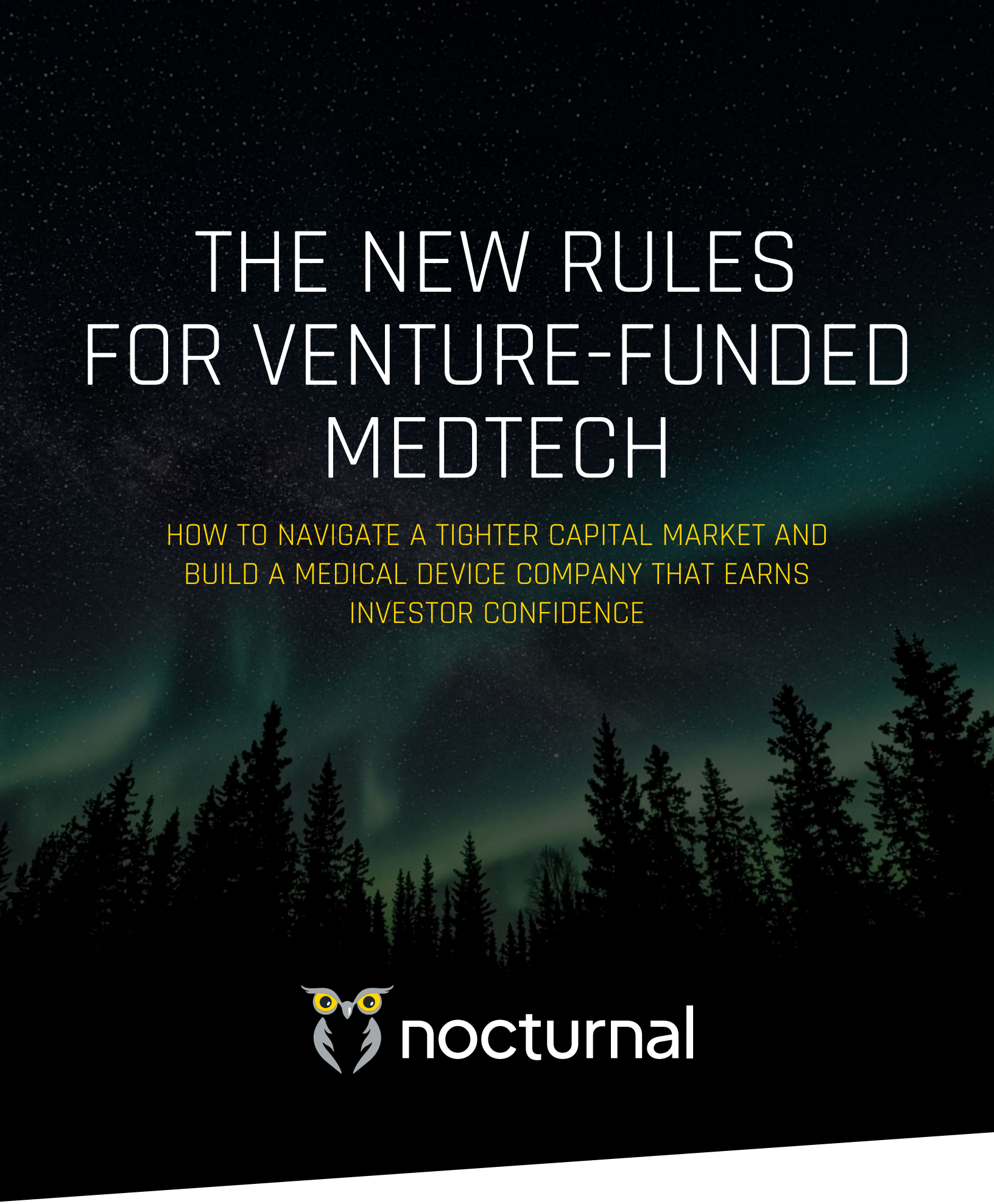
THE NEW RULES FOR VENTURE-FUNDED MEDTECH

HOW TO NAVIGATE A TIGHTER CAPITAL MARKET AND BUILD A MEDICAL DEVICE COMPANY THAT EARNS INVESTOR CONFIDENCE



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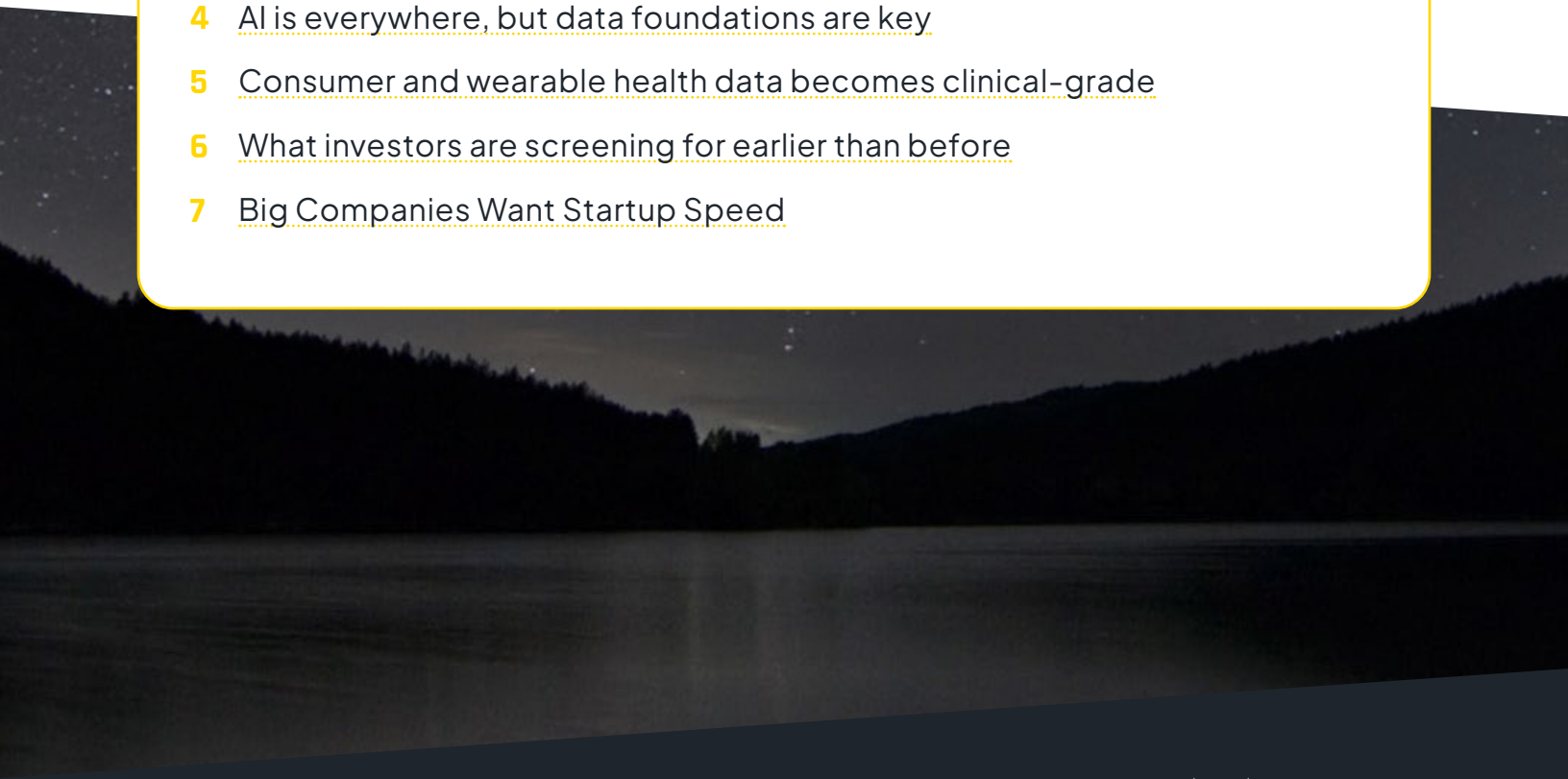
WHAT CHANGED IN MEDTECH FUNDING?

