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AI Tools in Pharmacovigilance (PV): FDA's InfoViP paradigm and lessons learned

TRENDING TOPICS

AI tools in PV, such as InfoViP, are decision-support tools that help, but do not replace, regulators' safety evaluators.

To support post-marketing safety surveillance, FDA's CDER Office of Surveillance and Epidemiology (OSE) has recently developed the Information Visualization Platform (InfoViP). InfoViP incorporates artificial intelligence (AI) and advanced visualizations to support OSE safety evaluator's (SE) examination of data or content to identify insights, predict or generate recommendations.

FAERS contains millions of individual case safety reports (ICSR) including mandatory safety reports from regulated industry such as pharmaceutical companies and voluntary MedWatch reports from patients and health care professionals. After the reports are submitted, OSE SEs analyze ICSRs to identify whether the reported AEs might be caused by the medical treatment.

The large and increasing volume of ICSRs makes it difficult for SEs to efficiently detect and evaluate safety concerns. Some ICSRs may have sufficient information while others lack clinically relevant details needed to assess causality. FAERS also contains duplicate ICSRs describing the same patient and AEs that patient(s), pharmaceutical company representatives independently submit. These challenges led OSE to consider AI technologies.

InfoViP was developed as a decision-support software tool to assist SEs, analysts and decision makers in making smarter decisions. InfoViP incorporates natural language processing (NLP) capabilities, machine learning (ML) and advanced data visualizations (ADV).

The InfoViP system uses context-driven interactive visualizations and informatics tools to assist safety evaluators in synthesizing data from multiple sources for their case series analyses.

Challenges	Solution by InfoViP's
SE's manually review ICSR narratives to identify and extract clinical concepts relevant to post-market safety surveillance.	**NLP technology** introduces the capability to automatically scan narratives to find and visually display relevant clinical information. NLP automatically identifies information from ICSRs to create a timeline of events, including when the drug was taken in relation to the AE.
The current, manual process of finding high-quality ICSRs is time intensive.	**ML approach** reduces the time to find high-quality ICSRs. It can simultaneously look at multiple data points in each ICSR and classify them based on their level of information quality. SEs can use this classification to triage high-quality ICSRs for priority review to detect safety concerns more rapidly.
Automatic substitution decisions allowed at pharmacy level	**NLP-based "deduplication" algorithm** can efficiently scan, extract and compare numerous data points to detect duplicates automatically and present them to SEs for confirmation.

InfoViP shows that there is a need to develop AI tools with an inherent "human-in-the-loop" component, so that human experts can understand and validate the quality of the tools' outputs.

At **PrimeVigilance**, we are evaluating new avenues and we always try to harness reliable technology which has been validated by regulators, as we believe that we face almost identical challenges.

References:

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