Lumanity

A New Framework to Engineer Breakthrough Value for Medicines

Value Inflection Points Across the Development Path

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Introduction

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In an era where the biopharmaceutical landscape is rapidly evolving, a comprehensive approach to demonstrating and communicating the real-world value of medical advances has never been more important.

Commercializing biopharmaceutical advancements has never been more challenging and fraught with risk. For years, clinical approval created the opportunity for organizations to invest heavily postlaunch to shape both the asset and the market, thereby building successful products through sustained commercial/promotional investment. Today, however, despite the continued need for innovative and clinically important medicines, biopharma companies face a harsher reality: an asset's fate is determined well before launch and once set can no longer be altered through sheer promotional muscle. Success now is predicated on an evidence-based, stakeholder-specific demonstration of value. Real-world outcomes, measurable economic impact, and assets designed to fit today's healthcare system are the new requirement.

With traditional frameworks of drug development and commercialization becoming obsolete, a new, integrated approach is essential. Companies must adapt to a landscape where demonstrating and communicating value are critical. Those who embrace a forward-thinking mindset and act decisively will be positioned to navigate complexity and sustain success.

Biopharma's new and evolving industry dynamics

Biopharma is at a paradoxical moment. Scientific innovation is sprinting ahead—gene therapies[1], RNAi,[2] incretins,[3] immune modulation,[4] AI-driven discovery[5]—but the path to market has never been slower, riskier, or more expensive. Breakthroughs alone aren't enough to win. Companies must demonstrate value early, make sharper bets, and navigate an environment where science, economics, and policy are colliding in ways the industry has never faced before.[6]

The economics are sobering. The average cost to bring a medicine to market has surged past $2.2 billion—up from $2.12 billion just a year earlier[7]—and this figure continues to rise at a pace that few would call sustainable. In this environment, smaller, venture-backed companies live and die by their ability to differentiate quickly. Larger firms may have the balance sheets to shoulder the cost for now, but going forward their challenge will be different: knowing which assets to push forward and which to cut, even when sunk costs and internal momentum argue otherwise.

While costs climb, healthcare delivery itself is being reshaped. With healthcare spending at nearly 18% of US GDP[8] (and lower double-digit levels across Europe and Asia[9]), payers and providers are implementing consolidation strategies in an effort to control costs.[10] Decision-making is shifting from individual physicians to centralized institutions that weigh efficacy and outcomes alongside economics and operational impact. For biopharma, success depends on engaging these stakeholders[11] with evidence that extends beyond clinical results.

On top of these structural shifts, the policy environment is more volatile than ever. The Medicare Drug Price Negotiation Program[12] and Most Favored Nations[13] proposal in the US, and Europe's new Health Technology Assessment Regulation[14] are examples of policymakers attempting to rewrite the playbook in real time. Blockbusters like GLP-1s and ultra-expensive rare disease treatments have become lightning rods in debates over what innovation is worth and have increased the importance of the patient as a consumer. Companies that adapt faster than the rules evolve will thrive, and those that don't risk falling behind. Speed and agility matter more than ever.

Patients, arguably the most critical stakeholder in the healthcare equation, are both more empowered and more burdened than ever. Out-of-pocket costs continue to rise, and insurance complexity confuses even the most sophisticated. A Cancer*Care* report found only half of US cancer patients understand their coverage, while 1 in 3 say insurance practices stand in the way of optimal care.[15] Meanwhile, digital health tools, apps, and wearables flood patients with data[16]—some of it useful; much of it noise. The irony is clear: people now have more health information at their fingertips than at any other point in history, but less clarity about how to act on it. Technology and data alone aren't enough; clarity and guidance are equally critical.

Taken together, these dynamics make one thing clear: the old drug development and commercialization playbooks no longer provide the right guidance and pathway to success in the marketplace. Evidence of value is now a critical driver of an asset's success. Stronger, earlier, and stakeholder-specific evidence of value secures funding, unlocks access, earns trust, and determines if an innovation reaches patients.

