EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

User Access Management

CTIS Training Programme – Module 3

Version 1.1 – November 2020

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, and user profile management

This training material describes and reflects preliminary versions of CTIS and will be revised in 2021 to match the Go-Live version and thereafter to match subsequent releases post Go-Live.

Therefore, this material is at this time to be considered DRAFT and is not to be further reproduced or distributed.

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FAQs

In this document, we list common questions regarding *Module 3: 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.

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

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 in order 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 worksapce) and a public website.

Access to the secured CTIS workspaces is possible for any user that has obtained valid user credentials 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) in order 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 organizations 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 in order to be available for CTIS are Sponsors or co-sponsors, third party contractor (e.g. CRO), EEA trial site, and Marketing Authoritsation Holders.

1.4. If CTIS is not working properly, who should I contact to 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. EMA's general Service Desk is available at:

https://servicedesk.ema.europa.eu/jira/servicedesk/customer/user/login?nokerberos&destination=portals.

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

2. Self-registration

2.1. How can I register in CTIS?

You need to self-register to obtain access to the secured CTIS workspaces. To do so, you will need to select the relevant workspace you need access to, according to your business activities, from CTIS welcome page and click on ‘Register New User’.

This will redirect you to EMA’s Account Management Portal where you will have to click on 'Create a new EMA account'.

You will be asked to complete the Self-service Registration Form, followed by a set of security

questions, and you will be sent a one-time-token via e-mail that you will need to enter to complete the registration process.

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

If you are not sure whether you already have an EMA user account, 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 3.

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

The one-time token, received in your e-mail, will be valid for a maximum of 24 hours.

You should be receiving the one-time token almost immediately. In case you do not receive it, please refer to question 2.3.

2.3. During the self-registration, I have not received the one-time token in my e-mail. What should I do?

In this case, please check that the e-mail with the one-time token has not been sent to your spam folder. In case you have not received the one-time token on your spam folder, please 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 I receive the confirmation e-mail?

It should occur almost immediately. However, in some cases, it could take a few hours. If you have not received it within one working day, please check your spam folder on your e-mail box as it could be stored there automatically.

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

2.5. Will my self-registration need to be validated by someone before I get access to a secured workspace in CTIS?

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

Bear in mind that, as a general rule, you will only be able to access clinical trials data/documents once you have been assigned roles by the administrator(s) of the organisation for which you will perform CT-business related activities (*organisation-centric approach*), or if you 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 you follow the CT-centric approach. Please refer to question 1.2 above.

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?

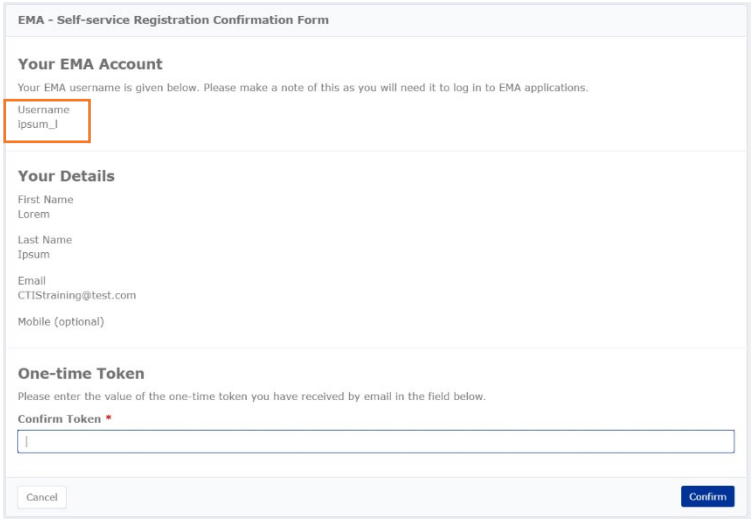
You can access a secured workspace in CTIS immediately after receiving a confirmation e-mail stating that your account is valid. Please note that, in some cases, it may take up to a working day until your account becomes active.

3.2. How do I log into a secured workspace in CTIS?

You must access the CTIS interface and populate the fields' username' and 'password' with your user credentials. After you have populated both fields, click on the button 'Login'.

3.3. Where can I see my credentials to access a secured workspace in CTIS?

Your username will be given to you 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 your last name and the first letter of your first name. Make sure to make a note of it in order not to forget it. The password will be the same that you entered at the beginning of the Self-registration process, concretely in the Self-service Registration Form. The username will also be sent to you in the account confirmation email.

3.4. Can I access CTIS in different languages? Where can I change my preferred language?

CTIS will be available in all the EU official languages, as per requirement in Article 81(8) of the Clinical Trials Regulation: "The user interface of the EU database shall be available in all official languages of the Union"[1]. This is applicable to both the secured workspaces and the public website.

The default language of CTIS workspaces is English. You can change the language from the top-right corner of the CTIS interface.

3.5. I have forgotten my password. What should I do?

If you have forgotten your password, here you have the steps you must follow:

1. Click on 'Forgot password?' on the login page.
2. Introduce your 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 your e-mail.
5. After you have entered the one-time token, you will be able to include a new password. Re-enter the password for confirmation and click on the 'Submit' button.
    a. Your 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.

