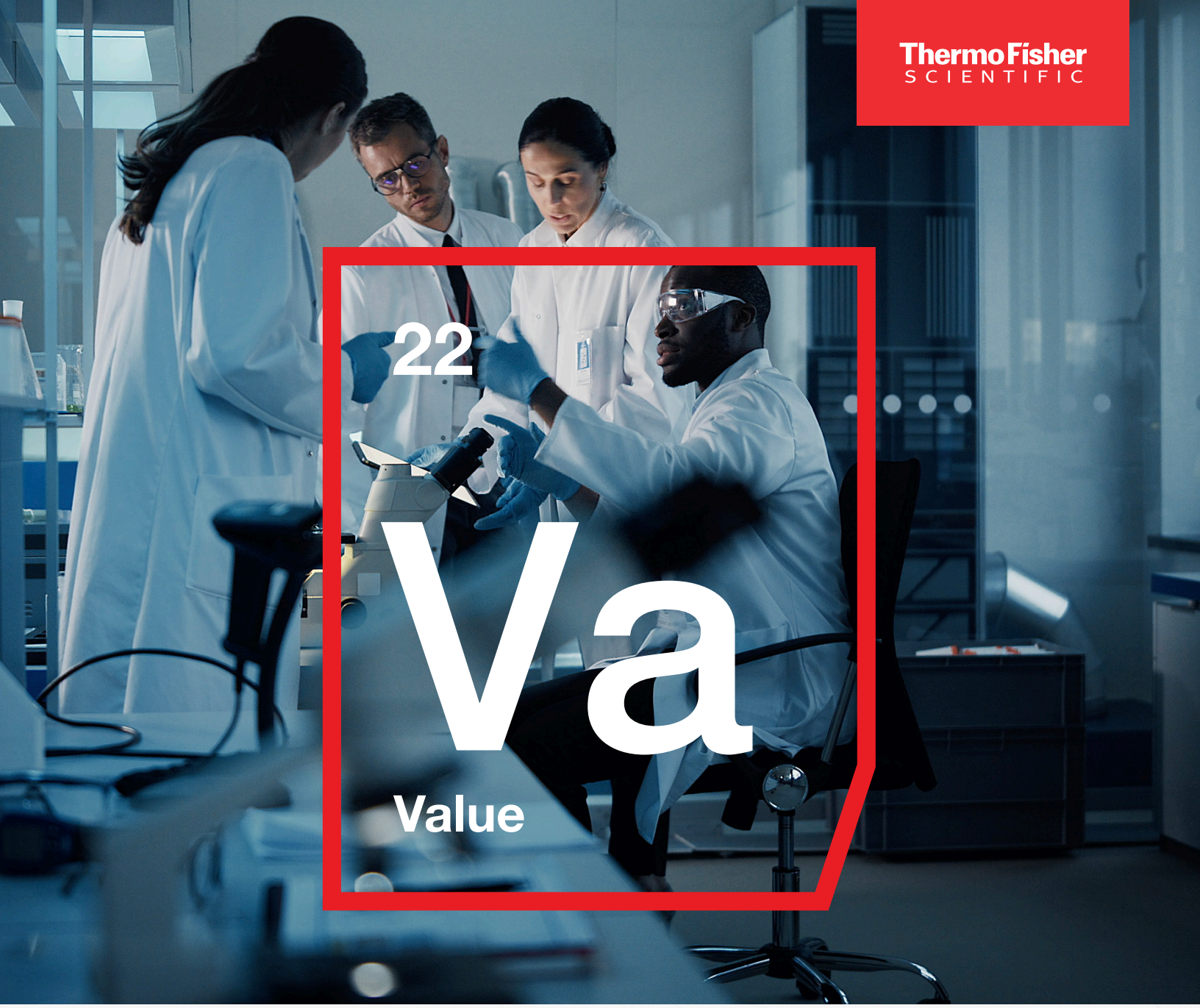


White paper

Redefining value in drug development:
A new model for success

Embracing value as a dynamic concept and adopting a strategic, connected approach across all phases of development empowers biotech and biopharma companies for long-term success.

