

# Leveraging Pharmacovigilance through Knowledge Engineering

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**Abstract** Medication safety is a priority worldwide. Improving procedures for drug surveillance and risk prevention is required in order to strengthen the pharmacovigilance process. In a pre-market setting, newly developed drugs are evaluated through clinical trials, in order to identify their potential Adverse Drug Reactions (ADRs). However, constant post-marketing surveillance is required to identify previously undiscovered ADRs throughout the time a drug is actively prescribed. Monitoring the safety of drugs has been mostly conceived as a data-intensive activity. This Workshop aims to present a knowledge-intensive approach for drug safety, illustrating the added value through exemplar research efforts that will be presented and discussed.

**Keywords.** Drug safety, Pharmacovigilance, Knowledge engineering, Heterogeneous data sources, Ontologies, Semantic integration, Semantic inference.

## Introduction of the topic

Drug safety is an important priority worldwide. Accurate and timely identification of drug safety risks requires the concurrent exploration of various types of data. Especially in post-marketing settings, these data span from spontaneous reports, observational healthcare data, scientific literature and even social media. The availability of this data deluge dictates the need to introduce high-throughput computational methods that will enable efficient knowledge extraction and management, compensating the underlying heterogeneity and complexity. Beyond discovery, knowledge representation, exploitation and management are necessary for effective drug monitoring and surveillance.

Knowledge engineering is the discipline that elaborates on the theories, methods and tools for developing knowledge-intensive applications, and can largely contribute in the realization of the above objectives. Recently, and especially with the maturation

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of Semantic Web technologies and standards, various interesting applications and paradigms of knowledge engineering have been presented targeting the domain of pharmacovigilance. These efforts illustrated well-promising results and the added value that may be anticipated.

### **1. Aim of the discussion**

The aim of this Workshop is to stimulate discussions through the presentation of exemplar research efforts in the field of pharmacovigilance, exploiting knowledge engineering methods and tools. To this end, the Workshop will present knowledge-based approaches to explore the various types of drug safety data, and particularly:

- a) spontaneous reports;
- b) observational healthcare data in Electronic Health Records (EHRs);
- c) social media content,

and conclude by presenting an integrated approach for the concurrent exploitation of the above data for drug safety.

Potential topics for discussion include:

- Current / emerging ontologies and knowledge bases for drug safety.
- Semantic mining of unstructured text with major focus on social media content for drug safety risk identification.
- Semantic vs. statistical inference for pharmacovigilance signal detection.
- Case studies on Semantic Web and linked-data applications and tools for pharmacovigilance.
- Semantically-enriched platforms for drug safety.
- Strategies for combining evidence obtained from heterogeneous data sources for drug safety risk identification.
- Facilitating spontaneous Adverse Drug Reaction (ADR) reporting by gathering patient context from the EHRs.

### **2. Contribution from each speaker**

The expected contributions from the speakers will be the following:

- Mr. Julien Souvignet / Dr. Cédric Bousquet will present an ontology-based approach (through ontoADR [1]) for organizing ADR knowledge and perform signal detection by exploring spontaneous reports. ontoADR has been elaborated in the scope of the PROTECT IMI (Innovative Medicines Initiative) project [2].
- Dr. Mustafa Yuksel will present work that is being conducted in the recently launched WEB-RADR (Recognising Adverse Drug Reactions) IMI project [3], which aims to deliver robust information technology tools to address the potential for the reporting of ADRs through mobile applications and the recognition of drug safety signals from user comments in social media and the Internet.
- Prof. Hans-Ulrich Prokosch will present the use of EHR data for drug safety. Focus will be given to a method for formalizing knowledge about ADRs, based on the Summary of Product Characteristics (SmPCs), and their relationship with ATC-coded drugs and LOINC-based laboratory results. Integrated in the EHR environment of a university hospital and linked with structured patient data, this

system was applied to generate safety signals with high sensitivity and specificity for ADR identification [4].

- Dr. Vassilis Koutkias will present a framework enabling semantic integration and reasoning for pharmacovigilance signals research [5]. The presentation will involve research conducted in the SAFER project [6], which is built upon the need for increased drug surveillance through the synthesis of various information sources, e.g., spontaneous reports, observational healthcare data, the literature, and social media content, complementing this way the previous presentations.
- Prof. Marie-Christine Jaulent will coordinate the Workshop and the discussions that will be held.

### 3. Expected results

The Workshop will increase the awareness of scientists interested in pharmacovigilance as an application area, with respect to the added value that knowledge engineering methods and tools may bring. In this respect, the Workshop aspires to gather a group of researchers that are working in the area, and explore synergies and future common actions. Among the envisaged actions include organization of a journal special issue, a mailing list for community building and communication, as well as a research agenda for potential collaborative activities.

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