EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

Introduction to CTIS for public users

CTIS Training Programme – Module 22

Version 1.1 – December 2021

What you will find

- Answers to questions regarding the different public website search functionalities.
- Answers to questions regarding how to view and download CTs and CTAs information in the public website.
- Answers to questions regarding how to request to remove information from the public website.
- Answers to questions regarding union controls.

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 22: Introduction to CTIS for Public Users.* They are categorised into questions regarding the different public website search functionalities; questions regarding the available information of CTs and CTAs in the public website; questions regarding downloading structured data and documents; questions regarding how to request to remove information from the public website; and questions regarding union controls. The specific learning objectives of this module are:

1. Remember what the CTIS public website is.
2. Understand how users can search for a Clinical Trial (CT).
3. Understand how to view and download the information displayed in a CT.
4. Understand how to remove information from the public website.
5. Remember how users can view union control reports.

We encourage you to read these questions and answers carefully. If you have any questions that 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.

For more information, users can refer to the Quick Guide of this module, available on the EMA website[1], which provides a basic introduction for the use of the CTIS Public Website for the general public.

[1] Information available at: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support#online-training-modules-section

1. Public website

1.1. What is the CTIS public website?

The Clinical Trials Information System (CTIS) public website is the part of the EU clinical trial database available to the public in order to access data and documents of the clinical trials conducted in the EU/EEA.

1.2. Where can users change the language of the CTIS public website?

Users can modify the language of the interface by selecting the flag of the country to which the language corresponds to. The public website is offered in the 24 official languages of the European Union.

1.3. How can users view instructions on how to use the CTIS public website?

Users can view instructions on how to use the functionalities of the public website by selecting the 'Help' button at the top-right corner of the public website.

The 'Help' page also includes useful links for questions on website performance/user feedback/help using the website, information on National Competent Authorities, patient and consumer organisations, healthcare professionals' organisations.

1.4. What CTs information can users view on the public website?

The public website includes all publishable information regarding CTs for which a decision has been submitted, with the exception of:

- Confidential information as well as quality-related information (i.e. IMPD quality, quality-related requests for information raised during the assessment, and quality assessment reports).
- Any draft assessment reports, versions of documents that are 'not for publication' and financial agreements between the sponsor and the investigator site.

- Data and documents that are subject to deferral rules, which are not made public until the deferral date is reached or when the clinical trial results are submitted, as applicable.

- Withdrawn information such as notifications, which will disappear from the public website once they have been removed.

2. CTIS search functionalities

2.1. How can users search for a clinical trial?

To perform a search, users can click on the 'Search Clinical trials' tab. In the tab, there are two search functionalities: one with Basic Criteria and one with Advanced Criteria.

2.2. What are the basic criteria?

A search based on basic criteria allows users to select if a search will retrieve results that include all the populated terms, any of the populated terms, or none of the populated terms. In order to add multiple terms, users can populate a parameter and click on the 'Enter' key and then populate another one and click again on the 'Enter' key. Users need to populate the terms and click on the 'Search' button to launch the search. If a user clicks on the 'Reset' button the search criteria are erased.

2.3. What are the advanced criteria?

A search based on advanced criteria allows users to search for clinical trials that match a set of specified criteria such as trial status, trial number, conditions, product, etc. This type of search offers more specific results, which therefore narrows down the search results obtained. In this sense, using multiple values within the same search field or criterion retrieves more results than using only one (more targeted search).

2.4. What information can users view in the search results?

By default, users can view the title of the clinical trial, trial number, overall trial status, Member States Concerned (EU country code), the overall start date of the trial (in the EU), the overall end date of the trial (in the EU), decision date and condition/s of the trials in the search results.

Moreover, users can select additional information to be displayed in the search results, using the 'Display options' tab. They can select among: therapeutic area, recruitment status, sponsor/co-sponsor, sponsor type, trial phases, endpoint, product, age group, gender, trial region, total number of subjects enrolled, overall end of the trial, primary endpoint, the first date of receipt of results and date of the last update.

2.5. How can users get updates on the results of a specific search?

When a user clicks on the 'Subscribe to Search' button, the user will subscribe to the specific search using their Feed Reader[2]. The public website will display the parameters of the search and will display the results added/updated in the last 7 days.

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

The search functionalities in the public website can retrieve a maximum of 200 results per search. For this reason, users are advised to narrow down their searches by using the advanced criteria search functionality. Users can decide the number of results to be displayed per page, between 20, 50, and 100.

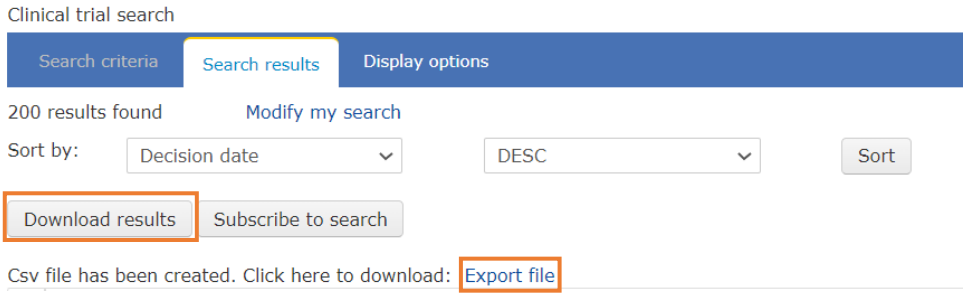
2.7. Can users download clinical trial information?

