IDC MarketScape

IDC MarketScape: Worldwide Life Sciences R&D Pharmacovigilance Technology Solutions and Consulting Services 2025 Vendor Assessment

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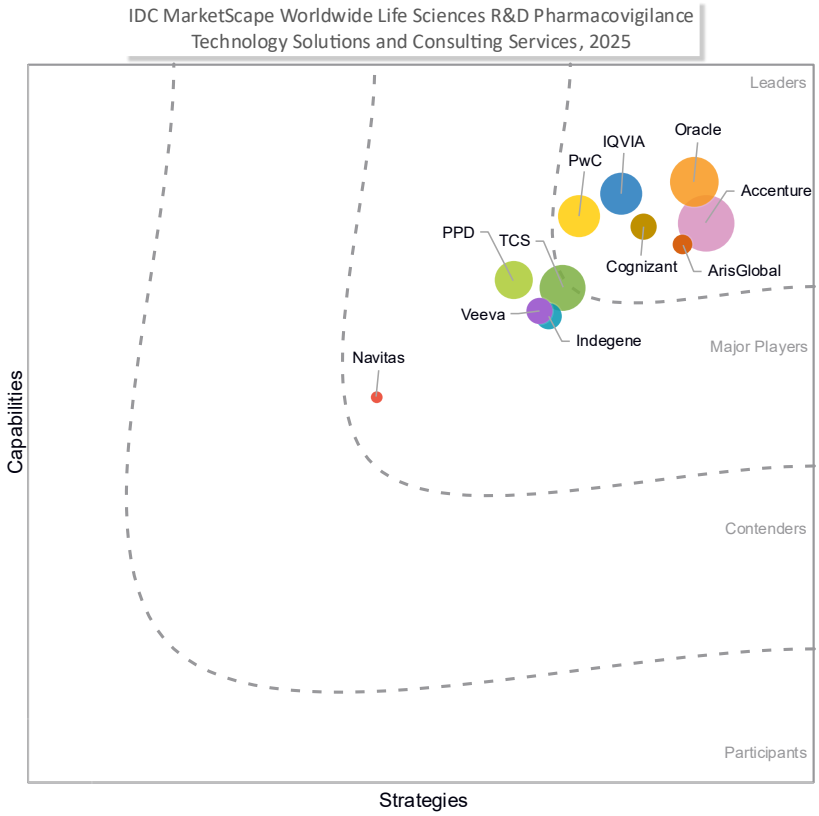
THIS EXCERPT FEATURES ORACLE AS A LEADER

IDC MARKETSCAPE FIGURE

FIGURE 1

IDC MarketScape Worldwide Life Sciences R&D Pharmacovigilance Technology Solutions and Consulting Services Vendor Assessment



Source: IDC, 2025

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Please see the Appendix for detailed methodology, market definition, and scoring criteria.

ABOUT THIS EXCERPT

The content for this excerpt was taken directly from IDC MarketScape: Worldwide Life Sciences R&D Pharmacovigilance Technology Solutions and Consulting Services 2025 Vendor Assessment (Doc # US53669225).

IDC OPINION

It is extremely concerning to note that the American Society of Pharmacovigilance (ASP) has reported that in 2025, adverse drug events now account for over 250,000 deaths annually and are the third leading cause of death in the United States, moving up from the fourth position in 2021. As Sara Rogers, ASP president rightly puts it, "We cannot afford to stand by while medication-related harm continues to grow. It's time for decisive action."

Even more concerning is the fact that up to 94% of adverse drug reactions (ADRs) are not reported by healthcare providers, delaying the detection of safety signals and negatively impacting clinical outcomes.

Yes indeed, lives are at stake, and this is the time for action, for both the pharma industry and the pharmacovigilance (PV) technology and consulting solution providers to join hands to address this challenge.

The industry is in the process of either building, acquiring, or composing intelligent drug safety platforms. Over half of the industry is following a compose strategy to build drug safety platforms, whereas one-fourth are purchasing these platforms and a fifth are building these internally. Almost half (45%) of the resources used to build and maintain drug safety platforms come from external resources (see *Worldwide GenAI Industry Use Case Early Adoption Trends, 2025: Life Sciences,* IDC #US53317424, April 2025).