Executive summary

Standing still is not an option in drug development. Companies that rely on outdated cost- and speed-driven strategies risk making decisions that undermine long-term success. Today's reality is that value is not defined by how little you spend or how fast you move—it's about making smarter, more strategic choices that drive efficiency, reduce risk, and position therapies for market success.

Yet, many companies still rely on an outsourcing model designed for a different era, where critical development functions are spread across multiple vendors. This fragmentation increases inefficiencies, delays timelines, and complicates risk management. In today's complex landscape, that approach is no longer viable. To navigate these challenges effectively, drug developers should reconsider multi-vendor transactional relationships and instead adopt a more integrated strategy. Consolidating expertise, infrastructure, and oversight within a single, strategically aligned partnership can help streamline operations, reduce risk, shorten timelines, and improve overall program success.

This paper explores the urgent need for a new approach to defining value in drug development, one that reflects its dynamic nature instead of relying on outdated cost-cutting measures. Readers will gain:

- Insights into how disjointed outsourcing models can create unnecessary risk
- A roadmap for adopting a more connected, strategic approach
- An understanding of how value drivers can shift over time and how dynamic value equations shape strategic decisions

The industry is evolving, and companies that cling to fragmented outsourcing models will fall behind. Now is the time to rethink value as a dynamic equation rather than a fixed metric and take decisive steps toward a smarter, more strategic development model.

Redefining value in drug development: A new model for success

Cost and speed are two of the most scrutinized factors in drug development, but while both contribute to value, neither defines it. Drug developers that don't recognize the difference risk making decisions that jeopardize their programs' success.

Companies often focus on reducing costs or accelerating timelines in the short term to gain an advantage, but this oversimplified approach ignores the broader forces that shape long-term success. A true value-driven strategy considers not just how much is spent or how fast a milestone is reached, but whether the decisions guiding those factors ultimately improve efficiency, reduce risk, and support sustainable progress.

In drug development, value is particularly complex and nuanced. Therapeutic area, company size, development stage, and strategic priorities all influence value, with each factor carrying a different weight depending on the context. A rigid focus on cost alone fails to account for these shifting priorities, ignoring the reality that value is a dynamic equation rather than a fixed metric.

Why the traditional outsourcing model no longer works

To stay competitive in this increasingly complex environment, companies must move beyond traditional, transactional views of value and take a more holistic approach to decision-making. Those that understand how multiple value drivers interact will be better positioned to navigate regulatory challenges, supply chain disruptions, and evolving market dynamics while ensuring long-term success. Built-in tamper evidence that eliminates reliance on adhesive labels, reducing the risk of label failure.

Yet, even as companies recognize the need for a more strategic approach to value, many still rely on outsourcing models that were built for a different era of drug development [1]. For too long, the industry has operated in silos—separating clinical research, manufacturing, and supply chain functions across multiple vendors. While this approach once made sense, today it introduces inefficiencies, increases costs, delays timelines, and complicates risk management.

In response, a new model is emerging—one that prioritizes cohesion over fragmentation. Rather than navigating a disconnected web of service providers, companies are increasingly looking for partners that can align expertise, infrastructure, and strategic oversight across the full development lifecycle [2]. In this new reality, value is defined by greater efficiency, reduced risk, and the ability to bring therapies to market faster. These factors create a sustainable advantage that extends beyond cost savings.

