WHITE PAPER

Biotech challenges and the crucial role of CRO partnerships

A KEY QUESTION

How can strategic engagement with CROs provide success for emerging biotech companies?

KEYWORDS Biotech, CRO Partnerships, Funding Challenges, Regulatory Hurdles, Innovation, Operational Efficiency

Biotech companies are playing an increasingly crucial role in drug development. In fact, larger pharmaceutical companies are finding that they are relying more and more on these smaller, more agile firms to drive innovative new therapies and fuel their pipelines.

Biotechs, defined here as emerging pharma companies with an R&D expenditure of $300 USD million or less, demonstrate an entrepreneurial spirit with the flexibility to address complex healthcare challenges through novel scientific approaches.

Emerging biotech companies rely heavily on outsourcing for various reasons, including limited internal resources, flexibility of scale, cost-effectiveness, finding specialists in particular fields, and strategic guidance. Outsourcing can help manage costly clinical development processes, allowing biotechs to focus on their core scientific research capabilities while still enabling them to navigate complex drug development landscapes. For the biotech, having a dedicated CRO as a long-term collaborator transcends the complexities of managing multi-country trials, offering deep knowledge for navigating investor and funding opportunities, asset prioritization, and regulatory and licensing strategy. Moreover, such a long-term collaboration can ultimately foster a transparent and synergistic relationship that evolves and scales together.

For all parties concerned, the primary goal is to maximize resources while maintaining high-quality, efficient drug development that can address unmet medical needs, particularly in specific areas such as rare diseases and oncology, where traditional pharmaceutical approaches often fall short

Fortrea

1. The importance of biotechs in drug development

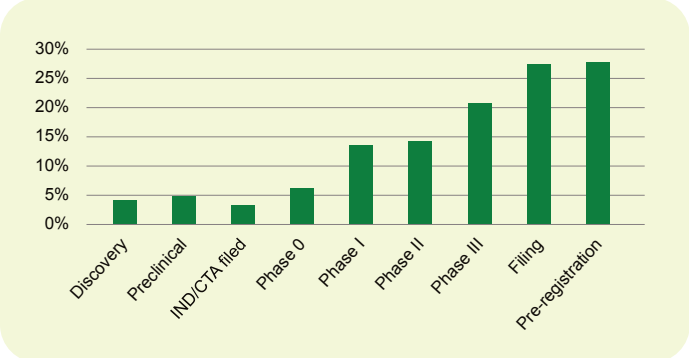
Biotechs have emerged as key players in helping the pharmaceutical sector overcome many of the complexities of developing effective and affordable medications. By leveraging cutting-edge technologies, including gene editing and advanced data analytics, biotechs innovate and streamline the drug discovery process, potentially making treatments more affordable and more widely available. This innovative approach establishes biotechs at the forefront of precision medicine and personalized therapies, supported by advancements in genome mapping and molecular biology.

The role of biotechs

According to data from GlobalData, just 5% of innovator drugs in today's drug development pipeline originated from the 50 pharmaceutical companies with the highest R&D expenditure, revealing that newest drug development now takes place within smaller, emerging companies.

Figure 1 provided by GlobalData shows a breakdown of today's drug development pipeline, highlighting the proportion of innovative drugs in each stage of development that are sponsored by these large companies. As the stages of development advance, the top 50 companies begin to play a more significant role in bringing innovative treatments to market, sponsoring 21% of the drugs in Phase III and 28% of those in pre-registration compared to just 5% of those in preclinical, for example.

Figure 1: The percentage of pipeline innovator drugs sponsored by top 50 companies for R&D spend

