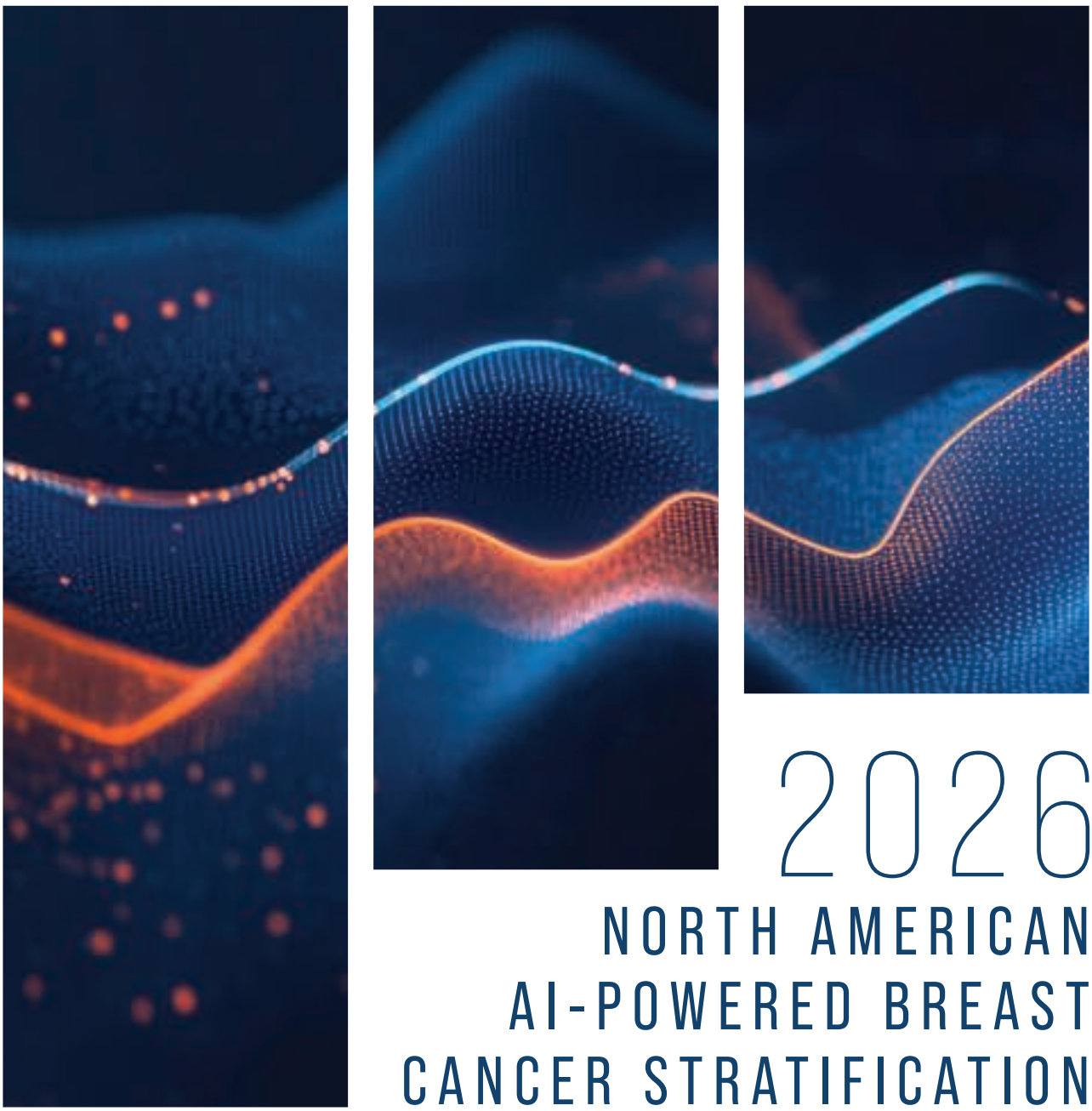
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BEST PRACTICES



