

Multi-institutional Research using Electronic Health Records: PCORnet

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Goals and objectives

- At the end of this presentation the audience members will:
 - Understand how electronic health record information can be leveraged for research
 - Appreciate the strength of the PaTH network and PCORnet for future research projects.



What is PCORI?

- **MISSION:** PCORI helps people make informed health care decisions, and improve health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community
- **MECHANISM:**
- PCOR (Patient-Centered Outcomes Research) and CER (Comparative Effectiveness Research)

WHAT IS PCOR (PATIENT-CENTERED OUTCOMES RESEARCH)?

“Outcomes that matter most to patients”



Introducing PCORnet: The National Patient-Centered Clinical Research Network



pcornet

The National Patient-Centered Clinical Research Network

Why PCORnet?

- Every day, patients and doctors face questions for which evidence is lacking to guide answers
 - “Does ibuprofen cause heart attacks or strokes? If so, how much does it increase my risk?”
 - Which dose of aspirin (81 mg or 325 mg) is carries the most benefit with least risk for CAD prevention?



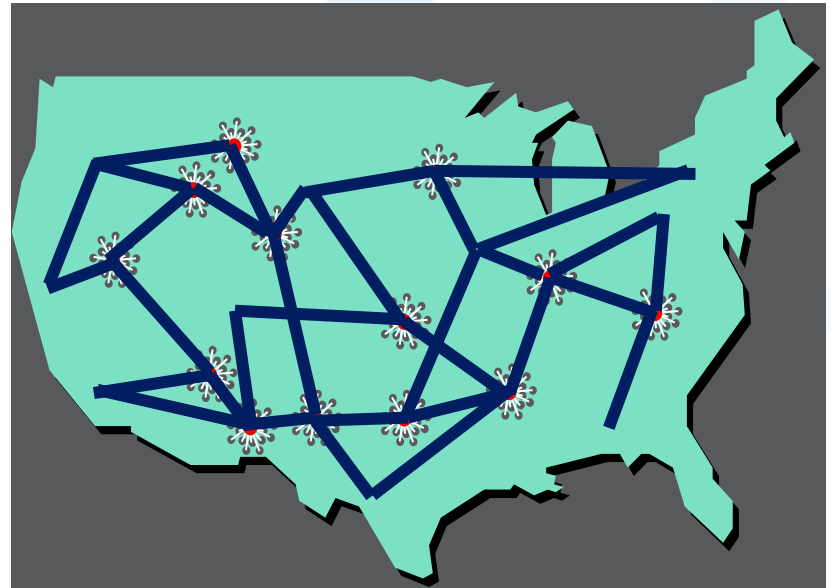
Our national clinical research system is well-intentioned but flawed

- ⊕ High percentage of decisions not supported by evidence*
- ⊕ Health outcomes and disparities are not improving
- ⊕ Current system is great **except**:
 - Too slow
 - Too expensive
 - Unreliable
 - Doesn't answer questions that matter most to patients
 - Unattractive to clinicians & administrators

We are not generating the evidence we need to support the healthcare decisions that patients and their doctors have to make every day.

Both researchers and funders now recognize the value in integrating clinical research networks

- 🌐 Linking existing networks means clinical research can be conducted more effectively
- 🌐 Ensures that patients, providers, and scientists form true “communities of research”
- 🌐 Creates “interoperability” – networks can share sites and data

