ALTASCIENCES

DRUG-DRUG INTERACTION CLINICAL TRIALS

Altasciences is a full-service, early phase CRO/CDMO with strategically located clinical pharmacology units.

Our team is well versed in designing stand-alone studies for each inhibitor or substrate, as well as developing "cocktail" studies to assess interactions of multiple CYP enzymes or transporters in one study.

25+ years of expertise

Expert Clinical Operations

- Clinical teams with expertise in dosing drug-drug interaction studies in both healthy normal participants and patients
- Our phlebotomy and laboratory staff is accustomed to the high demands of drug interaction studies, and are easily able to handle groups of over 60 patients at a time

Laboratory Capabilities

- Method development expertise includes sensitive and reliable bioanalytical methods for new molecular entities (NMEs) and commercially available compounds
- Various biological matrices
- Large number of common interacting substrates
- Adherence to timelines supported by:
  - innovative workflows developed by our scientists
  - use of state-of-the-art instrumentation to provide extremely low detection limits even with little sample volume
  - 24/7 production capabilities

Expert Scientific Guidance

- Scientific Affairs team delivers full service, customized insight for:
  - Study design
  - Clinical conduct
  - Data management
  - CSR (clinical study report) production
  - etc.

Should significant interactions be seen with the strong inducers or inhibitors, we will work with you to design follow-up studies with weak inhibitors, and offer guidance for dosing adjustments, if required.

- Rapid recruitment and study start-up
- Sizeable database of poor and extensive metabolizers of different CYP enzymes
- Routine genotyping as part of screening process, including:
  - 3A4
  - 2D6
  - 2C9
  - 2C19
  - HLA-B 5701

> 2600 genotyped

More than 34 LC-MS/MS instruments and ligand binding capabilities, and an extensive list of **validated assays** with a large number of interacting substrates, including:

- Theophylline – 1A2
- Efavirenz – 2B6
- Repaglinide – 2C8
- Warfarin – 2C9
- Omeprazole – 2C19
- Desipramine – 2D6
- Midazolam – 3A4/5
- Validated assays available for:
  - Ramipril
  - Cyclosporine
  - Carbamazepine
  - Dabigatran
  - Bupropion
  - Rosuvastatin
  - Furosemide
  - Caffeine

contact@altasciences.com
altasciences.com

Research Support Services

Available as stand-alone services, or part of a program

Program Management

- Program Manager (Project Leader) oversees the complete program conduct and deliverables.
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion.

Data Management

- CDISC standards fully integrated in workflow
- Database lock available typically within 2 to 4 weeks of last participant final visit

Protocol Development and Medical Writing

- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR) PK/PD data analysis and interpretation
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Clinical Monitoring

- Highly experienced, well-trained CRAs oversee all relevant aspects of clinicial trial conduct
- Ensures data integrity, patient safety, and compliance with your protocol and GCP

Biostatistics

- All programming done using SAS®
- Statistical analysis plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Creation of CDISC-compliant, FDA submission-ready package

Support Services for Preclinical Studies

- Analytical chemistry
- Analytical biology
- Toxicokinetics
- Specialized necropsies
- Anatomic pathology and clinical pathology
- Immunohistochemistry
- SEND - Standard for Exchange of Nonclinical Data
- Archiving

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