ALTASCIENCES

DRUG-DRUG INTERACTION CLINICAL TRIALS

Altasciences specializes in conducting comprehensive drug-drug interaction (DDI) clinical trials to provide you with the data you need to move forward confidently. Whether you need stand-alone studies or DDI trials embedded within larger Phase I studies, we have the expertise to deliver precise and reliable results, tailored to your project's unique needs.

We have conducted over **50 DDI studies**, including single interaction, multiple interactions across cohorts, multiple interactions within a cohort (cocktail), and interactions at subset dose levels or patient/participants within a larger trial.

Accelerated Study Start-Up for Drug-Drug Interaction Studies

We can mobilize quickly to accelerate start-up times, with trials having started in as little as four weeks. Our approach ensures seamless alignment between our internal teams and the sponsor, enhancing processes to reduce start-up timelines through:

- effective communication
- strategic planning
- a dual project management structure
- three clinical pharmacology units
- co-located bioanalytical laboratories in the U.S. and Canada
- dual regulatory pathways

A Turnkey Solution for Drug-Drug Interaction Trials

With a primary focus on early-phase drug development and a turnkey solution for your DDI studies, we can handle every aspect of your trial from start to finish. Our comprehensive DDI clinical trial services include:

- **Protocol review/writing:** Whether starting from scratch or refining an existing protocol, we streamline the process to support informed decision-making and meet your critical study milestones. We ensure comprehensive, regulatory-compliant study design—tailoring protocols to meet the specific requirements of custom drug-interaction studies.
- **Clinical conduct:** With three state-of-the-art clinics across North America, we are fully equipped to run your DDI studies. Our expert teams will manage dosing, sampling, and intensive monitoring.
- **CRA/Clinical monitoring:** To guarantee regulatory compliance and maintain data integrity we track pharmacokinetic (PK) and pharmacodynamic (PD) data, safety assessments, and adverse event reporting in real-time.
- **Bioanalytical services:** Our co-located bioanalytical labs offer over 685 validated methods, including a wide range of DDI comparators, to guarantee precise and timely PK data. We provide the reliable data needed to meet regulatory standards, for faster decision-making and comprehensive label information.
- **Data services and reporting:** We handle data management, analysis, and comprehensive reporting to deliver high-quality DDI clinical trial results on time.
- **Regulatory consulting:** Our regulatory experts can help you determine exactly when you need to conduct your DDI studies.

contact@altasciences.com
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Recruitment for Your DDI Clinical Trials

With a pool of over 400,000 healthy normal volunteers, special populations, and patients, and access to over 2,600 genotyped participants, we can rapidly meet enrollment targets, allowing your studies to progress without delay.

Our Clinical Trial Recruitment Strategy

- Dedicated recruitment teams and streamlined processes, from protocol approval to participant enrollment, for a quick turnaround.
- Well-established databases to pre-identify study participants and perform targeted outreach.
- Large participant pool from many demographics, ethnicities, special populations, and patient groups.
- Sizeable database of poor and extensive metabolizers for different CYP enzymes, for focused recruitment.

We routinely perform CYP genotyping as part of a screening process to identify appropriate participants, or stratify groupings for pharmacokinetic DDI studies.

- 3A4
- 2C19
- 2D6
- HLA-B 5701
- 2C9

Prioritizing Participant Safety

Our safety features, operations, and facilities are designed to ensure that participant safety is the primary objective in every trial.

- Feasibility/risk assessment—from receipt of first requirements until study completion
- Investigator assesses participants daily
- 24/7 Advanced Cardiac Life Support (ACLS) provider coverage on-site
- Basic Cardiac Life Support certification for all clinical staff
- Crash carts on-site
- Scenario-based response training
- Telemetry with pulse oximetry
- Strategically placed panic buttons

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