Odysseus Data Services, Inc
EHDEN (HMB) – Bayer
5/4/2023 at 10AM EST

Meeting notes for EHDEN (HMB) Kickoff

Attendance:

- Bayer: Carsten Moeller, Gianmario Candore, Parisa-Fatemeh Asad, Renate Schulze-Rath, Siir su Sayadam
- Oxford: Marta Pineda Moncusi
- Odysseus: Asieh Golozar, Martin Lavallee, George Argyriou, Lana Shubinsky

Minutes:

Review of Study Status

- Data Partners:
    - Aiming for 3 to 5 study partners in EHDEN network
        - University of Oslo, Dept of Pharmacy - Norway (issue with OMOP mapping not complete)
        - Semmelweis University - Hungary (presumed a go)
        - Hospital del Mar - Spain (low patient count for HMB)
        - LynxCare – Belgium (presumed a go)
        - STIZON – Netherlands (presumed a go)
    - Bayer and Oxford mentioned that there were some difficulties recruiting further data partners. Interested parties dropped due to OMOP mapping issues or other issues ruling themselves out
    - Bayer and Oxford mentioned that the criteria for selecting databases were:
        - Primary Care + Hospital data available
        - Hospital data available
        - Have sufficient hysterectomy data
    - Odysseus suggested the following potential data partners:
        - Estonia -> smaller database but has reputation of being collaborative.
        - MoH Israel -> hospital data.
        - Austria -> Bayer and Oxford reached out but no response.
        - Bordeaux -> SNDS has a long approval wait time. Odysseus mentioned Bordeaux University Hospital as another option.
    - BI to assist in this project (original project author there) but will not offer any data for this study.
    - Bayer will run study on US claims (MarketScan and Optum) and UK CPRD.
    - IQVIA was contracted to run original study on French and German data. They are not expected to participate in the expansion of this study to EHDEN network.
- Cohort Diagnostics
    - Several data partners have run cohort diagnostics. Change was made to one phenotype to capture patients in the Hungarian database.
    - Odysseus to review cohort diagnostics and ensure the definitions are comprehensive and capture all patients eligible to be included in the study.
    - Odysseus will assist in reviewing the concept set for HMB.

- Odysseus to assist in rerunning Cohort Diagnostics across the network following review of concept sets and phenotypes.

- Protocol
  - Protocol has been written and internally approved at Bayer but the protocol will be reviewed and simplified for the EHDEN network study.
    - Bayer commented that the focus will be on Cohort 2 HMB cohort and looking that the incidence and treatment patterns from this population.
- Ethical Approval
  - Each site has different processes for ethical approval which will vary the timelines.
  - Team has set a buffer of time to allow for data partners to satisfy internal approvals prior to running the study. Per slides this period will be May-June.
- Study Package
  - The characterization package has been developed and executed on Bayer and IQVIA data.
  - Question: Should the study package transition to using the DARWIN IncidencePrevalence R package instead of the ATLAS version
    - Review and comparison of the results from IncidencePrevalence (IP) and the original approach in CPRD can help identify the differences or similarities.
    - Pending decision on which route to take: keep old code or switch to IP although definite interest in using the new package to align with DARWIN work
  - Question: How will Treatment Patterns be handled?
    - Odysseus uses an adaptation of TreatmentPatterns for its analysis. Also displays results in Sankey instead of sunburst plots (the output of ATLAS)
    - Decision of direction tabled for later discussions.
  - Question: Bayer has migrated to snowflake, the old code was written for redshift. Will the code need to be updated or using old results?
    - Bayer suggests updating the code to work in snowflake.
    - Bayer and Odysseus to work offline on reviewing the code and identifying how to transition it to work with snowflake environment.
  - Odysseus to help adapt the study package to adapted protocol and assist with its execution for data partners.
  - Expected study execution time to take place in summer (between July and September 2023)
- Other Items
  - Study-a-thon
    - A study-a-thon is planned to take place in fall 2023 (September -November
    - A final decision on timing will be made based on progress of study over summer.
  - Manuscript
    - Team to work on manuscript aiming for December 2023 completion.
  - Bi-weekly meetings
    - Team agrees to catch up on progress via biweekly meetings to be scheduled.

Next steps/action items:

- Odysseus to review and potentially suggest new data partner (introduce Bordeaux, suggests others, and help with getting MoH Israel onboard if needed)
- Bayer/EHDEN try another time to bring in BI Japanese data.
- Bayer: internal meeting to discuss design and simplify the study/cohorts a follow up meeting with the rest of the team to discuss the changes and plan accordingly.
- Discuss treatment pattern analysis in future meetings after protocol is finalized.
- Odysseus to review the codes with Bayer to ensure it will run on snowflake.
- Biweekly meeting (agenda to be shared before the meetings)