

Promise *and* Peril: Navigating What's Next *in* Clinical Research

How Clinical Research Leaders are Addressing
Risk, Redefining Priorities, and Reimagining
Partnerships



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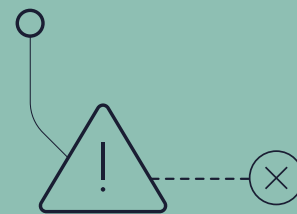
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Introduction

Today's clinical trial sponsors face both unprecedented opportunities and unanticipated obstacles



New technologies, like artificial intelligence (AI) and [digital twins](#), promise sizable R&D efficiencies, while therapies like GLP-1-based treatments for obesity are already delivering massive revenue streams.

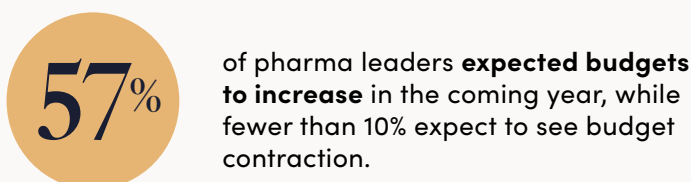
At the same time, headwinds from the Inflation Reduction Act (IRA) are [having negative impacts on profitability](#), with more to come. With rising competition from generics and [biosimilars](#), margins are under pressure across the industry. Drugmakers are spending more than [\\$2.3 billion dollars](#) on average to bring each new therapy to market, despite [trial failure rates nearing 90%](#).

With so much to gain and so much at stake, how can pharmaceutical organizations and their clinical research functions navigate both the promise and the peril? And how can they find the right partners to help them do that more effectively and efficiently?

To find out, we surveyed 500 industry executives coming into 2025. What we uncovered shows an industry that's eager for growth, optimistic about the future and the potential new technologies may offer, but also confronted by some familiar challenges.

Key Findings

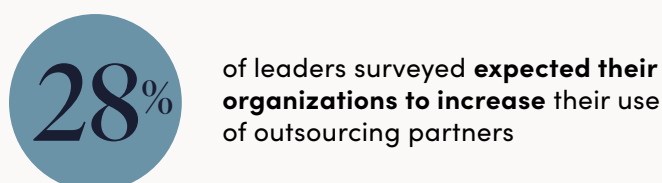
Budgets expand across the board:



Compliance challenges and security concerns linger:



Poor experiences with CROs cause pharma leaders to look for stronger partnerships elsewhere:



but those who primarily rely on CROs are more than twice as likely to report issues with flexibility and scaling as those using standalone FSP partners.

Technology continues to drive innovation:



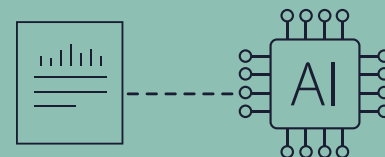
Another **20%** are optimistic about personalized and precision medicine.

Takeaways for Industry Leaders

Among drug development leaders, the mood of the moment is cautious optimism, and organizations are willing to spend more than in previous years to capitalize on the gains offered by new technologies, innovations in trial design, and more. But while they seek new paths to greater efficiency and profitability, they're still searching for solutions to their most pressing challenges. They're also eager to explore new opportunities for outsourcing with stronger, more strategic partners, especially since some traditional outsourcing models have clearly under-delivered in the past.

II. The clinical trials landscape *today*

Budgets expand, outlooks brighten, and optimism around AI is key



Our survey found that pharma leaders were broadly optimistic about the industry landscape coming into 2025 and with good reason.

Despite serious external challenges, like a number of leading drugs coming off patent and increasing competition from biosimilars, [S&P Global](#) expects pharma companies' revenue to continue growing steadily through 2027. Meanwhile, [Deloitte's Q1 2025 forecast](#) found that the average internal rate of return (IRR) for the top 20 biopharma companies continued its upward trajectory throughout 2023 and 2024 following a decade of diminished returns — both very positive signs for the future.

This growth is fueled, in part, by new market opportunities, like the explosive growth of obesity- and diabetes-treating GLP-1 drugs. At the same time, emerging therapies, like [oral selective estrogen receptor degraders \(SERDs\)](#) and [bispecific antibodies \(bsAbs\)](#) for some cancers, may revolutionize areas of oncology and create new market opportunities in the near term.

But despite the promise of new therapies and technologies, the same challenges the industry has faced in recent years were expected to linger through 2025 and beyond.

