



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

Supervise a CT – Ad Hoc Assessment

CTIS Training Programme – Module 17

Version 1.2 – November 2021

What you will find

- Overall guidelines on how to disseminate the knowledge.
- Overview of the audiences targeted in module 17.
- Overview of the training materials prepared as part of module 17.
- Recommendations on how to prepare and develop the training sessions.

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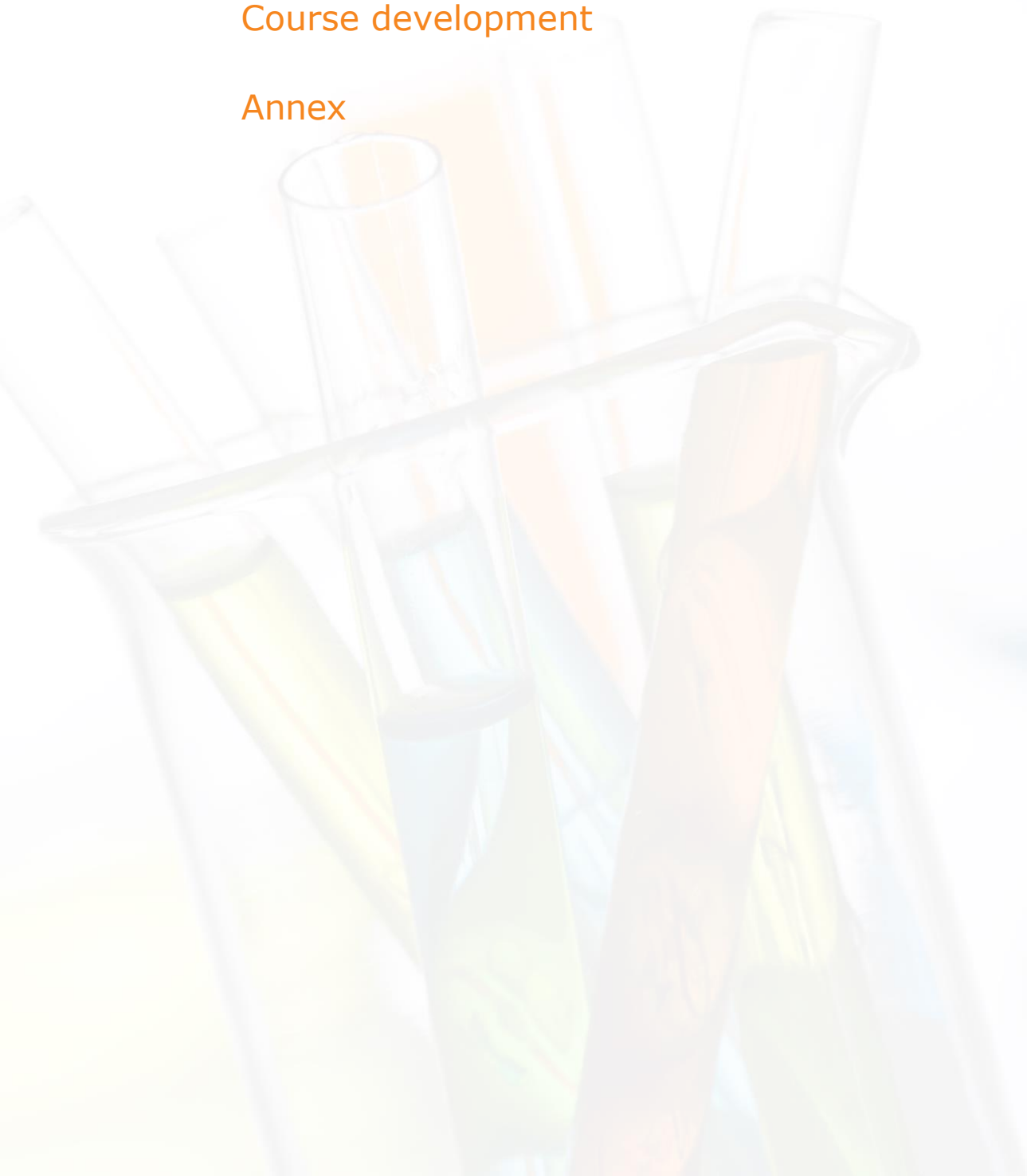


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01

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 **seventeenth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM17'). The module provides an overview of how to complete the ad hoc assessment form in CTIS as part of the supervision of a Clinical Trial (CT). **This guide contains** an overview of the audiences targeted with CTTM17, 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

CTTM17 targets **Member States**.

