

# How to work with the PCORI Research Network – From EMR data-only protocols to pragmatic clinical trials

## Objectives:

1. Describe the general organization of the PCORnet and PaTH research networks
2. Review the various types of research currently being done within PCORnet/PaTH
3. Learn why and how you might collaborate with PCORnet/PaTH for your own research

# Agenda

- The PCORnet and PaTH Research Networks: *Network Structures and Research Supported* (Dan Ford)
- The PCORnet Common Data Model (CDM): *Strengths and Weaknesses* (Harold Lehmann)
- How to Work with Us: *Collaborating with PCORnet/PaTH for your own research* (“GK” Gauvey-Kern)
- A Researcher’s Experience Using PCORnet/PaTH (Wendy Bennett)
- Q & A

# The PCORnet and PaTH Research Networks



Daniel Ford, MD, MPH

PI for PCORnet/PaTH at Johns Hopkins; Director of ICTR

# PCORnet: The big picture

Three things to know about PCORnet:

**Patient-Partnered**



Patients, and those who love and care for them, are integral to ALL PHASES OF PCORNET-ENABLED RESEARCH.

**Data-Driven**



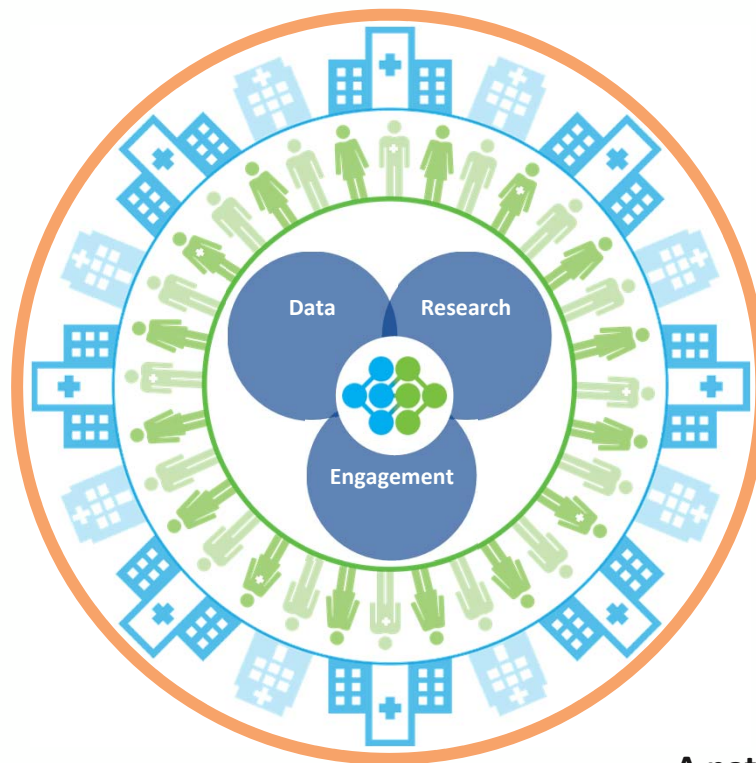
Data accessible via PCORnet draws from millions of EHRs with growing links to patient-reported and payor data, all consolidated using a common data model.

**Broadly Connected**



PCORnet connects you to thousands of clinicians and researchers who are committed to answering important questions that will improve patient lives.

