PCORnet® Webinar Series Part 1: PCORnet® 101

Moderator: Larisa Tereshchenko
Presenters: Michael Mead, Kim Marschhauser, & Claudia Grossmann

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SOCIETY FOR CLINICAL TRIALS

Today's Faculty

Michael Mead, PhD
PCORI

Kim Marschhauser, PhD
PCORI

Claudia Grossmann, PhD
PCORI

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Society for Clinical Trials

On Today's Webinar

- Our presenters will cover:
  - Description of PCORnet® Infrastructure
  - PCORnet® Common Data Model
  - Information on How to Work with PCORnet®
  - Demonstration of Relevant Use Cases
  - Panel Discussion/Q&A

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Before We Begin Our Presentations...

- We will hold a Q&A session after today's presentations.

- We encourage all webinar attendees to submit questions via the Question Box.

- If we don't get to your questions today, we will follow up with you after the webinar via email.

- Today's webinar is being recorded and will be available to SCT members in the Members-Only Area of the SCT website.

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Agenda

- PCORnet® Overview
- Using PCORnet®
- Case Studies
- PCORI Funding Opportunities

PCORnet® Contributes to PCORI's Mission and National Priorities for Health

PCORnet®

- Supports national-scale studies designed to help people make better informed healthcare decisions

- Catalyst for *Research Done Differently*
  - Embeds patient partnership and community engagement in all components of the network
  - Enhances capacity to conduct health research with real world data
  - Builds reusable infrastructure and capacity for continuous improvement at local, regional, and national levels

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

PCORnet® is Unique Among Large, Established Health Research Networks

To PCORI's knowledge, PCORnet is the only large, established health research network to include all of the following features:

Queries to Inform Study Feasibility and Design
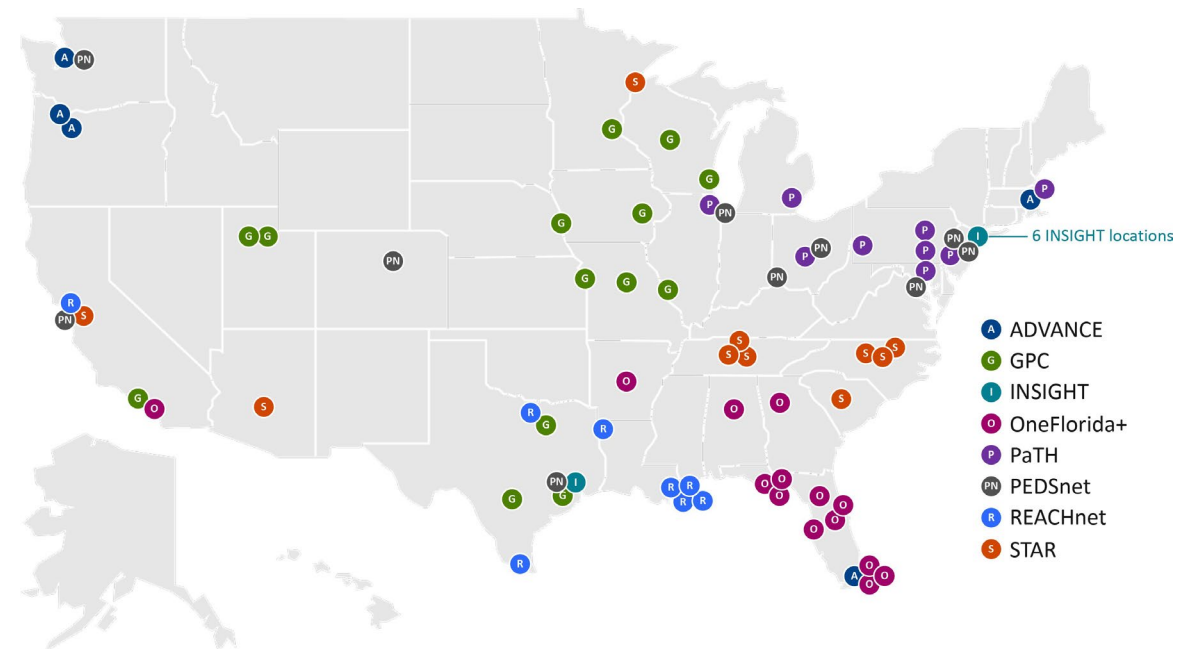
Patient Populations for Trial Recruitment

Coordinated Data Curation

Data Linkable to Patients and Providers, in Accordance with Applicable Federal and State Laws

