



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

Overview of CTIS workspaces and common system functionalities

CTIS Training Programme – Module 2

Version 1.1 – November 2020



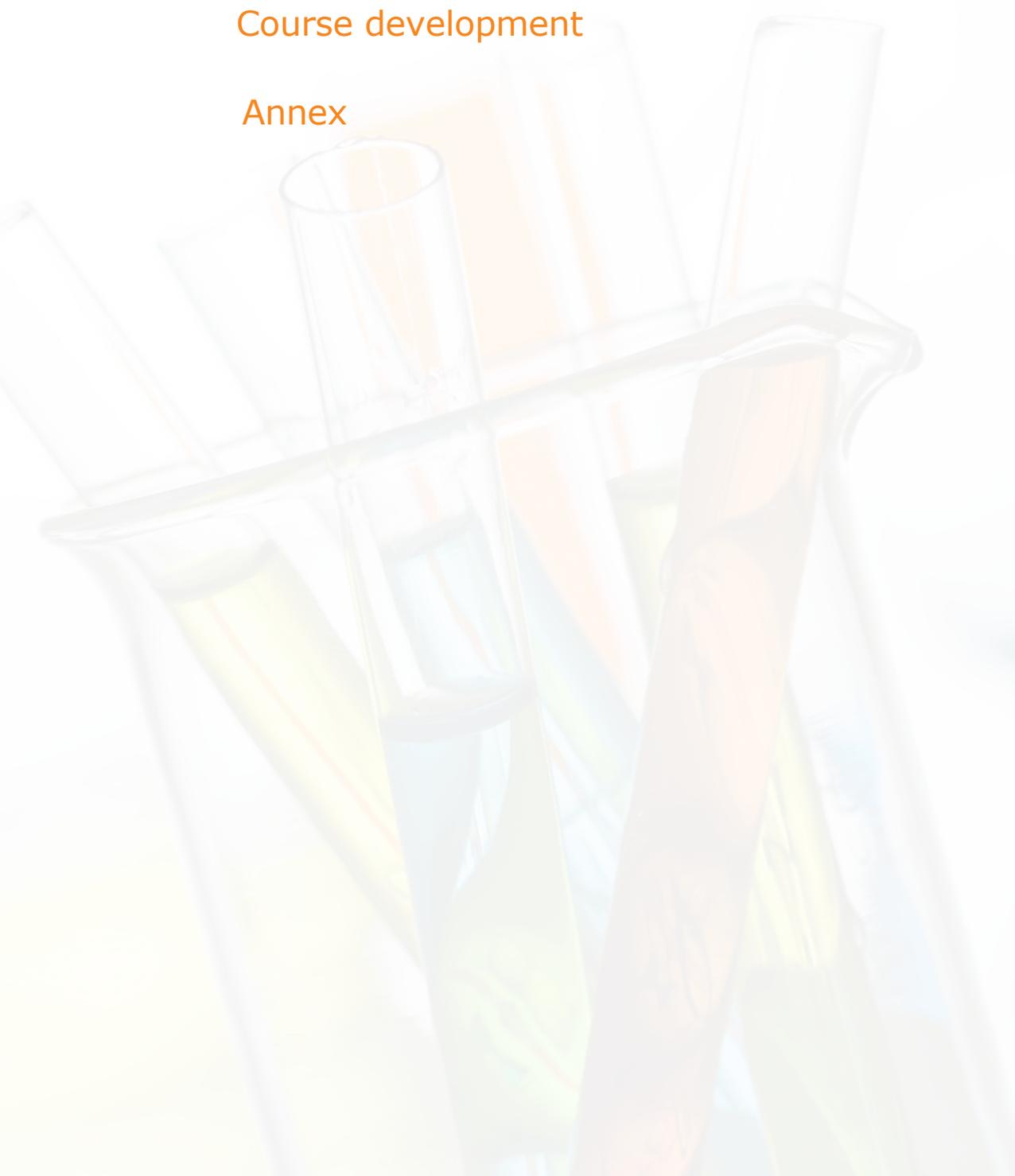
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Introduction



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 in your Member State or organisation.

More specifically, this guide is focused on the **second Module of the CTIS Training Programme** (hereafter referred to as 'CTTM02'), which provides a basic overview of CTIS workspaces and the public website, the databases and systems that CTIS interacts with, and an introduction to the system functionalities which are common in both workspaces. **This guide contains** an overview of the audiences targeted with CTTM02, 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

CTTM02 targets two main user groups: **authorities users**, including Member States' national competent authorities, Member States' ethics committees and the European Commission; and **sponsors**, 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.

