

Accelerating Safety Assessment to Proof-of-Concept ~Six Months Ahead of Industry Norms for a Novel Incretin-Based Therapeutic

THE BRIEF

A biotech developing a novel incretin-based therapeutic needed to move efficiently from nonclinical development to proof-of concept (POC) to achieve a key value-inflection milestone. Driven by formulation decisions, capital constraints, and competitive pressure, the sponsor required early pharmacokinetic and pharmacodynamic (PK/PD) data on an accelerated timeline.

THE CHALLENGE

Typical POC industry timelines for such programs can range between 27-51 months. Conventional sequential development models proposed by other CROs risk delaying first-in-human (FIH) data and limiting future development and investment flexibility. The sponsor required a partner capable of delivering with urgency and accuracy.

THE STRATEGY: ALTASCIENCES ACCELERATION PLATFORM

Altasciences implemented its **vertically integrated Acceleration Platform**—anchored by aligned planning, embedded bioanalysis, and continuous program leadership—to eliminate traditional bottlenecks and enable coordinated execution across functions.

This program leveraged key components of the platform, applying those most critical to accelerating early-phase decision-making and clinical transition.

The strategy centered on the Acceleration Platform:

- **Strategic Phase I: Inception and Integrated Alignment**

- Synchronized multi-phase orchestration: conducted a single cross-functional kickoff session at project inception to align nonclinical, bioanalytical, and clinical milestones into a unified development roadmap—supported by continuous, single-point updates to maintain alignment across all activities.
- Strategic decision-point mapping: proactively identified critical program milestones at study award to ensure a streamlined, informed progression.
- Targeted PK/PD data integration: defined essential pharmacokinetic and pharmacodynamic data requirements early in the cycle to facilitate an accelerated transition to clinical dosing.

- **Strategic Phase II: Parallel Workstream Integration**

- Concurrent bioanalytical and regulatory strategy: initiated bioanalytical method development at study award and parallelized assay development with nonclinical/clinical protocol design and regulatory package preparation to eliminate sequential delays.
- Integrated toxicology and clinical planning: initiated nonclinical safety assessments in tandem with clinical

- **Strategic Phase III: Clinical Execution and Data Acceleration**

- Synchronized multi-phase orchestration: conducted a single cross-functional kickoff session at project inception to align nonclinical, bioanalytical, and clinical milestones into a unified development roadmap—supported by continuous, single-point updates to maintain alignment across all activities.
- Strategic decision-point mapping: proactively identified critical program milestones at study award to ensure a streamlined, informed progression.
- Targeted PK/PD data integration: defined essential pharmacokinetic and pharmacodynamic data requirements early in the cycle to facilitate an accelerated transition to clinical dosing.
- trial design, ensuring data continuity and accelerated clinical study start.
- Dynamic IND compilation: commenced IND drafting concurrently with ongoing safety assessment studies, utilizing real-time data integration to refine documentation as results emerged.

THE RESULTS

IND Submission Readiness ~Six Months Earlier Than Projected.

With the Acceleration Platform, the client went from safety assessment to POC topline readouts **in just 22 months**, releasing critical funds to advance the program into further human studies.

Exceeded Industry Norms

Development Phase	Industry Typical Duration	Altasciences Accelerated for Client
Safety Assessment (IND-Enabling)	9-15 months	9 months
IND/CTA Preparation and Clearance	3-6 months	~2.5 months
Phase I (SAD/MAD Topline)	6-12 months	7 months
POC/POC-Equivalent (Topline)	9-18 months	6 months (12-weeks PD)
Safety Start to Phase I Topline	18-36 months	17 months
Safety Start to POC/POC-Equivalent Topline	27-51 months	22 months

Such programs typically require 27–51 months from assay initiation to topline POC results. Through coordinated planning and parallel execution, Altasciences enabled the sponsor to reach key milestones ~6 months ahead of industry norms.

SPONSOR VOICE

“Going from first dose to a Phase IIa press release in approximately nine months would not have been possible without this partnership. The team should be very proud of this data.”

— Chief Scientific Officer of Biotech

WHY IT MATTERS

The Acceleration Platform pathway provided the sponsor with the early PK/PD data to refine their formulation strategy, support internal funding decisions, and strengthen their competitive position within the incretin therapeutic landscape. By strategically bridging bioanalytical, nonclinical, and clinical operations and eliminating operational latency, Altasciences' synchronized critical workstreams accelerated development milestones by several months. This condensed timeline significantly enhanced program momentum, providing the sponsor with increased strategic optionality and an optimized return on investment.

ALTASCIENCES' VALUE IN ONE LINE

The **Early-Phase Acceleration Platform** synchronized integrated operations with scientific alignment, propelling the sponsor to critical clinical insights months ahead of conventional industry timelines.

[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.