EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

Management of roles and permissions

CTIS Training Programme – Module 7

Version 1.3– October 2022

What you will find

- Answers to questions regarding basic principles to access CTIS for the first time.
- Answers to questions regarding roles and permissions.
- Answers to questions regarding CTIS user management approaches.
- Answers to questions regarding user profile management.
- Answers to questions regarding the main user groups.

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	**Updated question:** 2.6. How are high-level administrators validated by EMA?	October 2022
1.2	**New questions:** 5.4. Which roles can Member State users have? **Updated questions:** 2.5. How can users obtain a role? 2.7. What documents do users need to request to the high-level administrator role for the first time? 6.1. How can a user request a role?	February 2022
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FAQs

In this document, we list common questions regarding *Module 7: Management of roles and permissions*. They are categorised into questions about roles and permissions; the two user management approaches available in CTIS; user profile and user administration functionalities to respectively view roles and allow user administrators to manage the roles of other users, as well questions regarding the types of roles that the various user groups can perform in CTIS. As a reminder, a few questions have also been added regarding users' first access to CTIS. The specific learning objectives of this module are:

1. Remember the basic principles of user management in CTIS.
2. Understand the roles hierarchy and the main categories of permissions and roles available in CTIS.
3. Understand the permissions linked to the roles and their implications to perform actions in CTIS.
4. Remember how administrators can manage users with the User Management functionality.
5. Remember how roles can be viewed and managed in the system.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact the Service Desk. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1. Basic principles of access to CTIS

1.1. How can users register in CTIS?

Users who do not have an EMA account need to self-register to obtain access to the secured CTIS workspaces. To do so, they will need to select the relevant workspace they need access to, according to their business activities, from CTIS welcome page and click on 'Register New User'. This will redirect them to EMA's Account Management Portal where they will have to click on 'Create a new EMA account'. Afterwards, they need to fill in the *EMA - Self-service Registration Form* and an automatic email confirmation will be sent to them to confirm the account registration. It is important to highlight that, during this process, users who want to have administrator roles (either for the authority or sponsor workspace) for a particular organisation, need to share specific documentation authorising them to be the administrator and becoming affiliated to that organisation.

For more information on the process of self-registration through EMA's Account Management Portal, refer to the training materials of *Module 3: User Access Management functionalities.*

1.2. What is EMA Account Management system?

EMA's Account Management system supports Identity and Access Management (IAM)[1] at EMA for all EMA systems and applications, including CTIS. It stores user-relevant data and provides information, such as first name, last name, e-mail, or user ID to CTIS. Users need to obtain user credentials via EMA Account Management Portal to be able to access CTIS.

1.3. Why are roles needed in CTIS?

CTIS is a system developed to implement the requirements laid down in Regulation (EU) No 536/2014 (hereafter referred as CT Regulation), which contains a set of obligations and responsibilities for the various actors involved in the submission, evaluation, supervision, and reporting of CTs. Users with EMA accounts have a default role that will allow them to access CTIS and perform a limited number of activities. However, to perform additional actions relating to the CTs and, in accordance with their responsibilities, they need to be assigned specific roles by user administrators. This supports the proper management and oversight of the users using the system.

1.4. What is a CTIS role?

A role is a predefined group of actions that users are able to perform in CTIS regarding a Clinical Trial Application (CTA), or regarding data and documents submitted during the trial life-cycle, in accordance with their responsibilities established in the CT Regulation.

[1] EMA Account Management portal, *Self registration & access management*. Available at: https://register.ema.europa.eu/identityiq/home.html

1.5. Do users get a default role when they self-register to CTIS?

Yes. Once users receive the automatic email confirming the account registration, they can use their credentials to access CTIS. Users receive a default role (birth-right permissions) enabling them to access the system and perform a limited number of actions. To perform additional actions, users need to be assigned specific CTIS roles by an administrator user.

1.6. What can users do with the default role in the system?

This role allows users to perform the following actions in the system:

- View their role(s) by clicking on the username button and then on 'My roles'.
- View, create and update their personal and employer information by accessing their personal profile. If a new employer organisation needs to be created, users can also upload documents.
- Request a role to a high or medium-level administrator of their affiliated organisation (only in sponsor workspace).
- Create an initial CTA, if the sponsor organisation selected for the CTA does not have a sponsor administrator role (only for sponsor users).

