ISG Provider Lens®

Life Sciences Digital Services

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

Customized report courtesy of:

Capgemini

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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

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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

Provider Positioning

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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

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)
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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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.

Clinical Development (Service Providers)

Who Should Read This Section

This report is valuable for service providers offering clinical development 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 providers' digital capabilities across clinical trial design, execution and analytics. The insights support informed decision-making while selecting partners that can enable decentralized trials, data-driven operations and patient-centric clinical development models.

Technology professionals

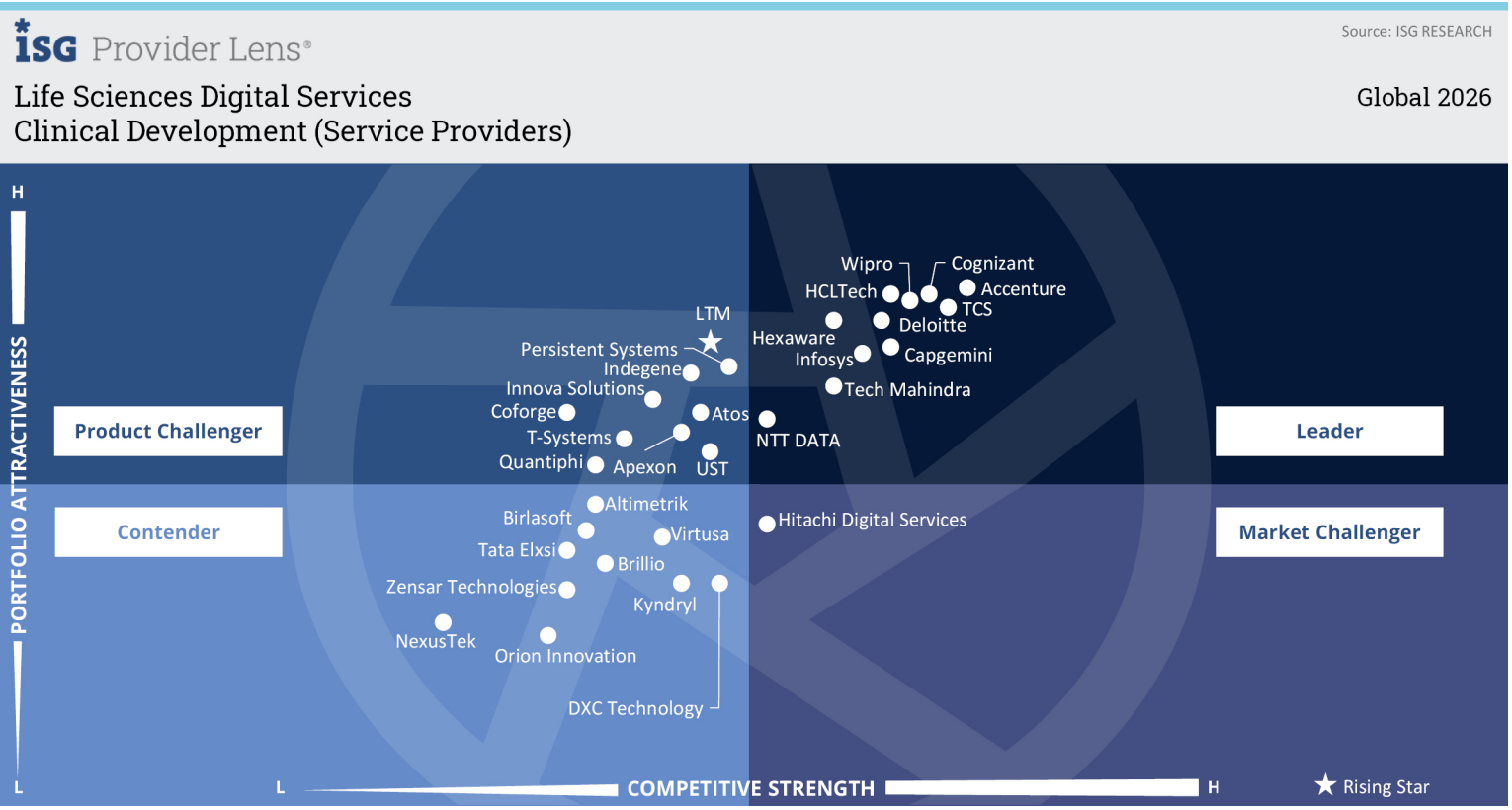
Should read this report to gain insight into platforms, data architectures, automation tools and advanced analytics leveraged by providers in clinical development. The report highlights key technology investments, innovation priorities and challenges influencing scalable and compliant digital trial execution.

Clinical operations and R&D practitioners

Should read this report to gain a deeper understanding of how providers support end-to-end clinical development workflows. The analysis enables stakeholders to evaluate solutions that enhance trial efficiency, accelerate timelines, improve patient engagement and generate measurable value throughout the development lifecycle.

Cybersecurity and compliance professionals

Should read this report to assess how providers manage data security, privacy and regulatory compliance across digitally enabled clinical development environments, including patient data protection, system integrity and adherence to global regulatory requirements. The report highlights providers' approaches to security architecture, governance, compliance management and risk mitigation in highly regulated life sciences settings.



The quadrant assesses providers on their ability to deliver **AI-enabled, end-to-end clinical development transformation** with measurable outcomes. It highlights strengths in **regulatory-grade execution, digital integration and scalable trial modernization.**

Rohan Sinha

Definition

This quadrant evaluates service providers based on their capabilities and strategic vision in clinical development, including technology and services that facilitate efficient, compliant and data-driven drug development. Clinical development spans the entire lifecycle of a clinical trial, across study design, site selection, patient recruitment, data capture, monitoring and regulatory submission. Service providers are assessed on their ability to deliver digital, AI-enabled and cloud-based solutions that improve trial speed, quality and patient engagement while ensuring GxP compliance.

The evaluation also considers innovation in decentralized and hybrid trial models, as well as the integration of real-world evidence (RWE) and platform-driven delivery. Providers that combine deep domain expertise with scalable technology platforms and collaborative engagement models are well positioned to lead the next generation of connected intelligent clinical development.

Eligibility Criteria

1. Long-term commitment to clinical innovation, investment in domain expertise and alignment with industry priorities such as **decentralized trials, AI adoption** and **patient-centric models**
2. Breadth and maturity of offerings across **eClinical platforms, data management, pharmacovigilance (PV)** and **regulatory solutions**
3. Expertise in delivering **validated, compliant and interoperable** systems leveraging **cloud, AI and automation**
4. Proven ability to **scale globally,** maintain **quality and compliance,** and deliver complex multiregion projects efficiently through **agile and automated delivery models**
5. Demonstrated thought leadership in **hybrid and digital trials, RWE integration** and **data-driven decision-making** using advanced analytics and GenAI tools
6. Evidence of measurable impact in **accelerating study timelines, reducing operational costs** and **enhancing data integrity.**
7. Positive client feedback and referenceable success stories, reinforcing market credibility
8. Strong alliances with t**echnology vendors, CROs** and **regulators,** enabling end-to-end transformation across the clinical value chain

Observations

The clinical development services landscape is evolving rapidly, shaped by increasing protocol complexity, decentralized trial models and growing regulatory scrutiny. Providers are repositioning from traditional functional outsourcing toward integrated, AI-enabled transformation partners. There is a visible shift from siloed clinical operations to connected, end-to-end lifecycle strategies that link study design, data management, regulatory alignment and post-approval evidence generation within unified digital ecosystems.

A defining theme is the rise of AI and advanced analytics as foundational enablers rather than experimental add-ons. Providers are embedding automation, predictive modeling and agentic workflows across feasibility, site selection, data review and document authoring, while emphasizing responsible AI governance in regulated environments. Platform-centric models and cloud-native architectures are becoming central to improving interoperability and enabling scalable, data-driven decision-making.

Another notable trend is the growing focus on patient-centricity and decentralized capabilities, supported by wearable integration, remote monitoring and real-world data utilization. Buyers increasingly expect measurable outcomes, operational resilience and global delivery scale alongside innovation. Differentiation in the quadrant is increasingly defined by the ability to combine domain depth, regulatory rigor, digital acceleration and execution maturity to develop cohesive, value-driven clinical transformation programs.

From the 40 companies assessed for this study, 32 qualified for this quadrant, with 11 being Leaders and one Rising Star.

accenture

Accenture positions clinical development within an end-to-end R&D reinvention strategy, combining AI, digital platforms and regulatory integration to improve speed, cost and outcomes. Its scalable digital core enables enterprise-wide, measurable clinical transformation.

Capgemini

Capgemini delivers an end-to-end clinical development strategy spanning design to closure, focused on measurable gains in speed, quality and success rates. Its AI-first, integrated delivery model combines consulting and operations to drive scalable, compliant transformation.

cognizant

Cognizant embeds clinical development within an end-to-end life sciences strategy spanning discovery to commercial. Its AI- and data-led priorities and orchestrated delivery model integrate clinical and regulatory systems to enable scalable, enterprise-wide transformation.

Deloitte.

Deloitte advances clinical development through next-generation study design, FAIR data architecture and integrated sample management. Its platform-led transformation and responsible GenAI enable intelligent, compliant and patient-centric trial execution across the lifecycle.

HCLTech

HCLTech embeds clinical development within an AI-first life sciences strategy that integrates regulatory and safety functions. Its proprietary, compliance-ready platforms and domain-led agentic AI enable scalable, decentralized trial execution with validation, security and GxP rigor.

HEXAWARE

Hexaware embeds clinical development in an AI-first strategy focused on faster cycles and improved data quality. Its EDC-agnostic automation platform and agent-based ecosystem deliver scalable, production-ready AI across feasibility and clinical workflows.

Infosys

Infosys drives AI-first clinical development, scaling GenAI and agentic AI across trials and documentation. Supported by domain expertise and production-grade deployments, it delivers measurable impact in regulated environments.

NTT DATA

NTT DATA advances AI-driven clinical development through agentic workflow redesign, end-to-end services and evidence-led analytics, enabling integrated and insight-driven trial execution.

TCS

TCS advances science-led clinical development through AI-driven decision intelligence and platform-centric transformation. Its modular digital suite, automation strength and deep system integration enable scalable, standardized execution across complex, global trial ecosystems.

Tech Mahindra

Tech Mahindra delivers agentic AI-led clinical development with compliance-by-design rigor. Its platform-centric approach and strong integration across decentralized trial systems enable scalable, patient-centric execution in regulated environments.

