How To Build a Comprehensive Response to Client Needs as a CRO

As a CRO, meeting client expectations can be an ongoing challenge. What can organisations do to make sure their research is as effective and efficient as possible?

Patrick Bennett, Jean Pierre Boutrand, and Vito Saccente at Alliance Pharma

Serving clients is the core of a contract research organisation's (CRO) business. The more comprehensive a CRO's service offerings, the more likely it is to attract and retain clients. Recent events – like the COVID-19 pandemic – have set in motion industry shifts. Such shifts demand CROs adapt so that they can continue meeting their clients' evolving needs (1). These changes are not just here to stay – they will likely accelerate.

For instance, the number of decentralised clinical trials has exploded since 2020, increasing demand for companies with a broad footprint (2). Cell and gene therapies (CGTs) are finally seeing approvals and increased resource commitments from regulators as that space rapidly expands (3). The rareness of many diseases targeted by CGT products gives CROs with global reach a distinct advantage over companies that do not.

But global capacity is far from the only need clients have. This means little without the ability to consistently deliver on time, and doing so requires uncommon capabilities. For example, clients want to know that a CRO can tailor services to meet the specific needs of a project, and larger laboratories that are part of complex organisations are often hindered in this regard. Small- to mid-sized companies are typically nimbler and more flexible.

The ability to consistently deliver customised services at a global scale and at an accelerated pace requires a culture that is sharply focused on delivering clients exactly what they need, exactly when they need it – if not sooner. This client-centric approach is a differentiating factor in a booming, highly competitive industry, and it can determine whether a client's drug is first to market.

Identifying industry needs and building the fastest possible response is the path to success. This article will take a closer look at the three client needs mentioned above: global reach, consistent delivery, and client centricity.

Global Reach

Clients increasingly want to partner with contractors that can service their studies across any geography. There are large, well-established companies with this ability, but they are often too entrenched in outdated systems and processes to adapt their services to the specific needs of a client's study. In other words, they are either unwilling or unable to work with clients one-on-one. CROs that are large enough to handle global Phase III studies but still adaptable enough to provide customised services to the client base bring a desirable choice to the market.

A CRO can build global capabilities relatively quickly by acquiring smaller organisations in geographical areas of need (4). This approach provides numerous benefits that are difficult to build from within: certainly, acquisitions and facilities with equipment and processes already in place, but also talented, experienced people with unique historical knowledge. Considering the current talent shortage in pharma, this is a massive benefit (5). Acquisitions can also capture the momentum of other organisations, which can then be fine-tuned to suit the acquiring company.

Anybody with the budget to do so can buy equipment and space. That, however, does not necessarily turn a given CRO into an organisation that can solve a client's problems. Strategic acquisitions provide a method for adding capacity and expertise, while

simultaneously positioning it to better serve clients with global needs.

Consistent Delivery

Client needs can only be consistently met by CROs that have a culture of execution and an infrastructure that can handle complex, time-sensitive requirements. The latter prerequisite is much easier to meet with relatively new or recently upgraded facilities. A blank slate allows companies to design workflows, examine process improvements, and implement the most advanced technologies in an effort to deliver higher quality results, on-time.

Tools that are optimised for industry-specific performance are essential for consistent and accelerated delivery. Software, for example, is particularly important for bioanalytical research, and the right solution can improve planning, resourcing, and the monitoring of important KPIs. Software can also be used to identify trends, communicate results, and gather regular feedback from clients. These are invaluable features for delivering on projects and ensuring the ability to support incoming workloads. Commercial, highly-customisable, off-the-shelf software is ideal. Custom-built code can create recurring issues (e.g., failed data transfer, general incompatibility) and fixes may require expensive, time-consuming, one-on-one support. It is far more efficient to select software that will easily integrate with other systems now and in the future.

Strength in this area is a gap in the industry. If a CRO's technologies are 20 years old, consistent on-time delivery and capacity are virtually impossible. Building or renovating facilities allows companies to put the right systems, software, equipment, and automation in place to deliver consistently, while proactively managing workload and capacity. This should be built into

new or rejuvenated facilities from the beginning and implemented globally as quickly as a company is able to do so.

Consistently delivering for clients in the booming CGT space comes with specialised requirements that most companies cannot meet. CGT clients want CROs that have purpose-built facilities for flow cytometry and molecular genomics, as well as dedicated cell-based immunogenicity and biomarker capabilities. Regulatory bodies also want to see these GLP facilities, so meeting that need can separate a company from its competition.

Another need that is typically missed by CROs is the comprehension that the complexities of CGT revolve around the patient. CGT is not just about the study; everything originates with the patient. Obtaining samples can cost over a million dollars, and because it might be necessary to fly an infant and family from a village to a city for treatment, these samples are incredibly precious. If they are not shipped and analysed appropriately, millions of dollars and those people's time are lost. There is no re-dosing with CGT; once the patient is dosed, it is done. Most companies are still focused on the technology, testing methodology, and results, rather than the sample. Doing this correctly means understanding how important the treatment is to the patient and how critical it is that samples are handled appropriately – the distribution, logistics, and regulations.

CGT clients need GLP partners who know what regulatory bodies want, and that is rare among CROs. As such, caring for samples with the highest level of integrity and knowing how to test them under the right regulations is a difference maker.

There is one more critical issue that impacts consistency of delivery in CGT studies: an increasing number of companies are involved in CGT testing, but they are distributing the testing to different labs in their network, which complicates overall study management and can impact data delivery.

