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

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Agenda

- The PCORnet and PaTH Research Networks: *Network Structures and Research Supported* (Dan Ford)
- The PCORnet Common Data Model (CDM): *Strengths and Weaknesse*s (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

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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.

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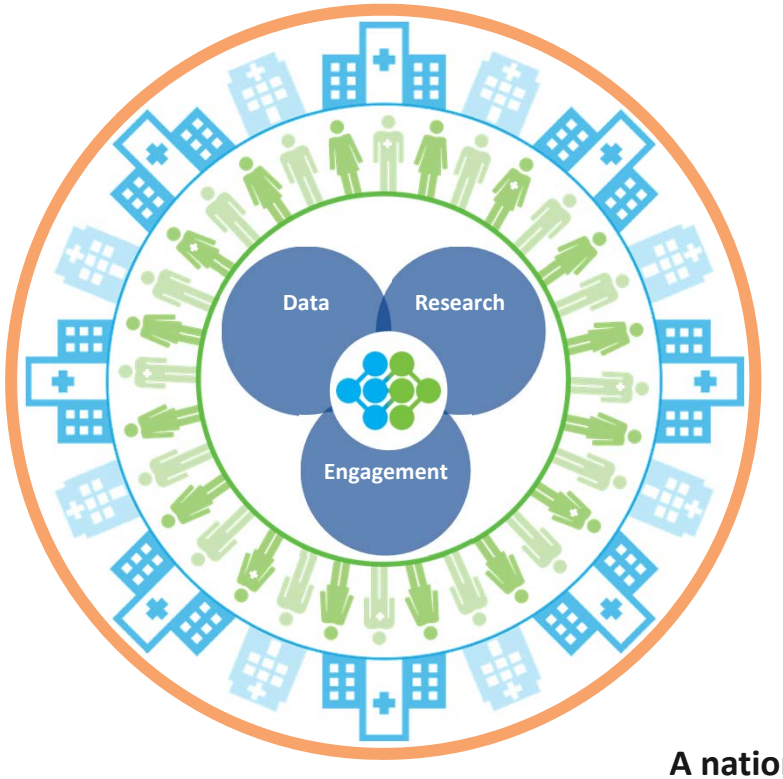
PCORnet is a "network of networks" that harnesses the power of partnerships



Clinical Research Networks (CRNs) + Health Plan Research Networks (HPRNs) + Patient Partners + Coordinating Center = A national infrastructure for people-centered clinical research

