

Medical Device Digital Services

A research report comparing provider strengths,
challenges and competitive differentiators



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The medical device industry is undergoing rapid digital transformation, driven by the need for innovative, connected, patient-centric healthcare solutions. Technologies such as AI, ML, IoT, cloud computing and digital twins are increasingly embedded into medical devices, enabling real-time monitoring, predictive diagnostics and improved clinical decision-making. This transformation is shifting the industry from traditional hardware-centric models to platform-enabled, data-driven ecosystems. In other markets, AI is being widely adopted, however in medical devices, it is currently in an early scaling phase across the U.S. and Europe. There is clear momentum and increasing integration across select use cases; however, adoption remains uneven and concentrated in specific domains. Most enterprises are still testing and assessing pilot programs and point solutions toward broader enterprise integration. It is in post-market enablement where data, analytics and pattern recognition is needed, that AI is emerging as a key enabler of innovation and differentiation, but it is not yet fully industrialized or consistently embedded

across the end-to-end medical device value chain. However, integrating these technologies presents challenges, including fragmented IT infrastructure, data interoperability issues and evolving regulatory requirements, especially for software as a medical device (SaMD). Ensuring data integrity, cybersecurity and compliance throughout the device lifecycle is critical.

To navigate these complexities and accelerate innovation, medical device firms are partnering with IT service providers for expertise in digital engineering, cloud integration, quality systems and regulatory technologies. These providers offer global delivery models, domain accelerators and co-innovation frameworks that reduce time to market, enhance operational efficiency and support regulatory readiness. As value-based care gains traction, the role of IT services in enabling scalable, patient-focused and compliant digital health solutions is vital. Strategic collaboration with IT partners is essential to drive innovation, improve outcomes and stay competitive in this evolving landscape.



This study provides insights into digital transformation solutions and services offered by providers in the **medical device industry**.

Digital Engineering and Product Development

Regulatory Compliance, Strategy and Quality Assurance

AI and Innovation Driving Post-Market Enablement

Simplified Illustration Source: ISG 2026

The ISG Provider Lens® Medical Device Digital Services study offers the following to business and IT decision-makers:

- Transparency on the strengths and weaknesses of relevant providers.
- A differentiated positioning of providers by segments on their competitive strengths and portfolio attractiveness.
- Focus on different markets, including the U.S. and Europe.

Our study serves as an important decision-making basis for positioning, key relationships and go-to-market considerations. ISG advisors and enterprise clients also use information from these reports to evaluate their current vendor relationships and potential engagements.



Digital Engineering and Product Development

Definition

In this quadrant, ISG evaluates providers delivering end-to-end digital engineering and product development services tailored to the medical device industry. It examines the providers' ability to support the design, development and enhancement of connected, software-driven, compliant medical devices. Key evaluation areas include expertise in embedded systems, firmware, hardware and software integration, cloud connectivity, mobile application development, usability and sustenance engineering. The quadrant also assesses the providers' expertise in applying emerging technologies such as AI and ML, digital twins, and edge computing to accelerate innovation, ensure regulatory compliance and reduce time to market. Focus is on coinnovation models, intellectual property/tool accelerators and track record in supporting the full product lifecycle — from concept and prototyping to post-launch optimization.

Eligibility Criteria

1. Demonstrate **experience in providing digital engineering** or product development services to medical device manufacturers
2. Exhibit proven track record in executing engagements in the past related to **device design, software development, embedded systems or digital product engineering for regulated medical devices**
3. Showcase knowledge and **implementation expertise aligned with FDA (21 CFR Part 820, 21 CFR Part 11), EU MDR, ISO 13485, IEC 62304 or similar regulatory standards** relevant to digital product development in medtech
4. Apply emerging technologies such as **AI and ML, digital twins, AR/VR** for training or simulation, edge computing and cybersecurity for connected devices
5. Have **a team of engineering talent with medtech product development expertise** supported by dedicated practice groups, CoEs or innovation labs
6. Have capability in providing **sustenance engineering services** for medical devices, including **component re-engineering, software updates, compliance upgrades, and post-market support**
7. Showcase use of **AI/GenAI** and automation in engineering, testing, or design



Definition

In this quadrant, ISG evaluates providers supporting medical device manufacturers with regulatory compliance, strategic consulting and quality assurance services across the product lifecycle. It examines the providers' ability to navigate global regulatory frameworks such as FDA, EU MDR, ISO 13485 and IEC 62304 while aligning digital and engineering initiatives with go-to-market (GTM) objectives. Key evaluation areas include regulatory submission readiness, embedded systems compliance, quality management system (QMS) implementation and risk-based validation processes.

