PCORI

Funding Opportunities using PCORnet®

Kim Marschhauser, PhD
Associate Director
Research Infrastructure & Innovation

pcori PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Get To Know PCORI®

PCORI

- Nonprofit that funds patient-centered comparative clinical effectiveness research (CER)
- Widely acknowledged as a leader in driving U.S. clinical research to become more patient-centered
- Provides funding for CER, engagement in research, dissemination and implementation and research infrastructure projects

Our Mission

Our Mission

Help people make better-informed healthcare decisions, and improve 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

PCORnet®

- National-scale resource to conduct patient-centered CER
- Research ecosystem also well suited to conduct:
  - Real-world evidence studies
  - Pragmatic clinical trials
  - Population health research
  - Health systems research
  - Studies on how best to engage patients in research

Multiple Funding Opportunities

Types of PCORI-Funded Projects

CER Awards

- Fund studies comparing two or more treatments, services or health practices

Dissemination and Implementation Awards

- Fund projects to deliver the evidence to those who can use it

Engagement Awards

- Fund projects to bring more patients, caregivers, clinicians and communities into the health research process

The Research Project Agenda Guides the Development of Near-Term Focused Funding Opportunities

Topic Themes

- Inform funding opportunities
- Address widespread health conditions and challenges
- Highlight evidence gaps to improve health outcomes and patient care

Research Funding Opportunities

Phased Large Awards for Comparative Effectiveness Research	Broad Pragmatic Studies	Topic-Focused	Science of Engagement	Methods
Large, meritorious and innovative studies with some risks	Studies aligned with at least one of PCORI's three funding categories, including PCORnet® studies	Stakeholder-driven topics, issues and questions of national significance	Development and validation of measures; development and testing of engagement techniques	Improve use of AI and ML, improve study design, support data research networks, ethical and human subject protections in CER
Up to $22M (for feasibility and full-scale study phases)	**1. Up to $5M** **2. $5 to 12M** **3. Up to $12M**	**Variable**	**1. Up to $1M** **2. Up to $1.5M**	**Up to $750K**

2026 Funding Cycle LOI Deadlines

Cycle 1: Jan. 6 | **Cycle 2:** Apr. 28 | **Cycle 3:** Sept. 8

*All funds and timeline noted above are subject to change

Category 3 for PCORnet® Studies
Broad Pragmatic Studies PFA

- Category 3 to support PCORnet® Studies
- Studies must:
  - Conduct PCORnet® Studies comparing at least two alternative approaches in alignment with one or more of PCORI's stated topic themes
  - Include two or more clinical research networks
  - 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 the PCORnet resources to improve the efficiency of the patient-centered research conducted (e.g., PCORnet® Common Data Model, single IRB, engagement resources)
- Note: Category 1 and 2 applicants can still use PCORnet if they do not meet the requirements for Category 3

PCORnet® Workshops

- **Overview of PCORnet® and PCORI Requirements for Broad Pragmatic Studies Category 3:** PCORnet® Studies Applicant Workshop

  View recording on our website

- **Taking the Next Step With PCORnet®:** A Deep Dive Into the PCORnet Network, Common Data Model and Engagement Resources

  View recording on our website

Stay Connected

Looking To Stay Current on All Things PCORI?

Sign up to receive our weekly email newsletter and alerts about:

- Funding opportunities
- Results from our funded research
- Webinars, meetings and events
- Our new strategic initiatives and more!

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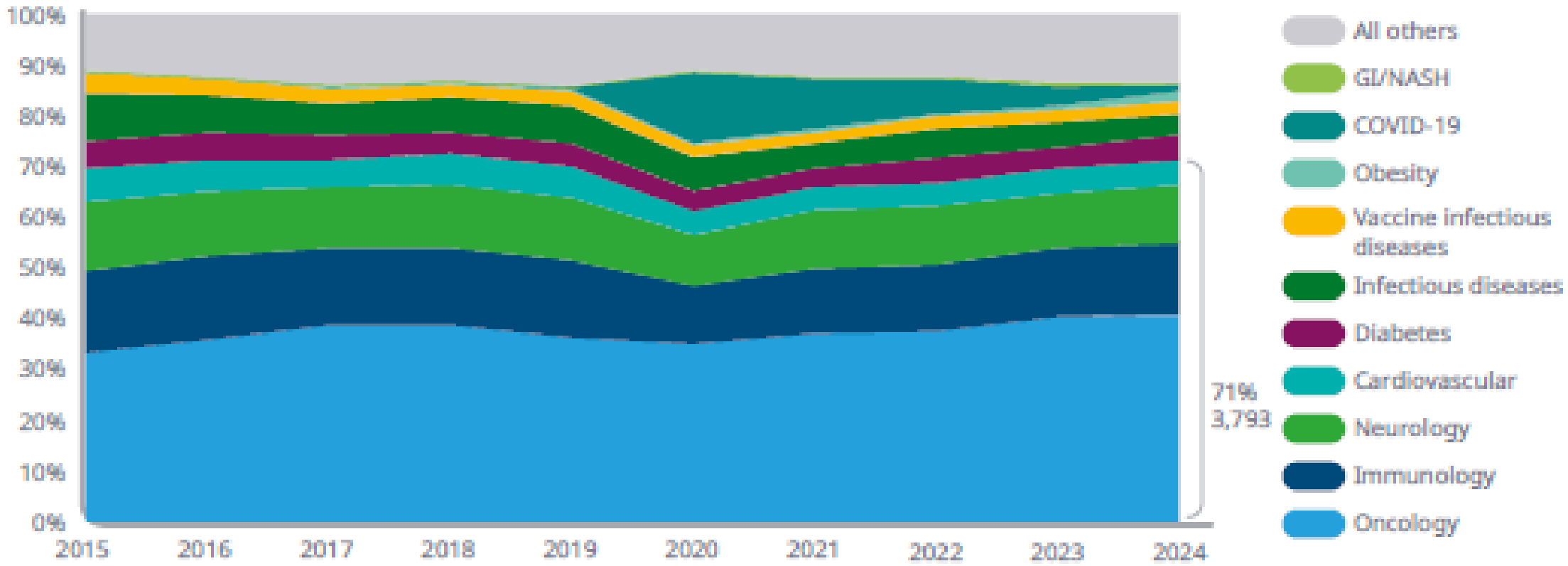
PCORnet®: An Overview

PCORnet® is intended to improve the nation's capacity to efficiently conduct patient-centered health research, particularly comparative clinical effectiveness research (CER), by providing a large, highly representative network of health data, research expertise, and patient insights. PCORnet has been developed with funding from the Patient-Centered Outcomes Research Institute® (PCORI®).

Updated
February 2026

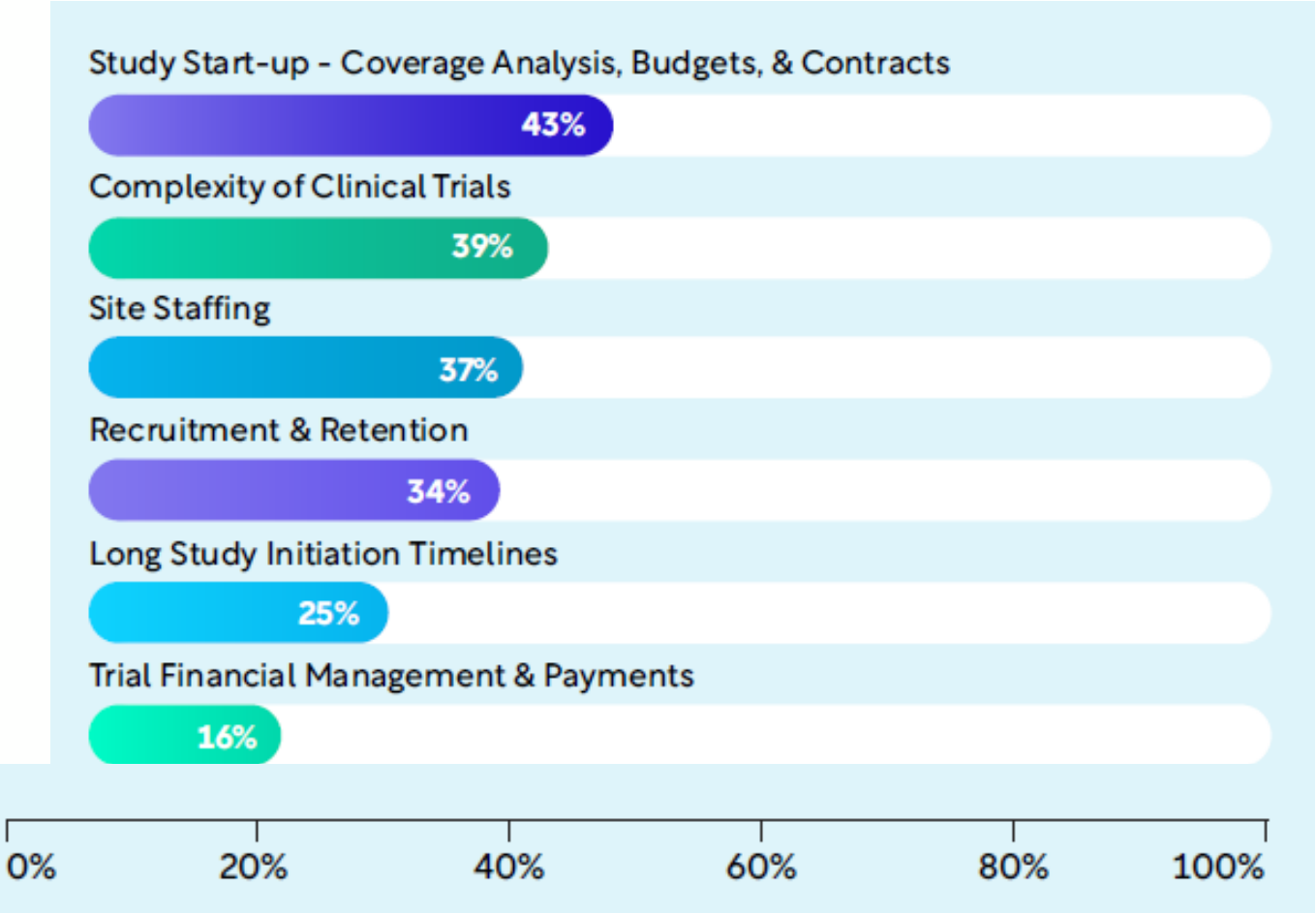
The Landscape

- Top four areas account for 71% of all trials.

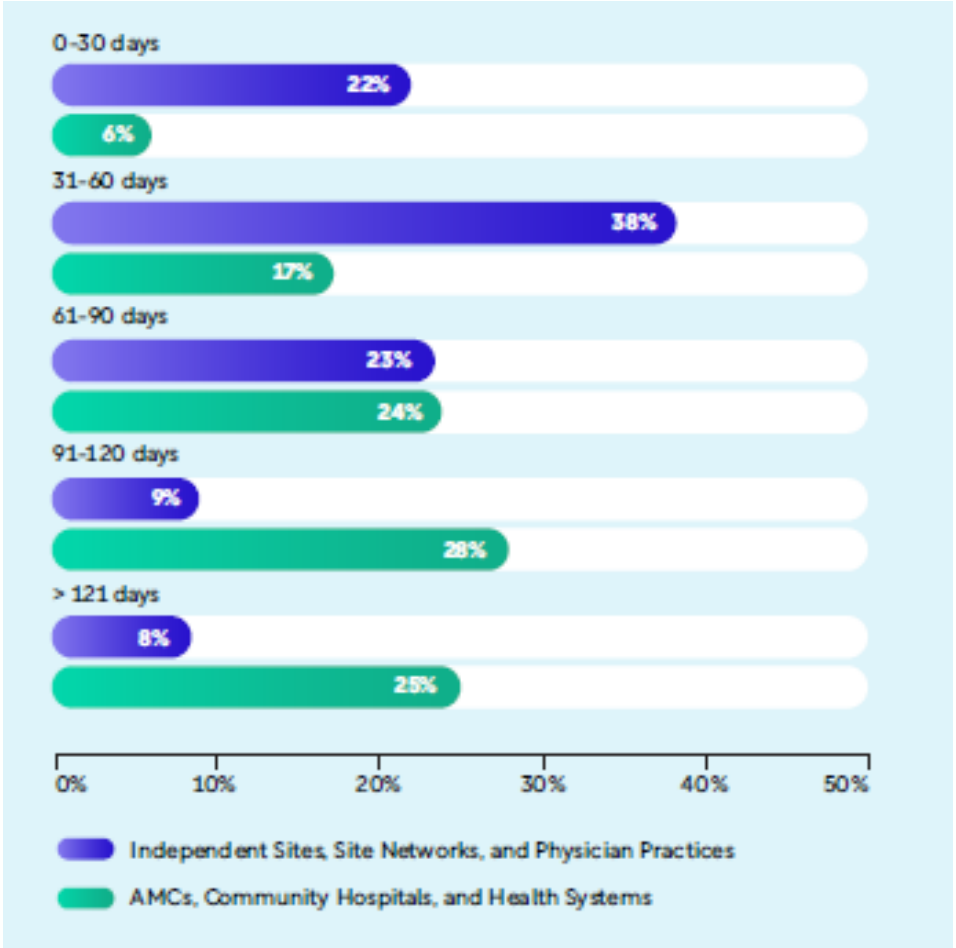


Top issues impacting academic, health system, and community hospital research sites

Top issues impacting ability to conduct research

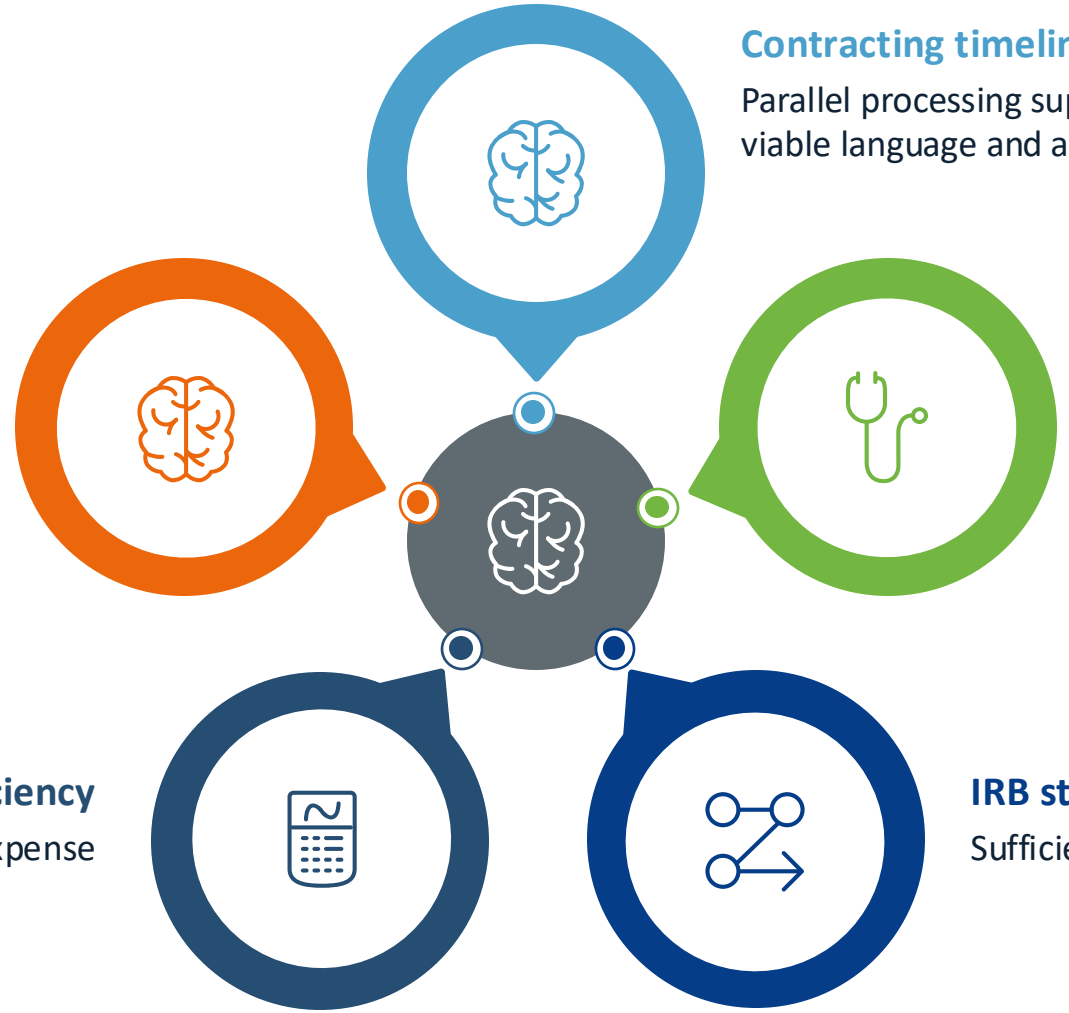


Reported start-up timelines



From: WCG Clinical 2024 Clinical Research Site Challenges Survey Report

Accelerating research in academic settings



Contracting timelines

Parallel processing suprior to sequential, minimal viable language and acceptance

Prioritization

Availability of Principle Investigators and incentivization

Intellectual property

Signfiicant divergence with non-academic sites

Cost and efficiency

Appropriate value for expense

IRB staffing and responsiveness

Sufficiency of expertise, availability, and focus

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What Gaps Can PCORnet Fill?

