

LifeSphere[®] Safety



Pharmacovigilance is evolving.
We'll help you stay ahead.

The life sciences industry – and pharmacovigilance teams– find themselves in a rapidly changing world.

As organizations strive to bring increasingly specialized treatments to market more quickly, they face evolving and complex global regulations, as well as pressure to deliver under tighter timelines and static budgets.

For PV teams, these trends are compounded by safety case volumes that are growing nearly 15% year-over-year.

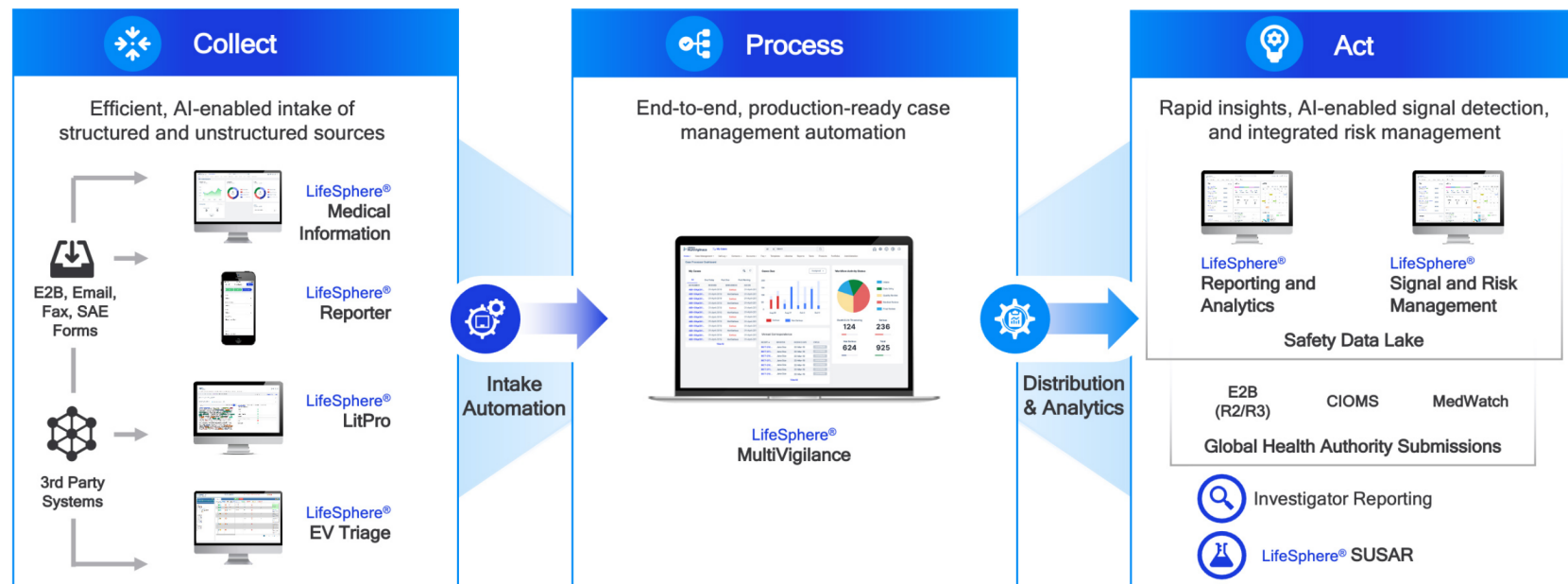
We have created LifeSphere Safety to help safety teams stay on top of the rapidly changing life sciences landscape.



What is LifeSphere Safety?

LifeSphere Safety is a unified, intelligently automated, end-to-end platform that helps safety teams save time, achieve scalable compliance, and make better decisions.

Its integrated cloud applications enable your team to **Collect** safety data efficiently, **Process** it accurately in a single global database, and **Act** on deeper insights with advanced analytics.



Industry Adoption

LifeSphere Safety is the industry's preferred safety platform and was recently recognized for this by leading analyst Frost & Sullivan. The platform is used by over 300 life science firms, including 7 of top-10 biopharmas and leading health authorities. Each year, millions of safety cases are managed in the platform by tens of thousands of users.