# PCORnet is a “network of networks” that harnesses the power of partnerships



Clinical  
Research  
Networks  
(CRNs)

+

Health Plan  
Research  
Networks  
(HPRNs)

+

Patient  
Partners

+

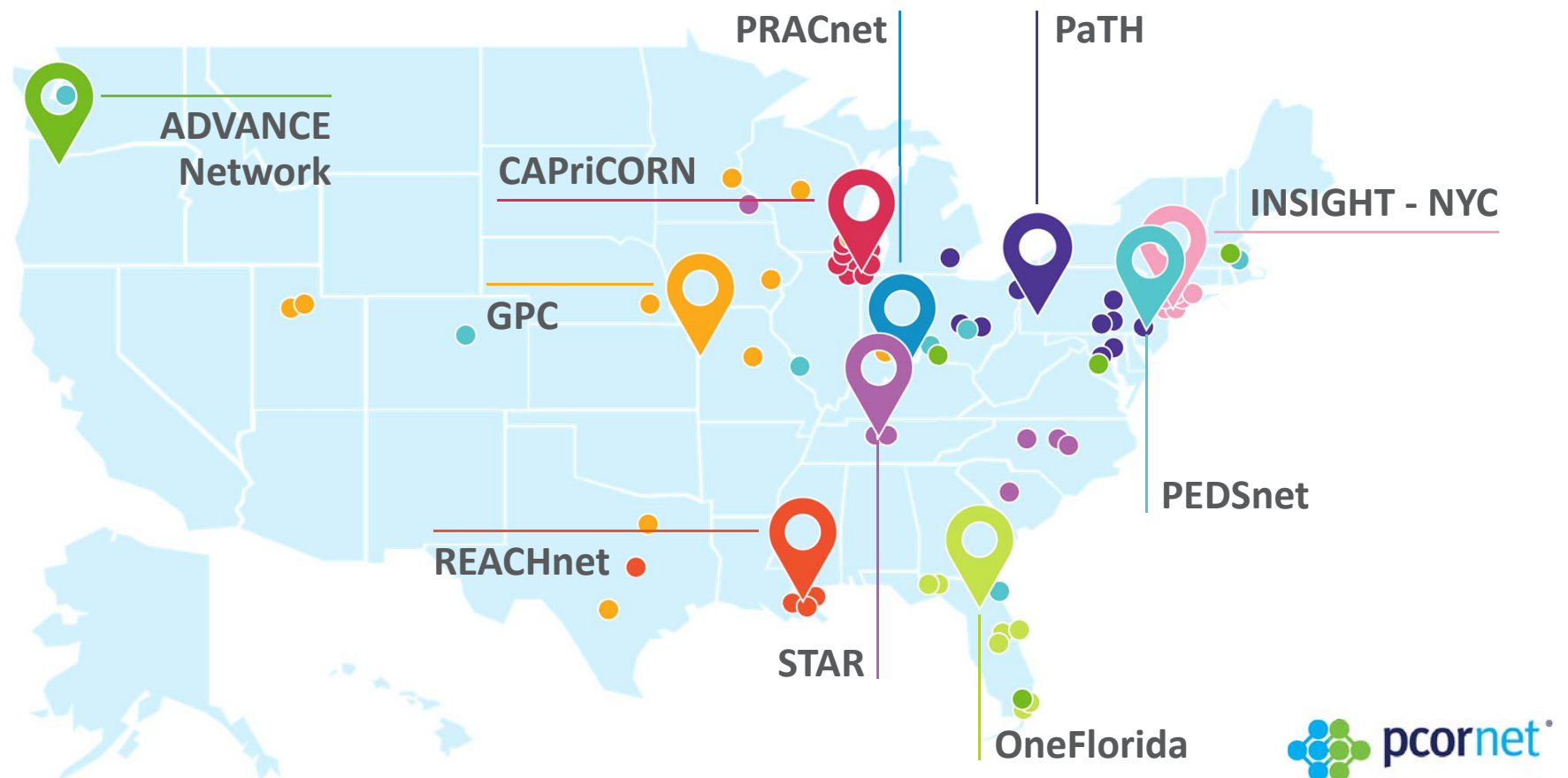
Coordinating  
Center

=

A national  
infrastructure for  
people-centered  
