



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

Introduction to CTIS for public users

CTIS Training Programme – Module 22
Version 1.1 – December 2021

Learning Objectives

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

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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

Once applicable, the Clinical Trial Regulation (EU) No 536/2014 (CT Regulation) will replace the current legal framework for authorisation and supervision of clinical trials in the EU, namely the CT Directive 2001/20/EC.

The CT Regulation aims to make the EU attractive for scientific research and innovation by simplifying the clinical trial application process for all actors involved in the Clinical Trial (CT) life cycle, in particular for multinational trials.

The CT Regulation increases the transparency of the information on clinical trials conducted in the EU/EEA, benefiting the general public (e.g. patients, healthcare professionals, clinical research associations, media, etc.). Data and documents uploaded in Clinical Trial Information System (CTIS) will be available on the public website, as soon as a decision on the Clinical Trial Application (CTA) has been reached by the MSCs, regardless of its outcome.

Principles described in Article 81(4) of the CT Regulation, commercial confidential information amongst others, will apply when making the clinical trial information public.

This guide provides a basic introduction for the use of the CTIS Public Website for the general public.

Sections of this quick guide

This quick guide is structured in three sections:



Overview of the public website

Guide for public users to understand the main sections and features of the public website.



Search, view and download CTs and CTAs information

Steps that public users can follow to search, view and download information of a Clinical Trial (CT).



View Union controls information

Steps that public users can follow to view information of Union Controls.

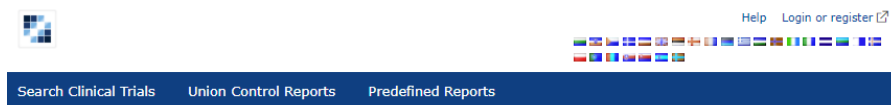
Overview of the public website



A set of buttons and tabs on the public website allow users to perform searches, access help or customise the language.

Public website sections

Once users have entered the CTIS public website, they can find a set of buttons on the top-right corner that allows them access to help and to change the language of the website. Below, users will also find three main tabs: 'Search Clinical trials', 'Union Control Reports' and 'Predefined Reports'.



Language of the public website interface

Users can modify the language of the interface by selecting it from the list of countries. Users are able to translate the public website into the 24 official languages of the European Union.

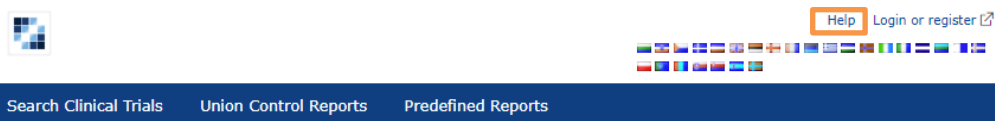


Help

Users can access indications on how to use perform a search in the public website by selecting the 'Help' button at the top-right corner.

The 'Help' page is structured in two parts:

- 'Help' where information related to CTs searches is specified:
 - Basic search.
 - Advanced search.
 - Search results.
- 'Useful contacts', where users can find information and links related to:
 - A specific clinical trial.
 - Website performance/user feedback/help using the website.
 - National competent authorities.
 - Patient and consumer organizations.
 - Healthcare professionals' organizations.



The 'Help' page also includes useful information on how to perform a search and relevant links for the users.

Help

Help

The search engine of the public website of the Clinical Trials Information System (CTIS) has been developed to allow searches for information entered into the CTIS database. From the "Search Clinical Trials" tab access the "Search Criteria" tab where you can use the basic search or advanced search.

Basic Search

Using this search functionality, you can:

- Perform the search to obtain clinical trials including **all** the terms that you have used in your search
- Perform the search to obtain clinical trial including **any** of the terms you have used in your search
- Perform the search to obtain clinical trials **excluding any** of the terms you have used in your search

Search, view and download CTs and CTAs information



The search functionality allows users to retrieve CTs that match a set of criteria.

Users can view information of the trials published on the public website.



If a user clicks on the 'Search' button without specifying any information, all CTs in the public website will be listed in the search results list.

How to search for a clinical trial

In the 'Search clinical Trials' tab there are three sub-tabs: 'Search criteria', 'Search results' and 'Display options'. To perform a search, users can click on 'Search Criteria', where they can find two search functionalities: **Basic** and **Advanced**.

Search criteria

Basic criteria

Users can **search for clinical trials containing all the terms populated, any of the terms populated, or none of the terms populated** and **click on the 'Search' button** to launch the search. In order to add multiple terms, users can populate the term and click on the 'Enter' key of their keyboard. If a user **clicks on the 'Reset' button** the search criteria are erased.

