

The Altascientist

SCIENTIFIC JOURNAL

THE SCIENCE OF EFFICIENCY: HOW INTEGRATION CAN OPTIMIZE EARLY-PHASE DRUG DEVELOPMENT TIMELINES

The most consequential delays in early drug development often occur not during a study, but between decisions coordinated across nonclinical, clinical, bioanalytical, manufacturing, and CRO services teams. A toxicology result may be available, yet the clinical protocol is still being revised. An assay may be technically feasible, yet its validation strategy has not been aligned with the first-in-human (FIH) sampling plan. Each team can meet its own milestone while the program as a whole loses weeks due to a lack of alignment between clinical operations, regulatory affairs, data management, biostatistics, and project management around shared decision points.

Published research from the Tufts University Center for the Study of Drug Development (CSDD) indicates that challenges persist in the increasingly complex environment of innovative drug development:

"Sponsors and contract research organizations (CROs) are generally adept at identifying problems. The proliferation of data dashboards, real-time analytics, and data monitoring tools has significantly enhanced signal detection. However, the conversion of these signals into decisive, coordinated action remains inconsistent… effective response requires synchronized action across [clinical trial] functions."

For sponsors, the practical question is therefore not simply whether data is generated on time, but whether CRO services teams can translate that data into protocol, regulatory, operational, and statistical decisions without avoidable handoffs.

In this issue, we discuss the recent research from the CSDD and review how intentional design can close the gaps between clinical development stages, fostering efficient, agile drug development with rapid decision-making informed by quality data.

We provide a detailed **case study** demonstrating how Altasciences reduced delivery of topline POC results for a novel incretin-based therapeutic by almost six months.

INCREASING COMPLEXITY LEADS TO LONGER TIMELINES

Time has always been a critical value driver in early-phase drug development, where data-driven insight and decisions help reduce costs, manage risk, and accelerate the path to later phases.

As therapeutic modalities become increasingly diverse and complex, particularly with advances in biologics and cell and gene therapies, clinical development has become more sophisticated and scientifically demanding. As a result, drug development timelines have become longer. Longer timelines are not due to increased regulatory review, but rather because novel therapies often require a deeper understanding of complex biological mechanisms, new biomarkers, and more sophisticated clinical trial designs. More time is needed for preclinical validation, dose selection, patient identification, and evaluation of safety and efficacy. At times, greater complexity contributes to operational challenges, such as specialized testing and advanced manufacturing, while the competing landscape can also prolong recruitment timelines



PAST AND CURRENT GAPS IN TRANSLATIONAL DRUG DEVELOPMENT

Translating discovery and nonclinical findings into scientifically sound, operationally feasible clinical trial designs remains a significant challenge in drug development. The CSDD white paper, ***Addressing the Execution Translation Gap in Clinical Trials***, states that approximately 90% of investigational drug candidates entering clinical development do not ultimately receive regulatory approval, with operational challenges contributing to nearly one-third of development failures.

Integration is useful when it changes how work is sequenced and decisions are made, including the coordination of clinical operations, monitoring, data management, biostatistics, medical writing, and regulatory affairs. Putting multiple services under one contract is not sufficient. Sponsors should look for an operating model that specifies evidence requirements, decision owners, escalation thresholds, and the latest responsible moment for committing resources.

The delivery model also matters. Depending on the program, sponsors may need full-service CRO support, selected functional services, or a hybrid approach spanning clinical research units and external investigative sites. Defining these interfaces early helps preserve sponsor oversight while avoiding duplicated coordination.

HOW INTEGRATION FOSTERS EFFICIENCY

Findings from the CSDD, supported by Altasciences' own research and data analysis, suggest that closing the execution translation gap requires a shift from reactive problem-solving to proactive planning and management across several critical areas.

Define Execution Risk Indicators (ERIs) upfront. In addition to traditional milestone reporting, establish a small number of ERIs that provide early warning of potential delays. Establishing trigger thresholds and having a risk assessment and mitigation plan in place allows for early action and setting targets creates awareness.

Align goals and accountability across scientific and CRO service functions. Performance metrics and key performance indicators (KPIs) should inform and drive cross-functional outcomes as opposed to disconnected milestones.

Continuous training programs should focus not only on compliance, but also on problem-solving, critical thinking, AI-co-working, and flexible execution.

Leverage technology advancements across study execution and CRO services. CROs already have comprehensive systems for record keeping and should now leverage advances in systems for reasoning and execution. AI and analytics should be part of decision workflows, enabling automated triggers and guided action paths for identified risks.

Foster agile operating models. Organizations should adopt more flexible, hybrid governance structures across workflows, allowing rapid decision-making, agile responses, and iterative improvement.



