



From Discovery to Approval

Where Drug Development Breaks Down and How to Get It Right

The Reality

Great science is not enough

Most development programs do not fail because of the science. They stall due to misalignment across regulatory, clinical, and CMC strategy.

The result:

- Delays in development timelines
- Increased costs and rework
- Missed regulatory opportunities
- Loss of investor confidence

Where Things Break Down

The gaps between strategy and execution



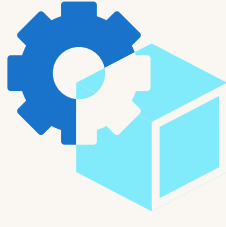
Early Planning Gaps

- Indication not clearly defined
- Target patient population not aligned with regulatory expectations
- No long-term regulatory strategy in place



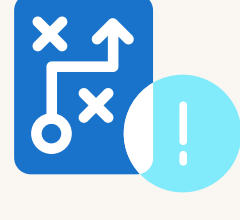
Clinical Development Gaps

- Trial design not aligned with endpoints regulators expect
- Phase progression not supported by the right data
- Missed opportunities for accelerated pathways



CMC Gaps

- Over-engineering too early
- Misalignment between clinical needs and manufacturing readiness
- Manufacturing changes that could impact safety or efficacy
- Phase-inappropriate CMC strategy



Regulatory Gaps

- Reactive vs proactive engagement with health authorities
- Unclear pathway to approval
- Lack of integrated global strategy

The Critical Questions

What must be answered early to avoid costly missteps

- What is the right indication and target population?
- What does success look like from a regulatory and clinical perspective?
- What data is required at each phase to progress?
- What is the most efficient pathway to approval?
- Is an accelerated pathway viable and if so, which one?
- How should clinical and CMC strategies evolve together?

Accelerated Pathways

Opportunity or risk if approached incorrectly

Accelerated pathways can significantly shorten time to market, but only if they are identified early and supported by the right strategy.

Common challenges:

- Choosing the wrong pathway
- Misaligned endpoints or data packages
- Late-stage realization of eligibility gaps

The key: Align regulatory, clinical, and CMC strategy early to support the chosen pathway.



An Integrated Approach to Regulatory Strategy

Syner-G expands beyond traditional CMC or regulatory support.

It connects every part of development into one cohesive, strategic plan.

Our approach aligns:

- Regulatory strategy
- Nonclinical requirements
- Clinical development
- CMC planning
- Commercial and funding goals



How Syner-G Supports You

From early planning through approval, we build a clear, actionable roadmap that defines what to do, when to do it, and why it matters.

Core Components:

Target Product Profile | Clinical Development Plan | Integrated Regulatory Strategy | Regulatory Roadmap



The Outcome

Clarity. Alignment. Momentum.

With the right strategy in place:

- Development pathways are clearly defined
- Teams and stakeholders stay aligned
- Risks are identified and managed early
- Programs move forward with confidence

Build a strategy that moves your program forward with clarity and confidence.

[Explore Syner-G Regulatory Strategy](#)