ISG Provider Lens®

Life Sciences Digital Services

Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)

A research report evaluating IT service provider and CRO capabilities across key areas

Customized report courtesy of:

Deloitte.

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AI and platform ecosystems are driving unified transformation across the life sciences value chain

This study shows the life sciences services landscape progressing beyond function-specific transformation toward value-chain-wide modernization, with IT service providers and CROs both repositioning around integrated, AI-enabled and platform-led delivery. Across clinical development, patient engagement, pharmacovigilance, regulatory functions for CROs, and manufacturing, supply chain and commercial operations for service providers, the shift is moving from isolated digital interventions to connected operating models that integrate data, workflows, compliance and outcomes.

A defining pattern across the market is the transition from digital enablement to intelligence-led execution. GenAI is being embedded into protocol design, documentation, safety processing, engagement orchestration and commercial decision support, while agentic models are beginning to reshape how decisions, content and workflows are coordinated across the life sciences value chain. Rather than functioning as a standalone innovation layer, AI is increasingly being treated as the operating fabric enabling speed, quality, compliance and personalization.

Rising operational complexity and reduced tolerance for fragmented execution are shaping current market dynamics. Clinical and safety environments face demanding regulatory expectations, higher reporting volumes, growing inspection pressure and the need to align interconnected processes across development, regulatory and post-approval functions. Meanwhile, data estates remain distributed across clinical, quality, safety, engagement and enterprise platforms, making interoperability and unified governance essential to achieving transformation success.

A structural shift toward cloud-native, interoperable and platform-centric

AI-native, platform-driven transformation is redefining life sciences value chains

architectures is accelerating. Unified data foundations, API-led integration, microservices and connected ecosystems spanning clinical, safety, regulatory, engagement and enterprise platforms are emerging as the backbone of scalable modernization. This reflects a broader need for longitudinal visibility, cross-functional intelligence and regulatory-grade traceability throughout the product lifecycle.

Another major shift is the acceleration of decentralized and hybrid models. Clinical development and patient engagement are moving toward lower-friction, more distributed participation models supported by digital tools, remote interactions and real-world data integration. This is expanding the role of technology from workflow support to experience orchestration, with patient-centricity now directly linked to enrollment, retention, adherence and data continuity.

Within this context, CROs are evolving from execution-focused delivery partners to technology-enabled strategic actors. Clinical execution, patient engagement and safety operations are increasingly evaluated together, and differentiation is shifting toward the ability to combine hybrid trial infrastructure, AI-enabled workflows, integrated governance and predictable delivery.

Enterprise buyers are prioritizing end-to-end data integration, governance and execution visibility over point solutions. Across the value chain, the emphasis is on connected data environments that support faster decisions, stronger auditability and better workflow coordination. In clinical development, this requires interoperable ecosystems spanning study design, trial management, data capture and regulatory documentation. In patient engagement, it requires unified patient views across multiple interaction channels. In pharmacovigilance and regulatory functions, it demands harmonized environments linking safety, regulatory, clinical and quality systems.

Enterprises are also investing in AI, GenAI and automation as foundational levers of operational performance. Key priorities include accelerating protocol design, improving site selection, automating data mapping, detecting anomalies, enabling AI-assisted documentation, strengthening signal detection, personalizing engagement, improving adherence, supporting intelligent case processing and orchestrating next-best actions. The expectation is that AI will simultaneously reduce cycle times, improve decision quality and strengthen compliance.

Expectations differ across partner types. Service providers are expected to drive enterprise-level transformation and business layers combining platform engineering, cloud modernization, data foundations, commercial enablement and manufacturing digitization. CROs are expected to deliver differentiated value where operational depth intersects with digital execution, particularly in clinical delivery, patient engagement, pharmacovigilance operations and flexible sourcing models.

GenAI and agentic AI adoption priorities also vary by function. Clinical development focuses on protocol optimization, feasibility and intelligent documentation. Patient engagement emphasizes hyper-personalized journeys and conversational interfaces. Pharmacovigilance and regulatory functions prioritize automation, signal detection and structured authoring. Commercial operations focus on decision intelligence and content generation, while manufacturing and supply chain functions emphasize predictive and real-time operational insights.

The ecosystem is evolving through a mix of convergence and differentiation. Service providers are expanding their role through platform engineering, AI enablement, consulting-led transformation and managed services spanning commercial operations, manufacturing, supply chain and enterprise IT layers. Their strength lies in integrating front-, middle- and back-office systems into cohesive, scalable architectures.