2. Roles

2.1. How many roles are there in CTIS?

CTIS has a total of 48 roles across both workspaces, including administrator and business roles:

- There are up to 18 roles in the sponsor workspace, including 15 roles for sponsor users and 3 for Marketing Authorisation Holders (MAH) users.
- There are up to 30 roles in the authority workspace, including 24 roles for Member State users and 6 roles for European Commission users.

One user can have more than one role, enabling each organisation or Member State to structure their work in a flexible way, according to their needs and resources.

2.2. How is the scope of a role defined?

For a role to be assigned to a user in CTIS, the administrator user needs to define the scope as well. There are two scopes available for a role:

- **All trials:** the role assigned to the user covers all trials under the umbrella of the affiliated organisation of the administrator. (*refer to question 4.2*).
- **Specific trial**: the role assigned to the user is only applicable to a specific clinical trial. This option is available in both user management approaches (*refer to*

questions 4.2 and 4.4).

2.3. What are the main categories of roles in CTIS?

All roles in CTIS can be split into the following two main categories:

- **Administrator roles**: roles responsible for the management and oversight of users of their affiliated organisation or Member State, or in the context of a specific CT. These roles have the permissions to assign, amend, or revoke roles/CT access to other users to be able to perform actions in CTIS. In the sponsor workspace, administrators can also approve/reject role requests submitted by other users. These roles can view and access the 'User administration' tab. (*refer to question 6.2*).

  There are two types of Administrator roles: high-level and medium-level administrators. Both can manage user roles, although with different permission limitations (*refer to question 2.4*). Only the first high-level administration role needs to be validated and assigned by EMA, all the subsequent requests will be managed by the existing high-level admin.

- **Business roles:** roles that reflect the responsibilities of users during the life-cycle of a CT, as defined in the CT Regulation. They are assigned by administrator users, and they are linked to specific business permissions.

2.4. What is the difference between high-level and medium-level administrators?

While both types of administrators have the same user management permissions, there are differences mainly in the way they are approved, and in terms of the users that they can manage.

- **High-level administrators:** roles that can manage all users of their affiliated organisation or Member State, as applicable. When assigning a role in CTIS, they can always choose the scope 'all trials' or 'specific trial' (*refer to question 2.2*). These roles are purely administrators, and they cannot perform any business activity in the system unless they assign a business role to themselves.

  The Sponsor Administrator and the Marketing Authorisation Holder (MAH) Administrator are the high-level administrators in the sponsor workspace, while the Member State Administrator and the European Commission Administrator are the high-level administrators in the authority workspace.

  As an exception, it should be noted that the MAH Administrator, although it is a high-level administrator, has also linked the permissions of the MAH business roles (CSR viewer and CSR submitter).

- **Medium-level administrator:** roles assigned by high-level administrators in CTIS. They can also be assigned by other medium-level administrators from the same organisation. They can manage a number of users or all of them, of their affiliated organisation, depending on whether their scope assigned is 'specific trials' or 'all trials', respectively.

  - **CT administrator:** medium-level administrator for the sponsor user group.

The CT administrator role has the permissions of the business roles linked to it. This means that besides the administration of users, these users can also perform all sponsor business activities in CTIS.

- **National Organisation Administrators (NOA):** medium-level administrator for the Member States user group. It operates as the administrator of a Member State organisation, different from the one of the MS Admin (such as Ethics Committees).
- There is no medium-level administrator either for the EU Commission or for the MAH, which only have high-level administrators.

- Administrator roles that do not have linked business permissions can assign business roles to themselves (in case they are expected to perform business activities in CTIS as well).

Note: the 'Administrator' role is called 'Admin' in the system.

2.5. How can users obtain a role?

High-level administrator users can obtain their role by first self-registering in the EMA Account Management Portal (in case they do not have an EMA account already), and then submitting relevant requests via the EMA Account Management Portal (*refer to question 1.1*).

The rest of the roles are assigned in CTIS by the relevant administrator roles (*refer to question 2.4*).

