FAQs

User Access Management

CTIS Training Programme – Module 03
Version 1.3 – April 2022

What you will find

- Answers to common questions regarding User Access Management in CTIS.

- An overview categorised in questions of a general nature and questions related to the processes of login to CTIS, user profile management, basic roles and permissions in CTIS, and organisations.

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FAQs

In this document, we list common questions regarding Module 03: User Access Management. They are categorised in questions of a general nature and questions related to: the process of login to CTIS and accessing the landing page; user profile management, the basic roles and permissions in CTIS; and organisations. The specific learning objectives of this module are:

1. Remember how to log into CTIS and access the landing page.

2. Understand roles and permissions (high level, introduction).

3. Understand user profile management functionality.

4. Understand how to search for an organisation and submit a request to create one in CTIS.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. 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. General information

1.1. What is EMA Account Management system?

EMA's Account Management system supports Identity and Access Management (IAM) at EMA for all EMA systems and applications, such as CTIS, SPOR, IRIS, EudraVigilance and UPD. 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 an EMA account to be able to access CTIS. They can create a new account by completing the Self-service Registration form, available in the EMA's Account Management system. *For more information, please refer to 'How to create a new EMA account' guide.*

1.2. If users already have an EudraLink account, do they need to re-register to access CTIS?

If users have already done the self-registration to obtain an EMA account and have credentials to access EMA systems and databases, for example, Eudralink or SPOR, there is no need to self-register again. They should be able to use their existing credentials to access CTIS.

It should be noted that administrator users will need to follow the additional steps to request an Admin role via the EMA Account Management Portal.

Please refer to the 'How to log in and use the site' page, to consult all the EMA-hosted websites or online applications linked to the IAM System, which credentials can be used to access CTIS.

If users need to recover their username or password, they can refer to the 'Recover your credentials and re-activate your account' guide on the EMA Account Management website.

1.3. If users change to a different company, what should they do with their accounts?

The appropriate course of action when users are changing company or organisation is to close their EMA account by opening a ticket with the EMA Service Desk and creating a new one. More information on how to register a new EMA Account and how to disable an old account is available at:
https://register.ema.europa.eu/identityiq/help/faq.html#changeemployer

1.4. Who can access CTIS?

CTIS is structured in two restricted and secured workspaces (sponsor workspace and authority workspace) and a public website.

Access to the secured CTIS workspaces is possible for any user that has obtained a valid EMA account (for any application managed by the EMA, e.g. SPOR, IRIS, EudraVigilance). If users do not have an EMA account, they will have to register through the self-registration process (*for more information, please refer to the* '*How to create a new EMA account'* *guide).* The sponsor workspace is accessible to sponsor users (industry and academia) and marketing authorisation applicants. The authority workspace is accessible to Member States' national competent authorities, ethics committees, the European Commission, and the European Medicines Agency. Access to the public website is possible for any user without the need for registration.

It should be noted that, as a general rule, roles must be given to registered users by the administrator(s) of the organisation and after registered users have already logged in one time in CTIS, using their EMA account credentials. This is always the case for authority users, who need to be assigned particular roles by the administrator user(s) to be able to work on CTIS.

The same applies to sponsor users who will work for an organisation that has a Sponsor Administrator user-appointed in IAM (so-called organisation-centric approach). However, no role is needed to be assigned to sponsor users when such users create a new Clinical Trial Application (CTA) for organisations that have no administrator users appointed in IAM (so-called CT-centric approach). In this latter case, the user will automatically receive a CT administrator role for the trial(s). Still, access will be strictly restricted to the trials created by the user, regardless of the existence of other CTAs created by other users using the same organisation.

1.5. What is OMS?

The Organisation Management Service (OMS) is a system managed by EMA which provides a single source of organisation data for CTIS, such as organisation names and location addresses. CTIS can also push information to this database when new organisations are created directly by the CTIS users. The organizations that need to be registered in OMS to be available for CTIS are Sponsors or co-sponsors, third party contractors (e.g. CRO - Contract Research Organization), EEA trial sites, and Marketing Authorisation Holders.

