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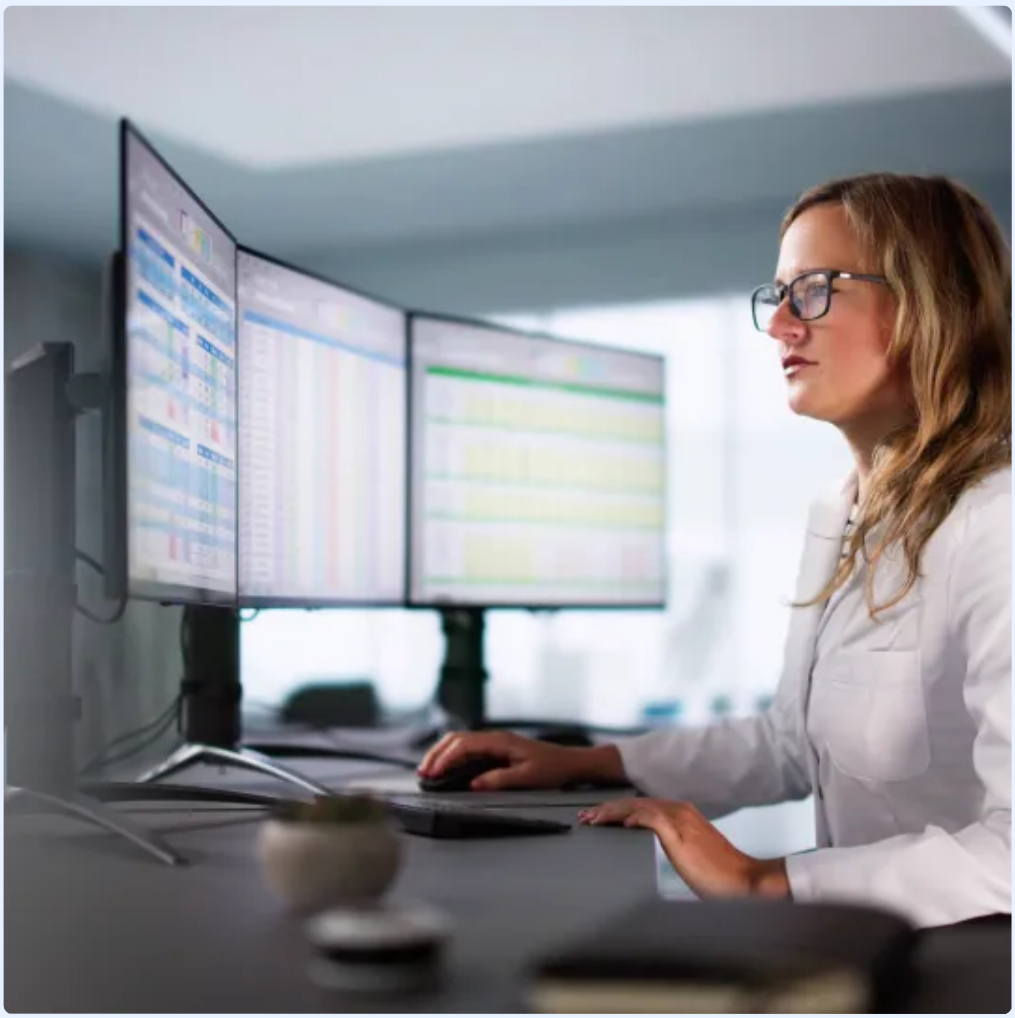

New targets for clinical trials in Europe

23 September 2025

500 authorised multinational clinical trials to be added over five years

News Human Clinical trials

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The European Commission (EC), the Heads of Medicines Agencies (HMA) and EMA have jointly developed two new targets for clinical trials, to monitor progress against the ambition to make the European Union (EU) a more attractive destination for clinical research and improve timely access to innovative medicines for patients. In five years, the aim is that:

- An additional 500 multinational clinical trials are added to the current average of 900 that are already authorised each year (i.e. an estimated 100 per year).
- Two thirds (66%) of clinical trials should begin recruiting patients within 200 calendar days or less from the date of application submission. This is in comparison to only 50% of clinical trials today.

These ambitious goals build on ongoing efforts to create a more supportive environment for clinical research. A key part of this is the Accelerating Clinical Trials in the EU (ACT EU) initiative, a collaboration between EC, HMA and EMA, which seeks to optimise how clinical trials are designed and run.

ACT EU focuses on several key areas to strengthen clinical research in Europe. These include a trial map to help patients find clinical trials recruiting in their area; pilots of advice to clinical trial sponsors to help them design impactful trials and make successful applications for authorisation, including for marketing authorisation applications; support to the implementation of the revised Good Clinical Practice guideline (ICH E6 R3); and, help for non-commercial sponsors to carry out more multinational trials. At the heart of ACT EU is a multi-stakeholder platform that fosters ongoing dialogue with stakeholders to better understand their challenges and needs.

Several complementary network initiatives are also contributing to the achievement of the new targets:

- The Clinical Trials Regulation (CTR) Collaborate initiative aims to foster interaction between national authorities and ethics committees to promote harmonised procedures and

reduce administrative burden.

- The COMBINE programme addresses the intersection of three separate legal frameworks governing clinical trials of medicinal products, clinical investigations of medical devices, and performance studies of in-vitro diagnostics. A first pilot (see EC news) to synchronise clinical and performance study assessments into a single streamlined process has been launched.
- MedEthicsEU, a forum of national representatives from medical research ethics committees, established by the EC, to support discussion and mutual learning between EU/EEA Member States Ethics Committees.

Progress updates on the Clinical Trial targets will be published monthly on the ACT EU website, starting in early February 2026.

EU clinical trials report – analysis of three years of data

Together with the new targets, the European medicines regulatory network has published a report analysing clinical trial data from 31 January 2022 to 30 January 2025. This period marks the three-year transition of the Clinical Trials Regulation (CTR). The report shows that since the use of the Clinical Trials Information System (CTIS) became mandatory, an average of 200 new clinicals trials were submitted every month. Of these, around 80 applications per month were for multinational clinical trials.

The figures included in the report reflect a transitional period during which sponsors and stakeholders were adapting to the new legal and procedural requirements introduced under the clinical trial framework. The CTR and CTIS are now fully implemented, laying the foundations for a more integrated and responsive clinical trial ecosystem in the EU, with greater transparency, efficiency and collaboration to boost clinical research. The full report is available on the ACT EU website.

Notes

1. On 24 September, EMA will host a LinkedIn live session LinkedIn live session to discuss the new targets for clinical

research. Speakers include Marianne Lunzer, Clinical Trials Assessor at the Austrian Agency for Health and Food Safety, Corinna Hartung, Policy Officer at the European Commission and Ana Zanoletty, Head of the Clinical Trials Transformation workstream. Participants can submit questions in advance or during the event.

Related content

Clinical Trials Information System

External content

Accelerating Clinical Trials in the EU (ACT EU)

ACT EU workplan

Clinical trials - Trial map

Good Clinical Practice guideline (ICH E6 R3)

ACT EU: Support for non-commercial sponsors

ACT EU: Multi-stakeholder platform

ACT EU: Mapping & governance

European Commission: The COMBINE programme

European Commission: MedEthicsEU

EU clinical trials report: EU clinical trials during the 3-year CTR transition period

Related EU legislation

Clinical Trials Regulation

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