

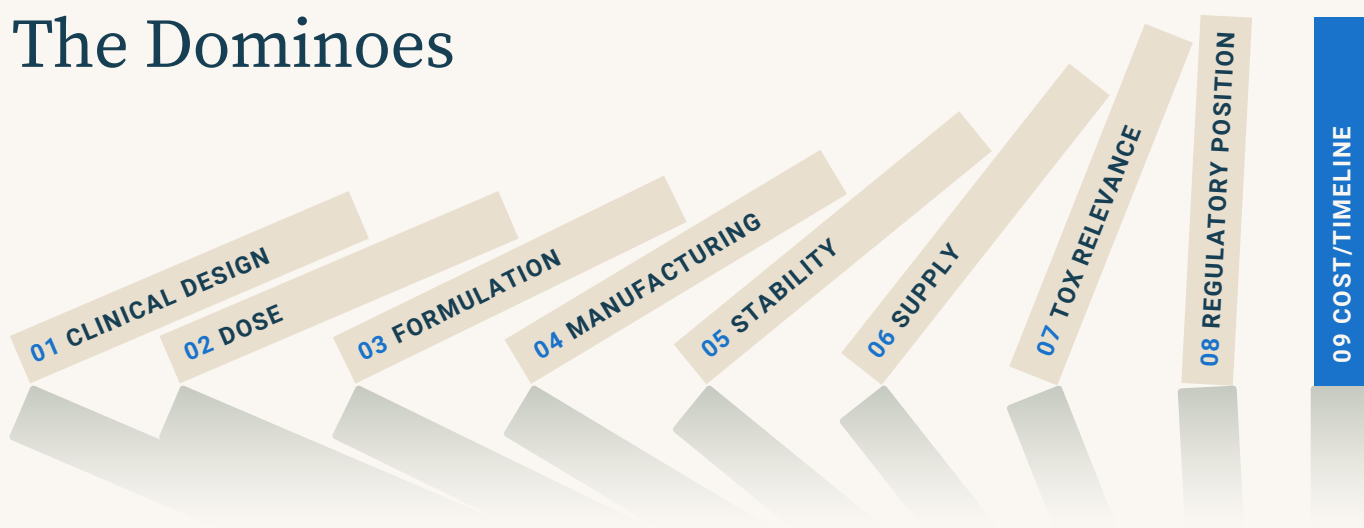
The Development Domino Effect

A single choice in clinical design can reach all the way to your budget and timeline.

Programs are tracked by function, but decisions travel across them. A manufacturing process becomes stability data, which becomes a shelf-life claim, which becomes a protocol duration.

When one piece moves, everything downstream moves with it.

The Dominoes



01 Clinical Design

Population, treatment duration, and endpoints set the bar every function downstream has to clear.

02 Dose

Dose and regimen set how much material you need and the exposure your safety margin must cover.

03 Formulation

A new excipient, particle size, or strength creates a new product that must be bridged to the one already tested.

04 Manufacturing

The process has to make enough material at the right scale. Scaling up for Phase 2 can take 12–18 months.

05 Stability

Stability data must cover the full treatment duration and every market you may want to enter.

06 Supply

Clinical supply must match the volume, duration, and dose changes the protocol calls for.

07 Tox Relevance

What was tested in toxicology must still reflect what patients receive. Longer trials may trigger new studies.

08 Regulatory Position

If the quality, nonclinical, and clinical stories no longer agree, FDA can place the study on clinical hold.

09 Cost/Timeline

Every unplanned bridging study, scale-up, or tox study lands on the critical path.

One Change, Full Cascade

A Phase 2 protocol extends dosing to 12 months. The Phase 1 process can't make enough material. Stability data stops short of the new duration. Repeat-dose tox no longer covers it. The result: a scale-up campaign, new stability work, and a long-lead tox study, all on the critical path at once.

12–18 months

to scale up manufacturing for Phase 2 supply

6–12 months

for long-lead nonclinical studies a longer trial may trigger

1–2 quarters

commonly added to Phase 2 start when early decisions are deferred

How to Stop the Chain

- ✓ **Design early, build later.** Define each decision, its owner, and its trigger up front, even if you don't act on it yet.
- ✓ **Check every change across functions.** When one domino moves, confirm CMC, nonclinical, and clinical still agree.
- ✓ **Name an owner for the whole chain,** not just each function.

How Syner-G Helps

Syner-G's integrated CMC360 model brings CMC, nonclinical, clinical, and regulatory expertise together, so a change in one area is tested against all the others before it becomes a delay.

**See the whole chain before it moves.
Connect with our team.**