Rethinking drug development for early-phase biotech

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Executive summary

Many early-stage biotech companies are building breakthrough science using development models that were not designed for the realities they now face.

In the past decade, a growing share of new drug approvals has come from companies with limited or no prior commercialization experience. These organizations are advancing innovative science under intense pressure to move quickly, conserve capital, and demonstrate value early—often with lean teams and limited internal infrastructure.

For early biotechs, the challenge is no longer scientific ambition alone. It is the ability to make high-stakes development decisions early—often before an IND is submitted—when visibility into downstream implications is limited and the margin for error is narrow. Decisions made at this stage increasingly determine not just whether a program advances into the clinic, but whether it remains viable through later phases.

This paper examines how early-phase biotech companies can:

- Reframe early development decisions to reduce downstream risk
- Identify where early complexity undermines momentum
- Evaluate connected development approaches for long-term value

The early biotech reality: Compressed decisions, amplified risk

Early-stage biotech companies operate in an environment defined by constraint. Lean teams are expected to generate compelling data, navigate complex regulatory expectations, establish manufacturing readiness, and satisfy investor milestones—often in parallel.

Unlike large pharmaceutical organizations, early biotechs typically lack in-house expertise across manufacturing, quality systems, regulatory strategy, and clinical operations. As a result, critical decisions are frequently made under time pressure and with incomplete visibility into downstream implications.

This dynamic creates a fundamental tension: Early decisions that carry long-term consequences are often being made using short-term, reactive development models.

When early planning is narrowly focused on advancing the science, broader considerations—such as scalability, data continuity, regulatory alignment, and operational resilience—can be deferred. The result is not just inefficiency, but accumulated risk that surfaces later as delays, rework, or regulatory setbacks.

How risk compounds as programs advance

To compensate for limited internal resources, many early biotechs rely on multiple specialized CROs and CDMOs. In theory, this approach offers flexibility and perceived cost control. In practice, it often introduces new challenges.

Fragmented outsourcing models can:

- Create data silos across development stages
- Complicate technology transfer and process alignment
- Delay issue identification when problems cross organizational boundaries
- Increase coordination burden on already lean internal teams

As programs advance, these inefficiencies compound. Decisions made independently, without shared context or long-term alignment, can lead to misaligned timelines, duplicated effort, and regulatory friction. What initially appears agile can become difficult to manage precisely when complexity increases.

For early-stage companies, the risk is loss of momentum at critical inflection points, when timelines, funding, and credibility are most vulnerable.

How IND readiness shapes long-term development outcomes

The IND submission is often viewed as a regulatory milestone. For early biotechs, it is more accurately understood as a test of control.

Regulatory agencies expect sponsors to demonstrate that their manufacturing processes, analytical methods, and quality systems are sufficiently defined, reproducible, and scalable to support clinical development. Weaknesses in chemistry, manufacturing, and controls (CMC) planning frequently surface at this stage—sometimes for the first time.

While the technical components of an IND submission are well established, the strategic challenge lies in how early these elements are addressed and how well they are aligned across development activities.

Early CMC decisions influence:

- The ability to scale manufacturing without disruption
- The reproducibility of clinical trial material
- The efficiency of regulatory interactions
- The likelihood of avoiding clinical holds or late-stage rework

For early biotechs, underestimating the importance of CMC strategy is a common and costly misstep. IND readiness is not simply about meeting minimum requirements; it is about establishing a foundation that supports the entire development pathway.

While regulatory expectations around CMC are well defined, meeting them alone does not ensure development continuity. What differentiates successful programs is how early and effectively these elements are aligned within a broader development strategy.

