World Academy of Science, Engineering and Technology
International Journal of Pharmacological and Pharmaceutical Sciences
Vol:13, No:11, 2019

A Review of Benefit-Risk Assessment over the Product Lifecycle

Authors : M. Miljkovic, A. Urakpo, M. Simic-Koumoutsaris

Abstract : Benefit-risk assessment (BRA) is a valuable tool that takes place in multiple stages during a medicine's lifecycle, and this assessment can be conducted in a variety of ways. The aim was to summarize current BRA methods used during approval decisions and in post-approval settings and to see possible future directions. Relevant reviews, recommendations, and guidelines published in medical literature and through regulatory agencies over the past five years have been examined. BRA implies the review of two dimensions: the dimension of benefits (determined mainly by the therapeutic efficacy) and the dimension of risks (comprises the safety profile of a drug). Regulators, industry, and academia have developed various approaches, ranging from descriptive textual (qualitative) to decision-analytic (quantitative) models, to facilitate the BRA of medicines during the product lifecycle (from Phase I trials, to authorization procedure, post-marketing surveillance and health technology assessment for inclusion in public formularies). These approaches can be classified into the following categories: stepwise structured approaches (frameworks); measures for benefits and risks that are usually endpoint specific (metrics), simulation techniques and meta-analysis (estimation techniques), and utility survey techniques to elicit stakeholders' preferences (utilities). All these approaches share the following two common goals: to assist this analysis and to improve the communication of decisions, but each is subject to its own specific strengths and limitations. Before using any method, its utility, complexity, the extent to which it is established, and the ease of results interpretation should be considered. Despite widespread and long-time use, BRA is subject to debate, suffers from a number of limitations, and currently is still under development. The use of formal, systematic structured approaches to BRA for regulatory decision-making and quantitative methods to support BRA during the product lifecycle is a standard practice in medicine that is subject to continuous improvement and modernization, not only in methodology but also in cooperation between organizations.

Keywords : benefit-risk assessment, benefit-risk profile, product lifecycle, quantitative methods, structured approaches
Conference Title : ICCPP 2019 : International Conference on Clinical Pharmacology and Pharmacovigilance
Conference Location : Rome, Italy
Conference Dates : November 11-12, 2019