The Biotech Journey: From Lab Development to Clinical Delivery

With COVID-19 fuelling the modernisation of clinical trials, coupled with increased investment in the biotech and emerging biopharma sector, the competition to get new therapeutics to market quickly is intensifying at a rapid rate

Erin Finot at IQVIA Biotech

Biotechnology and emerging biopharmaceutical companies face countless challenges as they look to advance their drug to market. From the increasing clinical trial costs through each phase of development, to the fierce asset and patient competition ubiquitous within each stage, it can often feel like a mad dash to the finish line. Furthermore, with the COVID-19 pandemic jump-starting rapid global modernisation of clinical trials, coupled with increased investment in the biopharma sector, there is mounting pressure to have technological solutions in place to recruit and retain patients and drive innovation, efficiency, and speed.

To increase the probability of efficient and effective global trials, as well as to bring value to each phase of drug development towards commercialisation, many biotech companies engage CROs for support. Considerations for selecting a partner that can de-risk the challenges of bringing a drug to market are paramount for the biopharma sector.

Criteria for Selecting a CRO

On the surface, the drug development goals of emerging biotech companies may appear the same as large pharma – bringing medicines to market – but biotechs have an incredibly distinct set of needs. Their ambitions are aggressive, as success ensures survival in a congested environment, and the earlier they can get expertise, the more

European Pharmaceutical Contractor, May 2021, pages 36-38.

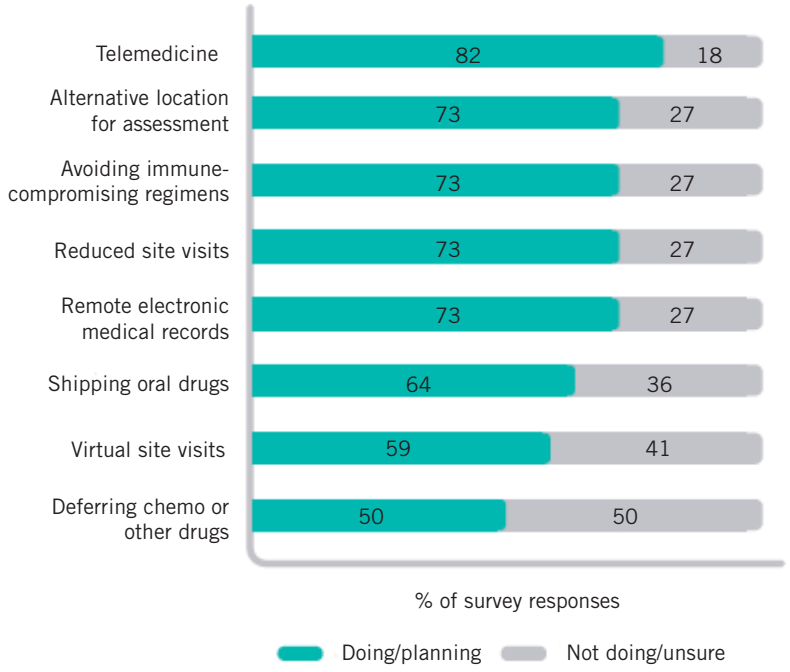

Figure 1: March 2020 survey for oncology investigators and key opinion leaders assessing how COVID-19 may affect ongoing and future clinical trials

likely they are to pass value to patients or to accelerate medicines to those with unmet needs.

Large pharma companies tend to work with CRO partners as tacticians that can reliably execute clinical trials, and are often contracted strategically and with substantial volumes across major portfolios. However, a biotech company may rely on a CRO for more services and deep expertise within a laser-focused pipeline. Biotech companies often benefit from involving a CRO very early in the process, prior to, or as part of, the Investigational New Drug (IND) submission process. For many emerging biotech companies, their IND submission is the company's first and only, and the CRO can help navigate and anticipate what is needed to get the IND approved, as well as identify solutions to operationalise the trial efficiently from the start. Early support by a CRO at, or prior to, the first regulatory agency submission can result in fewer protocol amendments and delays and superior trial performance.

Biotechs are also typically formed by industry-leading experts in one or more areas, but are too early in their corporate narrative to have all of the in-house specialists required to bring an asset to market. Gaps in expertise are different for each biotech company. Some may have lab or preclinical experts and not trial operational experts, or highly networked capital-raising experts without commercialisation experience. Undoubtedly, if left unaddressed, these gaps could contribute to corporate failure. That's why partnering with a versatile CRO, one that can provide a deeper understanding of all phases and offers a diversity of solutions along the way, can be critical.

When Looking for the Optimal Partner, It Is Important to Consider Several Key Criteria

Depth and Breadth of Services

A strong CRO partner should have a wide range of services that can help biotech companies move forward in their effort to get treatments to patients – from defining the target product profile for their asset to trial design and implementation, through launch and commercialisation. In today's landscape, and the landscape of the future, it is important to engage an agile CRO that can implement technology-based solutions that are fit for today, with capability to adeptly evolve and meet the needs of the future.

