

Europe Pharmacovigilance and Drug Safety Software Market Size and Forecast (2021 - 2031), 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 Country

<https://marketpublishers.com/r/E8AC4FB68E0CEN.html>

Date: October 2024

Pages: 205

Price: US\$ 3,550.00 (Single User License)

ID: E8AC4FB68E0CEN

Abstracts

The Europe pharmacovigilance and drug safety software market size was valued at US\$ 52.37 million in 2023 and is expected to reach US\$ 84.66 million by 2031; it is estimated to record a CAGR of 6.2% from 2023 to 2031.

Cloud-based pharmacovigilance and drug safety software is likely to remain a key

market trend.

Unlike traditional systems, cloud-based platforms offer real-time access to data from anywhere across Europe, enabling pharmaceutical companies to respond swiftly to emerging safety concerns. Cloud-based platforms enable real-time monitoring of adverse events that allow pharmaceutical companies to detect and respond to safety signals more quickly. With real-time data access, companies can generate safety reports on demand, significantly reducing the time required for decision-making. This immediacy is crucial in preventing adverse events from escalating into serious public health issues. Also, one of the most significant advantages of cloud-based drug safety solutions is their scalability. As a company grows or as the volume of data increases, the cloud platform can scale accordingly without requiring additional infrastructure investments. This flexibility is particularly important in pharmacovigilance, where the volume of data can fluctuate significantly depending on the stage of the drug's lifecycle. Cloud-based systems are enabling the creation of global pharmacovigilance networks, where data can be shared across borders in real-time. These networks will enable more comprehensive drug safety monitoring, with insights and safety signals being shared worldwide, leading to faster identification and mitigation of risks.

Cloud-based platforms enable real-time monitoring of adverse events, permitting pharmaceutical companies to detect and respond to safety signals more quickly. With real-time data access, companies can generate safety reports on demand, significantly reducing the time required for decision-making. This immediacy is crucial in preventing adverse events from escalating into serious public health issues. Various companies offer cloud-based pharmacovigilance and drug safety software, such as Clinevo Technologies, Sarjen Systems Pvt. Ltd, and others Therefore, cloud-based pharmacovigilance and drug safety software is expected to bring significant trends in the Europe pharmacovigilance and drug safety software market in the coming years.

The UK is witnessing advancements in the healthcare industry. The increased focus on digitizing healthcare and leveraging AI-powered analytics has fueled the adoption of pharmacovigilance and drug safety software in the country. Companies in the UK, including IQVIA, offer platforms that integrate AI and cloud solutions to improve real-time drug safety monitoring. These tools help organizations reduce the risks related to adverse reactions by using predictive analytics to preemptively identify potential issues, a critical feature in managing complex drug portfolios.

The Yellow Card Scheme is run by the Medicines and Healthcare Products Regulatory Agency (MHRA), where dentists, doctors, and hospital pharmacists are encouraged to

report all serious suspected reactions to established medicines and suspected reactions to new medicines. In the UK, most doctors report directly to the National Regulatory Authority rather than pharmaceutical companies. In the UK, Good Pharmacovigilance Practice (GPvP) is the minimum standard required for monitoring the safety of medicines on sale to the public. Therefore, the abovementioned factors are expected to contribute to the pharmacovigilance and drug safety software market in the UK during the forecast period.

Based on form, the Europe pharmacovigilance and drug safety software market is segmented into standard and customized. The standard segment held the largest Europe pharmacovigilance and drug safety software market share. Standard pharmacovigilance and drug safety software refers to pre-configured, off-the-shelf solutions that provide a comprehensive set of tools designed to meet the general needs of drug safety monitoring. This software offers essential features such as adverse event reporting, case management, signal detection, risk management, and regulatory compliance. Standard software are typically aligned with global pharmacovigilance regulations, such as those from the EMA, FDA, and ICH, making them suitable for a wide range of organizations. These software are mostly user-friendly and come with built-in templates, workflows, and automation capabilities to simplify safe data processing.

