ALTASCIENCES

CASE STUDY

Accelerating Decision-Ready Hepatic PK Data: Adaptive Strategy and Integrated Execution Deliver LPE 19 Days Early

Through a combination of scientific leadership, flexible study execution, and performance-based site partnerships, **Altasciences delivered decision-ready pharmacokinetic (PK) data faster with last participant enrolled (LPE) 19 days earlier than projected**. This acceleration supported timely dose selection, regulatory planning, and continued advancement of the sponsor's drug development program.

EXECUTIVE SUMMARY

Altasciences supported a biotech sponsor in executing a hepatic impairment study requiring rapid PK data across cohorts to inform downstream clinical decisions. The study included participants with moderate hepatic impairment and healthy controls, requiring accelerated timelines, coordinated cohort execution, and flexibility in response to evolving sponsor requirements.

By combining early scientific leadership, a risk-calibrated site strategy, and integrated Contract Research Organization (CRO) execution, Altasciences enabled rapid study start-up, accelerated enrollment, and ahead-of-plan clinical milestones. This approach delivered high-quality PK data within compressed timelines, enabling the sponsor to confidently advance its development program.

BACKGROUND

An established biotech sponsor required hepatic impairment PK/PD data to support critical development milestones. The study was designed to evaluate drug exposure in patients with mild, moderate, and severe hepatic impairment compared to matched healthy controls as part of a broader clinical pharmacology program.

Key program drivers included:

- Rapid generation of PK data to inform clinical development decisions
- Efficient study design to meet regulatory requirements
- Confidence in cohort assignment and data integrity
- Coordinated execution across trusted partner sites

Altasciences was selected for its expertise in early-phase patient studies, scientific leadership in protocol design, and proven ability to deliver integrated CRO solutions across site networks.

STUDY DETAILS

Category	Details
Drug Class	Confidential (small molecule, PK-driven program)
Study Type	Phase I, open-label, parallel design, multi-center, single dose study to assess the PK, safety, and tolerability in participants with hepatic impairment
Design	Parallel cohort design (up to eight participants enrolled per group)
Population	Participants with mild, moderate, and severe hepatic impairment (Child-Pugh A - C) and matched healthy controls
Endpoints	PK and safety endpoints to assess hepatic impact on exposure
Sponsor Collaboration	High-touch, hands-on engagement requiring real-time collaboration
Sites	Two U.S. clinical sites selected from a pre-qualified network of 12 candidate clinical sites

THE CHALLENGE

- **Compressed development timelines**, requiring rapid generation of hepatic impairment PK data to support dose selection, regulatory strategy, and downstream program milestones.
- **Recruitment of complex hepatic impairment populations**, with limited availability of well-characterized patients across Child-Pugh classifications and the need for appropriately matched healthy controls.
- **Stringent eligibility and safety requirements**, driven by significant comorbidities, concomitant medications, and the need to balance patient safety with study feasibility.
- **Integration and oversight of specialized external sites**, requiring centralized management, consistent execution, and seamless alignment with sponsor expectations.
- **Evolving study and sponsor requirements**, requiring operational agility to accommodate mid-study timeline adjustments while maintaining quality, data integrity, and study momentum.

With intensive oversight requirements, critical deliverables, and expedited timelines, the study demanded continuous collaboration, operational flexibility, and proactive risk management. Additionally, late-stage changes to sponsor timelines added further complexity, requiring Altasciences to accelerate study activities and deliverables without compromising data integrity, quality standards, or broader program objectives.

ALTASCIENCES' APPROACH

Strategic Clinical Pharmacology Leadership

Beyond study execution, Altasciences helped the client structure its hepatic impairment program to accelerate PK decision-making while managing patient access, cost, and operational risk.

Altasciences combined its scientific, medical, regulatory, and operational expertise to develop a fit-for-purpose hepatic impairment strategy aligned with the sponsor's development goals and regulatory expectations. By integrating study design, cohort planning, and execution strategy early, the team aimed to reduce risk and accelerate the generation of high-quality, decision-ready PK data.

Adaptive Engagement Model and Sponsor Partnership

Working within a high-touch sponsor environment, Altasciences established a collaborative governance model to enable rapid decision-making, clear accountability, and seamless integration of sponsor and CRO processes while maintaining study momentum.

Risk-Calibrated Site Strategy

Altasciences evaluated 12 pre-qualified hepatic impairment sites within its partner network and selected the two best-suited, high-performing clinical sites based on patient access, enrollment history, operational capabilities, and geographic coverage. Additional sites were identified as contingencies, reducing enrollment risk while maintaining a streamlined study footprint.

Integrated CRO Delivery

Altasciences provided a fully integrated solution spanning protocol development, regulatory support, clinical operations, data management, PK analysis, and reporting. This approach ensures consistent oversight, streamlined communication, and accountability across all study activities.

Decision Acceleration

Parallel execution of study start-up, clinical operations, data management, and reporting activities enabled Altasciences to respond quickly to evolving sponsor requirements while maintaining aggressive timelines.

THE OUTCOME

Altasciences' execution delivered accelerated start-up, rapid participant dosing and enrollment, and ahead-of-plan milestone achievement across the study, relative to broader industry expectations for clinical pharmacology and special population studies.

Study Start-Up and Site Activation

Following site selection, both sites progressed to Green Light Authorization (site selection to site Green Light) **within 7 weeks**, enabling rapid transition to study execution. Broader industry activation timelines are often measured in several months rather than weeks.

Time to First Participant Dosed

Both sites progressed from activation to first participant dosed in just **20 days**, reflecting strong site readiness, proactive participant identification, and effective coordination between the sponsor, Altasciences, and partner sites.

Enrollment Performance

Enrollment was completed in approximately **22 days per site**, demonstrating the effectiveness of Altasciences' performance-based site strategy in accelerating recruitment within a complex hepatic impairment population.

Milestone Delivery

Clinical execution remained ahead of plan throughout the study, with **LPE achieved 19 days earlier than projected**. This performance demonstrated not only speed, but also predictable and disciplined execution against critical sponsor timelines.

ACCELERATING THE PATH TO DECISION-READY PK DATA

By combining scientific leadership, a purpose-built partner site model, and integrated CRO execution, Altasciences accelerated study start-up and enrollment while maintaining predictable milestone achievement—enabling the sponsor to access decision-ready PK data sooner, support timely dose selection and regulatory planning, and advance critical development decisions with confidence.

From early clinical pharmacology strategy through study execution and PK analysis, Altasciences brings the scientific expertise, operational agility, and specialized site network needed to move hepatic impairment programs efficiently from study planning to decision-ready data.

Accelerate your next hepatic impairment study with an experienced clinical pharmacology partner. 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.