ICH E6 (R3)

Raising the Bar for Quality in Clinical Trials

Quality by Design

ICH E6(R3) emphasizes embedding quality into the design phase of clinical trials. Sponsors must identify Critical to Quality (CtQ) factors early and manage risks proactively.

Risk-Based Quality Management

Sponsors are now required to implement risk-proportionate quality systems across the trial lifecycle. This includes risk identification, evaluation, control, communication, and review.

Enhanced Monitoring Strategies

Monitoring must be tailored to risk, combining on-site and centralized approaches. ICH E6(R3) supports data-driven oversight, enabling early detection of anomalies and protocol deviations.

Technology & Data Integrity

The guideline mandates validated, secure, and auditable computerized systems, to ensure compliance, transparency, and data integrity throughout the trial.

Get in touch with TRI to start simplifying your RBQM strategy today

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