

# **United States Pharmacovigilance Market By Clinical Trial Phase (Pre-Clinical, Phase 1, Phase 2, Phase 3, and Phase 4), By Method (Spontaneous Reporting, Intensified ADR Reporting, Targeted Spontaneous Reporting, Cohort Event Monitoring, EHR Mining), By Service Provider (In-House, Contract Outsourcing), By End User (Hospitals, Research Organizations, Industries), By Region, Competition, Forecast and Opportunities, 2018-2028F**

<https://marketpublishers.com/r/U6FB9095148EEN.html>

Date: November 2023

Pages: 82

Price: US\$ 3,500.00 (Single User License)

ID: U6FB9095148EEN

## **Abstracts**

United States Pharmacovigilance Market is anticipated to project steady growth in the forecast period. Pharmacovigilance, a vital scientific discipline in healthcare, plays a crucial role in ensuring patient safety by focusing on the comprehensive detection, assessment, understanding, and prevention of adverse effects and other medicine-related issues. This field integrates the systematic collection and analysis of data from healthcare providers and patients, enabling the identification of potential risks associated with the therapeutic use of medicines. By proactively managing and mitigating these risks, pharmacovigilance aims to safeguard the well-being of patients worldwide and uphold the highest standards of healthcare. Through continuous monitoring and evaluation, pharmacovigilance strives to improve the understanding of medication safety profiles, enhance regulatory decision-making, and contribute to the development of safer and more effective treatments. By diligently carrying out its mission, pharmacovigilance supports public health initiatives and fosters confidence in the healthcare system by ensuring that the benefits of health interventions always outweigh the potential risks.

## Key Market Drivers

### Increasing incidence of Adverse Drug Reactions (ADRs)

The escalating incidence of Adverse Drug Reactions (ADRs) in the United States is anticipated to spur a significant surge in the demand for pharmacovigilance. ADRs, which refer to the harmful and unintended effects of medications, pose a considerable health risk to patients. These reactions can range from mild discomfort to severe complications that require hospitalization, prolonged illness, and in the worst cases, even death. The impact of ADRs goes beyond individual patients and extends to healthcare systems as well. The financial burden imposed by the treatment and management of ADRs places additional strain on already stretched healthcare resources. Pharmacovigilance plays a crucial role in ensuring patient safety. It involves the systematic collection, detection, assessment, and prevention of drug-related problems. By closely monitoring and evaluating the safety profile of medications, pharmacovigilance enables the early detection of ADRs. This timely identification facilitates the dissemination of updated drug safety information to healthcare providers and regulatory agencies. In turn, this can prompt necessary regulatory actions such as drug recalls or label changes to mitigate potential risks.

As the incidence of ADRs continues to rise, healthcare providers and regulatory agencies are increasingly recognizing the indispensability of robust pharmacovigilance systems. These systems not only serve as a means to detect and manage ADRs, but also enable the continuous monitoring and evaluation of medications post-market approval. By proactively monitoring the safety and efficacy of drugs, pharmacovigilance contributes to the overall improvement of patient care.

Consequently, the need to effectively manage, and ideally reduce, the incidence of ADRs is becoming more pressing. As a result, the demand for comprehensive, efficient, and proactive pharmacovigilance services is expected to rise significantly in the United States. This increased demand will necessitate the development and implementation of advanced pharmacovigilance strategies and technologies to ensure the safety and well-being of patients nationwide.

### Surge in the Approval of New Drugs

The recent surge in the approval of new drugs in the United States is anticipated to significantly ramp up the demand for Pharmacovigilance, a critical field prioritizing drug safety and efficacy. The Food and Drug Administration (FDA) has been green-lighting a

growing number of drugs annually, a trend that underscores the importance of robust post-market surveillance to monitor the safety of these newly-approved medicinal products. It is paramount to identify and assess adverse effects or any other drug-related issues once the drug enters the market and is used in a larger, more diverse population. The dynamic nature of the pharmaceutical landscape, coupled with the increasing complexity of novel drugs, necessitates a comprehensive and efficient pharmacovigilance system. This would help in swiftly detecting, assessing, and mitigating risks associated with these drugs, thereby safeguarding the health of the consumer. The evolving regulations and guidelines from the FDA mandating stringent safety data reporting also contribute significantly to the heightened demand for Pharmacovigilance. These factors, combined with the increasing public and health-care providers' awareness of drug safety, are set to propel the Pharmacovigilance industry in the United States to new heights.

