accelagen

The Smart **Launchpad**

A guide to designing global-ready clinical pathways from Australia

In early-phase clinical development, the biggest risk is not moving too slowly — it is **making decisions that do not hold up globally.**

Empirical data from a survey of more than 400 pharmaceutical, biotechnology and contract research organizations (CROs) showed that the overall study start-up process averages five to six months, with CROs completing site-related activities only six to eleven weeks faster than sponsors [1]. While claims of four-to-six-week study start-ups remain prevalent, accelerated timelines built on unvalidated assumptions can introduce regulatory friction. As global regulatory pathways continue to evolve, speed alone is no longer a viable differentiator without strategic foresight.

The industry baseline

Industry survey

400+

Pharmaceutical | Biotechnology | CROs

Organizations surveyed across the industry

Market average

5–6 months

0 12

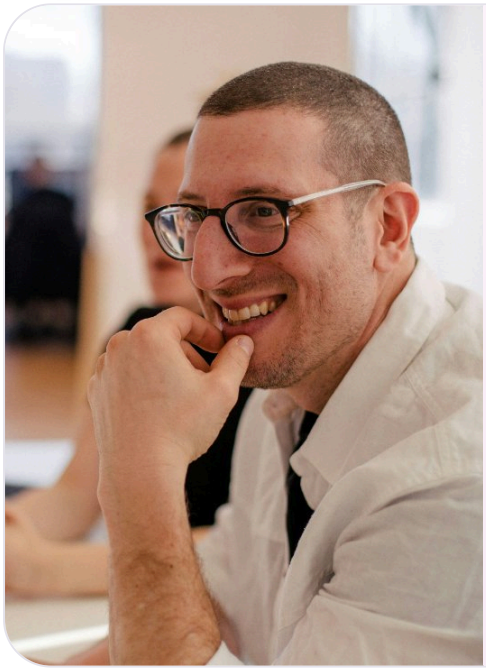
Average study start-up, from identification to activation

The outsourcing gap

6–11 weeks

0 12

Faster completion by CROs compared with sponsors



> At Accelagen, we champion an alternative philosophy: **predictable progress.**

At Accelagen, we champion an alternative philosophy: predictable progress. Predictable progress involves realistic, grounded planning and evaluating every project with the end in mind. The most successful clinical programs are those that align early clinical design with the final expectations of major international regulators, such as the U.S Food and Drug Administration (FDA) and the European Medicines Agency (EMA). By designing global-ready pathways from day one, sponsors can ensure that downstream delays and rework are minimized, preserving cash runway and translating early clinical milestones into lasting commercial value.

This guide outlines a blueprint for achieving predictable progress in early-phase development. It will explore how to apply reverse journey mapping, leverage Australia as a strategic enabler and build an accountable delivery model that helps turn the first clinical steps into lasting regulatory success.

