EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

Management of roles and permissions

CTIS Training Programme – Module 7

Version 1.2 –February 2022

What you will find

- Overview of the audiences targeted in Module 7
- Overview of the training materials included
- Guidelines to disseminate the knowledge
- Recommendations to prepare and develop the training session

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Introduction

Scope and objectives

This instructor guide is designed to help you, as a trainer, to disseminate the knowledge and the training materials prepared as part of the Clinical Trials Information System (CTIS) Training Programme to your target audience(s).

More specifically, this guide is focused on the **seventh Module of the CTIS Training Programme** (hereafter referred to as 'CTTM07'). **This module provides** an overview of the management of roles and permissions in CTIS, the two user management approaches available in CTIS, the user profile, and user administration functionalities, as well as the types of roles that the various user groups can perform in CTIS. **This guide provides** an overview of the audiences targeted with CTTM07, the training materials available, and a suggested methodology for disseminating the materials to end-users. Given the high-complexity of the contents of this module, we recommend conveying this module after participants already have had a first introduction to the structure of CTIS and its main functionalities, as well as to the evaluation parts of a Clinical Trial Application (CTA).

The training activities proposed in this instructor guide are available in English and have been designed for people with reading and hearing abilities. Please, feel free to enrich the course with your contributions and/or adapt it to your participants' needs, but always taking into account the learning objectives and key ideas presented.

For any questions regarding the materials, please contact the CTIS Training Programme team at CT.Training@ema.europa.eu.

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Course elements

Target audiences

CTTM07 targets **sponsor users** (including Marketing Authorisation Holders, MAH), **Member State users** (including Member States' national competent authorities and Member States' ethics committees), and **European Commission users**.

CTTM07 learning objectives

The learning objectives of CTTM07 are:

1. Remember the basic principles of user management in CTIS.
2. Understand the roles and permissions and their hierarchy 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 in CTIS.
5. Remember how roles can be viewed and managed in CTIS.

Materials available

- **CTTM07 eLearning presentation:** An interactive presentation to familiarise users with the purpose and main types of roles and permissions in CTIS, the two user management approaches, and the hierarchy to assign roles, as well as the main user groups interacting with the system and the roles that each of them can be assigned.
- **CTTM07 Step-by-step guide:** Short step by step document of the basic processes described in the module.
- **CTTM07 Frequently Asked Questions (FAQs):** List of common questions and answers regarding the contents covered in this module.
- **CTTM07 Supporting materials:** List of documents that help users to understand processes, permissions and alerts according to the different roles.

- Member States Business Processes and Roles.
- Sponsors Business Processes and Roles.
- Roles and permissions matrix summary for Member States.
- Roles and permissions matrix summary for Sponsors.
- Notices and Alerts per role.

- **Five video clips. The first three videos were** used at DIA's webinar organised on 21/09/2020 adapted to match CTIS Training identity guidelines:
  - **Video - Creating a clinical trial: Clinical trial centric approach vs organisation centric approac (2 minutes 23 seconds):** This video provides a live demonstration of how to create a clinical trial in both user management approaches (CT and Organisation centric approaches); the prerequisites to use both approaches; the consequences of creating a clinical trial with both approaches; and a demonstration of messages that the system will produce during the process.
  - **Video -How to request roles and how to assign roles to registered users in CTIS (5 minutes 38 seconds):** This video provides a live demonstration on how to request roles in the sponsor workspaces; and how to assign roles.
  - **Video – How to amed and revoke roles of registered users in CTI (1 minute 06 seconds):** This video provides a live demonstration of how to amend existing roles by the administrator (changing the time date of expiry of a role, etc.) and how to revoke existing roles.
  - **Video – How to request the CTIS high level Administrator roles via IAM (4 minutes 17 seconds):** This video provides a live demonstration of CTIS roles managed in IAM for sponsors, Member Stated and European commission, and how to request a high level Administrator role in IAM.
  - **Video - How to approve requests for CTIS Administrator role and how to remove CTIS Admin role (3 minutes and 37 seconds):** This video provides a live demonstration of how to approve requests for CTIS Administrator role, how to view list of Administrator users in IAM and how to remove the CTIS high level Administrator role.

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Course preparation

To ensure that the learning objectives of CTTM07 are met and that the training materials are optimally disseminated and consumed, we suggest that you follow a **blended learning approach** combining an activity where participants interact with the content individually and at their own pace and preferred timing (**asynchronous** learning), with an activity bringing together all participants at the same time (**synchronous** learning). For more information on this approach to learning, please refer to our general dissemination guidelines.

