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Saving lives by enhancing access

How an oncology manufacturer delivered proof of clinical outcomes for its therapy

Case study

The client situation

Imagine that your relatively new oncology product has made it through clinical trials, is being well received, and is developing a proven reputation for delivering meaningful clinical results. But competitive products claim to offer similar benefits and at potentially a lower price point. Payers, providers, and patients want to know why they should choose your therapy vs. a competitive therapy.

You know anecdotally that your product is superior because you have mounds of evidence demonstrating effectiveness under real-world conditions. But there is one big problem: all of your clinical evidence is scattered across thousands of patient records, and those records are extremely difficult to access and analyze. Where would you turn?

The Xcenda solution

Xcenda consultants met with this manufacturer's executives and asked a host of questions to ensure they understood the goals and objectives that the manufacturer was trying to accomplish. Xcenda consultants discussed a range of possible options for acquiring, analyzing, and presenting the product's real-world clinical efficacy data to stakeholders.

In sorting through options, Xcenda consultants acknowledged the challenge of using retrospective database studies to derive credible health economic and outcomes research evidence for an oncology product. One major problem is the virtual absence of clinical response data, which impacts clinical data and laboratory values and can therefore limit the effectiveness of the data accessible from a retrospective study. This frequently leaves researchers and health economists with chart reviews as a primary data source. Chart reviews are valuable yet not without challenges: they are very time consuming to review; the sample size is usually small, rendering the data questionable; and the review is inherently labor intensive and expensive.

Xcenda consultants discussed the option of drawing upon electronic medical records (EMR) as a primary data source. While the manufacturer's executives had some questions and concerns, they were quickly assuaged when they learned of Xcenda's strong track record in this area.

Ultimately, Xcenda's HEOR consultants recommended the manufacturer utilize the ION Solutions clinical data warehouse, a large diversified EMR database, as the primary data source. ION Solutions is a diversified, physician-services network whose membership represents about half of the private practice oncologists in the United States.

At the time of this study, this EMR database contained data from 175 unique providers over 25 large practices, encompassing 380,000 patients. Best of all, this information is usually very up-to-date, ensuring that the latest clinical evidence is available for study. While the ION Solutions EMR is not a perfect option to support HEOR for every type of oncology product, it can be a very valuable and efficient data source for specific types of products. Xcenda has a strong track record of gleaning high-value insights from ION Solutions EMR data, having developed efficient standard operating procedures that consistently deliver hidden clinical efficacy gems and shatter perceived limitations. This history of success was very attractive to the manufacturer.

The service package

Xcenda consultants recommended a 3-phase approach to the engagement: study design, study implementation, and study output. This methodical and rigorous approach consistently yields valuable clinical outcomes data.

In the study design phase, Xcenda health economists helped the manufacturer define the study time frame, inclusion/exclusion criteria, covariates, and other relevant factors utilized in evaluating the data. This resulted in the development of a study protocol and statistical analysis plan.

Variables of interest to this study included:

- Medication use
- Treatment plans
- Duration and cycles of therapy
- Amount charged for care
- Comorbid conditions
- Patient insurance
- Gender
- Age
- Labs
- Staging
- Histology
- Survival

This also provided an opportunity for Xcenda to discuss the framework and methodology of the study, ensuring that the methods and results were consistent with the manufacturer's expectations while maintaining the rigor and validity to make reliable extrapolations from the results.

During the study implementation phase, Xcenda health economists proceeded through 6 key stages of data collection and analysis:

01. Data procurement
02. Data validation
03. Patient selection
04. Results generation
05. Results validation
06. Results interpretation

This comprehensive and methodical approach ensured that the data were credible, accurate, and meaningful to the manufacturer's communication plan.

In the study output phase, Xcenda consultants provided a package of deliverables that were ready for field use to support the manufacturer's market position. Those deliverables included:

- A study protocol that indicated in detail the inclusion/exclusion criteria for the research population and statistical analysis plan
- A compendium of analyses that highlighted the study design, results, and limitations of the analysis
- A set of PowerPoint slides that summarized the technical report and communicated key findings
- An abstract for a clinical poster and podium speech for a conference

The outcome

In very short order, this manufacturer had credible real-world evidence of its oncology product's impact on patient outcomes. This evidence was broad based, having been derived from a data set that included hundreds of thousands of patients.

The evidence was valid because of the methodologically sound approach that was employed during the study construction, data acquisition, and analysis. The study was effective because it was packaged up neatly for the manufacturer's field and internal staff to press into service right away.

With this credible evidence in hand, the manufacturer was ready to defend its product's value, fend off competitors, and maximize patient access to its effective therapy.

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