

PROJECT DESCRIPTION

Description:	An open label, non-comparative, observational study to evaluate the efficacy, safety and tolerability of Drug X in patients with essential hypertension
Therapeutic Focus:	Cardiovascular
Study Phase:	IV
No. of Patients:	10,400
TAT Timeline:	<ul style="list-style-type: none"> - 15 business days for end-to-end Study Design including Protocol, CRF and ICF from date of receipt of Concept Sheet - 30 business days for closure of Database Design, Validation & Testing using CFR Part 11 compliant system Clintrial 4.6 - Data Entry over a 15 month period with DCF coordination with 50+ sites across APAC - DCFs raised and queries closed on a timely basis, SAE Reconciliation as per client specific TATs - Database lock within 2 weeks from receipt of last CRF - 15 business days for Statistical Analysis and CSR from database lock - 10 business days for Protocol

KEY CHALLENGES

- Large, multi-country, multi-centre Phase IV study with 10,400 patients and several ethnically diverse patient sub-groups
- Discrepancy Management and follow-up involved massive effort due to the size and multi-centric nature of the study
- Several queries had unresolvable status hence patient data had to be dropped from analysis
- Investigators non-adherence to dosage criteria laid down in Protocol led to data discrepancy

KARMIC'S APPROACH

- Protocol & CRF were designed in line with Sponsor's previous study data, inputs from subject matter experts and Sponsor's guidance
- Leveraged 21 CFR Part 11 compliant systems including **Clintrial 4.6, SAS 9.1.3, MedDRA 12.0 and WHO-DD** for fully compliant data management
- Intense query follow-up with sites across 8+ geographies for a 15 month period
- Customized reports to Sponsors on Accuracy, Productivity Query Aging and Resolution on a weekly and monthly basis throughout the study.

ACTIVITIES SUPPORTED

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| <ul style="list-style-type: none"> ▪ Study Design (Protocol, CRF& ICF) ▪ Database Design, Validation & Testing ▪ Double blind data entry with split screen format ▪ Discrepancy Management ▪ Medical Coding done by using MedDRA 12.0/WHO-DD | <ul style="list-style-type: none"> ▪ SAE Reconciliation done with the help of comparison with safety database and clinical database ▪ SAP Development ▪ Statistical Analysis ▪ Final Study Report as per ICH E3 |
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KEY ACHIEVEMENTS

- Karmic completed the study design phase with the help of medical domain experts in a very short span of time.
- DM Accuracy achieved for the project was 99.63%
- Closure of queries within an average 21 business days wing-to-wing basis after repeated site follow-ups
- Completed Statistical Analysis for 10,400 patients within 12 business days and provided Final Study Report to Sponsor
- Conducted country-wise sub-group statistical analysis and reports as a follow-up to the main statistical report