### Expansion of the Biologics Market

The burgeoning expansion of the biologics market is anticipated to drive a surge in the demand for pharmacovigilance in the United States. Biologics, complex products derived from living organisms, are transforming the healthcare landscape with their potential for targeted treatment of an array of diseases. However, their complexity and inherent variability necessitate extensive safety and efficacy monitoring, thus elevating the role of pharmacovigilance. Pharmacovigilance, the science of detecting, assessing, and preventing adverse effects or other drug-related problems, plays a critical role in ensuring patient safety. As biologics continue to dominate pharmaceutical innovation, the need for robust pharmacovigilance systems escalates. This is further heightened by the push towards personalized medicine, as biologics are often tailored to individual patient profiles, presenting unique safety and efficacy profiles that require diligent oversight. Moreover, the increasing regulatory scrutiny around biologics safety is adding pressure on pharmaceutical companies to invest in comprehensive pharmacovigilance strategies to meet compliance requirements. This confluence of factors, therefore, underscore the expected increase in demand for pharmacovigilance in the context of the expanding biologics market in the United States.

### Increasing Preference for Outsourcing Pharmacovigilance Services

The increasing preference for outsourcing pharmacovigilance services is anticipated to drive the demand for pharmacovigilance in the United States. As the pharmaceutical industry continues to expand, the inherent complexities associated with drug safety and post-approval surveillance have necessitated a shift towards specialized services.

Outsourcing provides access to a team of experts who can manage the intricate aspects of drug safety, effectively reducing the burden on pharmaceutical companies and allowing them to focus on their core competencies. Furthermore, regulatory compliance, a significant aspect of pharmacovigilance, can be better managed with outsourced services due to their expertise in global regulatory requirements. Additionally, the cost-benefit associated with outsourcing, including lower operational costs and reduced infrastructure investment, makes it an attractive option for companies, particularly small to mid-sized firms. The recent years have seen an upsurge in the number of firms offering pharmacovigilance services, reflecting the industry's recognition of the value these services provide. As such, the trend of outsourcing pharmacovigilance is expected to fuel the growth of the pharmacovigilance industry in the United States.

## Key Market Challenges

### Strong Regulatory Framework by the FDA

The Food and Drug Administration (FDA) of the United States, renowned for its robust regulatory framework, has implemented stringent guidelines and rigorous oversight mechanisms to ensure the safety and efficacy of pharmaceutical products. This commitment to safeguarding public health is evident in the FDA's emphasis on post-marketing surveillance, which involves continuous monitoring of drug safety profiles and prompt action to address potential safety concerns. By proactively monitoring and promptly addressing adverse drug reactions, the FDA has significantly reduced the occurrence of such events, thereby instilling greater confidence in the pharmaceutical industry.

Furthermore, the FDA's comprehensive approach extends to pre-market testing requirements, which are designed to identify and mitigate potential risks before a product reaches the market. Through thorough evaluation of clinical data, rigorous scrutiny of manufacturing processes, and close collaboration with industry experts, the FDA ensures that pharmaceutical products meet stringent quality standards and have a favorable risk-benefit profile. Although the FDA's proactive measures have contributed to a decreased demand for pharmacovigilance services, it is important to acknowledge that pharmacovigilance still plays a crucial role in ensuring drug safety and protecting public health. Pharmacovigilance activities, such as monitoring the safety of marketed drugs, detecting and assessing adverse drug reactions, and promoting the safe use of medications, remain vital to identify and manage potential risks associated with pharmaceutical products.

The FDA's unwavering commitment to safety and its comprehensive approach to regulation have significantly enhanced the safety and quality of pharmaceutical products in the United States. While the FDA's efforts have resulted in a decreased demand for pharmacovigilance services, the importance of continued vigilance and collaboration between regulatory agencies, healthcare professionals, and pharmaceutical companies cannot be overstated in ensuring the ongoing safety and well-being of patients.

