Welcome to the Greater Plains Collaborative Learning Engagement Conference (LEC) 2024

August 26 and 27, 2024

Russ Waitman and Jim McClay
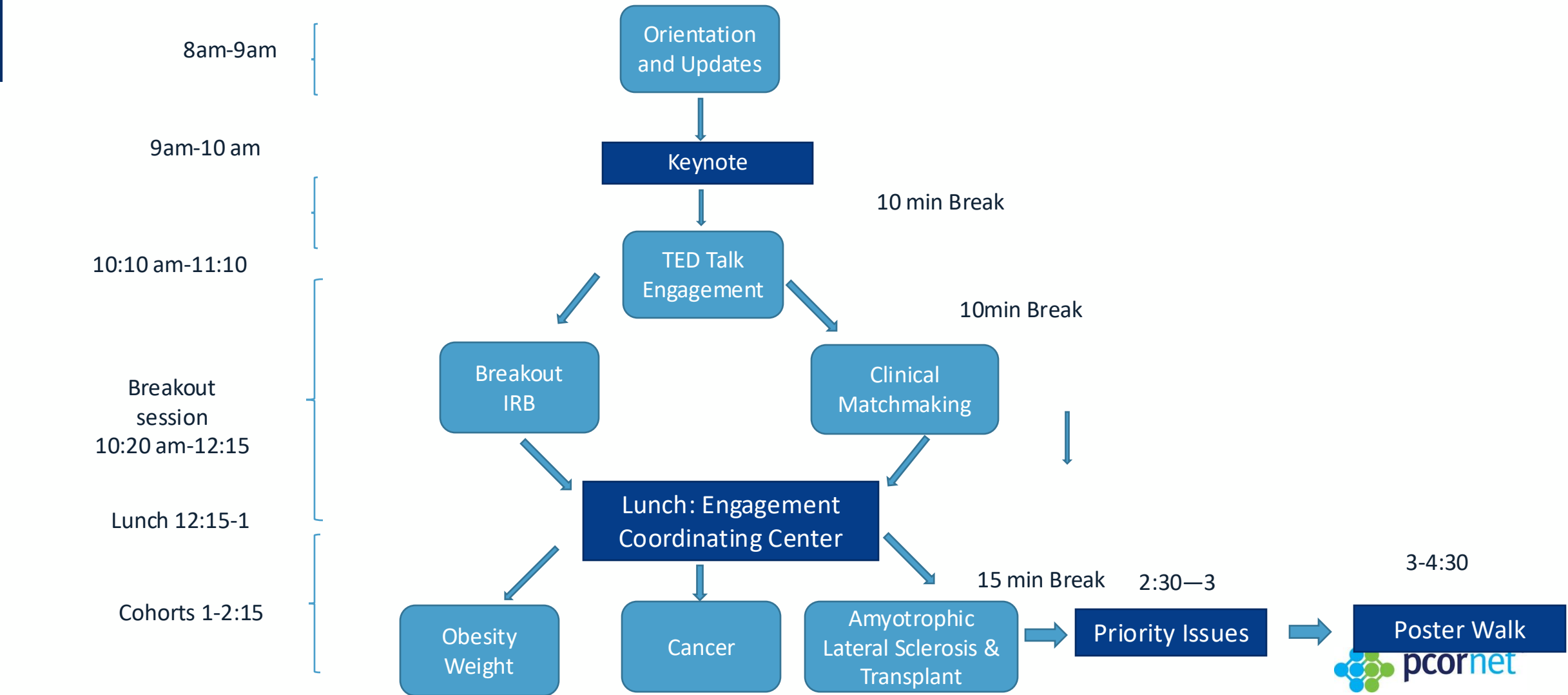
Overview
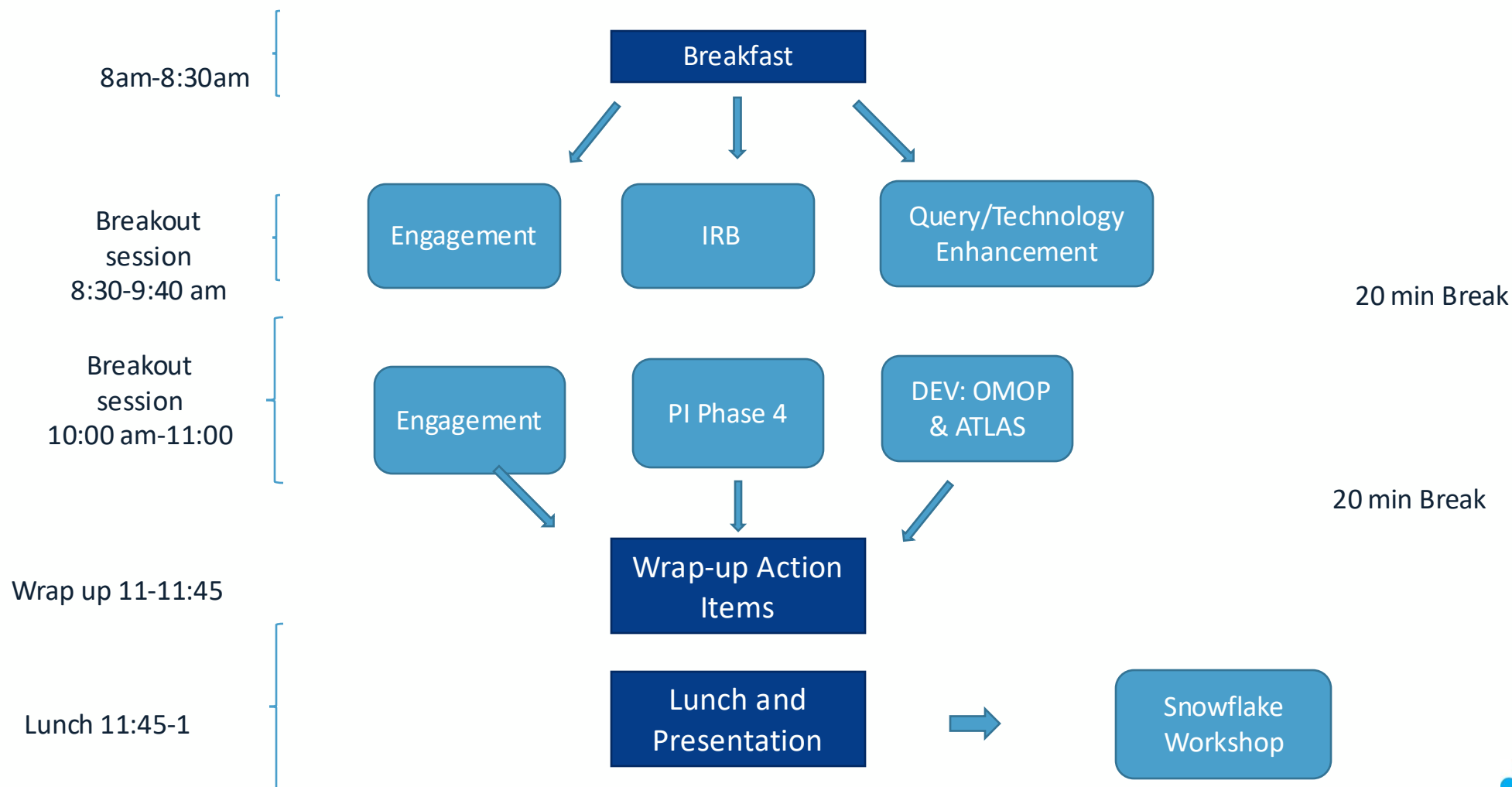
○ Welcome!

