

# Life Sciences Digital Services 2022

This report assesses the use of technology innovation to assist in drug and device development.



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### **Technology is facilitating the new normal for Life Sciences**

In the past year, as the world continued to recover from the challenges and restrictions implemented to manage the COVID-19 situation, leading life science companies and the providers that support them made significant advances in incorporating technology solutions into the DNA of their operations. This sector has historically been reluctant to embrace innovative approaches at scale, but the pandemic has catalyzed a permanent change. For starters, the pandemic made many formerly standard processes, such as in-person patient visits and just-in-time supply chain practices impossible, which created an unprecedented demand for innovative solutions. Leading solution providers not only intervened with existing technology solutions but also demonstrated their readiness to collaborate, innovate and invest with greater

flexibility and customer-centric focus than ever before.

Although the concept of Decentralized Clinical Trials (DCTs) is one of the first to come to mind as a reflection of these changes, there are multiple areas where innovative approaches are being broadly implemented. Top providers are employing automation, end-to-end integration, platform-agnostic software, cloud transformation and advanced analytics across the entire spectrum of life science opportunities. Furthermore, the availability of more powerful mobile connectivity opens up immense opportunities to realize true patient centrality. Within the past year, the market has shifted from piloting technology solutions to a demand for skills, software and platforms that support implementation at scale. Provider offerings which are in demand combine subject matter and technical expertise with the services and platforms to solve specific customer problems. While many solutions are customizable rather than custom, best-of-breed solutions are identifiable by their flexibility, agility and ease of adoption by users across the life sciences spectrum.

# Technology, collaboration, agility – Leader qualities



## Executive Summary

Another key defining trend in 2022 was a new openness to partnering and collaboration. Leading providers in the life science sector gave multiple examples of their foundational reliance on improving innovation through partnerships. Many cited collaborations with academia, start-ups, medical institutions and other potential innovators. All referred to engaging deeply with their life science clients to identify and progress opportunities for process improvement and technology solutioning. In addition, the ability to successfully collaborate with potential competitors has become a new competitive advantage.

End-to-end integration of solutions was also a differentiator and driver of competitive advantage in 2022. Top providers promoted their vision to ensure that work delivered in the development of drugs and devices was designed from the outset to support marketing imperatives. They also emphasized that the technologies and software employed in that development process offered the ability to integrate with and/or support solutions at least through the marketing phase. Some best-of-breed solutions also provided

functionalities that integrated with supply chain management. Top solutions relied on cloud infrastructure and provided user-friendly analytics and customizable reporting capabilities underpinned by strict adherence to regulatory compliance guidelines and a sophisticated understanding of cybersecurity.

While all quadrants assessed for 2022 showed substantial progress toward new ways of approaching long-standing challenges, some of the biggest changes can be seen in Clinical Development. This quadrant was historically seen as the dominant phase of drug and device development. It now needs to be treated as an integrated element of the overall product lifecycle. Technologies are not only used to escalate timelines for enrollment and data availability from clinical trials but also to support patient centricity, health care professional (HCP) engagement, marketing priorities, safety and regulatory reporting and supply chain management.

Equally substantive changes to the breadth and depth of new perspectives are evident in the Patient Engagement quadrant. While integrated

technologies at the patient level were initially a response to the challenges arising from the COVID-19 pandemic for both clinical trials and health management, they have now become a permanent element of life science patient interactions. By easing the burden on patients and facilitating remote HCP interactions, patient-level devices and technologies are helping to shorten clinical trial timelines and enhance safety and data management.

As with other life science quadrants, Manufacturing and Supply Chain has leveraged the opportunities resulting from the pandemic to embed improved ways of working into daily operations. A strategy of integration across the lifecycle, combined with a renewed emphasis on compliance, drives many of the innovations being implemented. Here again, there is a deep focus on using automation, real-time data access and integration of processes, inventories, machines and customer demand to streamline supply chain management. In addition, analytics capabilities have become more important for the optimization of global and complex supply chain structures.

Pharmacovigilance (PV), which has long been at the forefront of business process outsourcing, is again leading the way for many life science companies when it comes to implementing innovative solutions. NLP and machine learning are being widely used to enhance safety reporting processes, as well as improve data aggregation from unstructured sources. Additionally, Regulatory Affairs is rapidly catching up with the other life science quadrants in terms of leveraging automation and integrated solutions to support compliance, reporting and regulatory intelligence requirements.

MedTech, which has long been at the forefront of technology innovation, is also working on expanding the breadth and depth of technology enablement. In addition to continued focus on automation, cloud transformation, advanced analytics and increased efficiency, a key element of leading provider strategies is the focus on patient experience. Insights into how device connectivity and software enhancements can improve patient compliance and outcomes drove much of the innovation in this quadrant during 2022.




## Executive Summary

In summary, 2022 showed that the pace of change has been accelerated by COVID-19, and that there is permanence to the adoption of digital technologies, cloud, IoT, advanced analytics and automation across the entire life science value chain. Driven by what are likely irreversible shifts in preferred means of patient engagement, value derived from collaborations, reduced participant burden for both research and operations and the increased efficiencies needed for successful manufacturing and supply chain, life science organizations are integrating expected cost and efficiency savings into their strategic planning and budgeting processes. Leading providers in all quadrants analyzed are not just investing in their vision for the future but are closely collaborating with multiple stakeholders to ensure solutions are targeted toward the upcoming market needs. They have also developed a deep appreciation for the need to provide continuous support for ongoing innovation, broad integration across client ecosystems, end-to-end lifecycle management and patient experience. Their solutions are agile, flexible and adaptable to

changing market conditions. They appreciate the need to combine technology innovation with domain and process expertise and to minimize the disruption caused by transformation. Last but certainly not least, Leaders have also responded with innovation in their commercial models, showing an increased willingness to fund innovation, enter into co-development agreements and engage in outcome-based pricing models.


**Life science companies demand transformational solutions as table stakes.**



 Provider Positioning


	Clinical Development Digital Transformation Services	Patient Engagement Digital Transformation Services	Manufacturing Supply Chain Digital Transformation Services	MedTech Digital Transformation Services	PV and Regulatory Affairs
Accenture	Leader	Market Challenger	Leader	Leader	Leader
Apexon	Not in	Contender	Not in	Contender	Not in
Atos	Product Challenger	Leader	Leader	Leader	Not in
Birlasoft	Not in	Product Challenger	Product Challenger	Rising Star ★	Not in
Capgemini	Leader	Leader	Leader	Leader	Leader
Cigniti	Contender	Not in	Contender	Contender	Contender
Cognizant	Leader	Leader	Leader	Leader	Leader
Conduent	Not in	Product Challenger	Not in	Not in	Not in
EPAM	Not in	Not in	Not in	Contender	Not in
Genpact	Not in	Rising Star ★	Leader	Contender	Contender



 Provider Positioning

	Clinical Development Digital Transformation Services	Patient Engagement Digital Transformation Services	Manufacturing Supply Chain Digital Transformation Services	MedTech Digital Transformation Services	PV and Regulatory Affairs
HARMAN DTS	Contender	Market Challenger	Contender	Leader	Not in
HCLTech	Leader	Leader	Leader	Leader	Product Challenger
Hexaware	Rising Star ★	Leader	Product Challenger	Product Challenger	Not in
ICON	Product Challenger	Product Challenger	Not in	Not in	Product Challenger
IQVIA	Product Challenger	Leader	Not in	Not in	Product Challenger
LTIMindtree	Rising Star ★	Product Challenger	Leader	Not in	Contender
LTTS	Not in	Not in	Not in	Leader	Not in
Marlabs	Contender	Contender	Product Challenger	Contender	Product Challenger
Mphasis	Not in	Contender	Contender	Contender	Not in
NTT DATA	Not in	Product Challenger	Product Challenger	Product Challenger	Not in



 Provider Positioning

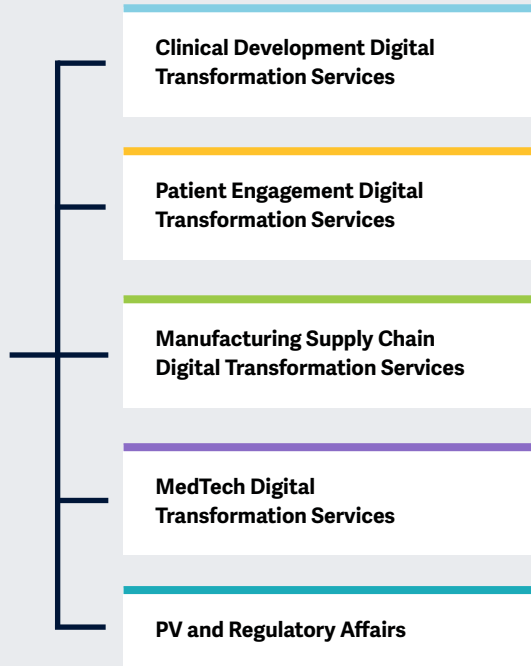
	Clinical Development Digital Transformation Services	Patient Engagement Digital Transformation Services	Manufacturing Supply Chain Digital Transformation Services	MedTech Digital Transformation Services	PV and Regulatory Affairs
Persistent Systems	Market Challenger	Rising Star ★	Product Challenger	Product Challenger	Market Challenger
PPD clinical research business of Thermo Fisher Scientific	Leader	Leader	Not in	Not in	Leader
Stefanini	Not in	Product Challenger	Product Challenger	Not in	Not in
TCS	Leader	Leader	Leader	Leader	Leader
Tech Mahindra	Leader	Product Challenger	Product Challenger	Product Challenger	Contender
UST	Contender	Product Challenger	Market Challenger	Not in	Not in
Verizon	Not in	Product Challenger	Not in	Not in	Not in
Virtusa	Contender	Product Challenger	Not in	Not in	Not in
Wipro	Leader	Leader	Leader	Leader	Leader
Zensar	Not in	Product Challenger	Contender	Contender	Not in





This study focuses on what ISG sees as drivers for **Life Science** innovation in 2022.

