CONTROL

CLINICAL TRIAL COSTS WITHOUT COMPROMISE

Manage the high cost of drug development

Navigate the factors driving up clinical development costs and unlock tactics to reduce their impact on your bottom line.

ppd

Predictable and efficient pathways to manage costs

In the constantly evolving clinical development landscape, one challenge dominates: the rising cost of clinical trials. The average price tag to progress a drug from discovery to launch increased from $2.12 billion in 2023 to $2.23 billion in 2024[1].

A confluence of factors has converged to drive up the costs of clinical development. Increasing complexity, along with economic and regulatory changes, makes it more difficult for sponsors to identify and implement predictable and efficient pathways to manage the costs of clinical trials.

To shed light on the drivers of the increasing costs, the PPD™ clinical research business of Thermo Fisher Scientific publishes ***The Pulse***, an annual survey of 150 leaders in biotechnology and pharmaceutical organizations worldwide. This report provides insights into the topics shaping clinical development, including top challenges, influential trends, and factors affecting clinical trial budgets.

As a companion to *The Pulse*, this report serves as a guide for drug developers navigating the rising costs of drug development. Use it to:

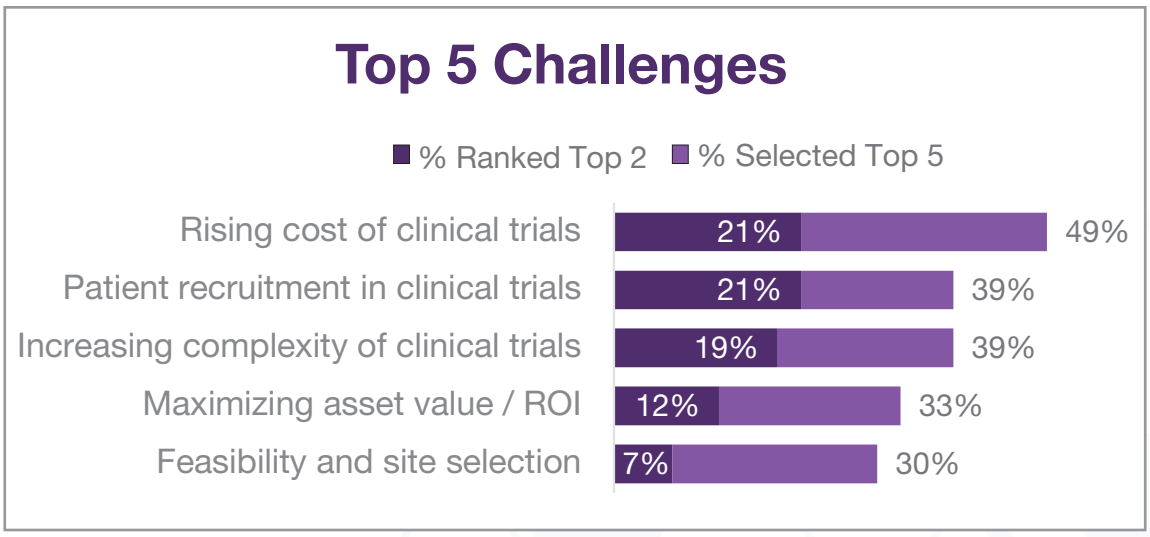
- Understand the key factors impacting increasing clinical trial costs.
- Discover solutions to manage common cost drivers.
- Explore strategies for addressing complexity and cost unpredictability.

To keep clinical trials on a path to success, sponsors must be able to anticipate and identify the consequential challenges that surface throughout the clinical development process and result in significant budget overruns. This report explores the factors responsible for driving up the cost of clinical trials and provides strategies to mitigate their impact.

Rising costs are the top concern

The high cost of drug development is top of mind for leaders across the industry. Asked to choose their top five concerns from a broad list of options, respondents across the board indicate the rising cost of clinical trials is their foremost concern, with one in five ranking it in the top two and nearly half ranking it among the top five.

