

# Chapter 16

## Predictive Analytics to Support Clinical Trials Get Healthier

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### ABSTRACT

*The concept of clinical big data analytics is simply the joining of two or more previously disparate sources of information, structured in such a way that insights are prescribed from examination of the new expanded data set. The combination with Internet of Things (IoT), can provide multivariate data, if healthcare organizations build the infrastructure to accept it. Many providers are able to integrate financial and utilization data to create a portrait of organizational operations, but these sources do not give a clear idea of what patients do on their own time. Embracing the centrality of the IoT would relinquish the idea that provider is the only pillar around which healthcare revolves. This chapter provides deeper insights into the four major challenges: costly protocol amendments, increasing protocol complexity and investigator site burden. It also provides recommendations for streamlining clinical trials by following a two dimension approach-optimization at a program level (clinical development plan) as well as at the individual trial candidate level.*

### INTRODUCTION

Despite the billions of dollars spent annually discovering and developing new drugs, the global output of innovative new medicines is at its lowest point in several decades. This is not as illogical as it first sounds. As an industry, we have become accustomed to expecting that financial investment will equate to positive outcomes - this in spite of the fact that we have seen more breathtaking failures in drug launches in the past ten years than ever before.

All that money was not necessarily spent in vain. The completion of the Human Genome, the deciphering of more mechanisms of actions of diseases than ever before, the ability to analyze millions of

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samples a day and new sophisticated detection platforms, are all fundamental to how we discover and develop drugs today and will continue into the future.

## **BACKGROUND**

In the last ten years, a “data deluge” has been created, with new and evolving methods of communication and processes of storing information. The increasing amounts of electronic data have been generated and stored daily in multiple forms and locations in almost every market (Tibco, 2011). Switzerland’s pharmaceutical giant, Roche, reported in 2010 that the company is producing so much data, that it is doubling every 15 months. These data are not just generated from internal research and development, but also from a networked clinical development model involving in-licensing, out-licensing, outsourcing, and collaborations with various contract research organizations, academia, pharmaceutical and healthcare partners. Their model serves as a prime example of why emerging technology that allows for the consolidation and rapid analysis of clinical and non-clinical data is so critical.

## **ISSUES**

### **The Rapid Growth in Clinical Development**

The number of clinical trials underway each year has been increasing steadily, worldwide. In the last five years alone, over 75,000 federally and privately supported trials have been registered with the National Institute of Health’s Clinical Trials registry with a growing trend in trials being conducted in Brazil, Russia, India, and China (Lodha, 2016).

With a broad range of study designs, varying data collection methods and time points, efficient data analysis in clinical development has become more important than ever. The more effectively study data are managed, the faster the data can be extracted and analyzed. The analysis of the data is important for each trial stage as valuable insights can be gained. For example, during the early stages of a clinical trial, access to data is vital not only for patient safety, but for solving problems while they are still manageable and before they become costly (Tibco, 2011).

### **Controversies of 4 “Vs” in IoT and Clinical Big Data Analytics**

Like big data in healthcare, the analytics associated with big data is described by three primary characteristics as per IBM: volume, velocity and variety. Over time, health-related data will be created and accumulated continuously, resulting in an incredible volume of data (Raghupathi, 2014). The already daunting volume of existing healthcare data includes personal medical records, radiology images, clinical trial data, FDA submissions, human genetics and population data genomic sequences, etc. Newer forms of big data such as 3D imaging, genomics and biometric sensor readings, are also fueling this exponential growth.

Fortunately, advances in data management, particularly virtualization and cloud computing, are facilitating the development of platforms for more effective capture, storage and manipulation of large volumes of data. Data is accumulated in real-time and at a rapid pace, or velocity (Raghupathi, 2014).

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