

GCL Market Trends

Clinical Trial Outsourcing is a Win-Win for Pharma & CROs

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The size of the global central labs (GCL) market is estimated to reach \$1.6 to \$2.3 billion this year, according to estimates from Barclays Capital in June 2009, as pharmaceutical and biotech companies outsource almost all central labs activities.

As lab budgets remain constricted, pharmaceutical and biotech labs are outsourcing preclinical services to create efficiency and off-load the need to maintain staff, instruments, and consumables for irregularly scheduled projects and projects that extend beyond their scope, states a new report from BioInformatics, LLC.¹ Increasingly, the model for drug development has the pharmaceutical industry devoting a large portion of its spending for late-stage clinical trials, according to a University of Rochester Medical Center study.

Barclays expects the GCL market growth to slow in coming years as overall growth rates for pharmaceutical and biotech R&D spending decrease. Although drug developers are improving R&D efficiency, in part by terminating more unpromising drugs earlier in development, their continued success will depend on how well they partner with other firms at specific points on the development spectrum, according to the Tufts Center for the Study of Drug Development (CSDD).

“Future success for many sponsors will depend on their ability to collaborate with other drug companies, and how well they engage and partner with outside service providers,” says Tufts CSDD Director Kenneth Kaitin in connection with the release of the Tufts Center's Outlook 2010 report on pharmaceutical and biopharmaceutical trends. He says more firms will focus on improving clinical protocol design to help reduce trial costs and speed development cycles and to mitigate a trend toward increased protocol complexity.

Specialty Pharma magazine asked two of the industry's top central labs about the benefits derived from partnering with them, their role in drug development, and the work they are being asked to perform for today's pharma and biotech organizations. The roundtable participants include Susan Johnson BS MT(ASCP), Director, Clinical Trials Services, PRL Central Laboratory Services; and Steve Lobel, PhD, Vice President, Global Laboratory Operations, PPD, Inc.

Q: What has been the biggest driver for Specialty Pharma to use a central lab in clinical trials? And what is the greatest benefit to Specialty Pharma?

Ms. Johnson: Standardization of procedures across all participating study sites is a significant driver behind the proliferation of the Central Laboratory Services delivery model. Costs associated with harmonizing data from multiple sources, plus the management of multiple laboratory facilities creates an unnecessary burden on Specialty Pharma companies. The successful central lab will assume responsibility for all aspects of the laboratory service and provide necessary updates and information as required by Pharma.

Dr. Lobel: In addition to significant cost and time savings generated from using a central lab, Specialty Pharma requires a single, global platform to access and manage their clinical trial data in as near real-time as possible. PPD is able to provide clients with this platform through PPD Clicks™, which delivers near real-time lab data from our global central lab facilities in Highland Heights, KY; Brussels, Belgium; Beijing, China; and Singapore. All of our labs have the same equipment, standard operating procedures, and calibrators, and there is no type of harmonization of data needed. Regardless of which lab is conducting the testing, our clients have the ability to view, sort, and filter all lab data quickly and easily to create customized reports.

Q: How critical is a central lab's participation in clinical trials for new drug development?

Dr. Lobel: As clinical studies become more complex, the central lab's participation in clinical trials becomes more important. Pharmaceutical companies want to get the most out of their clinical data to avoid additional testing once a drug has been submitted for regulatory approval. As a result, more innovative, collaborative partnerships are forming between biopharmaceutical companies and CROs with global laboratory expertise.



Last year, PPD entered a strategic collaboration with Merck & Co. in which we purchased its vaccines and biologics testing laboratory in Wayne, PA. The biologics and vaccines markets are among the fastest growing segments in the industry. The acquisition expanded our global central laboratory business, adding world-class vaccine and biologics testing, assay development, and sample storage capabilities to our current suite of laboratory services. As part of the agreement, Merck has committed to spending \$400 million with PPD global central and vaccine labs throughout the next 5 years, and we are Merck's exclusive provider of vaccine testing services and major supplier for global central laboratory services.

The agreement demonstrates an innovative approach to delivering high-quality, reliable, and timely laboratory services and data to key biopharmaceutical companies. We continue to invest in our lab by developing new technologies and assays to expand our immunochemistry and oncology vaccine testing services.

Ms. Johnson: Central laboratories participation is vital to the drug development process. Laboratory science is changing rapidly, and the central laboratory is an invaluable resource to ensure that the most current assays are selected to support protocol objectives. Laboratories also provide critical technical information to support the data that has been observed during a trial and assist with queries from the regulatory agencies. Keeping abreast of the transport and logistical challenges associated with different geographical regions is part of the daily routine for a central laboratory. These regulations change frequently, often with very little notice, creating a potential snare for very busy pharmaceutical project managers. The central lab will ensure that all study sites have the proper materials and documents to ship the required sample matrix.

Q: With biomarkers making up a majority of the work a central lab performs in clinical trials, how has this affected the types of services you need to offer?

