

# Safety Writing Services

## Challenge



Client looking to outsource PV activities to focus on core business activities and compliance function

- Need to increase the resources available for PV activities without increasing company assets
- Interest to have support from PV experts and collaborate with a service provider focused on PV
- Mitigate the risk of quality issues raised during inspections from health authorities

## Solution



PharmaLex periodically monitors timelines and quality of aggregate reports and RMPs

- Collaborated with Medical Safety on the preparation of aggregate reports and RMPs associated with client products: 10+ ACOs / 50+ PSUR/PBRER / 10+ RMPs / 20+ Other reports per year
- Aggregated reports and RMPs delivered to the client according to the timelines and quality agreed by both parties
- Performed the literature search and the medical review of the aggregate reports and RMPs
- Prepared safety specifications within RMPs

## Outcome



Smooth operations and delivery without impacting timelines and quality

- Timely submission to the authorities without missing due dates
- Retain suitably qualified and knowledgeable staff (2-3 FTEs)
- Ensuring a cultural fit with both teams being mainly local staff
- Better resource planning to manage peak of workload and unexpected leaves
- Reduce costs associated to Pharmacovigilance activities