PCORnet® Clinical Research Network Locations

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

- 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

6 INSIGHT locations

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

PCORnet® Clinical Research Network Sites
(as of August 2023)

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ADVANCE Collaborative

1. Fenway Health
2. Health Choice Network
3. OCHIN
4. Oregon Health & Science University Hospital System*
5. The University of Washington*

GPC – Greater Plains Collaborative

6. Allina Health
7. Intermountain Healthcare
8. Marshfield Clinic Research Institute
9. Medical College of Wisconsin
10. University of California, Los Angeles*
11. University of Iowa Healthcare
12. University of Kansas Hospital
13. University of Missouri
14. University of Nebraska Medical Center
15. University of Texas Health Science Center at Houston
16. University of Utah Health
17. UT Health San Antonio
18. UT Southwestern Medical Center
19. Washington University in St. Louis

INSIGHT Clinical Research Network

20. Columbia
21. Houston Methodist*
22. Montefiore
23. Mount Sinai
24. New York University Langone Health
25. New York-Presbyterian
26. Weill Cornell Medicine

OneFlorida Clinical Research Consortium

27. AdventHealth Orlando
28. Bond Community Health Center, Inc.
29. Emory University
30. Florida Medicaid
31. Jackson Health System*
32. Nicklaus Children's Hospital (NCH)
33. Orlando Health
34. Tallahassee Memorial Healthcare and Capital Health Plan
35. University of Alabama at Birmingham
36. University of Arkansas for Medical Sciences*
37. University of California, Irvine*
38. University of Florida and University of Florida Health
39. University of Miami and UHealth
40. University of South Florida and Tampa General Hospital

PaTH Network – patient empowered research

41. Boston Medical Center*
42. Geisinger Health
43. Johns Hopkins University
44. Ohio State University
45. Penn State University
46. Rush University Medical Center*
47. Temple University
48. University of Michigan
49. University of Pittsburgh

PEDSnet – A Pediatric Learning Health System

50. Children's National Hospital*
51. Cincinnati Children's Hospital
52. Colorado Children's Hospital
53. Lurie Children's Hospital
54. Nationwide Children's Hospital
55. Nemours
56. Seattle Children's Research Institute
57. Stanford Children's Health
58. Texas Children's Hospital*
59. The Children's Hospital of Philadelphia

REACHnet – Research Action for Health Network

60. Baylor Scott & White Health (BSWH)
61. DHR Health Inst. for Research and Development*
62. Louisiana Public Health Institute (Lead)
63. Ochsner Health
64. Ochsner LSU Health Shreveport*
65. Tulane Medical Center
66. University Medical Center New Orleans
67. University of California, San Francisco*

STAR – Stakeholders, Technology, and Research CRN

68. Duke University
69. Essentia Health*
70. Health Sciences South Carolina
71. Mayo Clinic
72. Meharry Medical College
73. Stanford Healthcare*
74. University of North Carolina at Chapel Hill
75. Vanderbilt Health Affiliated Network
76. Vanderbilt University Medical Center
77. Wake Forest University Health Sciences

Coordinating Center for PCORnet®

1. The Children's Hospital of Philadelphia
2. Vanderbilt University Medical Center
3. Duke University

*New CRN sites

Scope of Data Accessible Through PCORnet®

PCORnet represents data from everyday health care encounters with more than 47 million people across the U.S. each year.

