ArisGlobal®

2025 NEW PRODUCT INNOVATOR

Pioneering New Features and Functionality to Exceed Customer Expectations

RECOGNIZED FOR BEST PRACTICES IN THE NORTH AMERICAN INTELLIGENT MEDDRA CODING INDUSTRY

FROST & SULLIVAN

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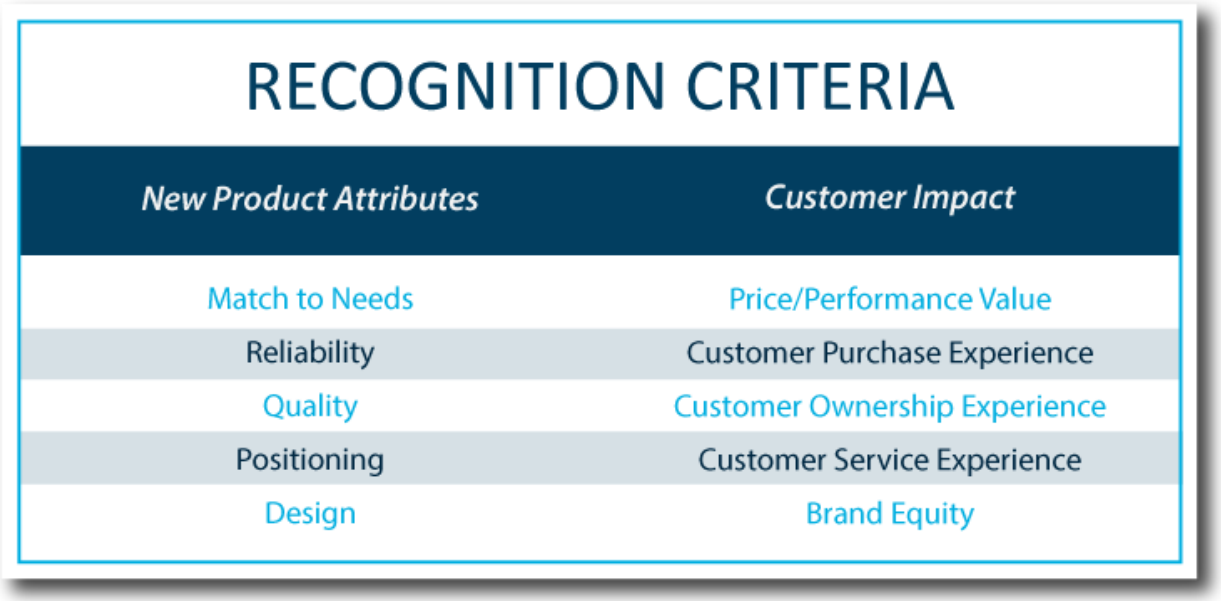
Best Practices Criteria for World-Class Performance

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. ArisGlobal excels in many of the criteria in the intelligent medical dictionary for regulatory activities (MedDRA) coding space.



Intelligent MedDRA Coding in North America

Intelligent MedDRA coding is experiencing a rapid transformation because of regulatory mandates, operational pressures, and the increasing sophistication of artificial intelligence (AI). The US Food and Drug Administration (FDA) mandates that all Individual Case Safety Reports submitted to the FDA Adverse Event Reporting System must use MedDRA terminology. In parallel, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E2B(R3) standard establishes the framework for the electronic transmission of individual case safety reports, ensuring consistency in safety data globally. Together, these requirements create a sustained demand for accurate, high-volume MedDRA coding and lay the foundation for advanced automation and intelligent solutions.

On top of this regulatory-driven need, pharmacovigilance (PV) teams across the United States are under pressure to manage rapidly increasing case volumes sourced from clinical trials, post-market surveillance, electronic health records, and patient-generated data from wearable devices. The diversity and multilingual nature of these data streams, combined with heightened compliance expectations from the FDA, underscore the urgency for scalable, intelligent automation technologies that deliver efficiency and accuracy.