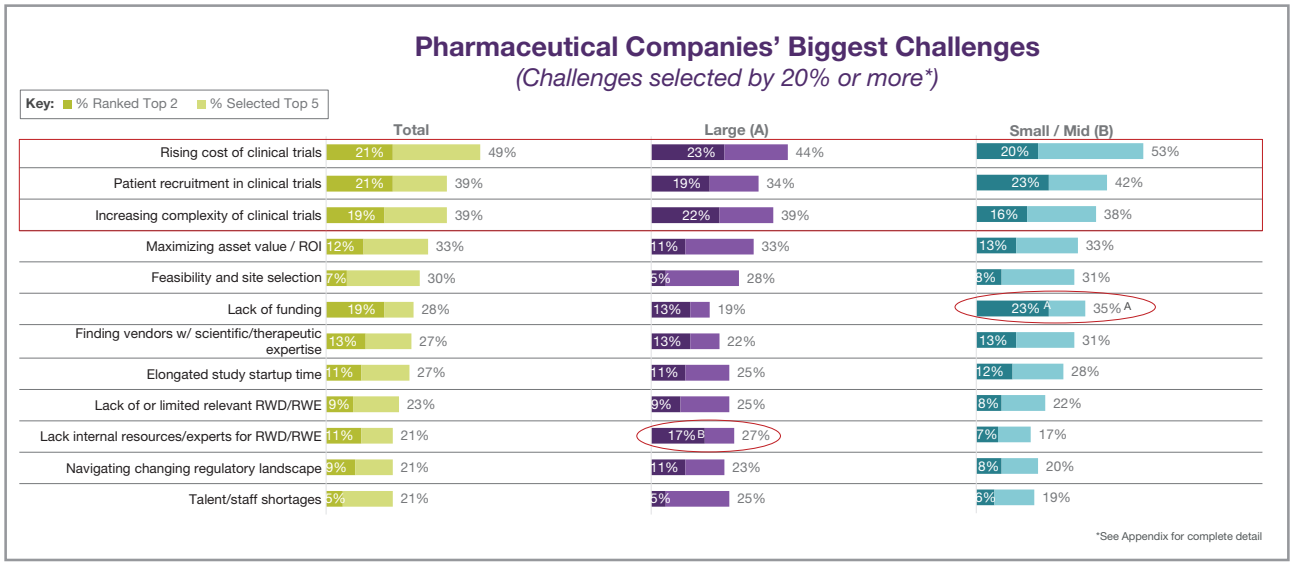
Interestingly, the majority of other challenges rounding out in the top five — patient recruitment, increasing complexity of clinical trials, and feasibility and site selection — are factors that can have significant cost impacts on clinical trials, further underscoring just how much of a concern rising costs are in the industry.



Cost is a universal concern, but the pressures behind it differ

Although respondents from both biotech and biopharma organizations consistently rate rising costs as their top challenge, there are subtle differences between organization types that shape this concern. For example, smaller companies are more likely to see costs as a top challenge than large organizations (53% and 44%, respectively).

However, smaller companies are much more likely than their larger counterparts to cite lack of funding as a top challenge, with 35% of participants from small or mid-sized companies identifying it as a top five concern, compared to just 19% of participants from large companies. Fluctuations in the biotech market can impact investor confidence and intensify the fiercely competitive investment environment biotech companies face. Without stable funding sources, costs become an even more significant concern for biotech organizations.



What's driving the rising costs?

As a complex and multifaceted process, drug development leaves a lot of room for competing elements to exceed budget allocations.

