JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 16, No. 12, December 2020 "Happy Trials to You"

Data-Driven Trial Feasibility Analysis for Study Sponsors

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Data-driven trial feasibility analysis helps ensure the scientific and operational success of clinical trials by ensuring that study designs and plans are based on asking the correct questions and answering those questions with thoughtful analysis of hard data. It gives clinical teams a better understanding of clinical development strategy, overall competition at global and local levels, patient population selection, standard of care in complex healthcare settings, regulatory approvals, and healthcare reimbursement.

Key Questions to Answer

Answering the following questions will help you design and plan your study and then make operational decisions related to country, site and investigator selection and other matters.

Patient access

Determine the correct patient population by answering the following questions:

- How will patient eligibility be determined, including specific biomarker or genomic information?
- What is the disease prevalence, incidence and mortality at the global, country or regional levels?
- Where will the patients come from? Will they arrive at a hospital or a clinic? Will they be seen first by general practice clinicians or by specialists?
- Will biomarker or genetic testing results be available for pre-screening?
- Will biomarker tests be available in routine clinical practice?

Treatment pathway

Assess how the clinical trial fits as a care option in the patients' journey through treatment by answering the following questions:

- How are different therapies used currently in different countries?
- How long does a patient normally stay on a particular therapy before switching to a different therapy and why?
- What potential advantages would the clinical trial bring to patients compared to existing therapies?

Trial sites

Determine what types of healthcare providers would work best for the clinical trial by answering these questions:

- What type of healthcare providers treat the target patient population?
- Do they treat them at the appropriate stage in the treatment journey?
- Do they have the medical and clinical research expertise and infrastructure to conduct the clinical trial?
- What competing clinical trials are they likely to be conducting?

Clinical researchers

Determine the necessary characteristics of investigators and support staff by answering the following questions:

- What medical specialties align with the study population, type of treatment, and stage of treatment?
- What research interests and experience are qualified investigators likely to have?
- What papers are they likely to have published and conference presentations to have presented?
- What patient populations should the investigators be able to access from their own or referring healthcare providers?
- What experience should the investigators have in similar studies?
- What supporting network (e.g., for patient referrals) should the investigators have?
- What personnel, departmental, service, equipment and other support should investigators have?

Competing trials

Identify issues with competing trials by answering the following questions:

- What clinical trials that compete for the same patients are likely to be active before or during this clinical trial, including those conducted by your own organization?
- To what extent will these trials directly compete for patients based on eligibility criteria, treatment stage, and other factors?

Market, regulatory and reimbursement landscape

Identify market, regulatory and reimbursement opportunities and issues by answering the following questions:

- What are the marketing history, status and prognosis of similar treatments?
- What are the regulatory review and approval history, status and prognosis of similar treatments and clinical studies?
- What are the reimbursement review and approval history, status and prognosis of similar treatments?

Data-Driven Study Feasibility Analysis

The questions above can best be answered by experienced study teams working with hard data in the following three main areas:

Real-world data

Real-world data for designing and planning clinical trials are available from hundreds of sources, such as electronic medical records (EMRs), registries, claims and prescription databases, lab and biomarker test result databases, and the study sponsor's own records.

The key point about real-world data is that it is not always what it seems to be. For example, just because a physician is writing a lot of prescriptions for a particular drug does not necessarily mean he or she will be a suitable investigator. Specialized data scientists and experienced clinicians can help select the best sources of data, merge them together, and interpret the results.

Trial intelligence data

Trial intelligence data include published information about clinical trials, pipeline development, investigators and hospitals, publications, conference presentations, etc. It also includes the sponsor's internal clinical trial records. These data sources can provide information, such as the following:

- Competing trials and their status
- Recent enrollment periods and recruitment rates for studies in a given indication
- Performance in similar trials by country, site and investigator
- Profiles of study sites and investigators
- Site and investigator relationships with competitive companies
- Investigator research interests and trends
- New investigators in specific research areas

Market intelligence data

Market intelligence information is available from numerous databases, reports and publications. Specialists can perform research to answer specific questions.

Regulatory intelligence data

Regulatory intelligence information (e.g., on FDA approvals and Medicare reimbursement decisions) can be collected from public and commercial regulatory intelligence reports.

Integrated Trial Feasibility Platforms

Acquiring this kind of information is expensive and time-consuming, so collect it in an integrated trial feasibility platform, where it can be analyzed and stored for reuse. A state-of-the-art trial feasibility platform automates information gathering, aggregation and analysis from various data sources internally and externally.

Collecting the information and setting it up for analysis takes time, so it is best to start well in advance and keep it up-to-date.

A trial feasibility platform cannot replace study teams and human judgment. It is a decision support tool best used by clinical research experts who know how to extract the meaning from the information to answer questions accurately and make decisions correctly.

Conclusion

The growing importance of precision medicine and numerous other factors make clinical research more challenging every year. Asking the right questions and answering them correctly based on hard data is essential for successful clinical trials in this demanding environment.

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