They are cost-effective and can be deployed relatively quickly. However, as the software is not tailored to specific needs, it might lack flexibility in handling unique processes or local regulatory requirements. A few examples of standard solutions include Oracle Argus Safety and Veeva Vault Safety, which cater to the broad requirements of most pharmaceutical and biotech companies.

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 Europe pharmacovigilance and drug safety software market players that are profiled in this market study.

The overall Europe 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 Europe 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 Europe pharmacovigilance and drug safety software market.

Contents

1. INTRODUCTION

- 1.1 The Insight Partners Research Report Guidance.
- 1.2 Market Segmentation.

2. EXECUTIVE SUMMARY

- 2.1 Key Insights.
- 2.2 Market Attractiveness.

3. RESEARCH METHODOLOGY

- 3.1 Secondary Research.
- 3.2 Primary Research.
 - 3.2.1 Hypothesis formulation:
 - 3.2.2 Macro-economic factor analysis:
 - 3.2.3 Developing base number:
 - 3.2.4 Data Triangulation:
 - 3.2.5 Country level data:

4. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET LANDSCAPE

- 4.1 Overview.
- 4.2 PEST Analysis.
- 4.3 Ecosystem Analysis.
 - 4.3.1 Software/Service Providers:
 - 4.3.2 System Integrators:
 - 4.3.3 Regulatory Bodies:
 - 4.3.4 End-Users:
 - 4.3.5 List of Vendors in the Value Chain.

5. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET – KEY MARKET DYNAMICS

- 5.1 Europe Pharmacovigilance and Drug Safety Software Market – Key Market Dynamics.

5.2 Market Drivers.

5.2.1 Rise in Incidences of Adverse Drug Reactions.

5.2.2 Globalization of Pharmacovigilance.

5.2.3 Surge in Drug Development Rates:

5.3 Market Restraints.

5.3.1 High Installation and Maintenance Costs.

5.4 Market Opportunities.

5.4.1 Integration of Software with AI, ML, and NLP.

5.5 Future Trends.

5.5.1 Cloud-Based Pharmacovigilance and Drug Safety Software:

5.6 Impact of Drivers and Restraints:

6. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS

6.1 Europe Pharmacovigilance and Drug Safety Software Market Revenue (US\$ Thousand), 2021–2031.

6.2 Europe Pharmacovigilance and Drug Safety Software Market Forecast and Analysis.

7. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS – BY OFFERING

7.1 Software.

7.1.1 Overview.

7.1.2 Software: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

7.2 Services.

7.2.1 Overview.

7.2.2 Services: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

8. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS – BY DEPLOYMENT

8.1 Cloud.

8.1.1 Overview.

8.1.2 Cloud: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

8.2 On Premises.

8.2.1 Overview.

8.2.2 On Premises: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

9. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS – BY ENTERPRISE SIZE

9.1 Large Enterprises.

9.1.1 Overview.

9.1.2 Large Enterprises: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

9.2 SMEs.

9.2.1 Overview.

9.2.2 SMEs: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

10. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS – BY FORM

10.1 Standard.

10.1.1 Overview.

10.1.2 Standard: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

10.2 Customized.

10.2.1 Overview.

10.2.2 Customized: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS – BY FUNCTIONALITY

11.1 Signal and Risk Management

11.1.1 Overview.

11.1.2 Signal and Risk Management: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.2 Issue Tracking and Adverse Event Tracking.

11.2.1 Overview.

11.2.2 Issue Tracking and Adverse Event Tracking: Europe Pharmacovigilance and

Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.3 Case Management

11.3.1 Overview.

11.3.2 Case Management: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.4 Clinical Safety Management and Clinical Trial Safety.

11.4.1 Overview.

11.4.2 Clinical Safety Management and Clinical Trial Safety: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.5 Quality and Compliance.

11.5.1 Overview.

11.5.2 Quality and Compliance: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.6 Medical Writing.

11.6.1 Overview.

11.6.2 Medical Writing: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.7 Audit Support and Training Compliance.

11.7.1 Overview.

11.7.2 Audit Support and Training Compliance: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.8 Healthcare Analytics.