> **Today's challenges demand not just new medicines, but an evolution of the evidence that proves their value.**
>
> *Jon Williams, CEO at Lumanity*

A new value framework to address the evolving landscape of medicine development

A unified foundation of strategy, evidence, engagement, and tech

Traditional frameworks of drug development and commercialization, which relied heavily on rapid registration and postlaunch, promotionally-driven market development and expansion, are no longer sufficient. Today, commercial success depends on 2 foundational elements:

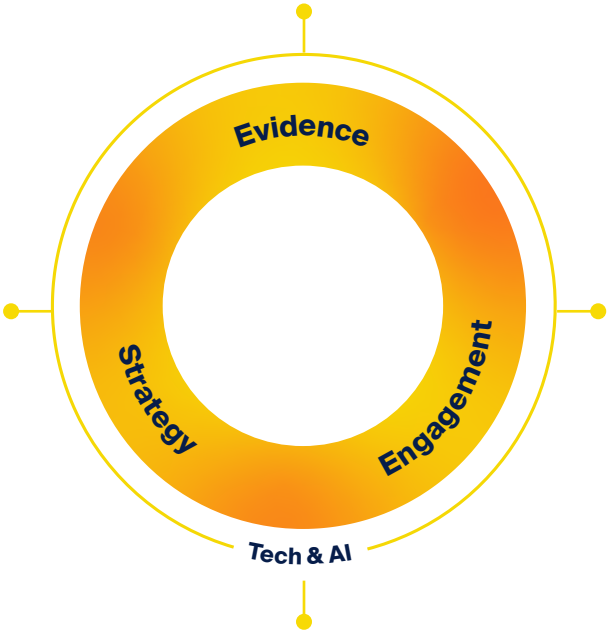
- A carefully crafted asset profile that is built on a deep understanding of health system stakeholder needs
- An evidence strategy, generation, and engagement plan that clearly demonstrates and communicates the real-world value and economic impact of treatments to each key health system stakeholder—including payers, providers, regulators, and patients

Navigating this complexity requires a new framework—**one that flows between strategy, evidence, and engagement, all enabled by advanced technology and AI solutions.** Failure to address this new commercialization reality is increasingly likely to result in assets that are misaligned to the demands of this more sophisticated environment, resulting in dramatic underperformance against expectations.

Key Components of the New Value Framework

Evidence

Designing and delivering evidence that fills data gaps, accelerates access, and demonstrates real-world value



Strategy

Shaping assets to maximize scientific, clinical, economic, and patient impact, ensuring stakeholder alignment and commercial success

Engagement

Translating evidence into actionable insights that drive stakeholder alignment, market access, and adoption

Tech & AI

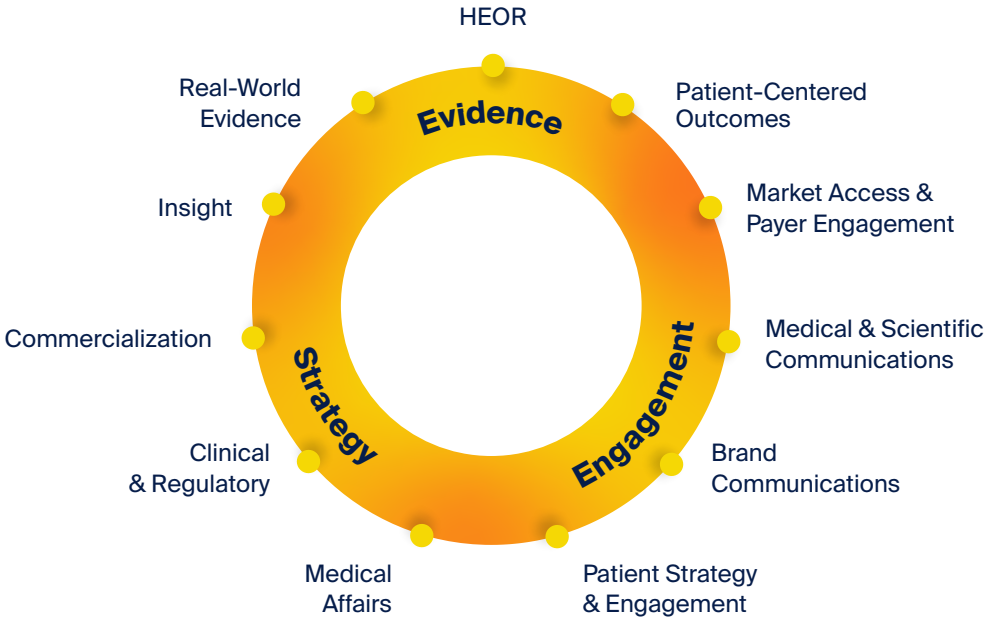
Applying technology and AI intentionally to interrogate data, accelerate decision-making, and unlock new value