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Section 1

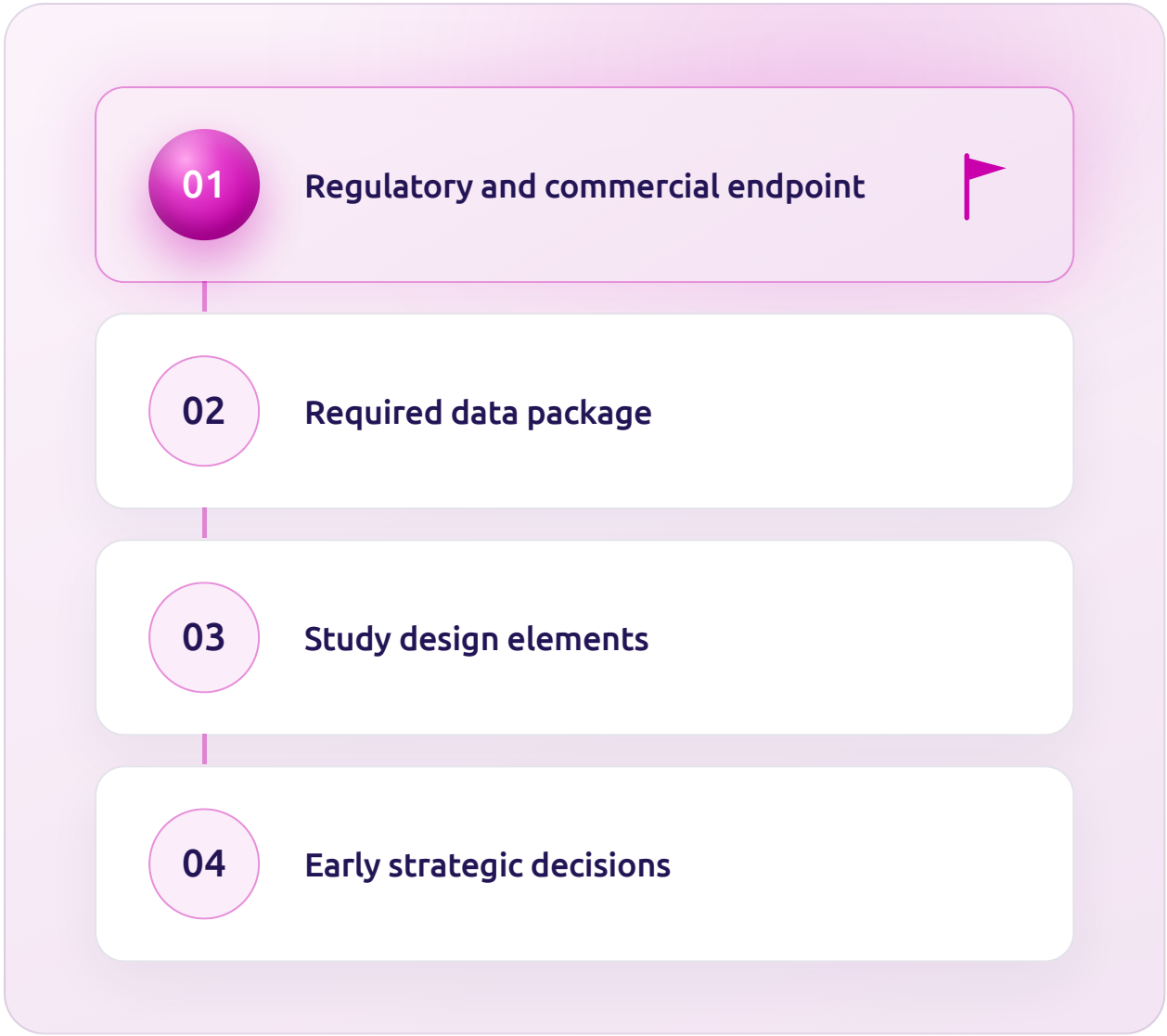
Designing for the **destination**

Aligning early clinical steps to global regulatory expectations.

Early-phase trials cannot be treated as isolated activities. To ensure a program is truly global-ready, decisions made at the very beginning must be linked to the desired commercial and regulatory endpoint.

The concept of 'reverse journey mapping'

A reverse journey mapping methodology, starting with the end in mind, can be used to guide early strategic decisions. Applying reverse journey mapping means asking what the program is trying to achieve and rigorously testing whether the pathway leads in that direction.



In practice, sponsors should start by defining their product and with it, the foreseen clinical program's ultimate vision before any operational steps are finalized. Key considerations include the specific target patient population, the intended method of product delivery in a real-world setting and the specific claims that will be made about the product. Gaining clarity on these factors allows sponsors to define the precise problem the therapy is aiming to solve and aligning the commercial and therapeutic claims with the final destination.

Securing this foundational information enables sponsors to reverse-engineer the specific developmental steps required. This approach empowers clinical strategists to objectively evaluate whether a proposed pathway will yield the required regulatory and commercial outcomes.

The role of the Target Product Profile (TPP)

A core component of reverse pathway mapping is a clear, rigorously defined Target Product Profile (TPP). Rather than treating the TPP as a static background document, development teams should actively use it to align the clinical strategy with short, medium and long-term objectives from day one. A robust TPP acts as the structural baseline for the program, allowing actions to remain aligned with the defined commercial and regulatory objectives.

When correctly implemented, the TPP serves several critical functions in early-stage design, including:

Defining the regulatory endpoint:
The TPP clarifies overarching goals, aligning early clinical steps to support the final data package required for global submission.

Synchronizing clinical and commercial timelines:
An asset's objectives span short-term funding milestones and long-term commercialization. The TPP calibrates study design elements with specific value-inflection points to prevent wasted capital or effort.

Enabling strategic adaptation:
Clinical targets inevitably evolve. The TPP provides a structured framework that adjusts to new trial data or shifting regulatory guidelines without losing sight of the final destination.

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Section 2

Mitigating risk early: The high cost of **ambiguity**

Anticipating downstream friction to protect momentum and capital.