1.6. If CTIS is not working properly, how can users get assistance?

Once the system goes live, a maintenance team will be set up to take care of the assistance requests. These will be communicated via a Service Desk, as in other systems managed by EMA in the following link EMA's general Service Desk.

In case users do not have credentials for CTIS, they can call the EMA Service Desk telephone number: +31 (0) 88781 7523.

2. Login and Landing page

2.1. How long does it take between submitting the registration form and being able to access a secured workspace in CTIS?

Users can access a secured workspace in CTIS immediately after receiving a confirmation e-mail stating that their account is valid. Please note that, in some cases, it may take up to a working day until the account becomes active.

2.2. How can users log into a secured workspace in CTIS?
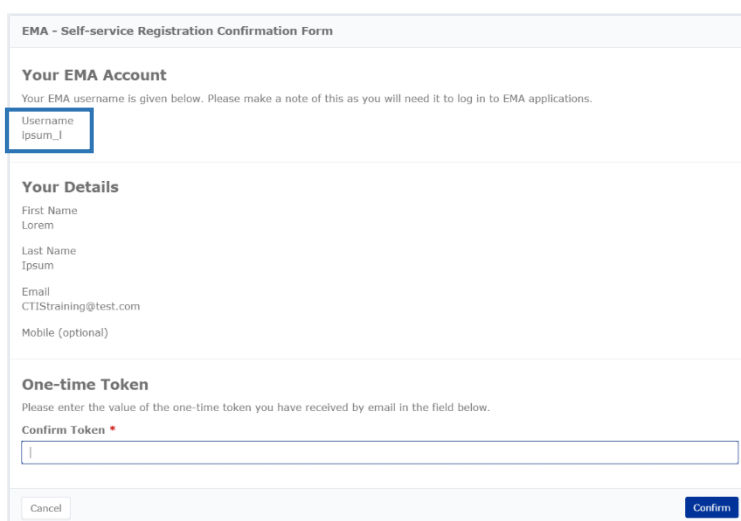
Users can access the CTIS interface through two workspaces:

- Authority: https://euclinicaltrials.eu/ct-authority-services/login

- Sponsor: https://euclinicaltrials.eu/ct-sponsor-services/login

Once they are in the corresponding workspace, they can populate the fields 'username' and 'password' with their user credentials. After users have populated both fields, they can click on the button 'Login'.

2.3. Where can users see their credentials to access a secured workspace in CTIS?

The username will be given to users at the end of the registration process in the EMA Account Management system, concretely at the Self-service Registration Confirmation Form. Please see the screenshot below:

The username is composed of the last name and the first letter of the user's first name. Users need to make sure to make a note of it in order not to forget it. The password will be the same that they entered at the beginning of the Self-registration process, concretely in

the Self-service Registration Form. The username will also be sent to the users in the account confirmation email.

2.4. What should users do if they have forgotten the password?

If a user has forgotten the password, they need to follow these steps:

1. Click on 'Forgot password?' on the login page.

2. Introduce the username in the EMA Account Management Portal.

3. Answer the security questions introduced at the time of completion of the self-registration form.

4. Introduce the one-time token sent to the e-mail.

5. After entering the one-time token, users will be able to include a new password. Re-enter the password for confirmation and click on the 'Submit' button.

The password must be at least 8 characters long and contain 4 different character types. For example, the following ones obey the rules; P4$$w0rd, Americ@52, M3d!cines.

3. User profile

3.1. How can users reset their passwords?

Users can reset their password by:

1. Accessing their 'Personal Profile', clicking on their 'Username' button at the top-right corner of the interface of CTIS.

2. Click on the tag 'Password reset'. This is a link, which will redirect them to the EMA Account Management system (IAM).

