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.

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

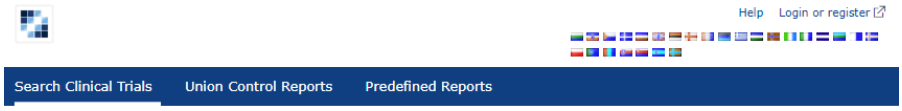
Steps that public users can follow to view information of Union Controls.

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

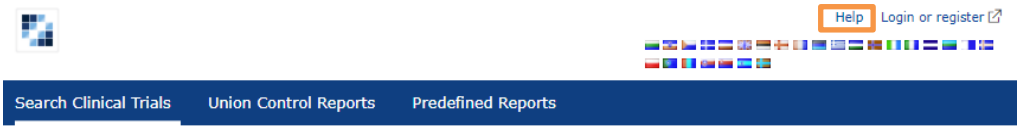
Users can modify the language of the interface by selecting it from the list of countries. Users are able to translate the public website into the 24 official languages of the European Union.

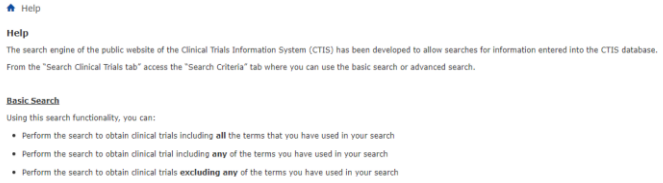
Help

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.





#CTIS insights

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

Search, view and download CTs and CTAs information

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

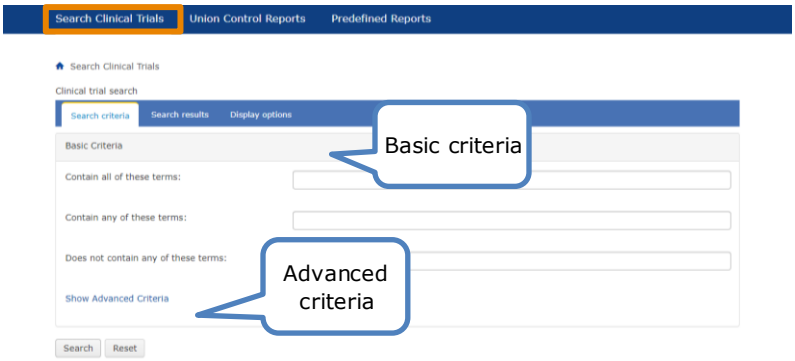
Users can view information of the trials published on the public website.

#CTIS insights

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**.



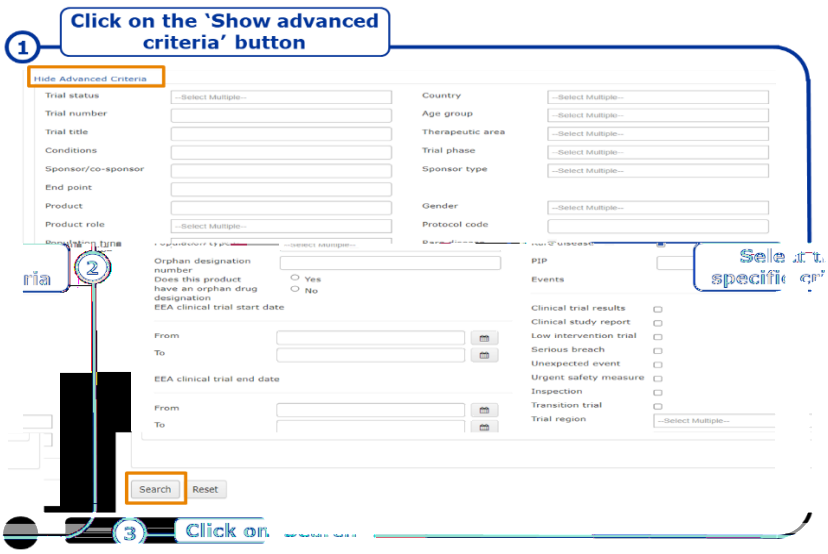
Search criteria

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).