CROs are advancing deeper into technology-enabled delivery within the regulated core of the value chain. They are embedding AI, analytics and digital platforms into clinical operations, patient engagement and pharmacovigilance processes to enhance execution quality, speed and predictability. Their evolution centers on combining operational depth with digital acceleration.

Executive Summary

Convergence is most visible in clinical data ecosystems, patient engagement and AI-driven orchestration. Both service providers and CROs are building capabilities around interoperable data platforms, workflow automation, predictive analytics and patient-centric models. Success in these areas depends on embedding intelligence directly into operational workflows.

Despite convergence, structural differentiation persists. CROs retain strengths in clinical execution, patient access, pharmacovigilance operations and flexible delivery models. Service providers maintain advantages in enterprise-scale transformation, including commercial platforms, manufacturing modernization, cloud infrastructure and cross-functional integration. The result is a complementary yet increasingly overlapping competitive landscape.

Ecosystem-led strategies are becoming more critical. Partnerships, co-innovation models and platform ecosystems play a key role in delivering integrated solutions that combine domain expertise, data interoperability and AI capabilities across the value chain.

The market is entering a new phase defined by progression from GenAI-enabled productivity to agentic coordination and, ultimately, more autonomous operations. Competitive advantage will increasingly depend on the ability to embed intelligence across end-to-end workflows spanning clinical development, patient engagement, pharmacovigilance, manufacturing and commercial functions.

Platformization will continue to intensify as unified data environments and interoperable architectures become essential for scaling AI in regulated environments. As a result, boundaries between service providers and CROs will continue to blur, particularly in clinical, patient and regulatory domains where data, execution and compliance intersect.

Future competitive shifts will be driven by the ability to combine regulatory-grade trust, connected data foundations, AI-native workflows and measurable business impact. The market will increasingly reward organizations that can translate value-chain complexity into integrated, intelligent and scalable operating models.

Life sciences enterprises are accelerating AI, GenAI and platform adoption to drive end-to-end integration across clinical, patient, regulatory and commercial functions. The convergence of service providers and CROs is reshaping delivery models, with increasing focus on data interoperability, intelligent workflows and patient-centric outcomes.

Provider Positioning

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	Clinical Development (Service Providers)	Patient Engagement (Service Providers)	Manufacturing and Supply Chain (Service Providers)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)	Commercial Operations - Digital Evolution (Service Providers)	Clinical Development (CROs)	Patient Engagement (CROs)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)
Accenture	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
Advanced Clinical	Not In	Not In	Not In	Not In	Not In	Product Challenger	Contender	Product Challenger
All for One Group	Not In	Not In	Product Challenger	Not In	Product Challenger	Not In	Not In	Not In
Allucent	Not In	Not In	Not In	Not In	Not In	Contender	Not In	Contender
Altasciences	Not In	Not In	Not In	Not In	Not In	Contender	Not In	Not In
Altimetrik	Contender	Not In	Product Challenger	Not In	Product Challenger	Not In	Not In	Not In
Apexon	Product Challenger	Product Challenger	Not In	Not In	Not In	Not In	Not In	Not In
Atos	Product Challenger	Market Challenger	Market Challenger	Not In	Not In	Not In	Not In	Not In
Beyondsoft	Not In	Contender	Not In	Contender	Not In	Not In	Not In	Not In
Birlasoft	Contender	Contender	Contender	Contender	Contender	Not In	Not In	Not In

Provider Positioning

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	Clinical Development (Service Providers)	Patient Engagement (Service Providers)	Manufacturing and Supply Chain (Service Providers)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)	Commercial Operations - Digital Evolution (Service Providers)	Clinical Development (CROs)	Patient Engagement (CROs)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)
Brillio	Contender	Contender	Contender	Not In	Contender	Not In	Not In	Not In
Caidya	Not In	Not In	Not In	Not In	Not In	Not In	Contender	Product Challenger
Capgemini	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
Celerion	Not In	Not In	Not In	Not In	Not In	Contender	Not In	Not In
Cencora Pharmalex	Not In	Not In	Not In	Not In	Not In	Product Challenger	Not In	Rising Star ★
CenExel	Not In	Not In	Not In	Not In	Not In	Contender	Contender	Not In
Charles River Laboratories	Not In	Not In	Not In	Not In	Not In	Market Challenger	Not In	Not In
CitiusTech	Not In	Product Challenger	Not In	Product Challenger	Not In	Not In	Not In	Not In
Clario	Not In	Not In	Not In	Not In	Not In	Contender	Rising Star ★	Not In
Coforge	Product Challenger	Product Challenger	Product Challenger	Product Challenger	Product Challenger	Not In	Not In	Not In