< 100,000 Encounters — > 100,000 Encounters — > 1,000,000 Encounters

Coordinating Center for PCORnet®
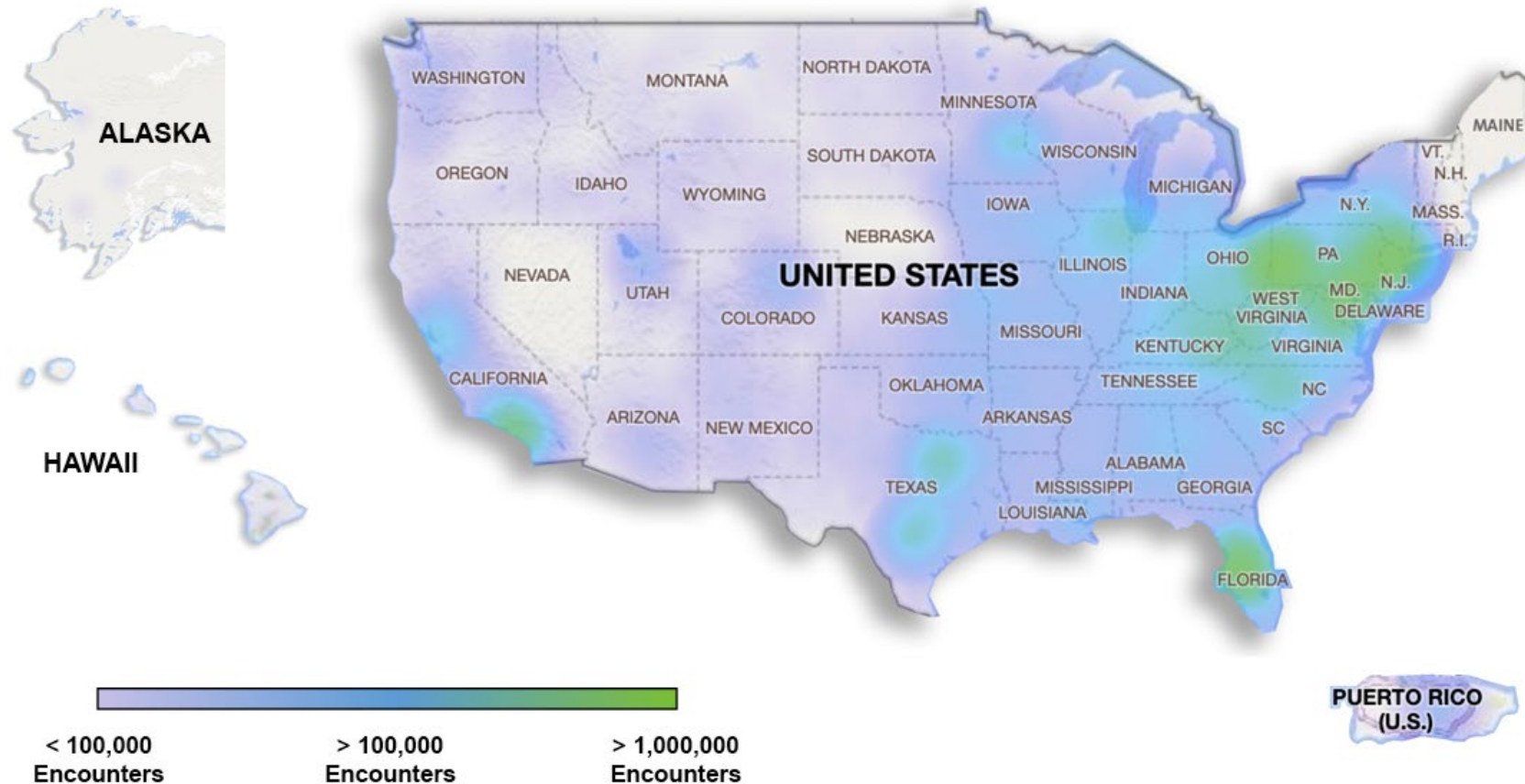
The Coordinating Center for PCORnet® serves as a central hub bringing the 8 diverse Clinical Research Networks and their participating institutions and patient partners together through shared communications, meetings, and initiatives.

Governance and Research Readiness

- Facilitates PCORnet governance, collaboration, and operations to enable PCORnet® Studies
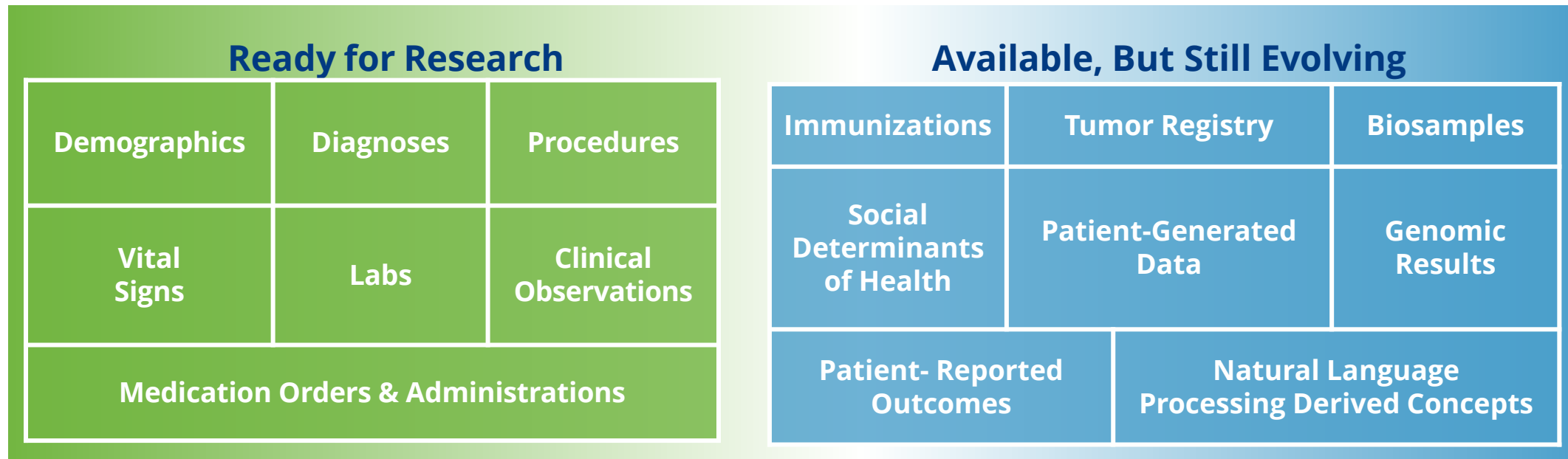- Manages PCORnet® Front Door

