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How CROs Are Helping With Healthcare's Data Problem

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By Sujay Jadhav

As the debate over reforming the nation's healthcare system rages on, there's at least one goal all sides can agree on: bring costs down. According to data the Centers on Medicare and Medicaid Services released in December, Americans collectively spent $3.2 trillion on healthcare in 2015. Yet as Dr. Joseph Dieleman, assistant professor at the Institute for Health Metrics Evaluation at the University of Washington, told NPR last month, "The U.S. stands out among high-income countries as having catastrophic medical expenditures that put people into poverty." Reducing the amount of money and time spent on clinical trials that all new drugs must pass before the FDA approves them is a priority, as they represent the biggest cost of drug development. That is driving a shopping spree for companies that possess a treasure trove of patient and site data that could be mined for operational trial insights.

Compiling virtual stacks of clinical research data is easy. The difficult part comes with trying to use that data to create standardized metrics to optimize clinical trial performance. Research by KPMG shows that the average return on R&D expenditure in the pharmaceutical industry fell from almost 18% in 1990 to only 10% in 2011. In 2016, it dropped all the way down to 3.7%.

To make matters worse, the percentage of drugs that successfully navigate the lengthy and costly clinical trials process is small. Pharmaceutical companies spent $169.3 billion on R&D in 2016, which accounts for approximately 85% of the entire global life sciences industry's total R&D spending. The cost to develop a new pharmaceutical drug now exceeds $2.5 billion, and it takes at least 10 years to develop a drug. Yet the percentage of drugs entering clinical trials resulting in an approved medicine is less than 12%.

The primary culprit behind this waste of time and money is that stakeholders too often struggle with data that is woefully inadequate at helping them spot risk factors and bottlenecks that both disrupt cycle times and swell budgets.

Along with conducting research and selecting sites, sponsors are also tasked with negotiating contracts, providing both the funding and staff for trials, securing approvals from multiple ethic committee and regulatory authorities, and ensuring that all pre-enrollment regulations are met. Yet our research shows that most still use some combination of manually intensive procedures such as updating spreadsheets, sending emails and using shared file drives to monitor progress for all of these activities. That makes keeping track of a project in real time virtually impossible.

Each of these steps requires sharing multiple documents among various stakeholders within the clinical team, institutional review boards (IRB), or ethics committees and regulatory agencies. Because of the volume of documents and the number of people engaged in communication, electronic systems are standard practice for capturing and handling the flow of information related to clinical trial operations.

These include eClinical tools designed for managing clinical trials during conduct, storage of documents for regulatory submissions and electronic capture of patient data throughout the study. But these systems were not designed for a study startup (SSU) — a perpetual bottleneck — which encompasses activities prior to enrolling the first subject in the study. These include selecting participating countries and the specific sites, negotiating contracts and budgets, and scheduling pre-study visits.

The combination of these factors is driving pharmaceutical companies to outsource clinical trials to contract research organizations (CROs), which allows them to leverage expertise and operational efficiencies while freeing them to re-focus their energies on core competencies (i.e., drug discovery). By 2020, the anticipation is that pharmaceutical companies will outsource 72% of clinical trials to CROs, up from 23% in 2012.

That's a positive development because CROs, often seen as the innovators in clinical trials, are leading the entire industry to the implementation of business intelligence (BI) solutions used for intelligent site profiling and data analytics and have been acquiring data sources for mining purposes. For example, in 2013, Pharmaceutical Product Development (PPD) acquired Acurian, a provider of clinical trial patient enrollment and retention solutions for the life sciences industry. LabCorp purchased Covance (Full disclosure: Covance is a customer of goBalto) in 2014 to gain collective data resources to drive greater R&D productivity. Last year, Quintiles merged with IMS Health to combine IMS Health's information solutions with Quintiles' product development capabilities.

Analyzing And Leveraging BI

Clinical trial managers must collect and analyze data generated during clinical trials so they can make more informed decisions. That need is driving CROs to explore how they can incorporate BI into their existing eClinical systems. The goal is to improve their views over an entire project by collecting and analyzing the data from trials to help guide their decision-making processes.

CROs can use business intelligence to aid in the selection of sites with the greatest likelihood of enrolling the required number of subjects on time and on budget. Currently, 37% of sites selected for clinical trial studies under-enroll, and 11% fail to enroll a single subject. Eventually, 89% of studies meet enrollment goals but often at the expense of sponsors faced with doubling the original timeline due to poor enrollment. This is according to research conducted by the Tufts Center for the Study of Drug Development.

By using business intelligence to predict or forecast the completion of important milestone tasks for a study based on benchmarking data and on-going progress indicators, this has a major implication in terms of strategic planning when it comes to resources and budgets in risk identification and mitigation strategies.

The ultimate goals for CROs are to shorten the SSU time frame and generate data that can be used for metrics that provide real-time insight into study status. This is where purpose-built SSU technologies fit in. Performance metrics become actionable when they are built from data coming from multiple sources. Replacing paper and spreadsheet-based methods for tracking the many steps of SSU with real-time data that can be fed into standardized performance metrics will allow stakeholders to conduct better risk analysis by spotting where processes are breaking down and where the various players may be lagging.

Sujay Jadhav
CEO | goBalto

Sujay Jadhav, *CEO of goBalto, has more than 20 years of experience at leading Silicon Valley software providers, with a life-sciences focus. Jadhav was most recently senior vice president of global corporate strategy and development at Model N, where he filled multiple roles, from corporate development to overseeing their life-sciences analytics and SaaS business unit. His career has also included strategic consulting at Booz Allen Hamilton, product strategy at CommerceOne and general management roles at Singapore Telecom. He received his undergraduate degree from the University of South Australia and an MBA from Harvard University.*