

Defining the true market

Case study: How real-world data and outcomes improved a major pharmaceutical company's launch strategy

Cardinal Health Specialty Solutions

Competing in a crowded marketplace

A major pharmaceutical company was just months away from FDA approval for its new hematology drug and was deep into developing its launch strategy. The challenge was clear: how should this drug be positioned to compete successfully in a crowded niche market where four other companies were also preparing for approval?

According to the available evidence and cost of care for the targeted disease, the company's initial value proposition and price strategy appeared sound. This perspective was based on an analysis of the clinical value triad—using clinical trial data—and the company's prior analysis of commercial claims.

The pharmaceutical company's perception of the **clinical value triad** for the new hematology drug:

The new drug was superior to the regimens currently believed to be standard of care, so efficacy would be a major driver of utilization.



The drug's favorable toxicity profile would reduce hospital admissions and visits to the emergency department compared to standard regimens.

The higher cost of the drug—compared to its competitors—would be justified because its better toxicity profile would result in a lower **total** cost of care.

Challenge

How does a major pharmaceutical company successfully market a new hematology drug, when four other companies are preparing for approval for competing products of their own?

Solution

Move beyond the traditional approach of using clinical trial data alone to create the value proposition. Add real-world outcomes data to reveal the true, untapped market opportunity.

Result

An improved launch strategy that more accurately reflects market needs. Our client shared the results as poster presentations at six international meetings.

Continue reading to learn how an accurate understanding of treatment patterns, adverse events and related costs helped this company to develop an effective launch strategy.

Challenging assumptions

Was clinical trial data providing an accurate picture of the new drug's market potential?

Was there a better way?

In years past, clinical trial data have driven the market positioning and potential of new products. But with the increased focus on value-based care, which relies on real-world clinical evidence, clinical trial data alone is no longer enough.

Clinical trial design does not always reflect physician behavior in the real-world setting. Payers are seeing this disparity and are adjusting reimbursements as a result.

Therefore, pharmaceutical companies can no longer rely solely on clinical trial data to make critical market decisions. Instead, they must test clinical trial findings and augment their strategy by studying real-world utilization data.

"We know that only 3% of cancer patients go on clinical trials, and hence that data is non-representative of the entire cancer population. . .

By studying how closely the findings of clinical trials are replicated in real-world patients, we will be better able to determine the true value of treatments and understand what is the best way to adapt those treatments, potentially leading to better overall results."

Peter Yu, MD

President, American Society of Clinical Oncology

Source: Onclive. "The Promise of Big Data Gets Closer to Fulfillment." October 21, 2014.

Choosing the right research partner

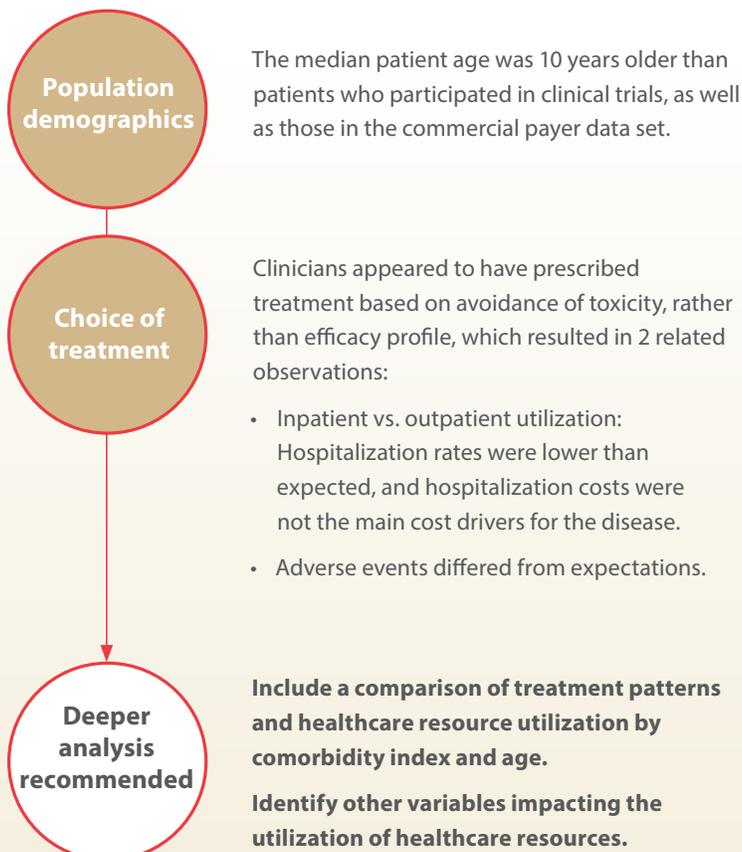
In order to gain more insight, the pharmaceutical company agreed to test its assumptions with real-world market analysis. Because of our deep oncology experience, analytics expertise, and access to generalizable source data, Cardinal Health Specialty Solutions was enlisted. And our initial analysis revealed two key insights:

- 1 Because clinical trials are skewed toward including younger and healthier patients, there was a concern that these patients did not accurately represent the drug's true market.
- 2 The drugs used in the comparative arm of the clinical trials were not reflective of current practice in the real world.

Confirming our initial insights

To test these assumptions and reveal the drug's true market, we performed an in-depth analysis of real-world data using a payer claims database with representative mix of Medicare, Medicaid, and commercial populations.

