OpenPVSignal Knowledge Graph: An openly available data source for pharmacovigilance signal reports

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Abstract

Pharmacovigilance (PV) Signal Reports (SRs) are the consolidation of numerous Individual Case Safety Reports (ICSRs) by experts for the early detection of causal relationships between Drugs and Adverse Drug Reactions using statistical correlations. These reports currently exist in a format not useable by Information and Communications Technology (ICT) systems. OpenPVSignal model was an effort to bridge the gap between the SRs and ICTs by converting them to OWL/RDF format. This paper presents the resulting data from the conversion of 108 SRs using OpenPVSignal as the base data model.

Keywords

Semantic Web, Real-World Data, Pharmacovigilance

1. Introduction

Pharmacovigilance (PV) is an integral part of healthcare (HC) systems that plays a pivotal role in the safety and efficacy of pharmaceutical products. Collecting, curating and analyzing data on adverse drug reactions (ADRs) enables HC professionals (HCPs) and regulatory authorities to promptly pinpoint potential safety hazards. Individual Case Safety Reports (ICSRs) typically submitted by HCPs and/or patients are subsequently examined by domain experts via statistical analysis (e.g. via the use of disproportionality analysis metrics). The Uppsala Monitoring Centre, the WHO reference centre for PV (WHO-UMC) maintains and hosts VigiBase (1), the biggest ICSR database in the world, collecting ICSRs from all over the world. They publish PV Signal Reports (PVSR) in a bimonthly newsletter spotlighting new potential drug-ADR relationships. These reports contain curated and novel information that can be crucial to the domain of Drug Safety (DS) but their unstructured format makes it difficult to be taken advantage of by Information and Communications Technology systems.

Natsiavas et al (2) have proposed OpenPVSignal, an ontological data model for PVSRs which is maintained in GitHub. This manuscript presents a Knowledge Graph (KG) built upon OpenPVSignal, using 101 PVSRs published by WHO-UMC for a decade between 2012 and 2019.

2. Methodology

The WHO-UMC data conversion to OWL/RDF has been an iterative process including multiple steps of data quality and validation while a set of researchers that consisted of 4 knowledge engineers and 2 domain experts (one pharmacologist and one physician) were involved in the process. Only a few signals were excluded because they did not focus on drug-ADR interactions, but rather incorrect drug usage or labelling. Figure 1 depicts a PVSR of the presented KG. The KG is openly available to download in Turtle syntax at a GitHub repository https://github.com/inab-certh/OpenPVSignal along with the methodology used for the data validation, while an openly published in a live RDF triple store exists to support exploration http://snf-893389.vm.okeanos.grnet.gr:7200/login.

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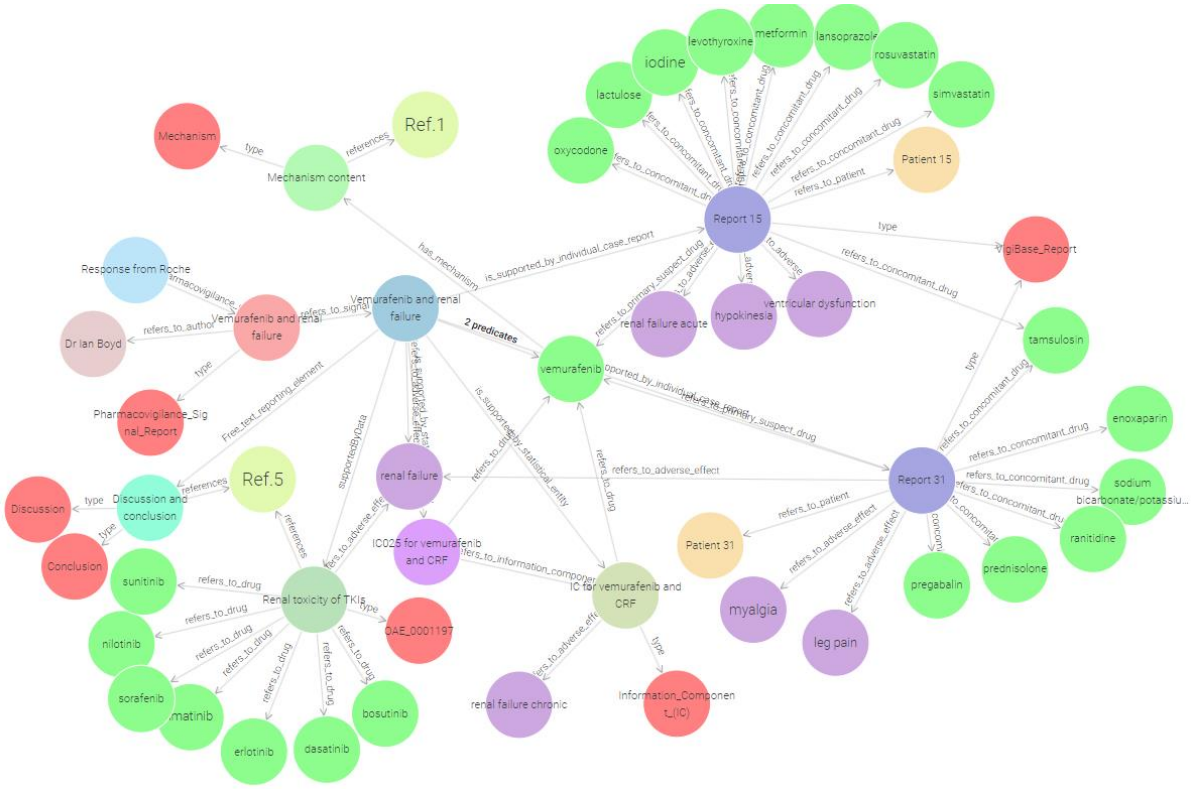

Figure 1 OpenPVSignal instance for PVSR: Vemurafenib and Renal Failure

3. Discussion

OpenPVSignal is an open data source that consists of PVSRs in a FAIR (Findable-Accessible-Interoperable-Reusable) compliant format. Having these data available in a FAIR format could promote their systematic reuse and their integration within ICT systems and research pipelines. Additionally, the OWL semantics along with the rationale of symbolic AI can enable automatic reasoning upon them, further enhancing their potential by uncovering latent relationships among their Drug and Disease elements. Thus, the OpenPVSignal KG could play a prominent role in improving the early detection but also regarding the identification of underlying mechanisms of newly reported ADRs.

4. References

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