Expanded budgets may be spent on AI and innovative trial design, though where — and to what end — remain unclear

The widespread optimism felt by drugmakers today can be seen in the broad budget expansion our survey uncovered. Eliassen Life Sciences Solutions' survey of U.S. pharma leaders found that:

NEARLY **57%** expected their organization's budgets to expand at least somewhat in 2025.

"The survey shows that budgets are pretty stable, and that aligns with what we're hearing from clients," said Steven Bené, Senior Vice President, Eliassen Life Sciences Solutions.

To find out where this budget might be spent, we asked pharma leaders to identify the leading opportunities within drug development today.

Where pharma budgets are headed

24% Innovative Trial Design

21% AI

20% Personalized/Precision Medicine

"AI and innovative trial design go hand-in-hand with the positive outlook pharma leaders have for the near future and the fact that budgets are expanding," Bené noted. "Given the way protocols will be likely developed over the next five to 10 years, organizations clearly expect that AI will play an instrumental part in making sure that they can identify better inclusion and exclusion criteria, as well as patient identification, engagement, and retention."

Benefits like these are likely among the reasons why [60% of pharma leaders in a Deloitte survey said they plan to increase investments in AI](#) across the value chain and why the global market for AI in healthcare is expected to reach [\\$188 billion by 2030](#).

But while the potential value of AI in clinical trials is slowly becoming clear, exactly how organizations will implement it is anything but.

"Everyone in pharma is talking about AI and with good reason," Bené said. "Clearly, there are benefits that could significantly enhance outcome assessments, particularly with the widespread use of wearables that provide real time data."

"However, the risks associated with data privacy, errors generated through bias, and global accessibility cannot be overlooked — one size will not fit all."

Data security and regulatory complexity are still a challenge and will likely remain that way

Optimism may be the order of the day for pharma leaders, but the industry still faces a number of headwinds.

When asked to identify the biggest challenges clinical research leaders face, more than a fifth of respondents to our survey (22%) cited meeting regulatory and compliance requirements, followed by ensuring data integrity and accuracy (16.8%) and managing tight budgets and resource constraints (12%).

Top challenges for clinical research leaders



“Each of these may seem like discrete challenges in their own right, but they’re actually interconnected throughout the clinical trial process,” said Antony Goncalves, Managing Director of Biometrics & Data Solutions & FSP for Eliassen Life Sciences Solutions.

“A leading pharmaceutical manufacturer we work closely with has more than 60 separate technology systems that have to integrate in order to gather data on every single patient in a given clinical trial,” she said. “Now scale that across multiple trials, multiple drugs, and even multiple countries. It’s a massively complex environment from a technology perspective.”

When the regulatory component is factored in – which, Goncalves stressed, varies by drug, by country, by whether it’s a medical device or vaccine, and more – the complexity compounds.

“It’s an environment that’s ever-changing, and the

challenges are rarely something you can plan for.”

On balance, however, pharma leaders’ positivity appears warranted. With emerging therapies creating novel opportunities for growth and new technologies poised to deliver more efficient trials, it’s little wonder that the overall clinical trials market is expected to reach almost [\\$100 billion by 2034](#), up from \$59 billion in 2024. To capitalize on that growth and maximize their chances for positive trial results, pharma leaders may want to think carefully about the kinds of outsourcing providers with whom they partner.

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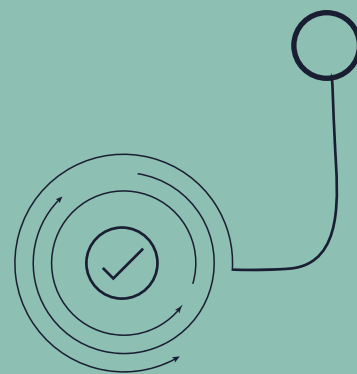
- Antony Goncalves,
Managing Director of Biometrics & Data Solutions & FSP for Eliassen Life Sciences

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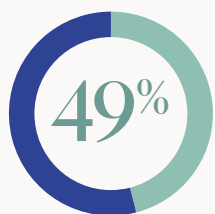


III. Full service, *functional* outsourcing, and the path to more *fruitful* partnerships

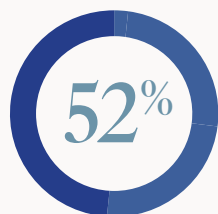
Organizations are staying the course on outsourcing, but all partners aren't necessarily created equal



Our research found that today's pharma leaders aren't just optimistic about thawing budgets and the potential for new technologies. They're also eager to continue leveraging outsourcing partners like standalone functional service providers and clinical research organizations (CROs) during clinical trials.



of pharma leaders surveyed said their **organizations already rely on outsourced solutions to execute clinical trials** today, and that that number is likely to increase substantially in the near future.



of leaders expect their **organizations' reliance on clinical outsourcing partners will either remain static or increase** during the next two years.

