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A Frost & Sullivan White Paper

Preparing the Technology and Resources to Be Best-in-Class in Clinical Trial and Real World Data Analysis

How Does Your Organization Measure Up?

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In Partnership with IBM

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Challenges in Clinical Trial Design and Execution

New sources of health data have created opportunities for life sciences organizations involved in clinical trials while shifting the processes and protocols that underpin clinical trial execution.

The COVID-19 pandemic impacted the clinical trials space as social distancing measures limited the number of face-to-face interactions conducted at trial sites and forced many studies to pause or stop, all of which delayed the research that supports development of much-needed novel drugs. However, the pandemic also demonstrated that physicians and site coordinators can interact with patients and perform numerous assessments remotely; thus, companies are racing to implement innovative solutions and move to decentralized trial models.[1]

Although the trend of including remote participants in clinical trials had been picking up prior to the pandemic, it has now accelerated. But the rapid adoption of hybrid and decentralized clinical trials presents many new challenges for researchers. Utilizing new processes and protocols means data is collected and analyzed differently, so data managers and site coordinators must adapt promptly to the new methods. These shifts have impacted all industry stakeholders, including the contract research organizations (CROs) supporting clinical trial execution.

As the development of new and innovative products in the pharmaceutical, biotech, and medical device sectors accelerates, regulatory entities have responded by requiring adherence to quality-assurance standards for data collection during the drug evaluation process. To meet the demands from both the medical products industry and regulatory authorities, a modular clinical data management system (CDMS) becomes essential in streamlining workflow and visibility for stakeholders across all trial phases.

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– Frost & Sullivan

In addition to accessing new sources of more frequently collected data during clinical trials, researchers can put to use the extensive data already available from existing patient data sets. The healthcare industry has been experiencing a surge in data sources, such as electronic health records (EHR), insurance claims, and vast patient health and medical information. This real-world data (RWD) holds valuable health information. For example, researchers can use RWD to help evaluate the epidemiology and burden of disease, comorbidities, treatment patterns, medication adherence, and outcomes of different treatments. Other uses of RWD include building external control arms to enhance analytic outputs and providing flexibility in insight and evidence creation.

1 Dr. Hilde Vanaken, “Modern Technologies & Partnerships Enabling Next Generation Patient Centric Research,” pharmavoice.com, https://www.pharmavoice.com/contributed-article/modern-technologies-partnerships-enabling-next-generation-patient-centric-research/, (accessed February 2021).

Raising the Bar on Research and Analytics in Preparing Commercial Strategy

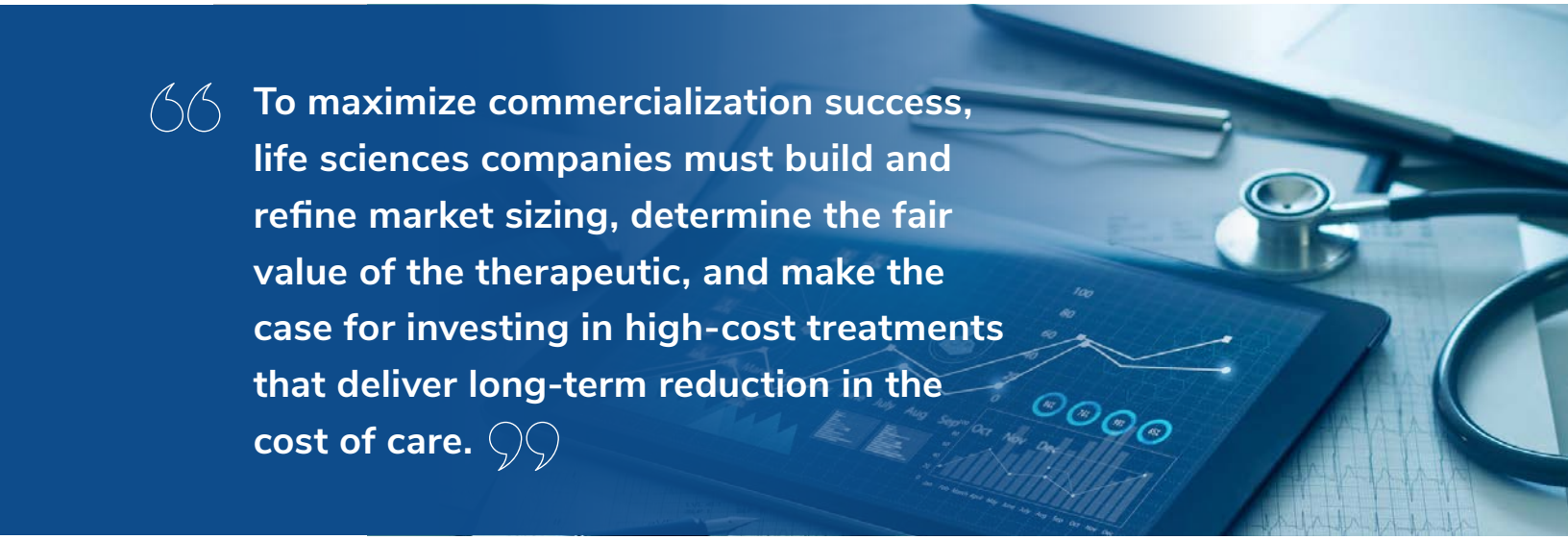
The utility of RWD affects all areas of patients' lives, with stakeholders across the entire healthcare value chain—providers; payors; regulatory bodies; CROs; and pharmaceutical, biotech, and medical device manufacturers—using real-world evidence to guide their decisions.