Ms. Johnson: The heightened reliance on biomarkers in clinical research requires us to be much more nimble and able

to adapt our test menu quickly. Our Clinical Pathology team is available to assess appropriate markers based on the target mode of action of the compound under investigation. Flexibility is the key here, with appropriate instrument systems and processes in place to accomplish rapid validation of an assay, resulting in a high-quality dataset.

With the changes looming to the healthcare system in the US and the movement to promote personalized medicine, the development of biomarkers to predict treatment success for a new drug may be beneficial to obtaining a spot on the formularies of third-party prescription drug payers.

Dr. Lobel: PPD brings more than 20 years of central laboratory expertise to our clients. We offer a comprehensive suite of laboratory services, which includes cGMP, bioanalytical and global central lab facilities, and a biologics and vaccine testing laboratory where we offer a comprehensive menu of assay development and testing services for vaccine clinical trials.

Given the importance of biomarker testing in drug development, we have tremendous expertise in assay development and have expanded our partnerships with biopharmaceutical companies by developing, qualifying, or validating specialized assays using a variety of high-technology platforms and tools. We are extremely flexible in how we work with our clients. Our clients may choose to use assays we develop, or we can work with our clients to validate their new assays using standard and specialized platforms and techniques. Validation of assays supports analysis of biomarkers and helps our clients better understand how assays will perform for regulatory submission. In addition, for inflammation, autoimmunity, immunodeficiency, and oncology indications, we routinely use flow cytometry to evaluate how drugs are impacting immune and cellular response.

While pharmaceutical labs usually oversee the identification and development of assays, they increasingly rely on us as compounds move through development. Phase II and III studies often require the analysis of thousands of samples, and we work closely with our clients during these phases to analyze and run assays to determine key indicators for a drug's efficacy. Our bioanalytical group is equipped to validate and test specialty assays that run on LC-MS/MS platforms.

Q: As clinical trial testing increasingly goes global, please explain how your central lab has established itself as a global player?

Dr. Lobel: In 2008, we expanded our global central lab capabilities into China through an exclusive agreement with Peking Union Lawke Biomedical Development Limited (PUL). The agreement allowed us to immediately provide biopharmaceutical clients in China with our full range of highly customized central lab services. It is extremely difficult to export lab samples to other countries for testing, and this agreement saves our clients time and money by giving us the capability to provide results more quickly without incurring expenses for exporting shipments.

Last year, we also expanded our central lab operations into Singapore, which strengthened our ability to provide clients an extensive range of customized laboratory services in Southeast Asia, a high-growth region for clinical research. Within weeks of opening this facility, we are already adding new assays and ordering new instrumentation to support flow cytometry and specialized lipid testing. In addition, we have central lab facilities in Highland Heights, KY, and Brussels, Belgium, to serve our North American and European clients, respectively.

We are also expanding our cGMP analytical testing services by opening a laboratory in Athlone, Ireland, to meet growing client demand in Europe, the Middle East, and Africa (EMEA) for these services. The facility will open in the first quarter of this year and offer method development and validation, stability, and quality control testing for all phases of drug development, with particular emphasis on inhalation and biopharmaceutical products. This facility builds upon the capabilities of our cGMP lab in Middleton, WI, and the bioanalytical facilities in Middleton and Richmond, VA. We continue to identify targeted areas for expansion where we plan to build fully owned laboratory facilities based on client demand.

Ms. Johnson: We have partnered with a global laboratory network, having members strategically placed around the world. Harmonization of procedures, cross-validation of laboratory assays, and the presence of one global database system link all data together. We assign a Global Project

Manager to be responsible for communications with each partner, with frequent communication regarding study progress. Having experienced, local staff in each region erases language barriers and makes for a more comfortable interaction with the local investigator sites.

Q: What is the one message you would stress to Specialty Pharma players about the relationship between them and the central lab in carrying out clinical trials?

Dr. Lobel: By beginning work with our clients early in the development process, we are able to develop a complete understanding of priorities, such as speed, costs, or logistics. Our comprehensive lab capabilities and flexibility in working with our clients allow us to deliver on time and according to our clients' specifications. Our goal is to get a safe, effective drug to market as quickly as possible, and time is important to each client with whom we work. Our ability to plan early allows us to create significant time savings for clients in design and start-up and later in the database lock process. By remaining flexible throughout the project, we can meet specific protocols, data reporting, and management information requirements.

Ms. Johnson: Everyone emphasizes open lines of communication, but to take that further, it is important to view the central laboratory as your partner. A successful trial has many moving parts that require synchronization. If the central laboratory understands the objectives and has the opportunity to suggest the best possible means to meet those objectives, the success rate will go way up. Each vendor engaged by the pharma company must be aware of how their piece of the project impacts others. We must all understand that perfection is not always possible, but the approach to issues resolution can greatly minimize or eliminate any potential damage. Trust and transparency are paramount. ♦

Reference

1. BioInformatics, LLC. The Contract Research Market for Drug Discovery Technologies: Opportunities for Life Science Supplier. February 2009.