

CASE STUDY: Comparative Effectiveness Study

 **CLIENT SIZE** Large Pharmaceutical Company

 **GEOGRAPHY** US

 **THERAPEUTIC AREA** Cardiovascular

CLIENT NEED

- ▶ The client was a large pharmaceutical company with offices worldwide
- ▶ Evidence of differences in the efficacy of dronedarone among subgroups of patients had been identified in clinical trial / interventional settings
- ▶ PharmaLex was contracted to examine the comparative effectiveness of dronedarone used to treat atrial fibrillation relative to other drugs with the same indication in a real world setting

Timelines:

- ▶ Protocol development (2 months)
- ▶ Data acquisition and analysis (36 months)
- ▶ Production of study reports (2 months)
- ▶ Manuscript development (1 month)

OUR SOLUTION

- ▶ Conducted retrospective cohort study in the US Department of Defense Military Health System electronic health records (EHR) database
- ▶ Developed Study Protocol and Statistical Analysis Plan
- ▶ Obtained data from database vendor
- ▶ Analyzed the data, and wrote study report

PHARMALEX VALUE TO CLIENT

- ▶ Strategic partnership with data vendor facilitated access to US Department of Defense Military Health System EHR database, with 10+ million patient lives and the largest number of dronedarone exposed patients at the time
- ▶ Expert study design considerations (e.g., propensity score matched analysis cohorts, consultation with clinical experts) maximized robustness of findings
- ▶ Poster presented at Boston Atrial Fibrillation Symposium

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

APPROVAL /
AUTHORIZATION

PRODUCT
MAINTENANCE