

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.
- Requested to develop a DSUR for compound jointly developed with a business partner while the safety database was still with earlier sponsor.
- For this innovator molecule, the clinical development was jointly undertaken by two global clients based out of the US and the EU and both parties (client and partner) had separate reporting obligations.
- The safety database was with the business partner while the DSUR submission responsibility was taken over by the client & SIRO was to drive the triangulated process throughout.

SIRO Solution

- SIRO facilitated the partner and the client to finalize the PV agreement first followed by streamlined the process for the DSUR creation and submission obligations.
- Developed a separate programming and safety database script for the DSUR requirement.

Dedicated Project manager was SPOC to execute the process and keep the necessary stakeholders connected.

Key Takeaways

- The safety database script developed by SIRO was accepted by both the client and the business partner and helped to execute the project needs smoothly.
- This one time solution provided permanent solution for all of the business partner products requiring DSUR submission internally and with other partners.