



Government to Regulate Clinical Research Organisations

[Source: LM](#)

The government has established [Standard Operating Procedures \(SOPs\)](#) for clinical research organizations to ensure **the safety of clinical trials**. These updated regulations are part of the **New Drugs and Clinical Trials (Amendment) Rules, 2024**.

- Under this the government has defined roles, duties and liabilities to monitor through registration, approval of licence and renewal, validity period, inspection, and suspension of license if found non-compliant.
- The aim is to **maintain product quality, expedite clinical trials** of novel medications and vaccines, and bring in more transparency.
- These have been framed after consultation with [the Drugs and Technical Advisory Committee \(DTAB\)](#).
- **Clinical Research Organization (CRO):**
 - A CRO is an entity that can be commercial, academic, individually owned, or an organization with legal status.
 - It is appointed by the sponsor to manage specific tasks, duties, or obligations.
 - These responsibilities relate to clinical trials, bioavailability, or bioequivalence studies.
 - The delegation or transfer of responsibilities must be done in writing.
- **Drugs Technical Advisory Board:**
 - It is a statutory body constituted under the [Drugs and Cosmetics Act, 1940](#).
 - Its function is **to advise** the Central government and State government **on technical matters related to drugs and cosmetics**.

Read More: [Drugs and Clinical Trials Rules, 2019](#)

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