Aggregate Report Writing and RMPs

Challenge

Quality issues raised during inspections related to the source data

- Client needs to handle increased workload in Pharmacovigilance
- Need to reorganize Pharmacovigilance activities outsourcing those that can be easily trained and transferred
- Client looking for an external provider to focus on PV and extensive experience in safety writing

Solution

Produce and publish safety reports with appropriate quality and timeliness

- Retrieved database outputs
- Reviewed previous information and requested report source data
- Organized and lead pre-kick-off and kick-off meetings, coordinating different teams and preparing meeting minutes
- Supported various writing activities: 30+ ACOs / 40+ DSUR / 40+ PBRER / 20+ RMP reports per year
- Decided as coordinating author which comments are relevant to be implemented
- Performed quality control (QC), report publishing and distribution

Outcome

Mitigated the identified risks associated to PV activities

- Client was able to focus on core business activities of Pharmacovigilance and outsource the most standardized activities
- Increased the resources dedicated to PV without increasing the company assets by hiring new employees (2-3 FTEs for writing activities)
- Improved the efficiency and productivity related to safety writing
- Reduced cost associated to PV activities outsourcing to PLX, a service provider with a competitive hourly rate and high-quality standards