Leveraging Semantic Technologies to Bring Active Pharmacovigilance at the Point of Care

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Abstract. Pharmacovigilance is recognized worldwide as an important public health issue. Nevertheless, there is a lack of comprehensive tools to support healthcare professionals in drug safety risk assessments in the clinical setting. In the scope of the PVClinical project, we employ semantic technologies for developing a point-of-care platform for the early identification and assessment of possible Adverse Drug Reactions (ADRs). Our approach relies on the following technical pillars: (a) leveraging the OMOP Common Data Model as a reference data model to encode relevant Electronic Health Record (EHR) data at the local site; (b) the *Linked Data* paradigm for integrating data from various and heterogeneous data sources beyond local EHRs (e.g. bibliographic databases, Spontaneous Reporting Systems, as well as social media platforms) in a common knowledge graph (KG), and (c) advanced *Analytics* for exploiting the KG, including text mining and statistical inference for risk assessment. The ultimate goal is to support clinicians in obtaining comprehensive information on potential drug safety risks that shall be assessed in their daily practice.

Keywords: Pharmacovigilance, Point of Care, Linked Data, Semantic technologies, Text mining, OMOP-CDM

1 Introduction

Adverse Drug Reactions (ADRs) occurring in the clinical environment cause significant patient safety consequences [1]. Among the routine tasks performed in hospital Pharmacovigilance (PV) centers/departments is the collection and review of available data for an ADR case of interest. If dominant PV databases such as Spontaneous Reporting Systems (SRSs) have no information, exploring other data sources (e.g. Electronic Health Records (EHRs), clinical trial databases, bibliography, etc.) is considered. However, there is a lack of comprehensive tools to support clinicians to accommodate this data deluge and obtain actionable insights via knowledge-intensive analytics [2].
PVClinical aims to address this unmet need by developing a point-of-care platform for the early identification and assessment of (possible) ADRs by leveraging semantic technologies. It aims to reinforce "active" pharmacovigilance enabling the prompt

assessment of potential drug safety risks, rather than waiting for a significant number of individual case reports to be gathered in SRSs to launch the assessment process.

2 PVClinical approach

The proposed platform is explicitly tailored to accommodate the point-of-care context. The key technical pillars for its implementation are:

- The *OMOP Common Data Model (CDM)* [3], a reference data model employed to encode EHR data at the local site for secondary use in the scope of drug safety risk assessment. The adoption of the OMOP-CDM mitigates the risk of vendor lock-ins and enables the reuse of tools developed by the OHDSI collaborative.
- The *Linked Data (LD)* and *Semantic Web* paradigms, employed to semantically annotate and integrate data from the various (heterogeneous) sources considered in PVClinical in a single Knowledge Graph (KG). Besides EHR data, the KG will include data from SRSs, bibliographic databases, social media platforms, as well as PV signal reports released by drug safety organizations expressed using the *OpenPVSignal* ontology [4].
- Finally, advanced *Analytics* for exploiting the KG, including text mining and statistical inference for risk assessment, will be employed. In particular, we will investigate how the KG semantics can improve typical statistical analysis applied in PV, e.g. disproportionality analysis and causality indexes calculation.

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