## Post-Marketing Surveillance

Post-marketing surveillance (PMS), a crucial aspect of the pharmaceutical industry, plays a vital role in ensuring drug safety and efficacy even after they have reached the marketplace. This continuous monitoring of drugs after they have been approved may potentially decrease the demand for Pharmacovigilance (PV) in the United States. PMS allows for the detection of previously unreported or unknown adverse effects that may arise in the general population, which is more diverse than the controlled groups used in clinical trials. It can also track long-term effects and effectiveness of a drug, facilitating a more comprehensive understanding of its impact, thus reducing the reliance on PV. Furthermore, the implementation of technological advancements in PMS like data mining, machine learning, and other predictive analytic tools can enhance the efficiency and accuracy of adverse event detection, rendering certain traditional PV practices redundant. However, it's crucial to note that while PMS may decrease the demand for traditional PV, it doesn't eliminate the need for it altogether. Both systems work synergistically to ensure the highest level of drug safety and efficacy, contributing to public health and confidence in pharmaceutical products.

## Key Market Trends

### High Investment in Research & Development

Investment in Research and Development (R&D) is of paramount importance in bolstering the demand for pharmacovigilance in the United States. Notably, high R&D investment can lead to the development of new pharmaceutical products, requiring rigorous pharmacovigilance to ensure their effective and safe use. R&D initiatives often uncover complex drug interactions and side effects which further necessitate a robust system of pharmacovigilance to monitor, document, and manage. Additionally, R&D investment drives innovation in pharmacovigilance methodologies themselves, such as automation and data analytics, which can enhance the efficiency and efficacy of pharmacovigilance systems. Increased technological capabilities can streamline the

detection of adverse drug reactions, thereby fostering greater trust and demand for these services. Moreover, a well-funded R&D environment attracts more pharmaceutical companies to the market, contributing to an expanded need for pharmacovigilance. In essence, high R&D investment is integral to advancing the pharmacovigilance landscape by catalyzing innovation, improving safety measures, and ultimately, increasing the demand for pharmacovigilance in the United States.

## Growth in the Pharmaceuticals & Biotechnology Sectors

The expected growth in the Pharmaceuticals & Biotechnology sectors in the United States is anticipated to significantly drive up the demand for Pharmacovigilance. This surge can be attributed to an increased focus on drug safety and efficacy, coupled with stricter federal regulations for drug approvals, post-marketing surveillance, and reporting of adverse drug reactions. The burgeoning growth of biotechnology firms and pharmaceutical companies also fuels the need for comprehensive pharmacovigilance to ensure patient safety and maintain public trust. The development of groundbreaking biologics and medications necessitates meticulous monitoring to mitigate any potential risks and side effects. Furthermore, the sophistication of modern pharmaceuticals and biotechnology introduces a more complex risk landscape, thereby necessitating robust pharmacovigilance systems. Lastly, the rise of personalized medicine and biologics underpins the need for expanded pharmacovigilance activities, as these novel treatments often involve higher risks and require more stringent safety monitoring. Hence, the projected growth in both sectors will undoubtedly magnify the demand for pharmacovigilance in the United States.

## Segmental Insights

### Clinical Trial Phase Insights

Based on the Clinical Trial Phase, Phase 3 trials play a pivotal role in the United States Pharmacovigilance Market. During this critical phase, the safety and efficacy of the drug are meticulously evaluated on a larger scale, typically encompassing several hundred to several thousand patients. This extensive testing and monitoring process involves rigorous data analysis, ensuring that any potential risks or adverse effects are thoroughly assessed. Consequently, Phase 3 trials are of paramount importance in pharmacovigilance activities, providing valuable insights into the overall effectiveness and safety profile of the drug under investigation.

### Method Insights

Based on the Method, Spontaneous Reporting remains the most commonly used method in the Pharmacovigilance Market. This method, although it has its limitations, is widely utilized due to its simplicity, affordability, and ability to detect new, rare, and serious adverse drug reactions (ADRs). By encouraging healthcare professionals and patients to report any suspected ADRs, the Spontaneous Reporting System plays a crucial role in identifying potential safety concerns associated with medications. Despite the emergence of other methods, such as Intensified ADR Reporting, Targeted Spontaneous Reporting, Cohort Event Monitoring, and EHR Mining, the Spontaneous Reporting System continues to be relied upon heavily in the U.S. market, ensuring the ongoing monitoring and evaluation of drug safety.