clinical research




# PCORnet – Partner Networks



# PCORnet - Data on a national scale

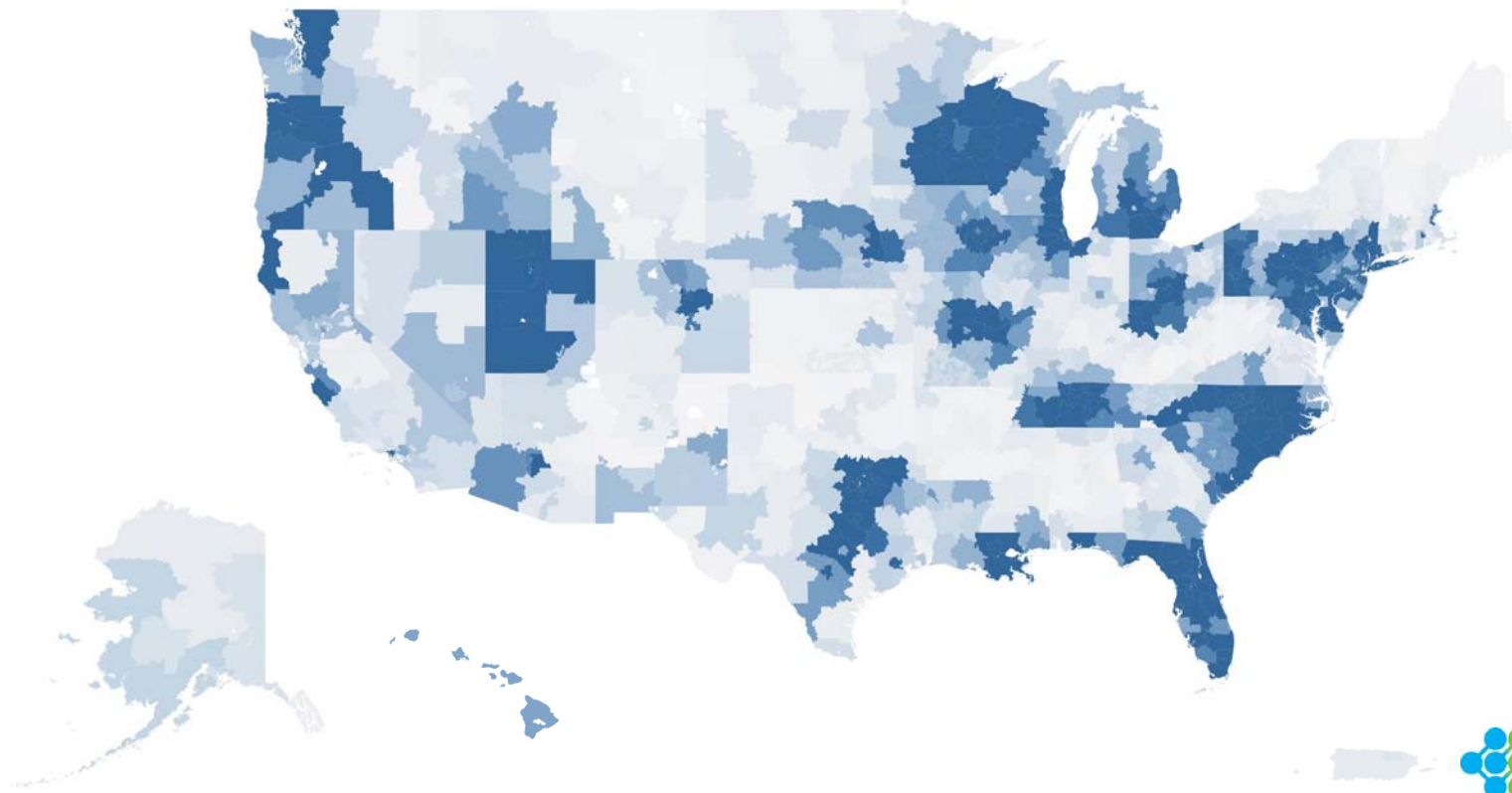
Those encounters with 70 million people result in data available throughout the nation in all types of communities. This map represents data from the PCORnet-partnered Clinical Research Networks.