But while each of these outsourcing models offers distinct advantages, they also come with their own distinct challenges.

Dramatic differences in priorities lead to different outsourcing choices

A sponsor organization's decision to work with a standalone FSP provider or a CRO may be driven by any number of factors. However, the most important of these factors are a sponsor organization's current priorities and available resources.

Eliassen's research found that:



1/3 of all pharma outsource clinical trials to CROs



48% Large pharma execute trials in-house



23.8% of smaller orgs prefer standalone FSP providers



24% Smaller pharma execute trials in-house

But why do some organizations choose traditional CROs, while others prefer to work with standalone FSP partners?

The primary factors driving outsourcing decisions often reflect competing priorities. Our survey found that more than 80% of organizations that primarily work with CROs cite data security and regulatory compliance as their top considerations when selecting an outsourcing partner.

Meanwhile, sponsor organizations that typically engage standalone FSP providers tend to prioritize cost-effectiveness, access to specialist expertise, and scalability. While the focus may differ, high standards

across all key areas, including compliance and data integrity, remain essential.

"Many sponsors outsource entire trials to CROs through their full service offering, but sometimes, the FSP model is a better fit. While CROs also have this option, it's not their primary focus due to the fact that 90% of their business focuses on the full service model" Bené said. "This is why, when functional outsourcing is needed, a standalone FSP provider is a better choice. They're more dynamic, cost effective, and a higher-touch option."

Today's leading standalone FSP providers can offer a robust pool of talent with demonstrated technical expertise and deep product knowledge. Plus, their solutions should be customizable, configurable, and scalable to fit any need, no matter how large or small.

"Outsourcing doesn't have to be one-size-fits-all," Goncalves stressed. "In fact, it shouldn't be. The right provider should be able to deliver a solution that meets the needs of the organization, the trial itself, and the regulatory and market environment of the moment. As a result, we frequently hear from pharma leaders who are ready to reconsider their outsourcing strategies and form more strategic partnerships."

CROs often promise "one-stop-shop" ease and efficiency — but fail to deliver

The efficiencies offered by CROs can deliver measurable

results, especially for organizations looking to outsource all aspects of a trial. But, as Gonçalves noted, many leading organizations are choosing to explore other solutions instead. The results from our survey indicate why:

ORGS PRIMARILY RELYING ON CROS	ORGS USING STANDALONE FSP PARTNERS
2x more likely to report issues with flexibility & scaling	✓ Report better outcomes with flexibility & scaling
27% report issues with quality	✓ Report better outcomes with quality

Even though the FSO model offers end-to-end trial support that can be appealing for smaller or mid-sized sponsors, many find its promises don't always match reality. These organizations often feel deprioritized, encountering rigid processes and limited flexibility that can slow progress and reduce the impact of their investment. This lack of personalized attention, combined with limited visibility and quality concerns, means that the full-service CRO model often falls short, particularly for those needing agility and close collaboration. As a result, many smaller sponsors are actively seeking alternatives, with standalone FSP providers emerging as a preferred choice for greater control and tailored service.

By entrusting a CRO with the entire trial, pharma organizations often sacrifice:

- **Oversight:** With CROs, trials can become a “black box,” with limited or no visibility from the sponsor organization. Most CROs have their own SOPs and clinical trial management systems (CTMS), which operate outside of a sponsor’s systems and processes.
- **Flexibility:** While FSP partners typically offer sponsor organizations the chance to change, supplement, or augment the team working on a given trial phase or function as the project needs change, CROs do not.
- **Speed:** When challenges appear or changes become necessary, lengthy changes to contract language are often required. This amendment process can take weeks or months, costing the sponsor organization precious time and money — and may even represent lost opportunity.
- **Quality:** CROs often staff trial functions with more junior employees, or whoever happens to be available, regardless of seniority or relevant experience. As a result, the quality of work output may diminish, causing further delays, increased costs, and — often — the sense among a sponsor’s teams that they’ve been victim of a “bait and switch.”

