Maximize your drug’s potential with data

Bringing new treatments to market is a complex journey with unexpected detours and obstacles that can make it hard to find the right path forward. But professionals in the life sciences industry are seeing increasing opportunities to use large, curated sets of data as a compass, and with the actionable insights they gain from that data, they can navigate with more confidence and adjust more quickly as new hurdles appear.

From the earliest stages of discovery through treatment delivery, analytics and the resulting insights have the potential to inform and enhance every stage of the drug development and commercialization process.

**Protocol design**

Because the protocol is the backbone of a study, every decision made about the protocol will ultimately impact how long the study will last, how many patients are needed and how much the study will cost.

Despite efforts to create resilient protocols, most trials ultimately require amendments. Amendments can add nearly $500,000 in unplanned expenses and 61 days to a trial timeline. The reasons for these costs and delays include needing to add more patients to a study or needing to go back and redo an earlier phase of the trial based on new information.

Adding more patient data and evidence-based insights to the early stages of the protocol design process could help protocol authors prevent decisions that lead to costly inefficiencies. Helpful advancements and findings could be incorporated into the protocol sooner, potentially resulting in better eligibility criteria for their trial.

**Trial execution**

Managing clinical trial data and ensuring standards are being met is no small feat, and one of the top inefficiencies in conducting clinical trials is data collection across numerous collaborators and stakeholders.

Data storage and access solutions can help companies achieve consistency by storing all data in a centralized database that contributors can securely access remotely and from various devices. Standards can be enforced by creating prompts and workflows that encourage data to be collected and organized in specific ways. Customized alerts,
reports and analytics can also help trial supervisors detect gaps or data integrity problems earlier so that corrections can be made as soon as possible and help reduce the need to recollect data or conduct additional tests.

Workflows that provide automatic notifications about trial progress can also streamline communication and help contributors keep track of their individual responsibilities.

**Trial review**

Few aspects of clinical trials are more nerve-wracking than deciding whether or not a trial should continue to the next phase. Regulatory agencies often require reviews by independent committees, such as endpoint adjudication, for trials to progress, and the review process can be costly and time-consuming. When initial results are ambiguous or just barely reach a threshold, companies can find themselves in a difficult position.

IBM experts believe that by pulling together critical insights from the latest published research, as well as current insights from deep, de-identified databases of patient and claims data, companies could efficiently conduct informed assessments of whether additional resources should be committed to a trial or how resources can be divided most effectively among potential projects to maximize their return on investment and therapeutic impact.

**Navigating a data-rich future**

The pace of new development in technology and medicine has accelerated, and the number of innovations and data organizations will have to keep track of to develop high-quality clinical trials is vast. IBM Watson Health is creating solutions that will give companies the ability to access consolidated, real-world data from multiple care settings when it could benefit their trials the most and provide invaluable, actionable context for each step in developing a new treatment.

No matter what, the drug development and commercialization process will be unpredictable. But with advancements in artificial intelligence (AI) and analytics, companies could use powerful insights as a guide to efficiently steer new treatments through unforeseen changes and reach markets sooner.
2 Ibid
4 Ibid
5 Duley, Lelia et al. "What are the main inefficiencies in trial conduct?" A survey of staff at registered clinical trials units.” Trials, 16 (2015).