

BUILDING BRIDGES

The function of central labs in the drug development process continues to evolve and become more critical to the efficient operation of clinical trials. As present-day clinical research becomes more complex and geographically dispersed, trial sponsors are faced with an urgent need for harmonized data. Furthermore, many pharmaceutical companies are recognizing that a preferred provider relationship with a central lab service provider can bridge processes across more than one project and enable a consistent platform across an entire drug program.



TOM WOLLMAN, senior vice president, Quintiles Global Central Laboratories, discusses how central lab support can play a strategic role in clinical research.

The ability to harmonize globally collected data is arguably the primary advantage of working with a central lab service. A lab service provider that can collect data from around the world has the ability to transmit harmonized, consistent data that can be submitted into a database immediately. By using a Web-based data-viewing tool, trial sponsors are able to monitor the progress essentially in real time and make adjustments when necessary and when appropriate to the trial's protocol. Trial monitors can see results in approximately 24 hours, which is a capability that wasn't available just a few years ago. There are still steps remaining before clinical data and lab data can be fully integrated, but being able to look at data in almost real time is a benefit of working with a central lab, and is of utmost importance as more trials employ an adaptive design.

EARLY ACTION

In order to maximize these benefits, however, it is best to include the input of the central lab early in the trial planning process. The most successful programs we run at Quintiles are those in which we've had some consultative role in the protocol design. When we're given the chance to work with sponsors early, we can provide advice on tests that might

be more suited to particular studies. For example, if a trial sponsor wants to look at biomarkers to see if certain populations have a specific genetic characteristic that makes a drug more effective or more toxic, an early discussion with a central lab could ensure that the right lab tests are included in the study design. At the same time, if a protocol has too much testing, extraneous data points that are unrelated to the effect of the drug might be produced. So a tight protocol—proving what needs to be proved—can be enhanced through a preferred relationship with a central lab service.

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Establishing an alliance relationship early also can bring consistency across an entire drug program as the compound progresses through the development stages. As an example, a sponsor may run protocols that include placebos and a competitor's compounds against a study drug at different dosages, and central lab support can ensure that process is streamlined from phase to phase. These development steps used to be treated as discreet transactions, but now we're trying to get ahead of the curve and have all the lab components for a trial run off of a very consistent platform.

When we have this type of relationship with a sponsor, it allows both parties to better manage resources and be more cost-efficient. By providing insight into their programs and their protocol, an established relationship allows the lab to be better prepared from a resource perspective. These alliance relationships also allow for more cross-sharing of information that enables both companies to be more efficient and effective.

Sharing information also can lead to better patient recruitment. Since approximately 30 percent of trial sites never enroll a single patient—and the cost to set up a site is usually between US\$25,000 and US\$30,000—having historical data on what sites have done in the past can amount to huge savings in both time and money. In addition to site performance, a central lab also can supply scientific data to help with the inclusion and exclusion criteria. All these factors again demonstrate the importance of involving the labs early in the process.

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ON THE HORIZON

Looking ahead, there are a few industry trends that will have a profound effect on the role of central labs. One important factor for trial efficiency is to have labs in the same

geographic region as the sponsor's investigative sites, and I think this geographic spread will continue. A trial can't simultaneously randomize patients in Eastern Europe and send blood samples to Kansas—it just wouldn't work.

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Another clear trend is the increase in biomarkers in the targeting and testing phases. As more clinically reliable biomarkers are developed—particularly in light of safety concerns and the increase in scientifically sound post-marketing studies—central lab support will play a significant role in the execution of these trials.

The most promising trend is the development of systems to combine clinical and lab data into one seamless interface. Using an integrated patient view, a sponsor could conceivably access clinical data for any trial participant in a given location, in real time. This isn't quite a reality yet, but it likely will be in the near future, and a system like this will greatly enhance the quality and efficiency of clinical trials.