Simplified Illustration Source: ISG 2022



### Definition

Life sciences companies are establishing new rules of engagement and operational strategies to overcome current crises resulting from the COVID-19 pandemic, supply chain and workforce disruptions and other resource constraints. Rapid innovation, patient-centric models and regulatory expertise are table stakes. The industry leaders that were traditionally conservative are now actively pursuing opportunities to adopt innovation at scale to ensure growth in the market. The cost of innovation, which has always been steep, has increased exponentially.

Many companies are focusing on improving the efficiency of their new business models using sophisticated, AI-empowered solutions. However, these solutions – new technologies, ways of working and the partnerships, services and customer expectations that go with them require investment at a faster rate than the traditional turnover cycle of medicines or, medical technology.

Life sciences innovators and suppliers rely on some elements to achieve efficiency, which include:

1. Increased pace of mergers, acquisitions and divestitures
2. Supply chain innovation that drives reliability
3. Non-traditional sources of innovation
4. Focus on the patient as both customer and partner
5. Creative thinking around monetizing non-traditional sources of revenue

Digital transformation continues to be the backbone of many solutions. Enhanced connectivity, mobile engagement and advanced analytics have become operational necessities, and they support increased direct patient interactions.

Leading life sciences companies are relying on outsourced solutions for expertise, bandwidth and support. Traditionally, outsourcing was often perceived as “supplemental” – a means to increase resources in well-established functional roles. However, many life sciences companies are now focusing on partnering with external providers for strategic support and expert technology advice, especially in areas such as cybersecurity, automation, back-office efficiency and organizational change management (OCM).



### Scope of the Report

In this ISG Provider Lens™ quadrant study, ISG includes the following five quadrants: Clinical Development, Patient Engagement Digital Transformation Services, Manufacturing Supply Chain Digital Transformation Services, MedTech Digital Transformation Services and Pharmacovigilance and Regulatory Affairs.

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

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 relationships and potential engagements.

### 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.

**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 a follow sensible market approach with a goal of becoming a Product or Market Challenger within 12 to 18 months.

**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.

**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 Digital Transformation Services

### Who Should Read This Section

This report is relevant to enterprises across industries and regions for evaluating providers of digital transformation services around clinical development.

In this quadrant report, ISG highlights the current market positioning of service providers that offer digital transformation services in the global clinical development space.

Hybrid or decentralized clinical trials are currently an important trend shaping clinical research. They combine the elements of both traditional on-site clinical trials and technological advances into an effective patient-centric design for at-home treatment/testing.

Community-based clinics and hospitals have the highest number of patients but limited clinical trial opportunities; therefore, medical professionals in these clinics readily join clinical trials to have a more diverse patient demographic.

The clinical trials market is driven by technological advancements, an increase in demand for innovative solutions in the healthcare sector and strong partnerships between pharma-biotech firms and clinical study companies.



**Life science leaders** should read this report to understand the relative positioning and capabilities of providers. This information will help them select appropriate digital services and solutions related to clinical development.



**Start-up digital health innovators** should read this report to understand the leading and emerging areas of investment, challenges faced by digital innovators and the key factors to achieving long-term success.



**Pharma and MedTech companies** should read this report to develop a deeper understanding of end-user solutions and create business models that not only help maximize patient outcomes but also create value for key healthcare stakeholders.

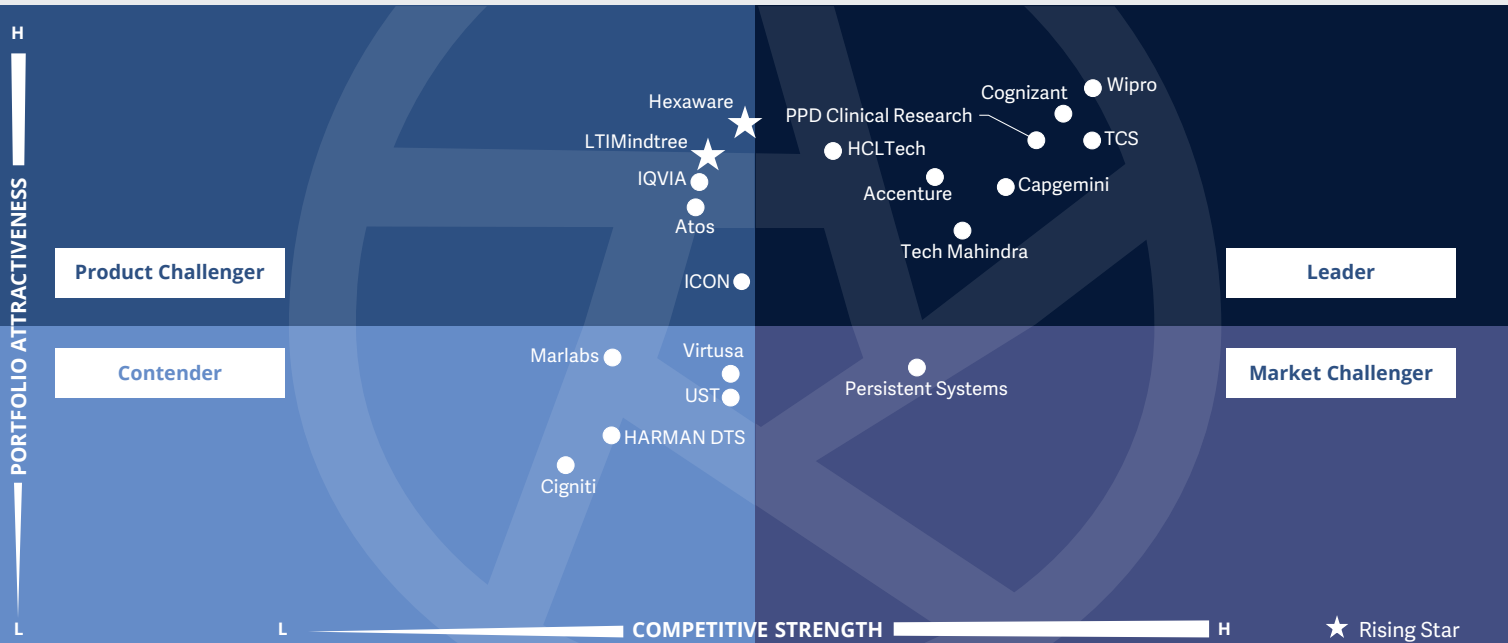


**Security and R&D leaders** should read this report to gain deeper insights into the ways in which service providers address significant challenges of compliance and security, while maintaining a seamless experience for end users.



Life Sciences Digital Services  
Clinical Development Digital Transformation Services

Global 2022



This quadrant focuses on **digital solutions specific to Clinical Development**. Leaders demonstrated innovation across multiple functions, often including integration of study design, data, operational metrics and reporting, and demonstrated **both technical and subject matter expertise**.

Frances Grote



## Clinical Development Digital Transformation Services

### Definition

This quadrant assesses the capabilities of service providers in helping life sciences companies develop products during all clinical phases. The high cost and failure rates of clinical trials require life sciences companies to continuously seek innovations and services that improve efficiency. Technology provides a substantial mechanism for identifying patients, monitoring and managing patient safety, achieving treatment efficacy and adhering to regulatory compliance. Digital solutions also support quality and reporting requirements, and the ability to use complex regulatory intelligence. Artificial intelligence (AI)-enabled solutions have also become key to achieving aggressive efficiency targets for these processes, as well as for accessing, managing and analyzing the significant volume of data generated from clinical trials.

Many life sciences innovators have accelerated the pace of their investment in AI-enabled solutions over the past year, after facing COVID-19-related challenges. They now increasingly leverage AI-powered solutions throughout the development lifecycle.

Service providers play a crucial role in helping companies keep up with the pace of ongoing innovation. They partner with these companies to provide expertise, competitive intelligence, resources and technology, which would be cost- or time-prohibitive for innovators to develop independently. Service providers also significantly contribute to innovation throughout the clinical design process. Some of the innovations service providers offer for clinical trials are AI in trial design, digital monitoring using predictive analytics and end-to-end automation for regulatory compliance and patient safety monitoring during clinical trials.