The rules for raising capital in MedTech are shifting. Investors are still committed to the market, but they have become more selective.

They're writing fewer checks, asking harder questions earlier, and expecting founders to arrive with answers that used to come two rounds later.

This guide breaks down seven realities shaping the current funding environment, and the operating principles that help founders navigate them.

IN THE FOLLOWING SECTIONS, WE WILL EXPLORE SEVEN REALITIES RESHAPING HOW MEDTECH STARTUPS RAISE CAPITAL.



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REALITY #1

RISK AVOIDANCE DRIVES A NARROWING MARKET

The numbers for MedTech venture funding over the past five years tell a nuanced yet clear story.

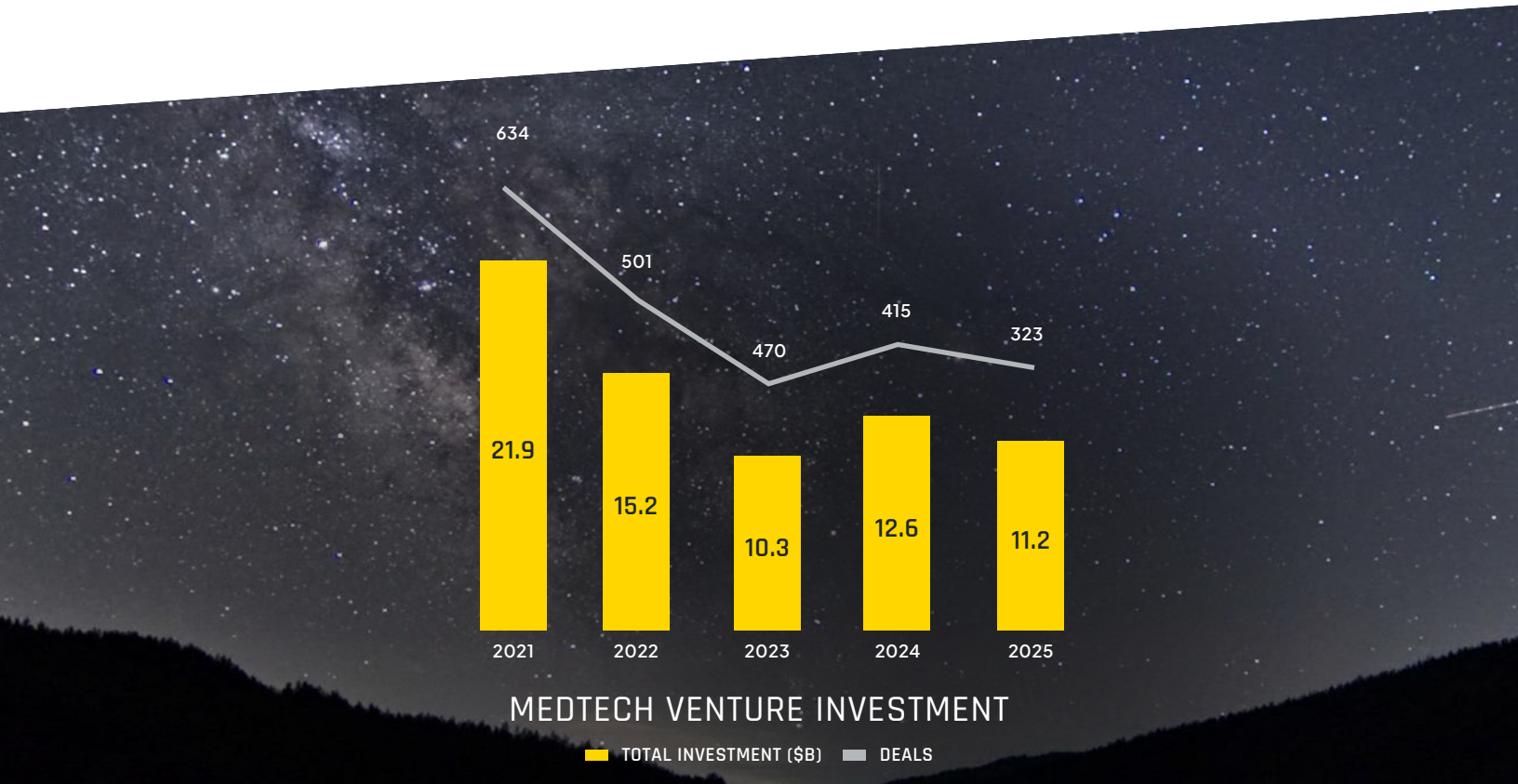
According to **J.P. Morgan's MedTech Report,** total venture funding for 2025 held steady at $11.3B, roughly in line with the prior two years.

While dollar volume stayed flat, deal count fell fast. The number of companies that secured investment dropped to **just 323 rounds, a new five-year low.**

Capital isn't shrinking, but access to it is increasingly limited to fewer startups.