11.8.1 Overview.

11.8.2 Healthcare Analytics: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

11.9 Others.

11.9.1 Overview.

11.9.2 Others: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

12. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET ANALYSIS – BY END USER

12.1 Pharmaceutical and Biotechnology Companies.

12.1.1 Overview.

12.1.2 Pharmaceutical and Biotechnology Companies: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

12.2 Contract Research Organizations.

12.2.1 Overview.

12.2.2 Contract Research Organizations: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

12.3 Business Process Outsourcing (BPO) Firms.

12.3.1 Overview.

12.3.2 Business Process Outsourcing (BPO) Firms: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

12.4 Others.

12.4.1 Overview.

12.4.2 Others: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

13. EUROPE PHARMACOVIGILANCE AND DRUG SAFETY SOFTWARE MARKET – COUNTRY ANALYSIS

13.1 Europe.

13.1.1 Europe Pharmacovigilance and Drug Safety Software Market

13.1.2 Europe Pharmacovigilance and Drug Safety Software Market Revenue and Forecast and Analysis – by Country.

13.1.2.1 Europe Pharmacovigilance and Drug Safety Software Market Revenue and Forecast and Analysis – by Country.

13.1.2.2 Germany: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

13.1.2.2.1 Germany: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Offering.

13.1.2.2.2 Germany: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Deployment

13.1.2.2.3 Germany: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Enterprise Size.

13.1.2.2.4 Germany: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Form

13.1.2.2.5 Germany: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Functionality.

13.1.2.2.6 Germany: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by End User

13.1.2.3 France: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

13.1.2.3.1 France: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Offering.

13.1.2.3.2 France: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Deployment

13.1.2.3.3 France: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Enterprise Size.

13.1.2.3.4 France: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Form

13.1.2.3.5 France: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Functionality.

13.1.2.3.6 France: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by End User

13.1.2.4 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

13.1.2.4.1 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Offering.

13.1.2.4.2 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Deployment

13.1.2.4.3 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Enterprise Size.

13.1.2.4.4 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Form

13.1.2.4.5 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Functionality.

13.1.2.4.6 United Kingdom: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by End User

13.1.2.5 Italy: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

13.1.2.5.1 Italy: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Offering.

13.1.2.5.2 Italy: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Deployment

13.1.2.5.3 Italy: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Enterprise Size.

13.1.2.5.4 Italy: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Form

13.1.2.5.5 Italy: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Functionality.

13.1.2.5.6 Italy: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by End User

13.1.2.6 Spain: Europe Pharmacovigilance and Drug Safety Software Market –

Revenue and Forecast to 2031 (US\$ Thousand)

13.1.2.6.1 Spain: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Offering.

13.1.2.6.2 Spain: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Deployment

13.1.2.6.3 Spain: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Enterprise Size.

13.1.2.6.4 Spain: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Form

13.1.2.6.5 Spain: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Functionality.

13.1.2.6.6 Spain: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by End User

13.1.2.7 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market – Revenue and Forecast to 2031 (US\$ Thousand)

13.1.2.7.1 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Offering.

13.1.2.7.2 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Deployment

13.1.2.7.3 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Enterprise Size.

13.1.2.7.4 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Form

13.1.2.7.5 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by Functionality.

13.1.2.7.6 Rest of Europe: Europe Pharmacovigilance and Drug Safety Software Market Breakdown by End User

14. COMPETITIVE LANDSCAPE

14.1 Heat Map Analysis by Key Players.

14.2 Company Positioning & Concentration.

15. INDUSTRY LANDSCAPE

15.1 Overview.

15.2 Market Initiative.

15.3 Merger and Acquisition.

16. COMPANY PROFILES

16.1 ArisGlobal LLC.

- 16.1.1 Key Facts.
- 16.1.2 Business Description.
- 16.1.3 Products and Services.
- 16.1.4 Financial Overview.
- 16.1.5 SWOT Analysis.
- 16.1.6 Key Developments.