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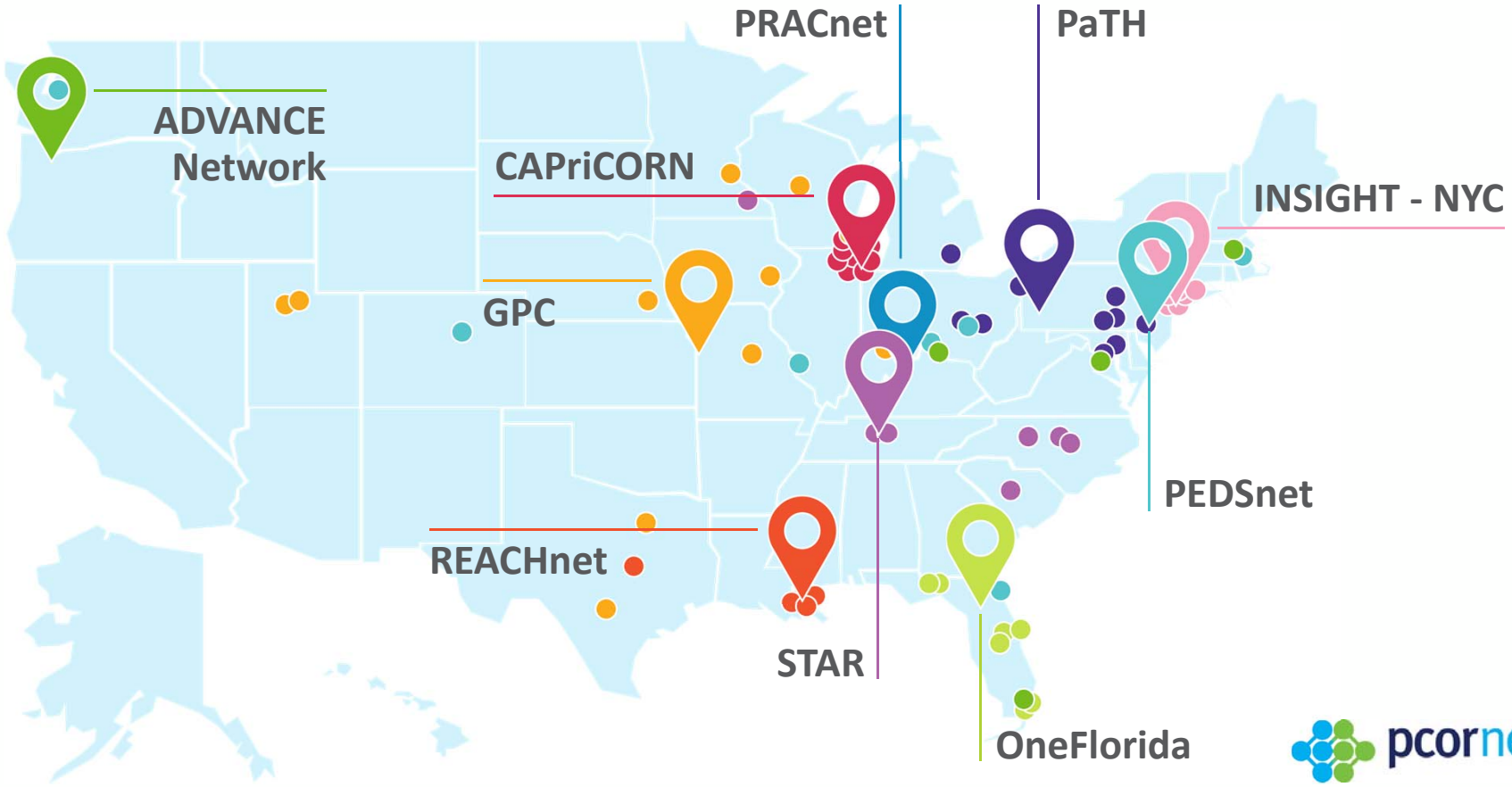
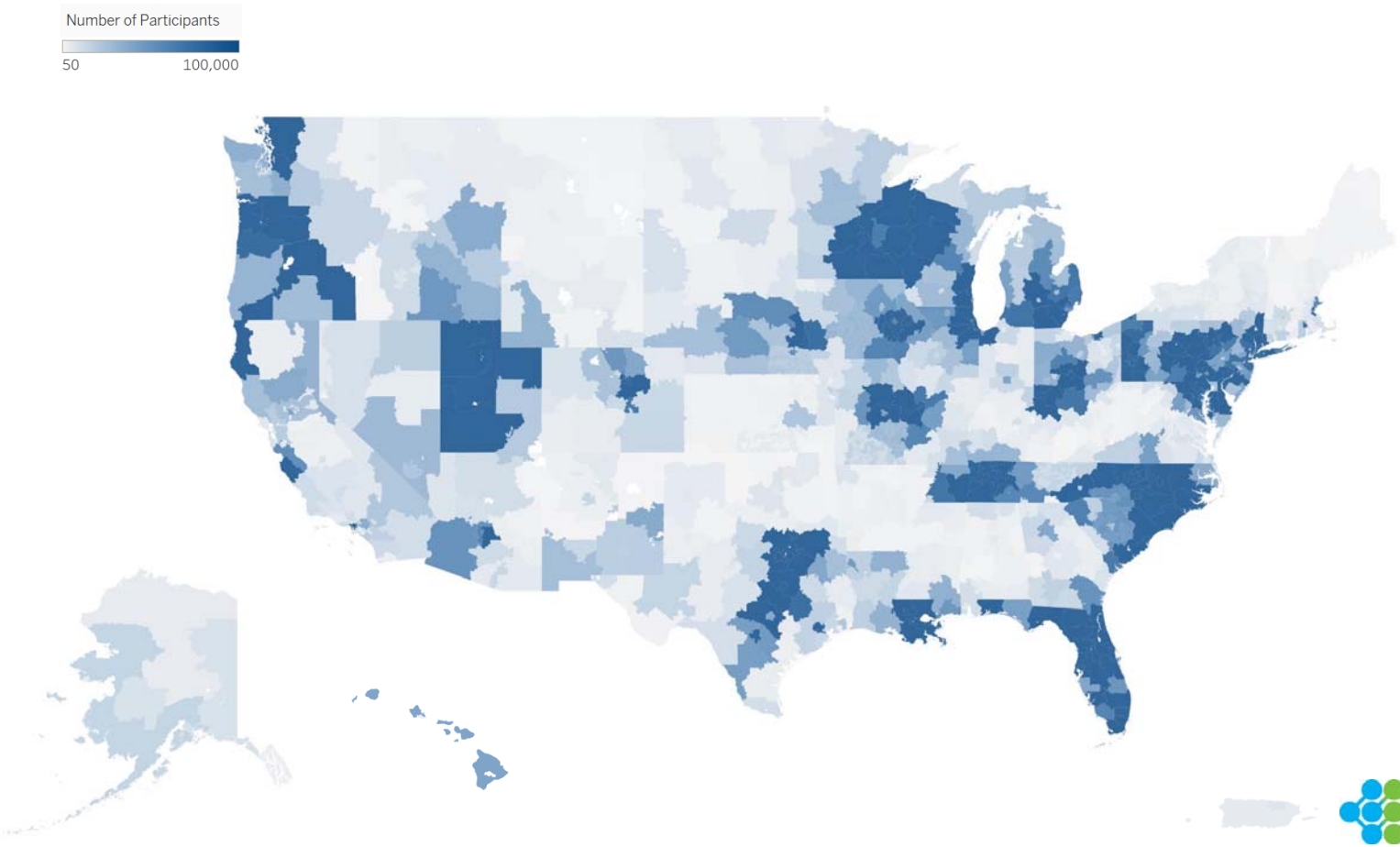
PCORnet – Partner Networks

