EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:
Introduction to the Clinical Trials Regulation (EU) No 536/2014

CTIS Training Programme – Module 1
Version 1.3 – February 2022

What you will find

- Overall guidelines on how to disseminate the knowledge.
- Overview of the audiences targeted in module 1.
- Overview of the training materials prepared as part of module 1.
- Recommendations on how to prepare and develop the training sessions.
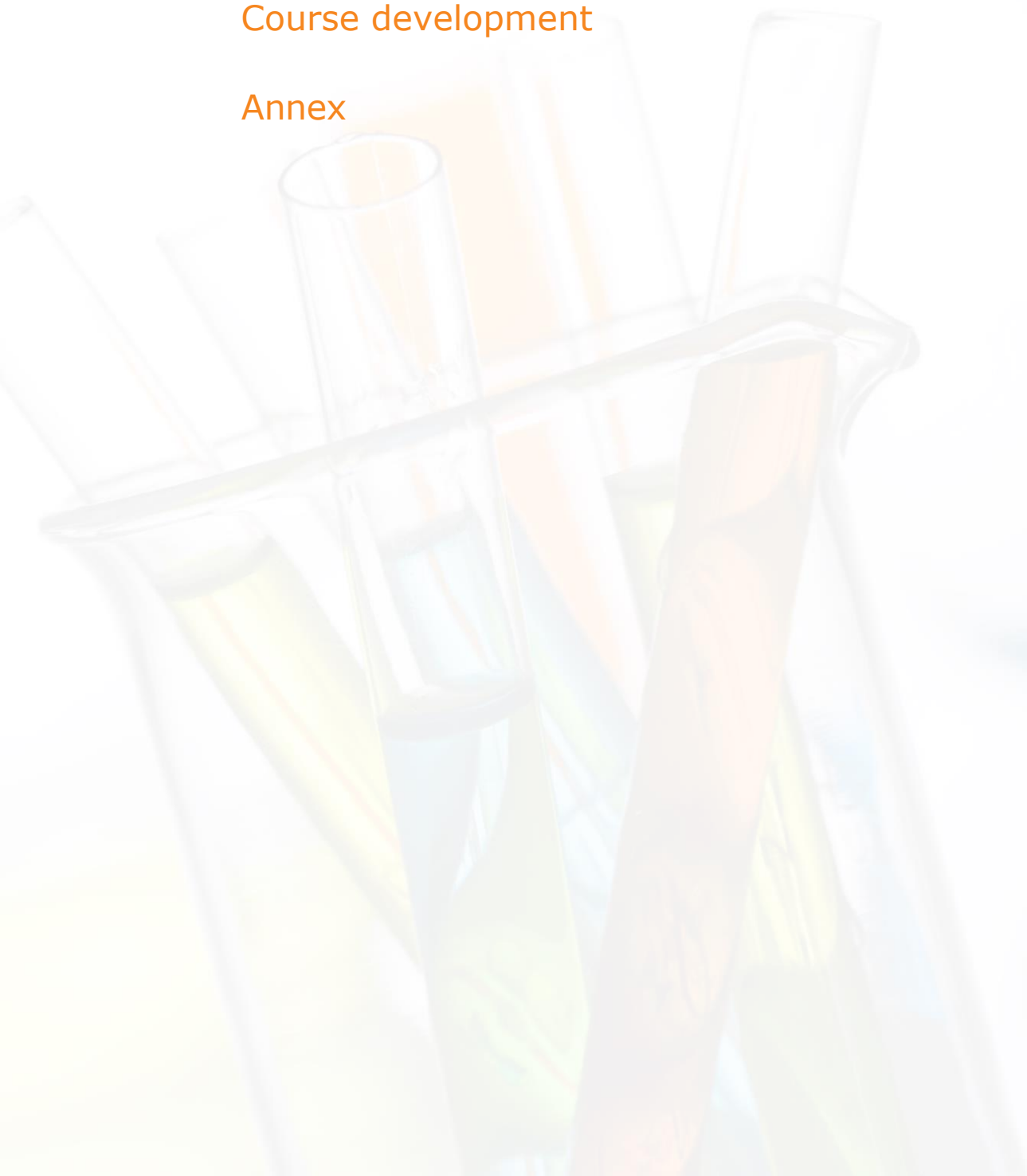
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Introduction

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 **first Module of the CTIS Training Programme** (hereafter referred to as 'CTTM01') which provides a basic introduction to Regulation EU No 536/2014 on clinical trials on medicinal products for human use (the Clinical Trials Regulation). **This guide contains** an overview of the audiences targeted, the training materials available, and a **proposal of a methodology** for disseminating the materials of CTTM01.

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 defined.

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

CTTM01 targets two main user groups: **Member States' authorities**, including national competent authorities and ethics committees, 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 groups or sub-groups.

CTTM01 Learning objectives

The learning objectives of CTTM01 are the following:

1. Understand the scope and objectives of the Clinical Trials Regulation.
2. Understand the key changes and new elements of the Clinical Trials Regulation compared to Directive 2001/20/EC (the Clinical Trials Directive).
3. Understand the transition period from the Clinical Trials Directive to the Clinical Trials Regulation.
4. Remember the actors targeted by the Clinical Trials Regulation and its benefits for each of them.

Materials available

- **CTTM01 Infographic:** Brief document that visually summarises the key elements of the Clinical Trials Regulation.

- **CTTM01 eLearning presentation:** Interactive presentation to convey more detailed information on the Clinical Trials Regulation.

- **CTTM01 FAQs:** List of Frequently Asked Questions on the key elements of the Clinical Trials Regulation, covered in CTTM01.

