Internal safety advisory groups: A win-win for effective decision-making in biopharmaceutical companies

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Introduction: Optimization of drug safety is a comprehensive process, critical during the entire lifecycle of a product. Signals of drug-induced toxicity must be detected early and evaluated expeditiously with patient safety at the forefront.

Objective: The primary objective of the Internal Safety Advisory Groups (ISAG) is to provide consistent, timely and objective review of safety data to determine a signal and to provide guidance regarding timely, scientifically accurate and effective communications with regulatory agencies, investigators, healthcare providers and patients.

Method: ISAGs assessed signals and recommended next steps. The advisory groups maintain metrics by comparing their recommendations to those from external experts and regulatory authorities.

Result: The ISAGs, led by multidisciplinary experts within AbbVie, evaluated over 20 products/programs over the course of a year and provided recommendations in the following areas: Evaluation of the impact of animal data in subsequent clinical trials, dosage adjustment in phase 1 and 2 clinical trials, determination of drug induced toxicity in single or multiple cases, pausing a clinical trial for a drug toxicity, review of integrated summaries of safety, recommendations for labeling language, appropriate placement of risk in a risk management plan, risk mitigation strategies, medical safety assessments in post marketing setting, guidance for regulatory responses. Metrics have, to date, demonstrated a remarkable consistency with ISAG recommendations. ISAGs also guide the organization regarding consistency in data collection and best practice statistical analytic methods.

Conclusion: ISAGs have provided AbbVie with a wealth of expertise that is immediately available, efficient and objective. These internal experts also convey expertise available in the scientific community for further advice on safety matters. Together, internal and external experts effectively collaborate and share experiences while interacting with regulators to advance the science of safety. This efficient and effective decision-making is a win-win for both patients and companies.

Biography

She is working as a Therapeutic Area Head (Infectious Diseases, Neurosciences, Men and Women's Health, Pharmacovigilance & Patient Safety, AbbVie. She served as a Medical director at Abbott Laboratories (2010-2013). In 2001, she worked as a Adjunct Associate Professor of medicine in Duke University Medical Center. M.B.B.S., Nagpur University (India), 1979 She did her M.D in Nagpur University (India) in 1984.

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