28 April 2014
Information and Communications Technology

How to search the EU Clinical Trials Register

Contents

1. Searching the EU Clinical Trials Register

The EU Clinical Trials Register search engine allows free-text searches of the information entered into the EU clinical trials database, EudraCT.

Access the EU Clinical Trials Register here: https://www.clinicaltrialsregister.eu/

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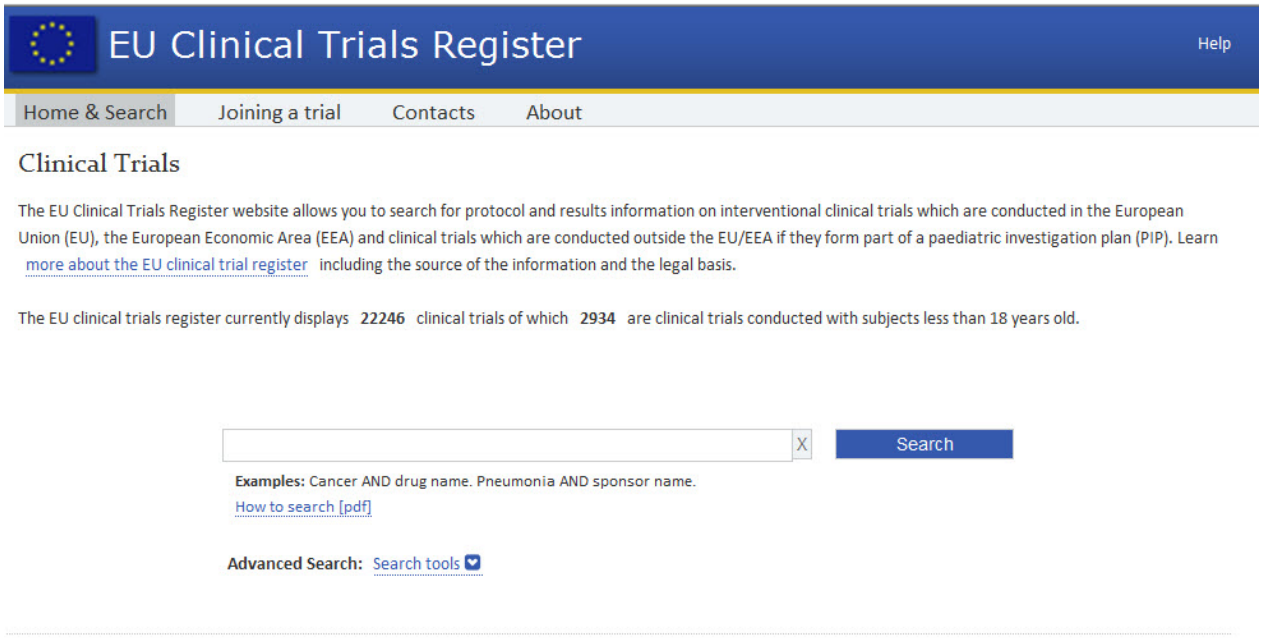


Note: The EU Clinical Trials Register user interface (UI) currently only supports English.

1.1. Basic search

Click in the search field and enter a word or phrase. For example enter `cancer` and `chemotherapy` and click Search. Your query will be matched against any instance of the words in any part of each trial record. The search results will be displayed below the search window and ordered by relevance.

Note: If you enter two words in the search field without using search operators, such as `cancer neoplasm`, the `OR` operator is automatically included (see information about search operators below).

The EU Clinical Trials Register makes use of thesaurus-enabled searching. This means that search queries look both for specified search terms and their synonyms in order to provide improved search results. A synonym is a different word with almost identical or similar meaning. For example, a search query for `high blood pressure` returns records containing more technical/medical terms, such as `hypertension`, in addition to records containing `high blood pressure`.

To clear the search field, click **X**.

1.2. Search operators

If you cannot find what you are searching for, try a search operator to narrow down your search results. Some of these operators are explained below. Search for either word (OR operator)

Enter `OR` (all upper case) between the words if you want to search for trial records that may contain just one of several words.

For example, a search for `cancer OR neoplasm` returns all trial records containing either word.

1.3. Search for multiple words (AND operator)

Enter `AND` (in upper case) between the words if you want to search for trial records that contain all of several words.

For example, a search for `cancer AND neoplasm` returns all trial records containing both words.

1.4. Search for required words (+ operator)

Enter **+** immediately before a word to specify that all search results must contain that word.

