Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (EU-ADR)


Research Areas

- Tool Development
- Data Sharing
- Data-Sharing Enabler

At a Glance

- Status: Completed Consortium
- Year Launched: 2000
- Initiating Organization: European Commission Seventh Framework Programme (FP7)
- Initiator Type: Government

Abstract

The Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (EU-ADR) consortium 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 (ADRs).

Mission

EU-ADR aims to create the capability to detect ADR signals by creating the infrastructure for large-scale monitoring of drug safety using electronic health records (EHRs). The platform will leverage EHRs consisting of demographics, drug use, and clinical data of more than 30 million patients from several European countries. Special attention will be paid 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).
This project will also study and compare a number of different techniques that, in essence, all aim to detect unexpected or disproportional rates of events. The algorithms to be studied originate not only from the field of pharmaco-epidemiology, but also from fields such as bioterrorism, machine learning, and classical signal detection.

EU-ADR’s specific objectives are to detect events, relate these events to drugs, develop hypothesis that explain adverse events, detect adverse events earlier, and avoid false positives.

**Consortium History**

Although many ADRs are detected by spontaneous reporting systems, these systems have inherent limitations that hamper signal detection. The major weakness is that these systems depend entirely on the physician’s ability to first recognize an adverse event as being related to the drug. Subsequently, the physician needs to actually report the case to the local spontaneous reporting database. The greatest limitations, therefore, are under-reporting and biases because of selective reporting. Investigations have shown that the percentage of ADRs being reported varies between 1 percent and 10 percent. These problems may lead to underestimation of the significance of a particular reaction and delay in signal detection, as well as spurious detections.

**Data Sharing**

The web-based platform is available at https://bioinformatics.ua.pt/euadr/Welcome.jsp;jsessionid=2E515CCB3629374C402D6A38129F9F63

**Impact/Accomplishment**

EU-ADR has had several spinout initiatives based on their initial deliverables (e.g., SOS, ARITMO) and has contributed to the ability to conduct better drug safety studies based on the reuse of healthcare data. Validation exercises have shown that, for example, an important adverse reaction ultimately leading to a drug being withdrawn in 2004 could have been detected using EU-ADR in 2000. By facilitating the early detection of ADRs, but also providing key information on populations at
risk, potential drug interactions, potential underlying mechanisms, and intervening pathways in adverse events, EU-ADR will allow for improved and more complete information to be available for drug and healthcare delivery, leading to increased patient safety and associated cost savings.

EU-ADR has targeted both the healthcare and research communities, as well as regulatory authorities, and aims in essence to constitute a risk assessment instrument focused on unexpected effects of marketed drugs. Being conceived as largely automatic and dynamic, the EU-ADR system is also expected to help the continuing monitoring and management of adverse drug events, in ways that spontaneous reporting and other current systems cannot attain. In that sense, it can be considered as a complementary tool to already existing pharmaco-vigilance systems. Should the system be widespread in the long term, it has the potential to contribute to the development of future EHR systems, insofar as the expected benefits of these innovative information technology tools are only fully attainable when EHRs develop in consistency, richness, and formats that allow them to be subject of such tools. In anticipation, EU-ADR has been designed to be modular and scalable, so that different EHR databases (other than those participating in the consortium) can be progressively “enlisted” in the future, adopt the software for data extraction, and therefore become susceptible to exploitation by the system, for maximum global effect. This has been enabled through the establishment of an EU-ADR Alliance, currently in the proof-of-concept phase, having been awarded three European Medicines Agency contracts. Together with the derived projects that apply EU-ADR technology (e.g., SOS, ARITMO, VAESCO, SAFEGUARD), this reinforces the applicability of the project results and will help maximize its impact.

Importantly, and beyond the drug safety field itself, EU-ADR has spearheaded the field of secondary use of healthcare data, which goes hand in hand with the subsequent OMOP and Food and Drug Administration (FDA) Sentinel initiatives in the United States. This trend is expected to be fully expanded in the context of the EMIF project (IMI), which will leverage the concepts behind EU-ADR and apply them to any research use, which is currently in the preparatory stages and expected to start by the end of 2012. In any case, EU-ADR is now widely acknowledged as a seminal project and mentioned as a pioneer in areas that will surely be at the forefront of biomedical research in the next decade.

Links/Social Media Feed

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