Risk management life cycle approach – key points

The health authorities’ activities are targeting public health protection from the harm of used medicines, emphasizing their role in medicines risk assessment. Such achievement requires optimization of their collaboration with industry, addressing criticalities. The interactions with the involved stakeholders have a pivotal role where transparency during assessment of medicines’ benefit–risk profile throughout its life cycle should be ensured. Structured benefit/risk assessment framework earlier in drug development is challenging for medicinal products approval that necessitate positive benefit-risk balance parameters. At the end, the key question is “Do the health authorities’ interactions with patients and healthcare professionals have a beneficial impact on the taken decision”?

Biography

Essam Ghanem is an experienced Physician and qualified person for pharmacovigilance with almost 25 years of experience in Clinical Research and Drug Development at academic institutes, pharmaceutical industry and clinical research organizations. He has eight years of working experience as EUQPPV and as Consultant Safety Physician in the pharmaceutical industry. He is the Founder of the pharmacovigilance consultation company Vigi-Care BVBA. Currently, he is Head of Drug Safety and Pharmacovigilance at Keyrus Biopharma.

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