Number of Participants

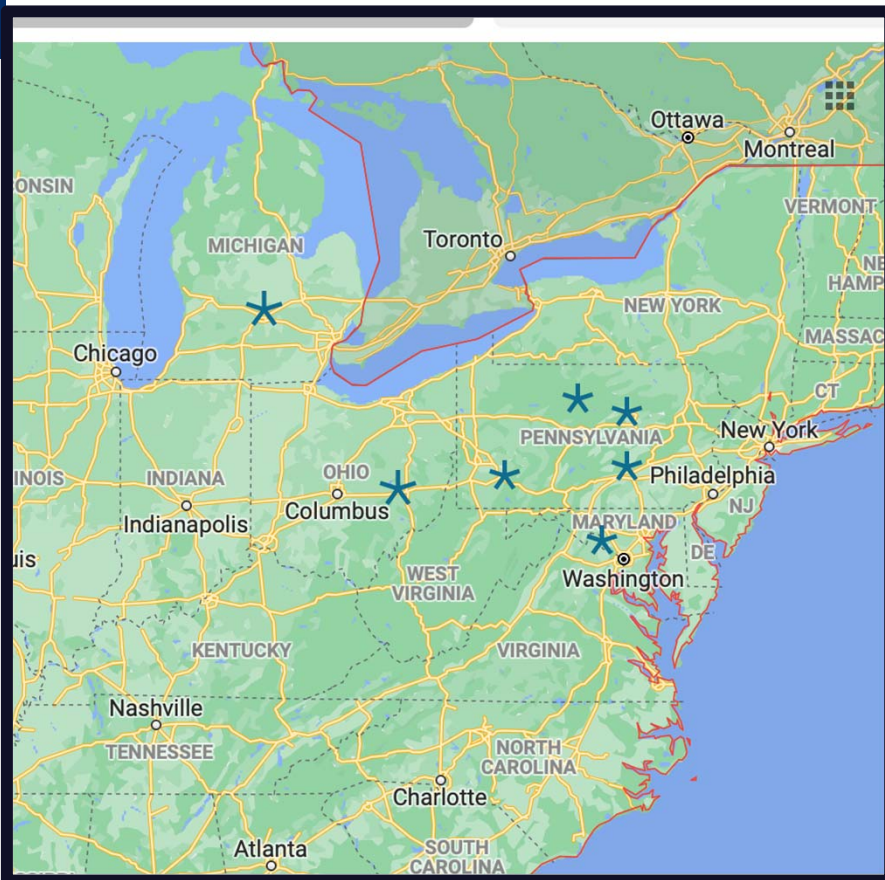


50 100,000

A horizontal color gradient bar ranging from light blue to dark blue, with '50' at the left end and '100,000' at the right end.



# The PaTH Network



The PaTH CDM includes > 14 million people with diversity in age, geography, and race/ethnicity (# or %)

## Institution\*

GHS	2,082,953
JHU	3,227,975
OSU	1,326,701
Pitt	3,769,209
PSCoM	1,188,031
TUHS	1,199,151
UMI	1,958,971
<b>Total</b>	<b>14,752,991</b>

## Age

17 and younger	15%
18-44 years	34%
45-64 years	25%
65+ years	26%

## Race/Ethnicity

Black/African American	13%
White	69%
Hispanic/Latino	4%
Other	14%



**PaTH Network**  
patient empowered research



# How can PCORnet help you?

PCORnet enables answers to questions like...

