

# Patient-Centered Outcomes After Bariatric Surgical Therapies

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# Disclosures

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- Employee of PCORI
- No other conflicts to disclose



# Overview

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- Introduction to PCORI and PCORnet - *Kim Marschhauser*
- PCORnet Bariatric Study - *David Arterburn*



# Our Mission and Strategic Goals

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PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from **research guided by patients, caregivers, and the broader healthcare community.**

## Our Strategic Goals:



Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions



Speed the implementation and use of patient-centered outcomes research evidence



Influence research funded by others to be more patient-centered



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# We Fund Patient-Centered Outcomes Research

PCOR is a relatively new form of Comparative Effectiveness Research (CER) that....

- Considers patients' needs and preferences, and the outcomes most important to them
- Investigates what works, for whom, under what circumstances
- Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options



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# We Fund Research That...

## What we mean by...

### **“Patient-centeredness”**

- The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
- Research questions and outcomes should reflect what is important to patients and caregivers



### **“Patient and stakeholder engagement”**

- Patients are partners in research, not just “subjects”
- Active and meaningful engagement between scientists, patients, and other stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought-out plan



# Our national clinical research system is well-intentioned but flawed

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

- ❖ High percentage of decisions are not supported by evidence
- ❖ Health outcomes and disparities are not improving
- ❖ Current clinical research system faces several problems:



Doesn't answer  
questions that  
matter most to  
people



Too  
slow



Too  
expensive

# PCORnet® : the National Patient-Centered Clinical Research Network



An innovative initiative funded by the Patient-Centered Outcomes Research Institute (PCORI), PCORnet is **a large, highly representative, national patient-centered clinical research network.**

The **vision** is to support a learning U.S. healthcare system and to enable **large-scale clinical research** conducted with **enhanced quality and efficiency.**

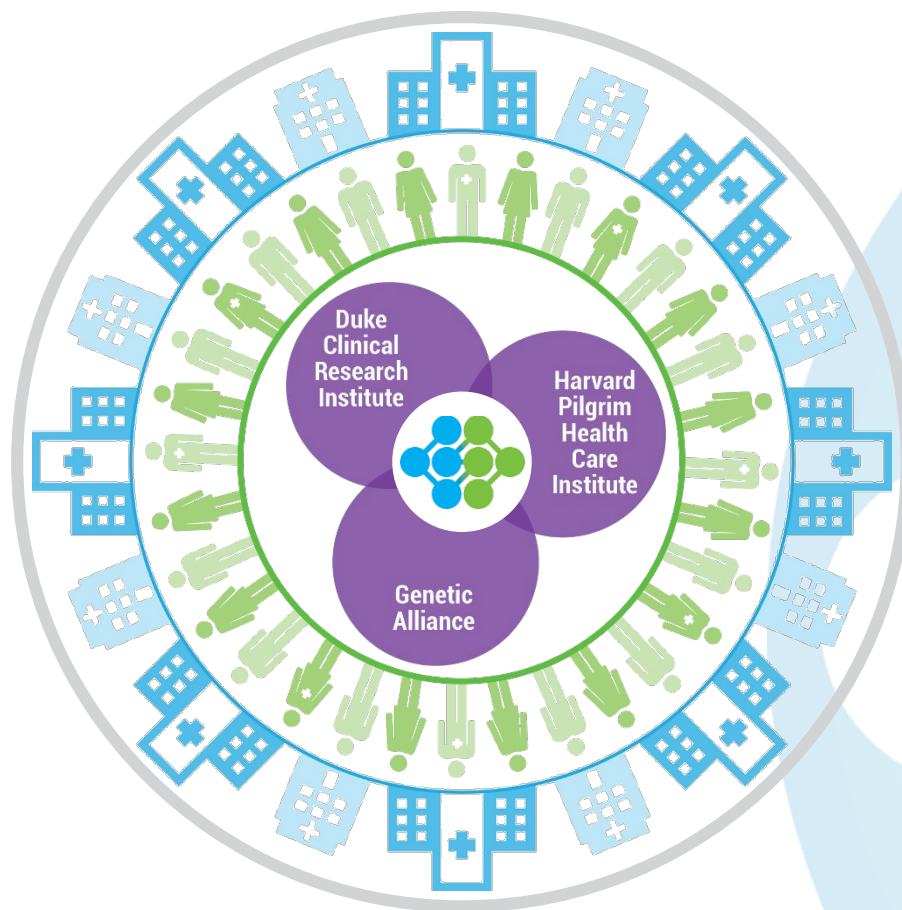
The **mission** is to enable people to make informed healthcare decisions by efficiently conducting clinical research relevant to their needs.