Provider Positioning

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	Clinical Development (Service Providers)	Patient Engagement (Service Providers)	Manufacturing and Supply Chain (Service Providers)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)	Commercial Operations - Digital Evolution (Service Providers)	Clinical Development (CROs)	Patient Engagement (CROs)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)
Cognizant	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
Deloitte	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
DXC Technology	Contender	Contender	Contender	Contender	Contender	Not In	Not In	Not In
Evotec	Not In	Not In	Not In	Not In	Not In	Product Challenger	Not In	Not In
Fortrea	Not In	Not In	Not In	Not In	Not In	Product Challenger	Product Challenger	Market Challenger
Frontage Laboratories	Not In	Not In	Not In	Not In	Not In	Contender	Not In	Not In
Genpact	Not In	Product Challenger	Leader	Market Challenger	Market Challenger	Not In	Not In	Not In
HCLTech	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
Hexaware	Leader	Leader	Not In	Not In	Rising Star ★	Not In	Not In	Not In
Hitachi Digital Services	Market Challenger	Product Challenger	Market Challenger	Not In	Not In	Not In	Not In	Not In

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	Clinical Development (Service Providers)	Patient Engagement (Service Providers)	Manufacturing and Supply Chain (Service Providers)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)	Commercial Operations - Digital Evolution (Service Providers)	Clinical Development (CROs)	Patient Engagement (CROs)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)
ICON plc	Not In	Not In	Not In	Not In	Not In	Leader	Leader	Leader
Indegene	Product Challenger	Product Challenger	Not In	Product Challenger	Leader	Not In	Not In	Not In
Infosys	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
Innova Solutions	Product Challenger	Contender	Product Challenger	Product Challenger	Market Challenger	Not In	Not In	Not In
IQVIA	Not In	Not In	Not In	Not In	Not In	Leader	Leader	Leader
Kyndryl	Contender	Contender	Contender	Not In	Contender	Not In	Not In	Not In
LTM	Rising Star ★	Product Challenger	Leader	Contender	Product Challenger	Not In	Not In	Not In
Marlabs	Not In	Not In	Contender	Product Challenger	Not In	Not In	Not In	Not In
Medpace	Not In	Not In	Not In	Not In	Not In	Rising Star ★	Product Challenger	Product Challenger
NexusTek	Contender	Contender	Contender	Contender	Contender	Not In	Not In	Not In

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	Clinical Development (Service Providers)	Patient Engagement (Service Providers)	Manufacturing and Supply Chain (Service Providers)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)	Commercial Operations - Digital Evolution (Service Providers)	Clinical Development (CROs)	Patient Engagement (CROs)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)
NTT DATA	Leader	Rising Star ★	Leader	Not In	Market Challenger	Not In	Not In	Not In
Orion Innovation	Contender	Not In	Not In	Contender	Not In	Not In	Not In	Not In
Parexel	Not In	Not In	Not In	Not In	Not In	Leader	Market Challenger	Leader
Persistent Systems	Product Challenger	Product Challenger	Product Challenger	Rising Star ★	Product Challenger	Not In	Not In	Not In
PPD	Not In	Not In	Not In	Not In	Not In	Leader	Leader	Leader
Quantiphi	Product Challenger	Product Challenger	Contender	Product Challenger	Contender	Not In	Not In	Not In
Stefanini	Not In	Product Challenger	Not In	Not In	Not In	Not In	Not In	Not In
Syneos Health	Not In	Not In	Not In	Not In	Not In	Leader	Leader	Leader
Tata Elxsi	Contender	Not In	Market Challenger	Contender	Not In	Not In	Not In	Not In
TCS	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In

