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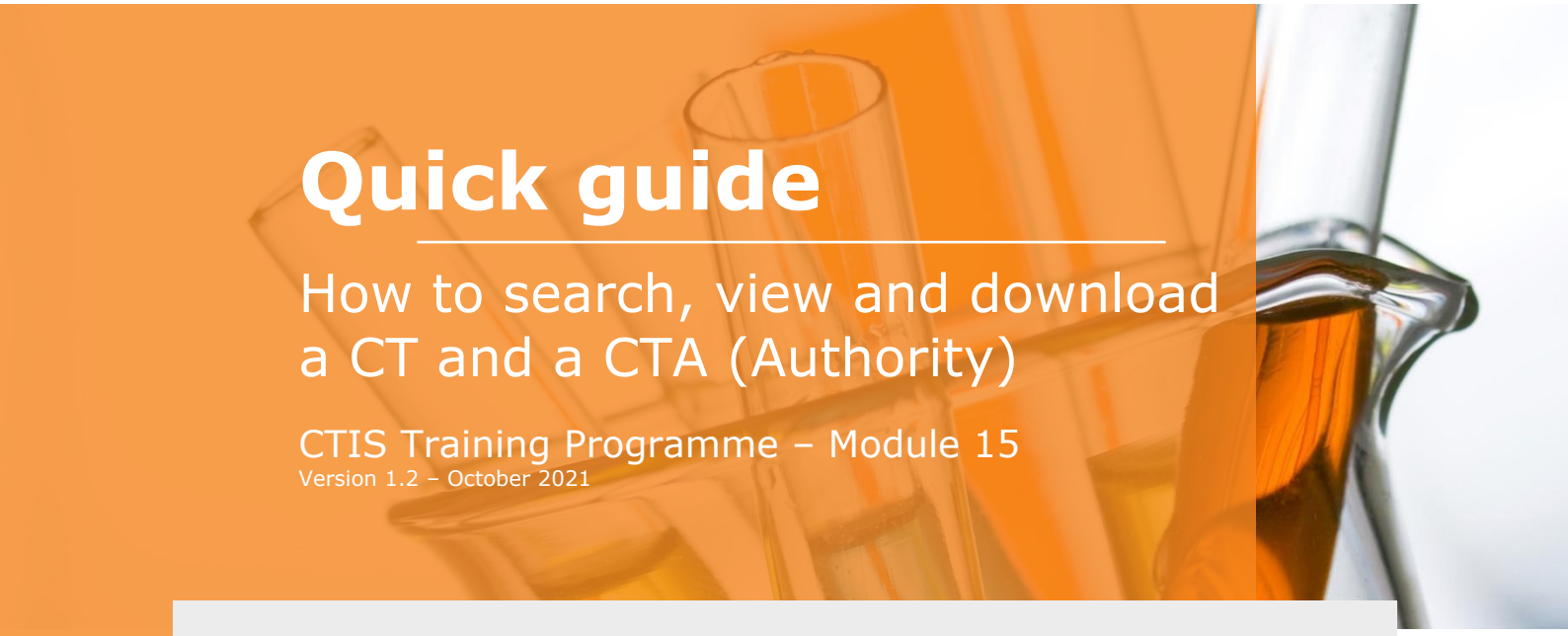


Quick guide

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

CTIS Training Programme – Module 15

Version 1.2 – October 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.
- Understand which user roles can view and download specific CT/CTA information.

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

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.

Member State users are able to perform actions regarding CTs and CTAs data and documents depending on the role they have been assigned by administrator users. This means, for example, that a user that only has Assessor Part II preparer role will not be able to perform actions in the 'Part I' section of a specific 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.

