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How to search EU Clinical Trials Register

For all users

Note: The EU Clinical Trials Register User Interface (UI) currently only supports English.

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1. Searching the EU Clinical Trials Register

The EU Clinical Trials Register search engine has been developed to allow free searches of the information entered into the European Union Drug Regulating Authorities Clinical Trials (or EudraCT) database.

 Ensure your browser is open on the EU Clinical Trials Register homepage: <u>https://www.clinicaltrialsregister.eu/</u>

To access the EU-CTR Search:

Click the Click to search for Clinical Trials button in the middle of the homepage.

Or

• Click on the menu item '**Search**' in the global navigation at the top of the page:

Home Search 1 Shout Glossary	/ Data Quality Joining a trial Contacts EudraPh Clinicaltrialsregister
Introduction to EU Clinical Trials Register	
 The EU Clinical Trials Register website allows you to search for information on clinical trials in European Area (EEA) and clinical trials which are conducted outside the EU/EEA if they form part of a paediatric investige 	Union (EU) member states and the European Economic stigation plan (PIP). More
 The information on the website is collected and entered by national medicine regulatory authorities or outside the European Union. They are required by European Union law to enter details of clinical trials into database is now being made publicly available through a new website, the EU Clinical Trials Register. In 	by the addressee of a PIP decision for trials conducted a database called EudraCT. The information stored in this nformation on the website dates from May 2004. <u>More</u>
 The website is hosted by the European Medicines Agency (EMA). National medicines regulatory authorities information in the EudraCT database, this information is then displayed through the EU Clinical Trials Regis 	and the addressees of PIP decisions collect and enter the ster website. More
 Users can find information on the design of each clinical trial, the sponsor, the investigational medicinal the clinical trial. <u>More</u> 	products and therapeutic areas involved and the status of
• If you require further information on a specific clinical trial published on the website, please contact the s trial. The EMA will not be able to provide any information on a specific clinical trial . <u>More</u>	ponsor (company or organisation) conducting the clinical
The EU Clinical Trials Register website is upgraded continually in order to meet user needs. More	
 The EU Clinical Trials Register has been a primary registry in the WHO Registry Network since September 2 is available on the <u>WHO ICTRP website</u>. 	2011 and is now a WHO Registry Network data provider. I
Click to search for Clinical Trials)

Figure 1

Click either to open the Clinical Trials search page: <u>https://www.clinicaltrialsregister.eu/ctr-search/</u>

2. How to perform a basic search

EU Clinical Trials Register Basic Search



Figure	2
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Highlighted I tem	Description
а	Click in search field and type a word or phrase (this is your 'search query').
b	Click Search once you have entered a search query in the search
	Tield (2). Any matched results appear below the search window
С	Click Reset to clear the search field.
d	Click Advanced Search to open the Advanced Search fields. See <i>Section 4</i> Advanced Search for information on using the advanced search functions.

• Should you require guidance on the results pages, see *Section 5. - Search Results Explained*, below.

2.1. Basic search explained

The Basic search functions as follows:

- Your search query is matched against any instance of the word(s) in any part of a single clinical trial record. This creates the list of results, summaries of which may be viewed beneath the Search window.
- In addition, the EU Clinical Trials Register makes use of thesaurus-enabled searching. Simply put, search queries look for both specified search terms and synonyms of certain known terms to provide improved search results.

Note: A synonym is a different word with almost identical or similar meaning. For example, a search query for 'high blood pressure' returns entries containing more technical/medical terms, such as 'hypertension', in addition to results containing 'high blood pressure'.

• The results will be ordered by relevance.

2.2. Multiple term search explained (Boolean operators)

For more specific searches, the use of multiple terms in your search queries is possible using search syntax known as Boolean search 'operators'. Some of these are detailed below.

• In each example, the entire search query as it appears in the search field is contained within the grey highlight.

2.2.1. Search for either term (OR operator)

Enter **OR** (all upper case) between words to return studies that contain **either** word or **both** words.

• e.g., Cancer OR Neoplasm returns all studies containing either term.

Note: If you enter two terms in your search query, such as Cancer Neoplasm, the AND operator is automatically included (though it does not appear in the search field). To avoid this, surround the two terms with quotation marks to define the two words as a phrase or multi-word term: "Cancer Neoplasm".

2.2.2. Search for multiple terms (AND operator)

Enter **AND** (in upper case) between each term to perform a search for multiple terms:

- A search query containing cancer AND chemotherapy returns all studies containing **both** words (or their known synonyms).
- A search for cancer AND chemotherapy AND Medicine Name returns all studies containing these words, where 'Medicine Name' is the name of a particular medicine.

