ALTASCIENCES
BIOANALYSIS & RESEARCH SERVICES

Bioequivalence and Bioavailability Services

Altasciences is a full-service contract research organization experienced at finding solutions to run a wide variety of clinical pharmacology studies. With over 25 years' experience, we successfully complete over 250 trials annually, of which approximately 200 are bioequivalence (BE) or bioavailability (BA) studies. With extensive experience working with a variety of compounds, we have an exceptional reputation for successfully conducting simple to complex BA/BE trials and submissions, and offering accelerated report timelines.

We offer comprehensive solutions including clinical conduct at three clinics in North America, Bioanalysis by LC/MS/MS or ligand binding, Data Management, Biostatistics, Regulatory Support and Project Management.

Study Design

Altasciences has built a database with thousands of study designs covering hundreds of different medications. The database contains details of the design as well as the variability seen in previous studies, providing us with valuable data to calculate the required sample size. Our expertise covers the full range of formulations, giving us a firm understanding of the specific pharmacokinetic (PK) requirement for each.

Participant Relationship Management

Thanks to our vast local networks, we are able to successfully recruit and retain healthy normal and patient populations. 95% of panels are filled on time, year after year.

Clinical Facilities

We have over 400 beds in strategically located facilities in the U.S. and Canada. Our purpose-built clinical pharmacology units are ideal for BA/BE studies with the capabilities to manage a large number of participants with a large volume of PK samples.

Expert Clinical Processes and Staff

Our procedures are designed to ensure that all study milestones occur on time and are documented precisely. Our teams are well versed in handling large or small studies, simple of complex, including those requiring multiple procedures in one day.

Formulation Types

- Caplets
- Capsules
- Creams/ Ointments
- Films
- Gels
- Granules
- Implants
- Injectables
- Lozenges
- Orally Disintegrating
- Patches
- Powders
- Rings
- Solutions
- Sprays
- Suppositories
- Syrups
- Suspensions
- Tablets

Therapeutic Indications

- Nervous System
- Gastrointestinal Tract
- and Metabolism
- Cardiovascular
- Genito Urinary System and Sex Hormone
- Anti-Infective for Systemic Use
- Antineoplastic and Immunomoduling Agents
- Musculo-Skeletal System

Formulation/Release Profiles

- Bimodal
- Controlled
- Delayed
- Extended
- Immediate
- Prolonged
- Slow and Sustained Release

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Our Commitment to Safety

Our safety program includes mock scenario training. Our clinical staff is trained on handling emergencies, basic life support, and CPR. Our physicians and key safety personnel are ACLS certified. Our facilities are equipped with defibrillators, oxygen tanks, crash carts and strategically located panic buttons, with all the necessary materials for intubation. All of our facilities are in close proximity to multiple major hospitals.

Bioanalysis

Our laboratories offer analysis of small and large molecules in many matrices, including blood and urine. We have over 35 LC-MS/MS systems and a laboratory for large molecule analysis using immunochemistry. We routinely develop and validate methods for novel compounds, and have a validated assay list of over 620 methods. We proactively develop methods so that we are ready when sponsors need them.

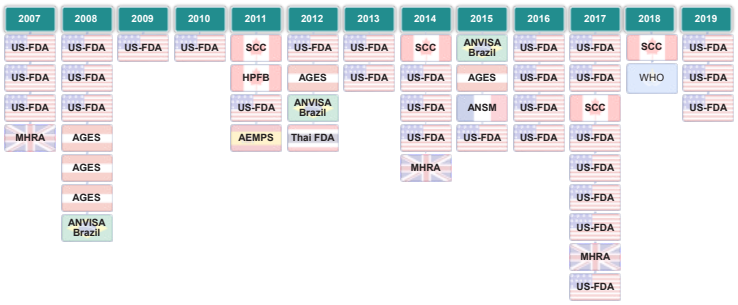
Quality Assurance

Our in-house Quality Assurance (QA) and Quality Control (QC) teams ensure trials are conducted per protocol and within ICH/GCP guidelines. We have real-time QC for all study processes, comprehensive SOPs and up-to-date employee training records, which are available upon request. In addition to sponsor audits, we regularly host successful regulatory inspections from agencies, such as the FDA, Health Canada, and EMA.

Accelerated Timelines

We can conduct BA/BE studies with efficient startup, recruitment, and reporting timelines. We have developed fast-to-file timelines for sponsors requiring an expedited submission.

A History of Regulatory Excellence



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 version of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last participant'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

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