EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:
Supervise a CT – Inspection records

CTIS Training Programme – Module 16
Version 1.1 – June 2021

What you will find

- Overall guidelines on how to disseminate the knowledge.
- Overview of the audiences targeted in module 16.
- Overview of the training materials prepared as part of module 16.
- Recommendations on how to prepare and develop the training sessions.
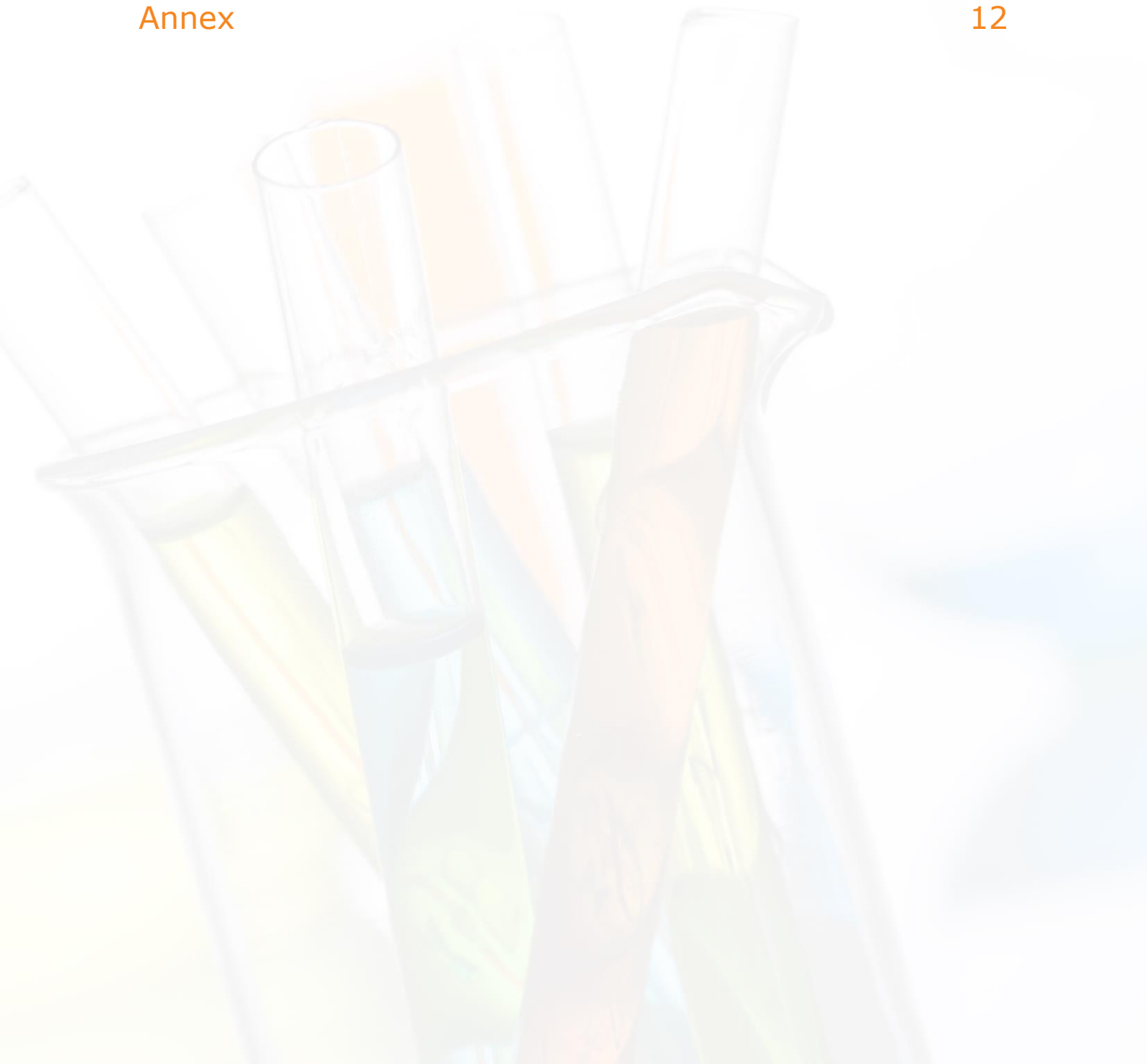
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Introduction

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.