- Stay friendly and police jargon
- Overview of Kauffman Center layout

○ Sessions but also time to break and engage one another

2024 GPC LEC Work Flow: August 26th

8am-9am

Orientation and Updates

9am-10 am

Keynote

10 min Break

10:10 am-11:10

TED Talk Engagement

10min Break

Breakout session 10:20 am-12:15

Breakout IRB

Clinical Matchmaking

Lunch 12:15-1

Lunch: Engagement Coordinating Center

Cohorts 1-2:15

15 min Break

2:30—3

3-4:30

Obesity Weight

Cancer

Amyotrophic Lateral Sclerosis & Transplant

Priority Issues

Poster Walk

pcornet

2024 GPC LEC Work Flow: August 27th

8am-8:30am

Breakfast

Breakout session 8:30-9:40 am

Engagement

IRB

Query/Technology Enhancement

20 min Break

Breakout session 10:00 am-11:00

Engagement

PI Phase 4

DEV: OMOP & ATLAS

20 min Break

Wrap up 11-11:45

Wrap-up Action Items

Lunch 11:45-1

Lunch and Presentation

Snowflake Workshop

pcornet

Goals for LEC

○ Welcome GPC participants,

○ Foster Current Activities,

○ Phase 4/Enhancement Award Submissions, and the work that lies ahead

- Phase 4 CRN proposal submitted in June; awards announced in November; will start January 1st for 4 years.

- Technology and Common Data Model enhancements submitted in July and August. Planned to start ~September for ~ 18 months

○ Bring things to the table that we should do to increase our impact; more supportive as a network/sites and lead studies that use PCORnet