One PCORnet® — Many Possibilities

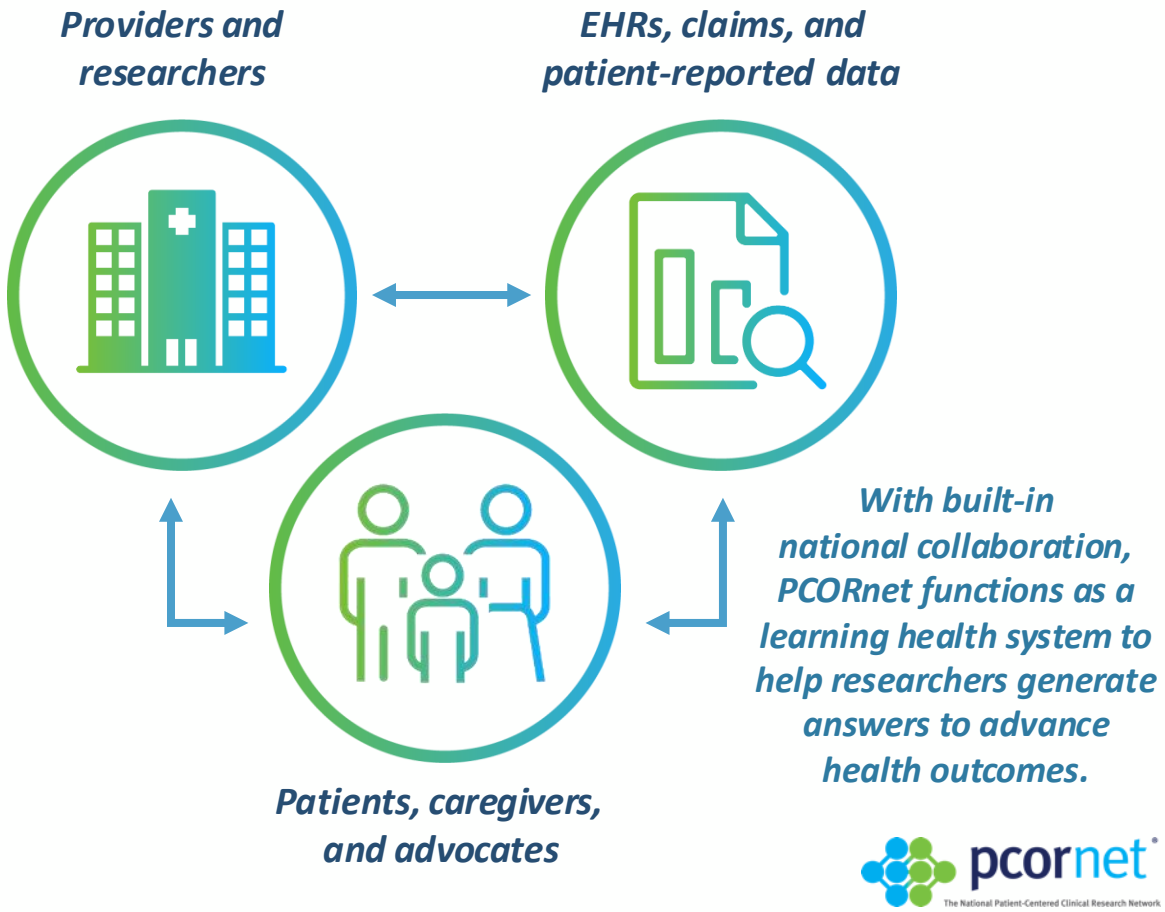
PCORnet is a national resource, funded by PCORI, that enables insights from high-quality health data, patient partnership, and research expertise to deliver fast, trustworthy answers that advance health outcomes.

Research Powered by PCORnet®

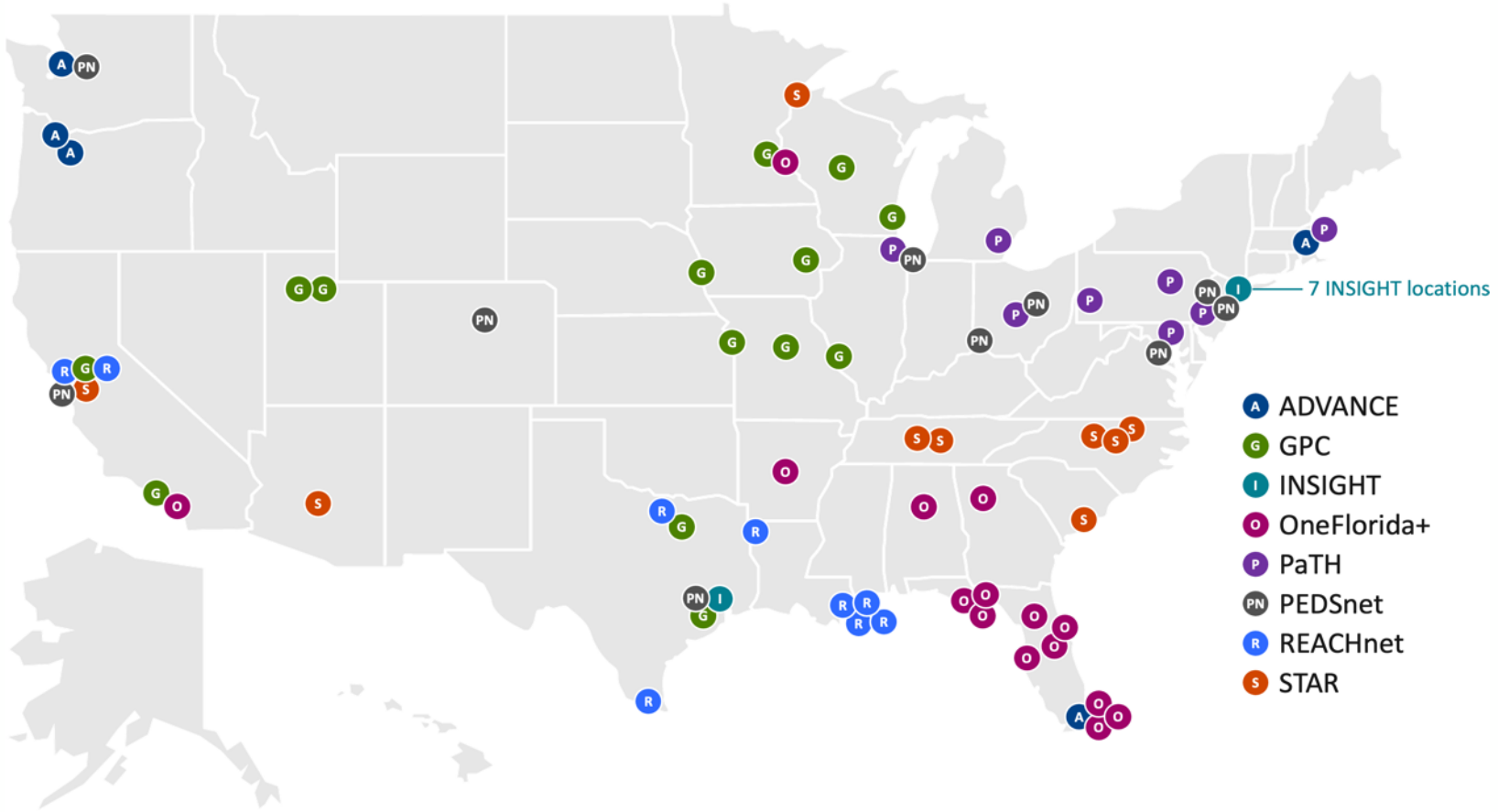
- Real-world evidence studies
- Comparative clinical effectiveness research
- Population health research
- Pragmatic research
- Health systems research
- Implementation science research
- And more

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.



PCORnet® Clinical Research Network Locations



What are Clinical Research Networks?

- Healthcare institutions from large academic health centers to local community clinics across the U.S.
- Committed to speed patient-centered research via PCORnet

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PCORnet® Clinical Research Network Locations

ADVANCE

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

GPC

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

INSIGHT

20. Columbia University Irving Medical Center
21. Houston Methodist
22. Montefiore Einstein
23. Mount Sinai Health System
24. New York University Langone Health
25. New York-Presbyterian
26. Stony Brook Medicine
27. Weill Cornell Medicine

OneFlorida+

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

PaTH

43. Boston Medical Center
44. Geisinger
45. Johns Hopkins University
46. Ohio State University
47. Rush University Medical Center
48. Temple University
49. University of Michigan
50. University of Pittsburgh

PEDSnet

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

REACHnet

61. Baylor Scott & White Health (BSWH)
62. DHR Health Institute for Research and Development
63. Louisiana Public Health Institute
64. Ochsner Health
65. Ochsner LSU Health Shreveport
66. Sutter Health
67. Tulane Medical Center
68. LCMC Health
69. University of California, San Francisco

STAR

70. Duke University (CC)
71. Essentia Health
72. Mayo Clinic
73. Medical University of South Carolina
74. Meharry Medical College
75. Stanford University School of Medicine
76. University of North Carolina at Chapel Hill
77. Vanderbilt University Medical Center (CC)
78. Wake Forest University School of Medicine

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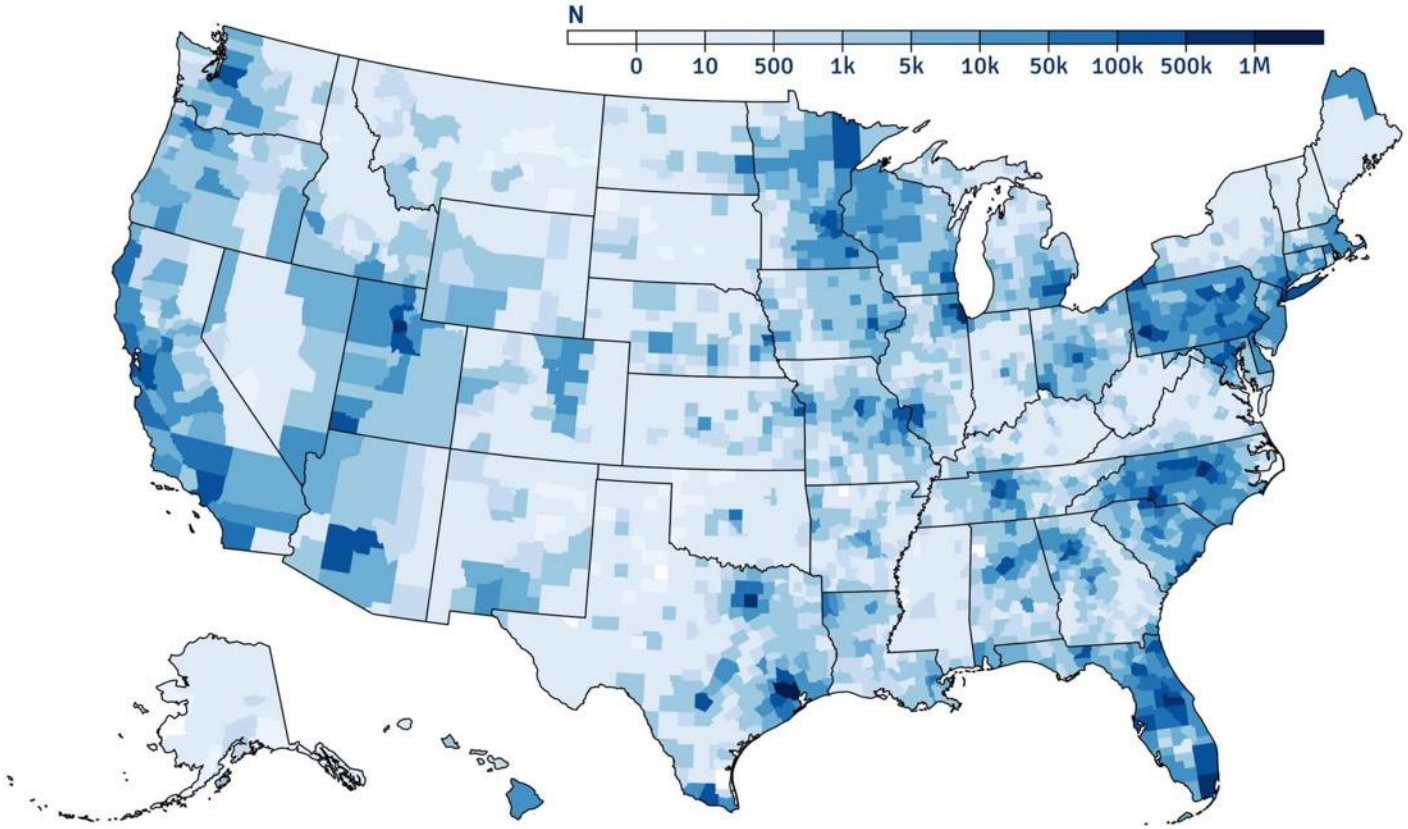
Scope of PCORnet-Accessible Data

PCORnet represents data from **everyday health care encounters with more than 47 million people** annually across the U.S., enabling large-scale, innovative, patient-centered health research.



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

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The PCORnet® Common Data Model

To be useful, data have to be standardized across systems. Frequent data curation and a single language enabled by the PCORnet® Common Data Model (CDM) deliver 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 from PCORnet® Clinical Research Networks available in the PCORnet® CDM and ready for use in research

Data available at some PCORnet® Clinical Research Networks that may not be in the PCORnet® CDM and require additional work for use in research

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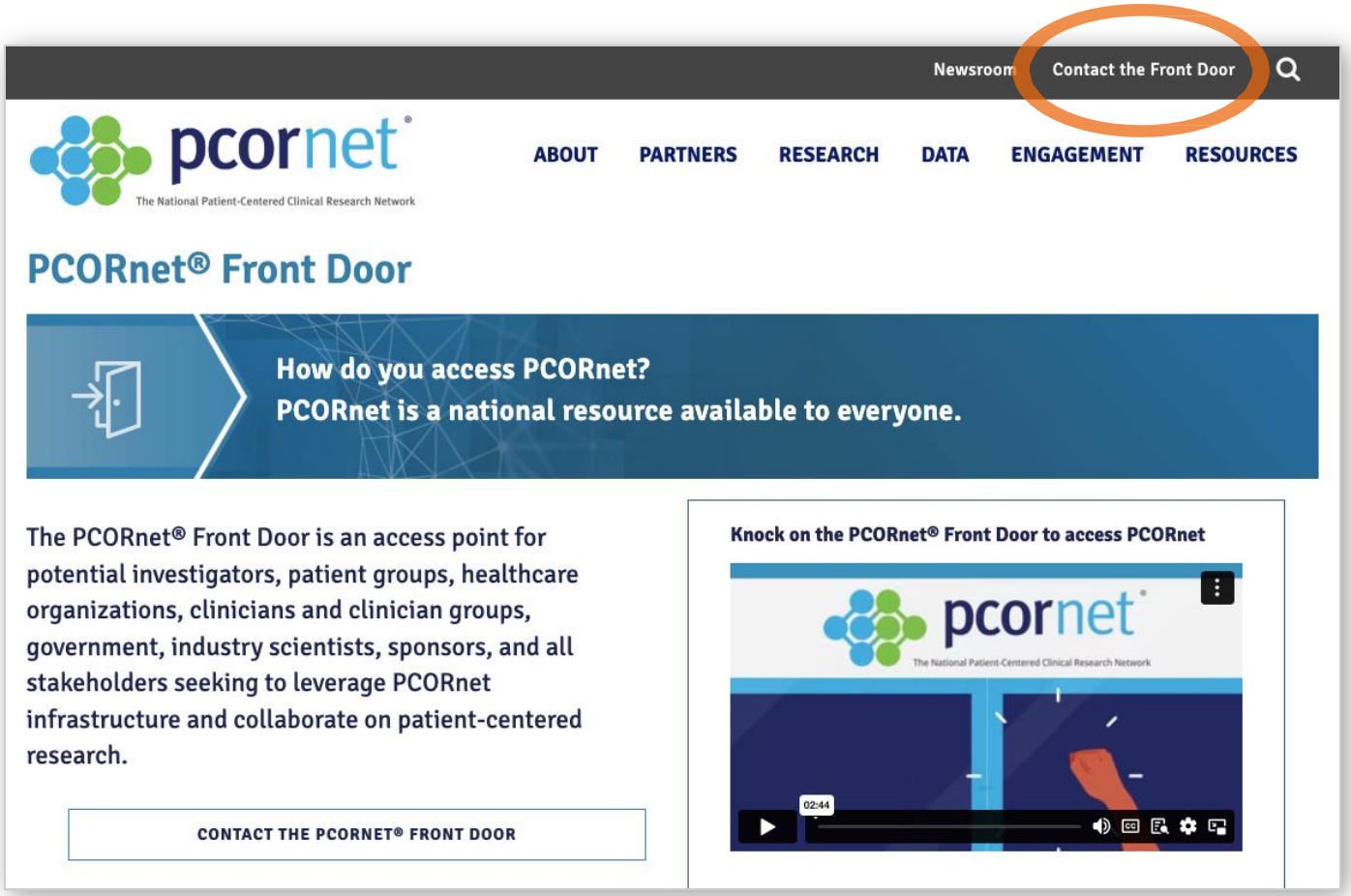
Work with PCORnet®



The PCORnet® Front Door

The access point for PCORnet resources and services

A “knock” on the PCORnet® Front Door can support:

STUDY DESIGN

Preliminary data for proposals, effect sizes, and potential study power

DATA NETWORK REQUEST

- Get data insights from PCORnet® Clinical Research Networks
- Obtain aggregated results for informing research project development

CONNECTIONS TO NETWORK COLLABORATORS

- Partners to co-design research
- People with specific expertise

PCORnet® STUDY SUPPORT

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

Learn More About the Front Door

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Research Using PCORnet®

A Vetted National Resource to Deliver Fast, Trustworthy Answers That Advance Health Outcomes

$1B+

Research Funding

325

Funded Studies

62

PCORnet® Studies

1074

Publications about Research Powered by PCORnet®

1805

PCORnet® Front Door Requests

Numbers reflect 2015-2026, except for PCORnet® Front Door requests which are from November 2018 - February 2026.

