SALUS

Post market safety surveillance is dependent on reports of adverse drug reactions written by healthcare professionals and patients. To support observational studies of medication problems more sources of data are often needed.

Goal

- Develop a framework for large scale screening to find side effects in distributed observational data sources
- Faster completion of individual case safety reports by utilizing available information in the observational data about the patient
- Link case safety reports to the observational data to allow absolute reporting rates to be calculated and provide additional information about the medical history of the patient

Motivation

Post market safety surveillance is largely dependent on reports of adverse drug reactions written by healthcare professionals and patients. To support observational studies of medication problems more sources of data are often needed. These sources have individually too few patients to study rare problems and all have different data models making method development difficult. With the Sentinel (http://www.mini-sentinel.org/) and OHDSI (http://www.ohdsi.org/) initiatives a push for creating a common data model for secondary use of electronic health records has been made.

Using the strengths of the different data sources, a more effective safety surveillance can be accomplished. An anonymized connection between patients in the electronic health records and the adverse drug reaction reports would give important insights into the course of the disease and enable safety assessors to make better decisions.

Our role

Using the open source tools that we had developed and evaluated in the OHDSI project we were able to adjust them to the SALUS framework to enable large scale screening of electronic health records.

We advised in the development of the system created for the detection of adverse drug reactions for single patients in the electronic health records.

We advised in the development of the system to create adverse drug reaction reports. These reports are sent to the regulatory authorities in the country where created and the country later sends the reports to the WHO programme for international drug monitoring.

Partners

1. SRDC
2. Eurorec
3. Uppsala Monitoring Centre
4. OFFIS
5. AGFA Healthcare
6. Electronic Record Services
7. Lombardia Informatica
8. INSERM
9. Technische Universitaet Dresden
10. F. HOFFMANN-LA ROCH