WHITE PAPER

Tips for Securing Funding and Providing Confidence to Investors

How partnerships with CROs advance biotechs in the race to secure capital

In 2023, the PPD® clinical research business of Thermo Fisher Scientific surveyed 150 global drug development leaders to assess industry trends, challenges and sentiments. The survey revealed that nearly 40% of respondents from biotech companies reported lack of funding as one of the challenges facing their organization.

A risk-averse financial climate, paired with a growing industry and a decline in biotech investing at scale, has created a difficult and competitive environment for emerging biotech companies that rely heavily on outside investors to bring new assets to market. As such, the recipe for success requires biotech companies to stand out among the sea of noise, bringing heightened assurance to investors that their projects will succeed.

This paper explores:

- The current and future state of the investment landscape,
- How biotech companies can become more attractive to investors, and
- How to bring clarity, speed and assurance to venture capital partners.

A Market in Flux

The financial landscape has seen high highs and low lows in recent years. The height of the COVID-19 pandemic brought record dollars flowing into biotech companies as global investment in the clinical development space soared. However, that bubble burst as the public market downturn hit in mid-2022, followed by a hard downturn in clinical development funding.

The environment remains challenging today and investors and drug developers alike are sitting on the edge of a significant capital deployment gap. While optimism and a return to normalcy are slowly growing, investors remain cautious to deploy the record amounts of money raised into funds in 2022. As venture capitalists (VCs) look for the initial public offering (IPO) window to reopen and watch the momentum in mergers and acquisitions (M&As), biotech companies are facing increased competition for available dollars, and intense scrutiny over the management and outcome of the investments they receive.

A recent study[1] by HSBC's innovation banking division found that early investment in biotech startups is on pace to decrease 40% compared to 2022, and 55% compared to 2021. Overall investments are also down, with a projected fall by more than half compared to the past three years. These trends signal a commitment to caution that emerged after the sector's peak, and for now, seem here to stay. In today's economy, VCs remain hesitant to take on emerging biotechs or new modalities as they focus on keeping their existing portfolio companies afloat. If they do back a new company, they are focused on minimizing risk by partnering with experienced teams.

For biotechs, the pressure is on to come to the table with solid clinical and financial data, strong planning and study design, and the backing of an organization that can fill gaps and supplement expertise.

Partnerships Make Biotechs More Attractive to VC Firms

As VC firms look for certainties in an uncertain market, emerging biotechs can benefit from the resources, expertise and longstanding reputations of contract research organizations (CROs). Strong CROs offer decades of experience navigating the evolving clinical development and financial landscapes, and typically, have developed relationships with VCs along the way.

For biotech companies, the benefit of aligning with a trusted CRO partner goes beyond the potential for growing their networks and gaining valuable introductions to investors.

Confidence Transference

In the current financial environment, VCs are more likely to double down on their existing assets rather than invest in a new, and potentially risky, company or therapy. This caution doesn't bode well for biotechs looking to break into the clinical development space or branch into new indications or treatments. While emerging biotech companies lack familiarity and trust from VCs that only years of positive dealings can provide, established CROs bring an element of stability and experience that proves crucial to building spend confidence.

When a CRO with a longstanding reputation for quality and success agrees to partner with a new biotech company, the CRO's belief in the project and ability to supplement resources and expertise translates to lower executional risk for the VC. Essentially, the VC can rest easier in their investment knowing the development is in experienced, trusted hands.

In a risk-averse market, the backing of a well-known CRO lowers the risk of new assets by giving investors the security of an established company that has stake in the biotech's success.

Capital Efficiency and Return on Investment

Reducing costs without sacrificing quality is essential to clinical development study success. It also drives return on investment (ROI), which benefits all parties and is paramount to securing funding and growing VC confidence.

The need to demonstrate asset value and ROI was reported as a top challenge facing nearly one in three (30%) respondents of our 2023 report, The Pulse: Global R&D Insights in Pharmaceuticals. Partnering with a CRO bends the cost-time curve, particularly when large organizations coalesce contract development and manufacturing organization (CDMO) and CRO services. A single CDMO-CRO vendor drives time and cost efficiencies through product continuity and creates economies of scale by powering clinical programs from research/discovery through commercialization/production, all under one roof.