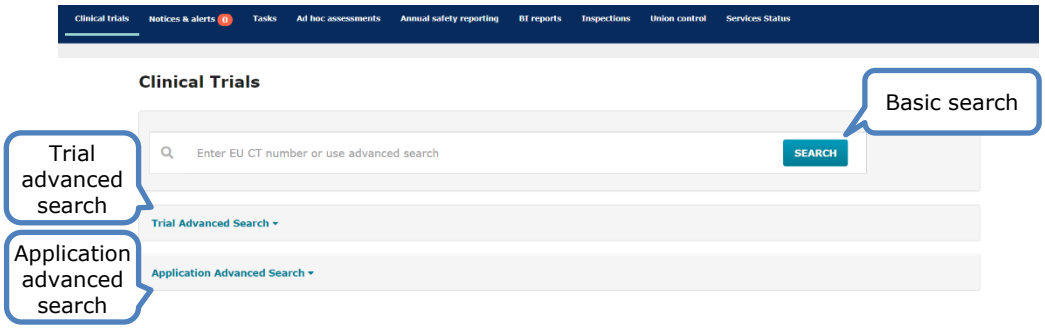
#CTIS insights

In both advanced searches, users can specify multiple values for most criteria. For example, users can search for trials in status 'under evaluation' and 'authorised' and select two therapeutic areas. The advanced search will look for trials in either of these statuses, with either of the two therapeutic areas.

How to search for a CT and a CTA

1. **Open the clinical trials tab** — Launch a basic search if you know the EU CT number or use the advanced search for a more specific search combining more criteria
2. **Run a search** — Find the clinical trial that you are looking for on the results list
3. **Open the CT** — Locate the specific information you are looking for within the clinical trial

To perform a search, users can 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 users to choose:



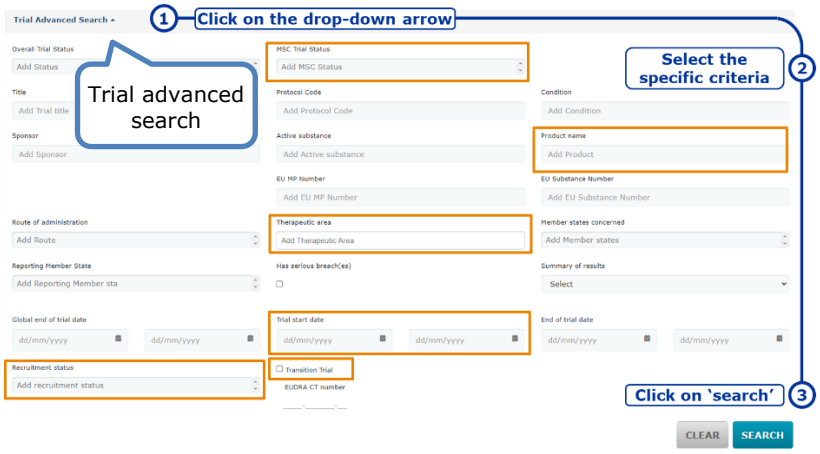
The **main difference** between them is that the **basic search** retrieves specific trials by their EU CT number (trial identifier code), while in the **advanced searches** the user can enter multiple criteria to search for trials or applications. Hence, the advanced searches are more useful for users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

Basic search

The basic search functionality allows users to look for specific CTs in the search bar of the Clinical trials tab. Users can **type the EU CT number** and **click on the 'Search' button** to launch the search. If a user **clicks on the 'Search' button** without specifying an EU CT number, all CTs that the user has permission 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**.