Unite data and communities for faster, more targeted research

One PCORnet®, Many Possibilities

PCORnet is a national resource, funded by PCORI, where high quality health data, patient partnership, and research expertise deliver fast, trustworthy answers that advance health outcomes.
- **Real-world evidence studies**
- **Comparative effectiveness research**
- **Population health research**
- **Pragmatic research**
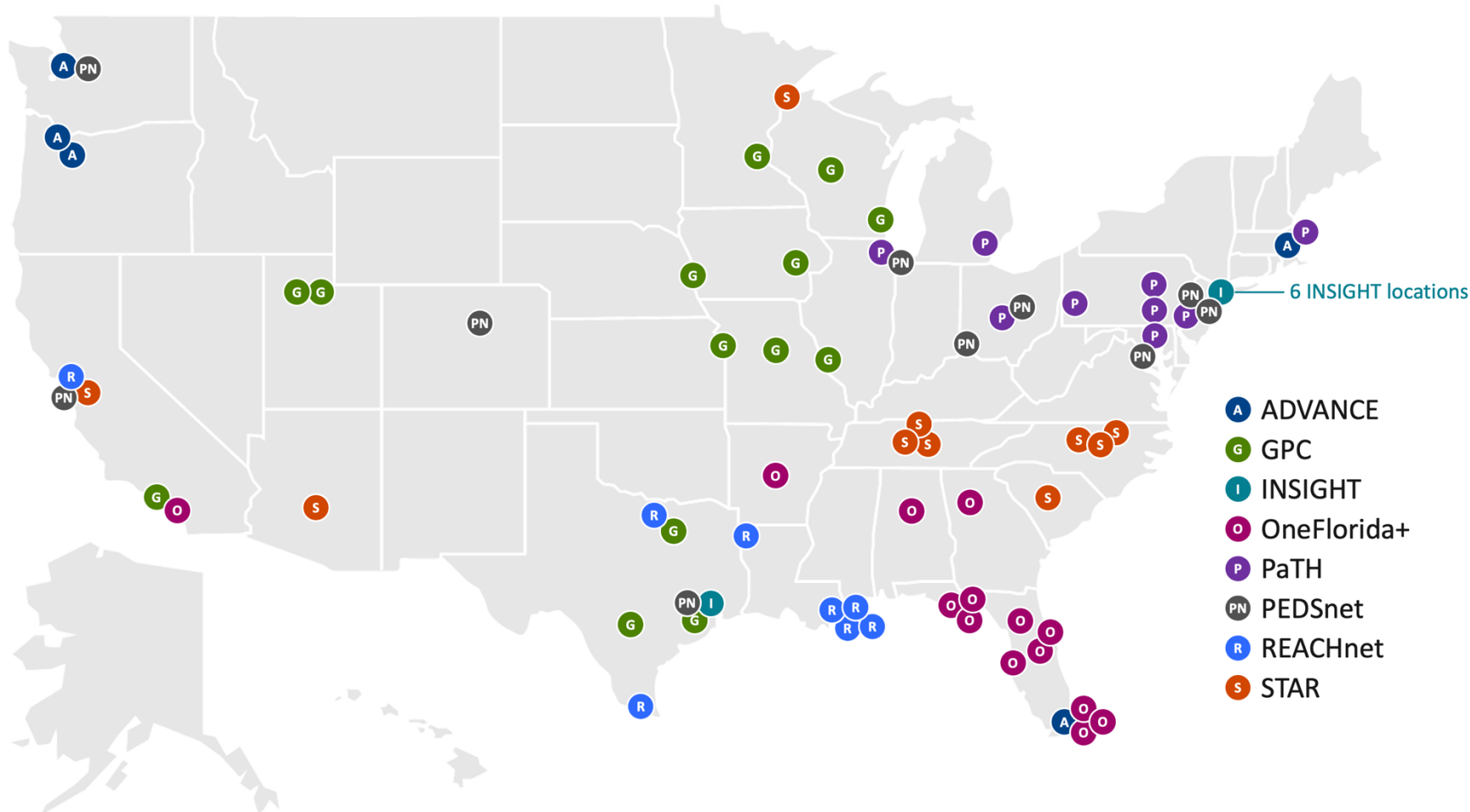- **Health systems research**
- **And more**

More Than a Data Network

Access to patient partners and **thousands of clinicians** with expert knowledge of PCORnet-enabled data = meaningful research targets and faster answers.

Providers and researchers

EHRs, claims, and patient-reported data

Patients, caregivers, and advocates
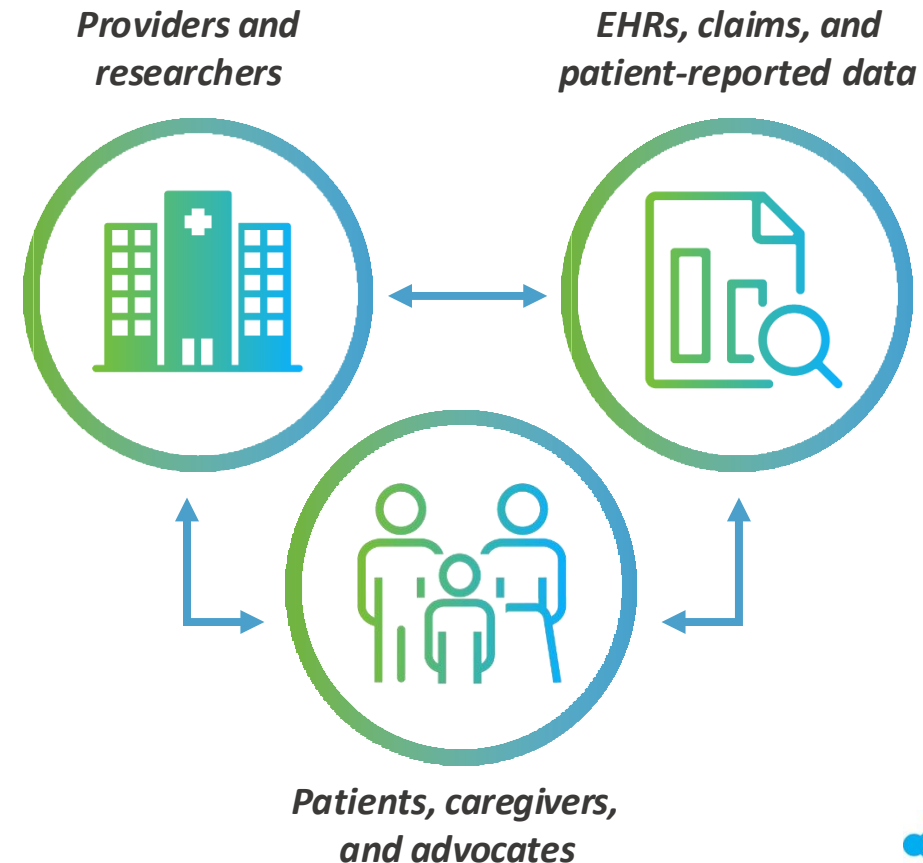
PCORnet® Clinical Research Network locations