The signal from investors is unmistakable:

They can live with the inherent uncertainty of MedTech, **but they have little tolerance for risk that disciplined execution can prevent.**



Source: J.P. Morgan's MedTech Report

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REALITY #2

EARLY ROUNDS LAND FEWER BETS, HIGHER COMMITMENT

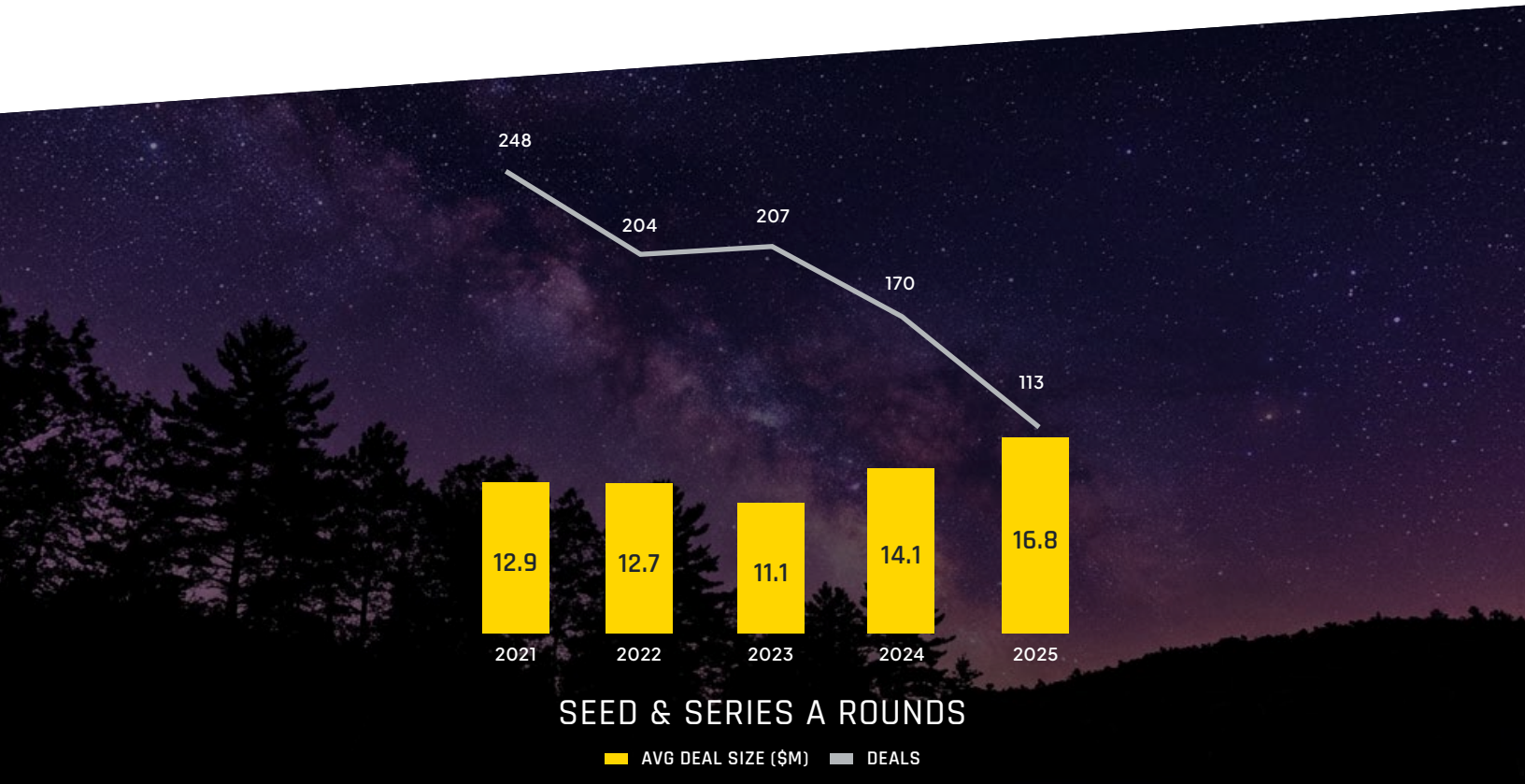
Nowhere is the narrowing of the market more evident than in early investment rounds.

In 2025, Seed and Series A companies raised **$1.9B across 113 rounds**. Investment dollars in these early rounds were down twenty percent from 2024 levels, and the lowest registered in the past five years.

The bigger story emerges when you look at deal count, which dropped significantly compared to prior years. This is a marked acceleration of a trend we have been observing over the past five years.

At the same time, **average early-stage deal sizes increased**, reaching their highest levels of the past several years. Investors are making fewer bets, but committing more capital when they do.

Taken together, these two trends show that early stage investment is no longer about proving an idea is interesting. **It's about proving it's buildable, regulatable, and worth scaling.**



