

Recent Industrial Developments

CDSCO introduced important regulatory updates in 2024 and 2025 to strengthen the clinical trial system. Key changes include:

- **CRO Registration:**

- The Gazette of India notification by Central Drugs Standard Control Organization (CDSCO) on 19th September 2024 mandates that all Clinical Research Organizations (CROs) operating in India must register online through the SUGAM portal starting from April 1, 2025
- This registration ensures that CROs meet specific criteria, including having qualified staff, adequate facilities and documented standard operating procedures (SOPs)
- The move aims to enhance the regulation, quality and transparency of clinical research activities in India, supporting patient safety and data integrity in line with the country's growing role in global clinical trials

Click here to refer to the gazette notification: [Gazette Notifications](#)

- **Submission of Clinical Trial Site Addition and change of Principal Investigator applications:** CDSCO announced submission of clinical trial site addition and change of Principal Investigator applications for global clinical trials, clinical trials of new drugs, subsequent new drugs, investigational new drugs, fixed dose combinations and bioavailability & bioequivalence studies via SUGAM portal through notice dated 26th December 2024

For more information click here: [Public Notices](#)

Recent Industrial Developments

FDA released important guidance updates for clinical trials in late 2024, aimed at modernizing trial design, using new technologies and boosting efficiency. Key updates are as follows:

- **Decentralized Clinical Trials:** The FDA's final guidance document provides recommendation on implementing decentralized trials to promote flexibility and access, clarify sponsor and investigator roles and enable virtual visits, local healthcare provider support and remote monitoring
Click here: [Conducting Clinical Trials With Decentralized Elements | FDA](#)
- **Use of electronic systems and technologies:** To support the growing use of digital tools in trials, the FDA finalized guidance on electronic records and signatures
Click here: [Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers | FDA](#)
- **Protocol Deviations:** The FDA issued draft guidance document to help sponsors, investigators and IRBs consistently define, identify and report protocol deviations, supporting data integrity and participant safety
Click here: [Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices | FDA](#)
- **Diversity Action Plans:** In June 2024, the FDA released updated draft guidance titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." This guidance outlines how sponsors should plan and report efforts to ensure clinical trials reflect the diversity of the populations likely to use the medical products
Click here: [Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies | FDA](#)

Recent Industrial Developments

In the year 2025, the EMA issued noteworthy guidance updates aimed at enhancing the conduct and oversight of clinical trials. Key updates include:

- **Clinical Trial Regulation:** As of 31st January 2025, all clinical trials in the EU now follow the Clinical Trials Regulation (CTR), replacing the old Clinical Trials Directive
Click here: [Clinical Trials Regulation | European Medicines Agency \(EMA\)](#)
- **Clinical Trials Information System:** On 31st January 2025, EMA announced that Clinical Trials Information System now supports submission, assessment and oversight of all trials in the EU
Click here: [Clinical Trials Regulation becomes fully applicable | European Medicines Agency \(EMA\)](#)
- **ICH-GCP E6(R3) Guidelines:** The ICH E6(R3) Good Clinical Practice guidelines were officially adopted by the International Council for Harmonisation (ICH) on 6 January 2025. **The European Medicines Agency (EMA) began applying them from 23 July 2025.** These guidelines provide a single uniform standard to facilitate the mutual acceptance of clinical trial data for ICH member countries and regions by the relevant regulatory authorities
Click here: [ICH E6 \(R3\) Guideline on good clinical practice \(GCP\) Step 5](#)