CASE STUDY

VALIDATED MARKET SIZING USING REAL WORLD DATA

DRG's Machine Learning Analytic Model Confirms Undiagnosed Patient Population using Claims Data

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DECISION RESOURCES GROUP

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Introduction to the Case Study

A diversified biopharma company whose core mission includes creating medications for patients suffering from serious illnesses, partnered with DRG to accurately size the market in preparation for their anticipated launch of a specialty drug treating a rare disease, currently in Phase III clinical trials.

Defining the Challenges

This rare disease can be a secondary side effect of diabetes, and significant evidence exists that its documented prevalence is widely inaccurate as a result of underdiagnosis. This is corroborated by Real World Evidence (RWE), in the form of claims data, which reveals that currently only 150K patients have a documented diagnosis. Disease experts, including the client's own clinical team of medical experts, believe the prevalence to be closer to 2-3 million individuals.

The problem this represented for our client's clinical medical team was two-fold:

1. Traditional epidemiologic measures of prevalence are not reflected in current rates of diagnosis, therefore posing a significant challenge to accurately assessing and verifying the market need for their potential therapy.
2. The team did not have a model for validating the true size of the market, which would enable them to confidently recommend a drug launch strategy, and allocation of resources to support it.

DRG was engaged to validate the size of the population, given that the condition is substantially underdiagnosed by treating physicians, who rarely assign the specific diagnosis code as a secondary condition to diabetes or other indications.

Our Solution

To validate our client's hypothesis that this rare disease is significantly under-diagnosed, DRG proposed a two-phased approach. To develop a right-sized estimation of the affected population, phase one of the DRG approach relied on standard epidemiological models and contributions from our own epidemiologists, coupled with a method to corroborate these findings using specific markers within our real world claims data. Phase Two of the project added a third level of validation, yielding deeper insight on the market by using machine learning to view the real world claims data using different underlying assumptions.

During phase one, DRG analytic experts collaborated closely with the client's own clinical experts to establish a set of analytic rules to be used in conjunction with the claims data.

These rules were specified as patient profiles, developed in concert with the client's clinical experts. For example: proof points were drawn from established medical research indicating that 50% of patients with the specific symptoms of this rare disease have diabetes as a co-occurring diagnosis.

Further extrapolation based on medical research revealed that 5% of all diabetics also have the rare disease for which our client is developing a treatment.

Once these rules were established, DRG was able to use claims data to accurately estimate volumes of patients with the rare disease, based on the likelihood of a diabetic co-morbidity. Other clinical triggers assisted in the prediction of undiagnosed patients in the general population as well. This provided a good estimate of the size of the disease market using RWE, and corroborated by standard epidemiologic and medical research.

In phase two of our approach, DRG recommended the use of a machine learning approach to confirm the population size without relying on an initial set of clinical assumptions. As a subset of traditional data-mining, machine learning uses large amounts of data to identify relationships within the data, some of which may be previously unrecognized. Machine learning models evolve over time, learning how one piece of data can be associated with another to yield patterns within large data sets. The analytical method delivers insights that do not rely on clinical assumptions, but instead are based on the relationships between data points themselves. The result is an independent validation of the estimated total disease population using all possible comorbidities in a multi-year dataset with tens of millions of lives. Moreover, new relationships discovered in the data can inform clinical thinking going forward.

The Result

The use of machine intelligence yielded several unexpected yet very valuable insights. For example, primary care physicians rarely diagnose the rare disease in question, while endocrinologists consistently do. This finding was new to our client, and proved to be an insight that was instrumental in determining their launch strategy. Based on this finding, our client was able to develop highly targeted sales and marketing strategies for the different physician audiences. The client is developing general education about this rare disease for primary care physicians, while focusing more on drug benefit communications for endocrinologists.

Ultimately, all three approaches, epidemiologic, real world claims data analysis and machine learning, confirmed definitively that our client's hypothesis was correct. The number of patients with this disease is substantially under-reported in the population based on diagnosis codes alone. All three approaches showed that the actual population size is between 2 – 3 million, as their clinical team had expected.

Takeaways

Our client is now confident that all angles have been considered in preparation for the launch of their novel therapy. Their strategy is rooted in Real World Evidence, found within the 304 million U.S. patient lives within DRG claims data, and guided by collaboration between experts of various scientific disciplines. As an industry leader in the application of complex analytics from various data sources, DRG was able to bring an additional level of cutting edge analysis to the project, a significant value-add that allowed our client to further refine their go-to-market strategy.

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