ALTASCIENCES ACCELERATION PLATFORM

Faster by Design

WHY ACCELERATION MATTERS

It Changes the Trajectory of Drug Development

In early-phase drug development, timing matters. Reaching key value-inflection points sooner can significantly influence the trajectory of an entire program, affecting valuation, financing strategy, and competitive positioning.

Programs that advance more quickly gain measurable advantages:

- Earlier access to capital and portfolio prioritization
- Stronger investor confidence
- Reduced burn rate on the path to clinical proof of concept
- Extended effective patent runway

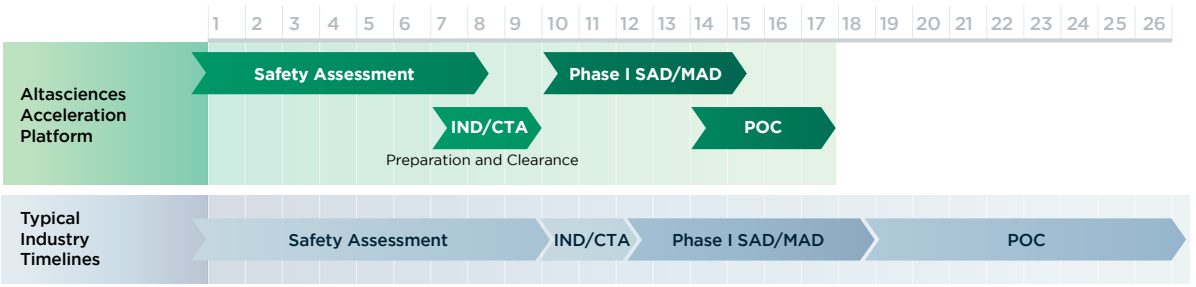
Acceleration is therefore not simply an operational benefit, it is a strategic advantage that can shape the overall success and value of a development program.

Altasciences can help reduce drug development timelines by up to 40%, with the potential to move from first safety assessment to clinical proof-of-concept in as little as 18 months, compared to traditional industry timelines of approximately 27 to 51 months.

THE ACCELERATION PLATFORM

Altasciences **Acceleration Platform** is designed to help sponsors advance programs from first safety assessment through IND readiness, first-in-human studies, and clinical proof of concept with greater speed, clarity, and confidence.

By integrating nonclinical research, clinical research, bioanalysis, formulation development, manufacturing, and regulatory support within a coordinated development strategy, the platform reduces operational gaps, enables parallel execution of activities, and accelerates informed decision-making.



The objective is not simply to shorten timelines, but to help sponsors reach critical development and value-inflection points sooner therefore reducing risk, optimizing resources, and generating the high-quality data needed to make confident program decisions.

HOW THE ACCELERATION PLATFORM WORKS

Faster by Design—Explained

Acceleration is achieved by replacing traditional sequential development with coordinated execution.

Altasciences aligns four core pillars to compress the timeline from first safety assessment to clinical proof-of-concept. Depending on program design, these pillars are applied as needed, with some programs leveraging all four and others emphasizing those most critical to their development pathway.

The Four Pillars of Acceleration

Aligned Nonclinical and Clinical Planning

Nonclinical strategy, regulatory positioning, and clinical design are developed in parallel. Early PK/PD modeling supports dose selection while safety studies are still in progress.

Embedded Bioanalytical Strategy

Bioanalytical methods are developed alongside early PK and toxicology work, ensuring assays are ready to support both safety interpretation and clinical endpoints from the start of clinical studies.

Early Manufacturing Alignment*

Formulation and manufacturing readiness are aligned with nonclinical development when required, ensuring clinical supply is ready without additional bridging work.

