Step-by-step guide

Management of roles and permissions
High-level Administrator registration

CTIS Training Programme – Module 07
Version 1.2 – February 2022

Learning Objectives

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

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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 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. 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 your Username and password.

3. Then they can click on the ‘Manage my access’ tile in the Account Management Portal dashboard.

4. Once they are in the Manage my access page, they can search the key word ‘CTIS’.

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.
5. Users can select the **High-level Administrator** role to be requested and then they can click on the ‘**Next**’ button.

6. Users can click on the ‘Attach’ button (paper clip icon).

7. Then they can attach the **Affiliation Letter** and select the ‘Ok’ button. *This step is mandatory only if no other High-level 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.*

8. Finally, they can click on the ‘Submit’ button.
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)

9. Once the users have attached the affiliation letter, they can click on ‘Complete form’ button.

10. Users can search and select the organisation for which they are asking the role of Sponsor Admin. Once they have it, they can click on ‘Submit Request’ button.

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

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.
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.

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.
# Member State and European Commission Administrator Organisations

<table>
<thead>
<tr>
<th>Member State/EEA country</th>
<th>MS ADMIN(S) ORGANISATION NAME</th>
<th>ORG ID</th>
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<tbody>
<tr>
<td>Austria</td>
<td>Bundesamt für Sicherheit im Gesundheitswesen (BASG)</td>
<td>ORG-100004043</td>
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<td>Belgium</td>
<td>Federal Agency for Medicines and Health Products (FAMHP)</td>
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<td>Bulgaria</td>
<td>Bulgarian Drug Agency</td>
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<td>Croatia</td>
<td>Ministry of Health</td>
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<td>Cyprus</td>
<td>Pharmaceutical Services, Ministry of Health</td>
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<td>Czech Republic</td>
<td>State Institute for Drug Control</td>
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<td>Denmark</td>
<td>Danish Medicines Agency</td>
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<td>Estonia</td>
<td>State Agency of Medicines</td>
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<td>Finland</td>
<td>Finnish Medicines Agency</td>
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<td>France</td>
<td>Agence nationale de sécurité du médicament et des produits de santé (ANSM)</td>
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<td>Germany</td>
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<td>Greece</td>
<td>National Organisation for Medicines (EOF)</td>
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<td>Hungary</td>
<td>OGYÉI-National Institute of Pharmacy and Nutrition</td>
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<td>Iceland</td>
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<td>Spain</td>
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<td>Sweden</td>
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### European Commission

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