



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

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

CTIS Training Programme – Module 15
Version 1.1 – December 2021

Learning Objectives

- Remember how to search for a clinical trial (CT) and a clinical trial application (CTA).
- Understand how to view the information displayed in a CT and a CTA.
- Understand how to download information and associated documents.

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How to search, view and download a CT and a CTA in the authority workspace

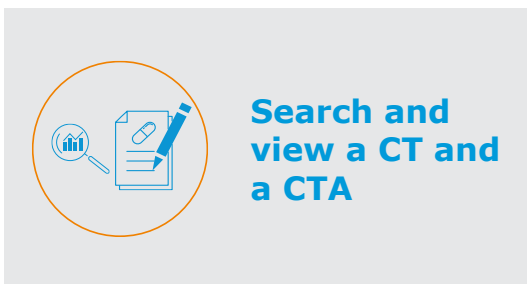
The search functionality enables users to retrieve Clinical Trials (CTs) and/or associated Clinical Trial Applications (CTAs), view information, and download structured data and documents associated with them.

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 information can be accessed through a CT page and a CTA page.

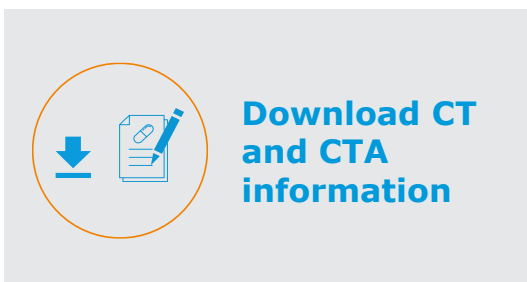
The CT page sub-tabs provide additional information on aspects of the trial. This information will be visible to the user according to the role assigned and include *Summary, Full Trial information, Notifications, Trial results, Corrective measures, Ad hoc assessments, Users and Inspection.*

The CTA page includes the information on the application, which users can view and manage by navigating through the sections on the left of the page. These sections include *Form, MSC, Part I, Part II, Evaluation and Timetable.*

This Step-by-step guide includes:



This section outlines the steps that authority users should follow to search for CTs and CTAs and how to view related information.

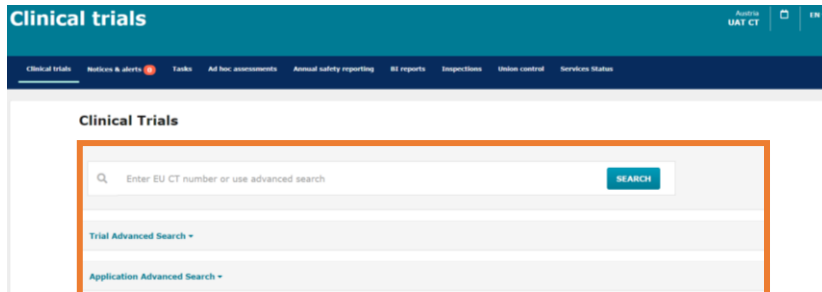


This section outlines the steps that authority users should follow to download CTs and CTAs related information.

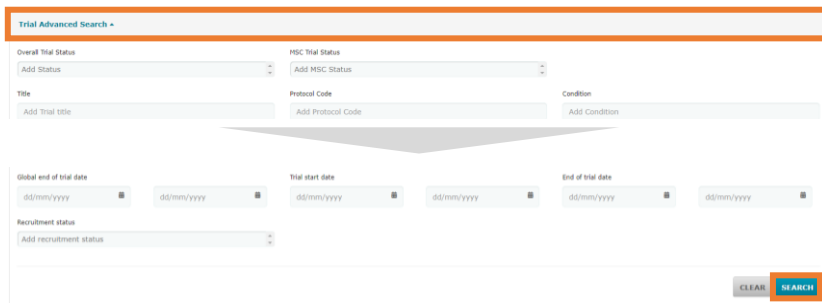
Search and view a CT and a CTA

How to search for a CT and/or CTA

1. Users can open the **Clinical trials tab** and **select the search functionality**. For a basic search, input the EU CT number.

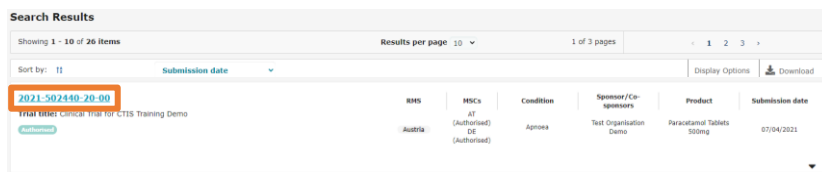


2. For an advanced search, input the criteria and click on the **'Search'** button.

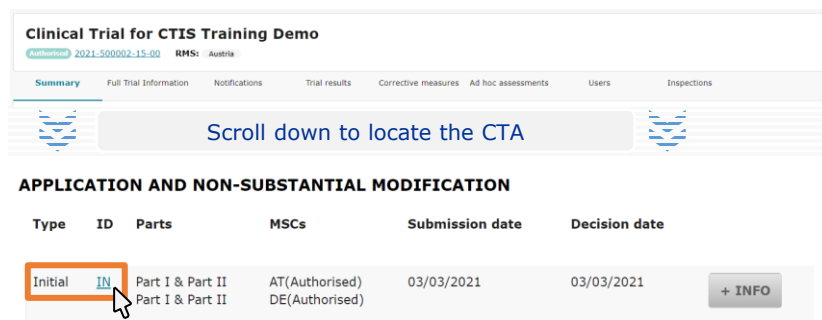


How to view CT and CTA related information

1. On a search results list, users can click on the **EU CT number** to open **CT page**.



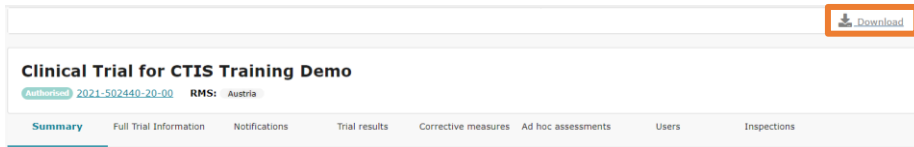
2. Users can scroll down on a CT page and open a **CTA page** by clicking on the CTA **ID reference**.