A value equation that adapts to industry needs

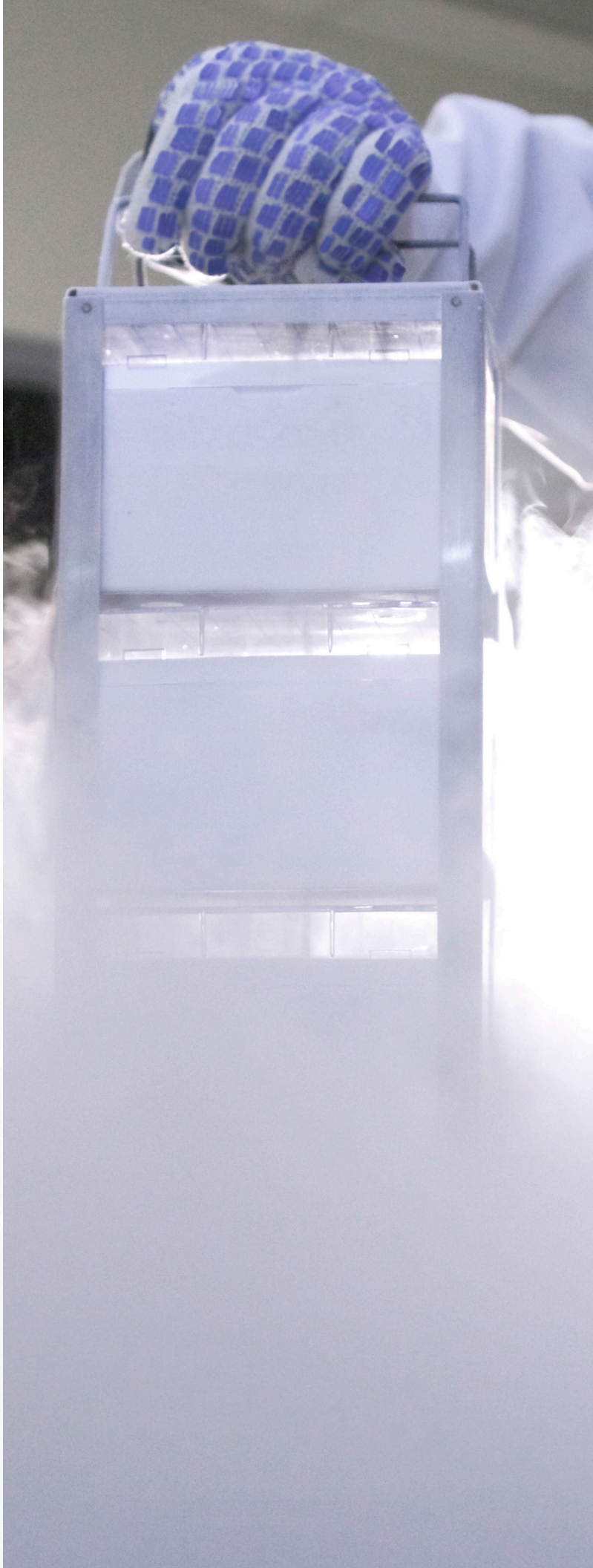
While integration can unlock efficiencies and reduce risk, its impact on value depends on how it is structured, the breadth and depth of capabilities it brings together, and how well it aligns with specific development and commercialization strategies. Value drivers are not the same for every company or program, and their relative importance shifts based on factors such as therapeutic area, development phase, business model, sponsor resources, and strategic objectives. Understanding these nuances is critical to making strategic outsourcing decisions that maximize efficiency while supporting long-term success.

For an early-stage biotech, value may center on flexibility, speed, and risk mitigation to navigate uncertainty with limited resources, while for a large biopharma organization, scalable capacity, regulatory expertise, and process optimization may be more critical for late-stage or commercialized assets.

Similarly, a biologics sponsor scaling up production may prioritize quality, risk mitigation, and supply chain resilience to maintain compliance and efficiency. Meanwhile, a cell and gene therapy developer, working on highly specialized, patient-specific treatments may focus on customization, rapid turnaround times, and stringent regulatory alignment.

In oral solid dosage (OSD) development, flexibility, cost efficiency, and manufacturing scalability often define value, particularly for high-potency APIs or complex formulations requiring specialized handling.

