

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

How to create, submit and withdraw a
Clinical Trial Application

CTIS Training Programme – Module 10

Version 1.2 – July 2022

What you will find

- Overall guidelines on how to disseminate the knowledge
- Overview of the audiences targeted in Module 10
- Overview of the training materials prepared as part of Module 10
- Recommendations on how to prepare and deliver the training sessions

© European Medicines Agency, 2021

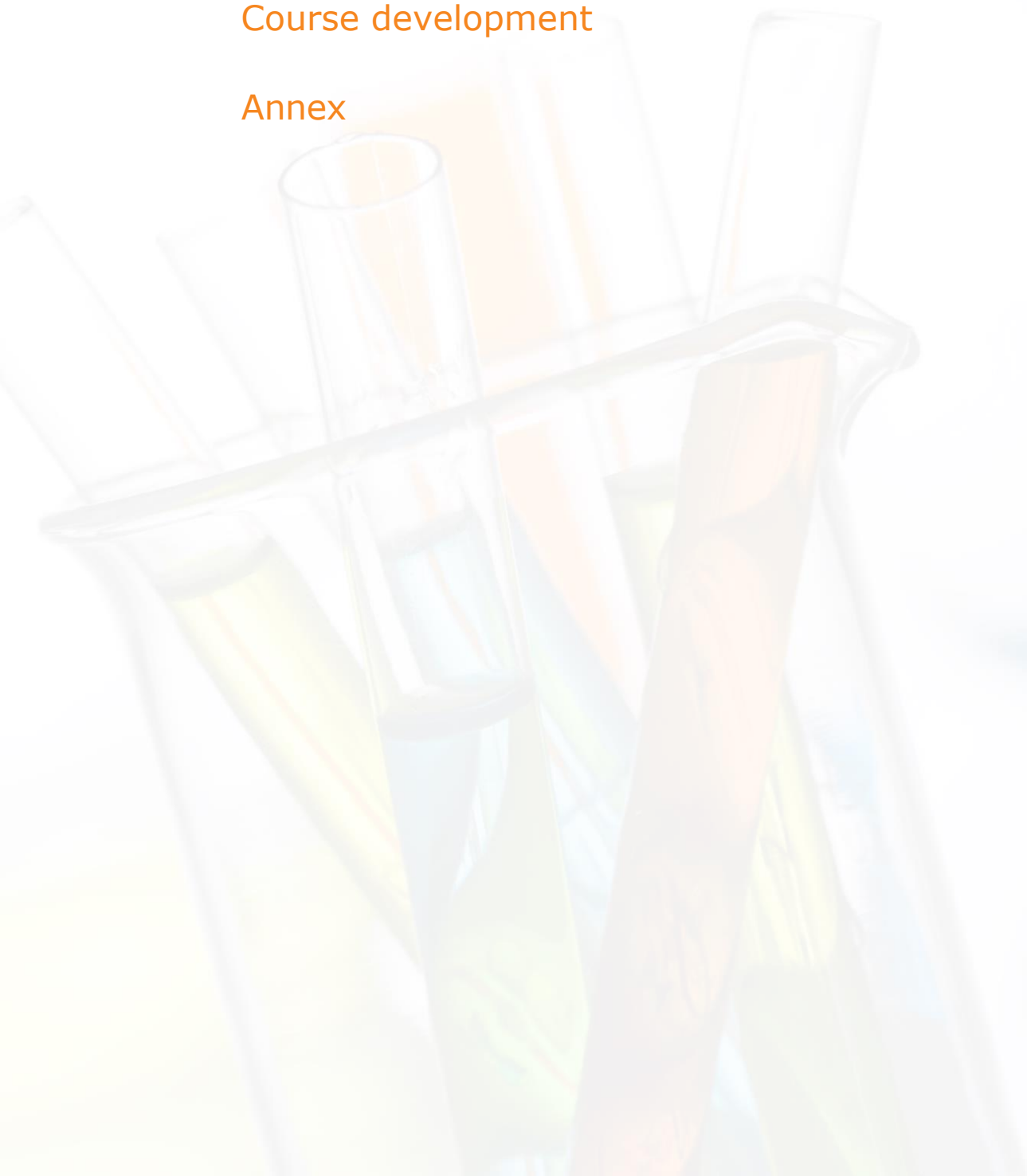


Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.

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.

Table of Contents

Introduction	4
Course elements	5
Course preparation	7
Course development	10
Annex	14



Record of updated versions

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1.2	Minor changes applied (e.g. new reference to the eLearnings, two documents instead of one)	July 2022
1.1	Training material version published at CTIS go-live.	November 2021

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 **tenth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM10'). The module provides an overview of how to how users can create, submit and withdraw a Clinical Trial Application (CTA). **This guide contains** an overview of the audiences targeted with CTTM10, 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

CTTM10 targets **sponsor users**.