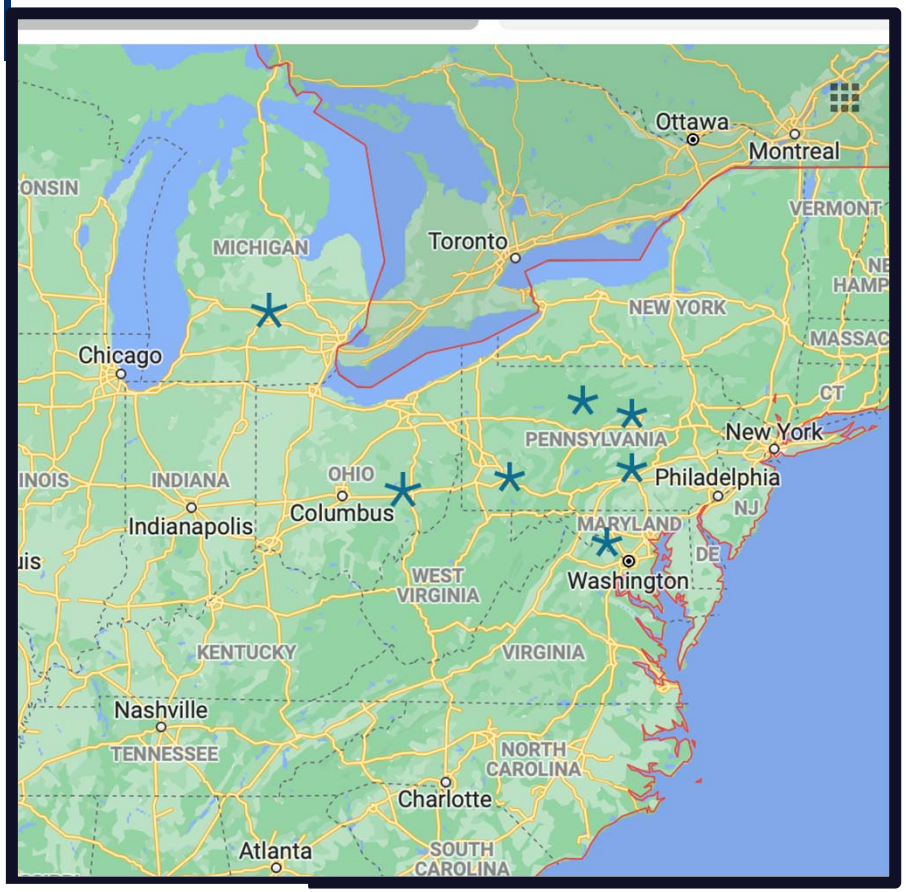


PCORnet - Data on a national scale

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.



