



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EU Clinical Trials Register – FAQs

Questions and answers relating to practical and technical aspects of the EU Clinical Trials Register

IMPORTANT: Refer to the [How to Search EU Clinical Trials Register guide](#) (under 'About here for more information' on the EU CTR Search page) for detailed guidance on using the search functionality.



Q.1. What is the EU Clinical Trials Register?

A. The EU Clinical Trials Register is part of EudraPharm. EudraPharm is the community database of authorised medicinal products. The website provides public access to information extracted from the EU clinical trials database, [EudraCT](#).

The EU Clinical Trials Register contains information on clinical trials with investigator sites in the EEA. Clinical trials where the investigator sites are outside the EEA are only included if they are marketing authorisation holder-sponsored and involve the use in the paediatric population of a medicinal product covered by an EU marketing authorisation (Article 46 of Regulation (EC) No 1901/2006), or if they form part of an agreed PIP (Paediatric Investigation Plan). The register offers users the ability to search for information on any paediatric clinical trial, and any Phase II-IV adult clinical trial recorded in EudraCT.

In addition to the above trials, the register also provides summary information about any paediatric trials 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). These trials are presented in a dedicated tab in the user interface.

Q.2. Why has the EU Clinical Trials Register been launched?

A. The EU Clinical Trials Register website provides the public with information held in the EU clinical trials database, EudraCT. EudraCT is used by national competent authorities to support supervision of clinical trials and was established as a confidential database, in accordance with article 11 of Directive 2001/20/EC. EU pharmaceutical legislation requires the European Medicines Agency (EMA), which maintains the EudraCT database on behalf of EU member states to provide information held in EudraCT to the public. This is described in article 57 of Regulation (EC) No 726/2004 and article 41 of the Paediatric Regulation (EC) No 1901/2006. Together, they established that data on clinical trials conducted in adults and in paediatric populations be made public. The EU Clinical Trials Register website puts these requirements into practice.

Q.3. What information can I find in the EU Clinical Trials Register?

A. The EU Clinical Trials Register website has:

- The description of **any phase II-IV adult clinical trial** where the investigator sites are in the European Union or the European Economic Area.
- The description of **any paediatric clinical trial** with investigator sites **in the European Union**.
- The description of **any paediatric clinical trial** that is **marketing authorisation holder-sponsored** and involves the use in the paediatric population of a medicinal product covered by an **EU marketing authorisation (Article 46 of Regulation (EC) No 1901/2006)**, including those where the investigator sites are **outside the European Union**.

- The description of **any trials which form part of an agreed paediatric investigation plan (PIP)** including those where the investigator sites are **outside the European Union**.
- Summaries of **results** of the clinical trials mentioned above (if results have been posted by the sponsor or marketing authorisation holder).
- Summaries of **results** (with a reduced set of data fields) of **paediatric trials** 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) [These trials are presented in a dedicated tab in the user interface.]

The EU Clinical Trials Register website **does not**:

- Provide information on **non-interventional clinical trials** of medicines (observational studies on authorised medicines).
- Provide access to the **authorisation document** from the national medicine regulatory authority or the **opinion document** from the relevant ethics committee.
- Provide information on clinical trials for **surgical procedures, medical devices or psychotherapeutic procedures**.
- Manage **the process for joining** any clinical trial published on the website.
- Provide navigation and web content in languages other than **English**.

* Information on non-interventional post authorisation safety studies can be found on the electronic ENCePP register of studies which provides a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.

<http://www.encepp.eu/encepp/studiesDatabase.jsp>

Q.4. What information is available?

A. Information on the design of each clinical trial, its sponsor(s), the investigational medicinal product(s) and therapeutic area(s) involved and its trial status (authorised, ongoing, complete, etc.) is available. Users can search all available data using the free text search and the advanced search filters..

- Clinical trials in the register are those which have been authorised by the national medicine regulatory authority and have a positive opinion of the ethics committee for clinical trials in the Member State where they have been run. Additionally, clinical trials including the paediatric population that have received a negative ethics committee opinion are also made public.
- Phase 1 clinical trials in adults are not being made public unless they form part of an agreed Paediatric Investigation Plan (PIP). These criteria are those established by the guidelines published by the European Commission.

Q.5. How do I find the EU Clinical Trials Register?

A. The EU Clinical Trials Register is part of EudraPharm and can be accessed from the [EudraPharm homepage](#)

The homepage of the EU Clinical Trial Register is: <http://www.clinicaltrialsregister.eu>

Q.6. Who provides the information?

