



The Database of the Pharmacovigilance Programme of India

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DESCRIPTION

Pharmacovigilance (PV) plays an important role in healthcare systems through the assessment, monitoring and detection of drug-drug interactions and their effects on humans. Pharmaceuticals and biotechnology medicines are used to cure, prevent, or treat disease. However, there are also risks of serious harm to the patient, especially Adverse Drug Reactions (ADR). Therefore, to ensure drug safety, it is necessary to monitor his ADR for each drug throughout its lifecycle, including during drug development.

PV deals with ADR detection, assessment, understanding, and prevention. Pharmacogenetics and pharmacogenomics have become an integral part of clinical research. Variations in the human genome are responsible for various drug responses and determined disease susceptibility and are critical for early drug discovery of PV. Additionally, PV has traditionally been involved in mining spontaneous reports submitted to national surveillance systems. Research focus shifts to using data generated by the platform beyond the traditional framework. Examples include electronic medical records, biomedical literature, and patient-reported data in health forums. An emerging trend in PV is to combine premarket data with human safety information observed at the post market stage.

The solar plant team will receive valuable additional information that builds on the scientific data contained in the original report and makes it more meaningful. This requires maximum demand for effective regulation of the drug approval process and conscious pre- and post-approval vigilance against adverse effects, especially in India. Adverse events reported by the PV system

may benefit the community as they are closer in language and knowledge to both the general public and public health professionals, facilitating electronic communication with reporters. Therefore, PV is a joint responsibility of industry, drug regulators, clinicians, and other health professionals to improve their contribution to public health to aid in patient recovery and to optimally or ideally prevent disease.

Continuous monitoring of drug efficacy, side effects, contraindications, and full adverse effects that can lead to high levels of morbidity and, in some cases, even mortality is essential to maximize benefit and minimize risk. is essential to Despite all the precautions taken during the preclinical and clinical trial stages, absolute safety cannot be guaranteed when medicines are marketed and prescribed to large populations nationally and internationally. Because clinical trials involve up to thousands of patients, uncommon side effects and ADRs are often unknown when a drug is launched. Post-market PV uses tools such as data mining and case report surveys to identify relationships between drugs and ADRs.

Pharmaceutical regulatory authorities are responsible for having well-established PV systems for monitoring ADRs during the drug development stage and later during the commercial drug lifecycle. The practice of drug safety surveillance involves complex and important relationships among many partners, including: Governments, Industry, Health Departments, Hospitals, Universities, Medical and Pharmaceutical Organizations, Addiction Centres, Health Professionals, Patients, Consumers, and the Media. Continued cooperation and commitment are essential to solve future PV challenges, develop and thrive.

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Received: 29-Aug-2022, Manuscript No. PDS-22-18494; **Editor assigned:** 01-Sep-2022, PreQC No. PDS-22-18494 (PQ); **Reviewed:** 15-Sep-2022, QC No. PDS-22-18494; **Revised:** 22-Sep-2022, Manuscript No. PDS-22-18494 (R); **Published:** 29-Sep-2022, DOI: 10.35248/2167-1052.22.11.278.

Citation: Mohamed A (2022) The Database of the Pharmacovigilance Programme of India. *Adv Pharmacoepidemiol Drug Saf.* 11:278.

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