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Faster access to clinical trial information in Europe

18 June 2024

Revised rules for Clinical Trials Information System (CTIS) become applicable

News Human Clinical trials

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The launch of a new version of the Clinical Trials Information System (CTIS) will allow earlier and more efficient access to information about clinical trials in the European Union (EU) for patients, healthcare professionals and other stakeholders. This is due to the revised transparency rules that become applicable today in Europe.

One of the key changes is earlier availability of information on authorised clinical trials. Importantly, the new rules eliminate the previously available deferral mechanism, which allowed clinical trial sponsors to delay publishing certain data and documents for up to seven years after a trial's completion to protect commercially confidential information. Under the new rules, approximately 4,000 clinical trials with issued decisions are now publicly accessible through the CTIS search. The CTIS portal will add approximately 500 newly authorised clinical trials per month. This includes ongoing trials that have been transitioned to CTIS from the Clinical Trials Directive. Over the next few months, additional features will be added to the CTIS public portal to further enhance overall usability.

The updated rules strike a balance between transparency of information and protection of commercially confidential information. They benefit patients, because key clinical trial information, that patients flagged as being most relevant for them, is published early. They also benefit clinical trial sponsors because they introduce process simplifications. Finally, they benefit healthcare professionals because the resulting system is more user-friendly, facilitating access to information on clinical trials and enrolment in clinical trials, and also increasing awareness of possible treatment options.

Several resources have been created to help sponsors understand the revised transparency rules, including a user guide and an overview of which data and documents with key information will be published. Dedicated support activities are also being organised, starting with an event on 20 June open to all sponsors of clinical trials including pharmaceutical companies, contract research organisations, small and medium-sized enterprises and academic organisations.

The revised transparency rules were adopted by EMA's

Management Board in October 2023 following a public consultation held between May and June 2023.

About CTIS

CTIS is the single-entry point for the submission and assessment of applications for clinical trials in the EU for sponsors and regulators. The system includes a public searchable database for healthcare professionals, patients and the general public to deliver the high level of transparency foreseen by the regulation. The authorisation and oversight of clinical trials is the responsibility of EU/EEA Member States while EMA is responsible for maintaining the CTIS. The European Commission oversees the implementation of the Clinical Trials Regulation.

Related documents

Revised CTIS Transparency Rules

Reference Number: EMA/263067/2023

English (EN) (377.41 KB - PDF)

First published: 06/10/2023

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