FAQs
User Access Management
CTIS Training Programme – Module 03
Version 1.2 – January 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 self-registration, login to CTIS, basic roles and permissions in CTIS, user profile management 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 self-registration in CTIS via EMA’s Account Management system; the process of login to CTIS and accessing the landing page; the basic roles and permissions in CTIS; and user profile management. The specific learning objectives of this module are:

1. Understand the process of self-registration of a user in IAM.
2. Remember how to log into CTIS and access the landing page.
3. Understand roles and permissions (high level, introduction).
4. Understand user profile management functionality.

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, 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.

1.2. 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 valid EMA credentials (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 described in question 2.1. 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 for which clinical trials-business related actions will be performed. 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 him/her, regardless if other CTAs have been created by another user using the same organisation.

1.3. 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.
1.4. 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. **Self-registration**

2.1. 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’.

They will be asked to complete the Self-service Registration Form, followed by a set of security questions, and they will receive a one-time token via e-mail that they will need to enter to complete the registration process.

After they have completed the registration process, an automatic notification will be sent to the e-mail address that was provided to confirm their account registration. In this email, they will find the username for their EMA account, composed of their last name and the initial letter of their first name. This username will be requested for accessing CTIS, along with the chosen password.

If users are not sure whether they already have an EMA user account, they can go to the EMA Account Management Portal and click on the ‘Not sure if you have an EMA account?’ to verify.

Please, find a video outlining the process of self-registration on our Training platform and our additional materials for training Module 03.

2.2. For how long is the one-time token received via e-mail valid?

The one-time token, received in the registration e-mail, will be valid for a maximum of 24 hours. Users should be receiving the one-time token almost immediately. **In case they do not receive it, please refer to question 2.3.**
2.3. If during the self-registration, users have not received the one-time token in their e-mail. What should they do?

In this case, users can check that the e-mail with the one-time token has not been sent to the spam folder. In case users have not received the one-time token on the spam folder, they can contact the EMA Service Desk at +31 (0) 88781 7523.

2.4. After completing the process of self-registration, how long does it take until users receive the confirmation e-mail?

It should occur almost immediately. However, in some cases, it could take a few hours. If users have not received it within one working day, they are advised to check the spam folder on their e-mail box as it could be stored there automatically.

In case users have not received the confirmation e-mail, they can call the EMA Service Desk telephone number: +31 (0) 88781 7523.

2.5. Does the self-registration need to be validated by someone before users get access to a secured workspace in CTIS?

There is no approval process for self-registering users. Users can access the CTIS landing page immediately after they have received a confirmation e-mail that their EMA account is valid. Please note that, in some cases, it may take up to a working day until the account becomes active.

Bear in mind that, as a general rule, users will only be able to access clinical trials data/documents once they have been assigned roles by the administrator(s) of the organisation for which they will perform CT-business related activities (organisation-centric approach), or if users are a CT Administrator for a clinical trial with a sponsor organization that has no sponsor administrator role registered (only applicable to the sponsor workspace) in case they follow the CT-centric approach. For more information, refer to question 1.2.

2.6. Apart from the username, does the system generate a password for the users?

No, the password is set up by the user. The system provides a one time-token via e-mail to be included in the in the Self-service Registration Confirmation Form. Before introducing the one-time token, users will see the username automatically generated by the EMA’s Account Management Portal, along with their personal information. This username will be requested, together with the chosen password, in order to log into CTIS, so users are advised to take a note of it. Once the self-registration request is submitted, an automatic confirmation email will be sent to the email address provided by users to confirm the account registration.
2.7. Is it mandatory for a user to update the EMA account password on a regular basis for it to remain valid?

No, users are not forced to reset their EMA password on a regular basis. However, if an EMA account has not been used for 6 months (14 months in the case of experts), it will be automatically disabled. Notifications are sent 2 weeks, 1 week and 1 day before disabling the account.

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

The appropriate course of action when a person is changing company or organisation is to close his/her EMA account by opening a ticket with the EMA Service Desk and to create a new one. More information on how to register a new EMA Account and how to disable an old account is available at:

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

If users have already done the self-registration and has 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 this link to check all the EMA-hosted websites or online applications linked to the IAM System, which will use the same credentials.

3. Login and Landing page

3.1. 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.

3.2. 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'.

3.3. 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 users 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.

3.4. 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, M3dlcines.

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 birth rights that enables 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 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 1.2 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, refer to question 1.3.

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. User profile

5.1. How can users reset their password?

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, M3dlcines.

Please, find a video outlining this process on our Training platform and our additional materials for training Module 3.
5.2. 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 of the IAM homepage.

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

In the Personal profile, 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.

5.4. 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 labour 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.

6. Organisations

6.1. 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.

6.2. 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 to
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.

6.3. 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 request 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 organisation, hospitals, 3rd world companies users.

For more information, refer to the Quick Guide of Module 03, as well as the documentation of OMS portal – document Z - SPOR User Registration Manual.

6.4. 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.

6.5. What is ‘Organisation ID’ in CTIS and how is it assigned?

The Org identifier (ID) is automatically generated by OMS at the time of 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 by 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.

6.6. 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.

6.7. 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’.

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

Once the change request is validated and processed by 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.