

Benefit-risk balance and signal detection in the eyes of the stakeholder

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Abstract

The need to achieve maximum benefit and assume the least harm had been the mainstay for human survival. The integration of all variables including new information in any decision-making is the reason for human successful evolution. Translating this in drug business language: the perception of benefit-risk (B/R) balance, which is continuously impacted by new signals (SD), is the essence of deciding on adopting any therapeutic modality. In the drug development process, a positive benefit-risk (B/R) balance is the most desired outcome on the minds of all stakeholders (pharmaceutical industry, health care providers and regulatory agencies and most importantly patients). The main element that can influence such balance is the outcome of the ongoing processes of signal detection (SD). However, the main challenges are in the differences in “perception” of such B/R balance in the eyes of each of the stakeholders in addition to the lack of consistent/transparent methodology in achieving regulatory decisions regarding B/R. The examples for such differences are worth contemplating and the need to have a consistent transparent yard stick by regulatory agencies accelerated in the last 7 years and resulted in a public law in 2012. The good news is that a real life example was delivered ahead of schedule. This speech will attempt to discuss many of the relevant points to the evaluation of these basic, yet complicated, concepts of S/D and B/R balance.

Biography

Ashraf Youssef is the president and founder of AYPharma Safety Consulting. Its vision is adding value through knowledge of drug safety and its mission is to provide services that enhance the process of drug approval with focus on all aspects of safety. He had moderated panels and presented workshops on signal detection, safety in drug development and in-licensing integrating his expertise and knowledge in clinical and non-clinical safety as well as business. He has > 20 years of drug safety experience, has authored multiple publications, taught graduate and postgraduate levels at Cairo University, Egypt and University of Illinois in Chicago. He received his medical and Ph.D. degrees from Cairo University, Egypt and his post-graduate training at University of Rochester, NY. He is board certified in Toxicology and earned an MBA from Lake Forest Graduate School of Management, IL.

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