For example, a search for `+cancer chemotherapy` returns all trial records containing `cancer` that *may* contain `chemotherapy`. This search would not return trial records containing `chemotherapy` which do not also contain `cancer`.

1.5. Search for an exact phrase (quotation marks operator)

Use quotation marks (`""`), if you want to search for trial records containing an exact phrase or set of words.

For example, a search for `"fallopian tube cancer"` returns all trial records containing this exact phrase.

Note: The quotation marks operator can be combined with the other operators described. For example: `"HIV infections" AND pneumonia`.

1.6. Search for one word whilst excluding another word (NOT operator)

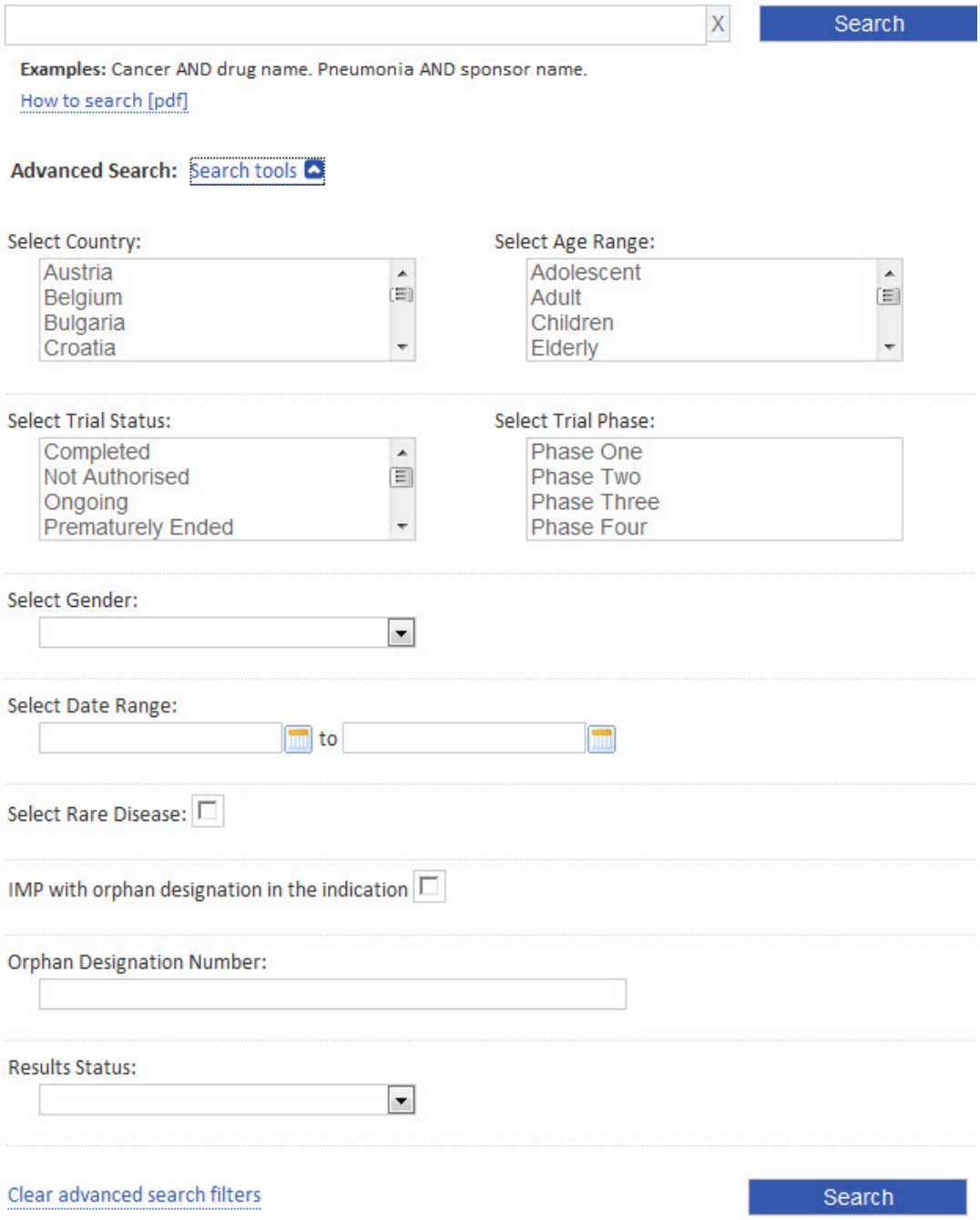
Enter `NOT` (in upper case) between the words if you want to search for trial records that do not contain the word after the `NOT`, but contain the first word.

