

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

How to evaluate a Clinical Trial Application:
Assessment and Decision

CTIS Training Programme – Module 08

Version 1.2 – September 2021

What you will find

- Overall guidelines on how to disseminate the knowledge.
- Overview of the audiences targeted in module 8.
- Overview of the training materials prepared as part of module 8.
- Recommendations on how to prepare and develop the training sessions.

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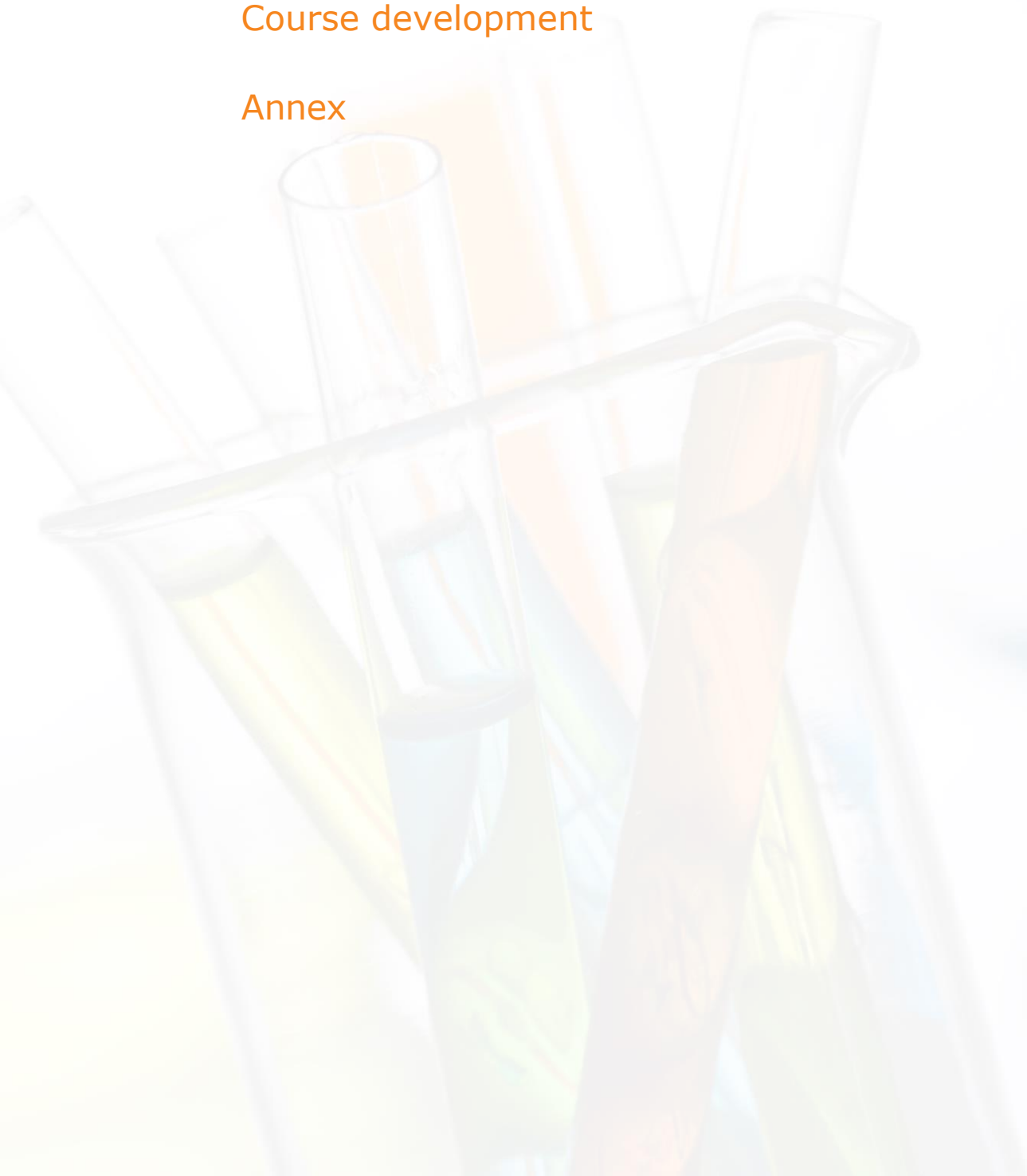


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01

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 **eighth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM08'). The module provides an overview of how to assess an Initial clinical trial application (CTA) and how to provide a Decision regarding its authorisation (or not). **This guide contains** an overview of the audiences targeted with CTTM08, 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

CTTM08 targets **authority users**, including Member States' national competent authorities and Member States' ethics committees.

CTTM08 learning objectives

The learning objectives of CTTM08 are to:

1. Remember the phases and associated timelines for evaluating an initial Clinical trial application (CTA).
2. Understand the process and the user roles involved in the Assessment of Part I II of an initial CTA as a Reporting Member State (RMS) and as a Member State Concerned (MSC).
3. Understand the process and the user roles involved in the Assessment of Part I II of an initial CTA as an MSC.
4. Understand the process and the user roles involved in the Decision regarding the authorisation of an initial CTA.
5. Remember the workload functionalities in CTIS that allow users to monitor their tasks during the evaluation of an initial CTA.

Materials available

- **CTTM08 Quick guides:** Practical and simple quick reference guide with images to prepare users on how to Assess Part I and II of an Initial CTA, and to submit a Decision regarding its authorisation (or not). This allows users to have useful information always at hand.
- **CTTM08 Step-by-step guides:** Short and practical documents that include the most relevant steps of the processes regarding how to evaluate an Additional MSC CTA, and how to evaluate a Substantial Modification CTA.
- **CTTM08 video-clips:** Three clips showing a demonstration of the process of the Assessment of Part I, Part II and Decision in CTIS.

