

Large multi-centric breast cancer trial involving challenging timelines & data monitoring

Situation: A Phase II Breast cancer study involving 10 sites & 46 patients to be recruited in 2 phases

Challenges:

- Strict inclusion-exclusion criteria set by the sponsor
- Projected screen failure rate was high due to one specific exclusion criteria relating to biochemical lab parameter
- IP required specialized transport & storage in order to prevent physico-chemical changes

SIRO Strategy:

- Selection of high enrolling sites to expedite recruitment
- Pre-identification of patients from site database to expedite screening rate at site
- SIRO team designed a 'daily newsletter' to imbibe competition amongst the sites for patient enrollment
- SIRO team designed a unique 'Screen patient information form' to ensure that non-eligible patients were not randomized
- SIRO team along with sponsor designed bi-monthly newsletter to facilitate knowledge sharing amongst the sites

Result:

- SIRO completed the enrollment as per the schedule.
- Sponsor was able to present the data at international oncology conference (ASCO).
- The successful execution of the project enabled the sponsor to plan their next phase of drug development.

Sponsor Feedback:

“I would like to thank the team in your efforts to accomplish this milestone. Good work!”

- A.J. Leyco – Associate Director, Clinical Affairs, Peregrine Pharmaceuticals Inc.

“Thanks everyone for all the extra effort in completing this very important study.”

- Joseph Shan, VP, Clinical and Regulatory Affairs, Peregrine Pharmaceuticals Inc.