



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Instructor's Guide:

How to search, view and download a CT  
and a CTA (Sponsors)

CTIS Training Programme – Module 09

Version 1.1 – October 2021

## What you will find

- Overall guidelines on how to disseminate the knowledge
- Overview of the audiences targeted in module 9
- Overview of the training materials prepared as part of module 9
- Recommendations on how to prepare and develop the training sessions

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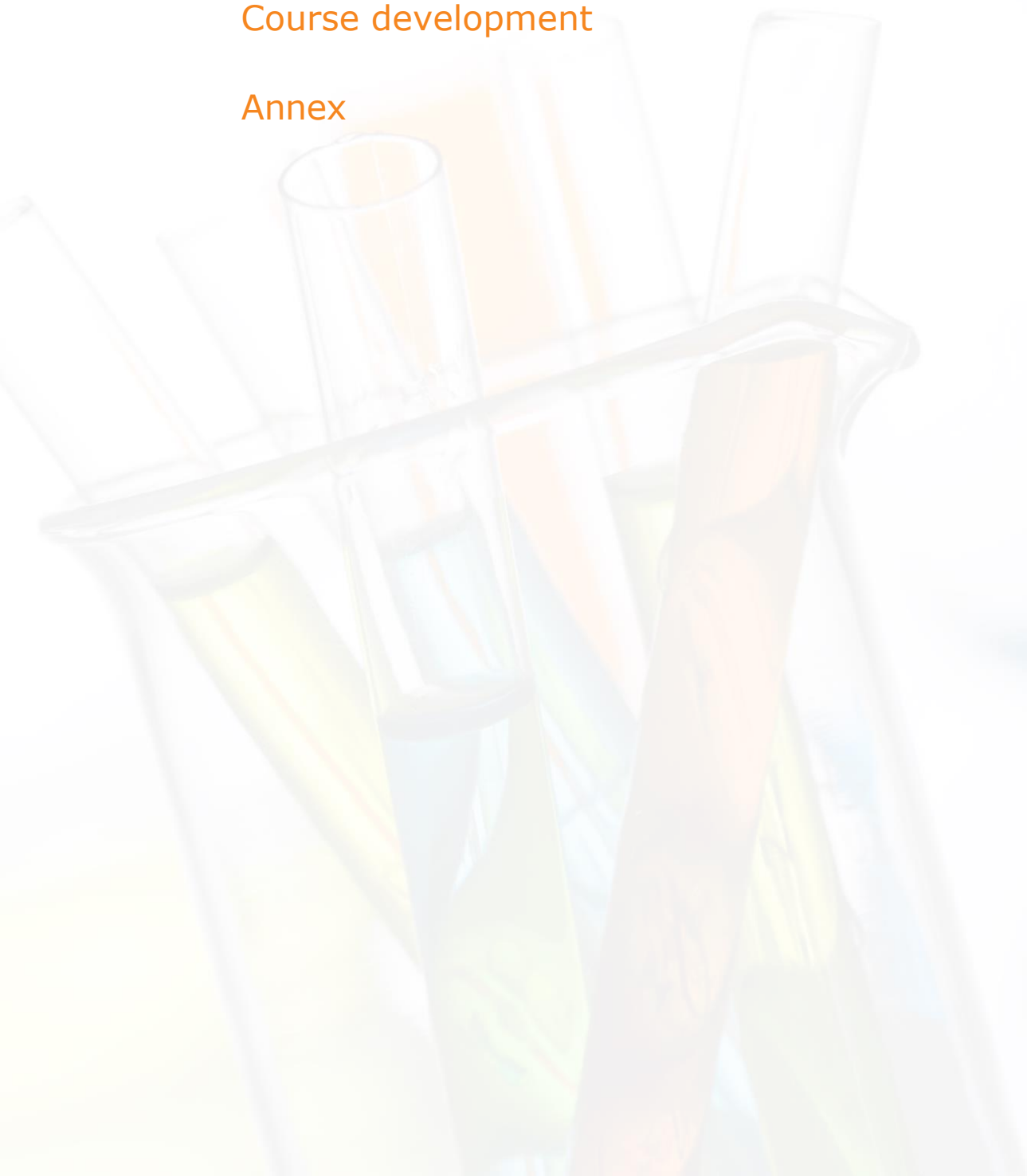


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# 01

## 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 **ninth Module of the CTIS Training Programme** (hereafter referred to as 'CTTM09'). The module provides an overview of how users can search for a Clinical Trials (CTs) and Clinical Trial Applications (CTAs), and how to view and download CT and CTA data and documents. **This guide contains** an overview of the audiences targeted with CTTM09, 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](mailto:CT.training@ema.europa.eu).