Providers are also assessed on cybersecurity and data protection strategies, ensuring product and patient safety in connected and software-driven environments. Emphasis is on strategic advisory capabilities, such as market entry planning, digital quality transformation and global regulatory intelligence, and the use of digital tools and accelerators to drive compliance automation, enhance audit preparedness and facilitate quick time to approval.

Eligibility Criteria

1. Exhibit proven experience in delivering regulatory compliance and quality assurance services to medical device manufacturers, including **adherence to standards such as Food and Drug Administration (FDA), EU MDR, ISO 13485, IEC 62304 and cybersecurity protocols (for example, FDA premarket cybersecurity guidance, National Institute of Standards and Technology [NIST])**
2. Demonstrate expertise in validating and verifying embedded systems within regulated environments
3. **Develop and implement QMS solutions, corrective and preventive action** (CAPA) processes and audit readiness frameworks
4. Showcase **established track record in strategic consulting for regulatory submissions**, risk management, GTM planning and compliance strategy
5. **Manage data security and patient privacy (Health Insurance Portability and Accountability Act [HIPAA] and GDPR)** as well as mitigate cybersecurity risks for medical devices
6. Highlight client references or case studies showcasing successful regulatory and quality assurance engagements
7. Showcase AI/GenAI-enabled regulatory processes



AI and Innovation Driving Post-Market Enablement

Definition

In this quadrant, ISG evaluates providers delivering digital solutions for post-market activities of medical device manufacturers, with a growing emphasis on AI and innovation as key enablers. It examines the providers' ability to enable real-time monitoring, device performance tracking, adverse event reporting and telehealth integration to ensure continuous product improvement, patient safety and regulatory compliance. Key evaluation areas include developing and integrating remote patient monitoring (RPM) systems, IoMT-enabled analytics, post-market surveillance tools and adverse event reporting systems (AERS) aligned with global regulations.

Providers are also assessed on their ability to transform real-world data (RWD) into real-world evidence (RWE), using advanced analytics, AI and ML and dashboarding tools to inform product enhancements and regulatory submissions. Emphasis is on secure data exchange, interoperability with electronic health records (EHRs) and health

systems, and patient-centric platforms that drive post-market engagement, support recall management and strengthen compliance across markets.

Eligibility Criteria

1. **Enable continuous, secure and compliant data collection from deployed devices**, including IoMT-enabled products
2. Integrate with EHRs, mobile applications and cloud platforms to **centralize data and support real-time decision-making**
3. **Use analytics, AI and ML, and digital twins to track device usage**, detect anomalies and predict maintenance needs
4. Possess tools and systems to capture, report and analyze adverse events in **compliance with the FDA, EU MDR and other regulatory bodies**
5. Connect device data to telehealth platforms and RPM solutions for ongoing patient engagement and clinical oversight
6. Have **mechanisms to collect, analyze and act on user or patient feedback for iterative product enhancements**
7. Adhere to post-market regulatory standards and data privacy laws such as HIPAA and GDPR
8. Demonstrate capabilities in RWE generation, RPM platforms, and patient engagement ecosystems



Quadrants by Region

As a part of this ISG Provider Lens® quadrant study, we are introducing the following three quadrants on Medical Device Digital Services 2026:

Quadrant	U.S.	Europe
Digital Engineering and Product Development	✓	✓
Regulatory Compliance, Strategy and Quality Assurance	✓	✓
AI and Innovation Driving Post-Market Enablement	✓	✓



ISG's Medical Device Digital Services Framework

Key characteristics of the proprietary framework:

- Encapsulates what enterprises are doing across the Medical Device Digital Services market and helps connect them to digital solutions
- Represents the entire value chain of supply and demand within the market
- Inner tiles represent themes of enterprise objectives
- Outer tiles represent initiatives
- Behind each outer tile is a specific set of capabilities with unique market-leading providers and solutions



The research phase falls in the period between April and July 2026, during which survey, evaluation, analysis and validation will take place. The results will be presented to the media in October 2026.

