

Running an OHDSI Network Study

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Pre-requisites

- Join the OHDSI community! https://www.ohdsi.org/join-the-journey/
 - Log onto the forums (http://forums.ohdsi.org/) and introduce yourself
 - Watch recent video on what OHDSI and OMOP are and how to utilize this common data model: https://www.ohdsi.org/past-events/2017-ohdsi-symposium-materials/2017-ohdsi-sympoium-videos/
 - Join the OHDSI community call on Tuesday 12-1PM Eastern Time, to again introduce yourself and your role/interests
 - Learn more about the various OHDSI analytic tools; open-source on Github (https://github.com/OHDSI/), the most important of which for clinical research is Atlas (http://www.ohdsi.org/web/atlas/)
 - Review ongoing research studies and protocols: http://www.ohdsi.org/web/wiki/doku.php?id=research:studies
 - o And at any point, feel free to reach out on the forums for any help or questions

Building and Running Network Research Studies

- Think of a study question that a network of EHR and claims databases could help answer
 - Review list of databases which are currently a part of the OHDSI network and utilize the OMOP CDM (list still being updated and constantly growing!): http://www.ohdsi.org/web/wiki/doku.php?id=resources:2017_data_network
- You've got the question, now you need the data. You will first need to generate the cohorts of
 interest—including the target cohort, control/comparator cohort, and outcome cohort. Then
 you will need to create the analysis using these cohorts. In order to do this, you have one of 2
 options:
 - ATLAS tool: Researchers can use the ATLAS tool (on http://www.ohdsi.org/web/atlas/ or via local instance of Atlas, if available) to create the desired cohorts and analysis for the study. This code will be used by each participating site to run the study on its local database. Atlas documentation available here:
 - http://www.ohdsi.org/web/wiki/doku.php?id=documentation:software:atlas Brief outline of steps below:
 - First click define new cohort on the home page. It will take you to the Cohort page, where you can name and save your cohort. You can also click 'Cohorts' on the left to search for cohorts that others have previously defined (but will need to double check how their definitions to ensure it fits what you are looking for)



- In order to build a cohort, you will need concept sets to help define inclusion and exclusion criteria for your cohort. Go to the concept sets tab (should be empty if new). You will need to build new concept sets or use previously defined concept sets by importing them when you define your inclusion and exclusion criteria on the 'Definition' tab
- If you are building a new concept set, select 'New Concept Set' button. Then go to 'Vocabulary' on the left menu to search for the concepts you are interested in (for example, if building a cohort of patients taking atorvastatin, you will need to select the atorvastatin concept; search for 'atorvastatin'). Click the shopping cart on the left of each row of the search results which match what you are looking for. You can do the same for diagnoses, procedures, drugs, labs, etc
- Next click on the back arrow at the top to the page to return to your cohort/concept set. You should see the list of concepts you selected in a new concept set, which allows you to save and group a selection of concepts. You should see all of the concepts you selected in the table. Name and save this concept set. Repeat this for each concept set you need to build
- Once all your concept sets are defined, return to 'Definition' tab in order to select all of the initial event inclusions for when a patient should enter your cohort (such as when a patient first starts atorvastatin). You can also add exit criteria for when patients exit the cohort
- Name and save your cohorts
- Try to generate the cohorts in the Generation tab to ensure you have patients in your cohort (and see how many patients). Local instances will be linked to your local database, the online public Atlas will link to synpuf, which is a synthetic Medicare database. You can also export the SQL script in any database dialect to generate these cohorts on your local database.
- Go to the 'Estimation' page (Population Level Estimation) or the 'Prediction' page (Patient Level Prediction) depending on the type of analysis you wish to run. Follow the instructions on each page to select the cohorts (the open folder button allows you to import ones that were previously created—including the ones you just created!). Then select the type of model you wish to use and other variables for each study
- Under 'Utilities' tab, you can see your research question and study design in text form under 'Print Friendly'. The code to execute these studies will be under 'R code'
- Manually writing the SQL script: There is always the choice to create the SQL script manually. There are OHDSI programmatic tools available to help render the code to any dialect of SQL.
 - You can import SQL scripts into Atlas as well under the 'Estimation' page (Population Level Estimation) or the 'Prediction' page (Patient Level Prediction)



- If possible, we recommend trying to run your study on your local OMOP database to ensure it runs successfully. Troubleshoot as needed.
- Decide how you want the results from other sites to be exported and shared back with you
- Once you know your study is accurate and successfully running, a study protocol needs to be written by the primary investigators. Additional references available here:
 http://www.ohdsi.org/web/wiki/doku.php?id=research:studies This protocol should provide detailed information about study, including information on the methods used, and is used by the participating sites to better understand the study.
- Use the template to create a wiki page in the OHDSI Research Studies section:
 <u>http://www.ohdsi.org/web/wiki/doku.php?id=research:project_proposal_template_3</u>. You may need to first request access to the wiki
- Once the code, wiki, and study protocol are written, it's time to engage the OHDSI community!
 Create a page on the forum announcing the study, under the Researchers topic:

 <u>http://forums.ohdsi.org/c/researchers</u> Then, on any weekly Tuesday community call, the lead investigators can announce their study. This is an opportunity for the researchers to give a general description of the study, including the motivations for the study, and to take initial questions about it.
- For the network to be able to participate, it needs the code! The initiating researcher needs to
 post to the OHDSI GitHub repository (https://github.com/OHDSI/StudyProtocols) all the relevant
 scripts and documentation, including any potential instructional manuals that a network
 member would need to successfully run the study at his/her site. Any willing network member
 could download the code and documentation from the repository if he/she wishes to
 participate.
- Collaborators will often have comments and revisions to suggest about the protocol, or run into
 issues when executing the code. They will post on the forums and contact the lead investigators
 to further discuss these issues.
- Allow for a few weeks-months for all participating sites to execute the study. You can set a study closure date on the wiki. During this time, the lead investigators can collaborate with other sites on various tasks, like paper development, code updates and data visualizations preparations.
- The work to complete the paper commences, including creating useful data tables, figures and visualizations.
- You've filled the gap in our understanding of something specific to evidence based medicine...now it's time to tell your peers about it! Find the journal that will do just that!