



A Future-Forward Perspective

From Syneos Health®

Drug Development That Moves at the Speed of Change



Introduction

During the past three decades, the life sciences industry has driven profound shifts in the nature of scientific innovation. Early trends that favored blockbuster medicines designed for broad patient populations have largely given way to advances in precision medicine, genomics and biomarkers that are unlocking new scientific possibilities. These same advances are also increasing the complexity of development programs and raising expectations for speed, efficiency and execution. As the science gets stronger, it is becoming a catalyst for rapid change affecting every part of the drug development ecosystem, from trial design, methodology and evidence generation to global regulatory strategy and commercialization.



In this context, artificial intelligence, advanced analytics and connected data streams are emerging as critical enablers of the drug development enterprise. Beyond yielding efficiencies, these tools are transforming protocol design, patient identification, study execution and evidence generation, and making possible data-based, real-time decision-making across the development lifecycle.

Together, these ecosystem catalysts and enablers are driving a fundamental shift toward a new model of adaptive drug development—one that requires organizations to combine scientific innovation, intelligent technology and delivery model flexibility with a level of agility that can scale at the pace of change.



Adaptive Drug Development: Why Now?

Few statistics illustrate the growing complexity of drug development more clearly than this fact: Nearly 6 million data points are now routinely collected during the average phase III clinical trial—a level of complexity that not only contributes to clinical trial costs but also jeopardizes study quality and places considerable burden on sites and participants.¹ But it's also true that within that complexity lies enormous value. Richer datasets can reveal patterns that would otherwise remain hidden, enabling more informed development decisions, more precise evidence generation and greater confidence that therapies will reach the patients most likely to benefit.

The path to realizing this potential is through operational excellence.

In today's drug development ecosystem, this means having the ability to orchestrate scientific strategy, clinical operations, regulatory/biostatistical discipline, data science, site partnership and patient engagement in a way that supports adaptive, data-driven decision-making throughout the development lifecycle.

According to a recent study from the Tufts Center for the Study of Drug Development (CSDD), there isn't one "best" operating or outsourcing model for achieving this.² Instead, what organizations increasingly require are fit-for-purpose models that can be reconfigured as scientific priorities, evidence expectations, regulatory requirements and resource needs evolve.

This matters because the contemporary drug development environment is defined by twin imperatives: greater scientific precision and shorter development timelines. Increasingly, success is measured not only by clinical endpoints, but also by the speed and quality of decision-making throughout the development process.

Adaptive Ecosystem Catalysts and Enablers

ACCELERATING SCIENCE

Powered by advances in precision medicine, genomics, biomarkers, disease biology and novel therapeutic modalities, sponsors are increasingly focused on developing therapies for highly targeted patient populations defined by specific genetic, molecular or clinical characteristics. The industry's movement away from broad-population therapies toward precision medicine is becoming more visible in both pipelines and product approvals. What began in oncology is now influencing development across rare disease, immunology, metabolic disease and other therapeutic categories.

As development programs become more targeted, the methodologies used to evaluate them are becoming more sophisticated as well. Smaller patient populations, evolving biomarker strategies, complex inclusion criteria and rapidly advancing scientific understanding require greater flexibility in how studies are designed and executed. Adaptive clinical trials, complex innovative trial designs such as basket trials, decentralized approaches, pragmatic clinical trials and real world evidence (RWE) strategies are creating opportunities to learn faster, generate evidence more efficiently and refine development strategies as new insights emerge.

EVOLVING REGULATORY EXPECTATIONS

As development becomes more precise and data-rich, regulatory frameworks are evolving to support earlier engagement, more flexible evidence strategies and faster pathways for new drug reviews and approvals. This evolution reflects an even broader industry imperative: reducing the time between scientific discovery and patient impact.

The FDA has expanded support for innovative trial designs, adaptive methodologies and RWE strategies. In a move to further compress development timelines and costs while maintaining scientific rigor, the agency has recently announced that a single, well-designed pivotal study, supported by confirmatory evidence, will be its default standard for new drug approvals.

As development becomes more precise and data-rich, there is growing recognition that regulatory systems must evolve alongside scientific innovation.

The FDA's Real-Time Clinical Trials (RTCT) initiative seeks to shift clinical development from periodic data review to continuous regulatory visibility, allowing FDA reviewers to monitor predefined trial signals in near-real time and potentially accelerate development and regulatory decision-making. RTCT represents a move toward continuous evidence generation and continuous regulatory engagement. Succeeding in this endeavor will require high levels of operational agility and technological enablement from sponsors and their drug development partners.

A joint Health and Human Services and FDA initiative called Operation TrialBlazer seeks to modernize clinical development by reducing unnecessary regulatory burden, supporting more flexible approaches to evidence generation and accelerating development timelines without compromising standards for safety and effectiveness. These efforts point toward a future in which clinical development, regulatory planning and evidence generation operate in a more connected and responsive manner.

The European Medicines Agency is pursuing similar goals. Initiatives focused on innovative methodologies, RWE and the use of health data are intended to support more efficient development and evaluation of new therapies. Efforts to streamline coordination across member states and improve trial execution reflect broader recognition that regulatory systems must evolve alongside scientific innovation.

Additional pressures on the ecosystem are coming from global economic and political shifts. For much of the past three decades, drug development benefited from increasing globalization. Clinical trials expanded across geographic regions. Commercialization strategies became more international. Development and manufacturing networks grew more interconnected. Today, many of the assumptions that shaped that era are being reconsidered. National governments are taking a more active role in determining how innovation fits within their economic priorities, healthcare systems and long-term competitiveness strategies. Organizations must navigate not only evolving science, but also geopolitical and policy fragmentation—an ecosystem in which government priorities, economic objectives and healthcare policy increasingly shape the conditions under which innovation reaches patients.