Site Selection and Cohort Identification	Descriptive Analytics	Data Characterization and Quality Assessments	Exposure and Outcome Assessments
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*Are patients who switched to a new heart failure medication achieving better symptom outcomes than their former treatment?*

*How do three popular bariatric procedures fare in an assessment of long-term comparative effectiveness?*

*What are the prescribing patterns for a newly approved medication?*

*Which aspirin dose offers the right balance of effectiveness and minimal risk of bleeding?*

*How do health systems compare across three well-established measures of quality in pediatric populations?*

# Accomplishments to Date

- Data Only Protocols
  - Long term outcomes for 40,000 individuals who had bariatric surgery
- Observational Protocols
  - Quality of life for patients with atrial fibrillation
- Pragmatic Randomized Clinical Trials
  - ADAPTABLE – Aspirin dose in patients with CVD

# Network Structure: Levels of Engagement

- **PCORNet** – National PCORI funded research network that includes nine clinical data research networks (CRNs) and a coordinating center (<https://pcornet.org/>)
- **PaTH** – One of the nine CRNs based at U Pittsburgh and includes Johns Hopkins (<https://www.pathnetwork.org/>)
  - Pittsburgh, Penn State, Temple, Geisinger, Ohio State, Michigan
- **Johns Hopkins PCORnet/PaTH program** – Site specific program within the Institute for Clinical and Translational Research (ICTR)

# Johns Hopkins PCORnet/PaTH Team

- Daniel Ford, MD, MPH – PaTH Johns Hopkins PI and Director of ICTR
- Harold Lehmann, MD, PhD – PaTH Co-PI and Informatics Director
- Megan “GK” Gauvey-Kern, MS – PCORnet/PaTH Program Director

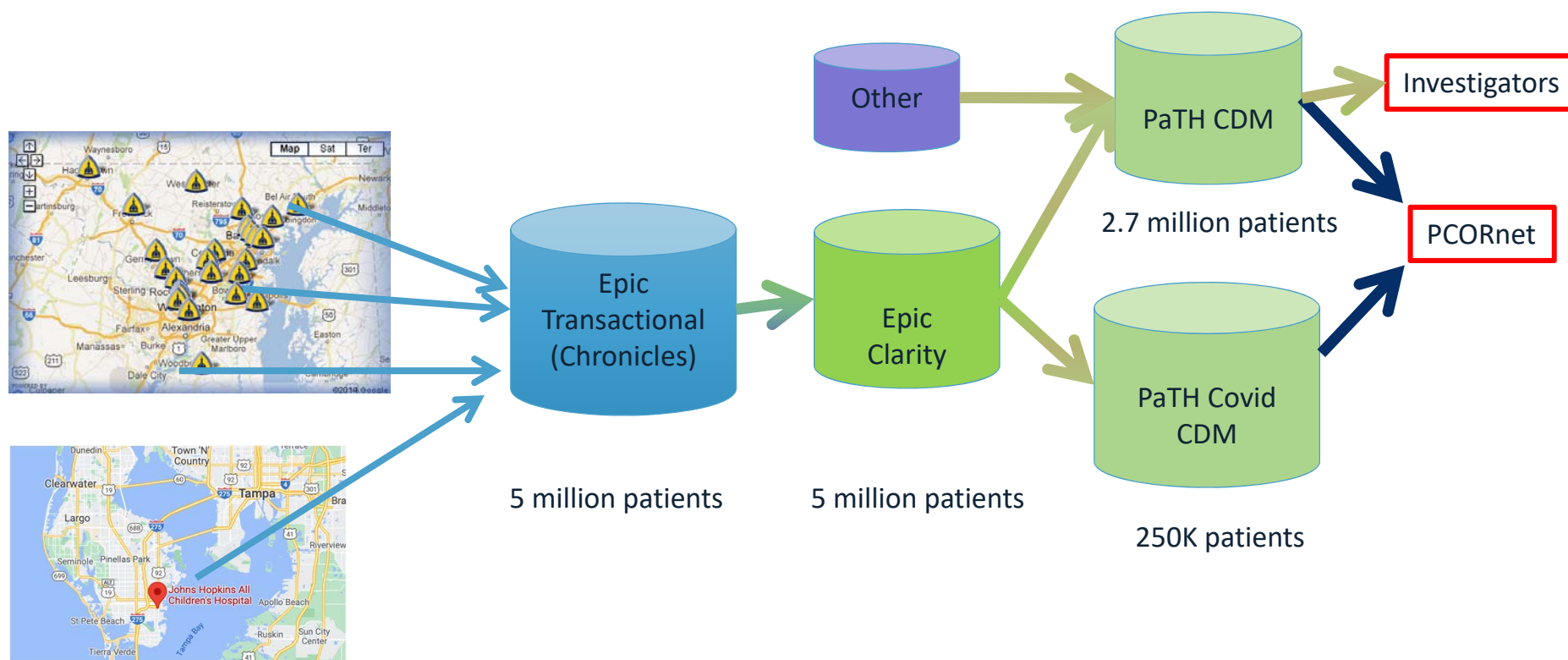
# Common Data Model (CDM): Strengths and Weaknesses



