EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trials Information System reaches major milestone towards go-live and application of the Clinical Trial Regulation

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EMA's Management Board confirmed that the clinical trial EU Portal and Database, one of the main deliverables of the Clinical Trial Regulation and the key component of the Clinical Trial Information System (CTIS), is now fully functional and on track to go live by 31 January 2022. The Board confirmed that it has verified that the system meets the agreed requirements during an extraordinary meeting held on 21 April following an independent audit of this new IT system.

"The findings from the audit have reassured the Management Board that the EU Portal and Database now meet the functional specifications drawn up by EMA in collaboration with the European Commission and the Member States. We are all prepared to start working with the system," said Christa Wirthumer-Hoche, chair of EMA's Management Board. "The implementation of the Clinical Trial Regulation and CTIS will increase efficiency in the registration, conduct and supervision of clinical trials in the EU, particularly those taking place in multiple Member States, while ensuring utmost transparency for the public. This is one of the most complex and ambitious IT developments carried out by EMA and we look forward to its go-live in early 2022."

"The EU is an attractive location for investment in clinical research and this development will further enhance its value as a large and dynamic clinical research area, enabling authorities and researchers to cooperate more effectively across Member States," added Xavier De Cuyper, Director of the Belgian medicines agency, speaking for the Heads of Medicines Agencies clinical trial network. "It also means we can further enhance the benefits for our citizens of new medicines, and better use of existing medicines, and provide them with access to increased public information on clinical trials as they are ongoing and their results when the trials are completed."

As a next step, the Board will inform the European Commission of this outcome. Once satisfied that the conditions set by the Clinical Trial Regulation have been met, the

European Commission will publish a notice in the Official Journal of the European Union and six months after this publication, the Clinical Trial Regulation will start to apply and CTIS will go live. It is the desire of the Board, EMA and European Commission that the system goes live on 31 January 2022, which would imply that the Commission notice in the Official Journal would be published on 31 July 2021.

This Clinical Trial Regulation aims to harmonise the registration and supervision processes for clinical trials throughout the EU. CTIS will streamline these processes, ensuring the EU remains an attractive location for investment into clinical research.

When it goes live, CTIS will be the single EU entry point for clinical trial applications. Clinical trial sponsors will be able to apply for a clinical trial in all countries of the European Economic Area (EEA) with one application instead of having to apply separately in every country. This single application will include the submission to national competent authorities and to the ethics committees for all involved countries.

CTIS will facilitate recruitment of trial participants by allowing sponsors and researchers to easily expand trials to other EEA countries, and will allow sponsors, researchers and national competent authorities to collaborate across borders for better results and knowledge-sharing.

The system will contain a public website with detailed information on and outcomes of all clinical trials conducted in the EU throughout their lifecycle, thus improving transparency and access to information for patients, healthcare workers and other interested parties.

The authorisation and oversight of clinical trials is the responsibility of Member States, however EMA manages CTIS. To prepare for the go-live of CTIS, training programmes for user groups have been initiated or are planned and extensive training materials have been made available on the EMA website. Commission guidance documents related to the implementation of the Clinical Trial Regulation can be found in EudraLex volume 10 .

Related content

- Extraordinary Management Board meeting on CTIS audit (21/04/2021)
- Clinical Trial Regulation
- Clinical Trials Information System (CTIS): training programme
- Management Board
- Heads of Medicines Agencies

External links

- European Commission: EudraLex - Volume 10 - Clinical trials guidelines

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