Milestones	Beginning	End
Survey Launch	April 1, 2026	
Survey Phase	April 1, 2026	May 8, 2026
Sneak Preview	July 2026	
Press Release & Publication	October 2026	

Please refer to the [ISG Provider Lens® 2026 research](#) agenda to view and download the list of other studies conducted by ISG Provider Lens®.

Access to Online Portal

You can view/download the questionnaire from [here](#) using the credentials you have already created or refer to instructions provided in the invitation email to generate a new password. We look forward to your participation!

Buyers Guide

ISG Software Research, formerly “Ventana Research,” offers market insights by evaluating technology providers and products through its Buyers Guides. The findings are drawn from the research-based analysis of product and customer experience categories, ranking and rating software providers and products to help facilitate informed decision-making and selection processes for technology.

In the course of the Medical Device Digital Services IPL launch, we want to take advantage of the opportunity to draw your attention to related research and insights that ISG Research will publish in 2026. For more information, refer to the [Buyers Guide research schedule](#).

Research Production Disclaimer:

ISG collects data for the purposes of writing research and creating provider/vendor profiles. The profiles and supporting data are used by ISG advisors to make recommendations and inform their clients of the experience and qualifications of any applicable provider/vendor for outsourcing the work identified by clients. This data is collected as part of the ISG FutureSource™ process and the Candidate Provider Qualification (CPQ) process. ISG may choose to only utilize this collected data pertaining to certain countries or regions for the education and purposes of its advisors and not produce ISG Provider Lens® reports. These decisions will be made based on the level and completeness of the information received directly from providers/vendors and the availability of experienced analysts for those countries or regions. Submitted information may also be used for individual research projects or for briefing notes that will be written by the lead analysts.



ISG Star of Excellence™ – Call for nominations

The Star of Excellence™ is an independent recognition of excellent service delivery based on the concept of “Voice of the Customer.”

The Star of Excellence™ is a program, designed by ISG, to collect client feedback about service providers’ success in demonstrating the highest standards of client service excellence and customer centricity.

The global survey is all about services that are associated with IPL studies. In consequence, all ISG Analysts will be continuously provided with information on the customer experience of all relevant service providers. This information comes on top of existing first-hand advisor feedback that IPL leverages in context of its practitioner-led consulting approach.

Providers are invited to [nominate](#) their clients to participate. Once the nomination has been submitted, ISG sends out a mail confirmation to both sides. It is self-evident that ISG anonymizes all customer data and does not share it with third parties.

It is our vision that the Star of Excellence™ will be recognized as the leading industry recognition for client service excellence and serve as the benchmark for measuring client sentiments.

To ensure your selected clients complete the feedback for your nominated engagement please use the Client nomination section on the Star of Excellence™ [website](#).

We have set up an email where you can direct any questions or provide comments. This email will be checked daily, please allow up to 24 hours for a reply.

Here is the email address:
isg.soe@isg-one.com



ISG Star of Excellence



Methodology & Team

The ISG Provider Lens® 2026 – Medical Device Digital Services research 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.

Study Sponsor:

Iain Fisher

Lead Analysts:

Rohan Sinha and Sneha Jayanth

Research Analyst:

Sneha Jayanth

Data Analyst:

Laxmi Sahebrao Kadve

Project Manager:

Donston Sharwin

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The research and analysis presented in this study will include data 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. ISG recognizes the time lapse and possible market developments between research and publishing, in terms of mergers and acquisitions, and acknowledges that those changes will not reflect in the reports for this study.