Different artificial intelligence (AI)–enabled PV initiatives are being pursued by pharma companies. Eli Lilly has built MosaicPV, an intelligent case intake platform, while AstraZeneca, Pfizer, and Roche have used AI to mine social media to identify ADRs up to 50% faster than usual, and Sanofi's AI-enhanced signal detection is reported to have achieved an 85% sensitivity and 75% specificity in identifying previously unrecognized safety signals and a six-month reduction in the time for identifying previously unrecognized safety signals. Pharma is also using digital assistants to enhance access to medical information and streamline the initial intake phase of adverse event (AE)

case processing. Pfizer, for example, is using Medibot in the United States; Fabi in Brazil; and Maibo in Japan.

However, the life sciences industry as well as PV technology solution and consulting services providers are dealing with their own unique challenges.

PV Life Sciences Industry Challenges

The real goal of the life sciences industry is to ensure a consistent positive benefit-risk profile for the drugs that it manufactures. However, this is not an easy task as organizations struggle with fragmented data sources, latency issues, and more.

PV database platforms that come with out-of-the-box features may need to be customized to align with the specific operational needs, unique drug profiles, or regional regulatory requirements of the life sciences industry. The customization, however, may result in the fragmentation of how PV activities are conducted across an organization.

Some of the key challenges that the life sciences industry faces are:

- Underreporting of adverse drug reactions, which decreases the chances of signal detection (It becomes more complicated when dealing with rare diseases, where the number of patients is significantly low, and patients are scattered far and wide, and the disease is, more often than not, diagnosed very late in the day.)
- Data overload and signal detection (Finding a needle in a haystack is never an easy task and there is a need for efficient tools to explore the vast amount of data that exists out there, and efficient tools are required to filter through the false positives and negatives, and the confounding factors [such as patient demographics or concomitant medications]. This can make understanding signal scores challenging.)
- Evolving global PV and technology regulations, which make global harmonization challenging
- Challenges in post-marketing surveillance, including challenges in gathering real-world data owing to patient noncompliance and insufficient data sources
- Data integration challenges and the lack of standardized reporting systems (There is immense diversity in the data sources, including structured/unstructured, formats of data, fluctuation in the volumes of incoming data, as well as variations in reporting standards across geos.)
- Counterfeit and substandard medicines that pose significant risks to patient safety
- Patient engagement and awareness, underlining the need for patient education and user-friendly reporting platforms

- The need to handle increasing annual caseloads and simultaneously reducing process costs while using legacy systems
- Limited number of resources with deep safety domain expertise
- Lack of maturity in AI adoption, change management issues, and concerns regarding compliance
- The added complexity of managing the increasing number of adverse events resulting from the growth of combination products and advanced therapy medicinal products (ATMPs), where the industry still lacks deep expertise

PV Vendor Challenges

- Navigating the fine balance between scaling efficiencies while ensuring compliance and minimizing risk
- Dealing with rising cost pressures across the value chain and a limited ability to invest from the industry, resulting in cuts in PV budgets
- The growing competition on pharma from generic manufacturers and biosimilars that intensifies the need for pharma to differentiate (This is pushing PV providers to innovate while managing tight margins.)
- A lack of willingness to see PV as a value driver rather than a cost center, resulting in the desire from the industry to prioritize incremental process improvements or cost cutting over larger, transformational initiatives
- Long duration PV contracts, significant transition costs, an aversion to transition to new vendors, and long decision cycles (more so in medium-sized enterprises) making it hard for incumbents
- Expanding portfolios and shifting investment priorities are demanding PV expertise in new therapeutic areas
- Hiring skilled PV resources with rich therapeutic area expertise and tech expertise continues to be a challenge
- While technology is transforming the PV landscape, at the end of the day, business processes also need to evolve in parallel to drive ROI (A lack of trust in AI, a lack of willingness to adapt business processes, and concerns regarding brand and regulatory risks often kill the potential gains in cost and process efficiencies.)

In the turbulent world of today that seems to be undergoing ongoing seismic shifts, it is the cutting-edge technologies that will serve as game changers, only if they are complemented by deep strategic PV expertise. Bottom line, for the life sciences industry, it is about patient safety and compliance.

IDC MARKETSCAPE VENDOR INCLUSION CRITERIA

IDC frequently has unique visibility into vendor selection processes within life science companies through clients and contacts in the industry. For a vendor to be considered for inclusion in this study, the vendor's services must have been significantly evaluated for the potential to engage clients within the target IDC MarketScape space.

