White paper

Value reimagined: Unlocking ROI and efficiency in drug development

Executive Summary

The pharmaceutical and biotechnology industries are at a crossroads. Escalating development costs, new modalities, increasing scientific and logistical demands, regulatory complexity, and mounting pressure to accelerate timelines are creating unprecedented challenges for drug developers.

The traditional reliance on multiple vendors to manage different aspects of development—from drug substance and drug product manufacturing to clinical research and clinical supply—further compounds these challenges. This fragmented model often introduces inefficiencies, miscommunication, and delays, making it even more difficult for sponsors to navigate an already complex landscape.

Amid these challenges, new research is shedding light on a more effective approach. This white paper explores findings from a recent study commissioned by Thermo Fisher Scientific and conducted by the Tufts Center for the Study of Drug Development. The study, which is currently under peer review, quantifies the financial and operational benefits of integrated Contract Development and Manufacturing Organization (CDMO), Contract Research Organization (CRO), and clinical supply solutions—a model exemplified by Thermo Fisher Scientific's **Accelerator™ Drug Development** framework.

By unifying manufacturing, clinical research, clinical laboratories, and clinical supply chain services through a single partner, sponsors have the opportunity to realize a new value equation—one that reduces handovers and white space, prioritizes speed, efficiency, and strategic advantage in an increasingly complex landscape. This shift has the potential to reduce risk, streamline operations, and accelerate the path to market, ultimately delivering greater impact for patients.

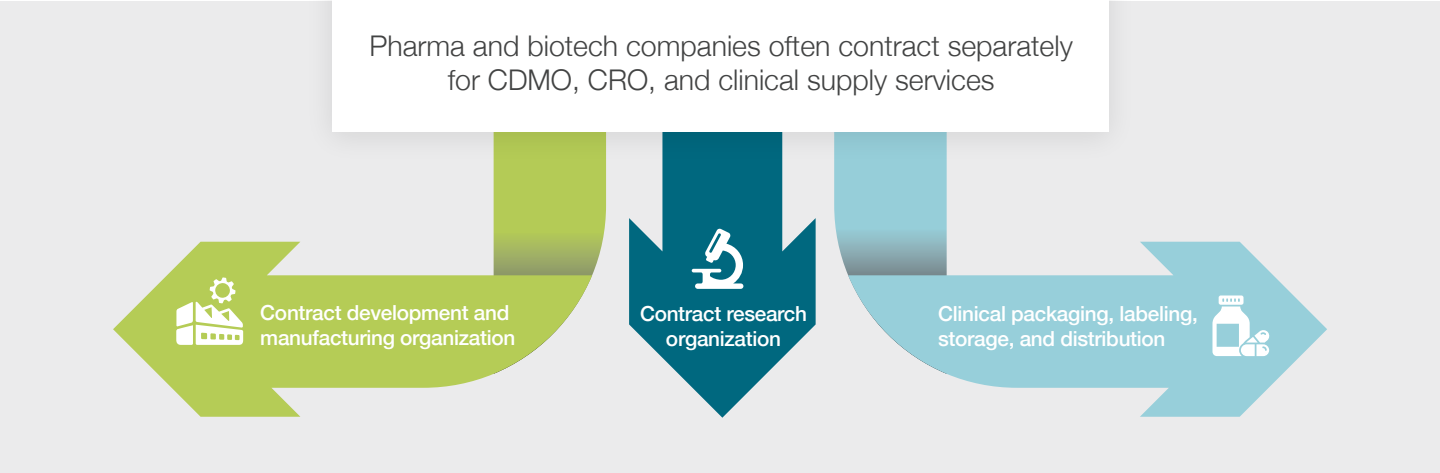
While the pressures of drug development impact companies of all sizes, the challenges—and the opportunities for value creation—differ depending on the company's development stage, pipeline strategy, and specific project needs. Emerging biotechs often face resource constraints and operational gaps that can slow progress or add risk, making access to a comprehensive network of clinical research, clinical laboratories, manufacturing, and supply chain services a strategic advantage. For large biopharma companies managing complex pipelines, streamlining these functions within a single, fully connected model that shares systems and data enhances efficiency, mitigates risk, and frees up internal resources for high-value innovation and market expansion. Regardless of company size or stage, aligning these functions within an integrated framework enables sponsors to manage complexity more effectively, reduce bottlenecks, and improve the path from early development to commercialization.

