Altasciences
CLINICAL RESEARCH
ALGORITHME PHARMA

Diabetes

Algorithme Pharma's Experience

- Over **50** early stage trials involving anti-diabetic and hypoglycemic agents
- **75** Type I and Type II diabetes patients enrolled over four weeks, in a single-center trial
- Pharmacodynamics and Immunogenicity assessment
- High-Glycemic Load Challenge/Tolerance Test
- Insulin-Induced Hypoglycemic Event in Type 1 Diabetes — assessment of potential rescue medications

Case Studies

» Evaluate the Immunogenicity of a Novel Glucagon Formulation

» Safety and Efficacy of a Novel Glucagon Formulation in Type 1 Diabetic Patients Following Insulin-induced Hypoglycemia

Patient Access

- **750+** Type I diabetics
- **1500+** Type II diabetics, on:
  - Metformin only: **500+**
  - Metformin + other oral hypoglycemic agent: **650+**
  - Insulin: **300+**
- Access to referring physicians and industry experts
- Searchable database to qualify Inclusion/Exclusion criteria for pre-existing conditions, demographics, medication use and BMI

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
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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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