FINDING THE RIGHT CRO FOR YOUR ONCOLOGY TRIAL

From dose escalation strategy to site engagement and market approval

PPD® Biotech

Challenges abound for small to midsize biotechs with an oncology asset preparing to enter the next phase in development. The transition from the discovery and preclinical stages to working with a large CRO can be daunting but necessary to advance your product whether your goal is market approval, the sale of your product or an acquisition.

What should you consider when choosing a CRO to help scale quickly, smoothly and successfully? For insight, we spoke with our leaders, Jai Balkissoon, MD, FACS, Vice President, Immuno-Oncology Global Product Development, and Todd Lehman, MS, Vice President, Biotech Portfolio Lead.

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WHAT SHOULD BIOTECHS KEEP IN MIND WHEN SEEKING A CRO PARTNER TO BRING THEIR ONCOLOGY ASSETS TO MARKET?

For these complex studies, it is important to have a CRO with deep oncology expertise across many indications, modalities, targets and mechanisms of action, as well as one that is easily adaptable to novel approaches and changing needs. “Look for a CRO that is able to pivot quickly, whether that means adding cohorts based on emerging data or augmenting your country strategy in-stream,” Balkissoon said. “Quick, real-time discussions help make those rapid changes without losing momentum.” A solid understanding of trial needs ideally comes from robust early engagement.

Early Engagement

Ensure early on that your CRO understands both your company and your product goals. “Often involved in groundbreaking work,” Balkissoon said, “biotech companies must focus on meeting endpoint expectations of agencies while ensuring patient safety and an efficient path to market approval. At PPD Biotech, we work closely with our clients to identify the right designs for their studies.”

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For example, in Phase I dose-finding studies, we collaborate to make critical decisions that will impact the life of the trial, such as:

- Selecting a 3+3, an adaptive continuous reassessment method (CRM) or other statistical design
- Focusing on a maximum tolerated dose (MTD)-based design or an optimal biological dose (OBD)-based design

"Having the right design can often be more efficient at finding the right dose and can reduce costs," said Balkissoon. "We walked through a CRM strategy for a company that was approaching a Phase I/Phase II trial and was initially uncomfortable with an adaptive model. They ultimately saw value in the new approach, which saved an estimated $1.5 million in patient costs and $2 million in timeline reduction."

Development Landscape Insight

While the size of a large, global CRO can be intimidating to an emerging company, it provides high levels of adaptability, stemming from multifaceted knowledge of what is and isn't working in the current development landscape. "For example, we have been able to help smaller clients source tissue for advanced therapies," Balkissoon said. "And with our frequent regulatory engagements, we can see when agencies take a more conservative approach to dose-limiting toxicity (DLT) periods for certain mechanisms of action." A large CRO can help clients plan for and navigate around these challenges.

Global Scale

The same is true for oncology trial strategy and execution — specifically identifying patient sources with confidence. We are seeing more rare genetic marker and specialty therapies. An increasing challenge is that genetic testing may not be standard of care in all places. "Proactively, we have been designing pathways for patients to join registries and get genetic testing," shared Lehman, who leads portfolio oversight for biotech clients, "to build a database of patients who might meet that biomarker requirement for a specific subtype. This allows us to possibly bring these patients into a new clinical study."

"Having boots on the ground makes a tremendous difference in more ways than you would think," said Lehman. "This tends to come with a detailed understanding of the intricacies of site engagement." Growing companies often lack brand recognition with sites. "Our teams understand that it's part of our role to act as the biotech's brand ambassador with sites and investigators," said Lehman. "As a large CRO, our existing relationships with investigators provide an excellent foundation for this."

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Recently, a small biotech had a metastatic breast cancer study that was facing significant recruitment challenges and delays with another CRO. PPD Biotech stepped in to rescue this study. "To revitalize the study, we became the voice of the client with sites and got investigators energized about what had been a languishing trial," said Lehman. "Within the first year, we doubled the percentage of actively enrolling sites from 48 percent to 98 percent, ultimately getting the study back on track and meeting timelines."

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FINDING A PARTNER THAT GROWS WITH YOU

Knowledge retention from a single development partner improves efficiencies and decision-making. “The trick is getting the appropriate level of service you need at the time and consistent prioritization from your CRO partner,” said Lehman.

PPD Biotech was established in 2014 specifically to address the needs of emerging oncology biotech, a growing client base. The success of this model prompted the coverage of all therapeutic areas. “In its mature and sophisticated form today,” continued Lehman, “we’ve long since expanded from a leadership focus to a robust operational structure. Through Biotech University, we cultivate staff who share a similar mindset with our biotech clients: ownership, passion and a rapid response to changing priorities.”

Our teams bring strength, experience and reach in oncology within a “small team” model.

“Think of it this way: These trials can be complex,” Lehman said. “There is a lot happening on the CRO side, and our clients don’t want to be inundated with communication coming from a multitude of functions within PPD. A priority for the PPD teams is to ‘handle the noise’ on our end, while still bringing clear communication, proactive assessment of risks and thoughtful solutions to our partners as we advance their oncology therapy to market.”

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