7 of the Top 10 Global Biopharmas

300+ Companies
Using LifeSphere Safety

3,500,000+

Safety Cases Managed in
LifeSphere Annually

30,000+

Users Working within
LifeSphere Safety

Industry Recognition



Safety Advisory Board



6 Major Health Authorities



Statens legemiddelverk
Norwegian Medicines Agency



Why LifeSphere Safety?

LifeSphere Safety is the only unified, end-to-end platform with automation in production. The leading health authorities and large biopharmas that choose LifeSphere Safety point to the unique attributes shown below.



The only end-to-end platform with production-ready automation



Unmatched end-to-end workflow efficiency



Built and deployed by the trusted experts in Safety



Always compliant with global regulations



Open architecture that avoids vendor lock-in

Deliver Deeper Safety Insights

LifeSphere Safety's intelligent automation reduces case management time by 30 percent or more. This efficiency frees resources to focus on extracting deeper insights from your safety data. This strategic approach to safety is enabled further with solutions that allow for data visualization and reporting, and AI-enabled signal detection and risk management, in a single platform.

We support three of the top COVID-19 vaccine developers.

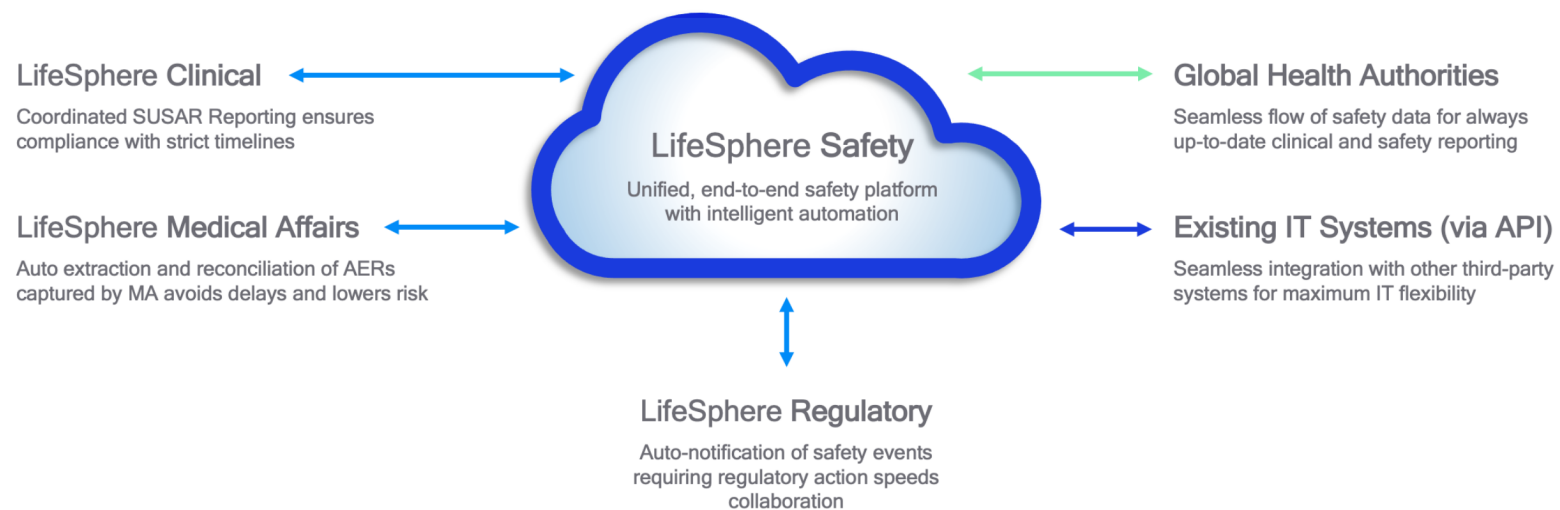


Check out our whitepaper on vaccine vigilance

[Learn More>>](#)

