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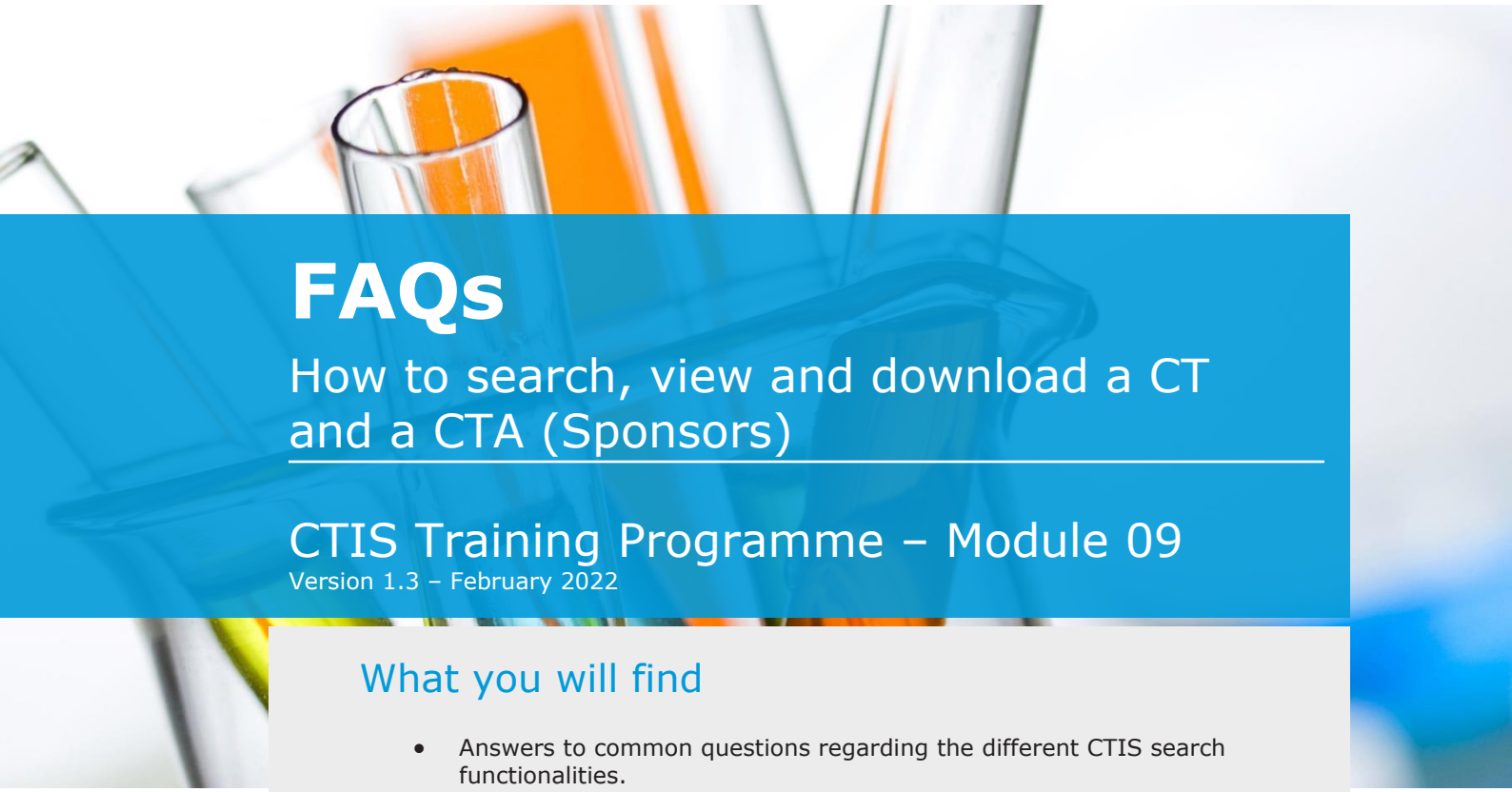

FAQs

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

CTIS Training Programme – Module 09

Version 1.3 – February 2022

What you will find

- Answers to common questions regarding the different CTIS search functionalities.
- Answers to common questions regarding the information displayed in the Clinical Trial sub-tabs and in the Clinical Trial Application sections within CTIS.
- Answers to common questions regarding the documents available for download in CTIS and the available formats.