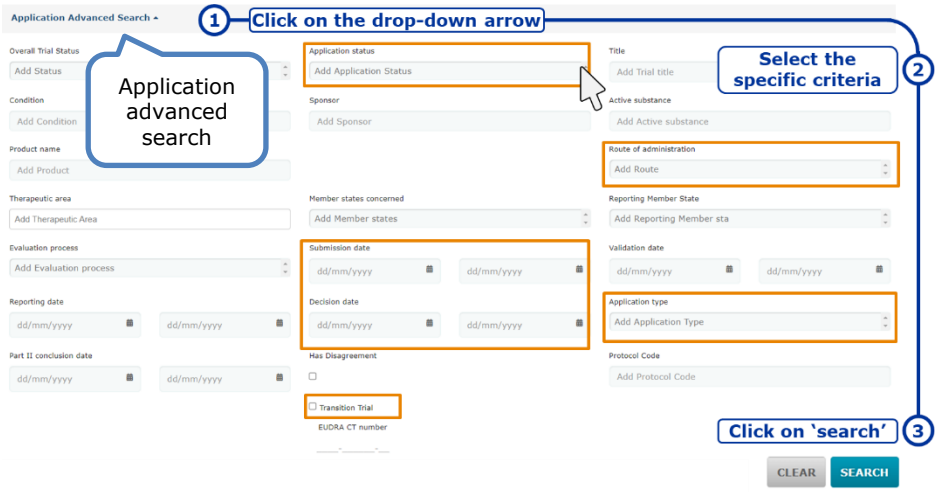
Search for a CT / CTA

The search results list contains 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.

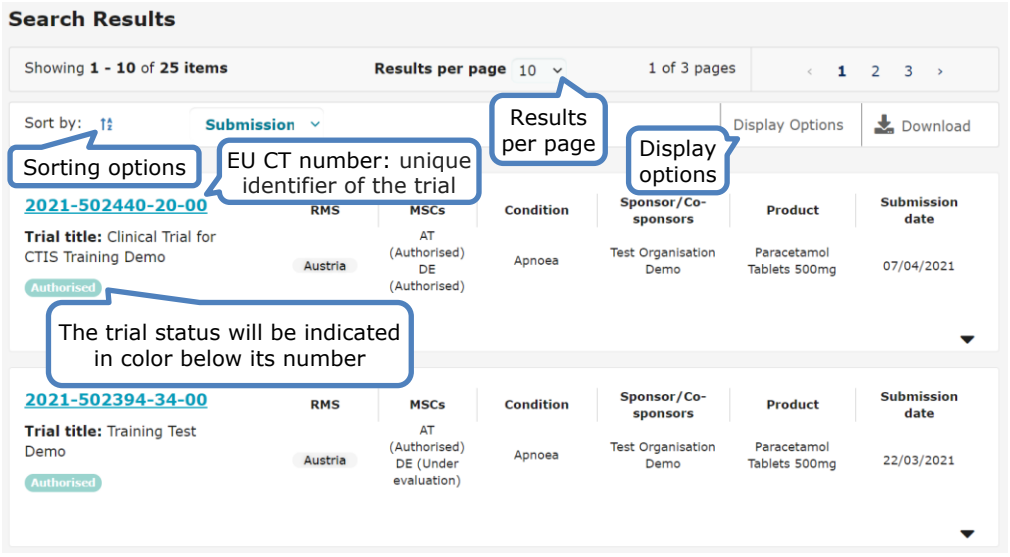
Application advanced search

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 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 (RMS), the MSCs, the condition, the sponsor who submitted the CTA, the product being tested, and the submission date. Users can **decide how many results will be shown per page** by clicking on the respective number on the top-center of the list (i.e. 10, 20, 50, 100). By clicking on the 'Display Options' button, users can **select more parameters regarding the trials to be shown in the list** such as trial type, overall start and end of trial, recruitment status, etc. The **results can be sorted** by the EU CT number, trial title, Reporting Member State, evaluation process, the sponsor who submitted them, overall trial status, etc. *Please go to the Frequently Asked Questions document of this module for more information*.



#CTIS insights

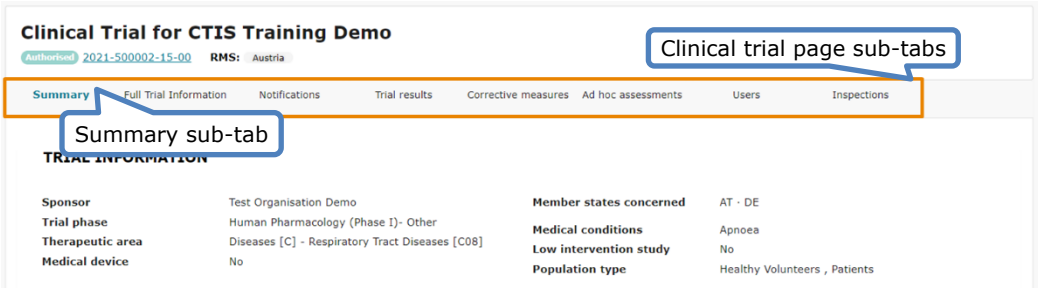
Some search criteria are common in both advanced searches, such as the overall trial status, the therapeutic area, the active substance, or search specifically for transitional trials, while others are specific.