PCORnet infrastructure offers access to real-world data through partnerships with Clinical Research Networks (CRNs)
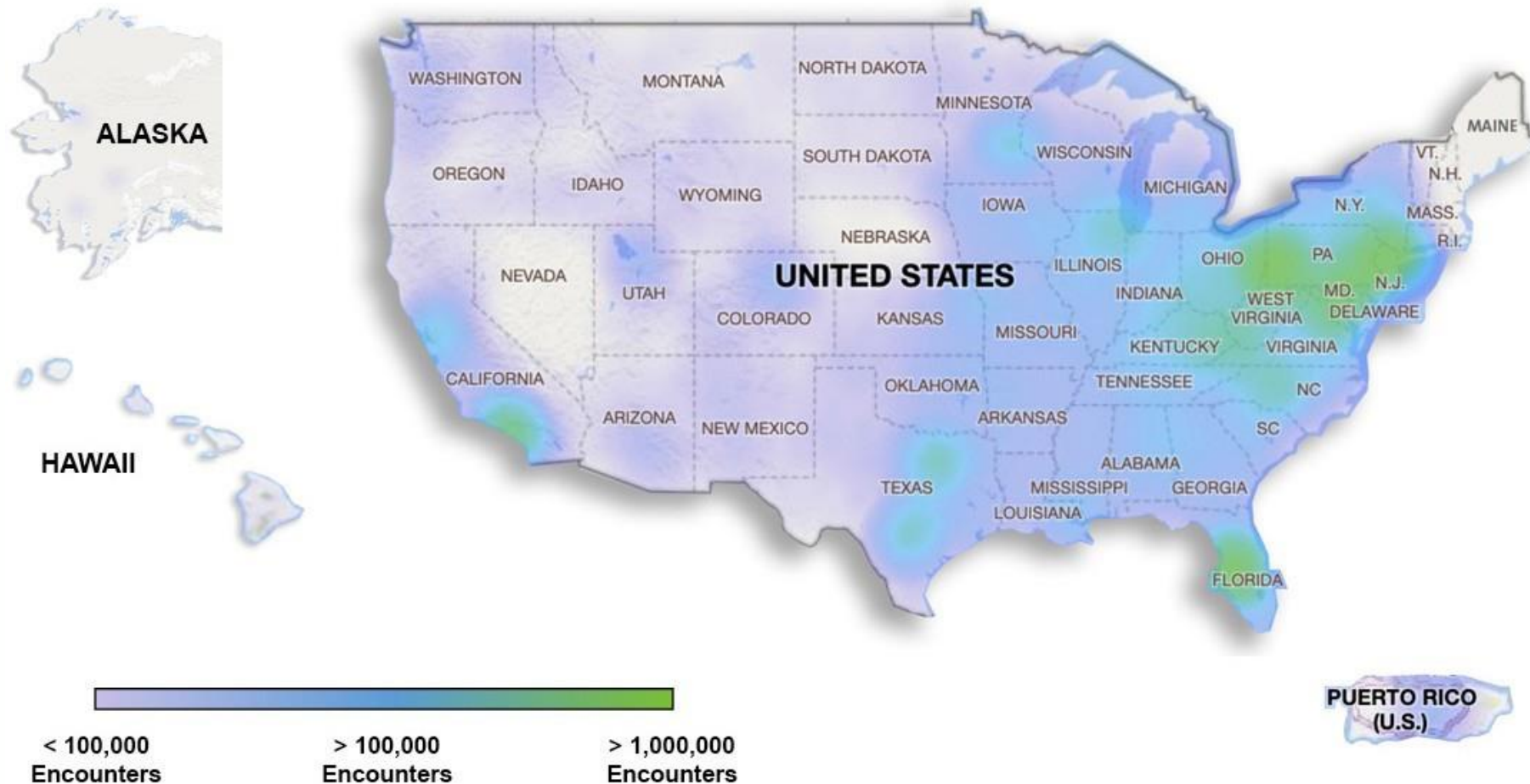

6 INSIGHT locations

Legend:
- A ADVANCE
- G GPC
- I INSIGHT
- O OneFlorida+
- P PaTH
- PN PEDSnet
- R REACHnet
- S STAR

What are Clinical Research Networks?

CRNs are groups of diverse healthcare institutions across the U.S., from large academic health centers to local community clinics, united by a commitment to speed patient-centered research via PCORnet.

pcornet®

Scope of PCORnet-accessible data

PCORnet represents data from **everyday health care encounters with more than 30 million people** across the U.S. each year.

Legend:
< 100,000 Encounters
> 100,000 Encounters
> 1,000,000 Encounters

*The data density maps illustrates single addresses that are associated with individual PCORnet Network Partner encounters.

9

The PCORnet® Common Data Model

For data to be useful, it has to be standardized across systems. Frequent data curation and a single language enabled by the PCORnet® Common Data Model delivers fast insights.

