Ujwala V Salvi, J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

PVG and drug safety- pharmacovigilance in India and emerging markets: An industrial perspective

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Development and implementation of evidence-based, public-health focused, collaborative, globally electronic and regulatory compliant approach is need of hour to gain comprehensive Pharmacovigilance (PV) system. The authors discuss development of a model for uniform PV data input-output across industry. Authors contemplate data collection; data analysis; data processing; medical review and data distribution systems as basic PV process. Data collection systems should include detailed process of collecting various adverse events (AEs) from literature searches, healthcare professionals (HCP), non-HCP, spontaneous, clinical trials, patient registries, post marketing surveillance etc. Data should be processed in CIOMS form I by using ARGUS, ARISg, MedDRA, WHO drug dictionary and company drug repository or local regulatory AE form, etc. It should be medically reviewed followed by distribution to respective regulatory authorities where thorough signal identification, prioritisation and investigation will be performed. Signal detection can be done by using Medline/PubMed, Springer, OVID database, reactions weekly, local publications etc. Non-english cases/literature reports should be translated to english via authorised vendor or in-house translation system. Safety data from license partners and third party manufacturers should be collected and processed by maintaining safety data exchange agreements (SDEA). PV model can be fully in-house end to end or part in-house and part outsourced or fully outsourced. In conclusion, an effective implementation of PV activities like robust PV systems, signal detection and SDEAs could definitely yield robust patient safety data from India and emerging markets.

Biography

Ujwala V Salvi has over 15 years of experience across the globe and local Pharmaceutical/CRO, tier I Medical Devices and BPO industry. She has an MBA from Indian Institute of Management, Kolkata and Doctorate in Applied Biology. She is trained in Six Sigma Black Belt and various project management tools, with core experience in a wide range of therapeutic areas, and worked at all stages of clinical development from Phase II to production of clinical documentation necessary for product license applications. She has worked in large global operations, managed strategic relationships, and played a key role in winning new business, setting up off-shored partnerships and in identifying new BU service lines and growing existing ones. Her areas of expertise include clinical trial operations, risk based monitoring, medical writing and data publication, clinical data management, and feasibilities of new drug development and analytics. She is an industry expert, has been involved in key global industry forums such as the DIA, SCDM, CII and CPHI.

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