EMA
EUROPEAN MEDICINES AGENCY

International Clinical Trials Registers & CTIS

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What are clinical trials registries?

A clinical trials registry is an official, **publicly accessible database** that records the **design, methods, and results of health-related research** involving human participants.

Registries **enhance** transparency, **prevent** selective reporting of results, **support** research, and allow patients or providers to **find** ongoing trials

Various Clinical Trials Registries exist globally

Not exhaustive

Primary registries in the WHO registry network include:

- Australian New Zealand Clinical Trials Registry (ANZCTR)
- Brazilian Clinical Trials Registry (ReBec)
- Chinese Clinical Trial Registry (ChiCTR)
- Clinical Research Information Service (CRiS), Republic of Korea
- Clinical Trials Information System (CTIS)
- Clinical Trials Registry - India (CTRI)
- Cuban Public Registry of Clinical Trials(RPCEC)
- EU Clinical Trials Register (EU-CTR)
- German Clinical Trials Register (DRKS)
- Iranian Registry of Clinical Trials (IRCT)
- ISRCTN
- International Traditional Medicine Clinical Trial Registry (ITMCTR)
- Japan Registry of Clinical Trials (jRCT)
- Lebanese Clinical Trials Registry (LBCTR)
- Thai Clinical Trials Registry (TCTR)
- Pan African Clinical Trial Registry (PACTR)
- Peruvian Clinical Trial Registry (REPEC)
- Sri Lanka Clinical Trials Registry (SLCTR)

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CTIS is the registry in Europe under the Clinical Trials Regulation (CTR) (Regulation - 536/2014 - EN - EUR-Lex)

Digitalisation & Improved Efficiency

Increased Transparency

Enhanced Patient Safety

Support to Innovation & Research

- Unique digital tool for **harmonised** submission, evaluation and supervision and storage of structured data and documents on clinical trials in the European Union.
- End-to-end **fully electronic process** over the life-cycle of a clinical trial.
- Member States benefit from tools for **collaboration and coordination**.
- Clinical trial sponsors can submit, manage and report on a trial in **one single place** throughout the lifecycle of this trial. CTIS allows flexibility to submit dossiers in parts.
- Easy access to structured data and documents on clinical trials for patients, healthcare professionals, **scientists** and the general public.

EU Clinical trial systems landscape

Secure Environment

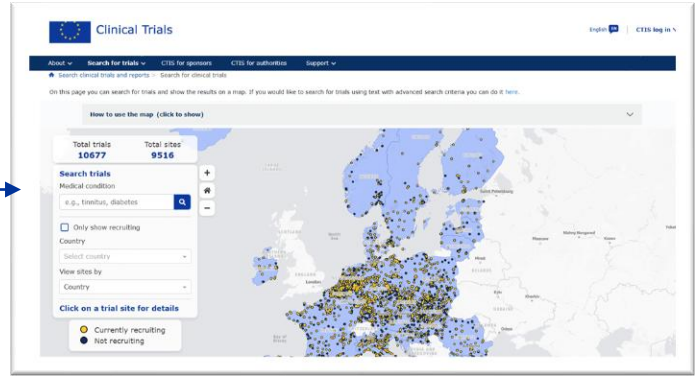
Sponsors & Academia

CTIS*

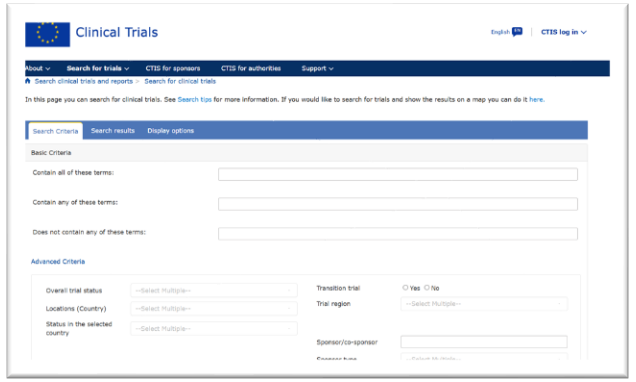
National Competent Authorities (NCAs)

CTIS Public portal

Trial Map



API / Opensource tools



Web Interface

* Clinical Trials Information System

What can you search for?
In the CTIS public portal

Information you can view on **each clinical trial includes**:

- Trial identifiers (EU clinical trial number, protocol code, title, any other ID)
- Therapeutic intent and objectives
- Endpoints and trial design
- Participants inclusion and exclusion criteria
- Trial locations, Sponsor(s) and contact information
- Start and end dates and recruitment timelines

You can also view the following trial **documents**:

- Protocol and protocol synopsis including recruitment arrangements, information sheets
- Summary of the products characteristics, when applicable
- Recruitment arrangements, Subject information and informed consent form
- Summary of Results, layperson summary and Clinical Study Report, when posted

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Thank you

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