The ALERT Project

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

Paul Avillach, Johan van der Lei
and all the consortium

Objective

The overall objective of the **Alert project** is the design, development and validation of a **computerized system** that **exploits data** from **electronic healthcare records** and **biomedical databases** for the ***early detection of adverse drug reactions***.

Challenges

The main challenges to accomplish the ALERT's objective are:

1. Federation of different databases of electronic medical records in order to create a large-scale resource for monitoring adverse events.

   In ALERT eight DBs containing medical records of more than 30 million European citizens are involved.

2. Exploitation of European diversity for routine drug monitoring.
3. Evaluation on a realistic scale of a number of data mining techniques.
4. Automated exploitation of heterogeneous sources of information to reduce the number of spurious signals.
5. Development of a computerized system that, compared with spontaneous reporting systems, provides the capability for earlier discovery of ADRs.

Challenges

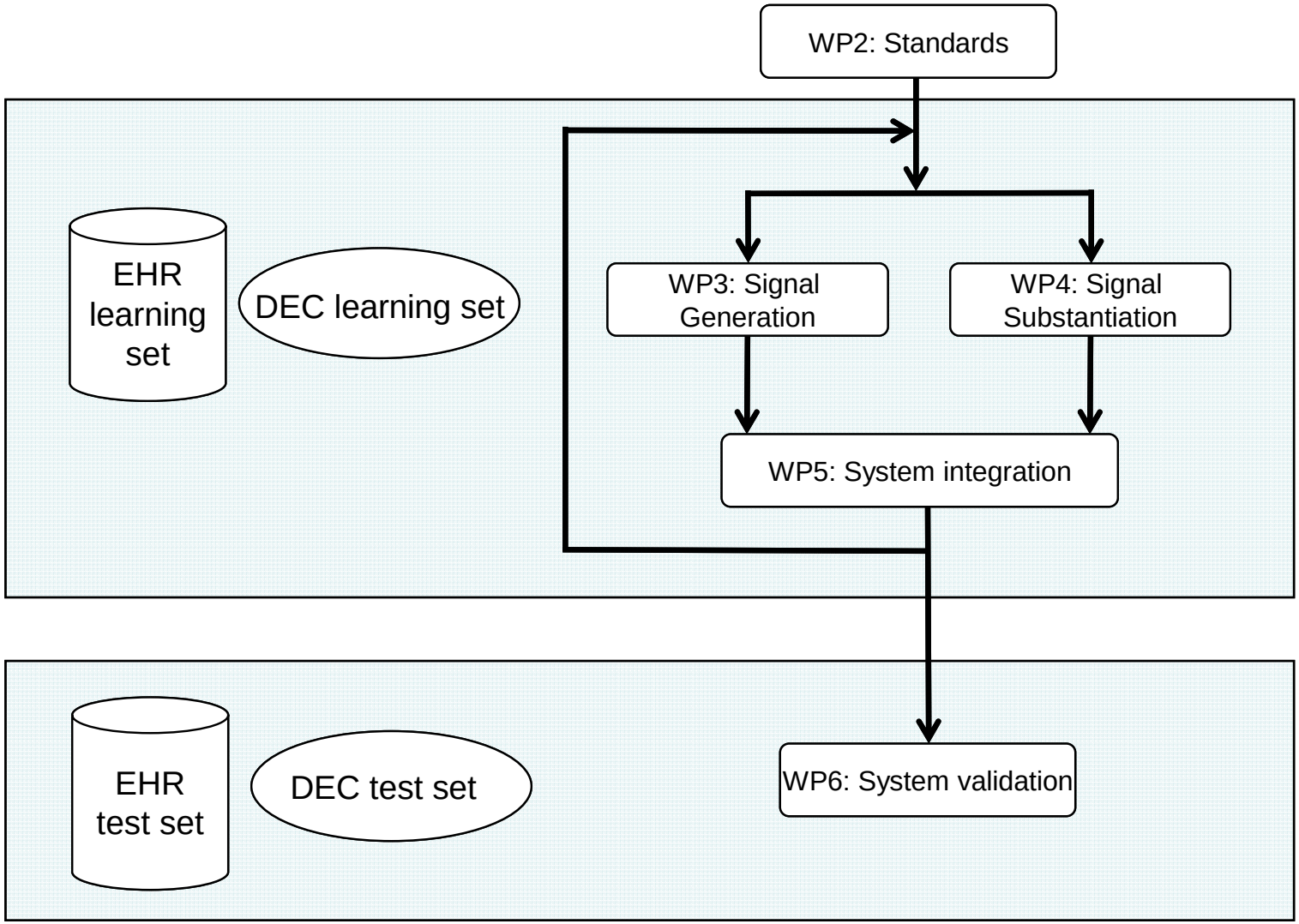
ALERT's specific objectives are:

- To detect events
- To relate these events to drugs
- To develop hypothesis that explain adverse events
- To detect adverse events earlier
- To avoid false positives

To achieve these objectives, the work plan is composed of 8 work packages:

1. Scientific Coordination
2. Standards
3. Signal Generation
4. Signal Substantiation
5. System Integration
6. System Validation
7. Dissem. & Exploitation
8. Project Management

Work packages



Consortium Members

The ALERT Consortium is composed of: 15 beneficiaries + 3 subcontractors

EHRs Databases

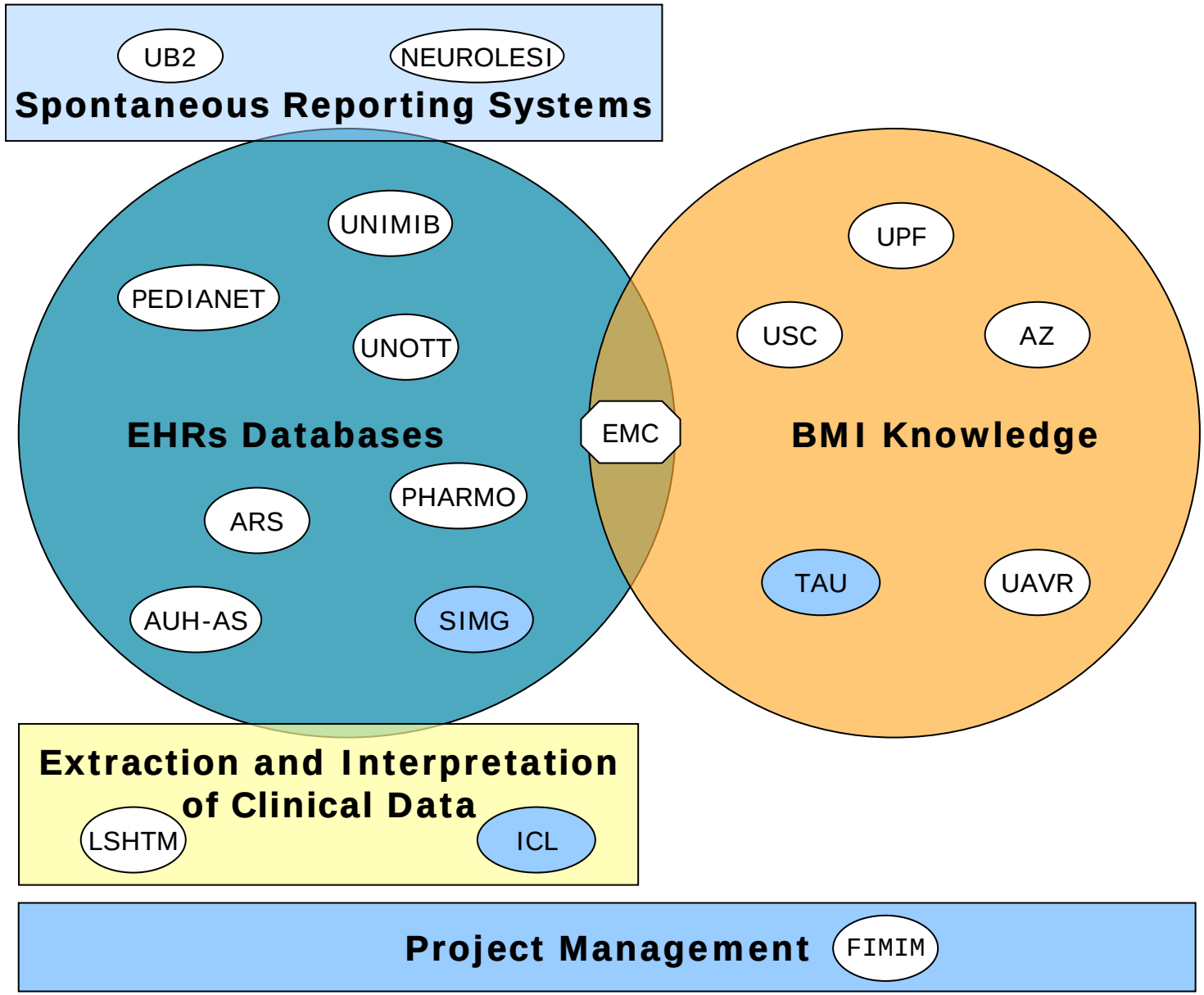
TAU (Tel–Aviv)

