Impaired Renal Function

Altasciences’ Patient Access

• 1300+ patients with mild, moderate and severe renal function impairment, and patients requiring dialysis
• Strategic alliance with Hôpital Maisonneuve-Rosemont hospital, an industry leading nephrology site
• Access to matching healthy control subjects through database of over 120,000 participants, 40,000 active
• Ongoing outreach efforts to maintain and increase patient database
• Searchable database to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use, and BMI

Experience

• Patient enrolment is consistently within three months for mild, moderate and severe patients
• Six months to complete a study for 32 patients from protocol to Clinical Study Report, including all three stages of impairment and healthy control subjects
• Pharmacokinetic assessment of dosage adjustment requirements for marketed drug products in patients with impaired renal function
• Study design in accordance to FDA and EMA guidances

Clinical Expertise

• Reduced and full PK studies with fast recruitment of mild and moderate patients if PK changes are seen in severe patients
• Full project management for multi-site trial, including operational support
• Setup for medical, scientific, regulatory and operational procedures
• Support services, including customized protocol design, data management, bioanalysis, biostatistics and reporting

» An Open-label, Non-randomized, Parallel Group Study in Subjects With Mild, Moderate, Severe, or No Renal Impairment
Bioanalysis
- Our 20,000-sq.-ft. GLP-Compliant Bioanalytical Facility for Preclinical to Clinical Support
- 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

Pharmacokinetic (PK) Analysis
- Comprehensive Clinical PK and PD Data Analysis and Interpretation
- Robust non-compartmental analysis using WinNonlin® v6 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

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

Medical Writing
- Team with over 20 years of experience
- Medrio’s eClinical EDC
- 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

Data Management
- 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

Project Management
- Project Manager (Project Leader) oversees the complete program conduct and deliverables from study protocol to reporting
- Extensive expertise in managing clinical trials across a wide range of therapeutic areas
- Close collaboration with key departments and external contractors to ensure seamless and timely communications for successful project completions