Safety Detection and Signal Management

Challenge

Efficient End to End Pharmacovigilance services according to GVP

- The marketing authorisation holder in the EU should continuously monitor the safety of their medicinal products and inform the authorities of any new information that might have an impact on the marketing authorisation [DIR Art 23(2), REG Art 16(2)] (GVP Module IX)
- Client was rapidly increasing portfolio with M&A with over 1500 marketing authorizations with complex partner network systems
- Implement a process for integrating the activities performed by PharmaLex into the client's system

Solution

Establishment of an ongoing safety monitoring strategy, implementing PharmaLex-owned Vigilit® application

- Creation of a client- and substance specific ongoing monitoring plan considering the substance-specific risk-profile
- Implement a process for detecting potential signals from ICSRs and literature for approximately 270 active substances resulting in review of about 160000 literature articles
- Provision of templates by PharmaLex for complete documentation of all relevant steps
- Preparation of signal reports for validated signals, including in-depth assessment and the recommendation for actions, as applicable
- Implementation Macro based EVDAS review tool

Outcome

The client now has a cost-efficient solution for End-to-End pharmacovigilance services

- Client received a cost-efficient solution for the signal management of the substances
- Medical review involved in every signal assessment
- Increased efficiency and reduced efforts by 50% for EVDAS review