Continuous Program Leadership

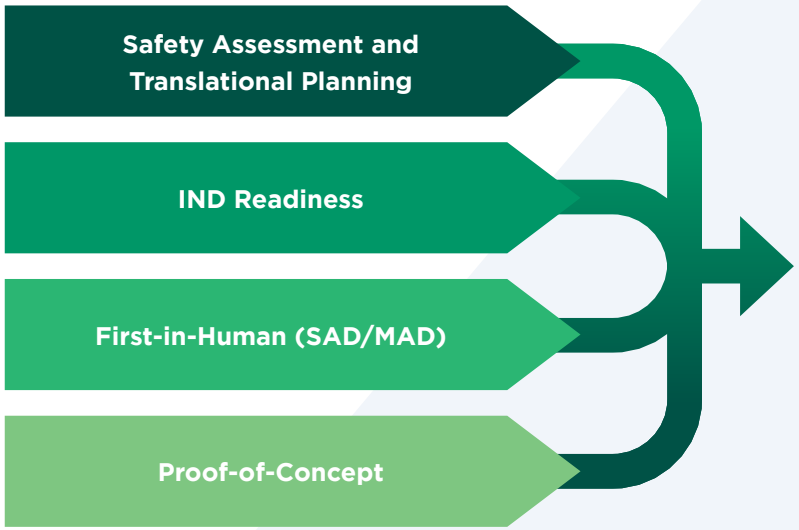
Programs are guided by a single scientific team from early development through clinical phases, preserving knowledge and enabling faster, more consistent decision-making.

**Applied when manufacturing or formulation development is required for small molecule program.*

HOW THE ACCELERATION PLATFORM COMPRESSES THE TIMELINE

When these four pillars are applied, development progresses through coordinated parallel execution.

Integrated Development Timeline



Parallel Execution Across the Timeline

- **Nonclinical safety studies are designed for speed without compromise**—parallel execution across toxicology, bioanalysis, and regulatory workstreams compresses what is typically a sequential handoff into a continuous workflow. In one mAb program, the transition from end of nonclinical in-life to clinical screening was achieved in approximately 1.5 months—with no idle time between phases.
- **Early regulatory planning begins before safety assessment is complete**—IND/CTA documentation, including the Investigator's Brochure and clinical protocol, is drafted concurrently with ongoing nonclinical studies, so regulatory submission is ready the moment data is available.
- **Proof-of-concept is built into the Phase I design from the start**—by incorporating POC endpoints into a unified SAD/MAD protocol, sponsors receive critical PK/PD data without a separate study, enabling POC readout in as little as 22 months from safety start versus the industry norm of 27–51 months.

Outcome

Altasciences can reduce drug development timelines by up to 40%, moving from first safety assessment to clinical proof-of-concept in as little as 18 months, compared to traditional industry timelines of 27–51 months, depending on program design, molecule characteristics, and clinical strategy.

Development Phase	Industry Typical Duration	Altasciences Acceleration Platform *Single NCE
Safety Assessment (IND-Enabling)	9-15 months	7.5 months
IND/CTA Preparation and Clearance	3-6 months	2 months
Phase I (SAD/MAD Topline)	6-12 months	5.5 months
POC/POC-Equivalent (Topline)	9-18 months	3 months
Safety Start to **Phase I Topline**	**18-36 months**	**15 months**
Safety Start to **POC/POC-Equivalent Topline**	**27-51 months**	**18 months**

Services Used

- Nonclinical
- Clinical
- Bioanalytical
- Regulatory
- Program Management
- CRO Support

**Actual timelines may vary depending on molecule class, toxicology design, and clinical strategy, and are contingent on established communication plans, and sponsor collaboration throughout the program.*

SPEED IN PRACTICE

Integrated Programs. Real Outcomes.

Timeline models can illustrate the potential benefits of an integrated development strategy, but real-world programs tell the story best.

Across small molecules, biologics, and emerging modalities, Altasciences has helped sponsors accelerate progress from first safety assessment to clinical evaluation by coordinating activities, reducing operational gaps, and enabling parallel execution across development phases.

The following case studies demonstrate how the **Acceleration Platform** translates integration into measurable results. While each program was uniquely designed to meet specific development objectives, together they illustrate how a coordinated approach can help sponsors reach critical milestones and value-inflection points sooner.

Where applicable, timelines are compared against typical industry ranges for similar stages of development.

Case Studies

1 **Small Molecule Program** - pg.8
Nonclinical study initiation to First-in-Human dosing in ~7 Months

2 **Monoclonal Antibody Program** - pg.9
Seamless Progression to First-in-Human Readiness

3 **GLP-1 Development Program** - pg.10
Safety Start to Proof-of-Concept in 22 Months

1 Small Molecule Program

Objective

A sponsor developing an extended-release formulation of an already-approved compound had their IND timeline disrupted when the FDA required additional nonclinical toxicology and PK/TK data before clinical trials could proceed. With a first-in-human target at risk, the sponsor engaged Altasciences to design and execute a bespoke rat PK/TK study on an accelerated timeline.

