

Tapping into Big Data for Optimal Outcomes

- ▶ The pharmaceutical industry is rich with data. From clinical trials, to research centers, to manufacturing and the supply chain, to patient reported outcomes and safety data, and beyond, the preponderance of data produces rich insights for companies to leverage.

As the industry's reach expands to include access to anonymized electronic health record (EHR) data and genomic data, the opportunity to gather learnings on disease and treatment patterns continues to grow.

The question companies face is how can they best manage big data to gain insights that will benefit the business and the patients they serve — providing the right patient with the right treatment at the right time? Without analytics, big data is nothing more than statistical patterns.

Making the Most of Big Data

According to Frost and Sullivan, the industrial Internet of Things (IIoT) is making it easier to quickly gather and analyze big data. However, gathering all the valuable insights needed can be a challenge. From a resource and skill issue, to having the necessary analytical tools, to being able to tap into unstructured data, companies will need to find ways to access what is of value and separate it from the noise.

Traditional methods of analyzing clinical data, which typically are structured and comprehensive, don't translate well to managing real-world data, which are often unstructured with missing values. In this less clear-cut environment, companies need to make use of technologies and data scientists who can extract value and meaning from often unclear datasets.

Establishing the architecture for a big data approach will require companies to assess the current environment and determine where gaps lie, such as enabling an agile reporting and analysis environment, and then incorporating third-party data sets.

In addition to having the tools and technology platform needed to extract and manage big data insights, companies must also implement thorough security and governance models to ensure data is sensitively handled and regulations are adhered to.

Many in the industry agree that the most

important component for realizing the value of big data is talent, in particular data scientists and statisticians. Biotech companies are increasingly turning to data scientists in areas such as genomics, discovery, safety, clinical trial effectiveness programs, predictive modeling, outcomes research, and business development and marketing.

Where the Value Lies

By drawing on data from the marketplace and literature, together with clinical data, patient adherence data, genomic profiles, and population data, companies can improve the clinical trial protocol and improve the discovery of new medicines. Applying machine learning to big data opens the possibility of discovering new drug or biotech therapies, or repurposing existing therapies, without the need for lab testing. For example, Stanford University applied its algorithms to large public databases of drug and genetic information to identify new uses for old drugs.

Predictive analytics applied to a big data solution also provides valuable clinical trial insights, thus helping companies to determine whether to continue or stop a trial before costs escalate. It is also possible to build virtual assays targeting specific therapeutic areas, which massively reduces the time spent on testing compounds.

Big data is enabling precision medicine. By combining big data with analytics, pharma companies and other researchers gain insights that can aid the drug development process. For example, ASCO's CancerLinQ Discovery enables all stakeholders — researchers, industry, government, and other medical societies — to translate big data from CancerLinQ's pool of deidentified patient data into insights to enhance cancer research.

Big data will likely become an important component in regulatory decision making. As the FDA considers the use of real-world data to evaluate the safety and efficacy of drugs — an objective of PDUFA VI — big

data and analytics will be a crucial component to understanding the right questions to ask, what the challenges are to generating and using this data, and how to tackle these challenges. To achieve those objectives, the FDA is strengthening staff capacity in key areas, including statistics to determine how to utilize real-world data.

According to a Best Practices report, medical affairs departments gain significant value from big data insights, drawing on data from medical records, clinical trial data, and claims information to gather post-launch product use and health outcomes insights.

With powerful big data and analytics tools, data from social media can also be tapped into to gain better insights into the efficacy and safety profile of a product. Big data is changing the approach to pharmacovigilance, using longitudinal observational data. The best example of this is the FDA's Sentinel system, which analyzes data from multiple health plans to monitor the safety of drugs.

Perhaps the most notable use of big data is in genomics with the rise of fast and cost-ef-

The Value of Big Data

- ▶ Accelerate drug innovation
- ▶ Determine clinical trial outcomes sooner
- ▶ Gain access to new markets
- ▶ Identify unmet medical needs
- ▶ Defend pricing and improved margins
- ▶ Improve safety signal detection
- ▶ Refine the trials list to the most viable targets
- ▶ Demonstrate comparative effectiveness
- ▶ Monitor patient adherence

Source: Oracle — Improving Pharmaceutical & Life Sciences Performance with Big Data

fective DNA sequencers. It opens the possibility of people globally having their genomes sequenced. The next step is to interpret these findings to enable insights that can lead to therapeutic development.

Putting Big Data into Practice

One company that has invested heavily in big data infrastructure is Genentech, which has built a platform to rapidly analyze billions

of patient records and has recruited a large team of skilled data scientists. According to a Harvard Business Review article, this team of data experts has resulted in some significant projects, such as a database containing historical data of patients diagnosed with cancer. The data was analyzed to provide insights into different patient subtypes and treatment regimens. The purpose of such data is to support therapeutic developments.

Several other pharmaceutical and biotechnology companies have been hiring more data scientists and bioinformatics experts to

leverage big data for research purposes. For example, Novartis has been applying big data for various purposes, including to gather side-effect data to determine whether a compound will cause adverse reactions before a clinical trial begins.

As more pharma and biotech companies realize the value of big data projects, the opportunity to use these insights to advance clinical trials, discovery, personalized or precision medicine, and business decision-making will escalate, creating new opportunities for the industry and its customers. **PV**

EXECUTIVE VIEWPOINTS



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Data Management is a Team Dynamic

Managing data effectively can create powerful insights, but it is also a challenge. Organizations that succeed at this critical practice decouple data from their company's core — and often siloed — systems, structure that data consistently, and integrate with data coming in from third parties to create a truly 360-degree view of whatever entity they are focusing on. The healthcare industry can benefit from rapidly growing big data only if a company can seamlessly manage all aspects of data collection and analysis. Developing a leadership team that can define clear goals for the data and is able to ask the right questions is equally important as selecting the right technology. A talented team that can not only skillfully analyze

statistics but can also organize large data sets and apply visualization techniques can help business leaders address their strategic issues.

Patient-Finding and Big Data

The broad applicability and access to big data sources are spurring even more creative analytics solutions. Marketers have integrated big data sets — particularly real-world data and claims data — into a number of strategic initiatives. The more traditional initiatives include market sizing, patient journey analysis, pricing strategy, customer segmentation, and marketing mix, among others. New areas, such as patient-finding in difficult-to-diagnose diseases and network-based marketing, help accelerate diagnosis and expedite the diffusion of therapeutic innovations to improve patient outcomes.



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Put Resources Against Today's Data Needs

Companies should be spending 95% of their time and resources on data that have an impact today. This means anything that has direct applications for clinical trial design, trial recruitment, marketing, audience insights, etc. Don't get distracted figuring out how to collect and manage data that might be useful down the road but doesn't have a clear use-case. Intriguing, but ultimately useless, data inevitably steals more than its fair share of attention.

Companies Now Own Their Customer Data

Data from wearables and digital medicines finally allow biopharma to own its customer data the same way that the big tech companies, such as Google, Amazon, and Facebook do. If companies are inclined, they can get a much clearer understanding of their therapies in the wild, not just in labs or trials. However, the jury is still out on whether companies are going to leverage these technologies as a rich data source for R&D.