



Clinical Development Services: Investigator Initiated Trial

Project Objective Investigator Initiated Trial

Therapy Area Diabetes

Client Academic Institution

Services Provided Clinical Development Services

- Provided Good Clinical Practice Training for investigational team and others.
- Assisted investigator in the development of Good Clinical Practice compliant protocol.
- Developed case report form, patient information sheet and other trial documentation.
- Set-up data-management contract, processes and procedures
- Arranged contract with provider of drug supplies for Qualified Person release and packaging of the clinical trial supplies.
- Prepared Project Mandate and Plan.
- Reviewed quality management system and prepared set of essential standard operating procedures. Arranged the appropriate training of clinical team members.
- Assisted investigator with Clinical Trial Application, ethics committee submission and Research & Development application.
- Provided project management and monitoring services.
- Currently managing risks & issues and maintaining trial master file.

Outcome Successful outcome to date – recruitment started on time and study is ongoing.