



Clinical Development Services & Project Management: First-in-Man Study

Project Objective	First-in-man Study with Antimicrobial
Therapy Area	60 Healthy Subjects
Client	Emerging Pharma and Device Company
Services Provided	<p>Clinical Development Services & Project Management</p> <ul style="list-style-type: none">➤ Led a team of freelance CRAs and specialist service providers for medical and safety management, statistics and data-management, regulatory and medical writing.➤ Provided Project Mandate, detailed Project Plan, trial protocol, case report form, patient information sheet/consent form, Monitor's Manual etc and other trial documentation.➤ Set-up quality management system and prepared set of essential standard operating procedures. Arranged the appropriate training of sponsor personnel and clinical team members.➤ Obtained Ethics Committee approval first-time and managed communication with Ethics Committee throughout the trial. Liaised with regulatory to ensure successful and timely regulatory applications.➤ Managed the clinical trial supplies ordering, arranged clinical trial insurance and assisted in the selection of the Clinical Pharmacology Unit.➤ Currently driving recruitment, managing risks & issues and maintaining trial master file.
Outcome	Successful outcome to the start of recruitment milestone, despite some ethics and subject identification issues – study ongoing.