

## EU-ADR

### Earlier detection of adverse drug reactions by integrative mining of clinical records and biomedical knowledge

**EU-ADR aims to develop and use advanced ICT technologies to demonstrate new ways of exploiting the existing wealth of clinical and biomedical data sources for the early detection of Adverse Drug Reactions.**

To enable the early detection and investigation of potential adverse drug reactions (ADRs), the EU-ADR system will use thousands of electronic healthcare records of European citizens. For this purpose, the system will gather information on the use of a drug in several European countries, as well as associated drug use and background rates of the events in the population. It will then use a series of statistical methods to assess signals and combine the evidence obtained. The EU-ADR system will also rely on the ever-increasing wealth of available biomedical knowledge to gather information on biological plausibility and potential genetic susceptibility of every signal, so as to minimise false positives. Ultimately, the EU-ADR system will facilitate the assessment of public health impact and provide background information on the evaluation of causality of potential ADRs, which will facilitate further research and regulatory decision making.

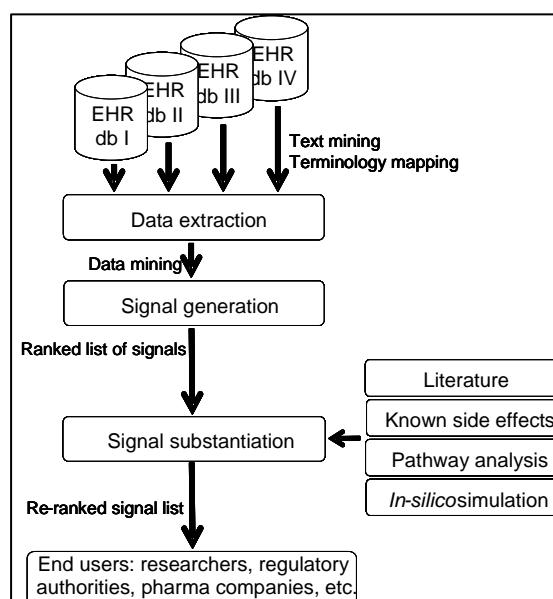
**Thanks to EU-ADR, an alternative approach towards the detection of ADR signals is being developed with the objective of overcoming the limitations of spontaneous reporting databases and providing a solid basis for large-scale monitoring of drug safety**

Before launching a new drug on the market, it is tested on a few thousand people. However, adverse reactions may not be detected until many more patients have used the drug.

Once the drug is on the market, clinicians

are responsible for recognising and reporting suspected side effects, which are collected in so-called spontaneous reporting systems. However, a number of recent, highly publicised drug safety issues showed that adverse effects of drugs may be detected too late, when millions of patients have already been exposed.

**Thanks to EU-ADR, an alternative approach towards the detection of ADR signals is being developed with the objective of overcoming the limitations of spontaneous reporting databases and providing a solid basis for large-scale monitoring of drug safety.** With EU-ADR a systematic calculation of the occurrence of diseases (potentially ADRs) during specific drug use will be based on data (time-stamped exposure and morbidity data) available in electronic patient records. Eight databases containing medical records of more than 30 million European citizens are involved in the project.



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

Two years into the project, EU-ADR has developed its core software modules, and a first prototype for the integration, development and management of an EU-ADR system has been elaborated. Validation of the system is being tackled to verify that its sensitivity and specificity is adequate.

*The main objective of EU-ADR 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 benefits*



### EU-ADR @ a glance

#### Partners:

- Erasmus University Medical Center, Department of Medical Informatics, Netherlands. Project Coordination.
- Fundació IMIM, European Projects Coordination Office, Spain. Project Management.
- Universitat Pompeu Fabra, Research Unit on Biomedical Informatics, Spain.
- University of Aveiro - IEETA, Portugal.
- IRCCS Centro Neurolesi "Bonino-Pulejo", Italy.
- Université Victor Segalen-Bordeaux II, Department of Pharmacology, France.
- London School of Hygiene & Tropical Medicine, UK.
- Aarhus University Hospital, Århus Sygehus, Department of Clinical Epidemiology, Denmark.
- AstraZeneca R&D, Safety Informatics and Modelling, Sweden.
- University of Nottingham, QRESEARCH, UK.
- Università di Milano-Bicocca, Unit of Biostatistics and Epidemiology, Department of Statistics, Italy.
- Agenzia Regionale di Sanità, Epidemiology Unit, Italy.
- Pharmo Coöperatie UA, Netherlands.
- Societa' Servizi Telematici SRL, Italy.
- University of Santiago de Compostela, BioFarma Research Group, Spain.
- Tel-Aviv University, Israel.
- Health Search - Italian College of General Practitioners, Italy.

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**Total cost:** 5,870,000 €

**European Commission funding:** 4,500,000 €

**Instrument:** Collaborative Project – Seventh Framework Programme (FP7)

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