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Health Sciences

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BUSINESS BRIEF

All This Data… and Meaning, Too

Today, cloud-based trials offer researchers easy access to huge amounts of big, real-world data from medical records, wearables, genetic profiles, social channels, and many more sources. There's so much available data out there that it can be intimidating to try controlling it, let alone, find meaning in it.

In mHealth, Applied Clinical Trials describes wearable sensors that are being used to deliver large amounts of patient data on activity levels, sleep, blood pressure, heart rate, brain activity (EEG), and heart activity (ECG) for clinical trial analysis support. These wearable sensors track real time/near real time parameters that can impact patient safety, protocol adherence, and drug efficacy.

For example, in a pain study, arthritis patients' sleep habits and activity levels are measured, as each activity can impact pain, and vice versa. Gathering data on these metrics can help investigators limit patient behaviors that could cause pain not connected to the drug being investigated.

Medivo, a healthcare analytics company, tracks and analyzes over eight (8.8) terabytes of data from 4,000 patient service centers, 176,000 physicians, and more than 50 million patients. This information, in anonymous formats, can provide a rich source of research data to support drug development and provide added insight into pharmaceutical therapy planning.

Also, at the point of care, advanced technologies (in voice recognition and clinical language) are enabling the collection of additional patient data for conversion into actionable information and use as part of a larger, real-world, knowledgebase data source in support of clinical research.

SRINIVAS KARRI
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Srinivas Karri leads Oracle Health Sciences' Data Management capabilities, and brings years of experience consulting on and managing large data volumes in complex clinical trials

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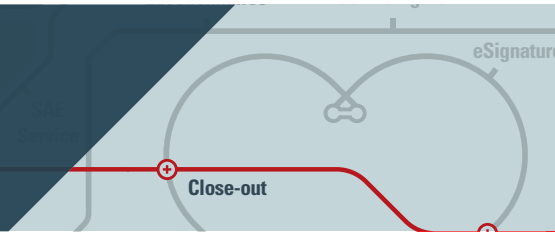
Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes, helping to bring new drugs to market faster.



Getting Meaning from Big Data

Pfizer, too, uncovered highly valuable meaning from big data. Using big data and analytics, the company was able to target a very specific population to develop a drug for lung cancer patients who weren't responding to other available treatments. It was a success story in making sense of big data to solve a real problem impacting patients.

Medical research showed that about five percent (5%) of lung cancer patients developed the disease, even though they hadn't abused their lungs, nor were they heavy smokers or coal miners. In these patients, lung cancer developed because of a mutation within their ALK gene.

By bringing together big data from genomic profiles, anonymous electronic medical records (EMRs), and its own high-scale clinical trial data, Pfizer was able to test Xalkori®, a drug developed specifically for lung cancer patients with the ALK mutation. It was approved by the Food and Drug Administration (FDA) in 2011. Through the big data analysis, Pfizer had been able to identify lung cancer patients with the ALK mutation who were most likely to benefit by participating in a clinical trial for the new drug.

According to Pfizer CIO Jeff Keisling, "Had this compound been tested against a broad spectrum of lung cancer patients, it likely would not have been found to be effective. With this analytics-based approach, it was found to be very effective. But, we had to be able to identify a subset of cancer patients with a specific gene mutation who previously did not have this treatment option."

5%

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JEFF KEISLING
CIO
PFIZER

The Value of Big Data Insight

As Pfizer showed, it's now possible to find very specific value in big data and leverage it to impact clinical trials positively. Information derived can provide relevant support for trial design, which can foster stronger backing for trial results and get life-saving drugs to market faster. Looking forward, big data analytics could also uncover hidden data relationships for potential new research directions and provoke life-saving questions that researchers didn't think to ask before.

Can big data deliver more meaning for your clinical trials?

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