20 questions to ask before your phase 1 trial

A quick self-check for biotech and pharma teams heading into first-in-human trials.

Great science is only part of what makes a phase I trial successful. Timelines, documentation, operational feasibility, regulatory strategy – these can make or break your momentum.

This short self-assessment is designed to help you pressure-test your readiness and decide whether to go it alone or bring in the right partner. **How many of these questions can you answer with full confidence?**

The 20 self-check questions

Study design & scientific rationale

A misaligned dose. Unworkable endpoints. Rigid protocols that don't adapt as new data emerges. When your trial design fails to deliver meaningful answers, progress toward proof-of-concept stalls. The questions below are designed to help you critically assess the scientific, clinical and operational soundness of your study plan.

1. Have you aligned your study design with long-term value milestones - scientific and strategic?
2. Have you defined what "success" looks like for your phase I – beyond safety?
3. Have you confirmed how your PK, PD or biomarker readouts will inform your phase II decisions?
4. Is your starting dose based on robust preclinical translation and modeling?

Documentation & consistency

Disjointed documentation is one of the most common (and costly) problems in early-phase studies. Your documents must tell a coherent, aligned story from synopsis to submission. Inconsistencies in documents lead to questions – and questions delay trials.

5. Is your medical writer aligned with your regulatory strategy – or just formatting documents?
6. Is your synopsis strong enough to build a protocol without rework or regulatory gaps?
7. Are your protocol and IB aligned – or were they written in separate silos?
8. Is your IB built to defend your dosing rationale – or just to tick boxes?

Regulatory foresight

Regulatory pushback is normal. But being ready for it? That's what separates fast-moving studies from slow-burning headaches. If you can't explain it, they won't accept it. This section helps you see what might trigger resistance – and whether you're prepared to respond.

9. Do you know what regulators are most likely to challenge in your protocol, investigator brochure (IB) or CTA?
10. Are your adaptive elements justifiable to regulators and executable by the site?
11. Are you ready to respond if regulators question your design assumptions?
12. Do you know how to push back professionally when feedback is overly conservative?

Operational readiness

Is your trial executable or just elegant on paper? Ambitious study plans can collapse fast when reality hits: logistics, recruitment, timelines, data flow. Execution matters just as much as design. If your study can't run smoothly, it won't run successfully. This section pressure-tests the practical side.

13. Have you involved a principal investigator or clinical unit in shaping your design feasibility?
14. Have you identified operational risks – like sample logistics, data flow or device training - that could delay your timeline?
15. Have you mapped out all study logistics, from sample flow to data timing?
16. Have you validated whether the site(s) can deliver on your protocol's complexity?

Internal capabilities

Do you really have the bandwidth or are you crossing your fingers? Full outsourcing doesn't mean you're off the hook. From regulatory reviews to project managing alignment, many sponsors underestimate what's still expected on their side. This section helps you check whether your internal team is equipped or overstretched.

17. Have you considered whether internal resources can handle full project oversight and documentation cycles?
18. Do you have internal expertise to manage the submission process confidently?
19. Will your team have bandwidth to review and align on multiple document rounds?
20. Do you have enough clinical trial experience to know what you might be missing?

How did you score?

If you hesitated on more than a few of these, you're not alone. Many biotech and pharma teams only discover the gaps once timelines slip or regulators push back.

15 – 20 yes answers: You're in strong shape – but a second pair of eyes could still de-risk your timeline.
10 – 14 yes answers: You're on your way. Time to talk to a partner who can help you tighten the plan.
Fewer than 10 yes answers: You're at risk of timeline delays, regulatory surprises or costly rework. Don't wait.

Need a thinking partner – not just a CRO?

SGS helps biotech and pharma companies going from pre-clinical into early-stage clinical trials navigate this phase smarter – with hands-on consultancy, full-scope support and clinical execution under one roof.

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