

# Case Study

DM

Multiple



*Karmic currently supports a Top 5 Global Pharmaceutical giant for data management across 15+ studies in multiple therapeutic areas over 14+ geographies across the globe*

Therapeutic Areas	Type of Studies	Our Approach
<ul style="list-style-type: none"><li>▪ Nephrology</li><li>▪ Hypertension</li><li>▪ Diabetes</li><li>▪ Arthritis</li><li>▪ Asthma</li><li>▪ Ophthalmology</li></ul>	<ul style="list-style-type: none"><li>▪ Phase II</li><li>▪ Phase III/Phase IIIb</li><li>▪ Phase IV/PMS</li><li>▪ Registry</li><li>▪ Epidemiological Studies</li></ul>	<ul style="list-style-type: none"><li>▪ Experienced Clinical Pharmacologists, Project Managers, Data Managers, Medical Writers, Statisticians, Team Leads and Data Associates managing various client requirements including query resolution, SAE reconciliations, study close-out, medical report writing etc.</li><li>▪ Leveraged best –in-class 21 CRF Part 11 systems including ClinTrial 4.6, SAS 9.1.3 and MedDRA 11.1 to manage the project in compliance with ICH-GCP and FDA guidelines</li><li>▪ Program focus on generating high quality scientific content, delivering high accuracy output in crunched turnaround times and robust SOP adherence</li><li>▪ Focus on robust Metrics Management including Accuracy, Productivity, Query Aging and Resolution, Database Lock period post LPLV, Statistical Analysis, Study Close-out and Final Report post database lock metrics</li></ul>
<b>Activities Supported</b> <ul style="list-style-type: none"><li>▪ Protocol, CRF &amp; ICF Design</li><li>▪ Database Design, Validation and Testing</li><li>▪ Data Entry, Validation &amp; Cleansing</li><li>▪ SAP Development,</li><li>▪ Randomization, Sample Size Calculation</li><li>▪ Statistical Analysis &amp; Study Report</li><li>▪ Medical Manuscripts</li><li>▪ Data Crunching &amp; PowerPoint Support</li><li>▪ Patent Research</li></ul>		