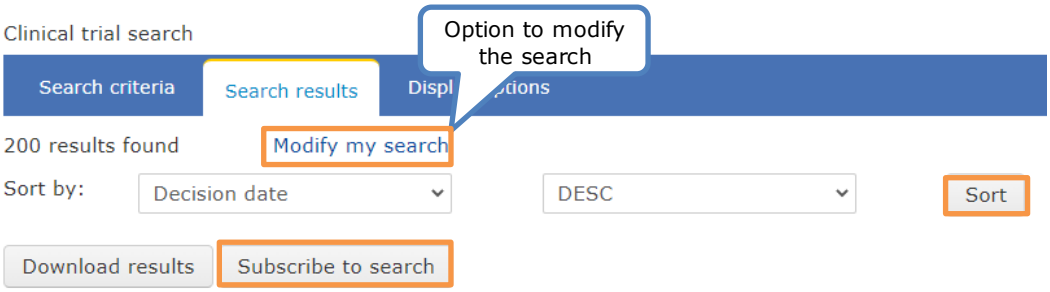
#CTIS insights

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

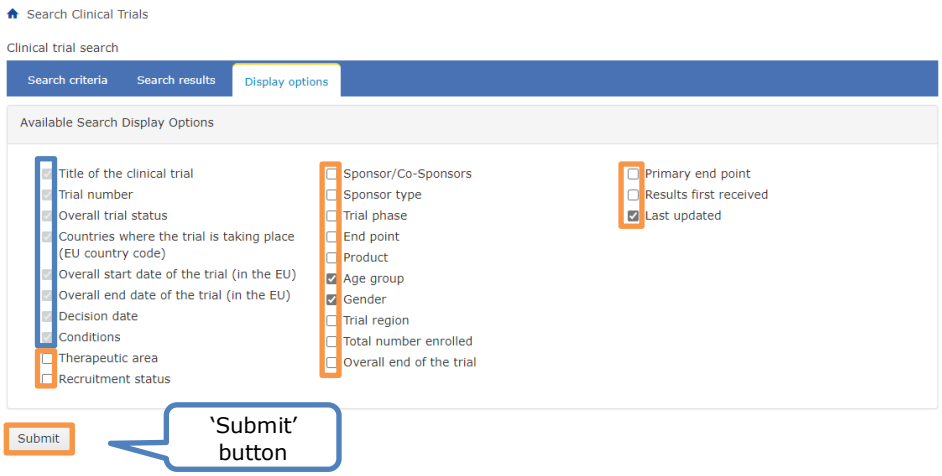
Once the search is launched, the results are displayed in a table below the search functionality. Users can view preliminary information selected on the Display Options page *(for more information refer to the following section)*. By clicking on the '**Sort**' button, users can sort the results according 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.

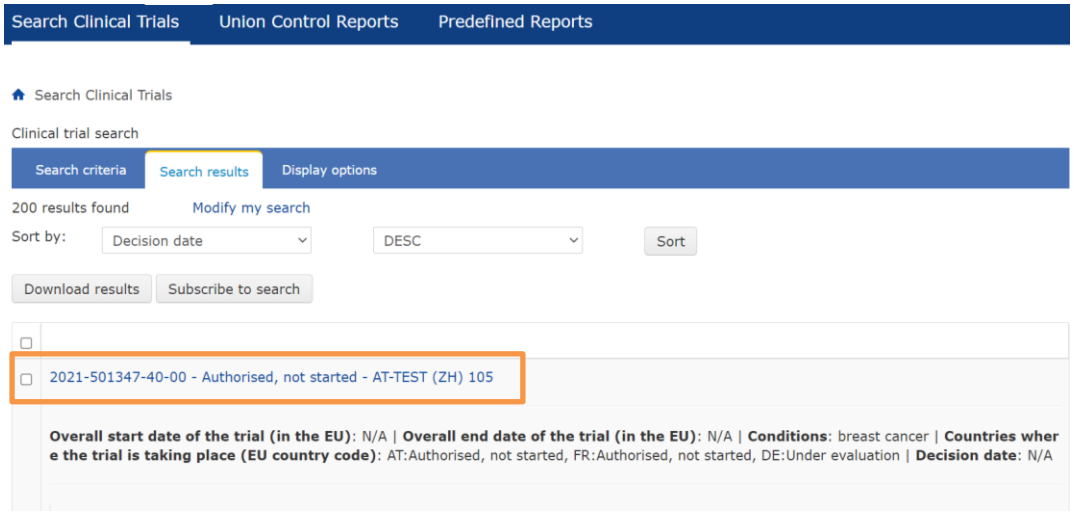


Search, view and download CTs and CTAs information

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.

