Frequently Asked Questions

EU Clinical Trials Register

URL: https://www.clinicaltrialsregister.eu/

What is the EU Clinical Trials Register? What does it do?

The EU Clinical Trials Register website is part of EudraPharm. EudraPharm is the Community database of authorised medicinal products and with the launch of the new website will also provide information on clinical trials of medicinal products with or without a marketing authorisation. The website provides public access to information extracted from the EU clinical trial database EudraCT. It provides the public with information on clinical trials which have been authorised in the EEA and also those which are part of a PIP (Paediatric Investigation Plan). It gives users the ability to search for information on any paediatric clinical trial and any Phase II-IV adult clinical trial recorded in EudraCT. The paediatric clinical trials included are those with investigator sites in the EEA and also those which form part of a PIP where the investigator sites are all outside the EEA. The adult trials are those with investigator sites in the EEA or listed in PIP

Why has https://www.clinicaltrialsregister.eu/ been launched?

The EU Clinical Trials Register website provides the public with information held in the EU clinical trial database, EudraCT. EudraCT is used by national medicine regulatory authorities to support supervision of clinical trials and was established as a confidential database, in accordance with article 11 of Directive 2011/20/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 724/2006 and article 41 of the Paediatric Regulation (EC) No 1901/2006. Together, they establish that data on clinical trials conducted in adults and in paediatric populations should be made public. The EU Clinical Trials Register website puts these requirements into practice.

Why was the EU Clinical Trials Register website launched later than expected?

When the EU clinical trial database, EudraCT was set up on 1 May 2004, the legal framework established it as a confidential database. This confidentiality was partially lifted by Regulation (EC) No 726/2004 and Regulation (EC) No 1901/2006. Both regulations needed to have implementing guidance prepared and published and these were published by the European Commission in July 2008 and February 2009. Originally the website was scheduled to be released at the end of 2009, but the challenges of converting the database to its current structure to support this and future developments, and additional difficulties

encountered in data migration and testing of the software meant that the release was delayed until March 2011.

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

The EU Clinical Trials Register website **contains:**

- the description of **a phase II-IV adult clinical trial** where the investigator sites are in European Union member states and the European Economic Area;
- the description of **any paediatric clinical trial** with investigator sites in the European Union and any trials which form part of a paediatric investigation plan (PIP) including those where the investigator sites are outside the European Union.

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

- provide information on the **results** of clinical trials;
- provide information on **non-interventional clinical trials** of medicines (observational studies on authorised medicines);*
- for the period May 2004-March 2011 provide information on clinical trials where investigator sites are all outside of the European Union and the European Economic Area**.** (However, information on clinical trials which are part of an agreed paediatric investigation plan (PIP) and were conducted outside the European Union and the European Economic Area will be published retroactively on the website by March 2012.);
- 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

What information is available <u>now</u>?

At the moment information on the design of each clinical trial, its sponsor, the investigational medicinal products and therapeutic areas involved and its status (authorised, ongoing, complete) is being made available. Users will be able to search all data available using free text search and filters for member state, age group and gender of trial subjects and phase of trial.

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. In addition, clinical trials including the paediatric population that have received a negative ethics committee opinion are also being made public. Phase I 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.

From the point at which the first clinical trial goes live on the website all future clinical trials recorded in EudraCT that meet these criteria will be made public. In addition the EudraCT database contains clinical trials eligible for publication that have been recorded since EudraCT was established in May 2004, so-called historical data. The Clinical trials already entered in EudraCT that meet the publication criteria are being made public from 22 March 2011.

The EMA is working to improve the functionality of the search tools to refine their ability to find trials relating to particular therapeutic areas, diseases, medicinal products and other criteria users will find helpful. In this respect the Agency's development team maintains close interactions with stakeholders including representatives of patients and consumer groups, healthcare providers, clinical trial sponsors and the national competent authorities of the EU.

How do I find the EU-CTR?

The EU CTR is part of EudraPharm and can be accessed from the EudraPharm homepage:

http://eudrapharm.eu/eudrapharm/selectLanguage.do?NOCOOKIE=NOCOOKIE&NEW_SESSION=true

Who provides the information?

