



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Quick guide

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

CTIS Training Programme – Module 09

Version 1.3 – February 2022

### Learning Objectives

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

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# | Introduction

The search functionality enables users to retrieve Clinical Trials (CTs) and/or associated Clinical Trial Applications (CTAs), view information, and download structured data and documents associated with them.

As a general rule, users are only able to retrieve CT and CTA information for those trials in which they are involved and have been assigned a role by an administrator within their organisation. Moreover, the possibility to view and download CTs and CTAs data and documents will be limited to the areas of action of each role assigned in CTIS. This means, for example, that a user that only has Part II preparer role will not be able to view or download Part I information of the CTA.

## Sections of this quick guide

This quick guide is structured in three sections:



### Search for a CT and a CTA

Steps that users need to follow to search for a Clinical trial or a Clinical trial application.



### View a CT and CTA information

Guide for users to be able to retrieve information of a clinical trial, an application or a non-substantial modification.



### Download CT and CTA information

Guide for users to download information when accessing a trial, an application or a non-substantial modification.

## Search for a CT / CTA



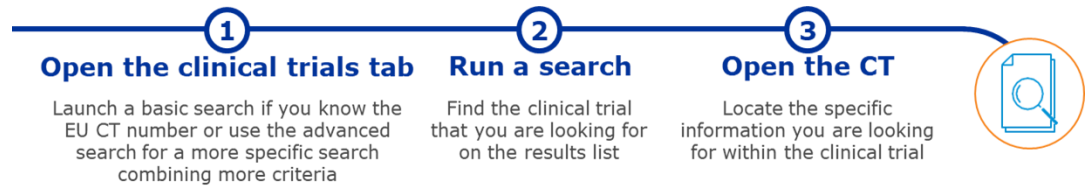
The search functionality enables users to search for CTs and/or related CTAs matching a set of criteria.

Users are able to view trials in which they are involved and for which they have been assigned a role by an administrator user.

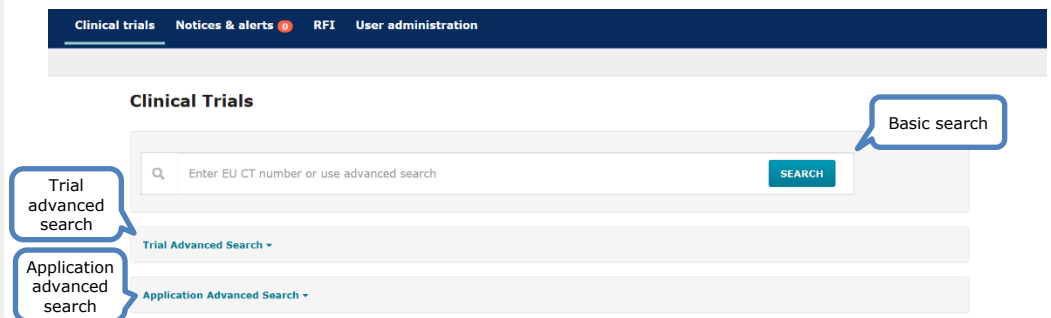


In both advanced searches, users can specify multiple values within each criterion. For example, a user can search for trials in status 'under evaluation' and 'authorised' and select two MSCs. The advanced search will look for trials in either of these statuses, taking place in either of the two countries.

## How to search for a clinical trial/clinical trial application



To perform a search, the user needs to click on the clinical trials tab (see figure below). Once in the tab, there are **one basic search** and **two advanced search functionalities** available for the user to choose:



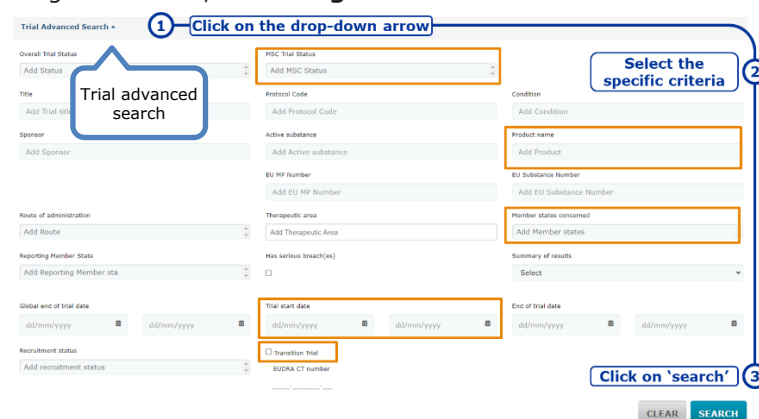
The **main difference** between them is that the **basic search** retrieves specific trials by their EU CT number (trial identifier code), while in the **advanced searches** the user can enter multiple criteria to search for trials. Hence, the advanced searches are more useful for organisations that manage numerous trials and need to monitor them through specific criteria.