Ready for Research

Available, But Still Evolving

Demographics	Diagnoses	Procedures	Immunizations	Tumor Registry	Biosamples
Vital Signs	Labs	Clinical Observations	Social Determinants of Health	Patient-Generated Data	Genomic Results
	Medication Orders & Administrations		Patient- Reported Outcomes	Natural Language Processing Derived Concepts	

Data available from Clinical Research Networks, in the PCORnet® Common Data Model and ready for use in research

Data available at some Clinical Research Networks, may or may not be in the PCORnet® Common Data Model and require additional work for use in research

pcornet®

Community Engagement via PCORnet®

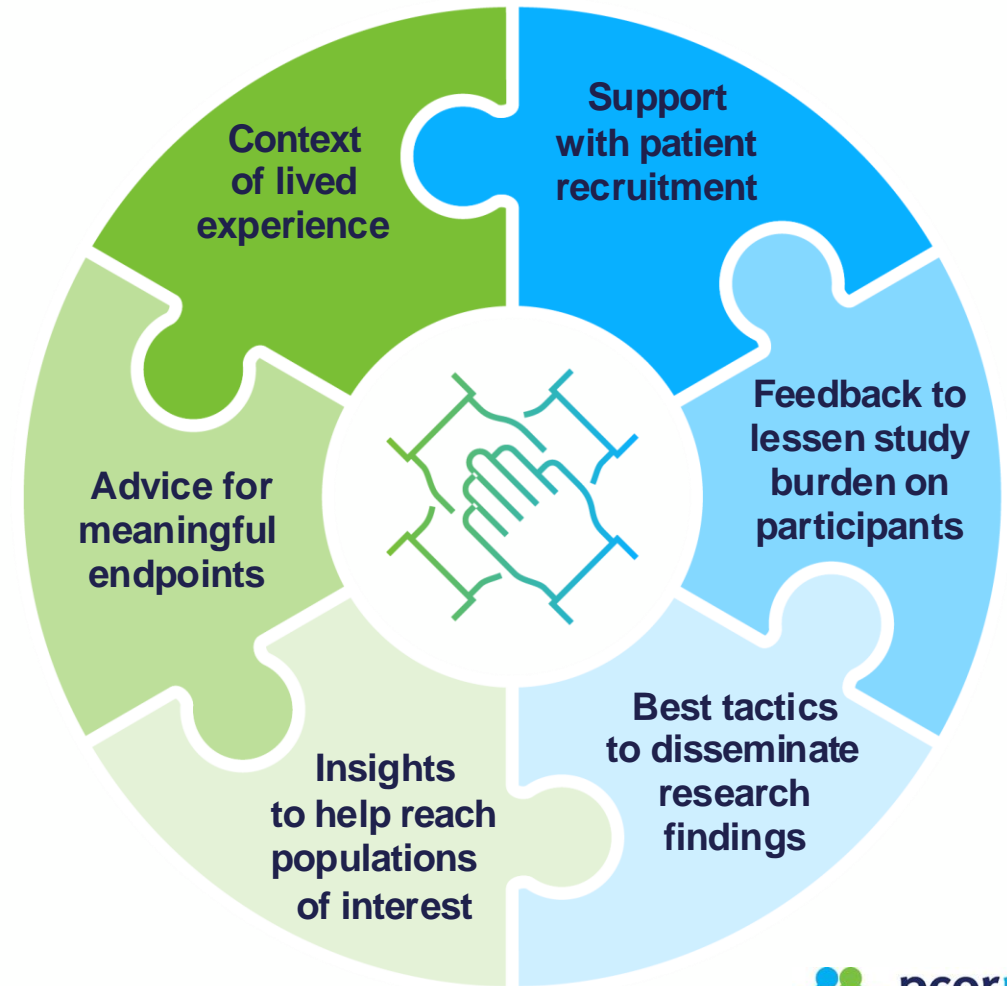The National Patient-Centered Clinical Research Network

Engaged communities drive better, faster research

What do we mean by "communities"?

- **Patients and caregivers,**
  who have a seat at the table of every PCORnet® Study, engaging as coequal collaborators with health professionals
- **Clinicians/Clinic Staff**
- **Insurers**
- **Policymakers**
- **Others**

"Good studies consider all relevant evidence — and no evidence is more relevant than the community experience."

— PCORnet Steering Committee Member

Context of lived experience

Support with patient recruitment

Feedback to lessen study burden on participants

Advice for meaningful endpoints

Insights to help reach populations of interest

Best tactics to disseminate research findings

pcornet®

The PCORnet® Front Door

The Front Door is the Access Point for PCORnet Resources & Services

A "knock" on the Front Door can also support:
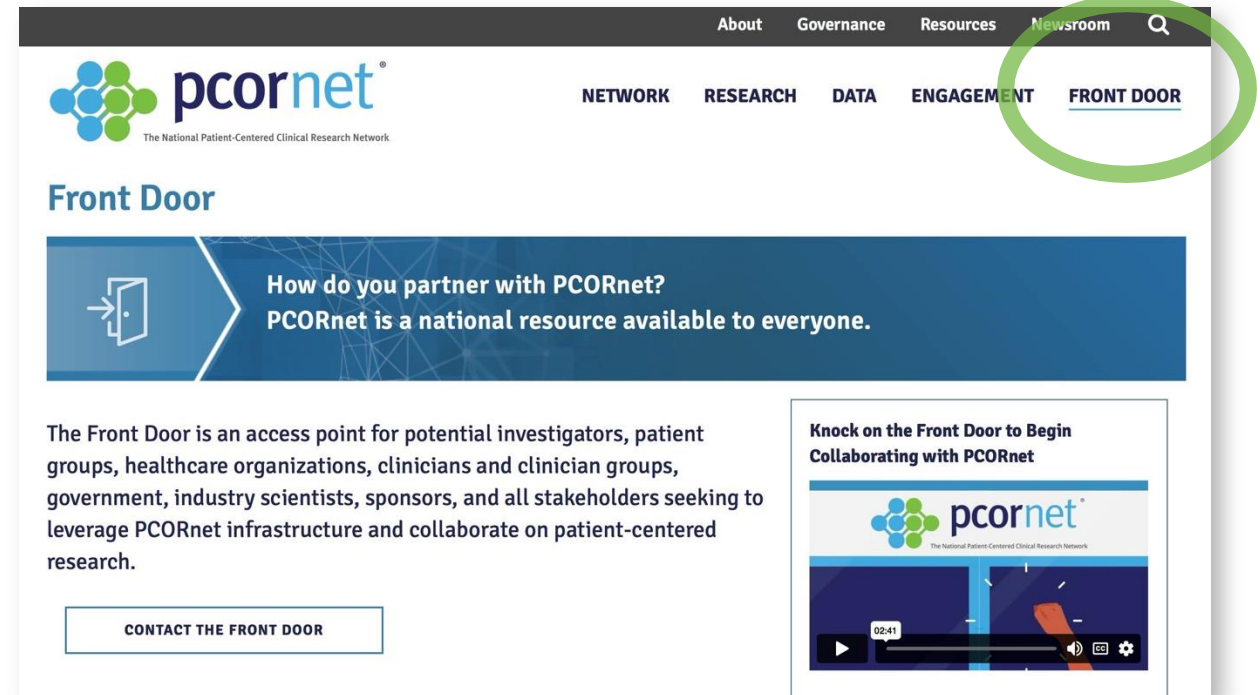
Study Design
- Preliminary data for proposals, effect sizes and potential study power