Wipro

Wipro embeds clinical development within its life sciences strategy, integrating trial, regulatory and safety functions. Its AI-first, digital approach and connected platform stack enable decentralized, data-rich, patient-centric trials with scalable, cloud-enabled execution.

LTM

LTM (Rising star) advances AI-first, outcomes-led clinical development focused on faster timelines and regulatory rigor. Its unified data and AI platform enables scalable, insight-driven decision support, backed by broad capabilities across decentralized trials, analytics and clinical technology transformation.

Leader

"Capgemini brings a bold, AI-led vision to clinical development, combining intelligent automation, integrated delivery and regulatory-grade execution to help sponsors accelerate trials and realize measurable impact at scale."

Rohan Sinha

Capgemini

Overview

Capgemini is headquartered in Paris, France. It has more than 342,700 employees worldwide. In FY24, the company generated €22.1 billion in revenue. Capgemini emphasizes patient-centric trial models, incorporating decentralized and hybrid approaches to improve recruitment, retention and participant experience. It leverages global delivery centers to provide scalable clinical operations and data support across geographies, enabling cost-efficient execution of multi-region trials.

Strengths

End-to-end clinical strategy: Capgemini presents a well-articulated Next Gen Clinical Development strategy spanning study design, conduct and closure. Clinical development is framed as a unified value chain rather than a collection of siloed services, strengthening credibility with sponsors seeking holistic trial transformation. This coherence supports enterprise-wide modernization instead of piecemeal optimization.

Outcome-driven performance focus: Capgemini anchors its clinical development narrative in explicit performance ambition, including reduced trial timelines, improved probability of success and enhanced patient and staff experience. By emphasizing time to market, trial quality and measurable value realization over pure IT modernization, the firm strongly aligns with executive priorities and value-based buying expectations.

AI-led, integrated delivery model: A key differentiator is Capgemini's AI-first vision, embedding GenAI and agentic AI across study design, operations, monitoring, analytics and submissions. This approach is reinforced by an integrated delivery model combining consulting, systems integration, managed services and scaled operations capabilities. With strong compliance and regulatory certifications, Capgemini is well positioned to deliver AI-enabled clinical development in regulated environments.

Caution

Capgemini's agentic AI-first positioning reflects an ambitious vision for clinical development and sets a high benchmark for production-scale execution. Providing clearer guidance on phased adoption, governance alignment and risk mitigation can help enterprises at varying levels of AI maturity confidently realize this vision.

Patient Engagement (Service Providers)

Who Should Read This Section

This report is valuable for service providers offering patient engagement 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 evaluate providers' patient engagement platforms, omnichannel strategies and digital tools that support patient recruitment, retention, adherence and ongoing engagement. The analysis highlights how providers utilize digital solutions to facilitate personalized patient-centric engagement models. These insights help digital leaders assess provider capabilities that align with broader digital transformation and patient experience objectives.

Technology professionals

Should read this report to understand the core technologies, data integration approaches and emerging digital tools that underpin modern patient engagement solutions. The report provides insights into platforms such as AI-enabled engagement systems, mobile health applications, analytics and interoperability frameworks. This perspective enables technology stakeholders to evaluate provider readiness to support integrated patient engagement ecosystems.

Patient engagement leaders

Should read this report to gain insights into patient-centric engagement models that enhance patient experience, participation and health outcomes throughout the lifecycle. The analysis highlights use cases and solution approaches that help organizations strengthen recruitment, retention and adherence while aligning with evolving clinical and commercial objectives.

Cybersecurity professionals

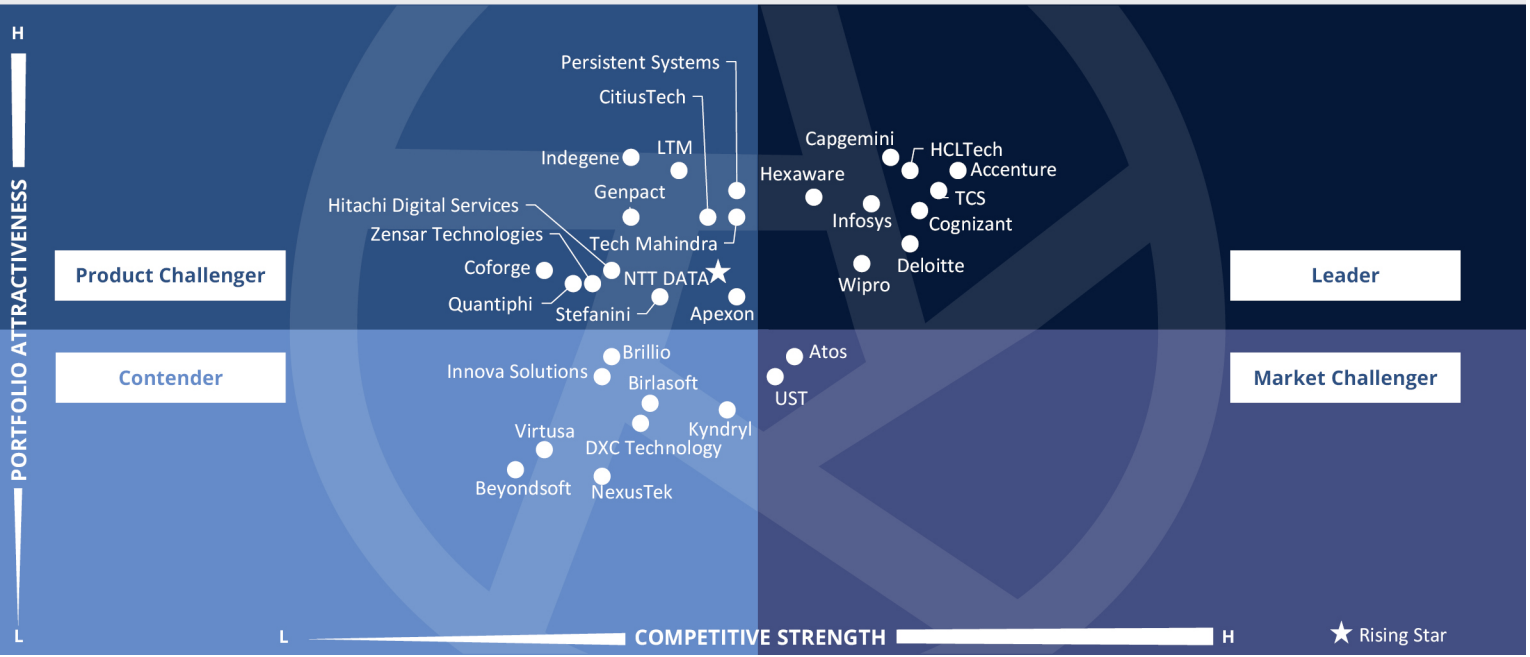
Should read this report to understand how providers ensure patient data privacy, consent management and regulatory compliance across digital patient engagement platforms. The report highlights approaches to securing sensitive patient information, managing data governance and meeting global regulatory requirements.

ISG Provider Lens®

Source: ISG RESEARCH

Life Sciences Digital Services
Patient Engagement (Service Providers)

Global 2026



The quadrant evaluates providers delivering **end-to-end patient engagement** with measurable impact. It focuses on strengths in **personalization, connected ecosystems and compliant, scalable execution.**

Rohan Sinha

Definition

This quadrant evaluates service providers' capabilities and strategic vision in patient engagement, focusing on how technology enables personalized, connected and compliant interactions across the patient journey. Providers are also assessed on their ability to deliver omnichannel engagement platforms, mobile health solutions and digital therapeutics that enhance patient adherence, education and retention. The evaluation also emphasizes the integration of AI, analytics and real-world data to drive actionable insights and improve outcomes.

Providers are also evaluated on their capacity to ensure data privacy, system interoperability and support for virtual care models, patient support programs and wearable-driven monitoring. Leading providers in this space should combine life sciences expertise with robust digital platforms to help biopharma and medtech companies build patient-centric ecosystems that foster trust, engagement and long-term health outcomes.

Eligibility Criteria

1. Clear focus on **patient-centric transformation,** investments in **digital health** and alignment with next-generation **experience-driven care models**
2. Comprehensive **omnichannel, mobile** and **digital therapeutic** platforms powered by **AI, analytics** and **remote monitoring** capabilities
3. Strong emphasis on **human-centered design**, creating seamless, accessible and **trust-building interface**s that boost patient satisfaction and adherence
4. Robust **data privacy, security** and **interoperability** frameworks ensuring compliance with the **Health Insurance Portability and Accountability Act (HIPAA), GDPR** and healthcare regulations
5. Proven innovation in **wearable integration, virtual care, chatbots** and **behavioral insights** for proactive patient engagement
6. Demonstrated ability to **deploy services globally,** maintaining high **reliability, compliance** and measurable engagement outcomes
7. Tangible improvements in **protocol adherence** and outcomes, and **care coordination,** supported by strong ROI and **ecosystem collaboration**

Observations

The patient engagement services landscape is undergoing significant evolution as healthcare and life sciences organizations shift from transactional outreach to continuous, experience-led engagement models. Providers are moving beyond traditional patient support programs toward integrated ecosystems that combine digital platforms, AI-driven personalization, remote monitoring and omnichannel orchestration. The focus is increasingly on creating seamless journeys that span awareness, access, onboarding, adherence and long-term care.

A defining trend is the rise of AI and agentic automation as foundational enablers. Conversational assistants, predictive risk modeling, next-best-action engines and hyperpersonalized content are being embedded across engagement workflows to improve responsiveness and reduce operational burden. Governance, privacy and responsible AI frameworks are becoming critical differentiators as patient-facing solutions scale in regulated environments.

Interoperability and connected care are also central themes. Providers are investing in platforms that unify data from electronic health records (EHRs), CRMs, wearables, remote monitoring devices and support programs to create longitudinal patient views. This data foundation enables proactive outreach, real-time insights and coordinated collaboration among patients, providers and support teams.

As the market matures, differentiation increasingly depends on the ability to combine human-centered design, scalable digital infrastructure, analytics and compliance rigor and offer measurable outcomes such as improved adherence, faster therapy initiation, enhanced access and sustained patient satisfaction.

From the 40 companies assessed for this study, 32 qualified for this quadrant, with nine being Leaders and one Rising Star.

accenture

Accenture delivers GenAI-enabled patient engagement anchored in scalable platforms and modular assets. Its augment-not-replace model and hyperpersonalized, insight-driven approach connect patient interactions to enterprise decision-making and continuous learning.

