https://register.ema.europa.eu/identityiq/help/useradmin.html

If multiple requests have been received, any of the already assigned CTIS High-level Administrator can approve or deny all requests by using the 'Approve all' or 'Deny all' button.

Appendix

Member State and European Commission Administrator Organisations

Member State/EEA country	MS ADMIN(S) ORGANISATION NAME	ORG ID
Austria	Bundesamt für Sicherheit im Gesundheitswesen (BASG)	ORG-100004043
Belgium	Federal Agency for Medicines and Health Products (FAMHP)	ORG-100003913
Bulgaria	Bulgarian Drug Agency	ORG-100003914
Croatia	Ministry of Health	ORG-100006835
Cyprus	Pharmaceutical Services, Ministry of Health	ORG-100003916
Czech Republic	State Institute for Drug Control	ORG-100003917
Denmark	Danish Medicines Agency	ORG-100003918
Estonia	State Agency of Medicines	ORG-100003919
Finland	Finnish Medicines Agency	ORG-100003920
France	Agence nationale de sécurité du médicament et des produits de santé (ANSM)	ORG-100003921
Germany	Bundesinstitut für Arzneimittel and Medizinprodukte (BfArM)	ORG-100003923
Greece	National Organisation for Medicines (EOF)	ORG-100003924
Hungary	OGYÉI-National Institute of Pharmacy and Nutrition	ORG-100003925
Iceland	Icelandic Medicines Agency	ORG-100003926
Ireland	Health Products Regulatory Authority (HPRA)	ORG-100003927
Italy	Agenzia Italiana del Farmaco (AIFA)	ORG-100003928
Latvia	State Agency of Medicines of Latvia	ORG-100003929
Liechtenstein	Amt für Gesundheit/ Office of Public Health	ORG-100003930
Lithuania	State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania	ORG-100003931
Luxembourg	Ministère de la Santé	ORG-100003932
Malta	Awtorità dwar il-Mediċini/ Medicines Authority	ORG-100003933
Netherlands	Central Committee On Research Involving Human Subjects (CCMO)	ORG-100010223
Norway	Norwegian Medicines Agency	ORG-100003936
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	ORG-100003937
Portugal	INFARMED - National Authority of Medicines and Health Products, I.P.	ORG-100003939
Romania	National Agency for Medicines and Medical Devices of Romania	ORG-100003940
Slovakia	Štátny ústav pre kontrolu liečiv/ State Institute for Drug Control	ORG-100003941
Slovenia	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	ORG-100003942
Spain	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)	ORG-100003943
Sweden	Läkemedelsverket/ Swedish Medical Products Agency	ORG-100003944

European Commission	ORG ID
Directorate General for Health and Food Safety	ORG-100003976

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