# With PCORnet®, we have developed a nationwide functional research network that...

- 🌐 **Engages** people, clinicians, and health system leaders throughout
- 🌐 **Creates** infrastructure, tools, and policies to support rapid, efficient clinical research
- 🌐 **Utilizes** multiple data sources including electronic health records, insurance claims data, data reported directly by people, and other data sources

# PCORnet<sup>®</sup> embodies a "network of networks" that harnesses the power of partnerships



20  
Patient-Powered  
Research Networks  
(PPRNs)



13  
Clinical Data  
Research Networks  
(CDRNs)

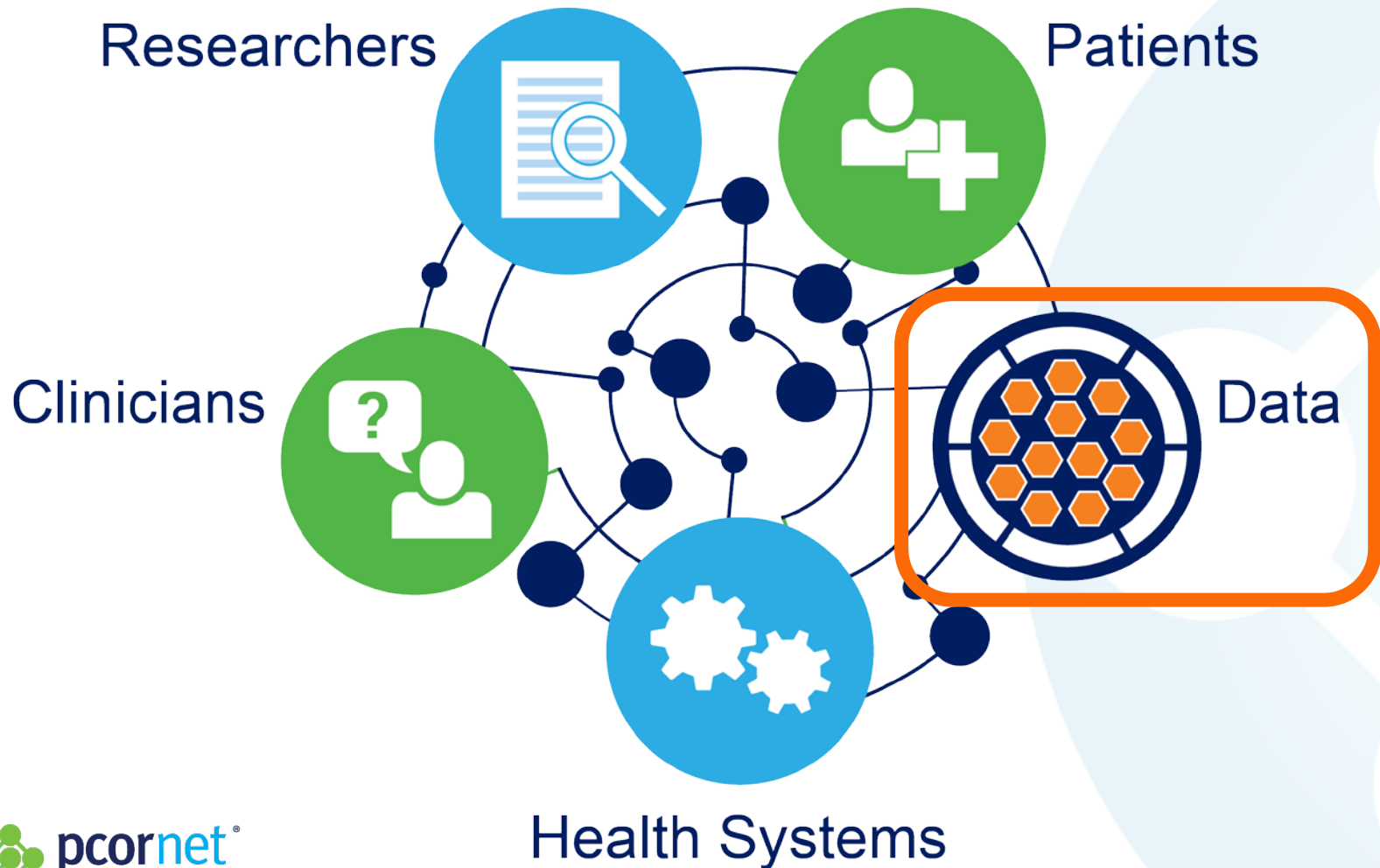


1  
Coordinating  
Center





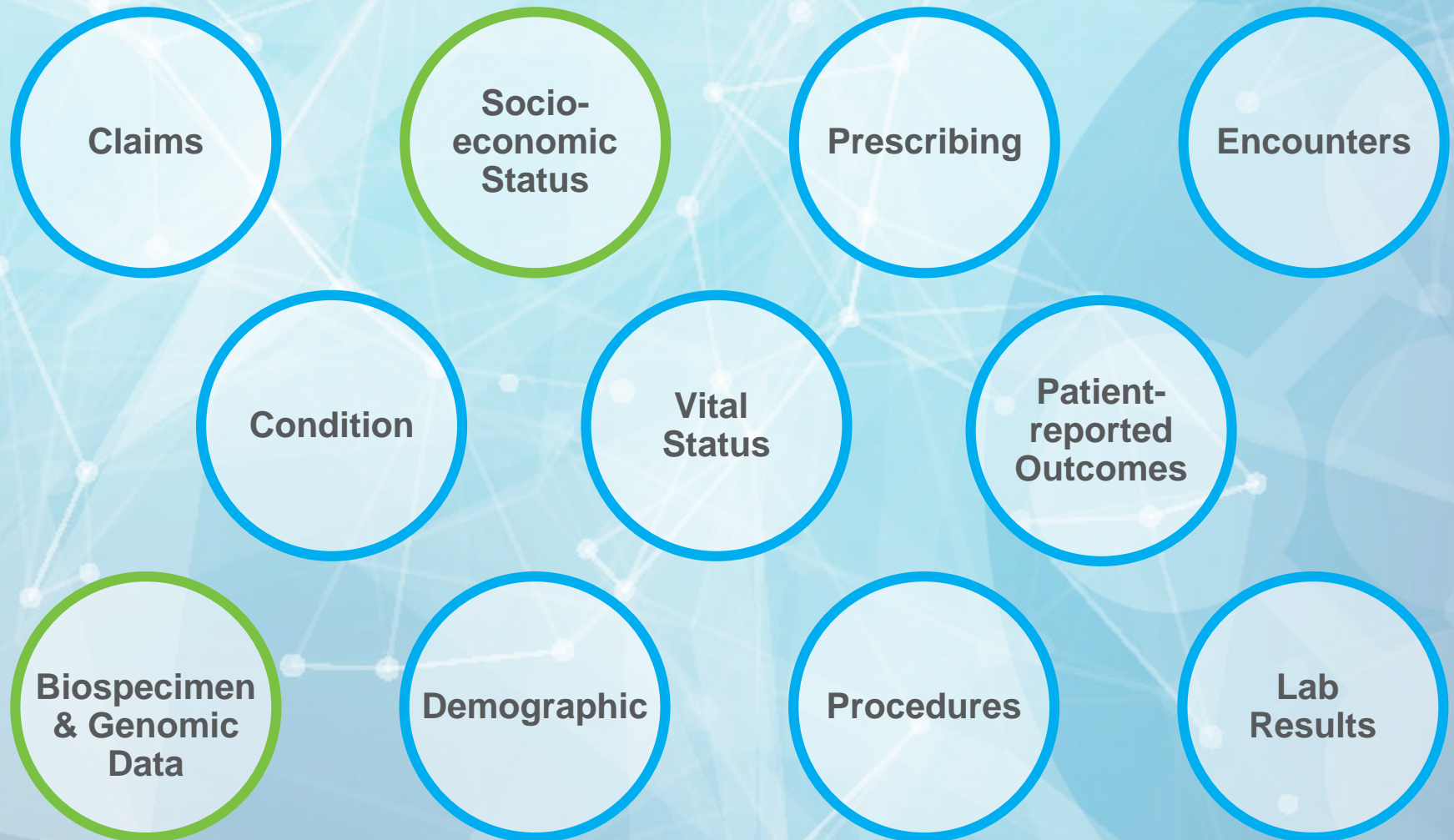
A national infrastructure  
for people-centered  
clinical research

