

## Summary

Stakeholder	Most Important Stakeholder Role/Responsibility
<b>Sponsor</b>	Funds and oversees the trial, ensuring it meets all ethical and regulatory standards
<b>Clinical Research Organisation</b>	Manages and conducts trial operations on behalf of the sponsor
<b>Ethics Committee</b>	Protects participant rights, safety and well-being by reviewing and approving the trial protocol
<b>Regulatory Authority</b>	Approves the trial and ensures it complies with laws and regulations
<b>Clinical Research Coordinator</b>	Coordinates daily trial activities and participant management at the site
<b>Clinical Research Associate</b>	Monitors trial sites to ensure compliance with the protocol and regulations
<b>Investigator</b>	Conducts the trial and ensures participant safety and accurate data collection at the site
<b>Investigator Site</b>	Provides the facilities and resources necessary to carry out the trial
<b>Trial Participant</b>	Consents voluntarily to participate in a trial and follows the trial procedures

## Reference Guidelines

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS dated 2017: [ICMR National Ethical Guidelines.pdf](#)

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019: As amended vide GSR 778(E) dated 14-10-2022, w.e.f. 14-10-2022 : [Circulars](#)

ICH HARMONISED GUIDELINE – GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3) dated 06 Jan 2025: [ICH Official web site : ICH](#)

## Recent Industrial Developments

The ICH-GCP E6 (R3) guidelines, adopted on January 6, 2025, introduce significant updates relevant to the various stakeholders involved in clinical trials. These changes are as follows:

**Sponsor:** More accountable for overall trial quality, with stronger oversight of service providers and use of risk-based management

**Clinical / Contract Research Organisation:** Recognized as service providers with delegated tasks, but sponsors retain ultimate responsibility

**Investigator:** Clearer responsibilities for participant safety, training and communication with Ethics Committees

**Clinical Research Coordinator:** Role acknowledged in supporting investigator duties and ensuring compliance

**Clinical Research Associate / Monitor:** Emphasis on risk-based, flexible monitoring using remote approach and digital tools

**Ethics Committee:** Enhanced focus on participant protection through thorough review and ongoing oversight

**Regulatory Authority:** Encouraged to support modern, flexible clinical trial designs

**Trial Participant:** Focus on safety, informed consent and patient-centric approaches to reduce burden

Overall, the guideline promotes flexibility, risk management, technological integration and clear accountability to improve trial quality and participant safety

For more information, please refer to the guidelines using below link: ICH Official web site : [ICH Official web site : ICH](#)

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

For more information, please refer to the gazette notification using below link: **Gazette Notifications**