16.2 Max Application.

- 16.2.1 Key Facts.
- 16.2.2 Business Description.
- 16.2.3 Products and Services.
- 16.2.4 Financial Overview.
- 16.2.5 SWOT Analysis.
- 16.2.6 Key Developments.

16.3 Oracle Corp.

- 16.3.1 Key Facts.
- 16.3.2 Business Description.
- 16.3.3 Products and Services.
- 16.3.4 Financial Overview.
- 16.3.5 SWOT Analysis.
- 16.3.6 Key Developments.

16.4 Veeva Systems Inc.

- 16.4.1 Key Facts.
- 16.4.2 Business Description.
- 16.4.3 Products and Services.
- 16.4.4 Financial Overview.
- 16.4.5 SWOT Analysis.
- 16.4.6 Key Developments.

16.5 IQVIA Holdings Inc.

- 16.5.1 Key Facts.
- 16.5.2 Business Description.
- 16.5.3 Products and Services.
- 16.5.4 Financial Overview.
- 16.5.5 SWOT Analysis.
- 16.5.6 Key Developments.

16.6 ICON Plc.

- 16.6.1 Key Facts.

- 16.6.2 Business Description.
- 16.6.3 Products and Services.
- 16.6.4 Financial Overview.
- 16.6.5 SWOT Analysis.
- 16.6.6 Key Developments.
- 16.7 Cognizant Technology Solutions Corp.
 - 16.7.1 Key Facts.
 - 16.7.2 Business Description.
 - 16.7.3 Products and Services.
 - 16.7.4 Financial Overview.
 - 16.7.5 SWOT Analysis.
 - 16.7.6 Key Developments.
- 16.8 Accenture Plc.
 - 16.8.1 Key Facts.
 - 16.8.2 Business Description.
 - 16.8.3 Products and Services.
 - 16.8.4 Financial Overview.
 - 16.8.5 SWOT Analysis.
 - 16.8.6 Key Developments.
- 16.9 Syneos Health Inc.
 - 16.9.1 Key Facts.
 - 16.9.2 Business Description.
 - 16.9.3 Products and Services.
 - 16.9.4 Financial Overview.
 - 16.9.5 SWOT Analysis.
 - 16.9.6 Key Developments.
- 16.10 Genpact Ltd.
 - 16.10.1 Key Facts.
 - 16.10.2 Business Description.
 - 16.10.3 Products and Services.
 - 16.10.4 Financial Overview.
 - 16.10.5 SWOT Analysis.
 - 16.10.6 Key Developments.
- 16.11 AB Cube S.A.S.
 - 16.11.1 Key Facts.
 - 16.11.2 Business Description.
 - 16.11.3 Products and Services.
 - 16.11.4 Financial Overview.
 - 16.11.5 SWOT Analysis.

16.11.6 Key Developments.

16.12 Laboratory Corp of America Holdings.

16.12.1 Key Facts.

16.12.2 Business Description.

16.12.3 Products and Services.

16.12.4 Financial Overview.

16.12.5 SWOT Analysis.

16.12.6 Key Developments.

16.13 Parexel International Corp.

16.13.1 Key Facts.

16.13.2 Business Description.

16.13.3 Products and Services.

16.13.4 Financial Overview.

16.13.5 SWOT Analysis.

16.13.6 Key Developments.

16.14 Qinecsa Solutions.

16.14.1 Key Facts.

16.14.2 Business Description.

16.14.3 Products and Services.

16.14.4 Financial Overview.

16.14.5 SWOT Analysis.

16.14.6 Key Developments.

16.15 Clinevo Technologies.

16.15.1 Key Facts.

16.15.2 Business Description.

16.15.3 Products and Services.

16.15.4 Financial Overview.

16.15.5 SWOT Analysis.

16.15.6 Key Developments.

17. APPENDIX

17.1 Word Index.

17.2 About the Insight Partners.

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