2026 NORTH AMERICAN AI-POWERED BREAST CANCER STRATIFICATION TECHNOLOGY INNOVATION LEADERSHIP

ARTERA

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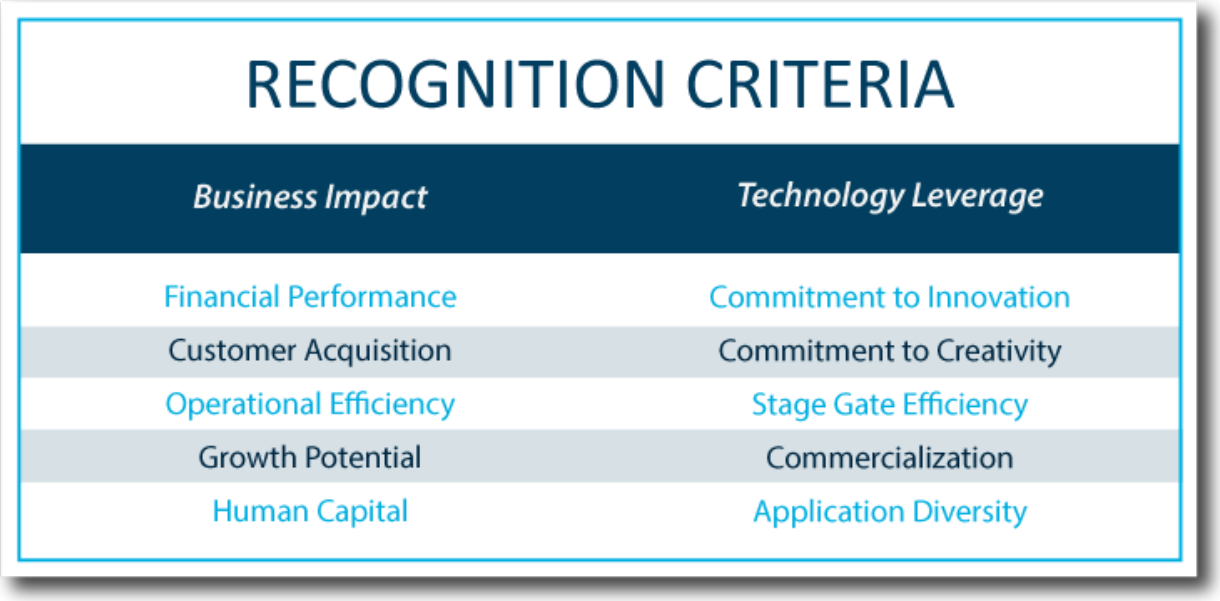
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Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each recognition category before determining the final recognition recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. ArteraAI excels in many of the criteria in the AI-powered breast cancer stratification space.



The Transformation of the AI-powered Breast Cancer Stratification Industry

> *"As AI-enabled precision oncology matures, sustaining competitive advantage increasingly depends on scaling impact without proportionally increasing infrastructure, workforce, or operating costs. Unlike traditional molecular diagnostics companies that expand through labs, sequencing equipment, and complex biological supply chains, Artera built a software-centric enterprise designed for efficient growth."*
>
> ***- Ashish Kaul,***
> ***Industry Analyst, TechVision***

The North American artificial intelligence (AI)-powered breast cancer risk stratification market is entering a period of transformation as oncology shifts from age-based screening to precision medicine and individualized treatment. Breast cancer remains the most prevalent cancer among women in North America, representing approximately 32% of new cases in the United States (US)[1] and 26% in Canada,[2] with more than 354,000 diagnoses projected across both countries in 2026[3,4]. Nearly 70% of these cases are hormone receptor-positive and human epidermal growth factor receptor 2-negative (HR+/HER2-),[5] where clinical decisions depend on detecting disease

[1] American Cancer Society, *Cancer Facts & Figures 2026* (Atlanta: American Cancer Society, 2026), 3–4, accessed July 27, 2026.
[2] Canadian Cancer Society, "Breast Cancer Statistics," last medically reviewed April 2026, accessed July 27, 2026.
[3] American Cancer Society, *Cancer Facts & Figures 2026* (Atlanta: American Cancer Society, 2026).
[4] Canadian Cancer Society, "Breast Cancer Statistics," accessed July 27, 2026.
[5] European Society for Medical Oncology (ESMO), *Early Breast Cancer: ESMO Clinical Practice Guideline for Diagnosis, Treatment and Follow-up*.

as well as on accurately predicting recurrence and metastatic risk. Expanded screening eligibility, breast density legislation, and greater participation in early detection programs also increase patient volumes and clinical complexity, highlighting technologies that improve risk stratification.

