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Role of risk management in pharmacovigilance

Manjunath H
Jagadguru Jayadeva Murugarajendra Medical College, India

The Risk management system is a set of Pharmacovigilance activities and interventions which are designed to identify, assess and prioritize minimize the risk of a medicinal product throughout its life cycle to improve its benefit/risk balance. The basic principle of risk management is to confirm that the benefits of a medicinal product exceed the risk by an achievable margin for the patient or to a target population as a whole. Despite Risk Management Plans (RMP) and Risk Evaluation & Mitigation Strategies(REMS) were originally created to attain stability and coordination during the post-marketing period for benefit of risk assessment and risk minimization,but now they are considered as part of Pharmacovigilance planning. Effective Pharmacovigilance planning includes safety specification, risk minimization and monitoring of the effectiveness of risk management, in which safety specification forms the basis. Pharmacovigilance can minimize the risks through interventions and communicating the risks to patients and health care providers. Along with this, additional Pharmacovigilance events like active surveillance, maintenance of patient registries, restricted access, specialized training, epidemiological trials, post authorisation safety studies and post authorisation efficacy studies may be included in the plans for better risk management. These measures might suffice in minimizing the harm and overall increasing the benefits against the risk. Hence by implementing the Risk management systems, various adverse effects of the medicinal product can be identified throughout the product life cycle.

Biography

Manjunath H has completed his MBBS from SS Institute of Medical Sciences and Research centre, Davangere and he is now pursuing his PG Pharmacology in JJM Medical Davangere. At present he is involved in three research paper.

drhmanjunath@gmail.com