3. Enter their username and password.

4. Answer the security questions introduced in the self-registration form.

5. Enter the new password and click on the 'Submit' button.

   a. The password must have the following characteristics: it must have at least 8 character(s); it must have at least 4 valid character types (out of lowercase letters, uppercase letters, digits, and special characters); it must have at least 1 uppercase letter(s), and; it must have at least 1 special character(s) For example, the following ones obey the rules; P4$$w0rd, Americ@52, M3d!cines.

3.2. How can users update their personal information?

Users can update their personal information (name, e-mail or any other details) by submitting a request via EMA Service Desk. For more information, refer to the FAQ's

[document on the IAM homepage](#).

3.3. How can users update their employer's information?

In the Personal profile in CTIS, users will see the button 'Update my employer information'. A screen will pop up where users will be able to search and select the organisation they work for. The data of their organisation will be updated in CTIS automatically. Users should populate that field with their employer information and do not include partner organisations (i.e. CRO employees will populate their CRO employers' details and not partners' details such as pharmaceutical companies).

3.4. What is the difference between 'my employer' and 'my affiliated organisation'?

The employer is the organisation that employs the user (i.e. the user has a working relationship with). The affiliated organisation is the authority/sponsor organisation that assigns a role to the user to be able to perform clinical trial actions on their behalf. The employer and sponsor organisation may be the same or a different one.

4. Roles and permissions

4.1. What are permissions?

Permissions are predefined levels of actions that can be performed on data and information stored in CTIS. These include: business permissions (e.g. create considerations, create responses to RFI), access permissions (view, prepare, and submit) and other types of permissions related to user management and task management. Access level permissions are structured in a cascade system, where viewing permissions are the lowest permission level, and submission permissions are the highest.

4.2. What are roles?

Roles are predefined groups of actions that users can perform in CTIS regarding a clinical trial application, or regarding data and documents submitted during the trial life cycle, in accordance with their responsibilities. They come with permissions attached (refer to question 4.1):

- **Administrator roles** are those that can assign roles to other users to be able to perform actions in CTIS for their organisation e.g. Sponsor Administrator/CT Administrator (sponsor workspace) and Member State Administrator/National Organisation Administrator/EU Commission Administrator/EMA Administrator (authority workspace).

- **Business roles** are those that reflect the responsibilities of the user during the life cycle of a clinical trial. They are assigned by administrator users as described above.

A CTIS user can be assigned one or a combination of roles, and such roles can be revoked at any moment. Find below a brief diagram with some examples matching roles and permissions in CTIS.
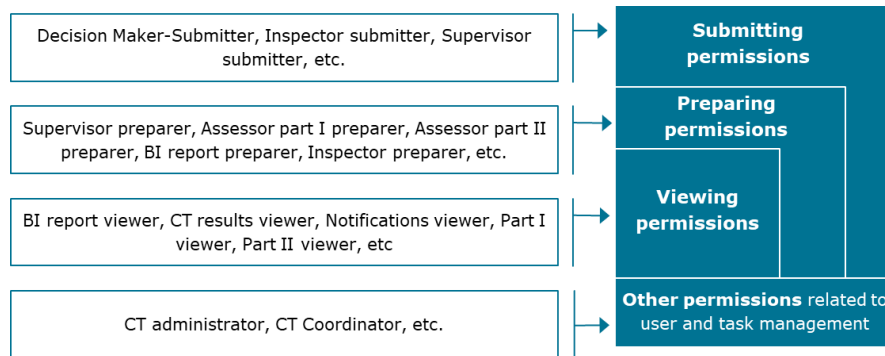
4.3. Do users need to be affiliated to or registered with an organisation to be given roles in secured CTIS?

No. All registered users receive a 'default' role in CTIS with birthrights that enable them to access the landing page of a relevant secured workspace in CTIS. Once the authority or sponsor landing page is accessible, users need to be assigned a role by a user with an administrator role to be able to perform actions in the system for that particular Authority or Sponsor Administrator organisation, as applicable. From the moment a role has been assigned to a user, he/she becomes automatically affiliated to that Authority or Sponsor organisation.