Harold Lehmann, MD, PhD

Co-I and Informatics Lead for PCORnet/PaTH at Johns Hopkins

# The Path to PaTH: Extract, Transform, Load (ETL)



# Computable Phenotypes

- “Atomic” data: What the computer can examine
  - Numbers, enumerated values (codes)
  - Inclusion criteria
  - Exclusion criteria
- Time
  - Enter the cohort
  - Leave the cohort
  - Event

# What We Now Bring In

PCORnet Common Data Model v6.0 Tables and Constraints				
<b>DEMOGRAPHIC</b> PATID	<b>VITAL</b> PATID VITALID MEASURE_DATE VITAL_SOURCE	<b>PRO_CM</b> PATID PRO_CM_ID PRO_DATE	<b>MED_ADMIN</b> PATID MEDADMINID MEDADMIN_START_DATE	<b>LDS_ADDRESS_HISTORY</b> PATID ADDRESSID ADDRESS_USE ADDRESS_TYPE ADDRESS_PREFERRED
<b>ENROLLMENT</b> PATID ENR_START_DATE ENR_BASIS	<b>DISPENSING</b> PATID DISPENSINGID DISPENSE_DATE NDC	<b>PRESCRIBING</b> PATID PRESCRIBING_ID	<b>PROVIDER</b> PROVIDERID	<b>IMMUNIZATION</b> PATID IMMUNIZATIONID VX_CODE VX_CODE_TYPE VX_STATUS
<b>ENCOUNTER</b> PATID ENCOUNTERID ADMIT_DATE ENC_TYPE	<b>LAB_RESULT_CM</b> PATID LAB_RESULT_CM_ID RESULT_DATE	<b>PCORNET_TRIAL</b> PATID TRIALID PARTICIPANTID	<b>OBS_CLIN</b> PATID OBSCLINID OBSCLIN_START_DATE	<b>HARVEST</b> NETWORKID DATAMARTID
<b>DIAGNOSIS</b> PATID DIAGNOSISID DX DX_TYPE DX_SOURCE	<b>CONDITION</b> PATID CONDITIONID CONDITION CONDITION_TYPE CONDITION_SOURCE	<b>DEATH</b> PATID DEATH_SOURCE	<b>OBS_GEN</b> PATID OBSGENID OBSGEN_START_DATE	<b>LAB_HISTORY</b> LABHISTORYID LAB_LOINC
<b>PROCEDURES</b> PATID PROCEDURESID PX PX_TYPE	<b>DEATH_CAUSE</b> PATID DEATH_CAUSE DEATH_CAUSE_CODE DEATH_CAUSE_TYPE DEATH_CAUSE_SOURCE	<b>HASH_TOKEN</b> PATID	New to v6.0	

## **New ETL: Coded (“atomic”) data**

- Chief complaint
- Surgical procedures not “ordered”
- Patient Reported Outcomes that are collected clinically
- Study data from other sources