Provider Positioning

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	Clinical Development (Service Providers)	Patient Engagement (Service Providers)	Manufacturing and Supply Chain (Service Providers)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)	Commercial Operations - Digital Evolution (Service Providers)	Clinical Development (CROs)	Patient Engagement (CROs)	Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)
Tech Mahindra	Leader	Product Challenger	Rising Star	Leader	Leader	Not In	Not In	Not In
TFS International	Not In	Not In	Not In	Not In	Not In	Contender	Contender	Not In
T-Systems	Product Challenger	Not In	Not In	Not In	Not In	Not In	Not In	Not In
UST	Product Challenger	Market Challenger	Market Challenger	Contender	Market Challenger	Not In	Not In	Not In
Veristat	Not In	Not In	Not In	Not In	Not In	Contender	Contender	Product Challenger
Virtusa	Contender	Contender	Contender	Not In	Product Challenger	Not In	Not In	Not In
Wipro	Leader	Leader	Leader	Leader	Leader	Not In	Not In	Not In
Worldwide Clinical Trials	Not In	Not In	Not In	Not In	Not In	Product Challenger	Market Challenger	Product Challenger
WuXi AppTec	Not In	Not In	Not In	Not In	Not In	Market Challenger	Market Challenger	Not In
Zensar Technologies	Contender	Product Challenger	Product Challenger	Contender	Product Challenger	Not In	Not In	Not In

This study focuses on **digital transformation solutions and services** for the **life sciences** industry.

Simplified Illustration Source: ISG 2026

Scope of the Report

This ISG Provider Lens® quadrant report covers the following eight quadrants for services/ solutions: Clinical Development (Service Providers), Patient Engagement (Service Providers), Manufacturing and Supply Chain (Service Providers), Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers), Commercial Operations - Digital Evolution (Service Providers), Clinical Development (CROs), Patient Engagement (CROs) and Pharmacovigilance and Regulatory Affairs - Digital Evolution (CROs)

This ISG Provider Lens® study offers IT-decision makers:

- Transparency on the strengths and weaknesses of relevant providers
- A differentiated positioning of providers by segments
- Focus on Global market

This ISG Provider Lens® study offers IT-decision makers: Our study serves as the basis for important decision-making in terms of positioning, key relationships and go-to-market considerations. ISG advisors and enterprise clients also use information from these reports to evaluate their existing provider.

Provider Classifications

The provider position reflects the suitability of providers for a defined market segment (quadrant). Without further additions, the position always applies to all company sizes classes and industries. In case the service requirements from enterprise customers differ and the spectrum of providers operating in the local market is sufficiently wide, a further differentiation of the providers by performance is made according to the target group for products and services. In doing so, ISG either considers the industry requirements or the number of employees, as well as the corporate structures of customers and positions providers according to their focus area. As a result, ISG differentiates them, if necessary, into two client target groups that are defined as follows:

- **Midmarket:** Companies with 100 to 4,999 employees or revenues between $20 million and $999 million with central headquarters in the respective country, usually privately owned.
- **Large Accounts:** Multinational companies with more than 5,000 employees or revenue above $1 billion, with activities worldwide and globally distributed decision-making structures.

The ISG Provider Lens® quadrants are created using an evaluation matrix containing four segments (Leader, Product & Market Challenger and Contender), and the providers are positioned accordingly. Each ISG Provider Lens® quadrant may include a service provider(s) which ISG believes has strong potential to move into the Leader quadrant. This type of provider can be classified as a Rising Star.

- **Number of providers in each quadrant:** ISG rates and positions the most relevant providers according to the scope of the report for each quadrant and limits the maximum of providers per quadrant to 25 (exceptions are possible).

Provider Classifications: Quadrant Key

Product Challengers offer a product and service portfolio that reflect excellent service and technology stacks. These providers and vendors deliver an unmatched broad and deep range of capabilities. They show evidence of investing to enhance their market presence and competitive strengths.

Leaders have a comprehensive product and service offering, a strong market presence and established competitive position. The product portfolios and competitive strategies of Leaders are strongly positioned to win business in the markets covered by the study. The Leaders also represent innovative strength and competitive stability.

Contenders offer services and products meeting the evaluation criteria that qualifies them to be included in the IPL quadrant. These promising service providers or vendors show evidence of rapidly investing in products/ services and follow sensible market approach with a goal of becoming a Product or Market Challenger within 12 to 18 months.

Market Challengers have a strong presence in the market and offer a significant edge over other vendors and providers based on competitive strength. Often, Market Challengers are the established and well-known vendors in the regions or vertical markets covered in the study.

★ **Rising Stars** have promising portfolios or the market experience to become a Leader, including the required roadmap and adequate focus on key market trends and customer requirements. Rising Stars also have excellent management and understanding of the local market in the studied region. These vendors and service providers give evidence of significant progress toward their goals in the last 12 months. ISG expects Rising Stars to reach the Leader quadrant within the next 12 to 24 months if they continue their delivery of above-average market impact and strength of innovation.