CTTM17 learning objectives

The learning objectives of CTTM17 are:

1. Remember what an ad hoc assessment is and when an MS can create one.
2. Understand how to create, cancel, save, and share an ad hoc assessment.
3. Understand how to raise an RFI, consult with other MSs, update and complete an ad hoc assessment.
4. Understand how to search, view, and download an ad hoc assessment.
5. Understand which user roles are involved in the ad hoc assessment process.

Materials available

- **CTTM17 eLearning:** An interactive presentation is an adequate format to present the information regarding the ad hoc assessment due to the complexity of the content, as well to present the steps that users need to follow to complete the process.
- **CTTM17 Step-by-step guide:** Short step by step document (maximum 3 pages) of the basic processes described in the module.
- **CTTM17 video-clips:** These clips will show a demonstration in the system about:
 - Clip 1: How to create an Ad hoc assessment (CT selection and Assessment details).
 - Clip 2: How to create an Ad hoc assessment (Discussion with MSs and raise RFIs).
 - Clip 3: How to update and complete the Assessment outcome of an Ad hoc assessment.
- **CTTM17 FAQs:** List of Frequently Asked Questions regarding general information

of ad hoc assessment; questions regarding the creation of an ad hoc assessment; questions regarding the requests for information and consultation with other MSs; questions regarding the update and completion of an ad hoc assessment; questions regarding the search, view, and download of an ad hoc assessment; and questions regarding the roles and permissions.

03

Course preparation



To ensure that the learning objectives of CTTM17 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 CTTM17 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.

- **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.

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 and Step-by-step guide individually

Time: One week before the webinar

Material: CTTM17 eLearning and Step-by-step guide

Objective: This activity consists of the review by participants of the CTTM17 eLearning and the 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 eLearning and the Step-by-step guide 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: CTTM17 eLearning, CTTM17 video-clips, CTTM17 FAQs, CTTM17 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 CTTM17 eLearning.
- Present the additional materials for the CTTM17.
- Answer any questions regarding the content of the CTTM17.
- 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 CTTM17 eLearning and the Step-by-step guide.
 - b. Launch an online quiz to check if participants understood the key concepts from the CTTM17 eLearning.
3. **Part 3:** Screening of CTTM17 video-clips (*approximately 20 minutes*).
 - a. Make a brief introduction to the CTTM17 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 17 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:** "Key buttons" exercise (approximately 30 minutes).
- a. The "Key buttons" is an exercise in which participants will reflect which button will be used in each step of the process of ad-hoc assessments. Participants will need to read the information about what each button triggers in the system before completing the exercise. After that, participants will need to select which button will be used in each scenario.
 - i. Explain what the function of each button in CTIS with the support of slide information provided in the Annex of this document.
 1. Separate your audience into groups (not more than 5 people per group).
 2. Give participants 15 minutes to select the answers to each of the user cases.
 3. Use approximately 10 minutes to discuss the outcome of the exercise.
 4. To engage with participants while they are presenting the outcome of the exercise, you can ask specific questions such as:
 - a. What other scenarios can be envisaged?
 - b. What happens if a user wants to update an ad-hoc assessment?
 - c. What other steps/actions do you consider important to be included?
 - d. Do you find this exercise difficult?

Break: (10 minutes)

5. **Part 5:** Questions and answers (*approximately 20 minutes*).
- a. Present the CTTM17 FAQs document (*approximately 5 minutes*).
 - b. Give some time to the participants to think and ask the questions they have on the material.
 - c. 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.*
 - d. Answer the questions using the CTTM17 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.

05

Annex



eLearning

A slide from an eLearning presentation. The header features the European Medicines Agency logo and name. The main title is "Supervise a CT – Ad hoc assessment". Below it, it says "CTIS Training Programme – Module 17" and "Version 1.0 – June 2021". At the bottom, it is labeled "eLearning Presentation".

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Supervise a CT – Ad hoc assessment

CTIS Training Programme – Module 17
Version 1.0 – June 2021

eLearning Presentation

FAQs

A document cover for "FAQs Supervise a CT – Ad Hoc Assessment". It includes the EMA logo and a list of topics covered: "What you will find" includes questions regarding general information, assessment criteria, and the role of participants.

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FAQs

Supervise a CT – Ad Hoc Assessment
CTIS Training Programme – Module 17
Version 1.0 – June 2021

What you will find

- Answers to questions regarding general information of all Ad Hoc assessments.
- Answers to questions regarding the criteria of all Ad Hoc assessments.
- Answers to questions regarding the requests for information and distribution of data to the field.
- Answers to questions regarding the validity and suspension of all Ad Hoc assessments.
- Answers to questions regarding factors to consider, when, checked and cancel all Ad Hoc assessments.
- Answers to questions regarding the role and participation.

