EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The EU clinical trial portal and database

Setting the world standard for transparency in public health and pharmaceutical research and development

An agency of the European Union

The European Union (EU) clinical trial portal and database will support a coordinated approach to clinical trial authorisation and supervision via a single application form for each clinical trial. The European Medicines Agency (EMA) will manage information stored in the database, and will make it publicly available subject to transparency rules.

The clinical trial application form and supporting dossier will cover all regulatory and ethics assessments from the Member States concerned. It will also include the public registration of the clinical trial and any subsequent updates.

Key benefits

- Harmonised electronic submission and assessment process for multi-Member State clinical trials
- Improved collaboration, information-sharing and decision-making between and within Member States
- Increased transparency of information on clinical trials
- Highest standards of safety for all participants in EU clinical trials

Clinical Trial Regulation

The goal of the Clinical Trial Regulation (EU) No. 536/2014 is to create an environment that is favourable to conducting clinical trials, with the highest standards of safety for participants and increased transparency of trial information.

It harmonises the assessment and supervision processes for clinical trials throughout the EU, via an EU portal and database. This increases the efficiency of all trials in Europe with the greatest benefit for those conducted in multiple Member States.

It aims to foster innovation and research, while helping avoid unnecessary duplication of clinical trials or repetition of unsuccessful trials.

The authorisation and oversight of clinical trials remains the responsibility of Member States, with EMA managing the database and supervising content publication.

Introducing the EU portal and database

The portal will be the single entry point for submitting clinical trial information in the EU, which will be stored in the database. The system will contain collaboration tools, workflow and document management capabilities, accessible via:

- the sponsor workspace – for clinical trial sponsors;
- the authority workspace – for clinical trial authorities;
- the public website – for the public.

Workspace overviews

The sponsor workspace

A secure workspace will assist clinical trial sponsors in preparing and compiling data to submit to the database to be assessed by Member States.

The workspace will allow sponsors to:

- search and access clinical trials;
- compile clinical trial application dossiers for new and updated trials;
- cross-reference to product documents in other clinical trials;
- supervise their own clinical trials and check progress;
- receive alerts and notifications for ongoing trials;
- record clinical trial results;
- upload documents for clinical trial application form submission;
- respond to requests for information and view deadlines;
- manage users and user roles.

The authority workspace

A secure workspace will support the activities of Member States and the European Commission in overseeing clinical trials.

The secure workspace will allow Member States to:

- view application dossiers;
- manage tasks related to the assessment of clinical trials;
- collaborate within and between Member States;
- receive alerts and notifications for ongoing trials;
- download documents submitted by clinical trial sponsors;
- record inspections to sites and clinical trials.

Public website

Through the website, members of the public can access detailed information on all clinical trials conducted in the EU, in all official EU languages.

The website will provide the following features:

- overview of clinical trial statistics;
- advanced keyword search;
- download data and pre-defined reports;
- site updates and announcements.

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Further information

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