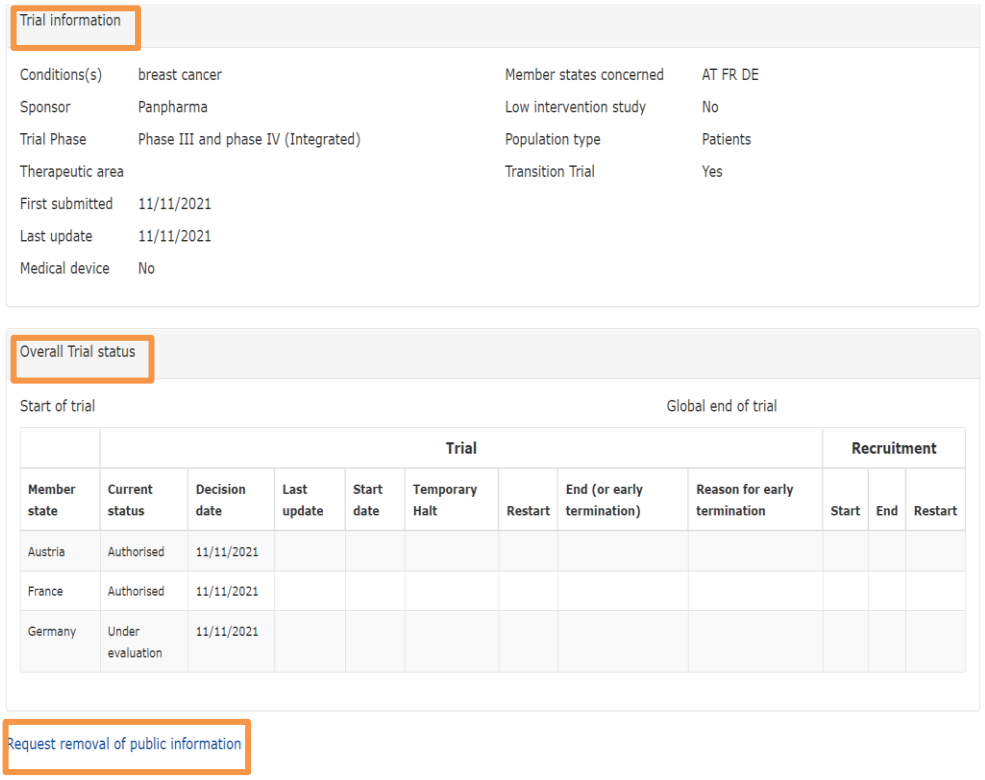
How to view CTs and CTAs information

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.



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.



Search, view and download CTs and CTAs information

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

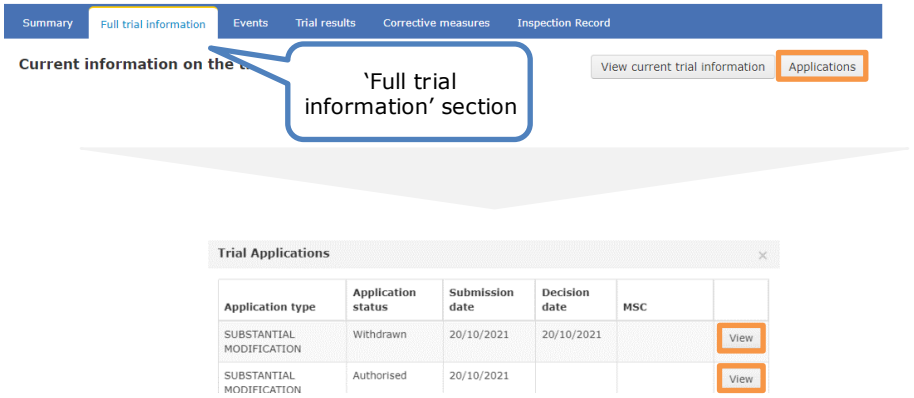
Clinical trial page sub-tabs

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.



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.

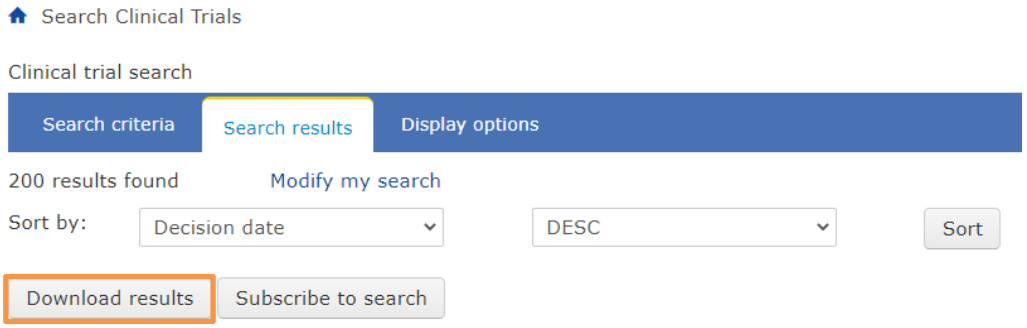
Download the Search results list

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

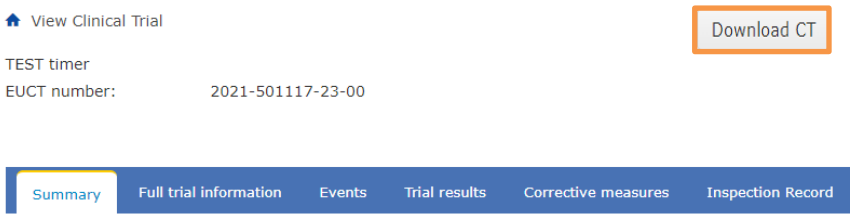
The public website allows users to download the CTs listed in the search.