For clinical-stage programs, value is shaped by supply chain precision, risk mitigation, and adaptability to evolving study demands. Depending on the trial, priorities may range from speed-to-site for patient recruitment to rigorous cold chain logistics for temperature-sensitive biologics and cell therapies. Optimizing this equation based on trial complexity and sponsor needs is key to maintaining product integrity, ensuring timely dosing, and supporting global trial success. (See: “Solving for multiple value equations”.)



Solving for multiple value equations

The factors that define value in drug development are not static; they shift based on therapeutic area, development stage, and sponsor priorities. While these drivers vary, they do not operate in isolation—each element influences the others, creating a dynamic equation unique to each program. Successful development strategies also depend on anticipating challenges before they arise, leveraging experience, data, and market insights to make informed trade-offs.

The following examples illustrate how different value drivers interact in various modalities and development scenarios. These are not rigid formulas but conceptual frameworks that highlight the trade-offs and priorities shaping strategic decisions. The right equation for one program may not be the right one for the next, and the balance of priorities shifts as development progresses.

Development and manufacturing

API: **(Quality + Expertise + Capacity) × (Cost + Regulatory Compliance)**
API development requires strict quality control, regulatory alignment, and deep process expertise, all while ensuring scalable production and cost efficiency.

Oral solid dosage: **(Flexibility + Scalability + Speed) × (Cost + Innovation + Technology)**
OSD manufacturing must balance high-volume production with the flexibility to handle complex formulations, high-potency APIs, and evolving market demands.

Biologics: **(Capacity + Expertise + Innovation) × (Quality + Speed + Risk Mitigation)**
Scaling biologics manufacturing requires significant capacity, deep scientific expertise, and stringent risk management, ensuring compliance while maintaining efficiency and speed.

Cell and gene therapies: **(Innovation + Customization + Expertise) × (Speed + Flexibility + Risk Management)**
Manufacturing for cell and gene therapies demands customized, patient-specific solutions with tight turnaround times and rigorous regulatory oversight.

Sterile dosage forms: **(Quality + Compliance + Expertise) × (Risk Mitigation + Cost)**
Sterile fill-finish processes are highly regulated, requiring absolute sterility assurance, risk mitigation, and cost-efficient production without compromising safety.

Clinical research and supply chain

Clinical development and trial management:
(Speed + Data Integrity + Patient Access) × (Regulatory Expertise + Risk Management)
Successful clinical development hinges on streamlined trial execution, real-time data insights, and regulatory expertise to ensure efficiency while maintaining compliance.

Laboratory and analytical services:
(Scientific Expertise + Standardization + Compliance) × (Speed + Scalability)
Advanced laboratory services accelerate clinical trial performance by providing high-quality, standardized testing that meets regulatory requirements and ensures reliable decision-making.

Clinical trial supply services: **(Speed + Reliability + Risk Management) × (Flexibility + Quality)**
Clinical trial supply chains must deliver fast, reliable distribution while managing protocol changes, patient-specific needs, and global logistics complexities.

Logistics and cold storage: **(Reliability + Speed + Risk Mitigation) × (Flexibility + Cost)**
Global logistics and cold storage solutions require temperature-controlled precision, regulatory compliance, and supply chain agility to avoid costly delays or losses.