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.

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FAQs

In this document, we list common questions regarding Module 9: How to search, view and download a Clinical Trial and a Clinical Trial Application. They are categorised into questions about the search functionalities in CTIS, how to view CTs and clinical trials applications (CTAs) information, and how to download CT and CTAs information. The specific learning objectives of this module 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.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1. CTIS search functionalities

1.1. How many search functionalities are available in CTIS?

Searches are a cross-system functionality available in different sections of the system. Specifically, the search functionality is available in each of the different tabs displayed in CTIS (e.g. Clinical trials, Notices & alerts, RFI, Annual safety reporting, User administration, etc.). Users will be able to view and use the different search functionalities available depending on the tabs that are displayed in their workspace. Each type of search contains a set of criteria that are relevant for the information displayed in the tab (e.g. users can select if they wish to look for a notice and/or an alert in the Notices & alerts tab, administrator users can look for user roles depending on their status e.g. requested, approved, rejected, etc.). In each tab, the search functionality offers a basic search option and one or more advanced search options allowing the user to combine multiple search criteria.

1.2. What information can users view when they search for a clinical trial or a clinical trial application?

In both workspaces, users are able to view the CTs and CTAs in which they have a role. However, users of the different workspaces do not view exactly the same information at the same time. For instance:

- Authority users are not able to view draft CTAs that are being prepared by sponsors – they only view submitted applications to the Member States Concerned (MSCs) for the evaluation.

- Sponsor users are not able to view an evaluation that is being conducted by the MSC - they can only view the final assessment report.

The same principle applies to other CTs data prepared and submitted to CTIS by both sponsors and authorities. Moreover, sponsor users can only see CT data for the organisation they are working on behalf of, and authority users can only view the full dossier of CTAs in which they are an MSC.

1.3. Is there a limit to the search results that can be retrieved?

The search functionalities in CTIS can retrieve a maximum of 200 results per search. For this reason, users whose organisations manage a high volume of CTs data are advised to narrow down their searches when using the advanced search functionalities (refer to question 2.1 for more information). The search results list can display a maximum of 100 results per page. Users can indicate how many results they want to see per page (10, 20, 50, or 100). These

principles are applicable to the search results across all the tabs in CTIS (Clinical trials, Notices & alerts, Tasks, RFI, etc.).

1.4. What roles are needed to use the search functionalities?

By default, the search functionality in the different tabs is available to all users. What users can retrieve, view and download after running the search will depend on the access permissions they have been assigned by a user with administrator permissions within their organisation or Member State.

2. Search functionalities to look for clinical trials and clinical trials applications

2.1. How can users search for a clinical trial or a clinical trial application?

To perform a search, users need to click on the 'Clinical trials' tab (also the landing page of CTIS when logging into the system). This tab offers one basic search functionality and two advanced search functionalities:

- **Basic search:** This search allows users to look for specific CTs and CTAs in the search bar of the Clinical trials tab. Users need to enter the EU CT number and click on the 'Search' button to launch the search (refer to question 2.3 for more information).

- **Advanced searches:** These types of searches allow users to retrieve all the CTs that match a set of specified criteria. The user does not need to recall a specific EU CT number. Both types of advanced searches share several search criteria (e.g. overall trial status, therapeutic area, active substance, product name, or MSC). However, the trial advanced search includes specific criteria to search for CTs, while the application advanced search includes specific search criteria to look for CTAs (see question 2.2 for more information):

    - **Trial advanced search:** This search allows users to search for CTs matching a set of specified criteria, such as trial start/end dates, MSC, therapeutic area product name, active substance, etc. This search is suitable when the user does not know the EU CT number and/or when he/she wishes to retrieve all the trials that match a set of criteria.

    - **Application advanced search:** This search allows users to search for CTs which contain application(s) matching specified search 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 matching a set of CTA-related criteria.