### Eligibility Criteria

1. Demonstrated **capability in assisting with implementation and support** of clinical trial and/or clinical data and analytics technology solutions
2. Knowledge of clinical trial process and requirements with **demonstrated experience providing technology support**
3. **Expertise in using technology solutions** in clinical development
4. Ability to offer **alternatives to in-person interactions** of researchers and participants such as mobile and internet-connected capabilities
5. Established or emerging **partnerships with clinical development technology** and consulting firms
6. Capability to support, **integrate and modernize legacy systems**
7. Competencies in developing plans for **deploying appropriate technologies and procedures**
8. Ability to **support, scale and update technology** tools and platforms



## Clinical Development Digital Transformation Services

### Observations

2022 was noteworthy for substantive innovation in Clinical Development. Hesitancy to adopt change in the way clinical trials were designed, conducted and reported has been replaced by a strong appetite for innovation. Key drivers for this change were increased patient empowerment and the concomitant demand for remote engagement, rapidly increasing sophistication of automated and integrated platforms and software, and the recognition of new modes of trial conduct by regulatory authorities. While the COVID-19 pandemic acted as an enabler of many of these trends, the ongoing impact of these changes on patient and HCP experience as well as substantial efficiency gains guarantee a permanent shift. Additionally, clinical trials are now widely seen as a key element in the drug or device lifecycle and are being designed to deliver value with that in mind.

Leaders in this quadrant demonstrate a keen interest in the changes impacting their clients. They offer the agility to collaborate with their clients and multiple other sources of expertise

to rapidly create customizable solutions that do not require disruptive transformation for implementation.

Of the 84 companies assessed for this study, 19 have qualified for this quadrant, with eight being Leaders and two Rising Stars.



**Accenture** continues to innovate its INTIENT™ platform with digital offerings across multiple clinical development functions. INTIENT™ focuses on bringing collaboration to the use of innovative automated solutions. Combined with Accenture's leading subject matter expertise in clinical development, the INTIENT™ platform provides substantial benefits in this quadrant.



**Capgemini** continues to expand its clinical development portfolio with multiple enhanced solutions that support digital trials, increase efficiency and accelerate timelines. With an emphasis on cross-functional collaboration, domain expertise and a dedicated study start-up unit, Capgemini is well-positioned to deliver on its goal of timeline efficiency.



**Cognizant** offers innovative solutions that focus on the value of data. Its Clinical Data Insights platform combines operational and patient data to yield real-time insights. Its Shared Investigator Platform has improved the study start-up process. With domain as well as technology expertise, it is well-positioned to support digital transformation.



**HCLTech** offers its Smart Clinical Trials platform to support multiple functions that accelerate clinical studies. Digital functionalities around trial conduct, patient engagement, data capture and safety monitoring deliver real-time insights. By integrating Clinical Development services with its core infrastructure services, HCLTech ensures best-of-breed support.



The **PPD clinical research business of Thermo Fisher Scientific** has leveraged its position as a top global contract research organization (CRO) to become a leader in the digital clinical trial space. Building on its advantage as an early adopter of automation, The business continues to enhance its integrated suite of cloud-based solutions. Following its recent merger with Thermo Fisher Scientific, additional investments in digital are expected.





## Clinical Development Digital Transformation Services



**TCS** combines its expertise around Clinical Development with a deep understanding of technology ecosystems to offer SaaS, BPaaS and outcome-based models for transformation. The TCS ADD™ platform leverages digital technology and advanced analytics to accelerate the pace of Clinical Development and integrate functionalities across the clinical value chain.



**Tech Mahindra** offers its Advanced Clinical Platform to support digital clinical trial conduct and enhance clinical operations workflows, as well as decision support and business process automation. It also offers a multichannel clinical trial patient engagement platform that provides an enhanced trial participant experience.



**Wipro** has added various functionalities to its cloud-based DICE (Digital Integrated Clinical Enterprise) cognitive platform to support end-to-end clinical development needs, as well as patient, investigator and site interactions. It also offers platforms to support feasibility, remote monitoring and analytics.



**Hexaware** is a Rising Star, thanks to its CarrotCube clinical platform that supports multiple areas of patient experience and clinical trial functionalities. It also supports work to maximize the value of client clinical trial ecosystems. With continued innovation in this quadrant, Hexaware has the potential to move into a leadership position.



**LTIMindtree** achieved the Rising Star status with its suite of pre-built configurable platforms that leverage automation to provide data and insights across the development spectrum. In addition to improving efficiency and accuracy, these platforms integrate with existing ecosystems. Further development of this strategy has the potential to move LTIMindtree to the Leader quadrant.





“Capgemini enables data value across Clinical Development with its Data-Accelerated Trials offering.”

Frances Grote

# Capgemini

## Overview

With its goal of increasing the ability to leverage data across the Clinical Development spectrum, Capgemini helps ensure its clients remain competitive in the evolving market. By providing innovative support for DCTs, it ensures both speed and agility, as well as an enhanced patient and HCP experience. Capgemini also helps improve clinical trial success while reducing costs and focuses on accelerating trials in their early stages by improving feasibility, protocol design and data governance.

## Strengths

**Breadth and depth of expertise across all aspects of Clinical Development:** Capgemini utilizes its deep expertise across Clinical Development to consistently innovate on process improvements and technology enhancements. It invests heavily in offering support to multiple forms of transformation in this area.

**Integrated suite of Clinical Development services:** The company's integrated suite of services supports activity throughout the development lifecycle to ensure end-to-end productivity and efficiency.

## Focus on supporting clients' competitive

**stance:** Capgemini uses its multiple technology offerings to help ensure successful client focus on go-to-market. Its technology offerings include clinical trial innovation, clinical supply provisioning, the conduct of DCTs and transformative activities around legacy systems.

## Caution

While Capgemini has a strong roadmap for continued service offerings, it will be important not to limit focus on some end-to-end development lifecycle support areas.

Additional broadening of automated solutions to support ongoing and planned innovations will strengthen Capgemini's position in this market.





# Patient Engagement Digital Transformation Services

### Who Should Read This Section

This report is relevant to enterprises across industries and regions for evaluating providers of digital transformation services around patient engagement.

In this quadrant report, ISG highlights the current market positioning of providers that offer digital transformation services in the global patient engagement space.

People are increasingly preferring a patient-centric approach to healthcare services over a disease-centric one. Therefore, organizations must collaborate with providers to offer personalized services, solutions and experiences in healthcare, which would enhance the patient experience.

The most suitable patient-centric tools and platforms effectively incorporate analytics to measure patient experience and enable constant learning. This ensures continuous improvement, supported by not only strategy but also data. Innovation in digital health tools, including mobile health apps and wearable sensors, has enabled new approaches to manage health conditions.

Globally, regulatory agencies are approving digital therapeutics for the treatment of diseases and considering them eligible for reimbursement. To keep stakeholders informed in the patient care lifecycle, data exchange should be compliant and connected technologies should be secure and efficient. The solutions must also adhere to the regulations being established as developers generate and submit high-quality data on their effectiveness to payers and employers.



**Life science leaders** should read this report to understand the relative positioning and capabilities of providers. This information will help them select appropriate digital services and solutions related to patient engagement.



**Start-up digital health innovators** should read this report to understand the leading and emerging areas of investment, challenges faced by patient engagement innovators and the key factors to achieving long-term success.



**Pharma and MedTech companies** should read this report to develop a deeper understanding of end-user solutions and create business models that not only help maximize patient outcomes but also create value for key healthcare stakeholders.

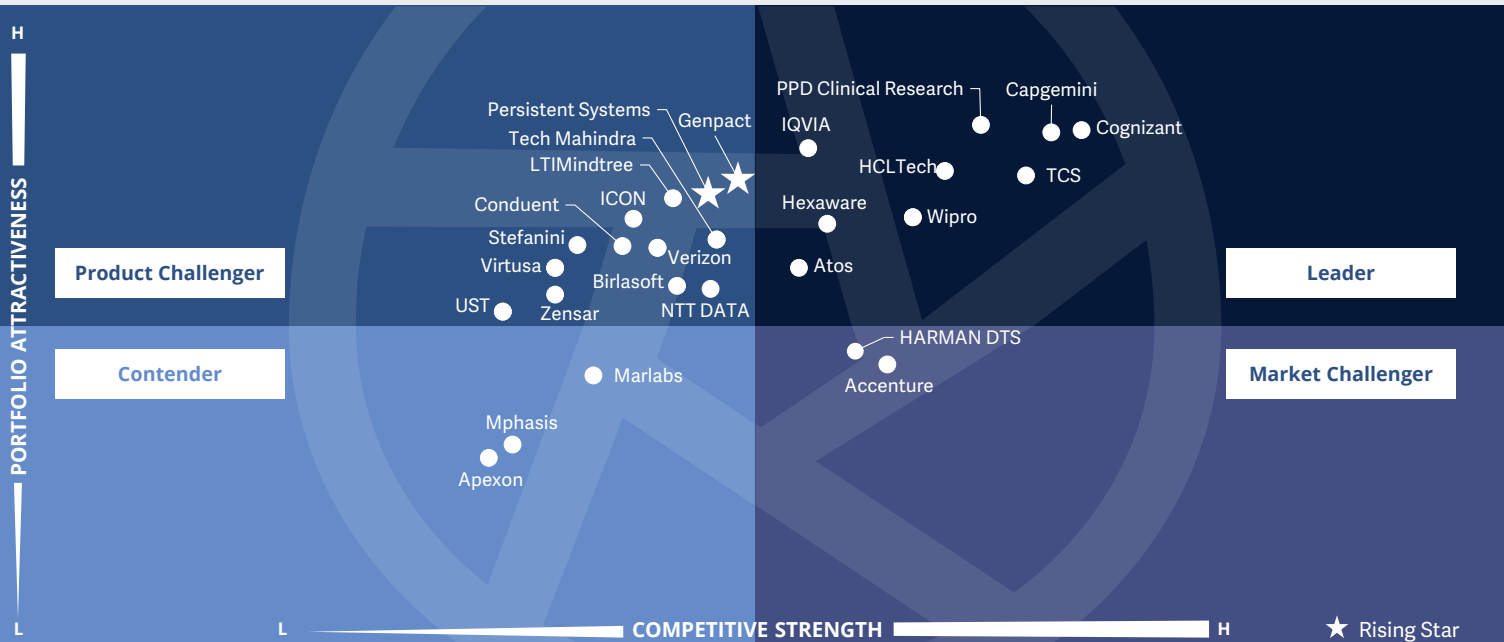


**Security and R&D leaders** should read this report to understand how service providers address compliance needs and security challenges, while maintaining a seamless experience for end users.