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What is a PCORnet® Study?

PCORnet® Studies represent a deep level of partnership to advance patient-centered comparative clinical effectiveness research and other national-scale research.

PCORnet® Studies are committed to:

1. Collaborating with two or more PCORnet® Clinical Research Networks (CRNs)
2. Ensuring participants and patients are engaged throughout the project lifecycle
3. Broadly disseminating findings and returning study results to participants
4. Sharing study progress, performance metrics, and best practices with the network regularly
5. Leveraging the PCORnet® Common Data Model as appropriate
6. Research powered by PCORnet® includes PCORnet® Studies and other research conducted using PCORnet data resources

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PCORnet® Studies

$703M

PCORnet® Study Funding

196+

PCORnet® Study Publications

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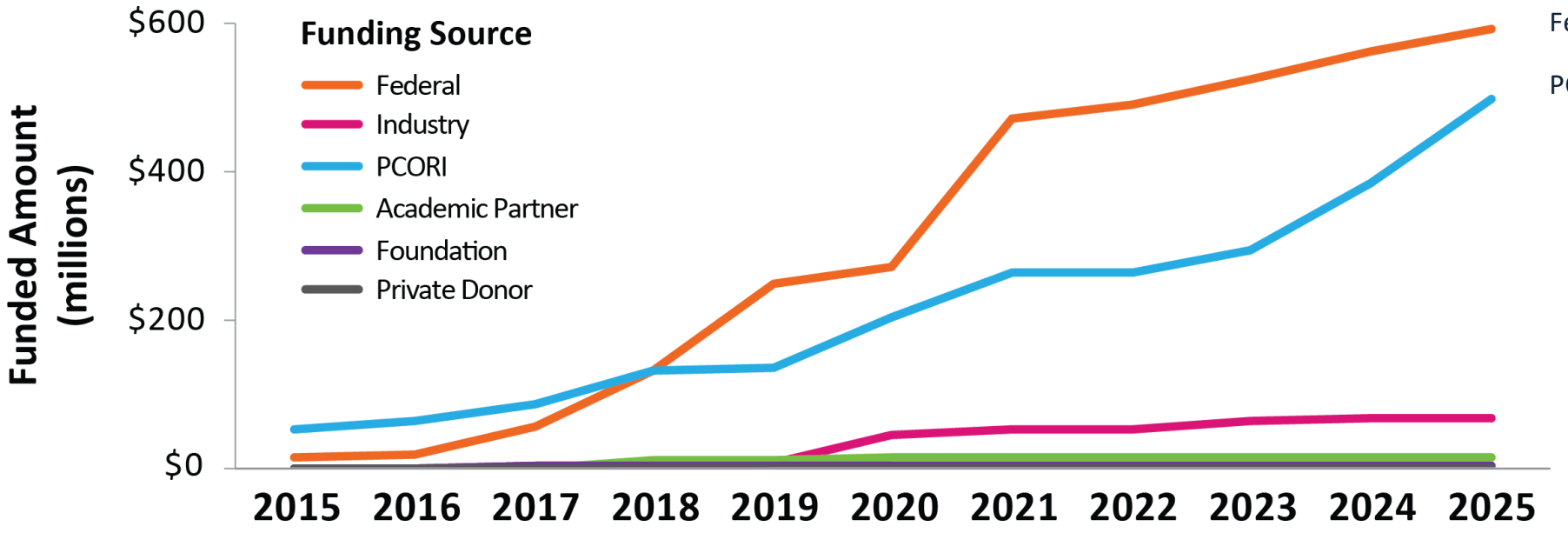
Multi-Sector Funding for Research Using PCORnet®

The PCORnet infrastructure supports research from a variety of funders including, but not limited, to PCORI.



Federal N=164, $595,289,535

PCORI N=65, $497,828,023

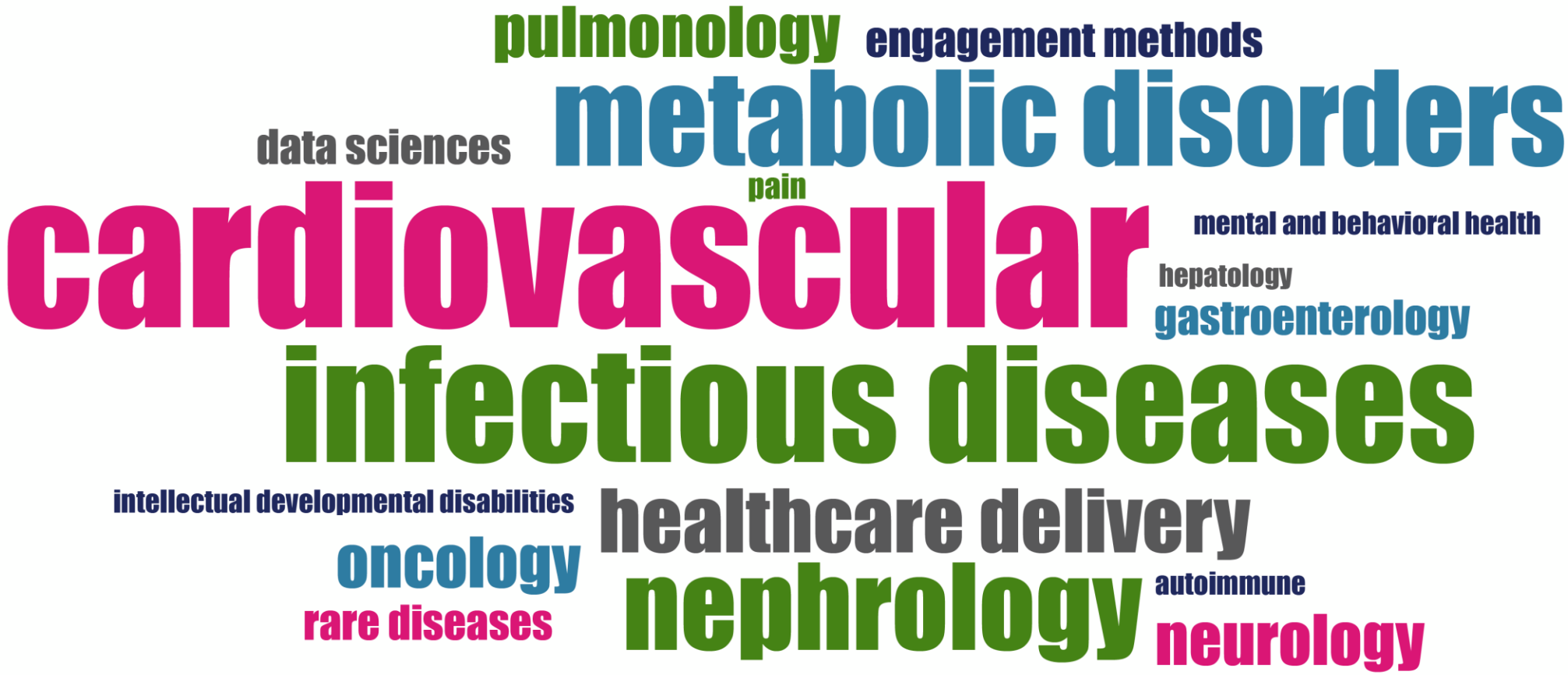
Industry N=40, $67,541,406
Academic Partner N=39, $13,146,464
Foundation N=16, $3,875,257
Private Donor N=1, $180,000

Research studies using PCORnet funded amount=$1,177,860,685. N=325

Data is self-reported from PCORnet® Network Partners.

Data as of February 10, 2026

Therapeutic Areas Researched in PCORnet® Studies



Data as of February 5, 2026

Research in PCORnet®

PCORnet is a national resource where high-quality health data, patient partnership, and research expertise delivers fast, trustworthy answers that advance health outcomes.

COMPARE
Clinical Outcomes of Medications Post Anti-TNF: Researching Effectiveness in Pediatric IBD

Adaptable
The Aspirin Study

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Morbidity and Mortality Weekly Report (*MMWR*)

Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022

COVID-19 DIABETES ASSESSMENT

Research | Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted | Has Results

Comparing Three Types of Weight Loss Surgery -- The PCORnet® Bariatric Study

PRECIDENTD
Prevention of Cardiovascular and Diabetic Kidney Disease in Type 2 Diabetes

PREVENTABLE
PRagmatic EValuation of evENTs And Benefits of Lipid-lowering in oldEr adults

HERO
Healthcare Worker Exposure Response & Outcomes

RECOVER
Researching COVID to Enhance Recovery

ACTIV-6

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PCORnet Resources

- Materials developed using PCORnet are shared to promote lessons learned and best practices in the Knowledge Repository located in the Resources section of **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.

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.

Data

Improve the quantity and quality of data used in your study with innovative resources and tools.

Engagement

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

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PCORnet® Playbook

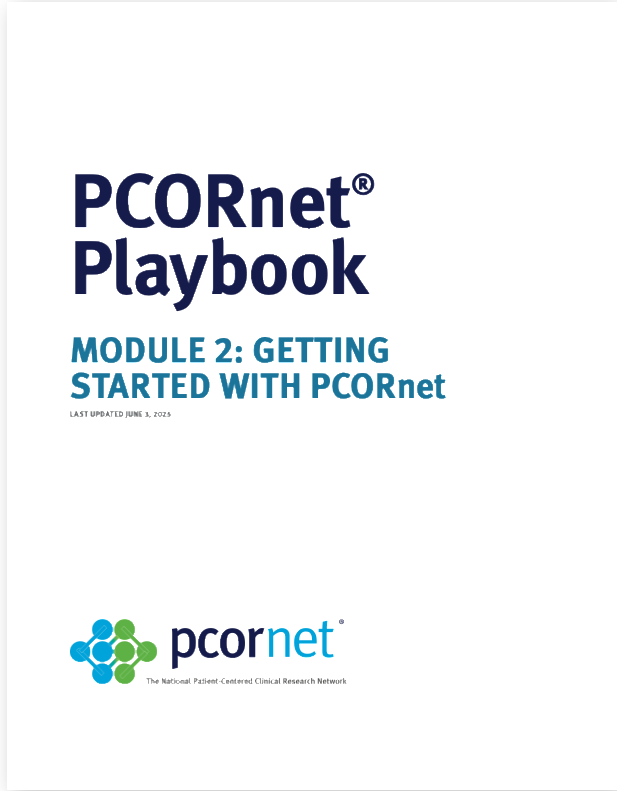
Your guide to using PCORnet for patient-centered research

Through this resource, you will learn:

How to use PCORnet resources to find fast, trustworthy answers to patient-centered health research questions.

How to design high-quality, large-scale research projects using PCORnet services, including engagement, data, and outreach support.

What to expect when collaborating with PCORnet® Network Partners.



Get started at pcornet.org/pcornet-playbook

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PCORnet Efficiencies

- PCORnet Common Data Model
- PCORnet Common Engagement Model
- Research Readiness Coordinators
- Data Flow Templates
- PCORnet Master Clinical Research Collaboration Agreement
- PCORnet Master Data Sharing Agreement
- Reliance on Single IRB and Commercial IRB

- **GOAL: Start-up in 90 Days!**

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Common Misperceptions

Does PCORnet = PCORI?

No! PCORI provides funding to support the infrastructure of PCORnet but does not dictate the operations of PCORnet. The sites and staff that support PCORnet do not represent PCORI.

Can only PCORnet Members conduct research using PCORnet?

No! PCORnet is a national resource available to anyone.

Is PCORnet research funded only by PCORI?

No! Research leveraging PCORI can be funded by PCORI, NIH, Industry, Foundations, etc.

Does a PCORnet® Study have to leverage electronic health data?

No! A study may be a PCORnet® Study if it utilizes at least two PCORnet® CRNs and embraces elements of patient engagement. Utilization of electronic health record data is not a requirement.

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Connect with PCORnet

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LEARN MORE ABOUT
the PCORnet® Front Door

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FOLLOW
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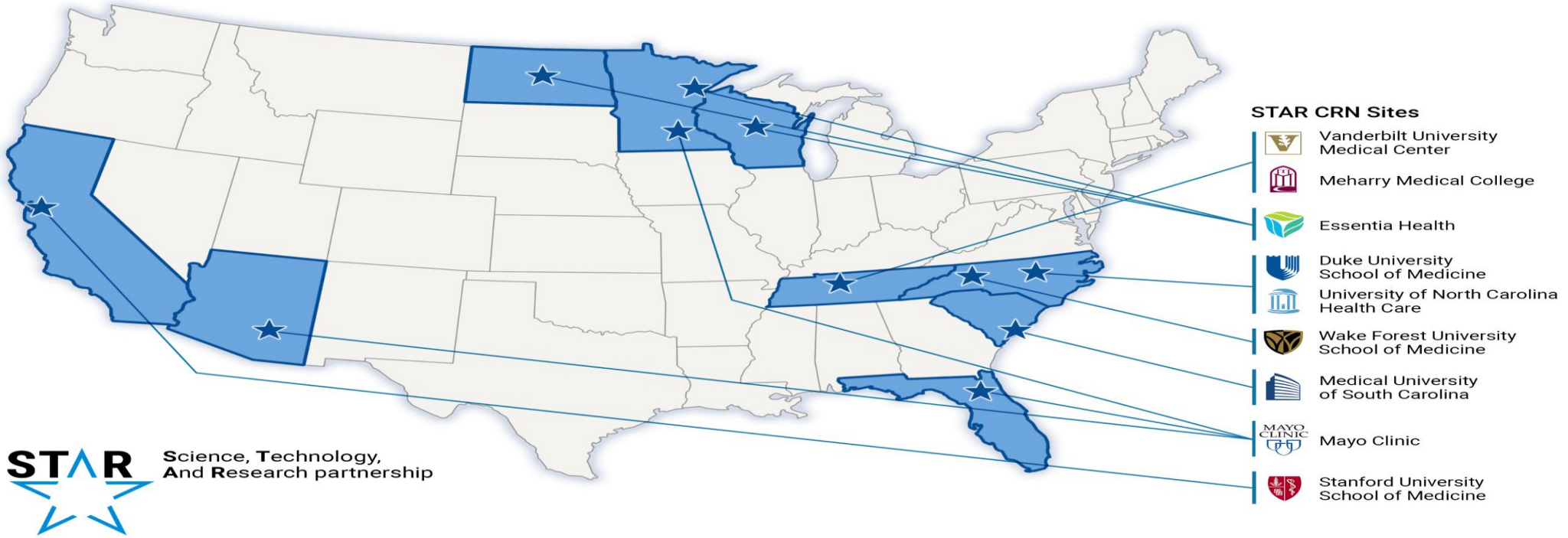
@PCORnetwork on X

STAR Clinical Research Network

STAR CRN Clinical Reach

Over 25 million patients across the country.

The STAR Clinical Research Network includes **clinical records** of patients **since 2004** and is updated on a quarterly basis.



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CDM Production Table – Cycle 17_1 Data Curation v6.10

Site	Sites in CDM	Patients in CDM	Encounters in CDM	CDM Dates	Production CDM Refresh Rate*
Vanderbilt	Vanderbilt University Health System	3,069,955	64,006,045	01/01/2009 – 10/31/2024	Quarterly update
Mayo Clinic	Mayo Clinic Rochester/Florida/Arizona, Mayo Clinic Health System	3,497,878	106,414,068	01/01/2010 – 08/31/2024	Quarterly update
UNC at Chapel Hill	UNC Health Care System	5,057,689	240,042,991	06/01/2004 – 04/05/2024	Quarterly update
Duke University	Duke University	3,537,891	105,990,063	01/01/2005 –03/31/2025	Quarterly update
MUSC	MUSC Health	2,121,842	26,079,960	07/01/2014– 03/31/2025	Quarterly update
Meharry Medical College	Meharry Medical College & Nashville General Hospital	446,656	2,446,475	01/01/2004 – 02/28/2025	Quarterly update
Wake Forest Baptist Health	Wake Forest Health Systems	6,581,929	277,608,978	01/01/2007 - 02/28/2025	Quarterly update
Essentia	Essentia Health	1,445,603	72,705,386	01/01/2012 – 04/01/2025	Quarterly update
Stanford	Stanford Health Care	2,596,473	136,142,844	01/01/2012 - 09/09/2024	Quarterly update

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* Production tables are updated after data characterizations have been approved by the Coordinating Center

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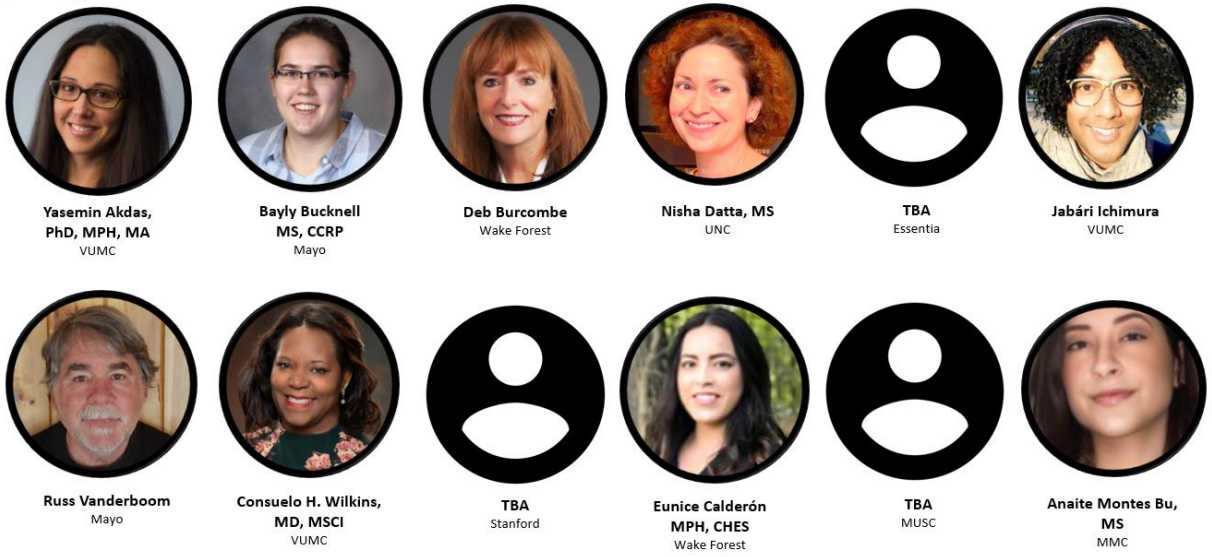
STAR Advisory Council

- (3) Attended 9/11/25 PaTH Roadshow
- (2) Patient Partners will attend 2025 PCORI Annual Meeting in D.C.
- In the process of completing the PCORnet 2025 annual engagement survey for patient partners
- Provided feedback on PCORI grant proposals and study materials

STAR Engagement Team



Onboarded (1) new Essentia SET member

(2) attending the 2025 PCORI Annual Meeting

Developed a STAR Intake Engagement Plan Checklist

Completed the 2025 PCORnet Annual Engagement Evaluations for CRNs

- Continue to collaborative across CRNs and PCORnet.