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

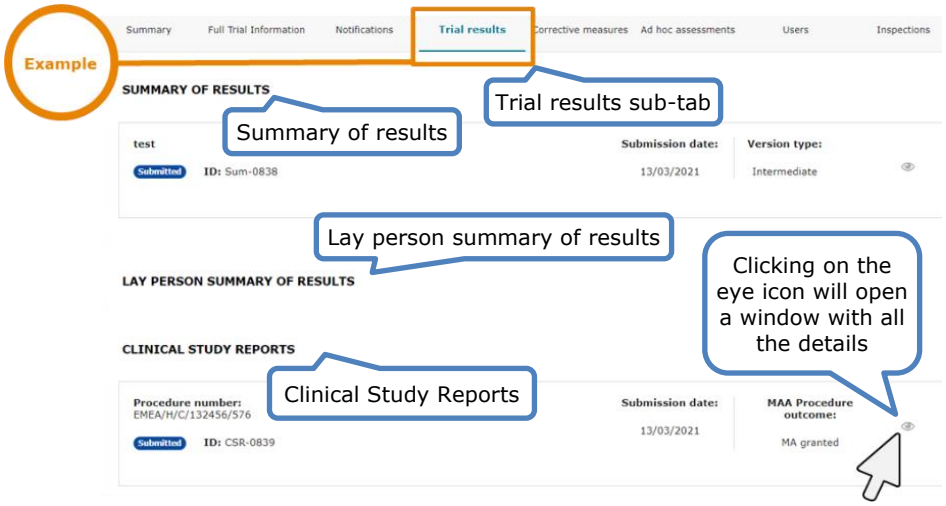
Users can access the CT page by **clicking on the EU CT number** in the search results list. After accessing a trial, they will land, by default, on the **'Summary' sub-tab** of a CT page, which displays key information of the CT.



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.
- **Inspections:** Lists the inspection records relevant to that specific trial.



