An Executive Summary

Clinical Data Management: Patients' Lives are on the Line

Vahan Simonyan, PhD
Lead Scientist
FDA

Ralf Russo
Senior Director and Global Head of Clinical Database Management
Pfizer

Michael Keech
Head of US Advisory Services
Kinapse

Maria Perkinson
Senior Manager
Kinapse

Srinivas Karri
Senior Director of Product Strategy
Oracle Health Sciences

Managing clinical data is complicated and challenging. In addition to ensuring data quality, clinical data management includes collecting, managing and ensuring the privacy of enormous amounts of data. Such data originates from diverse sources that encompass traditional lifestyle information, vital signs, pathology and clinical lab test results, specialty-specific test results (i.e., EKG, EEG and radiology), clinical study data and patient-specific personal and disease-associated genomic-sequencing data.

Many new medicines, especially those for cancer and genetic diseases, are tailored to individuals' genetic characteristics (personalized medicine) and have resulted in the collection of tremendous quantities of genomic data. This deluge of data, along with data collected for the Precision Medicine Initiative (e.g., medical records, genetic and metabolic profiles, environmental and life-style data, and other relevant information) has initiated the development of new paradigms, processes and technologies for optimizing data collection processes and storage infrastructure.

The FDA (consumer of the data), sponsors (generator, collector and user of the data) and numerous consulting firms (management consulting services to help sponsors develop standards, policies, processes and workflows, and technology solutions to collect and manage this data) are all invested in data management. Stakeholders from these areas offer their perspectives here. The full discussions are captured in a three-part *Pharmaceutical Executive* podcast series moderated by Srinivas Karri, senior director of product strategy at Oracle Health Sciences.

The FDA Perspective

In addition to evaluating traditional disease-focused clinical study data for new drug approvals, the FDA is seeing a "significant number of submissions for new drugs, new therapeutics, and new personalized medicine approaches using these types of data [diverse individual disease, genomic, and personal health and wellness data]…to develop products," says Vahan Simonyan, PhD, lead data scientist at the FDA.

From a regulatory perspective, the FDA's role is to ensure the safety and efficacy of medical products. But, what does this mean in terms of the management of data that is increasingly complex to deal with for complicated disease states? "The FDA needs to build the infrastructure. We have to build the intellectual capacity and expertise to analyze this complex data to fulfill this mission," notes Simonyan.

Individual subjects' data sets are huge; a single patient's data set can be as large as 100 gigabytes. That figure multiplies to several terrabytes of raw data as the FDA receives data on thousands of patients within a trial and then runs algorithms to detect things like genome mutations that could affect human health.

SPONSORED BY

ORACLE

Pharmaceutical Executive

This quantity and complexity of data for next-generation medicine poses new challenges for the FDA. The challenges start with the transfer of the data from the sponsor to the Agency, which, once received, needs infrastructure, hardware and storage to maintain petabytes of data over the product's lifecycle. "The challenge is multifaceted," says Simonyan. "Getting the data is difficult. Storing it is difficult and expensive. Analyzing it is humongously difficult and expensive, and visualizing and interacting with the data—even that is difficult. We have to build entire ecosystem [of] solutions to deal with these challenges."

In addition to the technical and intellectual challenges of processing large data sets, Simonyan observes that a major challenge is the lack of incentives to share data. "We train our algorithms and train our interpretation before we can trust our own judgment based on that data…To train our algorithms, we need access to data and that's our biggest challenge."

A Sponsor's Perspective

In his role as the senior director and global head of clinical database management at Pfizer, Ralph Russo, is looking at clinical data management in terms of technology and how clinical data is collected from various sources and transformed into a format that is usable for data managers, submission or other internal uses. "When we think about data collection, it's no longer just about an electronic data capture (EDC) tool or using paper case report forms, rather it is about all the different places where data comes from, capturing it, making it manageable, and sustaining those systems," he states.

"The FDA, sponsors and numerous consulting firms are all invested in data management."

So, Russo says he is "trying to understand the volume of studies that the company needs to manage and hiring staff that has experience with EDC and other data collection technologies."

He is also working on standards that Pfizer can leverage across all therapeutic areas and building a database that can meet Pfizer's needs. In creating such a clinical database, "it's important to understand the clinical science and the data-related needs required by the science," Russo believes.

Russo also observes that change is a significant part of the overall workload in clinical data management. "Many of these studies allow patients to live a lot longer. So, managing that and other changes, [protocol and other] amendments, and regulatory-driven changes impact how we collect data and what information we collect," says Russo.

With respect to industry collaboration, Russo agrees that the mining of databases containing data acquired for the Precision Medicine Initiative and aggregating it with Pfizer's rich information assets promises to provide greater insights for targeted drug therapies.

Consulting Service Provider Perspective

Recognizing that the value of the information in clinical databases extends beyond clinical study data for submissions, Kinapse works with its clients to "help them build that roadmap around the people, process and technology components," says Michael Keech, head of US advisory services at Kinapse. "We help our clients identify what that business case is going to look like and determine the drivers we're adjusting, modifying, and improving."

Then, the firm helps clients work through designing new processes, and developing those processes with new technology components. "We also look at the organizational structure and readiness and, at the very end, make sure sustainability components are in place to enable the organization to continue to evolve and change their business processes around clinical operations in R&D productivity."

Given that technology enables the collection of enormous quantities of data and a large part of the cost of clinical trials is cleaning and standardizing this data, "standards help streamline this process, aggregate the data faster, and speed the drug submission process," says Maria Perkinson, senior manager at Kinapse.

In addition, Keech observes that it is critical to get those components right the first time and to put together a very robust project that identifies the interdependencies and the tasks that have to be done: "With that vision, you can organize the effort, do the process improvement, look at the people in the organizational structure, and look at the technology components and how to enable them."

Perkinson also observes that there is more and more collaboration in the customer–supplier relationship. She states, "It used to be that the customer drove everything. I see collaboration bringing great improvements as we go forward not only with sponsors and their technology partners, but also among competitors. As we start to collaborate and partner more, we can get to market faster with some common practices."

For more of this discussion, listen to the *Pharmaceutical Executive* three-part podcast series.