Conventional diagnostic approaches do not align with these evolving clinical requirements. Medical technology innovators designed instruments like mammography, legacy statistical models, and first-generation computer-aided design to identify suspicious lesions over predicting disease progression. As a result, the solutions rely on manual interpretation and single-modality analysis, contributing to false positives, reader variability, and inconsistent performance across dense breast tissue and diverse patient populations. Additionally, these technologies provide limited guidance when determining which patients will benefit from chemotherapy. As healthcare systems prioritize personalized treatment and value-based care, demand shifts toward predictive technologies that generate actionable prognostic insights and enable more informed treatment decisions.

AI fulfills this need by transforming routinely generated clinical data into actionable prognostic insight. Deep learning models identify subvisual patterns associated with recurrence, metastasis, and treatment response, enabling clinicians to assess risk more precisely without collecting additional tissue or ordering complex tests. AI creates the greatest strategic value by improving the speed, consistency, and quality of clinical decisions instead of replacing physician judgment. Rising screening volumes, workforce shortages, and increasingly complex multimodal data also drive health systems away from isolated diagnostic tools and toward integrated decision-support platforms that automate routine workflows and translate clinical complexity into practical treatment guidance. Providers and payers increasingly favor solutions that improve outcomes, efficiency, and resource utilization.

However, basic technological capability and accuracy no longer differentiate precision oncology vendors. As operational risk continues to constrain hospital adoption, platforms must demonstrate rigorous clinical validation, deliver explainable insights, and integrate seamlessly into existing workflows to build physician confidence and reduce the risk of consequential treatment errors. Reimbursement uncertainty and capital-intensive infrastructure further raise adoption barriers while also increasing the difficulty of market entry. As these requirements become standard, strategic advantage will increasingly shift toward vendors that can scale multimodal intelligence across enterprise environments and embed deeply within legacy clinical systems.

Founded in 2021 and headquartered in Los Altos, California, Artera reflects this shift through its novel breast cancer platform by applying AI to standard digitized histopathology and patient variables to stratify early-stage HR+/HER2- patients by distant metastasis risk. An innovative tissue-preserving approach addresses critical needs in breast cancer management and positions Artera at the intersection of digital pathology, precision oncology, and AI-enabled clinical decision support.

Redefining Cancer Risk Stratification through Multimodal AI

Artera redefines breast cancer risk stratification through its proprietary multimodal AI (MMAI) technology, which combines routinely generated hematoxylin and eosin pathology images with structured data to deliver clinically actionable insights at scale. This technology powers ArteraAI Breast, the company's solution for early-stage HR+/HER2- breast cancer, extracting predictive and prognostic data

from routine pathology images without needing additional tissue, molecular tests, or specialized assays. By integrating seamlessly into existing clinical workflows, ArteraAI transforms digital pathology from a diagnostic record into a strategic clinical intelligence source, equipping physicians with earlier, more personalized treatment insights while reducing operational complexity and expanding access to precision oncology.

Central to this MMAI technology is a proprietary architecture designed to uncover disease biology beyond the limits of conventional model development. By utilizing self-supervised learning, Artera bypasses the limitations of human-annotated datasets that restrict algorithms to pre-identified features. Training directly on large-scale pathology image repositories enables the system to detect subtle tissue microarchitectural patterns and correlate them with long-term clinical outcomes that traditional computational pathology methods overlook. When combined with patient-specific clinical data, these insights provide a deeper understanding of disease biology while creating a continuously improving foundation that scales with new data. The result is a differentiated and durable technological advantage that enables more precise clinical insights and is difficult for conventionally trained models to replicate.

Scientific rigor reinforces the platform's technological differentiation. The company trained and validated ArteraAI Breast using data from six multinational Phase III randomized clinical trials, creating one of the most robust evidence foundations supporting an AI-enabled oncology diagnostic solution. Validation across diverse scanners, labs, and care settings demonstrates consistent prognostic and predictive performance under real-world conditions, helping the company to address a key barrier to adoption. A software-based approach further enhances accessibility by generating treatment-guiding insights from digitized biopsy images and clinical data. As a result, healthcare providers can incorporate advanced AI-driven decision support into existing workflows while preserving valuable tissue, reducing operational complexity, and expanding access to precision oncology.