Advanced criteria

This search functionality allows users to **retrieve CTs that match a set of specified criteria** (e.g. trial status, trial number, conditions, product, etc) which therefore narrows down the search results obtained. Users can populate multiple values in the fields of the advanced search such as trial status, product role, population type, country, age group, therapeutic area, trial phase, sponsor type, and gender. When different parameters are entered in the advanced search, the system will use the **AND-operator between all criteria/parameters**, and an **OR-operator between all selected values within one parameter**.

Search, view and download CTs and CTAs information



The search results list contains all the CTs that match the specified criteria in any of the search functionalities.

By default, the search results list displays the results according to the Decision date of the authorisation of a CT in a Descendent order (from new to old).



After users select the 'Submit' button on the Display options tab, the users are automatically redirected back to the search results list with the selected Display options applied.

Search results

Once the search is launched, the results are displayed in a table below the search functionality. Users can view preliminary information selected on the Display Options page (*for more information refer to the following section*). By clicking on the '**Sort**' button, users can sort the results according to the Decision date, Title of the CT, Trial number, Overall trial status, and Overall end of the trial in ascending (ASC) or descending (DESC) order.

The search can be modified by clicking on the '**Modify my search**' button at the top. Also, users can subscribe to the search performed by clicking on the '**Subscribe to search**' button. With this, users are able to view clinical trials that match their search criteria that have been published or updated in the last 7 days.

Display options of the search results list

Users can determine the **preliminary information** shown for each CT retrieved in the Search results list after launching a search by selecting the available **Display options checkboxes**. By default, users can view the Title of the clinical trial, Trial number, Overall trial status, Countries where the trial is taking place (EU country code), Overall start date of the trial (in the EU), Overall end date of the trial (in the EU), Decision date and condition/s. Users can customise the search results by adding additional display options (e.g. Therapeutic area, Recruitment status, Sponsor/Co-Sponsor, Sponsor type, Trial phases, Endpoint, Product, Age group, Gender, etc.). Once users have selected the desired filters, they can click on 'submit' to display the list with the search performed. Example: 'Gender', 'Age' and 'Last updated' are selected. Then the list including these filters will be displayed, as shown in the following images.

Search, view and download CTs and CTAs information



The public website includes all information of CTs **except for confidential information as well as quality related information** (i.e. IMPD quality, quality related to requests for information raised during the assessment and quality assessment reports), draft assessment reports, and financial agreements between the sponsor and the investigator site.

How to view CTs and CTAs information

Users can access the clinical trial 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 clinical trial page, which displays key information of the CT.

Search Clinical Trials
Union Control Reports
Predefined Reports

Search Clinical Trials

Clinical trial search

Search criteria
Search results
Display options

200 results found
Modify my search

Sort by:

Decision date

DESC

Sort

Download results
Subscribe to search

☐

☒
2021-501347-40-00 - Authorised, not started - AT-TEST (ZH) 105

Overall start date of the trial (in the EU): N/A | Overall end date of the trial (in the EU): N/A | Conditions: breast cancer | Countries where the trial is taking place (EU country code): AT:Authorised, not started, FR:Authorised, not started, DE:Under evaluation | Decision date: N/A

The information that appears in the selected CT consists of Trial information and Overall Trial Status. The 'Trial information' section displays information regarding condition(s), sponsor, Member states concerned, trial phase, therapeutic area, among others. 'Overall trial status' displays important information related to trial and recruitment period notifications.

On this same screen, users have the option to request the **removal of information of a specific CT**, if needed (e.g. personal data removal). In this case, users can select the 'request removal of public information' button. EMA Service Desk will consider this request and consider its approval or non-approval.

Trial information

Conditions(s)
breast cancer

Member states concerned
AT FR DE

Sponsor
Panpharma

Low intervention study
No

Trial Phase
Phase III and phase IV (Integrated)

Population type
Patients

Therapeutic area
Transition Trial

Yes

First submitted
11/11/2021

Last update
11/11/2021

Medical device
No

Overall Trial status

Start of trial

Global end of trial

Member state	Current status	Decision date	Last update	Start date	Trial				Reason for early termination	Recruitment		
					Temporary Halt	Restart	End (or early termination)			Start	End	Restart
Austria	Authorised	11/11/2021										
France	Authorised	11/11/2021										
Germany	Under evaluation	11/11/2021										

Request removal of public information

Search, view and download CTs and CTAs information



Users cannot see versions of documents in CTIS public domain that are 'not for publication'.

