

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

User Access Management

CTIS Training Programme – Module 03

Version 1.1 – January 2022

What you will find

- Overall guidelines on how to disseminate the knowledge
- Overview of the audiences targeted in the training module 3
- Overview of the training materials prepared as part of the training module 3
- Recommendations on how to prepare and develop the training

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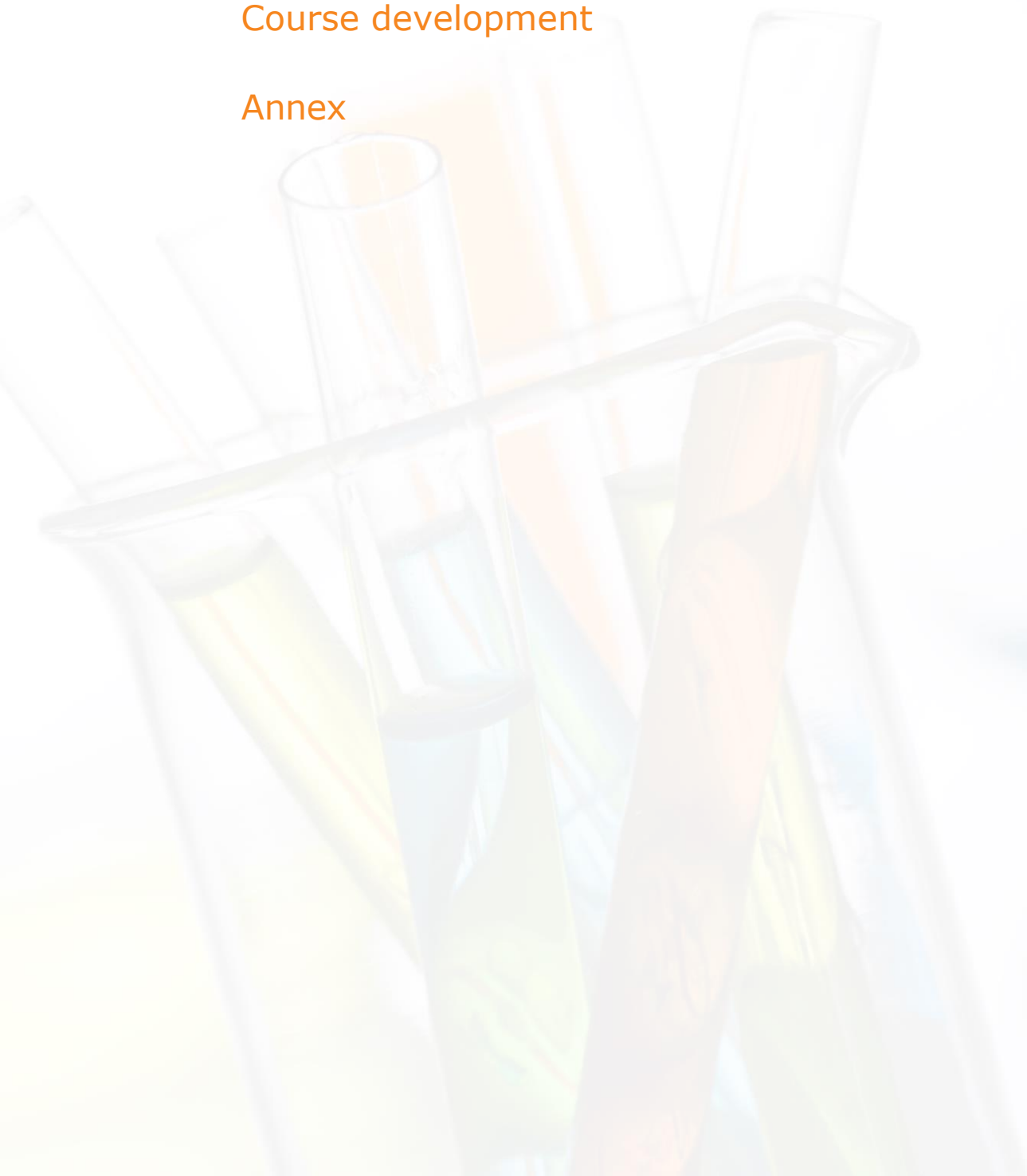


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01

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.