#CTIS insights

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

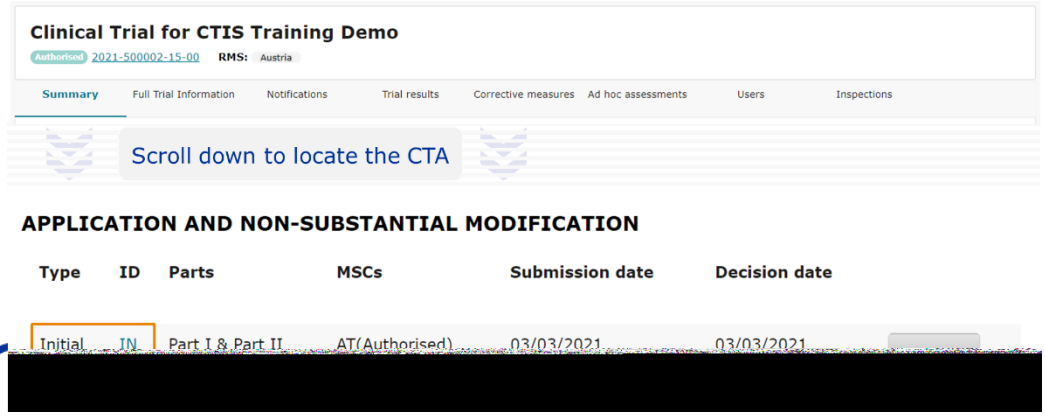
View CTA information

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

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

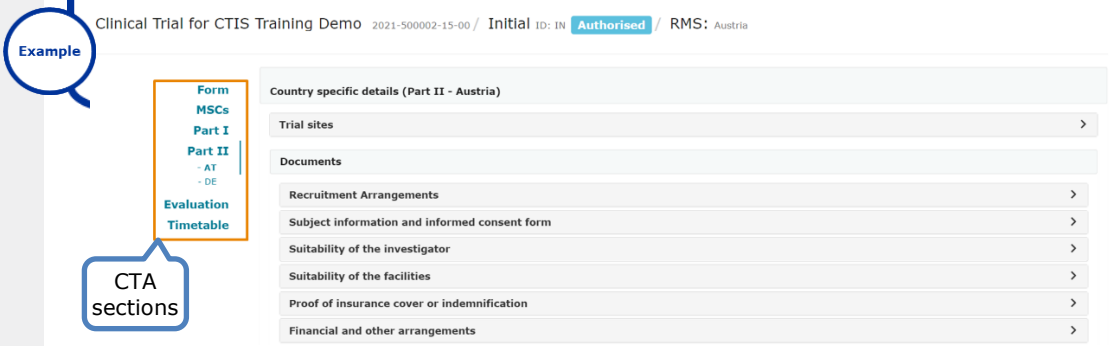
Overview of the clinical trial application and non-substantial modifications page

At the bottom of the 'Summary' sub-tab, 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.



Users can **open any of the available applications and non-substantial modifications by clicking on the ID reference**. This will open the CTA page, 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.

Example



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

#CTIS insights

In the CTA page users can view specific information regarding an specific CTA or a non-substantial modification related to a CT.

Download CT and CTA information

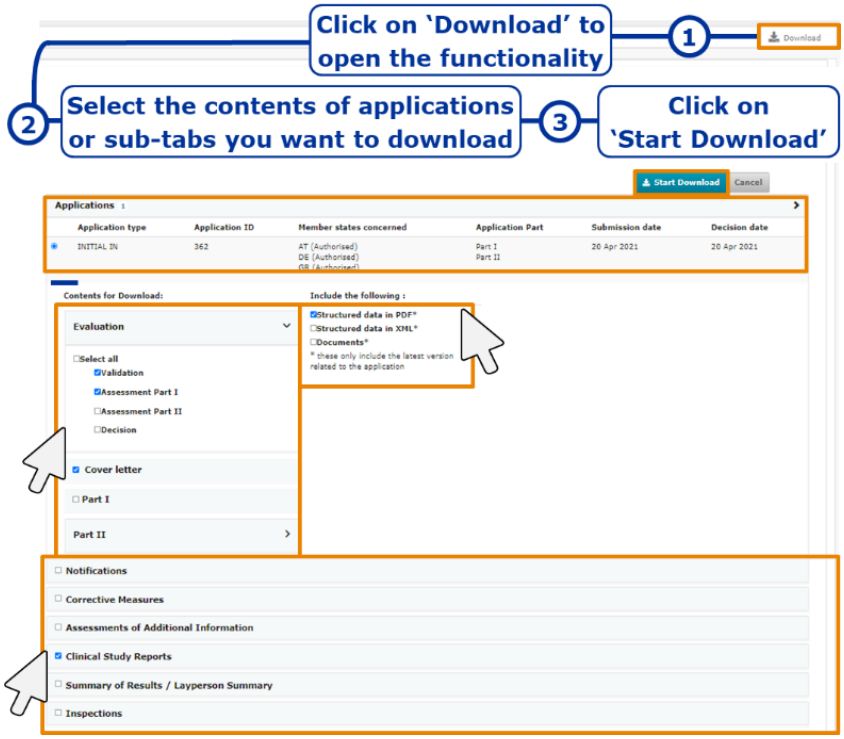
The 'Download' button allows users to download the latest versions of the structured data and documents they have permissions to access.

How to download clinical trial information

There are two ways of downloading CT and CTAs information. Users can download information from different pages and sections of CTIS. Data can be downloaded from the CT page and from the CTA page. The version of the documents downloaded is the last one submitted.

Clinical trial page

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 CT page. The user will download CT and CTA details of their choice (e.g. Evaluation, Cover letter, Part I, Part II, notifications, summary of results, etc.) in a ZIP folder.



Clinical trial application page

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

#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.

