ALTASCIENCES ACCELERATION PLATFORM

for Early-Phase Drug Development

Faster by Design

WHY ACCELERATION MATTERS

It Changes the Trajectory of Drug Development

In early-phase drug development, the timing of a few critical milestones can determine the trajectory of an entire program.

Key early development milestones include:

- IND readiness
- first-in-human dosing
- proof-of-concept clinical data

The timing of these milestones directly influences valuation, financing strategy, and competitive positioning. Programs that reach these milestones sooner **gain measurable advantages:**

- earlier access to capital and portfolio prioritization
- stronger investor confidence
- extended effective patent runway

Acceleration is therefore not simply operational efficiency; it is a strategic advantage in drug development.

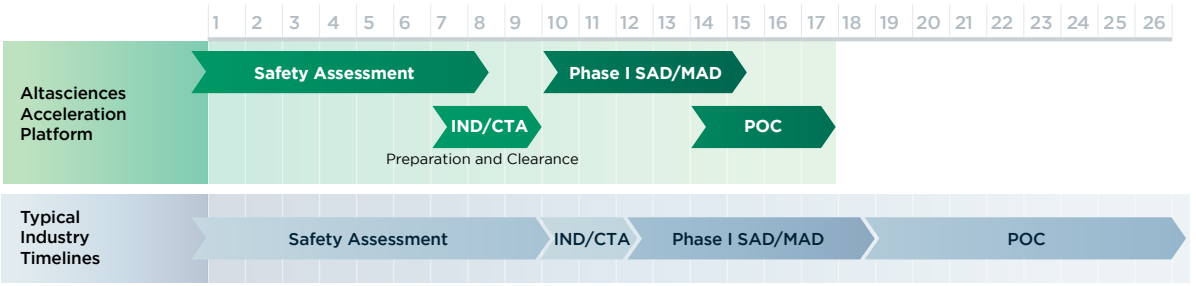
Achieving this level of acceleration requires more than working faster within individual functions. It requires structuring development so that critical scientific and operational decisions happen in coordination from the start.

THE ACCELERATION PLATFORM

Altasciences Acceleration Platform was designed to strategically compress timelines from first safety assessment through clinical proof-of-concept—without compromising quality or safety.

Rather than operating as separate services and phases, scientific and operational functions at Altasciences are aligned within a single coordinated framework.

This depth of integration allows programs to pick up momentum through **parallel execution rather than sequential handoffs**.



Our objective is clear:

Advance programs from first safety assessment to IND, first-in-human studies, and proof-of-concept with greater speed and clarity.

Altasciences is uniquely built to achieve this objective, with several structural principles that enable coordinated execution across early development.

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 *(when applicable)*

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

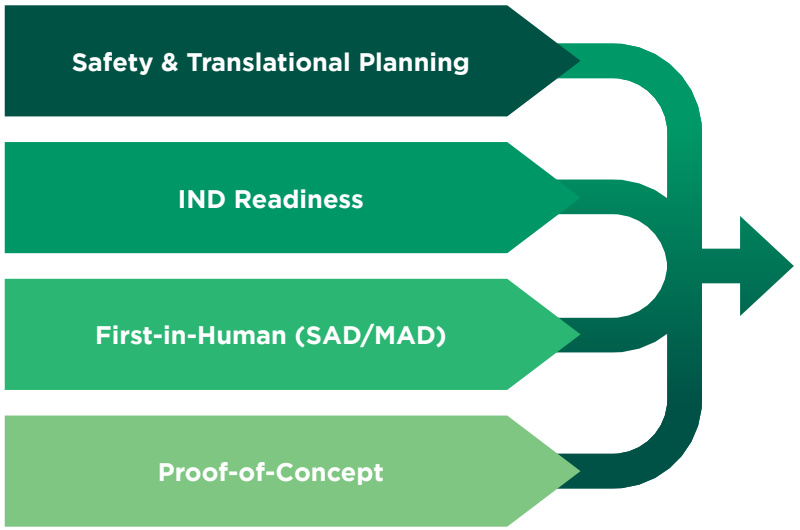
Continuous Program Leadership

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

HOW THE ACCELERATION PLATFORM COMPRESSES THE TIMELINE

When these four pillars are applied, development progresses through coordinated execution rather than sequential handoffs.