Connections to Network Collaborators
- Partners to co-design research
- People with specific expertise

PCORnet Study Designation Support
- Deeper partnership with PCORnet provides access to best practice sharing, patient engagement, and transparent quality improvement initiatives

About   Governance   Resources   Newsroom

NETWORK   RESEARCH   DATA   ENGAGEMENT   FRONT DOOR

Front Door

How do you partner with PCORnet?
PCORnet is a national resource available to everyone.

The Front Door is an access point for potential investigators, patient groups, healthcare organizations, clinicians and clinician groups, government, industry scientists, sponsors, and all stakeholders seeking to leverage PCORnet infrastructure and collaborate on patient-centered research.

CONTACT THE FRONT DOOR

Knock on the Front Door to Begin Collaborating with PCORnet

Learn More About the Front Door

Use Cases

The National Patient-Centered Clinical Research Network

PREVENTABLE

Pragmatic Evaluation of Events and Benefits of Lipid-Lowering in Older Adults

The Question

Can taking a commonly used heart medication prevent dementia in adults over the age of 75?

Strength of PCORnet®

A "one stop shop" for capturing 3 complementary sources of data (Medicare, EHR, & survey)

"I appreciate that PREVENTABLE is looking at a commonly prescribed drug to see if it could benefit seniors."

Minnie Jefferson, Patient Advisor

Study Snapshot

- **Pragmatic trial**

- **20,000 patients** aged 75 and older

- **100 U.S. sites** partnered with PCORnet & the National Veterans Affairs Network

- **Pragmatic design** used existing EHR/Medicare data plus phone surveys. Medications shipped directly to patients

PREVENTABLE
Pragmatic Evaluation of Events and Benefits of Lipid- Lowering in Older Adults

IMPACT

- Because of the pragmatic trial design, only one amendment was needed to the study protocol to respond to COVID-19

- Embedded expertise in PCORnet fueled rapid enrollment of the largest trial in people aged 75+ to date. Broad dissemination via *New York Times* article, AARP publications, & local senior guides

Takeaway

PCORnet can effectively support pragmatic studies in challenging populations where participation is a barrier.

ADAPTABLE
Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness

The Questions

1. *Which aspirin dose offers the right balance of effectiveness and minimal risk of bleeding?*
2. *Can PCORnet be used to find the answer using a clinical trial model wherein patients are drivers of engagement?*

Strength of PCORnet®

Adaptors: Nine patient partners from ADAPTABLE's clinical research networks.

- Offered study guidance
- Embedded at every study step, from study concept to completion and dissemination

Study Snapshot

- Pragmatic clinical trial
- **15,000 patients** living with heart disease
- Randomly assigned (1:1 ratio)
- Aspirin Dose- 81 mg/day vs. 325 mg/day

"I have lost three friends to heart disease; I don't want to lose more."
Ken Gregorie, Adaptor

pcornet®

ADAPTABLE

Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness

ADAPTORS CONTRIBUTED TO 3 KEY EFFORTS:

**Newsletter for
Enrolled Patients:**

Quarterly, included study updates
plus patients' personal stories

**493 participants have shared
their personal story to date**

Study Communication:

Revised study materials
to make them more understandable
for a patient audience and coached
the study team at limited sites
in mock calls to potential participants

Clinician Engagement:

Adaptors educated clinicians on
what aspects of ADAPTABLE
were engaging to them to
improve participation rates

Over 15,000 patients enrolled from 40 sites over 38 months
Results published May 2021, *New England Journal of Medicine*

Takeaway

PCORnet infrastructure supports patient partner engagement that
can fortify your study's efforts and contribute to faster
enrollment and improved retention.

BP Control Laboratory
A Reusable Platform for Efficient Surveillance and Comparative Effectiveness Research

The Question

Can PCORnet support a reusable platform to reduce patient/investigator burden and streamline evidence generation around new programs or technologies designed to help improve blood pressure control?