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
Total	14,752,991
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

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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

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?

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

What are the prescribing patterns for a newly approved medication?

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

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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

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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)

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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

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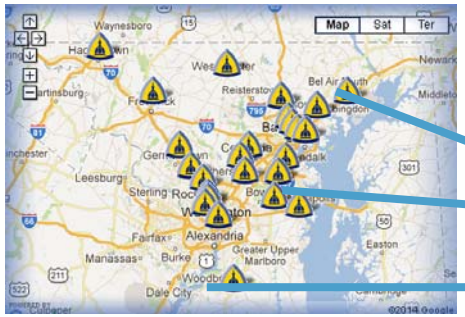
Common Data Model (CDM): Strengths and Weaknesses

Harold Lehmann, MD, PhD

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

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



Epic Transactional (Chronicles)

5 million patients

Epic Clarity

5 million patients

Other

PaTH CDM

2.7 million patients

PaTH Covid CDM

250K patients

Investigators

PCORnet

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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

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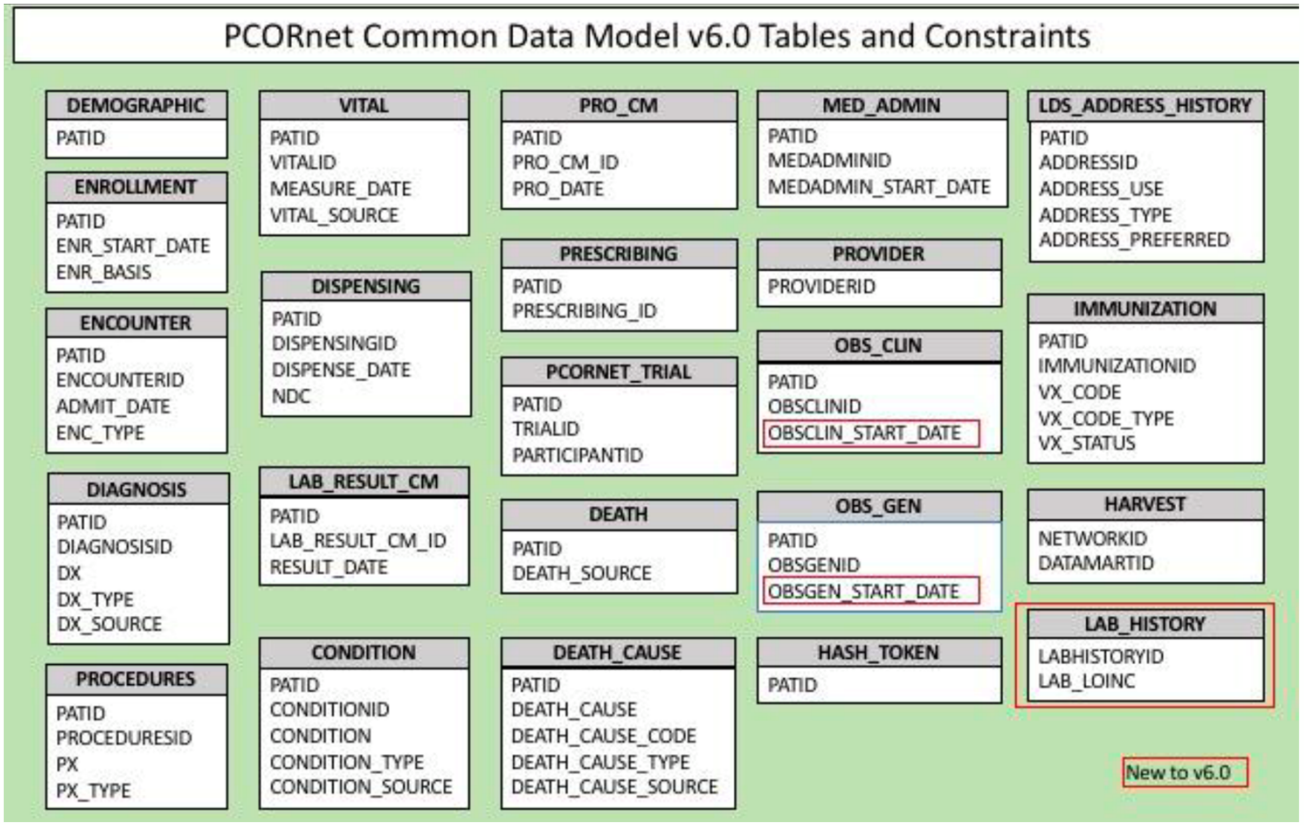
What We Now Bring In



