

PROJECT DESCRIPTION

Description:	A Phase I Study on the Safety, Pharmacokinetic Interaction and Efficacy of Drug X in Combination With Standard Therapy for Patients With Locally Advanced Non-Small Cell Lung Cancer
Therapeutic Focus:	Oncology
Study Phase:	I
Committed TAT Timelines:	- 20 business days for Protocol Development from date of receipt of Concept Sheet - 10 business days for CRF/ICF Development from date of receipt of Protocol - 15 business days for ICH E3 CSR Development
Geography:	United States

KEY CHALLENGES

- Lack of comprehensive pre-clinical and safety data from Sponsor
- Determination of the appropriate confidence interval and sample size to address US FDA regulatory requirements.
- Lack of available published literature references for the concerned disease condition
- Complication in developing study design because of combination therapy
- Reconciling of trial duration with the treatment cycles for the concerned drug
- Ambiguity with respect to Toxicity Standards defined by the National Cancer Institute and requirements of the local ethics committee
- Stringent IEC submission deadlines led to crunched timelines for Protocol & CRF development
- Consolidating clinical and PK parameters together to create a comprehensive Final Study Report

KARMIC'S APPROACH

- Karmic involved a team of renowned Oncologists in India and US with a consolidated experience of conducting over 14 lung cancer trials for the study design of the trial
- Comprehensive due diligence across leading oncology journals and clinicaltrials.gov website for similar clinical trials designs
- Created a comprehensive medical coding list to incorporate ADRs as per NCI and MedDRA 11.1 codes
- Worked with Bio-Analytical SME to get inputs on PK Analysis parameters (C_{max} , t_{max} , $t_{1/2}$, AUC)
- Project supported by an experienced Bio-Statistician for key statistical inputs pertaining to study design and statistically evaluate PK, Lab, Safety & Tolerability parameters

ACTIVITIES SUPPORTED

- Medical Journals/Literature Searches
- Template & Content Structure Design for all key study documents
- Statistical Inputs on Sample Size, Randomization and Protocol/CRF design
- Medical interactions and rigorous follow-ups with Sponsor's Medical Team on Inclusion Criteria, Exclusion Criteria, Study Procedures etc
- Protocol, CRF and ICF Design as per GCP guidelines
- CSR Preparation as per ICH E3 guidelines

KEY ACHIEVEMENTS

- Completed Protocol, CRF and ICF development within a record two weeks to enable the Sponsor to file for the local FDA Regulatory and EC approval
- Study Design approved with minor modifications by Sponsor SMEs
- Final Study Report successfully submitted and accepted by USFDA, drug approved for subsequent Phase IIa trials