



OUTSOURCING DRUG DISCOVERY AND DEVELOPMENT:

Considerations For Emerging Biopharma Companies





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The pharmaceutical industry has become increasingly dependent on outsourcing as a means of driving both discovery and development pipelines. As the trend toward early-stage discovery being the domain of small to mid-size – and even virtual – biotech companies grows, the decision of what to outsource (and to which supplier) has become more and more critical. When one considers that this stage is among the most time and cost consuming in the biopharmaceutical product life cycle, with the need for significant financing, human resources and infrastructure, it is unsurprising that in a survey of biopharma professionals conducted by Informa Pharma Intelligence in partnership with WuXi AppTec, 60% of respondents stated they

outsourced at least some aspects of this work.

For emerging biopharma companies, which often simply do not have the capacity to build this function internally, it becomes even more necessary for them to rely on expert Contract Research Organizations (CROs) to achieve long-term development goals. Collaborations with CROs enable companies to meet demand for innovation and strategic alliances, placing them in a favorable position for future growth and attracting investment. This strategy also provides a fast and efficient route to access expertise and resources that would otherwise need to be created internally, saving time and allowing such companies to be more nimble – a key driver for the success of biotechs. Given the continuing surge in investment

in early-stage biotech companies, resulting in the formation of many new, well-funded, organizations hungry to develop new ideas and technologies, we conducted further research into the considerations of emerging biopharma companies when choosing to outsource to a CRO, and the benefits and challenges of such partnerships.

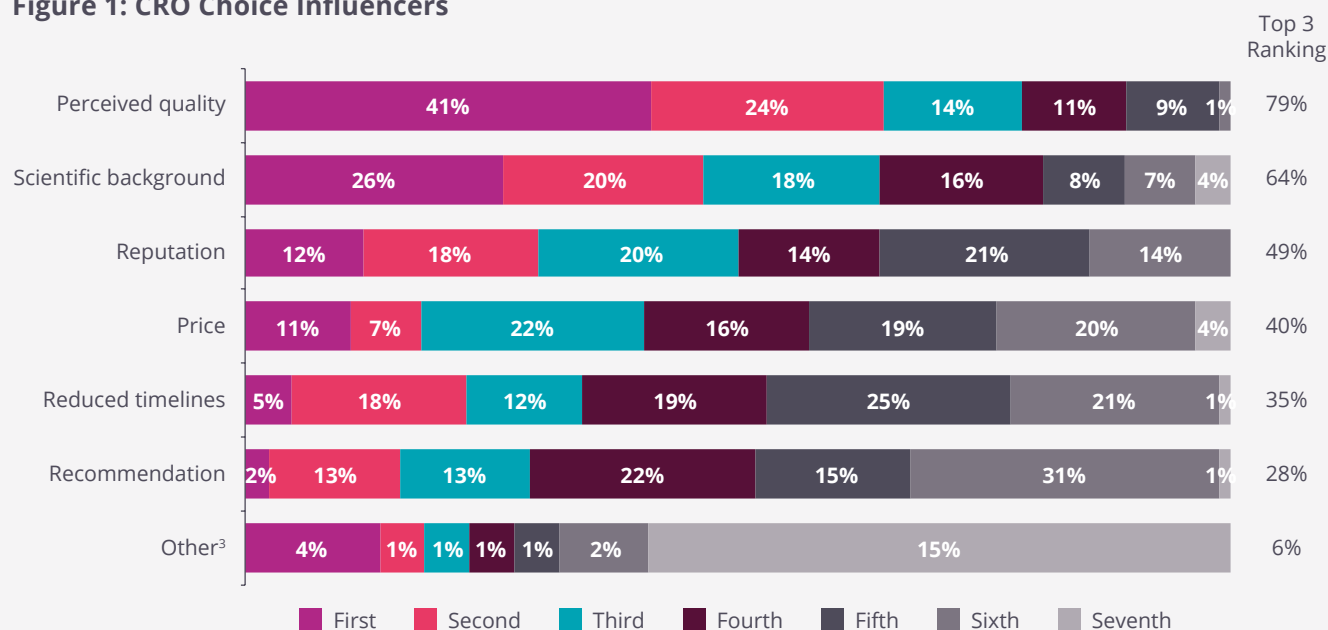
Quality And Scientific Expertise Take Precedence

For those who outsourced to a CRO, there were two clear key influencers in choosing with whom to partner. Each CRO will have a nuanced offering, but 79% of respondents placed the perceived quality of a CRO's service in the top three factors that would sway their decision, whereas 64% stated that scientific background was critical (see Figure 1). This reflects the importance placed on

good decision-making when it comes to selecting partners, with most respondents recognizing the positive influence the choice of a good collaborator can have on the quality, efficiency and success of their outsourced activities.