The Spontaneous Reporting System is an integral part of pharmacovigilance activities as it relies on voluntary reporting from healthcare professionals and patients. This system allows for the early detection of adverse drug reactions, including those that are rare or serious, which may otherwise go unnoticed. The simplicity and affordability of the Spontaneous Reporting method make it accessible to a wide range of healthcare providers, enabling them to contribute to the ongoing monitoring and evaluation of drug safety. While other methods have emerged in recent years to supplement the Spontaneous Reporting System, it remains a cornerstone of pharmacovigilance efforts in the U.S. market. The continued reliance on this system ensures that potential safety concerns associated with medications are promptly identified and addressed, ultimately safeguarding patient health and well-being.

## Regional Insights

The region that is currently dominating the United States Pharmacovigilance Market is the Northeast. This can be attributed to several factors, including the presence of a significant number of major pharmaceutical companies in the area. These companies have established a strong foothold in the region, contributing to its overall dominance. Moreover, the Northeast boasts well-established healthcare facilities that provide a solid foundation for pharmacovigilance activities. These facilities are equipped with state-of-the-art technologies and highly skilled healthcare professionals, ensuring the highest standards of safety and patient care. Additionally, the region is known for its robust research and development initiatives, with renowned universities and research institutions collaborating closely with pharmaceutical companies to drive innovation in the field of pharmacovigilance. This collaborative approach fosters the exchange of knowledge and expertise, resulting in the development of cutting-edge drugs and therapies.

Furthermore, the Northeast region benefits from a favorable regulatory environment, with stringent guidelines and regulations in place to ensure the safety and efficacy of pharmaceutical products. This regulatory framework provides confidence to both pharmaceutical companies and consumers, further consolidating the region's position as a key player in the pharmacovigilance industry. With all these combined factors, it is evident why the Northeast stands out as the leading region in the United States Pharmacovigilance Market, setting the benchmark for excellence and innovation in pharmaceutical safety and surveillance.

### Key Market Players

F. Hoffmann-La Roche & Co.

Laboratory Corporation of America Holdings

IBM Corporation

United BioSource Corporation

BioClinica Inc.

Novartis Corporation

ArisGlobal LLC

Cognizant Technology Solutions Corp

Accenture Inc.

Capgemini US LLC

### Report Scope:

In this report, the United States Pharmacovigilance Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

### United States Pharmacovigilance Market, By Clinical Trial Phase:

*United States Pharmacovigilance Market By Clinical Trial Phase (Pre-Clinical, Phase 1, Phase 2, Phase 3, and P...*



Pre-Clinical

Phase 1

Phase 2

Phase 3

Phase 4

United States Pharmacovigilance Market, By Method:

Spontaneous Reporting

Intensified ADR Reporting

Targeted Spontaneous Reporting

Cohort Event Monitoring

EHR Mining

United States Pharmacovigilance Market, By Service Provider:

In-House

Contract Outsourcing

United States Pharmacovigilance Market, By End User:

Hospitals

Research Organizations

Industries

United States Pharmacovigilance Market, By Region:

Northeast Region

Midwest Region

West Region

South Region

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the United States Pharmacovigilance Market.

Available Customizations:

United States Pharmacovigilance Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

## Contents

### **1. PRODUCT OVERVIEW**

- 1.1. Market Definition
- 1.2. Scope of the Market
  - 1.2.1. Markets Covered
  - 1.2.2. Years Considered for Study
  - 1.2.3. Key Market Segmentations

### **2. RESEARCH METHODOLOGY**

- 2.1. Objective of the Study
- 2.2. Baseline Methodology
- 2.3. Key Industry Partners
- 2.4. Major Association and Secondary Sources
- 2.5. Forecasting Methodology
- 2.6. Data Triangulation & Validation
- 2.7. Assumptions and Limitations

### **3. EXECUTIVE SUMMARY**

- 3.1. Overview of the Market
- 3.2. Overview of Key Market Segmentations
- 3.3. Overview of Key Market Players
- 3.4. Overview of Key Regions/Countries
- 3.5. Overview of Market Drivers, Challenges, Trends

### **4. VOICE OF CUSTOMER**

### **5. UNITED STATES PHARMACOVIGILANCE MARKET OUTLOOK**

- 5.1. Market Size & Forecast
  - 5.1.1. By Value
- 5.2. Market Share & Forecast
  - 5.2.1. By Clinical Trial Phase (Pre-Clinical, Phase 1, Phase 2, Phase 3, and Phase 4)
  - 5.2.2. By Method (Spontaneous Reporting, Intensified ADR Reporting, Targeted Spontaneous Reporting, Cohort Event Monitoring, EHR Mining)
  - 5.2.3. By Service Provider (In-House, Contract Outsourcing)