These findings broadly align with a 2022 McKinsey report that found that, across every aspect of clinical trials, [smaller biopharma organizations experience lower satisfaction with CROs than their larger counterparts](#). As a result, many smaller sponsor organizations are rethinking their reliance on CROs.

“Pharma companies of every size often tell us they’re looking to explore standalone FSP providers as a way to mitigate delays in delivery and increase their visibility into the trial process,” Bené said. “And since they know they’ll have more control over the study with an FSP provider, they can have greater confidence in the quality of the work they’ll receive.”

“One of the things we hear most frequently from smaller to mid-sized sponsors is that they don’t feel as though their trials are a priority when working with traditional CROs,” Bené noted. “Because they haven’t received the level of service they were expecting from these relationships, they’re very interested in alternatives to traditional CROs, and for most, standalone FSP providers fit the bill.”

Standalone FSP partners provide a valuable alternative, but misconceptions and lack of awareness may prevent organizations from capitalizing

With so much at stake during the trial process, it’s easy to see why more sponsor organizations are exploring the value FSP partners can offer. In fact, the market size for FSP providers is expected to grow from [\\$15.4 billion in 2024](#) to almost \$27.8 billion by 2032 — a compound annual growth rate (CAGR) of almost 9%.

But while interest and investment in FSP offerings are growing rapidly, their potential value to pharmaceutical companies may not be widely understood. While almost half (48%) of pharma leaders in our survey reported being at least somewhat familiar with the FSP model, a surprising number — almost 22% — said they were generally unfamiliar.

And even when they are at least broadly familiar, some pharma leaders are still unsure of the key advantages a standalone FSP partner can provide. They may even perceive a standalone’s careful approach to resourcing as a delay, rather than an asset.

“Within organizations that haven’t used standalone FSP providers, there may be a misconception that they work just like CROs, with hundreds of people sitting on a bench somewhere, just waiting to go to work,” Bené said. “But leading FSP partners take time to staff a sponsor organization’s team with the right people and skill sets. It might seem like a slower start to the engagement compared to CRO’s FSO model, but it’s really the FSP partner being thoughtful about the sponsor’s team, business needs, and the trial itself. Our average time to fill is 28 days.”

“That means that, in most cases, our resources are deployed, embedded, and productive in less than a month, and the sponsor retains full visibility into their work every step of the way.”

Sidebar: Standalone FSP partners versus CROs:

Key differences *and* competing priorities

Today's clinical trial sponsors have a range of outsourcing models to choose from. While those options aren't limited to just FSP or FSO solutions, these models are among the most common. But choosing the right model — along with the right partner — can be daunting.

How each model works

FSP solutions offered by both standalone FSP partners and CROs allow sponsors to outsource aspects of their clinical trials based on function, while traditional FSO options allow sponsors to outsource the entire trial. But how they operate and the relative benefits of not only each outsourcing solution, but each type of partner, can be dramatically different.

FSOs & CROs

As the most common outsourcing option offered by CROs, the full-service outsourcing (FSO) model gives sponsors the ability to outsource all facets and phases of trial execution. This means they relinquish control over study design, regulatory submissions, site selection and monitoring, data management, biostatistics, and more.

While sponsors using the FSO model get regular reporting from CROs, they have little or no control over how the trial is run and who works on their project.

Benefits of using a CRO for full-service outsourcing

- Requires minimal oversight from the sponsor throughout all trial phases
- Eliminates the sponsor's need to hire to bring critical trial expertise in-house
- CRO manages the trial independently, using its staff, technology, and processes

“Finding an outsourcing provider that doesn't just work on your business but in your business can mean the difference between failed trials and soaring costs or lasting success and profitability.

- Antony Goncalves

FSP solutions & standalone FSP partners

While CROs can offer both FSO and FSP solutions, standalone functional service providers offer unique perspectives and more valuable services to sponsors seeking to outsource discrete aspects and/or phases of a trial.

In addition to the general advantages of leveraging the FSP outsourcing model — as opposed to the FSO model — there are even more benefits in partnering with a standalone FSP provider for functional service outsourcing, especially when compared to CROs.

The most typical of these advantages include the FSP provider operating as an extension of the sponsor's internal team and using the sponsor's systems and SOPs. However, these are far from the only advantages of using a standalone FSP partner when pursuing FSP outsourcing.

