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Media and Public Relations

Six-month countdown to go-live for the Clinical Trials Information System (CTIS)

The European Commission has confirmed that the entry into application of the Clinical Trials Regulation and hence the go-live date for the Clinical Trials Information System (CTIS) will be on 31 January 2022.

As set out in the Clinical Trials Regulation, the entry into application of that Regulation is set by the publication of a notice in the Official Journal of the European Union [link], which confirms that the clinical trial EU Portal and Database, one of the main deliverables of the Regulation and the key component of CTIS, has reached full functionality. The application of the Regulation and the go-live of CTIS take place six months after the publication of this notice.

The Clinical Trials Regulation aims to harmonise the submission, assessment and supervision processes for clinical trials throughout the EU. CTIS will allow the streamlining of these processes, ensuring the EU remains an attractive region for clinical research.

CTIS will become the single entry point for clinical trial application submission, authorisation and supervision in the EU, and in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. Currently, sponsors must submit clinical trial applications separately to national competent authorities and ethics committees in each country to gain regulatory approval to run a clinical trial. With CTIS, sponsors can apply for clinical trial authorisation in up to 30 EEA countries with a single application. The Clinical Trials Information System will also, together with other EMA IT tools, support the coordinated assessment of safety reporting in the context of clinical trials and therefore contribute to the understanding of the benefits and the risks of medicinal products that are planned to enter or are already on the market of the Union.

The system will facilitate recruitment of trial participants by allowing sponsors and researchers to easily expand trials to other EEA countries, and will support collaboration 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, thus improving transparency and access to information for patients, healthcare workers and other interested parties.

Three-year transition period

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The Clinical Trials Regulation foresees a three-year transition period. Member States will work in CTIS immediately after the system has gone live. For one year, until 31 January 2023, applicants can still choose whether to submit their application to start a clinical trial according to the current system (Clinical Trials Directive) or according to the Clinical Trials Regulation. From 31 January 2023 onward, submission according to the Clinical Trials Regulation becomes mandatory and by 31 January 2025, all ongoing trials approved under the current Clinical Trials Directive will need to transition to the new Regulation and to CTIS.

While the authorisation and oversight of clinical trials is the responsibility of Member States, EMA will maintain the system. EMA has created an extensive training programme to help clinical trial sponsors, national competent authorities and ethics committees prepare for using CTIS.

The training catalogue consists of several modules, covering the full lifecycle of clinical trial submission, authorisation and supervision. Modules are available for use on the CTIS training programme webpage on the EMA website. The CTIS training programme webpage is progressively updated as more training materials become available. EMA has also published a sponsor handbook to provide clinical trial sponsors with the information they need to get ready for, and use, CTIS.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information about the Clinical Trials Regulation (Regulation (EU) No 536/2014) and CTIS is available here.
3. European Commission guidance documents related to the implementation of the Clinical Trials Regulation can be found here.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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