

PROJECT DESCRIPTION

Description:	Double-Blind , Randomized, Placebo Controlled study to evaluate anti-Inflammatory effect of Drug X as an adjuvant to chemotherapy in patients with breast cancer
Therapeutic Focus:	Oncology
Study Phase:	II
No. of Patients:	34 Patients
Number of sites	1
Committed TAT Timelines:	<ul style="list-style-type: none">- Patient Recruitment of 34 Patients in 3 Months- End-to-end Study Completion including Closure of Clinical Study Report within 7 Months from date of Site Initiation Visit- 1 Week for closure of DCFs at Site from LPLV- 2 Weeks for Final CSR Closure (ICH E3 Format)

KEY CHALLENGES

- No past clinical trial reports were available on study drug or dosing.
- Sample Size estimation was a challenge due to lack of reference literature and Adverse Events data.

KARMIC'S APPROACH

- Conducted comprehensive site feasibility assessment and enrolled one of the largest cancer sites in Central India as primary site and one site in Western India as back-up site.
- Recruited a leading Breast Cancer Specialist as PI for study.
- Developed Protocol and CRF after thorough research on similar adjuvants, developed primary and secondary efficacy parameters, inclusion and exclusion criteria.
- Researched and included global scales for pain measurement.

ACTIVITIES SUPPORTED

- Study Feasibility Assessment
- Sample Size Calculation
- Study Protocol & CRF Design
- Regulatory Approvals
- Site Selection & Feasibility
- Study Initiation
- Patients Recruitment
- Trial Monitoring
- Data Management
- Final Analysis and Report Closure

OUTCOME

- Study current ongoing, Site Initiation activities completed on time.
- 6 Patients enrolled within one week of site initiation.
- Screening Failure Rate of 0%, all 6 Patients Randomized post screening.
- Expected Study Closure within committed timelines and fixed study budget.