

3rd International Conference and Exhibition on Pharmacovigilance & Clinical Trials

October 27-29, 2014 Hyderabad International Convention Centre, India



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Hosted pharmacovigilance software databases - The emerging solution

Electronic reporting of adverse events to regulatory authorities is gradually becoming mandatory across the globe. It is evident that electronic reporting is beneficial in many ways. However, initial in-house implementation and ongoing maintenance of a comprehensive pharmacovigilance system are expensive, especially for smaller organizations which face an additional issue of unavailability of competent support personnel required to manage the complex information technology infrastructure involved. Further, it takes a lot of time and expertise to implement a traditional drug safety database in any organization. All these aspects put together tend to limit pharmacovigilance databases to large global pharmaceutical companies alone. Nevertheless, pharmacovigilance obligations are the same for all companies in a given market irrespective of their adverse event load. It is here that, hosted 'Software as a Service' (SaaS) model presents itself as the solution to make pharmacovigilance affordable for all companies. A hosted system offers everything that a conventional pharmacovigilance database offers, without its system overheads but with added advantages of secure access from anywhere over the Internet and the minimal cost implications for its set up and maintenance. Although a hosted system has its limitations of a perceived lack of data security and a lesser degree of software customization, they can be overcome by choosing the right service provider. To conclude, hosted pharmacovigilance systems have now emerged as the preferred inexpensive yet robust solution for organizations to comply with the regulations they are obligated to, without incurring huge fixed and recurring costs pertaining to the infrastructure and human resources needed to install and ensure the performance of a traditional pharmacovigilance software database.

Biography

J Vijay Venkatraman is a Diabetologist, Drug Safety Physician and Entrepreneur. He is the Founding Managing Director & CEO of Oviya MedSafe - a global Pharmacovigilance Consulting and Drug Safety Services Company based in India since 2012 and in the UK since 2014. He is an avid speaker in both national and international conferences and has published several articles in journals. He is an active promoter of Pharmacovigilance regulations for India.

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