Integrating OMOP-CDM Data Sources and OHDSI Analytic Services for the Investigation of Candidate Pharmacovigilance Signals

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Key definitions

Pharmacovigilance (PV): “the science and activities related with the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems”.

PV Signal: “... information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causual association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action”.

Background

Investigation of candidate PV signals requires the combined exploration of various evidence sources, including observational databases.

Pharmacovigilance Candidate Signal Investigation (PCSI) rationale

Focus of the OHDSI Pharmacovigilance Evidence Investigation Workgroup:

✓ data integration workflows
✓ exploiting Linked Data and semantic technologies
✓ user-centered design for PV analytics

Foundations of the current work:

✓ LAERTES (integration of data from various data sources, including OMOP-CDM)
✓ The Common Evidence Model:
  ✓ scalable, long-term maintenance
  ✓ based on dynamic and adjustable data integration workflows

Current project: The Pharmacovigilance Candidate Signal Investigation (PCSI) platform:

✓ User-friendly tool for investigating candidate PV signals by retrieving, combining and assessing data from various evidence sources

Pharmacovigilance Candidate Signal Investigation (PCSI) platform

PCSI extends the concept of data integration with evidence and analytic services integration, as each data source may provide different insights regarding PV signal investigation. For example, social media may provide information regarding the time evolution or trend of PV information, while scientific literature may provide information regarding the underlying mechanism of a PV signal.

Key features:

✓ Web-based User Interface
✓ Analytics customized for each data source (including OHDSI analytics)
✓ Aggregation of analysis results
✓ Support for customizable analysis workflows

PCSI currently in design phase:

✓ Two case studies elaborated
✓ Set of UI wireframes designed

References


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