Good Clinical Practice for Drug Trials

China – National Medical Products Administration, National Health Commission, National Administration of Traditional Chinese Medicine, National Disease Control and Prevention Administration

Main information

Scope of Application:

Alignment with ICH E6 (R3) international standard for GCP, adopted by the ICH in January 2025 and fully implemented in China after March 31, 2026

Effective Date:

May 21st, 2026

Related Provisions:

- Drug Administration Law
- Vaccines Administration Law
- Regulations for the Implementation of the Drug Administration Law

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Key Topics

Framework

- Full **integration and interaction with ICH harmonized international rules**: the 2026 GCP revision deletes the original chapters on the trial protocol, investigator's brochure, and essential documents management. Implementation details for these items will now refer directly to the ICH E6 (R3) guideline

What's new

- **New "Data Governance" Chapter**: The 2026 revision adds a dedicated chapter on data governance, a significant expansion from the 2020 version. This chapter mandates electronic data traceability throughout the entire process and the use of audit trails
- **Introduction of "Quality by Design" and "Risk-Proportionate" Concepts:** The revision formally incorporates the advanced concepts of "quality by design" and "risk-proportionate" approaches into the general principles, requiring that quality and risk management be embedded from the trial design stage

Sensitive Factors

- **Chain of responsibility**. The sponsor is the ultimate responsible party for the overall clinical trial activities, while the principal investigator is the ultimate responsible party at the trial site. Both parties bear ultimate responsibility for their delegated tasks
- **Electronic signature**. Under specific conditions, the e-signature is now recognized

Drivers

- **Regulatory Compliance for Market Access:** The revised GCP becomes **mandatory for all clinical trials from September 1, 2026**, and the 2020 version will be simultaneously repealed. Sponsors and sites must update their standard operating procedures (SOPs), systems, and processes to comply with the new requirements
- **International Mutual Recognition**: Full alignment with the ICH E6 (R3) standard paves the way for mutual recognition of clinical trial data with other major regulatory bodies through the "one clinical trial, global submission" model, significantly reducing the cost and time required for innovative drug companies to enter international markets