More specifically, this guide is focused on the **sixteenth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM16'). The module provides an overview of how to create, submit and update an Inspection record. **This guide contains** an overview of the audiences targeted with CTTM16, 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

CTTM16 targets **authority users** and more concretely Inspectors of national competent authorities.

CTTM16 learning objectives

The learning objectives of CTTM16 are:

1. Remember what an inspection record is and when an MSC can create one.
2. Understand how to create and submit an inspection record.
3. Understand how to search, view, update and cancel an inspection record.
4. Understand which user roles are involved in the inspection record process.

Materials available

- **CTTM16 eLearning:** Interactive presentation, used as the main reference material for the content covered in this module, can be viewed and completed by users at their own pace, expanding on detailed information as needed.

- **CTTM16 Step-by-step guide:** Short and practical document that includes the most relevant steps of the processes described in the module.

- **CTTM16 video-clips:** Three video-clips showing a demonstration in the system of how to create an inspection record and populate the General information section of the inspection form; how to populate the Inspection section; and how to populate the Overall inspection outcome and reports section, submit, search, update, and cancel.

  - Clip 1: How to create an inspection record and how to populate the General information section (3 minutes 52 seconds)

  - Clip 2: How to populate the Inspections section (6 minutes 51 seconds)

  - Clip 3: How to populate the Overall inspection outcome and update

and cancel an inspection record (3 minutes 53 seconds)

- **CTTM16 FAQs:** List of Frequently Asked Questions regarding the following aspects: General information of inspection records; Creation and submission of the inspection records; Inspection outcomes and reports; Search and update of Inspection records; and Roles and permissions.

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Course preparation

To ensure that the learning objectives of CTTM16 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 CTTM16 eLearning** 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 verify that participants understood the steps presented in the eLearning and preferably show them how to perform the described steps in practice during the webinar in order to address any question they may have.

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

- **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.

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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: CTTM16 eLearning

Objective: This activity consists of the review by participants of the CTTM16 eLearning by themselves, so they can have an overview of the process and identify questions that are not clear to them.

Steps:

1. Send the eLearning 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: CTTM16 eLearning, CTTM16 video-clips, CTTM16 FAQs, CTTM16 Step-by-step 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 CTTM16 eLearning.

- Present the additional materials for the CTTM16.

- Answer any questions regarding the content of the CTTM16.

- 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 CTTM16 eLearning.

   b. Launch an online quiz to check if participants understood the key concepts from the CTTM16 eLearning.

3. **Part 3:** Screening of CTTM16 video-clips (*approximately 20 minutes*).

   a. Make a brief introduction to the CTTM16 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 16 work in practice in the system.

   b. You may want to prepare a short slide deck with key concepts to display on the screen after viewing 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. Be ready to replay a video-clip once more if an aspect was not clear enough or covered too quickly.

4. **Part 4**: Case scenarios 'process puzzle' exercise (approximately 30 minutes).

   a. The process puzzle is an exercise in which participants will have to order the pieces of a puzzle to describe a logical sequence of a process. For this Module, we are proposing two case scenarios of different situations.

Participants will need to drag and drop puzzle pieces in a PPT file to have a sound sequence of steps/actions that can happen in each scenario.

b. Send out the provided PPT file with the exercise to the participants. Share only slide 2 and 3 (containing the explanation of the exercise and the example), and the case scenario process puzzles (slides 4 and 5).

   i. Explain the exercise with the support of slide 3.

   ii. Give participants 10 minutes to organise the pieces with the tasks/actions of the requested exercise.

   iii. 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:

      1. 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.

      2. In a virtual meeting where participants can share the screen, you can ask for volunteers to present their process puzzle. If nobody volunteers for it, you can pick one participant to do so or decide to share your screen and start organising the puzzle based on their input.

      3. 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. Once it is finished, give a couple of minutes to each group to present their exercise.

   iv. To engage with participants while they are presenting the outcome of the exercise, you can ask specific questions such as:

      1. What other scenarios can be envisaged?

      2. What happens if a user has to update the report?

      3. What other steps/actions do you consider important to be included?

      4. Do you find this exercise difficult?

Break: (10 minutes)

5. **Part 5:** Questions and answers (*approximately 20 minutes*).

a. Present the CTTM16 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 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 CTTM16 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 the 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.

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Annex

eLearning

FAQs

Video-clips

Dissemination guidelines

Process Puzzle