MedCity News

# To improve drug development, it's time to rethink clinical trial site engagement

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By Craig Morgan

For clinical development teams, there are many parallel and competing factors to consider when preparing for and conducting clinical trials. From finalizing the study protocol to ethical/regulatory reviews to coordinating drug product supply, there are multiple overlapping activities across different partners in the clinical trial ecosystem.

To date, much of the focus on the partners in the value chain has been on contract research organizations (CROs), and rightly so. CROs are critical players in clinical research studies. In fact, increasing demands on internal resources and falling productivity are driving pharmaceutical companies to increasingly outsource to CROs to achieve cost savings.

Last year saw a large rise in expenditure for outsourcing services, according to the recent Nice Insight Contract Research — Preclinical and Clinical Survey. The trend towards continuously escalating spend over the past five years has held steady. The survey found the majority of companies (38 percent) now spend $51 million to $100 million for outsourcing, while another 18 percent spend more than $100 million. This is up dramatically from 2015, where almost 64 percent of sponsor companies spent $10 million to $50 million on outsourcing. In 2015, just 23 percent of companies spent more than $50 million.

Given the growing reliance on CRO partners, sponsors are increasingly turning their attention towards promoting CRO engagement in areas such as study oversight — an operational area that can lead to significant cost reductions. Focusing the sponsor staff on the most impactful areas of oversight and providing the right data at the right time, the average sponsor oversight full-time equivalent (FTE) contract to CRO ratio can be reduced from 1:3 to 1:8, or even 1:15 in more advanced partnerships, according to a recent study from Parexel. This reduction in internal cost can be significant— equivalent to saving as much as 20 percent of the CRO professional fees for a typical project.

Beyond study oversight, better engagement brings the knowledge of both partners together – often resulting in streamlined protocols and other operational efficiencies. And the more insight a CRO has into the sponsor's pipeline and strategy, the better the CRO can plan and respond to their needs and avoid costly delays.

But as sponsors look to gain as much efficiency as possible from CRO partnerships, the clinical research landscape continues to grow in complexity. In 2015, the FDA approved a record 56 new drugs, with the majority of those approvals within specialty or complex indications, such as rare diseases, oncology, and autoimmune diseases. With the rise in specialty indications, the domain knowledge and expertise of clinical research investigative sites and their investigators has become more important than ever. In addition, as the patient-centricity movement gains footing, so has the awareness that the patient experience relies heavily on relationships with sites. With more complex study protocols come longer cycle times and patient recruitment difficulties.

Yet efforts to drive site engagement from the sponsor side have been lacking, with sponsors traditionally relying on CRO partners to manage site relationships and operations. Many times, sites do not know how they are being measured and how they can improve performance to achieve the goals of increasing quality and driving down costs. In a 2014 survey sponsored by Allergan, 100 percent of site participants indicated that they "rarely receive" metrics from sponsors. However, much of that is beginning to change, led by a cross-industry coalition.

To address the need for metrics and data transparency, in 2016, the Society for Clinical Research Sites (SCRS) launched a working group to lead the Site Study Dashboard initiative, an effort aimed at implementing a standardized, industry-wide Site Study Dashboard. The working group for this initiative is comprised of SCRS sites, sponsors, CROs and professional service providers. The dashboard is aimed at enabling data transparency for sites: highlighting study-specific level trends, enabling sites to access data about performance, and benchmarking their sites against the other sites within a study. And to enable a cost-efficient process, the group aims to standardize the process for sharing site performance information. The Site Study Dashboard Initiative focus includes:

- Creating standard site metrics which can be measured and shared with the sites during a study;
- Providing definitions for each metric;
- Determining the method of how the information should be shared with the site;
- Creating a universal Site Study Dashboard template to be adopted by industry;
- Contributing to the industry's adoption of the Site Study Dashboard project.

Several standard metrics have been targeted for the dashboard, including crucial indicators such as retention rate, number of subjects randomized, query rate, deviations, and time from site activation to first subject first visit (FSFV). This kind of data creates a common language across the research value chain and removes the ambiguity in understanding how sites are evaluated in on-going studies. And indicators show that investigators welcome the initiative. In the SCRS Summit Survey 2014, 79 percent of sites reported that they want to see a standardized site dashboard, while 62 percent said they believed it would them help improve the quality of their site.

Additional efforts are being made to reassess site engagement activities by evaluating earlier involvement, reducing burden, and establishing more permanent collaboration – often driven by patient centricity goals. CenterWatch captured some recent examples of these efforts by several companies.

For example, in 2012 Sanofi-Aventis developed a standard practice which involved engaging the principal investigators and clinical research coordinators in the design phase of its R&D studies. The result was a reduction in recruitment times, as well as, overall protocol amendment rates by nearly 50 percent. Novo Nordisk, a company which has consistently received high scores from investigators, launched a program which evaluates serious adverse effect flags to determine whether the flag is study-related or caused from an unrelated incident. Other measures were instituted because of site feedback, including partnerships with vendors to organize travel arrangement for trial participants and simplified paperwork processes for verification of trial supplies storage at the proper temperature.

CROs are also stepping up to promote engagement. INC Research recently launched the Catalyst Program to establish a framework for site collaboration. The program seeks to identify the needs of the sites, streamline development processes, and create new methodologies that can improve clinical research and site efficiency. Through the program, INC Research leveraged its Catalyst Site Network, a select group of global high-performing sites, to identify areas for potential improvement. As a result, INC Research developed revised processes and timelines that have led to significant efficiencies, particularly related to study startup.

Tracey Gashi, INC Research Executive Director, Site & Patient Access, said sites are foremost in the mind of the drug development industry. Sponsors and CROs alike are recognizing that building stronger site relationships can lead to higher-quality site performance, better patient engagement, and ultimately lower costs.

"Stakeholders are recognizing that sites are central to the drug development process and bringing new medicines to market," Gashi said. "Close collaboration is essential in order to improve drug development timelines, cost, and processes."

Looking ahead, the investigative site role will only continue to gain importance in clinical research as therapies become increasingly specialized and demand for more complex protocols and narrower patient populations grows. Sponsors and CROs will have to evolve to find new ways to incorporate site feedback into clinical development programs. With high-performing sites already in demand, increasingly investigators will choose to work with those organizations committed to their engagement and addressing site problems and concerns. The fact is that the next frontier in clinical research efficiency will be realized through close collaboration with the investigative sites – a critical, often overlooked partner in the value chain, with the closest tie to the patient. Patient centricity starts and ends with the investigative site.

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