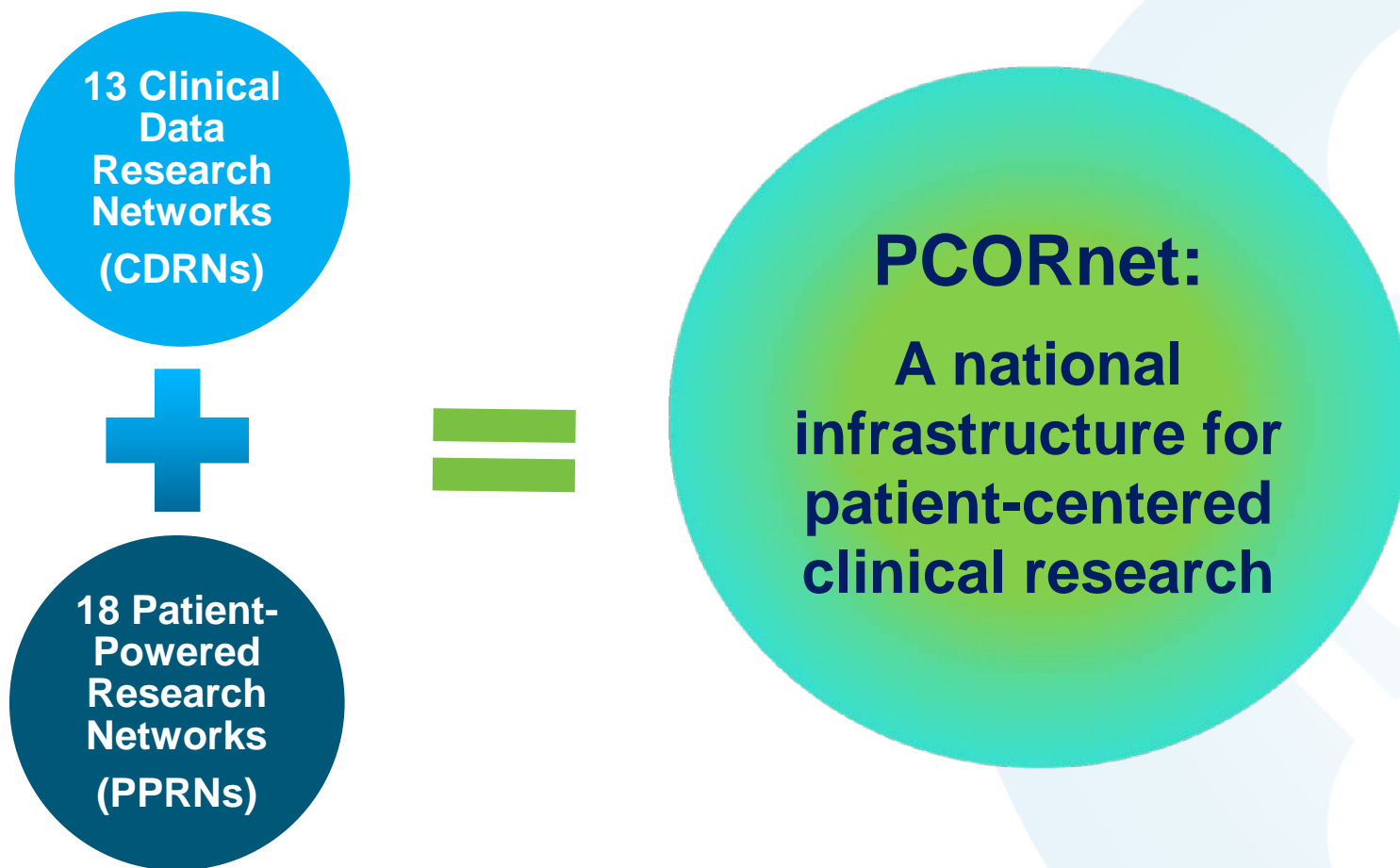


29 CDRN and PPRN awards were approved on December 17th 2014 by PCORI's Board of Governors



This map depicts the number of PCORI-funded Patient-Powered or Clinical Data Research Networks that have coverage in each state.

PCORnet embodies a “community of research” by uniting systems, patients & clinicians



PCORnet's goal



PCORnet seeks to improve the nation's capacity to conduct clinical research by creating a large, highly representative, national patient-centered network that supports more efficient clinical trials and observational studies.

Overall objectives of PCORnet: achieving a single functional research network

- 🌐 **Create** a secure national research resource that will enable teams of health researchers, patients, and their partners to work together on researching questions of shared interest
- 🌐 **Utilize** multiple rich data sources to support research, such as electronic health records, insurance claims data, and data reported directly by patients
- 🌐 **Engage** patients, clinicians & health system leaders throughout the research cycle from idea generation to implementation
- 🌐 **Support** observational and interventional research studies that compare how well different treatment options work for different people
- 🌐 **Enable** external partners to collaborate with PCORI-funded networks
- 🌐 **Sustain** PCORnet resources for a range of research activities supported by PCORI and other sponsors

How does Temple fit in?