IND readiness: Baseline CMC components

- ✓ Drug substance characterization
- ✓ Drug product composition and controls
- ✓ Manufacturing process definition and oversight
- ✓ Analytical methods and labeling
- ✓ Environmental and quality considerations

How integrated development approaches influence development outcomes

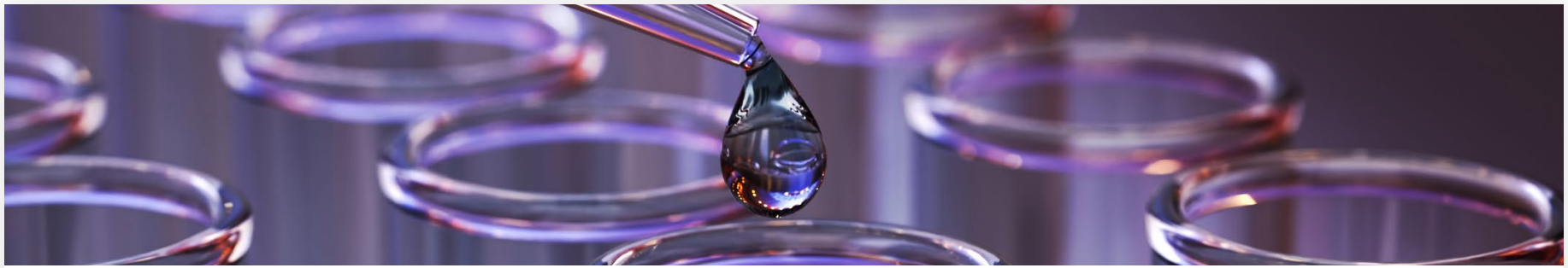
Data from the **Tufts Center for the Study of Drug Development (CSDD)** shows that earlier integration across development phases can reduce downstream friction, shorten timelines, and improve overall program value.

For the analysis, Tufts researchers applied a forward-looking financial model to evaluate how different development approaches affect risk, timing, and return. The model incorporated both financial and operational metrics drawn from real-world clinical development data.

The findings were consistent across modalities and phases:

- Programs that adopted integrated development approaches earlier realized measurable gains in expected net present value (eNPV)
- Early integration reduced development timelines and downstream friction
- Multi-phase integration amplified returns compared with late-stage consolidation

While late-phase integration delivers the most immediate and measurable financial impact, the data shows that integrating earlier allows those benefits to compound across phases, resulting in greater long-term program value. In practice, early alignment across development, manufacturing, and regulatory activities reduces the need for corrective action once programs are underway, when changes are more costly and timelines less flexible. Therefore, strategic choices made earlier in development have a disproportionate influence on long-term outcomes.



Five questions to evaluate development models

For early biotechs evaluating outsourcing strategies, the focus is not simply on individual partners, but on how the overall development model will perform as programs progress and complexity increases. The following questions help clarify whether a given approach is fit for purpose:

1. Does the development model adapt as the program evolves, or does it force repeated transitions?
2. Can regulatory, technical, and manufacturing needs be anticipated rather than addressed reactively?
3. Are scientific decisions connected to operational and commercial implications early on?
4. Does the model reduce or introduce coordination risk across vendors and phases?
5. Will the approach support continuity as complexity increases?

The answers to these questions help early biotechs gauge whether a development model will support continued progress or introduce friction as complexity grows.

How integrated development models address continuity challenges

The previous questions often reveal a common tension for early biotechs. While specialized outsourcing can address individual needs, it does not always provide the continuity required as programs advance and complexity increases.

In response, more early-stage companies are exploring integrated development approaches that bring CRO and CDMO capabilities together within a single framework—reducing handoffs, improving alignment, and enabling earlier coordination across development activities. Thermo Fisher Scientific's Accelerator™ Drug Development reflects this shift. Rather than treating development, manufacturing, and clinical supply as discrete activities, the model emphasizes early alignment, shared data, and coordinated decision-making across phases.

Key characteristics include:

- Development strategies that evolve with program needs
- Early regulatory and CMC foresight
- Centralized oversight to reduce handoffs and fragmentation
- Improved visibility into timelines, risks, and tradeoffs

Together, these characteristics illustrate how integrated development models address the continuity challenges identified earlier.