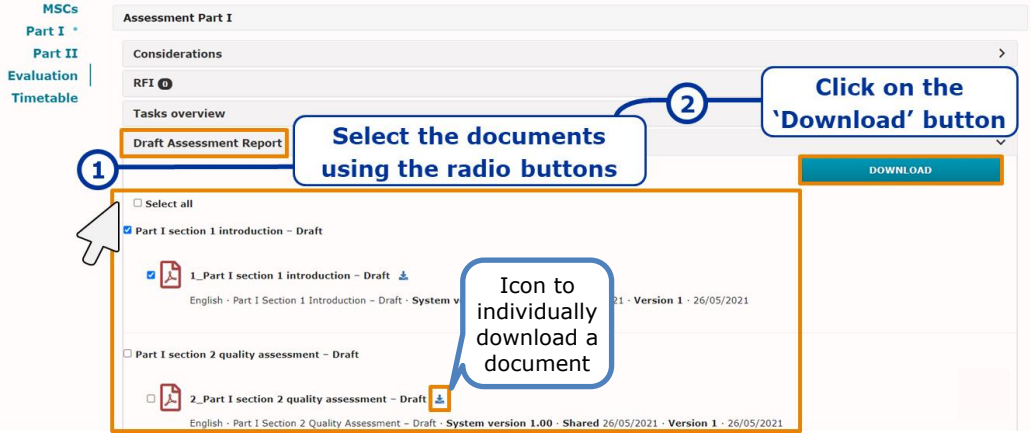
Structured data is all the structured information that has been entered manually in CTIS, such as written values, selections made via checkboxes or selections from a list.

Download CT and CTA information

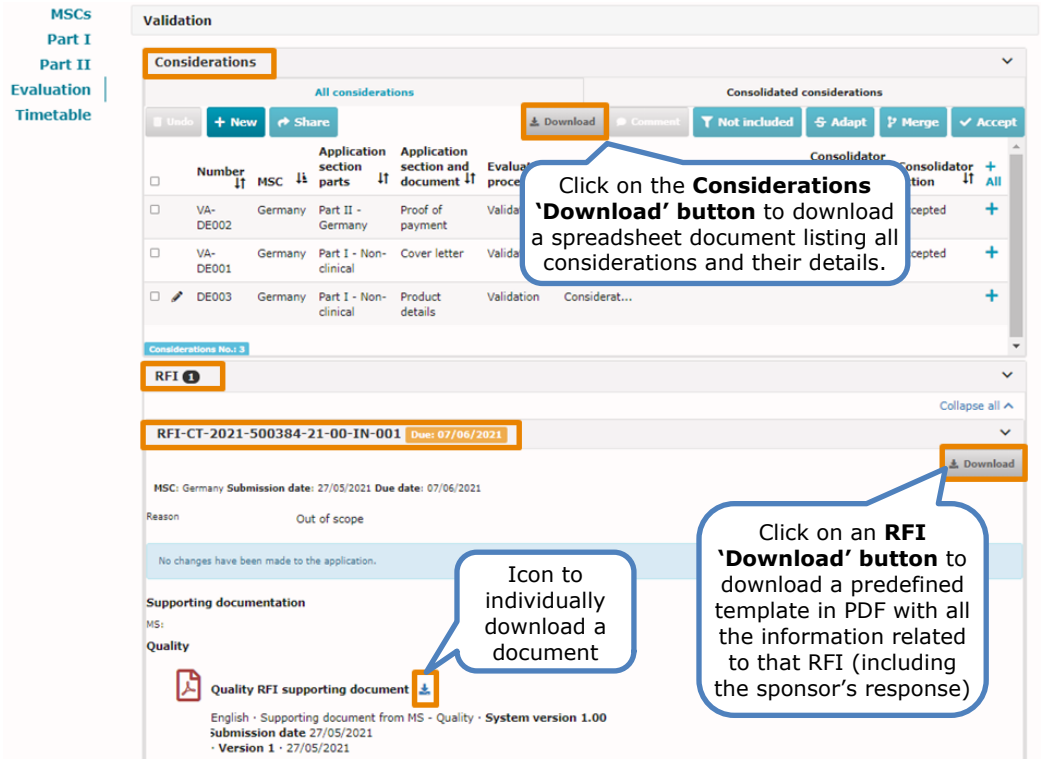
The download functionality allows users of the same organisations to share documents among each other outside of CTIS.

