

Enabling Technologies for better Signal Detection and Management

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Since their inception more than 20 years ago, signal detection technologies have seen an ongoing evolution. Initially, the focus was on statistical algorithms that can deal with large safety databases and effectively find lists of potential signals to evaluate. During the recent decade, the emphasis shifted to formalizing the process for managing signals and documenting compliance; detection algorithms moved out of the attention a bit up to a point where the choice of the algorithm was considered irrelevant. Recent research, however, is confirming that tailored statistical methods play an important role in optimizing signal detection performance and reducing false positives. Machine learning approaches can model even more complex effects, and provide the opportunity to incorporate additional non-clinical data sources for predictive signaling. This presentation explores new trends in signal detection and management, reviews the current state-of-the-art for using multiple safety data sources and maintaining GVP compliance effectively, and provides highlights from current research topics and the power of applying ML in the signaling space.



Biography

Robert Weber is Product Management Director in the Oracle Health Sciences Global Business Unit. His responsibilities include the Empirica Signal Detection and Management products in the Oracle Pharmacovigilance suite. Robert works with regulatory agencies, key industry partners and research organizations to provide direction and manage priorities for the Oracle Safety products, define areas for enhancements and identify new solution opportunities.

Robert Weber is a qualified physician with practice background in neurology. He has worked since 1995 in the area of drug development, clinical research and pharmacovigilance. Earlier positions included Senior Manager and Principal Consultant at PAREXEL International, a contract research organisation, in Berlin and London; Senior Project Manager at DocCheck Medical Services in Cologne; and Principle Consultant at Phase Forward's Lincoln Safety Group.