

PEI Pharmacovigilance Evidence Investigation Working Group



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Formally Laertes Working Group



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Formally the Knowledge Base Working Group



Drug Saf (2014) 37:557–567 DOI 10.1007/s40264-014-0189-0

CURRENT OPINION

Bridging Islands of Information to Establish an Integrated Knowledge Base of Drugs and Health Outcomes of Interest

Richard D. Boyce · Patrick B. Ryan · G. Niklas Norén · Martijn J. Schuemie · Christian Reich · Jon Duke · Nicholas P. Tatonetti · Gianluca Trifirò · Rave Harpaz · J. Marc Overhage · Abraham G. Hartzema · Mark Khayter · Erica A. Voss · Christophe G. Lambert · Vojtech Huser · Michel Dumontier

• The workgroup's mission is to develop an open-source standardized knowledge base for the effects of medical products and an efficient procedure for maintaining and expanding it. The knowledge base will make it simpler for practitioners to access, retrieve, and synthesize evidence so that they can reach a rigorous and accurate assessment of causal relationships between a given drug and HOI.



2014

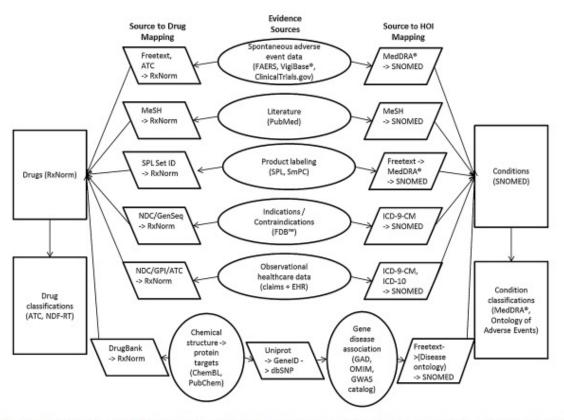


Fig. 1 Information sources proposed for the initial version of the OHDSI knowledge base. ATC Anatomical Therapeutic Chemical Classification System, EHR electronic health record, FAERS Federal Drug Administration Adverse Event Reporting System, FDBTM First DataBank, GAD Genetic Association Database, GPI Generic Product Identifier, GWAS Genome-wide association study, HOI health outcome of interest, ICD-10 International Classification of Diseases, Tenth Revision, ICD-9-CM International Classification of Diseases, Ninth Revision, Clinical Modification, MeSH Medical Subject Headings, NDC National Drug Code Directory, NDF-RT National Drug File-Reference Terminology, OHDSI Observational Health Data Sciences and Informatics, OMIM Online Mendelian Inheritance in Man, SmPC EU Summary of Product Characteristics, SNOMED Systematized Nomenclature of Medicine, SPL Structured Produce Labeling



2017

The Knowledge Base workgroup of the Observational Health Data Sciences and Informatics (OHDSI) collaborative Journal of Biomedical Semantics (2017) 8:11 DOI 10.1186/s13326-017-0115-3

Journal of Biomedical Semantics

SOFTWARE Open Access



Large-scale adverse effects related to treatment evidence standardization (LAERTES): an open scalable system for linking pharmacovigilance evidence sources with clinical data

The Knowledge Base workgroup of the Observational Health Data Sciences and Informatics (OHDSI) collaborative



2017

Journal of Biomedical Informatics 66 (2017) 72-81

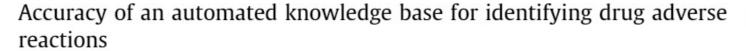


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- Common Evidence Model (CEM)
- Database bridging islands of information together with goal of supporting research of existing evidence about drugs and outcomes of interest.
- CEM replaces LAERTES
- CEM pulls together and standardizes the following types of data:





CEM_UNIFIED

Subset of information found in CEM_UNIFIED

concept_id_1 integer	concept_name_1 character varying(255)		concept_name_2 character varying(255)	source_id character varying(50)	unique_identifier character varying(2000)
1314273	rituximab	140352	Acute myeloid leukemia, disease	medline avillach	28419413
1314273	rituximab	140352	Acute myeloid leukemia, disease	medline avillach	28542862
1314273	rituximab	432574	Diffuse non-Hodgkin's lymphoma, large	medline avillach	25429725
1314273	rituximab	4344166	Adult onset Still's disease	medline avillach	29076903
1314273	rituximab	4344166	Adult onset Still's disease	medline avillach	29076903
1314273	rituximab	4098292	Antiphospholipid syndrome	medline avillach	21924936
1314273	rituximab	432310	Cryptococcal meningitis	medline avillach	21700684
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CEM_UNIFIED

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Case Reports > Leuk Lymphoma. 2013 Mar;54(3):643-5. doi: 10.3109/10428194.2012.717081. Epub 2013 Jan 2.

Early cryptococcal meningitis following treatment with rituximab, fludarabine and cyclophosphamide in a patient with chronic lymphocytic leukemia

Tony Marchand, Matthieu Revest, Pierre Tattevin, Sylviane Chevrier, Elsa Poullot, Thierry Lamy, Roch Houot

PMID: 22924391 DOI: 10.3109/10428194.2012.717081



PEI Moving Forward

- Always looking for new data sources to ingest
- Want to pivot to using the data more in research



We meet the last Monday of the month at 11:30AM EST

If you are interested in getting involved contact evoss3@its.jnj.com or ask to join the PEI Working Group