4.4. What should users do if they have access to the secured CTIS landing page, but they are not able to see any information?

As a general rule, users will only be able to have access to clinical trials data/documents once they have been assigned roles by the administrator(s) of the organisation for which the user will perform CT-business related activities (organisation-centric approach), or by the system (only applicable to the sponsor workspace) in case they follow the CT-centric approach. *For more information, refer to question 1.4 above.*

In the case of the sponsor workspace, users may also request a role to the relevant sponsor organisation administrator from the sub-section 'My roles', which is displayed when clicking on the username (top right-hand side of the screen). This is only possible if the organisation the user wishes to become affiliated to perform CT-business actions is registered in OMS. *For more information about OMS, r*efer to question 1.5.

In the authority workspace, administrator users will have to assign a role to the users and they cannot proactively request one via the system.

Please note that role updates in the system may take a few hours to process. Make sure to

log out and log in to CTIS to be able to see new roles updates.

4.5. Where can users see their roles?

Users can see their roles by clicking from the sub-section 'My roles', which is displayed when clicking on the username (top right-hand side of the screen).

4.6. Where are roles saved?

In general, the roles assigned to CTIS users are saved in CTIS and are created and managed by users with administrator roles. Yet, some administrator users are stored and managed in the EMA Account Management system. *For more information on how to get admin user credentials in CTIS, refer to question 4.7.*

4.7. How can users get an administrator role?

If users want to request one of the following high-level user administrator roles for their sponsor organisation or authority organisation (i.e. European Commission Administrator, Member State Administrator, Sponsor Administrator), they need to submit their request in the EMA Account Management portal and they might need to attach specific documentation, if applicable. These roles are appointed in EMA's Identity Access Management. EMA will be managing users' requests to become high-level administrators in organisations that do not have any other high-level administrators. If the organisations have high-level administrators, those administrators will manage any users' requests, not EMA.

Other administrator roles which are more limited in scope (i.e. CT admin, MAH admin and National MS admin) are managed directly in CTIS.

For more information, refer to questions 2.7 and 2.8 of Module 07 – FAQ's document.

4.8. Can one user be assigned more than one role?

Yes. 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.

5. Organisations

5.1. How can users check that the organisation exists in OMS?

Users can use the search functionalities in OMS portal or the organisation search functionalities in CTIS. If the required organisation is not found in the results, the

organisation does not exist in OMS. In that case, users will need to submit a request either via OMS or via CTIS.

More details can be found in the [Quick Guide OMS](#) of [Module 03](#), in the documentation, found on the [OMS portal](#) (on the 'Documents' subtab), or in [CTIS Handbook](#).

5.2. In case the organisation has different departments and clinics, should the user register them in OMS?

If all the departments belong to the same legal entity, users need to register only one organisation with one ID. If the departments and clinics belong to multiple legal entities, they will need to register as many organisations as the number of the legal entities.

If all the clinics and departments belong to the same organisation but are located at different physical addresses (i.e. clinic A is located to XYZ Street 03 and clinic B is located to XYZ Street 13), then users will need to register as many different locations as the number of the different physical addresses, always below the same organisation-ID. The details of the departments or clinics are neither populated nor maintained on OMS, but locally in CTIS, when users create and submit clinical trials. The details are populated in Part II, in the 'Department' field of the 'Investigator information' form. *For more information, refer to Module 10.*

5.3. How can users update the details of an organisation?

If users can find their organisation in OMS, but not the location they are looking for, they need to submit a request to update the details of an existing organisation via OMS. Users need to have a SPOR Industry/NCA (Super) user role to be able to submit such requests via OMS, regardless of the organisation the user is affiliated to.

SPOR Industry (Super) user roles can be requested by any user, including pharmaceutical companies, Contract Research Organizations (CROs), SME and Academia organisations, hospitals, 3rd world companies' users.