### Basic search

The basic search functionality allows users to look for specific CTs and CTAs in the search bar of the clinical trials tab. The user needs to **type the EU CT number** and **click on the 'search' button** to launch the search. If the user **clicks on the 'search' button** without specifying an EU CT number, all CTs that the user has permissions to view will appear on the results list.

### Trial advanced search

This search functionality allows users to **search for CTs matching a set of specified criteria** such as trial start/end dates, Member State Concerned (MSC), therapeutic area product name, active substance, etc. This search is more suitable when the user does not know the EU CT number and/or wishes to perform a more targeted search, **matching a set of CT-related criteria**.



## Search for a CT / CTA



The search results list the CTs that match the specified criteria in any of the search functionalities.

The trial status is indicated in colour under the CT number and title.

## Application advanced search

This search functionality allows users to **search for CTs that contain application(s) matching specified criteria** such as application status, types of applications, submission/decision dates, etc. This search is more suitable when the user does not know the EU CT number and/or wishes to retrieve one or more trials containing the CTAs **matching a set of CTA-related criteria**.

## Search results list

**Once the search is launched**, the results are displayed in a table below the search functionality. **Users can view preliminary information** of the trial, including the Reporting Member State, the Member State(s) concerned, the sponsor(s) who submitted the CTA, the product being tested, and the submission date. The **results can be sorted** by the EU CT number, evaluation process, the sponsor who submitted them, or the status (under evaluation, authorised, not authorised, withdrawn). Please go to the Frequently Asked Questions document of this module for more information.

**Search Results**

Showing 1 - 4 of 4 items 1 of 1 pages < 1 >

Sort by: Submitted Download Trials

EU CT number: unique identifier of the trial	Condition	Sponsor/Co-sponsors	Product	Submission date
2020-500177-33-00 Trial title: Test Trial AK01 Pending	CS	Test Organisation Demo		
2020-500178-14-00 Trial title: Test Trial AK02 Pending	RMS MSCs	Test Organisation Demo		

*Note: The trial status will be indicated in color below its number.*



Some criteria are common in both advanced searches, such as the overall trial status, the therapeutic area, the active substance, or search specifically for transitional trials, while others are specific.

Sponsors can retrieve draft CTAs that have not yet been submitted to the MSCs. Their status will be displayed as 'pending'.

## View CT information



Users will find all CTs-related information in the clinical trial page by clicking on the EU CT number of any trial.

## Overview of the clinical trial page

Users can access the clinical trial page by **clicking on the EU CT number** in the search results list. After accessing a trial, they will land, by default, on the **Summary sub-tab** of a clinical trial page, which displays key information of the CT.

**Clinical Trial for CTIS Training**  
 Authorised 2020-500257-41-00 RMS: Austria

Summary Full Trial Information Notifications Trial results Corrective measures Ad Hoc assessments Users

**TRIAL INFORMATION**

<b>Sponsor</b>	Test Organisation 1	<b>Member states concerned</b>	AT · DE · FR
<b>Trial phase</b>	Human Pharmacology (Phase I)- Other	<b>Medical conditions</b>	Apnoea
<b>Therapeutic area</b>	Diseases [C] - Respiratory Tract Diseases [C08]	<b>Low intervention study</b>	No
<b>Medical device</b>	No	<b>Population type</b>	Healthy Volunteers

Clinical trial page sub-tabs

## Clinical trial page sub-tabs

In addition to the **summary sub-tab**, there are **other sub-tabs** that provide additional information on other aspects of the trial. This information will be visible to the user according to the role assigned. The sub-tabs are:

- **Summary:** Displays key information of the CT, the trial status in the MSC, the therapeutic area, and, in consecutive order, a full list of CTAs and non-substantial modifications.
- **Full Trial information:** Displays comprehensive data and documents on the latest authorised application
- **Notifications:** Enables to view and manage the relevant events in the life cycle of an authorised CT which have been notified to the MSC (e.g. trial start date, temporary halt, unexpected event, serious breach, etc.).
- **Trial results:** Shows the summary of results of any intermediate analysis of data or the summary of results, with the corresponding layperson summary of results, submitted by the sponsor at the end of the trial and the Clinical Study Report submitted by the Marketing authorisation applicant, if applicable.
- **Corrective measures:** Displays the possible measures taken by MSC as part of their supervision activities to ensure adherence to the Clinical Trials Regulation.
- **Ad hoc assessments:** Lists the assessments done by the MSC on ad hoc basis as part of their supervision activities, following, for example, the submission of notifications, or safety-related information.
- **Users:** Lists all the users associated with a CT, as well as their role(s), sponsor organisation or authority organisation and employer.



