

Pharmacovigilance and Drug Safety Software Market Size and Forecast (2021–2031), Global and Regional Share, Trend, and Growth Opportunity
Analysis Report Coverage: By Offering (Software and Services), Deployment (Cloud and On-Premises), Enterprise Size (Large Enterprises and SMEs), Form (Standard and Customized), Functionality (Signal and Risk Management, Issue Tracking and Adverse Event Tracking, Case Management, Clinical Safety Management and Clinical Trial Safety, Quality and Compliance, Medical Writing, Audit Support and Training Compliance, Healthcare Analytics, and Others), End User [Pharmaceutical and Biotechnology Companies, Contract Research Organizations, Business Process Outsourcing (BPO) Firms, and Others], and Geography

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Abstracts

The pharmacovigilance and drug safety software market size was valued at US\$ 214.39 million in 2023 and is expected to reach US\$ 359.31 million by 2031; it is estimated to record a CAGR of 6.7% from 2023 to 2031.

The pharmacovigilance and drug safety software market is segmented into five major

regions—North America, Europe, Asia Pacific (APAC), the Middle East & Africa (MEA), and South & Central America. North America dominated the market in 2023, followed by Europe and Asia Pacific, respectively. The pharmacovigilance and drug safety software market in North America is segmented into the US, Canada, and Mexico. North America is witnessing tremendous growth in the pharmacovigilance and drug safety software market, owing to the presence of various market players such as IQVIA Oracle Corporation, who are continuously working on the advancement of pharmacovigilance and drug safety software. In July 2024, Oracle Corporation launched an AI-based Oracle Argus platform as a Safety One Intake solution. This solution helps life science organizations to meet growing regulatory requirements and to mitigate the rising volume of adverse event cases. This new pharmacovigilance platform aimed to increase productivity, improve data privacy, and enhance reporting. Thus, such product innovations by the market players in the region are fueling the growth of the pharmacovigilance and drug safety software market in the area.

Asia Pacific consists of various growing economies such as India, China, Japan, South Korea, Australia, and Rest of Asia Pacific. Asia Pacific is witnessing growing digitization in its healthcare sector. The governments of various countries in the region are taking different initiatives to enhance and digitize the healthcare system. For instance, China's healthcare expenditure of public financial officials reached US\$ 318.5 billion in 2023. According to the India Brand Equity Foundation, the Indian Healthcare industry was valued at US\$ 372 billion in 2023, driven by both the public and private sectors. Such rising healthcare expenditure across the Asia Pacific countries has created massive demand for the pharmacovigilance and drug safety software market growth during the forecast period.

Based on enterprise size, the global pharmacovigilance and drug safety software market is bifurcated into SMEs and large enterprises. The large enterprises segment dominated the market for enterprise size in 2023 owing to increasing investment by large companies in pharmacovigilance software. Large organizations with global operations must adhere to the pharmacovigilance guidelines of multiple regions. Pharmacovigilance software helps consolidate and standardize global safety data, ensuring that these organizations can monitor drug safety in real time across multiple geographies. Large organizations receive a high volume of adverse event data, both during clinical trials and post-marketing. Pharmacovigilance software helps these organizations manage and analyze the increasing data volume effectively, reducing the chances of noncompliance or missed safety signals. As pharmacovigilance software processes sensitive patient data, large organizations are adopting software solutions with robust data security and privacy features to ensure compliance with data protection

regulations such as the General Data Protection Regulation (GDPR) in Europe.

ArisEurope; ICON plc; Syneos Health; Accenture; IQVIA; Genpact; Cognizant; Paraxel International Corporation; Laboratory Corporation of America Holdings; Max Application; Clinevo Technologies; Qinecsa Solutions; AB Cube; and Veeva Systems are among the key pharmacovigilance and drug safety software market players that are profiled in this market study.

The overall pharmacovigilance and drug safety software market size has been derived using both primary and secondary sources. Exhaustive secondary research has been conducted using internal and external sources to obtain qualitative and quantitative information related to the pharmacovigilance and drug safety software market size. The process also helps obtain an overview and forecast of the market with respect to all the market segments. Also, multiple primary interviews have been conducted with industry participants to validate the data and gain analytical insights. This process includes industry experts such as VPs, business development managers, market intelligence managers, and national sales managers, along with external consultants such as valuation experts, research analysts, and key opinion leaders, specializing in the pharmacovigilance and drug safety software market.

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