CASE STUDY

Successful conduction of a BA/BE drug trial having a challenging inclusion/exclusion criteria, in Breast Cancer patients of a Metastatic setting.

The Challenge

- Real time monitoring of the PK dosing of each and every patient by SIRO team to ensure that the data submitted to USFDA is accurate.
- Very aggressive and stringent study timelines were requested by the sponsor.
- The study involved several logistic and administrative challenges which were not envisaged by sponsor while designing the protocol.

SIRO Solution

- SIRO allocated dedicated resources to hand hold sites right from pre-identification of patients, routine RMVs until DBL.
- CRA and sites were groomed for multi-tasking to ensure 100% compliance to study procedures/ time points, especially for the PK sampling part.
- Flexibility in monitoring visits was provided to ensure each data point is thoroughly reviewed on real time.
- SIRO's past experience in proactive vendor management proved beneficial to overcome several logistic requirements.
- Timely risk mitigation including both tactical and strategic level communications with the sponsor.
- Realignment of internal timelines, processes and resources to achieve study milestones like DBL and CSR.

Key Takeaways

- Recruited 46 patients with zero errors in patient eligibility and administration process.
- Cleared 10+ site/ process client audits without any significant findings.
- Trial data was successfully submitted to USFDA for review and approval.