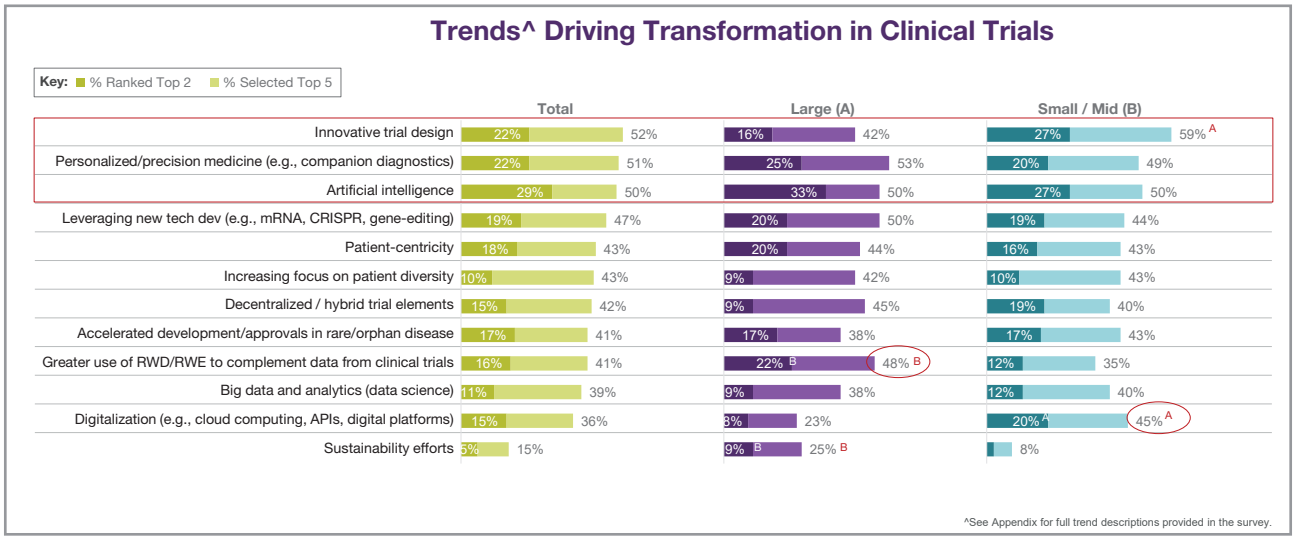
Clinical trial budgets are vulnerable to challenges such as increasingly complex protocols, difficulty recruiting patients, elongated trial timelines, innovative therapy development and regulatory compliance. Each of these factors has the ability to cause slowdowns or necessitate unplanned protocol deviations, which can lead to costs skyrocketing.

Shifts in the macroeconomic environment, such as inflation, recessions and exchange rates, can also have immense consequences for clinical trial costs.

The high cost of innovation

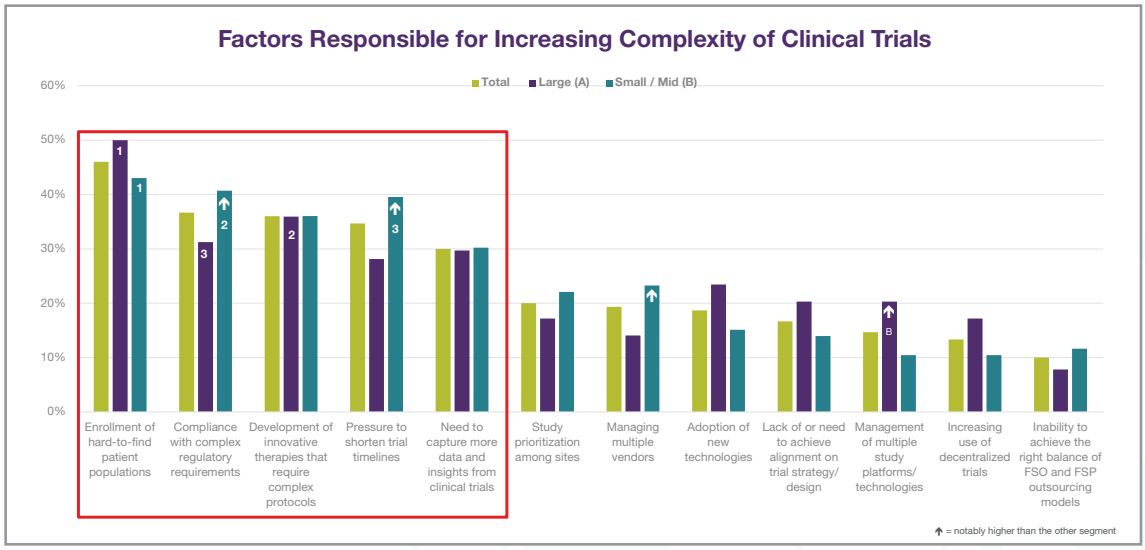
As drug developers feel pressure to adopt a continual flow of emerging technology and innovative tools, it's critical to understand the effect these trends have on trial costs. There is little consensus on which trends are the most impactful, but it's clear that today's sponsors are open to exploring new approaches that enable them to overcome challenges and enhance efficiency.

These innovations, however, come at a cost. While innovative trial designs offer potential savings and precision medicine has the potential for better health outcomes, the complexity of these approaches requires steep upfront costs. Additionally, the transformative power of artificial intelligence (AI) is a hot topic across the industry, but it's often overlooked that implementing and maintaining AI tools and hiring and training staff to effectively use them **can be cost prohibitive**[2] for many organizations.



Trial complexity is straining budgets

Trial complexity — driven by factors like hard-to-reach patient populations, complex protocols and regulatory requirements, and increasing data needs — takes a toll on budgets. As these challenges intensify, the opportunity for costs to balloon becomes even greater, making it imperative to find ways to optimize processes and improve efficiency to control costs.