Capgemini

Capgemini enables connected patient engagement through RPM, strong interoperability and integrated digital platforms, supporting device connectivity, EHR integration and coordinated journeys from trials to adherence.

cognizant

Cognizant provides end-to-end patient engagement through connected digital platforms and interoperable ecosystems. AI-driven automation supports personalized outreach, risk prediction and coordinated care across the patient journey.

Deloitte.

Deloitte advances patient engagement through human-centered design, integrated data platforms and AI-driven insights, enabling personalized care, improved adherence and measurable outcomes across the patient journey.

HCLTech enables AI-driven patient engagement through intelligent recruitment, agentic experience hubs and connected monitoring, supporting targeted outreach, adherence and personalized, compliant care across the therapy lifecycle.

Hexaware enables AI-first patient engagement with a unified Patient 360 platform, agentic assistants and secure interoperability across telehealth, RPM and CRM, delivering personalized, compliant care journeys.

Infosys delivers AI-driven patient engagement through predictive analytics and connected digital platforms, enabling personalized, compliant and scalable patient journeys across the care continuum.

TCS enables connected, AI-driven patient engagement through unified platforms, behavioral analytics and omnichannel support, delivering scalable and compliant experiences across clinical and care environments.

Wipro enables AI-driven patient engagement through digital journey platforms, virtual trial solutions and conversational AI, improving access, recruitment, adherence and personalized care across the patient lifecycle.

NTT DATA (Rising Star) delivers scalable patient engagement through interoperable virtual care platforms and agentic AI, enabling personalized treatment, remote monitoring and data-driven patient support across the care journey.

Leader

"Capgemini is transforming patient engagement through connected health platforms, intelligent interoperability and blended digital experiences that deliver personalized, data-driven care at scale."

Rohan Sinha

Capgemini

Overview

Capgemini is headquartered in Paris, France. It has more than 342,700 employees worldwide. In FY24, the company generated €22.1 billion in revenue. Capgemini supports patient engagement through digital health solutions that integrate CRM platforms, analytics and connected health technologies. Its work focuses on improving coordination across patient touchpoints, enabling data-driven insights and supporting interoperability within healthcare ecosystems. The firm also addresses digital accessibility and experience design to enhance patient interactions across channels.

Strengths

End-to-end remote patient monitoring: Capgemini delivers end-to-end remote patient monitoring solutions integrating device connectivity, data ingestion, analytics and AI-enabled engagement. Its platforms support configurable ePRO/eCOA, device management and real-time insights across clinical and real-world settings. This connected foundation enables scalable, data-driven engagement models that support adherence, recovery and longitudinal care coordination.

Deep interoperability and health IT integration: With cross-domain expertise in interoperability standards (HL7, FHIR, CDA), EHR integration, APIs and cloud-based frameworks, Capgemini enables secure, seamless data exchange across healthcare ecosystems. Proven experience in EMR integrations and hospital systems strengthens its ability to operationalize connected patient data environments.

Blended digital patient experience: Capgemini advances hybrid patient engagement models that combine digital companions, hub services and real-time prescription data. Through Patient 360 profiles and coordinated omnichannel journeys, it enables personalized, continuous engagement from prescription through long-term adherence.

Caution

Capgemini could further strengthen its patient engagement positioning by articulating clearer governance and data ownership models across remote patient monitoring (RPM), interoperability and omnichannel ecosystems, enhancing confidence in long-term scalability and ecosystem coordination.

Manufacturing and Supply Chain (Service Providers)

Who Should Read This Section

This report is valuable for service providers offering manufacturing and supply chain 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 life sciences manufacturing and supply chain operations. The analysis highlights providers' capabilities across smart manufacturing, digital plant initiatives, supply chain visibility, advanced analytics and automation. These insights help digital leaders evaluate providers that can improve operational efficiency in response to evolving business, quality and compliance requirements.

Technology professionals, such as IT leaders and enterprise architects

Should read this report to gain insight into the digital platforms, data architectures and automation technologies leveraged by providers. The report highlights how providers integrate operational technology with enterprise IT systems, supporting scalability, reliability and regulatory compliance. These insights help technology stakeholders assess provider readiness.

Manufacturing and supply chain leaders

Should read this report to understand how providers support end-to-end operational workflows across planning, execution, quality management and logistics. The analysis highlights practical solutions that improve visibility, coordination and decision-making across manufacturing and supply chain functions. These insights help practitioners evaluate providers capable of delivering measurable operational improvements and sustainable business value.

Cybersecurity professionals

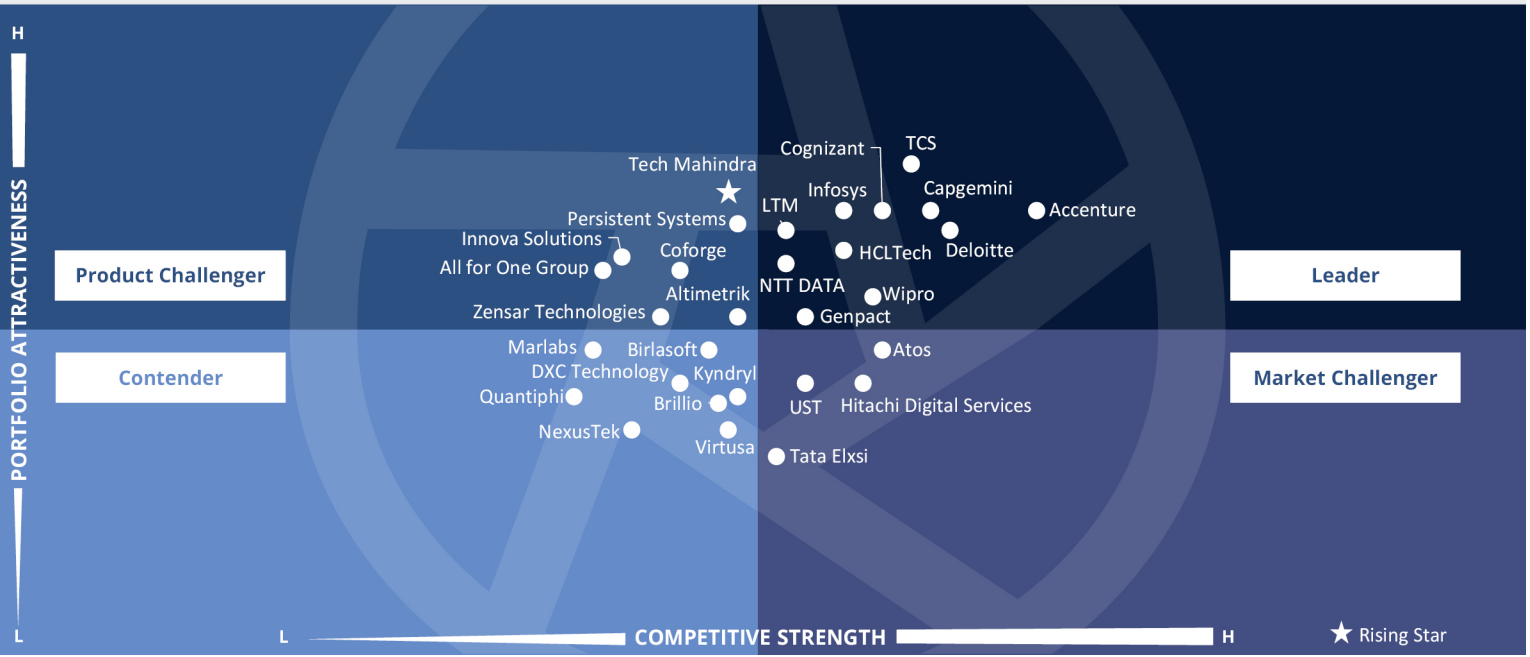
Should read this report to understand how providers address security, data protection and regulatory compliance across connected manufacturing and supply chain environments. The report highlights approaches to safeguarding operational systems, ensuring data integrity and managing cyber risk in increasingly digital and interconnected ecosystems.

ISG Provider Lens®

Source: ISG RESEARCH

Life Sciences Digital Services
Manufacturing and Supply Chain (Service Providers)

Global 2026



The quadrant evaluates providers' ability to deliver **digital manufacturing transformation and resilient life sciences supply chains** through **Industry 4.0, analytics, and integrated planning** across regulated production and distribution networks.

Rohan Sinha

Definition

This quadrant evaluates service providers' capabilities and strategic vision in manufacturing and supply chain within the life sciences sector. It assesses how providers facilitate digitally connected, compliant and resilient operations across drug and device manufacturing, logistics and distribution. Key assessment areas include smart factory initiatives, IoT-driven production, AI-based demand forecasting and real-time supply visibility. Providers are assessed on their ability to integrate manufacturing execution systems (MES), laboratory information management systems (LIMS), ERP and quality management systems (QMS) to ensure traceability, quality and compliance. The assessment also covers sustainability initiatives, cold chain integrity and digital twin adoption for process optimization. Leaders in this space should combine extensive life sciences expertise with strong digital engineering and analytics capabilities to build agile, adaptive supply networks that enhance efficiency, ensure product quality and accelerate time to patient access.

Eligibility Criteria

1. Clear road map for **digital manufacturing transformation,** aligned with life sciences priorities such as **regulatory compliance, sustainability** and **supply resilience**
2. Capability in integrating **MES, LIMS, ERP** and **QMS,** alongside **AI, IoT** and **digital twin** technologies for smart operations
3. Proven ability to drive **process automation, predictive maintenance** and **quality control** while ensuring **GxP compliance** and minimizing downtime
4. Capability to deliver **end-to-end traceability, real-time analytics** and **AI-based forecasting** to improve agility and demand-supply alignment
5. Expertise in **smart factory, connected plant** and **sustainable supply chain** initiatives that optimize efficiency and reduce carbon footprint
6. Global delivery strength, domain-certified talent and consistent performance in **multisite and cross-regional implementations**
7. Demonstrated outcomes in **cost optimization, cycle time reduction** and **enhanced compliance and quality metrics** through digital enablement

Observations

The Manufacturing and Supply Chain services landscape in life sciences is undergoing rapid transformation as organizations respond to increasing regulatory complexity, globalized production networks, and heightened expectations for supply reliability. Across the quadrant, service providers are helping companies modernize manufacturing operations and supply chains through digital technologies, advanced analytics, and integrated enterprise platforms. The focus is shifting from traditional efficiency-driven models toward resilient, data-enabled ecosystems capable of supporting faster product launches, complex therapies, and evolving regulatory requirements.

A major trend shaping the quadrant is the adoption of Industry 4.0 capabilities, including IoT-enabled shop floors, digital twins, predictive maintenance, and real-time production analytics. These technologies enable improved asset utilization, process optimization, and operational visibility across manufacturing networks. At the same time, manufacturers are digitizing laboratory operations, batch release processes, and quality systems to accelerate production cycles while maintaining regulatory compliance.