Further research and due diligence were then conducted to narrow the list of vendors to only those that IDC views as legitimate contenders for future deals within the life sciences space, based on an assessment of the vendor's capability in providing technology solutions and consulting services to support the implementation of a pharmacovigilance strategy.

The key inclusion criteria included:

- Vendors should have at least five customers for their PV offering for a duration of at least 12 months as of December 31, 2024.
- Vendors should provide technology solutions/platforms to support PV.
- Vendors should have guided customers on establishing audits, inspections, system gap assessment, SOPs, templates, workflows, the design of risk management activities, change management, benefit-risk assessment strategy, or other consulting activities for the implementation of PV.
- Vendors should have a minimum company revenue of $200 million.

ADVICE FOR TECHNOLOGY BUYERS

Just when the life sciences industry thought that the disruption caused by the COVID-19 pandemic was over and that the dust had settled, it has been once again rocked by evolving policies and regulations, tariffs, price control executive orders, geopolitical turbulence, the fear of a recession, and more.

The life sciences industry is absolutely seeing the need to invest in technology solutions and partnering with strategic PV technology solution providers but is waiting and watching cautiously for signs of stability. It recognizes that technology will save the day but is holding back its purse strings, waiting for the right moment.

In IDC's view of the PV technology solutions and consulting services ecosystem, key attributes that life sciences companies are looking for in their preferred PV solution providers include:

- Deep, proven PV-specific expertise, complemented by global regulatory expertise across PV and tech

- Expertise in embedding GenAI solutions and AI agents to scale efficiencies, complemented by an understanding of the regulatory landscape
- Scalable, modular, plug-and-play models that work for emerging biopharma
- Platforms with ongoing, seamless upgrades to ensure global regulatory compliance, while not disrupting operations
- Expertise in the enterprisewide implementation of PV solutions
- Consulting expertise in transforming PV business operations to integrate changes driven by new technology, while ensuring compliance
- The use of cloud-based technology platforms that accelerate the transition toward zero-touch case processing
- Unified platforms creating a single source of truth, error proofing the data and minimizing redundancies
- Ensuring the use of ethical and explainable AI solutions
- Implementing the right data governance models and data placement strategies
- Predictive analytics to support signal detection and management
- Guidance on selecting the right PV technology vendor, and providing the right vendor oversight model
- Expertise in setting up global capability centers (GCCs) for PV
- Compatible corporate cultures
- The ability to demonstrate accountability through outcome-based/risk-sharing pricing models
- Pay-for-use pricing models that offer flexibility to CROs, based on fluctuating business demands
- Strong referenceable clients

VENDOR SUMMARY PROFILES

This section briefly explains IDC's key observations resulting in a vendor's position in the IDC MarketScape. While every vendor is evaluated against each of the criteria outlined in the Appendix, the description here provides a summary of each vendor's strengths and challenges.

Oracle

After a close evaluation of Oracle's offerings and capabilities, IDC has positioned the company in the Leaders category in the 2025 IDC MarketScape for worldwide life sciences R&D pharmacovigilance technology solutions and consulting services.

Oracle is headquartered in Austin, Texas, and has over 270 offices globally, across 175 countries. Founded in 1977, it now has 160,000 employees globally. It acquired Cerner in June 2022. Within its life sciences business unit, 55–60% of employees are focused on tech and the rest on domain. From 20 to 25% come from the life sciences industry with an average of 10–15 years of industry experience.

In addition:

- **Strategic initiatives:** In February 2025, Oracle launched Safety One Argus with built-in AI/smart features and rule-based automations, and it aims to increase the efficiency of case processing workflows by up to 90%, by adding AI features with each release. It envisions using real-time, AI-powered surveillance of electronic health records (EHRs) and ongoing studies for a product to drive a precision PV strategy. It is focusing on enabling multimodal signal detection and on providing pharma and healthcare professionals with real-time updates on the benefit-risk profiles of drugs, vaccines, and medical devices. Oracle is bringing together its Safety One Platform, Oracle Real-World Data (ORWD), Health Data Intelligence (HDI) platform, and Oracle Cloud Infrastructure (OCI) AI services to drive its precision PV strategy. Oracle has invested close to $9 billion in 2024 in R&D and innovation.
- **M&As/partnerships:** Oracle has partnered with Accenture, Arithmos, C3i (an HCL company), Cognizant, Covigilant, LifeBee, Navitas, Nextrove, PharmaLex (a Cencora company), Perficient, RELICO (Reliable LifeSciences Consulting), SyNRG Solutions, TCS, Techsol, and Ultragenic for the implementation of Argus. In the life sciences and healthcare space, it has acquired Cerner, ClearTrial, goBalto, NetForce, Phase Forward, Relsys, and SiteWorks. Oracle Research Services (formerly Cerner Enviza) brings a deep understanding of the needs of key stakeholders in life sciences across the product life cycle with extensive experience delivering research, data, and consulting services to help address research questions in the clinical, RWE, PV, and commercial settings, and capabilities to support post-authorization safety studies (PASS).
- **Pricing models:** Oracle uses three pricing models. For on-cloud solutions, customers purchase a pool of cases to be consumed over the contract duration. Only initial cases are counted. Another on-cloud option involves the purchase of a pool of safety source documents to be consumed over the contract duration. The third is an on-premises option based on annual case volumes, where only initial cases are counted.

Strengths

Oracle has been providing PV technology solutions and consulting services for close to three decades. It estimates that its PV revenue will grow by 20% annually in the next

three years and reports that it owns close to 60% of the PV software market share. It has supported over 100,000 clinical trials, 90% of which included a PV focus. It has over 400 direct PV customers and has acquired close to 100 new customers in the past 12 months. Over 70% of all drug ICSRs and more than 90% of all vaccine ICSRs reported to the FDA since 2017 originate in Argus. Oracle conducts and publishes PV research in peer-reviewed scientific journals. All its PV customers use its technology solutions, and 65% use its consulting services. In detail:

- Safety One, Oracle's multivigilance platform hosted on Oracle cloud, includes four interoperable components, integrated with Oracle HDI that embeds AI/rule-based automation (RBA)/big data across the platform. The components include:
  - Safety One Intake, which enables the AI-powered extraction of data from safety source documents, eliminating the need for manual data entry (Oracle reports that this can increase efficiency gains by up to 90% when combined with other AI and automation features in Safety One Argus.)
  - Safety One Argus for safety case management including ICSR processing and regulatory reporting, wherein duplicate detection, MedDRA coding, narrative generation, and outbound translation have been automated using AI and RBA (Oracle reports that AI and RBA used together are driving seven times faster case processing for non-serious cases and three times faster for serious cases. In addition, Oracle reports that the automation of case processing workflows can drive 32–60% efficiency gains.)
  - Safety One Empirica for the complete safety signal management process including detection, validation, prioritization, assessment, confirmation or refutation, and the tracking of any risk mitigation and minimization actions (It utilizes algorithms designed to reduce the number of false positives and false negatives, and it can detect signals in multiple "big data" sets.)
  - Safety One Analytics, which leverages AI/ML for data analysis and visualizations, allowing business users to instantly generate ad hoc reports (It is prepopulated with Safety One Argus and Safety One Empirica data to provide a seamless experience for safety users.)
- Oracle has extensive experience with reporting to the U.S. Food and Drug Administration, European Medicines Agency, the Japan Pharmaceuticals and Medical Devices Agency, and other health authorities. Its Safety Consortium represents its customer and partner community with over 2,000 members across 500 companies. Over 300 of its customers have used Oracle's PV consulting services in the past four years across a wide spectrum of areas, driving hundreds of PV implementations, conducting over five PV audits per year, and providing guidance on nutrivigilance, cosmetovigilance, medical device/materiovigilance, vaccinovigilance, tobacco safety, and the safety of combination products and

biologics. Its most complex PV technology and consulting implementation engagement involved the migration and consolidation of 1.2 million cases from 42 different databases of a homegrown safety system combined with the simultaneous migration of 600,000 cases from a commercial safety system to Argus with 500 users.

"We are a global provider of PV services and started working with Oracle in 2019 and have about 400 customers on Argus. We felt that Oracle had a much more robust suite, and superior and more mature capabilities. We have one to two upgrades per year. Not excessive, not intrusive. I love that there's a lot of flexibility from their side to do the upgrades over weekends. Regulatory compliance is something we are very happy with. Argus J in Japan is tried and tested, works well; we have configured with PMDA, works smoothly where other safety systems struggle. No bolt-ons are required. I like that it's all-in-one system.