## New work (NLP, REDCap)

- Notes
  - “Natural Language Processing” (NLP)
  - Convert Text to “atomic” data
- Patient Reported Outcomes *not* collected clinically
  - Or, not reliably collected: Epic
  - Not clinically collected: REDCap

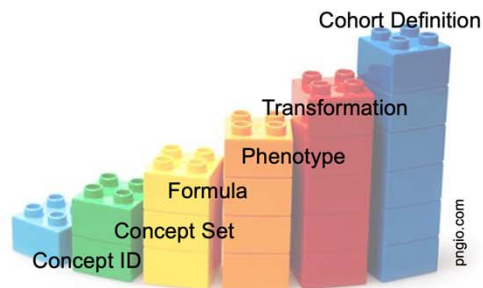
## New Linkages: Remember “Hash Token”?

- CMS Claims
- CRISP?
- Images?

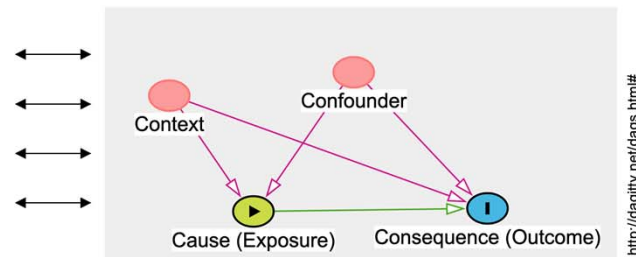
# Don't Forget the Analysis of “Real World Data”

- Think ahead
  - Negative controls
  - Instrumental variables
- Make sure your analysts and statisticians can deal with EHR data

Data Constructs



Analytic Variables



# How to Work with Us – Collaborating with PCORnet/PaTH for your own research



Megan E. Gauvey-Kern, MS ~ “gk”

Program Director for PCORnet/PaTH at Johns Hopkins

## Step 1: Start local

- If you are considering using the CDM for a research project, the first step is always to reach out to the Johns Hopkins PCORnet/PaTH team:
  - [PCORnet@jhmi.edu](mailto:PCORnet@jhmi.edu) and/or [mgauvey1@jhmi.edu](mailto:mgauvey1@jhmi.edu)
  - Provide as much information about the proposed project as possible

## Step 2: Meet with the JH team

- We'll schedule a brief (30 min) meeting for you to discuss your proposed research with Harold Lehmann and “GK” Gauvey-Kern.
  - Answer any questions
  - Provide feedback on feasibility and pros/cons of using the CDM
  - Discuss options and next steps

## Step 2a: Johns Hopkins-Only Studies

- e.g. pilot study that may want to expand beyond Johns Hopkins in the future
- If you decide you want to use the CDM only at Johns Hopkins, our team will continue to work with you directly.

## Step 3: Studies beyond Johns Hopkins – Engaging the PaTH Network

- The Johns Hopkins team will connect you to the central PaTH team and help you through our research intake process
  - Complete intake form and presentation template
  - Present to the PaTH Future Research Topics group
  - Confirm sites, data requirements, PaTH services requested
  - We provide a cost estimate (budget/justification) and LOS
- Note: if you would like to engage PCORnet sites beyond PaTH, we will facilitate this as well.

# Additional Features/Services

## ○ Proposal Development

- Prep-to-research queries
- Identifying collaborators
  - Ideal sites, Site PIs, Patient Partners, etc.

