Contributed by

JAMIE MACDONALD
Senior VP and Chief Operating Officer

Partnering with CROs:

ACHIEVING OPERATIONAL EXCELLENCE

Our industry is facing a challenge. In 2010, the FDA approved only 21 new drugs, down from 26 in 2009 and 24 in 2008. To counteract this decrease, biopharmaceutical companies are increasingly anxious to launch their products as quickly as possible to benefit from related revenue sooner. One way they're looking to speed their development process is outsourcing to CROs.

According to independent research by the Tufts Center for the Study of Drug Development, clinical trials conducted by CROs are completed up to 30% faster than those conducted in house. And these time savings ultimately lead to cost savings — crucial when pressure is growing to reduce the cost of drug development. But how do CROs achieve such savings? The answer may lie in operational efficiencies.

Operational efficiencies condense timelines and drive down costs by combining the right people, procedures, and technologies to enhance productivity. CROs are adept at realizing such efficiencies and because their main aim is to help companies develop products quickly, safely and cost effectively, it's fair to say these organizations have become masters of operational efficiency.

The ways in which CROs achieve these efficiencies are numerous and include collaborating through the "right type" of partnership, the utilization of emerging markets, and the development of innovative technology tools.

Partnership Models That Drive Efficiency

For a number of years we've seen our industry move from project-by-project outsourcing to more "synergistic" partnership models. While it is still early in the evolution of these partnerships, the benefits are becoming increasingly clear. The high volume of work under a number of partnership models can lead to significant efficiencies and cost savings without sacrificing quality. For example, more and more customers have come to embrace functional service provider (FSP) partnerships — a strategic model that uses dedicated expert teams to package together similar tasks (or related services) across an entire clinical development program. This creates operational efficiencies and generates premium-quality data by:

- Identifying functional overlaps and eliminating redundancies
- Standardizing processes across particular functions or entire sponsor programs
- Reducing time spent training because the same team can be used across numerous projects
- Managing a function through one vendor, rather than several, to streamline communications
- Bypassing the bid process to allow for the quick engagement of resources

Location, Location, Location

Biopharmaceutical companies are growing increasingly aware of the benefits of emerging regions like Asia/Pacific, Central and Eastern Europe, and Latin America. In addition to benefiting from the proven quality and increased efficiencies of these regions, benefits can be gained from establishing an early presence in areas of increasing commercial importance. China, for example, is predicted to become the world's second largest biopharmaceutical market by 2020. Biopharmaceutical companies must choose partners with the infrastructure and expertise to access these markets. Establishing this expertise and global reach in house can be cost prohibitive, which is why it makes sense to work with CROs that have proven track records for operating in these key markets around the globe.

Developing the Right Tools

In addition to the trend toward strategic partnerships between biopharmaceutical companies, another prevalent trend in clinical trials is the move toward embracing new technologies for better efficiency. There are a number of eClinical technologies contributing to faster clinical trials without compromising data integrity. Data monitoring technologies are driving efficiency by providing access to better data sooner as well as detecting unusual data patterns that help monitors identify inaccurate, incomplete or fraudulent data more quickly. The move toward this type of technology also is driving the trend for more adaptive trials. Faster, more reliable data are allowing trial designs to be modified, in pre-specified ways, in response to real results generated during studies. Providing opportunities to refocus or redirect trials midstream without compromising data integrity is invaluable to customers.

Another key area of the clinical development process being impacted by technology is patient recruitment. Unlike the past, when the patient recruitment experience was more anecdotal, it is now becoming increasingly data-driven with recruitment simulation models that mine historical data, take into account previous results, adjust for numerous variables, and generate realistic timelines and probabilities. Better upfront planning for the recruitment and retention of patients is an often overlooked component that has a significant impact on the outcome of clinical trials.

The Right Partner is Key

Choosing the right partner is everything and must entail more than just infrastructure and technology. Customers want definitive data sooner so they can know whether their drug is safe and efficacious so a decision about its future can be made earlier. Operational excellence requires your partner to provide more than just the right services. Your CRO also must be a good cultural fit with a deep understanding of your business ambitions as well as the flexibility, resources, and expertise to adapt to your needs. PV

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