Their holistic view of not just safety but also how they look beyond at a molecule, compound level, RWD. They have vision and thought leadership. When we were looking at how they are deploying GenAI and when I saw their road map — we realized that they have upped their game significantly. Their customer support is excellent, and they do help us with large strategic opportunities. Having the might of Oracle behind us really helps. Argus is the best for CROs because it has a multitenant feature and with each of their new releases they are making it more friendly. Global regulatory compliance, Argus tops the list," said the president of a PV CRO.

"We use Argus. Oracle does the maintenance of the database, installs the dictionaries. We also use Argus J for Japan. We use Oracle's consulting for Argus J — a complex new report in Japanese, they do the programming for the reports. The FDA initiated electronic submission for electronic reports — mandated compliance in three years — we implemented that with the help of Oracle. Argus compliance — no issues. They are a good solid partner," said the VP Global PV of a global biopharma.

Challenges

Oracle should work on its messaging since, while Argus is perceived to be a very robust and a stable platform, there is still a perception that the platform is old, and that a lot of new functionality has not been added. Oracle can be perceived to show less flexibility to make changes to meet customer's needs. Oracle resources are perceived to more of technology experts than PV experts. While Oracle's pricing in the United States is very competitive, it could be better for APAC, and for the biosimilars/generics market. Since with Oracle, customers have to sign up for a pool of cases, and it is not a tiered pricing model, it puts CROs at risk if the number of cases falls short. Oracle should consider embedding AI in areas such as literature search and labeling updates.

Oracle should also consider offering guidance on PV organizational design and offering guidance on developing safety data exchange agreements, and on PSMF.

Consider Oracle When

Consider Oracle when seeking a partner that brings to the table deep PV expertise; its wide footprint serving over 400 PV customers; its robust, AI-enabled, cloud-based Safety One multivigilance platform, HDI that integrates and transforms data from ORWD — the anonymized data of over 110 million patients); and the underlying OCI, which provides flexibility and scalability. In addition, Oracle provides access to a large PV industry consortium and guidance on PV regulatory compliance, strategy, database migration, and technology implementation.

APPENDIX

Reading an IDC MarketScape Graph

For the purposes of this analysis, IDC divided potential key measures for success into two primary categories: capabilities and strategies.

Positioning on the y-axis reflects the vendor's current capabilities and menu of services and how well aligned the vendor is to customer needs. The capabilities category focuses on the capabilities of the company and product today, here and now. Under this category, IDC analysts will look at how well a vendor is building/delivering capabilities that enable it to execute its chosen strategy in the market.

Positioning on the x-axis, or strategies axis, indicates how well the vendor's future strategy aligns with what customers will require in three to five years. The strategies category focuses on high-level decisions and underlying assumptions about offerings, customer segments, and business and go-to-market plans for the next three to five years002E

The size of the individual vendor markers in the IDC MarketScape represents the market share of each individual vendor within the specific market segment being assessed.

IDC MarketScape Methodology

IDC MarketScape criteria selection, weightings, and vendor scores represent well-researched IDC judgment about the market and specific vendors. IDC analysts tailor the range of standard characteristics by which vendors are measured through structured discussions, surveys, and interviews with market leaders, participants, and end users. Market weightings are based on user interviews, buyer surveys, and the input of IDC experts in each market. IDC analysts base individual vendor scores, and ultimately

vendor positions on the IDC MarketScape, on detailed surveys and interviews with the vendors, publicly available information, and end-user experiences in an effort to provide an accurate and consistent assessment of each vendor's characteristics, behavior, and capability.

Market Definition

For the purposes of this study, IDC follows the FDA definition of PV, namely, "PV is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems."

PV solutions within this IDC MarketScape are defined broadly as:

- The solution includes PV-specific technology solutions and consulting capabilities.
- The PV solution will encompass the capability of the technology solutions provided and will consider how vendors advise their customers on implementing a PV strategy.
- From a technology perspective, the PV solution would include the provision of a PV platform, and/or related automation solutions, and the use of RPA, AI/ML, NLP, NLG, OCR, computer vision, and so forth to automate case intake, case processing, signal management, narrative writing, aggregate reporting, and so forth, as well as PV technology implementation, data migrations and integration, and so forth.
- From a consulting perspective, the PV solution will encompass high-level management consulting and advisory services, including business value case development, business process transformation, PV vendor selection and oversight strategy, development of SOPs, PV organizational redesign and change management, global PV implementation strategy, PV regulatory strategy, inputs into the development of risk management plans, and PVAs.

