

PaTHways Real-World Evidence Publication Opportunity

Are you interested in evaluating a research question using the PaTH Clinical Research Network data marts with EMR data from multiple large health systems?

Eligible Publication Projects

Overarching

- Analyses can be cross-sectional or longitudinal analyses of health topics
- Projects should test hypotheses important to patients and providers that are suitable for publication and could potentially support the development of larger-scale research applications using PaTH and potentially other PCORnet sites.
- Patient partners should be included in the analysis/writing teams (PaTH can help facilitate team building if needed)
- A submission-ready manuscript should be completed within 1 year of data receipt.

Data

- Each project must use data from at least 2 health systems. We expect that most projects will be able to access data from all 7 PaTH sites.
- It is expected that projects will use only data that are currently standardized across PaTH-affiliated health systems in our Common Data Model (CDM) and ready for analysis. Please note that not all CDM tables are fully populated by all sites. Interested investigators should work with the PaTH team prior to submission to ensure that their data request is feasible (see local contact information at the end of this document).
- PaTH can provide applicants with preparatory-to-research (PTR) data and our informatics teams can work with investigators to help them understand what the appropriate scope is for PTR queries.
- Investigators are expected to justify the requested sample size if rare outcomes will be examined.
- We are only considering low-moderate complexity data requests for the PaTHways Publication Program at this time. Your liaison with the PaTH informatics team will inform

you of the technical complexity of defining your cohort after review of your data request and can help to revise requests to meet this requirement.

Costs & Regulatory Issues

- A de-identified dataset extracted using a single low-moderate complexity data query will be provided free of charge
- This initiative's focus is to provide data for analysis; no salary support for investigators or analysts is available.
- Data use agreements are in place, but the lead author will be responsible for obtaining project-specific IRB approval. No data can be released until appropriate regulatory measures are in place.

Collaboration

- Eligible projects must involve collaboration between investigators from at least two PaTH-affiliated institutions. Junior investigators are welcomed to apply in partnership with one or more senior research mentors. Investigators from each collaborating site must have demonstrable and substantial roles in the project.
- The paper team must include an analyst who has experience working with electronic health record data.
- At least one investigator from each site that provides data should have an opportunity to participate in the publication(s) that arise from the project. The PaTH team can help to facilitate connections with researchers at other PaTH institutions.
- We request that you include a PaTH informatics team member who is knowledgeable about PaTH/PCORnet data. Your local PaTH team and/or the coordinating PaTH team can help you to identify someone who can fill this role.
- Abstracts and other publications must be pre-approved by the PaTH Papers & Publications Work Group.

Feedback

- In support of ongoing data quality efforts, all project teams must complete a brief survey upon completion of their work, describing their experiences using PaTH data and ideas for expanding and improving this real-world-evidence resource.
- Publication details must be provided to PaTH in a timely manner, to fulfill reporting requirements to the network's funder.

Manuscript Proposal Submission Process

- A completed PaTH Publication Proposal Template should be emailed in pdf format to PaTHCDRN@pitt.edu
- Please use subject line: Attention: PaTHways Publication Proposal
- Applications will be reviewed by the PaTH Publications & Presentation Committee
 according to NIH review criteria of overall impact, significance, investigators, innovation,
 and approach. The Committee will specifically consider how well the project is suited for
 use of PCORnet data.
- Responses will be provided following a 3 week review period
- PaTH will support up to 12 projects per year; lead investigators from sites that have led fewer PaTHways projects in the past year will be prioritized.

Resources for proposal development:

PCORnet Common Data Model: <u>Common Data Model (CDM) Specification, Version 6.0</u> (<u>pcornet.org</u>)

PheKB Library (code lists): What is the Phenotype KnowledgeBase? | PheKB

Site Team Contact Information

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