In fact, interest in the field of health economics and outcomes research (HEOR) has grown exponentially as governments and other payers grapple with identifying how to support the best possible health outcomes at affordable costs.

As the pharma/biotech industry landscape expands and becomes more competitive across therapeutic areas, regulators, providers, and payers are looking for more specific data outputs on which to base their decisions. HEOR and epidemiology studies can help life sciences organizations build the type of robust evidence cases needed to get providers to prescribe and payors to cover the proper therapeutics; they can also support regulatory authorities in understanding drug safety in real-world conditions. Evidence generation planning, pre- and post-market studies, comparative effectiveness research, and case building for a range of target markets and geographies are among the critical applications of HEOR.

However, successfully transitioning from bench to marketplace requires the support of a complex web of ancillary businesses, particularly for companies that are scaling up rapidly. Collecting and analyzing broader data sets and providing the basis for detailed evaluation of the expected outcomes for new therapeutics is challenging for large life sciences organizations, and can be a source of significant delay or even lost opportunities for small and mid-size companies. Just as life sciences organizations use partners in the research, development, manufacturing, and even the sales side of their business, they should also consider partners who can support the development and analysis of strong data sets and outcomes insights.

To maximize commercialization success, life sciences companies must build and refine market sizing, determine the fair value of the therapeutic, and make the case for investing in high-cost treatments that deliver long-term reduction in the cost of care. Having the resources and



> **To maximize commercialization success, life sciences companies must build and refine market sizing, determine the fair value of the therapeutic, and make the case for investing in high-cost treatments that deliver long-term reduction in the cost of care.**

expertise to link datasets at the patient level and conduct complex analyses can help life sciences organizations show the impact of different therapeutic pathways and the total cost of care in treatment.

To be competitive, life sciences companies need to collect updated data from a diverse set of sources and utilize advanced economic modeling, outcomes research, and market analytics to build the case for their treatments. In addition, they must gain access to more data across more geographies to fill any existing gaps. Furthermore, both life sciences organizations and CROs should bolster existing remote participant engagement procedures for hybrid and decentralized trials to broaden recruitment and retention while minimizing future disruptions. This includes leveraging new monitoring and data collections systems as well as utilizing existing eConsent applications in enrollment and electronic patient recorded outcomes (ePRO) and electronic clinical outcome assessment (eCOA) solutions to capture outcomes data.

Role of Partners in Data Collection and Analytics

In an era of constant change, companies' real-world and clinical data capabilities must adapt quickly to ensure that products are brought to market safely and efficiently, meet accelerated timelines, and compete with best-in-class data insights. Organizations also seek insights from their data to inform strategic priorities in real-time. Yet much of the historical data and modeling formerly applied to anticipate behaviors and guide actions are proving far less predictive, or are proving irrelevant, in the wake of COVID-19, combined with the realities of payers looking to reduce the overall cost of healthcare at the population level. To address these challenges of bringing a new therapeutic to market, building a more comprehensive case, and responding to new requirements, companies must develop greater analytical agility.

Many companies aspire to foster a business culture that embraces data, analytics, and AI, as well as other new technologies, but few can build and manage the data sets and tools needed to sustain this environment on their own. A robust data collection, management, and analytics partner is crucial for most companies seeking to build systems that support an organizational foundation based on deep data analysis and agility. A strong partner (or set of partners) will empower a company to achieve better results by adding the appropriate skills, tools, and data sources needed to do so.

Another benefit of leveraging partners in data, management, and analytics is that life sciences organizations can keep their core team's focus on mission-critical outputs. Key to implementing this strategy is identifying experienced partners that can offer the desired skills and then determining the best time to integrate them into the different processes—spanning clinical trials, new product commercialization, ongoing post-market surveillance, and commercial optimization.

For more insights and to benchmark your organization against best-in-class industry competitors, click to access our benchmarking survey.

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