

The Challenge

- TA-Rare disease and complex study design.
- Patient population includes neonates to Adults.
- Hybrid (Paper+EDC) study.
- Double blind study-in which some roles would have access to the limited data and some roles were blinded.
- Communication challenges-Time zone difference.

SIRO Solution

- 800+ edit checks programmed and validated to ensure robust data review.
- eLearning video for training patients in different languages and age groups.
- ePRO/eCOA integration with EDC highlights-
 - a) Prompt e-mail and push notifications to Investigators and Sponsor at different data points.
 - b) alarm notifications as reminders for patients,
 - c) dynamism in place as per study design to minimize errors.
- Vigilant access matrix to ensure correct role specific access in EDC.

Key Takeaways

- eCOA-EDC integration facilitates prompt review of Safety data by Investigators.
- eLearning videos helped being interactive and responsive with the Subject.