STAR CRN Collaboration Requests

- STAR has received 350 requests and participated in >120 funded studies!
- Includes funding from NIH, PCORI, Industry, CDC, etc.

- Living with HIV (Bloomfield)
- RELIANCE (Krishnan)
- PREVENTABLE (Alexander)
- ODYSSEY (George)
- Safety of Rheum Drugs (Curtis)
- SISTER Study (Miller-Hughes)
- Med Weight (Block)
- HERO (Hernandez)
- PKIDS (Forrest)
- NET-PRO (O'Rorke/Chrischilles)
- PANDA (Merkel/Chen)
- PRESERVE (Forrest)
- Lennox-Gastaut (Rosenman, Berg, Lam)
- TEAMS-BP (Bushnell)
- PRECIDENTD (Wexler)

- Advanced HF (Dunlay)
- RECOVER (Kaushal, Forrest)
- De-implementation of inappropriate thyroid ultrasound (Brito)
- RESTORE (Saag)
- cvMobius2 (Shah)
- Gene ILD (Swaminathan)
- OBERON (Snyder/Mosher)
- USDHub (Hsi)
- AVW vs GRACE (Ritchie)
- CarvTop-ICD (Aktas)
- CODA (Rothman)
- Hypertension Guidelines (Tedla)
- CISTEM2 (Dharnidharka)
- Breathe Trial (Casey)
- CNS Meds (Pavon)
- Thriving Hearts (Stuebe)
- DOMINO (Maciejewski)
- Hodgkins Lymphoma (Mailhot)

- Dart (Flory/Ancker)
- COMPARE (Kappelman)
- RADx HCV (Aparicio, Lai, Fleurence)
- TRUST (Brown/Schnarrs)
- RSI Trial (Semler/Han)
- MASLD (Poynard)
- T2T (Pagidipati)
- The Dose Trial (Heerman)
- Measurement Matters (Cohen)
- THINK TTP (Onwuemene)
- APT Comparison (Schwedt/VanderPluym)
- Improve identification of patients with rare or underdiagnosed diseases (Hermann)
- Adv PH use of electronic health records (Block)
- UrogynCREST(Amundsen/Jelovsek)
- ED Visits (Schroeder/White)
- CDM Enhancement (Kripalani)
- Tech Enhancement (Lenert)

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STAR Engagement in PCORnet Designated Studies

STAR Led PDS

Study Title	Funder	Lead PI
ADAPTABLE	PCORI	Jones [Duke]
HF Outcomes	PCORI	Bachmann [VUMC]
TEAMS BP	PCORI	Bushnell [Wake]
COMPARE	PCORI	Kappelman [UNC]
GREENLIGHT PLUS	PCORI	Heerman [VUMC]
THINK-TTP	PCORI	Onwuemene [Duke]
USDHub	NIH	Hsi [VUMC]
CODA	NIH	Rothman [VUMC]
BREATHE Trial	PCORI	Casey [VUMC]
APT Comparison Study	PCORI	Schwedt [Mayo]
Greenlight Extension Study	PCORI	Heerman [VUMC]
Dose Study	PCORI	Heerman [VUMC]

STAR Supported PDS

Study Title	Funder	Lead PI
PREVENTABLE	NIH	Alexander [Duke]
NET-PRO	PCORI	O'Rorke/Chrischilles [GPC/UIowa]
PRECIDENTD	NIH	Wexler/Everett [Brigham]
COVID-19 Opiod OD crisis	NIDA	Cerda [NYU]
RECOVER	NIH	Kaushal/Forrest [Cornell/CHOP]
LGS	PCORI	Rosenman/Lam [Lurie Children's]
BACK-OFF JSpA	PCORI	Weiss [CHOP]
TEST 2 TREAT	AMGEN	Pagidipati [Duke/DCRI]
RESTORE	PCORI	Saag [UAB]
IRIS-CKD	BAYER	Pagidipati [Duke/DCRI]
Achieving Equity: CHD/NDDs	PCORI	John [CHOP]
ODYSSEY RCC	PFIZER	George [DCRI]
cvMOBIUS2	AMGEN	Shah [DCRI]
Measurement Matters	PCORI	Cohen [UMass Boston]
ACTIV-6	NIH	Hernandez/Self/Lindsell/Collins/Rothman
BASICS	NIH/NCI	Courcoulas/McTigue [UCSF]
PANDA	NIH	Yeng, Merkel [UPenn]
CISTEM-2	NIH	Axelrod [Iowa]

RESEARCH SUMMARY

Comparative Effectiveness of Aspirin Dosing in Cardiovascular Disease

Jones WS et al. DOI: 10.1056/NEJMoa2102137

CLINICAL PROBLEM

Aspirin is recommended in patients with established atherosclerotic cardiovascular disease to lower risk of serious adverse health outcomes. However, the appropriate dose is a subject of controversy.

CLINICAL TRIAL

Design: An open-label, pragmatic, randomized, controlled trial comparing the effectiveness of 81-mg and 325-mg doses of daily aspirin as secondary prevention in patients with established atherosclerotic cardiovascular disease.

Intervention: 15,076 patients were assigned to daily aspirin at a dose of 81 mg or 325 mg and were followed for a median duration of 26 months.

RESULTS

Effectiveness: The incidence of death from any cause, hospitalization for myocardial infarction, or hospitalization for stroke was similar in the 81-mg and 325-mg groups.

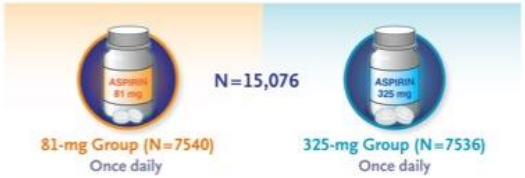
Safety and Adherence: The incidence of hospitalization for major bleeding with an associated blood-product transfusion was similar in the two groups. The 325-mg group had higher incidences of dose switching (41.6% vs. 7.1%) and aspirin discontinuation (11.1% vs. 7.0%) and fewer days of aspirin exposure.

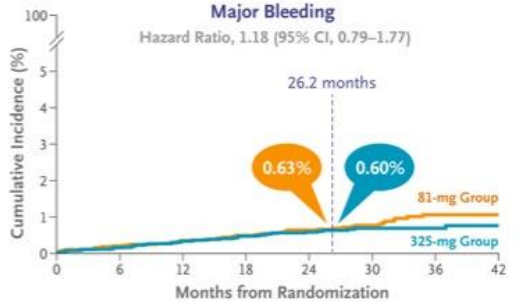
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Whether a high incidence of dose switching in the group assigned to the 325-mg dose affected trial results
- How results might differ with longer-term follow-up and a more diverse trial population
- What the incidences of nonserious adverse events and minor bleeding are and whether these affect adherence

Links: Full article | NEJM Quick Take | Editorial





CONCLUSIONS

Effectiveness and safety outcomes did not differ significantly with daily use of 81 mg as compared with 325 mg of aspirin in patients with established atherosclerotic cardiovascular disease, and adherence was better with the 81-mg dose.

Annals of Internal Medicine SUMMARIES FOR PATIENTS

Effectiveness and Safety of Bariatric Procedures for Weight Loss

From: Arterburn D, Wellman R, Emiliano A, Smith SR, Odegaard AO, Murali S, et al. Comparative effectiveness and safety of bariatric procedures for weight loss. A PCORnet cohort study. Ann Intern Med. 2018;169:741-50. doi:10.7326/M17-2786

This article was published at Annals.org on 30 October 2018.

What is the problem and what is known about it so far?
Weight loss (bariatric) surgery can help people with severe obesity lose weight. Bariatric surgery includes many different procedures, but they all make the stomach smaller so that people eat less and feel full. Three common procedures are Roux-en-Y gastric bypass (bypass), sleeve gastrectomy (sleeve), and adjustable gastric banding (lap band or band). Not much research has been done to look at how well these surgeries work to help people lose weight and keep it off over time.

Why did the researchers do this particular study?
The researchers wanted to compare how much weight patients lost at 1, 3, and 5 years after a bypass, sleeve, or band. They also wanted to compare short-term complications experienced by patients in the 30 days after each procedure.

Who was studied?
A total of 65,093 patients from the United States who had severe obesity; were aged 20 to 79 years; were having their first bariatric surgery; and had a bypass, sleeve, or band between January 2005 and September 2015 in one of 41 health systems in the National Patient-Centered Clinical Research Network.

How was the study done?
The researchers looked at information from patients' electronic medical records to identify their demographic characteristics (for example, age and race/ethnicity) and clinical characteristics (for example, health problems); the type of bariatric procedure they had; major complications within 30 days after their procedure; and weight before surgery and 1, 3, and 5 years afterward.

What did the researchers find?
The most common procedure was bypass, with 32,208 (49.5%) of the patients having this procedure, followed by 29,693 (45.6%) who had a sleeve and 3192 (4.9%) who had a band. Most patients (84%) had a weight measure 1 year after the procedure; 68% had one at 3 years, and 69% had one at 5 years. Patients who had a bypass lost more weight at 1, 3, and 5 years than those who had a sleeve. The least weight loss was seen for patients who had a band. However, there were more complications 30 days after a bypass (5.0%) than after a sleeve (2.6%) or a band (2.9%) procedure.

What were the limitations of the study?
Information on weight was not available for many patients at 1, 3, and 5 years. Also, the researchers looked only at short-term complications.

What are the implications of the study?
Patients with severe obesity who had a bypass lost more weight than those who had a sleeve or a band. However, early complications were more common in patients who had a bypass than in those who had the other procedures. People with severe obesity who are considering bariatric surgery should think about these tradeoffs in the benefits and risks of the procedures and discuss them with their doctor so that they can choose the procedure that best suits their personal preferences.

Summaries for Patients are a service provided by *Annals* to help patients better understand the complicated and often mystifying language of modern medicine.

Ann Intern Med. 2018;169:I-22. doi:10.7326/P18-0016

PRECIDENTD Study

PRECIDENTD
Prevention of Cardiovascular and Diabetic Kidney Disease in Type 2 Diabetes

- PCORI PLACER Award ($22M)
- Leadership
  - PIs: Wexler and Everett (MGB)
  - Recruitment and Data Support (PCORnet CC, S. Jones (Duke))
  - Engagement (Mayberry, Nelson, Rothman (VUMC))
- Pragmatic RCT of 6,000 patients with T2DM and CAD/elevated CV risk randomized to GLP1ra vs SGLT2i for prevention of CV disease and renal disease
- 8 Vanguard Sites including Duke, VUMC, MUSC, Essentia

Enrollment Numbers (As of 8/5/2025)

Site	Screened*	Randomized	Screen Failed	Pending	Days Since Last Screened	Days Since Last Randomized
Total	**2305**	**816 (18, 67)**	**1404 (4, 36)**	**85 (23, 38)**	**0**	**0**
Columbia	83	16 (0, 2)	64 (0, 0)	3 (1, 1)	0	11
Johns Hopkins	35	23 (0, 0)	11 (0, 0)	1 (0, 0)	225	208
MUSC	439	130 (1, 4)	298 (0, 3)	11 (1, 1)	1	5
Duke	151	123 (1, 6)	17 (0, 0)	11 (0, 0)	8	6
Vanderbilt	474	31 (0, 2)	437 (0, 7)	6 (0, 1)	12	12
Missouri	107	17 (0, 0)	86 (0, 0)	4 (0, 0)	274	250
MCW	188	64 (1, 3)	119 (1, 1)	5 (3, 5)	0	4
Essentia	342	153 (4, 11)	179 (2, 9)	10 (4, 9)	0	0

(#,#) Number changed since the past seven days, and since the past thirty days

*"Screened" accounts for dual therapy patients only once

JAMA®

QUESTION Can adding a health literacy–informed responsive text messaging and web-based dashboard intervention to health behavior counseling delivered by pediatric primary care clinicians support healthy growth over the first 2 years of life?

CONCLUSION Adding a digital intervention to health behavior counseling improved growth trajectories over the first 24 months among a racially and ethnically diverse population compared with health behavior counseling alone.

POPULATION

476 Female
424 Male

Healthy children aged 0 to 21 days, born after 34 weeks' gestation, with birth weight >1500 g

Median gestational age:
39.2 weeks

LOCATION

6
Medical centers
in the United States

INTERVENTION

900 Parent-child pairs randomized
896 Parent-child pairs analyzed

449
Clinic + digital intervention
Health behavior counseling plus a digital health behavior intervention

451
Clinic only
Health behavior counseling only

PRIMARY OUTCOME

Child weight-for-length trajectory over 24 months

FINDINGS

Obesity (body mass index ≥95th percentile) at 24 months

Clinic + digital intervention	7.4%
Clinic only	12.7%

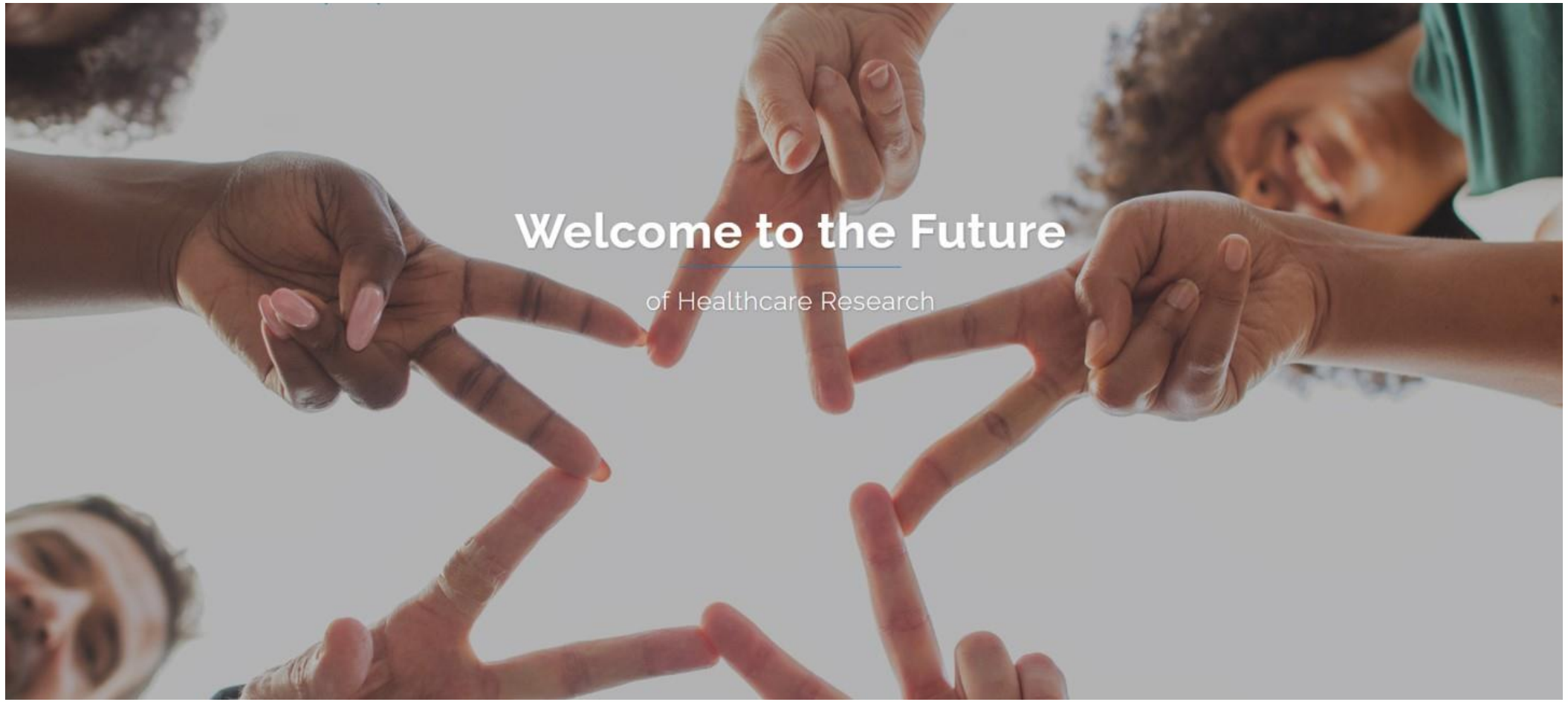
Between-group difference, −5.3%

Adjusted risk ratio,
0.56 (95% CI, 0.36 to 0.88)