2.2. What are the main differences between the basic and advanced searches?

The basic search retrieves the CTs/CTAs that match the specified EU CT number (trial identifier code). In the advanced searches, instead, the user does not need to know the EU CT number but may use a combination of criteria to retrieve all the trials that match those. The basic search is, therefore, useful to look for a specific CT and see all the details associated with that trial. In contrast, advanced searches are more useful for organisations or users that manage numerous trials and wish to monitor specific criteria of their CTs and/or CTAs (e.g. status of CTs in a specific MSC, number of trials authorised, number of CTAs under evaluation, etc.).

2.3. How does the basic search work?

Users need to enter 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 permissions to view will appear on the results list. Please note that this search type is equipped with a predictive feature that displays a dropdown list of autosuggestions of EU CT numbers when the user starts to type numbers in the search bar.

2.4. How does the advanced search work?

To use the advanced searches, users need to click on the advanced search type they wish to use to display the available search criteria (i.e. Trial Advanced Search and Application Advanced Search). Users may combine more than one criterion for more targeted searches.

When multiple search fields are used simultaneously with one value in each, the search interprets this as an 'AND' operator and the results list retrieves the CTs that comply with all the specified conditions (e.g. authorised trials in a given therapeutic area and with a specific Reporting Member State (RMS)). If multiple values are specified within the same field or criterion, the search interprets this as an 'OR' operator and retrieves the CTs that comply with either or all of the defined values. This means, for example, that if a user searches for CTs in status 'authorised' and 'under evaluation' in two MSC, the results list will retrieve all CTs taking place in either of the two MSC that have either of the two specified trial statuses. In this sense, using multiple values within the same search field or criterion retrieves more results than using only one (more targeted search).

2.5. What is the main difference between the trial and application advanced searches?

Both search functionalities retrieve a list of CTs that match the criteria specified by the user. The main difference between them is the criteria that can be selected in either of the searches. The trial advanced search is the preferred one when the user wishes to retrieve the CTs matching a set of criteria. In contrast, the application advanced search is recommended when the user is specifically interested in CTAs matching a set of criteria, as it has CTA-specific search criteria.

2.6. What are the common and the specific criteria in the advanced searches?

The table below presents a summary of the specific and common criteria for both types of advanced searches:

	Trial advanced search	**Application advanced search**
Common criteria (13)	• Overall trial status • Trial title • Protocol code • Condition • Sponsor • Active substance • Product name • Route of administration • Therapeutic area • Member states concerned • Reporting member state • Transitional trial • EUDRA CT number	
Specific criteria	• MSC trial status • EU MP number • Has serious breach(es) (Y/N) • Summary of results • Trial start date • End of trial date • Global end of trial date • Recruitment status	• Application status • Evaluation process • Submission date • Validation date • Reporting date • Decision date • Application type • Part II conclusion date • Has disagreement (Y/N)

2.7. What is the 'Evaluation process' field?

The evaluation process field allows users to search for CTAs according to the phase of the evaluation process they are in. The evaluation process for a CTA is divided into three main phases: Validation, Assessment which is divided into two parts (Part I and Part II), and

Decision. Once this search is launched, the user will retrieve a list of CTs which contain application(s) in the selected evaluation phase.

2.8. What is the 'Condition' field?

The field ‘condition’ refers to the Medical Condition introduced by the Sponsor when submitting the CTA. Only trials concerning the medical condition entered in the search will be retrieved.

According to the EudraCT glossary, a medical condition is “the description of intended indication for the product under development and object of the trial”[1].

2.9. Do users need to know the EU CT number to use the basic search functionality?

In principle, yes. Users need to know the specific EU CT number in order to find a CT in the basic search functionality of the Clinical trials tab. In the other tabs of CTIS such as ‘Tasks’ or ‘Notices & alerts’, they can also use the identifier for the Annual Safety Report (ASR ID).

In the Clinical trials tab, if users do not know the EU CT number, they can leave the search field blank and click on the ‘Search’ button to retrieve all the CTs they are involved in. In any case, if they do not know the EU CT number, it is advisable to use the advanced search functionality and specify other information regarding the CT for a more targeted search.