**Life Sciences Digital Services**  
**Patient Engagement Digital Transformation Services**

Global 2022



This quadrant assesses service providers that help Life Science companies to engage directly with patients through **patient-centric services for medication** and to improve their products and patient outcomes.

*Rainer Suletzki*



## Patient Engagement Digital Transformation Services

### Definition

This quadrant assesses providers that focus on life science customer services using supporting processes and platforms. Life Science companies are engaging directly with patients to deliver patient-centric services for medication and to improve their products and patient outcomes. This has increased patient interactions and expanded their role in decision-making in the treatment processes unlike the past, when the primary contacts of life science companies were the physicians. It is essential to improve patient experience during the development lifecycle all the way through outcomes, in collaboration with providers.

Driven by the experience of the recent pandemic, life science companies are leveraging remote monitoring for patient enrollment and engagement, while monitoring is done via connected sensors at home or in-care facilities. In addition to enhancing enrollment and participation in clinical trials, improved patient engagement helps ensure compliance with therapies and reduces drop-out rates.

Digital medicine is also an emerging area, with broad use of smart pills and wearables. Robotics and drones have the potential for enhancing the collection and value of data and therapeutic delivery. The connected technologies require secure, efficient and compliant data exchange to inform stakeholders in the patient care lifecycle, while adhering to regulations. In addition, the use of advanced analytics to adhere to the high standards of data privacy can help companies gain better insights about the success factors that are directly related with patient interactions.

### Eligibility Criteria

1. Ability to build a differentiated **patient experience**
2. Capability to **select, implement and manage** patient engagement services and platforms
3. Ability to **develop digital services** that provide **consumer-friendly interactions**
4. Deep knowledge of **technologies, devices and their connectivity**, including the ability to develop suitable **device strategies**
5. Strong competencies in **device security and data privacy** measures
6. Ability to **share data and analyses** in an integrated ecosystem for **communication, education and marketing**



## Patient Engagement Digital Transformation Services

### Observations

The patient engagement function within the digital transformation of life sciences companies has evolved in recent years from being primarily focused on the clinical development phases to a more consumerized approach. The broad availability of smart devices has led to numerous solutions that support patients with sophisticated solutions on their own devices during later phases of the product lifecycle. This requires significantly enhanced capabilities on the client's side as well as on the side of the technology partners on the digital transformation journey.

Of the 84 companies assessed for this study, 27 have qualified for this quadrant, with nine being Leaders and two Rising Stars.

The following providers achieved Leader positions in this quadrant:

### Atos

**Atos** provides a complete set of functionalities across the entire patient journey through a virtual care platform. The portfolio also includes an end-to-end electronic health record (EHR) solution for medical practices and web-based healthcare networks.

### Capgemini

**Capgemini** follows a strong patient-centric approach that integrates connected devices and the user interfaces for mobile and web around a patient. The company has shown strong growth in terms of scope and scale over recent years in parts through major acquisitions.

### cognizant

**Cognizant** offers a device-agnostic Internet of Medical Things (IoMT) platform covering remote device management for medical-grade and consumer-grade devices (wearables and smartphones). In the context of patient services, Cognizant is co-creating a solution for digital health support, based on the ServiceNow platform.

### HCLTech

**HCLTech** offers a complete spectrum of patient engagement solutions across the entire process chain, from consulting and design to implementation and operational support. Its several easy-to-implement predefined solutions are noteworthy.

### HEXAWARE

**Hexaware** has been one of the early innovators in combining digital capabilities with pharmaceutical products (digital therapeutics). Its solutions entail a high level of automation and extensive use of cloud-based data platforms.

### IQVIA

**IQVIA** offers a comprehensive portfolio for clinical studies, including functionalities such as telemedicine, patient eDiaries and questionnaires. The company's solutions take a data-oriented approach to a large extent toward life science-specific functionalities, which is clearly its USP.



## Patient Engagement Digital Transformation Services



The **PPD clinical research business's** solutions primarily support interactions with patients that participate in clinical studies. The company also has a strong position in providing remote patient monitoring functionalities. These functionalities exhibit a high degree of mobile enablement.



**TCS** provides patient-centric functionalities such as remote patient monitoring, telehealth and customized care programs. Effective integration is achieved by cloud-based data management with highly automated collection of patient-related data. Furthermore, TCS offers a variety of mobile apps with patient-centric functionalities, for instance, a digital companion app.



**Wipro** uses its broad IoT capabilities to offer an integrated solution that helps to continuously monitor and capture high volumes of biometric data and health indicators from connected devices, wearables and health applications. Wipro prioritizes achieving high efficiency in all relevant solutions by using automation.

The following providers have achieved the Rising Star status in this quadrant and exhibit the potential to achieve a leader position in future.



**Genpact** provides powerful end-to-end solutions for patient engagement on a global scale. The company's roadmap appears promising for future growth in this segment of the life science digital transformation



**Persistent Systems** can refer to a workforce where many employees have a life science background and, therefore, exhibit deep domain expertise. In addition to its technology capabilities, particularly focusing on Salesforce, the company has the opportunity to further grow in this segment.







“Based upon a strong portfolio, Capgemini is growing significantly in the area of patient engagement.”

Rainer Suletzki

# Capgemini

## Overview

Capgemini is a provider of consulting, technology and outsourcing services in more than 50 countries globally. Headquartered in Paris, France, Capgemini employs approximately 358,400 people. In FY21, the company generated €18.2 billion in revenue. With its merger with Altran and increased focus on digital transformation, Capgemini has demonstrated its focus on making its Life Science business a priority.

## Strengths

**Continuously strong growth in scale and scope:** In recent years, Capgemini has shown significant growth in its capacity as well as the scope of functions covered. This was realized through organic growth and acquisitions.

**Comprehensive integration scenarios for telehealth:** The portfolio follows a strong patient-centric approach that integrates connected devices and user interfaces for mobile and web around a patient. Central component is a connected platform with multiple solutions that generate a complete and secure back-end view for patients, doctors and pharmaceutical companies. The solutions also include comprehensive integration with electronic medical record (EMR) systems.

## Framework for Software as a Medical

**Device (SaMD):** According to ISO 13486, Capgemini is certified to offer SaMD and thereby provides a framework to support all relevant development phases. The main components are front-end development, back-end foundation and secure implementation of the front-end-to-back-end connectivity and systems integration.

## Caution

The company's numerous capabilities and solutions should be presented in a well-structured product and services catalog to help clients better understand its rich portfolio and realize value by using offered solutions.

Given the comprehensive capabilities for patient engagement, Capgemini should further enhance its footprint in the area of respective R&D-related functionalities, such as development of personalized medication.





# Manufacturing Supply Chain Digital Transformation Services

### Who Should Read This Section

This report is relevant to enterprises across industries and regions for evaluating providers of digital transformation services for the manufacturing supply chain.

In this quadrant report, ISG highlights the current market positioning of providers that offer digital transformation services for the global manufacturing supply chain space.

Many aspects of the manufacturing supply chain rely heavily on collaborative engagement between companies, and technology facilitates the engagement across incompatible systems or processes.

Life sciences companies must be able to integrate and subsequently aggregate large volumes of supply chain data to gain an understanding of aspects such as mix-level detail and material and capacity constraints to optimize production.

However, in the life sciences industry, gaining visibility is a major challenge as products are sourced globally, with varying lead times and highly complex cell and gene therapies. Managing costs while ensuring regulatory compliance and quality is a constant challenge. Therefore, flexibility in planning processes to adapt to short-term disruptive events is crucial for successful business operations.



**Life science leaders** should read this report to understand the relative positioning and capabilities of providers. This information will help them select appropriate digital services and solutions related to the manufacturing supply chain.



**Start-up digital health innovators** should read this report to understand the leading and emerging areas of investment, challenges faced by manufacturing supply chain innovators and the key factors to achieving long-term success.



**Pharma and MedTech companies** should read this report to develop a deeper understanding of end-user solutions and create business models that not only help maximize patient outcomes but also create value for key healthcare stakeholders.