Approach

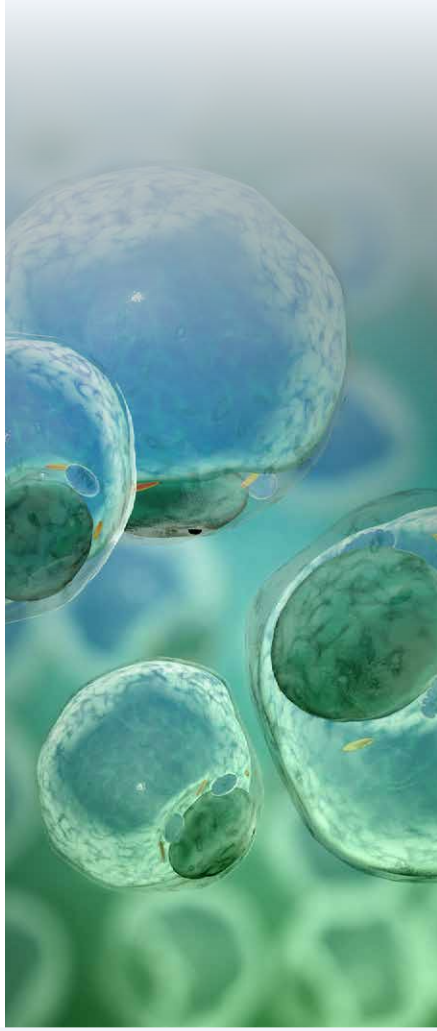
Faced with a compressed timeline driven by the FDA requirement, Altasciences executed in parallel across toxicology, bioanalysis, regulatory strategy, and clinical planning. The Investigator's Brochure and clinical protocol were drafted concurrently with the ongoing rat PK/TK study, ensuring regulatory submission was ready the moment data was available—with no idle time between nonclinical and clinical workstreams.

Outcome

First-in-human dosing achieved in approximately 7 months from nonclinical study initiation, meeting the sponsor's end-of-2023 target despite the late-stage FDA requirement for additional nonclinical data.

Industry Context

Typical timelines to first-in-human can range from approximately 18–24 months, depending on program design and regulatory requirements.



Why It Matters

Reaching first-in-human up to 17 months ahead of industry norms is not only a scientific achievement—it is a strategic one. Earlier clinical data strengthens the sponsor's position for the next funding round, supports portfolio prioritization decisions, and preserves more of the effective patent runway before competitors reach the same milestone.

2 Monoclonal Antibody Program

Objective

A sponsor advancing a monoclonal antibody program needed to progress from nonclinical development to first-in-human readiness without delays between phases. The complexity of mAb development—spanning tailored toxicology, immunogenicity assessment, and coordinated regulatory documentation—made a fragmented multi-vendor approach untenable. A single accountable partner was required.

Approach

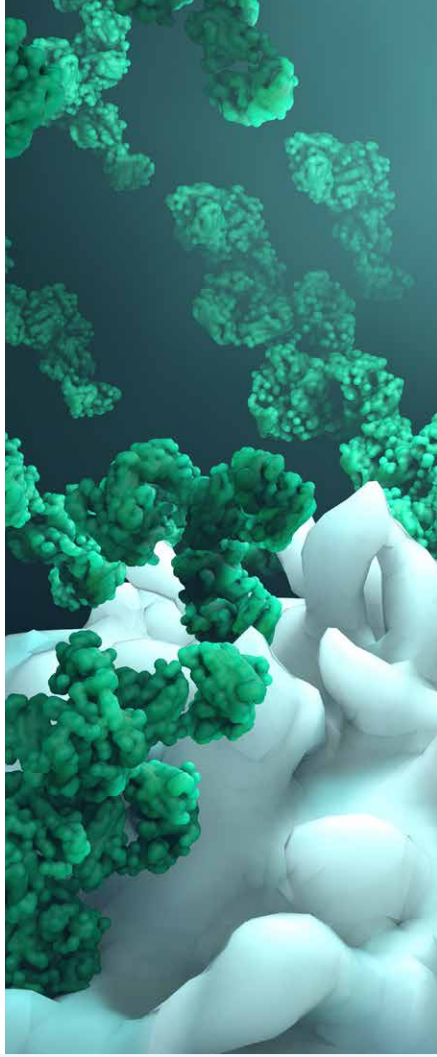
Altasciences established a unified roadmap from day one. Four toxicology studies ran in parallel with clinical planning, while nine bioanalytical methods were developed and validated concurrently with ongoing nonclinical work. The Investigator's Brochure, clinical protocol, and regulatory documentation were prepared alongside nonclinical execution, with real-time data sharing enabling continuous decision-making across all teams.