- Clip 1: How to assess Part I of an Initial CTA (6 minutes 35 seconds).
- Clip 2: How to assess Part II of an Initial CTA (4 minutes 37 seconds).
- Clip3: How to submit a Decision regarding the authorisation of an Initial CTA (1 minute 43 seconds).
- **CTTM08 FAQs:** List of Frequently Asked Questions regarding the content covered in this module, including common questions raised by system experts.

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Course preparation



To ensure that the learning objectives of CTTM08 are met and that the training materials of CTTM08 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 CTTM08 Quick guides and the Step-by-step guides** 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 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 Quick guides** 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 specific articles of the CT Regulation that outline the aim and processes of each phase of the Assessment and the Decision of an Initial CTA.
 - Article 6: Assessment report — Aspects covered by Part I.
 - Article 7: Assessment report — Aspects covered by Part II.
 - Article 8: Decision on the clinical trial.
 - Article 9: Persons assessing the application.
 - Article 11: Submission and assessment of applications limited to aspects covered by Part I or Part II of the assessment report.
 - While this Module focuses on the assessment of Initial CTAs, you may want to check as well the specific processes and timelines for assessing subsequent applications (i.e. additional MSC application and Substantial Modification). See Articles 14 and 18 to 23 of the CT Regulation.
 - See also sections 2 and 3 of the European Commission's Q&A document on the CT Regulation.¹
- **Review other relevant modules of the CTIS Training Catalogue.** Concretely, we recommend you to read Module 6, which covers the first two phases in the evaluation process, for a full overview:
 - Module 6: How to evaluate a CTA: RMS selection and Validation.
- **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 European Commission, *Clinical Trials Regulation (EU) No 536/2014 Questions & Answers DRAFT*, Version 4, July 2021. 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: Reviewing the Quick guides and Step-by-step guides individually

Time: One week before the webinar.

Material: CTTM08 Quick guides and Step-by-step guides.

Objective:

This activity consists in the review by participants of the CTTM08 Quick guides and the Step-by-step guides by themselves, so they can have an overview of the process and identify questions that are not clear to them.

Steps:

1. Send the Quick guides and the Step-by-step guides to the participants and ask them to review it 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: CTTM08 video-clips, CTTM08 FAQs, CTTM08 Quick guides, CTTM08 Step-by-step guides 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 understood the processes presented in the CTTM08 video-clips.
- Present the additional materials for the CTTM08.
- Show participants in detail how to assess Part I and II and submit the Decision of an initial CTA.
- Answer any questions regarding the content of the CTTM08.
- Receive feedback regarding the learning materials and the 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 CTTM08 video-clips.
 - b. Launch an online quiz to check if participants understood the key concepts from the CTTM08 video-clips. Make sure to have an answer ready to clarify all the quiz options and explain which one is the correct one.
3. **Part 3:** Screening of CTTM08 video-clips (*approximately 30 minutes*).
 - a. Make a brief introduction to the CTTM08 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 8 work in practice in the system.
 - b. You may want to prepare a short slide deck with key concepts (e.g.

dynamic workflow, tacit decision, DAR, FAR, etc.) to display on the screen after viewing the video-clips. This supports knowledge transfer in an online environment by keeping participants' attention. If you use a slide deck, make sure not to have too much text; use keywords and short sentences instead, as well as visual representations. Workflows and diagrams are particularly suitable for presenting complex processes (e.g. tasks related to each part of the evaluation, possible outcomes of the decision process, etc.).

- 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. 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 (see in the Annex) 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 tasks/actions that can happen after the review of Part I and Part II documentation.
- 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 on 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 do not submit a Part I or Part II conclusion?
 - iii. What happens in no considerations are raised?
 - iv. Do you find this exercise difficult?

Break: (10 minutes)

5. **Part 5:** Questions and answers (*approximately 20 minutes*).
 - a. Present the CTTM08 FAQs document (*approximately 5 minutes*).
 - b. Give some time for participants to think and ask any additional 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 CTTM08 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 guides



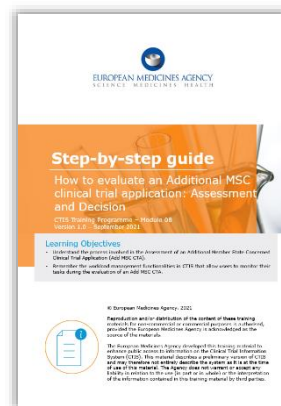
FAQs



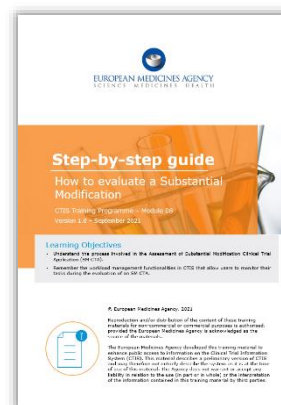
Video-clips



Step-by-step guide: Evaluate an Add MSC CTA



Step-by-step guide: Evaluate an SM CTA




Process puzzle

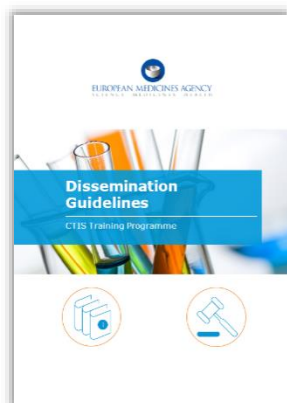
Process puzzle exercise

In this exercise we will ask you to apply your knowledge about the Assessment and Decision phases of the evaluation of an Initial 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 reach a Decision on a CTA.



Dissemination guidelines



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Clinical Trials Information System (CTIS).

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