Estimated weight-for-length reduction,
0.33 kg/m (95% CI, 0.09 to 0.57)

Heerman WJ, Rothman RL, Sanders LM, et al; Greenlight Investigators. A digital health behavior intervention to prevent childhood obesity: the Greenlight Plus randomized clinical trial. *JAMA*. Published November 3, 2024. doi:10.1001/jama.2024.22362

Questions



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The National Patient-Centered Clinical Research Network

41

Community Engagement via PCORnet®

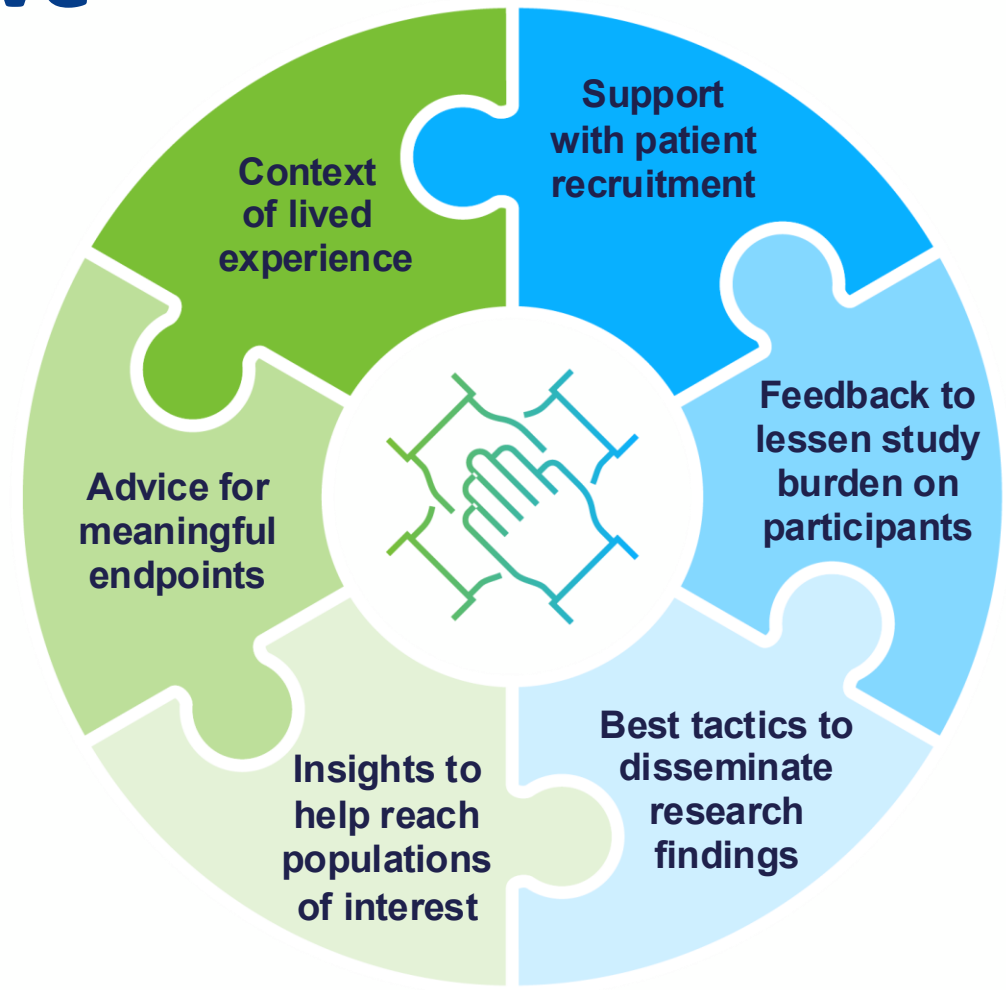
Engaged Communities Drive Better, Faster Research

What do we mean by "communities"?

- **Patients and caregivers,**
  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



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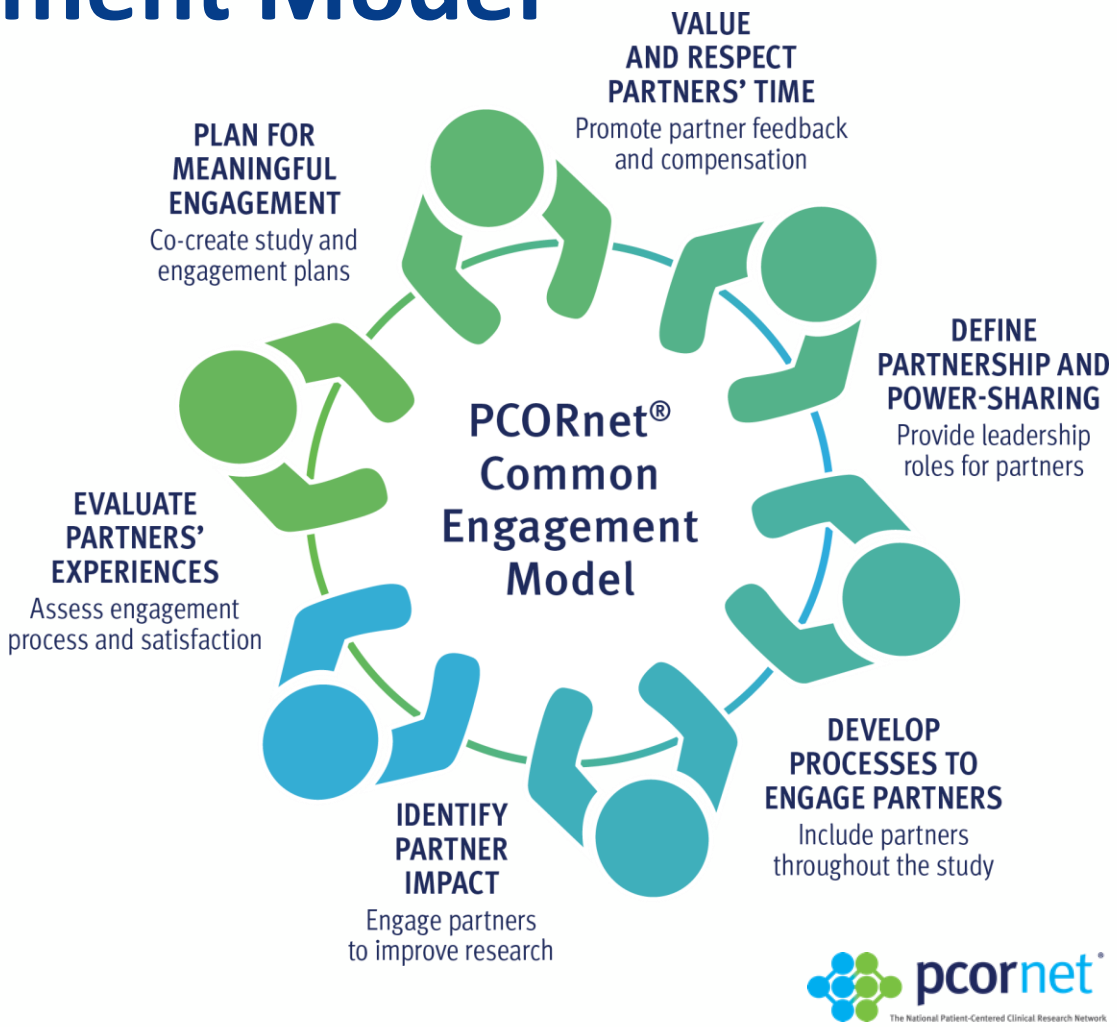
The National Patient-Centered Clinical Research Network

PCORnet® Common Engagement Model

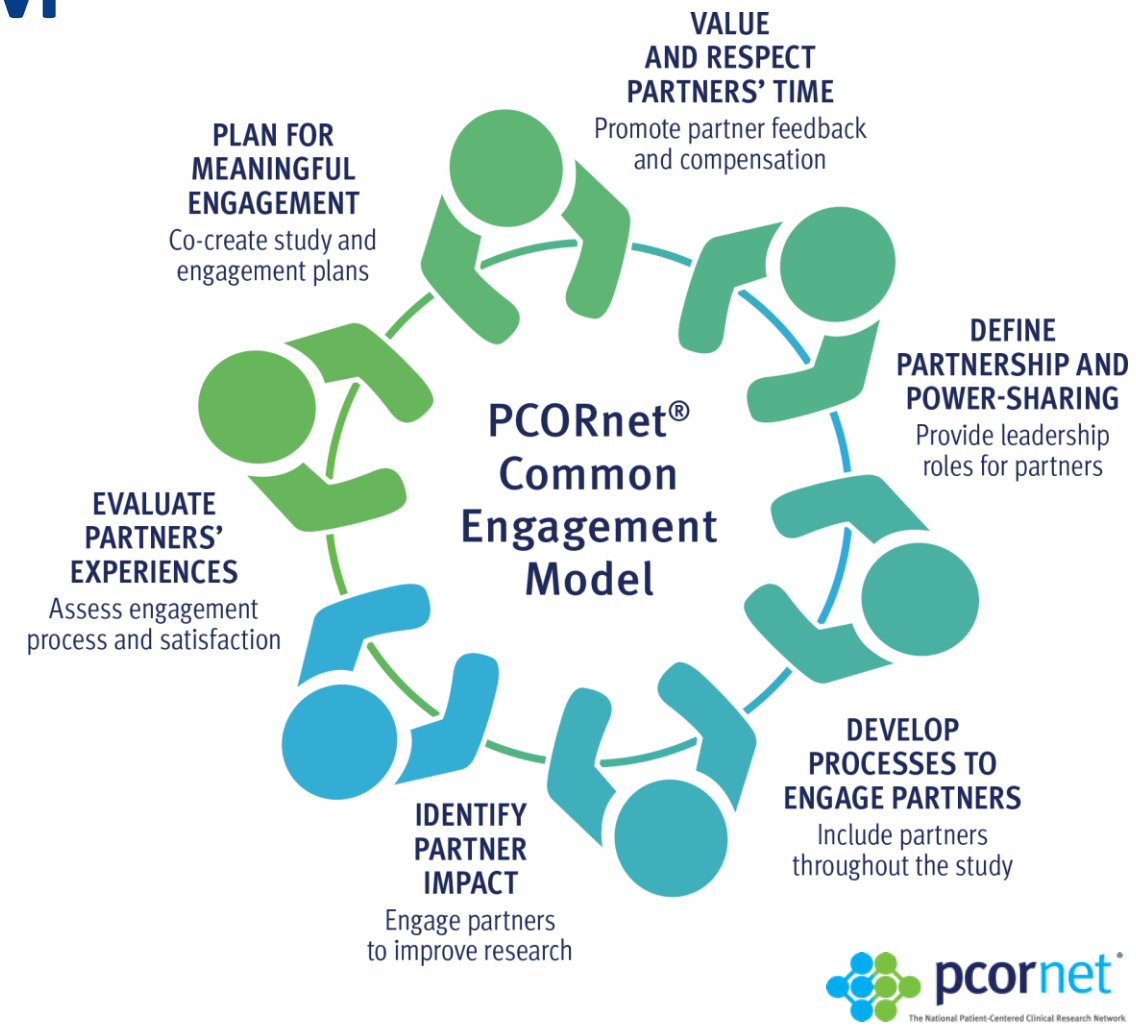
- The PCORnet® Common Engagement Model (PCORnet® CEM) encompasses the minimal **expectations for patient and other partner engagement in PCORnet research** and governance.
- This gives patients and other community partners **a seat at the table in every PCORnet® Study** so they can engage as coequal collaborators with investigators and the study team.
- Studies that engage patient partners have demonstrated the power of PCORnet to **improve research questions, quality, and results**.



Applying the PCORnet® CEM

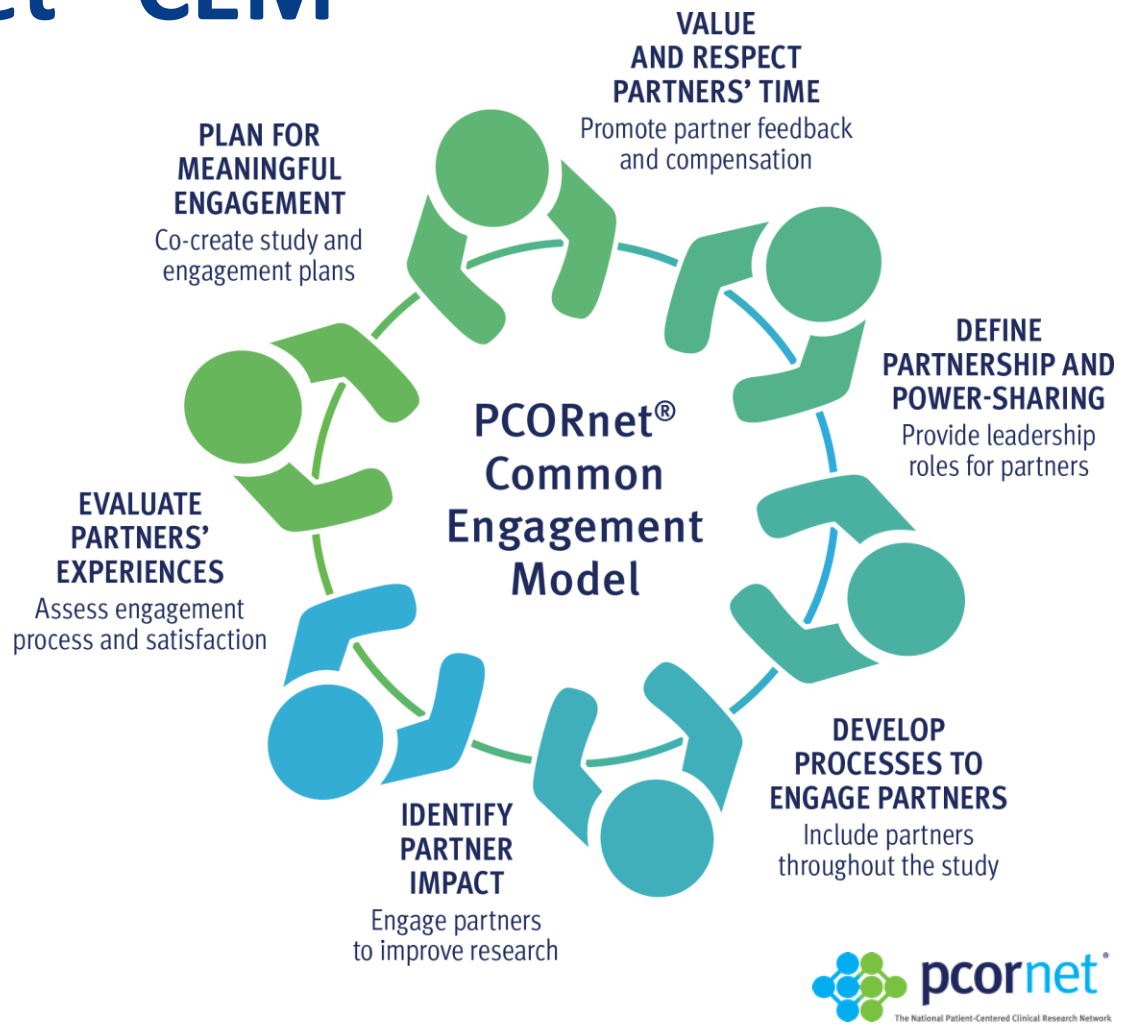
A set of components for meaningfully engaging partners in research supported by PCORnet

- PCORnet® Studies have an engagement plan that addresses each element of the PCORnet® CEM.
- Each research study is unique—approaches will vary.
- Contact the PCORnet® Front Door to request consultation about how to apply the CEM in your study.