Yes, users of the public website can download data from the search results list or specific information of a clinical trial on a clinical trial page.

2.8. How can users download the search results list?

Once users have launched a search in the 'Search results' sub-tab, they are able to download the search results via the 'Download results' button. This button triggers the creation of a CSV file, which users can download by selecting the link available in the message "CSV file has been created. Click here to download: 'Export file' under the 'Download results' button.

[2] A feed reader is an application (local or on the web) that subscribes to feeds and presents them in an interface for reading.



3. View and download CTs and CTAs information

3.1. Are data and documents subject to deferral rules publicly available?

Data and documents that are subject to deferral rules are not made public until the deferral date is reached or when the clinical trial results are submitted, as applicable.

Under the full trial information sub-tab, a notice is displayed to the public users to inform that the publication has been deferred with the estimated timing for the publication to occur.

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 the clinical trial. The page is structured in several sub-tabs listed horizontally that provide different information about the trial. The full list of sub-tabs includes:

- **Summary:** It displays two subsections:
    - Trial information of the CT including Condition(s), sponsors, trial phase, therapeutic area, date of submission, date of the last update, Member State(s) concerned (MSC), etc;
    - Overall Trial status in each MSC including decision date, last update, the start date of the trial, temporary Halt, recruitment start and end date, etc.
- **Full trial information:** Displays comprehensive data and documents of each CTA, including Trial specific information of Part I and Country-specific details. By default, the information displayed is concerning the latest authorised application for the trial.
- **Events:** Displays information on events that may have occurred during the conduct of the CT including (if applicable): unexpected events, serious breaches, urgent safety measures, inspection reports from countries outside the EAA, and temporary halts.

- **Trial results:** Displays the summary of results, layperson summary of results, and the Clinical Study Report submitted by the marketing authorisation applicant (if applicable).

- **Corrective measures:** Displays the possible measures taken by the MSCs as part of their supervision activities to ensure adherence to the Clinical Trials Regulation (EU) No 536/2014 (CT Regulation).

- **Inspection Record:** Displays information related to the inspections performed to the trial and/or system and facilities related to it.

3.3. How can users view all clinical trial applications of a CT?

By default, the information displayed in the 'Full trial information' sub-tab of the clinical trial page concerns the Initial application. By default, the information displayed is concerning the latest authorised application for the trial.

To view information of other applications than the Initial application, users can select the 'Applications' button of the 'Full Trial information' sub-tab and select the 'View' button next to the application of the clinical trial which they want to access.

3.4. How can users know if clinical trials information is updated?

Users are able to view the date of publication (First submitted) and the date of update or date of modification, if applicable (Last update) within the clinical trial page.

3.5. Can users request the removal of information?

Users can request the removal of information of a specific clinical trial, by selecting the 'Request removal of public information' link at the bottom-left corner of the clinical trial page. A link to the EMA Service Desk is available to request the removal of information from the public website by the EMA.

3.6. How can users download specific information about a clinical trial?

After launching a search for a clinical trial, users can select the EU CT number of the trial from the search results. This opens the clinical trial page, containing information about the trial. Additionally, users have the option to download information about the clinical trial through the 'Download CT' button located on the right side of the clinical trial page.

Once clicked, users can choose the information and documents to be downloaded by selecting the appropriate checkboxes. The download is carried out when the user clicks on the 'Download clinical trial' button.

4. Union controls

4.1. What are Union controls?

According to Article 79 of the Clinical Trial Regulation[3], Union Controls are performed by the European Commission in order to verify that the EU/EEA Member States correctly supervise compliance with the Regulation, and to verify that the regulatory system applicable to clinical trials conducted outside the Union ensures that point 8 of the Introduction and general principles contained in Annex I to Directive 2001/83/EC is complied with; or that the regulatory system applicable to clinical trials conducted outside the Union ensures that Article 25(5) of the Regulation is complied with.

4.2. What is a Union Control report?

The Union Control report is the outcome document of the control performed by the European Commission. The report is prepared and created outside CTIS, and when ready is uploaded and submitted in CTIS. The Union Control report is published on the CTIS Public Website as soon as it is submitted.

4.3. How can users view Union Control reports?

Public users have access to the Union Controls reports submitted by the European Commission on the 'Union Controls' tab of the CTIS public Website. Users can select one report using the radio button and click on the 'View' button; this way, users can see all the related information regarding the Union Control report via a pop-up window.

These reports include information such as Business Key, European Commission internal identifier, Start date, End date, Status, Purpose of control, Country, and the justification documents corresponding to the Union control.

[3] European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

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