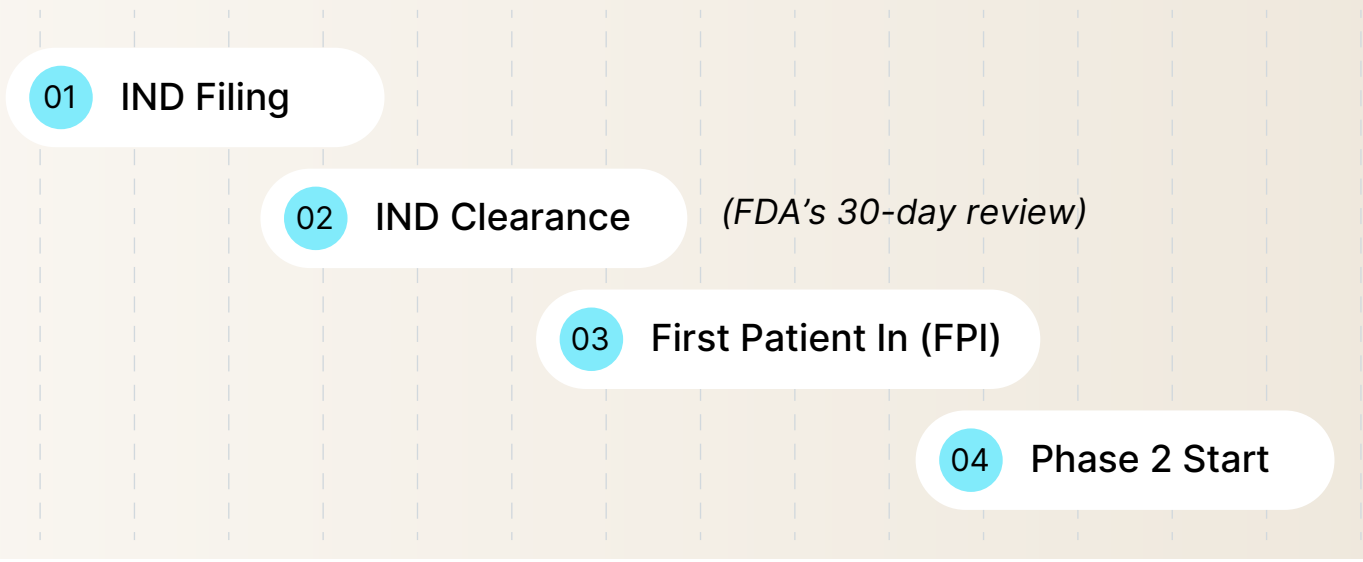


IND → FPI → Phase 2: The Decision Timeline

Every gate has one decision that is cheap to make on time and expensive to fix later.

Most programs track activities by function: a CMC timeline, a clinical timeline, a regulatory timeline. A gate-based roadmap asks a different question at each point: does everything coming together here still agree with everything else?



The Six Gates

	Decision Point	Cost of Missing It
01 Strategy Lock 12–9 months before filing	Lock the target product profile, population, route, and dose concept, and write down your global ambition.	A Qualified Person (QP) with defined training and experience requirements
02 Evidence Generation 9–6 months before filing	Choose vendors on quality first. Build QP release provisions into CDMO agreements and confirm the tox material matches the clinical material.	Reopening a signed agreement, or bridging two different products.
03 Filing Readiness 6 months through submission	Go/no-go to file: do the CMC, nonclinical, and clinical summaries tell one consistent story?	A clinical hold, on FDA’s least forgiving clock.
04 IND Clearance to FPIs Months 0–3	Have a post-IND execution owner in place before this gate opens, with a Phase 2 readiness plan and dated triggers.	A planning gap that can cost 6–12 months.
05 Learn and Adapt Months 3–12	Use Phase 1 data to start scale-up, place long-lead tox studies, and rebuild the Phase 2 protocol.	Each workstream’s full duration added to your timeline.
06 Phase 2 Enablement Months 12–24	Execute scale-up, complete triggered tox studies, and activate countries on schedule.	An unplanned quarter or two before Phase 2 can start.

Design Now, Implement Later

Not every decision needs to be executed early, but every decision that will matter later needs a defined shape, owner, and trigger. Designing it costs a conversation. Discovering it was never designed costs months.

6 gates from strategy to Phase 2	24 months from IND clearance through Phase 2 Enablement	12–18 months to scale up for Phase 2, which is why it starts during Phase 1
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How Syner-G Helps

Syner-G’s integrated CMC360 model runs the same gate discipline across your program and the ones that follow, so your second IND doesn’t start from a blank page.

Make every gate a decision, not a surprise.
Connect with our team.