EHDEN HMB Meeting Minutes

2023-06-01

# Topic: HMB Phenotype Discussion

## Attendance

* Bayer: Siir Su Saydam
* BI: Ron Herrera
* Odysseus: Martin Lavallee and Asieh Golozar

## Minutes

* **Review of HMB Project History**
  + Bayer contract with IQVIA to run HMB study using IQVIA European datasets (France and Germany) and Bayer internal assets (CPRD GOLD, AURUM, MarketScan, Optum)
  + IQVIA developed concept sets, cohorts and analysis
  + Analysis written for ATLAS
  + Concept sets and cohorts were developed but not formally evaluated using cohort diagnostics.
  + *Current Status*: Project remains on-going with IQVIA, finalizing incidence analysis. IQVIA not contributing to EHDEN part of study.
* **Issues with HMB Phenotype**
  + Mapping issue for ICD9 (626.2) *Frequent or excessive menstruation* in OMOP Vocabulary
    - concept maps to a vague SNOMED concept: *Finding of menstrual bleeding* (id:4078455)
    - issue found when noticed under-counting prior to 2015
    - In cohort definition added a search on the source concept
    - Issue is posted on [OMOP Vocabulary github](https://github.com/OHDSI/Vocabulary-v5.0/issues/588)
  + IQVIA does not require visit table so age censor based on measurement domain
  + Concept sets need work - use of multiple non-standard concepts
* **Improving the HMB phenotype**
  + HMB phenotype to be re-developed as seen to have too many errors and inconsistencies
  + Extend time period to all available data, no longer ending at 2020. Add COVID strata to analysis
  + HMB phenotype available from OHDSI phenotype library. Can use this as a starting point and refine.
  + Explore adding information from CHAPTER study to phenotype (unnatural menopause defined as women with Breast Cancer on endocrine therapy, for example)
  + Concern of under diagnosis of HMB in GP data. CPRD uses more concepts from the Observation table that may be more helpful in enumeration
  + Odysseus to help review concept sets
  + BI can run cohort diagnostics and assist in improving the HMB phenotype, however can not share characterization results.
* **Protocol Development**
  + Bayer sent draft of protocol amendment on May 30th to study team
  + Team agreed that it is a bit confusing separating the protocol by parts.
  + Preference of team to have a clean document to outline EHDEN portion of the analysis, suggest to create a Statistical Analysis Plan (SAP) that serves as our main guidance document for the study

## Action Items

* **Redo HMB Phenotype**
  + Team agrees to redo HMB phenotype using the [OHDSI phenotype library definition](https://github.com/OHDSI/PhenotypeLibrary/blob/main/inst/cohorts/300.json) as a starting point
  + Odysseus to build new HMB phenotype and concept sets by mid mext week
* **Run Cohort Diagnostics on new HMB Phenotype**
  + Odysseus to send new HMB phenotype to Bayer and BI to run cohort diagnostics on the new definition
  + Odysseus to set up new study repo with cohort diagnostics code to run
* **Develop SAP to complement Bayer Protocol**
  + Bayer to continue with protocol amendment for internal processes
  + Odysseus and Bayer to work on an overview of additional analysis for the protocol amendment
  + Odysseus to develop an SAP for the EHDEN part of the study. This document will be the main guidance document.