In other tabs of CTIS, such as ‘Notices & alerts’, all results will be automatically displayed once the user opens the tab.

2.10. Is there a minimum of search criteria required in the advanced search functionality?

No. Users can launch a search with one value in one of the criteria. However, if the search criteria used are somewhat reduced, it would lead to broad search results. Users are invited to consider narrowing the search down using more values and criteria in case they retrieve too many results

[1] Glossary - EudraCT, September 2020, European Medicines Agency on behalf of the European Commission. Available at: https://eudract.ema.europa.eu/help/Content/Glossary.htm

2.11. How are the search results listed in the Clinical trials tab?

Once a search is launched in the Clinical trial tab, the results are displayed in a table below the search functionality. Users can preliminarily view the following information: the RMS, the MSC, the medical condition, the sponsor(s) who submitted the CTA, the product being tested, the submission date, and the overall trial status, which is marked with colour below the EU CT number. More information is displayed by clicking on the EU CT number. The results can be sorted by several criteria, including the EU CT number, the trial status, the evaluation process, or the sponsor who submitted them, or the submission date.

2.12. Can users save a search?

No. There is currently no feature that allows users to save a search and its criteria. After a search has been launched, and the results are listed on the search results table, users can click on the CT they are interested in to view it. However, after they have opened it, they cannot go back either to the previous results table or the specified search criteria. If a user wants to view multiple CTs, it is advised to open them in different windows in the browser by right-clicking on the EU CT numbers.

3. View clinical trials and clinical trials applications information

3.1. Where can users view clinical trials and clinical trial applications information?

Users can access CT and CTA information through two main pages:

- **Clinical trial page:** This page includes high-level information on the trial, including the trial phase, the therapeutic area, the trial status in each of the MSC (in case of a multinational trial), and any related applications and non-substantial modifications, if applicable. Users will be able to access more detailed information throughout this page from the various sub-tabs and trial dossier, the access to which will depend on the roles users have. This page is displayed once a user opens a CT, for example, by clicking on its EU CT number in the search results list.

- **Clinical trial application page:** On this page, users will have access to all the relevant information regarding the CT dossier of a particular application. To access it, users need to go to the clinical trial page and click on the application ID reference number they are interested in at the bottom of the summary sub-tab where all available CTAs and non-substantial modifications are displayed.

3.2. Can sponsor users view clinical trials or clinical trial applications of other sponsors?

No. Users can only search and view CTs and/or CTAs submitted by their organisation if they have the appropriate permissions. This means, for example, that a Contract Research Organisation (CRO) working for multiple Marketing Authorisation Holders (MAHs) will be able to search for all trials they are working on.

3.3. What information is displayed on the clinical trial page?

On the clinical trial page, users will have access to all the relevant information regarding a particular CT. The page is structured in several sub-tabs listed horizontally that provide different information of the CT. In addition to the summary sub-tab, other sub-tabs provide additional information on relevant aspects of the CT. The full list of sub-tabs includes:

- **Summary**: Displays key information of the CT, the trial status in the MSC, the therapeutic area, the sponsor submitting the CT, the trial phase, the therapeutic area, the medical condition(s), the population type, the applications, and non-substantial modifications related to that CT in consecutive order, whether a medical device is being used, if it is considered a low intervention CT, etc.

- **Full Trial information**: Displays a comprehensive set of data and documents on the latest authorised application, visible to the user according to the role assigned. The full view includes six sections: Form, MSCs, Part I, Part II, Evaluation, and Timetable.

- **Notifications**[2]: Enables users to view and manage the relevant events occurred during the life cycle of an authorised trial which have been notified to the MSC (e.g. trial start date, temporary halt, unexpected event, serious breach, etc.). Notifications can only be submitted for trials that have been authorised in at least one MSC.

- **Trial results**[3]: 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 (CSR) submitted by the Marketing authorisation applicant, if applicable.

- **Corrective measures**[4]: Outlines the possible measures taken by MSC as part of their supervision activities to ensure adherence to the requirements of the Clinical Trials Regulation (i.e. suspension of the CT, revocation of the CT authorisation, or request to the sponsor to modify any aspect of the CT). This tab may be blank if no corrective measure has been taken regarding a particular trial.