Ultimately, VCs want positive return on capital investment. Partnering with a CRO that has a reputation for delivering high-quality performance and capital efficiencies fundamentally leads to better ROI.

Two Critical Factors for Securing Funding

The biotech industry is a growing and crowded space. By some estimates, there are more than 22,000 biotechs worldwide[2], forcing companies to compete for limited funding that's being more judiciously dispersed—and industry growth is poised to continue through the end of the decade. According to Precedence Research, the global biotechnology market is predicted to grow at a compound annual growth rate (CAGR) of 12.8% from 2023[3] to 2030. Compare that to year-over-year investment in the biotech industry at a post-pandemic low of approximately $85 billion to date in 2023[4] (versus nearly $150 billion in 2022), and it's easy to see the disparity.

In such a crowded and competitive environment, biotech companies must find ways to stand apart from their peers to attract VCs and earn the investment needed to move their assets forward.

High-Quality Data Makes the Difference

It's more essential than ever that biotech companies have pathways to generate clinical data and come to the table with as much concrete evidence and proof as possible. The ability to produce strong data will put biotech companies ahead, even if what they have is reliable animal data that guides their Phase I strategy.

Showcasing safety and efficacy data that is easy to understand and digest is critical to securing funding.

From protocol design to regulatory consulting, to advanced disease simulation and modeling, a strong CRO partner will fine-tune specific aspects of your trial strategy to optimize quality data collection. With an eye toward understanding your individual study needs, your CRO partner should bring a tailored approach to data throughout the product life cycle, whether they are optimizing study planning, forecasting performance, mitigating risk in real-time, or leveraging artificial intelligence.

Equally important to strong clinical data, biotech companies should prioritize financial reporting and forecasting to gain advantage when approaching VCs for funding. **A biotech company's ability to demonstrate an understanding of the capital needed to successfully move an asset through the clinical development process and to report on ongoing spend and return, equips VCs with the confidence needed to invest.**

Transparent, straightforward forecasting is critical, especially in early stages when investment funding is limited. Biotech companies can leverage their CRO partner's extensive experience creating custom financial reporting packages to better assess cashflow, helping to avoid surprises.