Diving deeper into the operating model referenced above, some of the detailed considerations that drive efficiency include:



Trial design and conduct needs to be adaptive, with each step informed by data from previous activities and coordinated with protocol development, clinical operations, data management, and biostatistics. Nonclinical learnings and CDMO insights need to be considered when designing clinical conduct. Transparent and consistent communication flow between key stakeholders, departments, and decision makers is crucial to ensure that as data comes in, impacts on next steps can be rapidly assessed, reviewed, and decided on.



Site and investigator engagement must consider whether a site can access the target patient population and provide the specialized capabilities required for the study. CRO services teams can support feasibility assessments, site selection, activation, monitoring, and ongoing performance oversight. Once sites are selected, performance is actively managed through predefined metrics and frequent proactive two-way communication rather than waiting for problems to become visible through missed milestones.



Project management connects CRO services with nonclinical, clinical, bioanalytical, and manufacturing workstreams. Strong cross-functional governance and rapid issue resolution is key, with clear interfaces among functional groups so that project management and other stakeholders are not operating as independent workstreams. For a mid-sized CRO, this integrated model can be an advantage: fewer organizational layers can enable more efficient communication and decision-making than may be possible within larger organizations.

Effective governance begins with established and agreed-upon roles, decision ownership, communication flow, escalation pathways, and performance expectations. Sponsors should have clear visibility into risks and direct access to an accountable project manager. Rather than treating each study as a collection of individual deliverables, integrated services can deliver a repeatable framework for optimized study conduct and continuous improvement, further strengthened by continuity of personnel and institutional knowledge.

OPTIMIZING OPERATIONAL EFFICIENCY

The objective is not simply to accelerate individual tasks, but to reduce overall development timelines by optimizing activities along the critical path while maintaining data integrity, participant safety, and regulatory readiness. CRO services play a central role in achieving this efficiency by translating integrated development strategies into executable clinical protocols, coordinated site operations, reliable data collection and analysis, and regulatory-ready documentation.

If dependencies are carefully managed, parallel execution can further accelerate progress. For example, preparing an Investigational New Drug (IND) submission while nonclinical studies are ongoing can save valuable time, as long as the final submission incorporates complete and appropriately evaluated safety data. This requires early alignment among clinical operations, data management, biostatistics, medical writing, and regulatory specialists to reduce avoidable protocol amendments, data reconciliation delays, and late-stage documentation gaps.

Ultimately, a regulatory submission must be comprehensive, scientifically sound, and supported by robust, accurately collected and analyzed data. It should anticipate and address potential regulatory questions, minimizing the risk of requests for additional information or studies that could delay development and increase costs. Preparing a high-quality regulatory submission should therefore serve as a shared, cross-functional objective, with every milestone along the critical path contributing to two essential priorities: development speed and scientific integrity.

Start With Planning

- Build a trusted, knowledgeable team that will foster program progress from start to finish. Focus on integration, cohesion, minimizing logistical roadblocks, and handoffs.
- Meet with regulatory bodies early if important questions remain.
  - U.S.A: INTERACT meeting or Pre-IND
  - Canada: Pre-CTA Consultation Meeting
- Work with an early-phase CRO who understands the regulatory environment and can optimize the regulatory pathway based on the sites, study, indication, and needs of the program.
- Include all the necessary assessments, but not more, in your IND or CTA. Rely on expert advice to determine how to build the appropriate package.

Implement Effectively

- Perform exploratory non-GLP studies if such data will contribute to more effective decision-making later in the program.
- Design nonclinical, bioanalytical, clinical, and CRO services approaches together, and adjust the clinical plan when relevant bioanalytical data becomes available.
- Initiate nonclinical work in a stage-appropriate approach to support initial clinical trials, as outlined in ICH M3 Guideline.
- Communicate openly and often so that scientific teams, CRO services, and sponsor stakeholders are aligned. Ensure program management has a consistent framework within which they collect and share information.

PROGRAM MANAGEMENT CONTRIBUTIONS FOR MULTI-SITE TRIALS

Maximizing efficiency when implementing an accelerated drug development program demands continuous cross-functional oversight and analysis. The objective is coordinated action: an integrated project team can maintain a single view of the critical path, track emerging scientific and operational risks, and escalate decisions before local issues affect site activation, database readiness, analysis, or reporting.

Built for Speed and Risk Reduction

Multi-site studies can accelerate development timelines, if managed properly. Project Managers can do this by:

- Identifying enrollment risks early and redistributing focus across sites
- Standardizing workflows so that each site follows a unified operational model
- Ensuring clean, synchronized data across all locations
- Resolving site issues before they impact your critical milestones

The goal is not just on-time delivery; it's reducing preventable delays at every stage.

Visibility and Control for Sponsors

Sponsors stay informed without being overwhelmed. Project managers provide them with:

- Dashboards with site-level performance metrics
- Timely status reports covering enrollment, data, safety, and risks
- Transparent budget tracking and accrual forecasting
- Clear escalation pathways when decisions are needed

Sponsors get complete visibility as the project management team handles day-to-day operational complexity.