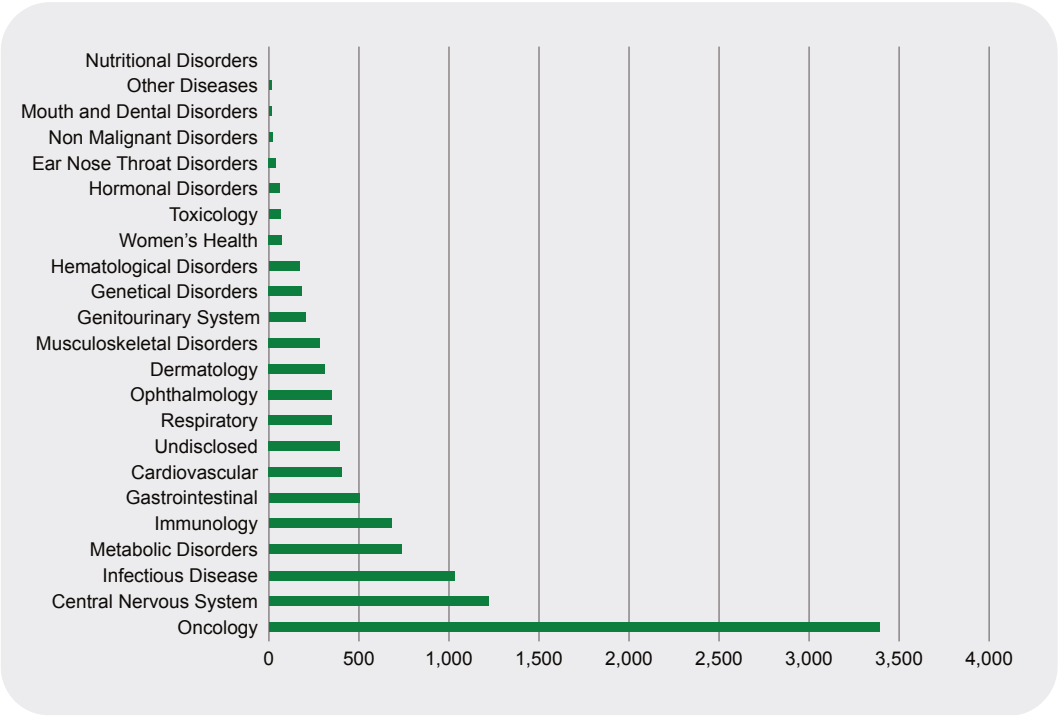


Inside the biotech pipeline from discovery to approval

As of April 2025, GlobalData's drugs database includes 8,684 investigative drugs under active development by emerging biotechs, almost half of which (46%) are in the preclinical stage of drug development, while 22% are in discovery. Of these developmental drugs, 57% are sponsored by companies who currently have no approved therapies in their portfolio, while 41% of the drugs are sponsored by firms who have never made it to Phase III trials.

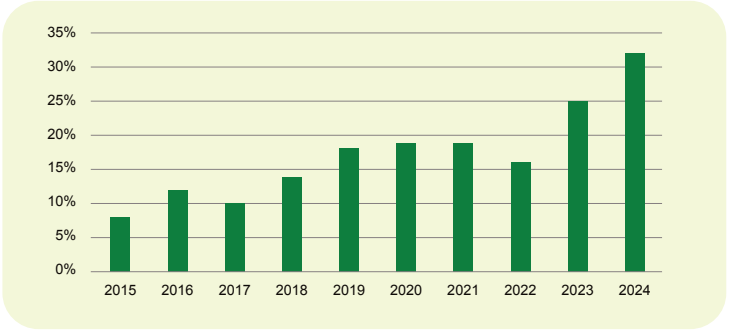
Biologics make up 57% of the innovative drugs under development by emerging biotech companies, followed by small molecules at 39% and oligonucleotides at 3%. As shown in **Figure 2**, biotech companies have a key focus on oncology research, which dominates their pipeline.

Figure 2: Innovative pipeline drugs sponsored by biotechs by therapeutic area



Lacking the resources for late-stage clinical trials, commercial-scale manufacturing, and multi-country drug launches, biotechs often sell the rights to their investigative drugs to larger pharmaceutical firms midway through the development cycle. This helps the biotech secure upfront payments for their discovery, while big pharma strengthens its pipeline via the acquisition of promising therapeutics. Nevertheless, the role of emerging biotechs in advancing drug approvals saw a significant increase in recent years. This can be seen in **Figure 3,** which tracks the percentage of innovative drugs approved in the US and currently marketed by biotechs each year since 2015. The chart shows that 2024 was a strong year for biotech approvals, with these companies accounting for 32% of the drugs approved by the FDA—a 300% increase from the 8% in 2015.

