ALTASCIENCES

CASE STUDY

Enabling Continuous Progression to First-in-Human Through Coordinated Execution

THE BRIEF

A sponsor advancing a monoclonal antibody program required an integrated approach to progress from nonclinical development to first-in-human (FIH) readiness with one coordinated program.

With integrated nonclinical, bioanalysis, regulatory strategy, and clinical planning, the program was designed from the outset to eliminate inter-vendor handoffs, enable real-time data sharing, and maintain continuous momentum across phases.

THE CHALLENGE

Monoclonal antibody programs are inherently complex, requiring tailored nonclinical toxicology strategies, robust bioanalytical method development (including immunogenicity assessment), and tightly coordinated regulatory documentation across development stages. When these activities are managed across multiple vendors, coordination gaps, delayed data transfer, and misaligned timelines introduce risk at every handoff.

Traditional development models—which often rely on multiple CROs executing activities in sequence—introduce delays at every transition point: between nonclinical completion, report generation, regulatory submission, and clinical start-up. Each handoff is an opportunity for miscommunication, idle time, and lost momentum.

The sponsor needed a single accountable partner with the capability to run multiple concurrent workstreams—maintaining alignment across all teams, reducing organizational overhead, and minimizing the interval between end of nonclinical in-life and clinical screening.

THE STRATEGY: ALTASCIENCES' ACCELERATION PLATFORM

By housing nonclinical, bioanalytical, regulatory, and clinical capabilities within a single organization, Altasciences implemented its Acceleration Platform to enable fully coordinated end-to-end execution—with one team accountable for program-wide progress from day one.

Rather than compressing individual activities or relying on external handoffs, the strategy focused on **aligning workstreams to progress in parallel and eliminating downtime between phases.**

Strategic Phase I: Integrated Alignment

- Established a unified roadmap across nonclinical, bioanalytical, regulatory, and clinical teams
- Conducted pre-CTA meeting with health authority to ensure seamless regulatory transition
- Initiated clinical and regulatory planning alongside design of the program of nonclinical studies
- Defined early requirements for PK, ADA, and biomarker data to support clinical readiness

Strategic Phase II: Parallel Workstream Integration

- Conducted four toxicology studies in parallel with clinical planning activities
- Developed and validated nine bioanalytical methods for nonclinical and human (PK, ADA, biomarkers) alongside ongoing studies
- Advanced two formulation strategies to support first-in-human readiness
- Developed Investigator's Brochure, clinical protocol, Informed Consent Forms (ICFs), and regulatory documentation concurrently with nonclinical execution

Strategic Phase III: Clinical Readiness and Execution

- Aligned regulatory submission strategy with ongoing nonclinical study execution
- Enabled real-time nonclinical data sharing to support continuous decision-making
- Prepared clinical operations in advance to ensure rapid transition into Phase I

THE RESULTS

Seamless end-to-end progression from nonclinical development to first-in-human readiness—with no inter-vendor handoffs or delays between phases, and a single team maintaining program oversight throughout.

TIMELINE HIGHLIGHTS

- Transition from **end of in-life to clinical screening achieved in approximately six months**
- No idle time between phases. Clinical and regulatory workstreams were active before nonclinical studies concluded, and made possible by integrated team visibility
- A single integrated team managed clinical start-up concurrently with nonclinical studies—enabling screening to begin immediately following regulatory clearance, with no re-onboarding or transition delays

WHY IT MATTERS

Managing a complex monoclonal antibody program through a single integrated partner fundamentally changes how risk is controlled. There are no handoff gaps between vendors, no delays waiting on external data transfers, and no misalignment between teams operating in silos. One organization holds full accountability for the entire program—changing what's possible.

A unified team with full program visibility can anticipate downstream requirements, make real-time decisions, and keep every workstream synchronized. For sponsors, this means fewer surprises, lower coordination overhead, and a clear view of program status at all times—without having to manage across multiple CRO relationships.

ALTASCIENCES' VALUE IN ONE LINE

One partner. One program. End-to-end accountability from nonclinical through first-in-human—with the Acceleration Platform keeping every workstream moving in parallel.

Learn how Altasciences can do the same for your program.

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 25 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.