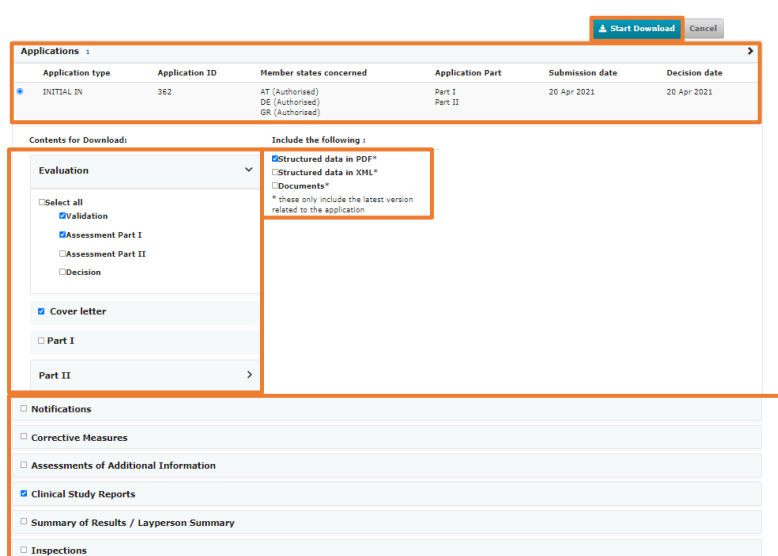
Download CT and CTA related information

Download from the CT page

1. On a CT page, users can click on the **'Download'** button



2. Users can select the contents, the file type and click on the **'Start download'** button.

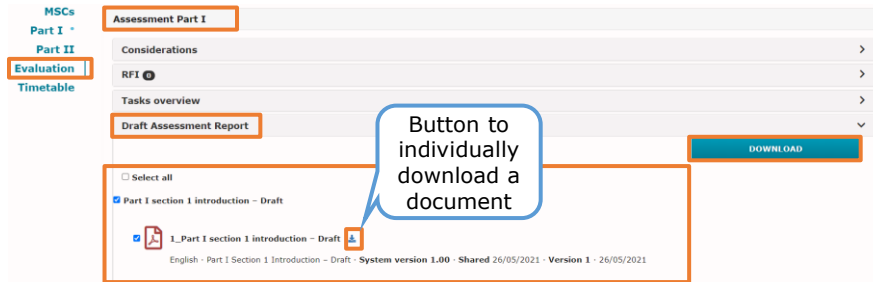


Download CT and CTA related information

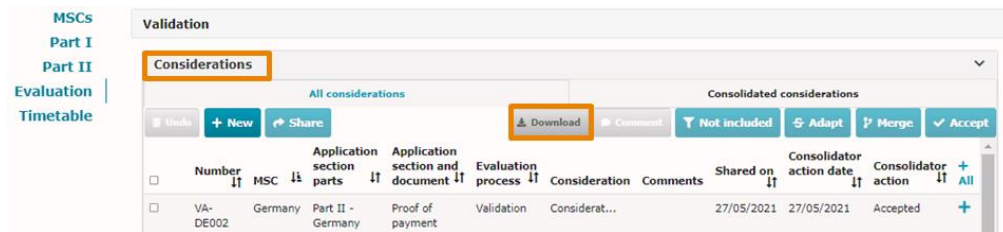
Download documents from the CTA page

Download specific documents from the evaluation section

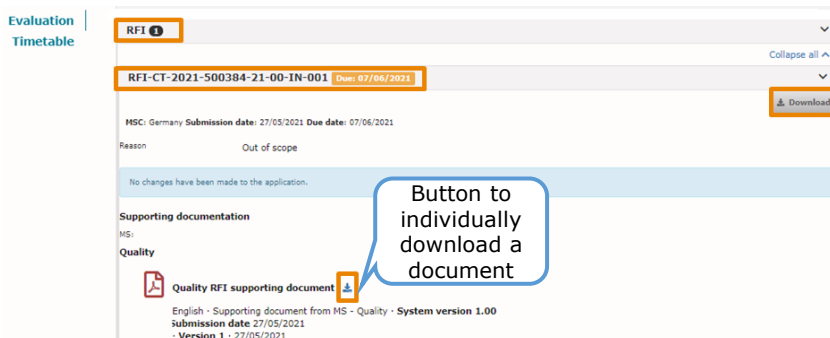
1. On the evaluation section of a CTA, users can select the documents they want to download using the radio buttons (e.g. **Draft Assessment Report** - Assessment Part I). Then, they can click on the **'Download'** button to download the selected document(s).



2. To download a document comprising the considerations raised during the evaluation of a CTA, users can click on the **'Download'** button of the Considerations sub-section in a CTA form.



3. To download a document containing the relevant information regarding an RFI, users can click on the **'Download'** button on the right side of an open RFI.



Download from the table of documents

1. On a CTA page, either on Part I or Part II section, users can scroll down and click on the document icon on the **'All documents'** 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	

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Clinical Trials Information System (CTIS).

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