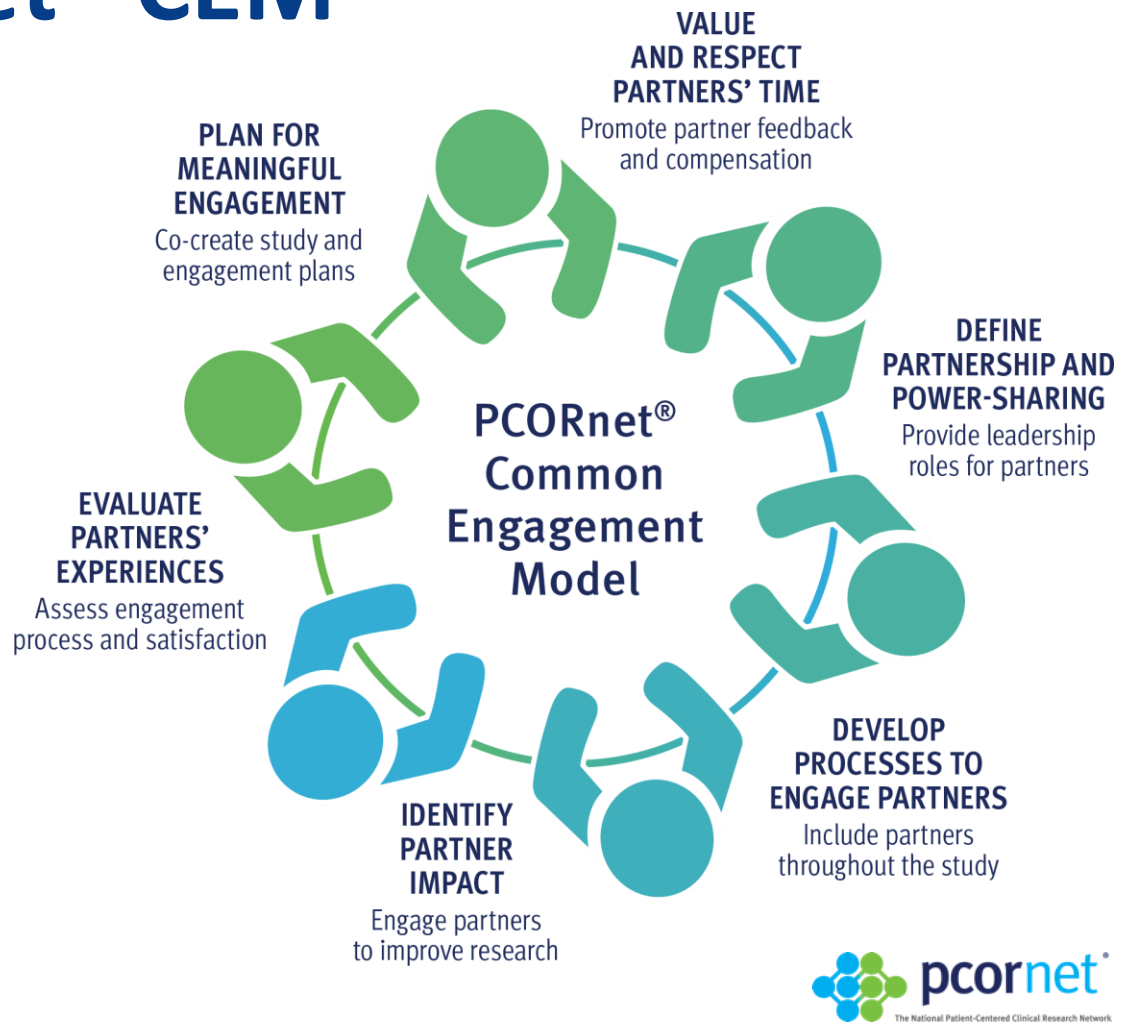
Components of the PCORnet® CEM

- **Plan for Meaningful Engagement**
  Determine strategy for how patients, caregivers, and other partners will contribute – regularly and substantively – to the research.
- **Value and Respect Partners' Time**
  Recognize partners' contributions, i.e., reliable payment process that compensate partners for their time.
- **Define Partnership and Power-sharing**
  Clearly described roles allow partners to participate in leadership discussions and decision making.



Components of the PCORnet® CEM

- **Develop Process to Engage Partners**
  There are many ways to include partners and activities may vary across studies and throughout the course of a study.
- **Identify Partner Impact**
  Communicate to partners which elements of the study the partners can help improve or change.
- **Evaluate Partners' Experiences**
  Listen to patient partners and collaborate to improve the engagement experience.

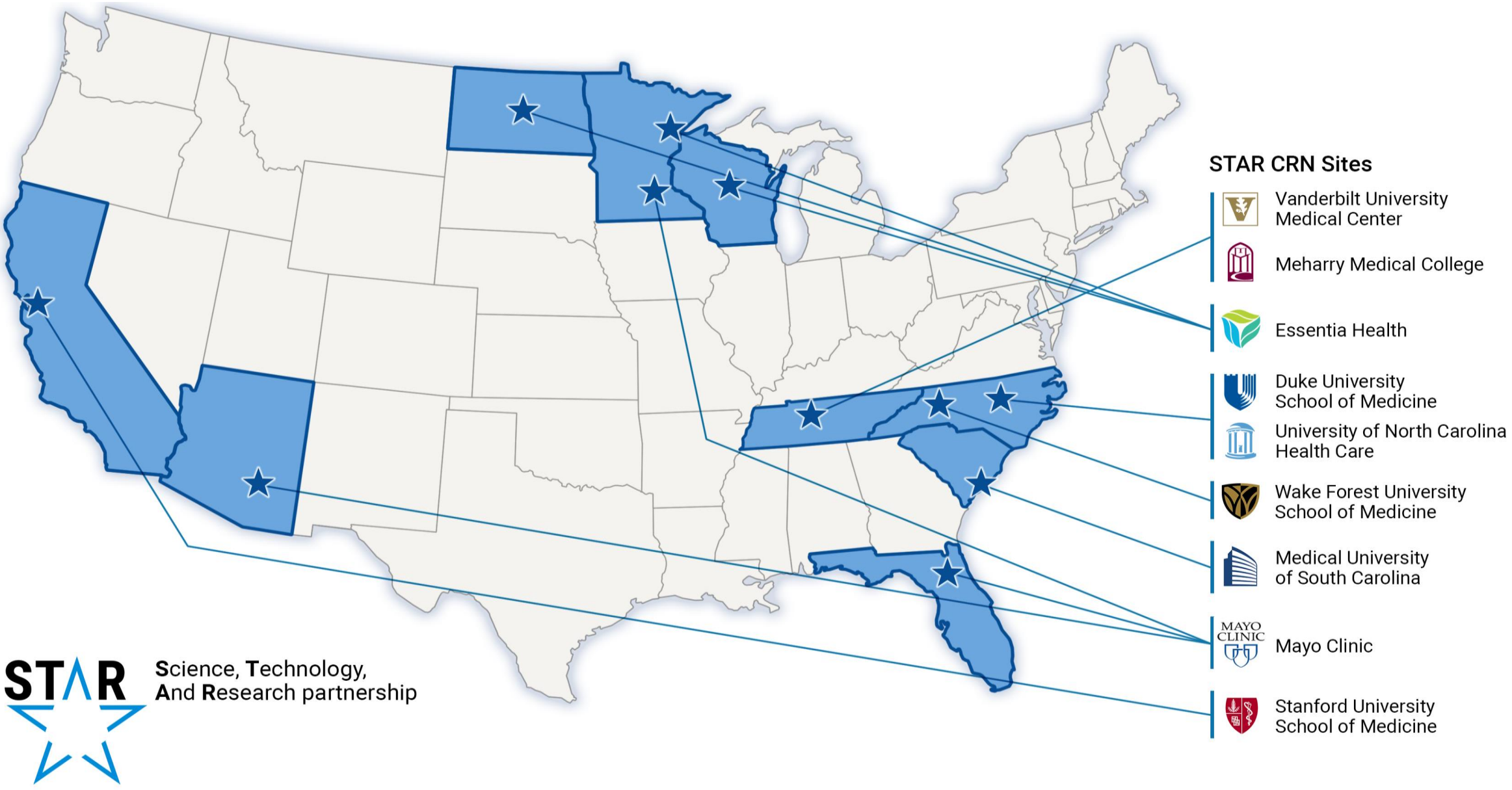


STAR Science, Technology, And Research partnership

Partnering with STAR CRN Engagement in Research

Yasemin Akdas, PhD, MPH | Jabári Ichimura, BS

STAR Engagement Operations Team
Office of Community Health & Engagement
Vanderbilt University Medical Center


STAR CRN Sites
Vanderbilt University Medical Center
Meharry Medical College
Essentia Health
Duke University School of Medicine
University of North Carolina Health Care
Wake Forest University School of Medicine
Medical University of South Carolina
Mayo Clinic
Stanford University School of Medicine
STAR
Science, Technology, And Research partnership

We partner with investigators through three core mechanisms

Mechanism	What it does	Examples
Review	Improve engagement plans and materials	STAR CRN Front Door intake **(preferred)**
Connect	Match investigators with patient partners	For advisory, co-investigation, feedback, dissemination roles
Convene	Create structured spaces for dialogue	Bimonthly SAC meetings where investigators present and solicit input

Collaborating with the STAR Engagement Team

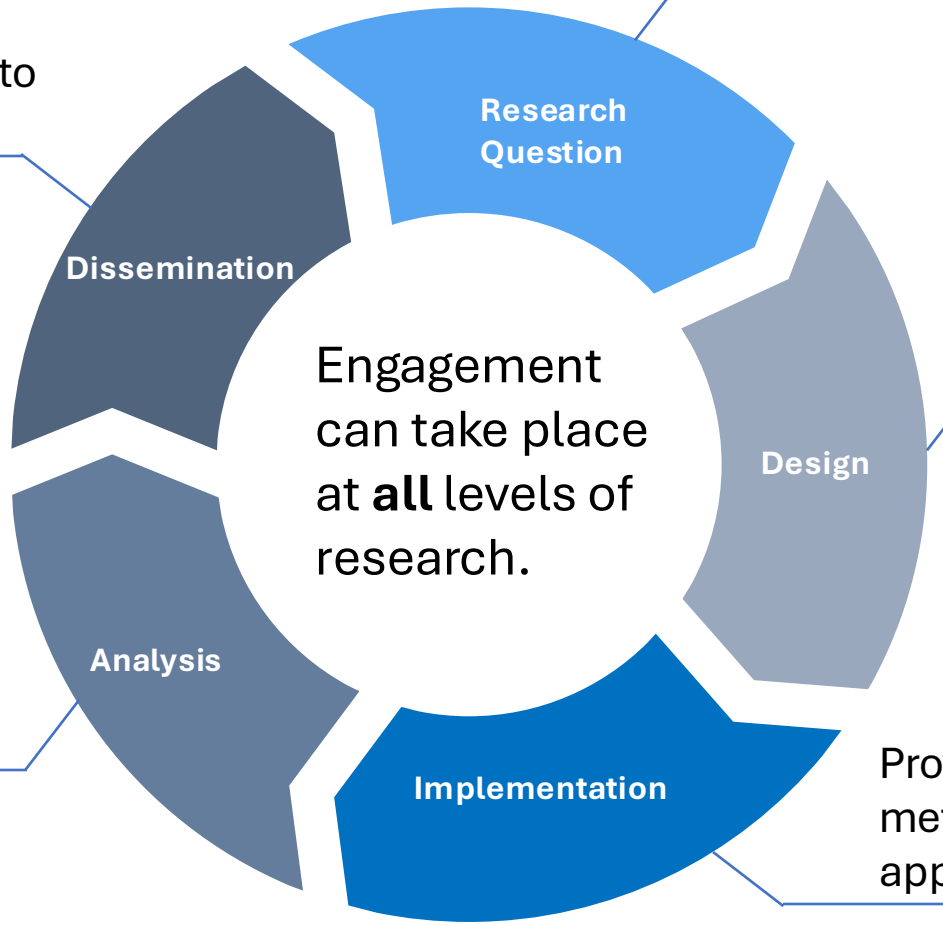
Identify and prioritize topics based on relevance, urgency, and real-world applicability

Ensure the conceptual framework is logically sound by considering potential confounders and confirming the importance of identified variables

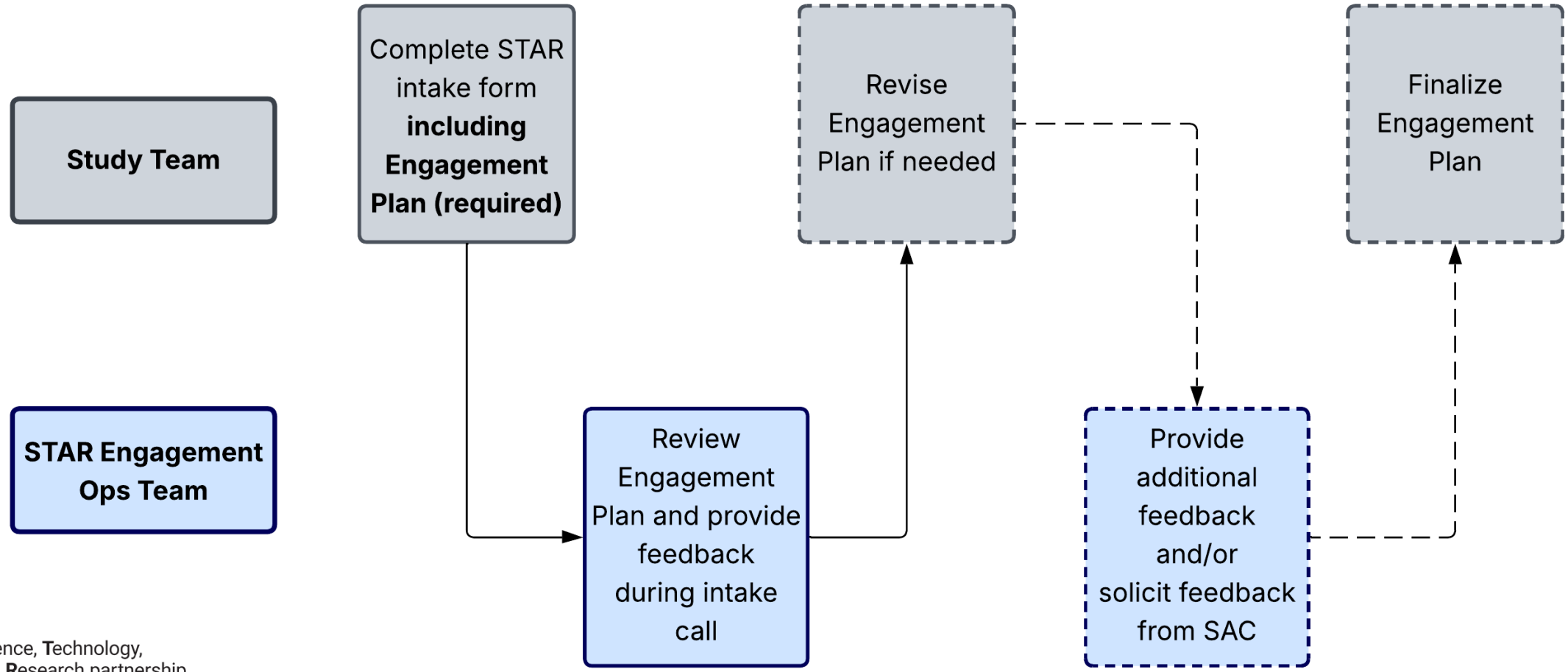
Provide input on data collection methods and assist in selecting appropriate data sources

Provide input on interpreting findings, including suggesting alternative explanations or perspectives

Communicate results effectively to diverse audiences



Engagement Plan Review: Our team aims to ensure strong and meaningful engagement in STAR studies



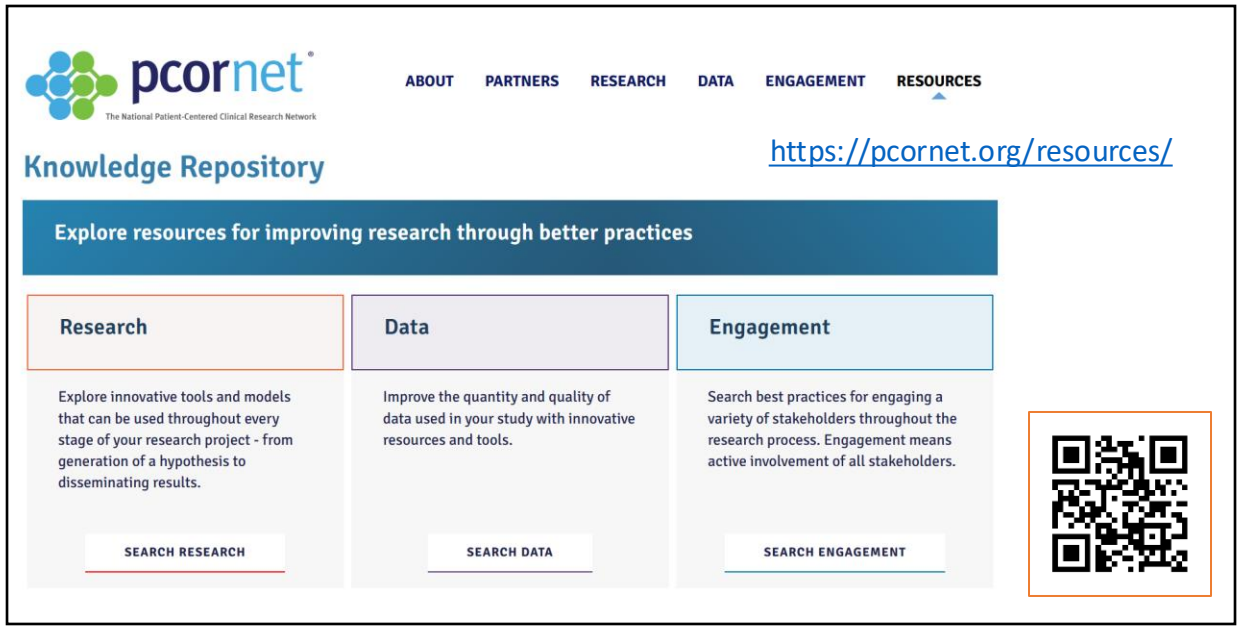
We invite patient partners to assess the person-centeredness of studies

STAR Advisory Council (SAC)