Key findings from the research include:

- Up to **113.1x ROI** and **$62.9M** expected Net Present Value (eNPV) gains for Phase III oncology programs (monoclonal antibodies - mAbs)
- Compounding benefits from multi-phase integration, with eNPV gains of **$16.4M** for Phase II + Phase III (mAbs)
- Up to **46.9x ROI** and **$25.1M** eNPV gains for small molecules in Phase III

Introduction: The fragmentation problem in drug development

Outsourcing is a common practice in drug development, with pharma and biotech companies relying on CDMOs, CROs, and other partners to manage critical aspects of clinical development, manufacturing, and supply chain operations. This approach allows sponsors to leverage specialized expertise, access advanced technologies, and scale operations efficiently.



However, the traditional outsourcing model in drug development, which relies on separate vendors for clinical research, clinical laboratories, manufacturing, and clinical supply functions, often leads to inefficiencies, miscommunication, and delays. These systemic challenges—rooted in coordination gaps, data silos, and fragmented processes—compound the escalating costs of drug development and the complexities of navigating a stringent global regulatory landscape.

These issues are particularly acute in high-stakes therapeutic areas like oncology, where timelines are critical, and the margin for error is exceptionally slim. The lack of integration in traditional models can result in delays, quality issues, and missed opportunities to optimize processes that could accelerate progress. In fields like oncology, neurology, and rare diseases where rapid advancements in science and technology demand agility, such inefficiencies can hinder the delivery of innovative treatments to patients in need.

To address these challenges, an integrated outsourcing model has emerged, streamlining multiple services into a cohesive, single-vendor framework that fosters seamless collaboration and accelerates progress. This approach has the potential to reduce redundancies and bureaucracy, enhance data flow, and improve alignment across critical functions, enabling faster, more informed decision-making with a single point of accountability. Whether a biotech working to rapidly advance an early-stage asset or a global pharmaceutical company optimizing multiple programs, having seamlessly aligned clinical research, manufacturing, and supply capabilities improves decision-making, reduces risk, and enhances operational efficiency at every stage of development.

The financial pressures driving this shift are significant. Total R&D cost per approved new drug has been estimated in recent studies with different methodologies at $1.3 billion to $2.8 billion, inclusive of the cost of research failures and the time value of money.[2,3,4,5,6] With clinical trials accounting for 70% of total R&D expenditures, inefficiencies in trial design and execution, supply chain management, and manufacturing coordination represent major cost drivers.

These inefficiencies not only inflate overall development expenses but also contribute to delays that can be particularly costly. Research indicates that each month of delay in a Phase III trial can result in up to $8 million[8] in lost revenue due to shortened market exclusivity and deferred market entry.

Given these stakes, improving coordination across clinical and manufacturing functions is not just an operational necessity but a strategic imperative. But how significant are these benefits? That is the question researchers from the **Tufts Center for the Study of Drug Development** set out to answer by measuring the financial and operational impact of integration using a robust financial model.

Quantifying the value of single-vendor integration

To measure the impact of integration, the Tufts researchers used a risk-adjusted valuation framework called expected net present value (eNPV). This approach evaluates the lifecycle costs, risks, and returns of pharmaceutical development projects, quantifying the incremental value of services integrated under a single-partner model versus traditional multi-vendor approaches.

The study focused on oncology programs, a therapeutic area characterized by high development costs, challenging timelines, and significant complexity. By selecting this demanding setting, researchers were able to evaluate the financial and operational implications of integration in a high-stakes context. The researchers conducted sensitivity analyses to account for variations in cost, timelines, and market conditions.