Important Note: Even if the AND operator is not added when two discrete words are entered in your search query (for example Cancer Neoplasm), the AND operator is automatically included (though it does not appear in the search field).

If you wish to avoid this, surround the two discrete terms with quotation marks to define the two words as a phrase or multi-word term: "Cancer Neoplasm".

2.2.3. Search for required terms (+ operator)

Enter + immediately before a term to specify that the term must be present in a study.

• A search for +cancer chemotherapy returns all studies containing 'cancer' that *may* contain 'chemotherapy'.

2.2.4. Search for exact phrase (Quotation marks operator)

Surround the search phrase with quotation marks (""), to return studies containing a specific phrase or multi-word term.

- e.g. "Fallopian tube cancer" returns all studies containing this exact phrase.
- The exact phrase function may be combined with the other operators described. For example: "HIV Infections" AND "Pneumonia".

2.2.5. Search for one term whilst excluding another term (NOT operator)

Enter **NOT** (all upper case) between words to search for studies that do not contain the word after the NOT, but contain the first word.

• **e.g.** "HIV Infections" NOT "Hepatitis" will list all the studies containing HIV Infections, where no reference to Hepatitis is made.

Note: The NOT operator cannot be used with just one term. For example, the following search will return no results: NOT "HIV Infections"

Note: The symbol **!** may be used in place of **NOT** for equivalent functionality.

• Clear the search box by clicking the **Reset** button.

3. Advanced Search

The Advanced search fields allow you to make a much narrower search query than the basic search, alone.

3.1. How to perform an advanced search

1. To view the advanced search options, click Advanced Search, which appears beside the

Reset button or under the search field, depending on the size of your browser window (see the top of the screenshot below).

The Advanced Search window

	Search Reset Advanced
Search	
Examples: Cancer AND Drug Click here for more informa	Name. Pneumonia AND Sponsor Name. <u>tion</u>
Search Tips: Under advanced Status, Date Range, Rare Dis add them to your search term	search you can use filters for Country, Age Group, Gender, Trial Phase, Trial eases and Orphan Designation. For these items you should use the filters and not s in the text field.
Select Country:	a Austria ▲ Belgium Bulgaria Cyprus ▼
Select Age Range:	In-Utero Preterm new born infants Newborn Infant and Toddler
Select Gender:	C ¥
Select Trial Phase:	d Phase One Phase Two Phase Three Phase Four ✓
Select Trial Status:	Prematurely Ended Suspended by CA Temporarily Halted Restarted
Select Date Range:	f to
Select Rare Disease:	g 🗆
IMP with orphan designa in the indication:	tion <i>h</i>
Orphan Designation Num	hore

Figure 3

а	 Select Country: A search filter based on the location of the clinical trial. This includes the 27 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.
b	 Select Age Range: A search filter based on a specified age range. Select the age range (or ranges) that interest you. Leaving this selection blank will retrieve records from all age ranges. CTRL + click to make multiple selections.
С	 Select Gender: A search filter based on the gender of the participants in a study. Include male or female participants ONLY, or BOTH to retrieve records with trials including both genders. Click the drop-down arrow to open the drop-down box and select a single option.
d	Select Trial Phase: A search filter based on studies that include at least one of the specified

Field Description

Field	Description
	 phases. Leave blank to retrieve trials in ANY of the four phases. See Glossary for definitions of each of the four phases. Please see Annex below for Trial Phase definitions. CTRL + click to make multiple selections.
е	 Select Trial Status: A search filter based on clinical trial status. Leave blank to return studies of ANY status. Please see Annex below for Trial Status definitions. CTRL + click to make multiple selections.
f	Select Date Range: Click the calendar to choose the start and end date. Performs a search based on the date when the study was first entered into the EudraCT database by a National Competent Authority. Note on Start Date: 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.
g	Rare Disease: Check this tick box to restrict your search to studies and trials concerning rare diseases only.
h	IMP with Orphan Designation in the indication: Check this tick box to restrict your search 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 'Orphan Designation' by a regulatory authority, such as the European Medicines Agency.
1	Orphan Designation number: If known, you can restrict your search to a particular orphan designation number.
j	Clear advanced search filters: This has the same effect as the Reset button and clears the entire query.
	Constant

- 2. Once the search query has been specified, **click** Search.
- 3. If matches to your search query are found, these matched results appear below the search window. See *Section 5. Search Results Explained* below.
- 4. In addition to the results of your query, the following new options become available:
- **Download Options** If required, choose how many of the results found you wish to download. See Section 6. - Download Results below.
- Subscribe to this Search _{RSS} search subscription options allow you to add a search to your RSS reader, so that any new results to your search will be automatically added to your RSS feed. See Section 7. Save a Search to your RSS reader.