Cost efficiencies are naturally also a key consideration, as early-stage companies are always under pressure to get as much "bang for your buck" as possible. In fact, 63% of respondents stated that cost effectiveness was a major motivator for deciding to outsource drug discovery services. Naturally, such a decision has to be accompanied by confidence that a CRO can deliver the required services to quality and timeliness standards that meet the client's expectations and drive its science forward. Hence, proven communication, organizational skills and scientific excellence are absolute requirements for a successful partnership.

Figure 1: CRO Choice Influencers



Question: Please select and rank the factors that have influenced your organization's choice of CRO?

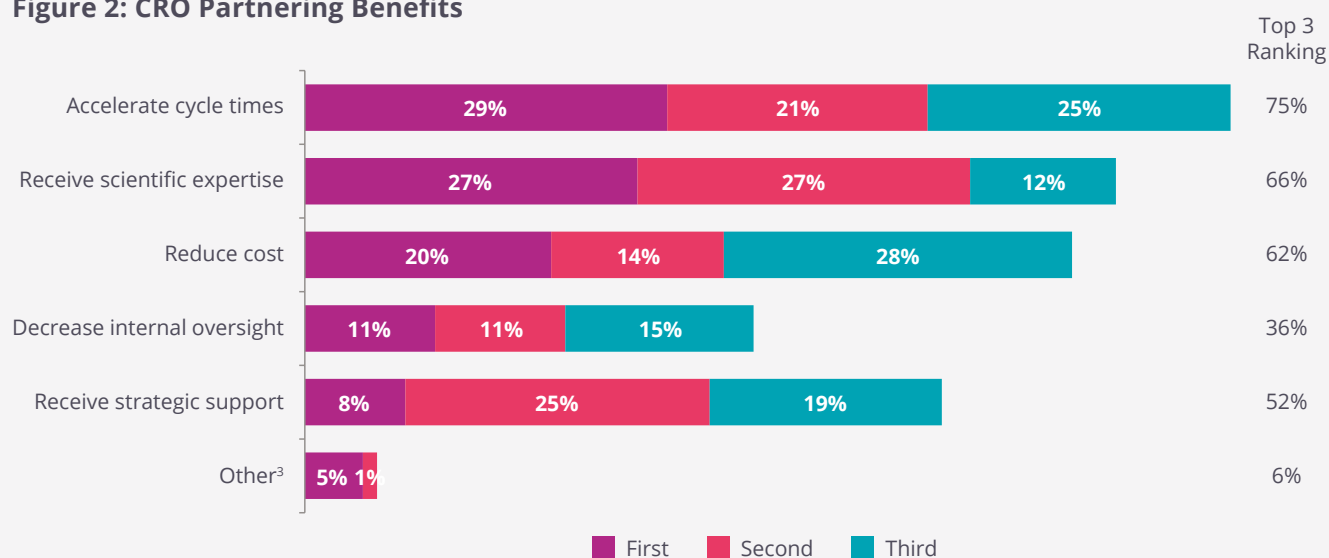
Base: Respondents leveraging CRO services¹ (n=85). ³Other includes: Breadth Of Support; Flexibility ; For; Location In Our Country; Na; None; Previous Experience; Project Manager Quality; Relationships, Project Team.

Further supporting this, when asked to specify the importance of specific characteristics for a CRO to possess, 94% chose reproducible data and reliable processes as of high importance, followed by 85% choosing specific experience. In contrast, only 26% viewed a CRO's location as equivalently important, and only 27% were concerned with size. This leads to the assertion that expertise must be tangibly proven in previous work as opposed to inferred by a global footprint. It also indicates that convenience is low in priority for emerging biopharmas; they would rather work with the most qualified CRO in another jurisdiction than one lacking such a reputation locally. It is evident that a CRO's ability to provide a quality service and the existence of

a proven scientific background and expertise are intrinsically linked by respondents.

Once in a partnership with a CRO, there are more advantages than just being trusted to carry out drug discovery and development diligently. When asked to rank the benefits of working with a CRO, accelerating cycle times was the most highly ranked advantage, with 75% putting it in the top three (see Figure 2). This was followed by receiving scientific expertise (66%) and cost reductions (62%). From this, it is clear that while efficiency is not the most important factor in choosing to partner with a CRO, it is recognized as an important consideration of such collaborations.

Figure 2: CRO Partnering Benefits



Question: Please select and rank the top 3 benefits for your organization in partnering with a CRO?

Base: Respondents leveraging CRO services¹ (n=85). ³Other includes: Access Labs And Equipment; Accessing Models/Techniques; Experience With Similar Development Compounds; Flexibility Of Cost (No Permanent Staff/Expertise Needed); Resources.

