



Early Detection of Adverse Drug Events by Integrative Mining of Clinical Records and Biomedical Knowledge

ALERT aims to develop and use advanced ICT technologies for demonstrating new ways to exploit the existing wealth of clinical and biomedical data sources for the early detection of Adverse Drug Reactions (ADR).

In this project, an alternative approach towards the detection of ADR signals will be developed with the objective of overcoming the shortcomings of spontaneous reporting databases and providing a solid basis for large-scale monitoring of drug safety. In **ALERT** a systematic calculation of the occurrence of disease (potentially ADRs) during specific drug use will be based on data (time-stamped exposure and morbidity data) available in electronic patient records.

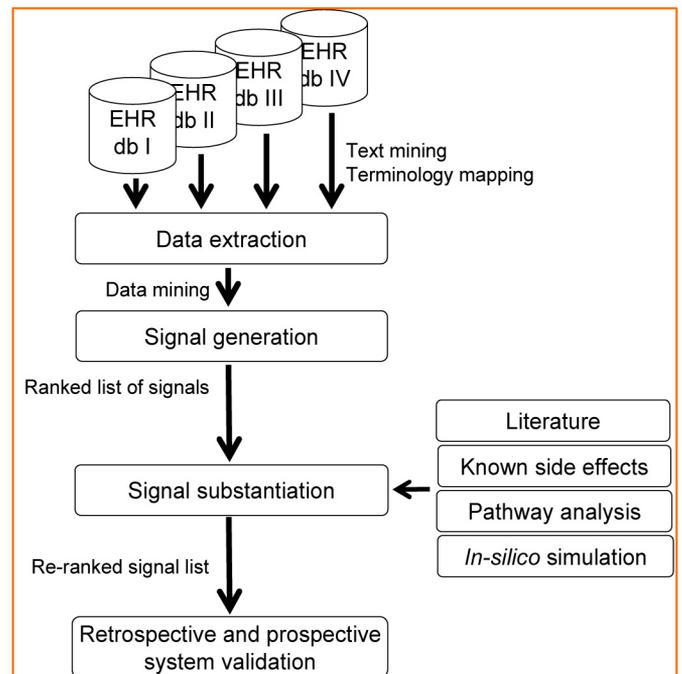
Special attention will be given to patient groups that are not routinely involved in clinical trials, for ethical or practical reasons (e.g. pregnant women, elderly people, people using many drugs simultaneously, and children).

Once generated, the signals will be substantiated by applying causality criteria (biological plausibility, known reactions). The purpose of this substantiation process is to place the signals in the context of the current biomedical knowledge that might explain the signal. Essentially, **ALERT** will be searching for evidence that supports causal inference of the signal.

The **key challenges** to accomplish the **ALERT** objectives are:

- Federation of different databases of electronic medical records in order to create a large-scale resource for monitoring adverse events. In **ALERT** eight databases containing medical records of more than 30 million European citizens are involved.
- Exploitation of European diversity for routine drug monitoring.
- Evaluation on a realistic scale of data mining techniques.
- Automated exploitation of biomedical knowledge and bioinformatics approaches to reduce the number of spurious signals.

- Development of a computerized system that, compared with spontaneous reporting systems, provides the capability for earlier detection of ADRs.



The **main outcome** of **ALERT** is to demonstrate that an earlier detection of adverse side effects of drugs is possible by using modern biomedical informatics technologies to efficiently exploit both the massive amounts of available electronic health records (EHRs), and the ever-increasing biological and molecular knowledge. The project should demonstrate that scientific and clinical evidence can quickly and directly be translated into patient safety and, thus, health benefit.

ALERT is carried out by an interdisciplinary team of researchers carefully selected by their scientific expertise and complementarity.

- Erasmus University Medical Center, Department of Medical Informatics, Netherlands. EMC. *Project Coordinator*.
- Fundació IMIM, European Projects Management Office, Spain. FIMIM
- Universitat Pompeu Fabra, Research Unit on Biomedical Informatics, Spain. UPF
- University of Aveiro – IEETA, Portugal. UAVR
- IRCCS Centro Neurolesi “Bonino-Pulejo”, Italy. NEUROLESI
- Université Victor-Segalen Bordeaux II, Department of Pharmacology, France. UB2
- London School of Hygiene & Tropical Medicine, UK. LSHTM
- Aarhus University Hospital, Århus Sygehus, Department of Clinical Epidemiology, Denmark. AUH-AS.
- AstraZeneca R&D, Safety Informatics and Modelling, Sweden. AZ
- University of Nottingham, QRESEARCH, UK. UNOTT
- Università di Milano-Bicocca, Unit of Biostatistics and Epidemiology, Department of Statistics, Italy. UNIMIB
- Agenzia Regionale di Sanità, Epidemiology Unit, Italy. ARS
- Pharmo Coöperation UA, Netherlands. PHARMO
- Pedianet - Società Servizi Telematici SRL, Italy. PEDIANET
- University of Santiago de Compostela, BioFarma Research Group, Spain. USC
- Tel-Aviv University, Israel. TAU
- Health Search - Italian College of General Practitioners, Italy. SIMG