ALTASCIENCES
CLINICAL SERVICES

NDA-ENABLING STUDIES

For over 30 years, we have been designing and running a broad range of **early-phase studies** required for NDA submissions. We are experts in the design and conduct of early clinical development plans and stand-alone studies. Our integrated manufacturing and analytical capabilities ensure timely availability of clinical supply, and pharmacy on demand delivers fast, accurate adaptations should they be required. Our success is greatly attributed to our focus on safety and quality, our ability to recruit and retain healthy normal volunteers and patient populations and our fully integrated supporting services in program management, bioanalysis, medical writing and more.

Study Type	Requirements and Design	Our Expertise
Single Ascending Dose (SAD)	SAD studies are always required for NDA submissions. This First-in-Human (FIH) study is conducted to assess a single dose of a compound, with a dose escalation until the maximum exposure is reached.	We work closely with our sponsors to design SAD studies, and prepare a detailed risk assessment to ensure the correct starting dose and escalation. Also, due to the increased safety risks associated with SAD/FIH trials, our clinics are outfitted with specialized safety monitoring equipment.
Multiple Ascending Dose (MAD)	MAD studies are required for all NDA submissions with the rare exception of a drug that would only be given to a patient one time (e.g. ambulatory rescue drug). Dose levels and dosing intervals are determined and used to elucidate the pharmacokinetic (PK), and sometimes pharmacodynamic (PD), of multiple doses of a compound.	Our facilities are equipped with amenities attractive to study participants and are ideal for the recruitment and retention of subjects for long overnight studies, common with MAD trials.
PK Bridging and Bioavailability	PK bridging and bioavailability studies are often required in clinical development, such as when a new formulation is used to compare the pharmacokinetics of the new and old formulations.	Our full-service model supports all aspects of innovator drug development. We routinely design, conduct and prepare reports for these studies.
Food Effect	The requirement for food effect studies varies. However, for any drug with an oral route of administration, it is required. These trials can be incorporated into multiple early-phase studies with an adaptive design, and are used to assess the absorption of a compound when administered with a meal (e.g. a high-fat breakfast).	Our team specializes in conducting studies independently, or under umbrella protocols where FIH studies are combined with other studies to assess early efficacy.
Proof-of-Concept (POC) in Special Populations	Proof-of-concept (POC) trials are not a requirement for NDA submission. However, they are beneficial to have before moving on to later phase trials to establish safety and activity in the target population. They can be single-dose or multiple-dose studies in the target patient population, depending on the intended clinical use.	We have designed POC trials across many different therapeutic areas and routinely work with our network of key opinion leaders. Our state-of-the-art clinics have been specially designed for complex clinical trials requiring multifaceted safety assessments and biomarkers.
Early Cardiac Safety Assessment	Early cardiac safety assessment is now a fully accepted alternative to a TQT study and allows for TQT statistical-like results to be obtained during a routine early phase clinical study.	Our clinical pharmacology units have been iCardiac Technologies Certified to conduct early phase cardiac assessment using High-Precision QT analysis to obtain the highest quality ECG data, and potentially eliminate the need for a full TQT study.

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SPECIALTY STUDY TYPES

Study Type	Design	Our Expertise
Renal Impairment	If a drug is excreted through the kidneys, a renal impairment study may be required. Such trials are completed with the participation of impaired patients, in a hospital setting.	Through alliances with local hospitals, we have access to patients with mild, moderate, and severe renal impairment. We offer full project management for multi-site trials, including operational support.
Hepatic Impairment	If a drug is excreted through the liver, a hepatic impairment study may be required. Such trials are completed with the participation of impaired patients, in a hospital setting.	Through an alliance with a number of leading research centers, we have access to patients with hepatic impairment. We offer adaptive designs as well as a full range of support services, including customized protocol design, data management, bioanalysis, biostatistics, and reporting.
Drug-Drug Interaction (DDI)	Most new products will need at least one drug-drug interaction study, if not several. DDI studies evaluate the changes in pharmacokinetics of the drug or other substrates by inhibition or induction of CYP enzymes or transporters.	By reviewing the sponsors' *in vitro* data, we can design stand-alone or cocktail DDI studies. We also have a robust database of validated methods for the common substrates.
Thorough QT (TQT)	TQT studies are run in parallel with Phase III trials to assess QT interval prolongation, if the evaluation is not done during a Phase I trial with early cardiac assessment.	Our ability to conduct traditional ECG monitoring makes us well positioned to support the current regulatory guidance and obtain the highest quality data for both traditional ECG, as well as holter monitoring.
Human Abuse Potential (HAP)	HAP studies are necessary for any drug with abuse potential. Most centrally-acting drugs are likely to need a HAP study, which are usually run in parallel with Phase II trials.	We are industry experts in the identification of appropriate study subjects for substance abuse studies, including nasal snorting, methadone/ buprenorphine, hydromorphone challenge, and alcohol interaction.
Cognitive Assessment Driving Simulation	With the finalization of the FDA guidance in 2017, driving simulation studies are now required for any drug that may affect cognition. They will assess the potential impact of drugs on driving skills (coordination, reaction time, judgment, ability to stay in a lane, maintain distance, focus, and perception).	We are fully-certified driving study specialists. Our driving simulator technology, combined with our scientific expertise and extensive database of study participants, provide the solution to test the impairing effects of a wide variety of drugs on driving abilities in both healthy normal volunteers and patient populations.
Elderly	Regulatory agencies recommend gaining substantial experience in elderly populations during the development of a new drug. Concomitant medications, comorbidities and altered drug metabolism capacity in elderly patients can potentially affect the efficacy and safety profiles of a drug, and therefore changes the risk-benefit ratio.	Having performed many studies on elderly participants in the past, we have a substantial database of male and female participants, in all age ranges typically studied for this population, totalling over 21,000 individuals.

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