CLINICAL LEADER

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Designing Clinical Trials With The Payer In Mind

By Jeremy Schafer, Precision for Value

Imagine your company just received FDA approval of a new pharmaceutical, the result of years of clinical research and difficult regulatory scrutiny. The product is being manufactured and is shipping to distributors and wholesalers. Providers and patient advocacy groups seem excited for the launch, and sales goals are considered aggressive. However, one key variable remains: coverage. Your company's best account manager is calling on a national health plan today that holds the keys to access for perhaps thousands of patients. After a brief — and tense — meeting, the account manager is told the clinical data is mediocre and does not seem applicable to the payer's business and concerns. The coverage decision may take as long as six months; unimpressed by what he saw, the payer customer is in no hurry to speed it up. While such a scenario represents a nightmare for a manufacturer at launch, it unfortunately is not uncommon. Preventing the issue requires strategy development stretching all the way back to the clinical trial phase.

What Payers Value

The value proposition of a pharmaceutical for a payer is markedly different than the value proposition for a provider or a patient. Providers and patients are primarily interested in how a drug will benefit an individual patient's condition and at what expense (in terms of safety). Quality of life is also a key consideration. For a payer tasked with managing the health of entire populations on a budget, the value a drug brings relates to how it improves health by reducing use of other healthcare services and lowering overall cost. Safety of a drug is important in the context of how adverse events may lead to additional medication or healthcare resource use. As payers grow and consolidate, their focus is on how a drug impacts the total cost of care. Manufacturers can tell a more effective story by keeping the payer in mind during clinical trial design.

Trial Endpoints And Considerations Impactful To Payers

Cost Avoidance

A primary interest of payers will always be cost avoidance, as money saved in one area can be spent in another. Manufacturers designing and conducting clinical trials should take the time to consider how a study drug avoids certain costs and use of healthcare services. Fortunately, this probably will not involve a slew of new endpoints but rather a different way of looking at existing endpoints. For example, if a manufacturer of a lipid-lowering medication is analyzing the impact on incidence of myocardial infarction (MI), the trial readout may include how many MIs occurred in each arm of the trial and compare them for statistical significance. For the cost-savings analysis, trial investigators may recruit the services of a healthcare economist who could research the mean costs of a hospitalization due to MI as well as supportive care medications. Length of hospital stay and associated emergency department (ED) costs may also be valuable. The benefits are that the manufacturer can then discuss the trial data in both clinical and financial terms and the financial analysis may also allow for a publication in a managed care journal, increasing the drug's visibility.

Trackable Endpoints

A recurring issue manufacturers have when presenting clinical outcomes to payers is the data may not be trackable by the payer audience. An ACR20 response in a rheumatoid arthritis trial or an improved HbA1c in a diabetes trial may be sufficient for the FDA, but such endpoints rarely show up in a health plan's data set. While the primary endpoint of a clinical trial will always need to follow FDA guidance, manufacturers designing trials should consider secondary or exploratory endpoints that payers can review in their

own data. Outcomes that lead to use of healthcare resources such as hospitalizations or visits to the ED or clinic are generally captured by payers — as is medication use. So if a study drug helps patients avoid the use of certain supportive or chronic drugs, payers can estimate the savings. Trackable endpoints provide another way for a manufacturer to strengthen the value message to a payer with data the payer can see in their own business.

Long-Term Data

Trials are designed for the shortest duration possible for good reason: to save money and get the drug to market. However, payer hesitancy in adopting new medications may be due to a lack of long-term data, an issue only solved by time. Manufacturers should plan for long-term extension analyses of pivotal trials and develop a publication plan to communicate the results. Long-term data communication is particularly important for emerging cell-based and gene therapies where payers are burdened by paying a significant cost up front with the hope of savings later on due to durability of response.

Quality Measures

The gradual shift to value in the U.S. healthcare market has increased the importance of quality measures. Health plans and integrated delivery networks (IDNs) may suffer financially for poor performance on quality measures. While not all diseases have associated quality measures, designers of clinical trials may consider reviewing the quality metrics of a study disease to inform endpoint selection. A drug that demonstrates a reduction in re-hospitalization, for example, may find a more receptive payer audience knowing that the medication can improve the quality scores of a plan or IDN.

Real-World Applicability

Clinical trials are conducted under controlled settings with a selective population. Payers know this. Payers also know that once a drug is marketed, the impacted population is likely larger than the clinical trial-eligible population. The result is potential variance in patient response, patient safety, and adherence. Payers may be hesitant to adopt new therapies without a better idea of the real-world impact. Designers of clinical trials should consider ways to show the payer audience how a trial population is similar to the larger patient community. In addition, manufacturers should develop a comprehensive real-world evidence strategy, together with a publication plan, so health plan customers can be educated on a drug's real-world experience and how closely it resembles the clinical trial data.

Conclusion

The focus on drug prices along with consolidation in the payer market will make payers an ever-more influential force in drug access. Clinical trial data is the vanguard of a drug's value proposition to the drug's customers, including payers. Clinical trial data shown in endpoints a payer understands and appreciates may improve the access environment and initial reception. For clinical trial designers, that means understanding what endpoints are of interest to payers and how clinical trial protocols can be designed to accommodate them. Manufacturers able to conduct trials that meet the needs not only of providers and patients but also of payers may gain a competitive advantage.

About The Author:

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