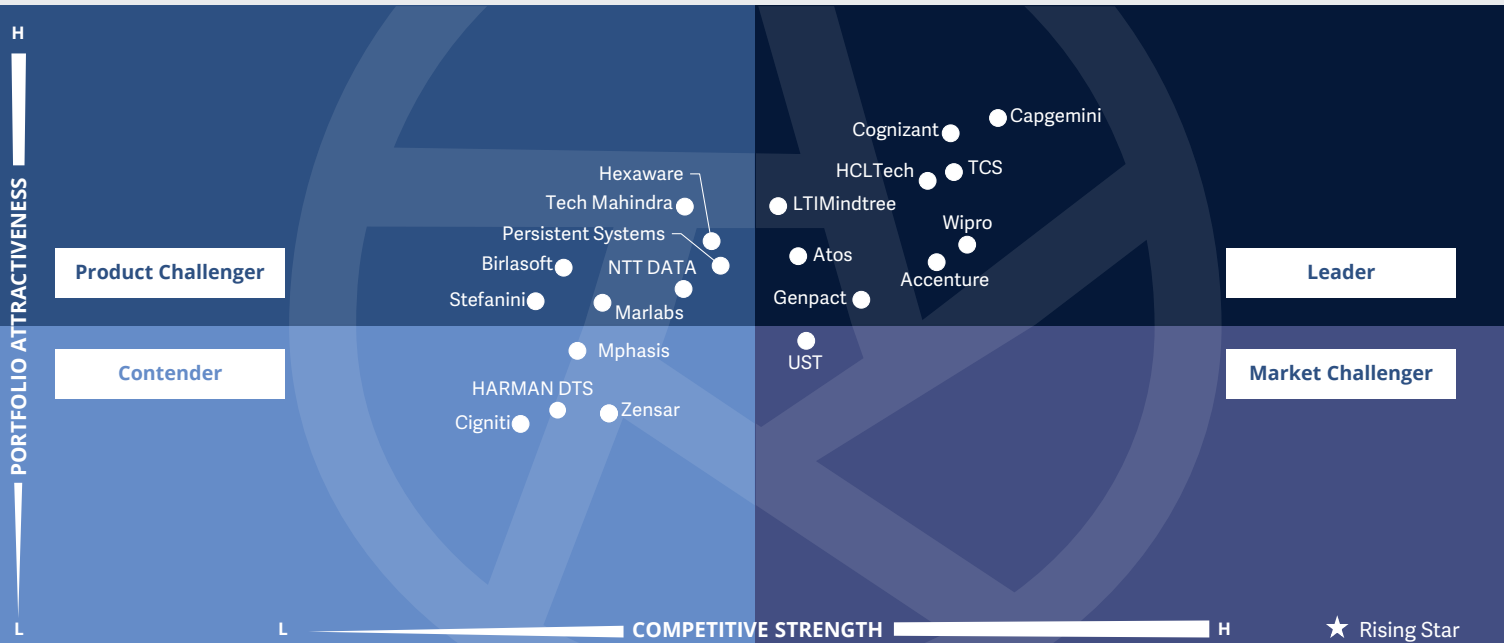


**Security and R&D leaders** should read this report to understand how service providers address compliance and security challenges, while maintaining a seamless experience for end users.



Life Sciences Digital Services  
Manufacturing Supply Chain Digital Transformation Services

Global 2022



This quadrant assesses service providers that support life science clients to **improve the operation** of the manufacturing supply chain by sophisticated IT solutions **on a global scale**.

Rainer Suletzki



## Manufacturing Supply Chain Digital Transformation Services

### Definition

This quadrant assesses service providers that work with their clients in life sciences to improve the operation of the manufacturing supply chain. With the recent COVID-19 pandemic, significant disruptions in the manufacturing supply chain are now well known. There have been shortages in personal protective equipment (PPE) and COVID-19 testing and treatments worldwide. Meanwhile, other global crises indicate that such disruptions may become a common and ongoing phenomenon. Hence, challenges such as restrictions in movement or changes in reporting requirements will most likely continue. For an industry dependent on ingredients from across the globe, disruptions in the supply chain are a major challenge. ISG expects life science companies to apply various measures, such as more emphasis on the localization of supply chains, to mitigate risk.

Many aspects of the manufacturing supply chain rely heavily on collaborative engagement between companies, and technology often provides the most effective mechanism to engage across incompatible systems or

processes. Appropriate analytics and AI are required to quickly move inventory to the desired location.

Despite the advent of advanced technologies such as automation and AI, making accurate forecasts on production schedules or shipments is an ongoing challenge for logistics managers. Visibility of the supply chain is hampered by expensive and variable manual processes that reduce the accuracy of the forecast. Logistics managers also struggle to provide accurate and real-time estimated times of arrival because of the complexity of current transportation logistics. Flexibility in planning processes, to adapt to short-term disruptive events, becomes crucial for successful business operations.

### Eligibility Criteria

1. Capability to assess existing **supply chains** and recommend strategy, process and technology changes to **improve efficiencies, lower risk and reduce costs**
2. Ability to **transform manufacturing** through **digital methods and the IoT**, using a variety of **automatic identification and data capture (AIDC)** technologies
3. Adept at providing **real-time visibility in logistics**, using **sensors** connected to systems that promptly provide status information (such as **location or temperature**) to the right people, while also changing routes as required and **predicting problems**
4. Ability to provide solutions for **complex supply chain structures**, including complex connectivity with **contract manufacturing** and advanced **technologies to track and trace**
5. Established or emerging **partnerships** with **manufacturing supply chain specialists** in life sciences and relevant technology providers
6. Expertise in **import/export** compliance



## Manufacturing Supply Chain Digital Transformation Services

### Observations

The COVID pandemic has been an important change driver for the global manufacturing supply chains of Life Science companies. The supply chains needed to adopt more quickly to disruptions, for instance due to temporarily closed plants. Furthermore, significant and short-term changes in demand for particular drugs needed to be covered. Hence, IT solutions for sophisticated support of demand and supply planning has become even more important than in the past. Beyond the changes induced by the pandemic some long term trends are still characteristic for the Life Science industry. The general trend to patient-centricity leads to a continuously growing demand for B2C-like functionalities where in the past the Life Science supply chains were mainly focused on the B2B business between manufacturers and wholesalers. This trend will become even more important in future because personalized medicine tailored for groups of patients or even single patients will gain additional traction. Another important aspect for the IT support of Life Science companies is given by

the need to higher integration between the PLM and the Manufacturing function. Primary goal is to speed up the transfer between R&D and manufacturing, based on a consolidated data foundation.

Of the 84 companies assessed for this study, 22 have qualified for this quadrant with nine being Leaders.

### accenture

**Accenture** combines strong focus on strategy development and business process design within its service portfolio, where supply chain is a key competency. Its extensive experience in life sciences enables the company to adequately offer its services in the regulated environment of this industry.

### Atos

**Atos** has comprehensive capabilities in ERP implementation, particularly for environments with a large degree of manufacturing functionalities. Within its portfolio, Atos addresses transfer of technologies and data among various functions within the lifecycle of a life science product.

### Capgemini

**Capgemini** offers powerful solutions across the supply chain, from planning functionalities and manufacturing executions to the various aspects around physical logistics. The strong growth in recent years, driven also by major acquisitions, has significantly increased Capgemini's capabilities in IoT-enabled solutions for integrating sensors, smart devices and wearables.

### cognizant

**Cognizant** leverages its deep expertise in manufacturing technology and related software packages, especially SAP ERP, to develop and maintain powerful solutions in the manufacturing supply chain digital transformation segment. Cognizant has enhanced its smart manufacturing offerings in recent years by various acquisitions, with primary focus on the shop floor.



The portfolio of **Genpact** includes a proprietary solution for continuous management of complex supply chains that serves as the central hub for planning and execution. Furthermore, the company can refer to compelling ERP expertise with focus on SAP S/4HANA.



## Manufacturing Supply Chain Digital Transformation Services

### HCLTech

**HCLTech** offers a variety of solutions, specifically for the life sciences industry. An important example is the Base90 solution, which is an SAP S/4HANA template for meeting life sciences customers. Sustainability, which is currently a key trend, is a focus area in the portfolio of HCLTech.



**LTI Mindtree** has achieved a Leader position in this year's study, stepping up from the Rising Star status last year. The company offers several platform solutions for the manufacturing supply chain, including the Digital Command Center (DCC), which aggregates data in real time and provides more than 150 business KPIs.



**TCS's** portfolio provides strong capabilities in ERP, including solutions for specific functions such as predictive maintenance of plant equipment and instruments. The transfer of information from product development to manufacturing using a product lifecycle management (PLM)-based collaboration platform is a key capability in the portfolio.



**Wipro** exhibits deep expertise for ERP solutions that support manufacturing and supply chain functionalities, specifically for SAP S/4HANA. Manufacturing intelligence applications for the use of advanced analytics on critical operating parameters are additional key offerings of Wipro.





“Capgemini provides impressive solutions for the Life Science manufacturing supply chain.”

