Role of Electronic Healthcare Database in the process of drug safety signal management

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In the recent years, a growing number of ongoing international research networks (e.g. Sentinel, OMOP, EU-ADR, PROTECT, ARITMO, SAFEGUARD, VAESCO etc.) have been set up by combining multiple electronic healthcare databases for the conduct of active surveillance studies in the area of drug and vaccine safety. The rationale for combining multiple healthcare databases is the earlier detection, strengthening and confirmation, and hence earlier management, of potential drug safety signals by augmenting statistical sample size and heterogeneity of exposure. Several technical challenges however are encountered when combining multiple healthcare databases, especially at European level, due to differences in the underlying healthcare systems, type of information collected, drug/vaccine and medical event coding systems, and language. In recent international projects several approaches have been developed for the harmonization of medical data extraction through homogeneous coding algorithms. Another challenge is the choice of the best performing work models for data management and analyses while respecting country-specific regulations concerning data privacy and anonymization.

The aim of this presentation is to provide an overview about benefits, pitfalls, and methodological challenges concerning the conduct of post-marketing multi-database drug safety studies, as documented in several European international initiatives.