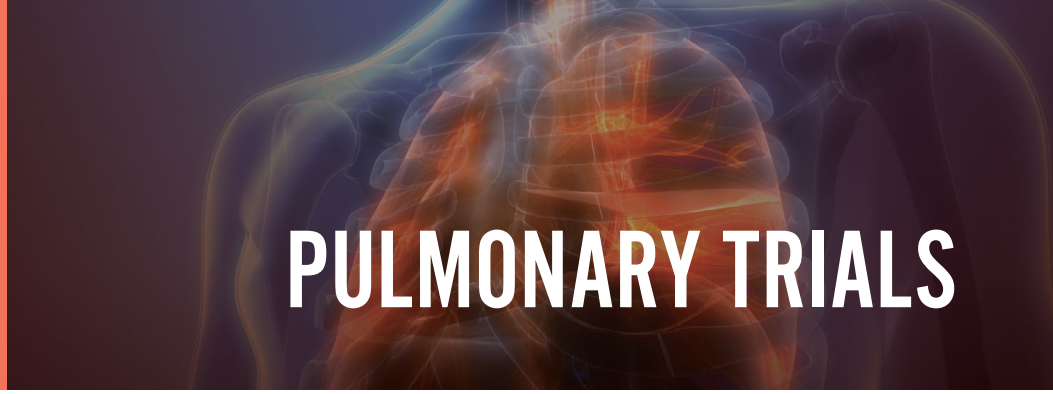
ALTASCIENCES
CLINICAL SERVICES



PULMONARY TRIALS

Altasciences is a full-service early phase CRO with significant experience in the conduct of clinical trials for pulmonary indications and inhaled or nasally delivered products. We have expertise in clinical trials for common respiratory diseases such as asthma, COPD and allergic rhinitis.

Pulmonary Function Tests (PFTs)

Spirometry

- Forced Expiratory Volume in One Second (FEV1)
- Expiratory Reserve Volume (ERV)
- Forced Vital Capacity (FVC)
- Forced Expiratory Flow (FEF)
- Functional Residual Capacity (FRC)
- Maximum Voluntary Ventilation (MVV)
- Residual Volume (RV)
- Peak Expiratory Flow (PEF)
- Slow Vital Capacity (SVC)
- Total Lung Capacity (TLC)

Challenge Testing

- Inhaled Allergen
- Methacholine
- Histamine

Staff and Training

Prior to study start, all clinic staff undergoes certification training, including several practice sessions, based on the spirometry system being used per the protocol.

To eliminate variability, each technician responsible for conducting spirometry measures undergoes identical training to ensure proper study subject coaching.

Prior to confirming their enrollment, we ensure all volunteers receive training on the use of the device and are able to consistently apply the technique correctly.

Recruitment

In addition to our established databases of participants, we partner with local physicians and hospitals to broaden our access to patients as well as provide access to highly specialized equipment such as plethysmography (body box).

Altasciences partners closely with PFT Global, a provider of advanced spirometry services. Their proficiency is unequaled when it comes to capturing high-quality study data and minimizing avoidable variability within spirometry data.

contact@altasciences.com
altasciences.com

Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 200 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, if needed), capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

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

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)

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

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

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

contact@altasciences.com
altasciences.com