



The Art of Phase-Appropriate Development

Phase-appropriate development isn't about doing less. It's about knowing what to build, what to plan, and what can wait.

Programs fail in two opposite ways: building everything early and spending on options they may never use, or designing nothing until a deadline forces it. The middle path is to sort every decision by when it actually needs to exist.

Must Exist Now

Required to file. Gaps here put the IND at risk.

- Target product profile, population, route, and dose concept
- A written statement of global ambition, even one sentence
- Clinical material that matches what was tested in tox, or a bridging argument
- Specifications backed by material actually tested for safety
- Stability and tox coverage for the full Phase 1 dosing duration
- One consistent story across CMC, nonclinical, and clinical summaries
- Vendors chosen on quality history, with a named sponsor quality owner

Design Now

Define the shape, the owner, and the trigger. Spend when the trigger fires.

- Phase 2 scale-up plan, starting with a placeholder batch size
- Long-lead tox studies mapped to the likely Phase 2 duration and population
- Phase 2 protocol as a scaffold, with milestones tied to Phase 1 data
- QP release strategy and supporting vendor agreement provisions
- Stability design with room for additional climate zones
- Labeling and packaging with room for country-specific requirements
- A post-IND execution owner, named before clearance

Defer

Real, but premature. Build it when the program earns it.

- A full EU-compliant quality system and dual QP infrastructure
- A formal multi-region regulatory strategy
- Tech transfer to a second, EU-capable manufacturing site
- Commercial-scale process validation
- Final Phase 2 dose, refined once Phase 1 data arrives
- Country activation for multi-region trials

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“Designing that now costs a conversation. Discovering the design does not exist when the trigger fires costs months.”

Three Questions to Sort Any Decision

01

Does the IND argument depend on it today?

It must exist now.

02

Will it be expensive to reopen later?

Design it now.

03

Does it only matter if a future event happens?

Defer it, but name the trigger.

How Syner-G Helps

Syner-G's integrated CMC360 model helps sponsors sort decisions by phase, so you invest where the program needs it today and keep tomorrow's options open.

Build what you need. Plan for what's next. Connect with our team.