

Lightning Talks

1:00 – 2:00pm

OHDSI in Denmark: from Ithaca to the bedside

Denmark has a long tradition of high quality digital health databases going back for more than four decades. In the era of big data and precision medicine, we are initiating the journey to identify an efficient way for getting the most out of such vast amount of information while targeting to improve citizens quality of life. We began by selecting ten distinct data sources from relative medical domains and continued with a global market research which highlighted OMOP CDM as the most popular unification framework for our data-sources with a high adoption level inside the EU. Our overall plan continues beyond the creation of a CDM with special interest on evaluating the current functionality of the OHDSI community tools in regards with quality control, governance, visualization, cohort selection and machine learning. Finally, we are interested to better understand the resources and the effort needed for tailoring those services to fully match the needs of our researchers and healthcare professionals.

Presenter: Ioannis Drakos, Chief Consultant, Region Zealand

Validation of Genomic CDM Extension with Real World Clinical Genomics Data

Genomic data from clinical NGS panels are becoming important in the era of precision medicine. There have been efforts to combine genomic data with existing clinical information during the past years; however, most were focused on research genomic data. Considering the objectives of OHDSI, a genomic CDM model needs to be verified using genomic data generated from real-world data. To implement the genomic CDM model, we added concept_id for gene symbols and categorical values used in genomic_meta, genomic_mutations, genomic_cnv, genomic_sv, genomic_expression tables. Then, we validated our proposed extended CDM model with real-world genomic data (mutations, copy number variations, structural variations) and clinical information from 600 patients which were treated with NGS panel sequencing in Asan Medical Center between March 2017 and November 2017.

Presenter: Kyu-pyo Kim, PhD, Associate Professor, Asan Medical Center

Condition Coding Practice Differences Between USA, Asia and Europe: Preliminary Results from European Birth Season – Disease Risk Study

Birth month impacts human health and disease states. Previous work has correlated birth season exposure with changes in climate and pollutant exposure using data from members of the Observational Health Data Sciences and Informatics (OHDSI) collaborative. We are working on expanding this work to OHDSI members in Europe to further confirm known findings. As part of this larger study, we investigated the differences in coding practice in USA, Asia, and Europe. We found that different codes are used in Asia, Europe and the USA limiting the number of 'exact' match condition concepts across the consortium. Because our birth month study requires conditions to be 'exact' matches, novel methods are required to handle coding issues/biases that occur across member



sites and to effectively harmonize results from across the OHDSI collaborative. We will discuss these findings at our talk.

Presenter: Mary Regina Boland, MA, MPhil, PhD, Assistant Professor, University of Pennsylvania

Considerations for Identifying Suitable Clinical Trials for Replication Using Electronic Health Records

In this study we sought to elucidate challenges for performing, using EHR databases alone, studies analogous to contemporary clinical trials. We manually reviewed the data requirements of 100 actively-recruiting Phase 4 trials from ClinicalTrials.gov, classified the challenges identified, and quantified their frequencies.

Presenter: Fabrício Kury, PhD, Postdoctoral Research Scientist, Columbia University

The value of negative controls for the self-controlled case series design

It is questionable if the recently reported large increased risk of acute myocardial infarction (AMI) following influenza diagnosis reflects a causal effect or residual bias. We replicated the self-controlled case series (SCCS) study specification that reported this finding and estimated the effect of influenza on a set of negative control outcomes to assess the hypothesis that residual bias was responsible for the reported effect. We observed large, positive effects of influenza on AMI and 28 of 31 negative control outcomes. The reported effect of influenza on AMI is likely the result of biased study design. Negative controls should be routinely used when conducting SCCS studies.

Presenter: James Weaver, Manager, Epidemiology Analytics, Janssen Research and Development

Comparison of existing bleeding risk prediction models to large scale patient-level prediction models

The patient-level prediction (PLP) framework, built as part of the OHDSI suite of tools, allows for consideration of over 10,000 covariates when constructing a prediction model. In this paper we compare the performance of models built using this framework to five existing risk prediction models (ATRIA, ORBIT, HAS-BLED, CHADS2, CHADS2-VASc) designed to predict major bleed events in new users of warfarin or direct oral anticoagulants (DOACs) with prior non-valvular atrial fibrillation. The PLP models consistently outperformed the existing models in the current setting, which further supports the value of this framework.

Presenter: Clair Blacketer, MPH, PMP, Manager, Epidemiology Analytics, Janssen Research & Development; Co-lead, OHDSI Common Data Model workgroup

Prediction and external validation of Heart Failure in patients with Type 2 Diabetes Mellitus

This study aims to develop and externally validate models for the prediction of Heart Failure (HF) in a cohort of patients with Type 2 Diabetes Mellitus (T2DM). The models are developed using the Patient-Level Prediction Package developed in OHDSI. The discriminative performance and calibration scores of the models are assessed on 11 databases. These databases are rotated as a development set and



external validation was done on the other three databases. The study shows that the development of prediction models with excellent external validation is feasible.

Presenter: Ross D. Williams, MS, PhD Student, Erasmus University Medical Centre

It takes a village: An open-science approach to improving quality and efficiency of the real-world evidence generation process

With the recent national launch of the National Institutes of Health All of Us Precision Medicine initiative, the advent of the 21st Century Cures Act and moonshot initiatives, there is increasing focus on the need to facilitate large scale research collaboration to improve our nation's health. Today, the vast majority of scientific research moves in a stepwise, linear progression. In 2017, the FDA Sentinel Initiative reported that a full real world safety analysis can be conducted in under 12 months. We believe that with the right collaboration framework, a high quality study protocol could be generated and executed in even less time. To test this, we conducted an experiment to evaluate the optimal process to improve quality and efficiency in generating high quality real-world evidence. For two working days, we convened a multi-disciplinary group of 52 researchers from 23 institutions. We called the exercise a "study-a-thon". The primary focus of the exercise was to focus on one specific common goal: to generate reliable evidence on one clinical problem. Our ambition was to get as close to generating a full real world safety analysis as possible. We administered pre- and post-tests to assess researcher perceptions on the quality, accuracy and reproducibility of real world evidence generation processes using observational databases. A total of 44 of the 52 investigators consented to be included in this analysis. In this presentation, we will discuss multiple axes of real world evidence generation and process optimization sharing insights and lessons learned from our study on studies.

Presenter: Kristin Feeney Kostka, MPH, Collaborator, OHDSI; Data Science Lead, Deloitte Consulting LLP