Elements of Person-Centeredness	Strongly Disagree	Somewhat Disagree	Neither	Somewhat Agree	Strongly Agree
1. There is evidence that **beliefs** relevant to the population of interest or to persons/community members in general are included or addressed in the research.	-2	-1	0	1	2
2. There is evidence that **attitudes** relevant to the population of interest or to persons/community members in general are included or addressed in the research.	-2	-1	0	1	2
3. There is evidence that **concerns** relevant to the population of interest or to persons/community members in general are included or addressed in the research	-2	-1	0	1	2
4. Person/community-centered goals and/or **outcomes** are included or addressed in the research.	-2	-1	0	1	2
5. Research **priorities** of interest to or identified by persons/community are included or addressed in the research.	-2	-1	0	1	2
6. The **needs** of persons/community are included or addressed in the research.	-2	-1	0	1	2
7. Individuals representing person and/or communities are **engaged** in the research as stakeholders, advisors, consultants, or team members (beyond serving as research participants or volunteers).	-2	-1	0	1	2

Wilkins et al. Development and validation of the Person--Centeredness of Research Scale. Journal of Comparative Effectiveness Research 2018 https://doi.org/10.2217/cer--2018--0046

STAR Engagement Resources



Leveraging PCORnet® for Trials and Cohort Studies

Adrian Hernandez MD MHS
Vice Dean and Executive Director, Duke Clinical Research Institute
PI, Coordinating Center for PCORnet®

Russell Rothman MD MPP
Director, Vanderbilt Institute for Population and Public Health
PI, STAR Clinical Research Network

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Pragmatic Clinical Research Benefits

Streamline Operations

- Increased efficiency
- Technological solutions for data capture
- Refined approach to adjudication

Reduce Burden

- Incorporated into routine care
- Enhanced enrollment
- Optimized site visits

Access Quality Data

- Real-world data sources
- Leveraging routine clinical data
- Integration of disparate data sources

Arrive at Valid Answers

- Efficient supporting of quality by design
- Scientifically valid answers
- Regulatory acceptance

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A Changed World of Possibilities: Pre-COVID to Post-COVID

Pre-COVID-19:
Site based visits & care

Possibilities:
Home based visits & care

https://ctti-clinicaltrials.org/our-work/digital-health-trials/running-a-decentralized-trial/

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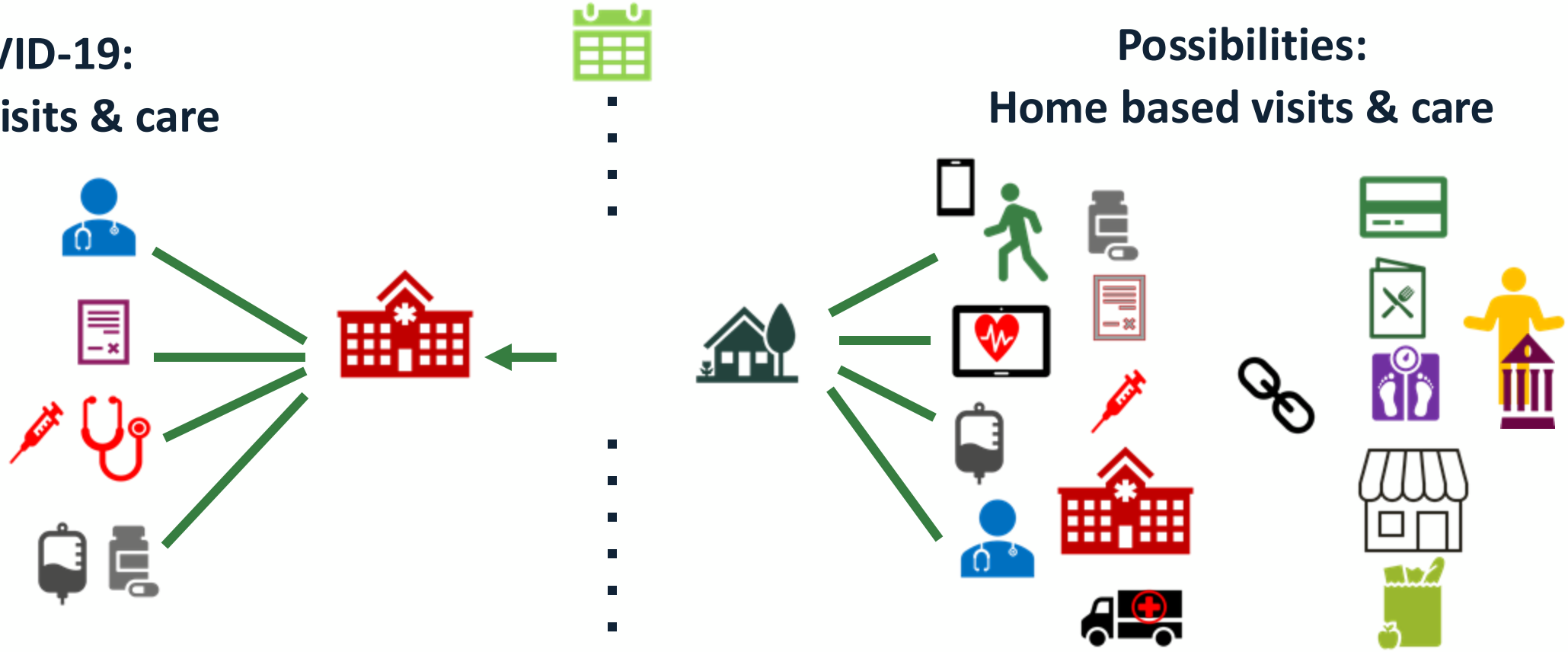

https://ctti-clinicaltrials.org/our-work/digital-health-trials/running-a-decentralized-trial/

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Sample Trial Workflow

Optimize study design

Step 1: Study Design
- Eligibility Criteria Refinement
- Patient Advisory Committee
- Target Sites Identified

Rationalized Protocol

Enrich with high-yield sites

Step 2: Site Selection
- Central Feasibility
- Site Evaluation
- Site Demonstrated Screening

Contract

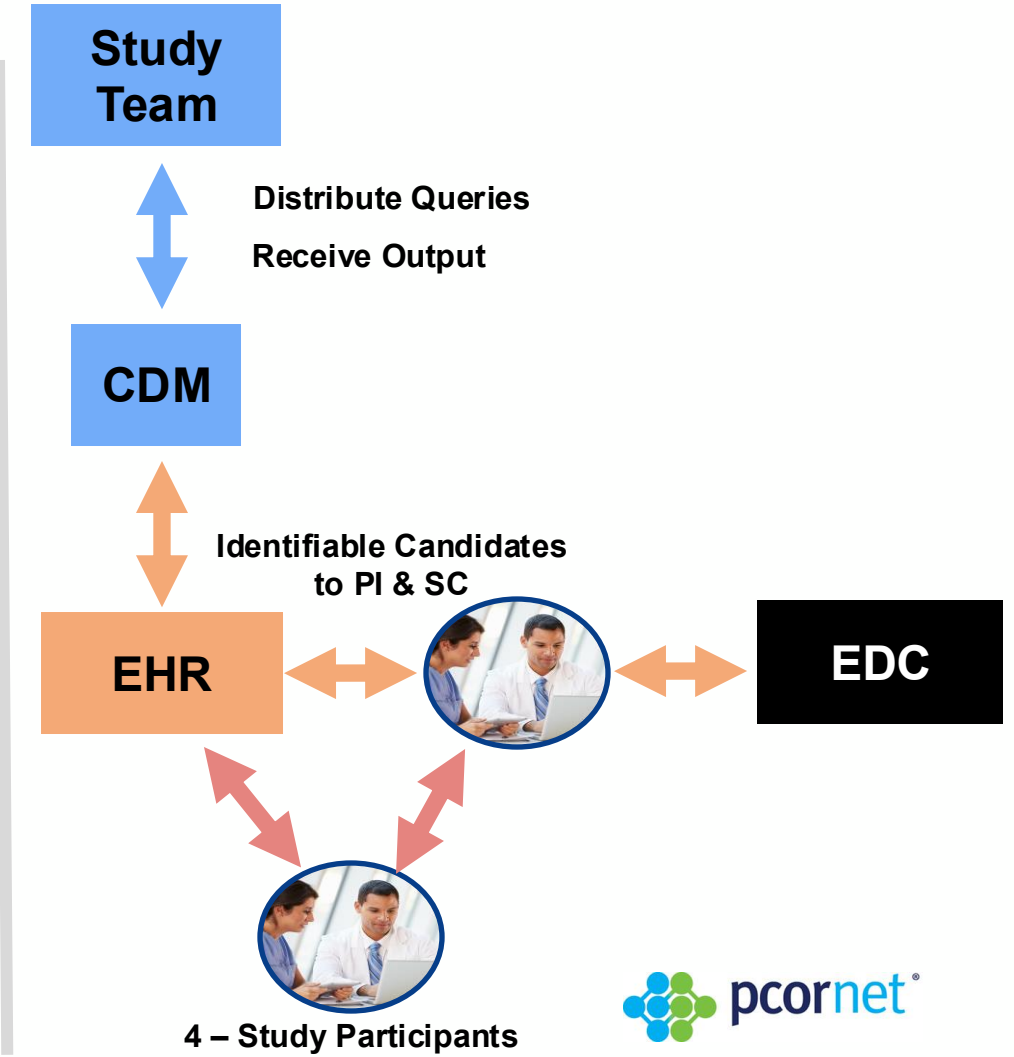
Validated Sites

Participant-centered Engagement

Step 3: Recruit & Retain
- Supported Campaigns
- Direct Messaging
- Pre-screened invitations

Contract

Complete Outcomes



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A Pragmatic Trial Checklist

- Design studies with pragmatic approaches in mind from the onset
- Embed research into clinical care to reduce patient burden
- Partner with patients for study design
- Improve patient population generalizability
- Tap into diverse data sources—requirements and regulations
- Understand regulatory environments and care patterns globally, regionally, locally
- Collaborate with a trusted partner to customize data collection
- Combine EHR data with other sources for a multi-dimensional picture of patient health
- Use patient-reported data

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ADAPTABLE

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

Adaptable
The Aspirin Study

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?

STUDY SNAPSHOT

- Pragmatic clinical trial
- **15,000 patients** living with heart disease
- Participants randomly assigned to take either 81 mg or 325 mg dose of aspirin

STRENGTH OF PCORnet

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

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

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

—Ken Gregorie,
Adaptor (Patient Advisor)

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In patients with established or pre-existing cardiovascular disease, is a strategy of 81 mg or 325 mg of aspirin better?

Everyday decision for patients (OTC medication)

The correct dose of aspirin may **PREVENT**:

Thousands of deaths / heart attacks

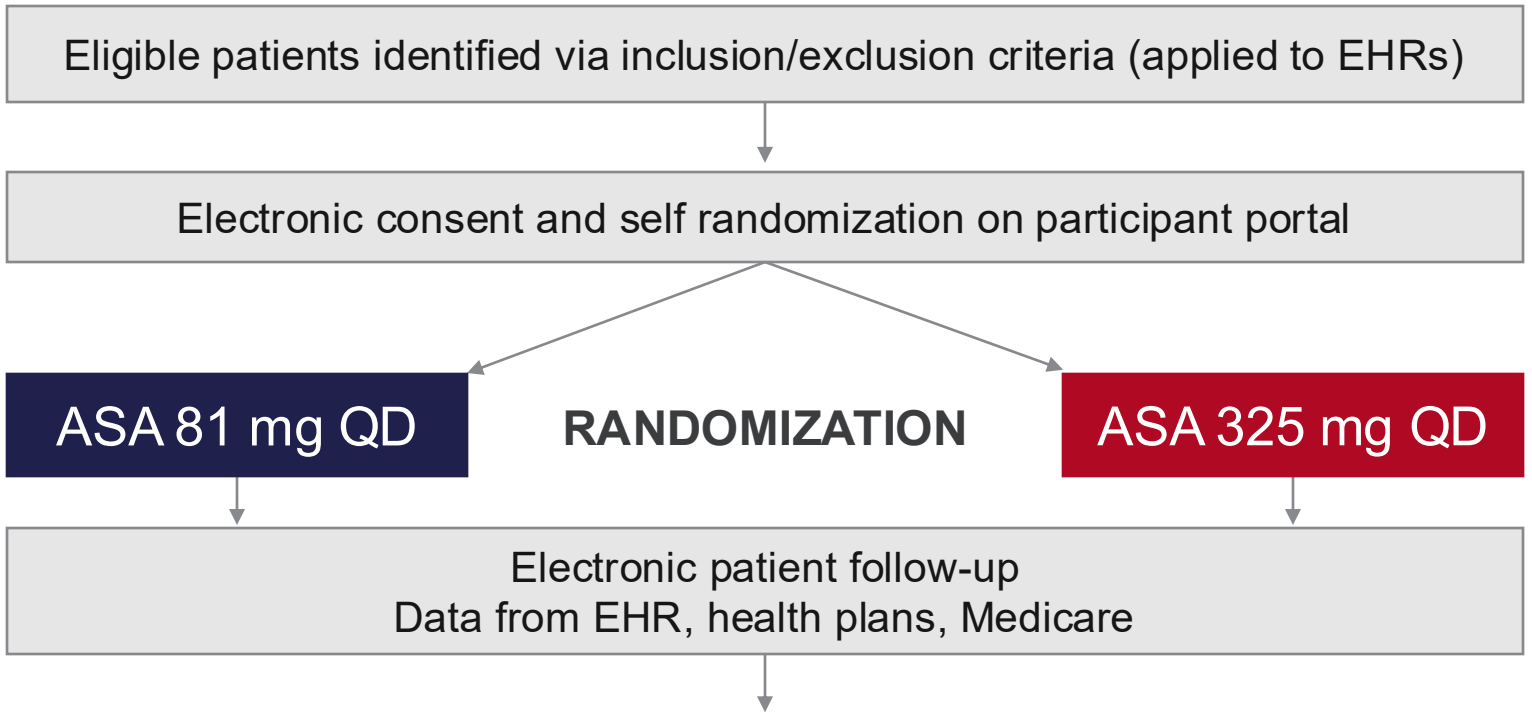
or

Thousands of bleeds

Annually in the United States

pcornet®

15,000 patients with known ASCVD + ≥ 1 “enrichment factor”



Primary Endpoint:
Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke

Primary Safety Endpoint:
Hospitalization for major bleeding

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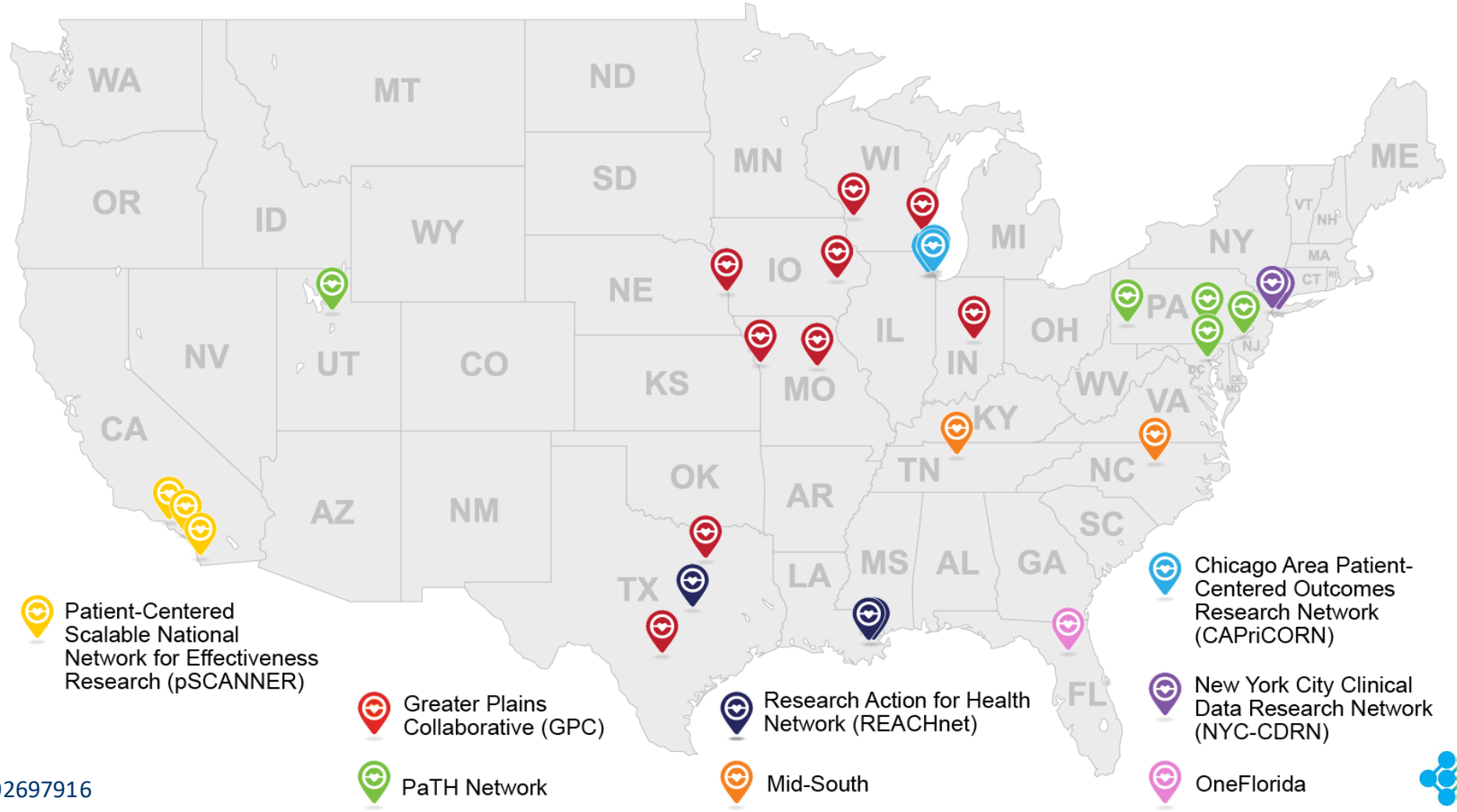
ClinicalTrials.gov: NCT02697916

