

Using Real-world Data to Support a Product Label Change



SITUATION

- A mid-size pharmaceutical company was interested in obtaining **real-world evidence** demonstrating the safety and effectiveness of higher dosage chemotherapy for a labeled oncology indication
- The company asked Magnolia Market Access to design and conduct a study **comparing survival outcomes** between the two dosing regimens for additional evidence to **support a label change**



APPROACH

- Magnolia Market Access conducted a **retrospective cohort study** in closed claims comparing **overall and progression-free survival** between the two dosage treatment cohorts
- **Inverse probability treatment weighting** was utilized to balance baseline differences between cohorts
- Cox proportional hazards models and Kaplan Meier curves to compare overall and progression-free survival



OUTCOME

- Results from the survival analysis were used in a **conference abstract** and **poster presentation**
- Results were also used as **additional evidence** in **supplemental NDA submission** supporting higher dosage option being added to the product label