Figure 3: Percentage of innovative drug approvals by the FDA for biotech sponsors year on year



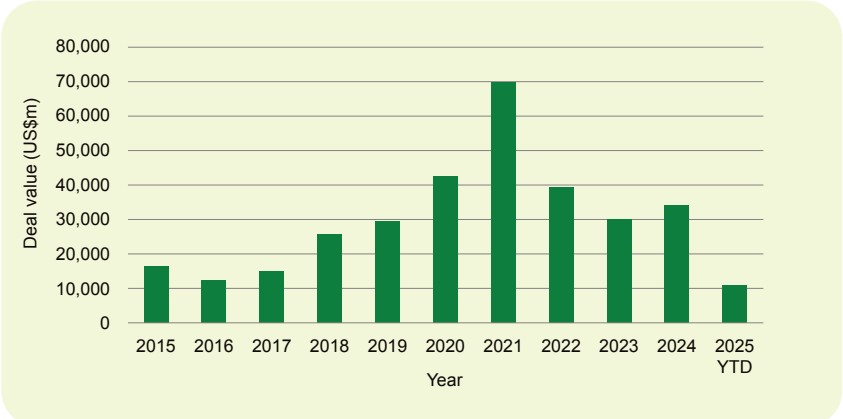
A dynamic deals landscape

At the same time, the volume of licensing agreements within the industry has recently declined, with large pharma organizations showing greater selectivity and opting for fewer but higher-value deals with stronger risk-adjusted returns. For instance, according to GlobalData's deals database, the value of licensing agreements for preclinical to Phase II-stage assets soared to $180.1 billion in 2024—the same year that the volume of such deals hit its lowest point across the decade.

Figure 4: Licensing agreements for preclinical to Phase II-stage assets

Meanwhile, recent venture financing activity highlights a challenging few years for these companies, with biotech funding seeing a marked downturn in 2023 (**Figure 5**). This is attributed to a combination of high inflation, rising interest rates, overvaluation of biotech firms, geopolitical instability, and a shift in investor focus toward existing assets. In 2024, deal value increased by 14% from 2023 figures, suggesting signs of a recovery.

Figure 5: Venture financing value (US$m)



Despite a collectively more cautious investment environment,[1] the 2025 edition of GlobalData's State of the Biopharmaceutical Industry survey showed 50% of respondents expressed an optimistic, or very optimistic, sentiment about the recovery of biotech funding over the next 12 months. Further, a high percentage of the survey respondents (45%) viewed enhanced industry partnerships as being the most helpful measure for mitigating this downturn in biotech funding, while 23% said it was improved access to investors.

According to the report: "Respondents favoring enhanced industry partnerships may indicate a shift in alternative sources to secure capital and may drive an increase in more partnership and licensing agreement deal-making between large pharmaceutical and biotech companies in order to sustain innovative drug development while mitigating R&D costs."

There are other positive indicators of a recovery, particularly in the US. According to the GlobalData report Cell and Gene Therapies: Current and Future Landscape, the US biopharmaceutical market saw a 46% ($2.8 billion) increase in deal value compared to Europe. There are currently more than 1,500 US venture-backed private companies with an active innovator drug, compared to more than 700 in Europe.

Venture capital funding has been essential to maintaining biotech innovation. Future biotech investment requires alternate funding sources, such as improved industrial alliances, government subsidies, and R&D tax incentives, as well as a stable market and a reduction in inflationary pressures. However, with recent events around tariffs, the US pharmaceutical industry is currently readying itself for a potential disruption in manufacturing due to the increased cost of imported products, despite the avoidance of direct tariffs on drug imports.[2] The recent events also created uncertainty in the economic environment, potentially impacting biotech investment decisions.

