



Clinical Project Management: Large Multi-Centre Study

Project Objective Multi-centre Study (50 centres)

Therapy Area 400 Patients with Musculo-skeletal Conditions

Client Large Multi-national Pharma Company

Services Provided Clinical Project-Management

- Led a team of 20 sponsor CRAs, data-management and regulatory.
- Provided Project Mandate, detailed Project Plan, trial protocol, case report form, patient information sheet/consent form, Monitor's Manual 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.
- Drove recruitment, in a challenging recruitment environment, 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.
- Successfully managed risks & issues and ensured generation of high quality data.
- Oversaw preparation of clinical study report and publication.

Outcome Successful outcome. Delivered study on time and on budget. Maintained a high level of motivation within the team throughout. Publication accepted in target journal.