CTTM10 learning objectives

The learning objectives of CTTM10 are:

1. Understand the different types of clinical trial applications and Non-substantial modifications.
2. Understand the process of creating, submitting, and cancelling a clinical trial application.
3. Understand the process of withdrawing a clinical trial application.
4. Understand the roles and permissions involved in the management of a clinical trial application.

Materials available

- **CTTM10 eLearnings:** Two interactive presentation, used as the main reference materials for the content covered in this module that can be viewed and completed by users at their own pace, expanding on detailed information as needed.
 - eLearning Initial CTA
 - eLearning Substantial Modification and Additional Member State Concerned CTAs.
- **CTTM20 Step-by-step guide:** Short step by step document (maximum 2 pages) of the basic processes described in the module
- **CTTM10 video-clips:** Three video clips showing a high-level demonstration in the system of how to create and submit an initial CTA end-to-end; a fourth video-clip

presenting the submission process of an Additional MSC CTA, and a fifth video-clip presenting the submission process of a Substantial Modification CTA¹.

- **Clip 1:** Submit an initial CTA – Create a CT: Form and MSC sections.
 - **Clip 2:** Submit an initial CTA – Part I section (this video is expected to be around 10 mins covering the Part I section. However, we will split it in three videos (one per subsection of the Part I of an initial CTA) with a duration of under 5 minutes each).
 - **Clip 3:** Submit an initial CTA – Part II section.
 - **Clip 4:** Submit a substantial Modification CTA.
 - **Clip 5:** Submit an Additional MSC CTA.
- **CTTM10 FAQs:** List of Frequently Asked Questions regarding the creation and submission of each type of CTA, and the data and information to be populated in the CTA dossier.

¹ The duration of the video-clips will be updated next to each video description.

03

Course preparation



To ensure that the learning objectives of CTTM10 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 suggest that you **share the CTTM10 eLearnings and Step-by-step guide** with the participants. This will allow them to understand 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 eLearning with the participants. This will allow you to check participants' understanding of the processes explained, 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. 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 eLearning presentation. 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. Make sure to include at least one test question to get participants familiarised with your chosen tool.

- **Send the eLearnings and Step-by-step guide** to the training participants one week in advance.

- **Review relevant documentation in advance.** In addition to reviewing all the training materials of this module, including the FAQs, we recommend you to familiarise yourself with the Clinical Trials Regulation², which establishes three different types of CTAs and how to create and submit a CTA. Concretely, we recommend you to read at least the following articles, which are related to aspects covered in this module:
 - *Chapter II: Authorisation procedure for a CT*
 - Article 5 - Submission of an application
 - Article 11 - Submission and assessment of applications limited to aspects covered by Part I or Part II of the assessment report
 - Article 12 - Withdrawal
 - Article 13 - Resubmission
 - Article 14 - Subsequent addition of a Member State concerned
 - *Chapter III: Authorisation procedure for a Substantial modification of a CT*
 - Article 15 - General principles
 - Article 16 - Submission of application
 - *Chapter IV: application dossier*
 - Article 25 - Data submitted in the application dossier
 - Article 26 - Language requirements
 - *Chapter XI: sponsor and investigator*
 - Article 71 - Sponsor
 - We also recommend you take a look at the latest version of the European Commission's Clinical Trials Regulation Q&A³, concretely:
 - Section 2: Applications submitted limited to Part I (article 11 of the CT Regulation, Additional MSC CTAs, and other measures related to the application procedure)
 - Section 3: Substantial Modifications.
 - Section 4: Withdrawals.

- **Review other relevant modules of the CTIS Training Catalogue.** In particular, we advise you to review Module 9, where you can find information about the Clinical Trial page in CTIS and the sections of a Clinical Trial Application.
 - Module 9: How to search, view and download a Clinical Trial and a Clinical Trial

² 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

³ European Commission, Clinical Trials Regulation (EU) No 536/2014 Questions & Answers DRAFT, Version 2.6, November 2020. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf

Application.

- **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.

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: Reviewing the eLearning individually

Time: One week before the webinar

Material: CTTM10 eLearnings and Step-by-step guide

Objective:

This activity consists of the review by participants of the CTTM10 eLearnings presentation and Step-by-step guide by themselves, so they can have an overview of the process and identify questions that are not clear to them.

Steps:

1. Send the eLearnings and Step-by-step guide to the participants and ask them to review 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: CTTM10 eLearnings, CTTM10 Step-by-step guide, CTTM10 video-clips, CTTM10 FAQs, 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 CTTM10 eLearnings and Step-by-step guide.
- Present the additional materials for the CTTM10.
- Answer any questions regarding the content of the CTTM10.
- Receive feedback regarding the learning materials and training delivery methodology.

