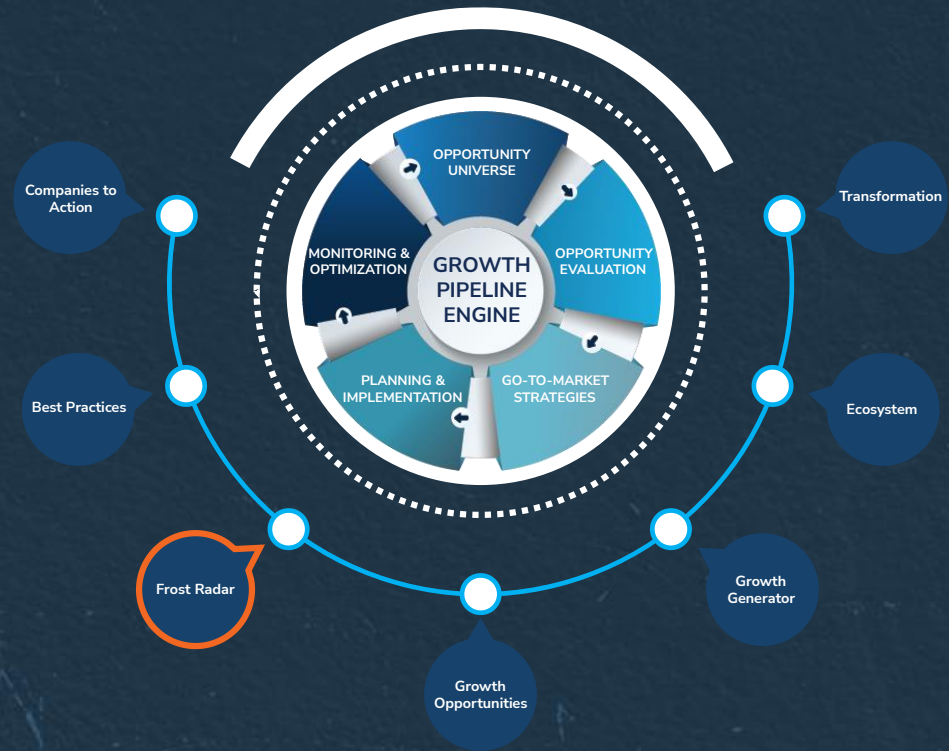


Frost Radar™: Life Sciences Regulatory Information Management Platforms, 2026

A Benchmarking System to Spark Companies to Action - Innovation That Fuels New Deal Flow and Growth Pipelines



PLTC-52

July 2026

Strategic Imperative and Growth Environment



Strategic Imperative

- A regulatory information management (RIM) platform is the operating layer that centralizes product, registration, submission, labeling, commitment, and health authority interaction data. It helps regulatory teams plan filings, prepare and publish submissions, track approvals and renewals, manage post-approval changes, and maintain a current view of what is approved in each market.
- Regulatory complexity is making platform centralization a necessity. Regulatory teams manage more markets, product types, and post-approval changes with leaner teams and tighter launch timelines. Requirements are moving from files and PDFs to structured data that can be reused across submissions, renewals, variations, labeling, and product information.
- Electronic Common Technical Document (eCTD) 4.0, Identification of Medicinal Products (IDMP), Substance, Product, Organization and Referentials (SPOR), the extended EudraVigilance Medicinal Product Dictionary (xEVMPD), and electronic product information (ePI) are shaping near-term platform buying decisions. The standards are moving regulatory operations away from document-only processes to structured, reusable, and connected data. eCTD 4.0 changes how submission content and metadata are exchanged with health authorities; IDMP and SPOR require consistent product, substance, organization, and reference data; and xEVMPD supports the submission and maintenance of medicinal product information in Europe. ePI extends this shift to digitally structured prescribing and product information.
- Japan made eCTD 4.0 mandatory in April 2026. Europe is expected to phase it in later, and the United States has not set a mandatory date. IDMP is legally required in the European Union, but operational rollout remains phased.

