



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

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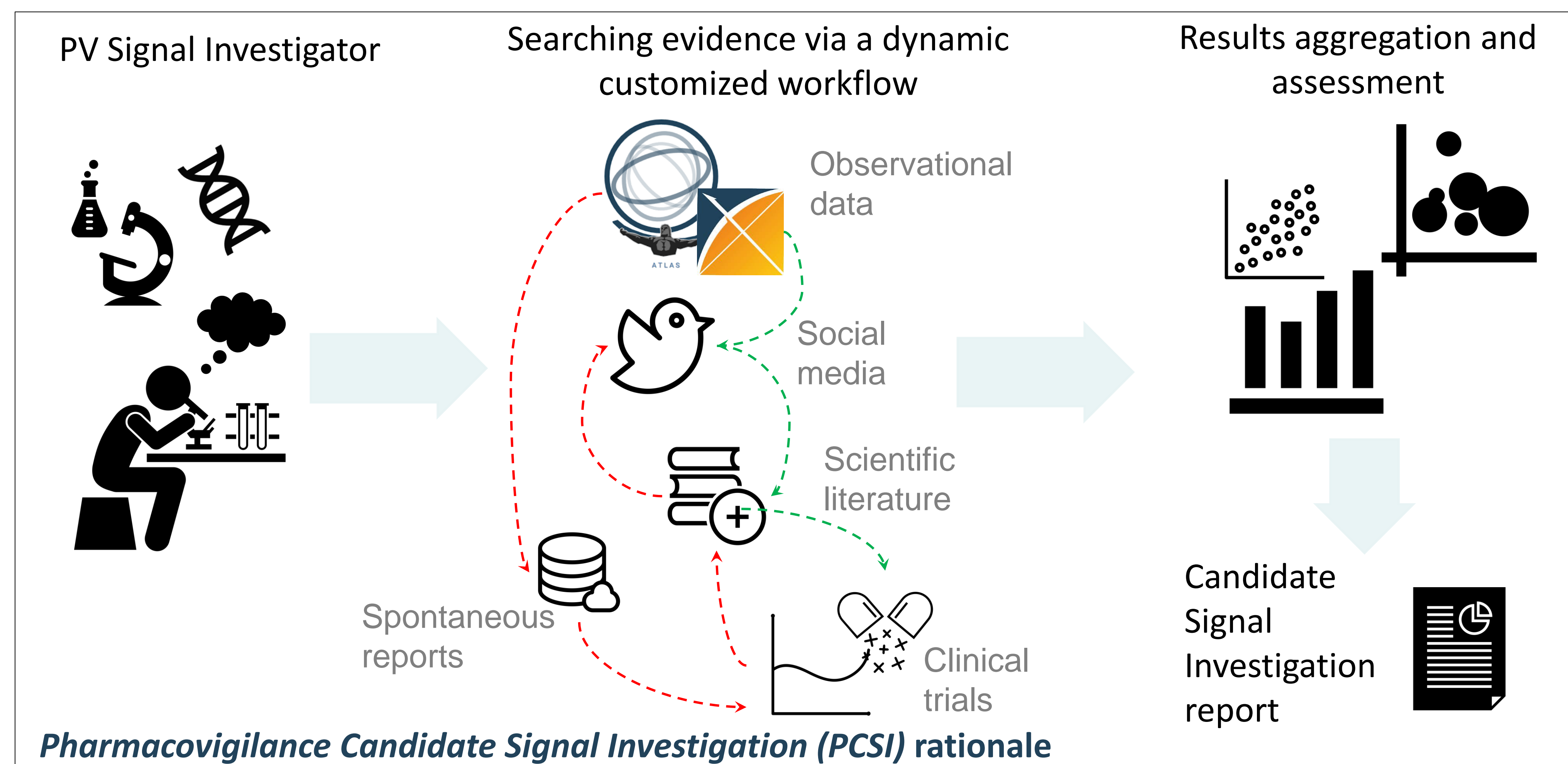
Key definitions

Pharmacovigilance (PV): "the science and activities related with the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems"¹.

PV Signal: "... information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal 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"².

Background

Investigation of candidate PV signals requires the combined exploration of various evidence sources, including observational databases³.



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)⁴

✓ **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 investigation⁵. 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 signal⁶.

Key features:

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

Data sources considered:

- ✓ Observational data based on the OMOP-CDM
- ✓ Spontaneous reports
- ✓ Summary of Product Characteristics (product labels)
- ✓ Scientific Literature
- ✓ Clinical trials
- ✓ Social media

PCSI currently in *design phase*:

- ✓ **Two case studies** elaborated
- ✓ Set of UI **wireframes** designed

The screenshot shows the PCSI platform interface. On the left, there's a table of 'Report collections' with columns for ID, Date, Age, Gender, and Medication. The main area displays a 'Study summary' for 'Candidate signal: trastuzumab - Left ventricular systolic dysfunction'. It includes a table with 'Cohort', 'Cohort size', 'Calibrated HR', and 'Link to study within Atlas'. Below the table are several charts: a density plot, a standardized difference of mean plot, and a Kaplan-Meier survival plot. At the bottom, there are buttons for 'Add report to collection', 'Import collection', 'Export collection', and 'Download collection'.

Example Use Case: Left Ventricular Dysfunction and Tyrosine Kinase Inhibitors

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https://docs.google.com/document/d/1sicZkWx79q-7BsFUo47RC-V9_cLBVZWbmMQfxhchXBA

References

1. World Health Organization. The importance of pharmacovigilance. Collaboration Centre for International Drug Monitoring 2002; Available at: <http://apps.who.int/medicinedocs/en/d/Js4893e/>
2. Council for International Organizations of Medical Sciences (CIOMS). Practical Aspects of Signal Detection in Pharmacovigilance, Council for International Organizations of Medical Sciences. Report of Working Group VIII 2010; Available at: <https://goo.gl/R2cgv2>
3. Boyce RD, et al. Bridging islands of information to establish an integrated knowledge base of drugs and health outcomes of interest, Drug Saf. 2014;37:557-67.
4. Knowledge Base workgroup of the Observational Health Data Sciences and Informatics (OHDSI) collaborative. Large-scale adverse effects related to treatment evidence standardization (LAERTES): an open scalable system for linking pharmacovigilance evidence sources with clinical data. J Biomed Semantics 2017;8(1):11.
5. Koutkias VG, Jault MC. Computational approaches for pharmacovigilance signal detection: toward integrated and semantically-enriched frameworks. Drug Saf. 2015 Mar;38(3):219-32.
6. Koutkias VG, Lillo-Le Louët A, Jault MC. Exploiting heterogeneous publicly available data sources for drug safety surveillance: computational framework and case studies. Expert Opin Drug Saf. 2017 Feb;16(2):113-124.

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