Supply chain transformation is another central theme. Providers are helping life sciences companies implement intelligent planning, supply chain control towers, serialization and track-and-trace capabilities, and cold chain monitoring to ensure product integrity across global distribution networks. The integration of advanced analytics, automation, and cloud platforms enables organizations to improve demand forecasting, optimize inventory placement, and strengthen logistics coordination.

As the quadrant evolves, differentiation increasingly depends on the ability to combine domain expertise, digital manufacturing capabilities, and end-to-end supply chain orchestration with strong compliance and governance frameworks. Organizations are prioritizing partners that can modernize manufacturing environments while improving supply resilience, traceability, and operational efficiency across regulated pharmaceutical and medical device ecosystems.

From the 60 companies assessed for this study, 30 qualified for this quadrant, with 11 being Leaders and one Rising Star.

accenture

Accenture drives enterprise-scale Manufacturing and Supply Chain transformation, leveraging SAP-centric ecosystems and advanced technologies to modernize global, regulated production networks.

Capgemini

Capgemini enhances life sciences manufacturing and supply chains through digital production systems, cloud-based planning frameworks, and lifecycle governance solutions that strengthen reliability, resilience, and compliance.

Cognizant strengthens life sciences manufacturing through IT-OT integration, AI-enabled production and lab automation, and intelligent supply chain solutions that enhance efficiency, compliance, and resilience.

Deloitte enhances life sciences manufacturing and supply chains through smart factory enablement, integrated planning, and analytics-driven operations that improve resilience and performance.

Genpact enhances life sciences manufacturing through integrated planning, analytics-driven operations, and control tower visibility that improve efficiency and supply chain coordination.

HCLTech enhances life sciences manufacturing and supply chains using Industry 4.0 technologies, AI-driven planning, and digital accelerators to improve visibility, traceability, and operational efficiency.

Infosys modernizes life sciences manufacturing through AI-driven transformation, cloud supply chain platforms, and SAP-based solutions that improve visibility, forecasting, and traceability.

LTM

LTM modernizes life sciences manufacturing through Pharma 4.0 solutions, intelligent supply chains, and manufacturing analytics that improve visibility, traceability, and efficiency.

NTT DATA enhances life sciences manufacturing through digital core modernization and analytics-driven supply chains, improving visibility, planning, and operational coordination.

TCS modernizes life sciences manufacturing through digital manufacturing systems, AI-driven operations, and integrated supply chain platforms, improving production efficiency, traceability, and operational visibility across regulated networks.

Wipro strengthens life sciences manufacturing and supply chains through AI-driven planning, digital control towers, and blockchain-enabled traceability, improving forecasting accuracy, disruption response, and compliance across global supply networks.

Tech M (Rising Star) modernizes life sciences manufacturing through connected plant operations, digital logistics visibility, and labeling management platforms, improving production monitoring, traceability, and regulatory compliance across supply networks.

Leader

"Capgemini integrates intelligent production systems with digital continuity to modernize life sciences manufacturing and supply chains. This data-driven approach enhances resilience, quality and performance."

Rohan Sinha

Capgemini

Overview

Capgemini is headquartered in Paris, France. It has more than 342,700 employees worldwide. In FY24, the company generated €22.1 billion in revenue. Capgemini optimizes life sciences manufacturing and supply chains through production planning, inventory management, network strategy, serialization and traceability, and logistics performance management. It integrates quality systems and regulatory controls with advanced data platforms to ensure seamless manufacturing operations. The firm improves supply continuity within regulated pharmaceutical and medical device environments through supplier collaboration, demand planning accuracy and operational risk mitigation.

Strengths

Digital lean manufacturing strategy: Capgemini's Intelligent Production System™ underpins its life sciences manufacturing strategy, combining Lean principles with Industry 4.0. Through Smart Factory capabilities, execution systems, technical transfer and digital operational excellence, it supports right-first-time production, faster release cycles and improved asset lifecycle performance while maintaining cGMP alignment.

End-to-end intelligent supply chain: Capgemini's intelligent supply chain offering modernizes Plan–Source–Make–Deliver processes using composable architecture and cloud-based platforms. Its key capabilities include network design, smart forecasting, integrated business planning, supplier collaboration and touchless order-to-delivery, enhancing resilience, service levels and sustainability across global ecosystems.

Digital continuity and next-gen labs: Capgemini integrates digital continuity and next-gen lab solutions to enable real-time data visibility, structured technical transfer, workflow optimization and lifecycle governance. This approach strengthens manufacturing agility, compliance and operational consistency across regulated life sciences environments.

Caution

Capgemini's broad intelligent industry portfolio should be clearly prioritized in complex manufacturing environments to ensure transformation programs remain aligned with site-level operational constraints and phased adoption readiness across global production networks.

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

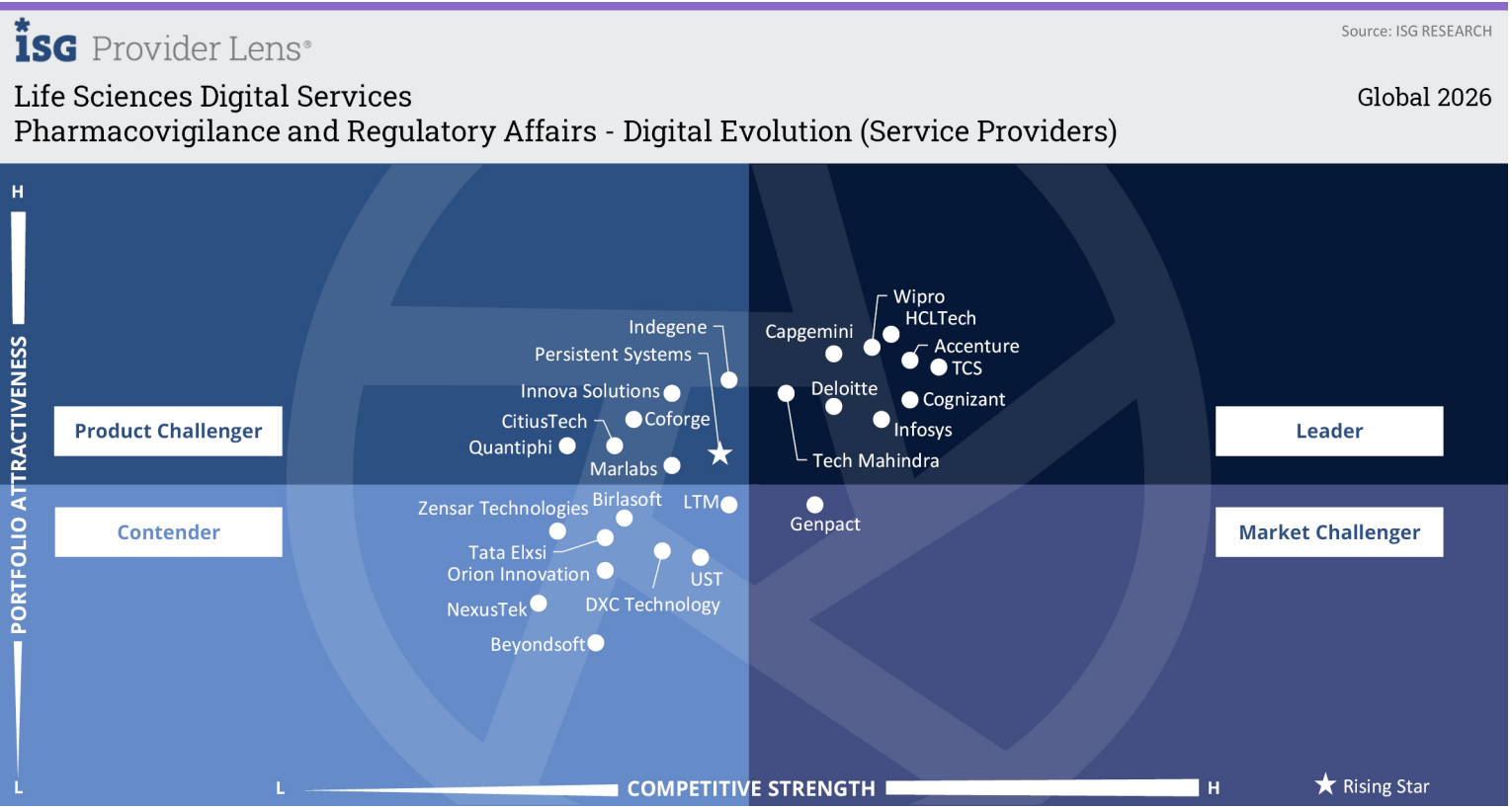
Should read this report to gain insight into the platforms, data models and automation tools supporting digital pharmacovigilance and regulatory processes. The report highlights providers' approaches to managing complex safety data, integrating legacy and modern systems, and supporting global regulatory 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 pharmacovigilance and regulatory affairs services 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

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

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

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

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

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

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

"Capgemini strengthens pharmacovigilance and regulatory affairs through intelligent regulatory, compliance and quality (RCQ) frameworks, digital compliance optimization and structured safety operations aligned to global standards."

Rohan Sinha

Capgemini

Overview

Capgemini is headquartered in Paris, France. It has more than 342,700 employees worldwide. In FY24, the company generated €22.1 billion in revenue. Capgemini provides regulatory affairs and pharmacovigilance support, including strategy development, submission documentation, audit preparation and quality system optimization. It aligns services with global regulatory frameworks such as FDA, EMA and GxP standards, and applies digital tools to support monitoring, reporting and inspection readiness across safety and compliance functions.

Strengths

End-to-end intelligent RCQ framework: Capgemini delivers integrated RCQ solutions that embed best practices across strategy, submissions, audits and remediation activities. Its capabilities span regulatory strategy development, documentation, gap analysis and alignment with global health authority standards.

Digital and data-driven compliance optimization: Through its Intelligent RCQ model, Capgemini digitalizes compliance workflows to improve monitoring, risk mitigation and operational performance. Advanced digital solutions enhance visibility into regulatory and quality activities, supporting de-risked operations and improved speed without compromising compliance rigor. Quality management systems (QMS) optimization and inspection readiness services further strengthen scalable regulatory and quality operations.

Operational PV and reporting expertise: Capgemini provides pharmacovigilance and risk management support across safety agreements, protocol reviews, signal detection and safety data aggregation. Its expertise in preparing and validating periodic safety reports, including RMPs, DSURs, PBRERs and related submissions, reinforces domain depth in safety operations and regulatory reporting within regulated environments.

