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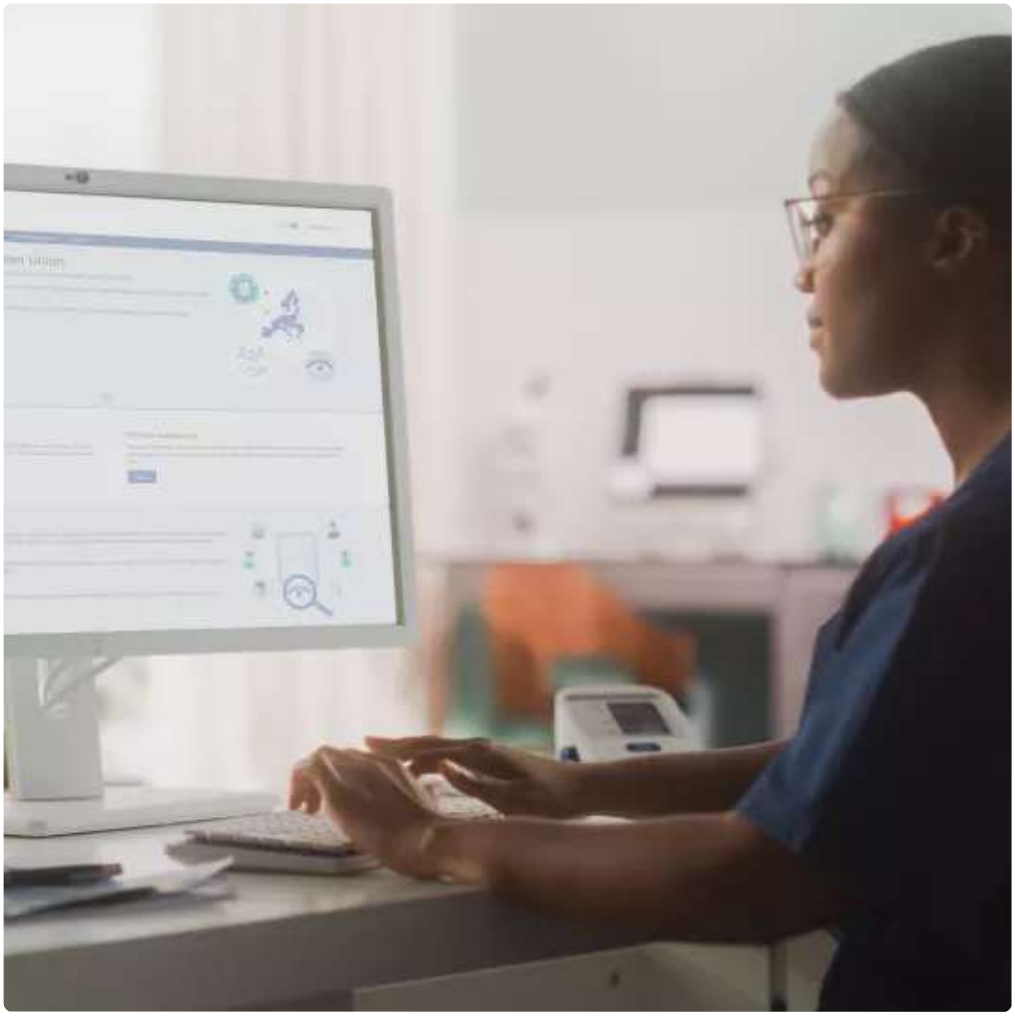

Clinical Trials Regulation becomes fully applicable

31 January 2025

Clinical Trials Information System now supports submission, assessment and oversight of all trials in the EU

News Human Clinical trials

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From today, all clinical trials in the European Union (EU), including ongoing trials that were approved under the previous legal framework, the Clinical Trials Directive (CTD), are governed by the Clinical Trials Regulation (CTR). This marks the end of a three-year transition period, during which more than 5,000 clinical trials were transitioned to the CTR through submission to the Clinical Trials Information System (CTIS), the single-entry point for sponsors and regulators for the submission and assessment of applications for clinical trials in the EU.

Remaining trials that are ongoing after 30 January and that were not moved to the new system may be subject to corrective measures applied by EU Member States. Transition procedures are no longer available and sponsors of ongoing CTD trials are required to submit a new application via CTIS.

CTIS 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. Throughout 2025, the performance and the user experience of CTIS will continue to be improved.

The full implementation of the CTR strengthens Europe as an attractive location for clinical research. The regulation streamlines the processes for the application and supervision of clinical trials, and their public registration: all clinical trial sponsors use the same system and follow the same procedures to apply for the authorisation of a clinical trial, no matter where they are located and which national competent authority (NCA) or national ethics committee they are dealing with.

Activities related to the CTR are supported by the

Accelerating Clinical Trials in the EU (ACT EU) initiative, a collaboration between the Heads of Medicines Agencies (HMA) in the Member States, the European Commission and EMA, which seeks to transform how clinical trials are initiated, designed and run. ACT EU features focus areas that are the basis for the ACT EU multi-annual workplan 2025-2026.

Related content

Clinical Trials Regulation

Clinical Trials Information System

Clinical Trials Information System (CTIS): training and support

Clinical Trials Information System (CTIS): online training modules

Accelerating Clinical Trials in the EU (ACT EU)

Clinical trials in human medicines

External links

Clinical Trials Regulation (Regulation (EU) No 536/2014)

Guidance for the transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation

CTIS public searchable database

European Commission - Accelerating Clinical Trials in the EU (Act EU)

ACT EU workplan 2025-2026

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