Not in means the service provider or vendor was not included in this quadrant. Among the possible reasons for this designation: ISG could not obtain enough information to position the company; the company does not provide the relevant service or solution as defined for each quadrant of a study; or the company did not meet the eligibility criteria for the study quadrant. Omission from the quadrant does not imply that the service provider or vendor does not offer or plan to offer this service or solution.

Pharmacovigilance and Regulatory Affairs - Digital Evolution (Service Providers)

Who Should Read This Section

This report is valuable for service providers offering pharmacovigilance and regulatory affairs — digital evolution globally, to understand their market position and for enterprises looking to evaluate these providers. In this quadrant, ISG highlights the current market positioning of these providers based on the depth of their service offerings and market presence.

Digital professionals

Should read this report to understand how providers enable digital transformation across pharmacovigilance and regulatory affairs functions. The analysis highlights providers' capabilities in areas such as safety case management, signal detection, regulatory submissions, analytics and workflow automation. These insights help digital leaders evaluate partners that can modernize safety and regulatory operations in increasingly complex and regulated environments.

Technology professionals

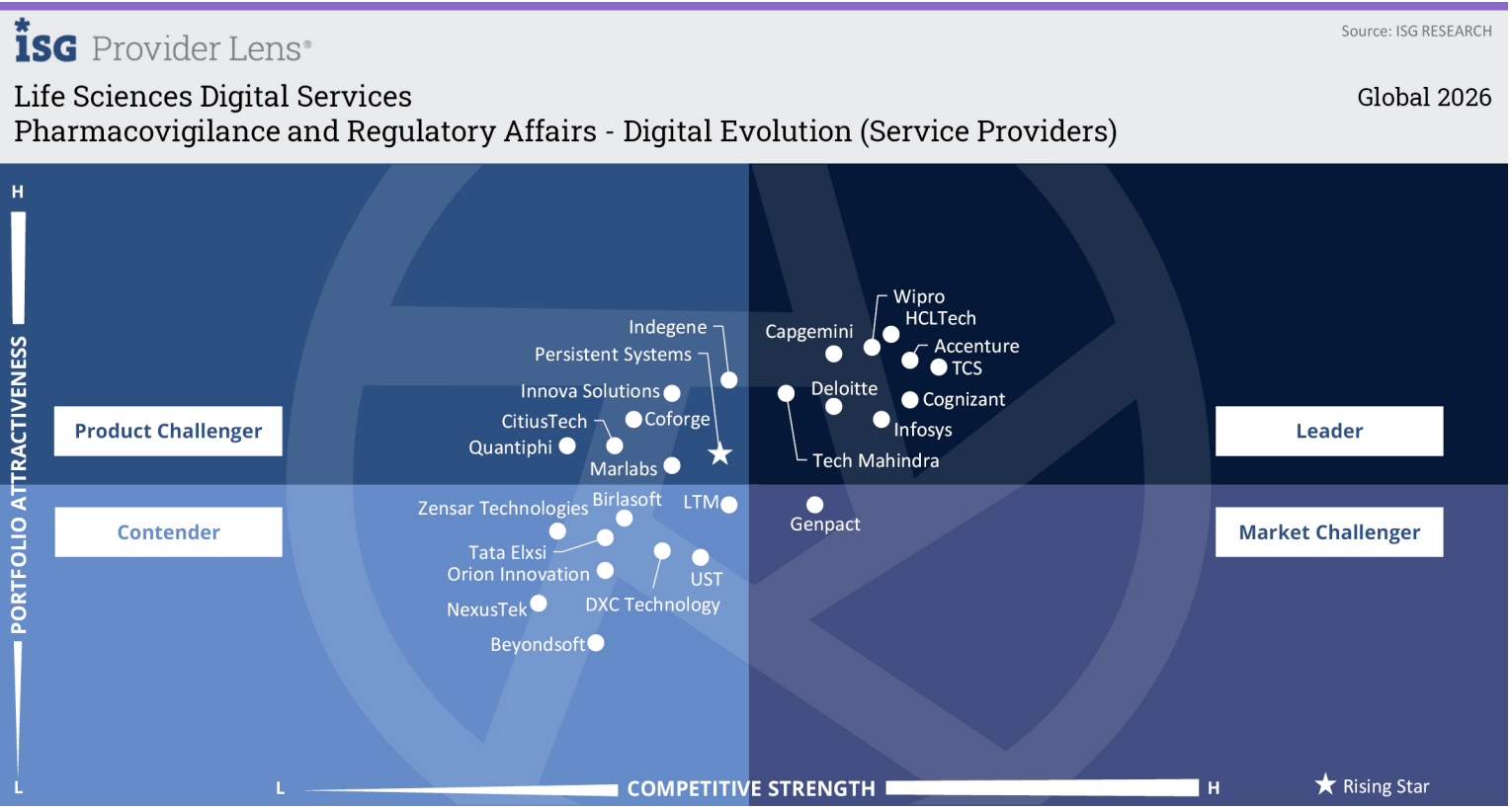
Should read this report to gain insight into the platforms, data models and automation tools supporting digital pharmacovigilance and regulatory processes. The report highlights providers' approaches to managing complex safety data, integrating legacy and modern systems, and supporting global regulatory requirements. These insights help technology stakeholders assess providers' readiness to deliver scalable, secure and compliant technology solutions.