Part of a Unified Platform Enabling a Frictionless Data Ecosystem

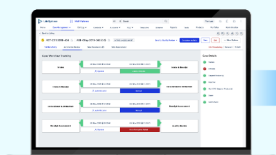
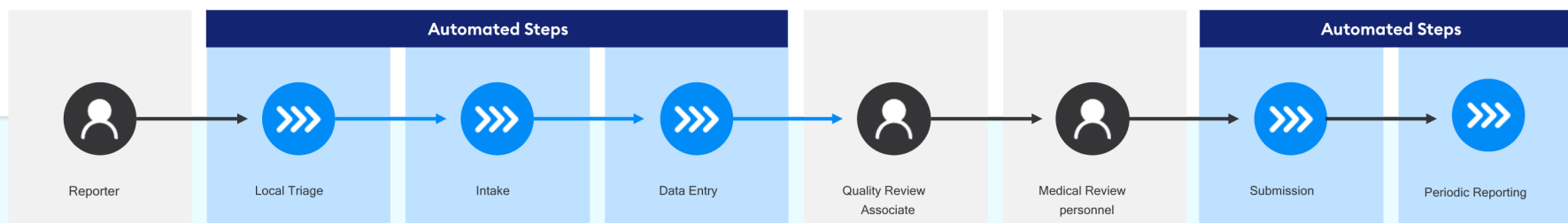
The LifeSphere Platform is a suite of cloud solutions that unify data and workflows across your R&D teams. LifeSphere's solutions for clinical, regulatory, and medical affairs provide the opportunity to harmonize your systems, increase collaboration, and simplify your IT stack.



AI Leadership in Drug Safety

Our safety database, LifeSphere MultiVigilance, is the only modern system with in-production automation, delivering significant and measurable efficiency gains to safety teams.

LifeSphere MultiVigilance automates key steps in the case management workflow:

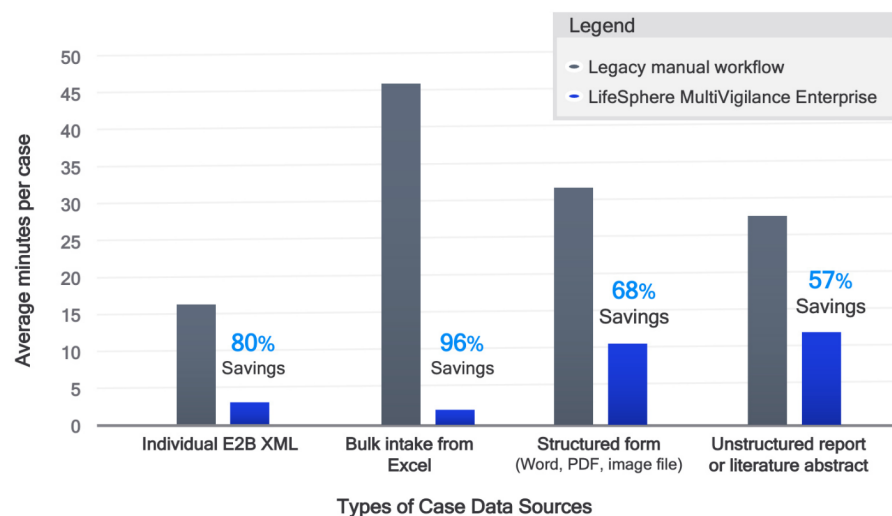


- Bulk Case Import
- Automated Case Intake
- Automated Case Data Extraction
- Automated Duplicate Check
- Automated Triage & Coding
- Automated Follow-Up
- Machine Translation-ready
- Intelligent Data Consistency Check
- Automated Submissions
- Touchless Workflows



Read the whitepaper
at arisglobal.com/pvautomation
[CLICK HERE](#)

Up to 30% End-to-end Case Processing Efficiency on Day One



Customers Succeeding with LifeSphere Safety

Replacing a Homegrown Safety System for a Top 5 Global Pharma

Situation

- Customer was experiencing compliance and technology challenges due to its 10-year old, homegrown PV application, which was struggling to handle 1MM annual AE cases (growing 15-20% YoY)
- Unsuccessful in upgrading the homegrown system, the company selected a large industry service provider to implement a competing safety application. This effort failed, as the new system ultimately lacked the flexibility and functionality to rapidly scale to the customer's needs

