



Clinical Project Management: Multi-Centre Study

Project Objective Multi-centre Study (20 centres)

Therapy Area 240 Diabetes Patients

Client Pharma/Biotech Company

Services Provided Clinical Project Management

- Led a team of 5 sponsor CRAs, data-management and regulatory.
- Provided Project Mandate, detailed Project Plan, patient information sheet/consent form, Monitor's Manual and other trial documentation.
- Piloted this study as the companies first electronic data capture study.
- 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.
- Drove recruitment by motivating the CRA team and with regular direct-to-investigator newsletters and investigator meetings.
- Worked with sponsor management to ensure satisfactory CRA resource throughout the trial, managed drug supplies, kept tight financial control, managed risks & issues and ensured generation of high quality data.
- Successfully managed risks & issues and ensured generation of high quality data.
- Oversaw preparation of clinical study report.

Outcome Successful outcome. Delivered study on time and on budget. Maintained a high level of motivation within the team throughout, despite major organisational changes.