Safety and regulatory operations leaders

Should read this report to understand how providers support the evolving needs of pharmacovigilance and regulatory operations. The analysis highlights practical solutions that improve case processing accuracy, reporting timelines, regulatory submissions management and overall compliance. These insights help operations leaders evaluate providers that can align delivery models with regulatory expectations.

Cybersecurity professionals

Should read this report to assess how providers manage data protection, system security and regulatory compliance across pharmacovigilance and regulatory platforms that handle highly sensitive safety and regulatory data. These insights support cybersecurity leaders in assessing provider capabilities to mitigate risk while enabling secure and compliant digital operations.



The quadrant assesses providers delivering AI-enabled PV and regulatory modernization while maintaining **global compliance and data integrity.** It focuses on **automation, RIM integration, signal intelligence and scalable governance frameworks.**

Rohan Sinha

Definition

This quadrant evaluates service providers' capabilities and strategic vision in pharmacovigilance (PV) and regulatory affairs (RA), with a focus on technology-enabled solutions for drug safety, compliance and submission efficiency. It assesses their ability to deliver AI-driven case processing, signal detection and regulatory intelligence platforms for real-time monitoring and expedited decision-making. Key evaluation areas include safety workflow automation, cloud-based regulatory information management (RIM) and data integration across global submissions. Providers are also assessed on their expertise in complying with evolving regulations, such as the Identification of Medicinal Products (IDMP), and the requirements set forth by the European Medicines Agency (EMA) and the FDA. Another criterion is their ability to drive predictive safety analytics and global regulatory harmonization. Industry leaders should combine domain knowledge with digital innovation to help life sciences organizations achieve end-to-end safety visibility, regulatory agility and risk-free product lifecycle management.

Eligibility Criteria

1. Clear focus on advancing **drug safety** and **regulatory transformation** through digital, AI and automation-driven strategies aligned with global compliance trends
2. Ability to deploy **AI-enabled case processing, signal detection, RIM** and **submission tracking** platforms
3. Proven ability to ensure adherence to **FDA, EMA** and **IDMP** standards through strong **audit readiness** and **data integrity** frameworks
4. Expertise in **workflow automation, NLP** for literature screening and **cloud-based PV/RIM modernization** to boost operational efficiency
5. Capability to unify **safety, clinical and regulatory data** for **real-time analytics, risk assessment** and **predictive signal management**
6. Competence in **AI-driven safety analytics, regulatory intelligence** and **global submission automation** to accelerate time to compliance
7. Demonstrated value through **expedited case closure, reduced compliance risk** and **enhanced transparency** across the product lifecycle

Observations

The PV and RAservices landscape is undergoing structural transformation as life sciences organizations respond to increasing data volumes, evolving global regulations and heightened inspection scrutiny. Providers are shifting from labor-intensive, transactional models toward AI-enabled, platform-integrated operating frameworks that emphasize automation, interoperability and real-time oversight. Safety case intake, signal detection, aggregate reporting, RIM modernization and IDMP readiness are increasingly embedded within unified digital ecosystems rather than siloed workflows.

A defining theme is the integration of GenAI, cognitive automation and predictive analytics across the PV and regulatory lifecycle. Providers are investing in automated ICSR processing, intelligent literature monitoring, structured content authoring, regulatory intelligence and eCTD publishing capabilities. Inspection readiness, validation, data integrity, including ALCOA+ principles, and GxP alignment remain critical guardrails as automation scales in regulated environments.