- *Download documents from the CTA sections*

Users can download files from the sections 'Form', 'Part I', 'Part II' and 'Evaluation'. From the sections 'Form', 'Part I' and 'Part II', MS users can obtain the files uploaded by the sponsors**. In the Evaluation section,** users can download the documents previously submitted (e.g. Draft or Final Assessment Reports) and 'dynamic' documents of the considerations (e.g. the spreadsheet containing them needs to be downloaded each time a new consideration is created to have the last version) and the RFI structured data document.
To download a document in this section, users can **click on the blue icon** next to each document. Users can also select as many documents as they want within one section using the checkboxes and click on the 'Download' button, as the example below shows:



Users can also download the 'dynamic' documents that comprise **the considerations** raised during the evaluation phases of a CTA, and also download a **document template containing the relevant information regarding an RFI**, as shown below:



#CTIS insights

The considerations file is a 'dynamic' document. If there are new shared considerations, users need to download the spreadsheet again for the last updated version.

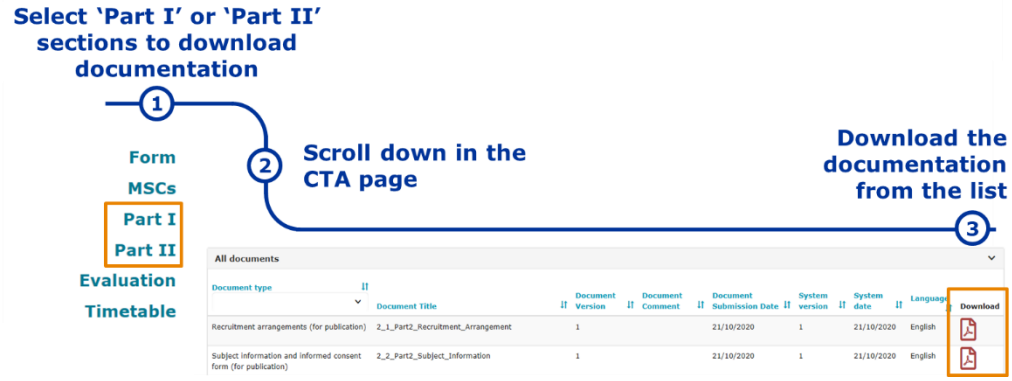
The document that users download of an RFI will only include the structured data. The RFI documents can be downloaded individually using the blue download icon next to each document.

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.

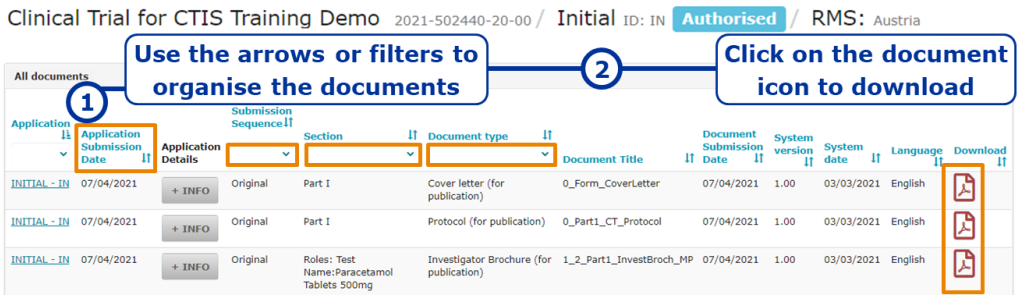
- *Download from the table of documents*

Users can also download files uploaded by the sponsor from a table of documents from the sections 'Part I' and 'Part II'.
Users can view and download a **full list of associated documents contained in a CTA or non-substantial modification**. To do so, they can access the CTA page, select the application they are interested in, and follow the steps below.



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:



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