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Building Relationships Key for Smaller Sponsors

Strong collaboration critical as trial development advances

Prior to the COVID-19 pandemic, biotech and emerging biopharma companies were increasingly turning to contract research organizations (CROs) to contain costs and secure therapeutic and clinical trial expertise to help meet their individual objectives. COVID-19 has necessitated the industry further modernize clinical trials. In navigating the pandemic's impact, growing investments in the sector and the related growing market competition, it can be a "make it or break it" time for these companies.

Biotech clinical trial sponsors often seek a CRO partner for strategic guidance, end-to-end services and solutions, and deep expertise for their pipeline with the ultimate outcome to streamline development processes and timelines to meet ambitious goals. These sponsors may find it beneficial to integrate a CRO partner prior to, or part of, the Investigational New Drug (IND) submission process, setting the foundation for a long-term partnership where a versatile CRO can help them identify the right solutions and services to operationalize trials with efficiency from the start and transition further into the development process.

Building the trust factor

For CROs to earn trust, it is important to enter into a partnership without preconceptions. Listening with intention to the sponsor's needs is key. Start-up biotech companies may not have the in-house resources to draw upon to develop an asset. A good partner listens, guides and asks the right questions to ensure success. A start-up's leadership team may have exceptional scientific, business or financial backgrounds with limited clinical trial, regulatory or commercialization experience. CROs are willing to collaborate and provide complementary support in every aspect of their clinical journey. As development goals evolve and business priorities change, communication and directional intent for an asset is critical.

In some cases, as trust grows, a well-balanced partnership may allow sponsor teams to focus their attention on strategic planning for future development. "Having the IQVIA Biotech project team's collective experience to manage a Phase I/II escalation expansion study for our lead immuno-oncology therapy was a huge lift for our team," said David Bohr, head of clinical operations at Bicara Therapeutics, a clinical-stage biotech company. "We were able to refocus on our long-term strategy and begin discussions with key thought leaders and advisory boards about what expanded programs may look like based on the team's planning and guidance."

Leveraging CRO expertise and solutions

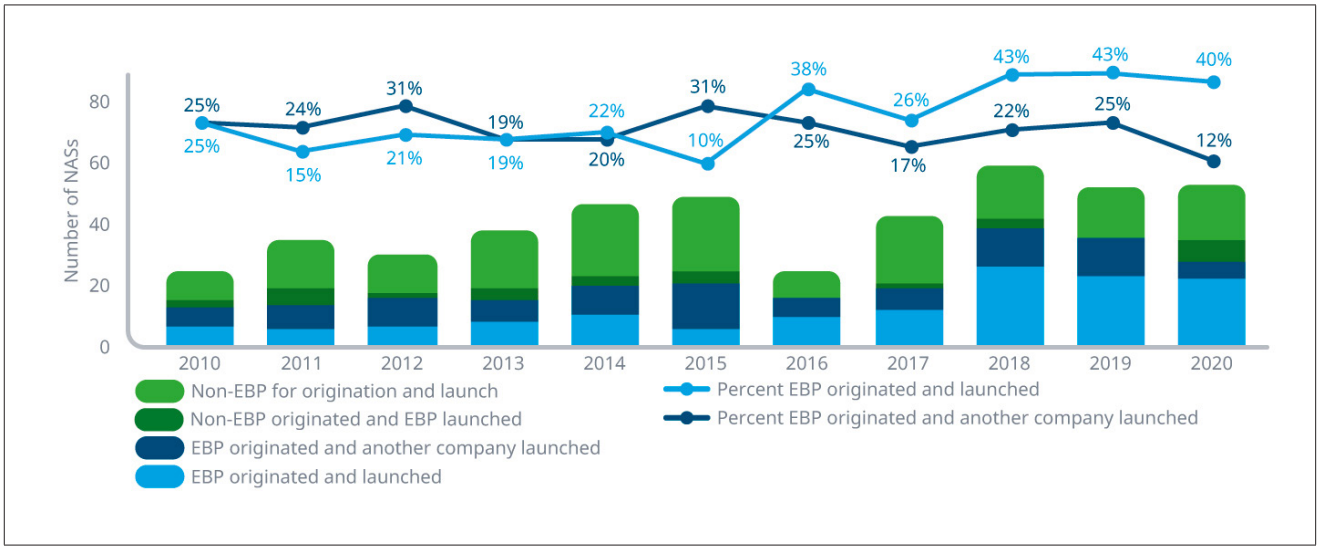
Many sponsors in this sector need a reliable partner to take a potential treatment from the bench to the clinic. A strong CRO-sponsor relationship is highly consultative, where sponsors can lean on a CRO's therapeutic expertise, technology and analytics capabilities, and global reach to overcome barriers to completion. As part of their working relationship, some specific ways biotech sponsors may lean on their CRO are noted below.

