

Towards linking pharmacovigilance evidence sources with clinical data using an open scalable architecture - LAERTES

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Abstract

Marketed drugs need to be monitored for public safety but the required evidence is stored in numerous disjointed sources. The current practice of reviewing this information is a highly manual time-intensive process wrought with opportunity for failure. Integrating multiple sources of evidence has been shown to have value for signal detection and existing frameworks have integrated various sources. However, none are both specifically designed to support regulatory and clinical use cases, and developed as an open architecture that would allow an interested scientist to add new sources. An OHDSI system called Large-scale Adverse Effects Related to Treatment Evidence Standardization (LAERTES) addresses this issue. LAERTES provides an open architecture can be extended to include many different sources. It leverages the OMOP Vocabulary to translate those sources to one terminology for drugs and one for conditions. At the time of this writing, five evidence sources have been loaded. Web API services are available that integrate LAERTES into a larger software environment provided by the OHDSI clinical research framework. We are currently designing a user interface for LAERTES to meet the needs of pharmacovigilance investigators corroborating spontaneously reported adverse events against known facts.