

EHDEN HMB Meeting Minutes

HMB Phenotype Discussion

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1 Attendance

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

2 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](#)

- 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

3 Action Items

- **Redo HMB Phenotype**

- Team agrees to redo HMB phenotype using the [OHDSI phenotype library definition](#) as a starting point
- Odysseus to build new HMB phenotype and concept sets by mid next 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.