EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

Support with workload management by workspace

CTIS Training Programme – Module 04

Version 1.2 – September 2021

What you will find

- Overall guidelines on how to disseminate the knowledge
- Overview of the audiences targeted in the training module 04
- Overview of the training materials prepared as part of the training module 04
- Recommendations on how to prepare and develop the training

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

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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 **fourth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM04'), which provides an overview of CTIS' functionalities that support the workload management in each workspace. **This guide contains** an overview of the audiences targeted with CTTM04, 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.

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Course elements

Target audiences

CTTM04 targets two main user groups through tailored materials: **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 different material presented in this guide to one or more of these groups or sub-groups.

CTTM04 learning objectives

The learning objectives of CTTM04 are:

- Remember the main system functionalities enabling efficient workload management in the authority workspace.
- Remember the main system functionalities enabling efficient workload management in the sponsor workspace.
- Understand the use of the Tasks functionality (available for authority users).
- Understand the use of the Requests for information (RFI) list functionality (available for sponsor users).
- Remember the use of the Notices & Alerts functionality (available in both workspaces).
- Understand the use of the Timetable supporting the monitoring of a specific clinical trial application (available in both workspaces).

Materials available

- **CTTM04 eLearning presentations:** Two interactive presentations (one for authority users and another for sponsor users) to familiarise them with CTIS' functionalities that support the workload management in each workspace, and highlight the commonalities and specificities of each of them, as well as those which are found in both workspaces.

- **CTTM04 video-clips:** Short clips of three to five minutes providing a practical demonstration of the use of CTIS' functionalities that support the workload management in each workspace, focusing in particular on the Tasks, the RFI list and the Timetable:
    - Clip 1: Overview of the Tasks functionality for authority users (approximately 5 minutes).
    - Clip 2: Overview of the RFI list functionality for sponsor users (approximately 4 minutes).
    - Clip 3: Overview of the Timetable (approximately 5 minutes).
- **CTTM04 Frequently Asked Questions (FAQs):** List of common questions and answers regarding the contents covered in this module.
- **CTTM04 Step-by-step guide:** Short step by step documents of the basic processes described in the module (one for sponsors and another one for authority users).

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Course preparation

To ensure that the learning objectives of CTTM04 are met and that the training materials of CTTM04 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 CTTM04 eLearning presentation** with the participants. This will allow them to absorb the contents of the presentation on their own and reflect on questions they may have. Depending on your target audience, you will share the eLearning presentation for **authority users** or **sponsor users**.

- 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 questions 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.

- **Send the eLearning presentation and the Step-by-step guides** to the training participants one week in advance. Remember, there is a tailored presentation depending on your audience group.

- **Review relevant documentation in advance.** In addition to reviewing the training materials of this module, including the FAQs, we recommend you to familiarise yourself with the Clinical Trials Regulation[1], which establishes the process of submission, assessment, and additional information of clinical trials. Concretely, we recommend you to read at least the following articles, which are related to the aspects covered in this module:

    - Article 5 (Submission of an application)
    - Article 6 (Assessment report — Aspects covered by Part I). See in particular paragraph 8 on the request for additional information from the sponsor.
    - Articles 7 (Assessment report — Aspects covered by Part II). See in particular paragraphs 2 and 3 on the request for additional information from the sponsor.
    - Article 20 (Validation, assessment, and decision regarding a substantial modification of an aspect covered by Part II of the assessment report). See in particular paragraphs 1 and 2 on when the Member State concerned shall notify the sponsor.
    - Article 22 (Assessment of a substantial modification of aspects covered by Parts I and II of the assessment report — Assessment of the aspects covered by Part II of the assessment report).
    - Clinical Trials Regulation Q&A,[2] concretely section 2, question 7 about RFIs; and section 4, question 4 and 5 about Tasks.