However, Artera's advantage extends beyond any single indication. The company built its MMAI technology on a common computation foundation designed for broader clinical applicability, enabling future expansion beyond prostate cancer as additional evidence and validation emerges. Each new application benefits from established models, validated frameworks, and accumulated insights, reducing the need to recreate core capabilities and enabling more efficient innovation. The successful expansion from prostate to breast cancer demonstrates how Artera's architecture translates across distinct clinical settings while maintaining scientific rigor and performance. This repeatable approach creates a durable foundation for future growth and positions the company to advance precision oncology across a broad range of cancers over time.

Scientific Rigor and Regulatory Speed Reinforce Innovation

As AI-enabled diagnostics mature, companies can gain a critical competitive advantage by compressing development timelines without compromising scientific rigor. Traditional software-as-a-medical-device (SaMD) frameworks require each new indication through independent validation and regulatory review which significantly delays market entry. Artera bypasses these repetitive delays by creating a MMAI architecture that continuously leverages existing data, validation, and software infrastructure across multiple disease areas. By utilizing a reusable AI infrastructure, the company differentiates itself from single-indication competitors by rapidly scaling its initial prostate cancer success to secure the US Food

and Drug Administration (FDA) clearance for ArteraAI Breast in May 2026, establishing a highly repeatable blueprint for market expansion.[6]

Artera's greatest acceleration occurs during clinical validation, historically the most time-intensive and resource-demanding stage of diagnostic development. The company expedites validation by applying locked AI models to digitized pathology slides from completed Phase III randomized clinical trials, comparing predictions directly against established long-term patient outcomes. This method eliminates the need to launch prospective studies and wait years for the data to mature. Applying locked AI models to digitized pathology slides from completed Phase III trials expedites validation by comparing predictions directly against established long-term patient outcomes. This method eliminates prospective studies, bypassing years of waiting for clinical data to mature. Consequently, Artera generates Level 1 clinical evidence rapidly, validating new indications through existing, high-quality datasets.

Beyond product approvals, Artera established a framework for continuous, compliant innovation through an FDA-authorized Predetermined Change Control Plan (PCCP). The PCCP creates predefined pathways for certain software modifications, enabling enhancements such as expanded pathology scanner compatibility without requiring a new regulatory submission. By embedding compliance directly into the software development lifecycle through standardized engineering practices, automated quality controls, and integrated audit processes, the company treats regulatory readiness as an enduring capability as opposed to a series of discrete approval events.

This approach receives support from a modern machine learning infrastructure built on Flyte, an orchestration system that automates workflow execution, version control, quality assurance, and failure recovery across large-scale development environments. Reducing infrastructure complexity and enforcing consistent governance allows engineering teams to focus strictly on model performances while maintaining absolute traceability. Automated controls block underperforming models from advancing, forcing innovation to proceed within a disciplined, auditable framework. Such structural discipline accelerates iteration and scales precision medicine solutions without compromising clinical quality or regulatory compliance.

A Hybrid Commercial Model Expands Access and Adoption

As precision oncology matures, commercial viability requires minimizing adoption friction while delivering quantifiable clinical and economic utility. Artera navigates these demands through a hybrid go-to-market model integrating a centralized, Clinical Laboratory Improvement Amendments-certified and the College of American Pathologists-accredited laboratory framework with scalable SaMD architecture. The dual structure optimizes immediate revenue via established diagnostic workflows, while simultaneously ensuring plug-and-play capability for distributed software deployment as digital pathology infrastructure expands. Leveraging this commercial versatility accelerates and decentralized clinical ecosystems.

The company’s flexible model also enables a fundamentally different approach to customer acquisition. Rather than relying primarily on a traditional account-by-account sales strategy, Artera embeds its technology within precision oncology ecosystems that clinicians already use and trust. Partnerships with organizations such as Tempus AI and PathNet integrate Artera directly into existing ordering and

[6] "Artera Receives US FDA Clearance for ArteraAI Breast, Expanding Its AI Platform to Breast Cancer," Artera Newsroom, May 6, 2026, artera.ai.

diagnostic workflows, expanding reach across large networks of oncologists and pathologists without requiring new software environments or specialized hardware. The company further supports market expansion through targeted regulatory and operational initiatives, including state laboratory licensing and European CE marking, reducing implementation friction for healthcare providers while increasing geographic growth.