Strategic Imperative (continued)

- AI is shifting regulatory work from manual processing to assisted execution, but the credible use cases are few. AI is useful when it supports narrow, controlled work: metadata extraction, document comparison, submission-readiness checks, correspondence tracking, and change-impact assessment. These tasks help teams work faster while keeping human review and audit control in place.
- Cloud delivery and collaboration are now baseline expectations. Differentiation comes from integration depth, data migration support, standards readiness, and the ability to connect regulatory work with quality, safety, clinical, and document systems.
- Many companies still run regulatory work on legacy or on-premises systems. This creates a replacement opportunity, but cloud delivery alone is no longer a differentiator. The real value is the ability to connect regulatory data with quality, safety, clinical, and document systems while keeping strong access control, audit trails, and change history.
- Global filing still requires local flexibility. Requirements are moving at different speeds across Japan, Europe, the United States, Asia-Pacific, Latin America, and the Middle East. Platforms need reusable core data and templates, but they also need local workflows, regional formats, and affiliate-level control.
- Compliance is shifting from periodic audit preparation to continuous inspection readiness. Buyers now ask how a platform protects data integrity, controls user access, records changes, and supports review of automated or AI-assisted work. Governance features, such as audit trails, role-based access, configurable alerts, and validation support, are becoming premium buying criteria.

Strategic Imperative (continued)

- Time-to-market pressure is making platform investment more urgent. Regulatory delays can defer revenue and reduce the value of market exclusivity, so faster submission planning, publishing, and post-approval maintenance are now senior-level priorities. Smaller and midsize companies feel this pressure most because they manage complex filing work with leaner regulatory teams.
- Vendor consolidation is reshaping the competitive field. Buyers are moving toward platforms that connect regulatory, quality, and safety work, which puts pressure on stand-alone point tools unless they integrate cleanly into a larger operating layer. AI-native entrants are also pushing established vendors to modernize faster. Partnerships with contract research organizations (CROs), consultancies, and hyperscaler cloud providers are becoming useful go-to-market and delivery differentiators.

Growth Environment

- Installed-base expansion drives most growth. Customers often begin with one capability, such as registrations, intelligence, or publishing, then add modules, products, and markets over time. A connected data model makes each adjacent module easier to add than a separate point tool, so expansion economics and net revenue retention are strong indicators of growth quality.
- Growth is concentrating in emerging markets, while mature markets anchor revenue. North America and Europe remain the largest revenue base, but the faster growth rates sit where regulatory modernization and export-driven filing are expanding the buyer pool from a smaller starting point: India, China, the wider Asia-Pacific region, and the Middle East and North Africa,. This shifts the next wave of growth toward vendors investing early in localized sales, regional content, and language coverage. Mature markets continue to drive absolute revenue and reference accounts, so the practical picture is a dual-speed market: scale in the West, and rate of growth in the East and South.
- AI maturity is splitting the vendor field. Narrow AI is now common across platforms, so it no longer separates vendors by itself. The stronger differentiator is whether multistep or agentic automation is in production, in pilot, or still on the roadmap.
- AI delivers value in bounded tasks. Production-grade AI is most common in publishing quality control, submission checks, document processing, document comparison, regulatory intelligence monitoring, and translation. These use cases work because outputs can be reviewed and validated before they affect regulated decisions.
- Agentic automation remains early. Many vendors market systems that can reason across regulatory processes and execute multistep work with limited human input, but most examples remain pilots or roadmap items. Cross-domain decision intelligence is still largely unreleased.