Integrated Development Timeline



Execution Across the Timeline

- **Early regulatory planning** begins before safety assessment.
- **Streamlined nonclinical safety studies** (typically 4–13 weeks) accelerate readiness for human studies.
- **Proof-of-concept is incorporated into a unified SAD/MAD protocol**, enabling earlier clinical insight.

Outcome

From first safety assessment to proof-of-concept in as little as 18 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**

**Actual timelines may vary depending on molecule class, toxicology design, and clinical strategy.*

SPEED IN PRACTICE

Integrated Programs. Measurable Outcomes.

While timeline models illustrate the potential impact of integrated development, their value is best demonstrated through real programs.

Altasciences has supported numerous early-phase programs across small molecules, biologics, and emerging modalities, where coordinated execution enabled faster transitions from nonclinical studies to clinical evaluation.

Timelines below reflect program-specific designs and are intended to illustrate the Acceleration Platform. Where applicable, comparisons reflect typical industry ranges for similar development stages.

1 Small Molecule Program

Objective:

Advance from nonclinical studies to first-in-human dosing on an accelerated timeline.

Approach:

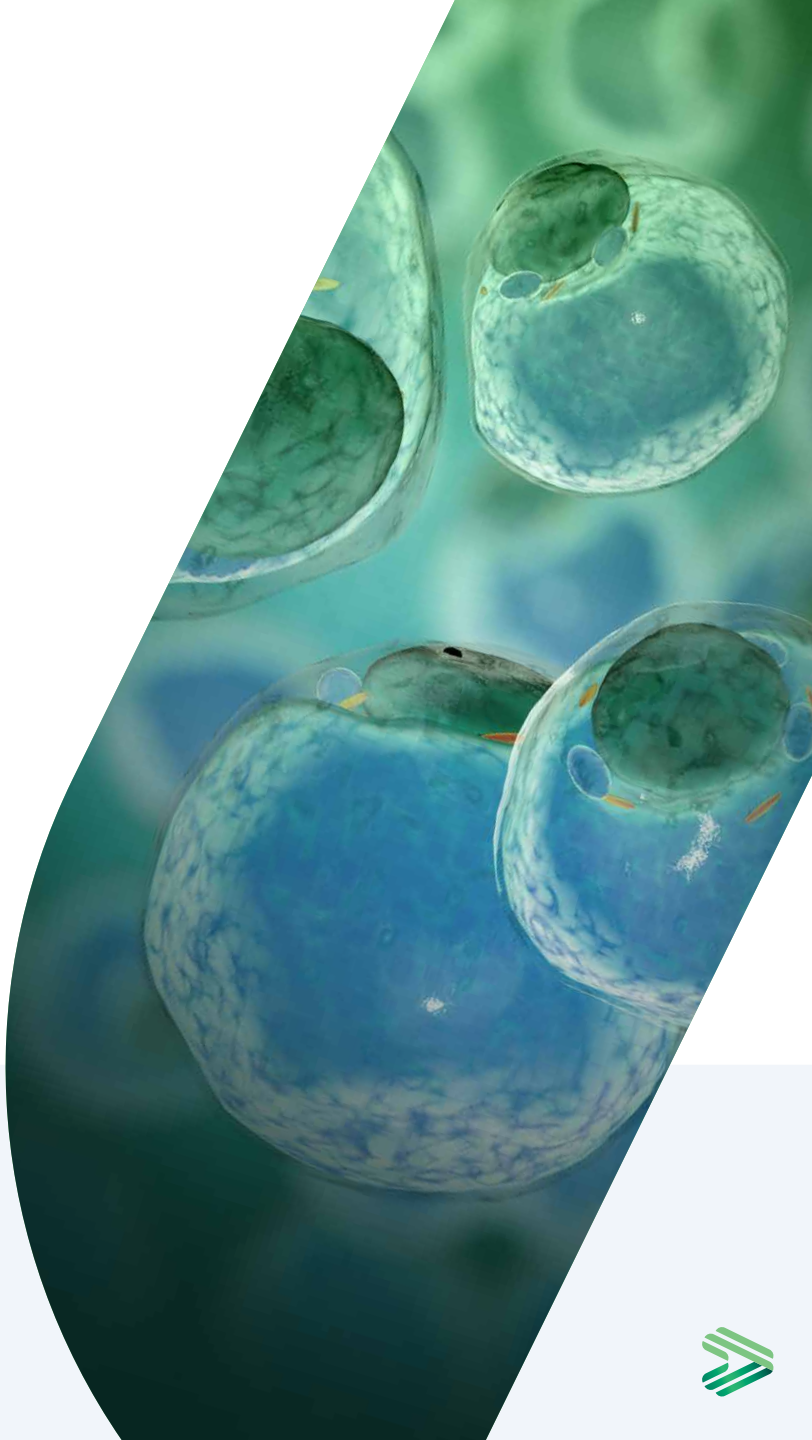
Parallel execution across toxicology, bioanalysis, regulatory strategy, and clinical planning, supported by integrated program management.