In the sponsor workspace, users can also proactively request a role from the 'My roles' tab under the username button. This request needs to be approved by the high-level administrator or the medium-level administrator of the organisation the sponsor is affiliated to (*refer to question 2.4*).

2.6. How are high-level administrators validated by EMA?

EMA is responsible for validating the first request of users to become CTIS high-level administrators of an organisation of sponsors (Sponsor Admin), Member States (MS Admin) and the European Commission (EC Admin). EMA manages requests of users only if the organisations/Member State/European Commission have no CTIS high-level Administrator or External Organisation Administrator (more information on https://register.ema.europa.eu/identityiq/help/useradmin.html#OrganisationAdmin). A named person or legal representative of the organisation needs to be assigned for managing the organisation and its users. To that end, users are required to provide specific documentation to EMA for review in the EMA Account Management Portal when requesting a High-level Administrator for the first time in an organisation *(refer to question 2.7 and 2.8)*. More information can be found in the following sources:

- Affiliation letter: https://register.ema.europa.eu/identityiq/help/affiliation%20template.docx
- EMA Account Management Portal Homepage: https://register.ema.europa.eu/identityiq/home.html

The exception to this rule is the MAH administrator, which is assigned directly in CTIS by the EMA administrator. (*more information on the process in Module 13*)

Roles can be assigned to a user once the user logs in CTIS for the first time. Blank users need to log in first using small letters for the username (e.g. *hu-training* instead of *HU-Training*).

2.7. What documents do users need to request to the high-level administrator role for the first time?

In case no other high-level administrators have been assigned for an organisation, the requesting high-level administrators need to upload a completed and signed copy of the 'Affiliation Template Letter' as proof of the authority to represent that organisation. This must be on the official company letterhead and signed by someone currently employed by the organisation for which the user will assume the Administrator Role (i.e. a person working for the organisation and who can legally represent it). If no document is attached while requesting the role, the request will be denied by the system. Please note that no resubmission of the affiliation letter is required in case the signer of the submitted affiliation letter changes in the future, provided that once the first Sponsor Admin is nominated he/she will handle future nominations without EMA intervention.

2.8. Do users always have to request the high-level administrator role through the EMA Account Management Portal?

EMA is involved only in the management of user requests to become high-level administrators in organisations that do not have any other prior high-level administrator. This means that if there is at least one high-level administrator, EMA will not be involved in granting high-level administrator roles. Any new requests will then be managed by the existing Administrator(s) of the organisation. In this, case when a high-level administrator has been already assigned to an organisation, the affiliation letter is not mandatory, it is up to each organisation to request it from the users.

2.9. How many high-level administrators can a Sponsor organisation/ Member State have?

There is no limit to the number of user administrator that a sponsor organisation or Member State can have. It is up to them to decide the number of high-level administrator roles. Every organisation is advised to have more than one high-level administrator, as every high-level administrator can manage the other high-level administrator users of his/her organisation (i.e. approve or reject a request, or remove an existing one). Any high-level Administrator can remove the role of the other high-level administrators, regardless of the order in which they were assigned the role.

In the case of the authority workspace, Member State administrators can also delegate user management permissions to National Organisation Administrators (NOAs), which may be national competent authorities or ethics committees. NOAs will only be able to assign roles and permissions within their own organisation.

Similarly for the sponsor workspace, sponsor administrators can assign the role of 'Clinical

Trial administrator' to users of their affiliated organisations or working on behalf of such organisation.

2.10. Is there a limit to the number of changes of the high-level administrators?

There is no limitation in terms of changes to the high-level administrator roles. The changes regarding a high-level administrator role can be administered internally by another high-level administrator *(refer to question 2.9)*. To that end, it is advised to have at least two high-level administrators per organisation.

2.11. Is there a limit to the number of roles that an user can have?

There is, in principle, no limit to the number of roles a user can have simultaneously. The limit is established by the number of roles available for each user group. It is up to administrator users to assess how many roles a user can perform in CTIS.

2.12. Is there a limit to the number of users that can have the same role?

There is, in principle, no limitation. Still, considering that CTIS follows a hierarchical user management approach, it is recommended that high-level administrators are limited to a small number (e.g. 2 or 3 users). The number can be higher for the medium-level administrators depending on whether other organisations will be given access to the system (e.g. Clinical Research Organisations, for the sponsor workspace, or Ethics Committees for the MS workspace).