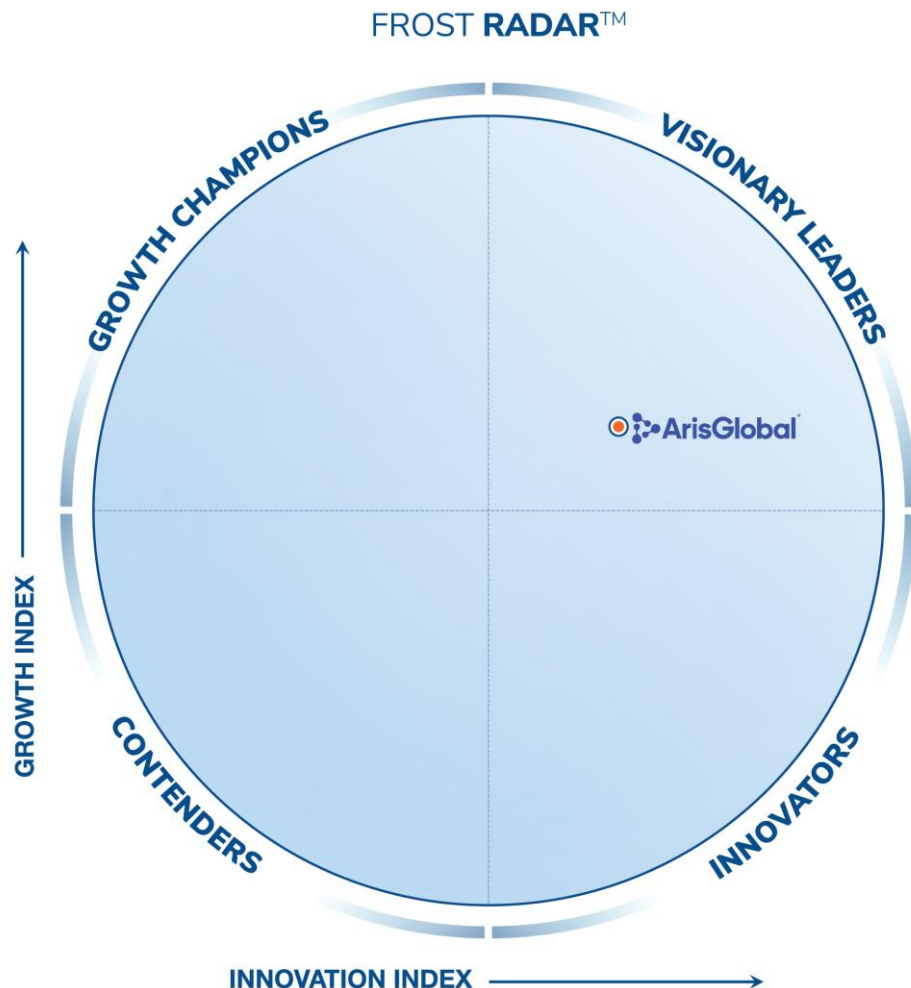
Growth Environment (continued)

- Execution constraints, not weak demand, are the main limit on growth. Implementation capacity, legacy data migration, and long enterprise buying cycles slow adoption. Large pharma remains well served, while small and midsize companies remain underserved. Fast deployment, lower entry pricing, and managed services are the clearest ways to convert that unmet demand.
- The market structure is tiered. One scale leader has the strongest executive-level brand pull. A group of regulatory specialists competes on product fit, flexibility, and global regulatory depth. A small set of submission and publishing vendors holds an authority-side compliance niche. Regional and modular vendors compete in focused segments.

Frost Radar™: Life Sciences Regulatory Information Management Platforms



Frost Radar™: Life Sciences Regulatory Information Management Platforms



In a specialized market with a focused pool of qualified regulatory technology vendors meeting Frost & Sullivan's scope criteria of productized software supporting day-to-day regulatory execution across pharmaceutical, biotech, or combination-product teams, Frost & Sullivan independently evaluated the landscape and selected just 11 companies to be benchmarked in this Frost Radar™. This small, carefully chosen group represents organizations that rise above the broader market, demonstrating not only strong growth but a clear capacity to innovate and lead. Inclusion is not simply recognition; it signals that a company is operating at the forefront of its industry.

This evaluation is led by Frost & Sullivan's experienced global analyst team, combining deep domain expertise with a rigorous, fact-based approach. Using our proprietary, multi-dimensional benchmarking methodology, applied consistently and validated by analysts. Frost & Sullivan ensures a fair, globally comparable, and defensible assessment of true market leadership.

Frost Radar™: Competitor Categories

GROWTH CHAMPIONS

- Companies that have achieved significant market growth through strong execution
- Compete by leveraging proven technologies, scalable business models, and operational efficiency
- Included for their ability to consistently capture demand and deliver results at scale
- Must increase investment in innovation to sustain long-term leadership

CONTENDERS

- Companies with focused strength in specific segments, use cases, or regions
- Compete through deep specialization and targeted customer relevance
- Included for demonstrating credible capabilities, though limited in scale or innovation breadth
- Must expand both market reach and innovation capabilities to compete at scale

VISIONARY LEADERS

- Companies that demonstrate leadership across both growth and innovation at scale
- Compete by combining transformative innovation with disciplined execution
- Included for their ability to shape market direction while delivering sustained growth
- Must continue to scale innovation while defending leadership in an increasingly competitive market

INNOVATORS

- Companies that lead in technology, product innovation, and market disruption
- Compete by introducing differentiated solutions and shaping future use cases
- Included for their strong innovation capabilities, despite more limited commercial scale
- Must strengthen go-to-market execution to translate innovation into sustained growth

