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Data analytics in Pharmacovigilance

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Pharmacovigilance (PV) is one of the most critical activities of any pharmaceutical organization. From the perspective of data analytics - Pharmacovigilance is a storehouse of actionable insights. If we could apply data analytics in a meaningful way to PV data -we would definitely generate highly actionable insights. We have PV Case data on one hand and PV Organization, operational data at the other. We could utilize both types of data to an organization's maximum benefit. PV Case data could be mined for Signal Detection and PV organizational data could be analyzed to achieve operational efficiencies. "Signal detection is the act of looking for and/or identifying signals using event data from any source". Spontaneous Reporting Systems (SRSs) constitute the dominant source of signals through which suspected cases are voluntarily reported by healthcare professionals (and lately patients) to regulatory authorities and other bodies. Prominent SRSs are the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS1) of US, EudraVigilance maintained by the European Medicines Agency and VigiBase3 maintained by the Uppsala Monitoring Center of the World Health Organization (WHO-UMC). PV Data Analytics could be done through any of the following tools depending upon the skill set of the user - Excel, VBA Macros, R, SAS, SAS JMP, and Tableau etc. Different sorts of Visual Dashboards could be prepared. The data sources could be - Company Internal Data, FDA AERS Data etc. Data Mining could also be done on safety databases like ARGUS Safety Database. Data Analytics could very well be applied on Social Media data. Mining of Adverse Event data from social media has its own set of problems for e.g. problem of structured vs unstructured data, the validity of data, intentions and data aggregation. Thus, PV Data analytics / visual analytics could provide us meaningful inferences which could be used to deduce highly actionable insights. These actionable insights may lead to increased operational and performance efficiencies.

Biography

Amit Srivastava has more than 10 years of experience in IT industry. He has worked on the tech side of Pharmacovigilance for clients like Novartis, Merck and Otsuka - both in India and US. He is currently pursuing a certificate program in Business Analytics from IIM Lucknow and is working full time with his startup Infocorp Solutions.

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