The information on clinical trials conducted in the EU Member States is provided, in electronic format, to the national medicine regulatory authorities by the trial sponsors as part of the sponsor's application for authorisation to conduct a trial. It is entered into the database by the national medicine regulatory authority which adds the authorisation and the ethics committee opinion, and later completes the end-of-trial information. The information on third-country clinical trials is supplied by Paediatric-Investigation-Plan (PIP) addressees who post the information directly onto the system via the EMA.

What are the plans for the future?

Plans for the future include the publication of summaries of results. This will be possible with the launch of EudraCT V 9.0. These summaries are not yet included in EudraCT, so cannot yet be made public. This feature is planned for late 2012 and its structure will be based on a Guideline to be published by the European Commission (EC). The draft version of that guideline was published for consultation from May to September 2010. See the guideline: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003642.pdf

The Agency is closely working with the National Institute of Health (US) which manages the http://clinicaltrials.gov/ registry, and with HL7's CTRR (Health Level 7 - Clinical Trial Registration and Results) project on the harmonisation of the data sets that should be submitted by the sponsor to clinical trial registers. The Agency is also working with the WHO in the context of the International Clinical Trials Registry Platform (ICTRP) http://www.who.int/ictrp/en/.

Data displayed for some clinical trials are incomplete. What will be done to improve data quality?

National medicine regulatory authorities and the Agency are working to develop, where possible, a more complete data set for historical trials (May 2004-March 2011 data entered in the EudraCT database). They are also working to improve the quality of the new records through enhanced automated checking and quality control from the launch of EudraCT V 8.0 onwards and through the increased use of standardised data. Now that the EU Clinical Trials Register website has been launched these issues are the key priority.

The keys to data quality are:

- the completion of all relevant fields
- the entry of data in a timely manner
- the use of controlled term lists rather than free text, wherever possible.

With the launch of version 8.0 of EudraCT in March 2011 a much more comprehensive set of validation rules are being put in place. These will ensure greater data completeness and consistency.

The active substance in medicinal products should be consistently coded from controlled term lists following further improvements later this year. In addition there will be further developments in 2012 that will ensure that medicinal products are all coded using new international standards.

The national medicine regulatory authorities and the Agency are working to ensure timely entry of information. This will apply to the loading of the initial data supplied by the sponsor, followed by the entry by national medicine regulatory authorities of their authorisation, the ethics committee opinion and later the end of trial information. In particular the availability of the new data warehouse starting with the new release of EudraCT that has just taken place enables the authorities to produce regular reports on data completeness and to ensure any gaps are promptly filled. In addition links are being established so that those national medicine regulatory authorities that also operate their own databases can load data directly from those systems.

Data quality and historical information:

Information on clinical trials entered into the database between 1 May 2004 and the release of the latest version of EudraCT (Version 8.0) is what is referred to here 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 be 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 have needed to be established. The validation rules applying to the data have been considerably upgraded and the Agency is working with national medicine regulatory authorities to ensure key data on the status of existing trials is completed.

Where do I get more information for a specific trial?

In order to obtain additional information on a particular trial of interest users should address their request directly to the sponsor of the trial. A sponsor contact list is provided in a link from the home page of the EU CTR to facilitate communication within the public and stakeholders. Please note that not all sponsors have yet been listed there. The Agency will add contact information for every sponsor providing that information, which should be sent to euctr@ema.europa.eu .

The requirement to provide public contact information is a new feature of EudraCT version 8.0 and was not previously requested. As a consequence this information is not available for the historical clinical trials as it was not to be provided by the sponsor in the past. Changes have been implemented in the new version of EudraCT so this information will be available for all the new clinical trials. If you can not find the sponsor contact details information in the clinical trial record or the list provided, you will need to look for information on the internet, from your patient or professional association, your healthcare provider or other sources.

What do I have to do if I want to join a trial?

If you believe that there is a trial that could be of your interest, 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 list of contact person per sponsor provided in the Register landing page. 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.

The clinical trial I am interested in is not in the EU Clinical Trials Register website? Why is that?

There can be different explanations for this including (the most likely):

- the clinical trial does not have a site in the EEA and it is not part of a Paediatric Investigation Plan (PIP);

- the trial has 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 correspond to the clinical trials being made public 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.

Why do some fields in the detailed clinical trial application view have 'Information not present in EudraCT'?

A: Potential reasons for this are:

- It is a new field for which data is only being collected from 10 March 2011 onwards – older trial records do not have this information.
- Historical records that have 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.