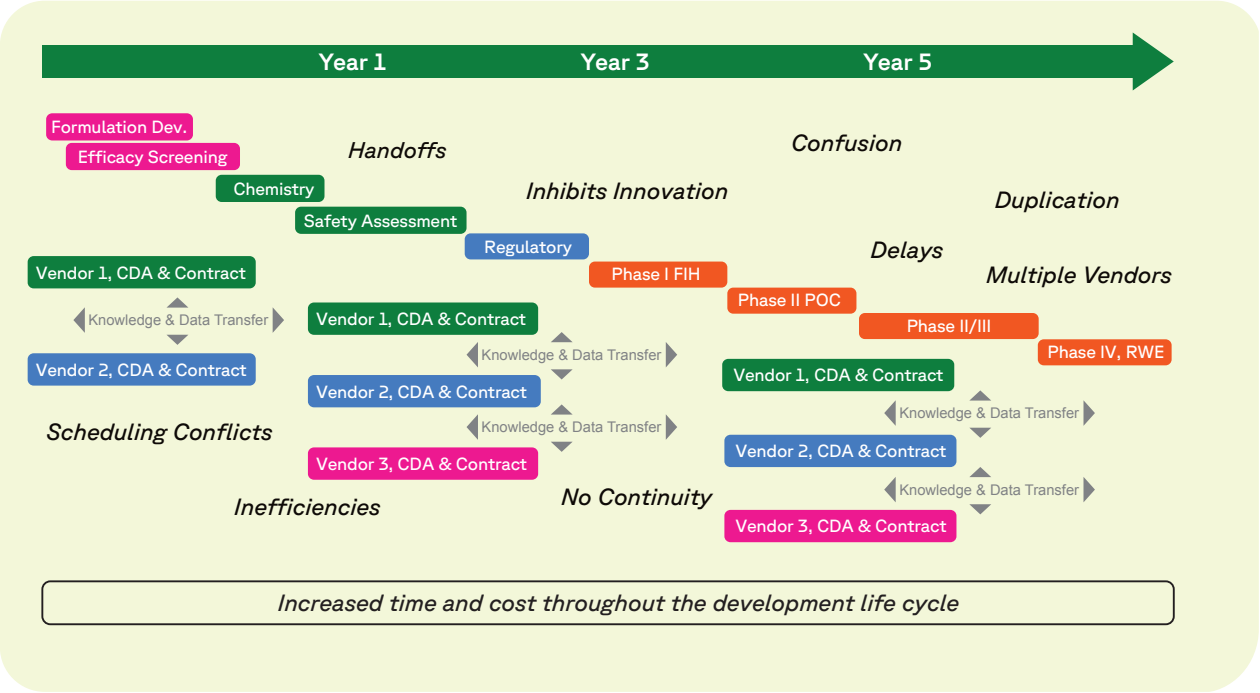
According to Ophelia Chan, senior analyst at GlobalData Healthcare: "Rising operational costs, shifting trade policies, and a downturn in biotech stocks are heightening investor caution. These factors increase the risk of a US recession, contributing to a more volatile funding environment in the near term. At this stage, investors are likely to adopt a wait-and-see approach as the long-term impact of these tariffs remains uncertain," she notes. **"However, we anticipate that the Federal Reserve may respond with more aggressive rate cuts this year, prompting investors to reassess their capital allocation strategies within biotech."**

2. Challenges faced by biotechs

Biotech companies face a multitude of challenges that can impede their growth and innovation. These include managing multiple vendors, navigating funding difficulties, and complying with stringent regulatory requirements. Drug development is a complex process that requires significant financial investment, taking around 10-15 years to create a new therapy,[3] with a high risk of premature failure. Addressing these challenges effectively is crucial for sustaining competitiveness in the ever-evolving biotech landscape.

One challenge is that biotech companies often rely on multiple vendors to augment operations, R&D, and manufacturing activity. For example, in the transactional outsourcing model, the biotech company is tasked with finding, managing, and tracking numerous vendors and coordinating knowledge and data transfers between these providers on a study-by-study basis. This hampers continuity between each phase and inhibits overall productivity and efficiency, increasing white space in the development lifecycle and diverting the biotech's focus from core innovation efforts early on. In later trials, delays and duplicated efforts become common as additional specialty vendors are brought in to support specific aspects of studies, as represented in **Figure 6.**

Figure 6: Transactional study outsourcing challenges
"Study-by-study" Bio-pharma-managed CRO business model



In addition, to attract funding and partnerships, biotechs need to keep up with emerging technologies and demonstrate innovation. The rapid advancements in biotechnology necessitate continuous investment, and biotechs must significantly invest in research and development to remain competitive. But, if new products and technologies do not gain market acceptance, it can adversely affect profits, creating a risk for companies that may already be in a loss-making phase during development. This cycle can hinder innovation as companies become hesitant to invest in new technologies due to the fear of failure. Further, funding tranches are usually dependent on achieving specific milestones, so limited resources mean biotechs must carefully choose which assets to pursue.

Another main challenge is around regulatory requirements. The biotechnology industry is heavily regulated, with numerous local, state, federal, and international laws governing product development and commercialization. Compliance with these regulations is paramount; failure to adhere can lead to significant operational and financial repercussions. As the asset development requires more focused regulatory guidance and approaches, working with multiple vendors can inhibit innovation as continuity between each phase of development is hampered

Additionally, the complexity of regulations around biologics, which dominate the biotech pipeline, is often more extensive than that for other pharmaceutical products due to the complexity of their manufacturing processes and the need for detailed documentation in the Biologics License Application (BLA), along with rigorous oversight by regulatory authorities. These factors contribute to a more comprehensive regulatory framework for biologics compared to other pharmaceutical products and careful, strategic planning is required for clinical trials and regulatory submissions.