For example, a search for `"HIV infections" NOT hepatitis` returns all the trial records containing `"HIV infections"`, where no reference to `hepatitis` is made.

Note: An exclamation mark (`!`) may be used in place of `NOT` for equivalent functionality.

1.7. Advanced search

The advanced search allows you to choose one or more filters to modify the results you see. To use the advanced search options, click Search tools. The following search filters will be displayed:



Advanced search filters:

Field	Description
Select Country	A search filter based on the location of the trial. This includes the European Union Member States as well as the European Economic Area countries (Norway, Iceland and Liechtenstein). Select the country that interests you. Leave this selection blank to run the query against ALL countries. • CTRL + click to make multiple selections.
Select Age Range	A search filter based on a specified age range of trial subjects. Select the age range(s) that interest you. Leave this selection

Field	Description
	blank to run the query against ALL age ranges. • CTRL + click to make multiple selections.
Select Trial Status	A search filter based on trial status. Leave this selection blank to run the query against ALL trial statuses. Please see Annex below for trial status definitions. • CTRL + click to make multiple selections.
Select Trial Phase	A search filter based on trials that include at least one of the specified phases. Leave blank to run the query against ALL trial phases. Please see below for trial phase definitions. • CTRL + click to make multiple selections.
Select Gender	A search filter based on the sex of the participants in a study. Include male or female participants ONLY, or BOTH to retrieve records with trials including both sexes. Leave blank to run the query against ALL gender selections. • Click the drop-down arrow to select a single option.
Select Date Range:	A search filter based on the date when the trial was first entered into the EudraCT database by a national competent authority or a third country data provider. • Click the calendars to select a date range to search the register. Please note – Clicking the **Done** button will close the calendar window.
Select Rare Disease	Check this box to restrict your query to trials concerning rare diseases.
IMP with Orphan Designation in the indication:	Check this box to restrict your query to trials concerning investigational medicinal products with orphan designation. That is, potential medicines for rare diseases which have yet to reach the market, but which have already been issued an 'orphan designation' by a regulatory authority, such as the European Medicines Agency.
Orphan Designation Number:	If known, you can restrict your search to a particular orphan designation number.
Results Status	A search filter based on the presence or absence of trial results. Select either clinical trials with results, or clinical trials without results. Leave this selection blank to run the query against ALL results statuses.
Clear advanced search filters	Click Clear advanced search filters to reset all search filters.

Note: You can combine different search filters or combine a basic search with advanced search filters.

Once the search query has been specified, click **Search.**

If the search does not return any results, a statement is displayed at the top of the page.

If matches to your search query are found, these are displayed below the search window. See Search Explained.

2. Search Results Explained

A list of search results is displayed in a summary view. The total number of clinical trials found is displayed at the top of the page.

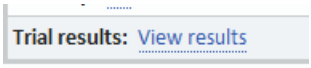
The view is divided into two tabs, one for trials with a EudraCT protocol, and another for paediatric studies in scope of Article 45 of the Paediatric Regulation, which do not have a EudraCT protocol.

2.1. Trials with a EudraCT protocol

The summary view lists the clinical trials that correspond to the search.

