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Pharmacovigilance & Drug Safety:

Pharmacovigilance also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The etymological roots for the word "pharmacovigilance" are: pharmakon and vigilare. As such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation). Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction.

Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature, plays a critical role in providing the data necessary for pharmacovigilance to take place. In fact, in order to market or to test a pharmaceutical product in most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority. (See adverse event reporting below.) Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.

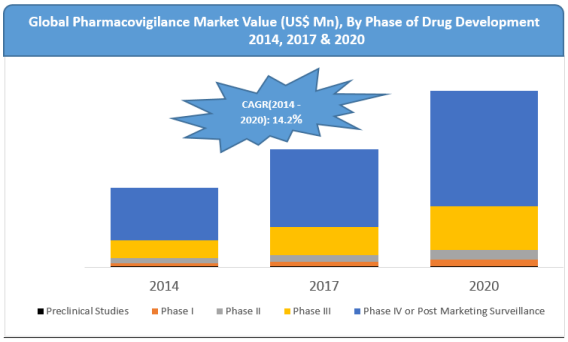
The key factors propelling this market are increasing drug consumption and drug development rates, growing incidence rates of adverse drug reactions and drug toxicity, and increasing trend of outsourcing pharmacovigilance services. The increasing incidence of lifestyle diseases, such as diabetes, hypertension, and cardiac disorders, as a result of sedentary lifestyles, lack of physical activities, changing lifestyle patterns, and poor diets lead to increasing consumption of drugs, which, in turn, indicates the high demand for drug monitoring and further fuels the growth of the pharmacovigilance market. With the growing drug consumption, the need for the regular monitoring of drugs has also augmented, eventually boosting the pharmacovigilance market. Human infectious diseases are also on rise due to the changing climate, pervasive poverty, and increasing urbanization, which also surge the drug consumption and drive the drug development process. Furthermore, new drug developments need to get regulated and stimulate the overall pharmacovigilance market.

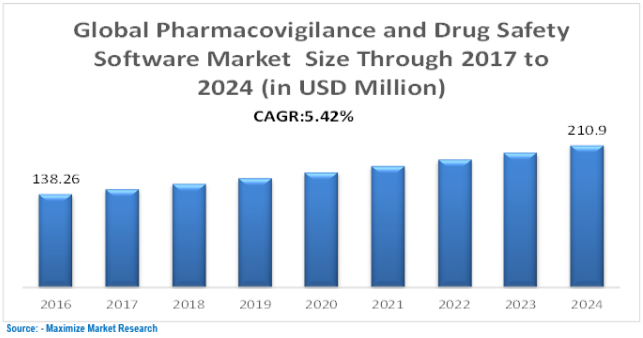
The role of pharmaceutical companies is to invest in the R&D of new compounds, have the commitment to bring a new drug to market to enhance the patients' health and quality of life, strict governance to conduct clinical trials, product development activities as well as conduct relations with patients and healthcare professionals in accordance with ethical and legal principles. A major pharmaceutical company, such as Astra, has over 100 permanent, experienced staff in pharmacovigilance within its R&D organization in Sweden and the United Kingdom, and a similar number in local operating companies worldwide. This development has been driven by the increased recognition of the role of pharmacovigilance, the investigation, and marketing of a wider range of diverse medicinal products and more stringent and detailed regulatory requirements.

Global Pharmaceutical Market 2019 Industry Research Report is a professional and in-depth study on the current state of the Global Pharmaceutical industry. This report studies Global Pharmaceutical in Global market, especially in North America, China, Europe, Southeast Asia, Japan and India with production, revenue, consumption, import and export in these regions, from 2014 to 2019, and forecast to 2025.

The global pharmacovigilance market size is expected to reach USD 11.64 billion by 2026, according to a new report by Grand View Research, Inc. It is projected to expand at a CAGR of 13.3% during the forecast period. Increasing incidence of Adverse Drug Reactions (ADR) is the key growth driver. The U.S. Food and Drug Administration (FDA) received approximately 253,017 serious adverse events and 44,693 deaths associated with ADRs in 2015. This shows the potential demand for implementing safety and Pharmacovigilance (PV) services.

According to the World Health Organization's (WHO) report on pharmaceuticals consumption, medicines to treat chronic diseases accounted for a larger proportion of the total volume of drug consumption in non-hospital set ups. Owing to this, there has been a significant rise in the number of medicines made available to healthcare consumers. Rising demand for drugs has significantly heightened the need for the development of novel therapeutics via extensive clinical trials, which is expected to serve this market with lucrative opportunities.





