

Realizing Big Impacts from Investing in Big Data

► The pharmaceutical industry is investing more and more in big data to transform different parts of the business and bolster pipelines.

Investment in big data is expected to grow to \$7 billion by the end of 2021, up from \$4.7 billion in 2018, comprising spending on hardware, software, and professional services.

The potential impact of that investment is extensive. According to McKinsey Global Institute, big data strategies could lead to \$100 billion in value across U.S. healthcare through improved innovation, greater research and clinical trial efficiency, and advanced tools for personalized care and medicine. For example, companies are investing in drug discovery platforms with big data combined with artificial intelligence being used to uncover promising compounds.

But what is big data? Early on, big data was regarded simply as datasets that were too large to be captured and stored in traditional databases. Today, the term encompasses both the datasets and the technologies needed to capture and make use of that data.

New technologies are emerging to enable and enhance the use of big data. These technologies combine techniques and processing methods to help companies achieve the desired results.

Perhaps most important are the processes that enable companies to make the most of big data. The first step is the integration of accurate and consistent data, a perennial challenge for pharmaceutical companies. Data must be brought together from many different parts of the organization — R&D, clinical, regulatory, manufacturing, marketing — for companies to derive real benefits. Integral to data integration is collaboration between all stakeholders in the product life cycle — both internal and external.

Decision-making about the portfolio also needs to be data-driven, and analysts advise that technologies that assist with those decisions should be prioritized. These include visual dashboards to examine data in greater detail and provide greater transparency on assets within the portfolio.

Big Data in Action

Analysts have posed some exciting devel-

opments with big data for the industry.

Perhaps most prominent for many pharmaceutical companies is the opportunity to enable new innovations, particularly in personalized medicine, through the application of big data for predictive modeling. One company that has shifted in this direction is GSK, which is using big data analytics to find the link between the immune system and diseases with the objective of understanding what makes people sick.

So far, GSK has invested significantly in personal genomics company 23andMe to gather data on specific diseases, starting with Parkinson's.

Smaller companies are emerging with a goal of using big data analytics and AI to uncover disease insights, which ultimately can be used to develop treatments and cures.

RDMD, a small rare-disease focused technology company, is using a big data approach to de-risk and speed up the research and clinical trial process for orphan diseases. RDMD combines big data and AI to gather insights from medical records in order to find commonalities in rare disease cases.

The effort to match disease with cures through big data is also being put into practice at hospitals. For example, Seattle Children's Hospital is using big data analytics to more rapidly find accurate diagnoses for patients and then offer personalized treatment.

Clinical and Real-World Advances

Clinical trials take on average six to seven years to complete, and trials often fail because companies struggle to enroll eligible patients. Traditionally, recruitment has involved manually reviewing clinicians' patient lists. However, big data analytics draw on many other data sources to enroll patients. The way it works is to scan data for genetic information, disease state, and other key trial characteristics to find patients who best meet the trial criteria.

Big data also enables trials to be monitored in real time to identify safety signals that need

to be acted on quickly and assess any potential operational issues.

And as the emphasis turns more and more toward real-world evidence, the ability to analyze many different data sources will give researchers greater insight into treatment patterns and clinical outcomes. For example, it offers insight into patients typically not involved in trials, such as the frail and elderly, and allows companies to assess challenges such as compliance.

But these approaches have their challenges, in particular the fact that big data comes in many formats and often data is missing. As a result, there is growing demand for data scientists who can assess the data, deal with the ambiguity, consider how best to address these issues, and understand the broader healthcare system.

One company that is addressing these challenges is Genentech, which has developed partnerships, analytics tools, and a platform to rapidly assess patient records. For example, Genentech created a database of patients who had been diagnosed with cancer to learn more about biomarkers and different treatment patterns. It then used the information to assist with drug development decisions.

The future for big data is exciting, not just in terms of clinical trials and drug development but across the entire healthcare spectrum, including getting drugs to patients in need. Drones, driven by big data, are another hot topic for the future in the pharmaceutical industry. It's thought they could be brought in to carry urgently needed drugs or devices to patients in remote locations.

There is still a long way to go for the industry as many companies grapple with uncertainty over how and where to invest in big data solutions, concerns over the value of their investments, and worry about how these investments will affect their regulatory obligations.

However, big data is becoming important to advancing many pharmaceutical operations and its impact will continue to grow as more companies become confident about investing in big data capabilities to realize growth and improved outcomes. **PV**

EXECUTIVE VIEWPOINTS**Richard Staub**

President, Research & Development Solutions, IQVIA

The Big Data Transformation

Big data — how we curate, synthesize, and apply it to our decision making — is transforming clinical development. Using predictive data modeling we can accelerate clinical trial efficiency and better target patients for clinical studies. Big data can also help identify new, targeted therapies based on genetic markers and biomarkers by enabling a better understanding of the biology of disease and why patients respond to therapies. Artificial intelligence and machine learning are helping us mine this data and giving us better insights into complex healthcare questions.

Big Data Disruption

Big data is driving innovation in the industry for master protocols, disease modeling, and phenotyping by providing new and more efficient approaches for hypothesis testing. Advances in analytics and artificial intelligence allow research teams to analyze large study data and enhance their ability to identify the most promising therapies. Master protocols can accelerate the clinical research process and enable rapid decision making by taking advantage of opportunities to combine studies and sharing data. All this innovation is exciting because it is driving advances in patient care, disease management, prevention, and treatment.

**Iyiola Obayomi**

Practice Lead, Marketing Analytics, Ogilvy Health

Translating Data into Commercial Advantage

The greatest big data areas of focus, consistent with what we've seen over the past year, have been around translating data into commercial results and advantage. The industry continues to make the biggest investments, partnerships, and pilots in areas of artificial intelligence, machine learning, and deep learning. Drug discovery remains the most visible application.

Cross-Disciplinary Datasets

Big data is disrupting the drug discovery process with the datasets, tool, and new forms of partnerships and competition. It's made possible cross-disciplinary datasets and sophisticated analysis tools that affect the discovery continuum — from hypothesis discovery, research prioritization, patient selection for clinical trials, and clinical trials execution. Because new technical skillsets are needed to harness the big data capabilities, the industry is grappling with nontraditional research alliances and competition.

**Mike Byrnes**

Executive VP, Sales Rx EDGE

Big Data and Innovation

Big data is being used to inform strategies for optimizing innovation, enhancing research and clinical trial effectiveness, and building innovative instruments for doctors, consumers, insurers, and regulators to deliver on the promise of more individualized treatment methods. Significant investments continue to be made in predictive analytic technologies that enable physicians to make data-driven choices in seconds and enhance therapy for patients. This is particularly useful for patients suffering from multiple conditions who have complex medical histories.

**Nate Lucht**

President and CEO, LPM and Rx EDGE Media

Going Beyond Human Computing

Billions of dollars have been spent developing electronic medical records to have better and more easily accessible health data. Billions more is being spent to make better use of that data. Massive computing and artificial intelligence systems are being developed to do just that. Take IBM Watson Health and MIT's Broad Institutes partnership to help identify cardiovascular diseases using EMR and genomics data to develop algorithms that predict certain diseases. Massive amounts of data, computing power, and AI are being used to solve problems no human(s) could ever solve on their own.