Frost Radar™ Competitive Environment

- The 2026 competitive environment reflects a focused group of global and specialist providers combining regulatory data models, submission and publishing depth, workflow automation, regulatory intelligence, labeling support, quality integration, and AI-enabled capabilities. The market is moving from document-centric compliance to data-centric regulatory operations. Innovation centers on structured product and registration data, eCTD 4.0 readiness, IDMP/SPOR alignment, health authority interaction management, analytics, practical AI use cases, and implementation models that reduce migration and adoption risk.
- ArisGlobal stands as the leading regulatory specialist alternative, with its LifeSphere platform covering investigational and marketed products, active substances, and devices across complex, multicountry, multiformat work. Native IDMP, SPOR, and xEVMPD support and dedicated reference data management give it real depth, and its NavaX generative AI is extending that into analytics and regulatory intelligence.

Frost Radar™: Companies to Action



ArisGlobal

VISIONARY LEADER

INNOVATION SCORE **4.30**

GROWTH SCORE **4.00**

INNOVATION

- ArisGlobal differentiates through the breadth of its LifeSphere Regulatory ecosystem, with LifeSphere RIM positioned as the central control layer for registration data, planning, tracking, and life cycle records. Unlike narrower RIM or publishing-led vendors, ArisGlobal combines RIM with product compliance, submissions, document management, labeling, regulatory intelligence, health authority interactions, analytics, and SPORIFY reference data management. This gives the platform a stronger structured data and regulatory operations backbone than point solutions that mainly manage registrations, documents, or publishing.
- Its strongest innovation differentiator is the move from a traditional system of record to AI-enabled regulatory execution. Through NavaX, ArisGlobal is applying advanced AI to practical regulatory use cases, such as regulatory intelligence intake, content extraction, health authority communication processing, automated classification, summarization, response drafting, and submission-related support. This is more defensible than generic AI positioning because the use cases are tied to high-friction regulatory workflows where manual effort, response consistency, and traceability matter.
- ArisGlobal's regulatory intelligence and health authority interaction capabilities are relevant differentiators. Regulatory intelligence helps convert external regulatory changes into searchable, actionable knowledge. Health authority interaction workflows support intake, classification, tracking, response preparation, and knowledge reuse around authority communications. These are important because many competitors still treat regulatory intelligence and health authority correspondence as adjacent capabilities rather than workflow-connected operating layers.

ArisGlobal (continued)

VISIONARY LEADER

INNOVATION SCORE **4.30**

GROWTH SCORE **4.00**

INNOVATION

- ArisGlobal's Product Compliance and SPORIFY capabilities strengthen its position around IDMP, SPOR, xEVMPD, product master data, and reference data governance. This is a key advantage as the market shifts from document-centric regulatory management to reusable product, registration, submission, and labeling data. Compared with vendors that depend more heavily on integrations or custom data models, ArisGlobal has a clearer native story around regulated product data and reference data synchronization.
- The ecosystem is also built for complex, global regulatory operations. ArisGlobal supports investigational products, marketed products, active substances, medical devices, and adjacent regulated categories, with workflows covering CTA/IND, MAA/BLA/NDA, CEP/ASMF/DMF, 510(k), PMA, and CE Mark scenarios. Its European regulatory heritage strengthens its ability to address multicountry, multiformat, and region-specific complexity, which can be a differentiator against more US-centric providers.

ArisGlobal (continued)

VISIONARY LEADER

INNOVATION SCORE **4.30**

GROWTH SCORE **4.00**

GROWTH

- ArisGlobal reports more than 60 regulatory organizations and over 100,000 users in the ecosystem, ranging from small specialist regulatory groups to top-20 pharmaceutical companies, with one such account running roughly 12,000 users on a single system. The company is strongest in pharma and biotech, with strength in generics. It employs about 1,500 people globally and is privately held and backed by Nordic Capital.
- Growth comes mainly from customers adding products or widening their footprint, with a steady flow of new logos as well. Sales are led mainly by the direct sales team. Recent traction has been strongest in India and the wider Asia-Pacific region, which ArisGlobal sees as underserved, and the newer analytics and regulatory intelligence capabilities are pulling demand. Churn is low and sits mainly in older, heavily customized accounts as the company moves them onto standard SaaS.
- Veeva remains stronger in executive-level brand pull and market leadership. ArisGlobal can win where regulatory business users prioritize product fit, global regulatory complexity, structured data, AI-enabled workflow automation, and openness to specialist providers. Its positioning is strongest when buyers want a more regulatory-specialized and flexible platform rather than a broad enterprise cloud standardization decision.
- Growth constraints include competition from larger vendors, migration complexity, implementation capacity, and the shift from legacy customization to SaaS best-practice deployments. This transition may create friction with heavily customized legacy customers, but it improves long-term scalability and upgradeability.