A. Protocol information on any clinical trial conducted in the EU Member States is provided, in electronic format, to the national medicine regulatory authorities by the trial sponsor as part of the sponsor's application for authorisation to conduct a trial. It is entered into the database by the national competent authority which adds the authorisation, the ethics committee opinion, and later completes the end-of-trial information.

The information on third-country clinical trials is supplied by the third country data providers (i.e. Paediatric-Investigation-Plan (PIP) addressees or Article 46 data providers) who enter the information directly to the system.

Result related information is entered by sponsors, marketing authorisation holders and PIP addressees directly to the system.

Q.7 Data displayed for some clinical trials is incomplete. How will data quality improve?

A. National competent authorities and the Agency are working to develop, where possible, a more complete data set for historical trials (May 2004-March 2011) entered in the EudraCT database. Furthermore, it aims to improve the quality of the new records through enhanced automated checking, quality control and through the increased use of standardised data.

Data quality and historical information:

Information on clinical trials entered into the database between May 2004 and March 2011 is referred to as historical data. It may be incomplete or contain inconsistencies. For instance, the end date of a trial may not have been entered, so the trial may appear to have a trial status of 'Ongoing' when in fact it has been completed. Member states implemented the Directive and started using EudraCT at different times between 2004 and 2006 and the links with the ethics committees needed to be established. The validation rules applying to the data have been upgraded and the EMA is working with national competent authorities to ensure key data on the status of existing trials is complete

Q.8 Where can I get more information about a specific trial?

A. In order to obtain additional information on a particular trial of interest address your request directly to the sponsor of the trial. To contact the sponsor, please refer to the contact point in the clinical trial record. Furthermore, a [sponsor contact information list](#) is accessible [here](#) and is also provided on the [Clinical Trial Sponsors page](#) of the EU Clinical Trials Register website to facilitate communication between stakeholders.

Please note that the sponsor contact information list is not exhaustive. The Agency will add new contact information as it is provided by sponsors. Sponsors should send contact information to euctr@ema.europa.eu.

Note that the requirement to provide public contact information was only introduced in March 2011. As a consequence this information is not available for trial records uploaded prior to that date.

If you cannot find the sponsor contact details information in the clinical trial record or the list provided, look for information from your patient or professional association, your healthcare provider, or other sources.

Q.9 What if I want to join a trial?

A. If you believe that there is a trial that could be of interest to you, it is recommended that you discuss this with your healthcare professional, where possible.

To contact the sponsor for further information, please refer to the contact point in the clinical trial record or the [Clinical Trials Sponsors](#) page of the EU Clinical Trials Register.

Patients should not interpret the information provided in the register as a recommendation to use the medicine or to participate in the trial. Patients should consult their treating physician or the trial investigator to discuss appropriate treatment options.

Q.10 The clinical trial I am interested in is not listed on the EU Clinical Trials Register website? Why is that?

A. There can be different explanations for this:

- The clinical trial does not have a site in the EEA and it is not part of an agreed PIP (Paediatric Investigation Plan).
- The trial started before the implementation of the Clinical Trial Directive 2001/20/EC in 2004.
- The clinical trial is part of historical data not yet publicly available.
- The trial does not meet the rules for publication, e.g. it is a phase I clinical trial conducted in adults, or it is not a clinical trial of medicines but of a medical device, or other therapeutic procedure.

Q.11 Why do some protocol related data fields read 'Information not present in EudraCT'?

A: Possible reasons for this are:

- Historical records provide less information, due to less stringent requirements for data completion, or absence of some fields in earlier versions of EudraCT.
- The information has not been entered by the sponsor.
- Some fields may not be relevant for some clinical trial designs, or the medicines being tested.

Q.12 What is RSS?

A: RSS stands for Really Simple Syndication. RSS allows you to receive updates to content from websites which provide a web feed (called an 'RSS feed'). To do this you subscribe to the web feed. The web feed is then gathered in your browser's RSS reader for you to view at your convenience. Different browsers support web feeds in different ways; search your browser's help for information on its particular implementation.

The EU Clinical Trials Register provides customised RSS feeds for any search you might make regularly on the website.

