Sponsor Oversight Evidence Checklist

4Cs

A practical self-assessment for outsourced clinical programs

The core test: For each important outsourced activity, can the sponsor show what it reviewed, what it decided, who acted, when escalation occurred, and how closure or effectiveness was confirmed?

Governance and decision evidence

- ☐ Current responsibility and interface map
- ☐ Governance calendar and attendance
- ☐ Decisions, owners, and due dates
- ☐ Escalation thresholds and routes
- ☐ Accepted risks and approval authority
- ☐ Challenge and closure of overdue actions

CRO and vendor oversight

- ☐ Measures connected to meaningful thresholds
- ☐ Trends and exceptions, not only averages
- ☐ Cross-vendor dependencies
- ☐ Recovery plans with accountable owners
- ☐ CAPA progress and effectiveness review
- ☐ Sponsor follow-up on weak performance

Risk, issue, and change control

- ☐ Current risk and issue registers
- ☐ Clear classification and escalation criteria
- ☐ Protocol, country, site, and vendor impacts
- ☐ Changes connected to decisions
- ☐ Closure evidence proportionate to significance

Medical and safety interfaces

- ☐ Defined question categories and intake routes
- ☐ Required information for review
- ☐ Named decision and escalation roles
- ☐ Response expectations and boundaries
- ☐ Documented decisions and follow-up
- ☐ Clear PV and operations interfaces

Inspection-ready continuity

- ☐ Oversight records filed as expected
- ☐ Trackers reconcile with essential records
- ☐ Transitions include risks and open actions
- ☐ Team can explain how risks were controlled
- ☐ Known gaps have accountable remediation

Rate each item

☐ Clear ☐ Partial ☐ Missing ☐ N/A

Prioritize gaps affecting participant protection, data reliability, major milestones, or the sponsor's ability to explain its oversight.