

Authoring for critical sections Benefit-Risk Evaluation (BRE) of PBRER and QC of these sections.

### 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.
- Required a dedicated Senior Writer to work on critical sections: BRE of PBRER; and QC of these sections, which is a critical step, often involves quick turn around and thorough understanding
- Owing to the criticality of the BRE sections of the PBRER, a dedicated experienced writer handle the task separately from overall PBRER.
- Unpredictability of the QC timeline and required a very quick turnaround.
- The process also require quick acclimatization with the data from diverse sources and with different data cut-off.

### SIRO Solution

- SIRO handles the end-to-end DSUR process annually and hence, the DSUR Coordinator and SIRO Writers are well versed with the safety profile of the innovator products.
- dynamically aligned assignments for DSUR & BRE QC maximizing cross-utilization of the knowledge with ultimate aim to give functional advantage for quality QC with quick turnaround.

### Key Takeaways

- Effective project management and thoughtful assignment from the SIRO Coordinator allowed valuable inputs for the BRE QC step.
- Seamless transfer of information while simultaneous update & finalization of these deliverables allowed harmonized safety profiling.