Rainer Suletzki

# Capgemini

## Overview

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## Strengths

### **Powerful framework for the Intelligent Supply Chain:**

The portfolio includes a variety of solutions along the entire supply chain, from planning functionalities over manufacturing executions to various aspects around physical logistics. The supplier relationship management is also covered through supplier scorecards and collaborative platforms to continuously improve supplier effectiveness.

**Focus on sustainability:** Capgemini pays high attention to the growing need to ensure sustainability within the supply chain covering functions such as sourcing, plant operations and outbound logistics.

### **Comprehensive smart factory model supporting production execution:**

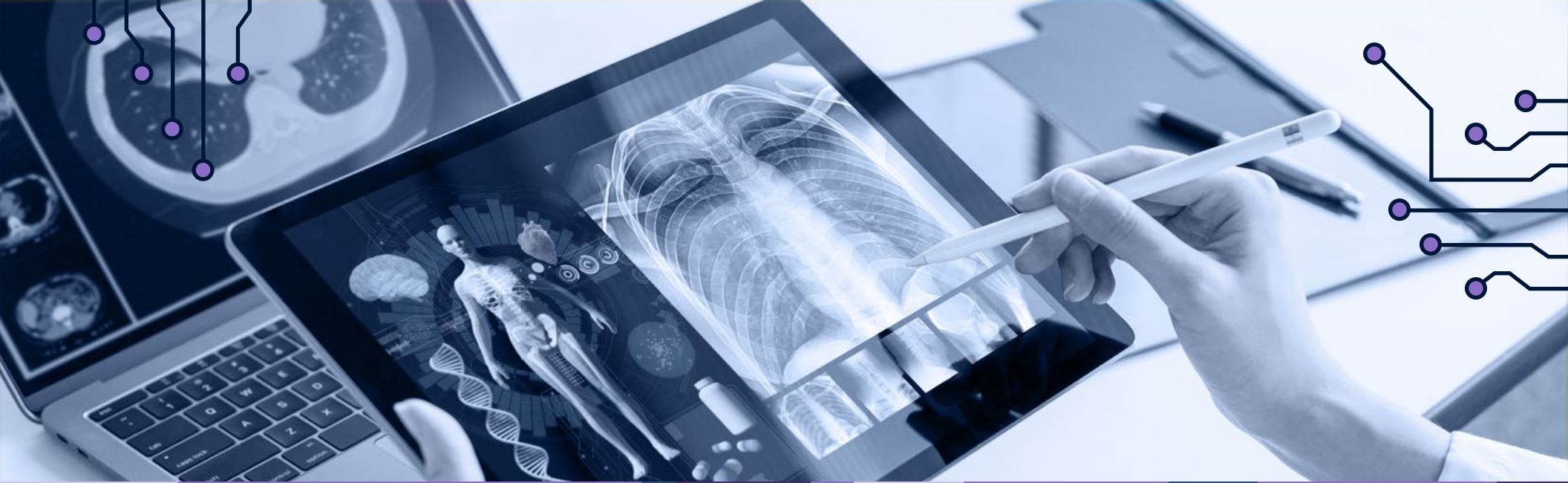
Capgemini’s smart factory model offers multiple solutions for an optimized production execution. It includes the integration of shop-floor functionalities, such as MES and LIMS, with ERP-level applications and numerous automation solutions for increased process efficiency. Furthermore, the integration between R&D and production is achieved through process and equipment validation, method transfer and regulatory approvals.

## Caution

While Capgemini’s portfolio shows strong capabilities for R&D and manufacturing supply chain, the integration between these two functional areas in PLM should be further strengthened. This will help establish a unified data management across functional areas and a seamless PLM.







# MedTech Digital Transformation Services

### Who Should Read This Section

This report is relevant to enterprises across industries and regions for evaluating providers of expertise, technology and support around MedTech digital transformation.

In this quadrant report, ISG highlights the current market positioning of providers of MedTech digital transformation services globally and how each provider addresses key challenges.

With big data becoming more assessable and manageable, healthcare is witnessing the increasing application of AI and ML. Patient-specific implants are a growing and advancing field in MedTech. The medical device industry is gradually shifting from mass production to mass customization.

Each individual is different, and the closer an implant can mimic the natural body the more effective it is considered. Customized implants have numerous benefits and high potential in healthcare. Therefore, an increasing number of manufacturers are seeking to make them mainstream.

Although navigating the medical device industry can be challenging, strong partnerships can be a key to success. Smart outsourcing in phases such as early design and development, manufacturing or aftersales can contribute to the availability of the required expertise and capabilities. It can also lend a competitive edge to providers and accelerate the overall time to market.



**Life science leaders** should read this report to understand the relative positioning and capabilities of providers. This information will help them select the appropriate services and solutions related to MedTech digital transformation.



**Start-up digital health innovators** should read this report to understand the leading and emerging areas of investment, challenges faced by MedTech innovators and the key factors to achieving long-term success.



**Pharma and MedTech companies** should read this report to develop a deeper understanding of end-user solutions and create business models that not only help maximize patient outcomes but also create value for key healthcare stakeholders.

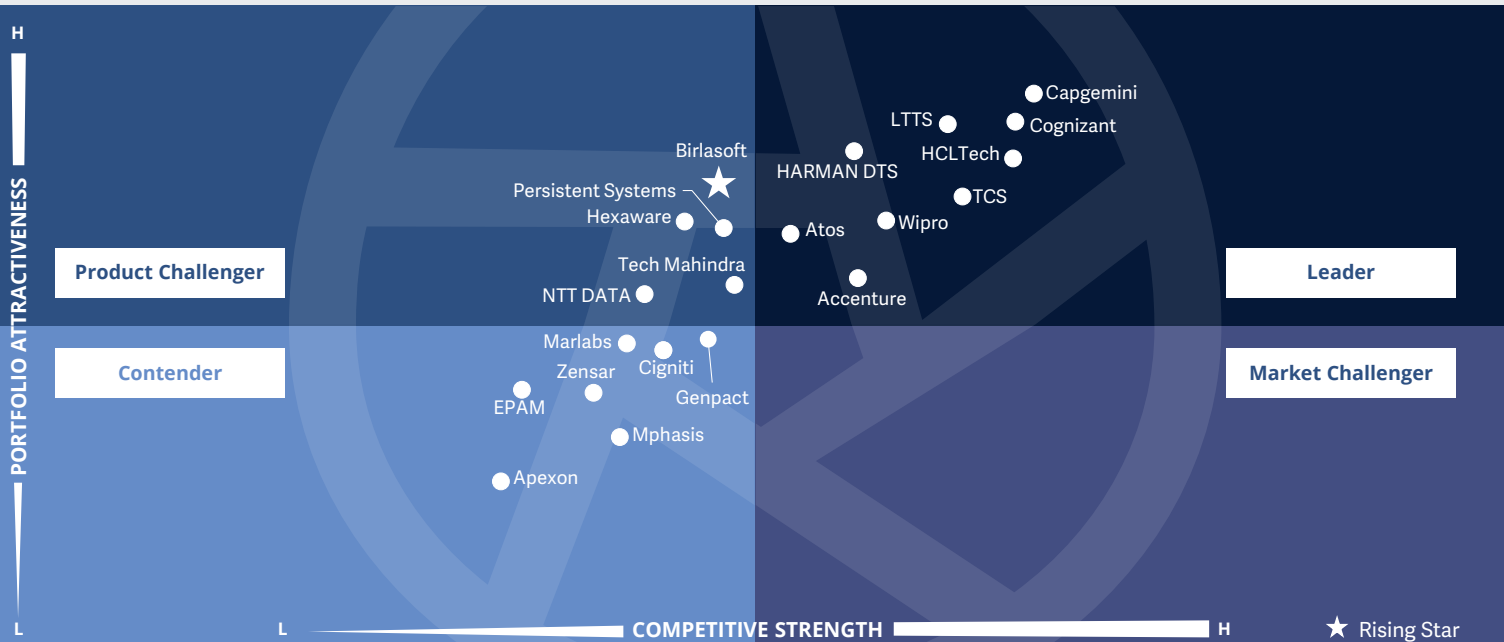


**Security and R&D leaders** should read this report to understand how service providers address compliance needs and security challenges, while maintaining a seamless experience for end users.



**Life Sciences Digital Services  
MedTech Digital Transformation Services**

Global 2022



This quadrant focuses on service providers that support MedTech companies in their **digitization** of product development, engineering, production and logistics. **High focus is on technology trends**, such as connectivity, mobile enablement and IoT.

Rainer Suletzki



## MedTech Digital Transformation Services

### Definition

This quadrant focuses on service providers that support MedTech companies in their journeys to digitization of product development, engineering, production and logistics. The most recent technology trends, such as improved connectivity, including mobile enablement, the IoT, advanced analytics and machine learning, have led to a massively transformed MedTech industry. For instance, these enable significantly improved integration of medical devices and products into the respective process chains and enable the processing of large data volumes that are collected – to a large extent remotely – during the product lifecycle. The COVID-19 pandemic has, as for many other industries, accelerated this transformation process in the life sciences space. Many essential operational activities such as maintenance or logistics operations can also be remotely executed to a large extent. Major functional areas that are considered in this quadrant are product lifecycle management, engineering services, logistics and distribution, and maintenance and repair.

Technology providers in this space are more often requested to deliver complete services across the various stages of the product development lifecycle and accept (co-) responsibility for self-contained parts of the business operations.