Five factors driving costs and how to manage them

It's difficult to manage the costs of clinical trials in today's complex and costly landscape, but there are ways to bring therapies to market without breaking the bank.

Our survey of 150 global drug developers revealed key obstacles that affect costs. With an experienced partner, you can anticipate and overcome these cost-related challenges, paving the way for life-saving treatments to be delivered to the patients who need them, on time and budget.

1

Complex protocol designs

Forty percent of drug developers say increasingly complex protocol designs–which can have a direct and cascading effect on multiple trial elements–are the top contributor to the rising cost of clinical trials.

Solution: Comprehensive collaboration during protocol development enables different stakeholders to identify and address any complexity-driven cost drivers before the trial begins. Be ruthless about cutting non-essential complexity early in protocol design to keep trials manageable and budget friendly.

2

Elongated timelines

Longer clinical trial timelines raise costs by extending site payments, project management labor, vendor fees and regulatory overhead–while also delaying revenue from commercialization.

Solution: A laser-focus on streamlining operations, improving patient recruitment and retention, enhancing oversight and responsiveness, and negotiating cost-protective contracts enables sponsors to curb the increased costs associated with elongated timelines.

3

Patient recruitment

Bringing in patients is one of the most expensive and unpredictable parts of running a clinical trial, as evidenced by the more than 30% of drug developers that name it as both a top challenge and key factor responsible for increasing costs.

Solution: Accelerating recruitment timelines is key to keeping costs contained. Improving targeting, streamlining site operations and reducing the time it takes to enroll the trial–as delays are often the biggest cost driver–are strategies sponsors can employ to lower patient recruitment costs.

4

Macroeconomic factors

Several external factors, including broad market, labor and regulatory conditions that affect every step of the trial process, are pushing up the cost of clinical trials across the industry.

Solution: While sponsors can't control macroeconomic forces, they can anticipate, budget for, and mitigate their effects by building flexibility and foresight into trial planning. Model "what-if" scenarios to plan for supply disruptions, major currency shifts or prolonged inflation spikes, and allocate 10–15% of the budget for contingency plans.

5

Regulatory compliance

One in five respondents reports compliance with regulatory requirements as a major factor adding to mounting clinical trial costs.

Solution: Regulatory compliance affects nearly every stage of the drug development process, but sponsors often underestimate its ability to add to clinical trial costs. To prevent these inevitable costs from spiraling, sponsors should treat regulatory strategy as an integral part of development. Engage in early planning, simplify where possible and leverage the expertise of an experienced regulatory partner for the best results.

Three strategies for keeping costs in check

With the average cost to progress a drug from discovery to launch exceeding $2 billion, it's critical that sponsors are mindful of containing costs. Clinical trials combine complex science, strict regulation, large-scale operations and high-risk timelines — all of which require specialized resources and meticulous oversight — and all of which come at a cost.

Awareness of cost drivers and the root causes of cost unpredictability is a must for drug developers. By understanding these factors, sponsors are better equipped to more predictably and efficiently manage clinical trial costs.

1. Design for operational efficiency from the start

Most cost overruns originate in the protocol. Complex protocols involve more procedures, endpoints, and restrictive eligibility criteria that typically result in longer enrollment periods, more sites, the potential for higher screen failure rates, and higher data management costs. This added complexity increases the risk of mid-trial amendments, which are notoriously expensive.

Overly complex designs, excessive endpoints, and narrow eligibility criteria drive up recruitment, site, and data costs. Strategically excising non-essential complexity early in protocol design is an effective way to keep trials on budget.

To design for operational efficiency, sponsors are encouraged to:

- Streamline endpoints and assessments to focus only on what's absolutely essential for regulatory approval and scientific validity.
- Simplify eligibility criteria where possible to increase the eligible patient pool and avoid geographic overexpansion.
- Pilot test protocol feasibility with high-performing sites and get patient advocacy input before launch.
- Use adaptive designs to gather more information per patient and allow protocol adjustments without full amendments.

A leaner protocol reduces site burden, shortens recruitment timelines, and limits monitoring and data management overhead, which can save sponsors a significant sum across a drug development program.

