

The IND Dependency Web

Every function can sign off on its own work, and the IND can still fail. Readiness depends on whether the connections between them hold.

Programs are planned in functional swim lanes, but risk lives at the interfaces, where one function's output becomes another's input. A tox NOAEL becomes a clinical dose ceiling. A CDMO contract becomes a global release path.

Here's how the pieces connect.



Key Connections

CMC ↔ Nonclinical

Same product? The material in the clinic must match what was tested in tox, or the difference must be bridged.

Nonclinical ↔ Clinical

Same exposure? The safety margin must use the same route, regimen, and dose the protocol proposes.

CMC ↔ Clinical

Same duration? Stability data and repeat-dose tox must cover the full treatment period.

Regulatory ↔ CMC

FDA expects any differences between tox and clinical material to be disclosed.

Clinical ↔ Clinical Supply

A larger, longer Phase 2 may need more material than the Phase 1 process can make.

Quality ↔ Vendors

A quality agreement creates obligations, not oversight. Oversight takes risk-based audits and a named owner.

Vendors ↔ Global Development

EU-inspected capacity and QP release provisions keep a European path open.

Global Development ↔ Clinical Supply

US-only stability conditions and labeling can force costly rework later.

12–18 months

to scale up manufacturing for Phase 2 supply

6–12 months

for long-lead nonclinical studies a Phase 2 protocol may trigger

30 days

for FDA to review an IND — the least forgiving time to find a gap

The Reconciliation Test

Read your Module 2 summaries (2.3, 2.4, 2.5) back to back, as a reviewer would. Do they describe the same product, the same exposure, and the same duration? If not, the argument doesn't close.

How Syner-G Helps

Syner-G's integrated CMC360 model treats the connections as the work. Our cross-functional teams test the full development argument at every gate, from strategy through Phase 2, so contradictions are caught internally, not under review.

Build an IND that holds together. Connect with our team.