- First, we propose you to **share the relevant CTTM07 eLearning presentation** with the participants ahead of the training session. This will allow them to absorb the contents of the presentation on their own and reflect on questions they may have.

- Second, we propose that you organise **a webinar** around one week after having shared the eLearning presentation with the participants. This will allow you to check participants' knowledge absorption, address any question they may have, and collect input on the training materials and methodology.

As the instructor, you are the **sole responsible for organising and hosting the webinar** with the materials provided by the CTIS Training Programme team. You may, of course, prefer to arrange a face-to-face session if the resources and the availability allow you to do so.

Please note that this guide only provides recommendations and suggestions on how to convey the knowledge to the participants. You may choose to adapt it to your needs and preferences.

Preparation of a webinar

This section summarises some useful tips to help you organise a webinar successfully.

- **Prepare an online quiz** to be launched during the webinar with some questions for the participants as an 'icebreaker' and to check whether the participants have understood the key concepts of the eLearning presentation. As opposed to the self-assessment quiz at the end of the eLearning material, the purpose of this activity is to start the webinar in an interactive manner and see if participants have acquired some basic information beforehand. The feedback gathered in this exercise will help you to better adapt your speech and presentation to the participants' knowledge level. It is recommended to always include one or two test questions to allow participants to test the tool before starting the quiz.

- **Send the eLearning presentation** to the training participants one week in advance. Remind them in the email how much time it will take them approximately to complete the material so that they can plan accordingly.

- **Review relevant documentation in advance.** In addition to reviewing all the training materials of this module, including the FAQs and Step-by-step guide, we recommend you to familiarise yourself with the Clinical Trials Regulation[1], which establishes the different types of applications and the principles and processes for assessment. Concretely, we recommend you to read at least the following article, which is related to aspects covered in this module:

    - Recital 18, which concretely addresses the determination of the appropriate body or bodies to be involved in the assessment of the application.

- **Review other relevant modules of the CTIS Training Catalogue**. Concretely, we recommend you to read:

    - Module 2: Overview of CTIS workspaces and common system functionalities (concretely the section on User administration).

    - Module 3: User Access Management.

- **Choose the right platform** to host your webinar, and make sure that participants are aware of the connection requirements by sharing with them the instructions in advance.

- **Limit participation** to a maximum of 20 participants and up to a maximum of two hours whenever possible, to maintain optimal interaction and keep the participants focused. This is applicable in the case of online events. The number of participants and the session duration may be longer in a face-to-face environment.

[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*, L 158/1. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

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Course development

In this section, we describe the proposed timings for each activity, the material to be used, the objective of the activity, and the steps to be followed by you as a trainer:

Activity 1: Completion of the eLearning presentation individually

Time: One week before the webinar

Material: CTTM07 eLearning presentation

Objective:

This activity consists in the completion by participants of the CTTM07 eLearning presentation. Due to the interactive design of this material, which is specially conceived for self-learning, it is recommended that participants complete it autonomously prior to the webinar/session to get acquainted with the content of the presentation at their own pace and identify questions that are not clear to them.

Steps:

1. Send the eLearning presentation to the participants and ask them to complete it by a given date.

2. Send an email reminder one or two days before the webinar, asking them to write down any questions they may have ahead of the webinar.

Activity 2: Webinar

Time: Ca two hours

Material: CTTM07 eLearning presentation, CTTM07 Step by Step guide, CTTM07 Supporting materials, CTTM07 FAQs, five videos, and password-protected feedback form built by the CTIS Training Programme team with the EU survey tool to collect participant's feedback on their satisfaction with the training experience.

Objective:

This proposed activity consists in the organisation of a webinar to:

- Assess if participants have understood the knowledge presented in the CTTM07 eLearning presentation;
- Present the additional materials for the CTTM07;
- Answer any questions regarding the content of the CTTM07;
- Receive feedback regarding the learning materials and the training delivery methodology.

