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What to Consider When Looking for a CRO

GEN Provides the Guidance You Need to Select the Right Contract Research Organization

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Most contract research organizations (CROs) offer a wide variety of services ranging from preclinical studies and consultancy/advice to full clinical trials and regulatory support. Customers usually pick and choose the services they need from a vast menu of options, which can be overwhelming. In addition, the business is highly competitive, with what seems like an infinite number of firms, adding to the abundance of choices for customers.

GEN recently conducted a roundtable discussion with several CROs to help our readers better understand how to find the right CRO for their needs.

GEN: At what point should a company seriously consider engaging the services of a CRO?

Dr. HART: When they have the need for a specific skill set or technology expertise that they do not possess or wish to establish for themselves. Identifying a competent CRO that has particular niche skills and technologies complementary to in-house capability has significant advantages. Also, clients may require increased capacity for in-house programs but do not wish to recruit additional staff to cover fluctuations in demand.

Dr. NEWTON: As soon as any project is decided to be worthy of external or internal investment, and maybe even before such investment is agreed upon, especially if the project will be wholly or partly externally resourced. In some cases, our input can help justify investment in a project with a grant funding body, or internally.

Dr. GILLETT: There is significant pressure on companies to enhance efficiency and productivity, and optimize internal resources. By partnering with CROs, clients have the ability to use external infrastructure and capacity to conduct a broad range of studies led by scientific experts. This allows pharma and biotech clients to maximize internal resources and focus on advancing R&D goals.

As an industry, we have shifted our focus from therapeutic areas that have proven medicines to targeting unmet medical needs in very complex diseases. Today, the need for innovative medicines requires drug developers that have deep expertise in a range of specialty areas—a model difficult for any one company to fully achieve. When companies do not have the internal expertise required, collaborating with a CRO with robust capabilities can help companies meet their goals.

Dr. SOMBERG: We encourages clients to engage as early as possible in their research and development process. Drug development is highly iterative. For example, clinical studies depend on the nature of the preclinical work done, plans for biomarker validation must be made across development phases, and patient-reported outcomes require advance planning.

CROs with broad drug development capabilities are able to assist clients by providing both consultative and planning services, in addition to the execution of specific laboratory or clinical work.

Ms. GLADWELL: Although the exact timing will depend on a sponsor's in-house capabilities and outsourcing strategy, generally speaking, the earlier you make contact the better. You don't need to have an RFP ready or a protocol in hand

to start talking to a CRO. A good CRO will help you with planning and strategy decisions that can help you save time, money, and headaches when it comes time to outsource.

Dr. BASU: CROs lately are increasingly being viewed as external innovation partners. For large pharmaceutical companies the consideration to engage with a CRO is usually the need for speed in achieving a goal, and high quality coupled with reduced research cost. For mid-sized pharmaceutical companies the primary consideration is increase in research expertise and bandwidth.

For smaller pharma/biotech companies the primary consideration is being enabled to focus on core science and drive innovation without having to invest in infrastructure and bother about facility management.

GEN: What key factors do you take into account before finally deciding that you will take on a particular biotech or pharma company as a client? Have you ever turned anyone down, and why?

Dr. HART: The main factors that lead us to work with biotech/pharma companies revolve around scientific engagement and clarity of objectives, both at a strategic and tactical level. Getting this in place up front establishes a professional relationship, manages expectations, and minimizes the chance of issues arising. We do not engage with prospective partners who lack the expertise to know what they want as this makes it difficult to establish a clear plan of work with defined milestones and objectives.

Dr. NEWTON: We obviously have to be able to perform a project technically, and we do assess that a client has the ability to pay the price of a project. That said, we pride ourselves on being able to work with any culture and any size and type of organization.

Yes, we have declined a project based on our view that we did not have the technological ability to perform a project. We do not think we should spend a client's money without real chance of success.

Dr. GILLETT: We work with all types of companies to build customized drug development programs with the goal to develop safe and effective new medicines; however, the clients with whom we have the most successful partnerships are those who fully utilize CRO expertise and infrastructure, viewing CROs as an extension of their own team.