More specifically, this guide is focused on the **third Module of the CTIS Training Programme** (hereafter referred to as 'CTTM03'). The module provides an overview of how to self-register and obtain user credentials to access CTIS; how to log into CTIS and access the landing page; the main features of the user profile management functionality, and a high-level introduction to the roles and permissions (further developed in another module dedicated to the system role matrix). **This guide contains** an overview of the audiences targeted with CTTM03, the training materials available, and a suggested methodology for disseminating the materials.

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.

02

Course elements



Target audiences

CTTM03 targets two main user groups: **Authority users**, including Member States' national competent authorities, Member States' ethics committees and the European Commission; and **sponsor users**, including commercial and non-commercial. Depending on your audience, you will be disseminating the material presented in this guide to one or more of these groups or sub-groups.

CTTM03 learning objectives

The learning objectives of CTTM03 are to:

- Understand the process of self-registration in CTIS through EMA's Account Management Portal.
- Remember how to log into CTIS and access the landing page
- Understand the basic roles and permissions in CTIS
- Understand how the user profile management functionality works

Materials available

- **CTTM03 quick guides:** Brief and practical guides with system screenshots to show users how to create an account in EMA Account Management system in order to obtain user credentials for CTIS, how to log into CTIS, an introduction to the roles and permissions available in CTIS, how to navigate through the user profile functionalities, and how to use the Organisation Management Service (OMS).
- **CTTM03 video-clips:** Two short clips of three to five minutes showing how to self-register through the EMA's Account Management Portal, how to log into CTIS, and the main features regarding user profile functionality.
 - Clip 1: Steps to follow to obtain credentials to access CTIS (approximately 3 minutes).
 - Clip 2: Steps to register an organisation in CTIS via the Organisations Management Service (OMS) (approximately 3 minutes).
 - Clip 3: Steps to log into CTIS, recover your password and manage the user profile (approximately 5 minutes).
- **CTTM03 Frequently Asked Questions (FAQs):** List of common questions and answers regarding the contents presented in this module.
- **CTTM03 Step-by-step guide:** Short step by step document of the basic processes described in the module.

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Course preparation



To ensure that the learning objectives of CTTM03 are met and that the training materials of CTTM03 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 suggest that you **share the CTTM03 video-clips** with the participants. This will allow them to absorb the contents of the module at their own pace and reflect on questions they may have.
- Second, we suggest that you organise **a webinar** around one week after having shared the video-clips with the participants. This will allow you to verify that participants understood the steps presented in the videos and preferably show them how to perform the described steps in practice during the webinar in order to address any question they may have, rather than asking them to do it beforehand.

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. Do not hesitate to adapt it to your needs and preferences, including the possibility to combine one or more modules in the same webinar.

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 video-clips. 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.

- **Send the video-clips** to the training participants one week in advance.
- **Review relevant documentation in advance.** In addition to reviewing the training materials of this module, we advise you to familiarise yourself with existing guidance materials on OMS and the IRIS from other EMA programs, which will help you to get acquainted with the pre-requisite and steps before accessing the platform.
 - **IRIS guide to registration**¹: IRIS is the EMA's secure online platform where users can carry out certain regulatory procedures with EMA. This specific guide helps new users to complete the pre-requisite steps before accessing the platform.
 - **Organisations Management Service (OMS) webpage**²: 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. It is important to have a look at this page as it provides relevant information given that OMS stores master data comprising organisation name and location address for organisations such as marketing authorisation holders, sponsors, regulatory authorities and manufacturers.
 - **Learning Module on Overview of OMS**³: This video provides an overview of OMS with key information about OMS to understand its purpose, know how to request access, and understand its operating model.
- **Choose the right platform** to host your webinar, and make sure the participants are aware of the connection requirements by sharing with them the instructions.
- **Limit participation** to a maximum of 20 participants and up to a maximum of two hours duration, to maintain optimal interaction and keep the participants focused.