Outcome

Seamless progression from nonclinical development to first-in-human readiness with no delays between phases, including transition from end of in-life to clinical screening in **approximately 1.5 months**.

Industry Context

Monoclonal antibody development typically follows a sequential model, where nonclinical studies, reporting, regulatory submission, and clinical start-up occur in distinct phases.



Why It Matters

Compressing the nonclinical-to-clinical transition to 1.5 months with no inter-vendor handoffs reduces coordination overhead, protects program momentum, and keeps investor-facing milestones on track—preserving both capital and strategic optionality.

3 GLP-1 Development Program

Objective

A biotech developing a novel incretin-based therapeutic needed to reach proof-of-concept on an accelerated timeline to hit a critical value-inflection milestone. Driven by capital constraints and competitive pressure, the sponsor required early PK/PD data urgently, and needed a partner who could deliver with both speed and accuracy.

Approach

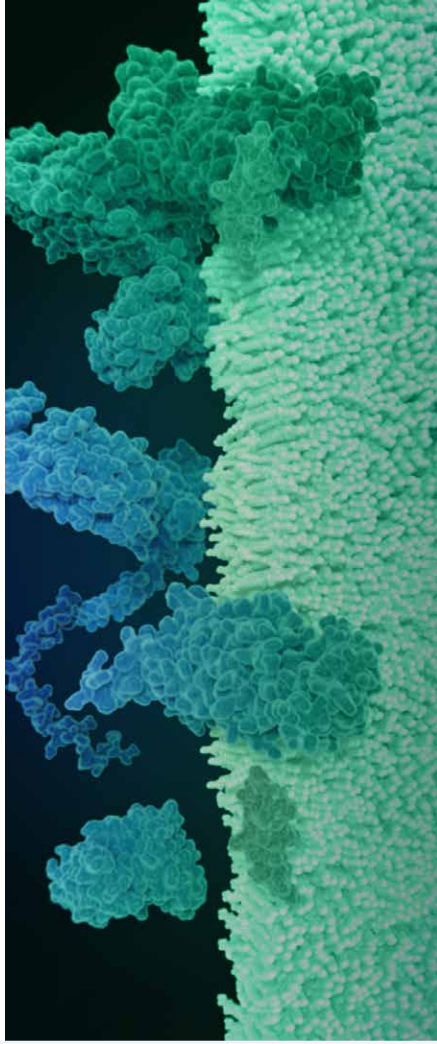
Altasciences implemented its **Acceleration Platform** anchored by aligned nonclinical and clinical planning, embedded bioanalysis, and continuous program leadership. A single cross-functional kickoff aligned all nonclinical, bioanalytical, and clinical milestones into one unified roadmap. Bioanalytical method development was initiated at study award and ran in parallel with nonclinical/clinical protocol design and regulatory package preparation. IND drafting commenced concurrently with ongoing safety assessment studies.

Outcome

Proof-of-concept achieved in 22 months from safety assessment start—versus the industry norm of 27–51 months—releasing critical funds for further clinical studies.

Industry Context

Typical timelines from safety assessment to POC range from **27–51 months**; depending on clinical design and sequencing of development activities.



Why It Matters

Reaching POC up to 29 months ahead of industry norms unlocked critical program funding, delivered a high-visibility Phase IIa press release strengthening investor confidence, and reinforced the sponsor's competitive position in the incretin landscape. Every month saved before POC is a month of additional patent runway and an earlier path to returns on investment.

ENTERPRISE IMPACT

Why Acceleration Helps Your Bottom Line

Acceleration in early development translates directly into financial and strategic impact, and allows organizations to:

- create potential for premium transactions or share-price appreciation
- preserve development capital
- accelerate time to market and outpace competitors
- maximize patent protection time

"Early-phase drug development should move with clarity and momentum. By intentionally aligning the path from first safety assessment through clinical proof-of-concept, we help sponsors reach meaningful clinical insight sooner, sometimes in as little as 18 months."