- We are part of a CDRN called PaTH
- Lead Organization: University of Pittsburgh
- PaTH sites:
 - University of Pittsburgh Medical Center
 - Penn State Hershey Medical Center
 - Temple University Hospital
 - Johns Hopkins University Health System
 - New in 2015- University of Utah and Geisinger!

- So....
- How does this all work anyway?

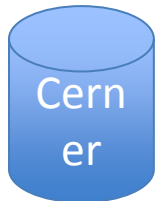


Phase I- build the system

- Connect the EHRs of the four health systems-
- Test the interconnectivity
- Recruit three cohorts of patients-
 - Atrial fibrillation (common condition)
 - Idiopathic pulmonary fibrosis (rare condition)
 - Obesity aka weight cohort (PCORnet wide cohort)
- Develop mechanisms for answering PCORnet queries – the “million cohort”
- Develop sustainability plans for the future

Connecting the EHRs- initial status

EHR Systems



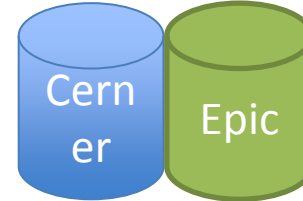
PSU



Temple



JHU

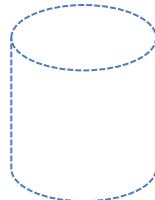


UPMC

i2b2



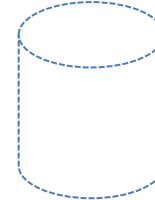
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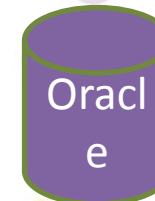


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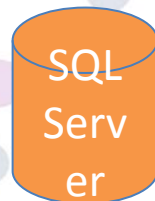
Databases



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Early challenges

- Getting the EHR's to “talk” to one another
- Understanding the quality of EHR data and what is and is not possible
- Clinicians and clinical researchers understanding how to communicate with IT/informatics and vice versa



Understanding the data quality

- Semantic equivalence:
 - Does an ICD9 **billing code** for hypertension mean the same as finding hypertension in the **problem list and the same as an elevated BP in vitals?**



Understanding the data quality

- Can you really aggregate results across sites?
- For example:
 - is PFT using **nitrogen** the same as one using **helium**?



Communicating across disciplines

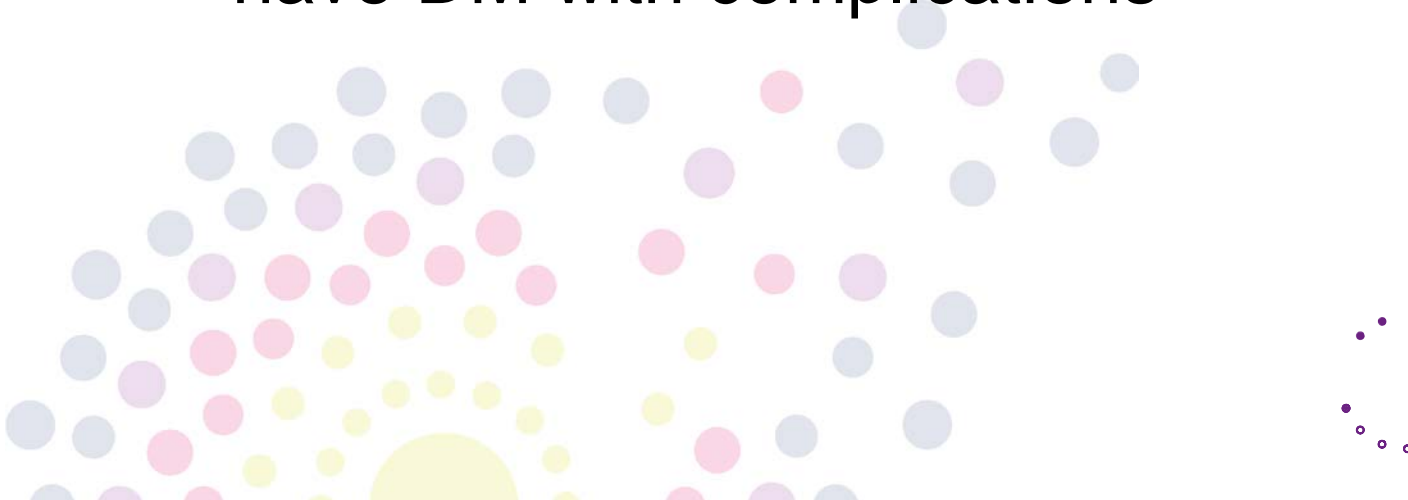
- Clinician vs. Informatician Viewpoint
Billing codes can be highly inaccurate
v/s