# A community of research that unites data from patients, clinicians, and systems



# The Common Data Model

-  Data domains in the CDM
-  Domains that can be added

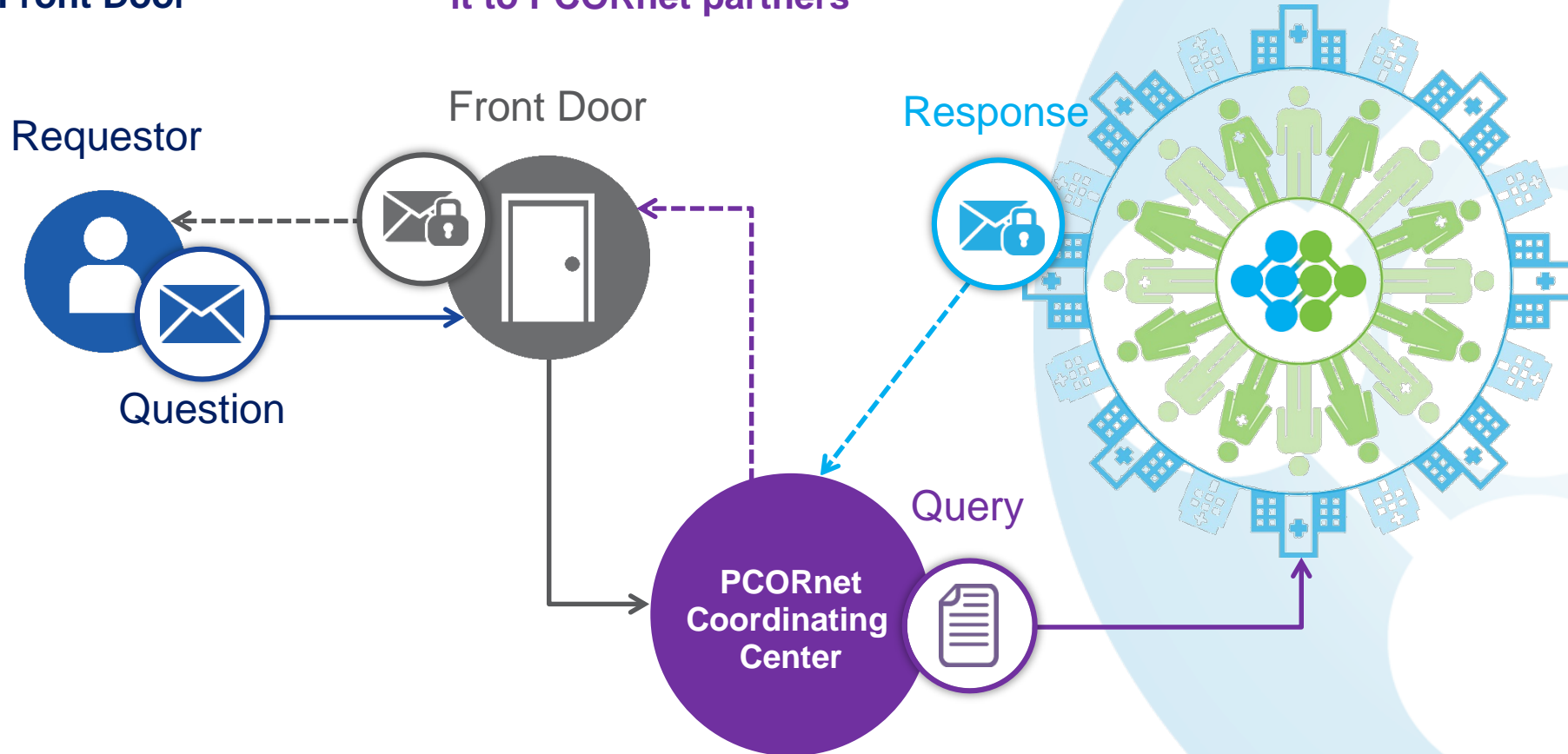


# Here's how the PCORnet<sup>®</sup> distributed research network works

The Requestor sends a question to the PCORnet Coordinating Center through the Front Door