- 5.2.4. By End User (Hospitals, Research Organizations, Industries)
- 5.2.5. By Region
- 5.2.6. By Company (2022)
- 5.3. Market Map

## **6. NORTH-EAST PHARMACOVIGILANCE MARKET OUTLOOK**

- 6.1. Market Size & Forecast
  - 6.1.1. By Value
- 6.2. Market Share & Forecast
  - 6.2.1. By Clinical Trial Phase
  - 6.2.2. By Method
  - 6.2.3. By Service Provider
  - 6.2.4. By End User

## **7. MID-WEST PHARMACOVIGILANCE MARKET OUTLOOK**

- 7.1. Market Size & Forecast
  - 7.1.1. By Value
- 7.2. Market Share & Forecast
  - 7.2.1. By Clinical Trial Phase
  - 7.2.2. By Method
  - 7.2.3. By Service Provider
  - 7.2.4. By End User

## **8. WEST PHARMACOVIGILANCE MARKET OUTLOOK**

- 8.1. Market Size & Forecast
  - 8.1.1. By Value
- 8.2. Market Share & Forecast
  - 8.2.1. By Clinical Trial Phase
  - 8.2.2. By Method
  - 8.2.3. By Service Provider
  - 8.2.4. By End User

## **9. SOUTH PHARMACOVIGILANCE MARKET OUTLOOK**

- 9.1. Market Size & Forecast
  - 9.1.1. By Value

## 9.2. Market Share & Forecast

- 9.2.1. By Clinical Trial Phase
- 9.2.2. By Method
- 9.2.3. By Service Provider
- 9.2.4. By End User

## **10. MARKET DYNAMICS**

- 10.1. Drivers
- 10.2. Challenges

## **11. MARKET TRENDS & DEVELOPMENTS**

- 11.1. Recent Development
- 11.2. Mergers & Acquisitions
- 11.3. Product Launches

## **12. POLICY & REGULATORY LANDSCAPE**

## **13. UNITED STATES ECONOMIC PROFILE**

## **14. UNITED STATES PHARMACOVIGILANCE MARKET: SWOT ANALYSIS**

## **15. PORTER'S FIVE FORCES ANALYSIS**

- 15.1. Competition in the Industry
- 15.2. Potential of New Entrants
- 15.3. Power of Suppliers
- 15.4. Power of Customers
- 15.5. Threat of Substitute Products

## **16. COMPETITIVE LANDSCAPE**

- 16.1. F. Hoffmann-La Roche & Co.
  - 16.1.1. Business Overview
  - 16.1.2. Product Offerings
  - 16.1.3. Recent Developments
  - 16.1.4. Financials (As Reported)
  - 16.1.5. Key Personnel

16.2. Laboratory Corporation of America Holdings

16.3. IBM Corporation

16.4. United BioSource Corporation

16.5. BioClinica Inc.

16.6. Novartis Corporation

16.7. ArisGlobal LLC

16.8. Cognizant Technology Solutions Corp

16.9. Accenture Inc.

16.10. Capgemini US LLC

## **17. STRATEGIC RECOMMENDATIONS**

## **18. ABOUT US & DISCLAIMER**

## I would like to order

Product name: United States Pharmacovigilance Market By Clinical Trial Phase (Pre-Clinical, Phase 1, Phase 2, Phase 3, and Phase 4), By Method (Spontaneous Reporting, Intensified ADR Reporting, Targeted Spontaneous Reporting, Cohort Event Monitoring, EHR Mining), By Service Provider (In-House, Contract Outsourcing), By End User (Hospitals, Research Organizations, Industries), By Region, Competition, Forecast and Opportunities, 2018-2028F

Product link: <https://marketpublishers.com/r/U6FB9095148EEN.html>

Price: US\$ 3,500.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

[info@marketpublishers.com](mailto:info@marketpublishers.com)

## Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/U6FB9095148EEN.html>

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:  
Last name:  
Email:  
Company:  
Address:  
City:  
Zip code:  
Country:  
Tel:  
Fax:  
Your message:

**\*\*All fields are required**

Customer signature \_\_\_\_\_

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms

& Conditions at <https://marketpublishers.com/docs/terms.html>

To place an order via fax simply print this form, fill in the information below  
and fax the completed form to +44 20 7900 3970