Data

- Maintenance and development of the PCORnet Common Data Model, data characterization, and privacy preserving record linkage
- Supports study consultation and query and analytic tool development to enable PCORnet® Studies

Engagement and Public Awareness

- Supports communications (e.g., website, social media, newsletter) to continue building awareness that expands the use of PCORnet resources
- Supports the broad range of PCORnet stakeholders to fully participate in PCORnet activities, including PCORnet governance
- Facilitates peer learning and dissemination of tools and resources to support engagement across PCORnet
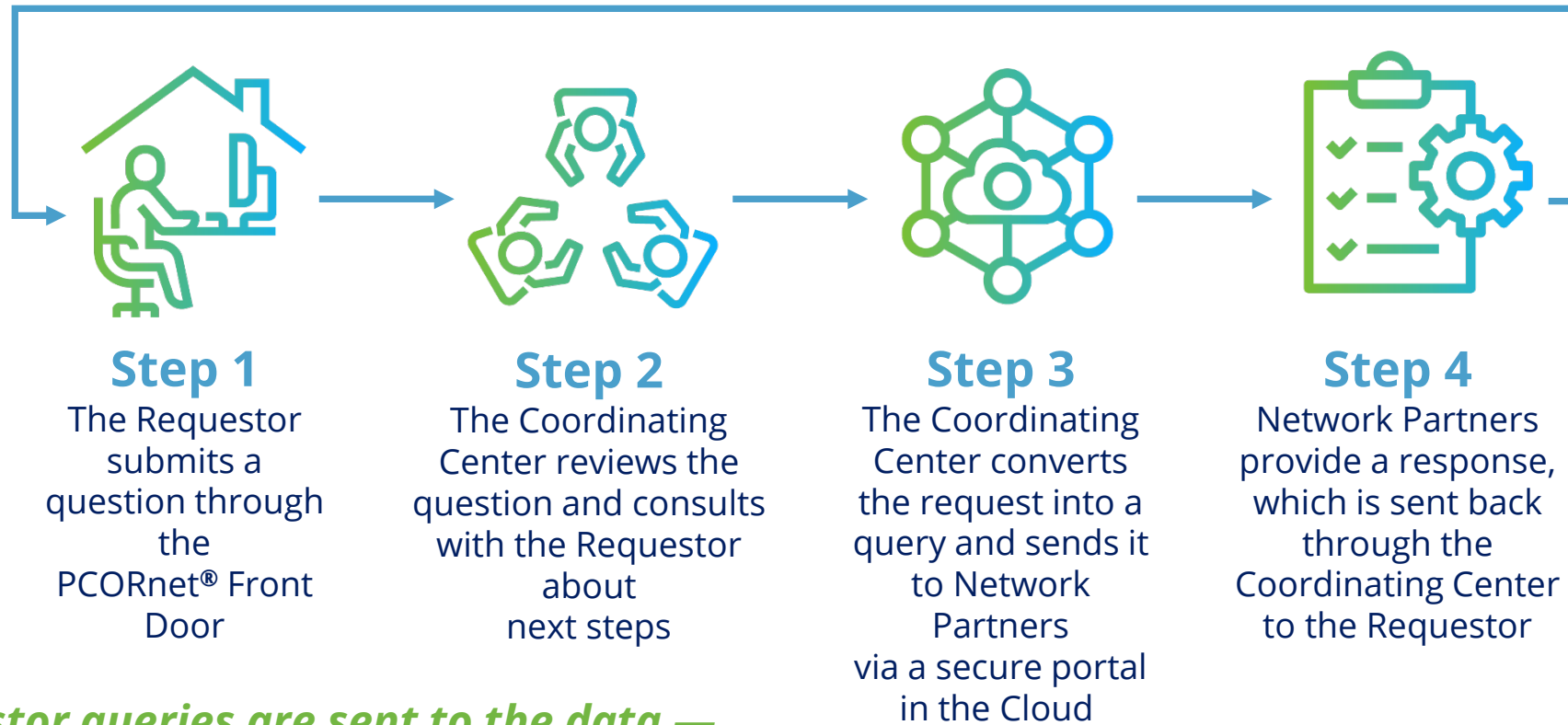
The PCORnet® Common Data Model