Rather than performing CGT testing in 'for-purpose' designed bioanalytical labs, many clients and bioanalytical labs are sending samples to their central labs, which are clinical diagnostic operations that work under different regulatory compliance (e.g., Clinical Laboratory Improvement Amendments), rather than bioanalytical labs. The reason for this is that, historically, flow cytometry and molecular testing are performed in clinical diagnostic labs. No bioanalytical lab has the comprehensive bioanalytical capabilities that can support CGT studies in a global multi-lab setting for time sensitive testing (e.g., flow cytometry and biomarker testing), as well as full testing capabilities in at least one location. This results in multiple vendors or lab partners for the comprehensive testing of these precious samples. The ability to provide this combined global and comprehensive level of service and consistently meet timelines will be a key competitive advantage going forwards.

A Client-Centric Approach

Taking care of each client individually and providing the necessary customisation for their study without impairing efficiency is paramount. Unfortunately, this is also a gap in the industry. A CRO must be accountable and accelerate decision-making to ensure on-time delivery. It must have a culture of being flexible whenever it is necessary – with systems and processes.

Effective communication is foundational to client centricity. Well-timed, consistent communication (providing updates and strategies to clients) overcomes many of a CRO's challenges. It is essential in building trust and long-term business relationships. Whether the news is good or bad, proactive communication on project status is key, and systems that support and automate this are essential. Becoming a global entity that still caters to individual clients also requires a company-wide sense of responsibility. This, in turn, breeds energy and innovation. Scientists should not expect managers to solve all problems. They should not ask, "What do I do next?" and then simply do as they are told. That will not grow an organisation or its people's experiences, and it will not keep employees' focus where it should be: on meeting clients' needs. Employees should be enabled, trained, and trusted to contribute to improving efficiency or finding creative ways to deliver on time to clients. A manager's role should be to facilitate and guide change, growth, and innovation so the client's needs are prioritised and everyone is successful.

The Final Ingredients

A new approach is needed to consistently meet clients' needs in the CRO space. Companies must focus on building systems, SOPs, and creating a harmonised organisation that is global, modern, and adaptable. Acquiring high-quality organisations in strategic locations is a powerful way to leverage the experience of a team of SMEs while increasing global reach. In the right company culture, this can dramatically strengthen a CRO's ability to deliver, though there are other factors that leadership must keep in mind.

CROs should aim to grow by evaluating their approach to talent acquisition. Alongside resumes, they should consider competencies like resilience and aptitude. Talent acquisition should begin internally by providing upskilling and scientific development, personal enablement, and career mapping.

This way, each team member becomes more committed to making meaningful contributions to the company. Building relationships with community partners and educational institutions is another way to simulate contributions to an organisation while also contributing to the scientific community. Programmes such as Women in STEM will allow innovation and advancement, as will listening to all voices regardless of

tenure (6). And if those who are new to bioanalysis are guided to flourish through a years-long global training regimen, they will become part of a cohesive unit. Overall, this approach will yield a team with essential core values:

- Innovative mindset
- Committed to helping others achieve their goals
- Appreciative of leaders who are continually learning and teaching

Onboarding, training, and engaging the right people is challenging in the current environment. CROs must have an innovative hiring mindset (whom they are looking for) and continue to invest in skill development and support individual advancement from day one. Training systems that are supported by a dedicated team will accelerate the increase of knowledge, especially for subject matter experts (SMEs) and technical teams.

CROs must also have a vision that permeates the organisation from top to bottom. This vision should include everything – from how recruiting, onboarding, and training are managed to the lab's processes, procedures, and workflows – to create company-wide alignment on foundational topics like client and staff needs, SOPs, processes, and software solutions.

There should be an established workflow that accounts for every step, up through getting data to the client. Dedicated consultants can help map out this vision and implement it in well-timed bursts; it does not have to be done all at once. The crucial factor here is establishing a culture that prioritises constant improvement. Changes that improve effectiveness and efficiency should be welcomed by scientists doing the work.

Personal responsibility for each person's contribution to a shared vision requires clear, honest communication among the departments and levels of an organisation. There are many ways to encourage and facilitate this, including 'town hall' meetings, in which employees can freely ask questions and bring problems forward. Whatever the forum or method, frequent communication and transparency keep people engaged and trained on the company's mission.

Rapidly driving all the changes that have been discussed requires a high level of investment, but the benefits to customers are enormous. Being large enough to support global Phase III studies while retaining the ability to customise services is an edge over the larger entities and a profound value proposition. Leadership teams that understand what clients need will adapt their services to meet the void in the market.

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Patrick Bennett has over 35 years of experience in pharmaceutical analysis and laboratory management. Now CEO at **Alliance Pharma**, Patrick's experience includes the roles of Strategic marketing Director for Pharma with Thermo Fisher Scientific, LabCorp, and Vice President of Strategy and Development with PPD.

pbennett@alliancepharmaco.com

Jean Pierre Boutrand, COO at **Alliance Pharma**, has over 30 years of experience evaluating and developing medical technologies. JP's experience includes division and operation leadership for Contract Research Organisations such as LabCorp Drug Development Central Laboratories, and North American Scientific Associates.

jpboutrand@alliancepharmaco.com

Vito Saccente, CCO at **Alliance Pharma**, has over 25 years of sales leadership experience in the life science/CRO industry, including all aspects of nonclinical, clinical, and CMC product development of vaccines. Vito's experience includes Vice President of Sales, Vaccines, and Biosciences for Q2 Solutions, where he oversaw the commercial strategy and growth for vaccine, bioanalytical, and ADME testing services.

vsaccente@alliancepharmaco.com