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 type 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.

[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, *EU Official Journal* L158. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

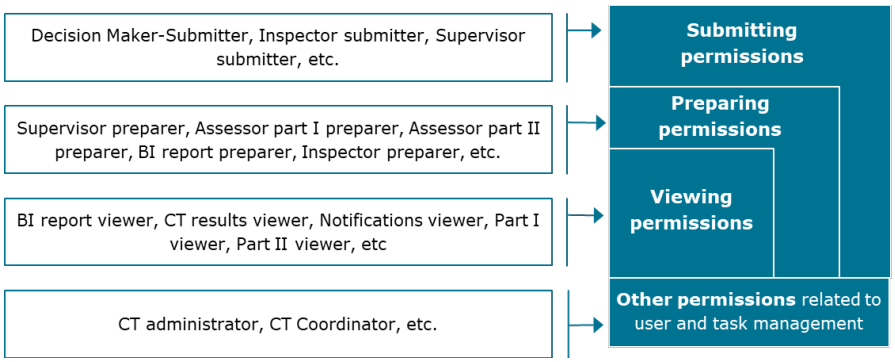
4.2. What are roles?

Roles are predefined group 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 in order 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 Comission 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 brif diagram with some examples matching roles and permissions in CTIS.



4.3. Do I 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, you need to be assigned a role by a user with an administrator role in order 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 you, you become automatically affiliated to that Authority or Sponsor organisation.

4.4. I have access to the secured CTIS landing page, but I am not able to see any information. What should I do?

As a general rule, you will only be able to have access to clinical trials data/documents once you have been assigned roles by the administrator(s) of the organisation for which you will perform CT-business related activities (*organisation-centric approach*), or by the system (only applicable to the sponsor workspace) in case you follow the CT-centric approach. Please refer to question 1.2 above.

In the case of the sponsor workspace, you 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 provided that the organisation that you want to become affiliated to in order to perform CT-business actions is registered in OMS. Refer to question 1.3. to read more about OMS.

In the authority workspace, administrator users will have to assign a role to you and you 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 logout and login to CTIS to be able to see new roles updates.

4.5 Where can I see my roles?

You can see your 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. See question *4.7. How can I get user administrator credentials in CTIS?* for more information on how to get admin user credentials in CTIS.

4.7. How can I get user administrator credentials in CTIS?

If you want to request one of the following high level user administrator roles for your sponsor organisation or authority organisation (i.e. EMA, European Comission, Member State), you will have to attach specific documentation while registering via the EMA Account Management system. This is so because these roles are appointed in EMA's Identity Access Management and follow a specific procedure outside of CTIS.

Other administrator roles which are more limited in scope (i.e. CT admin, MAH admin and National MS admin) are managed directly in CTIS and are appointed, respectively, by the aforementioned Admin roles which are superior in terms of hierarchy. The EMA Admin is responsible for appointing the MAH (Marketing authorisation holder) Admin, the Sponsor Admin is responsible for appointing the CT Admin for a particular trial or trials, and the MS Admin is responsible for appointing the National Organisation Admin (NOA) .

5. User profile

5.1. How can I reset my password?

You can reset your password by:

1. Accessing your 'Personal Profile', clicking on your 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 you to the EMA Account Management system (IAM).

3. Enter your 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. Your 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

Please, find a video outlining this process on our Training platform and our additional materials for training module 3.

5.2. How can I update my personal information?

You can update your personal information:

1. Accessing your 'Personal Profile', click on your username button at the top-right corner of the page of CTIS.

2. Click on the tag' Update personal information'.

3. In the EMA Account Management Portal, click on 'View Identity'.

4. In the 'Identity details' page, click on Edit identity.

Bear in mind that the only fields that can be edited are the e-mail address and your mobile phone. Once updated in the EMA Account Management Portal, your personal information will also be automatically updated in CTIS.

Please, find a video outlining this process on our Training platform and our additional materials for training module 3.

5.3. How can I update my employer's information?

In the Personal profile, you will see the button 'Update my employer information'. A screen will pop-up where you will be able to search and select in OMS the organisation you work for. The data of your organisation will be updated in CTIS automatically.

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

Your employer is the organisation that employs you (i.e. you have a labour relationship with). The affiliated organisation is the authority/sponsor organisation that assigns a role to you in order to be able to perform clinical trial actions on their behalf. The employer and sponsor

organisation may be the same or a different one.

5.5. If my employer organisation does not appear, can I register one?

If your employer organisation is not registered in OMS, you can register it as follows:

1. Access your Personal Profile.
2. Click on your username button at the top-right corner of CTIS.
3. Once in your Personal Profile, select 'Update employer information'.
4. Search for your organisation.
5. Once the search returns no results, you will be able to click on '+New organisation'.
6. Complete all the fields required.

The registration process of a new organisation in OMS takes from five to ten working days. This same process also applies to any other area in CTIS where you are requested organisation data, including when creating a clinical trial.

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Frequently Asked Questions
User Access Management