Solution

- LifeSphere MultiVigilance safety system was selected after a detailed RFP process, thanks to the platform's ability to meet the customer's global needs with out-of-the-box functionality and automation capabilities
- ArisGlobal deployed its Organizational Readiness offering and Managed Services team to successfully implement and onboard 2,500 end users, going live on time and with zero business interruptions

Replacing Oracle Argus at a Top 5 Global Pharma

Situation

- Company A acquired Company B and were in the middle of integrating the two organizations. Company B used LifeSphere Safety, while the larger Company A used Argus. They had a decision to make.
- A and B both had keen interest in standardizing overall PV processes and leveraging a modern, automation-enabled safety platform

Solution

- Based on positive feedback from Company B, Company A engaged ArisGlobal and initiated an intense due-diligence process to review its next-gen platform, LifeSphere Safety
- After a detailed review from the IT and functional perspective, Company A selected LifeSphere Safety thanks to its best-in-class automation and ability to deliver large scale change management to global safety teams.

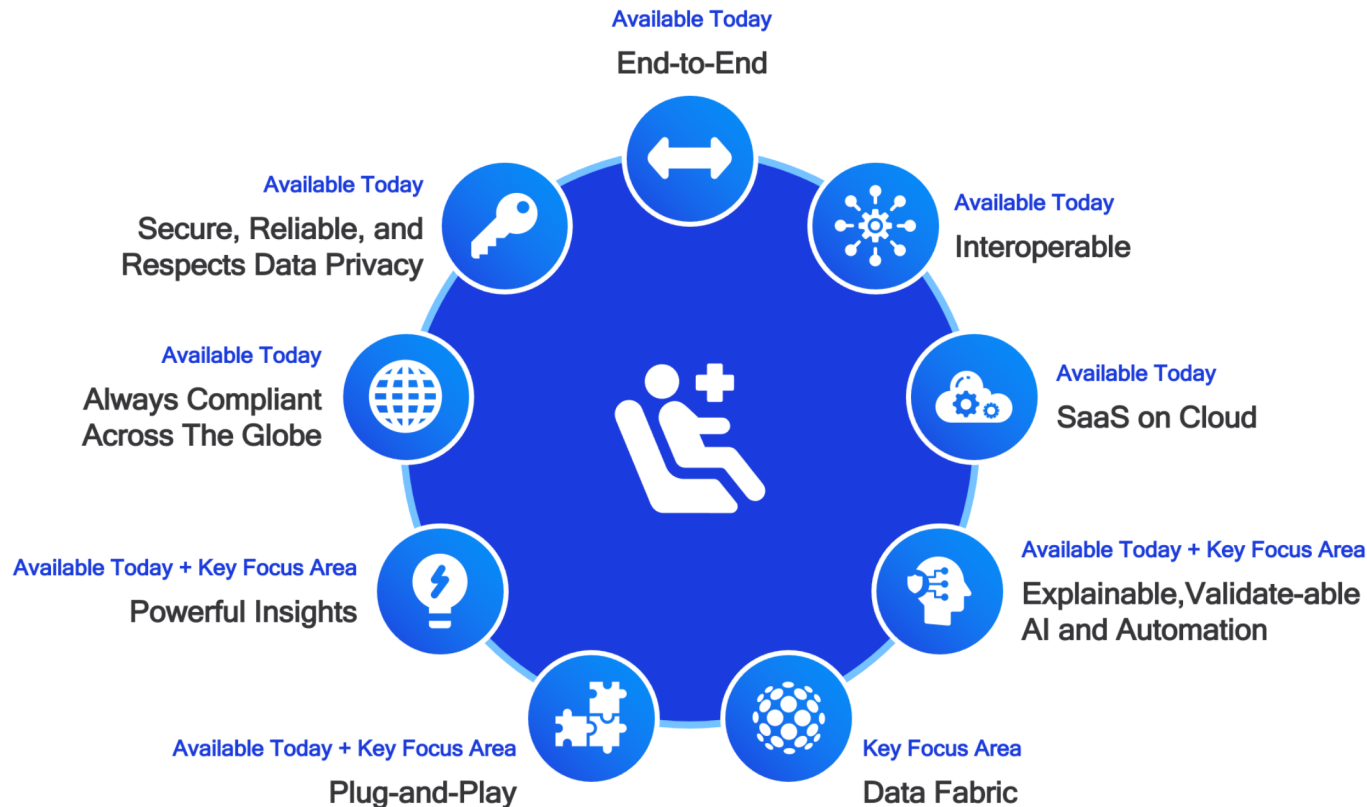
Supporting Global Biopharmas with Japanese Safety Operations

