PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Descriptive analysis of a rare and fatal adverse event within the FDA Adverse Event Reporting System (FAERS)

CLIENT SIZE Large pharmaceutical

GEOGRAPHY Global

THERAPEUTIC AREA Multiple

CLIENT NEED

- The client was a large pharmaceutical company with offices worldwide
- Part of the pharmacoepidemiology evaluation of progressive multifocal leukoencephalopathy (PML) described in the product's Enhanced Pharmacovigilance Plan as agreed upon with U.S. FDA in August 2007
- PharmaLex was contracted annually over a 10-year period to develop methodology and conduct a longitudinal review on PML cases
- Objectives:
  - Conduct a cumulative descriptive analysis on all PML cases identified between November 1997 and December 2016
  - Identify relational trends or reporting patterns of PMS
  - Evaluate underlying variables to provide insights into susceptibilities of this AE

OUR SOLUTION

- Retrospectively analyzed electronic records and MedWatch form narratives
- Developed a novel de-duplication algorithm to identify unique cases
- Applied clinical criteria to classify cases as "Confirmed", "Possible", and "Unconfirmed"
- Measured frequencies of comorbidities, primary suspect drugs, time on therapy, and time to event

PHARMALEX VALUE TO CLIENT

- Long-term commitment by our project team that allowed consistency in research and reporting
- Familiarity with data source and subject matter by project team that included a physician, pharmacist, biologist, and a data analyst
- Fulfilment of recurring regulatory commitments
- Presented findings in an annual study report, presentations, and multiple conference posters
- Generated testable hypotheses on the potential risk factors for this rare and typically fatal AE

DISCOVERY / NONCLINICAL | CLINICAL DEVELOPMENT | MARKET & LAUNCH | PRODUCT MAINTENANCE