# 02

## Course elements



### Target audiences

CTTM09 targets **sponsor users** including Marketing Authorisation Holders (MAH).

### CTTM09 learning objectives

The learning objectives of CTTM09 are:

1. Remember how to search for a Clinical trial (CT) and a Clinical Trial Application (CTA).
2. Understand the information displayed while navigating through a CT and a CTA.
3. Understand how to download information and associated documents.
4. Understand which user roles can access download specific CT/CTA information.

### Materials available

- **CTTM09 Quick guide:** Practical and simple step-by-step guide with system screenshots to show users how to search for a CT and a CTA, the information displayed in the clinical trial page sub-tabs and clinical trial application page sections, and the information and formats available for download.
- **CTTM20 Step-by-step guide:** Short step by step document of the basic processes described in the module.
- **CTTM09 video-clips:** Two video-clips showing a demonstration in the system of how to search for a CT, the information displayed in the clinical trial page sub-tabs and clinical trial application page sections, and the information available for download.
  - Clip 1: How can users search for a CT/CTA? (4 minutes 15 seconds)
  - Clip 2: How can users view and download CT/CTA information? (*timing to be updated*)
- **CTTM09 FAQs:** List of Frequently Asked Questions regarding the following aspects: Search functionalities available in CTIS, how to view CTs and CTAs information, and how to download CT and CTAs and available formats.

# 03

## Course preparation



To ensure that the learning objectives of CTTM09 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 CTTM09 Quick guide and Step-by-step guide** 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 Quick guide with the participants. This will allow you to verify that participants understood the steps presented in the Quick guide 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 Quick guide and Step-by-step guide. 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.

- **Review other relevant modules of the CTIS Training Catalogue**, such as Module 2, where a first introduction to the search functionality is presented:
  - Module 2: Overview of CTIS workspaces and common system functionalities
- **Send the Quick guide and 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 Quick guide individually

**Time:** One week before the webinar

**Material:** CTTM09 Quick guide and Step-by-step guide

**Objective:**

This activity consists in the review by participants of the CTTM09 Quick guide and 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 Quick guide and 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:** CTTM09 quick guide, CTTM09 Step-by-step guide, CTTM09 video-clips, CTTM09 FAQs, 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 CTTM09 Quick guide and Step-by-step guide.
- Present the additional materials for the CTTM09.
- Answer any questions regarding the content of the CTTM09.
- 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 CTTM09 Quick guide and Step-by-step guide.
  - b. Launch an online quiz to check if participants understood the key concepts from the CTTM09 Quick guide and Step-by-step guide.
3. **Part 3:** Screening of CTTM09 video-clips (*approximately 20 minutes*).
  - a. Make a brief introduction to the CTTM09 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 9 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 also ready to replay a video-clip once more if an aspect was not clear enough or covered too quickly.
4. **Part 4:** How to view, search, and download activity (*approximately 30 minutes*).
  - a. Share the document (*see Annex*) with the participants explaining the activity.



Indicate the time they have to read and solve it. There are **six cases** described with **three possible solutions** in each case, only one being correct. Please refer to the exercise document in the Annex of this document to find out the correct answer.

- b. We suggest that you give them up to 15 minutes to read the document and complete the solution table on the third page of the document with the solution that best suits each case description.
- c. Use the remaining 15 minutes estimated for this activity to discuss the scenarios that participants have selected for each case and address any question or incorrect answer.
- d. Key for the instructor: the table below outlines the correct scenarios for each of the cases.