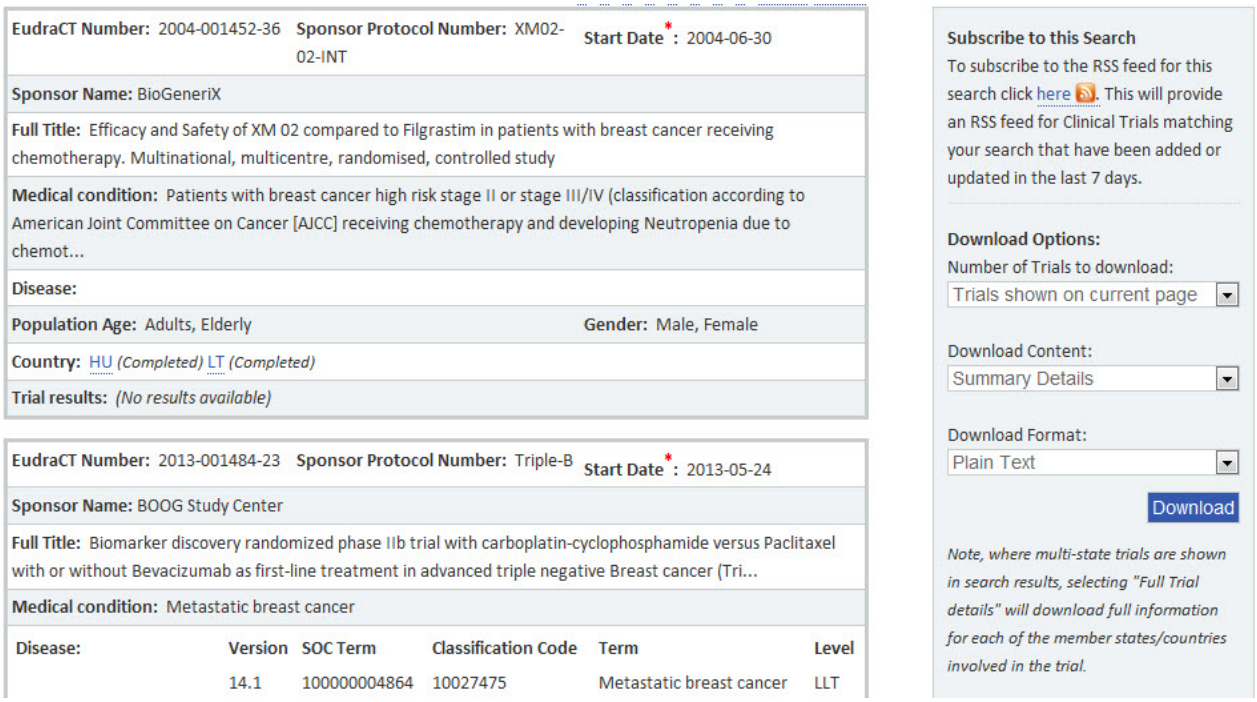
For each clinical trial:

- To see a detailed view of a clinical trial conducted in the named country, click on the Country ISO code. In the example below, it is HU. The protocol-related data can be accessed by clicking on the country code.
- To see the trial results (if available); click on “View results”



Note that the statement “no results available” is displayed when results have not yet been published.

Note that multiple pages of search results can be accessed using the navigation bar above the summary of results.



EudraCT Number: 2004-001452-36 **Sponsor Protocol Number:** XM02-02-INT **Start Date*:** 2004-06-30

Sponsor Name: BioGeneriX

Full Title: Efficacy and Safety of XM 02 compared to Filgrastim in patients with breast cancer receiving chemotherapy. Multinational, multicentre, randomised, controlled study

Medical condition: Patients with breast cancer high risk stage II or stage III/IV (classification according to American Joint Committee on Cancer [AJCC] receiving chemotherapy and developing Neutropenia due to chemot...

Disease:

Population Age: Adults, Elderly **Gender:** Male, Female

Country: HU *(Completed)* LT *(Completed)*

Trial results: *(No results available)*

EudraCT Number: 2013-001484-23 **Sponsor Protocol Number:** Triple-B **Start Date*:** 2013-05-24

Sponsor Name: BOOG Study Center

Full Title: Biomarker discovery randomized phase IIb trial with carboplatin-cyclophosphamide versus Paclitaxel with or without Bevacizumab as first-line treatment in advanced triple negative Breast cancer (Tri...

Medical condition: Metastatic breast cancer

Disease:	Version	SOC Term	Classification Code	Term	Level
	14.1	100000004864	10027475	Metastatic breast cancer	LLT

Subscribe to this Search

To subscribe to the RSS feed for this search click here. This will provide an RSS feed for Clinical Trials matching your search that have been added or updated in the last 7 days.

Download Options:

Number of Trials to download: Trials shown on current page

Download Content: Summary Details

Download Format: Plain Text

Download

Note, where multi-state trials are shown in search results, selecting "Full Trial details" will download full information for each of the member states/countries involved in the trial.

The clinical trial overview record has the following fields:

Field	Description
EudraCT Number	When registered, each trial is issued with a unique EudraCT number, which identifies the protocol and trial throughout its lifespan.
Sponsor Protocol Number	This is the unique identifier number for the Protocol e.g. Sponsor acronym and numbering system (UCL 07/095).
Sponsor Name	The individual, company, institution, or organisation that takes responsibility for the initiation, management or financing of a clinical trial.
Full Title	The full title of the clinical trial as specified in the study protocol and other documents submitted as part of the Clinical Trial Application.
Start Date	The date upon which the clinical trial commenced within the European Economic Area (EEA). **Note:** Outside the EU/EEA (i.e. paediatric investigation plans), the start date is actually date the study was submitted into the EudraCT database, **which may not be the actual start date of the study**.
Medical condition	Medical condition or disease under investigation. Description of intended indication for the product under development.
Disease	The MedDRA classification, including the version of MedDRA, its classification code, the term and its level in the MedDRA terminology hierarchy. **Key to MedDRA hierarchical levels (highest to lowest):** SOC