For more information, refer to the [Quick Guide](#) of Module 03, as well as the 'Z - SPOR User Registration Manual document', found in the [OMS portal](#) (under 'Documents' subtab).

5.4. If a trial site and a CRO have the same physical address, do users need to maintain different organisation IDs?

It depends on the legal entities of the trial site and the CRO (i.e. a start-up, or a CRO owned by a big university). If the same legal entity owns both organisation and CRO, only one organisation-ID needs to be registered to OMS. If the two organisations under the same legal entity happen to have the same physical address, only one location should be registered under the organisation-ID for both trial site and CRO. If they have different physical addresses, then one location for each organisation needs to be registered under the same organisation-ID.

5.5. What is 'Organisation ID' in CTIS and how is it assigned?

The Org identifier (ID) is automatically generated by OMS at the time of the creation of an organisation. This ID is specific for each organisation, which means organisations within the same company with different names will have different IDs. The Org ID is composed of ORG-1000 plus a random number created by the system.

The Organisation ID is communicated to the user via e-mail once the new Organisation record has been created in OMS. If a user does not have this information at hand and would like to view it, he/she can retrieve it by searching for their organisation in OMS.

5.6. Does the Institutional Review Board (also known as an independent Ethics Committee) need to register in OMS?

Yes, ethics committees' organisations have to be registered in OMS before they can log into CTIS. OMS is an already functional database maintained by EMA and some organisations such as NCAs are already registered. Any ethics committee aiming to use CTIS should be registered in OMS, ideally before CTIS go-live.

5.7. Can a trial be created before the organisation is validated?

The ID provided by the system at this point is not the final Organisation ID and its status is 'Pending' instead of 'Active', however, it can be used this time to allow users to submit the data that they have prepared (CTA submission, notification submission, inspection record submission, etc.).

The status will remain as pending in the record of the trial even though OMS has positively validated the organisation. An RFI can be raised so the sponsor can explain that the organisation has been validated but the status will remain as pending.

Next time the user accesses the system, the validated organisation can be selected, and the status will be displayed as 'Active'.

Sponsors				
Name	**Organisation type**	**Country**	**Type**	**Status**
Test Organisation Italy	Industry	Italy	Commercial	Pending

5.8. How do users know if the organisation has been validated?

Once the change request is validated and processed by the OMS team, the user will receive an email acknowledgement with the outcome:

- **Approved Change request:** acknowledgement that will contain the outcome and the correspondent Organisation-ID.

- **Rejected Change Request:** acknowledgement that will contain the outcome, reason for rejection and, when applicable, guidance on necessary steps for a successfully approved change request.

5.9. Can users submit multiple requests to create organisations in OMS?

Yes. Users should note that the validation and approval of the requests to OMS might take up to 10 working days, depending also on the correctness of the provided documentation. If users need to be able to submit multiple requests for various organisations (without waiting for prior requests to be handled) they need to obtain the role of the NCA (Super) user or Industry (Super) user for an organisation already registered in OMS (not necessarily theirs; it can be an organisation they represent). *For more information, please refer to the 'Z - SPOR User Registration Manual document', found in the [OMS portal](#) (under 'Documents' subtab).*

Users become affiliated to this organisation once the requested role is assigned to them. Users need to request one of the aforementioned roles via EMA Account Management. On how to request various roles via EMA Account Management, including the NCA or Industry (Super) User role, users may consult the [relevant documentation from EMA Account Management homepage](#), and particularly the tile '[Request access on behalf of an organisation](#)' or the '[request user access](#)' guide.

In case there is no registered organisation in OMS to be affiliated with (either the user employer or an organisation to be represented), users will need to submit a request for a new organisation and wait until the request is approved. After approval of the request, users can request one of the aforementioned roles for the new organisation and be able to submit multiple requests at the same time.

Clinical Trials Information System (CTIS)
FAQs: User access management.