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

Demographics	Diagnoses	Procedures
Vital Signs	Labs	Clinical Observations
Medication Orders & Administrations		

Available, But Still Evolving

Immunizations	Tumor Registry	Biosamples
Social Determinants of Health	Patient-Generated Data	Genomic Results
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

A Secure Infrastructure Makes Real-World Data Accessible

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Step 1
The Requestor submits a question through the PCORnet® Front Door

Step 2
The Coordinating Center reviews the question and consults with the Requestor about next steps

Step 3
The Coordinating Center converts the request into a query and sends it to Network Partners via a secure portal in the Cloud

Step 4
Network Partners provide a response, which is sent back through the Coordinating Center to the Requestor

Requestor queries are sent to the data — and answers, not data, are sent back to requestors.
Read the PCORnet® Privacy Statement

Engaged Communities Drive Better Research

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"Good studies consider all relevant evidence – and no evidence is more relevant than the community experience."
– PCORnet® Steering Committee Member

What does "communities" mean in this context?

- **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**

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

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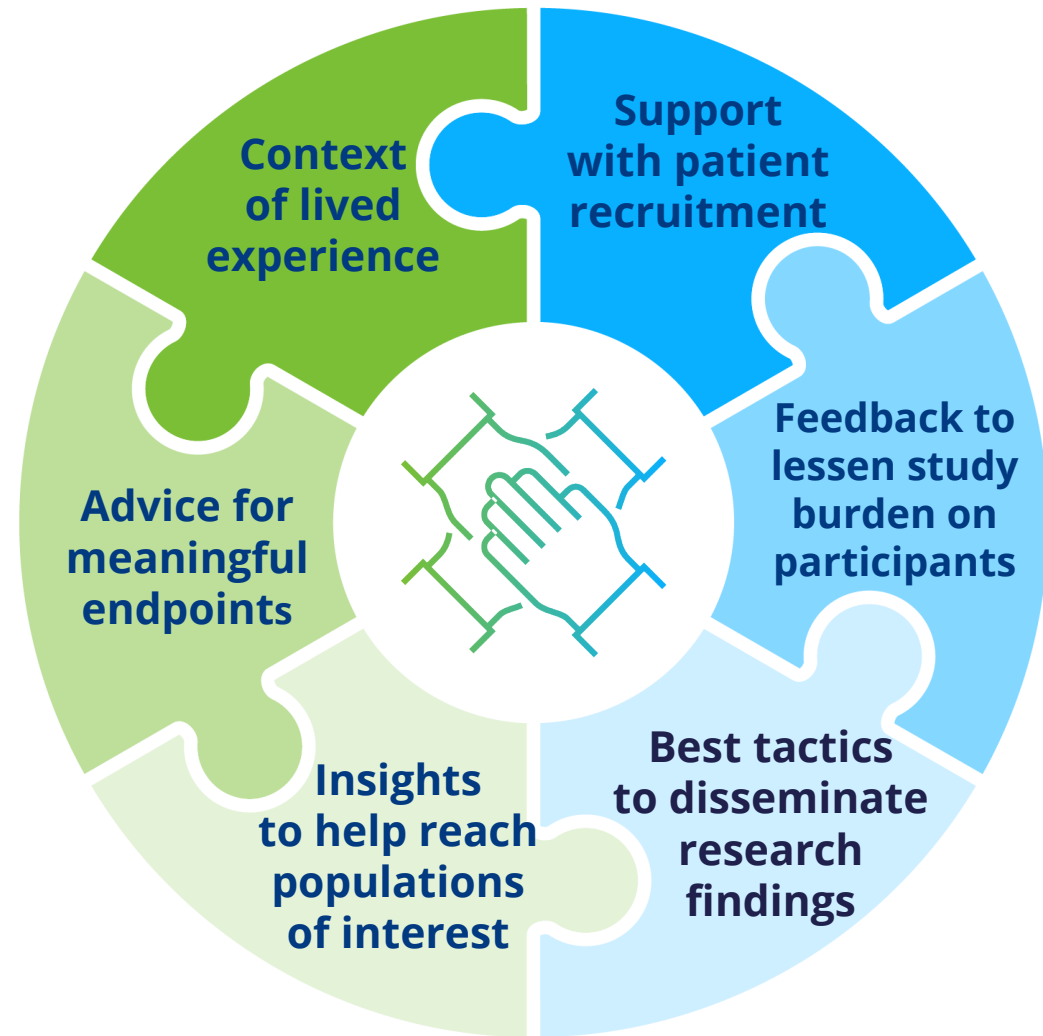
The Front Door is the Access Point for PCORnet Resources & Services

