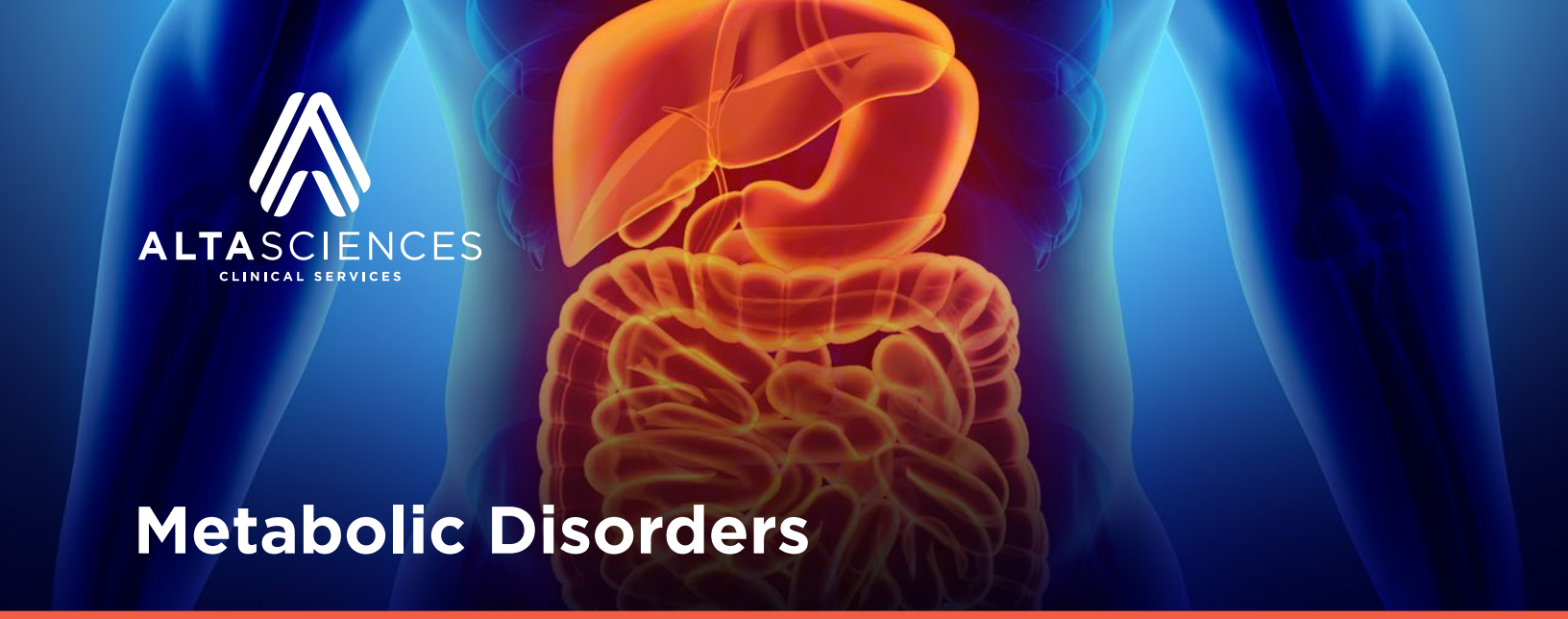

ALTASCIENCES
CLINICAL SERVICES

Metabolic Disorders

Altasciences has been providing clinical research services to the global biopharmaceutical industry for over 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 250 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
- Blood Glucose Monitoring (e.g., Dexcom, YSI)

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.

contact@altasciences.com
altasciences.com

Patient Access

We have a vast searchable database of over 345,000 participants to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use and BMI, which include:

- 20,000+ Metabolic Syndrome patients
- 35,000+ 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 additional access to extensive patient populations
- Access to referring physicians and industry experts

Bioanalytical assays developed include:

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

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

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

Updated July 2019.

contact@altasciences.com
altasciences.com