Consortium Members

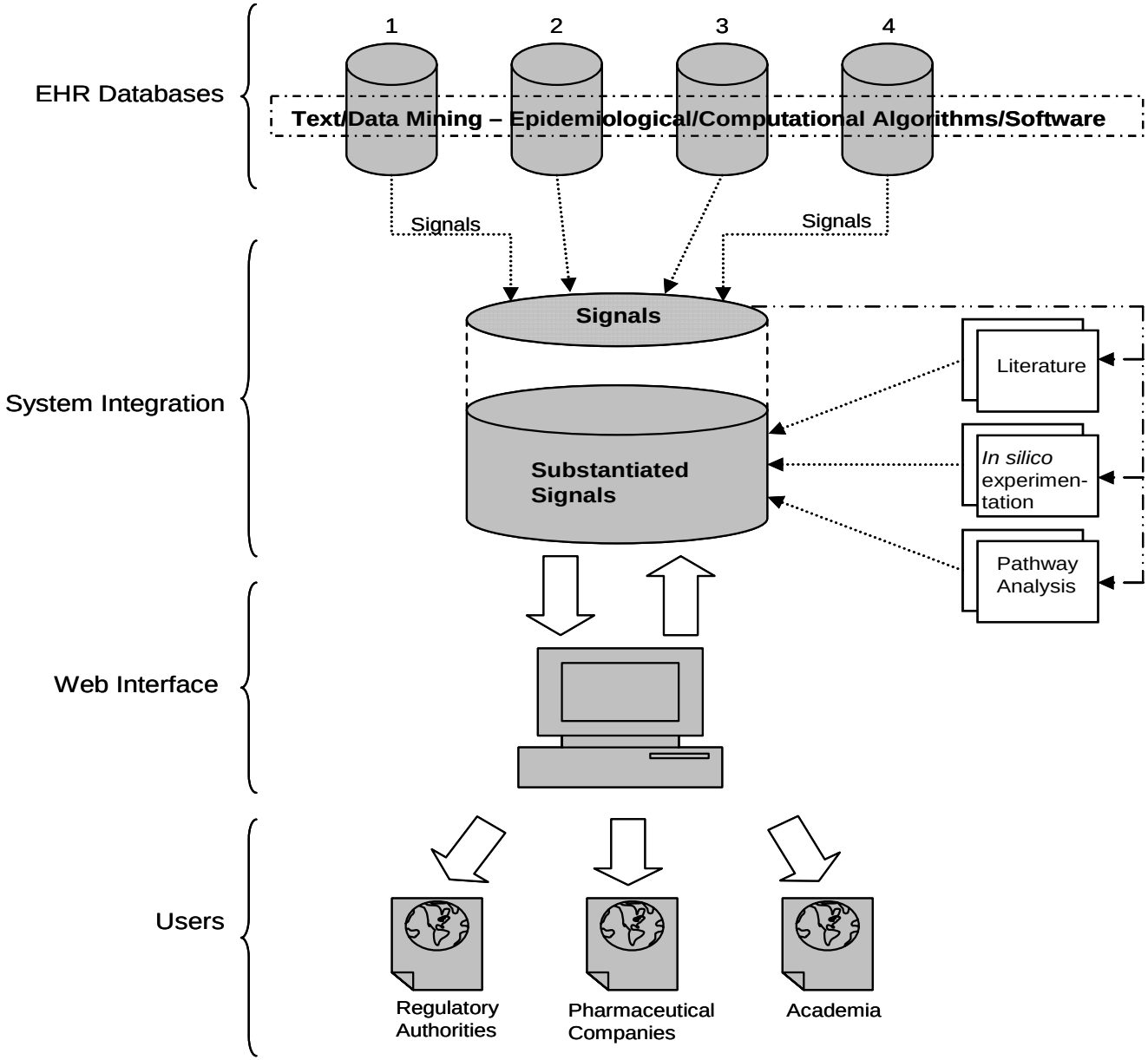
Participating institutions:

- Aarhus University Hospital, Århus Sygehus, Denmark
- Agenzia regionale di Sanità, Italy
- AstraZeneca AB, Sweden
- Erasmus University Medical Center, Netherlands
- Fundació IMIM, Spain
- Health Search - Italian College of General Practitioners, Italy
- Imperial College London, UK
- IRCCS Centro Neurolesi “Bonino-Pulejo”, Italy
- London School of Hygiene & Tropical Medicine, UK
- PHARMO Coöperation UA, Netherlands
- Pedianet - Societa’ Servizi Telematici SRL, Italy
- Tel-Aviv University, Israel
- Università di Milano-Bicocca, Italy
- Université Victor-Segalen Bordeaux II, France
- University of Aveiro – IEETA, Portugal
- University of Nottingham, UK
- University of Santiago de Compostela, Spain
- University Pompeu Fabra, Spain

Consortium Profile



ALERT System Working Flow



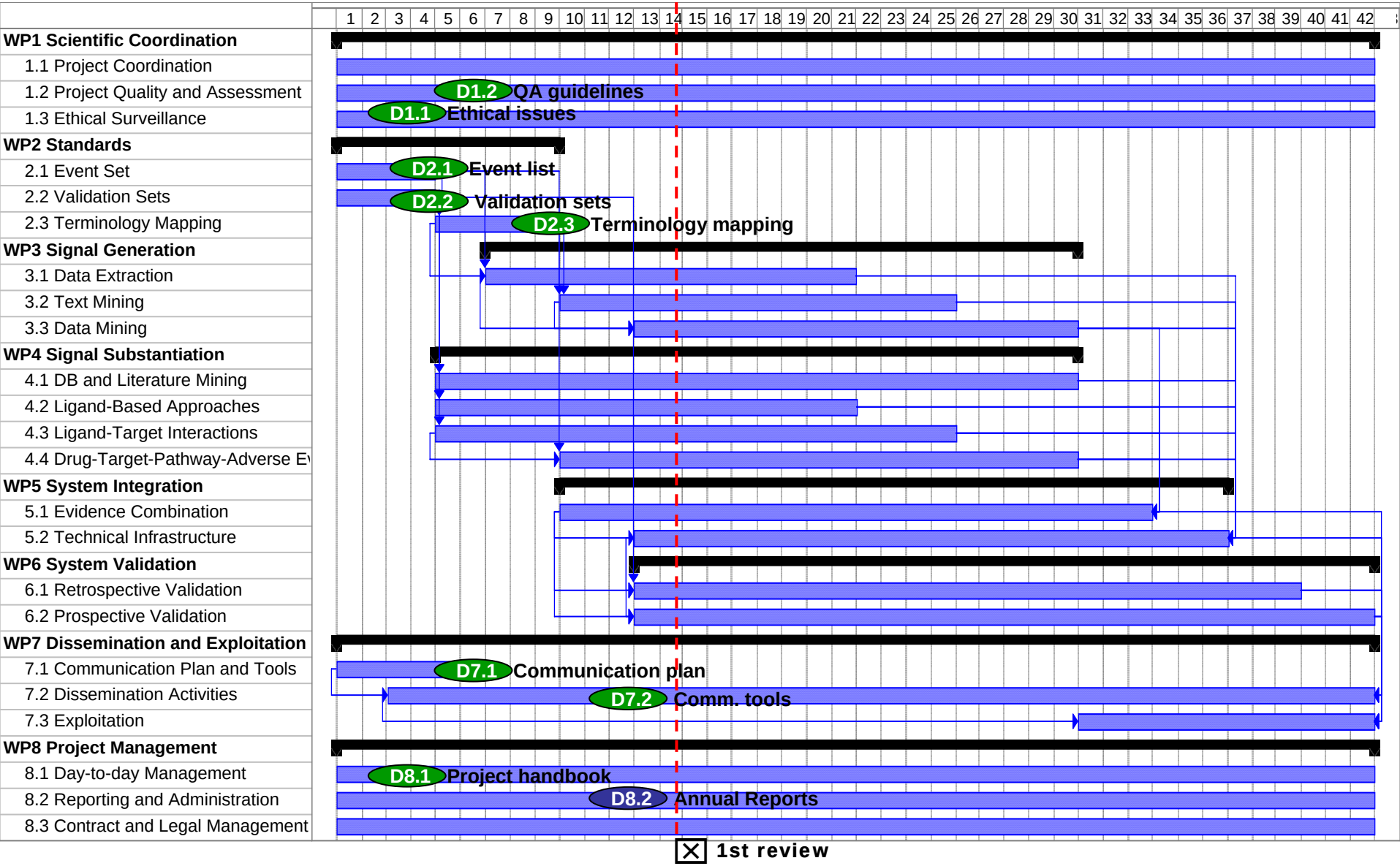
Validation

The ultimate objective of ALERT is to **demonstrate** that an **earlier detection** of adverse side effects of drugs **is possible using electronic healthcare records**.

Retrospective validation studies included in the project will test the system on historical data to prove that ALERT could have detected known side effects earlier (e.g., in retrospect we would have significantly reduced the lag-time for discovering the Vioxx issue).

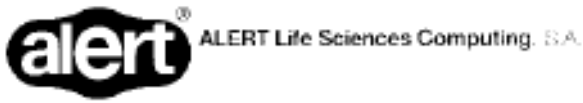
Finally, by analysing new signals, ALERT will provide a further quantifiable outcome **(prospective validation)**.

Achievements and status



ALERT to EU-ADR

- Conflict with ALERT Life Sciences Computing S.A. on regarding project acronym - **trademark infringement and unfair competition notice**.



- A decision to change the acronym to EU-ADR was made.

Website: www.euadr-project.org

alert

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Welcome to the EU-ADR website

The **EU-ADR** project aims to develop an innovative computerized system to detect adverse drug reactions (ADRs), supplementing spontaneous reporting systems. To achieve this objective, **EU-ADR** will exploit clinical data from electronic healthcare records (EHRs) of over 30 million patients from several European countries (The Netherlands, Denmark, United Kingdom, and Italy). In this project a variety of text mining, epidemiological and other computational techniques will be used to analyze the EHRs in order to detect 'signals' (combinations of drugs and suspected adverse events that warrant further investigation). **EU-ADR** is carried out by an interdisciplinary team of researchers who share the ultimate objective 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 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.

European Commission Information Society and Media

EU-ADR is a Research and Development project funded by the Information and Communication Technologies (ICT) Area of the European Commission under the VII Framework Programme

5th EU-ADR Consortium Meeting, June 2009

ALERT project is now EU-ADR

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Next slides only if questions

To automatically detect scientifically and mechanistically sound explanations for the signals obtained in WP3 by means of a combination of:

- analysis of relevant databases,
- mining of biomedical literature,
- *in silico* prediction of biological annotations,
- pathway mapping.

WP4 underlying scientific strategy