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

Learn More About the Front Door

What Are PCORnet® Studies?

- PCORnet® Studies meet a higher bar for PCORnet involvement and exemplify the type of national-scale patient-centered research PCORI envisioned when developing the network. These studies:
  - Include 2 or more Clinical Research Networks (CRNs)
  - Share study progress, performance metrics (e.g., Days to IRB, Number of days to first patient enrolled) monthly
  - Share best practices at least annually with the Network (e.g., PCORnet® Steering Committee), as outlined in additional PCORnet® Study milestones
  - Use PCORnet resources to improve the efficiency of the patient-centered research conducted (e.g., PCORnet® Common Data Model, single IRB, engagement resources)
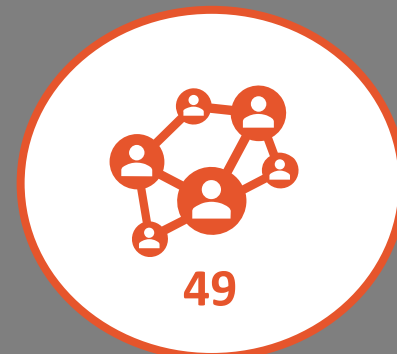- Note: Only PCORnet® Studies have permission to use the PCORnet name and logo (PCORnet Branding Guidelines)

PCORnet® is Accelerating National-Scale Patient-Centered CER and other Health Research
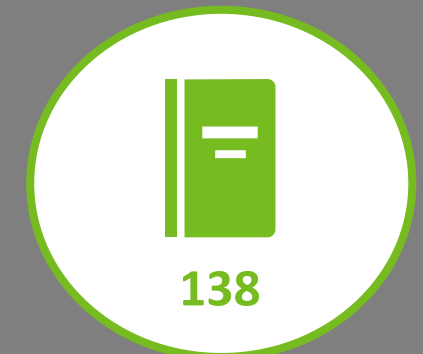
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47M — Annual Patients with Encounters

13K — Clinical Care Sites

49 — National Scale PCORnet® Studies

$530M — PCORnet® Study Funding

138 — PCORnet® Study Publications

pcornet®
The National Patient-Centered Clinical Research Network

PCORnet® Compared with Other Research Networks

PCORnet infrastructure brings a full spectrum of capabilities, plus connection to communities

	Feasibility queries	Identify patient populations for trial recruitment	Coordinated data curation	Connection to patients and providers
PCORnet	🟢	🟢	🟢	🟢
ENACT	🟢	🔴	🔴	🔴
TriNetX	🟢	🟢	🟡	🔴
OPTUM	🔴	🟢	🟡	🔴
OHDSI	🟢	🔴	🟡	🟡
Sentinel	🟢	🟢	🟢	🟡

🟢 = Capabilities   🟡 = Limited capabilities   🔴 = Lacks capability

Case Studies

TIV-6

t of the Accelerating COVID-19 Therapeutic Interventions and cines (ACTIV) Partnership

estion:

n medications already approved by the
people with mild-to-moderate COVID-19
r faster?

to date:

eatment with Fluticasone, Ivermectin,
xamine improved time to recovery
tpatients with COVID-19 in the US.