Situation

- Company 1 is a large multinational pharmaceutical company with 4,000 employees and HQ in Japan. Unhappy with Argus as its global database, Company 1 has harmonized all global safety units on LifeSphere MultiVigilance
- Company 2 is a midsize multinational pharmaceutical company with 2,500 employees and HQ in Japan. Company 2 selected LifeSphere MultiVigilance as their single cloud-based global safety system, migrating their safety systems from Clinical Works 5 (Japan) and Argus (RoW).
- Company 3 is a Top 5 pharma with global operations. After experiencing issues with their Argus database, LifeSphere MultiVigilance was selected as the single global database, including for Company 3's teams in Japan.
- Company 4 is the largest pharma company in Japan and a top-10 global pharma. Seeking advanced automation for intake of Japanese-language safety cases, the company selected ArisGlobal's LifeSphere Intake & Triage and LifeSphere Reporter to streamline data collection.

The Future of LifeSphere Safety: Where are we going from here?

We believe that the future of the PV department is one that serves as a strategic business driver, rather than an operational cost center. To achieve this, safety teams will need a cutting edge application ecosystem. The below represents our high-level roadmap for delivering upon this vision through LifeSphere Safety:



To enable this future, we are investing heavily into a few key areas:

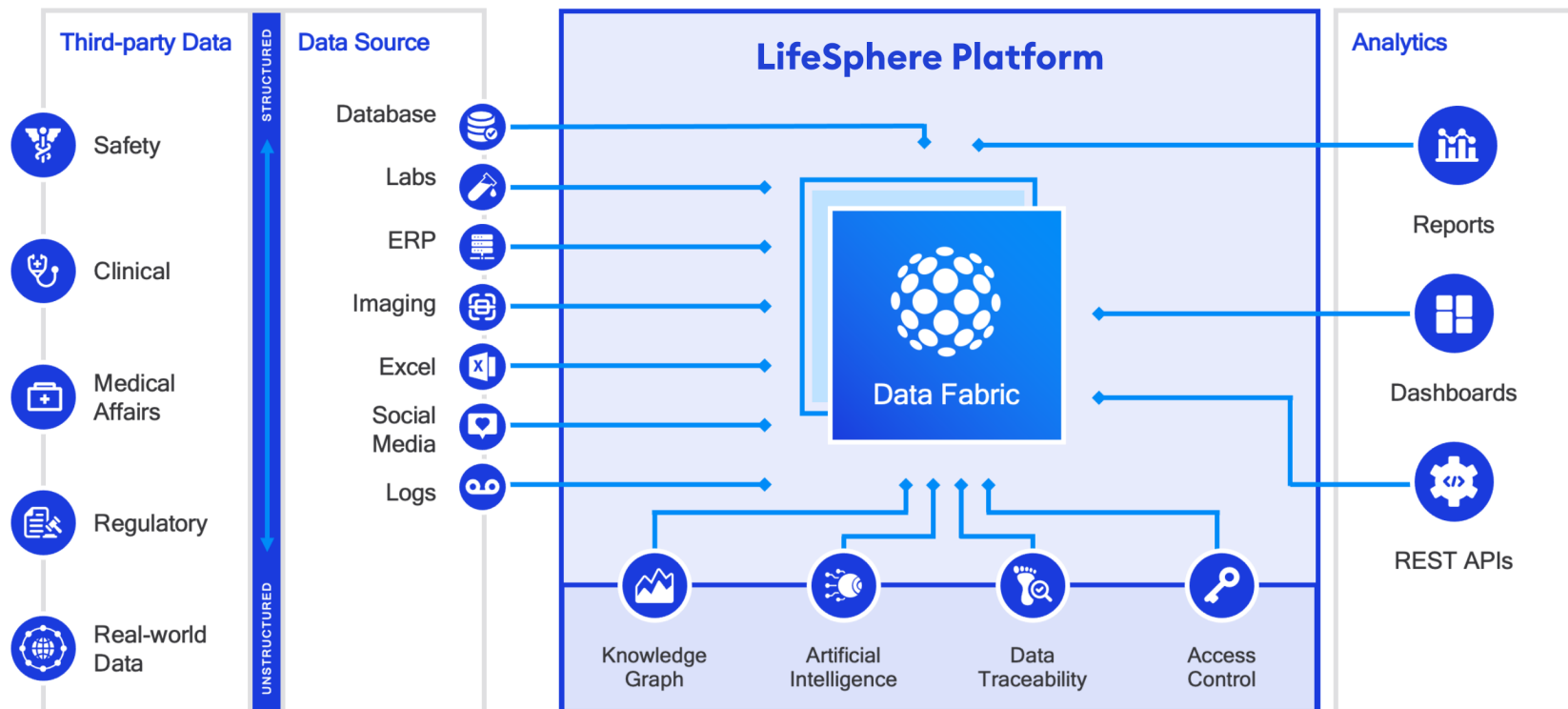
Focus Area	Available Today	Key Focus Area – Future Roadmap
Explainable, Validate-able AI and Automation	AI, RPA, rule-based automation across case intake, case management and distribution for industry prioritized use cases Pre-validated, pre-trained models in production	Investment in automation capabilities for additional use cases including medical review and assessment
End-to-End Platform Plug-and-Play	End-to-end safety system Mature multi-tenant architecture in production	Enabling more interoperability across domains Continuing to reduce total cost of ownership
Data Fabric	Technology center of excellence with focus on maximizing the value of data for our customers	Evolve data fabric architecture with RWD data stream ingestion and cross-platform analytics