Why wouldn't the clinician bill the right codes in the first place?

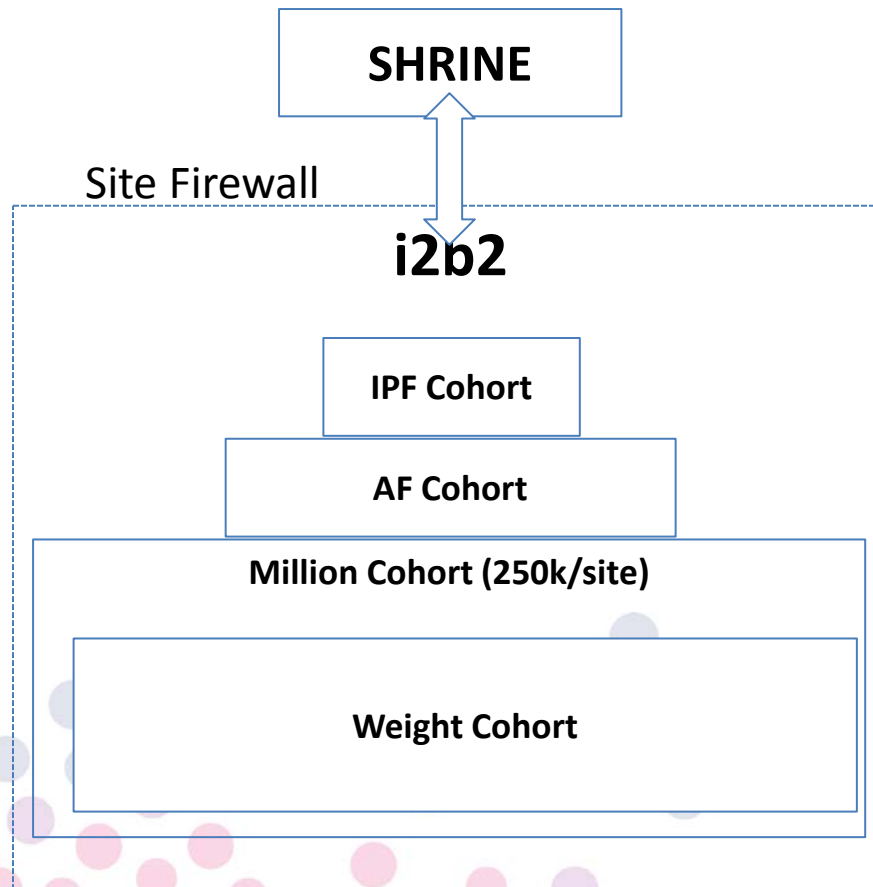


Communicating across disciplines

- Informatician= ICD 9 code of 250.00 means the patient has controlled DM
- Clinician:
 - “Well...it could be whatever code popped up when the MA triaged the patient; patient could have DM with complications”



Getting EHR data to communicate: PaTH SHRINE Network



- All 6 sites house their data in one i2b2 “instance” behind their firewall
- The patients will be classified with one or more flags based on the study:
 - AF Cohort
 - IPF Cohort
 - Million Cohort
 - Weight Cohort

Phase II: Use the system!

- Building on strength in numbers we have a few irons in the fire:
 - ADAPABLE- national PCORnet study of two strengths of aspirin for CAD prevention
 - Bariatrics outcome study
 - SAFE: Seniors avoiding falls through exercise
 - Other proposals in pipeline....



What about IRB? Data privacy?



