Datavant Life Sciences Case Study:

Trial Tokenization and Linking to Real World Data: Extending the effectiveness and safety analysis of a new focal seizure treatment

Client Situation

Recently, a biopharmaceutical company completed at 36 week Phase IV study of 175 patients across 40 trial sites to evaluate the effectiveness and safety of a recently approved anti-seizure medication as adjunctive therapy in focal seizure. Patient retention was the primary efficacy endpoint and seizure frequency was a secondary efficacy endpoint. The study also looked at tolerability. The initial study results showed that a substantial number of patients remained on therapy and experienced reduced seizure frequency.

Client Need

Client sought specific insights coming out of the study including understanding of:

1. the patient's historical seizure frequency (pre-trial) and total cost of care
2. the impact of therapy on healthcare utilization during and after the trial
3. factors that contribute to patient discontinuation and adverse events
4. long-term effectiveness and safety of the therapy at 6 months and 1 year of exposure

How Datavant Helped

Datavant supported each trial site's access to the Datavant software to upload, tokenize and de-identify each trial participant's trial data. This data was linked to tokenized claims data from a real world data partner in the Datavant ecosystem. The linkage created a single data set that included payer claims for the four year period preceding the trial through a one year period after the trial concluded. The resulting dataset is being used to:

1. establish a baseline of healthcare utilization and measure the new thearpy's impact on the total cost of care and
2. evaluate long term effectiveness and safety by measuring seizure frequency and continuation of therapy over an additional year as a sign of tolerability.

Answering these questions will help expand the drug's clinical and economic value to provider's payers and patients.