# ICH E6(R3) Clinical Trial Site Quality System Consulting

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## What to have ready

Each item ties to ICH E6(R3) (final version adopted 6 January 2025, as issued by FDA in September 2025) or to 21 CFR Part 312 as cited.

- A list of current and planned studies, marked against the guideline's scope (E6(R3), Scope [https://database.ich.org/sites/default/files/ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf]), showing which are interventional trials of investigational products headed to regulators and which are other interventional trials where only the Principles may help.
- Your current SOPs, so they can be read against the guideline's call for risk-based, proportionate methods.
- A delegation log that shows who was handed which trial tasks. E6(R3) 2.3.3 scales the documentation to how significant the task is, and notes that delegation records may not be needed where the work is part of ordinary clinical practice.
- A way to show investigator oversight of delegated work. E6(R3) 2.3.1 leaves final responsibility with the investigator and sets the level of oversight by the nature of the delegated work and the risk to participants and data.
- Written, documented agreements with vendors that carry out trial tasks (E6(R3) 2.3.4).
- A procedure for hosting sponsor monitoring and audits, regulatory inspection and IRB/IEC review (E6(R3) 2.3.5).
- A records retention schedule that meets 21 CFR 312.62(c) for drug and biologic studies and any longer period in the sponsor agreement or other applicable requirements: records kept "for a period of 2 years following the date a marketing application is approved" for the indication, or "until 2 years after the investigation is discontinued and FDA is notified" (21 CFR 312.62(c) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/section-312.62]).
- Investigator CVs and training records that show investigators are "qualified by training and experience as appropriate experts to investigate the drug" (21 CFR 312.53(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/section-312.53]).