



Our Global Experience. Your Success.

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





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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.