Watch LifeSphere Safety's product management leaders discuss how we're enabling the future of PV through our product roadmap.

Our **LifeSphere Data Fabric** vision recognizes the rising prominence of data and the priority to turn internal and external data sets into strategic and actionable insights.

By integrating and managing safety information with other diverse data sources, and providing technologies to readily draw out insights, the LifeSphere Safety Data Fabric will help speed go-no-go decisions, reduce time to market, identify safety issues earlier, and more.



Why ArisGlobal?

- 1 The Trusted Experts in Safety** – Our solutions embed over 30 years of safety industry collaboration and are backed by our professional services team that has hundreds of combined years of experience deploying safety systems
- 2 Built with industry** – We developed LifeSphere Safety in partnership with the world's best life sciences companies. Our pragmatic approach to safety automation remains guided by our Safety Customer Advisory Board and Industry Standard Practices initiative.
- 3 The Most Innovative and Mature Safety Platform** - The only unified, end-to-end safety platform with automation in production – first to market with production-ready automation and aggressive ongoing investment toward practical and validated applications of AI and ML
- 4 Always Globally Compliant** – Our proactive approach to implementing regulatory updates lets you rest easy knowing your safety operations are always up to date with the latest global regulations
- 5 Open Architecture** – And you get an open architecture that maximizes IT flexibility, avoids vendor lock-in, and seamlessly integrates with other third-party systems including your solutions for clinical and regulatory domains.
- 6 Industry Proven** – LifeSphere Safety is the industry's preferred safety platform and is in use by hundreds of life science firms around the world, including 7 of top-10 biopharmas and leading health authorities.

Let's Connect.

We thank you for your time. We look forward to discussing more about the LifeSphere Safety platform and your organization's needs.

About ArisGlobal

ArisGlobal is transforming the way today's most successful Life Sciences companies develop breakthroughs and bring new products to market. Our end-to-end drug development technology platform, LifeSphere®, integrates our proprietary Nava® cognitive computing engine to automate all core functions of the drug development lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, LifeSphere® is a unified platform that boosts efficiency, ensures compliance, delivers actionable insights, and lowers total cost of ownership through multi-tenant SaaS architecture. Headquartered in the United States, ArisGlobal has regional offices in Europe, India, Japan and China. For more updates, follow ArisGlobal on LinkedIn and Twitter.