Benefits of using a standalone FSP provider for functional service outsourcing

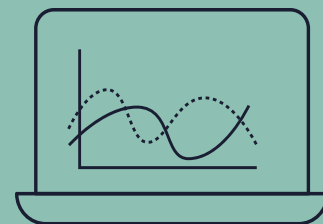
- Offers sponsors more direct access and the ability to work more cohesively with the FSP provider, while maintaining visibility into trial operations
- Standalone FSP partner maintains curated bench of resources, enabling them to provide a better fit to the sponsor's team, business needs, and the trial itself
- Helps the sponsor build and retain internal knowledge and capabilities as existing team members learn from outsourced personnel
- Provides greater budget transparency, since sponsors only pay for resources that are deployed

The right solution for the right problem

The decision to partner with a standalone FSP provider or leverage a CRO for either an FSO or FSP solution is complex. Ultimately, Goncalves said, the right outsourcing solution is flexible and scalable, capable of speeding new drugs to market, and capable of becoming a trusted long-term partner.

IV. The role of the right outsourcing partner in clinical research

Why your choice of partner matters more than ever



Great partners will have a broader perspective on the market and the competitive landscape than a single sponsor ever can.”

– Steven Bené
Senior Vice President,
Eliassen Life Sciences Solutions

With so many opportunities for efficiency and innovation just over the horizon, it’s no wonder that so many of today’s trial sponsor organizations have a positive outlook toward the near future. But turning today’s opportunities into tomorrow’s revenue gains may, more than ever, hinge on those sponsors’ abilities to select the right partners for their unique outsourcing needs.

Key questions for finding the right outsourcing provider

“Evaluating potential outsourcing partners may start with understanding their capabilities, but it doesn’t — or shouldn’t — end there,” Goncalves said. “Capabilities are certainly critical, and sponsors should always look at whether or not a provider has demonstrated successes in the areas they’re looking to outsource, as well as the caliber of personnel they offer to deploy. But those things are table stakes in outsourcing today.”

“The real difference maker”, she said, “is an outsourcing provider’s ability to work not just on your business, but in it and with it, as well.”

“More sponsor organizations today need to look beyond just asking ‘Can they do it?’ and devote more attention to how they do it,” Goncalves stressed. “Case studies and past wins are hugely important, but they rarely answer questions about a potential partner’s processes and priorities — and in today’s competitive environment, those are questions sponsors can’t afford

to ignore.” To understand a potential outsourcing provider’s approach, Goncalves suggested that sponsor organizations should ask the following questions:

- **Are they able and willing to devote the time up front to understanding the needs of the trial, as well as how your organization operates?** “Every organization is different, and every trial is unique in its own ways,” she said. “The right partner will understand that, and they’ll make the time and effort to develop and deploy people and processes that align with your needs, goals, and ways of working.”
- **Do they act consultatively to help you anticipate challenges and mitigate risk?** “Great partners will have a broader perspective on the market and the competitive landscape than a single sponsor ever can,” Bené added. “As such, they should leverage that perspective to help your organization anticipate obstacles, mitigate risks, and manage complexity.”
- **Can their solutions flex and scale with your organization’s changing budgets, timelines, and needs?** “What your trial needs today might not be what it needs tomorrow,” Goncalves noted. “Likewise, budgets and timelines may change. Whether those changes require new therapeutic expertise, more resources, different personnel — or something else entirely — the right partner should be able and willing to craft a solution without lengthy contract amendments or delays.”

Lastly, both Goncalves and Bené agreed that a one-size-fits-all solution rarely meets the needs of today’s sponsor organizations, and may even do more harm than good.

“One thing I tell every sponsor organization I speak with today is that an outsourcing provider that insists on servicing your trial in the same ways — and potentially even with the same people — as another isn’t truly acting in your best interest,” Goncalves said. “They’re acting in theirs.”

Methodology

From October 6 to December 1, 2024, Eliassen surveyed 500 employees in the U.S. pharmaceutical, biotech, and life sciences sectors. The online survey, fielded anonymously, collected responses from participants within small- to mid-sized (annual R&D spend of less than \$1 billion US) and large (annual R&D spend of \$1 billion or more) organizations.

The research in this white paper excludes responses from participants who identified as senior managers, managers, and entry- and staff-level employees. It includes only responses from directors, senior directors, vice presidents, senior vice presidents, and C-suite leaders. All responses included herein were weighted equally, regardless of geographic location, number of employees, annual company revenue, respondent function or seniority, or other demographic or organizational characteristics.

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