Source: J.P. Morgan's MedTech Report

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REALITY #3

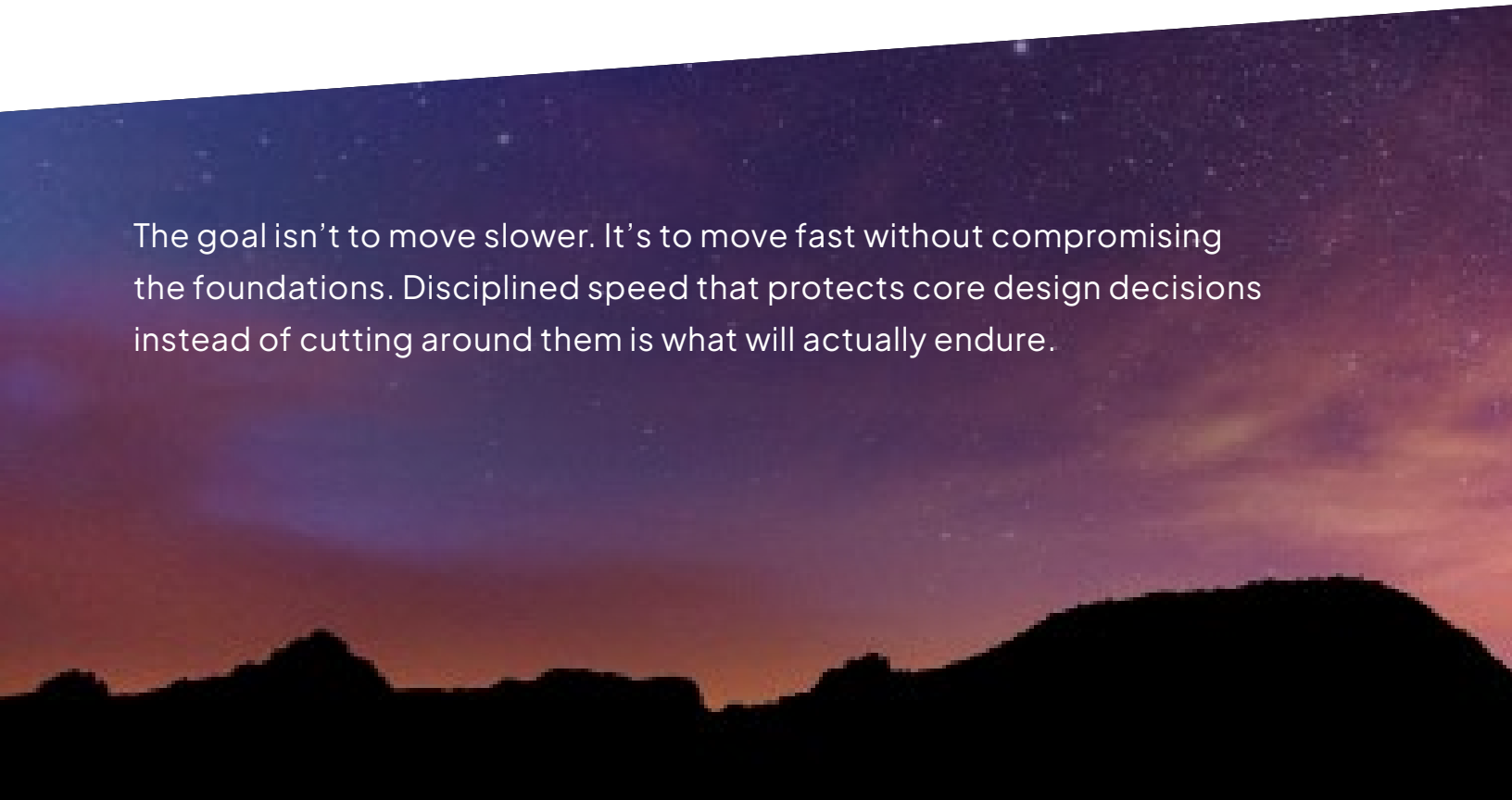
SPEED STILL MATTERS

Speed has always mattered in MedTech. But speed built on weak foundations is fragile. And fragile speed doesn't survive contact with regulators, clinical data, or scaling.

As devices become more connected, more data-driven, and more reliant on AI, shortcuts taken early tend to resurface later—usually at the worst possible moment.

Recent FDA updates have made expectations clearer for connected devices and software-heavy products — especially around quality systems, traceability, and cybersecurity documentation.If your device collects data, connects to other systems, or supports clinical workflows, weak foundations will become a regulatory stumbling block in design reviews, premarket submissions, and quality audits.

Secure data pipelines, traceable system architecture, and disciplined documentation are no longer back-office concerns—they are foundational to regulatory durability from day one.



The goal isn't to move slower. It's to move fast without compromising the foundations. Disciplined speed that protects core design decisions instead of cutting around them is what will actually endure.

REALITY #4

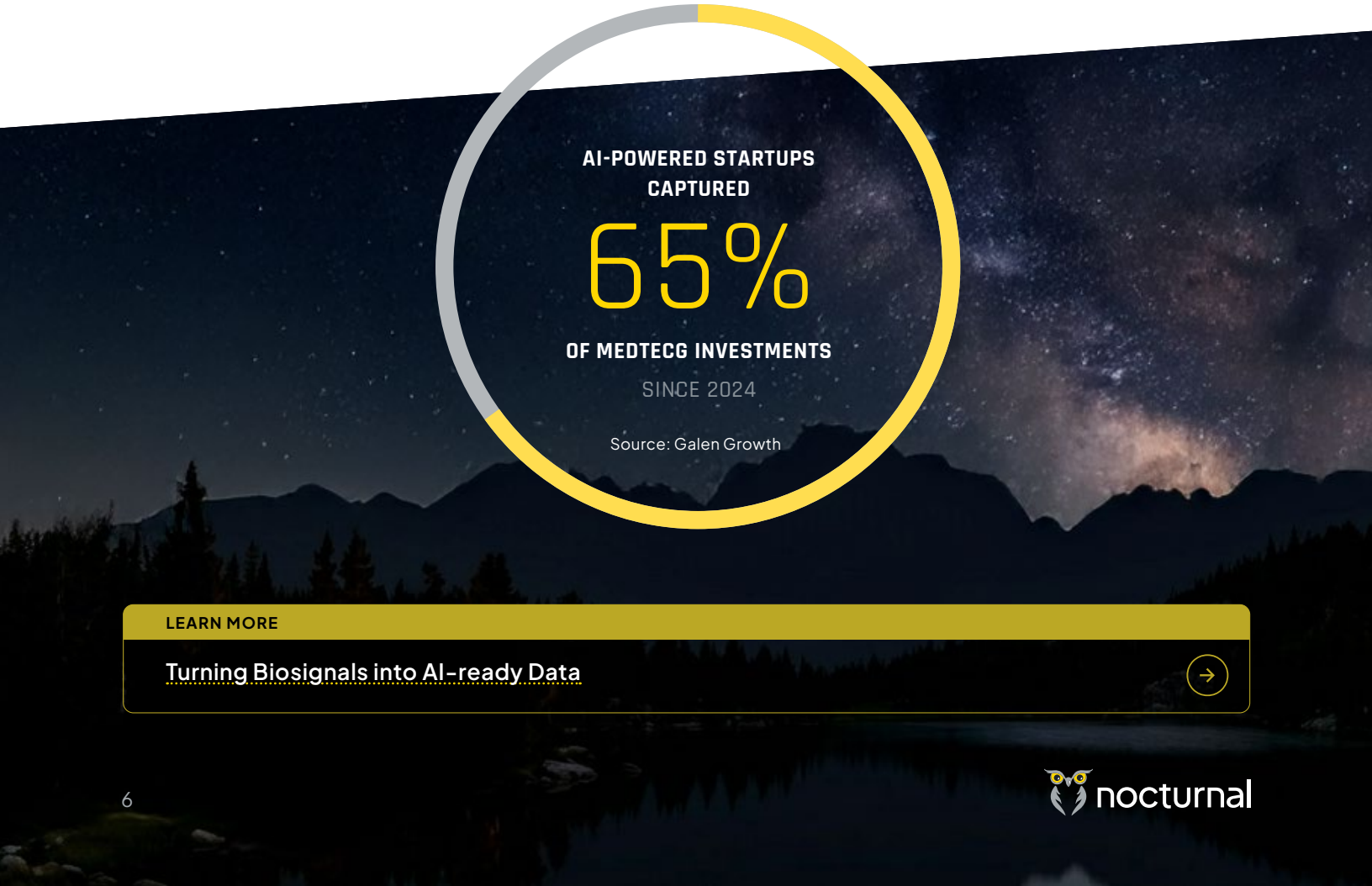
AI IS EVERYWHERE, BUT DATA FOUNDATIONS ARE KEY

Investment in AI-related medical device startups has skyrocketed in the past two years, with no signs of slowing down.