PaTH regulatory mechanisms

- PNPRC: PaTH Network Protocol Review Committee
 - Includes IRB member and patient stakeholder from each site
- Reliance Agreements
- JHU serves as the IRB of record
- Data use agreements with Pitt cover data transfer for PaTH queries
- Data use agreements for PCORnet queries are being executed



Working with PaTH

- How do I access the network?
- What research is supported?
- Does it cost anything to work with PaTH?

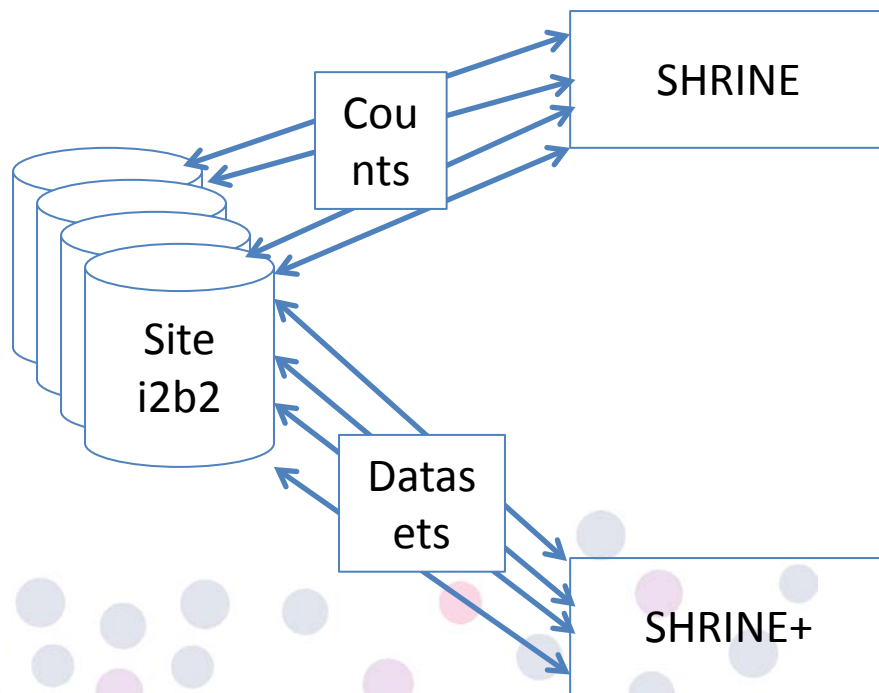


TU PaTH

- Project Manager: Cecilia Dobi
- RA: Yasmin Islam
- Tech/informatics: Alice Livshits, Aaron Sorenson and Mark Weiner
- PI: Anuradha Paranjape
- Co-Is: Sharon Herring, Francis Cordova and Jeff arkles



