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Social media and public database usage for prediction of serious adverse events (SAE'S) and adverse events (AE'S)

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Signal Detection using public healthcare databases like Vigibase from WHO, Eudravigilance from EMA and AERS from FDA that intend to open up for public access with Open FDA guidance effective from June 2014 and social media usage guidance from FDA for capturing AE's/SAE's are the next generation safety database management measures that biopharmaceutical and medical device companies are looking forward. ADR reporting is a reactive approach currently, once a AE/SAE happens that gets reported to regulators instead way forward it would be a proactive approach of detecting the possible AE's/SAE's from public databases and reporting to regulators that would in turn prevent mortality and morbidity rate would be useful for well being of the society and pharmaceutical industry globally.

Biography

Siva Rama Krishna Sidda is the Subject Matter Expert (SME) in Research & Development space member of Tech Mahindra Healthcare & Life Sciences Practice, an information technology enabled service (ITES) provider that focuses on Drug Safety, Regulatory Affairs and other support services in Clinical Research & Allied Services. He has a Masters Business Administrator (MBA) and Advance Program in Strategic Management (APSM) from Indian Institute of Management-Calcutta (IIM-Calcutta) and over 11 plus years of experience in the healthcare industry prior to Tech Mahindra, Siva Ram was Vice President responsible for Asia Pacific operations with Oracle partner company and even was responsible for operations at SAS partner company. He has several non profit bodies professional memberships like IASCT (Indian Association for Statistics in Clinical Trials), DIA (Drug Information Association), ISCR (Indian Society of Clinical Research Professionals) and has association with many more like RAPS, SCDM, ACRP etc.

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