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Optimizing Enrollment: The Need for Broad, Timely Data and Powerful, Yet Simple Analytics

Thought Leadership In Association with Medidata Solutions

by

Access to data and the ability to mine it for insights into patient availability are key drivers of efficient clinical trial enrollment. The explosion in healthcare data means the raw material needed to generate insights is available in huge quantities. The problem is study teams have limited ability to standardize, aggregate and analyze these vast datasets. Addressing these shortcomings will optimize enrollment by empowering teams to be more effective at bringing awareness of relevant clinical trials to patients and considering how to bring patients to the clinical trials that can potentially offer life-saving treatment options.

Today, many trials struggle to efficiently identify, recruit and retain participants. A significant minority of trial sites never enroll a single patient, which results in significant recruiting challenges and adds time and cost to the study lifecycle. This has a downstream commercial impact for sponsors and, more importantly, means patients must wait longer for potentially life-saving new treatments.

The recruitment conundrum remains unsolved despite concerted efforts to improve feasibility and design clinical trials around the needs of sites and the patients they enroll. These efforts have yielded many benefits, but predicting the true availability of patients at the time of

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enrollment is still beyond their reach. Organizations have responded by sourcing data to improve their predictions, with often mixed results.

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Why early data initiatives have struggled

The modern healthcare system is rich in data, including a wide breadth of sources like electronic medical records and laboratory results. Equally, data depth is provided by large private payers and integrated systems in the United States and national single payers in Europe. These organizations have records on tens of millions of patient lives.

Large pharmaceutical companies have accessed some of these networks to help predict where they will find patients eligible to participate in clinical trials. Yet the effect on the bottom line of recruitment rates has been mixed, and enrollment rates in many trials remain suboptimal.

The struggles of early data initiatives reflect the need for access to broader, more real-time data. Although an abundance of data is available, most sponsors have relatively few affiliations to the networks that control it. Thus, decisions intended to optimize enrollment are made on the basis of a narrow subsection of all the data that could inform those choices.

A study team with access to real-world evidence from payers, prescribers, diagnostic testing laboratories and hospital patient records is better placed to predict subject availability than one equipped with data from a single network. Getting access to very robust, extensive records from multiple organizations in multiple geographies will give sponsors a global data pool capable of getting trials to patients, and getting patients to the physicians running those trials.

The need for competitive intelligence

Access to such broad data gives study teams a good idea of where to locate trial sites. What it cannot do is say whether those sites will be able to enroll patients when the study goes live. Historic data, however broad and deep, can be rendered ineffective by changes on the ground, such as targeting the same patient population as a competitive trial. To fully optimize enrollment, companies need competitive intelligence that factors the geographic distribution and inclusion/exclusion criteria of rival clinical trials into forecasts of patient availability.

Study teams look for early competitive intelligence while building country strategies and coming up with lists of potential investigators in their targeted geographies. The need for intelligence becomes more pressing when the team is pre-qualifying sites during the site assessment phase. If, for example, 40% of a study's top 30 potential investigators are actively involved in a

competitor's clinical trial, it is vital that the study team is aware and mitigates the risk of a protracted site selection process.

That level of understanding can only be achieved through intelligence that illuminates similarities between trials that are competing for the same population of patients. Minor differences in inclusion/exclusion criteria will influence which studies recruit patients in droves and which struggle to enroll at all. Study teams that explore these nuances in protocol design can better anticipate challenges in the site selection process and offset the potential effect of a competitor's trial on recruitment rates.

These factors are crucial to the optimization of enrollment. Competitive intelligence and an intelligent trial design will move study teams closer to the ideal scenario: being able to view patient availability across the entire clinical trial process, from protocol feasibility up to actual recruitment by sites.

What end users need to glean insights

Pools of broad, timely data incorporating competitive intelligence will give companies a far more accurate picture of patient availability than they have today. Accessing the data is just the first step; the multitude of data sources must also be standardized, aggregated and analyzed in a simple and consumable format.

Housing data from a large number of networks in a single platform will enable powerful, predictive enrollment modelling. Tools that ingest and use real-time electronic patient data to make predictions about enrollment are available in the market today. Expanding the data available to these models will result in more accurate predictions about where patients are, and their potential for inclusion in a clinical trial.

A significant minority of trial sites never enroll a single patient

It is important to ensure the system mines the breadth of the data. Applying analytics that are too targeted to the resource will undermine efforts to create broad datasets through affiliations with global networks. Conversely, such overly-targeted analytics subset the repository to the point where it effectively covers only a narrow spectrum of information.

Analytic platforms must also consider the user experience. End users will be clinical development professionals—not data scientists. The system must be easy to access, navigate and use within the context of existing processes while also providing powerful analytics, predictive models and visualizations. Failing to meet this user experience standard will lead to a significant

failure rate.

Developing effective analytics based on broad and timely datasets are big challenges, but they will also yield big rewards. By rising to these challenges, the industry can unlock the potential of data-driven insights that connect patients to clinical trials and clinical trials to the patients who want to take control of the full scope of their healthcare options.

About Medidata Solutions

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations. info@mdsol.com | mdsol.com