



Clinical Development Services & Project Management

Project Objective	Phase II Cardiovascular Trials
Therapy Area	120 Patients with Ischaemic Heart Disease
Client	Emerging US Biopharma 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.➤ Contributed to the development of the trial protocol, case report form, patient information sheet/consent form and other trial documentation.➤ 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.➤ Ensured patient recruitment and the collection of good quality data.➤ Successfully managed SUSAR/safety issues.➤ Managed clinical trial supplies and laboratory kits.➤ Ensured competent monitoring and proper close-out of all sites
Outcome	The first trial was successful and led on to two further studies that were managed in the same way. The two studies also completed on time and were inherently successful, although the product progressed no further in clinical development.