The analysis revealed new information that confirmed our initial insights:



Revealing new knowledge

After implementing our recommendations, we refined our customer's understanding of the new drug's market in three key areas:

Patient cohort

Richer data analysis further defined the target patient. The average age of patients in the data sample was significantly higher than those in the clinical trial, consistent with expectations based on the epidemiology of a disease largely affecting an older population. Patients had a high comorbidity index at the time of diagnosis that increased as they received treatment.

Competitive landscape

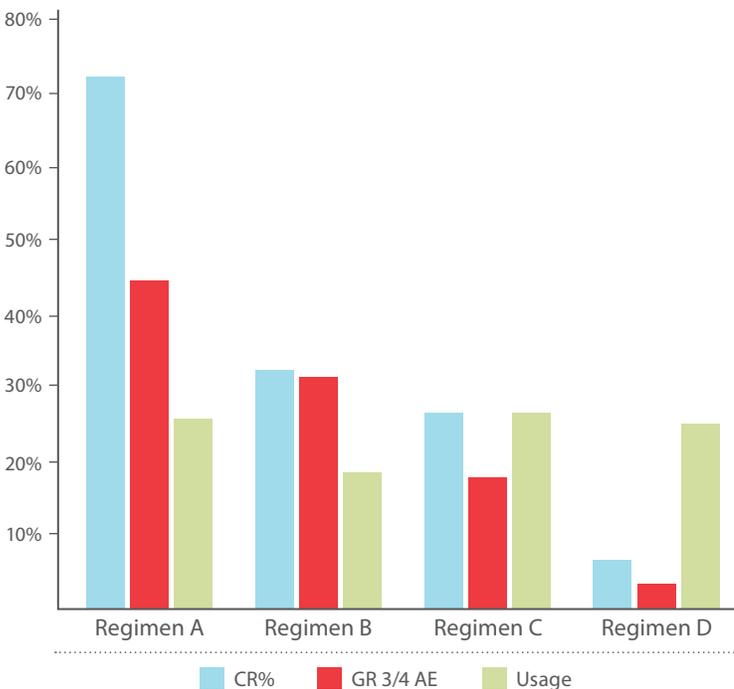
The treatment regimen with the highest utilization didn't even have label indication. Based on clinical trial data, it also had the lowest complete response (CR) rate of any of the top four regimens and was used in one-third of patients, similar to the therapy with the highest CR rate. Interestingly, the therapy with the lower CR rate had the best toxicity profile compared to all other therapies identified in the analysis. This implied that perceived toxicity might trump efficacy when identifying treatment choices for the vast majority of patients with this diagnosis.

This conclusion was further confirmed when treatment patterns were evaluated by age group. Older patients with a higher comorbidity index were more likely to receive therapy with lower efficacy and a lower toxicity profile than younger, healthier patients.

Cost implications

In contrast to initial assumptions, the impact of this less toxic treatment choice resulted in 80 percent of the cost attributed to outpatient care. And the adverse event with the highest cost was emesis, not infection.

Better efficacy does not lead to higher drug utilization



Real-world data provides actionable insights

We maintain a comprehensive array of data comprised of Point-of-Care Claims, Payer Claims, and EMR/EHR data. This depth of data allows us to perform real-world research based on a representative mix of government and commercial patient populations.

The study summarized in this report was based on a retrospective review of our large payer claims database, with a balance of Medicare, Medicaid, and commercial patients.

The result

A patient mix more representative of our client's target population and a launch strategy based on real-world evidence.

Refining business direction

The results of this retrospective outcomes study were clear:

The target patient profile was substantially different than originally assumed.

The study determined that patient tolerability of the new hematology drug was more important than efficacy alone.

This more in-depth analysis provided this pharmaceutical company with **an accurate picture of the new drug's opportunity, based on real-world data and expert analysis.** This company now has a more complete understanding of the new drug's patient market, competitors, and cost implications—all of which improved the go-to-market strategy.

Turning insights into action

Based on this study's results, we recommended two significant changes to the strategic direction of the new drug's launch:

Refine the launch strategy to focus more on tolerability than efficacy.

Modify future clinical trials to consider real-world treatment patterns, making the appropriate comparisons of experimental treatment to therapies with higher utilization in a real-world setting.

Sharing results with the hematology community

This outcomes study was designed so that the results would be readily available for publication. The results were developed into eight abstracts, which were all elevated to the poster level at six international meetings.

Ready to make a more informed move?

Contact Cardinal Health Specialty Solutions.

Whether you are preparing to launch a new product—or want to reposition an existing one—we have the data resources, analytical expertise, and communications resources to turn insights into effective action. So you can make more informed decisions about product and evidence generation strategies.

Visit: cardinalhealth.com/BioPharmaAnalytics
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Call: 972.773.8600

Changing the way healthcare stakeholders think about data

The success of this outcomes study confirms a fundamental truth:
the right data is key to making the right decisions.

But data alone is not the answer. In fact, even the best data can lead to costly mistakes if misunderstood.

The key is sound interpretation based not on assumptions, but real-world data analysis performed by oncology experts. To maximize success, this analysis must follow a structured path—from raw data to wisdom.

Our clinical experts used this structured path to help this pharmaceutical company refine and improve its go-to-market strategy for their new hematology drug.

Turning real-world insights into action

Wisdom

Recommend specific actions to improve future research and marketing strategies.

Knowledge

Create a deeper knowledge base—built on a foundation of real-world data and interpretation.

Information

Confirm initial insights and recommend further research to yield richer information.

Data

Reveal gaps in existing data that could lead to inaccurate analysis of true market opportunity. Then, identify the right data sources to fill those gaps.

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