Seamless Integration Between Internal and External Teams

Project managers work closely with internal functional groups (clinical operations, bioanalysis, data management, biostatistics, regulatory, medical writing) and external partner sites, for:

- Faster resolution of issues
- Immediate access to scientific or operational expertise
- Consistent communication across all partners
- Alignment of timelines, deliverables, and expectations

The result: a multi-site study that operates as a single, cohesive project.

Designed for the Realities of Phase Ib to II Development

Early patient studies require agility, protocol amendments, adaptive cohorts, dose escalations, and evolving data. Project managers are trained specifically for these environments, allowing them to:

- Coordinate adaptive changes quickly
- Manage complex sample logistics
- Support PK/PD-driven decisions
- Align safety reviews across dispersed clinical teams

Your multi-site trial remains flexible and tightly controlled.

CASE STUDY

ACCELERATING SAFETY ASSESSMENT TO PROOF-OF-CONCEPT ~SIX MONTHS AHEAD OF SCHEDULE FOR A NOVEL INCRETIN-BASED THERAPEUTIC

Purpose

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

The Challenge

Typical POC industry timelines for such programs can range between 27 to 51 months. Conventional sequential development models proposed by other CROs risked 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: The Altasciences Acceleration Platform

Altasciences implemented its vertically integrated Acceleration Platform—anchored by aligned planning, embedded bioanalysis, coordinated CRO Services, and continuous program leadership—to reduce 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.

Strategic Step 1: Inception and Integrated Alignment

- **Synchronized multi-phase orchestration:** Conducted a single cross-functional kickoff session at project inception to align nonclinical, bioanalytical, clinical, and relevant CRO services 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 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 Step 2: Parallel Workstream Integration

- **Concurrent bioanalytical, regulatory, and CRO services planning strategy:** Initiated bioanalytical method development at study award and parallelized assay development with nonclinical and clinical protocol design and regulatory package preparation to eliminate sequential delays.
- **Integrated toxicology and clinical planning:** Initiated nonclinical safety assessments in tandem with clinical planning.
- **Dynamic IND compilation:** Commenced IND drafting concurrently with ongoing safety assessment studies, utilizing real-time data integration to refine documentation as results emerged.

Strategic Step 3: Clinical Execution and Data Acceleration

- **Rapid FIH transition:** Facilitated an immediate shift to clinical dosing upon IND clearance through pre-validated operational readiness.
- **Synchronized clinical conduct:** Orchestrated a high-precision workflow aligning screening, dosing, and bioanalytical analysis for maximum throughput.
- **Data-driven milestone progression:** Expedited PK and safety data reporting to enable rapid, collaborative decision-making for dose-escalation and formulation optimization.

The Results: IND Submission Readiness Achieved ~Six Months Earlier Than Projected

With the Altasciences 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**

The **Acceleration Platform** 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, including CRO services, 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.



HOW ALTASCIENCES CAN HELP

Working with integrated early-phase drug development services at Altasciences can save you significant time by reducing handoffs, running activities in parallel whenever feasible, and having a single team accountable for the first phases of the development program. Integrated services do more than make individual activities faster; they compress the entire timeline by removing white space and coordination bottlenecks and allowing interdependent work to move together.

For sponsors, the practical benefit is greater continuity and control: one connected development ecosystem can reduce vendor interfaces and duplicated oversight while maintaining transparent governance and flexible service delivery. The value comes from shared context and timely decisions, not from the number of services offered under one roof.

The Altasciences Acceleration Platform is at the core of an early-phase solution framework for delivering rapid, reliable data to clients. We are able to synchronize integrated operations with scientific alignment, propelling the sponsor to critical clinical insights months ahead of conventional industry timelines.

RELATED RESOURCES

The Altascientist

Navigating the IND Submission Process

Planning Your First-in-Human Trial

Building Your Early Phase Clinical Data, From Protocol to Regulatory Submission

eBooks

Project Management—Where Science, Strategy, and Operations Converge

Regulatory Edge: Smart Solutions for Drug Development

Altasciences Acceleration Platform: Faster by Design

Clinical Trials Without Boundaries: Multi-Site Solutions at Altasciences

Fact Sheet

Integrated CRO Services

Webinars

Collaborative Innovation: The Role of CROs and CDMOs In Shaping the Future of Drug Development

The Benefits of Conducting a Clinical Trial in Canada

The Path Forward—Altasciences' Approach to Project Management

Demystifying the Conduct of Clinical Trials in Canada

Services and Solutions

Comprehensive CRO Services

Clinical Trial Site Identification and Selection

Data Management

Scientific Guidance and Regulatory Affairs

Program and Project Management

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 leading 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, Altasciences helps clients reach critical milestones faster.

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