

Dyslipidemia

Altasciences' Patient Access

- Database of over 120,000 participants, 40,000 active
- 4000+ participants with lipid profile (TG, LDL-C and HDL-C) and varying degrees of dyslipidemia available in our database
- Strategic alliances with hospitals for additional access to extensive patient populations
- Ongoing outreach efforts to maintain and increase database
- Searchable electronic database to qualify Inclusion/Exclusion criteria use and BMI



Experience

- Completed 100+ PK studies involving lipid profile assessment at screening and on-study, following single and multiple doses
- Investigation of pre-and post-treatment postprandial lipid profile changes
- PK studies under fasting and fed conditions for TPD, FDA, EMA submissions
- Vast expertise in supporting bioanalytical capabilities and the ability to develop/transfer methods

Clinical Expertise

- Adaptive designs involving healthy subjects and patient arms
- Setup for medical, scientific, regulatory and operational procedures
- Support services, including customized protocol design, data management, bioanalysis, biostats and reporting
- Administration of medication via multiple routes, including oral, injection and transdermal formulations, etc.

Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- High throughput bioassays for drug quantitation (operating 24/7), capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Biostatistics

- All Programming done using SAS®
- Randomization list
- Statistical Analysis Plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data e.g. safety lab
- Creation of CDISC-compliant FDA submission-ready package