Outcome:

First-in-human dosing achieved in approximately 7 months from nonclinical study initiation.

Industry Context

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



This program reflects a model where activities were executed in parallel rather than sequentially, enabling earlier progression to clinical dosing.

2 Monoclonal Antibody Program

Objective:

Advance a monoclonal antibody program from nonclinical development to first-in-human readiness without delays between development phases.

Approach:

Parallel execution across toxicology, bioanalysis, regulatory strategy, and clinical planning enabled continuous progression across all phases.

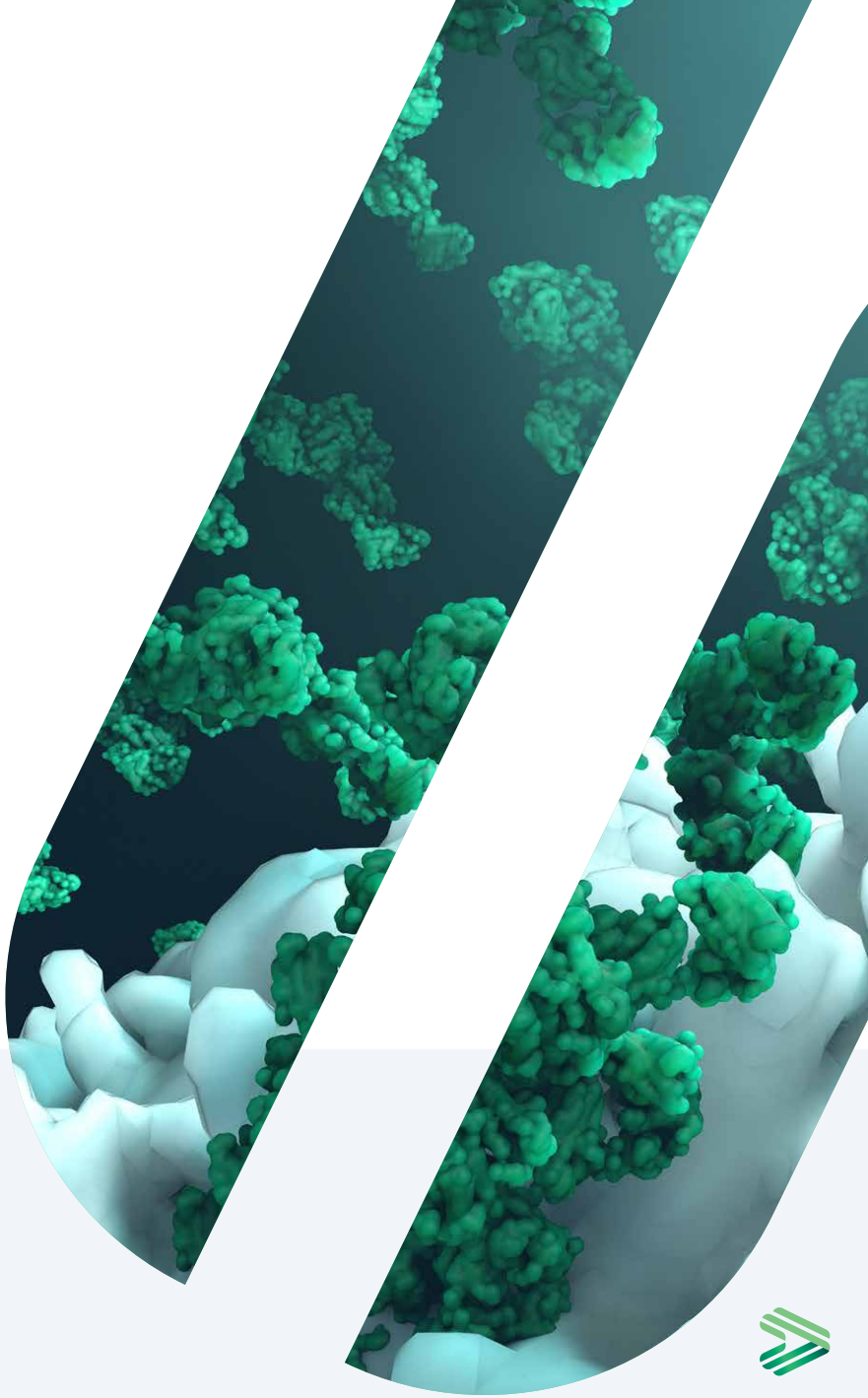
Outcome:

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.

In this program, overlapping execution enabled these activities to progress concurrently, maintaining continuity across development stages.



3 GLP-1 Development Program

Objective:

Accelerate IND-enabling studies and enable earlier progression to clinical proof-of-concept.

Approach:

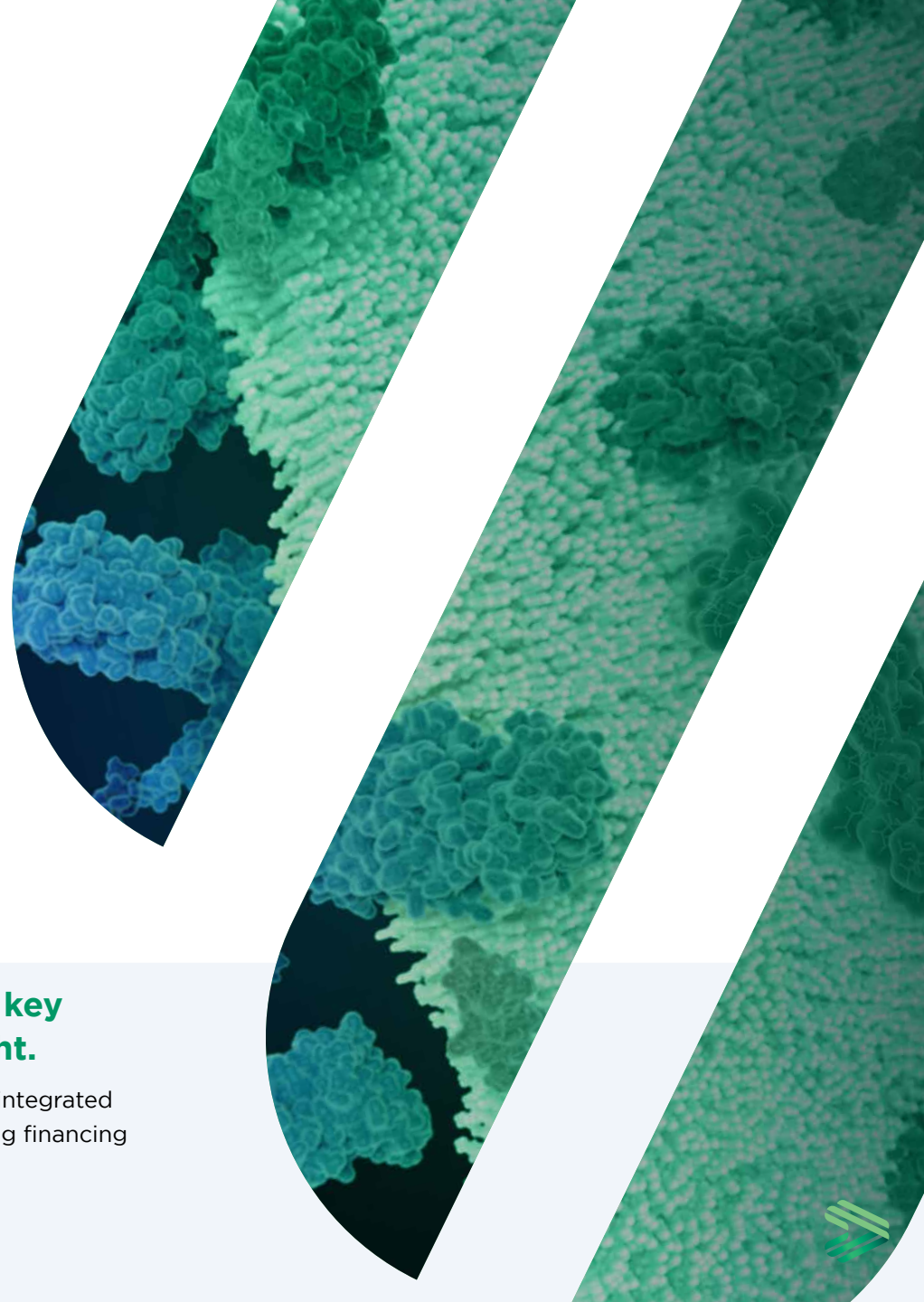
Integrated planning across toxicology, bioanalysis, and clinical pharmacology ensured alignment from early development through clinical execution, enabling parallel progression of key activities.

Outcome:

Proof-of-concept achieved in **22 months from safety start**.

Industry Context

Typical timelines to proof-of-concept range from **27–51 months**; depending on clinical design and sequencing of development activities.



This program reflects a coordinated approach where key activities were aligned to enable earlier clinical insight.

Whether through compressing timelines or eliminating delays between phases, integrated development enables earlier access to critical clinical data—ultimately influencing financing strategy, partnership opportunities, and overall program value.

ENTERPRISE IMPACT

Why Acceleration Matters to Your Bottom Line

Acceleration in early development translates directly into financial and strategic impact.

Integrated development models that reduce delays between phases can enable earlier progression to key clinical milestones, including:

- first-in-human readiness in as little as **7–13 months**
- IND readiness supported by coordinated execution
- proof-of-concept achieved in as little as **22 months**, compared to typical industry timelines of **27–51 months**

Delays in early development are not only scientific—they are financial.

Each additional month before proof-of-concept extends timelines to critical decision points, delaying access to clinical insight and increasing overall program risk.

Earlier clinical POC validation allows organizations to:

- increase asset value
- secure funding sooner
- hit financial milestone sooner
- create potential for premium transactions or share-price appreciation
- preserve development capital
- accelerate time to market and outpace competitors
- maximize patent protection time

The speed at which your program moves will not only determine your scientific timelines, but also your enterprise's value.

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 strategy, and early clinical development within a single operational network. By thoughtfully 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.

Altasciences... Drug Development, Reimagined.™

Contact us **Learn more**

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