All these challenges make biotechs highly dependent on strategic partnerships and innovative approaches to survive, advance, and succeed.

3. The need for strategic engagement

Contract research organizations (CROs) play a crucial role in the drug development process by offering specialized services that biotechs may not have the resources or expertise to handle internally. For instance, many smaller biotech companies lack the infrastructure and personnel to conduct clinical trials in-house. CROs offer scientific, operational, and regulatory knowledge and facilities to manage trials effectively. This is particularly important for virtual biotech companies that have minimal overheads and no wet labs, as they outsource their drug development to CROs to avoid unnecessary capital expenditure.

Biotechs often engage with CROs to tap into their extensive know-how, manage costs, and access specialized services. This collaboration allows biotechs to stay focused on their core strengths like drug discovery and development. CROs offer a range of specialized services such as regulatory support, patient recruitment, and data management, while also providing the flexibility to scale operations based on trial requirements—a crucial aspect of managing the dynamic nature of drug development. Additionally, CROs often have a global presence, making them advantageous for conducting multinational clinical trials, navigating different regulatory environments, and accessing diverse patient populations.

To support biotechs in their journey towards success, it is essential for the CRO to act as a true ally; thinking like a drug developer and providing holistic, comprehensive support. This includes funding navigation, asset prioritization, regulatory strategy, technological solutions, risk sharing, and a focus on milestone achievements. These services enable biotechs to solve broader business challenges beyond their clinical development, helping them generate compelling narratives for investors and navigating complex regulatory landscapes.

4. Fortrea's collaboration models

Fortrea is a leading global provider of clinical development and patient access solutions to the life sciences industry and a key asset to emerging and large biopharmaceutical, medical device, and diagnostic companies, with over 30 years of experience in the space. More than 85% of the company's client base are biotech customers who benefit from Fortrea's flexible models and comprehensive support, including risk sharing, funding support, technological innovation, and regulatory and commercial guidance.

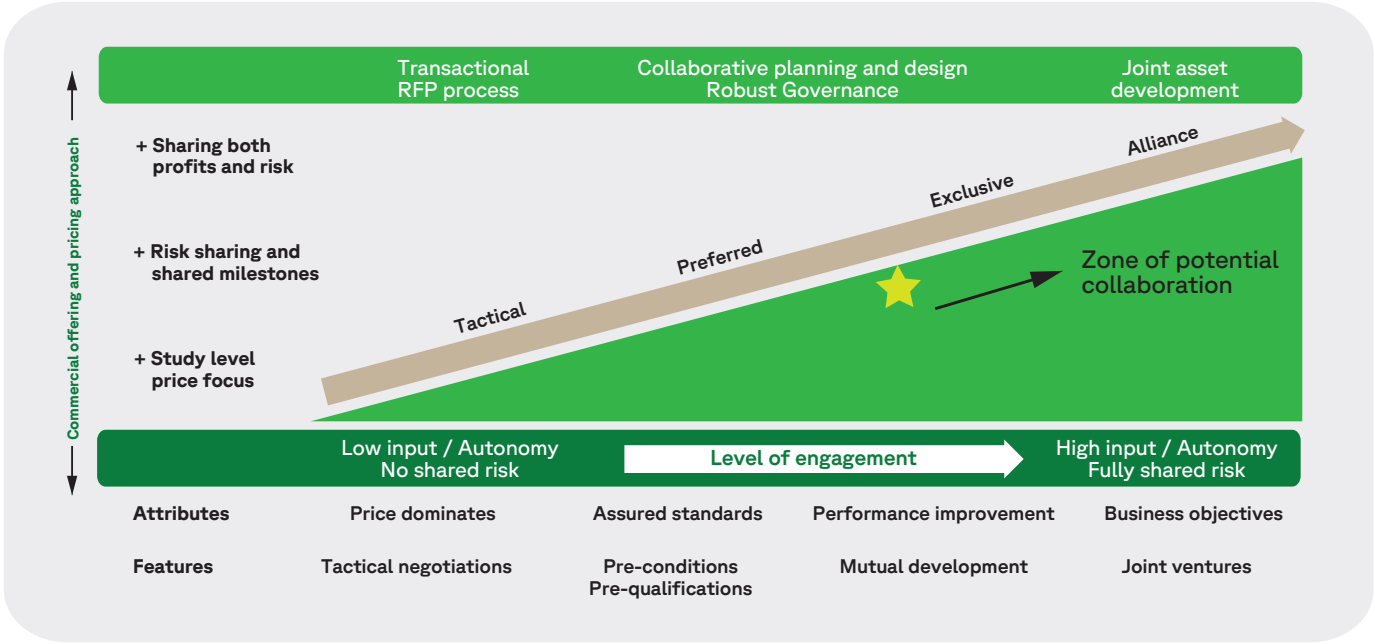
Fortrea provides tailored approaches based on specific biotech needs, ensuring adaptability to different stages of development. The company's full service outsourcing (FSO) solutions are generally best-suited for emerging biotechs without an internal oversight structure, and the functional service provider (FSP) model is often availed by more established biotechs with some internal resources that they wish to supplement. The flexibility of hybrid outsourcing can be instrumental for biotechs seeking a strategic and fully customized combination of in-house and outsourced services to optimize cost savings and time-to-market. Whatever the model, Fortrea's unwavering commitment to being goes beyond traditional CRO services and actively supports biotechs' success from multiple angles.