The Coordinating Center converts the question into a query with an underlying executable code, and sends it to PCORnet partners

PCORnet partners review the query and provide a response, which is sent back through the Front Door to the Requestor



# You can use PCORnet<sup>®</sup> for many kinds of research



## Pre-research

- Feasibility queries
- Engagement
- Match-making



## Observational studies

- Cross-sectional
- Epidemiology
- Health services
- Comparative effectiveness or safety



## Interventional studies

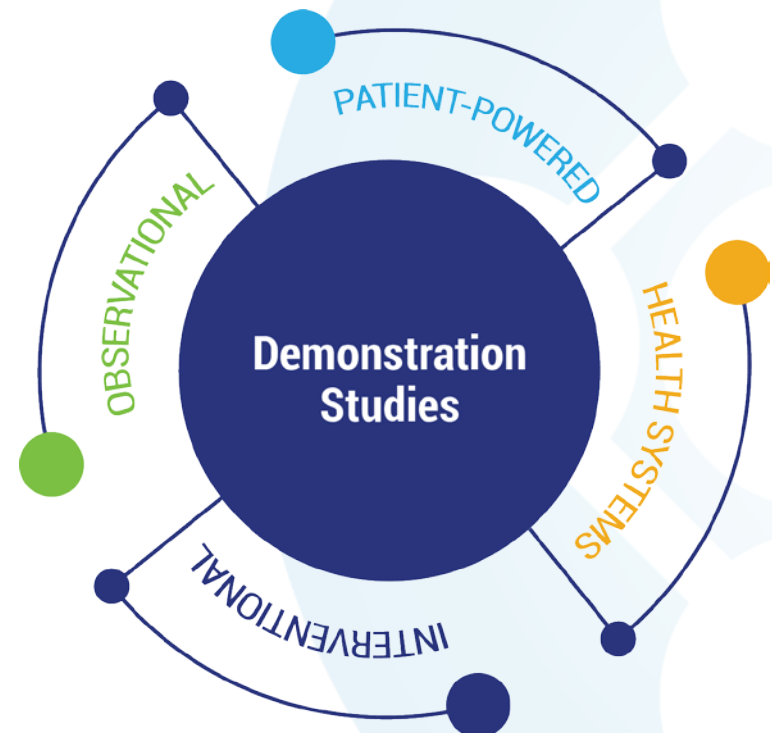
- Clinical trials
- Pragmatic randomized clinical trials
  - e-Identification
  - e-Consent
  - e-Randomization
  - e-Follow-up
- Cluster randomization

# We've tested the system's functionality in multiple research settings

14 PCORI-funded PCORnet demonstration studies are answering critical research questions while also testing the infrastructure and key functional aspects of PCORnet.

- 🌐 Interventional studies
- 🌐 Observational studies
- 🌐 Patient-powered research network (PPRN) studies
- 🌐 Health systems studies

Learn more about [PCORnet Demonstration Studies](#)





# PCORnet Bariatric Study

## Short- and Long-Term Outcomes related to Bariatric Surgery



**pcornet**<sup>®</sup>

The National Patient-Centered  
Clinical Research Network



# Disclosures

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- Employee of Kaiser Permanente Washington
- Research Support >\$10,000 from PCORI and the NIH in the area of bariatric surgery.

# Three Study Co-PIs

- David Arterburn, clinical investigator, PORTAL CDRN
  - Bariatric surgery researcher
  - Leader of several multisite bariatric studies
  - Kaiser Permanente WA Site-PI for PORTAL
- Kathleen McTigue, clinical investigator, PaTH CDRN
  - Obesity researcher
  - Lead PI, PaTH CDRN
  - Co-chair of the Bariatric Topic Brief Team
- Neely Williams, patient partner, Mid-South CDRN
  - Community engagement leader
  - Patient co-investigator, Mid-South
  - Bariatric surgery patient



