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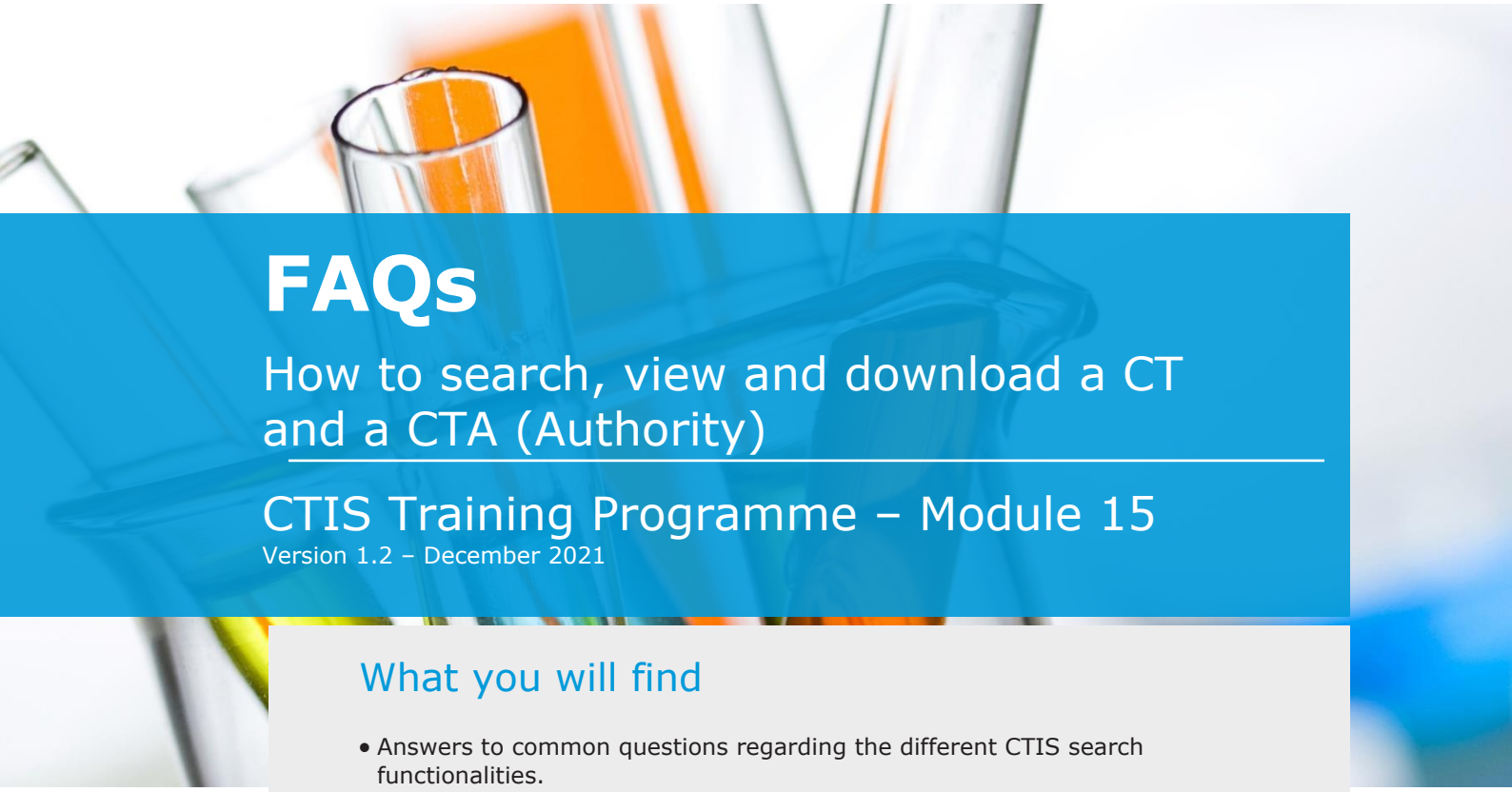

FAQs

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

CTIS Training Programme – Module 15

Version 1.2 – December 2021

What you will find

- Answers to common questions regarding the different CTIS search functionalities.
- Answers to common questions regarding the information displayed in the sub-tabs of a clinical trial and in the sections of a clinical trial application.
- Answers to common questions regarding the documents available for download in CTIS and the available formats.

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FAQs

In this document, we list common questions regarding *Module 15: How to search, view and download a CT and a CTA (Authority)*. They are categorised into questions about the search functionalities in CTIS, how to view Clinical Trials (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 users can search for a clinical trial (CT) and a clinical trial application (CTA).