Using a combination of industry data and operational metrics from clinical trials managed by Thermo Fisher, the researchers estimated the impact of integration on timelines and costs. Key inputs to the model included:

Development timelines and costs, adjusted for oncology-specific durations and budgets, using benchmarks from Tufts CSDD databases and industry sources

Phase-specific success rates, illustrating the increased likelihood of regulatory approval success as assets progress through clinical development

Operational efficiencies, derived from integration-driven reductions in study durations and resource costs, as observed in Thermo Fisher-managed clinical trials

Financial metrics, including peak sales, market exclusivity, and post-approval lifecycle costs, which influence long-term value

This robust dataset enabled the researchers to model six scenarios, ranging from single-phase integration to full integration across all clinical phases, and to evaluate the incremental value provided by these approaches.

The results of the study indicate that aligning clinical research, manufacturing, and supply chain functions under a single partner can provide significant financial and operational advantages. These include shorter development timelines and improved return on investment. [See next page: “The measurable impact of Accelerator™ Drug Development”]

While gains were evident across all clinical phases, the benefits of integration were particularly pronounced in later-stage development, where the likelihood of commercialization is higher.

The analysis demonstrates that integration delivers operational efficiencies, such as improved coordination and streamlined workflows, which were the primary drivers of value, enabling drug developers to accelerate progress while maintaining quality and compliance. This is especially valuable in high-stakes therapeutic areas where even incremental improvements in speed can translate into significant financial and clinical impacts.

The measurable impact of Accelerator™ Drug Development

The Tufts study modeled the financial and operational benefits of integrating clinical research, manufacturing, and supply chain functions under a single partner as enabled through Thermo Fisher's Accelerator™ Drug Development. The findings highlight measurable advantages across all phases of clinical development.

The findings indicate that integration delivers both financial returns and strategic value, particularly in high-stakes therapeutic areas like oncology.

Phase-specific results:

Clinical Phase	eNPV Gain (mAbs)	ROI (mAbs)	eNPV Gain (Small Molecules)	ROI (Small Molecules)
Phase I	$1.45M	5.9x	$45K	0.2x
Phase II	$3.14M	5.8x	$1.55M	2.9x
Phase III	$62.9M	113.1x	$25.1M	46.9x

Multi-phase integration results:

Clinical Phase integration scenario	eNPV Gain (mAbs)	ROI (mAbs)	eNPV Gain (Small Molecules)	ROI (Small Molecules)
Phase I + Phase II	$2.92M	5.9x	$717K	1.5x
Phase II + Phase III	$16.4M	24.9x	$6.8M	10.6x
Full integration (Phases I–III)	$9.11M	16.5x	$3M	5.8x

Why later-phase integration has greater impact

In Phase III oncology programs, integration delivered an eNPV gain of $62.9 million and an ROI of 113.1x for monoclonal antibodies (mAbs)—highlighting the significant financial value of applying integration at the stage when the likelihood of regulatory success is highest and time-to-market is most critical.

By focusing integration efforts on these later phases, companies can unlock greater efficiencies, maximize financial returns, and gain competitive advantages. The key factors that make late-phase integration particularly impactful are explored below.

- **De-risking of assets**
  In Phase III, assets have already demonstrated success in earlier trials, significantly reducing the uncertainty inherent in drug development. This de-risking amplifies the value of integration by ensuring that resources are focused on high-potential programs. Aligning clinical research, manufacturing, and supply chain functions during this phase reduces delays and helps companies capitalize on the heightened probability of success.
- **Time savings and market entry**
  The ability to accelerate timelines in Phase III is crucial in achieving faster market entry. In competitive therapeutic areas like oncology, even a slight reduction in time-to-market can result in substantial financial gains by earning returns sooner and extending the period of market exclusivity. Integrated approaches help companies streamline processes, eliminate redundancies, and focus on rapid execution to achieve earlier launches.
- **Sensitivity analysis: Demonstrating robustness in Phase III**
  The Tufts study demonstrates that the financial and operational benefits of Phase III integration remain robust even under varying market conditions. Sensitivity analyses confirmed that even when accounting for variability in development timelines, resource costs, and financial parameters, Phase III integration consistently delivered the highest ROI. This reinforces its value as a critical driver of development efficiency, even under fluctuating market conditions.

Setting the stage for long-term value

While later-phase integration delivers the most immediate financial returns, the strategic choices made in Phase I play a crucial role in maximizing long-term value, shaping the efficiency, scalability, and overall success of a development program.

