

The Challenge

- Pharmaceutical major that offers a wide range of therapeutics, including innovative products for Oncology, Immuno-therapeutics, mental health, Infectious disorders, and Vaccines.
- Requested to prepare a DSUR for single country.
- In Korea, the Ministry of Food and Drug Safety (MFDS) requires a DSUR via an Investigator in the E2F style. Specific guideline mandates limited scope document compared to global report.

SIRO Solution

- SIRO proposed to create the Executive Summary of the DSUR without any line listings to follow the requirements in Korea while eliminating chances of unblinded of the investigators.
- Additionally, prepared a cover letter where the provision to provide the line listings in an unblinded manner was included based upon requests.

Key Takeaways

- SIRO team provided customised solution to meet the regional requirement while maintaining the blinding as per global ICH requirements.