Market Analysis

Slowly, but surely, the PV landscape is changing. There is a shift from treating PV as a cost center to considering it to be a value driver, to proactivity instead of reactivity, from manual activities and RPA to more of GenAI and agents, from focusing only on clinical trial data to increasingly evaluating both clinical trial and real-world data (RWD), and from reactive responses (responding to adverse events that have already happened) to proactive measures, identifying signals, to determine potential risk in advance and preempt undesired outcomes, and leveraging AI and analytics to inform upstream target selection and validation processes.

Sedgwick, a product recall provider, has reported that class I pharmaceutical product recalls (the most serious category) increased to 14 in 1Q25 from six in 4Q24. There needs to be an increased emphasis on ensuring drug safety and on getting it right the first time. The need to embed a precision PV strategy across the life cycle of a medicinal product, to embed a safety-by-design strategy into product development, is becoming the reality of today.

The prevailing geopolitical scenario, the potential impact of tariffs, the "most favored nation" drug price executive order, and more, have all put immense pressure on pharma to cut costs and scale efficiencies. "Automation everywhere" is becoming a reality for pharmacovigilance. From automated case intake, case triaging, and case processing to translations, causality assessments, to PV report generation and signal detection, AI is everywhere.

To date, too many people have suffered as a result of the side effects of drugs. Drugs are meant to help us, not harm us, and the life sciences industry is hell bent on setting this right. Technology is offering immense promise in driving precision PV strategies, generating real-time insights to detect safety signals, prevent serious adverse events, and improve clinical outcomes and in enabling the industry to embed safety-by-design strategies through effective feedback loops providing critical data insights into the design of experiments (DoE) to design drugs with improved benefit-risk profiles.

LEARN MORE

Related Research

- *The Technology Impact of the New Trump Administration, 2025: Life Sciences, Medtech Companies, Healthcare Providers, and Healthcare Payers* (IDC #US53552525, June 2025)
- *IDC MaturityScape Benchmark: AI-Fueled Life Sciences Organization Worldwide, 2025* (IDC #US53345625, May 2025)
- *Worldwide GenAI Industry Use Case Early Adoption Trends, 2025: Life Sciences* (IDC #US53317424, April 2025)
- *How AI and GenAI Are Redefining the Life Sciences Industry* (IDC #US53163925, February 2025)
- *IDC MarketScape: Worldwide Life Science R&D Pharmacovigilance Solutions 2022 Vendor Assessment* (IDC #US48061622, December 2022)

Synopsis

This IDC study focuses on a combination of PV technology solutions and consulting services. This IDC MarketScape provides a qualitative and quantitative assessment

based on criteria that should be important to life sciences companies when considering the selection of a strategic PV solution provider to help provide guidance for strategic, operational, and tactical transformation issues within the PV space, as well as technology platforms and build capabilities. This is the third time that an IDC MarketScape assessment of PV solutions for life sciences R&D has been performed.

Dr. Nimita Limaye, research VP, Life Sciences R&D Strategy and Technology at IDC, noted, "Slowly but surely, the transition is happening. Pharmacovigilance is gradually beginning to be seen as a value driver rather than a cost center, with tech as the game changer, fueling precision PV strategies. From automated case intake to rapid signal detection, automation and AI are being embedded across the PV value chain. Ensuring transparency will be key toward building trust, scaling adoption, and driving patient safety."

ABOUT IDC

International Data Corporation (IDC) is the premier global provider of market intelligence, advisory services, and events for the information technology, telecommunications, and consumer technology markets. With more than 1,300 analysts worldwide, IDC offers global, regional, and local expertise on technology, IT benchmarking and sourcing, and industry opportunities and trends in over 110 countries. IDC's analysis and insight helps IT professionals, business executives, and the investment community to make fact-based technology decisions and to achieve their key business objectives. Founded in 1964, IDC is a wholly owned subsidiary of International Data Group (IDG, Inc.).

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