4. Search Results Explained

Below, the results of a successful search query are explained.

4.1. Summary

The results of the search are displayed in a summary view. Note that multiple pages of results may be accessed through the navigation bar above the summary of results bar.

- To see the detailed view of a clinical trial conducted in the named country, click on the **Country ISO code** (**GB** in the below example).
- The summary view displays the **oldest record as a default**. This is the clinical trial which was first recorded in the EudraCT system.

Download Options 🛛 🔊 Subs	cribe to th	is Search		1 2 2 4 5 6 7 8 0	- Novta Lactaa
	Query re	turned 193 doo	cument(s). Displaying pag	e 1 of 10.	9 NEXL# Last##
Fuder OT Newsham, 2000, 0000	Query re		and Numbers 1101 07/005	C I OI IO.	and the data
Eudraci Number: 2008-0008.	37-23	Sponsor Proto	col Number: UCL 07/095	Sponsor Name: University Coll	ege London
Full Title: mEOC: A GCIG Intergroup multicentre trial of open label carboplatin & paclitaxel +/- bevacizumab compared with oxaliplatin & capecitabine +/- bevacizumab as Start Date [*] : 2009-02-19 first line chemotherapy in patients with					
Medical condition: Mucinous or	varian cance	r, stages II-IV a	nd stage I recurrent		
	Version	SOC Term	Classification Code	Term	Level
Disease:	9.1		10033128	Ovarian cancer	LLT
	9.1		10066697	Ovarian cancer recurrent	LLT
Population Age: Adults, Elderly Gender: Female					
Country: GB (Ongoing)					
EudraCT Number: 2010-0222	09-16	Sponsor Proto	col Number: ICON8	Sponsor Name: Medical Resear	r <mark>ch Counci</mark> l
Full Title: ICON8: An international phase III randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primar Start Date [*] : 2011-04-08					
Medical condition: Newly diagnosed high risk early stage (FIGO stage IC/IIA, grade 3 or clear cell histology only) or advanced stage (FIGO stage IIB-IV, all grades and all histological types) epithelial ovarian, fall					
	Version	SOC Term	Classification Code	Term	Level
Disease	13		10061328	Ovarian epithelial cancer	LLT
Disease:	13		10016180	Fallopian tube cancer	LLT
	13		10052171	Peritoneal carcinoma	LLT
Population Age: Adults, Elderly	/			Gender: Female	
Country: GB (Ongoing)					

Results Summary screen crop

Figure 4

Element	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	Unique Identifier number for the Protocol e.g. Sponsor acronym and numbering system (UCL 07/095).
Sponsor Name	The individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Description
The full title of the clinical trial as specified in the study protocol and other documents submitted as part of the Clinical Trial Application.
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 or disease under investigation. Description of intended indication for the product under development.
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 (System Organ Class) HLGT (High Level Group Term) HLT (High Level Term) PT (Preferred Term) LLT (Lowest Level Term). See <u>MedDRA website</u> for more information.
The age range(s) of those taking part in the study.
The gender(s) of those taking part in the study.
The country 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 <u>ISO website</u> for the complete list.

4.1.1. Clinical Trials in Multiple Countries

The results of the search displayed for multiple countries for the same EudraCT Number are **NOT** translations. The countries are those in which the trial was conducted.

- Click on the **ISO country code** (in the **Country** field as a blue hyperlink) to view the clinical trial details specific to that country.
- Some fields may appear to be blank or carry a default value 'Information not Present in EudraCT'. Please refer to the <u>FAQ</u>, which is also accessible under the '<u>About</u>' section of the EU Clinical Trials Register website for further details.

5. Download Results

Download results of a search query in plain text format.

- Once you've run a successful search, the **Download Options** link appears just above the results.
- Click the link to view the options available:

Download Options 🛛 🔊 Subscri	be to this Search
Number of Trials to download:	Trials shown on current page \bigcirc Selected Trials only \bigodot
Download Content:	Summary Details 💿 Full Trial Details 🔿
Download Format:	Plain Text 💌
Note, where multi-state trials are sh download full information for each of	own in search results, selecting "Full Trial details" will f the member states/countries involved in the trial.
Download	

-

	Figure 5
Element	Description
Number of Trials to download	Click the 'Selected Trials only' radio button and then click the check box beside each result on the page you are currently viewing. Note: This option is only available on a page by page basis.
Download Content	Click the radio button to select a précis of the information (Summary Details) or the entire entry 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 chosen your download options criteria.