A business user cannot have the same role twice. The number of users with the same business role will depend on the number of users and CTs that each organisation or Member State carries out/manages.

2.13. How is the name of the business roles composed?

The names of the business roles reflect the area of action of a CT (e.g. Part I, ASR, Union Control) in which users are involved, and their access level permissions (e.g. viewer, preparer, or submitter) (*refer to question 3.1*).

3. Permissions

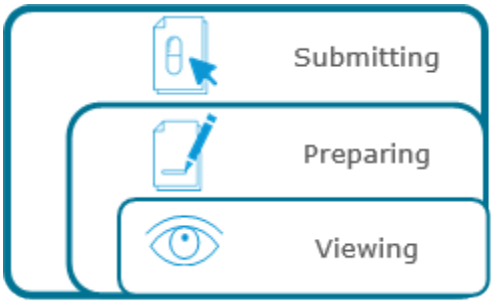
3.1. What are permissions, and what types are there?

Permissions are predefined levels of actions that users can perform on data and documents stored in CTIS. There are three types of permissions: User management permissions, Task management permissions, and Access level permissions.

- **User management permissions** allow administrator users to manage users of their affiliated organisation or a clinical trial.
- **Task management permissions** allow users with the CT Coordinator role to assign business tasks to MS business users and ensure optimal workflow management. This role is only available in the MS user group.
- **Access-level permissions:** allow business users to perform a set of actions on data and documents stored in CTIS. They are structured in cascade (*refer to question 3.2*).
    - **Submitting permissions** allow users to share, submit, and withdraw data/documents, and to update submitted data/documents (including all preparing and viewing permissions listed below).
    - **Preparing permissions** allow users to create, edit, upload documents, save and copy information from existing CTA to create a new one, as well as deleting or cancelling draft items (including also viewing permissions listed below).
    - **Viewing permissions** allow users only to view and download structured data and documents in different formats.

3.2. How are access-level permissions structured?

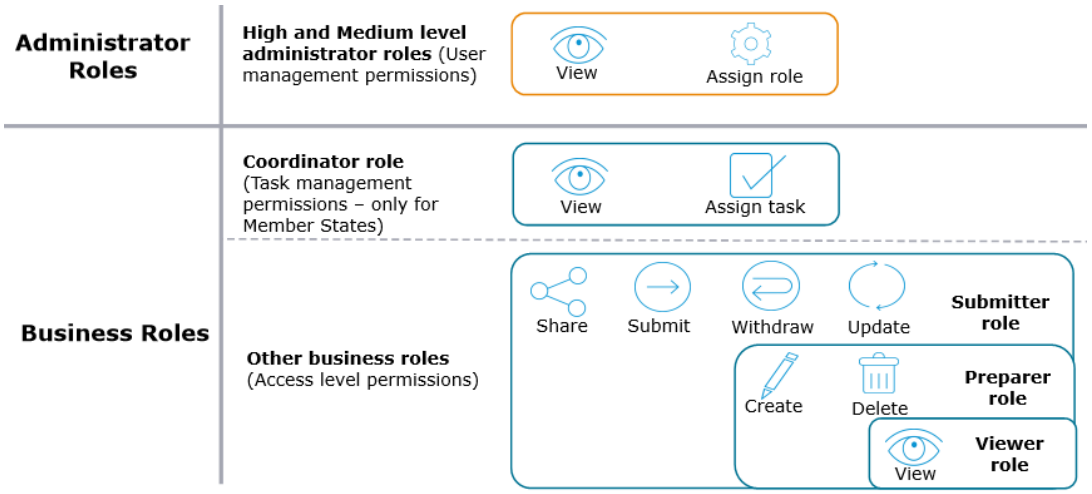
There is an established hierarchy for access-level permissions where submission permissions are the highest level, followed by preparing permissions and then by viewing as the basic set of permissions. They are structured in such a way that each level includes the permissions of the lower levels (i.e. submitting includes preparing and viewing, and preparing includes viewing permissions). This cascade system structure provides flexibility to the system. These permissions are linked to the different business roles.