Integrating functional areas for commercial success

Siloed decision-making is one of the main reasons biopharma companies fail to fully realize the potential of their medicines. A biopharma company successfully developing and commercializing a medicine is like an orchestra playing a symphony: many instruments playing in harmony to create the desired outcome. Unfortunately, many biopharma companies often work in silos—equipped with instruments but not playing in sync. Clinical teams, for example, may design Phase 2 and 3 programs with an almost exclusive focus on regulatory approval, limiting both commercial and access potential.

To optimize commercialization, biopharma companies need to integrate the instruments of the orchestra—aligning commercialization, clinical and regulatory strategy, medical affairs, insight and analytics, real-world evidence, HEOR, patient-centered outcomes, medical and scientific communications, brand communications, patient engagement, and market access—so they play in harmony. Leveraging deep expertise across these domains, and ensuring seamless communication and collaboration, is critical to transforming strategy into impact.

Functional Areas for Commercial Success



Biopharma companies often have deep expertise in-house, but integrating it effectively across disciplines remains a challenge. Many turn to service providers for support, but find they aren't all created equal. Most service companies tend to fall into 3 categories:

Biopharma Service Archetypes

01

Single offering companies

Strong capabilities in narrow domains, but often lacking the ability to address complex, end-to-end challenges.

02

Holding companies and networked agencies

Broad capabilities under one roof, but often lacking coordination to deliver maximum impact.

03

Tightly integrated solution providers

Built for collaboration, innovation, and measurable results. These providers drive meaningful impact by connecting expertise across all stakeholders involved in the commercialization journey.

The third category—tightly-integrated solution providers—is the least common but often the most impactful. These organizations are built to provide end-to-end support across the commercialization process, helping biopharma companies navigate market complexities from initial strategy to market execution. We built Lumanity with this objective in mind, and as a result our integrated capabilities work across every stage of the commercialization journey.

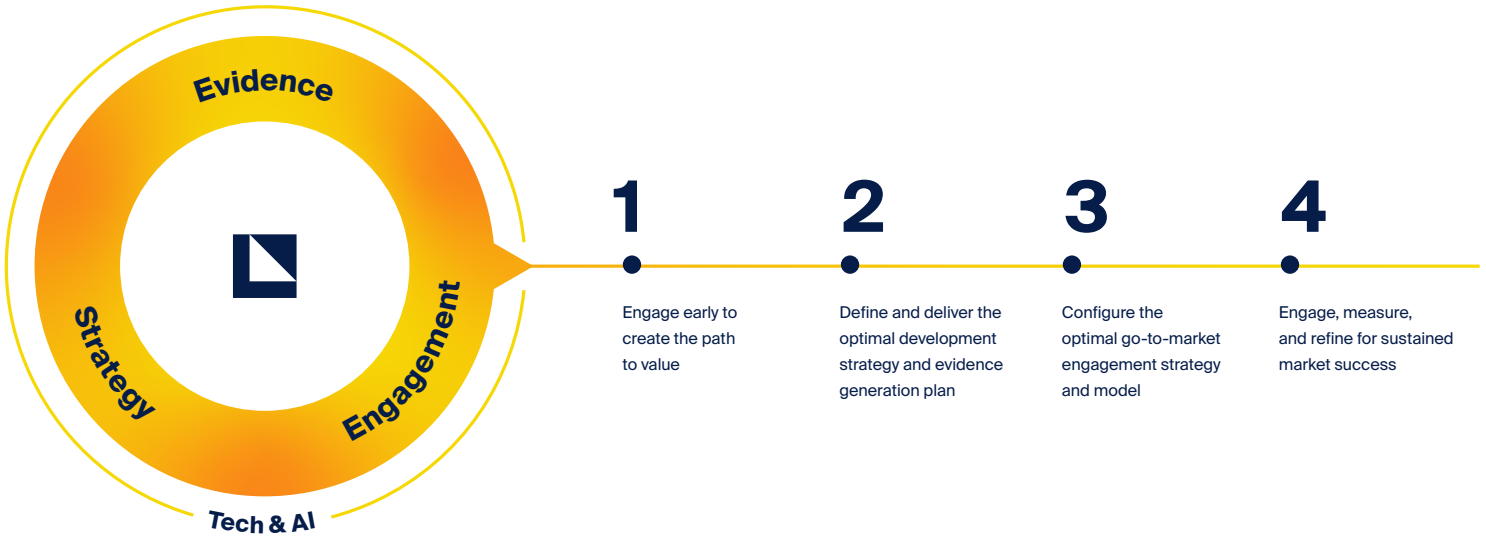
A capable partner should have integrated systems, processes, incentives, and culture to ensure seamless collaboration across and between a global team of experts. This approach ensures every strategic decision contributes to a medicine's commercial success and optimized patient outcomes. By combining deep expertise with integrated operations, the right partner will help identify where value can be gained—or lost—at every stage of the commercialization journey.