[2] For more information, please refer to the FAQs document of *Module 5: How to manage a CT (Notifications, Ad hoc assessment, Corrective measures and trial results), Available at: https://www.ema.europa.eu/en/documents/other/faqs-how-manage-ct-ctis-training-programme-module-05_en.pdf*
[3] Ídem
[4] Ídem

- **Ad hoc assessments**[5]: Lists the assessments done by the MSC on an ad hoc basis as part of their supervision activities, following, for example, the submission of notifications or safety-related information.

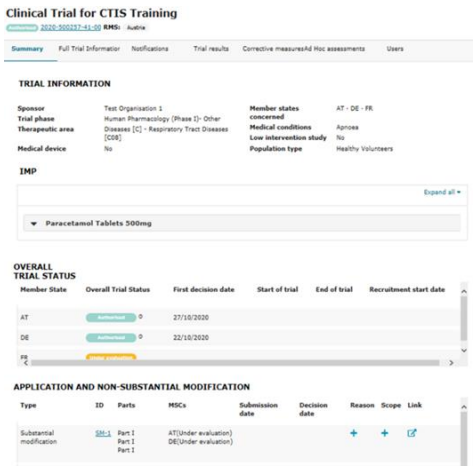
- **Users**: Lists all the users associated with a CT, as well as their role(s), the sponsor organisation or authority organisation, and the employer.

3.4. Can users filter clinical trials information by the MSCs involved?

Yes, users can access CT information, and the most recent information of their associated authorised CTAs in each MSC involved, in case of multinational trials. To do this, users need to go to the Full Trial Information sub-tab of a clinical trial page. On that page, they need to select the MSC they want to see information about by clicking on the dropdown list below the 'Member State' label on the upper left side of the screen. By doing this, users will get the most recent information of the authorised CTAs associated with that CT in a given MSC.

3.5. How can users access the information of a clinical trial application or of a non-substantial modification?

At the bottom of the Summary sub-tab of the clinical trial page within a CT (*refer to question 3.1 to review the steps to access a CT page*), users will find all the CTAs (initial, addition of a new MSC or substantial modification) and non-substantial modifications related to that CT. Users can open any of the CTAs or non-substantial modifications by clicking on their ID reference number (second column of the table listing the CTAs and non-substantial modifications), and they will be re-directed to the clinical trial application page. See the image below to view how this looks in the system:



[5] For more information, please refer to the FAQs document of *Module 5: How to manage a CT (Notifications, Ad hoc assessment, Corrective measures and trial results), Available at: https://www.ema.europa.eu/en/documents/other/faqs-how-manage-ct-ctis-training-programme-module-05_en.pdf*

3.6. What type of information is available on the clinical trial application page?

The clinical trial application page is located inside the CT page (refer to question 3.5 for the steps to access it), and it provides relevant information for any application type available for a given CT. Once inside an application, the page is structured in a series of sections listed vertically on the left side that allow users to view and navigate inside the CTA. The default section that users will land on is 'Part I', which provides trial-specific information, such as the trial identifiers, trial information including the CT objectives and information about the subjects, protocol information, the scientific advice and paediatric investigational plan, any associated clinical trials, the sponsor submitting it, the products being tested, etc. There are a total of six sections:

- **Form:** Displays the 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**: Shows information such as the MSCs involved in the application, the proposed RMS, the countries outside of the EU/EEA where the trial is intended to be conducted (if applicable), and the estimated total population that is going to be used for testing the trial.

- **Part I**: Displays trial-specific information (data and documents) of the CTA common to all MSC such as the protocol, trial design, product quality, inclusion and exclusion criteria, medical conditions to be treated, therapeutic area, etc.

- **Part II**: Displays MSC-specific documents of regulatory nature of the various MSC involved, including the trial sites, the arrangements for recruiting the patients, the information provided to the subjects and the informed consent form, the proof of insurance cover, compliance with national data protection requirements, etc.