Interoperability and master data governance are also central differentiators. Modern PV and RIM programs increasingly require integration across safety databases, clinical systems, quality platforms, labeling tools and enterprise data lakes. As regulatory expectations evolve globally, buyers prioritize partners that combine compliance depth, scalable infrastructure and measurable operational efficiency with sustainable governance models.

From the 32 companies assessed for this study, 26 qualified for this quadrant, with nine being Leaders and one Rising Star.

accenture

Accenture strengthens PV and regulatory services through platform augmentation, assetized AI tools and automation with human oversight, improving efficiency and compliance within existing safety and RIM ecosystems.

Capgemini

Capgemini's regulatory, compliance and pharmacovigilance services are supported by digital RCQ tools that enhance monitoring, risk management and safety reporting within regulated environments.

cognizant

Cognizant provides AI-enabled pharmacovigilance and regulatory services, integrating end-to-end case management, cloud RIM and global submission support within a unified compliance-focused operating model.

Deloitte.

Deloitte's ElevateSafety™ platform provides multi-lingual case intake and cognitive automation across pharmacovigilance, supporting AI-driven signal detection, reporting and compliant safety operations.

HCLTech delivers AI-enabled PV and regulatory platforms with integrated safety and RIM systems, supported by compliant cloud infrastructure for scalable, inspection-ready operations.

Infosys provides regulatory and PV services, including RIM, submissions and end-to-end safety operations, supported by AI-driven automation and validated platform integration.

TCS enables AI-driven safety and regulatory operations through automation, predictive analytics and integrated platforms, improving compliance, efficiency and end-to-end pharmacovigilance and regulatory processes.

Tech Mahindra provides AI-enabled PV and regulatory platforms with automated case processing, integrated RIM and validated governance frameworks to support compliant, scalable operations.

Wipro delivers AI-enabled PV and regulatory services spanning case processing, submissions and labeling, supported by global delivery and automation for compliant, scalable operations.

Persistent Systems (Rising Star) provides AI-driven PV and regulatory services with automated case processing, signal detection and integrated RIM support for compliant global submission management.

Leader

"Deloitte is reshaping pharmacovigilance through cognitive automation, intelligent intake and GenAI-enabled safety workflows that enhance compliance, insight and lifecycle-wide decision-making."

Rohan Sinha

Deloitte

Overview

Deloitte is headquartered in London, U.K. It has more than 473,000 employees across over 150 countries. In FY25, the company generated $70.5 billion in revenue. Deloitte provides services in PV and RAthat include regulatory strategy support, compliance assessments and quality system reviews. It works with global regulatory frameworks such as GxP, MDR and IVDR and supports organizations in managing regulatory change and inspection readiness. Its capabilities also cover risk management, safety oversight and operational compliance across regulated environments.

Strengths

Intelligent multi-lingual intake and persona-based capture: Deloitte's ElevateSafety™ platform includes an intelligent intake portal supporting multiple use cases across geographies and languages. Configurable user personas enable case capture in formats familiar to reporters and internal stakeholders, improving usability and data consistency. Seamless integration within the broader platform supports standardized intake and structured case handling at scale.

Cognitive automation and continuous learning: ElevateSafety™ leverages advanced AI and cognitive models to extract and interpret structured and unstructured safety data. Automated translation, contextual reading and cognitive recommendations assist users beyond basic extraction. Embedded continuous learning mechanisms refine case decisions over time, enhancing accuracy and operational efficiency across safety workflows.

Lifecycle-wide cognitive vision and GenAI enablement: ElevateSafety™ applies decision-based exception reviews rather than replicating legacy processes. Its cognitive capabilities extend across signal detection and aggregate reporting, supporting proactive safety oversight. By embedding GenAI across the PV lifecycle, Deloitte advances a model that reduces reliance on traditional safety database structures while maintaining regulatory alignment and audit readiness.

Caution

Deloitte's cognitive PV model that rethinks traditional safety database structures may require careful alignment with organizations that rely on established legacy systems to ensure smooth transition, interoperability and regulatory acceptance globally.

Appendix

Methodology & Team

The ISG Provider Lens® 2026 – Life Sciences Digital Services study analyzes the relevant software vendors/service providers in the Global market, based on a multi-phased research and analysis process, and positions these providers based on the ISG Research methodology.