Caution

Capgemini's strong digitalization focus in RCQ and PV may require ongoing alignment between technology modernization and evolving regulatory interpretations to ensure automation initiatives remain fully synchronized with changing global compliance expectations.

Commercial Operations — Digital Evolution (Service Providers)

Who Should Read This Section

This report is valuable for service providers offering commercial operations — 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 commercial operations, including sales, marketing and customer engagement functions. These insights help digital leaders evaluate partners that can modernize commercial models, improve CX and enable scalable, insight-led decision-making aligned with evolving market and customer expectations.

Technology professionals

Should read this report to assess the technology ecosystems supporting digital commercial operations. The report provides insight into CRM platforms, analytics tools, data integration frameworks and automation technologies used by providers. These insights help technology stakeholders evaluate provider scalability, integration capabilities and compliance in complex commercial environments.

Commercial and business leaders

Should read this report to understand how providers support operational excellence and customer-centric commercial models. These insights help leaders evaluate providers that can enable measurable business impact, optimize go-to-market strategies and support sustainable revenue growth through digitally enabled commercial operations.

Cybersecurity and risk management professionals

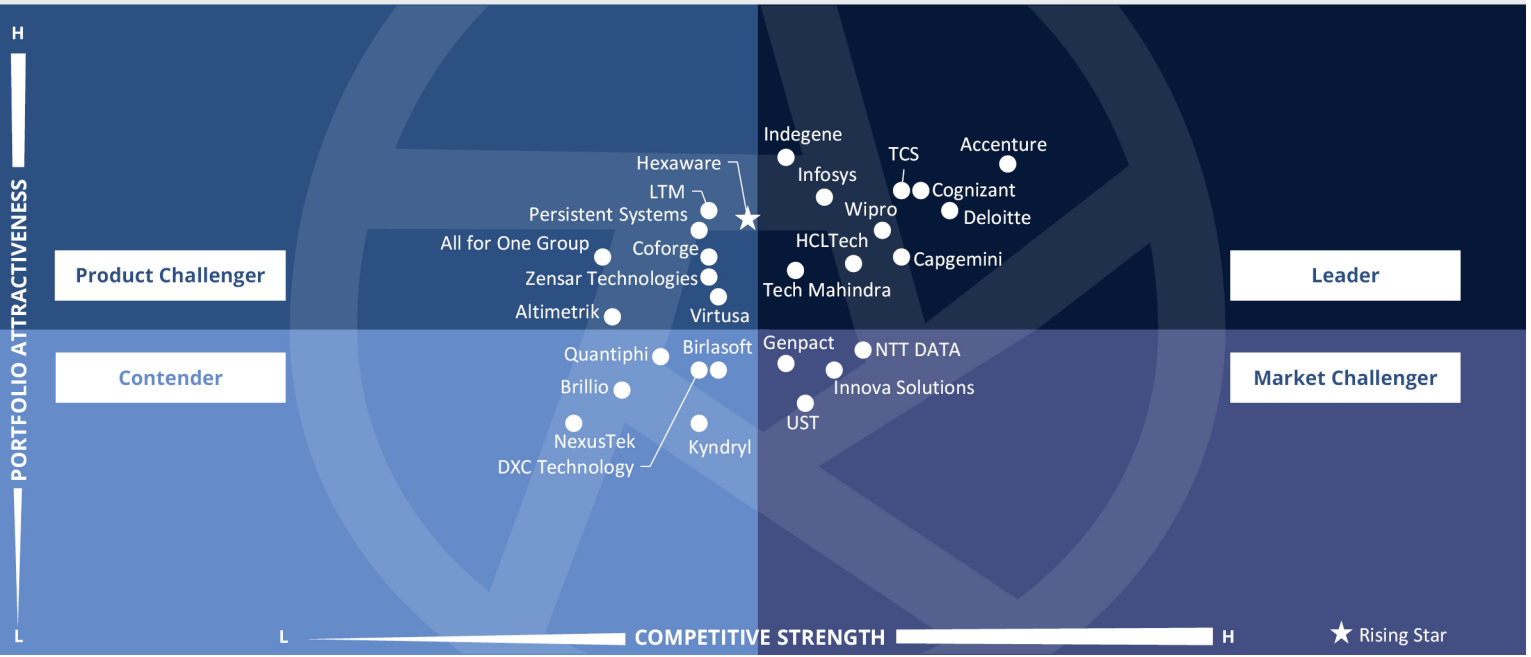
Should read this report to understand how providers address data security, privacy and regulatory compliance across digitally enabled commercial operations. These insights support cybersecurity leaders in evaluating provider capabilities to mitigate risk while enabling secure and trusted digital commercial environments.

ISG Provider Lens®

Source: ISG RESEARCH

Life Sciences Digital Services
Commercial Operations - Digital Evolution (Service Providers)

Global 2026



This quadrant assesses providers delivering **commercial operations transformation** across life sciences, including **CRM modernization, omnichannel engagement and AI-driven analytics.** It evaluates their ability to enable **data-led sales effectiveness, compliant engagement and measurable revenue impact** at global scale.

Sneha Jayanth

Definition

This quadrant evaluates service providers' capabilities and strategic vision in commercial operations, focusing on how their technology enables data-driven, omnichannel engagement and commercial excellence for life sciences organizations. It assesses providers' ability to deliver integrated solutions for CRM modernization, marketing automation, field force effectiveness and advanced analytics that enhance CX and sales performance. Key evaluation areas include AI-driven insights, next best action models and content personalization to optimize healthcare provider (HCP) and patient engagement. Providers are also assessed on their ability to integrate data, comply with regulations and connect commercial, medical and market access functions through unified digital platforms. Leaders in this space should combine in-depth life sciences domain expertise with strong analytics, automation and cloud capabilities to drive commercial agility, customer centricity and sustainable growth in an evolving digital marketplace.

Eligibility Criteria

1. Clear road map for **commercial digital transformation,** focusing on **omnichannel engagement, customer centricity** and **data-driven decision-making**
2. Expertise in **CRM modernization, marketing automation, field force enablemen**t and **analytics platforms** that unify sales, marketing and medical operations
3. Strength in deploying **AI and ML models, next-best-action engines** and **predictive insights** to optimize customer outreach and commercial performance
4. Proven capability to integrate **real-world data, HCP engagement data** and **market intelligence** into cohesive, compliant ecosystems
5. Track record of delivering **large-scale CRM transformations, campaign orchestration** and **cloud-based solutions** with measurable business impact
6. Expertise in **personalization, content automation** and **digital engagement platforms** that elevate CX
7. Demonstrated outcomes in **sales productivity, marketing ROI** and **go to market,** backed by strong CSAT and measurable KPIs

Observations

The Commercial Operations quadrant reflects a market transitioning from standalone CRM deployments to integrated, AI-enabled commercial transformation. Life sciences enterprises increasingly expect providers to combine strategy, platform modernization, data integration and managed services to drive measurable revenue impact, improved sales effectiveness and compliant omnichannel engagement. Competitive differentiation is shifting toward proprietary IP, embedded analytics, GenAI-driven content automation and stronger linkage between insights and field execution.

Compared with last year, several providers have strengthened their positioning by expanding AI-led personalization, next-best-action orchestration and unified data foundations integrating CRM, real-world data and engagement analytics. Movement within the quadrant largely reflects increased investment in industry-specific accelerators, deeper Salesforce, Veeva and IQVIA partnerships and scaled managed services capabilities. Competition has intensified as global SIs deepen vertical specialization while niche life sciences players enhance regulatory depth and platform-centric offerings.

M&A activity continues to influence the landscape, particularly acquisitions in Salesforce and Veeva consulting, digital experience agencies, marketing automation and analytics specialists. These investments aim to accelerate omnichannel maturity, strengthen content supply chains and embed GenAI across commercial workflows. Overall, the quadrant highlights a clear shift toward data-led, AI-infused and outcome-oriented commercial operating models delivered at global scale.

From the 36 companies assessed for this study, 28 qualified for this quadrant, with 10 being Leaders and 1 Rising Star.

accenture

Accenture positions commercial transformation within a broader enterprise reinvention agenda, leveraging digital core modernization, GenAI, industry platforms and a strong ecosystem to enable hybrid omnichannel strategies and next-best-action intelligence.

Capgemini

Capgemini differentiates through its integrated Customer First and Continuous Business Reinvention (CBR) methodologies, blending strategy, design, technology and operations to deliver patient-centric commercial transformation at scale.

cognizant

Cognizant combines strong health sciences domain depth with AI-powered commercial analytics, omnichannel orchestration and compliance-focused accelerators, positioning it as a strategic partner for large-scale CRM and engagement transformations.

Deloitte.

Deloitte differentiates through its integrated commercial strategy, ConvergeHEALTH assets, GenAI-led engagement models and Operate services footprint, positioning itself as a full lifecycle transformation partner across commercial, patient and regulatory domains.

HCLTech

HCLTech differentiates through its integration of HCLTech Specialty Ops (erstwhile C3i) with digital and AI capabilities, enabling end-to-end commercial coverage from product launch and sampling to HCP concierge, MLR automation and omnichannel engagement hubs.

Indegene

Indegene differentiates through its deep life sciences specialization, proprietary NEXT and Invisage platforms and integrated content-to-analytics operating model, enabling scalable omnichannel orchestration and measurable commercial ROI.

Infosys

Infosys combines strong Salesforce, Veeva and IQVIA commercial expertise with AI-driven accelerators such as its Commercial Insights Platform and GenAI-enabled MLR automation, positioning it as a scaled transformation partner rather than a pure-play CRM SI.

TCS

TCS differentiates through its portfolio of proprietary accelerators (MLR Automation, Crystallus™, 360 reporting suites) and GenAI-led use cases such as Patient Co-Pilot and Next Best Action, backed by strong advisory frameworks and global innovation ecosystems.

Tech Mahindra

Tech Mahindra differentiates through its design-led acquisitions (Born Group, Mad*Pow), Veeva-integrated accelerators and GenAI COEs focused on MLR, personalization and journey orchestration, targeting measurable efficiency gains.

Wipro

Wipro differentiates through AI/ML-enabled MLR automation, advanced analytics CoEs and emerging innovations such as metaverse engagement pods and blockchain-based transparency, supported by strong CRM and ecosystem integration capabilities.

HEXAWARE

Hexaware (Rising Star) differentiates through strong Salesforce, Veeva and IQVIA partnerships, a validated Salesforce-based Cell & Gene platform and an AI-enhanced Digital Content Factory supporting scalable, compliant omnichannel engagement.