Export file" under the 'Download results' button.

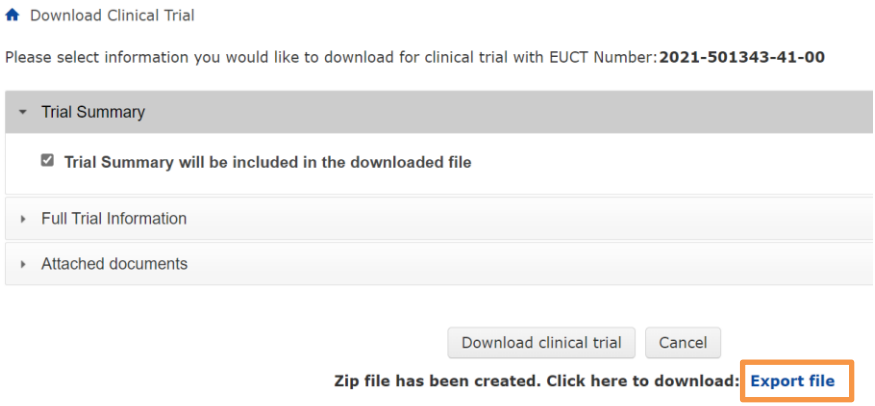


Download CT data

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.



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.



#CTIS insights

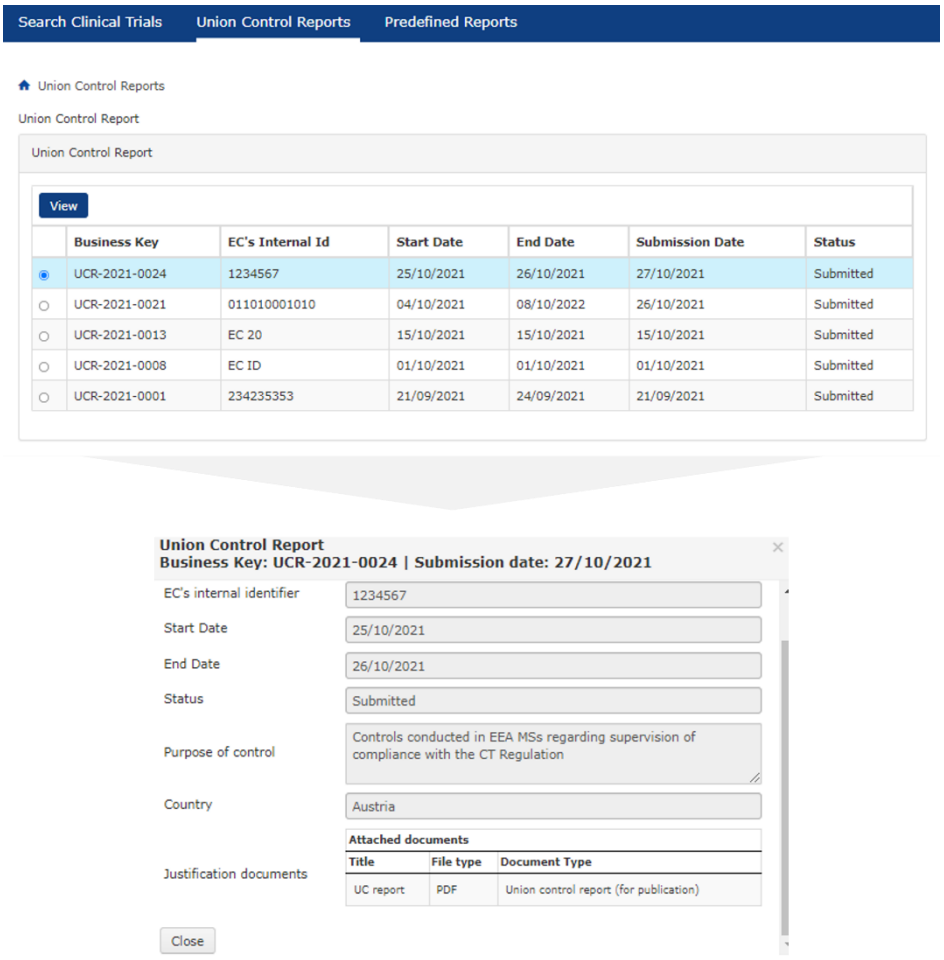
Users can download specific data and documents of each CT.

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).



#CTIS insights

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

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Clinical Trials Information System (CTIS).

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