

Recent Industrial Developments

The ICH-GCP E6 (R3) guidelines, adopted on January 6, 2025, has following impact on various departments of Sponsor / Clinical Research Organisation involved in clinical trials:

Regulatory Affairs: Must align submissions and communications with enhanced risk-based and quality-by-design principles

Clinical Operations: Expected to implement flexible trial designs and proactive quality planning

Central Laboratory: Needs to ensure data integrity and traceability within updated digital and governance frameworks

Clinical Data Management: Must adopt stronger data governance and validation practices, especially for digital system

Statistics: Required to support adaptive designs and ensure statistical methods align with risk-based approaches

Medical Affairs: Plays a greater role in protocol design and risk mitigation strategies to enhance participant safety

Pharmacovigilance: Must integrate safety monitoring with real-time data systems and risk-based oversight

Quality Assurance: Central to implementing quality-by-design, ensuring systems and processes prevent critical errors

These updates promote flexible design, digital systems and proactive quality across all departments.

For more information, please refer to the guidelines using below link:

ICH Official web site : [ICH](#)