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>
> ***- Samantha Fisher,***
> ***Best Practices Research Analyst***

An evidence-generation strategy reinforces commercial execution by driving adoption through clinical validation instead of promotion alone. Artera consistently prioritizes rigorous clinical evidence, regulatory leadership, reimbursement, and guideline inclusion to lower adoption risk for physicians, health systems, and payers. The company's ArteraAI Prostate Cancer Test became the first and only AI-enabled assay incorporated into the NCCN Clinical Practice Guidelines and secured Medicare reimbursement, establishing clinical credibility and economic justification for broad use. Thus, this strategy shifts commercialization from product marketing toward institutional acceptance, allowing demonstrated clinical utility to become a primary driver of demand.

The combination of ecosystem-based distribution, workflow-native deployment, and clinically actionable intelligence ultimately defines Artera's competitive position. While traditional genomic diagnostics often depend on centralized laboratory operations, tissue-intensive testing, and resource-heavy sales models, and many digital pathology vendors focus primarily on workflow efficiency, the company directly informs treatment decisions through prognostic and predictive insights derived from existing pathology data. By lowering implementation barriers while strengthening clinical and economic value, Artera creates a scalable commercialization engine that becomes increasingly difficult for molecular diagnostics providers and point-solution AI vendors to replicate as precision oncology continues to evolve.

Operating Leverage Strengthens Long-Term Competitive Advantage

As AI-enabled precision oncology matures, sustaining competitive advantage increasingly depends on scaling impact without proportionally increasing infrastructure, workforce, or operating costs. Unlike traditional molecular diagnostics companies that expand through labs, sequencing equipment, and complex biological supply chains, Artera built a software-centric enterprise designed for efficient growth. Because technology analyzes routinely generated digital pathology images instead of physical specimens, scaling test volume requires minimal incremental investment in facilities, equipment, or logistics.

Artera's cloud-native architecture further strengthens this operating leverage through extensive automation. The automated machine learning infrastructure orchestrates large-scale digital pathology workflows, automating execution, monitoring, resource allocation, and recovery. Combined with an Infrastructure-as-Code model, the company can rapidly deploy compliant environments and standardize operations across multiple markets. Digital slide ingestion also eliminates many of the shipping, tissue-handling, and logistics requirements associated with conventional genomic testing. The result is a scalable

operating model that expands throughput and geographic reach without replicating the physical infrastructure required by laboratory-based competitors.

Operating under a software-defined framework allows Artera to concentrate resources on capabilities that drive competitive differentiation. Instead of scaling capital-intensive laboratory operations, the company invests in multidisciplinary expertise spanning AI, pathology, software engineering, and clinical research. Embracing this integrated structure connects scientific discovery directly to regulatory strategy and market execution. Consequently, knowledge generated in one indication accelerates development in subsequent programs, a synergy demonstrated by the platform's expansion from prostate to breast cancer.

Together, software scalability, intelligent automation, and concentrated domain expertise create a business model that differs fundamentally from traditional diagnostics companies and emerging AI vendors. Legacy molecular diagnostics organizations often require additional laboratories, equipment, and personnel to support growth, while many software companies lack the clinical, regulatory, and commercial capabilities needed for broad adoption. Artera instead directs a greater share of its resources toward algorithm development, evidence generation, and product innovation. As precision oncology increasingly shifts toward software-enabled diagnostics, this operating model creates a durable and compounding competitive advantage.

Clinical Credibility and Software Economics Drive Growth

To succeed in the increasingly competitive and fragmented breast cancer risk stratification market, vendors must evolve beyond standalone diagnostics to scalable solutions that support recurring software revenue while navigating lengthy reimbursement cycles, high clinical validation costs, and operational complexity. Artera's SaMD model addresses these bottlenecks by evaluating routine histopathology images, eliminating reagent production, specimen shipping, and centralized processing.