The ability to collect patient data continuously in real-world settings has unlocked new possibilities for AI-powered diagnostics, personalized treatment, and predictive care at scale.

While data is the key to unlocking AI potential, it is also the gating factor to AI success. It's important to recognize that the future of AI-driven healthcare depends on **smarter, more relevant, and more efficient clinical data, rather than simply more data** signals.

In our survey of medical device innovators, 40% of the respondents cited clinical data collection as a bottleneck they would like to accelerate. This shouldn't come as a surprise. Clean signal acquisition, traceable pipelines, and design controls that anticipate future claims are critical foundations for AI-driven solutions.



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Turning Biosignals into AI-ready Data

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REALITY #5

CONSUMER AND WEARABLE HEALTH DATA BECOMES CLINICAL-GRADE

Consumer wearables are becoming more capable. What began as activity tracking and lifestyle insights is evolving into longitudinal, multi-signal datasets that can support triage, remote monitoring, and even reimbursable care pathways.

This shift is driven by advances in sensors and data fusion. Heart rate, ECG, SpO_2, motion, temperature, and behavioral context are no longer viewed in isolation. When combined over time, these signals can produce clinically meaningful insights.

Late-2025 FDA guidance on **the use of real-world evidence to support regulatory decision-making for medical devices** further clarified how wearable data may contribute to regulatory submissions. The agency also signaled flexibility in certain data requirements, lowering practical barriers for some device developers.

While these developments are encouraging, they have also created a misconception: that the boundary between consumer-grade and regulated medical devices has blurred beyond relevance.

In reality, the distinction remains binary. There is no "almost medical." A product is either a regulated medical device — with validated claims, documented risk controls, and regulatory oversight — or it is not.

Many founders underestimate the gap between collecting signals and generating defensible clinical evidence. Clinical defensibility depends on both relevance (the data captures the right outcomes in the right populations) and reliability (the data is accurate, consistent, and traceable).

That materially raises the bar. Clinical-grade wearables must demonstrate signal integrity, operational robustness, algorithm transparency, and reproducible validation — and investors are increasingly screening for these foundations early.

LEARN MORE

From biosignals to clinical insights – how to derisk and accelerate your path to market

REALITY #6

WHAT INVESTORS ARE SCREENING FOR EARLIER THAN BEFORE

By 2026, early-stage diligence looks less like a pitch review and more like a risk audit.

Here's what many investors are effectively screening for—often before they say yes to a first meeting.

Regulatory credibility

- A realistic pathway and rationale
- Early alignment between indications, claims, and evidence
- No major unanswered regulatory questions parked for "later"

Technical readiness

- System architecture that can evolve without major rework
- Clear tradeoffs across power, size, performance, and cost
- Evidence the design can survive verification and validation

Manufacturability awareness

- Prototypes that can transition to pilot and low-volume builds
- Early understanding of NRE, tooling, and supply chain risk
- Clear visibility into scalability beyond early builds

Data quality

- Data that is structured, traceable, and usable
- Early signals that future clinical, AI, or commercial claims will hold up

Reimbursement strategy

- Understanding of economic buyer
- Alignment between cost and reimbursement economics
- Existing CPT/DRG code, or a credible strategy to obtain one (a higher risk proposition, but possibly with a higher reward)

Capital efficiency

- A plan that preserves runway while increasing certainty
- Spend focused on proof points that increase valuation
- Milestones tied to risk reduction, not calendar time

> **None of these are new concepts. What's changed is how early investors expect these risks to be already understood and planned for at the Seed or Series A stage.**

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Why investors say No →

REALITY #7

BIG COMPANIES WANT STARTUP SPEED

Startup-style operating discipline is no longer just for startups. It is becoming a competitive advantage across the MedTech spectrum.

In a tightening capital environment — even inside large MedTech companies — disciplined execution is becoming an operational necessity. Budgets are scrutinized more closely, and internal projects compete harder for resources. Leadership expects clearer proof points before committing incremental capital.

The challenge is not a lack of capability. Large organizations have deep technical expertise, regulatory infrastructure, and manufacturing scale. What they often struggle to preserve is agility. When new initiatives enter complex corporate structures, decision cycles lengthen, scope expands, and risk accumulates instead of being systematically reduced.

As a result, innovation leaders inside larger companies are increasingly seeking startup-style discipline: clearly defined milestones, tight scope control, focused technical proof, and measurable risk reduction at each stage.

The goal is not simply to move faster. It is to create accountability around progress — linking investment to tangible de-risking events rather than calendar timelines. Structured, milestone-driven execution provides that transparency. It allows teams to advance strategically, pivot deliberately, or stop early when data dictates.