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"LifeSphere® NavaX has the potential to set a new benchmark for pharmacovigilance and regulatory operations globally. By enhancing accuracy, shortening cycle times, and ensuring transparent compliance, it empowers pharma companies to deliver safer therapies, expedite regulatory submissions, and improve patient outcomes. While competitors remain focused on routine process automation, LifeSphere® NavaX is differentiated by its future-proof platform designed to scale with evolving industry needs"

- Pooja Suresh,
Tech Vision Analyst

The opportunity in this market lies in the ability of intelligent MedDRA coding systems to enhance efficiency and quality. Leveraging AI and natural language processing, these solutions interpret refined clinical narratives and recommend accurate MedDRA terms in real time. This capability reduces manual workload, accelerates regulatory submissions, and ultimately strengthens patient safety outcomes. Early North American adopters have already demonstrated measurable gains in first-pass accuracy, reduced cycle times, and substantial efficiency improvements, showing a clear return on investment. Emerging trends signal a decisive shift in the industry from static, rule-based systems to context-aware, agentic AI. The integration of coding and end-to-end PV workflows, coupled with real-world evidence from electronic health records and insurance claims, is strengthening contextual understanding and decision-making.

However, significant challenges remain. Intelligent MedDRA coding solutions must undergo rigorous validation to meet stringent FDA regulatory requirements. Integration with legacy PV systems is often complex, requiring a careful balance between innovation and operational continuity. Data privacy regulations, such as the Health Insurance Portability and Accountability Act, necessitate strict safeguards when AI models are trained on sensitive patient data. Regulators demand transparent rationales for AI-driven coding decisions, and PV professionals must be equipped to supervise, validate, and defend outputs. Change management, therefore, is a crucial enabler of adoption as safety teams transition from manual processes to AI-augmented workflows.

ArisGlobal Profile

ArisGlobal, an AI-first technology company and creator of LifeSphere®, is transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. The company's software solutions advance drug safety, regulatory compliance, and medical affairs. Founded in 1987 and headquartered in the United States, it serves more than 220 organizations globally, including top biopharmaceutical firms, contract research organizations, and government health agencies, such as the FDA.

The company's flagship platform, LifeSphere®, provides an integrated suite of solutions that streamlines end-to-end PV and regulatory operations. It is trusted by leading pharmaceutical and biotechnology firms to automate critical workflows, reduce compliance risks, and accelerate the delivery of safe and effective therapies. LifeSphere® NavaX (the cognitive computing engine that powers the LifeSphere® platform) enables organizations to leverage the latest technologies, such as generative AI (GenAI) and agentic AI. This allows pharmaceutical firms to move beyond manual processes and adopt intelligent, data-driven safety and regulatory operations.

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Recognition from independent analysts reinforces ArisGlobal's credibility. In 2023, Frost & Sullivan acknowledged the company for its innovation leadership, market positioning, and customer impact, highlighting ArisGlobal's dual strengths: its proven ability to deliver transformative value to clients and its role as a strategic thought leader in shaping the future of PV technology.

ArisGlobal Product Innovation: MedDRA Coding Agent powered by LifeSphere® NavaX

ArisGlobal has expanded its leadership in innovation with the launch of the MedDRA Coding Agent powered by LifeSphere® NavaX, a breakthrough in PV automation utilizing agentic AI. Unlike traditional automation tools that rely on keyword matching or rigid rules, the MedDRA Coding Agent applies context-aware autonomy to interpret nuanced clinical language, dynamically select tools, and learn continuously from reviewer feedback. By mimicking the cognitive capabilities of experienced human professionals, the MedDRA Coding Agent moves beyond simple automation to deliver adaptive, auditable, and enterprise-ready PV solutions.

Its MedDRA coding functionality leverages semantic understanding to classify medical terms precisely, significantly reducing reviewers' workload and minimizing the risk of coding errors. The MedDRA Coding Agent's case collaboration capability ensures that only the most complex or ambiguous scenarios are escalated to human reviewers, accompanied by ranked coding suggestions and transparent rationales.

Technological sophistication and alignment with industry needs distinguish the MedDRA Coding Agent. It is enterprise-ready and capable of multilingual processing, and easily integrates with existing safety databases. Its scalability ensures suitability for global deployments across pharmaceutical organizations of all sizes. Importantly, the MedDRA Coding Agent was conceived not as an incremental enhancement but as a paradigm shift in PV—introducing cognitive, agentic AI to redefine MedDRA coding and broader safety operations.

Remarkable Differentiation and Competitive Edge

ArisGlobal emphasizes that the MedDRA Coding Agent is a first-of-its-kind solution because agentic AI has not been widely applied to PV solutions. This clear distinction sets the MedDRA Coding Agent apart from competitors' solutions that primarily focus on task automation. The MedDRA Coding Agent offers context-aware autonomy that mirrors human reasoning. For instance, it correctly interprets the phrase "threw up everything" as "vomiting"—a nuance that rule-based systems often misclassify. The ability to apply deep clinical context ensures that outcomes are more accurate and clinically meaningful.