Case ID	Correct solution	Comments/justification for the instructor
1	<b>A</b> Basic search	The best search to find the CT, in this case, is the basic search, as the user knows the <b>EU CT number</b> .
2	<b>C</b> Application advanced search	<b>The user knows specific criteria only available in the application advanced search</b> , such as application status and the submission period, making this a better choice.
3	<b>B C</b> Both are correct	Either of the advanced searches is suitable for this search given that <b>the criterion the user knows about the required CTs (the MSC) is a parameter common in both searches</b> .
4	<b>B</b> Trial advanced search	Since the user knows two possible MSCs in which the CT is being conducted, and the recruitment status is either pending or ongoing, <b>the user should launch a trial advanced search</b> because: 1) these criteria are unique in this search 2) the user can enter two values in a search parameter and will get the results matching either of them.
5	<b>C</b> Clinical trial page (full trial information sub-tab)	Since the user wants to have a <b>comprehensive look at all the relevant information about a CT</b> such as protocol information, objectives, the population of trial subjects, or recruitment arrangements, <b>the best place to view that information is in the full trial information sub-tab</b> . Other sub-tabs in the clinical trials page show more narrowed down information.
6	<b>A</b> Search results list	The best way for a sponsor to <b>download all the documentation would be to do it from the search results list</b> . In there they would select the trial they are interested in, and click on the download button to retrieve <b>all the CT information, data and documentation</b> that the user has permissions to see in a <b>Zip folder</b> .

**Break:** (10 minutes)

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

- a. Present the CTTM09 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 the 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 CTTM09 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](mailto: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 guide



FAQs



Video-clips



Step-by-step guide

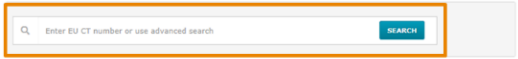
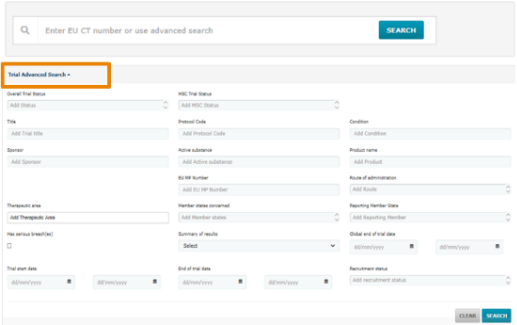
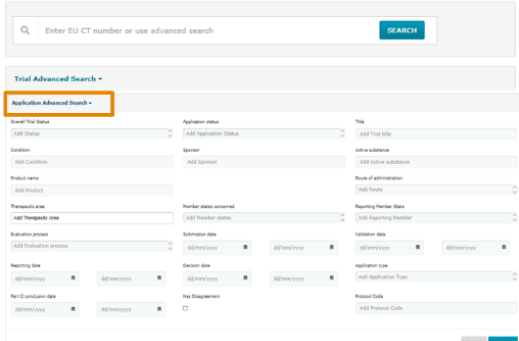
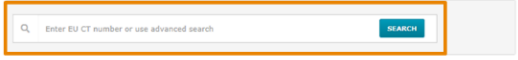
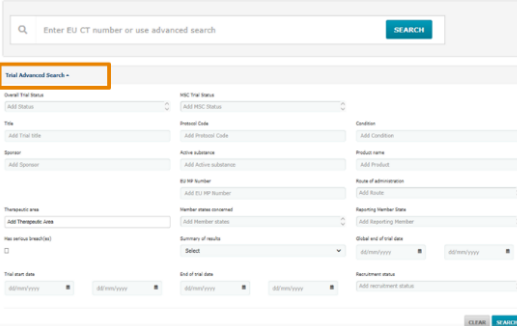
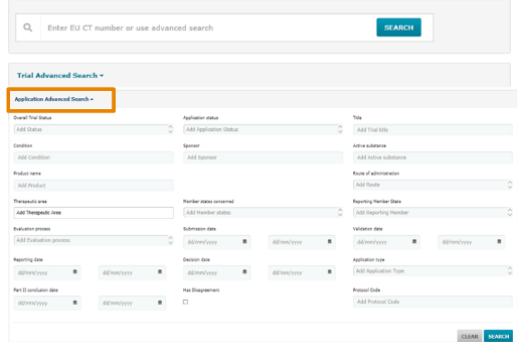