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



Contacts For This Study

Study Sponsor



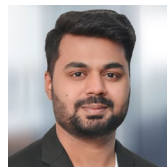
Iain
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Director



Donston
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Project Manager



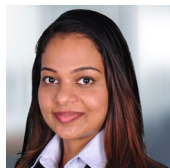
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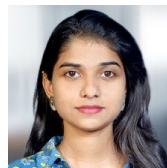
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Sneha
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Research Analyst



Laxmi Sahebrao
Kadve

Data Analyst



ISG Provider Lens Advisors Involvement Program

ISG Provider Lens offers market assessments incorporating practitioner insights, reflecting regional focus and independent research. ISG ensures advisor involvement in each study to cover the appropriate market details aligned to the respective service lines/technology trends, service provider presence and enterprise context.

In each region, ISG has expert thought leaders and respected advisors who know the provider portfolios and offerings as well as enterprise requirements and market trends. On average, three advisors participate as part of each study's quality and consistency review team (QCRT). The QCRT ensures each study reflects ISG advisors' experience in the field, which complements the primary and secondary research the analysts conduct. ISG advisors participate in each study as part of the QCRT group and contribute at different levels depending on their availability and expertise.

The QCRT advisors:

- Help define and validate quadrants and questionnaires,
- Advise on service provider inclusion, participate in briefing calls,
- Give their perspectives on service provider ratings and review report drafts.

ISG Advisors to this study



Jenn
Stein

**Partner,
Health Sciences**



Michael
Fullwood

**Partner,
Health Sciences**



Ryan
Hamze

Principal Consultant



Sven
Geissler

Director



Invited Companies

If your company is listed on this page or you feel your company should be listed, please contact ISG to ensure we have the correct contact person(s) to actively participate in this research.

1MED SA	Celegence	Ezen Digital	Impact Advisors
Accenture	CitiusTech	Firstsource	Indegene
ACL Digital	Clinitude	Gainwell Technologies	Infinite Computer Solutions
Agilisium	Coforge	GAVS Technologies	Infogain
All for One	Cognizant	Genpact	Infosys
Allscripts – Veradigm	Conduent	HARMAN Digital Transformation Solutions	Innova Solutions
Altasciences	Dell Technologies	HCLTech	Intmed Software
Apexon	Deloitte	HCTec	IntuitiveCare
Atos	DXC Technology	Health Catalyst	IQVIA
ATS Global	Emergo by UL	Healthbit Ltd	ITC Infotech
Beyondsoft	EMIDS	Hexaware	Kapstone Medical
Biomapas	EPAM Systems	Hitachi	KPMG
Birlasoft	EXL	HTC Global Services	Kyndryl
Brillio	Extreme Digital Solutions - EDS	Huron	LTIMindtree
Capgemini	EY	IBM	LTTS



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Marlabs	PTC	Tegria
Mastek	PwC	TEKsystems
Med-Di-Dia Limited	Qserve Group	T-Systems
Mphasis	Quantiphi	Unisys
Nordic Global	Rackspace Technology	UpFlux
NorMed Consulting	RSM US LLP	UST
NTT DATA	Sagility Health	Veranex
Obelis Group	Softtek	Virtusa
Omega Healthcare Management Services	Sopra Steria	WellSky
Optum	Stefanini	Wipro
Orion Innovation	Sutherland	WNS
Perficient	Switzerland	Yash Technologies
Persistent Systems	Tata Elxsi	ZenBit Tech
Pivot Point Consulting	TCS	Zensar Technologies
ProPharma	Tech Mahindra	



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, while 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.

For more information about ISG Provider Lens® research, please visit this [webpage](#).

ISG Research™

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

ISG offers research specifically about providers to state and local governments (including counties, cities) as well as higher education institutions. Visit: [Public Sector](#).

For more information about ISG Research™ subscriptions, please email contact@isg-one.com, call +1.203.454.3900, or visit research.isg-one.com.

ISG

ISG (Nasdaq: III) is a global AI-centered technology research and advisory firm. A trusted partner to more than 900 clients, including 75 of the world's top 100 enterprises, ISG is a long-time leader in technology and business services sourcing that is now at the forefront of leveraging AI to help organizations achieve operational excellence and faster growth.

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

For more information, visit isg-one.com.





APRIL, 2026

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