Field	Description
	(System Organ Class) HLGT (High Level Group Term) HLT (High Level Term) PT (Preferred Term) LLT (Lowest Level Term). See MedDRA website for more information.
Population age	The age range(s) of those taking part in the study.
Gender	The gender(s) of those taking part in the study.
Country	The countries in which the study is based. Click on the ISO country code to view full details of the clinical trial. ISO two letter Country Codes (also known as ISO 3166-1-alpha-2 code) are used in the EudraCT database to record all country references. See the ISO website for the complete list.
Trial results	The summary results of the trial. Click on the link “view results” if available to review the results of the trial. Note that the statement “no results available” is displayed when results have not yet been published.

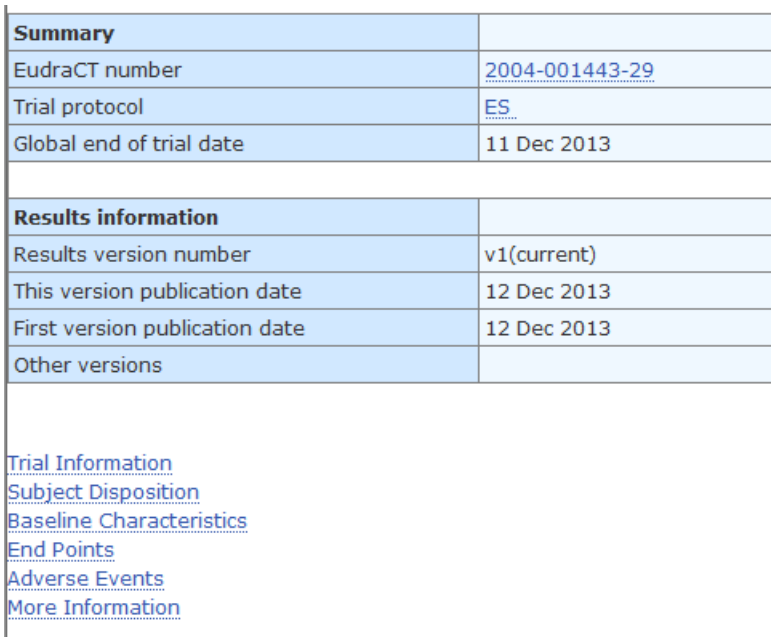
2.1.1. Protocol records

For a given clinical trial there may be several protocol records (Clinical Trial Applications (CTAs), third country files) according to the number of countries where the trial was authorised. By default, the summary view displays information of the oldest record. This is the record first entered in the EudraCT system.

Some fields may appear to be blank or carry a default value ‘Information not present in EudraCT’. For more information refer to the FAQ, which are also accessible under the About section of the EU Clinical Trials Register website.

2.1.2. Results records

For a given clinical trial, there may be several versions of results available which correspond to the versions published by the sponsor over time. View each version by clicking on the Results version number field.



Summary	
EudraCT number	2004-001443-29
Trial protocol	ES
Global end of trial date	11 Dec 2013
Results information	
Results version number	v1(current)
This version publication date	12 Dec 2013
First version publication date	12 Dec 2013
Other versions	

Trial Information
Subject Disposition
Baseline Characteristics
End Points
Adverse Events
More Information

The results related summary section has the following fields:

Summary	
EudraCT number	The unique reference given to each trial which identifies the protocol and trial throughout its lifespan
Trial protocol	Links to the protocol records of the trial.
Global end of trial date	The date the trial ended globally.
Results information	
Results version number	The version number for this set of results
This version publication date	The date this version of results was published.
First version publication date	The date the first version of results was published.
Other versions	Links to the other versions of results of the trial.

Each set of trial results is divided into the following sections:

Section	**Description**
Trial information	Details of the trial (e.g. full title of the trial, study identifier, sponsor details, population of the trial). Additionally it also shows details on the results analysis stage.
Subject Disposition	A summary of the progress of subjects through each stage of the trial.
Baseline Characteristics	Data collected at the beginning of the trial for all subjects and for each arm or comparison group. These data include demographics, such as age and gender, and study-specific characteristics.
End Points	Planned measurements described in the protocol that are used to determine the effect of interventions on subjects in a clinical trial.

