ALTASCIENCES

CASE STUDY

ACCELERATING RECRUITMENT IN RENAL IMPAIRMENT TRIALS: LEVERAGING SPECIALIZED EXTERNAL SITES

STUDY OVERVIEW

A biopharma company contracted Altasciences to recruit up to 64 participants with varying degrees of renal impairment, as well as healthy controls, at clinical research units in the U.S. The sponsor required pharmacokinetic concentration data through Day 57 to inform critical Phase III decisions in less than seven months. The study population included patients with severe renal impairment, who are often difficult to recruit due to comorbidities, complex medication regimens, and limited study benefits.

The timeline was critical, and an unexpected investigational product (IP) delay further compressed the study timeline by nearly four weeks. Despite these challenges, the first patient was enrolled approximately three months after the award, and enrollment was completed in about six weeks.

STUDY DETAILS

Study Title	A Phase I, parallel-design, open-label, multi-center, single-dose study to assess pharmacokinetics, safety, and tolerability.
Therapeutic Area	Metabolism and endocrinology (GLP-1).
Study Design	A single subcutaneous dose at clinical research units in the U.S.
Population	Up to 64 participants: 8 each with mild, moderate, or severe renal impairment; 8 with end-stage renal disease (ESRD); and 8–32 with normal renal function (serving as matched controls).
Timeline	• Standard start-up to first subject screened • Accelerated 6-week enrollment from first screen to last subject enrolled.

RESULTS

To overcome challenges with recruiting a complex patient population and an unexpected delay in IP availability, Altasciences activated experienced clinical sites, collaborating with specialty clinics for targeted recruitment, and ensuring operational flexibility to maintain a competitive enrollment environment. The study achieved significant success, with 71% of participants enrolled within two weeks. Altasciences' rapid recruitment and efficient study management led the sponsor to select the same sites for an additional study with a different compound just a few months later.

Targeted Site Activation

Altasciences activated six highly motivated and experienced Phase I site partners with known access to patients with eGFR <30 mL/min. Timelines were significantly accelerated by leveraging longstanding relationships, previously negotiated contract language, and a centralized IRB.

Specialized Recruitment

The team partnered with clinics and investigators with a proven track record of successfully recruiting this challenging population. Site selection emphasized geographic diversity to minimize regional bottlenecks and ensured participant access across multiple U.S. regions.

Operational Flexibility

Altasciences coordinated site activation timing to ensure all sites were ready to begin screening simultaneously, supporting a competitive enrollment environment. A centralized investigator meeting streamlined protocol training and enabled faster site initiation visits. Continued support from project management, clinical research associates, and data management ensured sites could begin screening immediately upon activation.

SUCCESS IN THE NUMBERS

- First subject screened two days ahead of target.
- 71% of participants enrolled within two weeks, compared to 25% planned.
- Recruitment was paused within three days of activation since nearly all groups had sufficient participants scheduled to meet enrollment targets upon confirmed eligibility.
- Healthy match strategy optimized: 14 participants were successfully matched across multiple renal impairment cohorts.
- Sponsor selected the same sites for an additional study due to strong collaboration and high performance.

ALTASCIENCES' DIFFERENTIATORS

- **Specialized Recruitment Expertise:** Successfully enrolled a complex renal impairment population—71% within two weeks—by partnering with specialty clinics and experienced investigators, even amid compressed timelines.
- **Accelerated Site Activation:** Leveraged long-standing site relationships, centralized IRB, and pre-negotiated contracts to activate six experienced Phase I sites rapidly, gain access to patients with severe renal impairment, and accelerate study start-up timelines.
- **Operational Flexibility Under Pressure:** Adapted quickly to an unexpected IP delay, coordinating site readiness and protocol training to maintain momentum and meet aggressive enrollment goals.
- **Proven Performance and Sponsor Confidence:** Delivered high-quality execution on a high-stakes study, leading the sponsor to select the same sites for a subsequent trial.

Contact us today to get your program started with Altasciences.

ABOUT ALTASCIENCES

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 30 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.