Strategic execution further strengthens this advantage. In 2026, Artera established key elements of the regulatory and reimbursement infrastructure required for broader market adoption, including FDA clearance, CE marking, and dedicated current procedural terminology (CPT) codes supporting AI-enabled breast cancer analysis. Clinical credibility reinforces this commercial foundation. ArteraAI Breast builds on one of the strongest clinical evidence bases in AI-enabled breast cancer diagnostics, reinforcing provider and payer confidence while strengthening its competitive position. Together, regulatory authorization, clinical validation, and reimbursement readiness increase provider and payer confidence while raising barriers to entry for competitors.

Future expansion relies on the same scalable software architecture that drives Artera's operating efficiency. Established connectivity with approximately 45% of US pathology laboratories enables instant digital deployment over costly physical distribution networks. New regulatory approvals and payer coverage seamlessly translate into immediate clinical utilization with minimal incremental investment. The company's highly efficient business model positions the platform to capture international opportunities, particularly across Europe, where healthcare systems actively seek cost-effective, digital alternatives to traditional molecular testing.

By industrializing self-supervised learning across routine pathology images, Artera establishes the infrastructure necessary to transition precision oncology from static diagnosis to dynamic, predictive disease management. As global healthcare networks digitize and seek alternatives to cost-prohibitive molecular assays, a software-centric architecture positions the company to anchor next-generation, decentralized clinical decision-making.

Conclusion

As precision oncology advances from molecular testing toward software-defined clinical intelligence, market leadership will increasingly depend on a company's ability to generate scalable, evidence-based insights from data already embedded in routine care. Artera leads this transition through its proprietary multimodal artificial intelligence (AI) platform. Technology converts routinely generated pathology images into prognostic and predictive intelligence without requiring additional tissue, specialized assays, or disruptive workflow changes. By uniting scientific rigor, regulatory agility, operational scalability, and workflow-native deployment, the platform creates a differentiated foundation that extends beyond any single product or indication.

As healthcare systems accelerate digital pathology adoption and seek more accessible, cost-efficient alternatives to resource-intensive molecular testing. Artera can expand its software-centric platform across cancer types, care settings, and geographies. The company reuses validated infrastructure to accelerate evidence generation and support decentralized deployment. As new data accumulates, the platform strengthens its models and compounds competitive advantage. Through this strategy, Artera advances breast cancer risk stratification while helping define the next generation of predictive, AI-enabled oncology decision support.

With its strong overall performance, Artera earns Frost & Sullivan's 2026 North American Technology Innovation Leadership Recognition in the AI-powered breast cancer risk stratification industry.

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What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Recognition identifies the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Recognition Analysis

For the Technology Innovation Leadership Recognition, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall business performance is achieved in terms of revenue, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Leveraging innovative technology characterizes the company culture, which enhances employee morale and retention

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Best Practices Recognition Analytics Methodology

Inspire the World to Support True Leaders

This long-term process spans 12 months, beginning with the prioritization of the sector. It involves a rigorous approach that includes comprehensive scanning and analytics to identify key best practice trends. A dedicated team of analysts, advisors, coaches, and experts collaborates closely, ensuring thorough review and input. The goal is to maximize the company's long-term value by leveraging unique perspectives to support each Best Practice Recognition and identify meaningful transformation and impact.

		VALUE IMPACT	
STEP		WHAT	WHY
1	Opportunity Universe	Identify Sectors with the Greatest Impact on the Global Economy	Value to Economic Development
2	Transformational Model	Analyze Strategic Imperatives That Drive Transformation	Understand and Create a Winning Strategy
3	Ecosystem	Map Critical Value Chains	Comprehensive Community that Shapes the Sector
4	Growth Generator	Data Foundation That Provides Decision Support System	Spark Opportunities and Accelerate Decision-making
5	Growth Opportunities	Identify Opportunities Generated by Companies	Drive the Transformation of the Industry
6	Frost Radar	Benchmark Companies on Future Growth Potential	Identify Most Powerful Companies to Action
7	Best Practices	Identify Companies Achieving Best Practices in All Critical Perspectives	Inspire the World
8	Companies to Action	Tell Your Story to the World (BICEP*)	Ecosystem Community Supporting Future Success

*Board of Directors, Investors, Customers, Employees, Partners

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Generator™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fueled by the Innovation Generator™.

Learn more.



Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- Megatrend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)

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