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. Only the public information will be visible to the users. The sub-tabs are:

- **Summary:** Displays Trial information of the CT (e.g. condition(s), sponsors, trial phase, therapeutic area, date of submission, date of the last update, Member State(s) concerned (MSC), etc); and Overall Trial status in each MSC (e.g. decision date, last update, the start date of the trial, temporary Halt, recruitment start and end date, etc.).
- **Full trial information:** Displays comprehensive list of the latest data and documents authorised for each CTA, including Trial specific information of Part I and Country-specific details.
- **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 CT Regulation.
- **Inspection Record:** Displays information related to the inspections performed to the trial and facilities related to it.

Clinical trial applications information

To have access to the trial applications other than the initial, users can select the 'Applications' button of the 'Full Trial information' section, and select the 'View' button next to the application of the CT which they want to access.

The screenshot shows the 'Full trial information' section of the CTIS interface. A callout box points to the 'Full trial information' tab in the navigation bar. Below the navigation bar, there is a section titled 'Current information on the trial' with a 'View current trial information' button and an 'Applications' button. The 'Applications' button is highlighted with a red box. Below this, a table titled 'Trial Applications' is displayed, showing two rows of applications with 'View' buttons next to them.

Application type	Application status	Submission date	Decision date	MSC	
SUBSTANTIAL MODIFICATION	Withdrawn	20/10/2021	20/10/2021		View
SUBSTANTIAL MODIFICATION	Authorised	20/10/2021			View

How to download clinical trial information

Users of the public website can download data from the Search results list or specific information of a CT.

Download the Search results list

Once users have launched a search in the Search results 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 sentence "CSV file has been created. Click here to download:

Search, view and download CTs and CTAs information



The public website allows users to download the CTs listed in the search.

Export file" under the 'Download results' button.

Search Clinical Trials

Clinical trial search

Search criteria

Search results

Display options

200 results found

Modify my search

Sort by:

Decision date

DESC

Sort

Download results

Subscribe to search

Download CT data

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

View Clinical Trial

Download CT

TEST timer

EUCT number: 2021-501117-23-00

Summary

Full trial information

Events

Trial results

Corrective measures

Inspection Record

After clicking on the 'Download CT' button, users can choose the information and documents to be downloaded by selecting the appropriate checkboxes. The download is carried out when users click on the '**Download clinical trial**' button. The documents are created in Zip format, afterwards, users can click on 'Export File' to finish the download.

Download Clinical Trial

Please select information you would like to download for clinical trial with EUCT Number: **2021-501343-41-00**

▼ Trial Summary

☒ Trial Summary will be included in the downloaded file

► Full Trial Information

► Attached documents

Download clinical trial

Cancel

Zip file has been created. Click here to download:

Export file



Users can download specific data and documents of each CT.

View Union controls information



The public website includes all information of findings of each Union control carried out and recommendations (if applicable). The European Commission submits those reports through CTIS.

How to view Union controls

Users can also view information on Union controls performed by the European Commission from the 'Union Control Reports' tab. To do so, users can select the union control and then click on view. These controls include information such as Business Key, European Commission internal identifier, Start date, End date, Status, Purpose of control, Country corresponding to the Union control (i.e. the Union Control Report).

Search Clinical Trials Union Control Reports Predefined Reports						
Union Control Reports						
Union Control Report						
Union Control Report						
View						
	Business Key	EC's Internal Id	Start Date	End Date	Submission Date	Status
☒	UCR-2021-0024	1234567	25/10/2021	26/10/2021	27/10/2021	Submitted
☐	UCR-2021-0021	011010001010	04/10/2021	08/10/2022	26/10/2021	Submitted
☐	UCR-2021-0013	EC 20	15/10/2021	15/10/2021	15/10/2021	Submitted
☐	UCR-2021-0008	EC ID	01/10/2021	01/10/2021	01/10/2021	Submitted
☐	UCR-2021-0001	234235353	21/09/2021	24/09/2021	21/09/2021	Submitted

Union Control Report

Business Key: UCR-2021-0024 | Submission date: 27/10/2021

EC's internal identifier

1234567

Start Date

25/10/2021

End Date

26/10/2021

Status

Submitted

Purpose of control

Controls conducted in EEA MSs regarding supervision of compliance with the CT Regulation

Country

Austria

Justification documents

Attached documents		
Title	File type	Document Type
UC report	PDF	Union control report (for publication)

Close



Users cannot select multiple Union controls to see their information at the same time. They have to select one Union control at a time.

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000

Send a question

www.ema.europa.eu/contact

Clinical Trials Information System (CTIS).

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