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The research and analysis presented in this report includes research from the ISG Provider Lens® program, ongoing ISG Research programs, interviews with ISG advisors, briefings with service providers and analysis of publicly available market information from multiple sources. The data collected for this report represent information that ISG believes to be current as of April 2026 for providers that actively participated and for providers that did not. ISG recognizes that many mergers and acquisitions may have occurred since then, but this report does not reflect these changes.

All revenue references are in U.S. dollars ($US) unless noted otherwise.

The study was conducted in the following steps:

1. Definition of Life Sciences Digital Services market
2. Use of questionnaire-based surveys of service providers/ vendor across all trend topics
3. Interactive discussions with service providers/vendors on capabilities and use cases
4. Leverage ISG's internal databases and advisor knowledge & experience (wherever applicable)
5. Detailed analysis and evaluation of services and service documentation based on the facts & figures received from providers and other sources.
6. Use of the following key evaluation criteria:
   * Strategy and vision
   * Innovation
   * Brand awareness and presence in the market
   * Sales and partner landscape
   * Breadth and depth of portfolio of services offered
   * Technology advancements

Lead Author

Rohan Sinha

Senior Manager and Principal Analyst

Rohan Sinha is a seasoned professional with over a decade of experience as an analyst in the healthcare and life sciences industries. He has been at the forefront in offering strategic guidance to industry CIOs, leveraging a wealth of published research and extensive interactions with industry stalwarts.

His work has been instrumental in shaping the strategies and decisions of organizations in these critical industries. Rohan also possesses a keen interest in the world of AI and GenAI, where he continually explores the significant impact of these cutting-edge technologies on the said industries.

Lead Author and Research Analyst

Sneha Jayanth

Lead Analyst

Sneha Jayanth is a Lead Analyst at ISG with over eight years of experience in ICT-related market intelligence and thought leadership. She plays a pivotal role in leading and co-authoring ISG Provider Lens® studies across Healthcare, Life Sciences, Medical Devices, and custom research engagements. Her work has contributed to shaping enterprise strategies by delivering actionable insights on market trends and technology adoption.

Sneha's background includes research on transformative technologies such as IoT, AI, cloud, and Analytics and developing thought leadership in the ICT sector. She also leads the creation of IPL reports that capture key trends and insights relevant to the broader provider landscape. Her research is recognized for its depth, clarity, and strategic value in guiding decision-makers in complex and evolving industries.

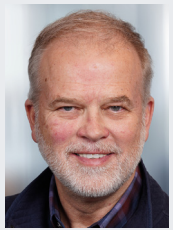
Study Sponsor

Iain Fisher
Director, Research

Iain Fisher is ISG's head of industry research and market trends. With over 20 years in consulting and strategic advisory, Iain now focuses on cross industry research with an eye on technology led digital innovation, creating new strategies, products, services, and experiences by analyzing end-to-end operations and measuring efficiencies focused on redefining customer experiences. Fisher is published, known in the market and advises on how to achieve strategic advantage. A thought leader on Future of Work, Customer Experience, ESG, Aviation and cross industry solutioning. He provides major market insights leading to changes to business models and operating models to drive out new ways of working.

Fisher works with enterprise organizations and technology providers to champion the change in customer focused delivery of services and solutions in challenging situations. Fisher is also a regular Keynote speaker and online presenter, having authored several eBooks on these subjects.

IPL Product Owner



Jan Erik Aase
Partner and Global Head – ISG Provider Lens®

Mr. Aase brings extensive experience in the implementation and research of service integration and management of both IT and business processes. With over 35 years of experience, he is highly skilled at analyzing vendor governance trends and methodologies, identifying inefficiencies in current processes, and advising the industry. Jan Erik has experience on all four sides of the sourcing and vendor governance lifecycle - as a client, an industry analyst, a service provider and an advisor.

Now as a partner and global head of ISG Provider Lens®, he is very well positioned to assess and report on the state of the industry and make recommendations for both enterprises and service provider clients.

ISG Provider Lens®

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ISG Research™

ISG Research™ provides subscription research, advisory consulting and executive event services focused on market trends and disruptive technologies driving change in business computing. ISG Research™ delivers guidance that helps businesses accelerate growth and create more value.

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ISG

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The firm, founded in 2006, is known for its proprietary market data, in-depth knowledge of provider ecosystems, and the expertise of its 1,600 professionals worldwide working together to help clients maximize the value of their technology investments.

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