3.3. How are permissions linked to the roles?

Every role contains a set of permissions already linked to it, enabling users to perform a different set of actions in the system (*see figure below*).

- **Administrator roles** have user administration permissions and therefore are able to view and manage users and their roles, of their affiliated organisation, Member State or within a CT.
- **Business roles** are linked to specific access-level and/or task management permissions, which reflect their responsibilities during the life-cycle of a CT in accordance with the CT Regulation. They are assigned by administrators and can be classified into two sub-types:
    - **The CT coordinator** (only available in the authority workspace): responsible for the administration of tasks, being able to view, assign or release tasks to/from preparers and submitters business roles.
    - **Other business roles**: roles with access-level permissions (view, prepare, or submit) related to their activities in the system. They perform specific activities in CTIS for a specific CT or all CTs of their affiliated organisation or Member State. For example:
        - For sponsors: *Part II preparer role* can create and delete drafts of Part II of the application dossier of a CT; the *Application submitter* can share, submit, withdraw and update the final version of an application while the *Part II viewer* can only view the information of Part II, but not edit it.
        - For Member states: The *Assessor part I preparer full rights* can create and delete drafts of the Assessment report and conclusion of Part I of the application dossier of a CT, but only the *Assessor part I submitter full rights* can share it, submit it, withdraw it, or update it in/to CTIS.



4. User management approaches

4.1. What user management approaches exist in CTIS?

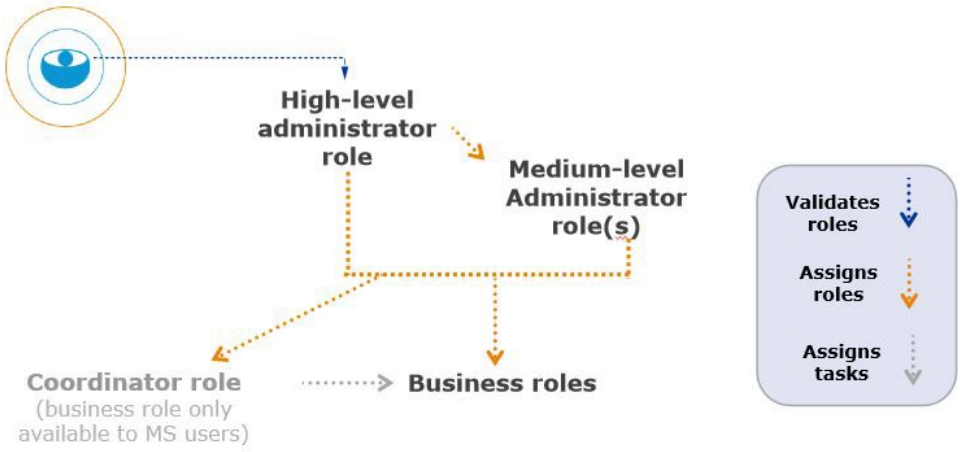
There are two user management approaches in CTIS, which enable organisations to manage their users according to their needs and resources: the Organisation-centric approach and the Trial-centric approach. The user does not choose the approach, but it is rather established automatically when the user performs certain actions in the system (*refer to questions 4.2. and 4.4*).

4.2. What is the organisation-centric user management approach?

Organisation-centric approach: general user management approach in which a high-level administrator, previously validated by EMA for the first time, is required. This approach is intended for big organisations managing a high number of users and CTs. It is optional for the sponsors, but it is mandatory for the MAH, the Member States and the European Commission. In the case of the sponsors, if the organisation for which a CTA is going to be created has a high-level administrator registered and validated by EMA, the applicable approach will be automatically the organisation-centric. Users will need to have roles assigned by the high-level administrators or delegated medium-level administrators to perform any action in the system. The users that have been assigned roles by the administrators become affiliated with their organisations. The high-level administrator will be able to manage and monitor all users of his/her organisation or the Member State, as applicable.

It should be noted that administrator users are able to assign a role to users for all CTs or for a specific CT that the organisation manages.

This approach is intended especially for authorised users, and big commercial sponsor organisations with a large number of users and that manage many CTAs and/or trials.