Dissemination guidelines





# How to view, search and download activity

<p><b>Use case 1</b></p>	<p>You are the CT admin of Medicalical Pharmaceuticals. You need to open the initial CTA of a CT for which you know the EU CT number (2020-123000-12-34). <b>What search would you use to find the trial?</b></p>		
<p><b>Possible Solutions</b></p>	<p style="text-align: center;"><b>A</b></p>  <p style="text-align: center;"><b>Basic search</b></p>	<p style="text-align: center;"><b>B</b></p>  <p style="text-align: center;"><b>Trial advanced search</b></p>	<p style="text-align: center;"><b>C</b></p>  <p style="text-align: center;"><b>Application advanced search</b></p>
<p><b>Use case 2</b></p>	<p>The sponsor Romstel Pharmaceuticals is conducting more than 100 trials in different Member States Concerned (MSC). A CT Admin needs to find the initial application of a CT being performed with the product Salbutamol. The user knows that the initial CTA is authorised, that it was submitted in January 2020 and that Latvia is the only MSC. <b>What is the best search functionality to find the trial?</b></p>		
<p><b>Possible Solutions</b></p>	<p style="text-align: center;"><b>A</b></p>  <p style="text-align: center;"><b>Basic search</b></p>	<p style="text-align: center;"><b>B</b></p>  <p style="text-align: center;"><b>Trial advanced search</b></p>	<p style="text-align: center;"><b>C</b></p>  <p style="text-align: center;"><b>Application advanced search</b></p>

### Use case 3

The sponsor Sainz Pharmaceuticals is performing more than 50 trials in different MSCs. A CT Admin wants to extract a list of all the CTs being conducted in Spain. **What search should he/she use to find the trial?**

### Possible Solutions

A

Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Basic search

B

Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Trial Advanced Search -

Overall Trial Status: Add MSC Status

Title: Add Protocol Code

Sponsor: Add Sponsor

Therapeutic area: Add Therapeutic area

Has serious threat(S):

Recruitment status: Add recruitment status

SEARCH

Trial advanced search

C

Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Trial Advanced Search -

Application Advanced Search -

Overall Trial Status: Add Application status

Condition: Add Condition

Product name: Add Product

Therapeutic area: Add Therapeutic area

Submission process: Add Submission process

Reporting date: Add Reporting date

SEARCH

Application advanced search

### Use case 4

The sponsor Virtualmedics Pharmaceuticals is conducting one CT with the product Levofloxacin. The CT Admin is unsure whether the CT is conducted in Italy or Spain, and also the user is unsure about the recruitment status being either pending or ongoing. **What is the best search functionality to find that CT?**

### Possible Solutions

A

Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Basic search

B

Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Trial Advanced Search -

Overall Trial Status: Add MSC Status

Title: Add Protocol Code

Sponsor: Add Sponsor

Therapeutic area: Add Therapeutic area

Recruitment status: Add recruitment status

SEARCH

Trial advanced search

C

Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Trial Advanced Search -

Application Advanced Search -

Overall Trial Status: Add Application status

Condition: Add Condition

Product name: Add Product

Therapeutic area: Add Therapeutic area

Submission process: Add Submission process

Reporting date: Add Reporting date

SEARCH

Application advanced search

## Use case 5

The sponsor Ioxiox Pharmaceuticals is conducting a CT with the product Amylinx. The CT admin would like to have a comprehensive look at all the relevant information about that CT (e.g. protocol information, objectives, trial duration, population of trial subjects, recruitment arrangements, etc.). **Where can he/she retrieve all the CT information?**

## Possible Solutions

**A**

**Search results list**

**B**

**Clinical trial page (summary sub-tab)**

**C**

**Clinical trial page (full trial information sub-tab)**

## Use case 6

The sponsor Alfabetha Pharmaceuticals is conducting one CT with Paracetamol. The CT Admin needs to download all the documentation and structured data of that CT. **What is the download functionality that would work best to download all the CT data and documents?**

## Possible Solutions

**A**

**Search results list (download functionality)**

**B**

**Clinical trial page (download functionality)**

**C**

**Clinical trial application page (initial application Part I download functionality)**

## Solutions table

Case ID	Correct solution
1	
2	
3	
4	
5	
6	



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Clinical trials information system (CTIS)

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