For instance, the impact of the COVID-19 pandemic on routine methods of patient care has made sponsors and sites more responsive to direct-to-patient approaches. Market research indicates that before the pandemic, study investigators expressed some interest in the use of digital tools and technologies and just a few months into the COVID-19 pandemic, interest increased, and most were keen to implement technology solutions for future trials. IQVIA and the Cancer Research Institute co-conducted a survey among oncology investigators and key opinion leaders in March 2020 to assess how COVID-19 may affect ongoing and future clinical trials (see **Figure 1**). Findings showed that remote tools and strategies were highly ranked for trial assessments (1).

Biotech sponsors and CROs that pivoted to respond to the pandemic were able to foster trial continuity and effectively bring the trial to the patient, leveraging telemedicine visits or remote monitoring capabilities, for example. A focus on the right digital tools and innovative capabilities is critical for current and future clinical trial needs, and a way for CRO partners to support the biotech community to bring medicines to market.

Therapeutic Expertise

Having a CRO with therapeutic domain expertise is crucial to the success of a clinical development programme since many of these assets are coming right off the bench. By understanding the tailored needs of each biotech's therapeutic area and indication, a CRO can enable the company to follow a smoother journey to patients and a more clearly defined path to success.

Fit for Purpose Clinical Processes

In addition to finding a CRO with specific therapeutic expertise, biotech firms should look for a partner that has the ability to tailor offerings to specific needs and goals. There is no one-size-fits-all approach. For some biotechs,

the primary objective isn't always advancing a drug, but may be compiling enough data to potentially partner with a large pharma company or validating a proof of concept. A strong partner will understand the company's unique definition of success and complement their ambitions.

Strong Communication

This is a high-stakes environment and communication is key. Having a clear communication channel between scientists and the operations team helps improve decision making, which results in higher probability of success. The right CRO will have a project manager whose goal is to simplify and improve communications between the two teams, ensuring everyone is on the same page.

Streamlined Approach

A streamlined process is beneficial because there's a simplicity and ease with a single point of contact. Maximising the services and solutions from just one partner can go a long way towards success. Consequently, there is a strong need for a single CRO with an end-to-end consultative approach, a therapeutically aligned partner that can address needs at each milestone on the clinical development paths.

The Need for a High Touch, End-To-End Approach

Many emerging biotech companies lack the internal resources or capacity to go from lab development to clinical delivery. The right partner can help overcome many of these barriers. With an end-to-end approach, companies gain access to analytics, innovative technology, and experts who collectively provide guidance at each step in the process, helping drive efficiency and innovation.

Partnering With the Right CRO Can Bring Value to Each of These Stages:

Preclinical

Companion diagnostics (CDx) are often co-developed alongside a therapeutic during its journey because they can help identify patient responders based on efficacy or safety. In fact, the FDA released guidance deeming it essential to consider CDx early in drug development, and to plan for co-development of the product with a companion diagnostic. This means having an *in vitro* diagnostic partner, with central laboratory services, that can work with pharma development programmes from the early stages of biomarker selection, biomarker testing for clinical trials, and commercialisation.

Early engagement helps circumvent issues during preclinical development and provides a clear understanding of the processes and associated risks from clinical trials forward for commercialisation. A strong partner should lead discussions on assay validation and the regulatory paths to take for approval. The risks, relative costs, feasibility, and timelines should be identified upfront during early engagement.

In addition, many clinical development programmes require testing at sites around the world – making sure your laboratory services provider has global reach will be an important consideration.

Trial Delivery

Partnering with a CRO can be a strategic investment to support global asset ambitions, enrich the sponsor's expertise and experience, deliver to patients with unmet needs, provide technology and innovation enhancements, and increase the probability of trial success. CROs with data insights are also able to de-risk study delivery through predictive or machine-learning approaches and provide direct insight to patient populations for improved trial performance.

Market Launch

With commercialisation comes needs for brand strategy, market access, clinician engagement, and continuous support for patient retention. Launch means addressing similar needs from the trial delivery phase – therapeutic knowledge, patient journey, and tailored approach – in a larger depth and breadth. A CRO that can leverage best practices and lessons learnt from the trial, and partner with the biotech to differentiate the treatment, communicate broadly, earn payer approvals, and, ultimately, drive better disease understanding and quality of life, are all important considerations for launch.

Conclusion

Now more than ever, biotech companies require specific therapeutic expertise and tailored offerings to their specific needs and goals. The COVID-19 pandemic has further increased that need due to a push towards modernisation of clinical trials. A single CRO with an end-to-end, consultative approach can provide appropriate infrastructure and insight to bringing the trial to the patient – a necessity to be successful in today's clinical trial environment – and can do so as a development partner for the biotech sponsor.

Reference

1. *Visit: www.nature.com/articles/d41573-020-00093-1*

Erin Finot, MBA, is Vice President of Immuno-Oncology at **IQVIA Biotech.** She is responsible for leading the team's strategic direction to help sponsors focused on immuno-oncology trial programmes meet their goals. As advancements in immuno-oncology continue to transform cancer care, Erin guides sponsors through a dynamic landscape with more than 20 years of experience in global clinical research and drug development processes, including adoptive cellular trials. Erin has a Bachelor's in Biology from the University of California, Berkeley, US, and a Master's degree in Immunology from the University of Virginia, US, providing a solid foundation for her therapeutic expertise.