ArisGlobal (continued)

VISIONARY LEADER

INNOVATION SCORE **4.30**

GROWTH SCORE **4.00**

FROST PERSPECTIVE

- ArisGlobal sits as a high-innovation challenger—a credible and regulatory-specialized alternative to the incumbent rather than the overall share leader.
- ArisGlobal can press its data-centric position into the IDMP, SPOR, and PMS deadline cycle (where document-led rivals are weakest) and convert the India and Asia-Pacific traction it describes as underserved into named reference accounts.
- ArisGlobal should move NavaX from demonstrated use cases to referenceable production outcomes, since AI is now judged on proof rather than positioning, and publish customer-validated results to support the score.
- ArisGlobal must carry its heavily customized legacy accounts onto standard SaaS without churn or delivery strain, because that migration—and the partner and implementation capacity behind it—is the main brake on faster growth.

Best Practices & Growth Opportunities



Best Practices

1

Start with validated AI in high-value tasks, such as publishing quality checks, document processing, and regulatory intelligence monitoring. Scale toward agentic workflows only after pilots show clear results and GxP oversight is in place.

2

Prioritize open, API-first architecture and a connected data model. Offer pre-built connectors and low-code configuration so new regional and standards requirements can be absorbed without re-implementation.

3

Use repeatable playbooks for migration, onboarding, expansion, and renewal. Pair platform and services delivery so legacy data migration becomes a managed service, not a deal blocker.

Growth Opportunities

1

Agentic AI is the strongest near-term lever, executing across renewals, variations, and labeling with premium pricing potential. Capturing it depends on validated production deployment and on clearing skills and validation barriers.

2

The structured-data shift across eCTD 4.0, IDMP, and SPOR creates a multiyear replacement pipeline. Vendors with working capability against live mandates, starting with Japan, will win first.

3

Platform consolidation and emerging-market expansion create the largest deal opportunities. Retiring point tools onto one platform makes contracts stickier, while India, APAC, MENA, and China expand the buyer base.

Frost Radar™ Analytics



Frost Radar™: Benchmarking Future Growth Potential

2 Major Indices, 10 Analytical Ingredients, 1 Platform

Growth Index

Growth Index (GI) is a measure of a company's growth performance and track record, along with its ability to develop and execute a fully aligned growth strategy and vision; a robust growth pipeline system; and effective market, competitor, and end-user focused sales and marketing strategies.

GI1

MARKET SHARE (PREVIOUS 3 YEARS)

This is a comparison of a company's market share relative to its competitors in a given market space for the previous 3 years.

GI2

REVENUE GROWTH (PREVIOUS 3 YEARS)

This is a look at a company's revenue growth rate for the previous 3 years in the market/industry/category that forms the context for the given Frost Radar.

GI3

GROWTH PIPELINE™

This is an evaluation of the strength and leverage of a company's growth pipeline system to continuously capture, analyze, and prioritize its universe of growth opportunities.

GI4

VISION AND STRATEGY

This is an assessment of how well a company's growth strategy is aligned with its vision. Are the investments that a company is making in new products and markets consistent with the stated vision?

GI5

SALES AND MARKETING

This is a measure of the effectiveness of a company's sales and marketing efforts in helping it drive demand and achieve its growth objectives.

Frost Radar™: Benchmarking Future Growth Potential

2 Major Indices, 10 Analytical Ingredients, 1 Platform (continued)

Innovation Index

Innovation Index (II) is a measure of a company's ability to develop products/ services/ solutions (with a clear understanding of disruptive megatrends) that are globally applicable, are able to evolve and expand to serve multiple markets and are aligned to customers' changing needs.

II1

INNOVATION SCALABILITY

This determines whether an organization's innovations are globally scalable and applicable in both developing and mature markets, and also in adjacent and non-adjacent industry verticals.

