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Artificial intelligence in pharmacovigilance (A big wave)

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In today's world of empowered patients and increased attention to drug safety, role of pharmacovigilance has never been more crucial. Pharmacovigilance processes, however, are traditionally highly manual and resource intensive. As such, adverse events are reported across the globe in multiple languages and formats and in structured, unstructured and handwritten documents from affiliates, partners and distributors. In addition, companies scan scientific literature to identify, extract and capture additional adverse event-related information. Typically, large pharma companies receive anywhere from 300,000 to 500,000 adverse events a year. Although automation incorporating artificial intelligence (AI) has been used in other industries, the nature of AE case processing is comparatively complex, and no providers currently offer a comprehensive AE case processing solution. Most companies had started automation journey by building RPA-based bots that automate data extraction from documents and enter it into the safety system. Implementing *robotic process automation*, human can involve into more creative task instead of doing data entry, reduced training cost- trained once and used for ever in lifetime, process life cycle (RPA will run 24*7), benefit cost saving- leads to reduced case processing costs, 20% to 50%, increased speed of signal detection & improvised quality – it works without any error. It is feasible to use AI-based technology to support extraction from AE source documents and evaluation of case validity. In addition, it is viable to train the machine-learning algorithms using the safety database data fields. It is imperative for all stake holders industry, service providers and regulators – to provide an environment in which such a transformation can take place without ever compromising safety of the individual patient, and ideally providing additional benefit for patients and thus utilizes modern technology to capture and analyze new sources of medical information that will transform the current reactive system into a more proactive risk benefit management system.

Recent Publications

1. Navitas Life Sciences PVNET Benchmark Survey 2016.
2. Segura-Bedmar, I. & Martinez, P. Pharmacovigilance through the development of text mining and natural language processing techniques. *J. Biomed. Inform*
3. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/
4. Botsis, T., Nguyen, M.D., Woo, E.J., Markatou, M. & Ball, R. Text mining for the vaccine adverse event reporting system: medical text classification using informative feature selection. *J. Am. Med. Inform. Assoc.* 18, 631–638 (2011).

Biography

Sunil Nighot had completed his master's in pharmacology from the Mumbai university in 2008. Sunil worked as Quality & Compliance lead in Johnson & Johnson and work in Pharmacovigilance team for Individual case safety reports. He had more than 10 years of experience in pharmacovigilance and consider as pharmacovigilance subject matter experts. He is deeply involved in the automation and read multiple articles on artificial intelligence, Robotic process automation and machine/deep learning. Attended multiple pharmacovigilance conferences in India and learn more about the automation part in pharmacovigilance. Currently collaborating with the vendors to implement Robotic process automation within the process to reduce the case processing costs.