

ICH-GCP:



ICH-GCP (International Council for Harmonisation Good Clinical Practice) emerged in 1996, is a set of international rules for doing clinical trials ethically and scientifically. It was established to make sure research is done the same way across countries with an aim of improving quality and efficiency particularly as the pharmaceutical industry became increasingly globalized

Key aspects of ICH-GCP:

Ethical Considerations	<ul style="list-style-type: none">• Clinical trials must follow ethical principles rooted in the Declaration of Helsinki• The rights, safety, and well-being of participants• Review and approval of trials by Independent Ethics Committee (IEC) or Institutional Review Board (IRB) before initiation
Risk-Benefit Analysis	<ul style="list-style-type: none">• Anticipated benefits must justify the foreseeable risks• Ongoing assessment to ensure ethical and scientific validity• Trials should be terminated or modified if risks outweigh benefits
Informed Consent	<ul style="list-style-type: none">• Freely given, documented consent• Clear, non-technical information about the trial's purpose, risks, benefits, and alternatives• Special provisions for vulnerable populations and emergency situations
Data Integrity	<ul style="list-style-type: none">• Accurate, complete, and verifiable data• Traceability, audit trails, and secure data handling• Data governance – validation, protection
Qualified Personnel	<ul style="list-style-type: none">• Qualified by education, training, and experience• Delegation of tasks with documentation• Adequate resourced and expertise

Reference Links:

Federal Food, Drug, and Cosmetic Act (FD&C Act) | FDA

<https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act>

Ethical Codes & Research Standards | HHS.gov

<https://www.hhs.gov/ohrp/international/ethical-codes-and-research-standards/index.html>

Promoting Safe and Effective Drugs for 100 Years

<https://www.fda.gov/files/Promoting-Safe-and-Effective-Drugs-for-100-Years-%28download%29.pdf>

The Belmont Report | HHS.gov

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

ICH Official web site : ICH

<https://www.ich.org/page/efficacy-guidelines>

Recent Industrial Development(s):

As the clinical research industry continues to evolve, several new regulations and guidelines have been introduced in 2024 and 2025 to improve transparency, safety, and global alignment. The table below highlights the key regulatory changes, their relevance to the industry and provides direct links to each official guideline for easy access and deeper understanding:

Guidelines/Regulations	Key Updates	Type (Global/India specific)	Link to access the document
The International Council for Harmonisation (ICH) E6(R3) guideline - January 2025,	<ul style="list-style-type: none">• Restructured Format• Additional clarity on scope• Adoption of Quality By Design (QbD)• Proportionate Risk based approach• Fit for purpose strategy• Technology and data governance• Enhanced comprehension relevant to Informed Consent Process	Global	ICH Official web site : ICH
Declaration of Helsinki - October 2024	<ul style="list-style-type: none">• Stronger focus on safeguarding vulnerable populations in clinical trials• Ensuring informed consent• Providing post-trial access to beneficial treatments	Global	WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association
The World Health	<ul style="list-style-type: none">• Emphasis on designing trials to produce	Global	Guidance for best practices for clinical trials

Organization (WHO)'s "Guidance for best practices for clinical trials" – September 2024	<p>scientifically sound answers</p> <ul style="list-style-type: none"> • Respect participant rights and well-being • Collaboration and transparency • Importance of feasibility, effective quality management, and proactive risk management 		
Conducting Clinical Trials With Decentralized Elements – September 2024	<ul style="list-style-type: none"> • What are Decentralized Clinical Trials (DCTs) • Protocol considerations • Remote visits, activities including Informed Consent • Roles and responsibilities – Sponsor and Investigator • Investigational products in DCTs • Use of Digital Health Technologies (DHTs) 	Global	Conducting Clinical Trials With Decentralized Elements FDA
New Drugs and Clinical Trials (Amendment) Rules, 2024 – effective April 1, 2025	<ul style="list-style-type: none"> • Process of mandatory registration of Clinical Research Organization (CRO) with Central Licensing Authority • Role and responsibilities of CRO 	India specific	Gazette Notifications