

## Clinical trials

# Clinical trial quality health checklist for drug developers

Quality isn't a box to check at the end of a study—it's the foundation that ensures speed, compliance, and trust in your results.

Assess whether your trial is truly quality-ready:



## 1. Build quality in from the start

- Identify and document Critical-to-Quality (CtQ) factors during protocol design, as outlined in ICH E6(R3) and Quality by Design (QbD) guidance.
- Take a proactive QbD approach—anticipating risks rather than fixing them later.



## 2. Establish strong governance

- Put a Clinical Quality Management System (CQMS) in place that integrates quality and operations across sponsors, CROs, and sites.
- Define roles and responsibilities clearly across all stakeholders.
- Embed quality into every conversation with routine risk assessments, audits, and transparent CRO collaboration.



## 3. Ensure regulatory & GCP compliance

- Confirm full adherence to Good Clinical Practice (ICH E6) and train staff accordingly.
- Maintain compliance with 21 CFR Part 11 for technology and data integrity.



## 4. Protect data integrity with risk-based operations

- Implement strong controls to safeguard trustworthy data and maintain audit trails.
- Use Risk-Based Monitoring (RBM) to focus on the highest-risk processes instead of relying on blanket checks.



## 5. Apply technology with purpose

- Introduce digital tools (EHR integration, AI, digital endpoints) only when they add real value.
- Validate all systems and ensure they meet regulatory standards before deployment.



## 6. Align operations for speed and quality

- Design protocols that are right-sized—comprehensive but not unnecessarily complex.
- Integrate training, SOPs, deviation tracking, and corrective actions into daily operations.

**Bottom line:** A trial that is **quality-ready from the start** avoids costly delays, reduces risk, and accelerates results.

Explore how **quality is the true accelerator of speed** in clinical research: [Read the blog](#)

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