Strength of PCORnet®

- Broad reach into a large percentage of the U.S. population
- Established connections across major health systems
- Shared Common Data Model to standardize disparate electronic health record (EHR) data codes

Study Snapshot

Platform supported three demonstration studies:

- **BP Track**, a national surveillance project

- **BP MAP**, a cluster randomized controlled trial

- **BP Home**, an individual level randomized controlled trial

BP Control Laboratory

A Reusable Platform for Efficient Surveillance and Comparative Effectiveness Research

- Pragmatic design allowed for direct patient engagement and collection of patient-generated health data (Eureka)
- Assessed EHR data from 25 participating health systems via PCORnet

- Development of the novel platform was featured in *Circulation: Cardiovascular and Quality Outcomes*
- Results from BP Track featured in the *Journal of American Heart Association*
- Results from BP Home featured in *JAMA Internal Medicine*

Takeaway

PCORnet can be used to accelerate evidence generation and translation of innovative healthcare delivery solutions into major population health benefits.

CDC COVID-19 Collaboration
Shaping the national understanding of COVID-19

The Question

Can the PCORnet infrastructure be used for real-time reporting and surveillance of COVID-19 patterns across the country?

Strength of PCORnet®

Partnership with diverse health systems that hold electronic records for health encounters for more than 30 million people across the U.S. each year

" As a massive research network that can capture information from many healthcare systems, PCORnet has an important role to play during a pandemic response."
Tom Carton, PCORnet Steering Committee

Project Snapshot

- **Surveillance effort** in collaboration with CDC

- **Bi-weekly exploration** of deidentified records for more than half a million patients with a COVID-19 diagnosis or respiratory condition

pcornet®

CDC COVID-19 Collaboration

Shaping the national understanding of COVID-19

IMPACT

Answered crucial questions relevant to public health via numerous journal publications
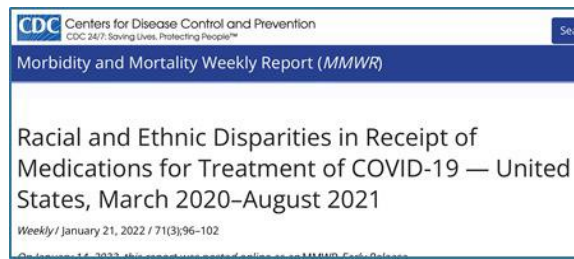
Racial and ethnic disparities in the use of monoclonal antibodies

Understanding "long COVID"
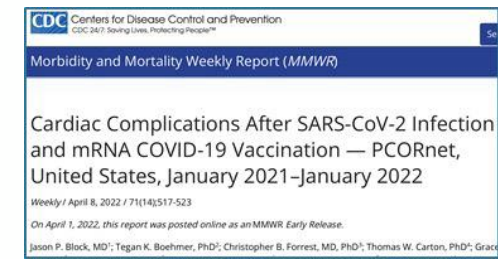
Myocarditis and pericarditis rates after COVID-19 vaccination

Takeaway

PCORnet can effectively support national surveillance studies with near-real-time reporting to unlock valuable insights in times of crisis when answers can't wait.

PCORnet® Resources

- Materials developed using the Network are shared to promote lessons learned and best practices via the Resources page on **PCORnet.org**.

- Resources are sorted by Research, Data, and Engagement and searchable by keyword. They include **engagement case studies**, **lay audience glossaries**, the **PCORnet® Common Data Model**, and more.

Explore our resources for improving research through better practices

Research

Explore innovative tools and models that can be used throughout every stage of your research project - from generation of a hypothesis to disseminating results.

SEARCH RESEARCH

Data

Improve the quantity and quality of data used in your study with innovative resources and tools. Data networks should follow the principles of efficiency, interoperability, transparency, reproducibility, security, and inclusivity of stakeholders.

SEARCH DATA

Engagement

Search best practices for engaging a variety of stakeholders throughout the research process. Engagement means active involvement of all stakeholders.

SEARCH ENGAGEMENT

Phase 3: Perspective on Health Data Evolution and PCORnet

Develop EHR, AI & Commercialize	EHR Adoption -> Data Reuse + LHS concept	PCORnet & National Networks	Transition and Reauthorization	PCORnet Phase 3
1994-2010	**2010-2013**	**2014-2018**	**2018-2021**	**2022-**
• Vanderbilt experience • Great Clinical decision support and workflow • No standardization or interoperability	• $30+ billion in funding for EHRs • PCORI created • IOM Learning Health System • CTSAs harness EHR data for research to generalize discovery (i2b2)	• Standardize data • Governance • Network of • Networks	• Operate/Sustain	• PCORI's priorities: definitive trials, maternal health, intellectual and developmental disabilities • Expansion of sites and network • capabilities (SDoH) • Cloud infrastructure • Data Linkage with external sources • Regional Network innovations

Greater Plains Collaborative Entering Phase 4

Table 1. Clinical Research Network (CRN) Population	
Number of Unique Patients 38,455,948	*Total number of unique patients (% of patients)*
Demographics	
Age	
• Mean Age 44.78	
• 0-19	*7,126,450 (18.53%)*
• 20-44	*12,745,009 (33.14%)*
• 45-64	*9,083,600 (23.62%)*
• 65-74	*4,398,493 (11.44%)*
• Older than 75	*4,928,700 (12.82%)*
Sex	
• Female	*20,234,432 (52.62%)*
• Male	*18,101,244 (47.07%)*
• Other	*120,029 (0.31%)*
Race	
• American Indian or Alaska Native	*186,540 (0.49%)*
• Asian	*1,056,733 (2.75%)*
• Black or African American	*3,428,908 (8.92%)*
• Native Hawaiian or Other Pacific Islander	*120,864 (0.31%)*
• White	*22,446,259 (58.37%)*
• Multiple Race	*236,048 (0.61%)*
• Refuse to answer	*551,732 (1.43%)*
• Unknown	*5,318,158 (13.83%)*
• other	*4,490,337 (11.68%)*
Hispanic	
• Yes	*4,080,604 (10.61%)*
• No	*24,235,916 (63.02%)*
• Other	*9,874,091 (25.68%)*