### Eligibility Criteria

1. Ability to provide a **comprehensive service offering** in several of the functional areas mentioned above
2. Capability to conduct IT-focused **engineering services and software development** for **medical devices**
3. Deep **integration** knowledge and capabilities to develop enhanced **connectivity for mobile devices**, including mobile enablement
4. Competencies in applying **IT security technologies** and services along the entire product lifecycle of **medical devices**
5. Broad competency in **data management** and advanced **analytics technologies**
6. Potential to support **organizational transformation** needed to implement **digital transformation**
7. Strong capabilities in **product lifecycle management** and willingness to accept (co-) responsibility for significant parts of the **development processes**



## MedTech Digital Transformation Services

### Observations

The digital transformation of the MedTech industry has become a key trend, particularly by the significantly increased demand for connected health solutions during the COVID pandemic. Two categories of providers driving this transformation can be distinguished. The first is the large globally operating IT providers that are continuously expanding their footprint in MedTech. They invest significantly in their engineering capabilities to support the development of physical devices. The second category comprises engineering-focused providers with extensive experience in designing and developing physical devices that are expanding their expertise in developing software solutions for these devices. The future development of the industry will lead more overlaps between these two categories.

Of the 84 companies assessed for this study, 21 have qualified for this quadrant, with nine being Leaders and one Rising Star.

The following providers achieved Leader positions in this quadrant:



**Accenture** offers a strong and innovative methodology that is based upon design thinking for the development of medical devices. The portfolio includes numerous services for managing the entire product lifecycle of a system or product.



**Atos** has deep expertise regarding device technology and engineering and offers full lifecycle support. Furthermore, its portfolio includes a powerful IoT platform that provides numerous methods to connect with IoT devices.



**Capgemini** has a strong technology foundation based upon laboratories and delivery facilities across regions. Its digital health solutions in the MedTech space are developed using relevant innovative technologies such as AI, automation, cloud data platforms and analytics.



**Cognizant** offers sophisticated development capabilities in combination with comprehensive support offerings, such as remote maintenance. This includes powerful platforms that enable a comprehensive product lifecycle management (PLM) for medical devices.

### HARMAN DTS

**HARMAN DTS's** portfolio has a strong focus on digital device engineering activities. The company achieves high productivity in the development activities using its own platform solutions that cover various aspects of the development process. HARMAN DTS partners with clients to develop novel solutions such as the digital pill.

### HCLTech

**HCLTech** exhibits a compelling cross-functional expertise in product engineering, development of digital platforms and use of AI. HCLTech serves all top 10 leading medical device companies and can refer to the broad coverage of many functional areas.



## MedTech Digital Transformation Services

### L&T Technology Services (LTTS)

**L&T Technology Services (LTTS)** has impressive domain expertise in engineering services along the entire product development lifecycle. LTTS focuses strongly on all aspects of connected health solutions. It also offers comprehensive test support.



**TCS** offers its own PLM solution that is well-suited for applications in the MedTech industry. The powerful global delivery model is a key capability that is of value, particularly for large enterprise clients.



**Wipro's** engineering services comprise the entire array of functionalities related to the realization of medical devices. Wipro proves its deep domain and technology expertise by operating dedicated centers of excellence (CoEs) for medical devices and MedTech, along with IoT and Industry 4.0 focus groups

The following provider achieved the status of a Rising Stars in this quadrant and exhibits the potential to achieve a Leader position in the future:

### Birlasoft

**Birlasoft** has strong capabilities in the development of medical devices. The company maintains strong relationships with technology partners, life science companies and institutions (such as universities).





“Capgemini’s MedTech offerings exhibit compelling expertise along the entire product lifecycle.”

Rainer Suletzki

# Capgemini

## Overview

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## Strengths

**Strong capabilities for developing connected devices:** Capgemini maintains laboratories and delivery facilities across regions, covering various technologies such as medical imaging and therapeutic devices. The portfolio exhibits a strong focus on connected medical devices in the areas of therapeutics, clinical development and the development of smart devices for consumer and non-hospital settings. Another core capability is given by the comprehensive support along the entire product lifecycle including powerful test automation.

**Deep understanding of clinical workflow and the associated MedTech ecosystem:** A deep bench of MedTech experts supported by a strong understanding of regulatory compliance and product standards, combined with capabilities to support all phases of the product lifecycle, enables efficient and innovative client support.

**Leveraging leading innovative technologies:** Digital health solution offerings the MedTech space are developed using relevant innovative technologies such as AI, automation, cloud data platforms and analytics.

## Caution

The integration of various technology-oriented solutions with cloud-based data management (data collection, views for doctors and nurses, analytics, etc.) should be considered. Data privacy and security by respective de-identification of data needs to be considered.

Capgemini offers numerous MedTech point solutions and related expertise. At the same time, it has scope to develop more strategic consulting capabilities.





# PV and Regulatory Affairs



### Who Should Read This Section

This report is relevant to enterprises across industries and regions for evaluating providers of digital transformation services around pharmacovigilance and regulatory affairs.

In this quadrant report, ISG highlights the current market positioning of providers of pharmacovigilance and regulatory affairs transformation services globally and how each provider addresses the key challenges in this space.

Regulatory and pharmacovigilance processes in 2022 focused on applying and advancing technological innovations such as AI, ML and RPA. While failing to implement such technologies may lead to obsolescence, service providers that are agile and swift in adopting such advancements will forge better partnerships and drive growth in the coming years.

Pharma service providers are faced with the dilemma of finding a balance between scaling/aggregating services and developing/demonstrating therapeutic and scientific expertise. They also face the challenge of a stratified competitive landscape, a consequence of solving specific customer needs. In this environment, changes due to digital medicine will require more intensive and sophisticated reporting, and new technologies that manage the increased volume of data should be secure, efficient and compliant with regulations.



**Life science leaders** should read this report to understand the relative positioning and capabilities of providers. This information will enable them to select the appropriate services and solutions related to pharmacovigilance and regulatory affairs.



**Start-up digital health innovators** should read this report to understand the leading and emerging areas of investment, challenges faced by pharmacovigilance and regulatory affairs innovators and the key to achieving long-term success.

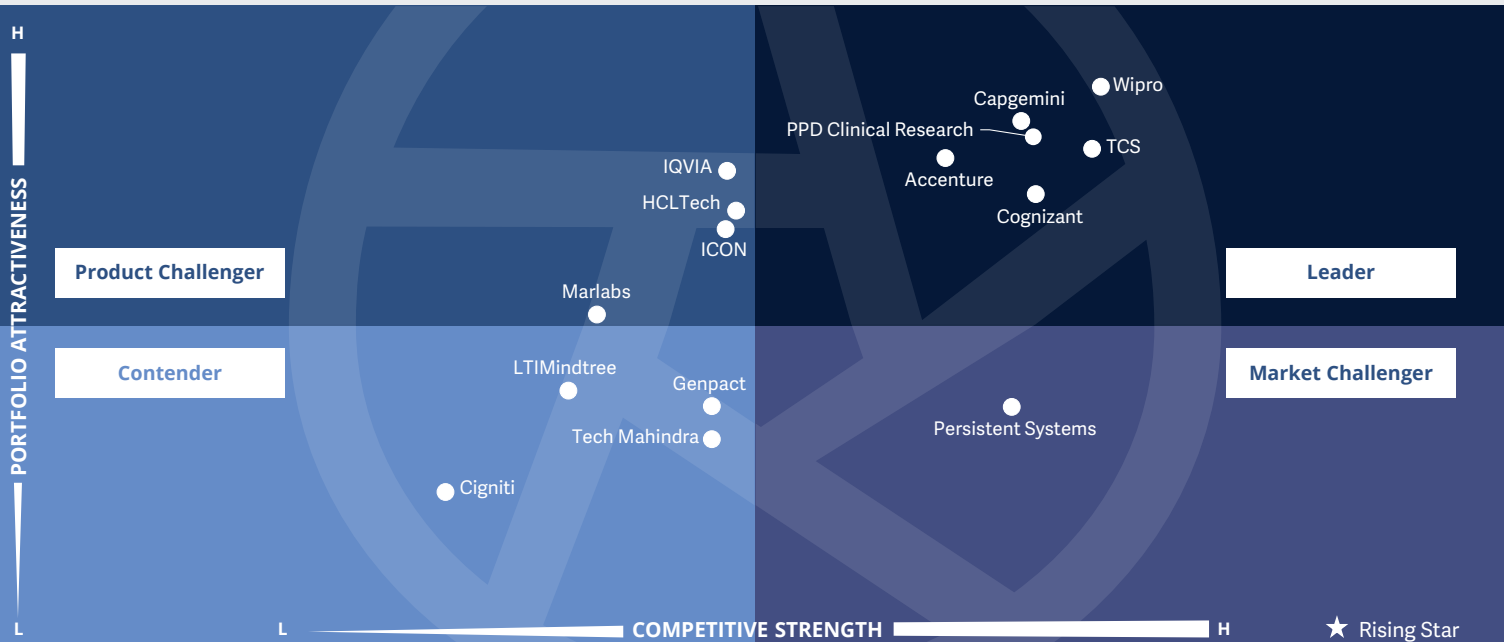


**Pharma and MedTech companies** should read this report to develop a deeper understanding of end-user solutions and create business models that help maximize patient outcomes and value for key healthcare stakeholders.



