EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

EU Clinical Trials Register

www.clinicaltrialsregister.eu

An agency of the European Union

The EU Clinical Trials Register provides public access to information from the European Union (EU) clinical trial database (EudraCT).

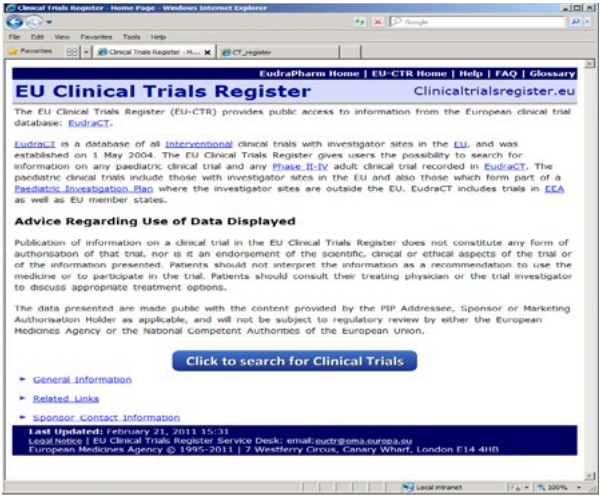
It forms part of EudraPharm, the EU database of authorised medicinal products.

The EU Clinical Trials Register gives users the possibility to search for information on any paediatric clinical trial, any Phase II-IV adult clinical trial recorded in EudraCT, and any trial listed in a paediatric investigation plan.

The paediatric clinical trials include those with investigator sites in the EU and also those which form part of a paediatric investigation plan where the investigator sites are outside the EU.

EudraCT includes trials in EEA as well as EU Member States.

EU Clinical Trials Register website



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What the EU Clinical Trials Register contains

The EU Clinical Trials Register website provides access to information on interventional clinical trials on medicines. The information available dates from 1 May 2004, when national medicine regulatory authorities began populating EudraCT, the application that is used by national medicines regulatory authorities to enter clinical trial data.

The website, launched on 22 March 2011, enables users to search for information that has been included in the EudraCT database.

Users are able to view:

- description of phase II-IV adult clinical trials where the investigator sites are in EU Member States or the European Economic Area (EEA);

- description of paediatric clinical trials with investigator sites in the EU and trials which form part of a paediatric investigation plan (PIP), including those where the investigator sites are outside the EU.

The EU Clinical Trials Register website does not:

- provide information on the results of clinical trials (this will come later);
- provide information on non-interventional clinical trials of medicines (observational studies on authorised medicines);
- provide information on clinical trials for surgical procedures, medical devices or psychotherapeutic procedures.

Clinical trial description

Details in the clinical trial description include:

- the design of the trial;
- the sponsor;
- the investigational medicine (trade name or active substance identification);
- the therapeutic areas;
- the status (authorised, ongoing, complete).

Data sources

Information that appears on the EU Clinical Trials Register website is originally provided by the company or organisation responsible for the clinical trial, and is a component of its application to a national medicine regulatory authority for authorisation to conduct a trial.

The information from the company or organisation is loaded into the EudraCT database by the national medicine regulatory authority. The authority adds to this information the authorisation of the clinical trial and the opinion from the relevant ethics committee. The information on clinical trials that are part of a PIP and are conducted outside of the EU or the EEA is supplied by the company or organisation responsible for the PIP.

Advice regarding use of data displayed

Publication of information on a clinical trial in the EU Clinical Trials Register does not constitute any form of authorisation of that trial, nor is it an endorsement of the scientific, clinical or ethical aspects of the trial or of the information presented. Patients should not interpret the information 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.

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