4.3. What are the advantages and disadvantages of the organisation-centric approach?

Advantages:

- It creates the opportunity to manage access and roles across trials and have good visibility of an organisation/MS CTIS users and workload.
- It improves security as access to CTs is centrally managed and enabled by role assignment/approval.
- In the sponsor user group, it prevents the submission of CTAs using any sponsor organisation, ensuring data quality (less duplication of data) and integrity.

Disadvantages:

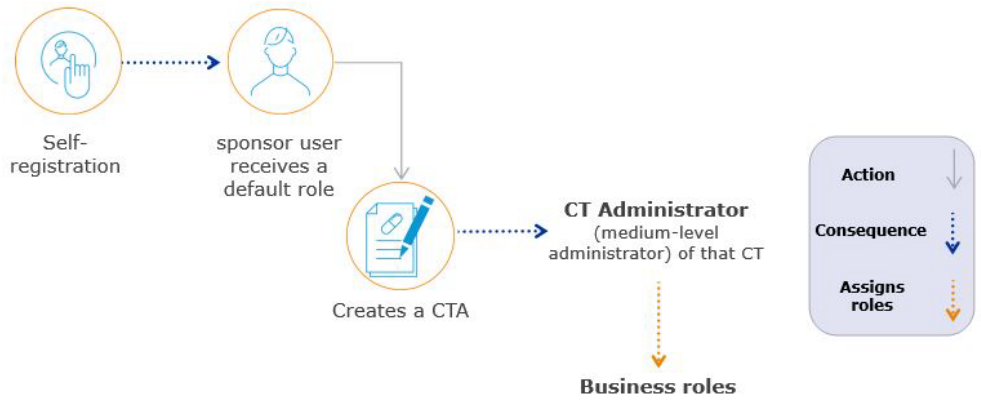
- It requires a formal registration process as the high-level administrator needs to be validated by EMA and appointed in the EMA Account Management portal.

4.4. What is the trial-centric user management approach?

Trial-centric approach: it is expected to be used by non-commercial sponsors managing a small number of users and CTs. This approach is only available for sponsors. It is the default approach if the organisation for which a CTA is created does not have a high-level administrator registered in IAM. It follows a bottom-up model since a high-level administrator is not required, as opposed to the organisation-centric approach. This increases the agility when submitting a CTA or when managing a small number of users. Any registered sponsor user can follow this approach by creating an initial CTA with the default role obtained when self-registering in EMA Account Management Portal (*refer to questions 1.4. and 1.5*).

The management of users under this approach is done by the CT Admin role, which is automatically created at the trial level.

This approach has been implemented in CTIS to facilitate the conduct of CTs by organisations with a small number of users and which manage few CTAs and/or trials (e.g. academia).



4.5. What are the advantages and disadvantages of the trial-centric approach?

Advantages:

- Allows a faster and less complex process when submitting a first initial application, as no validation process is required.

Disadvantages:

- Becomes less convenient when an organisation applies for or runs multiple trials.
- Provides the possibility for any user to create a CTA with a sponsor organisation if a sponsor administrator has not been registered and validated by EMA. This may have a negative impact on data quality and integrity and lead to data duplication.

5. User group roles

5.1. Which roles can sponsor users have?

Sponsor users can have high-level administrator roles (Sponsor Admin), medium-level administrator roles (CT Admin) and business roles, including:

- **Viewers:** Part I Viewer (exc Q-IMPD), Part II Viewer, Q-IMPD Viewer, Notifications Viewer, CT results Viewer.
- **Preparers:** Part I Viewer (exc Q-IMPD), Part II Viewer, Q-IMPD Viewer, Notifications Viewer, and CT results Viewer.
- **Submitters:** Application submitter, Notification submitter, CT results Submitter, ASR Submitter.

Please refer to the Roles and permissions matrix summary *(sponsors workspace)* document to get a visual representation of the roles available for sponsor users.

5.2. Which roles can MAH users have?

Marketing authorisation holders can have high-level administrator roles (MAH Admin) and business roles, including:

- **Viewer:** CSR viewer.
- **Submitter:** CSR submitter.

Please refer to the Roles and permissions matrix summary (sponsors workspace) document to get a visual representation of the roles available for MAH users.

5.3. Why is there a distinction between Sponsors (Industry and Academia) and Marketing Authorisation Holder (MAH) user roles?