Value inflection points across medicine development:

Key milestones in which value is gained or lost

In the complex, high-stakes world of biopharmaceutical commercialization, countless decisions shape a medicine's trajectory. Yet a select few consistently determine its ultimate success or failure. We call these **value inflection points.** These pivotal moments ensure that a medicine not only reaches the market but also achieves sustained success—meeting patient needs, satisfying regulatory requirements, and demonstrating clear value to all stakeholders.

Lumanity Value Inflection Points



Value inflection point 1

Engage early to create the path to value

The first step to commercializing a successful medicine is understanding the unmet needs and defining a clear path to value. Lay the foundation for an asset's success by identifying market challenges and medical priorities and shaping a differentiated value proposition.

Define market and patient needs

Identify unmet needs, quantify opportunities, and prioritize indications through deep market insights that can help reveal the nuances of disease, populations, and future requirements to address them.

Perform in-depth technology and scientific assessments

Broaden the lens to understand the full scope of scientific advances that may impact a particular disease, considering technologies de-risked elsewhere that could accelerate entry into the target market.

Understand and navigate competitive and regulatory changes

Monitor market trends, develop strategic plans, and create proactive regulatory strategies.

Define asset value proposition and stage-gating criteria

Develop a compelling value proposition and identify strategic market opportunities to align with commercial goals.

Identify program value drivers and risks

Evaluate key value drivers, perform detailed market access evaluations, and identify potential risks.

Value inflection point 2

Define and deliver the optimal development strategy and evidence generation plan

Optimizing the development of your asset requires a harmonized, evidence-backed strategy. Ensure your development plan maximizes differentiation and commercial viability, setting the stage for success.

Understand all stakeholder requirements

Conduct multi-stakeholder analyses and set strategy that aligns best with the interests of healthcare professionals, patients, regulators, and payers.

Build a strong value-based asset proposition

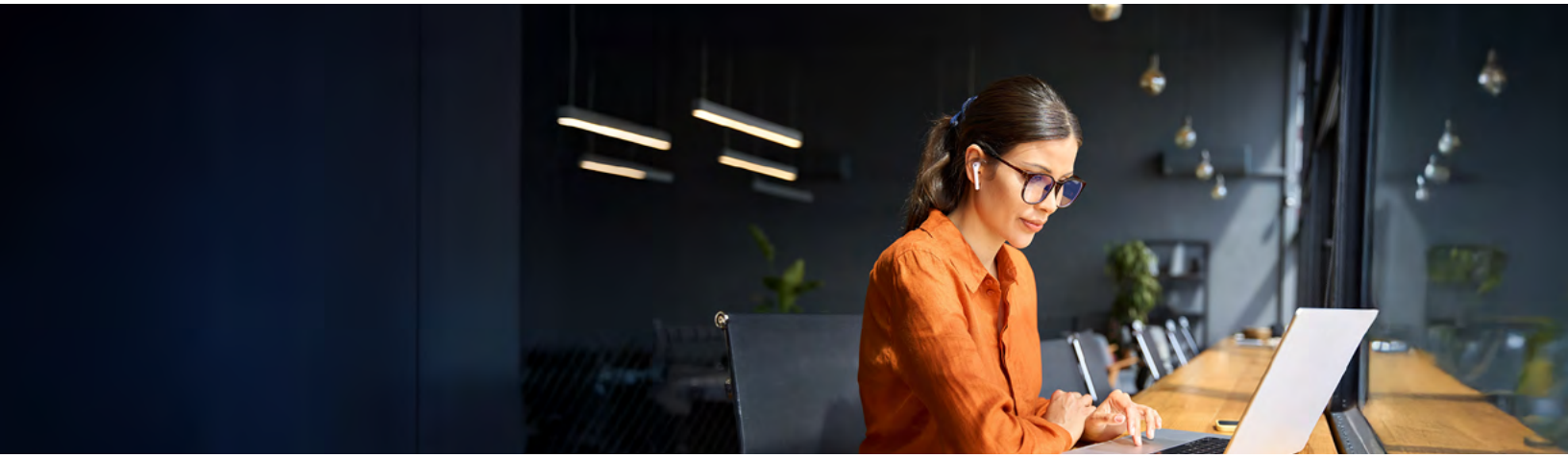
Integrate market analysis, stakeholder insights, health economics, and patient-centric outcomes into the proposition.

