Background

The EU-ADR Alliance is a network of EU-based researchers and databases set up to conduct real-world evidence studies to evaluate short- and long-term drug safety in clinical practice, the effectiveness and safety of drugs in specific populations, drug utilisation, and health outcomes research.

The EU-ADR Alliance was established in 2013 built on the results of the EU-ADR project “Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge”.

Principles and membership

The network is based on the concept of federated databases, non-competition with its members, independence and scientific interest. Initially, there were eight research centres from five EU countries (the Netherlands, UK, Denmark, Italy and Spain) participating in the EU-ADR Alliance, and the network is progressively expanding to new databases and countries. Source data are routinely collected data from electronic health records (primary care databases, dispensing records and hospital linkage) and additional linked data sources. The EU-DR Alliance databases include over 21 million of active patients, enabling us to access a broad range of participants including paediatric populations.

Since 2013, eight observational studies have been conducted in the respiratory, musculoskeletal and cardiovascular fields, resulting in different publications and conference presentations.

Procedures

The EU-ADR Alliance studies follow a standardised structured process which has been validated during more than five years of experience. A number of instruments and methods have been developed for data curation and analysis. The EU-ADR Alliance researchers actively explore methodological opportunities and challenges that arise in this distributed pharmacoepidemiology network. The methodological challenges encountered in the course of these studies were recently analysed during a bespoke workshop organised by the EU-ADR Alliance network.

Conclusions

The EU-ADR Alliance provides an unprecedented amalgamation of expertise with a solid governance structure and tested working methods allowing to run centralised powered studies and produce clinically meaningful results, thus generating valid and reliable evidence. Furthermore, the network has a capacity to investigate challenges for methods research in pharmacoepidemiology using distributed data. Given the recent incorporation of new databases and increase request for the research questions, the need for methodological innovations will continue to grow.