## ○ Regulatory

- DUAs – PCORnet and PaTH already have DUAs in place for sharing most de-Identified data. Experience with DUAs for LDS, etc.
- PaTH sIRB processes in place
- Contracting

# Key Take-Aways

## ○ Start Local

- Always come to the Johns Hopkins PCORnet/PaTH team first (PCORnet@jhmi.edu)

## ○ Start Early

- Recommend at least 5-6 weeks prior to deadlines, particularly when engaging multiple sites

## ○ More than just data

- Wrap-around services (study development and implementation)
- Established relationships, several years experience working together



# A Researcher's Experience Using PCORnet/PaTH



Wendy Bennett, MD, MPH

Johns Hopkins Researcher who Lead a PCORnet/PaTH Study

# The Impact of Timing of Eating on Weight: A Multi-site Cohort Study using the Daily24 Mobile Application

- 6 month Cohort Study
- Aimed to assess association between timing of eating and weight over time using a mobile App called Daily24
- Participants identified and recruited from 3 PaTH sites using EHR-based computable phenotype
- Data collection involved EHR data, Online Survey, Daily24 mobile app



# Electronic recruitment, consent and app downloading process

## This is the Informed Consent Process.

You will learn more about the purpose of the research study and what will happen if you join. After learning more, you will be able to give your permission to join.

### Your Progress

10%

Below is a summary of the Daily24 Informed Consent. Please click "Next Page" to download and view a full copy.

### Audio

▶ 0:00 / 2:19

This is a research study. In this research, we want to determine whether the time of day people eat and sleep may affect their weight.

If you decide to join this study, the following things will happen:

You will complete an online survey at the beginning, the middle (3-months), and the end (6-months) of the study about eating and exercise habits, general health and technology use.

You will download the Daily24 mobile application to your phone and use it to record your meal and sleep times off and on for a 6 month period.

Selected health information and your weight at previous clinic visits will be extracted from your medical record and included in this study.

You have just a few more steps before joining the Daily24 study!

The first is to take a handful of online surveys about yourself, your eating and use of a cell phone. This process can take anywhere from 20-30 minutes to complete. A few things to keep in mind:

It is ideal to finish them in one sitting.

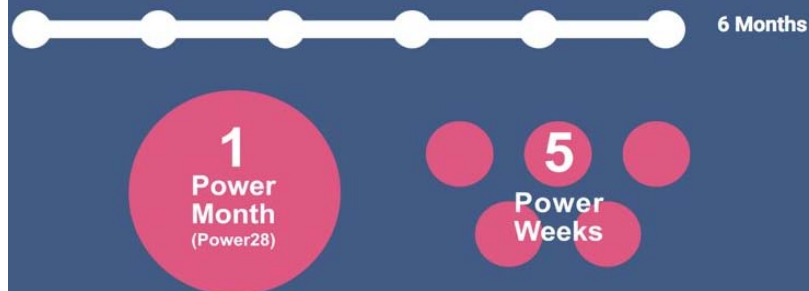
If at any point you must stop before finishing, or you accidentally close your browser, do not worry! Your answers will be saved and you will receive an email within 10-15 minutes with a link that allows you to pick up where you left off when convenient.

Now, please **CLICK SUBMIT** below to begin the baseline surveys...

<< Previous Page

Submit

For the next six months of the study, we are asking you to focus on one initial month of tracking (POWER28!) and 5 monthly POWER Weeks.



What is a Power28?



## Key Strengths of study design using PCORnet/PaTH: Recruitment

- Low touch recruitment using EHR patient portal and emails → rapid recruitment over 6 months (>1000 participants) from 3 PaTH sites
  - Used MyChart at JH
  - Used Email at other 2 PaTH sites
- Designed “hand off” from 2 other sites to primary team following participant consent to enable streamlined approach

## Key Strengths of study design using PCORnet/PaTH: Data Linkages

- Linked 3 sources of data using “electronic token” – EHR data, Daily24 App data, REDCap survey data
- Built cohort/dataset – available for multiple secondary analyses aligned with aims; data storage at the coordinating center

# Thank You.

The Johns Hopkins PCORnet/PaTH Research Team

[PCORnet@jhmi.edu](mailto:PCORnet@jhmi.edu)



[www.pcornet.org](http://www.pcornet.org)



[www.pathnetwork.org](http://www.pathnetwork.org)

*Find us on the Johns Hopkins ICTR website – updates coming soon*