**Security and R&D leaders** should read this report to understand how service providers address compliance needs and security challenges, while maintaining a seamless experience for end users.





This quadrant focuses on **Pharmacovigilance and Regulatory Affairs digital solutions**.

Leaders demonstrated substantial innovation across multiple functions, especially applications of AI, ML and NLP in previously unaddressed areas, and exhibited **technical and subject matter expertise**.

*Frances Grote*



### Definition

This quadrant assesses the capabilities of service providers offering life sciences services that support patient safety monitoring and reporting, compliance with global and local regulatory requirements, and reporting via processes and platforms. Life sciences companies are under increasing scrutiny, by both regulatory agencies and consumer watchdog groups, to ensure patient safety and monitor quality and compliance across their products and activities. The primary goal is to conduct all activities and deliver a quality-driven product, while ensuring patient safety and complying with all local and global reporting and regulatory requirements.

While there is already a successful history using AI to support some aspects of these activities, recent successes with natural language processing (NLP) and machine learning among life sciences enterprises have created opportunities for innovation and efficiency in these areas. Lessons from the pandemic are also resulting in improved patient outcomes, driven by enhanced

services in pharmacovigilance and regulatory affairs. However, the changes due to digital medicine will also require more intensive and sophisticated reporting, and new technologies that manage the increased volume of data should be secure, efficient and compliant.

### Eligibility Criteria

1. Ability to **create, manage, monitor and continuously improve upon a differentiated service offering** in one or both of these areas
2. Demonstrated **expertise with global, regional and local regulations**, reporting requirements, patient safety reporting processes and other compliance measures
3. Clearly delineated **quality and compliance** processes and related employee training programs
4. Capability to **select, implement and manage pharmacovigilance or regulatory affairs services** and platforms
5. Ability to **integrate with internal service offerings** in adjacent areas and with external platforms
6. Experience providing **consumer-friendly interactions** with digital services
7. Deep knowledge of relevant technologies and **ability to develop suitable strategies**
8. **Competencies in data, platform and system security** and data privacy measures
9. Ability to share data and analyses in an **integrated ecosystem** for communication, reporting and education
10. Potential to **support organizational transformation** needed to implement digital transformation



### Observations

The digital market for Pharmacovigilance and Regulatory Affairs grew substantially in 2022 but is still in its early stage. Digital tools and patient-reported outcomes, combined with regulators' growing desire to use real-world evidence, continue to drive exponential increases in the volume of data to be analyzed. Regulations around medical device development and the increasing ability to integrate data-reporting capabilities have also impacted PV volumes. While outsourced services have been used to support PV activities for some time, there is an increased appetite for innovation and technology because of the rapid expansion of AI-powered capabilities and challenges in managing the higher incidence of pandemic-related adverse events. Digital solutions for extracting information from unstructured data, monitoring social media and ensuring compliance with quality and regulatory standards are increasing the adoption of innovative solutions.

In Regulatory Affairs, historically innovation-averse, AI is emerging as a key driver of expanded opportunities. Particularly in regulatory intelligence and periodic reporting requirements, technology delivers improved productivity and decreased resource burden. Cloud adoption has also increased in both PV and Regulatory Affairs to provide more efficient ways to consolidate, analyze and report on the growing quantities of data in real time. Leaders in this quadrant, faced with the need to become more agile and better able to rapidly implement new approaches, are leveraging solutions across their enterprises as the foundation to transform services.

Of the 84 companies assessed for this study, 15 qualified for this quadrant, with six being Leaders.



**Accenture's** INTIENT™ platform provides a cloud-based approach to integrated AI solutions for the intelligent extraction and analysis of data, with advanced analytics and integrated visualizations as outputs. Combined with Accenture's leading subject matter expertise, the INTIENT™ platform provides substantial benefits in this quadrant.



**Capgemini** offers an integrated PV and regulatory affairs solution in a center of excellence (CoE). By combining its domain and technology expertise, Capgemini provides customized digital solutions and strategies focused on de-risking PV and regulatory affairs activities while enhancing compliance.



**Cognizant** provides a suite of services in this quadrant that combine subject matter and technology consulting expertise with several digital platforms. Based on its successful history as a leading ITO and business process outsourcing (BPO) provider for PV and Regulatory Affairs, Cognizant is able to rapidly customize client-specific solutions.



The **PPD clinical research business** continues to leverage its expertise as a top global contract research organization (CRO) to build and enhance its end-to-end PV and Regulatory Affairs service offerings. With a deep bench of subject matter experts and a comprehensive suite of technology-enabled services, the business is focused on compliance and expediting usable data.



## PV and Regulatory Affairs



**TCS** combines expert consulting services with the integrated functionalities of its AI-enabled TCS ADD™ platform to provide insights, analytics and compliance support for PV and Regulatory Affairs. Readily scalable, fully integrated with TCS's clinical trial technology and with the ability to maximize ML and NLP, TCS ADD™ supports end-to-end functionality.



**Wipro's** Smartance platform provides AI-enabled PV support, extracting data from both structured and unstructured sources to populate multiple databases. Wipro also offers automated solutions for various steps in the regulatory process, combined with extensive subject matter expertise to provide end-to-end regulatory affairs support.





“Capgemini provides expert services in strategy and delivery across PV and Regulatory Affairs.”

*Frances Grote*

# Capgemini

## Overview

Capgemini supports PV and Regulatory Affairs in one integrated unit focused on optimizing business process, compliance, safety management and regulatory activities. Although it does not offer a proprietary technology solution, Capgemini has expertise in designing digital strategies and implementing digital solutions supported by its dedicated compliance CoE. It also partners with other organizations to develop digital approaches, including AI-enabled tools, analytics and NLP-powered automations.

## Strengths

**Focus on quality and compliance:** With a dedicated compliance CoE, Capgemini ensures a quality-centric approach.

**Significant bench strength:** Capgemini has a substantial team of dedicated professionals in both PV and Regulatory Affairs that provides strategy and delivery.

## Deep expertise combined with integrated delivery:

Capgemini has deep subject matter expertise across the spectrum of PV and Regulatory Affairs services and provides those services through an integrated business unit.

## Caution

Capgemini currently does not have a proprietary digital offering in this quadrant, although AI-enabled solutions are on its roadmap.

Capgemini has additional opportunity to highlight use cases for its digital strategic consulting in this quadrant.





# Appendix

## Methodology & Team

The ISG Provider Lens™ 2022 – Life Sciences Digital Services analyzes the relevant 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.

### Lead Authors:

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Pragathi Thimmaiya

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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 services providers and analysis of publicly available market information from multiple sources. The data collected for this report represents information that ISG believes to be current as of January 2023, for providers who actively participated as well as for providers who did not. ISG recognizes that many mergers and acquisitions have taken place since that time, but those changes are not reflected in this report.

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

The study was divided into 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 & use cases
4. Leverage ISG's internal databases & advisor knowledge & experience (wherever applicable)
5. Use of Star of Excellence CX-Data
6. Detailed analysis & evaluation of services & service documentation based on the facts & figures received from providers & other sources.
7. Use of the following key evaluation criteria:
  - \* Strategy & vision
  - \* Tech Innovation
  - \* Brand awareness and presence in the market
  - \* Sales and partner landscape
  - \* Breadth and depth of portfolio of services offered
  - \* CX and Recommendation





## Author & Editor Biographies

*Lead Author*



**Rainer Suletzki**  
**Lead Author**

Rainer Suletzki brings more than 30 years of experience in various IT Management functions within a global German Life Science corporation. His main areas of expertise comprise IT application management, IT architecture, data modelling as well as IT sourcing strategy and execution. Currently he acts as independent consultant in various projects at ISG with focus upon application management for SAP, specifically for SAP HANA, and for Salesforce.

This includes ISG Provider Lens Studies as well as various projects supporting companies in defining IT strategies and the corresponding sourcing decisions.

*Lead Author*



**Frances Grote**  
**Distinguished Analyst**

Frances Grote joined the ISG IPL Life Sciences team in 2021. Prior to this, she led ISG's Life Sciences Digital Drug Development practice, which she helped to design and establish in 2016. Frances has over 25 years of experience in leading global biopharma R&D Strategic Sourcing organizations, prior to joining ISG.

She is a recognized innovator in building supplier partnerships in drug development as well as in implementing digital technologies in biopharma R&D. She holds an MBA with a focus on Strategic Planning and has completed graduate training in negotiations.





*Enterprise Context & Global Overview Analyst*

**Sandya Kattimani**  
**Senior Research Analyst**

Sandya Kattimani is a senior research analyst at ISG and is responsible for supporting and co-authoring ISG Provider Lens™ studies on Contact Center, Life Sciences, Mainframes. Sandya has over 6 years of experience in the technology research industry and in her prior role, she carried out research delivery for both primary and secondary research capabilities. Her area of expertise lies in competitive intelligence, customer journey analysis, battle cards, market analysis and digital transformation.

She is responsible for authoring the enterprise content and the global summary report, which includes market trends and insights.



*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 research director 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, 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](#).

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