Engaging with a single, scalable, global partner early in the process can help mitigate challenges associated with tech transfers, contract renegotiations, and shifting regulatory strategies—all of which can introduce delays and added costs.

By aligning clinical research, development, drug substance and drug product manufacturing, and supply strategies from the outset, drug developers can build continuity into their programs, ensuring seamless data flow, process consistency, and regulatory alignment as assets progress through clinical phases. This integrated approach not only reduces operational risk but also enables greater flexibility to adapt to evolving development needs.

Additionally, an outsourced strategic development unit can provide guidance in asset management, clinical planning, and regulatory interactions, supporting informed decision-making and helping companies optimize resource allocation from Phase I onward. Establishing this foundation early can streamline scale-up, reduce complexity in later phases, and position programs for a smoother transition into commercialization.

As drug developers evaluate their approach to integration, understanding the long-term impact of early-phase decisions is just as critical as recognizing the benefits of later-phase efficiencies. Whether engaging in a fully integrated model or selectively aligning high-impact functions, continuity across development and manufacturing remains a key driver of success.

Real-world impact: Single-vendor approach delivers tangible results

Across the pharmaceutical industry, drug developers have begun leveraging Accelerator™ Drug Development solutions to help streamline operations, mitigate risk, and speed up timelines. Recent customer projects illustrate the measurable impact of this integrated approach in different phases of development.

As evidenced through these examples, aligning critical functions under a single, integrated partner can reduce complexity, de-risk programs, and bring life-changing therapies to patients faster.

Case study 1

Customer: An emerging biotech company

Situation: Potential 18-month delay in its First-in-Human (FIH) study due to underdeveloped API characterization criteria and testing methods.

Solution: Combining expertise in CMC, global regulatory, global clinical trial design, and preclinical consulting saved significant time and money.

Outcome: The Thermo Fisher team helped the company **accelerate the study start by 12 months** and **save more than $1 million** in projected costs.

Case study 2

Customer: A large biopharma company managing multiple clinical studies across **450+ sites** and **800 patients**

Situation: Sponsor struggled with fragmented governance and startup inefficiencies.

Solution: Leveraging a single vendor approach with centralized oversight, integrated KPIs, and dedicated specialists improved alignment and efficiency.

Outcome: As a result, the company activated its first site **13 days ahead of schedule**, **cut customer meeting time by 35%**, and **saved $200K** in operational costs.

Case study 3

Customer: A global Phase III vaccine trial

Situation: Complex ultra-cold packaging, labeling, and distribution spanned **170 sites** in **20 countries** for **6,000+ patients**, threatened critical timelines putting milestones at risk.

Solution: Global clinical supply chain expertise, proactive risk mitigation, and alignment of quality agreements prevented trial start-up delays.

Outcome: The company **streamlined operations**, **shortened IMP release by five weeks**, and **ensured on-time shipments**—meeting First Patient In (FPI) targets.

Conclusion

The Tufts study underscores a vital shift in how we define and deliver value chain functions under a single partner. Biotech and biopharma companies can accelerate timelines, streamline workflows, and, most importantly, bring critical therapies to patients faster. In an industry where every day counts, these efficiencies translate into lives changed and hope delivered.

These advantages apply across the industry. For emerging biotechs, having a fully integrated network of clinical research, manufacturing, and clinical supply services helps accelerate development while preserving resources. For established pharmaceutical companies, a unified approach across these functions enables smarter trial design, better scalability, and stronger pipeline management—ultimately driving both speed and quality in drug development.

As drug developers contend with increasing pressures to deliver both innovation and efficiency, integrated, single-partner solutions represent a clear path forward. As the industry continues to evolve, companies that adopt integrated solutions will be better positioned to navigate complexity, address customer and investor expectations, seize opportunities in high-growth areas, and bring life-changing therapies to market more efficiently than ever before.

Looking for a fully integrated CDMO and CRO solution?
Contact us here to learn how Accelerator™ Drug Development can streamline your path from early development to commercialization.

Focused on CDMO solutions?
Contact us here to explore how our manufacturing and development expertise can help advance your program efficiently.

Need CRO support?
Contact us here to partner with a team that delivers strategic clinical research solutions tailored to your needs.

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