The pitfall: The trap of unvalidated assumptions

Ambiguity in early-phase clinical design can be a costly liability. A common trap is designing a program without a clear goal or making the outcomes so complicated that it fails to define how the study measures success. Similarly, applying outdated clinical study designs that fail to reflect current regulatory guidelines can severely impact a program's applicability for future submissions.

The commercial cost of regulatory friction

The commercial and operational consequences of these foundational oversights can be far-reaching. When clinical endpoints are overly complex, they can yield data that regulators struggle to interpret and interrogate. This lack of clarity creates friction during the review process, triggering extensive queries and prolonged evaluation cycles that delay the study start.

Engineering vulnerabilities out of the journey

Multidisciplinary interrogation helps verify that proposed endpoints are:

- Commercially viable
- Aligned with current global regulatory standards
- Capable of generating robust, unambiguous data that will withstand rigorous international review

Where initiating a new clinical program is delayed by extended review periods, this can stall momentum and potentially challenge investor confidence. In international programs, regulatory pushback in one jurisdiction must be communicated to other authorities, which can complicate parallel trial activities. A misalignment between early design and current global expectations often means unplanned, supplementary studies. For an investor-backed biotech, this level of rework places unnecessary pressure on cash runways, complicates subsequent funding milestones and impacts the asset's broader commercial trajectory.

Engineering vulnerabilities out of the journey

Mitigating the potentially high cost of ambiguity requires rigorous, cross-functional scrutiny. By involving distinct functional experts during the initial program review stage, development teams can proactively identify key risks and structural challenges in the study design. This multidisciplinary interrogation helps verify that the proposed endpoints are commercially viable, actively aligned with current global regulatory standards and capable of generating robust, unambiguous data that will withstand rigorous international review.

> “Protecting investor capital and ensuring predictable progress requires engineering vulnerabilities out of the pathway before they materialize”

Transitioning from early design to active execution, this foundational clarity is what makes a highly accountable, realistic timeline possible. Moving forward, achieving clinical milestones requires an operational model built entirely on predictable progress.

3

Section 3

The mechanics of **predictable progress**

Building realistic timelines grounded in the active clinical landscape.

To develop a global-ready clinical pathway effectively, sponsors must apply rigorous early-phase design and operational execution that is entirely grounded in reality. While the industry frequently prioritizes speed, accelerated timelines built on unvalidated assumptions often struggle during real-world clinical execution. True acceleration is achieved through predictable progress and a systematic approach that prioritizes operational precision and realistic pacing over optimistic acceleration.

Grounded planning over unvalidated assumptions

To build clinical timelines that hold up in practice, planning must account for the complexities of the active clinical landscape. Standard, templated enrollment projections are a common point of failure. Instead, robust timeline construction requires evaluating the real-world variables that directly impact study execution, including:

The current therapeutic landscape:

Thoroughly assessing the current standard of care and existing treatments to understand the baseline clinical environment.

Competing clinical trials:

Mapping concurrent studies targeting the same patient cohorts to gauge recruitment viability.

Geographical patient distribution:

Evaluating the true reach of patients and physicians beyond major metropolitan centers, ensuring real demographic data drives site selection rather than operational convenience.

Study attractiveness:

Gauging the trial's appeal to patients and physicians to ensure it is engaging and practically feasible.

By anchoring early projections in these landscape realities, development teams can successfully build on validated assumptions. The result is a highly viable recruitment strategy and operational timelines that reflect actual, real-world clinical capacity.

Partnerships to help set the right pace

For many sponsors, translating early-phase clinical strategy into reality means partnering with a CRO. However, achieving predictable progress also requires a move away from a transactional vendor dynamic toward a true partnership model.

A genuine clinical development partner is deeply invested in a sponsor's long-term outcomes and will never commit to an implausible deliverable simply to win a new project. When study teams prioritize aggressive, artificial deadlines over dependable progress, they introduce systemic risk. Missed milestones trigger compounding delays, resource strain and a rapid erosion of trust in the partnership.

Operating with foresight means setting the right pace from the outset, with a delivery model that is engineered to prioritize steady, uninterrupted advancement. This helps ensure that every milestone achieved is robust, fully compliant and capable of supporting the next phase of development without requiring corrective rework.

Institutional oversight and risk mitigation

Maintaining predictable progress throughout the clinical pathway requires structured governance, continuous monitoring and proactive risk management. This requires senior leadership to maintain comprehensive oversight of all project statuses and key performance metrics, and work in unison to manage risk at the project level. Embedding this oversight into the ongoing trial management helps ensure that execution is constantly measured against the original strategy.

By recognizing the earliest signs of operational strain and addressing these deviations immediately, the trial maintains its momentum without accumulating risk.