- **Evaluation**: Provides information related to the evaluation of the application, for example, the RMS selection process in case of multinational trials, the validation process and considerations uploaded, the process and conclusion of Part I and Part I assessments, and the decision on the application.

- **Timetable**: Provides a visual overview of the evaluation status and progress of the CTA, by showing the completed phases and tasks, as well as a forecast of the due dates for the upcoming ones.

4. Download clinical trials and clinical trials applications information

4.1. How can users download clinical trials or clinical trials applications information?

There are two main ways available for users to download CTs and CTAs information:

1. From the clinical trial page.

2. From the clinical trial application page inside the CT page.

Each type of download feature allows users to access different information and documents.

The 'Download' button is always displayed on the right side of the screen, except inside the CTA page, where the user needs to scroll down to the bottom of the page, under the 'Documents' section, and select individually the document they wish to download. The version of the documents downloaded is the last one submitted.

4.2. What is structured data?

Structured data is all the structured information on CTIS that has been entered manually, such as written values, selections made via radio buttons, or selections from a list (not documents uploaded to CTIS). The structured data can be downloaded in aggregated pre-defined templates in PDF, including the content labels where the data have been entered.

4.3. What information can be downloaded from the clinical trial page?

Users can download all CT and CTA details of their choice (e.g. Evaluation phase documentation, cover letter, Part I, Part II documents) in a zip folder and the structured data in PDF. Also, users can download notifications, Corrective Measures (CM), Request for Information (RFI), assessments of additional information (Ad hoc assessment), Clinical Study Reports (CSRs), summary of results/layperson summary, and inspections.

4.4. How can users download information from the clinical trial page?

Users can download the information and associated documents of the CT by clicking on the 'Download' button in the upper-right corner of the clinical trial page. The user will download the CT and CTA details in a zip file. To do this, users need to go to the clinical trial page *(refer to question 3.1 for more information),* click on the 'Download' button to open the functionality, select the contents to download, and click on 'Start download'.

4.5. What information can be downloaded from the clinical trial application page?

Users can download specific documents from a full list of documents contained in Part I or Part II of a CTA or a non-substantial modification, such as the cover letter, the protocol, the compliance with the Regulation (EU) 2016/679, the study design, the Investigational Medicinal Product Dossier, the Investigator Brochure, the authorisation of manufacturing and import, or the proof of insurance, amongst other documents.

4.6. How can users download information or documents from the clinical trial application page?

Users need to go to the clinical trial application page (refer to question 3.3 for more information on how to access this page), click on either Part I or Part II sections, scroll down in the clinical trial application page, and a list with the documents contained in each part that are available for download will be displayed at the bottom of the page. Users will need to click on the file icon to open it.

4.7. Which versions of an application can be downloaded?

Users can download the latest submitted version in a zip file that contains all the structured data and the latest versions of the attached documents. Users may access and view all the submitted versions of an application by clicking on the 'Versions' button available on the clinical trial application page. They can download the previous versions of the attached documents. Users can only view the structured data of earlier versions, but it cannot be downloaded. However, in case they would like to download it, they can use their browser's functionalities to print the CTA pages in PDF.

4.8. How can users download information regarding the assessment of a clinical trial application?

On a CT page, users can download the information they need regarding the assessment of a CTA. They can click on the 'Download' button and select the documentation they want to download and the file type. Then, users can click on 'Start download'.

4.9. Can users download individual documents from a CTA?

Yes. Users can download individual/single documents of a CTA either from the blue download icon next to each document in the CTA form, or through a table of documents on the bottom of either Part I or Part II sections of a CTA.

4.10. How can users download documents from a table of documents?

Users can access a CTA page and click on either Part I or Part II sections, scroll down, and a list with the documents available for download contained in each part will be displayed. 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 in a spreadsheet style. This means that users can use the arrows next to each criterion 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.

4.11. How can a Clinical Study Report be downloaded?

Users can download a Clinical Study Report (CSR) by accessing a CT page and opening the Trial results sub-tab. After that, they locate the CSR submitted by the sponsor, click on the eye icon, and they will be able to download the CSR by clicking on the document icon.

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Clinical Trials Information System (CTIS).

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