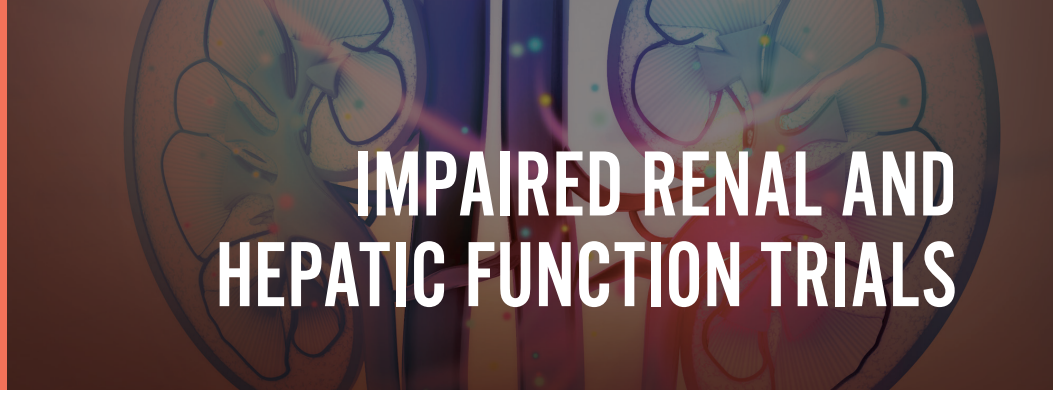
ALTASCIENCES
CLINICAL SERVICES



IMPAIRED RENAL AND HEPATIC FUNCTION TRIALS

At Altasciences, we have successfully designed, conducted, analyzed, and reported numerous clinical trials focused on renal and hepatic impairment across a wide range of therapeutic areas. With a commitment to patient care, our dedicated team of clinical experts is equipped to navigate the complexities of these unique populations. Patients in these cohorts often present with intricate medical issues and polypharmacy, necessitating a deep understanding of their distinctive needs. Our goal is to deliver high-quality data while prioritizing patient safety and ensuring a smooth study process.

A Turnkey Solution with the End in Mind:

- **Accelerated Patient Enrollment:** Seamless recruitment across all levels of impairment, from mild, moderate, and severe, to end-stage—with healthy matches.
- **Extensive Patient Database:** Access to over 400,000 patients and healthy control participants for faster recruitment.
- **Comprehensive Expertise:** Proficiency across all indications, therapeutic areas, and drug formulations/routes.
- **Experienced Clinical Teams:** CRAs and medical monitors with deep expertise ensure patient safety and maintain data integrity.
- **Adaptive Study Designs:** Compliance with FDA and EMA guidelines through traditional or adaptive trial designs for maximum efficiency.
- **Established Site Networks:** Dedicated clinical sites with a proven track record of rapid enrollment and compliance.
- **Expert Project Management:** End-to-end operational support across study-sites ensures seamless clinical trial conduct.
- **Full-Service CRO Solutions:** Tailored protocol design, data management, bioanalysis, pharmacokinetics, biostatistics, and comprehensive reporting.

Impairment Services Highlights:

- Meticulously designed studies to meet the latest FDA and EMA guidelines.
- Impairment regulatory and scientific guidance experience, including determining necessary studies depending on the drug's characteristics.
- Access to 5,000+ patients with renal impairment and 2,500+ patients with hepatic impairment.
- Access to end-stage renal disease (ESRD) patients, and ability to accommodate protocol-related dialysis procedures.
- Strategic collaborations across North America, partnering with leading sites in Canada and the U.S.
- Precision dosing pharmacokinetic (PK) assessments to determine dosage adjustments for patients with renal or hepatic impairment.

Proven Track Record:

- Full enrollment of patients with mild, moderate, and severe impairments, as well as healthy control participants, consistently completed within approximately six months.
- Average timeline from last patient enrollment to clinical study report is just four months.
- 800+ successfully enrolled impairment patients.

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Targeted Recruitment for Renal Impairment:

- Ongoing outreach to expand patient database, with a searchable system to qualify participants based on inclusion/exclusion criteria, including pre-existing conditions, demographics, medication use, and BMI.
- Efficient recruitment of eight patients per group, including those with varying levels of renal impairment and healthy controls.
- Access to 5,000+ renal impairment patients and ESRD patients.
- Collaborations with a wide network of physicians and experts to maintain a robust database.
- Access to a database of 120,000+ participants, including 45,000 actively engaged participants, ensuring easy matching of healthy control subjects for studies.
- PK assessments for dosage adjustments in renal impairment patients.

Targeted Recruitment for Hepatic Impairment:

- Expertise in evaluating the impact of hepatic impairment on drug pharmacokinetics.
- Expertise in administering investigational drugs to groups with mild, moderate, and severe hepatic impairment via multiple routes, including parenteral injections.
- Access to 2,500+ patients across the spectrum of hepatic impairment, including those with alcohol-induced or non-alcoholic causes like NASH and Child-Pugh categories.
- Use of full and two-stage adaptive integrated designs that align with FDA and EMA guidelines.
- Studies assess how hepatic metabolism and excretion affect a drug's PK profile.
- Critical insights provided for informed dosing recommendations, ensuring a better understanding of drug safety and efficacy in patients with hepatic impairment.
- Patients with hepatic impairment are divided into two categories: those whose disease is due to alcohol abuse and those whose disease has other causes.

Comprehensive Turnkey Solution:

Our experienced clinical experts are dedicated to navigating the complexities of renal and hepatic impairment trials from start to finish, providing everything from protocol design to patient recruitment, clinical conduct and monitoring, bioanalytical support, data management, biostatistics and report writing. By integrating robust project management and operational support, we facilitate seamless multi-site trials that comply with FDA and EMA guidances. With our extensive expertise and resources, we are committed to delivering high-quality results that drive informed decision-making for your drug development programs.

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