Adverse Events	A summary of unfavourable changes in the health of subjects that happen during a clinical trial or within a certain time period after the trial is over.
More Information	Additional information about the trial.

Note that for older trials the legislation allows summary attachments to be posted instead of the full dataset. In such case, the sponsor may have provided only an attachment as a mean to provide summary results and the full data sets would not be available.

2.2. Paediatric studies in scope of Article 45 of the Paediatric Regulation

Paediatric studies that were completed by 26 January 2007 in respect of products covered by an EU marketing authorisation (Article 45 of Regulation (EC) No 1901/2006) are presented in a dedicated tab in the user interface due to their data format being different from other trial records included in the register.

The study overview record has the following fields:

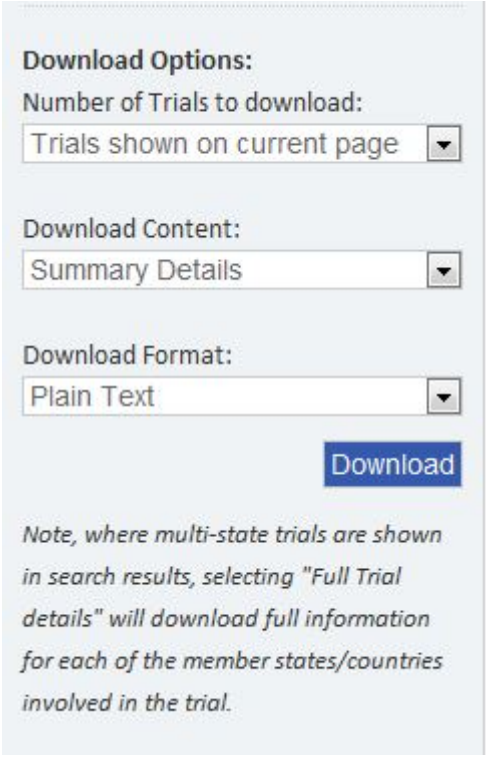
Field	Description
Study title	The full title of the study as specified in the study protocol.
Active substance	Active substance(s) studied.
Study summary document link (including results)	Links to a document containing a summary of the study results (e.g. copy of a medical journal article or a synopsis in accordance with Annex I to the ICH Topic E 3 guidance). ***Note** that this link is only provided if the sponsor / marketing-authorisation holder has submitted such a document.*
View full study document link	Provides further basic information about the study, such as therapeutic area, brand name(s) and population of study subjects.
Document reference	A reference number automatically assigned by the EMA.

3. Download search results

Note: This functionality is only available for trials with a EudraCT protocol, but not for paediatric studies in scope of Article 45 of the Paediatric Regulation.

Once a successful search has been run the search results can be downloaded in plain text format.

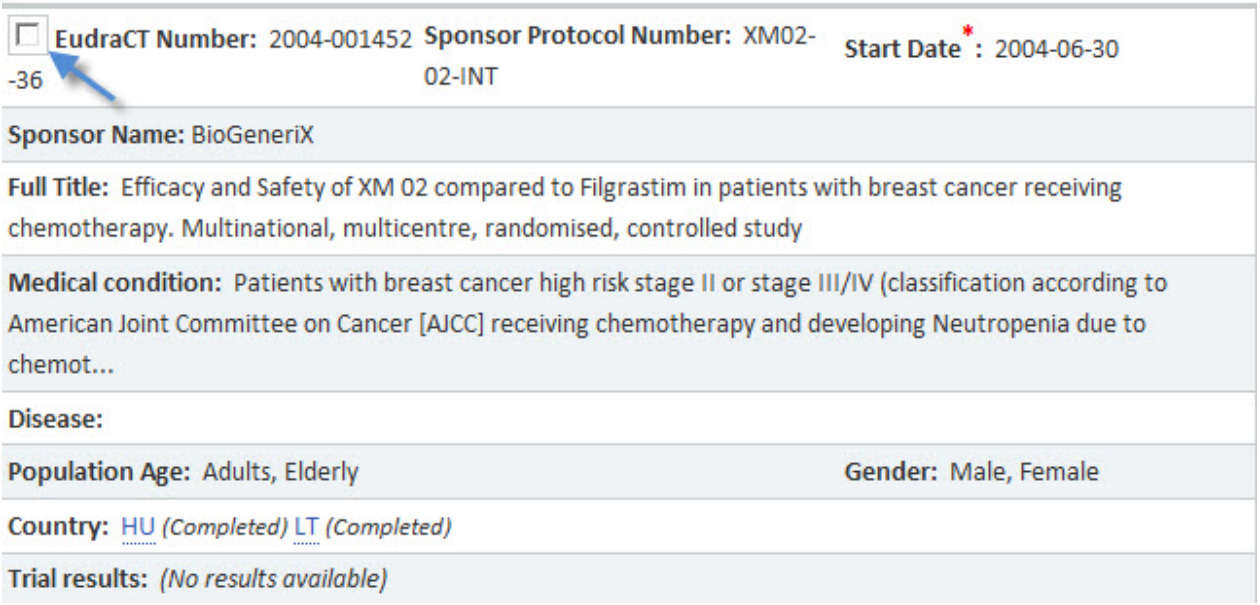
Using the menu below you can select the options to download by using the drop-down menus