Define asset data needs

Build an integrated evidence plan designed to systematically shape understanding of the disease, treatments, differentiation, and stakeholder needs.

Set development and commercialization priorities and business case

Build a business case to support sustained commitment to the evidence generation plan.



Value inflection point 3

Configure the optimal go-to-market engagement strategy and model

Creating the conditions for a high-impact market launch and growth plan requires meticulous planning, strategic alignment, and a commitment to refinement. Configure the optimal go-to-market (GTM) strategy, ensuring internal readiness and external market alignment. Recognize that traditional broad HCP promotional strategies may no longer be relevant, and instead build a foundation that clearly defines each stakeholder's role in disease management.

Translate the asset value proposition into a stakeholder-centric asset strategy

Understand how the asset fits within the requirements and needs of each stakeholder and build tailored strategies to address.

Develop market access and pricing strategy

Assess pricing landscapes and develop strategies for optimal market access.

Engage medical stakeholders

Build relationships with key opinion leaders and develop tailored communications.

Embrace a strategic approach to patient engagement

Develop patient engagement programs and incorporate patient insights.

Design specialized organization

Identify organizational gaps, build structures for scale-up, and enhance capabilities.

Establish KPI framework across workflows

Define KPIs to measure market access, stakeholder engagement, and brand communications.

Value inflection point 4

Engage, measure, and refine for sustained market success

Sustained market success requires continuous engagement, measurement, and refinement. Leverage ongoing stakeholder engagement, insight-driven strategy refinement, and real-world evidence to ensure your asset remains the clear choice.

Engage and educate stakeholders

Implement engagement plans and develop educational programs for stakeholders.

Develop a compelling scientific narrative to bring evidence to life

Create and disseminate a strategic scientific narrative supported by key opinion leaders.

Produce real-world data and insights

Conduct real-world data analyses and capture patient-reported outcomes.

Manage performance and learnings

Track outcomes and refine engagement strategies based on feedback.

Plan lifecycle and investment strategy

Identify lifecycle management opportunities and develop risk management strategies.

Key scenarios where the value inflection point framework drives success

Certain scenarios demand a rigorous, integrated approach to ensure the success of both the medicine and the company. These are precisely the moments where the Value Inflection Point Framework excels—often as the only way to achieve meaningful results.

The following are just a few examples of situations in which strategic planning, evidence generation, stakeholder engagement, and advanced technology coming together are most critical.

Medicines affected by the evolving policy landscape

Recent shifts in policy in the US and Europe have challenged the status quo and are reshaping how drug manufacturers commercialize their medicines. The EU Joint Clinical Assessment (JCA) Regulation, enacted earlier this year, standardizes clinical evaluations and changes how new medical advances reach the EU market. In the US, the Medicare Drug Price Negotiation (MDPN) process, part of the Inflation Reduction Act of 2022, requires negotiation of lower prices for certain high-cost drugs covered by Medicare. Additionally, a proposed Most Favored Nations (MFN) drug pricing policy would set US drug prices at the lowest level paid by comparable wealthy nations.