<div style="border:1px solid #e0a800; background:#fffbe6;">

Study Snapshot
* Decentralized, platform randomized clinical trial
* Patients ≥30yr with mild/moderate COVID-19
* Medications tested:
  * Ivermectin
  * Fluvoxamine
  * Fluticasone
  * Montelukast (still open)
* NIH funded

</div>

ORnet® :

ecentralized: On-line enrollment, consenting, and randomization;
medication shipped to participants' homes; all data collection
h online/phone surveys

ment resources: Leveraging patient and clinician engagement
ructure to provide study guidance through a stakeholder advisory

r national-scale recruitment: National reach of study sites, including

How does the study work?

Learn about ACTIV-6 online, on the radio, or from health systems, pharmacies, testing centers, or community partners.

Test positive for COVID-19.

Enroll online or over the phone. activ6study.org

Receive assigned study medication and directions at home. **Take** the study medication as directed.

Complete surveys about how you feel online or over the phone.

What makes ACTIV-6 different?

ACTIV-6 is testing several medications that are approved to treat conditions other than COVID-19 and can be found at your local pharmacy. This provides options to participants and helps

Participate from home — study medication is mailed directly to participants who can sign up and complete surveys online or over the phone.

ECIDENTD
vention of Cardiovascular and DiabEtic kidNey disease
ype 2 Diabetes

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uestion:

edication treatment is most
at reducing major health events,
heart attack, stroke, kidney
, and death in adults with type 2
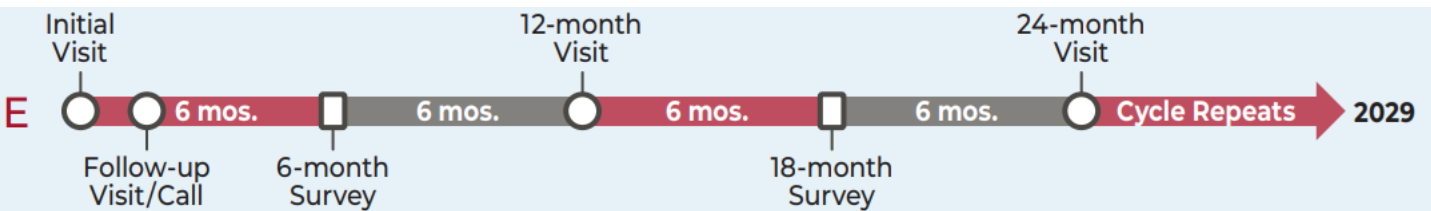and heart disease or high heart
risk.

to date:

uiting.

Study Snapshot
- Patient-level randomized, open-label, pragmatic, comparative effectiveness trial
- 9,000 adults with type 2 diabetes and atherosclerotic cardiovascular disease
- Medications tested:
  - SGLT2i
  - GLP-1 RA
  - Combination

Use of PCORnet® :
- *Recruitment: participants enrolled in partnership with 20-30 PCORnet healthcare systems across the US.*
- *Outcome data: medical outcomes captured through queries of the electronic health records at PCORnet affiliated sites using the PCORI common data model.*
- *Engagement: engaged local patient stakeholders and received feedback from patients as well as PCORnet investigators on project design and outcomes*

Initial Visit · Follow-up Visit/Call · 6 mos. · 6-month Survey · 6 mos. · 12-month Visit · 6 mos. · 18-month Survey · 6 mos. · 24-month Visit · Cycle Repeats · 2029

PCORI Funding Opportunities

5 Research Award Funding Opportunities

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Up to $22M
Feasibility and
-scale study
phases

Phased Large Awards for Comparative Effectiveness Research
Large, meritorious and innovative studies with some risks

Up to $5M
$5–12M
Up to $12M

Broad Pragmatic Studies
Investigator-initiated awards in alignment with the National Priorities for Health
(Three funding categories, including PCORnet® studies)

o to $750K

Methods
Improve use of AI and ML, improve study design, support data
research networks, ethical and human subject protections in CER

Up to $1M
Up to $1.5M

Science of Engagement
Two funding categories: Development and validation of measures
Development and testing of engagement techniques

Variable

Focused
Stakeholder-driven topics, issues and questions of national significance

Funding Cycle LOI Deadlines

Cycle 1: Jan. 14

Cycle 2: May 13

Cycle 3: Sept. 23

Category 3 for PCORnet® Studies

Cycle 2 of 2023, Category 3 was added to the Broad Pragmatic Studies (BPS) ORI Funding Announcement (PFA) to support PCORnet® Studies that advance ORI's National Priorities for Health

dies must:

- Address PCORI's National Priorities for Health
- Include 2 or more Clinical Research Networks (CRNs)
- Share study progress, performance metrics (e.g., Days to IRB, Number of days to first patient enrolled) monthly
- Share best practices at least annually with the Network (e.g., PCORnet® Steering Committee), as outlined in additional PCORnet® Study milestones
- Use PCORnet resources to improve the efficiency of the patient-centered research conducted (e.g., PCORnet® Common Data Model, single IRB, engagement resources)

...rd sizes with varying requirements/limitations allowed across all four ...onal Priority Areas for Health

...Category 1: Total direct costs $\leq$ $5 million
...Category 2: $5 million < Total direct costs $\leq$ $12 million
...Category 3: Total direct costs $\leq$ $12 million

...licants seeking budgets greater than $5M, must provide brief additional ...rmation to:

...ustify the large size and scope of their proposed research

...Describe how additional funds are necessary with respect to the scale, scope, and ...omplexity of personnel and material resources needed

...ubject to additional merit review considerations

Category 3 Requirements

Applicants to Category 3 must contact the PCORnet® Front Door before LOI submission.

- Please include your Front Door number (FD#XXX) in your LOI

The full application, applicants must submit Letters of Support from at least two CRN sites that have agreed to participate.

Category 3 PCORnet® Studies will include additional milestones that specify:

- Share study progress and best practices regularly with the network, such as through annual presentations to the PCORnet® Steering Committee,

- Report performance on study site metrics (e.g., time to IRB, enrollment rates) monthly to the Coordinating Center for PCORnet to promote continuous learning and improvement.

n Category 1 and 2 applicants use PCORnet®?

Category 1 and 2 applicants can still use PCORnet if they do not meet the requirements for Category 3

w will PCORI verify that Category 3 applicants have contacted the PCORnet® Front Door?

icants will be required to include a Front Door number in the submitted LOI for a Category 3 study. This number provided as part of the Front Door consultation.

w should Category 3 applicants obtain Letters of Support from PCORnet® Clinical Research twork sites?

PCORnet® Front Door (https://pcornet.org/front-door/) can assist applicants in identifying potential collaborators. nts can also reach out to investigators associated with PCORnet sites directly. A complete list of all PCORnet ating sites is available at https://pcornet.org/network/.

ust all Category 3 submissions include use of the PCORnet® Common Data Model?

Category 3 submissions must include the use of the PCORnet resources to improve the efficiency of the patient- ed research conducted (e.g., PCORnet® Common Data Model, single IRB, engagement resources). This can

...ditional PCORnet® Workshop

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...T PCORnet Webinar Part 2 (Date TBD)

...will be presented by members of the Coordinating Center for PCORnet® and will ...build upon part 1

...Will include:

- Ways that PCORnet supports research
- Deeper dive into the PCORnet® Common Data Model
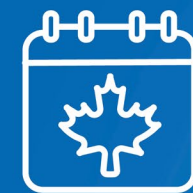- Resources for stakeholder engagement

nk you

pcori ® PATIENT-CENTERED OUTCOMES
RESEARCH INSTITUTE

46th ANNUAL MEETING

May 18-21, 2025

VANCOUVER CANADA

SAVE THE DATE

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T Membership Benefits

ow are some of the many benefits you receive as a member of SCT:

Networking
Continuing Education
Webinars
Subscription to the *Clinical Trials* Journal
Substantially discounted registration fees to SCT Annual Meetings
Professional development, leadership, and presentation opportunities
Social outreach and communication

s://sctweb.org/membership.cfm

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erested in presenting a future T Webinar?

the SCT website, click on the Member Sign-In button and login.

the Members-Only Area Home page, click on "Propose a SCT binar!" in the menu on the righthand side.

mplete and return the Webinar Proposal Form to contact@sctweb.org the SCT Education Committee's review and consideration.

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...ve you completed your SCT member profile?

...SCT leadership is making a concerted effort to learn more about our ...mbership community in an effort to develop more appropriate programs and ...ices, increase engagement, and ensure members' voices are heard regarding ...iers in clinical trials research and education. As such, we ask that you please ...ate your member profile.

...omplete your SCT member profile, please follow the steps below:

...Log onto the Members-Only Area of the SCT website.
...Click on the "Your Membership Account" option in the right-hand side menu.
...Complete the optional questions on the "Profile" tab.

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