Selected Trials Only:

Once the 'Selected Trials only' radio button is selected, you may then select trials (by EudraCT Number) on the page you are currently viewing.



Figure 6

• Click the

Download

button when you have selected the trials to download.

• You may 'Open' the text file or 'Save' it to your local file structure.

6. Save a Search to your RSS reader

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

- Once a search query is subscribed, you'll 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. Below, are the instructions for subscribing to a search in Internet Explorer 8.

Subscribe to search feed in IE8

- Once a search query has been created, click Subscribe to this Search.
- 2. Now, **click** the word 'here' and your default RSS tool will give you options to subscribe to the search query. In this example, the Internet Explorer RSS feed screen is shown:

EU Clinical Trials Register RSS Feed	Displaying	0/0
You are viewing a feed that contains frequently updated content.		
Ipdated information from the feed is automatically downloaded to your computer and can be viewed in Internet Explorer and other programs.	• All	0
earn more about feeds.	Sort by:	
🖨 Subscribe to this feed	▼ Date	
	Title	

Figure 7

3. Click 'Subscribe to this feed' and the 'Subscribe to this feed' dialogue appears:



Figure 8

- 4. If you wish, you can amend the 'Name' of the feed to something more specific (e.g. Search Query: "HIV" NOT "PNEUMONIA") and manage the location of the feed.
- 5. **Click Subscribe** and the search is added to your RSS feeds:

Add to Favorites Bar 🔹 🗙	A Clinical Trials Register 🛛 👔 🔹 🔊 🖆 🖶 🔹 🎽
Favorites Feeds History EudraCT feeds Hicrosoft Feeds EMA/EU Telematics 'Approve' Website Feed StrAlEU Telematics Website Feed EU Clinical Trials Register - Cancer AND Chemotherapy search EU Clinical Trials Register RSS Feed EU Clinical Trials Register RSS Feed	You've successfully subscribed to this feed! Updated content can be viewed in Internet Explorer and other programs that use the Common Feed List. Displaying 0 / 0 Updated content can be viewed in Internet Explorer and other All 0 Sort by: Date Title View feed properties

Figure 9

6. If additional results which match your search query are added, the RSS feed will indicate additional results are available to view. Click the link to view the latest results summary in EU Clinical Trials Register.

7. Annex

The Annex contains definitions clinical trial phases and statuses. You may also find the <u>EU Clinical</u> <u>Trials Register Glossary</u> useful to explain other unfamiliar terms and acronyms which may be encountered in viewing clinical trials records.

The EU Clinical Trials Register Glossary is also available through the top bar on each page of the EU Clinical Trials Register website:

Home Search About Glossary	Data Quality Joining a trial Contacts EudraPharm
Degistor	Clinicaltrialeregister eu

Figure 10

7.1. Clinical Trial Phase Definitions

Phase	Definition
Phase I	Phase I is the first stage of a clinical trial. It is to ensure a treatment is safe for people to take, rather than 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	The second phase in clinical trials 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 drug license.
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.

7.2. Clinical Trial Status Definitions

Status	Definition
Ongoing	Is a clinical trial which has received an opinion of Ethics Committee and Authorisation from Competent Authority in Member States concerned and has not ended or being interrupted.
Not- authorised	Within EU-CTR all clinical trials displayed have an authorisation from competent authority however we also display those Paediatric trials for which a negative ethics committee opinion was issued. Since without the ethics committee opinion a trial may not proceed, these are labelled as not authorised.
Temporarily Halted	Trial has been temporarily interrupted. Potential reasons for such an interruption are very varied ranging from an interruption in supply of an IMP, a need to wait for substantial amendment to a protocol or quality issue.
Restarted	Temporarily Halted or Suspended trial that has been re-started.

Status	Definition
Prematurely Ended	Trial has ended without completing all events described in the protocol. This can be for many reasons including these related to safety, or efficacy or lack of feasibility of trial.
Completed	Trial has been completed in accordance with full requirements of the protocol.
Prohibited by National Competent Authority	National Competent Authority has prohibited the trial conduct reasons may be related to safety and efficacy of product or to non-compliance by some of those involved.
Suspended by National Competent Authority	National Competent Authority has suspended the trial conduct reasons may be related to safety and efficacy of product or to non-compliance by some of those involved. A suspended trial could be re-started.

8. Feedback

If you have any feedback, corrections or comments on this document, please contact:

euctr@ema.europa.eu and request that your feedback is passed onto the development team.