CASE STUDY

Major EU-RMP Update with consolidation.

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 an EU-RMP authoring with expedited timelines and involved consolidation of multiple interim RMP updates.
- This rare scenario of EU-RMP update appeared as a result of multiple updates based on parallel regulatory procedures for multiple target indications.
- Due to regulatory variations requirements, the earlier RMP versions had multiple data-lock points and even multiple base versions.
- The current regulatory sequence additionally demanded updates within short time span in multiple modules with newer data and change in the risk profile.

SIRO Solution

- SIRO pitched in to work with the client's Lead Writer and proactively proposed a sequential consolidation strategy to resolve the most critical consolidation challenge.
- Besides providing technical solution, SIRO also provided swift authoring support to complement the EST – IST time zones resulting in doubling the speed of the work.

Key Takeaways

- Worked proactively hand-in-hand right from developing a strategy till finalization.
- Overall process involved SIRO's close interaction with client's expert regulatory team and QPPV office.