THL Insights

Biopharma R&D Outlook | June 2025

Forward Through Uncertainty

What Biopharma Leaders Are Saying About the FDA, R&D Investment | THL Survey

Key Takeaways

- Recent FDA changes have generated uncertainty across the biopharma sector, with questions mounting around approval timelines, shifting trial expectations, and regulatory consistency.
- In May and June 2025, THL surveyed 100 biopharma decision-makers—spanning early-stage biotechs to top 50 pharma companies—to better understand how today's regulatory and market dynamics are influencing R&D investment.
- Most respondents plan to maintain or grow their R&D budgets, even amid uncertainty—underscoring the critical role that pharma services partners play in helping companies adapt and bring new therapies to market.

In a year marked by FDA workforce reductions, regulatory transitions, and an evolving news cycle, the biopharma industry finds itself navigating a uniquely complex environment. Recent headlines paint a fragmented picture—some citing delays, others touting adaptive trials and faster pathways—and questions persist about how the structure and pace of drug development may shift.

In many industries, this kind of uncertainty stalls progress. But THL's Biopharma R&D Outlook Survey of 100 biopharma decision-makers tells a more nuanced story: one of quiet resilience, cautious optimism, and a market trying to navigate uncertainty rather than wait it out. The bottom line: biopharma companies are continuing to invest in R&D (only 20% expect any level of decreased spend) and new delays aren't as prevalent as headlines suggest (just 22% report having experienced slowdowns).

"There's a lot of noise out there, and we wanted to go straight to the source—to the biopharmas navigating these FDA changes," said Megan Preiner, Managing Director, THL.

"The survey reveals a market in recalibration, where companies remain committed to innovation and show a readiness to adapt—placing CROs, CDMOs, and other pharma service providers in an increasingly pivotal role."

The survey offers a snapshot of how companies across the ecosystem—from early-stage biotechs to top 50 pharmas—are thinking about R&D investment, regulatory shifts, and what's next. Here are the highlights.

R&D Budgets Growing — Especially for Biotechs

Despite broader market volatility, THL's survey shows a generally positive outlook for R&D spend over the next year:

69% of respondents expect R&D budget increases, while 9% will keep budgets flat.

51% expect budget increases greater than 6%.

Only 20% anticipate decreased spend.

The optimism is most pronounced among pre-revenue and early-stage biotech firms—a segment that has endured significant capital pressure in recent years.

"It's encouraging to see that biotech leaders are overwhelmingly leaning into more R&D despite the macro pressures facing the space," said Ben Stern, VP, THL Partners.

"We believe that if good science exists, it will continue to attract funding and continue to advance."

Regulatory Uncertainty Exists, but Actual Impact is Limited

Regulatory uncertainty remains a top concern across the biopharma ecosystem. Growing anecdotal and institutional evidence points to a bifurcated agency in transition—one that is simultaneously accelerating and stalling depending on the context. According to media reports, recent mass layoffs, which have impacted more than 3,500 FDA employees, including senior leaders, have led to delays in trial guidance and clinical feedback loops, particularly for smaller biotech firms. At the same time, new leadership under Commissioner Marty Makary and CBER Director Vinay Prasad is publicly emphasizing expedited approvals, conditional pathways, and real-world data as cornerstones of a reformed process. At a recent BIO conference, Makary affirmed that the agency is on target to meet Prescription Drug User Fee Act (PDUFA) approval decision targets.[i]

Just 10% of respondents view recent structural and policy changes at the FDA as positive. Sentiment is especially strained among those working in rare disease therapies (70% negative) and CNS (64% negative)—two areas often at the forefront of innovation and regulatory complexity.

Still, only 22% of respondents report direct experience with FDA-related delays. This stands in contrast to the 77% who expect a slowdown, suggesting that fast-moving headlines and policy shifts may be shaping outlooks more than facts on the ground.

"Uncertainty around delays is far more widespread than the actual experience of it," said Preiner.

"That mismatch is meaningful, especially for companies making long-term decisions. It speaks to an industry that's on alert but still pressing forward."

Innovation Remains Active Across Biopharma Ecosystem

Generally speaking, biotechs tend to be more bullish, while large pharma remains more cautious in outlook. Survey data reflect this dynamic while also signaling growing optimism across the wider biopharma landscape:

76% of pre-revenue and early commercial-stage companies expect to ramp up development.

63% of top 50 firms anticipate growth in development activity.

"We're seeing both ends of the ecosystem—nimble biotechs and established pharmas—lean into development in their own ways," added Joshua Nelson, Managing Director and Head of Healthcare, THL.

"This research reinforces our view that their collective efforts are strengthening the entire biopharma value chain."

Looking Ahead: Trusted Partners in a Shifting Landscape

As regulatory ambiguity continues to shape the drug development landscape, biopharma companies aren't pulling back—they're adapting. And behind that adaptation is a growing reliance on the partners who help make progress possible.

In a sector where scientific discovery is the first of many steps, pharma services providers play a critical role in transforming R&D investment into real-world impact. From navigating regulatory hurdles to scaling manufacturing and enabling commercialization, these partners are the connective tissue that helps biopharma companies bring therapies from the lab bench to the patient bedside. As the industry adapts to uncertainty, their value—as enablers of speed, precision, and access—has never been more essential.

THL's survey confirms this trend, with 61% of biopharma decision makers reporting that they intend to maintain or increase their current spend with outsourced clinical resource organizations (including fully 35% of those who expect R&D budgets to decrease.)

Companies like **Adare Pharma Solutions, CSafe Global,** and **Red Nucleus** are enabling forward momentum across the value chain.

> **“In our roughly 25 years investing in pharma services, we’ve seen our share of ups and downs in the market,” said Nelson.**
>
> **“Today, we see an industry that’s not pulling back—it’s steering into the storm. Science is moving forward, companies are still investing, and the demand for trusted partners has never been greater.”**

To learn more about THL’s perspective on drug development and our experience in **Pharma Services,** contact the Healthcare team.

Joshua Nelson

Managing Director,
Head of Healthcare

jnelson@thl.com

Megan Preiner

Managing Director

mpreiner@thl.com

Ben Stern

Vice President

bstern@thl.com

Survey Methodology

THL’s Biopharma Outlook Survey was conducted by THL in partnership with AlphaSights between May and June 2025. It captured responses from 100 biopharma decision-makers across clinical operations, development, and vendor management. Respondents represented a balanced mix of pre-commercial biotech firms, early commercial-stage companies, and large global pharmaceutical organizations. The survey was distributed via a secure online platform and included quantitative questions about FDA sentiment and R&D outlook.

[i]Drug Development Is Slowing Down After Cuts at the FDA,” WSJ, April 17, 2025; "FDA’s Prasad Vows to Make Rare Disease Drugs Available at ‘First Sign of Promise,” BioSpace, June 2025.