The Download Options menu has the following fields:

Field	Description
Number of Trials to download	Choose 'Trials shown on current page' in order to download all the trials shown on the page you are currently viewing. Choose 'Selected Trials only' and then click the check box beside each result that you are interested in in order to download only selected trials. (Please see screenshot below.) **Note:** This option is only available on a page by page basis.
Download Content	Select from the drop-down list to select a précis of the information (summary details) or the entire record of the study (full trial details).
Download Format	Currently, only a plain text output is provided (.txt file extension)
Download	Click the Download button when you have selected your download options.

If you choose to download 'Selected Trials only', you may select trials (by ticking the EudraCT Number) on the page you are currently viewing



Click the **Download** button when you have selected the trials to download. Open the file or save it locally.

4. Subscribe to a search

Note: This functionality is only available for trials with a EudraCT protocol, but not for paediatric studies in scope of Article 45 of the Paediatric Regulation.

The EU Clinical Trials Register offers the option to save a specific search (or an advanced search) query as a Really Simple Syndication (RSS) 'feed'.

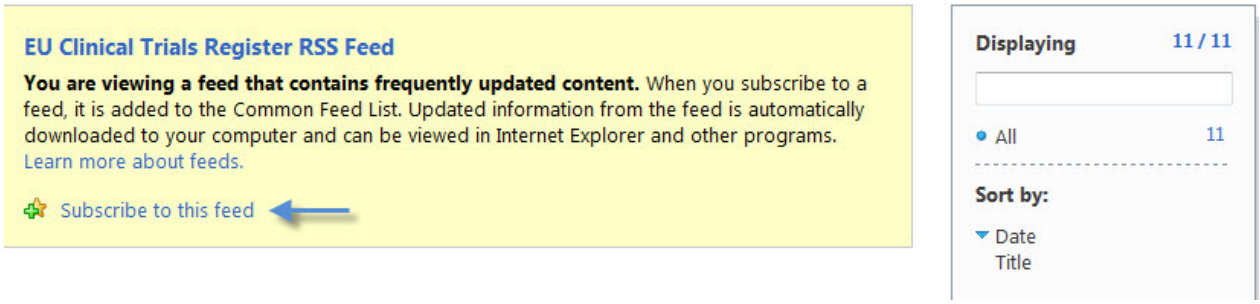
- Once a search query is subscribed, you will be notified in your RSS reader if the search query returns new results.
- The method of subscribing to an RSS feed varies between browsers, but involves no more than a couple of mouse clicks.

Note: If you are interested in this feature, and are not sure whether your browser supports RSS feeds, please refer to your browser's Help, which is accessible through the browser's options bar. The following are instructions for subscribing to a search in Internet Explorer 8.

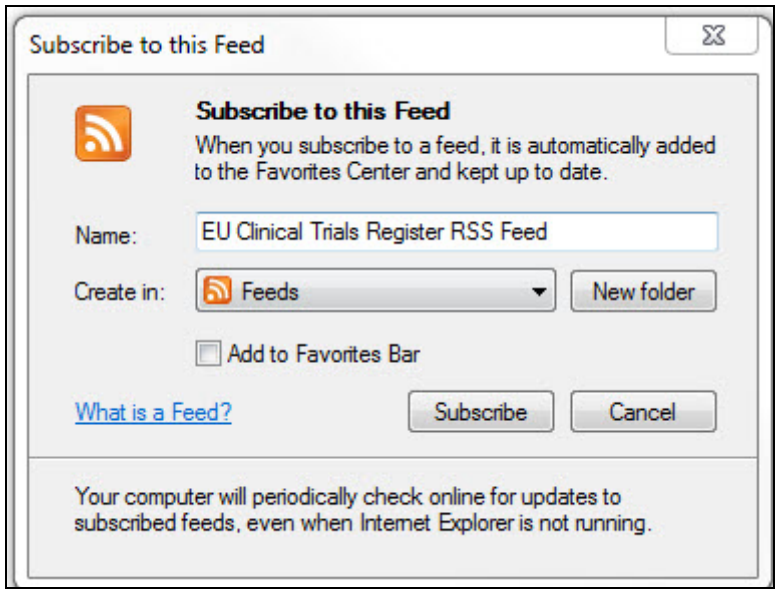
Subscribe to search feed in IE8:

1. Click the word 'here' from the Subscribe to this Search menu:

2. The following screen is displayed:



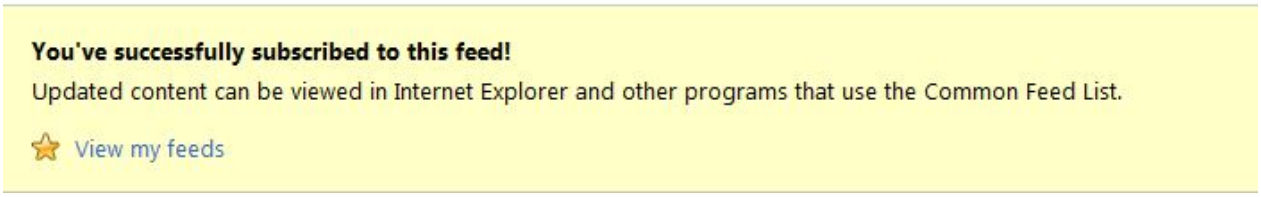
3. Click Subscribe to this feed:



Once a search query has been created, click **Subscribe**.

If additional records matching your search query are added to the database, the RSS feed will indicate that additional results are available to view. Click the link to view the latest results summary in the EU Clinical Trials Register.

Click Subscribe and the search is added to your RSS feeds:



5. Annex

The Annex contains definitions of clinical trial phases and statuses. You may also find the EU Clinical Trials Register glossary useful to explain other unfamiliar terms and acronyms that may be encountered when viewing clinical-trial records.

Clinical trial phase definitions

Phase	Description
Phase I	Phase I is the first stage in the clinical development of a medicinal product. It is to ensure a treatment is safe for people to take, rather than

Phase	Description
	to try to treat a condition. These trials are very small, (typically around 30 people), and usually involve healthy volunteers or sometimes patients.
Phase II	Phase II aims to investigate the safety and effectiveness of a potential therapy. Usually between 100 and 300 people will be enlisted to take part with the aim of determining whether the treatment will be safe and effective to treat a condition.
Phase III	If previous trials have indicated a treatment is safe and that it also shows promise in being able to treat a condition, phase III clinical trials begin. These involve large numbers of participants, usually from several hundred to several thousand subjects, and are often spread between different hospitals and countries. If these trials show that a drug is safe and effective, the manufacturers can apply for a marketing authorisation.
Phase IV	Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Clinical trial status definitions

Phase	Description
On-going	A trial that has received a positive opinion of an ethics committee and authorisation from a competent authority in the Member State(s) concerned and has not ended or is being interrupted.
Not Authorised	In the European Clinical Trials Register, all trials displayed have an authorisation from a competent authority. However, paediatric trials for which a negative ethics committee opinion was issued are also displayed. Since a trial with a negative ethics committee opinion cannot proceed, these are labelled as not authorised.
Temporarily Halted	A trial that has been temporarily interrupted. Reasons for such an interruption are varied, ranging from an interruption in supply of an investigational medicinal product, to the need to await the authorisation of a substantial amendment to the protocol.
Restarted	A trial that was temporarily halted or suspended and has subsequently been restarted.
Prematurely Ended	A trial that has ended without completing all events described in the protocol. Reasons for a premature end can be related to lack of safety or efficacy of a product, or lack of feasibility of the trial.
Completed	A trial that has been completed in accordance with the full requirements of the protocol.
Prohibited by National Competent Authority	A trial whose conduct a national competent authority has prohibited. Reasons may be related to lack of safety or efficacy of a product, or to

Phase	Description
	non-compliance by some of the people involved.
Suspended by National Competent Authority	A trial whose conduct a national competent authority has suspended. Reasons may be related to lack of safety or efficacy of a product, or to non-compliance by some of the people involved. A suspended trial can be restarted.