

GCP Compliance Checklist

Healthcare

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Produces an ICH-GCP (E6 R2) compliance checklist for trial conduct at a site — ethics, consent, investigator responsibilities, source documentation, IP accountability, safety reporting and essential documents — with India regulatory notes. For the ethics submission use the Ethics Committee Submission Guide.

Purpose of this tool & output

Check trial conduct against ICH-GCP

How the output is used

Use the checklist to check trial conduct against ICH-GCP and to close gaps before monitoring or audit.

Important cautions

AI-generated checklist; a QA/regulatory professional must verify.

Companion documents

- Clinical Trial Protocol Review
- Informed Consent Form Reviewer
- Ethics Committee Submission Guide
- CRF Design Helper

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.