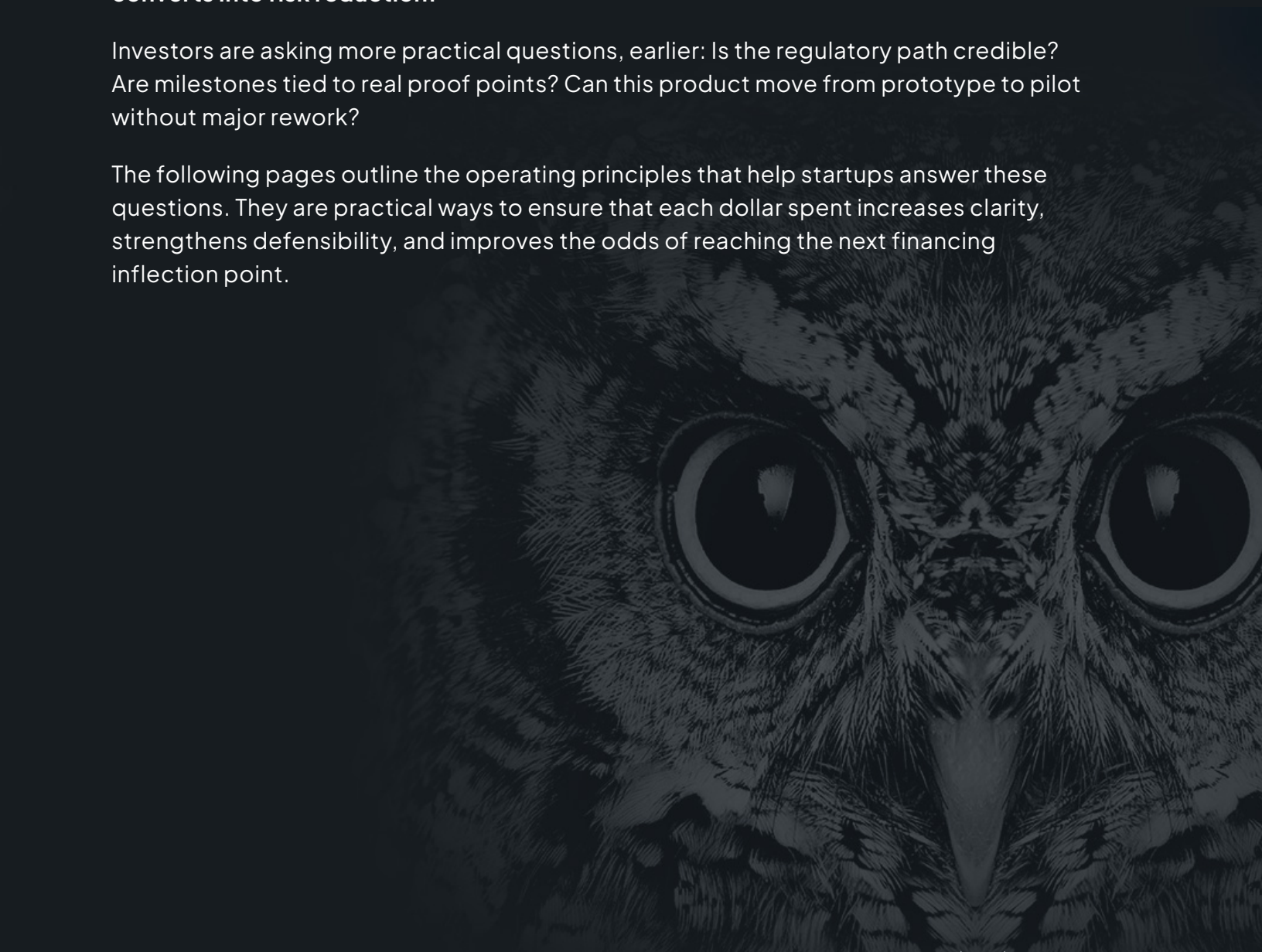
THE 2026 MANDATE FOR FOUNDERS: PRIORITIZE CAPITAL EFFICIENCY AND RISK REDUCTION

The funding data tells a clear story about investor tolerance for risk. In this environment, capital is no longer a runway to "figure it out." It is expected to produce measurable reductions in uncertainty.

The mandate is straightforward: structure your program so that capital systematically converts into risk reduction.

Investors are asking more practical questions, earlier: Is the regulatory path credible? Are milestones tied to real proof points? Can this product move from prototype to pilot without major rework?

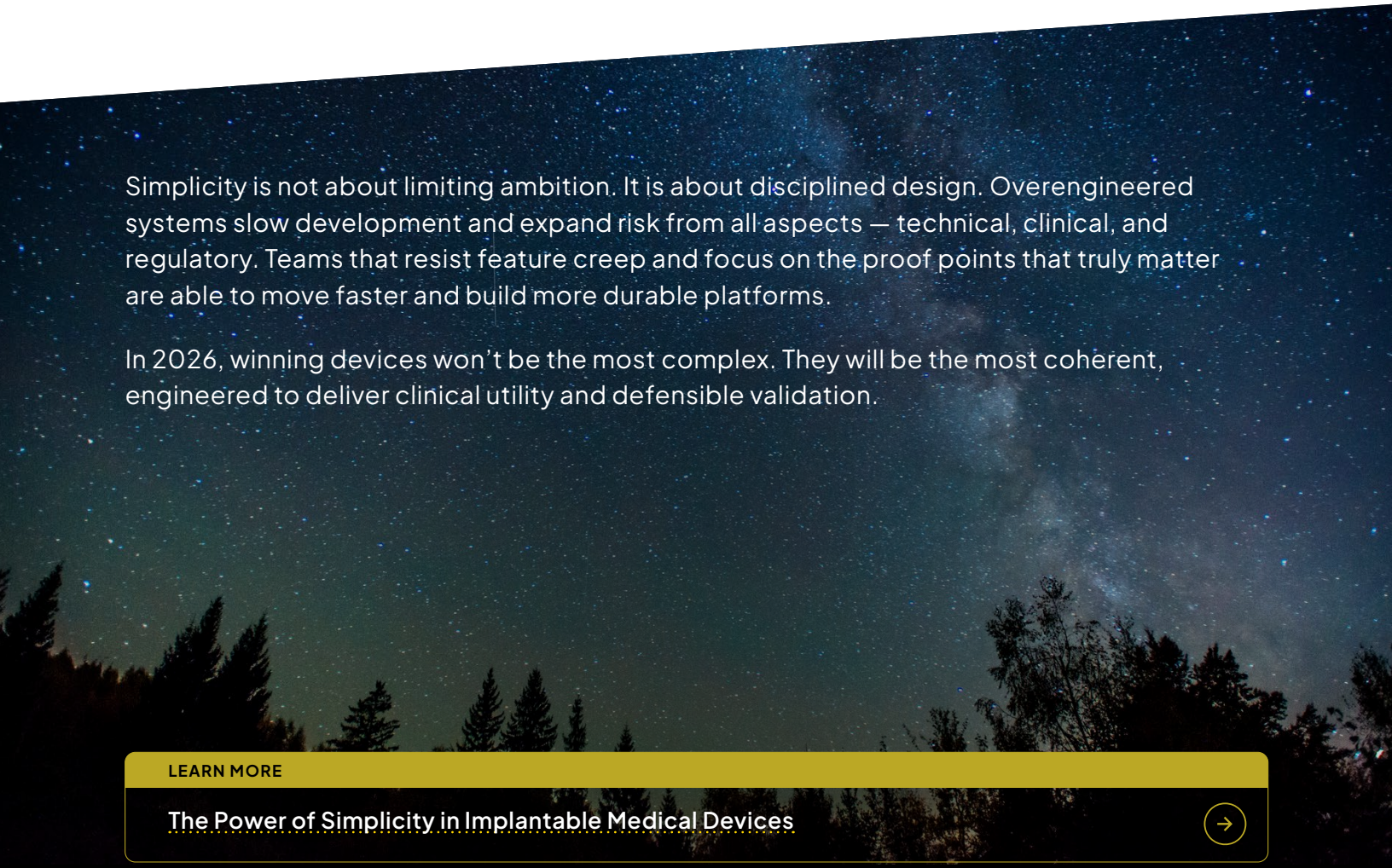
The following pages outline the operating principles that help startups answer these questions. They are practical ways to ensure that each dollar spent increases clarity, strengthens defensibility, and improves the odds of reaching the next financing inflection point.