Major pharmaceutical companies are involved in extensive R&D initiatives for development of innovative therapeutic molecules. This has resulted in increased drug development activities. Manufacturers are now focusing on remodeling their product development processes in an attempt to cater to patient needs across the globe. These factors are anticipated to fuel the demand for pharmacovigilance services during the forecast period.

Moreover, leading pharma companies in developed countries are focusing on outsourcing PV service in an attempt to reduce cost and to minimize operational expenses. This is anticipated to serve as an opportunity for contact research organizations in developing regions to gain more revenue share.

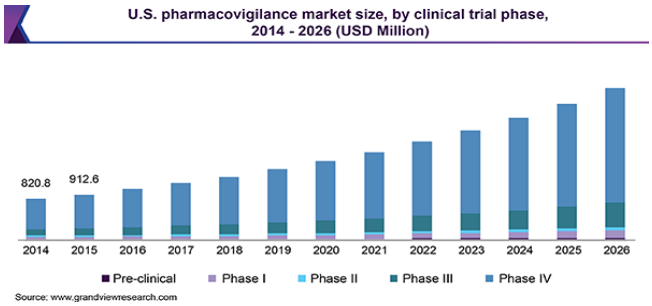
The companies operating in the pharmacovigilance market are undertaking strategic initiatives such as collaborations with the PV service providers to gain access to medical information and to manage PV workflows. For instance, In April 2017, Accenture entered in a collaborative agreement with BioCelebrate to develop a platform for aggregating and analyzing clinical information for improved drug developing efficiency, thus enhancing its R&D capabilities. These factors are anticipated to fuel the market growth.

Importance and Scope:

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The main purpose of pharmacovigilance is to improve the patient's safety and enhance his care in terms of the use of medicines, including paramedical interventions. Pharmacovigilance also supports public health programs by providing reliable information for the efficient assessment of the risk-benefit profile of medicines, contribute to the assessment of benefits, uses, side effects, harm, effectiveness and risk of medicines, encouraging the safe, rational and more effective (including cost-effective) use of various medicines. Promote education, understanding and clinical training in Pharmacovigilance and its effective availability to the public. Additionally, health regulatory authorities such as the U.S. FDA and EMEA (European Medicines Agency) are now emphasizing on electronic submission of data which is also expected to drive the pharmacovigilance market.

Pharmacovigilance Market, by Phases of Drug Development:

- Preclinical Studies
- Phase I
- Phase II
- Phase III
- Phase IV or Post Marketing Surveillance



Pharmacovigilance Market, by Type of Methods:

- Spontaneous Reporting
- Intensified ADR Reporting
- Targeted Spontaneous Reporting
- Cohort Event Monitoring
- EHR Mining

Pharmacovigilance Market, by Type of Service:

- In-House
- Contract Outsourcing

Target Audience:

- Pharmacovigilance Students, Scientists
- Pharmacovigilance Researchers
- Pharmacovigilance Faculty
- Medical Colleges
- Pharmacovigilance Associations and Societies
- Business Entrepreneurs
- Training Institutes
- Software Developing Companies
- Manufacturing Medical Devices Companies
- Data Management Companies

Association & Societies:

1. International Society of Pharmacovigilance & Drug Safety
2. Association of Clinical Research Professionals (ACRP)
3. American Association of Pharmaceutical Scientists
4. Association of British Pharmaceutical Industry
5. Society of Clinical Research Associates (SOCRA)
6. Canadian Association of Professionals in Regulatory Affairs Clinical Research Society (CRS)
7. European Association for Clinical Pharmacology (EACPT)
8. International Society of Pharmacovigilance (ISOP)
9. Pharmaceutical Information and Pharmacovigilance Association (PIPA)
10. Association of CROs Czech Republic (ACRO-CZ)
11. European Clinical Research Infrastructures Network (ECRIN)
12. European Society for Clinical Investigation (ESCI).
13. International Society of Pharmacovigilance: (ISOP)
14. Indian Society for Clinical Organization Research (ISCR)
15. Indian Society for Clinical Research
16. The Society of Clinical Research Associates
17. Association of Clinical Research Organization
18. Japan CRO Association (JCROA)
19. Pan-Asian Clinical Research Association (PACRA)
20. Central Society for Clinical and Translational Research (CSCTR)