¹ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration_en.pdf

² <https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/organisations-management-service-oms>

³ https://www.youtube.com/watch?v=eRJ9kmyGuhY&list=PL7K5dNgKnawbJ_02eU7h4w76XsJmXn_z2

04

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: Viewing of the video-clips individually

Time: One week before the webinar

Material: CTTM03 video-clips

Objective:

This activity consists in the viewing by participants of the CTTM03 video-clips. The dynamic demo-like feeling of the video-clips will allow participants to absorb the content of this module fast and easy, and identify questions that are not clear to them.

Steps:

1. Send the video-clips to the participants and ask them to watch them before the webinar day.
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 and a half

Material: CTTM03 video-clips, CTTM03 FAQs, CTTM03 quick guides, CTTM03 Step-by-step guide and password-protected feedback form built by the CTIS Training Programme team with EU survey tool for participants to provide feedback anonymously.

Objective:

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

- Assess if participants have gathered the knowledge presented in the CTTM03 video-clips;
- Present the additional materials for the CTTM03;
- Show participants how to register in the system in practice and ask them to register and provide assistance as needed.
- Answer any questions regarding the content of the CTTM03.
- Receive feedback regarding the learning materials and training delivery methodology.

We propose to structure this activity in eight 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.
 - c. Open a quick roundtable to allow participants to introduce themselves briefly.
2. **Part 2:** Questions on the material reviewed and interactive knowledge check (*approximately 25 minutes*).
 - a. Ask if participants have any questions regarding the CTTM03 video-clips.
 - b. Launch an online quiz to check if participants understood the key concepts from the CTTM03 video-clips.
3. **Part 3:** Demo on how to register in the system and login to access landing page and manage user profile (*approximately 25 minutes*).
 - a. Let participants know that you will run a demo of the self-registration process on the EMA's Account Management portal and for them to follow the same steps afterward.
 - b. Run the demo to participants on how to register in the system and login to access landing page and manage user profile.
 - c. Ask if participants have any questions regarding the process presented.
4. **Part 4:** Present the CTTM03 quick guides and CTTM03 Step-by-step guide summarising key steps (*approximately 10 – 15 minutes*).

5. **Part 5:** Give participants time to perform the process on their own while you assist them on the spot (*approximately 20 minutes*).
-

Break: (10 minutes)

6. **Part 6:** Questions and answers (*approximately 20 minutes*).
- a. Present the CTTM03 FAQs document (*approximately 5 minutes*)
 - b. Give some time to the participants to think and pose the questions they have on the material.
 - c. 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.*
 - d. Answer the questions using the CTTM03 FAQs. *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 the CTIS Training Programme Team (CT.Training@ema.europa.eu), who can support you with preparing the answers. You should disseminate the answers to all the participants of the webinar.*
7. **Part 7:** Gather feedback about the training materials and methodology (approximately 15 minutes).
- a. Share the link of the feedback form on EU Survey and the credentials to access it with the participants.
 - b. Give them 15 minutes to complete it. *If the time is not enough, you may decide to share the link to the survey with the participants via email and ask them to complete it after the webinar.*
8. **Part 8:** Wrap up the webinar (*approximately 5 minutes*).
- a. Conclude the webinar and reference for future training modules and/or training sessions.
 - b. Allow participants to ask final questions.

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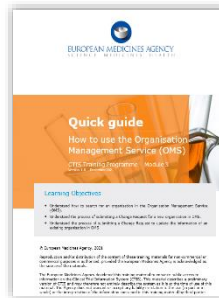
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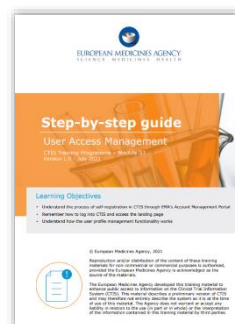
Quick guide



Quick guide OMS



Step-by-step guide



FAQs



Video-clips



Dissemination guidelines



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Clinical trials information system

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