How integrated development models improve continuity

- Earlier identification of technical and regulatory risks
- Greater data continuity across development phases
- Fewer late-stage corrections and delays
- Faster issue resolution as programs scale

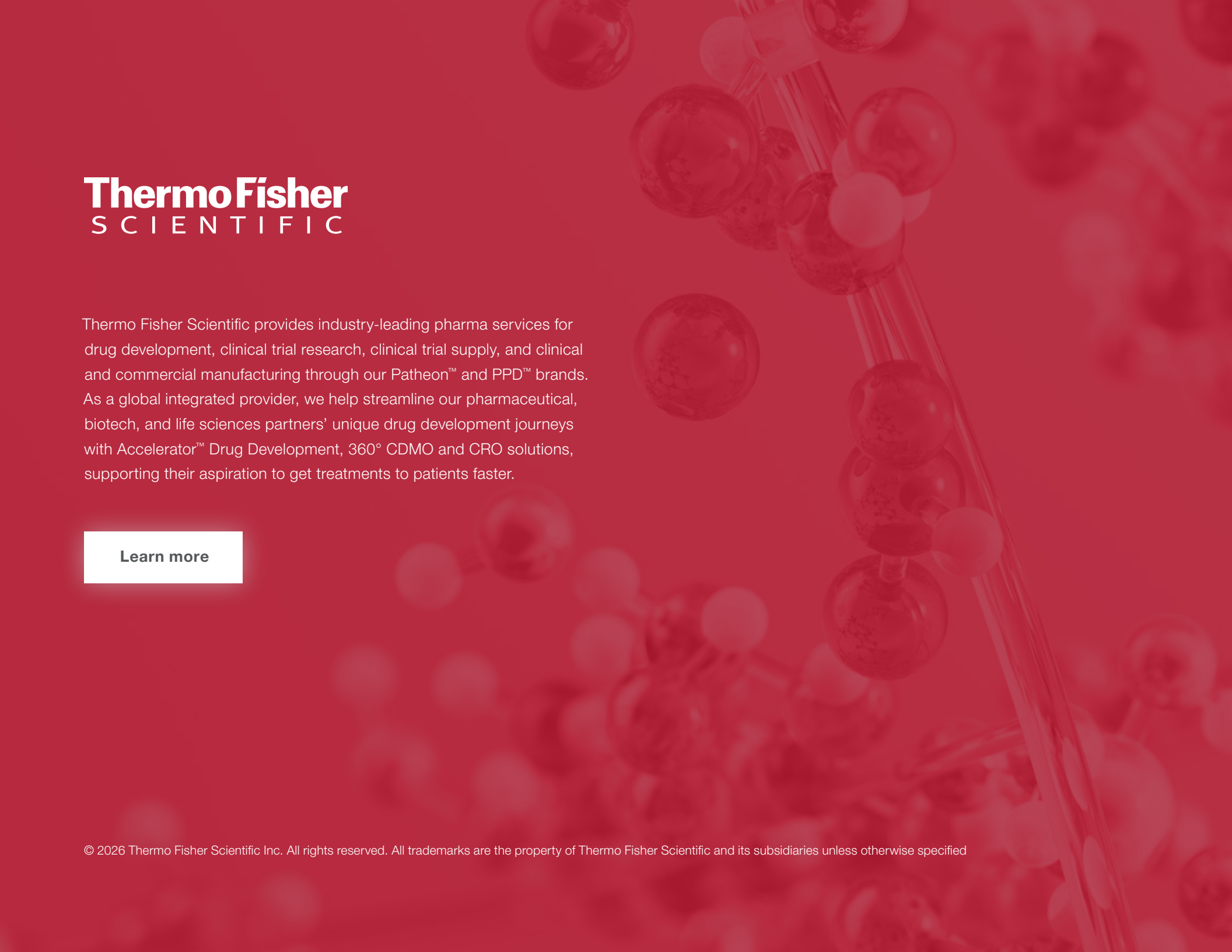
What differentiates successful early-stage programs

Early-phase drug development will always involve risk. What differentiates successful programs is not the absence of uncertainty, but how deliberately it is managed as complexity increases.

Across early development, the most resilient programs share a common approach:

- They prioritize continuity early, rather than relying on late-stage fixes
- They treat IND readiness as a strategic foundation, not a discrete milestone
- They adopt development models designed to evolve, rather than fragment, as programs advance

By aligning scientific ambition with operational foresight, early-stage biotechs can make earlier decisions with greater confidence—building development strategies that support sustained progress through the clinic and beyond.



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