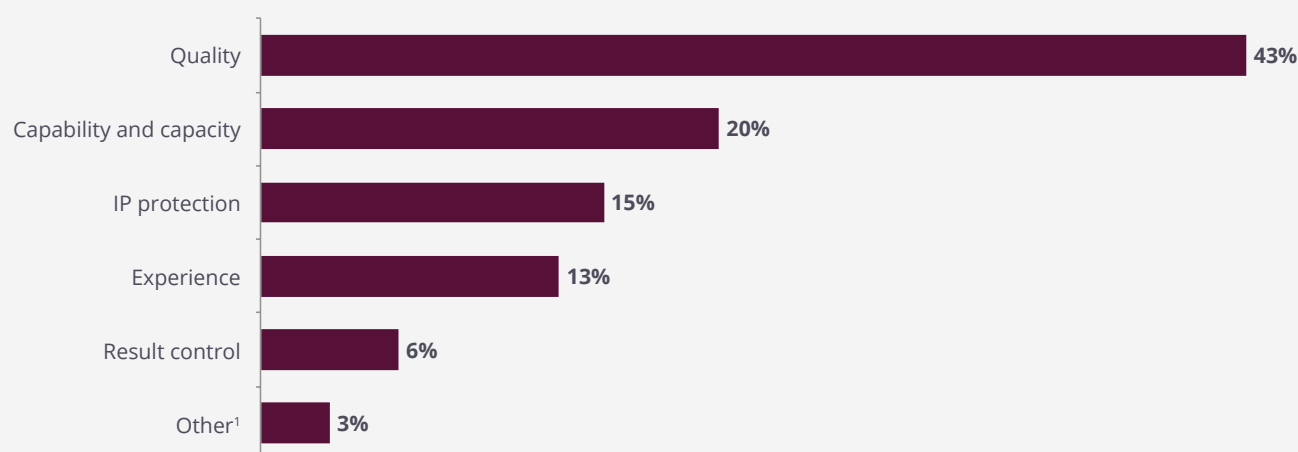
Nevertheless, to reap these benefits, partnerships must be well-matched and successful. For respondents, the key criteria for ensuring this was the expertise of the CRO team, with 86% selecting this. This points to the fact that as well as lacking the financial resources to build infrastructure, emerging biopharma companies often do not have the capacity to expand their talent pool to bring in this expertise. Furthermore, there has been an increase in the number of emerging companies making a distinct choice to utilize the “virtual” pharma business model, and therefore they have no plans to build this knowledge base internally. However, they still require technical and scientific support to develop their ideas and technologies, making CRO partnerships a crucial part of their strategy.

Overcoming Collaboration Challenges

While there are clearly many benefits to working

with a CRO, many emerging biopharma companies may approach delegating such a pivotal part of their operations to another party with understandable caution. When questioned about this, the issue of quality was again at the forefront of respondents’ minds, with 43% stating ensuring quality was their primary concern in outsourcing to a CRO (see Figure 3). This was followed by capability and capacity (20%), which is also related to a CRO’s ability to provide an effective service. In addition, results showed that these concerns were by no means unfounded, as for those companies that had outsourced to CROs, most had found the biggest challenge was quality control (26%), followed by project management (24%) and communication (20%). It is therefore crucial that emerging biopharma companies partner with CROs that can assuredly meet their needs and maintain the highest standards of quality, project management and communication.

Figure 3: Concern in CRO Outsourcing



Question: What is your organization's biggest concern when it comes to outsourcing to a CRO Service?

Base: Qualified respondents (n=143). ¹Other includes: responses include Cost; Financial; University Hospital.

Survey respondents also reflected on objections to outsourcing drug discovery and development work to CROs. Despite the positive cost efficiencies highlighted by many respondents, and discussed above, for a subset of respondents the cost of outsourcing remained a barrier to working more extensively with CROs, with 91% stating financial considerations as one of the top three biggest issues. A focus on managing costs was also indicated when respondents were asked about the importance of flexible estimating and financing processes for their organization, with 65% of respondents saying it was either extremely or very important. It has been established that emerging biopharma companies have more limited financial resources than their larger counterparts, so it is unsurprising that the prospect of spending a proportion of those resources with an external provider can be daunting. However, as shown when considering the benefits of partnerships, in the long term it is more cost-efficient to outsource than to build infrastructure and talent pools internally.

The potential for time delays, for example in providing results, ran closely behind financial considerations, with 86% ranking it in their top three deterrents. Again, this is an issue that is particularly prevalent for companies in the early stages of growth, which are keen to prove their products' worth to secure funding and proceed further along the drug development pipeline. It is also reflective of a wider imperative to ensure treatments are available for patients as soon as possible, particularly for those where none currently exist. The high level of concern over delays makes it ever more important that the selection process focuses on the CRO's expertise and past proven successes, including the ability to deliver on time.