The Accelagen approach: Active senior accountability

True partnership means taking absolute responsibility for the final clinical outcome, rather than simply fulfilling a checklist of tasks, which is why our senior leadership team takes an active, structured role in the ongoing oversight of every clinical program.

Through formal, systematic reviews of real-time operational metrics, we continuously interrogate project data against the baseline strategy. This direct line of sight ensures that potential friction points are identified and decisively resolved before they compound into timeline delays.

Sponsors retain direct access to senior decision-makers who are deeply invested in their success. This translates into faster issue resolution, superior strategic decision-making under pressure and the delivery of predictable progress.

The result: Transparency and confidence

An operational model built on predictable progress fundamentally changes the dynamic of clinical execution. When biotech leadership can clearly see, review and interrogate all aspects of the delivery model and the data driving it, the process inherently builds both transparency and confidence.

By grounding timelines in reality and actively managing risks, and providing senior governance, sponsors can be more confident that their capital is being deployed efficiently and effectively. Predictability in early-phase execution removes operational noise, allowing the asset's true clinical value to take center stage as the program moves toward global markets.

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Section 4

The smart use of **Australia**

Generating globally credible data from a strategic launchpad.

While early-phase design and predictable execution are critical, the geography of the jurisdiction plays an equally vital role. Australia has established itself as a premier location for early-phase clinical trials. However, its true strategic value extends far beyond the commonly cited benefits of rapid start-up timelines and financial incentives. For biotechs prioritizing global regulatory success, Australia is best used as a strategic enabler for rapid, high-quality data generation that aligns into a comprehensive global pathway.

Global credibility: Engineering data for the FDA and EMA

One of the key advantages of executing early-phase trials in Australia is the quality and global acceptability of the data generated. Australia has strategically aligned its regulations with strict international standards and guidelines, including the FDA, the EMA and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This deliberate regulatory alignment minimizes divergence in clinical outcomes between Australia and other key regulated jurisdictions.

Australia's diverse population demographics allow trial sponsors to evaluate new products across a wide range of ethnicities within a single program, fulfilling critical diversity requirements for regulators without needing to engineer this into the study design.

> "For early momentum to translate into late-stage success, operational execution must hold up to the highest level of international scrutiny."

Recognizing the rigorous standards set by major regulators requires designing clinical processes, systems and specifications must be designed to adhere to FDA and EMA requirements from the very outset. Applying these requirements early maximizes data quality and supports international acceptance.

Calibrating expectations by understanding the regulatory threshold

Understanding where the jurisdiction's strategic advantage begins and ends is key to conducting trials in Australia. By design, the Australian regulatory system provides a robust and pragmatic framework that moves development steps forward quickly. A common and challenging misconception is interpreting this pragmatism as a "lower bar" to cross to enter human studies, or assuming it permits lower standards of data generation.

When sponsors omit important foundational studies from their development program to save costs or accelerate timelines, reviewing authorities will inevitably identify these gaps. Taking shortcuts early directly leads to prolonged requests for additional information and increases the risk of a negative regulatory outcome downstream. Instead, using Australia's framework develops a defensible data package that comprehensively supports the safety and efficacy considerations necessary for high-quality initial data generation.

Strategic enabler vs. the whole strategy

Recognizing the difference between a strategic launchpad and a final destination is important when developing a clinical pathway. As programs progress into later clinical phases, the requirement for sheer patient volume naturally scales beyond the capacity of any single mid-sized market.

The smart launchpad

Engineering global readiness from your first stride.

1

Rapid clinical activation

Initiating early-phase execution in Australia to establish a robust proof of concept

2

Generating global-ready data

Capturing and structuring clinical evidence designed for immediate FDA and EMA evaluation.

3

Scaling to international markets

Expanding your program through a comprehensive pathway for late-stage global development.

Rather than treating this as a regional limitation, it should be recognized as a natural inflection point in the asset's lifecycle. Complex, late-stage pivotal trials inherently require the alignment of broader international infrastructure to achieve the necessary global scale. Australia is most effectively positioned as a highly strategic enabler — a jurisdiction that can rapidly initiate human studies and generate globally recognized proof-of-concept data, while serving as a powerful launchpad to a cohesive, worldwide development strategy.

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Section 5

CRO partnership and **accountability**

Delivering senior-led oversight and uncompromised continuity.