AI AND TECHNOLOGY INTEGRATION

For decades, drug development has operated much like a relay race, with teams passing work from one phase to the next as programs advance through a linear sequence of milestones. Adaptive drug development requires a different model—one in which information, evidence and operational insights can be connected and acted upon in real time.

AI and advanced technologies are poised to facilitate exactly this kind of agile adaptation. Empowered by AI-enabled scientific reasoning, simulations and evidence synthesis, it is becoming possible for teams to strengthen protocol strategy, feasibility planning and competitive trial intelligence to support faster, evidence-backed decisions. Real-time, connected, agentic-powered environments—informed by deep scientific, therapeutic, methodological and operational human expertise—become places where evidence, trial design, execution and submission continuously inform one another as conditions evolve. Epidemiology, RWE, commercial intelligence, site performance, patient journey data and healthcare provider behavior serve as dynamic inputs into development strategy, becoming living signals. Options are simulated, pressure-tested and optimized before execution begins. As a study moves into start-up, things such as feasibility, activation, enrollment, risk signals, protocol deviations, site burden and patient engagement are continuously monitored.

Then, as the data matures, teams can begin preparing for what's next. Real-time oversight capability supports a more adaptive trial environment by giving teams better visibility, faster feedback loops and greater ability to course-correct while in motion. Trials become more adaptive, transparent and responsive, creating opportunities to deliver better outcomes for patients.

However, a caveat:

The most successful organizations will not be defined by AI alone. They will be those that design systems where human expertise and machine intelligence reinforce each other. In such environments, AI manages complexity, orchestrates information and handles the repetitive edge cases of scientific work. It is humans who remain stewards of meaning—interpreting results, making ethical judgments and guiding the direction of discovery.

Real-time oversight capability supports a more adaptive trial environment by giving teams better visibility, faster feedback loops and greater ability to course-correct while in motion.



Operating Models: Toward a New Perspective

There is growing need for partnership approaches that simplify complexity and meet the demand for solutions that can adapt alongside changing portfolio priorities, evidence requirements, regulatory expectations and resource needs.

In today's more complex drug development ecosystem, sponsors are reevaluating how the work gets done, which capabilities should remain in-house and where external expertise can create greater value. They are becoming more intentional about which capabilities they want to retain internally and where they can benefit from specialized knowledge, scalability and global reach.

This is consistent with findings from the Tufts CSDD benchmarking study suggesting that no single resourcing approach consistently outperforms any other.² The study focused on outsourcing models and found that full-service outsourcing is as good as functional service provider (FSP) arrangements, with both blended and in-house models in delivering clinical trial timelines and quality. Instead, there is growing need for partnership approaches that simplify complexity (e.g., fewer vendors is associated with decreased risk, according to the Tufts CSDD research), and increasing demand for solutions that can evolve and adapt alongside changing portfolio priorities, evidence requirements, regulatory expectations and resource needs.

Key characteristics of such models include:

Flexible, fit-for-purpose delivery. Future-forward drug development demands customized solutions that can adapt to the needs of the asset, portfolio, organization, development stage and evolving business requirements.

Integrated partnerships and shared execution. Success increasingly depends on alignment between sponsor and outsourcing partner around the long-term vision for the development program. Organizations need teams that can adapt alongside them, proactively bring new ideas to the table and help them navigate change while staying focused on their priorities.

Model-agnostic, value-centric approaches. The industry is moving beyond discussions centered on delivery model labels and toward discussions focused on outcomes and value creation. Sponsors increasingly evaluate operating models based on their ability to help achieve strategic objectives, not whether they are classified as FSP, full-service, hybrid or another structure. Accountability is shifting to measurable outcomes, such as reduced decision time and improved patient results.

In short, flexibility, responsiveness and continuous alignment are becoming more important than adherence to fixed models or ways of working. Organizations will continue to look for advisors who can bring perspective, help navigate increasingly complex decisions, and identify opportunities they may not see on their own.

To that end, adaptive drug development requires a workforce that can operate in increasingly data-rich, technology-enabled environments. Scientific expertise, operational excellence, digital fluency and human judgment are now foundational across the development lifecycle. AI and advanced technology are shifting work toward high-value activities, enabling teams to focus more time on interpreting insights, anticipating challenges, strengthening stakeholder relationships and supporting better development decisions.

Workforce readiness in an adaptive drug development environment requires:

New capabilities. Organizations are already placing greater emphasis on learning agility, adaptability, integrative thinking and continuous skill development as important indicators of future workforce readiness.

Workforce agility at scale. Talent availability, workforce readiness and organizational flexibility directly influence development speed, execution quality and the ability to scale innovation.

Adaptive drug development depends on technology, data and AI, but it also depends on people who can interpret complexity, build trust, apply judgement and translate insight into action.



Conclusion

Next-generation drug development will not be defined by any single breakthrough in science, regulation or technology. It will be defined by the industry's ability to continuously learn and adapt as all three evolve in real time. The next frontier is a drug development ecosystem where every major patient and site interaction generates decision-grade insights, making trials faster, safer and less burdensome.

In this environment, competitive advantage will belong to organizations that can simplify complexity and translate change into action through adaptive drug development powered by agility that can flex at scale.

SYNEOS HEALTH CONTRIBUTORS

Michael Brooks

Chief Operating Officer

Diana Cucos

Global Head, FSP 360 & Modular Solutions

Gregory Licholai, MD, MBA

Chief Medical Officer

Rajneesh Patil

Head, AI & Innovation | Clinical Development

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Contact us

Syneos Health
1030 Sync Street
Morrisville, NC 27560
Phone: +1 919 876 9300