Leader

"Capgemini enables life sciences commercial reinvention with its customer-first framework, combining experience-led transformation, omnichannel engagement and data-driven personalization to drive measurable patient and HCP outcomes."

Sneha Jayanth

Capgemini

Overview

Capgemini is headquartered in Paris, France. It has more than 342,700 employees worldwide. In FY24, the company generated €22.1 billion in revenue. Capgemini delivers customer-centric transformation for commercial operations through omnichannel engagement, launch excellence, marketing modernization and intelligent sales enablement. It supports life sciences organizations globally through integrated consulting, design, engineering and managed services, enabling scalable, AI-driven commercial models and connected healthcare professional (HCP) and patient experiences across markets.

Strengths

Customer-first framework for life sciences commercial transformation: Capgemini's customer-first framework offers a life sciences–specific model for customer-centric reinvention, enabling CX and commercial leaders to redesign end-to-end HCP and patient journeys across digital and physical channels. It integrates experience design, journey orchestration and data-driven personalization, connecting clinical, launch and commercial functions to deliver consistent, insight-led engagement.

Omnichannel engagement and intelligent customer operations: Capgemini enables omnichannel marketing through personalized content activation, marketing automation and commerce across B2C, D2C and B2B models. Its Brand Experience Centers ensure scalable, localized engagement, while AI-driven sales and service operations improve effectiveness, compliance and commercial performance.

Continuous business reinvention (CBR) and end-to-end delivery model: Through its CBR methodology, Capgemini combines strategy, design, engineering and managed services to help clients build and scale new commercial models. Leveraging innovation, analytics and ecosystem partnerships, it enables disruptive, scalable transformation across the life sciences value chain.

Caution

Capgemini's experience-led and reinvention-focused approach is compelling. However, differentiation in highly regulated, platform-centric CRM and analytics engagements may require clearer articulation of proprietary life sciences commercial IP relative to more analytics-heavy or SaaS-aligned competitors.

Clinical Development (CROs)

Who Should Read This Section

This report is valuable for service providers offering clinical development (CROs) 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 gain a comprehensive understanding of CROs' digital capabilities and market positioning within clinical development. These insights help digital leaders evaluate CRO partners that can deliver scalable, patient-centric and technology-enabled clinical development services aligned with evolving research strategies and operational requirements.

Technology professionals

Should read this report to understand the leading technologies, investment areas and innovation priorities shaping digital clinical development within CROs. The report provides insight into platforms for data management, analytics, interoperability, and automation, as well as challenges related to integration and scalability. These insights help technology stakeholders assess CRO readiness to support secure, compliant and future-ready digital trial environments.

Clinical operations and R&D leaders

Should read this report to enhance their understanding of how CROs deliver end-user solutions across the clinical development lifecycle. The analysis highlights delivery models and operational capabilities that support trial efficiency. These insights help leaders evaluate CROs that can generate measurable value, optimize study outcomes and align service delivery with broader clinical and business objectives.

Cybersecurity professionals

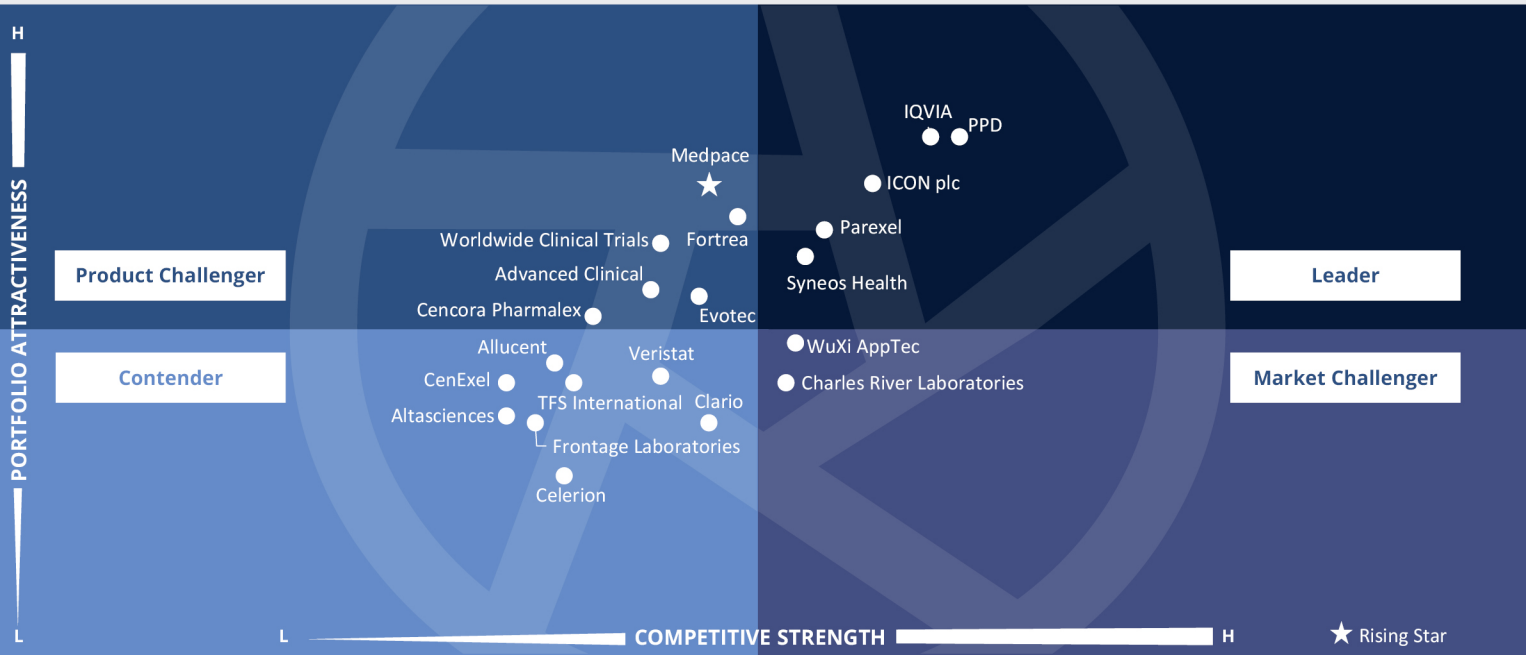
Should read this report to gain insights into how CROs address data security, privacy and regulatory compliance across digitally enabled clinical development environments. The report highlights approaches to protecting sensitive patient and trial data, managing access controls and meeting global regulatory requirements. These insights help cybersecurity leaders assess CRO capabilities in mitigating risk while ensuring secure and compliant digital trial operations.

ISG Provider Lens®

Source: ISG RESEARCH

Life Sciences Digital Services Clinical Development (CROs)

Global 2026



This quadrant evaluates CROs delivering **clinical development digital transformation,** assessing their ability to combine **technology platforms, analytics, and patient-centric execution** to improve trial efficiency, scalability, and measurable development outcomes.

Sneha Jayanth

Definition

This quadrant evaluates service providers based on their capabilities and strategic vision in clinical development, including technology and services that facilitate efficient, compliant and data-driven drug development. Clinical development spans the entire lifecycle of a clinical trial, across study design, site selection, patient recruitment, data capture, monitoring and regulatory submission. Service providers are assessed on their ability to deliver digital, AI-enabled and cloud-based solutions that improve trial speed, quality and patient engagement while ensuring GxP compliance.

The evaluation also considers innovation in decentralized and hybrid trial models, as well as the integration of real-world evidence (RWE) and platform-driven delivery. Providers that combine deep domain expertise with scalable technology platforms and collaborative engagement models are well positioned to lead the next generation of connected intelligent clinical development.

Eligibility Criteria

1. Focus on **clinical innovation,** investment in **digital transformation** and alignment with sponsor needs for trial **speed, quality and patient centricity**
2. Proven ability to deliver **end-to-end clinical services,** from **protocol design** to **regulatory submission,** with high efficiency and compliance
3. Strength in leveraging **AI, automation and analytics** to enhance **trial design, monitoring** and **data-driven decision-making**
4. Capability to execute decentralized clinical trials **(DCTs)** and **hybrid models** using **remote monitoring, eConsent** and **telehealth** tools for improved patient engagement
5. Effective use of **data platforms, EHR and RWE integration** and **cloud-based trial management systems** to ensure transparency and scalability
6. **In-depth domain knowledge** and specialized capabilities across multiple **therapeutic areas** and **complex study designs**
7. Strong record of **sponsor collaboration, on-time delivery** and measurable outcomes in **cost reduction** and **trial acceleration**

Observations

The Clinical Development Digital Transformation Services quadrant continues to reflect accelerating demand for digitally enabled, data-driven, and patient-centric trial models. Life sciences organizations are prioritizing scalable platforms, decentralized and hybrid capabilities, AI-enabled analytics, and integrated data ecosystems to improve speed, quality, and predictability across global programs. As a result, competitive strength is increasingly defined by the ability to combine operational scale with advanced technology integration, real-world data utilization, and measurable outcome improvements.

Compared with last year, several providers have strengthened their positioning through expanded decentralized trial capabilities, deeper AI-led automation across safety and clinical data workflows, and tighter integration between clinical, regulatory, and real-world evidence functions. The market has also seen continued consolidation and targeted acquisitions aimed at enhancing digital platforms, expanding geographic footprint, and strengthening therapeutic depth. M&A activity has largely focused on augmenting data assets, patient engagement technologies, pharmacovigilance automation, and regulatory information management capabilities to support end-to-end lifecycle integration.

Overall, the quadrant shows a gradual shift from traditional service-led differentiation toward more platform-enabled and analytics-driven models. Providers that demonstrate both industrialized global execution and embedded digital innovation are moving upward in competitive strength, while those with narrower technology ecosystems face increasing pressure to expand capabilities or pursue partnerships to remain competitive.

From the 32 companies assessed for this study, 21 qualified for this quadrant, with 5 being Leaders and 1 Rising Star.

ICON plc

ICON plc stands out for its Control Tower governance, robust RBM frameworks, and strong global study execution discipline. While its AI-data ecosystem breadth is slightly narrower than IQVIA's, its operational rigor and monitoring depth remain highly competitive.

IQVIA

IQVIA combines the industry's deepest data backbone with global delivery scale, tightly integrating analytics, RBM, FSP, labs, and financial operations. Its platform-led model enhances visibility, governance, and execution discipline across complex, multi-country trials.

