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Challenges in benefit-risk evaluations during co-development among partnerships and alliances

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Abstract

The significance of partnerships during the process of drug development cannot be overemphasized. However the challenging issues in managing safety-related issues among partners/alliances are more than the sum of each partner's issues and at many occasions are more significant than challenges in other areas of collaboration. This presentation aims to review approaches affecting the multiple processes, agreements and models during co-development. It reviews expectations by regulatory agencies and recommendations for best practices in managing safety issues among partners/alliances.

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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