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New ETL: Coded (“atomic”) data

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

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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

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New Linkages: Remember “Hash Token”?

- CMS Claims
- CRISP?
- Images?

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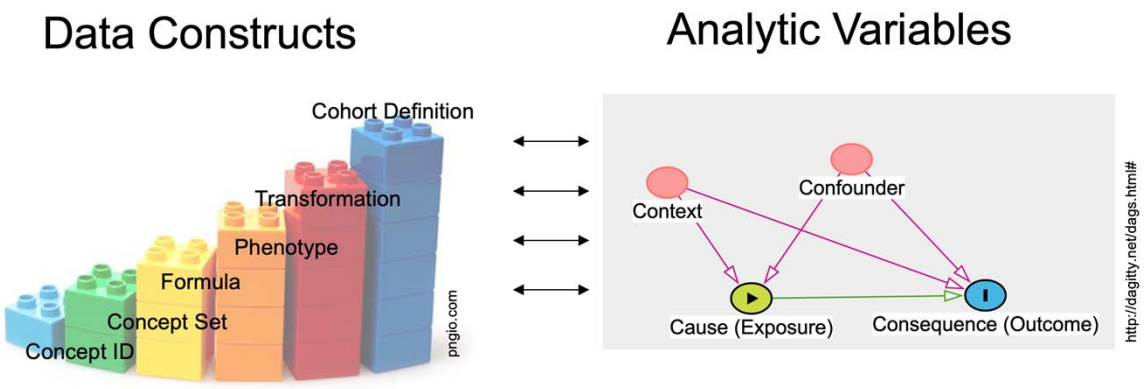
Don’t Forget the Analysis of “Real World Data”

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



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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 and/or 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

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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