In the CT summary page the user can also view the overall trial status in all the MSCs.

Example

Summary Full Trial Information Notifications **Trial results** Corrective measures Ad hoc assessments Users Inspections

**SUMMARY OF RESULTS**

test **Submitted** ID: Sum-0838 Submission date: 13/03/2021 Version type: Intermediate

**LAY PERSON SUMMARY OF RESULTS**

**CLINICAL STUDY REPORTS**

Procedure number: EMEA/H/C/132456/576 **Submitted** ID: CSR-0839 Submission date: 13/03/2021 MAA Procedure outcome: MA granted

Summary of results

Trial results sub-tab

Lay person summary of results

Clinical Study Reports

Clicking on the eye icon will open a window with all the details

## View CTA information



Users will find all information related to CTAs and non-substantial modifications on the bottom of the CT summary sub-tab.

This page is composed of six sections outlining the specific information of the CTA.

## Overview of the clinical trial applications and non-substantial modifications page

At the bottom of the summary sub-tab within a CT, users will find all the CTAs (initial, addition of a new MSC or substantial modification) and non-substantial modifications related to that CT, as shown in the figure below.

**Trial \_ CTIS Training**  
 Pending 2020-500376-29-00 Proposed RMS: Austria

Summary Full Trial Information Notifications Trial results Corrective measures Ad Hoc assessments Users

Scroll down to locate the CTA

**APPLICATION AND NON-SUBSTANTIAL MODIFICATION**

Type	ID	Parts	MSCs	Submission date	Decision date	Reason	Scope	Link
Substantial modification	SM-1	Part I Part I Part I	AT(Under evaluation) DE(Under evaluation)					+ + ↗
Additional MSC	AM-3	Part II	FR(Under evaluation)	28/10/2020		-	-	- + INFO
Initial	IN	Part I & Part II Part I & Part II	AT(Authorised) DE(Authorised)	22/10/2020	22/10/2020	-	-	- + INFO

The user can **open any of the available applications and non-substantial modifications by clicking on the ID reference. Once inside the application or non-substantial modification**, users will be able to **view and manage** the information displayed by navigating through the **sections on the left of the page**, as shown below.

Clinical Trial for CTIS Training 2020-500257-41-00 / Additional MSC ID: AM-3 Under evaluation / RMS: Austria

Withdraw Copy

**Country specific details (Part II - FR)**

CTA sections: Form, MSCs, Part I, Part II - FR, Evaluation, Timetable

Drop-down list where the versions of the submitted CTAs will be listed

Trial sites

Documents

Recruitment Arrangements

Subject information and informed consent form

Suitability of the investigator

Suitability of the facilities

Versions

## #CTIS insights

In case users submit new versions of a CTA (for example, to respond to modifications requested from MSCs through an RFI), they will be able to view the older versions of those CTAs via clicking on the archive icon located on the right side of a clinical trial application page (see figure).

### Clinical trial applications sections

There are various **sections** that provide additional CTA information:

- **Form:** Displays application form details including the cover letter, proofs of payment for each MSC, and the publication timing for data and documents, with deferrals, if applicable.
- **MSC:** Displays information such as the MSCs of the application, the proposed RMS, the countries outside of the EU where the trial is intended to be conducted, an estimated total subjects population for the trial per MSC, etc.
- **Part I:** Displays trial-specific information (data and documents) of the CTA common to all MSC such as protocol information, trial design, product quality, inclusion and exclusion criteria, conditions to be treated, therapeutic area, etc.
- **Part II:** Displays for each MSC the trial sites (data) and documents of the CTA (e.g. informed consent, recruitment arrangements, etc.).
- **Evaluation:** Displays information related to the evaluation of the CTA (e.g. the outcome of the validation, assessment of Part I and Part II and the decision).

## Download CT and CTA information



The 'Download' button allows users to download the latest versions of the structured data and documents they have permissions to access.

## #CTIS insights

On the clinical trial page, users can download the documentation related to the clinical trials and its applications by selecting the sections they are interested in.

Structured data is all the structured information that has been entered manually in CTIS, such as written values, selections made via checkboxes or selections from a list.

- **Timetable:** Provides a visual overview of the evaluation status and progress of the CTA, including completed phases and a forecast of upcoming tasks.

