

Integrating regulatory drug label information to facilitate evaluation of adverse events in pharmacovigilance

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Pharmacovigilance (PV) is the science and activity in detection, evaluation, and management of Adverse Events (AE) reported for medicinal products. In either clinical trials or post-marketing surveillance, qualitative and quantitative methods have been developed to identify the AEs that are associated with the target drug, and further evaluations are carried out to determine whether the drug has likely caused the AEs before decisions can be made on the management of them – once confirmed, an AE is termed Adverse Drug Reaction. This process which requires expertise from trained scientists and physicians is very resource intensive because there are often many AEs in a study case or spontaneous individual case safety report, as well as many interfering Concomitant Medications (CM) that might have contributed to the reported AEs. This article introduces a systemic approach to extract those case CMs that are Known Implicating Medications for each AE according to public regulatory information from drug labels – FDA Structured Product Labeling or EMA Summary of Product Characteristics. This makes critical information readily available for users to discern possible interferences from CM and make informed decisions on the evaluation of the AE – saving time while improving quality. In the future, it's expected that this concept and automation will be fully integrated into commercial signal detection and management software packages so that they will be easily accessible and may even lead to reduced False Positive rate in signal detection for PV industry.

Biography

Zhou (Tom) Hui has a MD in Clinical Medicine from Nanjing Medical University and MS in Biomedical Engineering from University of Texas Southwestern Medical Center at Dallas. He is a Senior Principle Scientist – Medical Safety at Takeda, a premier pharmaceutical company. He has published 2 papers recently in the field of Pharmacovigilance and Productivity Management.

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