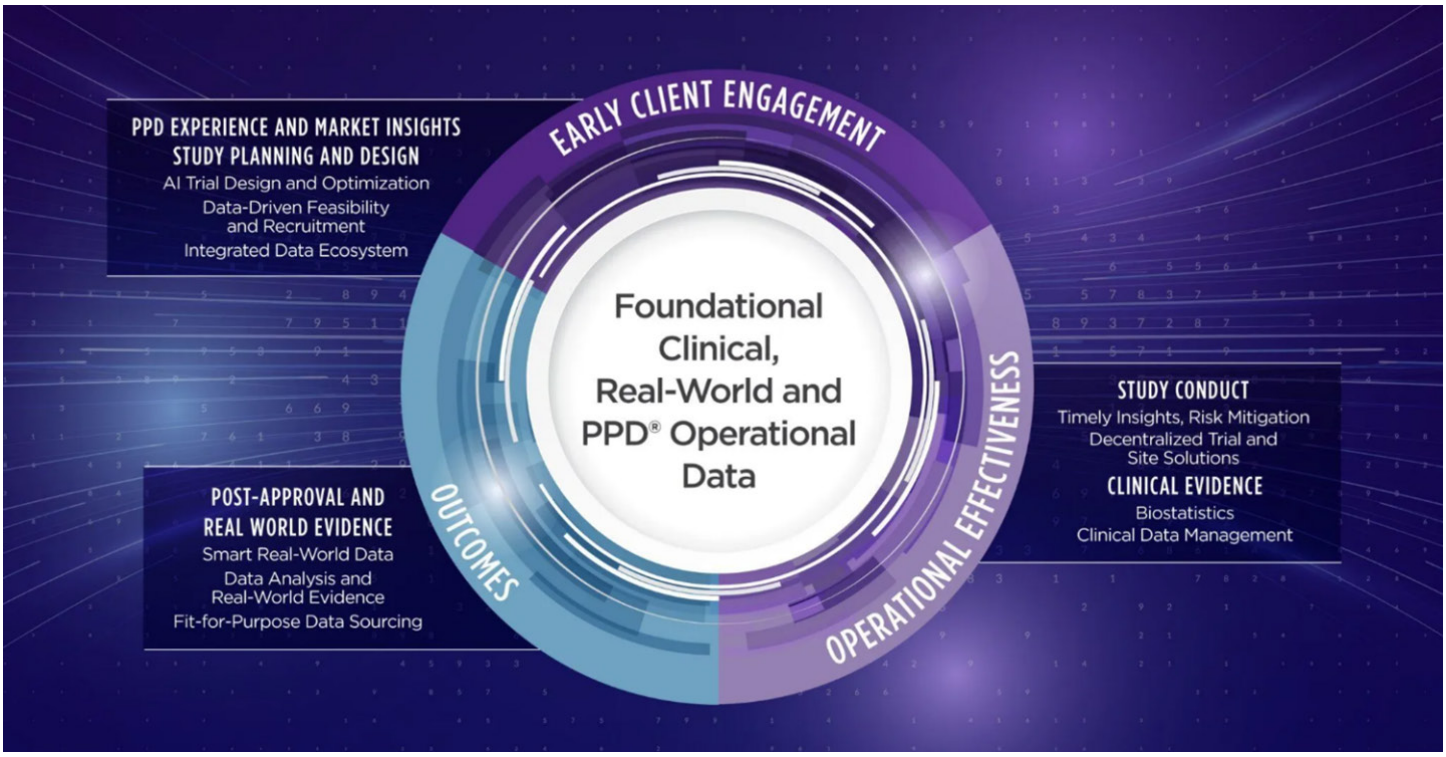

Figure 1 – The PPD clinical research business commitment to data throughout the product lifecycle

Look for a CRO that provides:

- Monthly and quarterly forecasts for the life of the study for all costs
- Individual study reports that roll up into a portfolio view
- Easy transitions from summary values to details
- Scalable and customizable reports

Stand-Out Study Design Drives Confidence

Whether a VC is a seasoned biotech investor or new to the clinical development space at large, coming to the table with a well thought-out development plan is essential for biotech companies seeking investment. If a VC firm is going to invest in the current economic climate, it will be looking for companies that know their market exceptionally well. This means biotech companies must be expertly versed in subjects like their mechanism of action, modality, and regulatory implications and hurdles. Knowledge of and experience in running global trials is also a key factor to earning investment as VCs consider capabilities like the expansion of drugs to new markets and the financial advantages of trials conducted in various locations.

Emerging biotechs will benefit greatly from partnership with a global CRO that has broad early development capabilities. With limited resources and experience, biotechs often struggle with these foundational elements. However, we have seen that when a biotech has the assistance of a strong CRO partner with the tools, staff and expertise to put the essential pieces strongly in place, biotech companies become more attractive to secure VC funding.

Find a CRO that Brings Clarity, Speed and Assurance to VC Partners

With a growing market and a cautious investment landscape, biotech companies are challenged to secure funding from increasingly competitive pools. Only those that demonstrate efforts to mitigate risk and grow investor confidence will succeed in the race toward financial backing. Emerging companies that need funding to move their projects forward in 2024 must find ways to stand out among the crowd of competing assets and voices.

The bottom line: **having a trusted CRO partner creates assurance that assets are being developed in capable hands and will produce a positive ROI.**

Thermo Fisher Scientific's PPD Biotech solutions has been on the leading edge of bringing value to biotech companies for more than 35 years. We've done this by building processes and shifting the mindset of organizations, from senior executives to boots-on-the-ground CRAs, with an aim to simplify the drug development journey of emerging, often under-resourced, organizations.

Our end-to-end capabilities, strong data and early clinical development services bring greater clinical trial reliability and quality, and as a result, enable outcomes that build confidence in investment. We have a longstanding history of working with VC firms to accelerate the biotechs in their portfolio, providing value in the form of capital efficiencies and speed, and have supported more than 500 biotech companies through over 2,500 clinical trials in the past five years.

PPD Biotech solutions has the expertise and resources to enable your success, whether you're new to the clinical development industry or looking to expand. Backed by a reputation for quality and a suite of offerings that span the product lifecycle, our teams empower your company to deliver clarity, speed and assurance to VC partners.

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