The strategic model creates deeper relationships on both sides, which results in better service, consistent communication, and stronger commitments. In addition, the scientists within the CRO become part of the client's team because there is more knowledge sharing, which creates a greater level of trust.

Dr. SOMBERG: In assessing a potential opportunity, we focus on the molecule and the development plan, considering both the safety profile of the molecule and the proposed plan. For example, we want to see molecules in which the risk to subjects is appropriate for the potential benefit. We also assess the opportunity to be sure we will be able to deliver for the client in terms of assay development, subject recruitment, or whatever the particular opportunity entails.

We may turn down a client if we think their molecule is unsafe or if the planned studies pose excessive risk. We also may turn down a client if we feel our expertise and experience is not a match for the needs of their scientific or clinical program—though given the breadth of our experience and broad scope of services, this is infrequent.

Ms. GLADWELL: Expertise and availability are the key factors we consider before taking on new work. A cross-functional team reviews the RFP or protocol and any other relevant information gathered from previous conversations with the client. The team determines whether we have the necessary expertise and the staff available to provide a high-quality customer experience.

We have turned down work when we could not commit the necessary resources to complete the work without sacrificing quality.

Dr. BASU: One of the key factors in taking up work for us is to match our competency with what the client's project requires. Since each project is unique and requires dedicated resources we also take a hard look at the desired timelines, project management, and communication mechanism, if any are proposed by the client.

We have declined projects where we have found ourselves lacking in the particular scientific domain expertise which the client's project demanded.

GEN: What is the most widely held misconception regarding working with a CRO, and how do you address this issue?

Dr. HART: The generation and delivery of data in an oversimplified manner without scientific context or critical review. We believe it is key that scientists from both parties agree on the experimental approach and critically review the data routinely to ensure its validity and integrity. They must engage directly, removing any company or management barriers, to ensure ongoing scientific validation of the work to deliver maximum benefit to the client's project.

Dr. NEWTON: That a CRO is a second class organization that just does what it is told by the client. I prefer to rename a CRO such as ours an "IPG" (Intellectual Property Generator). Our business is the invention of intellectual property by our scientists for our clients, which the client then owns. We address it by displaying the pedigree and capability of our scientists.

Dr. GILLETT: One misperception is that CROs are inflexible. For Charles River, this could not be further from the truth. Flexibility is key. Every study is different; every study design is different; and client reports are different. We understand that one size does not fit all and it is essential to work closely with clients to customize drug development programs to meet individual needs. We listen to our clients and provide robust scientific expertise and efficient study design recommendations.

Dr. SOMBERG: The CRO industry has doubled in size since 2001, but we still have a lot of growth potential. The biopharmaceutical industry outsources less than 30 percent of their R&D spend. This is steadily increasing as companies look to make their fixed costs more variable.

One of the most widely held misperceptions I hear is that large CROs work only with large pharma. In fact, we work with many small biotech and pharma companies across the drug development spectrum. We do this through dedicated teams that focus on the particular needs of the client.

For example, our program management teams in nonclinical safety assessment guide clients "start to finish" through the planning and execution of IND- or CTA-enabling programs, whereas our molecule development teams provide comprehensive guidance to take clients through proof-of-concept and beyond.

Another misconception is that CROs are used primarily for execution, rather than for scientific consultation and planning. At Covance, we have an outstanding team of scientists and physicians who work with clients on issues ranging from innovative nonclinical imaging to biomarker validation to complex global clinical trial planning to novel-end point development, among many other areas. Moreover, we make use of proprietary analytic tools to mine public data and our own data to help guide this planning.

Ms. GLADWELL: There is a misperception that research done by CROs does not have the same quality or scientific rigor as those trials where CRO services are not used. A good CRO employs highly qualified individuals and holds them to high scientific standards. Some ways to tell if the CRO can meet your high standards is to review CVs of proposed personnel, ask about research published in peer-reviewed journals within your therapeutic area, and inquire about references.

Dr. BASU: CROs struggle to communicate scientific failures well. We address it up front by clearly defining working specific operating processes and putting enormous emphasis on communication from both sides.