These policy shifts represent significant change and a host of new and unprecedented challenges for biopharma companies. Finding solutions wouldn't be possible without broad and deep strategic thinking across the value inflection points, and the ability to move at full tilt to mobilize teams of cross-disciplinary experts that can work together. This is exactly what we've been able to do with our team of experts at Lumanity, and our integrated Value Inflection Point Framework has been applied to deliver readiness trainings on the EU JCA regulation[17] and in our work on 5 of the first 25 drugs to go through the MDPN process[12], positioning our clients for success.

Supporting first-time commercializers

For biopharma companies that are preparing to launch and commercialize their first product, the move from development to commercialization represents a decisive point in time—one where execution quality and value demonstration carry more weight than ever before. Unlike established players, first-time commercializers often face the dual challenge of building commercial infrastructure from scratch while navigating unfamiliar regulatory, payer, and provider landscapes. Additionally, their teams tend to be lean and may lack the breadth and depth of expertise required to manage the complexity of evidence generation, market access, and stakeholder engagement at launch.

Careful observation of the Value Inflection Point Framework can save biopharma companies from inefficiencies, misalignment, and diluted value communications and pivot them to alignment across evidence, stakeholder engagement, and launch execution. Our expert teams at Lumanity have helped countless first-time commercializers deliver a coherent, credible, and well-supported market introduction, and we work to support the launch of over 80 new brands and indications per year.

Transforming biopharma companies for competitive advantage

Even established biopharma companies face organizational pressures that demand bold action. Modernizing internal team structures, capabilities, and processes is essential to remain competitive. However, legacy systems, functional silos, and fragmented workflows can slow decisions, reduce market impact, and weaken the ability to demonstrate and communicate value to stakeholders. Advanced technologies like AI, quantum computing, and predictive analytics offer powerful opportunities—but only when culture, capabilities, and operations are aligned to leverage them effectively.

Organizations succeed when they take an integrated approach, connecting commercial, clinical, and scientific capabilities with evidence generation and stakeholder engagement across critical value inflection points. The result is high-impact commercialization: differentiated GTM strategies, credible stakeholder value, and a sustained competitive advantage that positions the organization to lead in an evolving market. Lumanity is proud to be working with many global biopharma companies, including all of the top 25, to help transform organizations, align culture with capability, and deliver lasting competitive advantage.

Conclusion

Given rapid scientific advancements and heightened global competitive pressures, traditional frameworks of drug development and commercialization are no longer enough. Success in today's biopharmaceutical landscape hinges on a comprehensive, integrated approach that seamlessly combines strategy, evidence, engagement, and advanced technology solutions. By fully addressing each critical value inflection point, biopharma companies can ensure that their medicines not only reach the market but achieve sustained commercial success by meeting patient needs, satisfying regulatory requirements, and demonstrating clear value to all stakeholders.

Lumanity is more than a strategic partner: we are a catalyst for transformation. Our deep expertise and comprehensive specializations empower us to tackle the most complex challenges our clients face. By fostering a collaborative culture, we turn insights into practical, well-rounded solutions tailored to the dynamic demands of the biopharmaceutical market. We prioritize seamless integration and a solution-focused mindset, working across functions to ensure ideas are shared, implemented, and executed efficiently.

Our commitment to improving patient health outcomes guides every decision. With Lumanity, clients leverage a wealth of knowledge and experience to navigate the complexities of commercialization, identify opportunities to create value, and ensure innovations achieve lasting impact. Together, we can engineer breakthrough value and ensure your medical innovations make a lasting impact.

Diverse industry experts driving global impact

Lumanity is a global strategic services partner, combining deep scientific, clinical, medical, regulatory, and commercial expertise with advanced technology and AI-driven tools to support complex decision-making and execution across the medicine value creation and demonstration journey. With offices in North America, the United Kingdom, the European Union, and Asia, and work conducted in over 50 countries, Lumanity's 1,200 experts collaborate with the top pharmaceutical companies and over 100 biotech companies worldwide.

Our diverse team of highly specialized experts works together, seamlessly integrating strategy, evidence, engagement, and technology to empower our clients to navigate market complexities with confidence, achieve commercial success, and ultimately improve patient health outcomes.

Lumanity: Engineering breakthrough value that transforms lives.

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