CASE STUDY

RSI consolidation for a Vaccine DSUR

The Challenge

- This pharmaceutical major that offers a wide range of therapeutics, including innovative products for Oncology, Immuno-therapeutics, mental health, Infectious disorders, and Vaccines.
- Sponsor requested for a Vaccine DSUR where two separate IBs were used for safety evaluation in two trials of the same vaccine.
- For the singl e DSUR, a single RSI document should be used. Two different Investigator Brochures (IBs) were being used for two trials due to inherent differences and posed process as well as content challenges.

SIRO Solution

- Analysed and explained the rationale of the two IBs; suggested appropriate presentation.
- The labelling assessment consulted with the clinical leader.
- Team members advised investigators and the clinical leader the need and strategy to combine the safety data and create the Development Core Safety Information (DCSI) as recommended by the CIOMS Working Group.
- Extended expert advisory to the client to help streamline to develop single RSI and remain compliant.

Key Takeaways

- SIRO team generated the DSUR within timelines and submitted to the US FDA as well as the EU countries.
- Going beyond serviced process, SIRO extended expert advisory to the client to help streamline to develop single RSI and remain compliant.