2. Use real-time performance tracking and adaptive resource allocation

Delays — especially in patient recruitment — are a significant driver of increasing clinical trial costs. Every extra month of a trial incurs added unplanned costs that include ongoing site payments, vendor costs and monitoring fees. Sponsors who rely on monthly or quarterly reports often become aware of problems too late.

By tracking key performance indicators of the trial in real time, sponsors are empowered to identify problems more quickly, enabling them to reallocate budget as needed before costs spiral.

To leverage real-time tracking and adaptive resource allocation, sponsors should:

- Deploy dashboards for enrollment, screen failure, site activation, monitoring frequency and budget burn rate.
- Set trigger thresholds to act immediately on underperforming sites (e.g., if a site enrolls less than one patient per month for two months, shift resources).
- Manage recruitment spend geographically or operationally based on live data, not end-of-quarter reports.
- Reallocate recruitment spend dynamically (e.g., move advertising or outreach budget to geographies and sites performing above target).
- Proactively close or replace underperforming sites rather than keeping them on the payroll.

Real-time cost control keeps emerging problems from turning into catastrophic budget overruns. Live performance tracking allows sponsors to identify and solve problems before they snowball, protecting the trial's timeline and budget.

3. Build flexibility and risk management into vendor and site contracts

Macroeconomic volatility, supply chain disruption and labor shortages are inevitable over the clinical trial lifecycle. Without contractual protections, these costs can get passed directly to the sponsor. Flexible, well-structured contracts are essential to protecting clinical trial budgets from external stressors.

To shield against macroeconomic cost drivers, sponsors are wise to:

- Negotiate fixed or capped annual increases for key vendor services.
- Use multi-currency planning and hedging for global trials.
- Include backup vendors and sites in master service agreements to avoid high-cost emergency onboarding.
- Use milestone-based or performance-based payments to align incentives with efficiency.

Contracts that anticipate external shocks are better able to prevent mid-trial cost escalations and give sponsors operational flexibility without reactive overspending.

Manage costs with an experienced partner

Managing the costs of clinical trials shouldn't be a solo pursuit for sponsors. Collaborating with a strong contract research organization (CRO) provides sponsors with a cost predictability partner. Together, sponsors and their CRO partner can strategize how to tackle trial complexity before it starts, stop problems before they become unmanageable and prepare for any potential fallout from external forces.

Collaborating with a CRO brings further cost-related advantages, including:

- **Data and tech stack leverage:** Most CROs have robust tech stacks and extensive operational data across various therapeutic areas and regions, allowing them to use tools to benchmark costs and timelines more accurately and quickly than what most sponsors are capable of internally.
- **Operational know-how:** Rather using time and resources to build operational muscle in-house, sponsors can turn to a trusted CRO that is ready to deploy site networks, patient recruitment tools and vendor relationships to get clinical trials up and running, faster and more cost effectively.
- **Global reach with local expertise:** CROs have the knowledge and experience critical for navigating country-specific regulations, currency fluctuations and patient availability. Without this expertise, sponsors are liable to overlook details that can result in increased costs.
- **Continuous improvement loop:** Whether a clinical trial novice or an experienced hand, a CRO partner has an accumulated a wealth of expertise that benefits clinical development at every level. CROs have the experience to apply lessons learned from past trials to develop protocol designs and operational plans that are less vulnerable to cost overruns.

When it comes to managing costs, the PPD clinical research business of Thermo Fisher Scientific enables sponsors to protect their budgets by more accurately predicting what to expect throughout the clinical development process. Recognized as the No. 1 provider of clinical research solutions, we stay ahead of industry trends and provide the insights and expertise sponsors need to navigate the complex — and expensive — clinical development landscape. With an experienced and agile partner by your side, you'll be empowered to manage costs without compromising the ultimate goal of delivering life-saving treatments to the patients that need them.

Learn more at **ppd.com**

ThermoFisher SCIENTIFIC

Ready to manage your budget with predictability and precision?

Get started today with a partnership that pays off.

References

1. Deloitte, "Global pharma R&D returns rise as GLP-1 drugs help drive forecast growth," 25 March 2025, https://www.deloitte.com/uk/en/about/press-room/global-pharma-rd-returns-rise-as-one-glp-drugs-help-drive-forecast-growth.html
2. Pharma Now., "AI in Clinical Trials: Improve Efficiency and Save Money," https://www.pharmanow.live/ai-in-pharma/ai-in-clinical-trials-enhancing-efficiency-and-reducing-costs

Learn more at **ppd.com**

ppd