Accessing the data

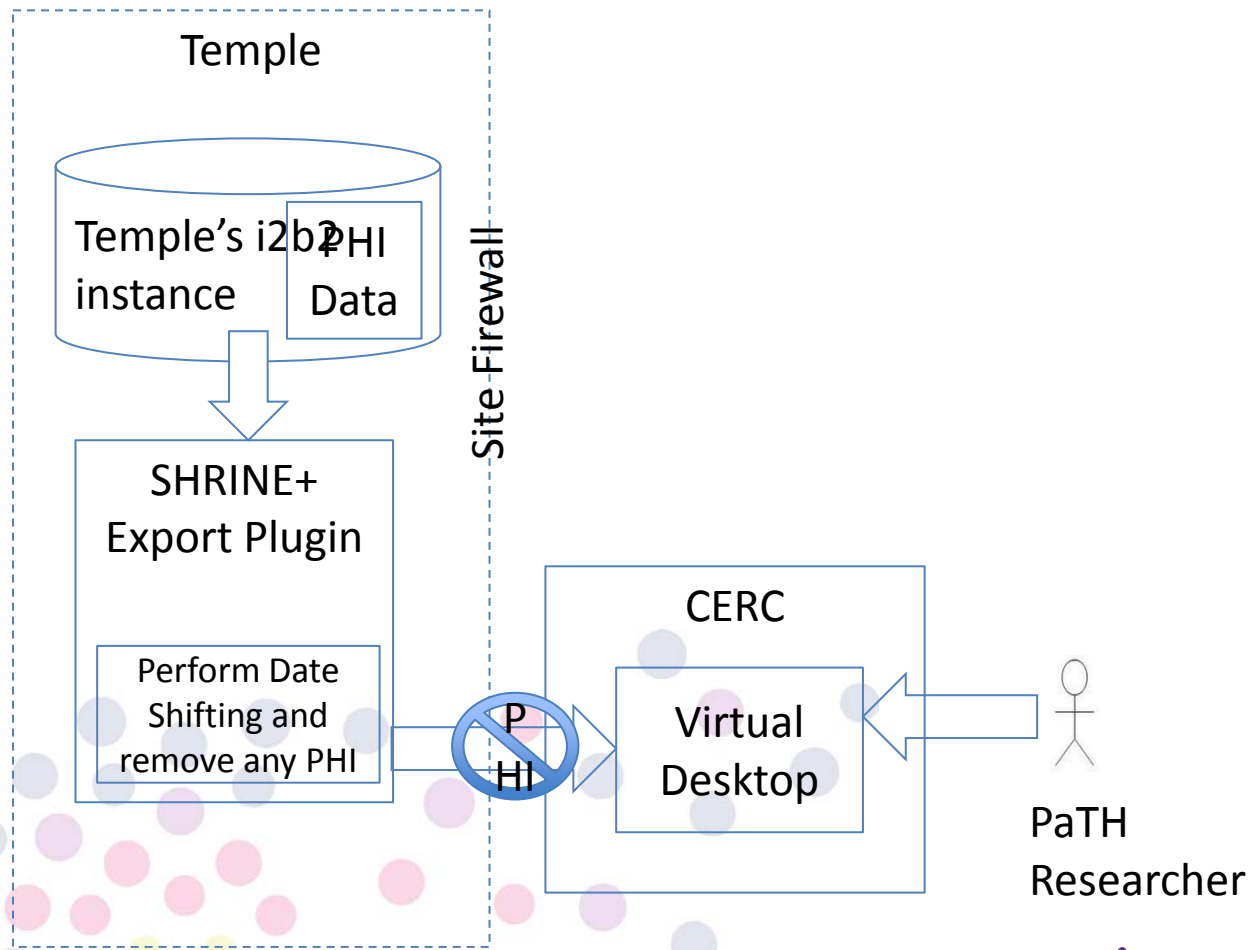


“How many patients have disease PaTH X?”
Researcher

“Can I have the dataset for patients with disease PaTH X?”
Researcher



SHRINE+, PaTH Network and PHI



Future PaTH Proposals

- Is it practical for the network?
 - Are there enough prospective subjects for this study?
 - Do the data exist in the health system or do I have to collect them?
 - Are the data harmonized?



Future PaTH Proposals

- Are there partners at each site?
 - Investigators
 - Patient stakeholder
 - Clinician stakeholder



How much would it cost to use PaTH?

- What you get for using PaTH at Temple
 - Project management expertise
 - Data infrastructure expertise
 - Regulatory infrastructure
 - Research support
 - Statistical support
- We are currently developing cost models for use



**But I have my own
people...**



Why use our research staff

- Familiar with network and players
- Assists with implementation
- Familiarity with data pulls, can anticipate problems with data pulls
- Can hit the ground running
- Flexible time



How do I design a study in PaTH?

- Pragmatic clinical trials
- Integration into clinical care
 - Intervention
 - Data collection
- Naturalistic experiments



Some additional design considerations

- PCORI will look for stakeholder involvement
- Stakeholder role:
 - Ensure the outcome matters to patients, families, clinicians, and policy makers
 - The intervention can be implemented
 - Eligible individuals will participate in the intervention



Some additional design considerations

- PCORI is interested in patient reported outcomes (PROs)
- Outcomes that matter- not will the patient live longer but will experience less dyspnea
- Consider
 - What are the best measures for the construct?
 - How should I administer my PROs?
 - (paper/tablet-redcap/EPIC)
 - Patient input into PROs

Best Practices Across Sites

- What works well in Philly may not work well in Hershey.
- Draw on larger amounts of experience
- Planned governance
- Standard policies





We have
come a long
way...