Parexel

Parexel stands out for regulatory depth, strong global study execution, and mature FSP flexibility. While more execution-driven than platform-led competitors, it demonstrates robust DCT capabilities and disciplined, risk-based delivery across complex trials.

ppd

PPD stands out in decentralized and hybrid trial delivery, combining AI-enabled forecasting, mature RBM, and integrated lab-data streams. Backed by Thermo Fisher's infrastructure, it delivers scalable Phase I–IV programs with strong patient access and operational acceleration.

Syneos Health

Syneos Health combines therapeutic depth with patient-centric hybrid execution and predictive analytics. Its FSP 360 flexibility strengthens sponsor alignment, though its proprietary technology ecosystem is comparatively lighter than larger data-platform competitors.

Medpace

Medpace (Rising Star) demonstrates strong clinical development capability through its vertically integrated model and proprietary platform ecosystem, enabling seamless coordination across EDC, labs, imaging, and analytics. Its adaptive monitoring and embedded AI/ML support efficient, data-driven execution across complex global trials.

Patient Engagement (CROs)

Who Should Read This Section

This report is valuable for service providers offering patient engagement (CROs) 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 gain a clear understanding of CROs' digital capabilities and market positioning in patient engagement. These insights help digital leaders evaluate CRO providers that can deliver scalable, patient-centric engagement solutions aligned with evolving clinical trial designs and broader digital transformation objectives.

Technology professionals, such as IT leaders and digital architects

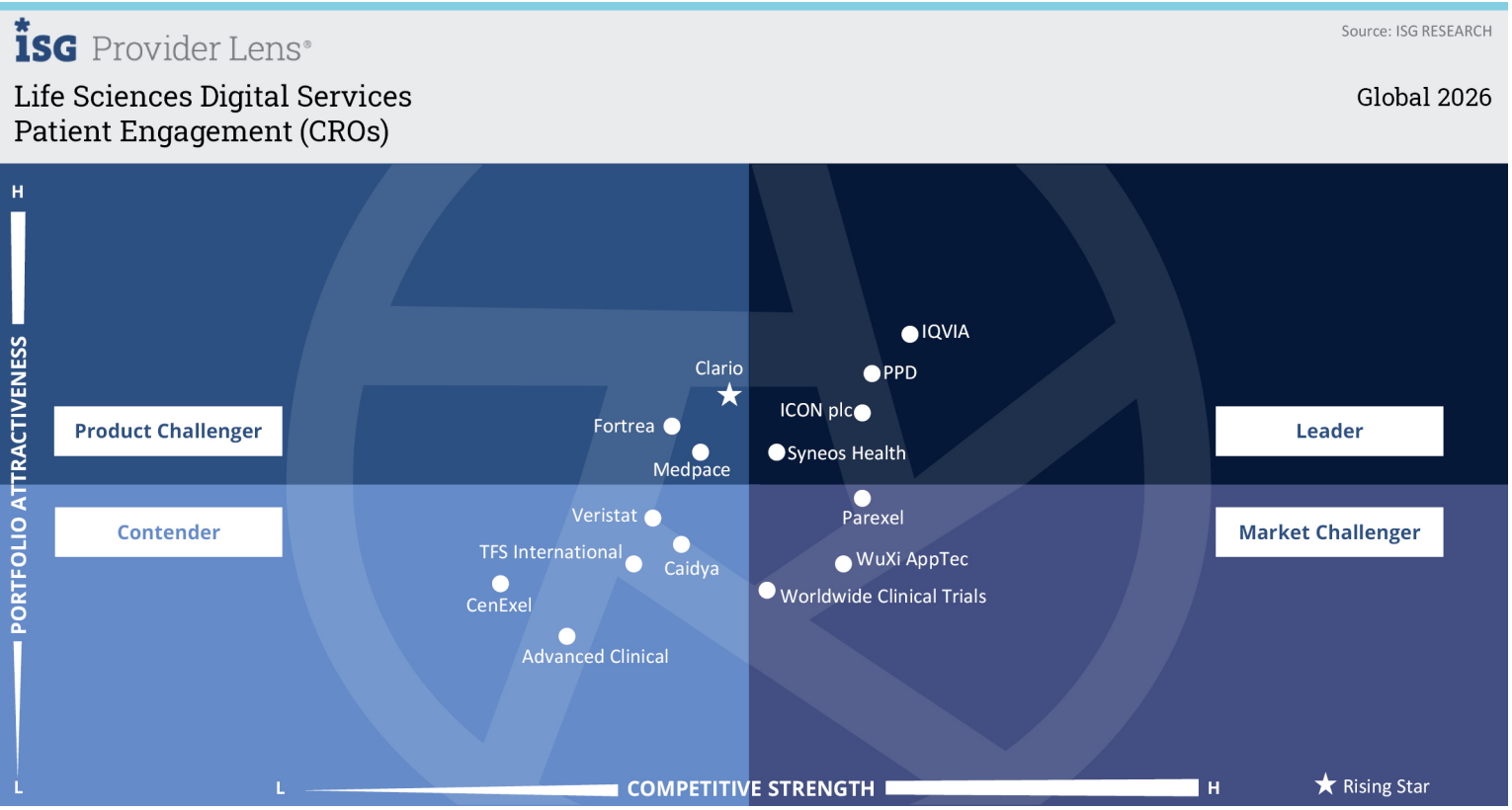
Should read this report to understand the leading technologies, investment priorities and innovation challenges shaping patient engagement within CROs. These insights enable technology stakeholders to assess CRO readiness for supporting interoperable, compliant and future-ready patient engagement ecosystems across global trial environments.

Patient engagement leaders

Should read this report to enhance their understanding of how CROs design and deliver end-user engagement solutions across the clinical trial lifecycle. These insights help leaders evaluate CROs that can generate measurable value, optimize trial performance and align engagement strategies with sponsor expectations and regulatory requirements.

Cybersecurity and compliance professionals

Should read this report to gain insights into how CROs address data privacy, security and regulatory compliance across digital patient engagement platforms. These insights support cybersecurity leaders in assessing CRO capabilities to mitigate risk while enabling secure, compliant and seamless patient engagement experiences.



The quadrant evaluates CROs delivering **digitally enabled patient engagement by** combining **AI-driven recruitment, decentralized models and human support frameworks** to improve enrollment, retention, diversity and overall trial experience globally.

Sneha Jayanth

Definition

This quadrant evaluates CROs' capabilities and strategic vision in driving patient engagement across the clinical development lifecycle. It assesses how CROs leverage digital technologies, data and behavioral insights to enhance patient recruitment, retention and experience in both traditional and decentralized trials. Key evaluation areas include their omnichannel engagement platforms, mobile applications, wearables and AI-driven analytics that enable personalized, real-time interaction with participants. The evaluation also considers CROs' ability to ensure data privacy, regulatory compliance and inclusive trial design for diverse patient populations. Leaders in this quadrant should integrate patient-centric strategies with advanced technology ecosystems, helping sponsors improve study participation, adherence and outcome quality, while building long-term trust and transparency in clinical research.

Eligibility Criteria

1. Strong commitment to **patient-centric clinical research,** supported by investments in **digital engagement** and **behavioral science–based strategies**
2. Strength in deploying **omnichannel solutions, mobile applications, wearables** and **virtual engagement tools** that enhance patient connectivity and experience
3. Proven ability to improve **patient identification, onboarding and retention** through **AI-driven targeting, education** and **personalized communication**
4. Focus on **inclusive trial design** and **community engagement** to expand reach among **underrepresented populations**
5. Strong frameworks ensuring **HIPAA and GDPR compliance, secure data management** and transparent consent practices
6. Use of **real-time analytics** and **predictive models** to monitor engagement, identify risks and optimize study outcomes
7. Demonstrated impact in **reducing recruitment timelines, enhancing adherence** and **improving trial success rates** through patient-first approaches

Observations

The Patient Engagement (CROs) quadrant shows a continued shift toward digitally enabled, data-driven and diversity-focused trial participation models. Life sciences organizations are increasingly prioritizing integrated engagement ecosystems that combine AI-driven recruitment, decentralized and hybrid capabilities, multilingual support and real-time analytics to improve enrollment speed, retention and representativeness. As patient access and experience become strategic differentiators, providers are expected to demonstrate measurable outcomes across the areas of recruitment efficiency, dropout reduction and operational scalability.

Compared with 2025, several providers have strengthened their positioning through expanded decentralized trial infrastructure, deeper AI integration into patient identification and dropout prediction, and a more structured diversity action planning. The competitive landscape shows gradual upward movement for providers that can offer both digital scale and human-enabled support models. At the same time, the market has seen selective M&A and partnership activity focused on enhancing digital community reach, patient concierge capabilities, reimbursement platforms and real-world data integration to broaden engagement depth.

Overall, the quadrant highlights a clear shift from tactical recruitment services toward comprehensive, platform-enabled patient engagement strategies. Providers that combine large-scale data assets, predictive analytics, hybrid trial delivery and structured governance frameworks are gaining competitive strength, while the ones with narrower digital ecosystems are under pressure to expand capabilities through investments or collaborations.

From the 20 companies assessed for this study, 15 qualified for this quadrant, with 4 being Leaders and 1 Rising Star.

ICON plc

ICON plc combines eConsent, telehealth and Accellacare in-home services within fully virtual and hybrid models. Reported outcomes include 97 percent retention (versus 33 percent traditionall) and approximately 40 faster enrollment, reinforced by a 2025 Mural Health partnership.

IQVIA

IQVIA delivers a comprehensive hybrid engagement model, integrating eConsent, telemedicine, eCOA, connected devices and AI-based dropout prediction with patient navigators and educators, demonstrating strong, measurable gains in compliance, retention and travel reduction.

ppd

PPD combines AI-based probability-to-enroll scoring, HealthUnlocked's over 2 million member community reach, StudyGage burden modeling and high-volume multilingual prescreening with navigator-led support to create a powerful digital-plus-human recruitment engine.

Syneos Health

Syneos Health integrates AI-powered EHR/claims/RWE identification and diversity action plans with real-time tracking and concierge-led engagement to deliver 29 percent higher enrollment, which positions it as a leader in digitally scaled, diversity-driven outreach.

Clario

Clario (Rising Star) delivers patient engagement through digital outreach, remote data capture and integrated support services that enhance recruitment and retention. Its platforms provide real-time engagement visibility and seamless clinical workflow integration, improving participant experience, compliance and trial efficiency.

