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Using Data-Driven Insights To Systematically Improve Clinical Trial Feasibility

by

Sponsors have long sought to develop patient and site-centric trials to help improve enrollment and retention. These considerations typically occur during protocol design while leveraging a broad range of subjective sources like investigator and patient input, but can also occur, more ideally, during the protocol feasibility process. Nevertheless, objective sources are often still lacking when measuring patient and site burden.

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Data-driven insights are vital to robust and comprehensive feasibility processes and to efficient and effective development programs. The process is best served by objective assessments of foundational elements of the protocol concept such as objectives, endpoints and procedures. Clinical development organizations have come to recognize the benefits of this objective approach and to incorporate feedback from potential investigators and insights from real- world data sources into their protocol designs. The result is the development of protocols that meet the clinical and statistical outcomes of the trials while minimizing site and patient burden.

How to optimize the feasibility process

The downstream benefits of applying data-driven insights to the design and optimization of study protocols are significant. Protocols created without such insights rely on subjective experiences, repetition of previous or unproven trial design strategies and guesswork. This can

lead to slow enrollment and poor retention rates. To improve the chances of success, study teams incorporate epidemiological data, objective analyses of earlier studies and feedback from key investigators and opinion leaders into their feasibility processes.

Epidemiological data gives clinical development teams a historical snapshot of the disease incidence and prevalence within a patient population and helps shape the early feasibility strategies. However, the evaluation of the restrictiveness of inclusion/exclusion criteria during the protocol concept design phase provides the greatest insight into the ability to successfully recruit for the trial.

If the criteria place too many constraints on the clinical investigators who are recruiting for the study, the overall rate of enrollment will suffer. Data-driven study design practices that look at patient availability relative to the inclusion/ exclusion criteria shed a light on which variables may cause the greatest challenge to recruitment. The sometimes elusive end goal of identifying the greatest number of patients available in an active disease state at the time of enrollment is further complicated by a highly restrictive protocol design with many onerous procedures that may deter site and patient participation.

Traditional protocol feasibility practices evaluate the inclusion/ exclusion criteria in addition to the planned procedures in the Schedule of Events to assess the likelihood of identifying patients for the trial and keeping those patients engaged for the duration of the study. The feedback from key investigators and opinion leaders has been central to this process. Without a data-driven approach to these discussions, determinations of protocol viability have been consistently driven by this subjective process. However, novel technologies and data sources are beginning to shape a much more focused and intelligent path to patient and site-centric trial design.

Quantifying patient and site burden

Clinical development teams seek objective insights about the complexity of the study design in order to assess the impact on the site personnel executing the study and patient volunteers. Without applying a quantitative measure of site and patient burden, changes to trial design based on potential impact to patient recruitment and retention remain wholly subjective.

The industry's struggle to operationalize its approach to patient and site-centric trial design is evident in data on protocol complexity. A focus on the needs of patients and sites should result in studies that have the minimum number of visits and procedures required to meet the outcomes of the trial.

However, as the complexity of the science behind clinical trials has evolved in recent years, so too has the inclination of clinical scientists to increase the number of objectives, endpoints and associated procedures. Yet the number of visits, procedures and the frequency of those procedures per protocol have increased sharply over the years.

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This leads to an opportunity for data- driven insights into the patient and site experience to improve clinical protocols and drive downstream operational efficiencies. To realize this future, the industry must seek ways to quantify the patient and site experience.

The number of times a patient needs to visit the site, the number of procedures they undergo at each visit and the time commitment to participate in the study are the main drivers of patient burden. Additional details such as the degree of invasiveness, pain and anxiety associated with the individual procedures also contribute significantly to the overall perception and experience of burden that a patient will endure over the duration of a trial.

These variables have a similar impact on the reduction in site burden as well. Protocols with fewer visits and procedures per subject, in addition to the selection of procedures that are typical for studies of similar indication and phase, result in less work for site personnel.

The benefits of operationalizing patient and site-centric design

The benefits of making trials less burdensome for patients and sites will be far reaching. A higher portion of patients will consider participation in a clinical trial and will be committed to remaining in the trial to its completion. Sites will have more time for recruitment, retention and other patient relationship management tasks that are critical to the efficient generation of high-quality clinical data and positive patient experiences in clinical research.

The business partnership between sponsors and sites are further strengthened by the opportunity for investigators to work on well-designed trials that place their needs and those of patients at the forefront of the clinical program development effort.

Sponsors are the ultimate beneficiary. Confidence in the stability and integrity of the clinical program within a sponsor further bolsters the critical relationship between high-quality sites and the clinical teams. Ultimately, this results in trials that successfully recruit patients and collect data faster and more efficiently during study conduct. This is the reward that awaits companies that bring objectivity to the currently- subjective process of patient and site-centric trial design.

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Authors

Diane Carozza
Managing Senior Engagement Consultant,
Strategic Consulting Services

Stacey Yount
Managing Principal, Strategic Consulting