## Data management in pharmacovigilance

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The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, evaluation, understanding, and prevention of adverse reactions to medicines or any other medicine-related problems. In 1893, *The Lancet* first reported an established drug safety reporting system for suspected adverse drug reactions (ADRs). Since then, the definition and scope of pharmacovigilance have evolved as a systems approach. Pharmacovigilance is a highly sensitive field as it involves monitoring of the safety of medicines and taking action to reduce risk and increase benefit. The pharmacovigilance data management starts with the data collection and, it is imperative to address the report origin, triage cases, enter information in drug safety database, make medical assessment, request report follow-up information and mode for regulatory submissions. All these stages require a high and complex degree of technical skill and judgment to ensure that accurate conclusions and right decisions are made during the establishment of benefit-risk profile for a product. A poor pharmacovigilance data management not only jeopardizes patient safety, it also increases the risk of investing in the development of wrong product which causes a huge loss to a pharmaceutical company. Therefore, it is very important to establish a robust pharmacovigilance data management system which complies with the stringent regulatory guidelines, global pharmaceutical norms and ultimately safeguard the pharmacovigilance end users, the patient. An ideal model would be implementation of business management software (e.g. Microsoft Dynamics NAV/SAP ERP) for better data management, process harmonization, enhanced data security and reduction in delay due to high manual dependence.

### Biography

Ajay Francis Christopher, MSc (Molecular Biology & Biochemistry from Guru Nanak Dev University, India) served as PV Scientist, Senior Quality Scientist and Subject Matter Expert-PVQA for blue-chip pharmaceutical companies at a premier CRO in India. He has one Young Scientist Award and various appreciation awards to his credit. He successfully led various international projects (global transition in narrative writing for regulatory submission, customization and validation of Oracle Argus Safety 5.0.2, etc). He has published and presented research articles on microRNA expression in medulloblastoma and gliomas, plasmid profiling, unique mutations in beta-thalassemia and presently working on miRNAs targets of herbal extract with potentials of anti-cancer drug.

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**Notes:**

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Page 42