# Health Systems Participating (Contributing Data) in the PCORnet Bariatric Study

## CaPriCORN

Northwestern

Loyola  
University

University of  
Chicago

University of  
Illinois

## GPC

University of  
Nebraska

Kansas  
University

U of Iowa  
Health Care

Medical College  
of Wisconsin

Marshfield  
Clinic

UT  
Southwestern

U of Wisconsin -  
Madison

## PaTH

Johns  
Hopkins

University of  
Pittsburgh

Temple  
University

University of  
Utah

Penn State  
and Hershey

Geisinger

University of  
Utah

## NYC - CDRN

Mount Sinai

NYU

Weill Cornell

Montefiore/  
Einstein

## PORTAL

KP – Southern  
California

Health  
Partners

KP -  
Colorado

KP - Northwest

KP -  
Washington

KP – Mid  
Atlantic

## SCHILHS

Partners  
Healthcare

Boston  
HealthNet

Wake Forest  
Baptist

Beth Israel  
Deaconess

## PEDSnet

Cincinnati  
Children's

Nemours

Nationwide

## pSCANNER

UC - Irvine

UCLA

## OneFlorida

UF Health

Orlando  
Health

Tallahassee Memorial  
Health System

## Mid-South

Vanderbilt

Greenway

UNC

## REACHnet

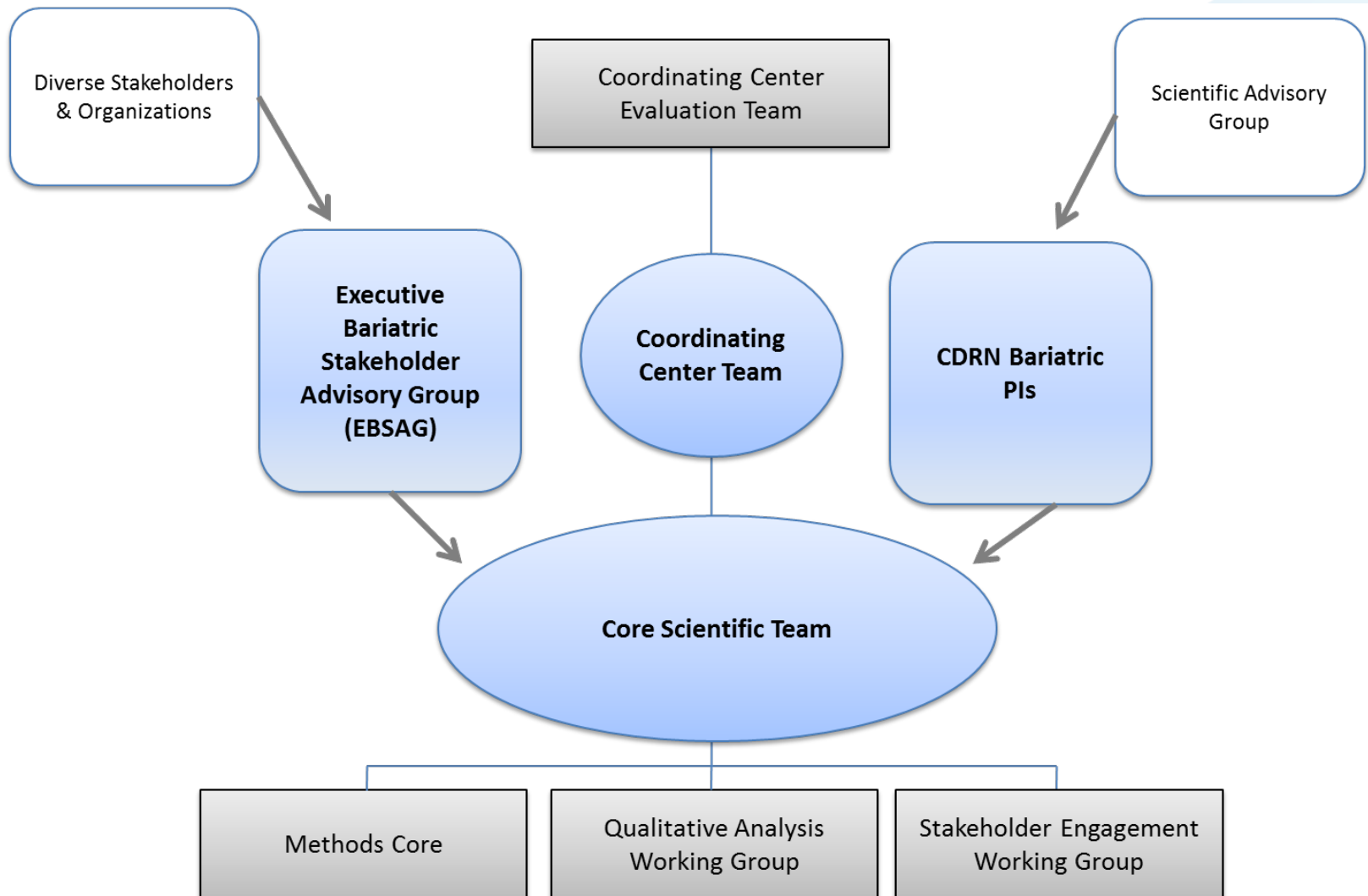
Tulane

Baylor Scott  
& White

Ochsner

Systems are  
organized into  
Clinical Data  
Research  
Networks.  
See [pcornet.org](http://pcornet.org)  
for more info.

# Overall relationship between the team components



# Stakeholders play a key role in the PBS

## Executive Bariatric Stakeholder Advisory Group

- Includes
  - patients
  - pediatric & adult bariatric surgeons
  - primary care and specialty physicians
  - researchers
  - leaders of patient-level policy and advocacy organizations
- Works with the PBS research team to make decisions on research questions, how we collect data, analyze it, & share findings

# Stakeholders are involved with:

- ❁ Formulating research questions
  - Quantitative aims
  - Focus on post-operative care; surgeon perspectives
- ❁ Collecting data
  - Review medication listings
  - Review bariatric procedure code listings
- ❁ Analyzing data
  - Prioritization of heterogeneity of treatment effects analyses
- ❁ Sharing findings
  - Help connect researchers to professional societies
  - Contribute to abstracts

# PCORnet Bariatric Study (PBS): Specific Aims

- ❁ Aim 1: To what extent does weight loss differ across the three bariatric procedures (RYGB, AGB, and SG) at 1, 3, and 5 years?
  - Sub Aim: explore heterogeneity by race/ethnicity, pre-op BMI, age