Step-by-step guide

A document cover for "Step-by-step guide Supervise a CT – Ad Hoc Assessment". It includes the EMA logo and lists learning objectives: "Understanding how to create, cancel and stop an Ad Hoc assessment", "Understanding how to close a Publication for information, consult with other EMA, a lot of non-EU variables or Ad Hoc assessment", and "Understanding how to create, check and engage a notification of an Ad Hoc assessment".

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Step-by-step guide

Supervise a CT – Ad Hoc Assessment
CTIS Training Programme – Module 17
Version 1.0 – June 2021

Learning Objectives

- Understanding how to create, cancel and stop an Ad Hoc assessment.
- Understanding how to close a Publication for information, consult with other EMA, a lot of non-EU variables or Ad Hoc assessment.
- Understanding how to create, check and engage a notification of an Ad Hoc assessment.

Video-clips



Dissemination guidelines



Key buttons exercise

In this exercise, you will be asked to establish which button will be selected the Member State users in the different steps of the process of an ad-hoc assessment. But first, you must know what each button triggers in CTIS. Below we outline the function of each of the buttons:

- **Share:** Allows users to share data and documents with other Member States.
- **Save:** Allows users to save their work and make it visible to other users who have been assigned the necessary permissions within the same organisation.
- **Submit:** Allows users to submit documents to the EU CT database in order to be accessed in the other workspace (sponsor and authority workspace).
- **Cancel:** Allows user to cancel an item after saving it.
- **Close:** Allows users to close a window to go back to the original tab. This does not have any implications for the content of the item closed.
- **Complete:** Allows users to finalise an item.

After reading the explanations above, please scroll down to find the 'Key buttons' exercise and select the answer.

Use case 1	A sponsor submits a notification to the MS regarding an unexpected event while the CT is being performed. The MS creates an ad-hoc assessment and populates the 'Clinical Trials linked to the assessment' section and the 'Assessment details' section. Which button will the MS click then?				
Possible Solutions	Complete <input type="checkbox"/>	Cancel <input type="checkbox"/>	Share <input type="checkbox"/>	Submit <input type="checkbox"/>	Save <input type="checkbox"/>
Use case 2	After saving the ad-hoc assessment, the MS considers that it is not necessary to make an ad hoc assessment anymore. Which button will the MS click then?				
Possible Solutions	Complete <input type="checkbox"/>	Cancel <input type="checkbox"/>	Share <input type="checkbox"/>	Submit <input type="checkbox"/>	Save <input type="checkbox"/>
Use case 3	After populating the 'Assessment details' section, the MS determines that additional information to complete the ad-hoc is necessary. To do that the MS will raise an RFI to the sponsor. Which button will the MS click then?				
Possible Solutions	Complete <input type="checkbox"/>	Cancel <input type="checkbox"/>	Share <input type="checkbox"/>	Submit <input type="checkbox"/>	Save <input type="checkbox"/>
Use case 4	The MS has raised an RFI to the sponsor requesting more information to complete de ad-hoc assessment. After the sponsor has submitted the RFI response, the MS wants to initiate a Discussion with other MS regarding the ad-hoc assessment performance. Which button will the MS click then?				
Possible Solutions	Complete <input type="checkbox"/>	Cancel <input type="checkbox"/>	Share <input type="checkbox"/>	Submit <input type="checkbox"/>	Save <input type="checkbox"/>
Use case 5	An MS to which the ad-hoc assessment has been shared, reviews the sponsor response. After reviewing it, the MS wants to go back to the ad-hoc assessment tab. Which button will the MS click then?				
Possible Solutions	Complete <input type="checkbox"/>	Cancel <input type="checkbox"/>	Close <input type="checkbox"/>	Submit <input type="checkbox"/>	Save <input type="checkbox"/>
Use case 6	The MS has finalised the ad-hoc assessment outcome and has populated the 'Assessment outcome' section. Which button will the MS click then?				
Possible Solutions	Complete <input type="checkbox"/>	Cancel <input type="checkbox"/>	Share <input type="checkbox"/>	Submit <input type="checkbox"/>	Save <input type="checkbox"/>

Solutions table

Case ID	Correct solution
1	Save
2	Cancel
3	Submit
4	Share
5	Close
6	Complete

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Clinical Trials Information System (CTIS)

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