SIMPLICITY AS A COMPETITIVE ADVANTAGE

In medical devices — whether implantables, wearables, or connected biosensor platforms — complexity is often mistaken for progress. More features, more signals, more dashboards, more AI layers. But every added component increases power demands, validation scope, integration risk, and regulatory burden.

In constrained systems, complexity compounds quickly. Low-power implantables and wearables must balance battery life against signal fidelity. Biosensors must maintain reliability over time across diverse environments. AI models and data layers must be secured, clean from bias, and monitored.



Simplicity is not about limiting ambition. It is about disciplined design. Overengineered systems slow development and expand risk from all aspects — technical, clinical, and regulatory. Teams that resist feature creep and focus on the proof points that truly matter are able to move faster and build more durable platforms.

In 2026, winning devices won't be the most complex. They will be the most coherent, engineered to deliver clinical utility and defensible validation.

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The Power of Simplicity in Implantable Medical Devices

KEEP YOUR EYE ON THE NEXT MILESTONE

Investors are not funding your roadmap. They are funding your next proof point.

Running out of funds before reaching a market-ready product is a common pitfall for medical device companies. It's crucial to prioritize and focus on the essentials of what the company needs to prove at each stage in order to raise additional capital.

Clear sequencing heading into 2026 means aligning technical decisions directly with financing inflection points:

- **POC validates feasibility.**
- **V1 generates defensible clinical evidence.**
- **V2 optimizes for market scale.**

When new ideas or feature requests arise, carefully consider what goals they support and where you are in the product development cycle. In most cases, you'd be better off putting these requests on the list of considerations for a future version rather than disrupting the timeline for the current version.

Working with a partner on a fixed price for predetermined milestones can be helpful for controlling scope drift. It makes your team clearly aware of the time and cost that out-of-scope feature requirements would add to the project. When these tradeoffs are clear, it is easier to make the right decision.

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How we manage fixed-cost projects

INNOVATE ONLY WHERE IT MATTERS

Capital efficiency requires focused innovation. The last thing investors want to see is reinventing of the wheel. That's also not where you want to burn your hard-earned investment dollars.

Medical device startups often believe their challenges are entirely unique, leading them to try to create everything from the ground up. However, originality in the wrong layer is just a misallocation of resources.

Your competitive advantage is anchored in your clinical insights, unique algorithms, and therapy differentiation. Leveraging proven product designs, manufacturing processes, regulatory strategies, and clinical trial plans can provide a strong foundation for your team to build on while saving valuable time and resources.

Often overlooked is the fact that much of the necessary know-how is transferable between different devices and medical fields. Core competencies such as system architecture, **signal acquisition**, **power management**, **embedded firmware**, and verification strategy are transferable across therapeutic areas.

Identifying where these existing technologies and expertise can be used and adapted can significantly lower the cost, time, and risk involved in product development.

> "The scalable software platform developed by Nocturnal demonstrated its capabilities for supporting our expanded product roadmap, and using off-the-shelf computational hardware has kept product costs competitive."

BRUCE FERGUSON, MD, CHIEF MEDICAL OFFICER & CO-FOUNDER, PERFUSIO

"JUST-IN-TIME" DESIGN CONTROLS

> Contrary to formal teaching, it does not always make sense to follow the full formal medical product development process right away."

KC ARMSTRONG, NOCTURNAL FOUNDER AND CEO

Formal design controls and documentation are important—but they're not always the right starting point. In the early days, your priority should be proving the product works and that there's a real market need.

In the early stages, the most urgent goal is demonstrating technical feasibility and functional value. Why? Because that's often the key that unlocks your next round of funding.

Investors don't fund documentation. They fund momentum—proof that your product solves a real problem and can be built in the real world.

Rather than sinking time and money into detailed specifications before anything is validated, consider a lighter-weight approach:

Capture user needs, key hazards, and product requirements informally

- **Build quick prototypes**
- **Test the concept**
- **Validate key assumptions**

Any medical device will absolutely need formalized design inputs, traceability, and risk management at some point. But leading with lean, fast-moving development gives you the traction you need to secure additional funding—and then scale your compliance process with additional time and resources.

LEARN MORE

How to combine speed with compliance using smart design controls

ALIGN MANUFACTURING STRATEGY WITH PRODUCT MILESTONES

Manufacturing is not a handoff. It is a strategic variable that must be aligned to each development stage.

Early-stage teams routinely underestimate how difficult it is to secure high-quality, low-volume builds for verification, validation, pre-clinical, or first-in-human studies. Contract manufacturers often decline small orders. When they don't, non-recurring engineering (NRE) fees can be disproportionate and prohibitive.

At the other end of the spectrum, startups often find themselves with a device that doesn't lend itself to cost-effective manufacturing at scale. That mistake compounds under commercial timelines and margin pressure.

Successful startups integrate manufacturing readiness into the product architecture and milestone plan from day one. They treat small-quantity builds as engineering deliverables, with proper controls, test procedures, documentation, and traceability.

They also evaluate contract manufacturers early and plan transfer to volume production as a milestone—with proven process instructions, documented testing requirements, and clearly defined acceptance criteria.

Manufacturing misalignment is expensive. In capital-constrained environments, discipline at each stage protects both timeline and valuation.

LEARN MORE

How we provide manufacturing support for early-stage MedTech teams

BUILD THE RIGHT TEAM AND KEEP IT TOGETHER

In our **MedTech startup survey**, many founders pointed to challenges in hiring and retaining skilled talent, managing payroll, and maintaining cohesive teams under financial pressure.

Cutting costs and downsizing the team can be demoralizing and lead to a loss of valuable talent. To mitigate these risks, be conservative with your early hiring decisions, only bringing on board essential personnel that you know you'll need for the long-run.

An equally important challenge mentioned in the survey is finding partners who share their standards for clarity, usability, and defensibility—trusted collaborators who can complement internal expertise and accelerate progress without compromising quality.

Outsourcing strategically provides access to specialized skills while maintaining a predictable cash burn rate. It allows early-stage companies to reach critical milestones without overcommitting. By preserving financial flexibility, you'll be better positioned to adjust the mix of in-house versus outsourced expertise as your program matures.

