Pharmaceutical Risk Assessment and Predictive Enrichment to Maximize Benefit and Minimize Risk – Issues in Product Life Cycle Evaluation

Robert T. O'Neill*, U.S. Food and Drug Administration

Abstract

Human exposure to medical products, food additives, health supplements, and virtually any environmental agent carries with it a need to assess the risks associated with the benefits afforded by these exposures and uses. This conference is about risk assessment and risk prediction, a broad methodological topic with many subject matter applications. This talk will focus on FDA's response to a variety of safety issues in the pharmaceutical arena that have received broad public attention in the last few years and on the extremely important role that statistics is playing and will play in shaping the nation's future systematic approach to addressing the many facets of medical product quantitative risk assessment and management. The emphasis will be on the life cycle evaluation of risk which includes the pre-market assessment of risk and the post-market or post-approval period of medical products as they are used by populations of all ages and ethnicities, alone and in combination, for short and for very long periods of time. Additionally, the advent of the genomic revolution , the interest in personalized medicine and the search for predictive biomarkers to aid patient selection and treatment strategies has also opened up many methodological challenges for which statistics can substantially support. Clinical trial study designs to evaluate targeted therapy and enrich study populations are a major focus of this area. This talk will touch on both of these areas from the perspective of pharmaceutical development and evaluation.

* Presenting author