Sharing the risk

In addition, Fortrea's risk sharing models focus on establishing shared objectives that drive the success of the collaboration by adding an element of accountability for the Fortrea team. By taking on some of the financial risk of the project, Fortrea becomes even more invested in the biotech's success, helping to take performance, quality, and timeliness to new highs.

Depending on the model itself, it may also help biotechs with limited budgets to defer or reduce their upfront payments in exchange for milestone-based compensation. Each risk sharing model is tailored to the biotech's unique needs, reflecting their development journey, value inflexion points, project specifications, and key milestones.

Figure 7: Flexible strategic partnering models



Helping biotechs access capital

Since securing funding across the various stages of drug development is one of the key challenges faced by the biotech market, Fortrea's private equity/venture capital engagement solutions can be instrumental for increasing these companies' chances of success. This solution incorporates an investment network approach, which leverages existing relationships with private equity and venture funds to introduce biotechs to trusted investment opportunities. It also includes investment story development, asset prioritization, funding navigation strategies, risk mitigation techniques, commercialization potential assessment, and market positioning. The primary goal is to make biotechs more attractive for investors by addressing investors' concerns and highlighting the potential of their research assets.

According to Samir Kagrana, Global Head of Strategic Deals at Fortrea, "Recent geopolitical developments and the uncertain regulatory landscape have put tremendous pressure on several innovative biotech companies (especially those from the Asia-Pacific region) for global capital access. This has led to several companies pursuing a NewCO strategy for cross-border investor participation and mitigation of regulatory and operational risks amidst evolving geopolitical and market dynamics."

Fortrea assists biotechs in generating funding through various other strategies. These include credibility enhancement, strategic asset prioritization, comprehensive evaluation support, implementation of the NewCO strategy, risk mitigation strategies, and a milestone-based funding approach. Fortrea helps biotechs identify promising research assets, analyze market viability, and generate evidence for investors.

The ultimate goal is to be a strategic partner that helps biotechs overcome challenges and maximize their potential for success. The company provides comprehensive support, risk management, and technological innovation, including the use of AI. Fortrea integrates AI-driven solutions to enhance clinical trial efficiency and provide predictability and transparency. The company's skill set includes clinical, medical, and commercial perspectives, bringing specialized regulatory and market knowledge.

5. Conclusion

Emerging biotech companies often rely on outsourcing for flexibility, cost-effectiveness, and finding specialists in specific fields. A CRO can proactively anticipate downstream challenges and provide a multi-disciplinary approach, considering the entire drug development journey from bench to market. This approach minimizes trial design risks and maximizes continuous scientific dialogue as the strategic relationship gains momentum. A CRO should have a drug development mindset that embraces the sponsor's goals as if they were their own.

A dedicated CRO, such as Fortrea, serves as a long-term ally to seamlessly navigate the complexities of drug development that can otherwise impede the biotech's growth and innovation. When most effective, such partnerships are built on flexibility, ownership, creative problem solving, and mutual trust, and can be crucial for sustaining competitiveness in the ever-evolving biotech landscape.

To find out more about our services and scalable, flexible delivery models for biotechs, please get in touch at **fortrea.com**

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