CTTM02 learning objectives

The learning objectives of CTTM02 are:

- Understand what CTIS is, its two workspaces, and the public website it is composed of.
- Understand the databases and systems that CTIS interacts with.
- Remember CTIS functionalities which are common in both workspaces.
- Remember the main CTIS functionalities specific for each workspace.
- Understand the goals of the public website and what public users will find there.

Materials available

- **CTTM02 eLearning presentation:** Interactive presentation to familiarise the user with CTIS workspaces, the common functionalities in both workspaces, and provide a short introduction to the public website.
- **CTTM02 quick guide:** Brief and practical guide with system screenshots to show users how to use CTIS functionalities which are common in both workspaces.
- **CTTM02 video-clips:** Short clips of three to five minutes offering an introduction to both CTIS workspaces and public website, and showing the user how CTIS common functionalities are used in practice in the system.
 - Clip 1: Introduction to CTIS workspaces and interaction with other systems (3' 30'')

- Clip 2a: Overview of common functionalities: Clinical Trials' overview and Notices & alerts (5' 39'')
- Clip 2b: Overview of common functionalities: User administration and Annual safety reporting (4' 58'')
- Clip 3: General overview of specific functionalities per workspace (3' 10'')
- Clip 4: Introduction to the public website (1' 53'')
- **CTTM02 Frequently Asked Questions (FAQs):** List of common questions and answers regarding the contents presented in this module.

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Course preparation



To ensure that the learning objectives of CTTM02 are met and that the training materials of CTTM02 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 CTTM02 eLearning presentation** with the participants. This will allow them to assimilate 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. Feel free 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. For further details and recommendations on such activities, please refer to the [dissemination guidelines](#).

- **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.

- **Send the eLearning presentation** to the training participants one week in advance.
- **Review relevant documentation in advance.** In addition to reviewing the training materials of this module, you should familiarise yourself with the Clinical Trials Regulation¹, which establishes the system functionalities that CTIS must have. Concretely, we recommend you to read at least the following articles, which are related to the aspects covered in this module.
 - Article 25 (data submitted in an application dossier)
 - Articles 36-38 (notifications of start, end, temporary halt and early termination of a clinical trial)
 - Articles 40-44 (safety reporting)
 - Article 80 (EU Portal)
 - Article 81 (EU Database)

Additionally, it is also advised to take a look at the following pages of the European Medicines Agency and the European Commission regarding the Clinical Trials Regulation and CTIS:

<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation>

https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

- **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 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

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: Completion of the eLearning presentation individually

Time: One week before the webinar

Material: CTTM02 eLearning presentation

Objective:

This activity consists in the completion by participants of the CTTM02 eLearning presentation. The interactivity and user-friendliness of this presentation allows the participants to absorb the content of this module at their own pace. Hence, this material should be completed autonomously by the participants prior to the webinar to allow them to get acquainted with the content of the presentation 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 and a half

Material: CTTM02 eLearning presentation, CTTM02 video-clips, CTTM02 FAQs, CTTM02 quick 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 CTTM02 eLearning presentation;
- Present the additional materials for the CTTM02;
- Answer any questions regarding the content of the CTTM02.
- Receive feedback regarding the learning materials and training delivery methodology.

We propose to structure this activity in five 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 CTTM02 eLearning presentation.
 - b. Launch an online quiz to check if participants understood the key concepts from the eLearning presentation for CTTM02.
3. **Part 3:** Screening of CTTM02 video-clips (*approximately 40 minutes*).
 - a. Make a brief introduction of the CTTM02 video-clips, so that participants have an initial understanding of the content they are about to watch.
 - b. Display each CTTM02 video-clips at the webinar.
 - c. After each video-clip, allow five minutes so that participants can ask questions on the video-clip.
4. **Part 4:** "Fill in the blanks" exercise (*approximately 15 minutes*).
 - a. Display the CTTM02 quick guide with certain missing words that the participants will have to fill (*maximum 10 blanks throughout the document*).
 - b. Share the original version of the quick guide with the participants and explain its purpose.

Break: (10 minutes)

5. **Part 5:** Questions and answers (*approximately 20 minutes*).
 - a. Give some time to the participants to think and pose 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 CTTM02 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.*

6. **Part 6:** 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.*

7. **Part 7:** 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.

05

Annex



Quick guide



eLearning presentation



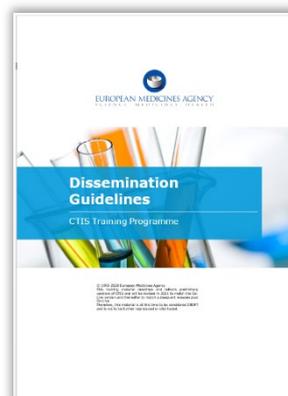
FAQs



Video-clips



Dissemination guidelines



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Clinical trials information system
Instructor's guide: Overview of CTIS
workspaces and common system
functionalities.