Continuous learning is another defining strength. Unlike static systems whose accuracy stagnates over time, the MedDRA Coding Agent dynamically improves through reviewer feedback, organizational customization, and adaptation to evolving medical terminology. The result is sustained gains in accuracy and workflow efficiency.

Intelligent collaboration further enhances the MedDRA Coding Agent's impact. The solution intelligently selects from various tools—validators, normalizers, and other AI models—depending on the complexity of each case. Difficult or ambiguous cases are escalated to human reviewers with ranked suggestions and detailed explanations, streamlining reviewer workload while ensuring clinical accuracy. Every AI-driven

decision is traceable and supported by rationales, meeting the most stringent requirements of regulatory inspections. This transparency satisfies auditors and builds confidence among PV professionals.

The MedDRA Coding Agent's performance metrics underscore its competitive advantage, delivering efficiency gains in coding automation exceeding 80%. This dramatically reduces reviewer workload and eliminates noise without sacrificing accuracy.

Frost & Sullivan recognizes the MedDRA Coding Agent as a technological breakthrough that moves beyond routine task automation toward a cognitive and future-proof solution. The solution's ability to combine accuracy, adaptability, and compliance positions ArisGlobal as a leader in the North American intelligent MedDRA coding space.

Innovation and Leadership in GenAI

> *"ArisGlobal places innovation at the center of its growth strategy, with the MedDRA Coding Agent serving as the industry's first agentic AI solution. Built on large language models and advanced cognitive computing, the MedDRA Coding Agent is a transformative PV solution."*
>
> ***- Norazah Bachok,***
> ***Best Practices Research Analyst***

ArisGlobal places innovation at the center of its growth strategy, with the MedDRA Coding Agent serving as the industry's first agentic AI solution. Built on large language models and advanced cognitive computing, the MedDRA Coding Agent is a transformative PV solution.

Frost & Sullivan's analysis confirms that the ArisGlobal MedDRA Coding Agent's context-aware intelligence, adaptability, and scale place it at the forefront of modern MedDRA coding, leading to strategic advantages for its users. Its adoption trajectory signals strong market traction and reshapes competitive dynamics in North America.

Leveraging its GenAI capabilities, ArisGlobal expands functionality across its Safety and Regulatory suite. Advanced Intake delivers up to 90% accuracy and 50% efficiency improvements in data capture.[1] Health Authority Interactions accelerate and clarify communications with regulators. Regulatory Intelligence automates the monitoring and dissemination of global regulatory updates, reducing compliance risks.

ArisGlobal's Early Adopters Program includes 10 global pharmaceutical companies whose aim is to pilot and refine innovations in real-world settings. This program ensures that development is grounded in practical application and measurable outcomes. The GenAI Council, founded in 2024, unites global executives, academics, and technology leaders to examine the practical applications of AI in life sciences. By shifting industry discourse from hype to measurable return on investment, ArisGlobal reinforces its role as a technology provider and a thought leader.

Enterprise Readiness, Governance, and Strategic Outlook

The full power of LifeSphere® NavaX is engineered for enterprise-wide adoption, offering modular AI architecture that spans case intake and processing, MedDRA coding, signal detection, compliance monitoring, and safety reporting. This creates a unified, AI-forward solution for pharmacovigilance and regulatory operations that scales seamlessly across large, global organizations. Its multilingual processing

[1] https://www.arisglobal.com/media/press-release/significant-case-intake-efficiencies-found-in-newly-launched-life-sciences-generative-ai-solution

capabilities ensure suitability for diverse markets, while integration with existing PV systems minimizes disruption and enhances operational efficiency.

Crucially, auditability and governance remain central to all NavaX capabilities. Every output is fully traceable, rationalized, and compliant with stringent regulatory standards, ensuring that organizations remain inspection-ready and minimizing compliance risk. This governance-first approach reinforces organizational trust while supporting the transparency required by regulators.

At a strategic level, the MedDRA Coding Agent represents a paradigm shift for intelligent MedDRA coding and broader safety operations in North America and beyond. By moving away from manual workflows and rigid, rule-based systems, it introduces agentic AI that is adaptive, autonomous, and explainable, positioning the MedDRA Coding Agent as one of the most advanced automation solutions in the industry.

Looking ahead, LifeSphere® NavaX has the potential to set a new benchmark for PV and regulatory operations globally. By enhancing accuracy, shortening cycle times, and ensuring transparent compliance, it empowers pharmaceutical companies to deliver safer therapies, expedite regulatory submissions, and improve patient outcomes. While competitors remain focused on routine process automation, LifeSphere® NavaX is differentiated by its future-proof platform designed to scale with evolving industry needs.