### How to download clinical trial information

There are two ways of downloading CTs and CTAs information. Users can download information from different sections. Data can be directly downloaded from the clinical trial page and from the clinical trial application page. The version of the documents downloaded is the last one submitted.

#### Clinical trial page

The screenshot shows the 'Trial \_ CTIS Training' interface. At the top right, there is a 'Download' button. Below it, a 'Start Download' button is visible. A callout box labeled '1' points to the 'Download' button with the text 'Click on 'Download' to open the functionality'. Another callout box labeled '2' points to the 'Start Download' button with the text 'Click on 'Start Download''. A third callout box labeled '3' points to a list of content options with the text 'Select the contents of applications or sub-tabs you want to download'. The list includes 'Evaluation', 'Cover letter', 'Part I', 'Part II', 'Notifications', 'Corrective Measures', and 'Summary of Results / Layperson Summary'. There are also checkboxes for 'Structured data in PDF\*' and 'Documents\*'. A note below these checkboxes states: '\* these only include the latest version related to the application'.

Users can **download the information and associated documents** of the CT and its CTAs by clicking on the '**Download**' button on the up-right corner of the clinical trial page. The user will download CT and CTA details of their choice (e.g. Cover letter, Part I, Part II, notifications, summary of results, structured data related to the Evaluation, etc.) in a ZIP folder including PDF files.

#### Clinical trial application page

Users can download specific documents from the different sections of a CTA page (including the documents related to the evaluation of the CTA), and also from a table of documents in 'Part I' and 'Part II' sections.



## Download CT and CTA information



The download functionality allows users of the same organisations to share documents among each other outside of CTIS.

- *Download documents from the CTA sections*

Users can download files from the sections 'Form', 'Part I', 'Part II', and 'Evaluation'. **In the Evaluation section**, users can download documents regarding Requests for Information or Final assessment reports, amongst others. To do so, users need to expand the sections by clicking on the arrow and then they can **click on the blue icon** next to each document, as in the example below:

Form  
MSCs  
Part I  
Part II  
**Evaluation**  
Timetable

Assessment Part I

RFI 1

Expand all

RFI-CT-2021-500655-31-00-IN-002 Due: 10/12/2021

MSC: Greece Submission date: 28/11/2021 Due date: 10/12/2021

Changes to the application

No document available

No document has been uploaded.

Supporting documentation

MS:

Quality

No document available

Non-Quality

Icon to individually download a document

Non quality document

English · Supporting document from MS - Non Quality (for publication) · System version 1.00  
submission date 28/11/2021  
· Version 1 · 28/11/2021

- *Download documents from the table of documents*

Users can also view and download a **full list of associated documents contained in a CTA or non-substantial modification**. To do so, they need to go to the clinical trial application page, select the application they are interested in, and follow the steps below.



The RFI documents can be downloaded individually using the blue download icon next to each document.

In case the user wants to download the formation, it should be done by downloading the TC

Select Part I or Part II sections to download documentation from

✓ Check Save Cancel Submit

1 Form MSCs Part I Part II Evaluation Timetable

2 Scroll down in the CTA page

3 Download the documentation from the list

Document type	Document Title	Document Version	Document Comment	Document Submission Date	System version	System date	Language	Download
Recruitment arrangements (for publication)	2_1_Part2_Recruitment_Arrangement	1		21/10/2020	1	21/10/2020	English	
Subject information and informed consent form (for publication)	2_2_Part2_Subject_Information	1		21/10/2020	1	21/10/2020	English	



## Download CT and CTA information



On the clinical trial application page, users can download the associated documentation related to the 'Part I' or 'Part II' of a CTA from the table of documents at the bottom of the page.

The documents will appear in a table format outlining different details of the documents in a table with 14 columns. Each column (e.g. application type, submission date, etc.) can be sorted out and filtered by its content. The columns will preliminarily display a set of details of each specific document.

The sorting and filtering options work following a spreadsheet logic. This means that users can use the arrows next to each criterion name on top of each column to **sort the documents in alphabetic order**. Additionally, some criteria have **filtering options** that users can select via a drop-down list, as shown in the example below:

All documents

Document type	Section		Document Title	Document Version	Document Comment	Document Submission Date	System version	System date	Language	Download
Cover letter (for publication)	Part I	Original	0_Form_CoverLetter	1		09/11/2021	1.00	09/11/2021	English	
Protocol (for publication)	Part I	Original	0_Part1_CT_Protocol	1		09/11/2021	1.00	09/11/2021	English	

Annotations: 1 Use the arrows or filters to organise the documents. 2 Click on the document icon to download.

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Clinical Trials Information System (CTIS)

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