Prioritizing Emerging Innovators

Emerging biopharma companies are truly driving innovation within the life sciences industry, accounting for 72% of all late-stage pipeline activity in 2018. These developments are critical for the health and well-being of patients across the globe. However, some respondents indicated that more could be done by potential CRO partners to seize the opportunity and value of their work, with 42% stating they felt that there was a level of reduced eagerness from CROs to work with smaller biotechs. Reasons provided as to why possible partners would be less invested in such partnerships revolved around the idea that smaller biotech companies were perceived as having less to offer – whether this was potential revenue, scale of project or level of prestige associated with the work. Hence, CRO partners that make additional efforts to support small to mid-sized biopharma clients are viewed more favorably and seen as having a preferred service level.

With regards to revenue prospects and scope for projects involved in partnerships with emerging biopharmas, there is evidence to support the notion that there is potential for extensive opportunities if CROs prioritize these partnerships. Of respondents, 54% stated that they utilize the services of their CRO partner between one and 10 times per year, while a further 28% do so more than 10 times annually. Only 13% work with a CRO less than once a year, indicating that any perception that emerging biopharma companies have less work to offer is unfounded.

Specific contributions from survey respondents on their experiences working with large CROs included that they were provided with “junior staff support” on their outsourced projects and that proposals supplied by CROs were “one size fits all and too big.” Some specified that these issues

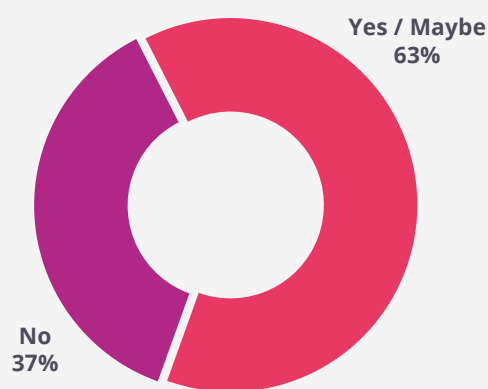
appeared to be exacerbated when working with larger CROs, with one respondent recounting, “It seems like they rank us as second-tier companies, but this only happens with big CROs. Smaller CROs tend to work better with small biotechs.” This reflected a general trend in the choices of emerging biopharma companies with regards to the size of their CRO partner, with medium CROs being the most commonly elected (44%) followed by global (29%) and smaller, domestic CROs (20%).

Nevertheless, these preferences in partner size did not supersede respondents’ focus on quality of service, with 63% conceding that a designated executive and account team could influence their decision to partner with a larger CRO over another CRO type. When asked to delve deeper into their

reasoning for this, recurring themes centered around the scope such services give for improved communication and project management, which as mentioned previously, were two of the top three collaboration challenges cited by respondents.

Communication and project management are not just key from a customer service perspective, but are critical criteria for achieving the benefits, avoiding the pitfalls and overcoming the challenges of such partnerships. This was encapsulated by one respondent, who stated, “Close communication and project management would help reduce risks of process breakdown. I believe a dedicated team would enable more rapid turnaround time on most studies and ultimately reduce cycle time for development programs.”

Figure 4: Execs & Account Teams Influence



Please explain the reason(s) for your answer?¹ (Summary)

- Communication
- Continuity
- Project management
- More attention and resources

Question: Would a designated executives and account team influence your organization's decision to partner with a larger CRO, over other CRO types?¹

Base: Respondents leveraging CRO services (n=84).

Question: Please explain the reason(s) for your answer?¹

Base: Respondents leveraging CRO services (n=32).

Embracing Partnerships To Drive Development

The results of this research show that there are significant benefits to partnering with a CRO for emerging biopharma companies. Being in the early stages of growth, not only do most emerging companies lack the infrastructure and facilities in-house to conduct drug discovery and development, but also they may not have the necessary expertise to navigate the process. It is therefore unsurprising that these companies are most concerned about the quality of the service and the scientific know-how of their CRO partners. While there are indications of other influences and preferences – such as CRO size and costs – all are intrinsically linked back to the idea that where quality processes and expertise exist, efficiency and results will follow.

There are characteristics emerging biopharma companies can be mindful of when looking for a prospective CRO partner to ensure they are provided with reliable and knowledgeable service. One such example is that of a dedicated executive and account team, which can help early-stage companies navigate the process – an invaluable service for those that are relatively new to drug discovery and development. This, in addition to consistent service, scientific expertise, high quality, speed and a proven track record of delivery, demonstrates a CRO's commitment to taking the time to understand its customers' needs. With this approach to decision-making, prospective biopharma companies can be assured that they will receive a quality service and dedicated partner to support their success.



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