- ❁ Aim 2: Do Type 2 Diabetes outcomes differ across RYGB, AGB, and SG at 1, 3, and 5 years?
  - Rate of remission from diabetes (HbA1c <6.5%, off DM medications)
  - Rate of relapse of diabetes following initial remission
  - Change in HbA1c
- ❁ Aim 3: What is the frequency of major adverse events following RYGB, AGB, and SG procedures at 1, 3, and 5 years?
  - Major adverse events: hospitalization, re-operations, revisions
  - Mortality

## Secondary Aim

- 🌐 To elicit patient preferences around the risks and benefits regarding the choice of (a) whether to undergo bariatric surgery; (b) which bariatric procedure to utilize; and (c) optimal follow-up care after bariatric surgery.
- 🌐 We are conducting focus groups in two patient groups:
  - Adults and children with severe obesity who are eligible for but have not had bariatric surgery
  - Adults and children who have had bariatric surgery.  
(including minority patients and individuals of lower socioeconomic status in both groups)
- 🌐 We are also conducting interviews with surgeons and other bariatric medicine providers



# PBS Adult Cohort Description (2009-2015)

- Over 65,000 adult bariatric patients from 42 health systems
- Mean age of 45 years; 3,335 patients age 65+ (5.1%)
- 79% female; 72% Caucasian, 21% African American, 24% reported ethnicity as Hispanic.
- Mean BMI at baseline 49 kg/m<sup>2</sup>, with 37% BMI ≥50kg/m<sup>2</sup>
- 59% hypertension diagnosis in their EHRs; sleep apnea (49%), dyslipidemia (47%), gastroesophageal reflux disease (GERD) (41%), diabetes (36%), depression (30%), anxiety (21%), and non-alcoholic fatty liver disease (NAFLD) (20%).

# Some key observations

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- 🌐 Ongoing major shift in procedures in PCORnet sites & US
- 🌐 Significant variability in procedure choice across sites

# Upcoming results... 2017 and 2018

## Major reports forthcoming

- Cohort description
- Differences in weight loss across procedures in adults
- Differences in weight loss across procedures in adolescents
- Differences in diabetes outcomes across procedures in adults (too few adolescents with diabetes for separate CER analysis)
- Differences in safety outcomes across procedures in adults and adolescents
- Attitudes and preferences of patients and providers
- Methods paper examining the impact of using privacy-preserving methods to analyze these same data