We propose to structure this activity in seven 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 CTTM10 eLearnings presentation and Step-by-step guide.
 - b. Launch an online quiz to check if participants understood the key concepts from the CTTM10 eLearnings and Step-by-step guide.
3. **Part 3:** Screening of CTTM10 video-clips (*approximately 20 minutes*).
 - a. Make a brief introduction to the CTTM10 video-clips, so that participants have an understanding of the content they are about to watch. Explain that the aim of the video-clips is to show them how the functionalities of Module 10 work in practice in the system.
 - b. You may want to prepare a short slide deck with key concepts to display on the screen prior to the video-clips.
 - 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, or show any particular aspect of the eLearning presentation. Be also ready to replay a video-clip once more if an aspect was not clear enough or covered too quickly.
4. **Part 4:** 'Process puzzle' exercise (*approximately 30 minutes*).
 - a. The process puzzle is an exercise in which participants will have to

complete a puzzle describing a process. Participants will need to drag and drop figures in a PPT file to have a sound sequence of sequence of steps/actions that can happen after the sponsor user clicks on the '+ New Trial' button to start the creation of an initial CTA.

- b. Send out the provided PPT file with the exercise to the participants. Share only slides 1, 2 and 3 (explanation of the exercise, an example, and the puzzle itself, respectively).
- c. Explain the exercise with the support of slide 1, and show what participants would need to do based on the example of slide 2.
- d. Give participants 10 minutes to organise the figures with the tasks/actions of the requested exercise.
- e. Use approximately 20 minutes to discuss the outcome of the exercise. This activity can be performed in different settings. Here are some tips on how to handle them:
 - i. In a virtual meeting where participants cannot share their screen, you should share your screen and start organising the process puzzle exercise based on the participants' input.
 - ii. In a virtual meeting where participants can share the screen, you can ask for a volunteer to present their process puzzle. If nobody volunteers to it, you can pick one participant to do so or decide to share your screen and start organising the puzzle based on their input. You may choose to add complexity to the exercise with the bonus activity suggestions provided in slide 5 of the PPT file.
 - iii. In a face-to-face session, you can organise participants in groups, have the figures printed and cropped, and request the groups to do the process puzzle together. You may decide to add complexity to the exercise with the bonus activity suggestions provided on slide 5. Give a couple of minutes to each group to present their exercise.
- f. To engage with participants while they are presenting the outcome of the exercise, you can ask specific questions such as:
 - i. What other scenarios can be envisaged?
 - ii. What happens if users complete only Part I or Part II of the CTA?
 - iii. What other steps/actions do you consider important to be included?
 - iv. Do you find this exercise difficult?

Break: (10 minutes)

5. **Part 5:** Questions and answers (*approximately 20 minutes*).
 - a. Present the CTTM10 FAQs document (*approximately 5 minutes*)
 - b. Give some time to the participants to think and ask the questions they have on the material.
 - c. Prepare a blank slide as an empty whiteboard where participants can add relevant information, raise questions or pinpoint different logics to use the search and download functionalities not foreseen in the materials.
 - d. 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.*
 - e. Answer the questions using the CTTM010 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 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.*

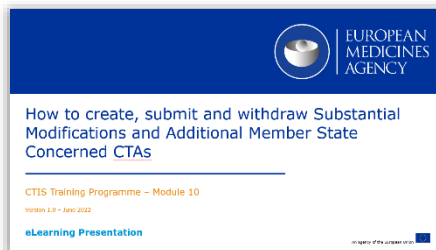
7. **Part 7:** Wrap up the webinar (*approximately 5 minutes*).
 - a. Conclude the webinar and reference for future training modules and/or training sessions.
 - b. Allow participants to ask final questions.

05

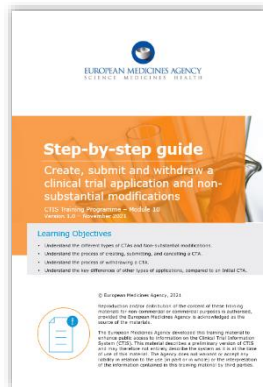
Annex



eLearnings



Step-by-step guide



FAQs



Video-clips



Support document




Process puzzle

Process puzzle exercise

In this exercise we will ask you to apply your knowledge about the creation and submission of an Initial Clinical trial application (CTA) through a visual representation: a **process puzzle**.

The aim of this exercise is to make you reflect on the steps that need to be followed to submit an initial CTA.



European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000

Send a question

www.ema.europa.eu/contact

Clinical trials information system Instructor's guide:

How to create, submit and withdraw a Clinical Trial Application

© European Medicines Agency, 2020.

Reproduction is authorised provided the source is acknowledged.