  Additionally, it is also advised to take a look at Regulation 1182/71 of the Council determining the rules applicable to periods, dates, and time limits:

  Regulation 1182/71 of the Council

- **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

[2] Clinical Trials Regulation (EU) No 536/2014 Q&A. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_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: CTTM04 eLearning presentation and Step-by-step guides (depending on who your target audience, you will share the eLearning presentation for authority users or sponsor users)

Objective:

This activity consists of the completion by participants of the CTTM04 eLearning presentation and the reviewing of the Step-by-step guides. The interactivity and user-friendliness of this presentation allow the participants to absorb the content of this module at their own pace. Due to the design of this material, which is specially conceived for self-learning, these presentations 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 and the Step-by-step guides to the participants and ask them to review them 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: CTTM04 eLearning presentation, CTTM04 video-clips, CTTM04 FAQs, CTTM04 Step-by-step guides (according to your audience) 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 CTTM04 eLearning presentation;
- Present the additional materials for the CTTM04;
- Answer any questions regarding the content of the CTTM04.
- Receive feedback regarding the learning materials and 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.
    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 CTTM04 eLearning presentation.
    b. As an 'icebreaker', launch an online quiz to check if participants understood the key concepts from the eLearning presentation for CTTM04.
3. **Part 3:** Screening of CTTM04 video-clips (*approximately 40 minutes*).
    a. Make a brief introduction of the CTTM04 video-clips, so that participants have an initial understanding of the content they are about to watch. You may want to prepare a short slide deck with key concepts to display on the screen while you are presenting. This supports knowledge transfer in an online environment by keeping participants' attention. However, if you use a slide deck, make sure not to have too much text; use keywords and short sentences instead.
    b. Display each CTTM04 video-clip at the webinar.
    c. After each video-clip, allow five minutes so that participants can ask questions. Be ready to have CTIS open to be able to show how something works on the system in practice.

Break: (10 minutes)

4. **Part 4:** 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 CTTM04 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 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.*

5. **Part 5:** 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 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.

    b. Allow participants to ask final questions.

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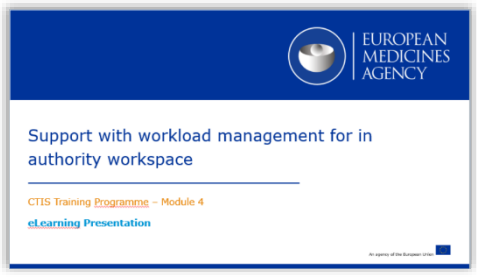
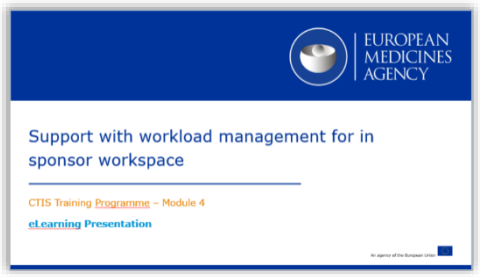
Annex

eLearning presentations

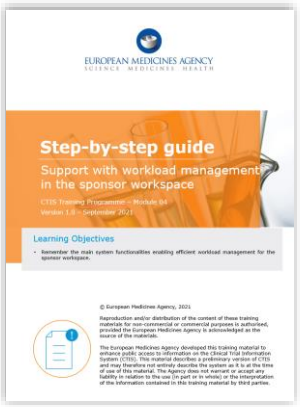




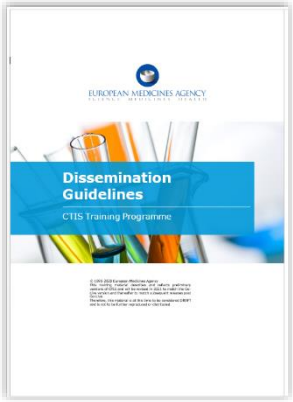
FAQs

Video-clips

Step by step guides



Dissemination guidelines



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Clinical trials information system (CTIS)

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