The sponsor and MAH have different roles as they are responsible for performing different actions during the life cycle of a clinical trial. The Sponsor roles are responsible for the whole clinical trial process, including for the submission of the summary of results, while the MAH has only one function in the system, which is uploading the Clinical Study Report after the marketing authorisation has been granted. The MAH user performs actions in the sponsor workspace.

5.4. Which roles can Member State users have?

Member State users can have high-level administrator roles (MS Admin), Medium-level administrator roles (National Organisation Administrator or NOA), and business roles, including:

- **Viewers:** Viewer Part I full rights, Viewer Part I restricted rights, Viewer Part II, and BI Report viewer.
- **Preparers:** Validator preparer full rights (Part I & II), Validator Preparer rest. rights (Part I exc. Q-IMPD & II), Validator preparer Part II, Assessor Part I preparer full rights, Assessor Part II preparer, Supervisor preparer, Inspector preparer, BI Report preparer, and ASR assessor.
- **Submitters:** Validator submitter full rights (Part I and II), Validator Part II submitter, Assessor Part I submitter full rights, Assessor part II submitter, Supervisor submitter, Inspector submitter, Decision maker-submitter, and ASR Decision Maker-Submitter.
- **Coordinators:** CT coordinator.

Please refer to the Roles and permissions matrix summary *(Authority workspace)* document to get a visual representation of the roles available for Member States users.

5.5. Can an ethics committee be both a CT Coordinator and a National Organisation Administrator (NOA)?

CTIS allows assigning any type of role to any organisation. An ethics committee who has been delegated user management permissions as a NOA by a MS admin can also manage and assign tasks to users within its organisation, provided that he/she has been assigned a CT Coordinator role in combination with a business profile (e.g. Assessor Part II). In that case, that user will be able to manage and assign tasks to users of its own organisation, but will be limited to the business roles that he/she himself has been assigned by the MS Admin.

5.6. Which roles can European Commission users have?

European Commission users can have high-level administrator role (EC Admin), and business roles including:

- **Viewers:** Union Controller Viewer, and BI Report Viewer.
- **Preparers:** Union Controller Preparer, BI Report Preparer.
- **Submitters:** Union Controller Submitter.

Moreover, the EC Admin can also be assigned viewing roles corresponding to action areas of the Member States (Viewer Part I full rights, Viewer Part I restricted rights, Viewer Part II, and BI Report viewer). These roles are assigned by the MS Admin to the EC Admin and are meant to support the European Commission in fulfilling its oversight role.

Please refer to Roles and permissions matrix summary *(Authority workspace))* document to get a visual representation of the roles available for European Commission users.

5.7. What roles can EMA have?

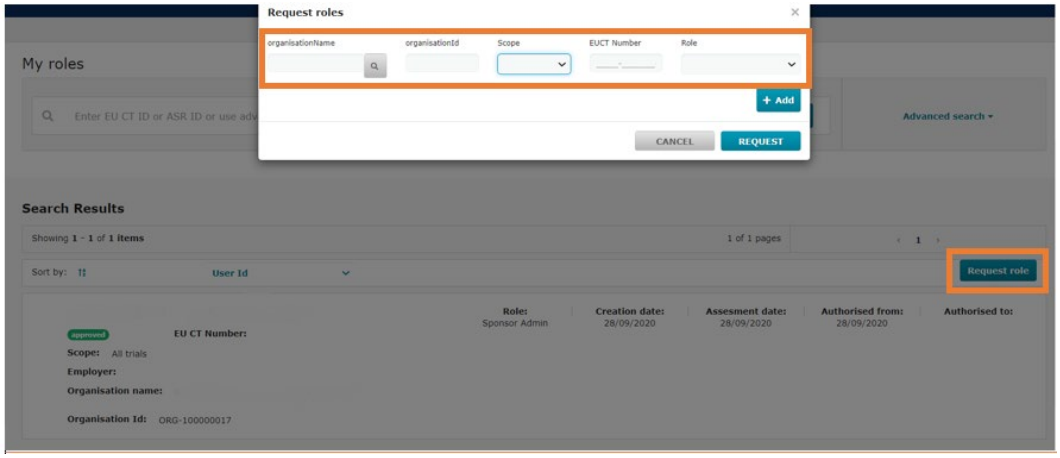
EMA users can only have a high-level administrator role (EMA Admin).