2. Understand how to view the information displayed in a CT and a CTA.

3. Understand how to download information and associated documents.

4. Understand which user roles can view and 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. The search functionality is available in most of the tabs displayed in CTIS (e.g. clinical trials, Notices & alerts, Tasks, 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, users can look for tasks depending on the application type, etc.). In each tab offering the search functionality, users can choose between a basic search and one or more advanced search options. The advanced searches allow users to combine multiple search criteria for more targeted searches.

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 Clinical Trials (CTs) and Clinical Trial Applications (CTAs) in which they have a role. 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 MSCs - they can only view the final assessment report.

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

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

The search functionalities in the Clinical trials tab can retrieve a maximum of 200 results per search. For this reason, users whose MSC manages a high volume of CTs data are advised to narrow down their searches by using the advanced search functionalities *(refer to question 2.1 for more information)*. Users can decide the number of results to be displayed per page, between 10, 20, 50, and 100.

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 launching the search will depend on the access permissions they have been assigned by a user with administrator permissions within their Member State or organisation.

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 launch 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 then access their associated 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, trial title, protocol code, condition, sponsor, active substance, product name, etc.). 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 (*refer to 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, recruitment status, etc. This search is suitable when users do not know the EU CT number and/or when they wish to retrieve one or more trials matching a set of CT-related criteria.

    - **Application advanced search:** This search allows users to search for CTs that contain application(s) matching specified search criteria, such as application status, types of applications, submission/decision dates, etc. This search is more suitable when users wish 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 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 can enter the EU CT number on the search bar 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 the 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 drop-down list below the search bar with automatic suggestions of similar EU CT numbers when the user starts typing numbers in the search bar.

2.4. How does the advanced search work?

To use the advanced searches, users can click on the advanced search type that suits their needs (i.e. Trial Advanced Search and Application Advanced Search) to display the available search criteria. 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 of all the defined values in that field or criterion. This means, for example, that if a user searches for CTs in status 'authorised' and 'under evaluation', and two MSCs in the MSC criterion, the results list will retrieve all CTs that have either of the two specified trial statuses, and also with either of the two MSCs. In this sense, using multiple values within the same search field or criterion retrieves more results than using only one.

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 (i.e. Medical 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 • EU Substance Number • Has serious breach(es) (Y/N) • Summary of results (Y/N) • Trial start date • End of trial date • Global end of trial date • Recruitment status	• Application status • Evaluation process (i.e. phases) • Submission date • Validation date • Reporting date • Decision date • Application type • Part II conclusion date • Has disagreement (Y/N)

2.7. Can Member State users search for trials of one sponsor organisation?

Yes. In both advanced searches, there is a criterion to look for the sponsor organisation name. This criterion field is equipped with a predictive feature that displays a drop-down list with automatic suggestions of similar sponsor organisation names when the user starts typing in the field.

2.8. Can users input multiple values for all available search criteria?

Not all the search criteria allow users to input multiple values. For example, users can input many values out of a drop-down list in the criteria for overall trial status, MSCs, therapeutic area, etc. Users can input only one value in the criteria for sponsor organisation name, active substance, product name, etc. Below, a table outlining the criteria that accept multiple values:

	Trial advanced search	**Application advanced search**
Common criteria (5)	• Overall trial status • Route of administration • Therapeutic area • Member states concerned • Reporting member state	
Specific criteria	• MSC trial status • Recruitment status	• Application status • Evaluation process • Application type

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 via 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 'Tasks' or '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.

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

Once a search is launched in the Clinical trials tab, the results are displayed in a table below the search functionality. Users can preliminarily view the following information: the RMS, the MSCs, 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.

Users can add other parameters to be displayed in the search results list. By clicking on the 'Display Options' button, a list will appear with more criteria such as trial type, phase, the start and end of trial, recruitment status, etc. By clicking on the wished criteria and then in the 'Confirm' button, users will have a preliminary view of the selected criteria and the criteria that appears by default in the list.

The results can be sorted by several criteria, including the EU CT number, the trial title, the RMS, the sponsor who submitted the CTA, the overall trial status, the submission date, the trial type, etc.

More information is displayed by clicking on the EU CT number. By doing this, users will open the clinical trial page (*refer to question 3.1 for more information*).

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 all the relevant information about a trial. Users will be able to access detailed information throughout this page from the various sub-tabs and trial dossier *(refer to question 3.2 for more information on the sub-tabs)*, access to which will depend on the roles that users have. By default, users will land on the Summary sub-tab of the clinical trial page once a user opens a CT, for example, by clicking on its EU CT number in the search results list. The Summary sub-tab shows high-level information on the trial, including the sponsor, 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.

- **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 can access 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. 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. Scrolling down, there is a list with the overall trial status per MSC, and below another list with the applications and non-substantial modifications of the related trial.

- **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**: Enables users to view and manage the relevant events that occurred during the life cycle of an authorised trial. Events that have been notified by the sponsor organisation 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:** 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 Reports (CSR) submitted by the marketing authorisation applicant, if applicable.