— **Marie-Hélène Raigneau**,
CEO, Altasciences

HOW WE ACCELERATE TOGETHER

Moving in Unison

The fastest development programs are built on more than efficient execution, they begin with early alignment, transparent communication, and a shared commitment to achieving program goals.

1 Program Alignment

A cross-functional kickoff session unites your team and ours, covering program goals, regulatory strategy, key milestones, and risk identification from day one. This single session establishes a unified development roadmap and replaces weeks of back-and-forth before work even begins.

2 Partnership Agreement

Before work begins, we formalize roles and responsibilities, decision-making authority, escalation pathways, and committed turnaround times for reviews and approvals. This removes ambiguity and ensures both teams are operating under the same commitments throughout the program.

3 Communication Plan

A tailored communication plan defines update cadence, meeting structure, and points of contact across all workstreams. This includes routine milestone reporting, ad hoc meetings within 24–48 hours and direct access to functional leads so decisions are never delayed by a communication gap.

4 Parallel Execution

With alignment, agreements, and communication structures in place, all workstreams launch concurrently. Your dedicated program manager maintains real-time visibility across nonclinical, bioanalysis, regulatory, manufacturing, and clinical teams, keeping every activity synchronized and every milestone on track.

What You Can Expect From Us

- A single point of accountability from nonclinical through clinical phases
- Proactive risk identification before delays occur
- Real-time data sharing across all workstreams
- A team that treats your timeline as their own

What We Ask of You

- Early engagement—the sooner we align, the more we can compress
- Committed participation in review cycles and milestone decisions
- Open communication when priorities or program parameters shift

CONFIDENCE WITHOUT COMPROMISE

Informed Decision-Making

In the modern landscape of drug development, speed is a byproduct of precision. As development costs continue to rise, sponsors are looking to bring forward only the most promising molecules, for more confident **go/no-go decisions**.

With our **Acceleration Platform**, your program will break free of the limitations of linear, siloed processes and the slowdowns caused by a fragmented vendor ecosystem. Altasciences' platform integrates nonclinical research, bioanalysis, manufacturing, and early clinical development within a single operational network. By strategically overlapping key activities, scientific insight, regulatory strategy, and operational execution remain aligned throughout the program lifecycle.

In this integrated structure, our framework ensures that the transition from nonclinical safety to human clinical data is seamless and *faster by design*. You won't just reach POC faster; you'll arrive with a better understanding of your molecule's potential.

ADDITIONAL RESOURCES

Case Studies:

Integrated GLP-1 Program Case Study

Monoclonal Antibody Development Program

Small Molecule Integrated Program

Webinars and Podcasts:

Podcast: Three Laboratories—One Vision, With Dr. Lynne Le Sauteur

Webinar: Overcoming Bioanalytical Challenges for PK/PD Assessment in Phase I Biologic Studies

Webinar: Bioanalysis by Hybridization ELISA for Antisense Oligonucleotides

Publications:

One Integrated Solution for Meeting Your Preclinical to Clinical Drug Development Needs

Bioanalytical Developments for the Analysis of Antisense Oligonucleotides

Altasciences' Facilities: Moving in Unison

The Altascientist, Issue 4: Key Considerations for Biosimilar Clinical Pharmacology Studies

ABOUT ALTASCIENCES

Altasciences is a drug development organization dedicated to safely accelerating early-phase development for biotech, biopharmaceutical, and pharmaceutical companies. By combining the scale and expertise of a large CRO/CDMO with the flexibility and personalized approach of a mid-size partner, Altasciences delivers unified solutions across nonclinical, clinical, bioanalytical, formulation, and manufacturing services. Through intentional integration and true collaboration, the company removes barriers from lead candidate selection to clinical proof of concept—helping sponsors save time, reduce complexity, and make confident, data-driven decisions that enable earlier returns on investment. Guided by over 30 years of experience and a commitment to quality, integrity, and partnership, Altasciences enables clients to reach critical milestones faster and with greater confidence.

Drug Development, Reimagined.™

Contact us **Learn more**

ALTASCIENCES

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