

PROJECT DESCRIPTION

Description:	A study to assess safety and efficacy of Drug X in patients at moderate risk of Coronary Artery Disease
Therapeutic Focus:	Cardiology
Study Phase:	III
Trial Sites:	6 primary sites and 2 back-up sites
No. of Patients:	200 patients
Committed TAT Timelines:	<ul style="list-style-type: none">- Regulatory and EC approvals closed within 12 weeks- Patient Recruitment and Screening of 200 Patients completed in 12 Weeks- End-to-end Study Completion within 30 Weeks from date of Site Initiation Visit- 2 Week for closure of DCFs at Sites from LPLV- 2 Weeks for Final CSR Closure (ICH E3 Format)

KEY CHALLENGES

- Determination of the appropriate confidence interval and sample size to address US FDA regulatory requirements
- Stringent Regulatory/IEC submission deadlines led to crunched timelines for Protocol & CRF development
- Absence of ICH-GCP trained skilled resources at a couple of sites
- Investigators had to be convinced on certain study procedures

KARMIC'S APPROACH

- Karmic Medical Writing team developed protocol taking inputs from leading Cardiologists
- Conducted comprehensive study feasibility assessment, took opinion from several leading cardiologists
- Identified 6 primary and 2 back-up sites for sourcing of CAD patients per inclusion/exclusion criteria in protocol
- Involved leading sites with ICH-GCP trial conduct experience and faster patient enrollment
- Provided ICH-GCP trained Clinical Research Coordinators at sites which did not have trained professionals

ACTIVITIES SUPPORTED

- Study Feasibility Assessment
- Site Identification
- Study Protocol and CRF Design
- Sample Size estimation and Statistical Plan design
- DCGI and Local Ethics Committee approvals
- Study Initiation
- Trial Monitoring & Audits
- Data Management using 21 CFR Part 11 compliant systems
- Final Analysis and Clinical Report Closure

OUTCOME

- Was able to enroll prestigious Sites/Investigators from among well-reputed Cardiologists for study
- Was able to close study design and initiation activities within 4 weeks
- Was able to close the study in 10 months on schedule and on budget
- Database lock within 2 weeks of LPLV, Statistical Analysis and Final Study Report within 4 weeks of close-out
- Currently working on publication of report in leading journal
- Provided 40%+ savings to sponsor against comparative study budgets in US