GPC participates in 15/26 PCORnet designated studies and leading 2 designated studies NET-PRO, CISTEM2

GPC Snowflake-based data sharing now across PEDSnet and GPC for self service queries; expansion in phase 4
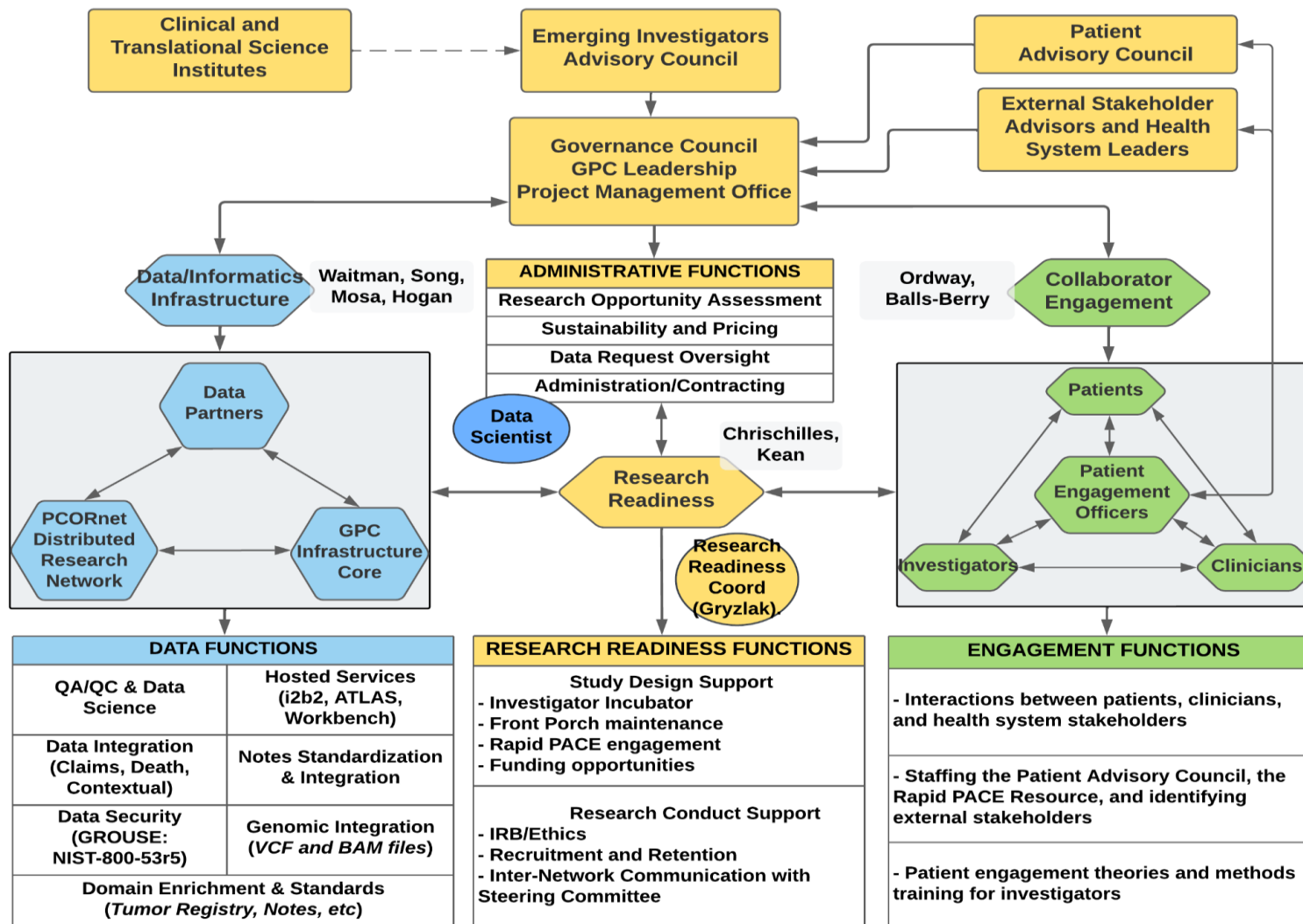
BASICS, a study of bariatric surgery and cancer risk to add tumor registries ala GPC

Linked 1.5 million Veterans and military to GPC population

Efficiently organized billions of free text notes across all GPC sites for NLP/AI

Phase 4: Increase data quality, scale analytics, research readiness with or stakeholders

Phase 4 GPC Governance, Structure, New elements

Emerging Investigators Council
Research Readiness Coordinator
Investigator Incubator
Engagement methods and training

Greater use of cloud (Snowflake) for queries/analyses– quarterly updates, Vanguard sites link genomics (VCF,BAM) ATLAS OMOP as well as i2b2 with CDM Death status via NIST

CDM Enhancements: PROs, home meds, geocode linkage to Social Determinants, mom-baby/sibling linkage for maternal health and intellectual disabilities

- Increase data quality, scale analytics, research readiness