- **Corrective measures**[1]: 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.

- **Ad hoc assessments**[2]: 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. Users can only see details of other users working for the same organisation.

- **Inspections**: Opens a search functionality to retrieve the inspections. There is a basic search where users can input the Record ID to find related inspections or use the advanced search with inspection-related criteria.

3.3. What is a Clinical Study Report?

A Clinical Study Report (CSR) is a report of an individual study of an investigational medicinal product, in which the clinical and statistical description, presentations, and analyses are integrated[3]. At the moment of the submission, the information contained in the CSR will become public.

As per Article 37 of the CT Regulation, the marketing authorisation applicants/holders must submit a CSR to CTIS, within 30 days after the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for the marketing authorisation has withdrawn the application.

[1] For more information, please refer to the FAQs document of *Module 14: Supervise a Clinical Trial – Corrective measures.*

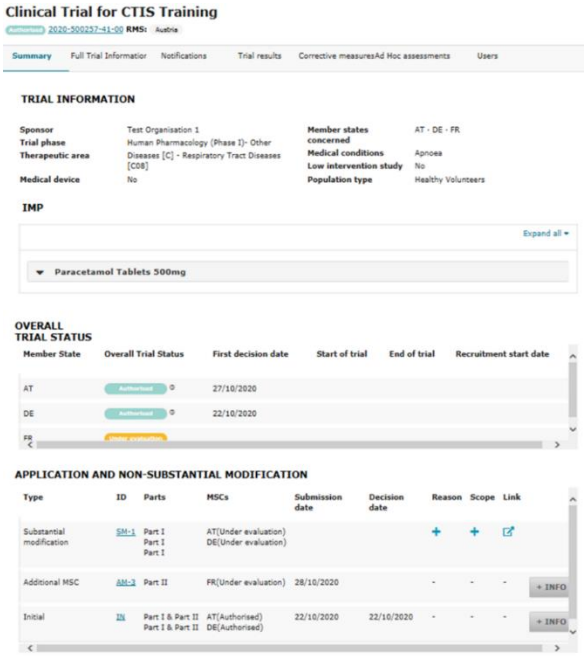
[2] For more information, please refer to the FAQs document of *Module 17: Supervise a CT – Ad hoc assessment.*

[3] ICH Topic E 3 Structure and Content of Clinical Study Reports, July 1996, European Medicines Agency. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-content-clinical-study-reports-step-5_en.pdf

MS users can find the CSR in the Trial results sub-tab of the CT page.

3.4. How can users access the information of a clinical trial application or 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:



3.5. 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 3.4 for more information on 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 three main ways available for users to download CTs and CTAs information:

1. Directly from the search results list (i.e. table below the basic search and advanced searches in the Clinical trials tab).

2. From the clinical trial page.

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

Each type of download feature allows users to access structured data 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 the desired file type (e.g. PDF or XLM), 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 the file type of their choice (PDF and/or XML). Also, users can download notifications, corrective measures, assessments of additional information, 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 on the upper-right corner of the clinical trial page. The user will download the CT and CTA details of their choice in a zip file, including PDF and/or XML files. To do this, users can access 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 (IMPD), the Investigator Brochure (IB), 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 can access the clinical trial application page *(refer to question 3.2 for more information on how to the clinical trial application 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 download 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. 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.

4.9. 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.

4.10. How can users download the considerations raised in the context of a Request for Information?

On a CTA page, users can download a spreadsheet with the considerations shared in the context of a Request for Information (RFI). To do this, users can access the evaluation section of a CTA page, and open the subsection with the considerations raised during the evaluation phases of a CTA. By clicking on the 'Download' button, users will be able to download a spreadsheet document listing all considerations and their details. 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.

4.11. How can users download documentation regarding a Request for Information sent to the sponsor?

On a CTA page, users can download a PDF predefined template containing all the information related to that specific RFI (including the sponsor's response). To do this, users can access the evaluation section of a CTA page, and open the subsection with the submitted RFIs. Users can open each RFI and click on the 'Download' button that appears on the right side of the screen. By clicking on the 'Download' button, users will download the above-mentioned PDF predefined template.

The document that users download of an RFI will only include the structured data of such RFI including the sponsor's responses. The supporting documents of the RFI can be downloaded individually using the blue download icon next to each document.

4.12. Can users download the Draft Assessment Report and Final Assessment Report?

Yes. On a CTA form, users can download individual documents previously submitted such as the Draft or Final Assessment Reports on the evaluation section. This can be done by clicking on the blue download icon next to each document for that purpose. Or select as many documents as they want within one section using the radio buttons, and clicking on the 'Download' button.

4.13. How can a Clinical Study Report be downloaded?

Users can download a 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).

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