WHAT STARTUPS LOOK FOR IN A DEVELOPMENT PARTNER

Deep technical expertise is decidedly the top consideration for startups when engaging a development partner.

While cost efficiency is important, relevant experience, regulatory expertise, and a collaborative approach are equally top of mind for startups in their evaluation of development partners.

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NOCTURNAL: TURN UNCERTAINTY INTO CONFIDENCE

The challenges of medical device funding bring the need for better cash flow control into greater focus.

Nocturnal's Chief Business Officer Eyal Dayan hears these concerns in his conversations with clients:

> "The consistent message we hear from early-stage companies is that funding takes longer these days. The framework of a milestone-based pricing project gives them a level of confidence in meeting their critical product milestones without incurring unexpected costs and delays, so they can get to their next round of financing without running out of cash."

Medical device development is complex, and projects often take unexpected turns. It's no surprise that the concept of fixedcost, milestone-based pricing was met with skepticism. But that's where Nocturnal saw an opportunity for a more collaborative and transparent approach.

As Founder and CEO KC Armstrong explains:

> "Our business model is designed so that our success is intrinsically tied to our client's success. Unlike traditional hourly billing, where there's a risk of projects going off track and leading to increased costs and delays, our fixed-cost pricing model creates a mutual incentive for both parties to stay focused and reach milestones efficiently.
>
> Our clients are often pleasantly surprised when we deliver exactly what we promised without any additional price changes. This not only establishes a strong foundation of trust but also proves that we're as committed to the success of their project as they are."

"Working with Nocturnal has dramatically accelerated our time-to-market. In just one year, Nocturnal took our implantable cardiac monitor from a concept to a fully functional device with a mobile application and secure cloud connectivity."

JAESON BANG, FOUNDER AND CEO, FUTURE CARDIA

WHY NOCTURNAL?

Cash-preserving result-based pricing
Our milestone-based pricing allows you to plan your budget with confidence and draw a viable path to commercial success.

→ Learn more

Hard to find expertise in implantable and wearable devices
"Been there, done that" does make a difference when it comes to complex class II and class III device development.

→ Learn more

Device-ready building blocks for a quick head start
Using our rich library of hardware designs, software code, and documentation templates — we can get you faster to the finish line while minimizing project risk.

Senior-level engagement from day one
We are a small team so you always work directly with our best and brightest, because that's all we have.

No surprises. Period.
Complete transparency throughout the project so you always know where you are.

"This was my first experience with milestone-based pricing, and I will never go back to hourly billing.

Nocturnal's process ensures all parties are fully aligned and incentivized for success, and the results speak for themselves."

ALEX COOPER, CEO, RELIEF CARDIOVASCULAR

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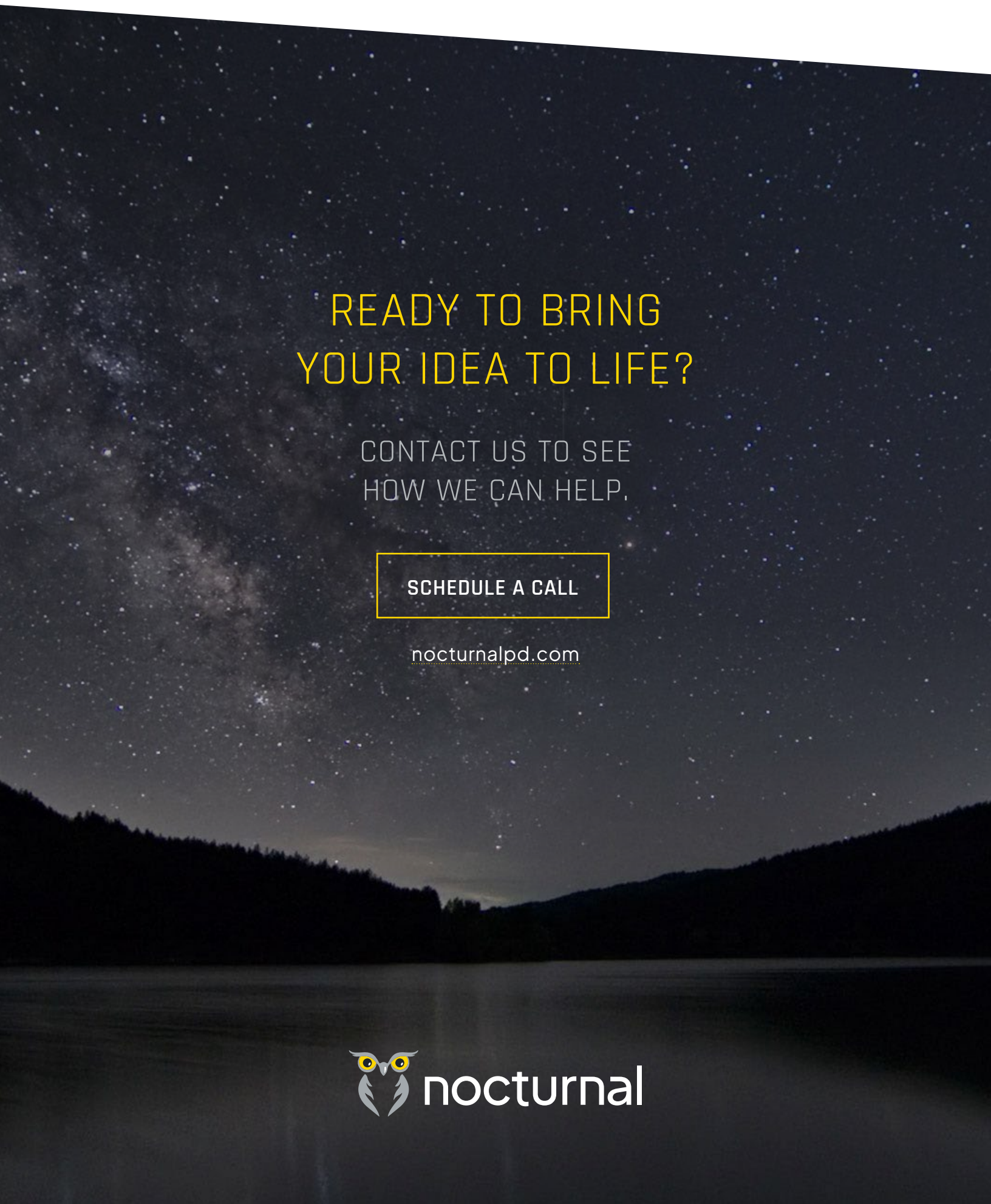
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