This leadership is reinforced by Frost & Sullivan's recognition of ArisGlobal for innovation, market leadership, and customer impact. As adoption accelerates, LifeSphere® NavaX is poised to strengthen the company's position as a global leader in safety automation and regulatory affairs—and to redefine the role of AI in life sciences.

The dual focus on delivering practical innovation while leading industry dialogue strengthens ArisGlobal's leadership position while extending its influence across the broader PV technology ecosystem. Ultimately, the company's enterprise readiness, combined with its innovation leadership, positions LifeSphere® NavaX as a transformative force in the North American PV market. Its ability to balance technological sophistication with regulatory compliance ensures adoption and long-term sustainability.

Customer Momentum and Adoption

Over the last 18 months, ArisGlobal's LifeSphere® Unify platform experienced remarkable growth, signaling widespread adoption across the pharmaceutical industry. The company welcomed 11 net new top-tier pharmaceutical customers and saw 91 existing clients expand their use of LifeSphere® solutions, underscoring continued confidence in the platform.

The Asia-Pacific region stood out with a 40% year-over-year increase in new customers, highlighting ArisGlobal's expanding global footprint. Implementation success was equally impressive, with a 23% rise in go-lives worldwide, including rollouts for three of the top 10 pharmaceutical companies.

These milestones reflect LifeSphere®'s growing role in enhancing operational efficiency, reducing costs, and driving innovation across regulatory and safety workflows with advanced AI and automation features powered by LifeSphere® NavaX. Frost & Sullivan emphasizes that the combination of innovation and execution is a defining advantage. In a market where many vendors struggle with developing and scaling

AI solutions, ArisGlobal's consistent client wins and rapid deployment record validate its position as a trusted leader in intelligent MedDRA coding.

Conclusion

ArisGlobal is a leader in intelligent MedDRA coding with the launch of its MedDRA Coding Agent powered by LifeSphere® NavaX, a first-of-its-kind agentic AI PV solution. By integrating context-aware autonomy, continuous learning, intelligent collaboration, and rigorous auditability, the MedDRA Coding Agent goes beyond traditional automation to deliver adaptive and enterprise-ready safety operations.

Proven results include efficiency gains in MedDRA coding exceeding 80%. Its modular architecture, scalability, and multilingual support position it for global deployment, enabling organizations to modernize PV at scale, even if they are not current LifeSphere® Safety customers.

ArisGlobal's innovation leadership is reinforced by its GenAI and agentic AI initiatives, the Early Adopters Program, CXO Connects, and AI Councils, which together shift the industry focus from potential to measurable outcomes. As regulatory scrutiny intensifies, the MedDRA Coding Agent positions ArisGlobal as a technology provider and strategic partner shaping the future of safety operations. The MedDRA Coding Agent introduction marks a pivotal moment for intelligent MedDRA coding in North America, addressing current challenges while laying the foundation for safer drugs, faster regulatory submissions, and better patient outcomes.

ArisGlobal earns Frost & Sullivan's 2025 North American New Product Innovation Recognition for its strong overall performance in the intelligent MedDRA coding industry.

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What You Need to Know about the New Product Innovation Recognition

Frost & Sullivan's New Product Innovation Recognition is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

Best Practices Recognition Analysis

For the New Product Innovation Recognition, Frost & Sullivan analysts independently evaluated the criteria listed below.

New Product Attributes

Match to Needs: Customer needs directly influence and inspire the product portfolio's design and positioning

Reliability: Product consistently meets or exceeds customer performance expectations

Quality: Product offers best-in-class quality with a full complement of features and functionality

Positioning: Product serves a unique, unmet need that competitors cannot easily replicate

Design: Product features an innovative design that enhances both visual appeal and ease of use

Customer Impact

Price/Performance Value: Products or services offer the best ROI and superior value compared to similar market offerings

Customer Purchase Experience: Purchase experience with minimal friction and high transparency assures customers that they are buying the optimal solution to address both their needs and constraints

Customer Ownership Excellence: Products and solutions evolve continuously in sync with the customers' own growth journeys, engendering pride of ownership and enhanced customer experience

Customer Service Experience: Customer service is readily accessible and stress-free, and delivered with high quality, high availability, and fast response time

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty, which is regularly measured and confirmed through a high Net Promoter Score®

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)