6. User profile management

6.1. How can a user request a role?

Only sponsor users can request a role; this option is not available for users in the Authority workspace, which can only be given a role upon invitation. In the sponsor workspace, a user can proactively request a role for a specific clinical trial or for all clinical trials managed by the organisation to the administrator user of that organisation. To request a role, users need to:

1. Click on their username button at the top-right corner of the CTIS interface and then click on 'My roles'.
2. Click on the 'Request role' button under 'Search results' of the 'My roles' sub-tab.
3. Populate the organisation name, ID, the scope of the role they are requesting, the EUCT number, and the desired role out of the ones displayed in the drop-down menu. The requesting users can limit the role to one trial (by selecting 'specific trial') or request the role for all trials that the organisation manages (by selecting 'all trials') from the scope drop-down menu.
4. Once the role is requested, it will need to be approved/rejected by the administrator user.



Note: users have to press 'Search' in order to view the roles as the system does not display then by default.

6.2. How can the administrator approve or reject a role request in the sponsor workspace?

Administrator users can access the 'user administration' tab, select the relevant role request received, and click on 'approve'. The administrator can also reject it. To do so, he needs to select the request and click on the 'Reject' button.

6.3. How can an administrator user assign a role to other users?

Administrator users can acces the 'User administration' tab and click on the 'Assign new role' button. In the pop-up form displayed, they need to populate the User Id, the EU CT number (only if the scope selected is 'specific trial'), the organisation name and Id, the role, the scope (-all- or –'specific trial'), the authorisation period (if applicable), and in the case of the authority workspace, also the NOA organisation name (mandatory field when assigning a role to a NOA). It should be noted that the role scope will limit the access to one CT only (if the option 'specific trial' is selected) or will cover all the trials that the organisation manages (if the option 'all trials' is selected).

6.4. How can an administrator user revoke a role?

Administrator users can revoke a role through the 'User administration' tab. In the results page of this tab, the administrator user can view all the roles that have been assigned in his/her organisation, or for the CTs under his/her role scope. In order to revoke a role, the user needs to select the role from the list by clicking on the box on the left-hand side of the relevant role, and then click on the 'Revoke' button, next to the 'Assign new role' button. High-level administrators cannot be revoked by other high-level administrators; only the EMA administrator can do this. This is the reason why the ticking box is not displayed for such users whose roles cannot be revoked.

6.5. How can an administrator user amend a role?

Administrator users can amend a role also through the 'User administration' tab. In that tab, the user can view all the roles that have been assigned and can amend one by selecting the role from the list, clicking on the box on the left-hand side of the role in question, and then on the 'Amend' button. A pop-up window will be displayed, which will need to be completed to finalise the process. Please note that the roles of high-level administrators cannot be amended.

6.6. How can users view their roles?

Users can view their roles by clicking on their username button at the top-right corner of the CTIS interface and then on 'My roles'. There, users can view the role(s) they have been assigned by an administrator user. Roles can be sorted by alphabetical order, user ID, email, employer, organisation name, organisation ID, role type, scope, EU CT number, creation date, assessment date, status, authorised from, or authorised to (dates).

6.7. How can users consult how long their roles will last?

In 'My roles' section (*refer to question 6.6*), users can view the roles they have been assigned. Among the information displayed for each role, on the right side of the screen, users will find the date from which the role is authorised ('Authorised from') and the date in which this role will finish ('Authorised to'). This period is determined by the administrator when assigning a role and can be amended by Administrator users (*refer to question 6.5*). Please note that the authorisation period is not a mandatory field. If the administrator user does not fill it out when assigning the role, both dates will be left blank.

6.8. How can administrators search for a specific user?

Administrator users can search for a user by clicking on the 'User administration' tab. In this page, they can use two search functionalities to look for users:

- **Basic search:** by populating the EU CT ID or ASR ID.
- **Advanced search:** by populating one or several of the following parameters: EU CT number, organisation name, organisation ID, user ID, user email, status, or period of creation of the role.

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Clinical Trials Information System (CTIS)
FAQs: Management of roles and permissions.