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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