Early engagement and planning–Before a single patient is enrolled into a trial, sponsors should reach out to their CRO to support the development of a comprehensive clinical development plan to create alignment in strategic direction and ensure the probability of success.

For sponsors, integration of a research partner early in the process can help circumvent issues during preclinical and clinical development. Particularly in oncology, a skilled partner can be instrumental in the generation of a comprehensive biomarker strategy together with the ensuing operational execution, including the identification of companion diagnostics. Working in concert with a specialized clinical trial in vitro laboratory can make the process more seamless. A CRO can help by leading discussions on assay validation and regulatory pathways for approval, while keeping feasibility, risks, costs and timelines in mind as well. CROs may also be able to enhance study delivery through predictive or machine-learning approaches and provide direct insight to patient populations and sites of interest to improve trial performance and timelines.

"For Bicara, it is important to work with a team that shares the same voice as us," said Bohr. "This way, the CRO team is readily available to have discussions around patient safety with site investigators

COMPANIES ORIGINATING AND FILING FDA REGULATORY SUBMISSIONS FOR NASs AND PERCENT OF LAUNCHES BY NAS LAUNCH YEAR



THE SHARE OF EMERGING BIOPHARMA COMPANIES THAT ORIGINATED AND LAUNCHED THEIR OWN THERAPIES HAS BEEN STEADILY GROWING.

SOURCE: IQVIA Institute, Dec. 2020

or help pre-select target patients based on clinical and biomarker data insights, which improve efforts on companion diagnostics. It would require a lot of in-house resources for us to successfully oversee all those key activities."

Therapeutic and clinical trial expertise–With exploratory drug development often focused on multiple indications, a CRO with depth of therapeutic expertise can optimize clinical delivery enhancing quality and reducing timelines. Furthermore, years of therapeutic expertise and interaction with investigational sites ensure site engagement with heightened interest and attention to the target patient population. That long-standing base of knowledge regarding delivery challenges within the therapeutic space allows the CRO to prioritize the work needed for the sponsor while knowing what challenges to anticipate.

Scalable solutions–Though a strong CRO partner should have a wide range of end-to-end services to assist biotech companies, capabilities must be scaled to best meet their individual needs.

The pandemic is a prime example, opening up a greater degree of patient-centered approaches by sponsors. Through remote monitoring capabilities, telemedicine, digital tools and other decentralized solutions, sponsors and CROs worked together to pivot strategies and maintain trial continuity. Implementing technology-based solutions that fit today's needs, and can evolve and meet the sponsor's future needs, will increase probability of trial success.

Bohr notes, "During the pandemic, we were unsure of how we would continue to collect quality data with overburdened hospitals and no on-site clinical research associates. Working with our CRO partner, the team quickly pivoted to coordinate with site institutions, through their established relationships, to determine needs such as at home study coordinators and telemedicine to continue collecting verified data critical to understanding therapeutic dosage while keeping patient safety top of mind."

Staying agile–Understanding that biotech companies are under tremendous pressure to meet business objectives—especially one developing a single asset—a CRO that can pivot on strategy and execution can help in this fast-paced environment. CROs should be ready to support delivery of critical milestones, co-development with a pharmaceutical partner, or commercialization.

The right partnership between a sponsor and CRO can fuel success through optimized clinical trials. With clear communication and growing trust between both groups, CROs can be an aligned collaborator to provide strategic guidance and help address needs at each milestone on the clinical development pathway, which is critical as the development landscape continues to evolve.