Altasciences
CLINICAL RESEARCH

Metabolic Disorders

Metabolic Syndrome, Obesity, Diabetes, NASH

Altasciences Clinical Research has been providing clinical research services to the global biopharmaceutical industry for 25 years. As a leading full-service clinical pharmacology research CRO, we have extensive expertise in the execution of a wide range of early phase studies, successfully completing **over 200 clinical trials annually.**

Through alliances with a number of leading research centers, we have access to a large database of **patients with metabolic disorders.** We also offer adaptive designs as well as a **full range of support services** that ensure your clinical trials are successfully completed.

Our Experience

- Over 50 completed early stage trials involving anti-diabetic and hypoglycemic agents:
  - Insulin, GLP-1, SGLT-2, DPP-4, and others
- 75 Type I and Type II diabetic patients enrolled over four weeks in a single-center trial
- Pharmacodynamics and immunogenicity assessments:
  - High-Glycemic Load Challenge/Tolerance test
  - Glucose clamp
  - Insulin-induced hypoglycemic event in Type I diabetes
  - Anti-drug antibody
- Dietician-designed meals for different caloric intake

Clinical Expertise

- Vast experience with FIH, adaptive designs, 505(b)(2), and PK assessments 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 parenteral, intranasal, intramuscular and subcutaneous, etc.

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Patient Access

We have a vast searchable database of over 225,000 participants to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use and BMI, which include:

- 20,000+ Metabolic Syndrome patients
- 63,000+ Obese patients (BMI >30)
- 10,000+ Morbidly obese (BMI >40)
- 250+ Non-Alcoholic Steatohepatitis (NASH)
- 750+ Type I diabetics
- 1,500+ Type II diabetics
- Strategic alliances with hospitals for access to extensive patient populations
- Access to referring physicians and industry experts

Bioanalytical assays developed include:

- Exenatide
- Glucagon
- Insulin Glargine, M1, M2
- Insulin Asparte
- Metformin

Additional assays can be developed and tailored to your program upon request.

Support Services

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)

Data Management

- 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

Project Management

- Scientific 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

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

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