In early-phase clinical development, the choice of CRO often dictates the trajectory of the entire program. As the clinical research landscape continues to scale, the traditional sponsor-vendor dynamic can shift toward a standardized, transactional model. In these environments, a structural distance emerges between the senior leaders who design the strategy and the operational teams executing the trial. While this model may deliver baseline compliance, it introduces subtle operational risks. Without deep, shared accountability, critical strategic nuances can be lost in translation and early warning signs overlooked.

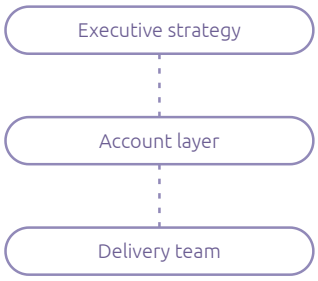
Achieving predictable progress requires a fundamental shift from a transactional service model to a true strategic partnership. It requires a clinical partner that is deeply invested in the outcome, rather than simply fulfilling a checklist of contracted deliverables.

Senior-led accountability

At Accelagen, this strategic partnership is structurally engineered into the delivery model. Unlike traditional structures where executive leadership is separated from active trial management, senior management does not separate itself fully from daily clinical operations. By dissolving the layers between executive oversight and ground-level execution, the program benefits from continuous, high-level scrutiny.

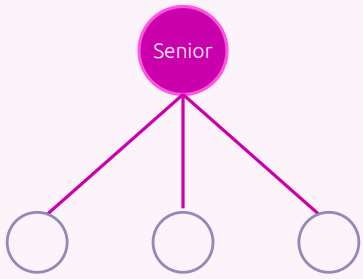
The traditional model

Layers of structural distance separate the senior leaders who design the strategy from the operational teams executing the trial.



Accelagen's strategic partnership

Senior management does not separate itself from daily clinical operations, dissolving the layers between executive oversight and ground-level execution.



Direct line to delivery

This aligned collaborative structure provides several distinct operational advantages, including:

- **Real-time operational troubleshooting:**
  Senior leaders work directly alongside project management teams to actively interrogate day-to-day clinical outcomes and resolve operational friction before it compounds.

- **Strict commercial alignment:**
  Continuous executive oversight helps ensure that granular project details remain aligned with the sponsor's overarching corporate strategies and long-term milestones.

- **Unfiltered strategic access:**
  Sponsors maintain direct lines of communication with senior decision-makers who are genuinely invested in the program's success.

This operational commitment to taking responsibility for outcomes results in faster issue resolution, highly responsive risk management and superior strategic decision-making under pressure.

Aligning clinical design with commercial value

The tangible impact of senior-led oversight is best demonstrated when early strategic intervention prevents costly downstream errors.

THE PROBLEM

During the initial evaluation of a mid-stage US biotech program, Accelagen's leadership identified that the originally proposed Phase 2 pathway would not generate the evidence necessary to support their intended commercial claims.

THE SOLUTION

Accelagen facilitated a strategic workshop to bridge this gap, instead of simply executing the unfavourable study design. This collaborative process resulted in a complete protocol redesign.

THE RESULT

The updated pathway ensured the data supported IND advancement while securing additional, high-value regulatory designations.

By acting as a strategic partner rather than a transactional vendor, Accelagen prevented a massive capital investment into data that would have otherwise yielded zero commercial value.

The proof is in the end product

Designing a global-ready clinical pathway requires navigating complex regulatory environments and executing with operational discipline. Australia offers a uniquely powerful launchpad for this journey, but only when leveraged with strategic precision.

Australia provides an exceptional, globally recognized environment for early-phase validation. To maximize this advantage, Australia should be viewed as a strategic enabler for rapid, high-quality data generation. Building this defensible clinical foundation locally generates early momentum, supporting a smooth transition into the broader international infrastructure required for complex, late-stage global success.

The most significant risk in early clinical development is making foundational decisions that fail to hold up to global regulatory scrutiny. Protecting assets requires moving past generic, purely speed-driven metrics and partnering with an organization that values predictable progress over optimistic acceleration.

Accelagen provides a highly accountable delivery model built fundamentally on quality, reliability and enduring commitment to commercial success.

We can actively guide your first clinical steps toward lasting global success. Contact our team to discuss your clinical pathway and build a global-ready program from day one.

Enduring partnership. **Predictable progress.** Built for your ascent.

Contact our team

- **Reference(s)**

1. Lamberti, M. J., Wilkinson, M., Harper, B., Morgan, C., & Getz, K. (2018). Assessing Study Start-up Practices, Performance, and Perceptions Among Sponsors and Contract Research Organizations. Therapeutic Innovation & Regulatory Science, 52(5), 572–578.