- **Dissemination Guidelines:** General recommendations to support the dissemination of CTIS Training Programme's materials (these are not specific for CTTM01).

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Course preparation

To ensure that the learning objectives of CTTM01 are met and that the training materials of CTTM01 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 CTTM01 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

In the context of this module, we suggest that you organise a webinar, incorporating audio and visual elements, as well as audience interaction, providing you with a flexible delivery methodology to convey knowledge. 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 on the Clinical Trials Regulation. 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 this case, apart from reviewing the training materials of this module, we recommend you to review the Clinical Trials Regulation[1], which establishes the main basis for the training materials of this module. Moreover, we recommend you to review the Clinical Trials Regulation Q&A[2] (concretely section 1, section 9 and section 11), and the Impact assessment report on the revision of the "Clinical Trials Directive" 2001/20/EC[3] (concretely section 2, section 3 and section 6).

  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:

  [European Medicines Agency – Clinical Trials Regulation](#)

  [European Commission - Clinical trials - Regulation EU No 536/2014](#)

- **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 2h duration, to maintain optimal interaction and keep the participants focused.

Tools needed for the webinar

A list of tools needed for webinar participation is provided below, along with some recommendations on the use of those during the session:

- **Strong broadband internet connection** to ensure a smooth running of the webinar.

- **One laptop per participant** to connect to the webinar.

- **Mobile phones** (if required) to connect to the webinar and/or engaging in interactive activities during the training session (e.g. participating in an online quiz).

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[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
[3] Impact assessment report on the revision of the "Clinical Trials Directive" 2001/20/EC. Available at: https://ec.europa.eu/health//sites/health/files/files/clinicaltrials/2012_07/impact_assessment_part1_en.pdf

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Course development

As mentioned in the previous section, we suggest a blended approach combining asynchronous learning (activity 1) with synchronous learning (activity 2) for an optimal learning experience and outcomes. In this section, we describe the objective of each activity, along with proposed timings, material to be used, and the steps to be followed by you:

Activity 1: Completion of the eLearning presentation individually

Time: One week before the webinar

Material: CTTM01 eLearning presentation

Objective:

This asynchronous activity consists of the completion by participants of the eLearning presentation on the Clinical Trials Regulation. The interactivity and user-friendliness of this presentation allow 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 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.

Activity 2: Webinar

Time: Ca 2 hours

Material: CTTM01 Infographic and CTTM01 FAQs (in addition to the link to a feedback form).

Objective:

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

- Assess if participants have gathered the knowledge presented in the CTTM01 eLearning presentation.

- Answer any questions regarding the content of the CTTM01 eLearning presentation.

- Receive feedback regarding the learning materials and training delivery.

We propose to structure this activity in five parts, described below:

Steps:

1. **Part 1:** Introduction to the webinar (*approximately 15 minutes*)

   a. Introduce yourself as a trainer and the basic rules of the session.

   b. Explain the aim of the webinar briefly.

   c. Open a roundtable to allow participants to introduce themselves briefly.

   d. Launch the online quiz prepared to assess knowledge acquired on the Clinical Trials Regulation.

2. **Part 2:** 'Spot the mistakes' exercise (*approximately 20 minutes*)

   a. Display the CTTM01 Infographic on the screen of the webinar with seven slight errors in the content (included in the Annex of this document).

   b. Once the participants have identified the errors, show them the correct version of the [infographic](), and clarify the errors.

   c. Share the link to the original version of the infographic with the participants.

3. **Part 3:** Questions and answers. (*approximately 30 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. *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.*

Break: (15 minutes)

4. Part 4: 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.

5. Part 5: Wrap up the webinar (*approximately 5 minutes*)

   a. Conclude the webinar and reference future training modules and/or training sessions.

   b. Allow participants to ask final questions.

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Annex

Infographic

eLearning
presentation

FAQs

EUROPEAN MEDICINES AGENCY

EXERCISE

The Clinical Trials Regulation

Increasing transparency, efficiency and cooperation on clinical trials information in the EU

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

What is it?

Regulation (EU) No 536/2017 (the Clinical Trials Regulation) aims at creating an environment that is favourable for **conducting clinical trials (CTs) in the EU** with the highest standards of **safety** for participants and increased **transparency** of CTs **information**. It will replace and expand the scope of the existing EU Clinical Trials Directive 2001/20/EC.

What will the Clinical Trials Regulation do?

Ensure the highest **safety** standards for all participants in CTs

Strengthen reliability, robustness, and **transparency** of patients' data in the European Union

Increase the **efficiency** for the **submission** and **assessment** of CTs applications within established deadlines

Harmonise the **authorisation** process of CTs, resulting in a single decision for all Member States concerned.

Provide **tailored-made provisions** governing CTs in different Member States

Improve the **cooperation** between Member States and sponsors, and among Member States in the assessment of a CT application

Establish clear **rules** at EU level for unbiased and **informed consent** of participants in CTs including for those who are unable to provide said consent

Introduce a **risk-adapted approach** with more stringent rules for those trials conducted with authorised medicines and low-risk CTs

Reinforce **supervision** of CTs by introducing Union Controls to ensure compliance with the Clinical Trials Regulation

Who will the Clinical Trials Regulation benefit?

Authorities
Member States national competent authorities, ethics committees, European Commission and EMA

Sponsors
Academia

General Public
Patients, scientists, healthcare professionals, clinical research associations, media, citizens

The implementation of the Clinical Trials Regulation will be supported by...

The Clinical Trials Information System (CTIS)

The rules established in the Regulation will be supported through a dedicated EU Portal and Database (the Clinical Trials Information System) that will become the **single entry point** for submitting CTs information in the EU and will support the **daily business processes** of Member States.