For example, if you are interested in clinical trials concerning 'bowel cancer', you can tailor your search within the EU Clinical Trials Register search page and simply subscribe to the RSS feed for your search by clicking the RSS link:  [Subscribe to this Search](#)

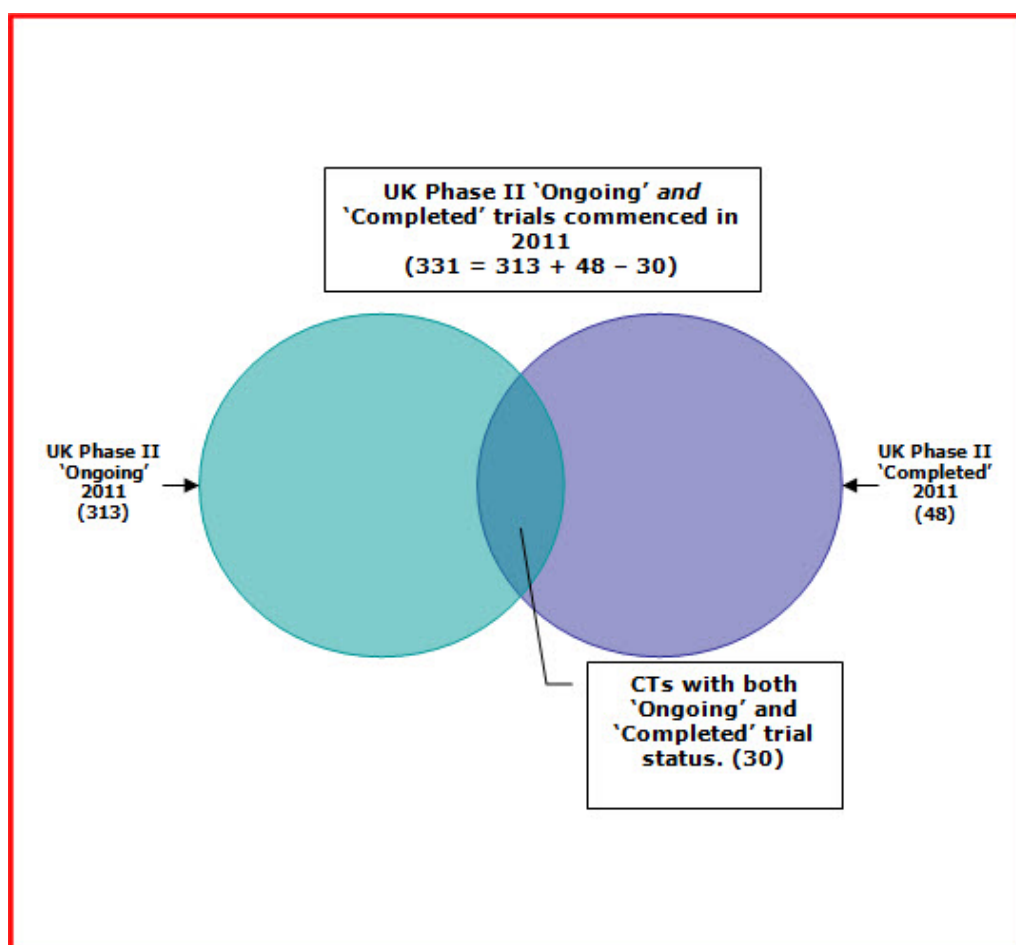
Once subscribed, you will be able to see when your search returns additional results via your RSS reader. (Note that this feature is not available in Internet Explorer 6.)

Q.13 When I select United Kingdom with the status 'Ongoing', why do the search results return clinical trials with the status for United Kingdom 'Completed'?**A:** Such a search returns a list of clinical trials for which the values 'GB' and 'Ongoing' are present. It should be noted that this does not mean that the status 'Ongoing' is necessarily associated with the country 'GB', but rather that it is associated with the clinical trial itself which may have multiple trial statuses across all participating countries.

Q.14 Why is for example the sum of returned trial records of a search for United Kingdom phase II ongoing trials commenced in 2011 and that of United Kingdom phase II completed trials commenced in 2011 not the same as the sum of returned trial records of United Kingdom phase II ongoing and completed trials commenced in 2011?

A: Both trial statuses of 'Completed' and 'Ongoing' may be present for a single clinical trial, because trials frequently take place in multiple countries. For example, a clinical trial taking place in the United Kingdom and France might, at some point in time, have a trial status of 'Completed' in France and 'Ongoing' in the United Kingdom.

Such clinical trials therefore belong to the intersection between the two sets of search results, since they fulfil search criteria (i.e. **UK Phase II ongoing trials commenced in 2011** and **UK Phase II completed trials commenced in 2011**) as the following Venn diagram illustrates:



Simply adding up the numbers of set 1 (UK Phase II 'Ongoing' 2011 (313)) and set 2 (UK Phase II 'Completed' 2011 (48)) would result in double counting 30 clinical trials in the intersection, so these must be subtracted to reach an accurate total.

Q.15 What should I do if my question is not answered here?

A: If your question regarding the EU Clinical Trials Register is not answered here, or in the [How to Search EU Clinical Trials Register guide](#), please send your question to euctr@ema.europa.eu.