



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sponsor user management

SME and academia Clinical Trials Information System (CTIS) two-part training webinar

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Key principles



User management are a set of features and capabilities that enable CTIS administrators to **manage user** access to CTs through role assignment as well as for each user to manage their **own roles/profile.**

Only users previously self-registered in the EMA Identity and Access Management system (IAM) can be assigned with CTIS roles.



The CTIS User Management follows a **hierarchical approach**.

The CTIS **administrator roles** (Sponsor, MSs, EC, MAA, EMA) are the ones responsible to manage users through the CTIS user management functionality.



More than one user administrator per organization or per CT is possible in CTIS.

The CTIS users will have **access** to the CT system functions **according to their role**, so the system will display the appropriate data and also the appropriate activities for them.



The **profile of a user** can be built by combining roles.

User Management also allows any user:

Manage their roles: view, request (only in the sponsor workspace), amend role/provide access to CTs
Manage user profile (personal details and employer information).



User management hierarchy

User management hierarchy

A structured top-down approach to maintain the integrity of the system



Assigned in IAM after validation

High-level administrators
(Sponsors, MAA^{1,2}, Member States, EU Commission)

Assigned in CTIS

Medium-level administrators
(Clinical trial administrator¹ and MS national organisation administrators)

Assigned in CTIS

Business users

Self-registration



Administrator Roles

- Assign new role/CT access
- Amend role/CT access
- Revoke role/CT access
- Approve/reject user requests for a role (only applicable to sponsor users)

Business roles

- Role allocated to perform CT related activities in the system

1 The MAA role is the only high level administrator role that will be assigned in CTIS by the EMA Administrator
 2 These roles have also mapped the permissions of business roles: able to perform CT actions in CTIS on top of user administration



User management overview

User management overview



Management of Users



Management of own roles/ profile

User Administration:

Invitation (Admin users)

My Role:

Request (All users)

- Assign New Role/CT access
- Amend Role/CT access
- Revoke Role/CT access
- Approve/amend/reject role/CT access requests

- View/update profile
- View existing roles
- Request New Role/CT access
- Amend existing CT access

- Assign New Role/CT access
- Amend Role/CT access
- Revoke Role/CT access

- View/update profile
- View existing roles

(Authority roles will be by invitation only)

(Authority roles will be by invitation only, hence users do not have access to request new roles/access to CT)



Sponsor Workspace
(Sponsors, MAA)



Authority Workspace
(MS, EC, EMA)



User management approaches



User management approaches

Organisation Centric

- Available to all groups of users (sponsor, MSs, EC, MAH)
- A high level administrator is required i.e. needs to be assigned in IAM (sponsor admin, MS admin, EC admin) or in CTIS by the EMA Admin (MAA admin)
- Management of the users by this Administrator is at organizational level
- Users become affiliated to the organization of the high level administrator

Expected to be used by commercial sponsors

Trial Centric

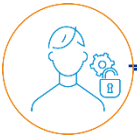
- Available only to sponsor
- Only feasible if no Sponsor Administrator is registered in IAM
- The user will be able to create a CTA through this approach becoming CT Administrator for that specific CTA
- Management of the users by the CT Administrator is at trial level
- Users to are not affiliated to any sponsor organization

Intended to facilitate the conduct of CTs by non-commercial sponsors

Role scope

“ALL”CTs: access to all trials under the umbrella of the organization of the administrator

Specific CTs: allows access to a subset of trials under the umbrella of the organization of the CT administrator





Video clips

EMA CTIS training programme Module 03 – User access management



Click [here](#) for online training materials related to this module.

EMA CTIS training programme Module 07 – Management of registered users and role matrix



Click [here](#) for online training materials related to this module.

EMA CTIS training programme Module 07 – Management of registered users and role matrix



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Any questions?

Further information

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