

# REAL-TIME DATA ACCESS

**DAVID SPAIGHT**, President, MDS Pharma Services, discusses an innovative new study management system that gives clients access to study data anytime, anywhere.



## What are the most innovative aspects of Apollo? How does real-time global access factor into these benefits?

The Apollo system offers a number of competitive advantages that allow MDS Pharma Services to provide timely and efficient service to clients. On the provider side, Apollo is a central lab business management system that integrates all central lab management activities from the initial bid on a project right through to invoicing. In addition, this unique system allows MDS Pharma Services and its clients full transparency and real-time access to information about any trial run globally, in multiple regions. The real-time factor has many advantages as it allows specific decisions to be made instantly based on data retrieved from one system rather than multiple systems. For example, if a competitive recruitment process is being conducted for a trial, real-time access to recruitment data makes it possible for sponsors to stop recruitment when the target number of randomized patients has been reached. Another advantage of Apollo is that it offers a full global view of sample life cycles, which helps tremendously when planning database lock activities and final retrieval of all tubes, globally. One single access allows the MDS global project leader to make instant decisions if tubes could not have been recalled. Because the system is fully integrated, every single activity performed by each MDS Pharma Services central lab facility can be fully tracked for the budget/invoice comparison.

## Apollo proffers a single interface for all aspects of protocol management. How does this impact clinical trials and, in particular, global clinical trials?

Apollo supports consistency and harmonization in our approach to global clinical trials by offering one global study setup that is instantly applicable to the six fully-owned MDS labs around the world. Regardless of where a patient is recruited in the world, the investigator will receive the same kits, documents and most importantly, the same high-quality results. Another benefit is the flexibility the system offers to seamlessly re-route samples to another MDS central lab facility due to capacity or other issues. Samples can instantly be rerouted to any of our other facilities in order to provide full testing as defined by the protocol. No intervention is necessary as the single global setup directs all of our labs. This is a major benefit for clients working in the global arena.

## How does Apollo facilitate the process of running a clinical trial?

The full harmonization of the trial protocol and data allows immediate trend analysis from anywhere around the world, giving sponsors the information they need to make immediate informed decisions regarding their trials and compounds.

## What research measures are taken to ensure compliance with federal and global regulatory agencies?

Apollo is fully 21 CFR 11 compliant.

## In regards to research, how is MDS Pharma Services growing in the areas of drug development and biotechnology? What strategies help MDS Pharma Services stay competitive?

We believe that the Apollo system offers an important competitive advantage to clients of our central lab line of business. Also within the central lab line of business, our dedicated R&D lab produces more than 40 new biomarkers every year and is developing strong relationships with our pharma customers to streamline and accelerate technology transfers at the early stages of a compound coming through the pipeline.

Through our development and regulatory services line of business, MDS Pharma Services offers full development program support, which is attractive to biotech sponsors who may not have the in-house resources of big pharma. Across our business, the MDS Pharma Services brand promise of high quality, on-time delivery of services is helping us stay competitive. Our operations are being optimized through LeanSigma and other process improvement methodologies to deliver more efficient client service. For example, the 65-bed cardiac safety testing center at our new 300-bed Phase I facility in Phoenix uses a LeanSigma-optimized process that allows thorough QTc studies to be run in large groups, expediting these important studies. As a result, we have seen an increase in TQT efficiency and quality. Twice as many participants can now be enrolled in a QTc study at one time without a significant change in staffing requirements. This has reduced overall study timelines for clients while maintaining the economic feasibility of conducting these critical studies. **FP**



DAVID SPAIGHT, President of MDS Pharma Services ([www.mdsp.com](http://www.mdsp.com)), has more than two decades of experience in the global life sciences industry and a track-record of successfully building strong businesses. Prior to joining MDS in April 2006, he served as Senior Vice-President, Global Sales and Marketing at Fisher Scientific Products. In 2008, he was named Chairman of the Board of Directors of the Association of Clinical Research Organizations (ACRO — [www.acrohealth.org](http://www.acrohealth.org)) which represents the clinical outsourcing industry to regulators, biopharmaceutical clients, policy makers and the public in the United States and around the world.

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