Inspection Readiness Starter Checklist

Twenty focused questions to help a sponsor team assess governance, evidence, study oversight, people, and sustainable readiness.

How to use	Mark each question **Yes**, **Partial**, or **No**. Capture one evidence reference and one action for every Partial or No response. Prioritize gaps that could affect participant protection, data reliability, regulatory commitments, or the ability to demonstrate sponsor oversight.

Governance & ownership

#	Readiness question	Y / P / N	Evidence or action
01	Is there a named inspection lead with a documented command-center structure?		
02	Are roles, decision rights, escalation routes, and backup personnel current?		
03	Does leadership review a prioritized readiness risk dashboard on a defined cadence?		
04	Are sponsor and vendor responsibilities aligned for likely inspection requests?		

Evidence & systems

#	Readiness question	Y / P / N	Evidence or action
05	Can the team quickly locate the authoritative record for each critical process?		
06	Have data flows, system owners, access controls, and archival paths been mapped?		
07	Are critical deviations, CAPAs, protocol deviations, and quality issues reconciled?		
08	Is the TMF complete, contemporaneous, quality-controlled, and inspection navigable?		

Study conduct & oversight

#	Readiness question	Y / P / N	Evidence or action
09	Is sponsor oversight demonstrable through decisions, actions, and follow-up evidence?		
10	Are vendor and site risks stratified, trended, and connected to oversight intensity?		
11	Can the team explain key protocol decisions and risk-control effectiveness?		
12	Are safety oversight, DMC/DSMB governance, and escalation evidence coherent?		

People & response readiness

#	Readiness question	Y / P / N	Evidence or action
13	Have likely SMEs been identified, briefed, and trained on interview fundamentals?		
14	Do core topics have concise storyboards with facts, chronology, risk, and evidence?		
15	Has the organization run realistic mock interviews and request-management drills?		
16	Are response drafting, review, approval, translation, and submission steps practiced?		

Sustainability

#	Readiness question	Y / P / N	Evidence or action
17	Is there a dated remediation plan with owners, dependencies, and objective closure proof?		
18	Are readiness metrics focused on risk reduction rather than activity volume alone?		
19	Are lessons from audits, quality events, and simulations incorporated into controls?		
20	Can readiness continue through staff changes, leave, or competing program priorities?		

Suggested triage

Priority 1	Participant protection, data integrity, regulatory commitment, or systemic oversight risk. Escalate and act immediately.
Priority 2	Inspection response, record traceability, or control-effectiveness weakness. Remediate with dated ownership.
Priority 3	Efficiency, consistency, or maturity opportunity. Track through the readiness plan and routine governance.

This checklist is a practical starting point, not legal or regulatory advice. Tailor it to the product, phase, applicable regulations, inspection type, organizational model, and known risk profile.