II2

RESEARCH AND DEVELOPMENT

This is a measure of the efficacy of a company's R&D strategy, as determined by the size of its R&D investment and how it feeds the innovation pipeline.

II3

PRODUCT PORTFOLIO

This is a measure of a company's product portfolio, focusing on the relative contribution of new products to its annual revenue.

II4

MEGATRENDS LEVERAGE

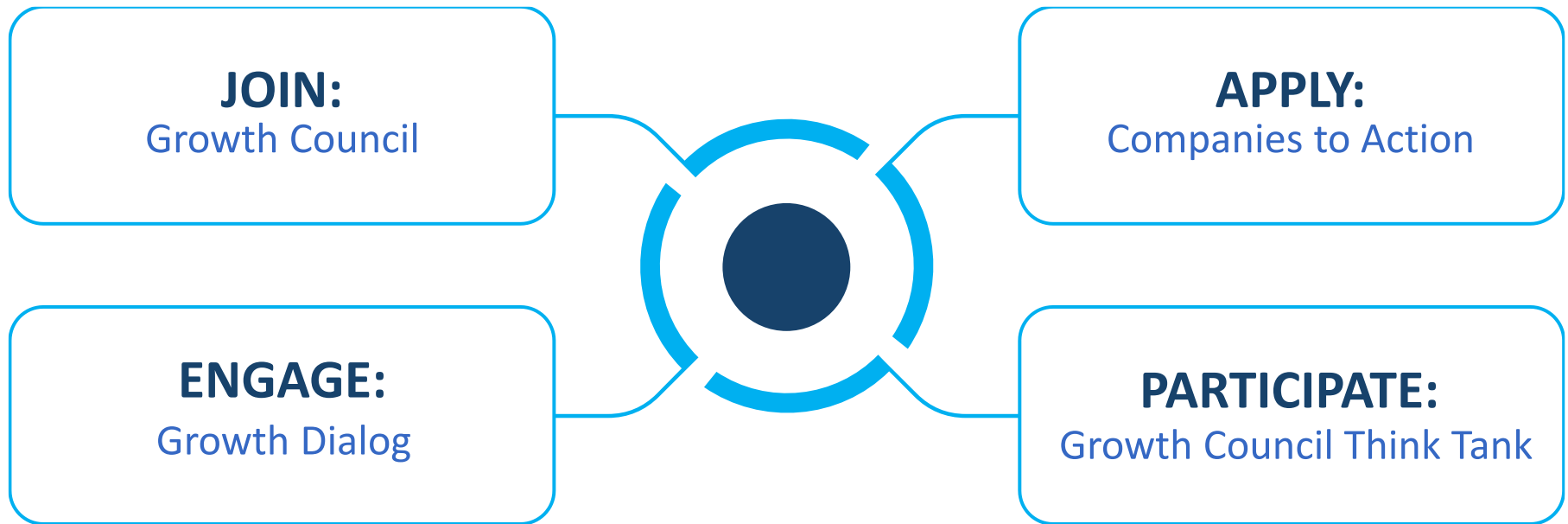
This is an assessment of a company's proactive leverage of evolving, long-term opportunities and new business models, as the foundation of its innovation pipeline. An explanation of megatrends can be found [here](#).

II5

CUSTOMER ALIGNMENT

This evaluates the applicability of a company's products/services/solutions to current and potential customers, as well as how its innovation strategy is influenced by evolving customer needs.

Next Steps



Does your current system support rapid adaptation to emerging opportunities?

Legal Disclaimer

Frost & Sullivan is not responsible for any incorrect information supplied by companies or users. Quantitative market information is based primarily on interviews and therefore is subject to fluctuation. Frost & Sullivan research services are limited publications containing valuable market information provided to a select group of customers. Customers acknowledge, when ordering or downloading, that Frost & Sullivan research services are for internal use and not for general publication or disclosure to third parties. No part of this research service may be given, lent, resold, or disclosed to noncustomers without written permission. Furthermore, no part may be reproduced, stored in a retrieval system, or transmitted in any form or by any means—electronic, mechanical, photocopying, recording, or otherwise—without the permission of the publisher.

For information regarding permission, write to: permission@frost.com

© 2026 Frost & Sullivan. All rights reserved. This document contains highly confidential information and is the sole property of Frost & Sullivan. No part of it may be circulated, quoted, copied, or otherwise reproduced without the written approval of Frost & Sullivan.