EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

Assess an annual safety report

CTIS Training Programme – Module 20

Version 1.1 – September 2021

What you will find

- Overall guidelines on how to disseminate the knowledge.
- Overview of the audiences targeted in module 20.
- Overview of the training materials prepared as part of module 20.
- Recommendations on how to prepare and develop the training sessions.

Table of Contents

Introduction 3

Course elements 4

Course preparation 5

Course development 7

Annex 11

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 **twentieth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM20'). The module provides an overview of how to assess an annual safety report in CTIS as part of the supervision of a Clinical Trial (CT). **This guide contains** an overview of the audiences targeted with CTTM20, 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

CTTM20 targets **authority users.**

CTTM20 learning objectives

The learning objectives of CTTM20 are:

1. Remember what an Annual Safety Report (ASR) is and when a sponsor can submit one.
2. Understand the phases of the assessment of an ASR.
3. Understand how to search, view, and download an ASR.
4. Understand how to assess an ASR.
5. Understand how to request additional information to the sponsor.
6. Understand the roles and permissions involved in the ASR process.

Materials available

- **CTTM20 eLearning:** An interactive presentation is an adequate format to present the information regarding the ASR assessment process due to the complexity of the content, as well as to present the steps that users need to follow.
- **CTTM20 Step-by-step guide:** Short step by step document (maximum 2 pages) of the basic processes described in the module.
- **CTTM20 video-clips:** These clips will show a demonstration in the system about:
    - Clip 1: Search and view an ASR and saMS selection (5 minutes 53 seconds).
    - Clip 2: Circulate draft ASR-AR, create and consolidate considerations (7 minutes 33 seconds).
    - Clip 3: Submit ASR RFIs, assess RFI responses, and finalise ASR assessment (4 minutes 51 seconds).
- **CTTM20 FAQs:** List of Frequently Asked Questions including general questions on

ASR, the process of assessing an ASR, the process of creating a Request for Information (RFI) related to an ASR, and the ASR roles and permissions.

03

Course preparation

To ensure that the learning objectives of CTTM20 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 CTTM20 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 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 interactively 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.
- **Review relevant documentation in advance.** In addition to reviewing all the training materials of this Module, including the FAQs, we recommend you familiarise yourself with the articles of the Clinical Trials Regulation[1] related to the safety reporting processes in the context of a clinical trial. We recommend you read at least the following articles, which are related to aspects covered in this Module:
    - *Chapter VII: Safety Reporting in the Context of a Clinical Trial.*
        - Article 43 – Annual reporting by the sponsor to the Agency.
        - Article 44 – Assessment by Member States.
        - Article 45 – Technical aspects.
        - Article 46 – Reporting with regard to auxiliary medicinal products.
    - We also recommend you take a look at the latest version of the European Commission's Clinical Trials Regulation Q&A[2], concretely:
        - Section 7: Safety Reporting. Specifically, provided that the section is composed of multiple sub-sections, take a look at sub-section 7d regarding Annual Safety Reports from question 7.33 to question 7.45.

- **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] 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] 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 eLearning and Step-by-step guide individually

Time: One week before the webinar

Material: CTTM20 eLearning and Step-by-step guide

Objective: This activity consists in reviewing CTTM20 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 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: CTTM20 eLearning, CTTM20 video-clips, CTTM20 FAQs, CTTM20 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 CTTM20 eLearning and Step-by-step guide.
- Present the additional materials for the CTTM20.
- Answer any questions regarding the content of the CTTM20.
- 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 CTTM20 eLearning and the Step-by-step guide.
    b. Launch an online quiz to check if participants understood the key concepts from them.
3. **Part 3:** Screening of CTTM20 video-clips (*approximately 20 minutes*).
    a. Make a brief introduction to the CTTM20 video-clips, so that participants have an understanding of the content they are about to watch. Explain that the video-clips aim to show them how the functionalities of Module 20 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, give 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**: 'Crossword puzzle' exercise (approximately 30 minutes).

    a. The crossword puzzle is an exercise in which participants will have to discover intersecting words, from definitions or suggestions and from words that have been found. For this module, we propose eleven questions of different situations on how to assess an ASR. Participants will need to identify the correct word for each question.

    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 crossword puzzle).

        i. Explain the exercise with the support of slide 2.

        ii. Give participants 10 minutes to discover the words.

        iii. Use approximately 10 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 the crossword 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 the crossword puzzle. If nobody volunteers for it, you can pick one participant to do so or decide to share your screen and start discovering the words based on their input.

            3. In a face-to-face session, you can organise participants in groups, have the black crossword printed, and request the groups to do the crossword 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 steps/actions do you consider important?

            2. What roles do users need to complete the different scenarios?

            3. Do you find this exercise difficult?

Break: (10 minutes)

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

    a. Present the CTTM20 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 CTTM20 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

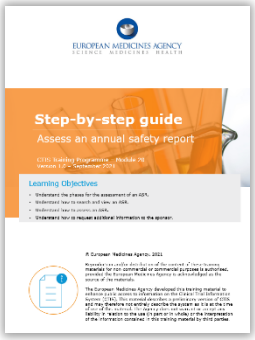
Annex

eLearning

FAQs

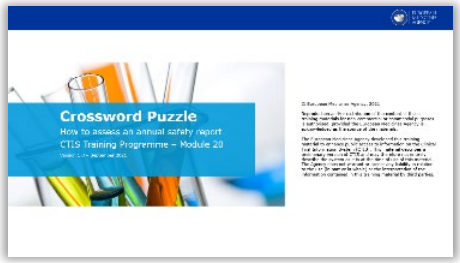
Video-clips

Step-by-step guide



Dissemination guidelines

Crossword Puzzle



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 (CTIS)

Instructor's guide: Assess an annual safety report