Daily24

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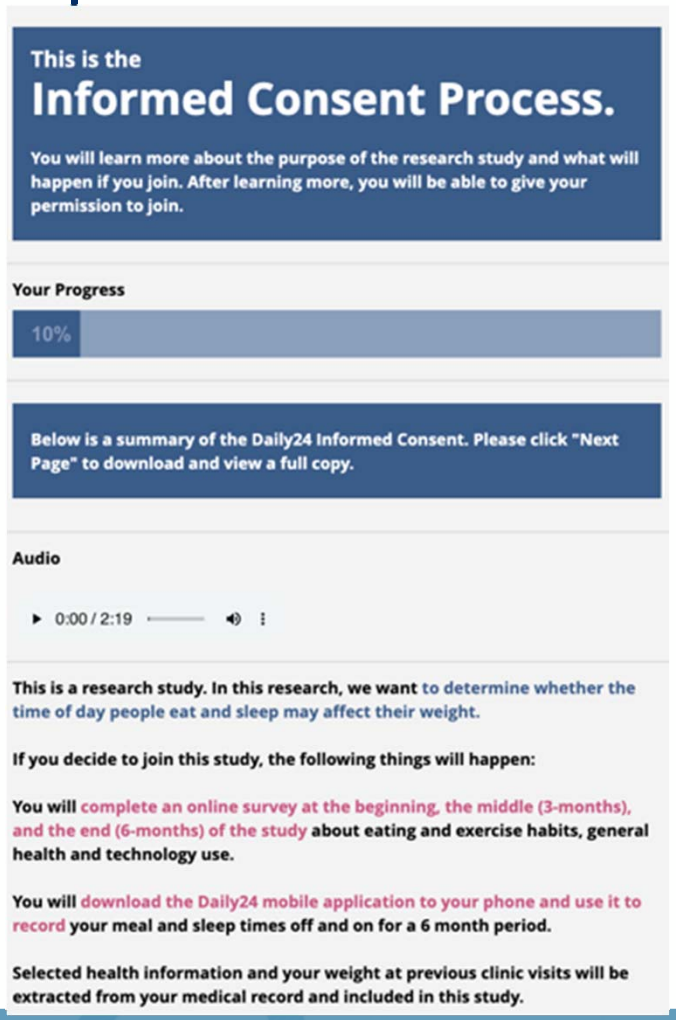
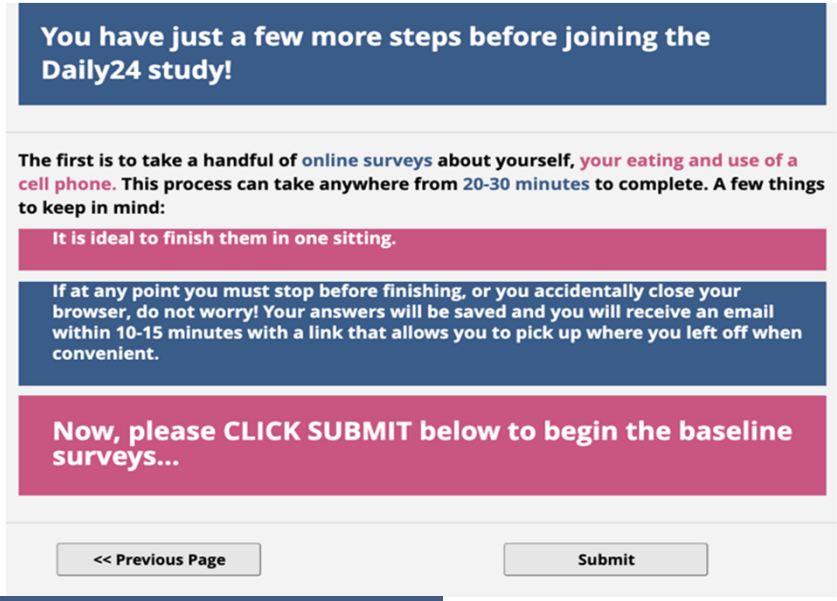
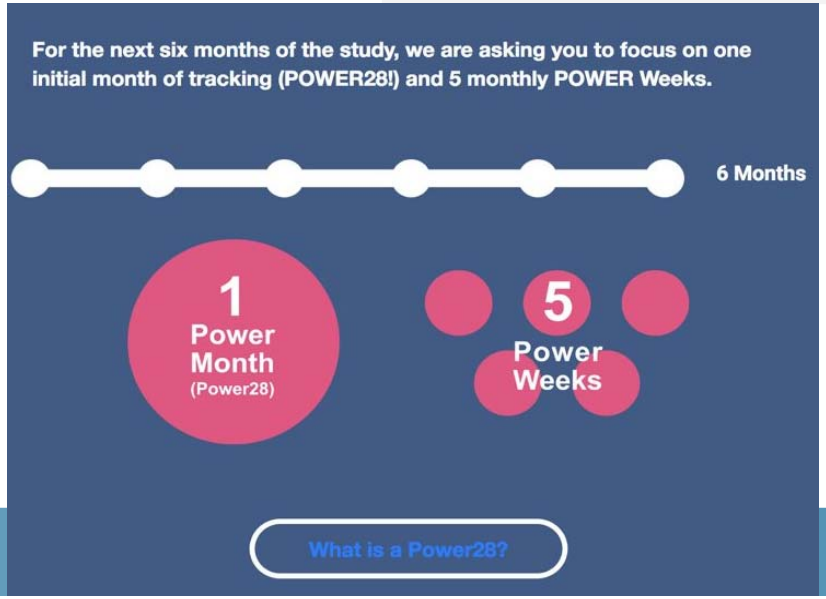
Electronic recruitment, consent and app downloading process







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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

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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

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Thank You.

The Johns Hopkins PCORnet/PaTH Research Team

PCORnet@jhmi.edu

www.pcornet.org

www.pathnetwork.org

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

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