Pharmacovigilance and Regulatory Affairs — Digital Evolution (CROs)

Who Should Read This Section

This report is valuable for service providers offering pharmacovigilance and regulatory affairs — digital evolution (CROs) 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 gain a clear understanding of the digital capabilities and market positioning of CROs supporting pharmacovigilance and regulatory affairs. These insights help digital leaders evaluate CRO providers that can modernize safety and regulatory operations while improving efficiency, compliance and data-driven decision-making across global clinical programs.

Technology professionals, such as IT leaders and digital architects

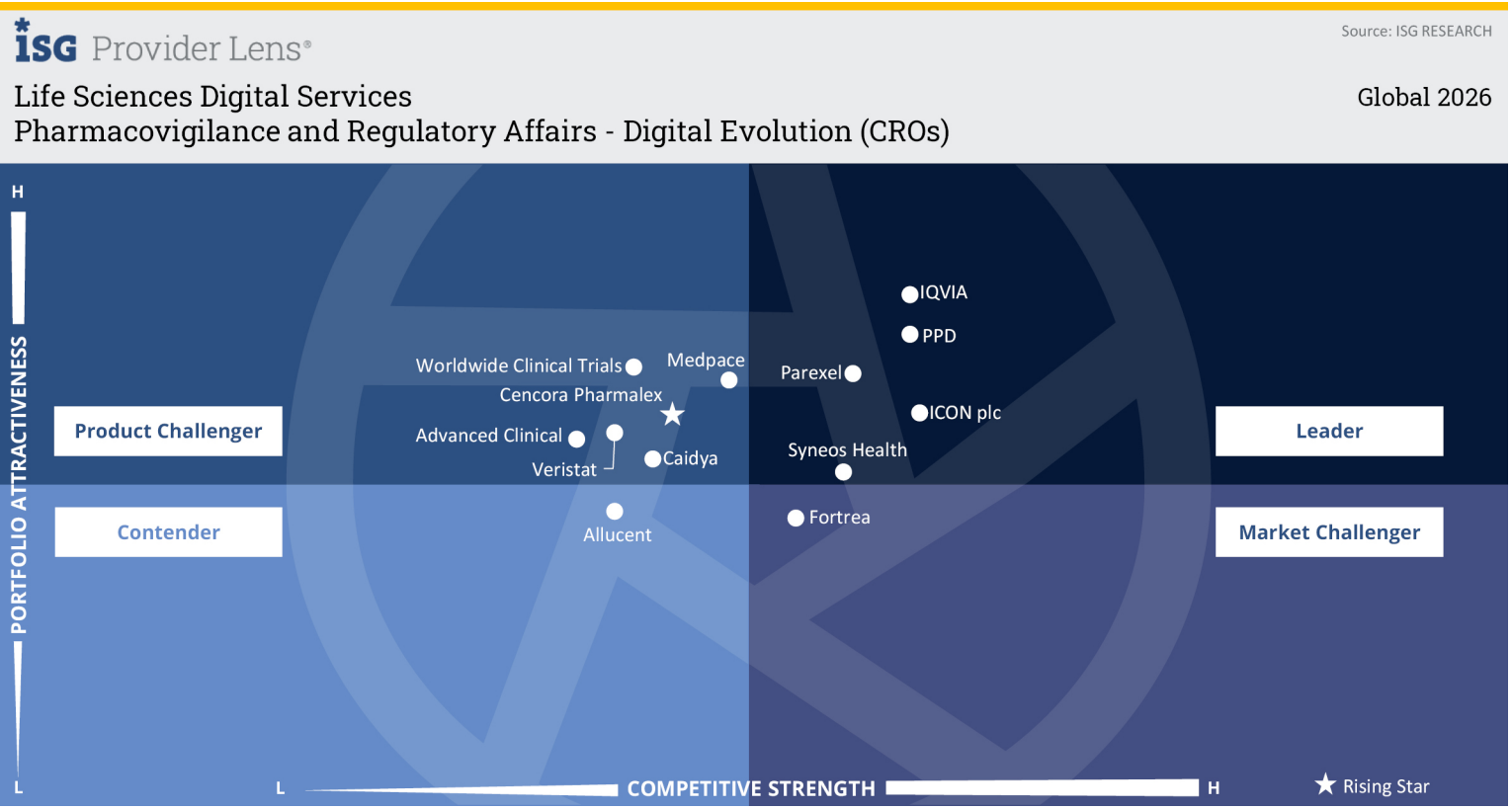
Should read this report to understand the leading technologies, investment priorities and innovation challenges shaping digital pharmacovigilance and regulatory operations within CROs. These insights help technology stakeholders assess CRO readiness to support scalable, secure and compliant digital safety and regulatory environments.

Safety and regulatory operations leaders

Should read this report to enhance their understanding of how CROs deliver end-user solutions across pharmacovigilance and regulatory affairs functions. These insights help leaders evaluate CRO providers that can generate measurable operational value, align with evolving regulatory expectations and support consistent global safety and regulatory execution.

Cybersecurity professionals

Should read this report to gain insights into how CROs address data protection, system security, and regulatory compliance across pharmacovigilance and regulatory platforms that handle sensitive safety data. These insights help cybersecurity leaders assess CRO capabilities in mitigating risk while enabling secure, compliant and seamless digital safety operations.



This quadrant evaluates CROs delivering **digitally-enabled PV and regulatory operations for** their ability to combine **automation, AI and advanced analytics** for scalable safety monitoring, inspection readiness and proactive risk management across a product lifecycle.

Sneha Jayanth

Definition

This quadrant evaluates CROs' capabilities and strategic vision in PV and regulatory affairs, focusing on their effectiveness in managing drug safety, compliance and global submissions. It assesses how CROs leverage AI, automation and analytics to enhance case processing, signal detection and regulatory intelligence. Key evaluation areas include end-to-end safety operations, risk management planning and cloud-based RIM systems that ensure efficiency and accuracy. The evaluation also considers expertise in navigating regulations established by the FDA and EMA and adherence to IDMP standards, along with the ability to manage complex multiregion submissions and post-market surveillance. Leaders in this quadrant should combine scientific depth, digital innovation and operational excellence to help sponsors achieve compliance, fast approvals and proactive safety monitoring across the product lifecycle.

Eligibility Criteria

1. Focus on advancing **drug safety** and **regulatory excellence** through digital innovation, automation and strong domain expertise
2. Proven ability to deliver **end-to-end PV services,** from **case intake** and **signal detection** to **risk management,** with consistency and compliance
3. Deep understanding of **global health authority requirements,** such as those set by the FDA, EMA and Medicines and Healthcare products Regulatory Agency (MHRA), as well as IDMP standards, combined with experience in managing **multiregion submissions**
4. Strength in using **AI, ML** and **RPA** for **case processing, literature screening** and **regulatory intelligence automation**
5. Robust frameworks for **data integrity, audit readiness** and **secure, validated systems** that ensure end-to-end compliance
6. Ability to use **predictive analytics** and **real-time dashboards** for proactive **signal management** and performance monitoring
7. Demonstrated success in **reducing case turnaround times, enhancing submission accuracy** and **improving regulatory response efficiency**

Observations

The Pharmacovigilance and Regulatory Affairs — Digital Evolution (CROs) quadrant reflects a definitive shift toward AI-enabled, industrialized safety operations embedded within broader clinical and regulatory ecosystems. Life sciences organizations are prioritizing scalable case processing, proactive signal detection, and inspection-ready compliance frameworks that can manage rising case volumes, evolving global regulations and increasing data complexity. Competitive differentiation is increasingly defined by the ability to combine automation, advanced analytics and human medical oversight within integrated, end-to-end safety models spanning clinical and post-marketing phases.

Compared with 2025, several providers have strengthened their positioning through deep deployment of GenAI, natural language processing (NLP)-driven literature review, automated coding and narrative drafting, and enhanced dashboard-based governance. The quadrant shows upward movement for providers that can demonstrate measurable efficiency gains and a strong link between pharmacovigilance (PV), regulatory information management and real-world data analytics. At the same time, the market continues to experience targeted M&A and partnership activity, aimed at expanding safety technology platforms, enhancing signal detection capabilities and integrating safety workflows with broad clinical data ecosystems.

Overall, the competitive landscape is evolving from labor-intensive safety processing models toward automation-led, insight-driven pharmacovigilance. Providers that successfully integrate AI, multi-source data ingestion, regulatory alignment and scalable global delivery are gaining competitive strength, while those relying primarily on traditional manual workflows are facing increasing pressure to modernize their safety infrastructure and analytics capabilities.

From the 20 companies assessed for this study, 13 qualified for this quadrant, with five being Leaders and one a Rising Star.

ICON plc

ICON plc combines a global workforce of over 1,000 pharmacovigilance (PV) experts with around 700,000 post-marketing cases, processed over five years, claiming more than 99 percent compliance. Automation, NLP literature mining and disproportionality analytics strengthen efficiency and signal detection for the company.

IQVIA

IQVIA combines SaaS-based vigilance automation, GenAI/NLP-driven case processing and integrated real world evidence (RWE)-clinical signal analytics with SmartSolve® RIM and RADDS, positioning PV and regulatory as embedded, end-to-end capabilities within its CRO ecosystem.

Parexel

Parexel combines AI-driven MedDRA coding, narrative generation, causality support and literature automation with human oversight. Cloud-based Argus integration and risk based quality management (RBQM)-aligned analytics enhance safety governance and reporting efficiency.

ppd

PPD combines automated case intake, global physician-led safety review and multi-platform database support (for example, Argus and ArisGlobal) to manage high individual case safety report (ICSR) volumes with strong on-time compliance and operational rigor.

Syneos Health

Syneos Health applies AI across intake, triage, coding and signal workflows along with human oversight. Platforms such as Synopsis™ Connect and GRMR enable centralized visualization, predictive risk detection and global safety governance.

Cencora PharmaLex

Cencora PharmaLex (Rising Star) delivers automated PV and regulated operations through its psiXchange 3.0 platform, combining workflow automation, embedded regulatory intelligence and global scalability across safety reporting and submission processes.

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.

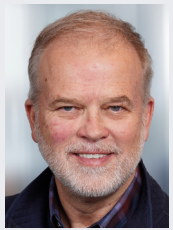
Study Sponsor

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®

The ISG Provider Lens® Quadrant research series is the only service provider evaluation of its kind to combine empirical, data-driven research and market analysis with the real-world experience and observations of ISG's global advisory team. Enterprises will find a wealth of detailed data and market analysis to help guide their selection of appropriate sourcing partners. ISG advisors use the reports to validate their own market knowledge and make recommendations to ISG's enterprise clients. The research currently covers providers offering their services across multiple geographies globally.

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APRIL, 2026

REPORT: LIFE SCIENCES DIGITAL SERVICES