We propose to structure this activity in six parts, described below:

1. **Part 1:** Introduction to the webinar (*approximately 15 minutes*).
    a. Introduce yourself as a trainer and remind participants of the basic rules of the session.
    b. Explain the aim of the webinar and describe briefly the materials that will be used for the session, composition of the webinar, and send the supporting materials (Business processes, Roles and permissions matrix summary and Notices and alerts per role).
    c. Open a roundtable to allow participants to introduce themselves briefly.
2. **Part 2**: Questions on the material reviewed and interactive knowledge check (*approximately 30 minutes*).
    a. Ask if participants have any questions regarding the CTTM07 eLearning presentation.
    b. Show the five videos on the CT centric and Organisation centric user management approaches; request and assign roles; amend and revoke Roles and request, approve and remove CTIS admin roles.
    c. As an 'icebreaker', launch an online quiz to check if participants understood the key concepts from the eLearning presentation for CTTM07. Make sure to explain how the tool works and allow at least a test question before starting the quiz.
3. **Part 3**: Explanation of the Supporting documents (*approximately 10 minutes*).
    a. Ask if participants have a general knowledge of the main activities that their user group can do in CTIS and the phases of evaluation of a CTA. Plan for one or two background slides in case they do not remember the basic concepts.

Break: (10 minutes)

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4. **Part 4:** Questions and answers (*approximately 20 minutes*).

    a. Give some time to the participants to think and ask the questions they have on the material.

    b. Note the questions of the participants. Allow them to ask them orally or via the chat. *We suggest gathering all questions at the beginning of this exercise to make sure that all questions are captured without time constraints.*

    c. Answer the questions using the CTTM07 FAQs as a support, and take this opportunity to show participants this material. *We suggest that you note the questions of the participants that you are not able to answer surely. After the training session, you can send the unanswered questions to EMA Service Desk who can support you with preparing the answers. You should disseminate the answers to all the participants of the webinar.*

5. **Part 5:** Gather feedback about the training materials and methodology (*approximately 15 minutes*).

    a. Share the link of the feedback form on the EU Survey tool and the credentials to access it with the participants.

    b. Give them 10 minutes to complete it. *If you are running out of time, you may decide to share the link to the survey with the participants via email and ask them to complete it after the webinar.*

6. **Part 6:** Wrap up the webinar (*approximately 5 minutes*).

    a. Conclude the webinar and reference for future training modules and/or training sessions.

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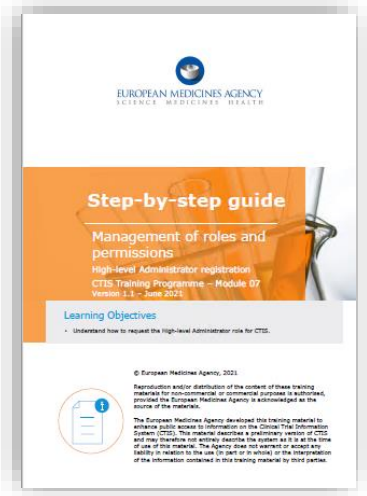
Annex

eLearning presentation

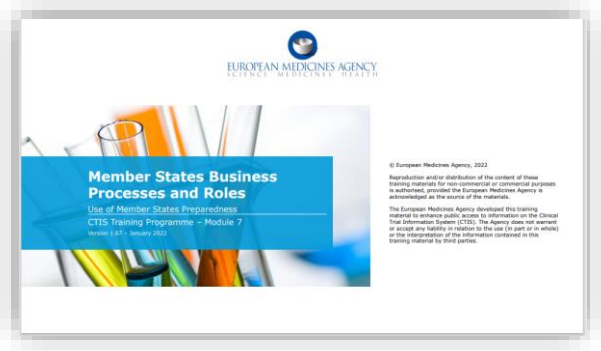
Step by Step Guide



Supporting materials

Business processes and roles

Member States



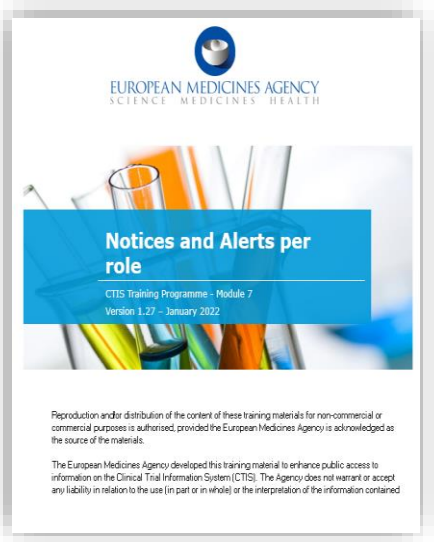
Sponsors

Roles and permissions matrix summary

Member States

Sponsors

Notices and Alerts per role



FAQs


EUROPEAN MEDICINES AGENCY
FAQs
Management of roles and permissions
CTIS Training Programme – Module 7
What you will find

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Clinical trials information system (CTIS)

Instructor's guide: Management of roles and permissions.