A model for the future

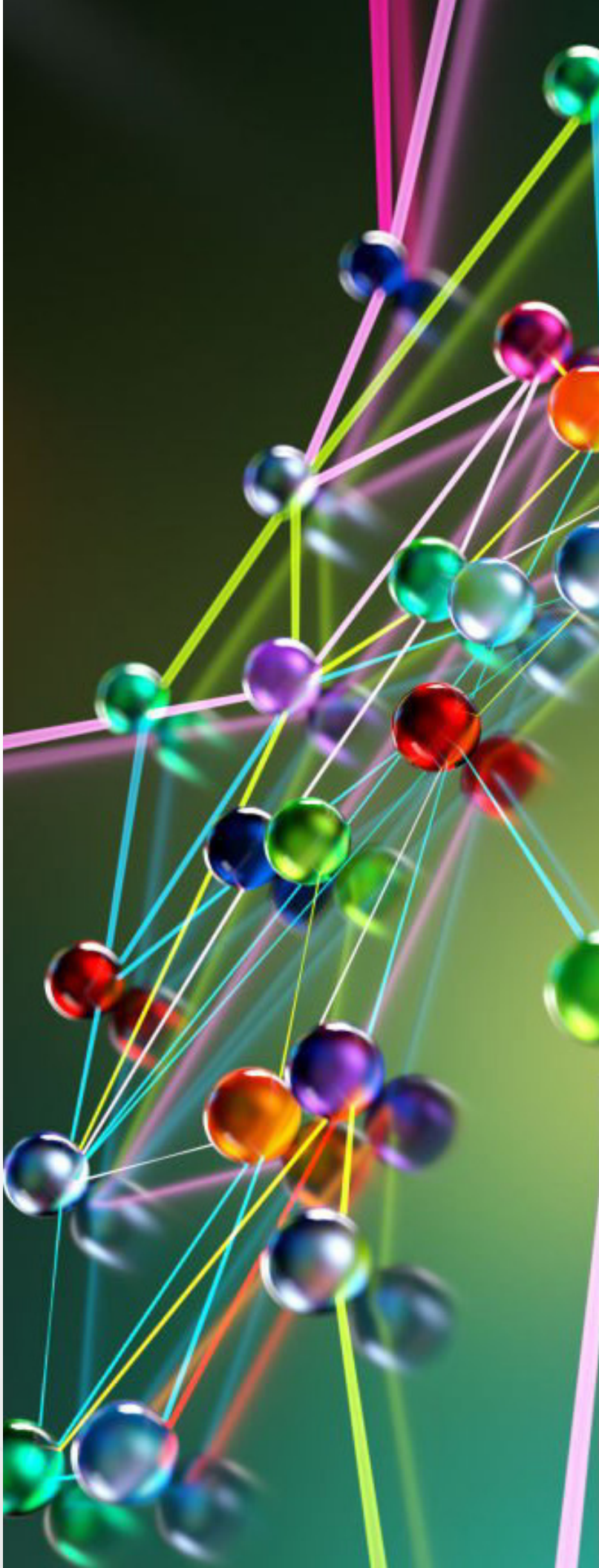
Success in drug development depends on the ability to align critical functions—drug substance, drug product, clinical research, and clinical supply—within a cohesive framework. A fragmented approach slows progress and increases risk at every stage, making it harder to meet development milestones and adapt to evolving demands.

Companies that take a fully connected approach can streamline operations, reduce inefficiencies, and anticipate challenges before they cause delays. Integrating these capabilities under a single strategic partner provides the flexibility to scale, manage risk, and optimize resources, creating a stronger foundation for innovation and commercialization.

Now is the time to evolve

The industry is shifting, and the stakes are high. Success in this new era of drug development will belong to those willing to challenge outdated ways of thinking. As pressures mount, companies that embrace a more holistic view of value will be better positioned to bring therapies to market efficiently and effectively.

Taking decisive steps now by investing in the right partnerships and aligning development strategies is critical to gaining an edge and sustaining long-term success. Fragmented outsourcing models add cost, delay timelines, and increase risk. An integrated approach eliminates inefficiencies and strengthens development. If your development model isn't actively reducing risk, improving efficiency, and enhancing scalability, it's time to rethink your strategy.



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Value

Accelerator™ Drug Development

360° CDMO and CRO drug development solutions

Success in drug development depends on a strategic approach that optimizes resources, reduces risk, and keeps programs on track. The right partner can provide the expertise, infrastructure, and flexibility needed to streamline operations and adapt to changing demands. **Accelerator™ Drug Development** by Thermo Fisher Scientific enables a more connected approach by aligning CDMO, CRO, and clinical supply capabilities to eliminate inefficiencies and accelerate time to market.

References

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