CRNs and Health Care Systems Participating in ADAPTABLE



ClinicalTrials.gov: NCT02697916

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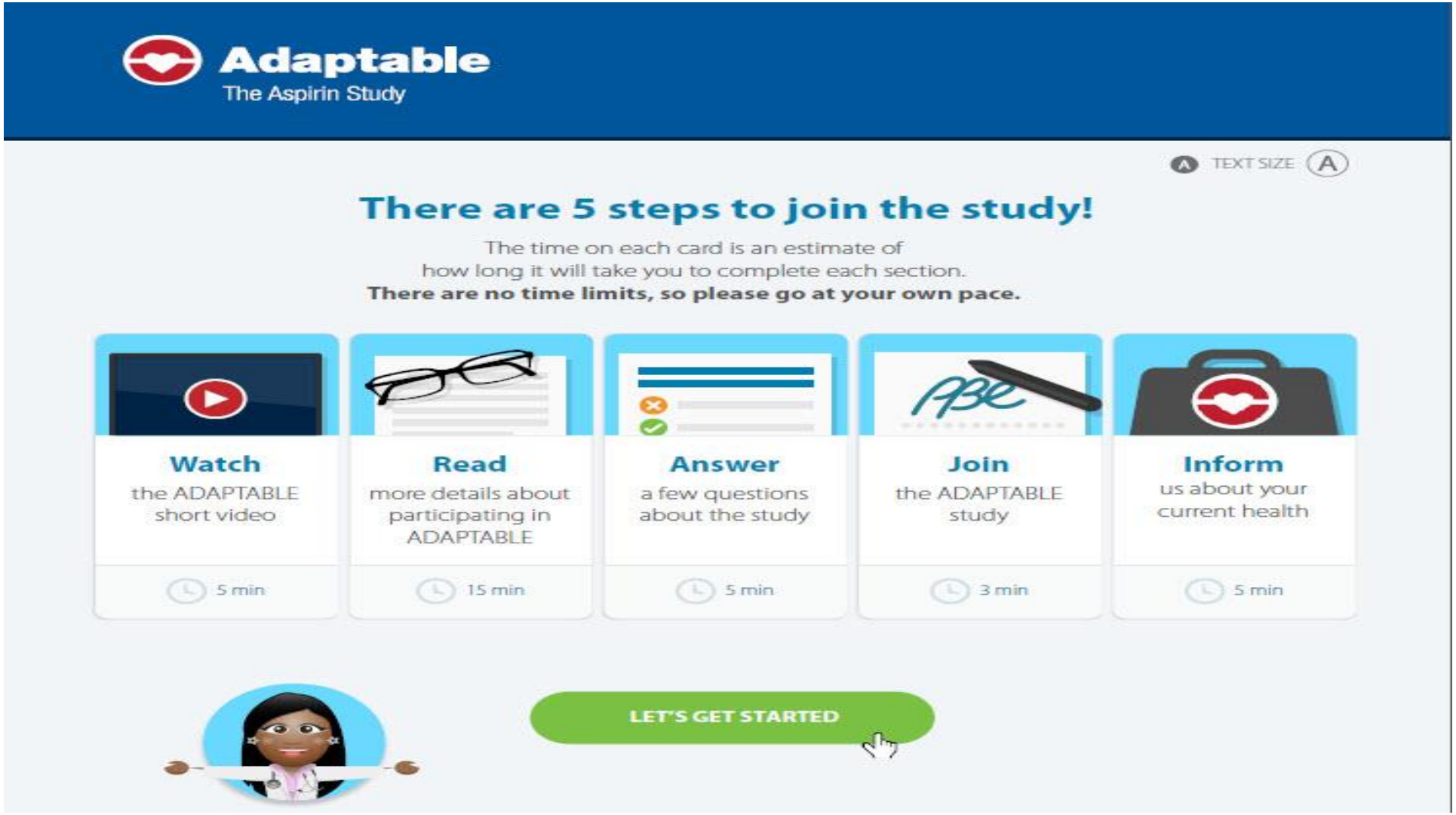

ClinicalTrials.gov: NCT02697916

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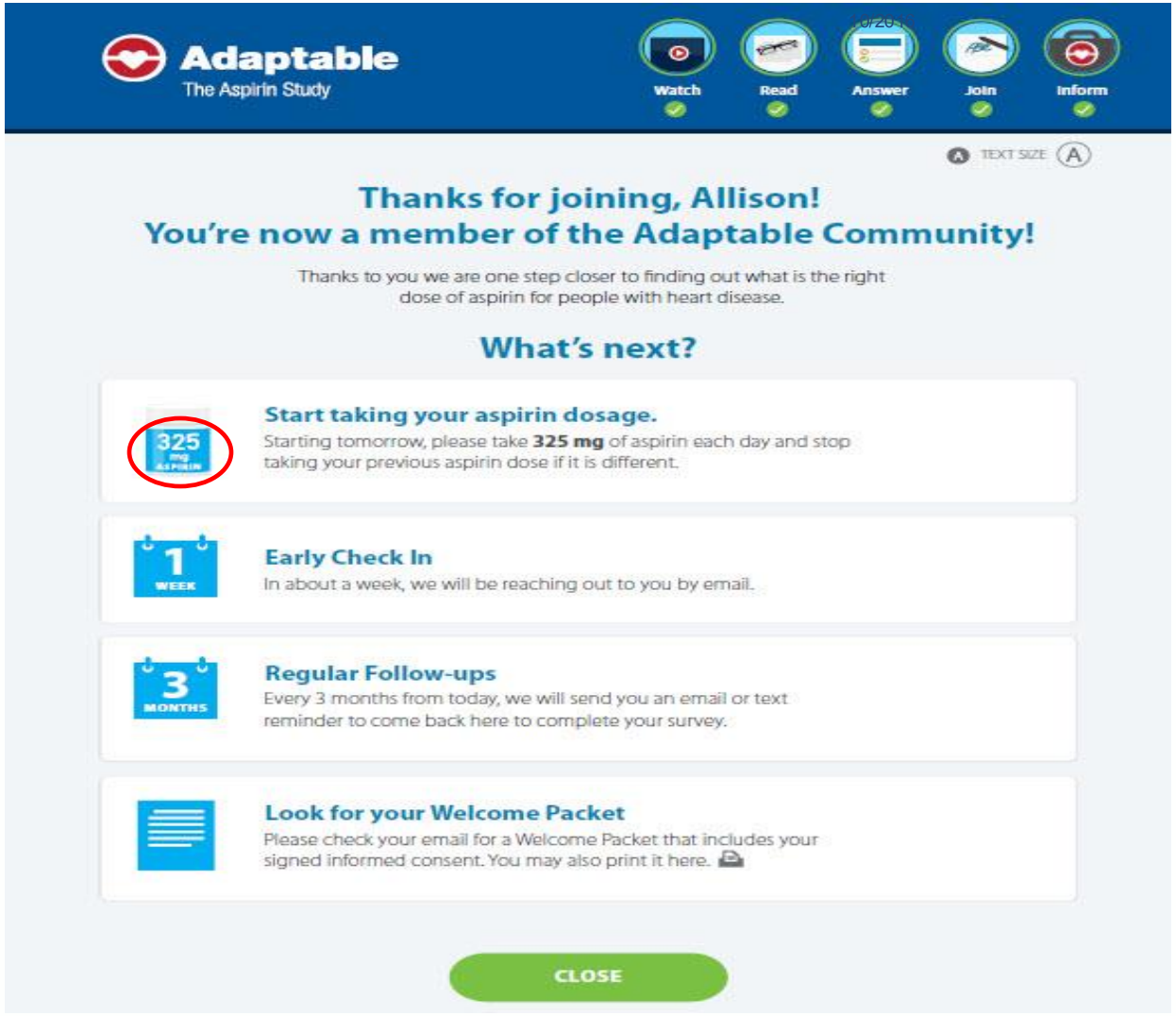
Web-Based Randomization

- Randomized treatment assignment (aspirin dose) provided directly to patients after informed consent
- Reminders for electronic follow-up contacts given at time of randomization
- Patients randomized to follow-up contacts every 3 months vs. 6 months
  - Embedded feature



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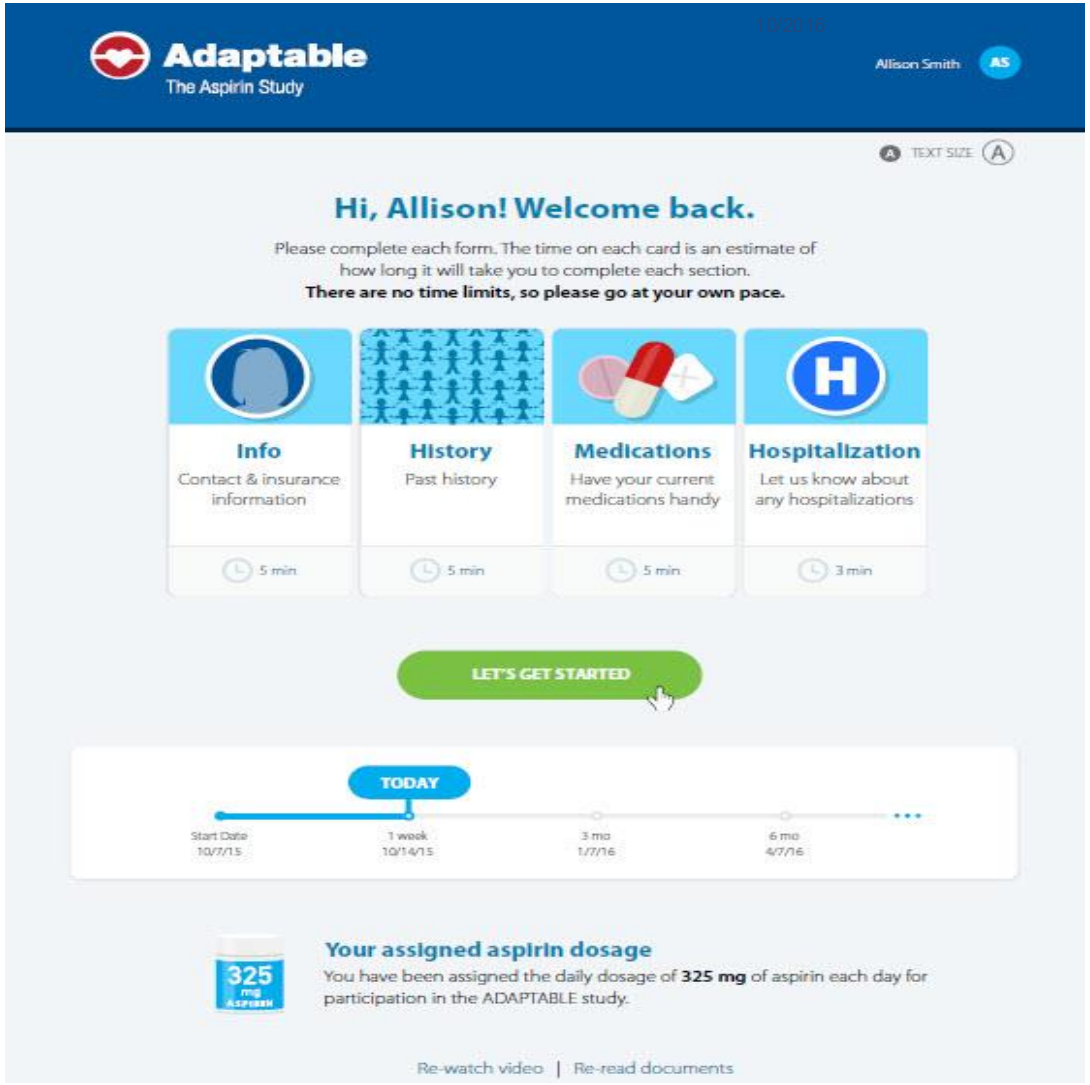
Electronic Follow-Up

- Patients receive email reminders to visit web portal for regular contacts every 3 vs. 6 months
- Central DCRI Call Center performs telephone contacts when needed
  - Non-internet participants
  - Participants who miss at least 2 scheduled electronic contact



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Electronic Data Collection and Follow-Up

N=15,000

ADAPTABLE enrollee

Baseline data

Web portal follow-up
- *Randomized to 3 vs 6 mos contact*
- *Patient-reported hospitalizations*
- *Medication use*
- *Health outcomes*

DCRI call center
- *Patients who miss 2 contacts*
- *Patients without internet access*
- *Validated coding algorithms for endpoints*

PCORnet Coordinating Center follow-up
- *Via Common Data Model*
- *Validated coding algorithms for endpoints*

CMS and private health plans follow-up
- *Longitudinal health outcomes*
- *Validated coding algorithms for endpoints*

Death Ascertainment

- CDM and Social Security Databases
- Alternate contacts via DCRI Call Center

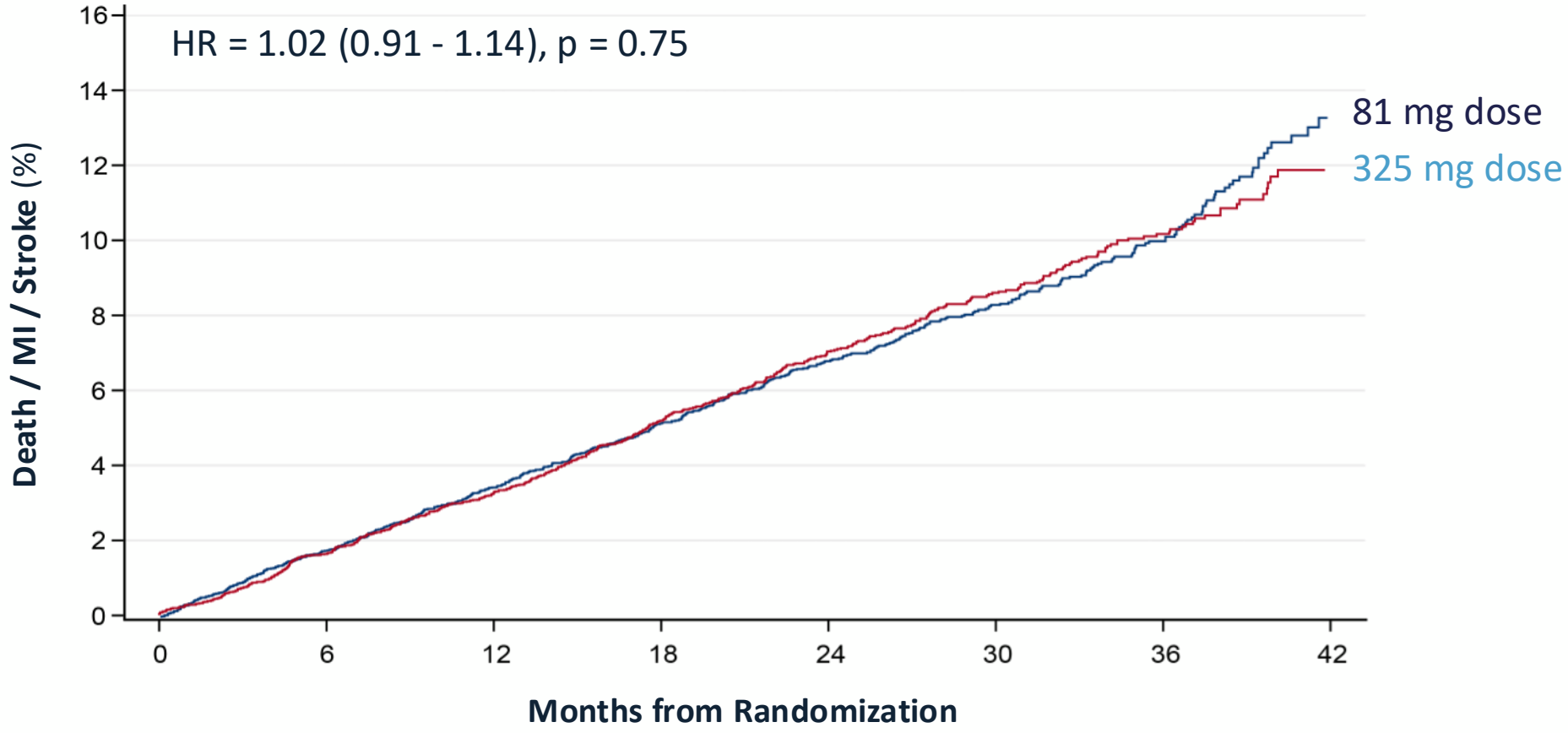
ClinicalTrials.gov: NCT02697916

Primary Effectiveness Endpoint

(All-cause death, **hospitalization** for MI, or hospitalization for stroke)

Caveats

- Open label
- Dose switching



	At risk							
81 mg dose	7540	7357	7177	5627	4190	2712	1558	636
325 mg dose	7536	7297	7095	5544	4090	2613	1489	592

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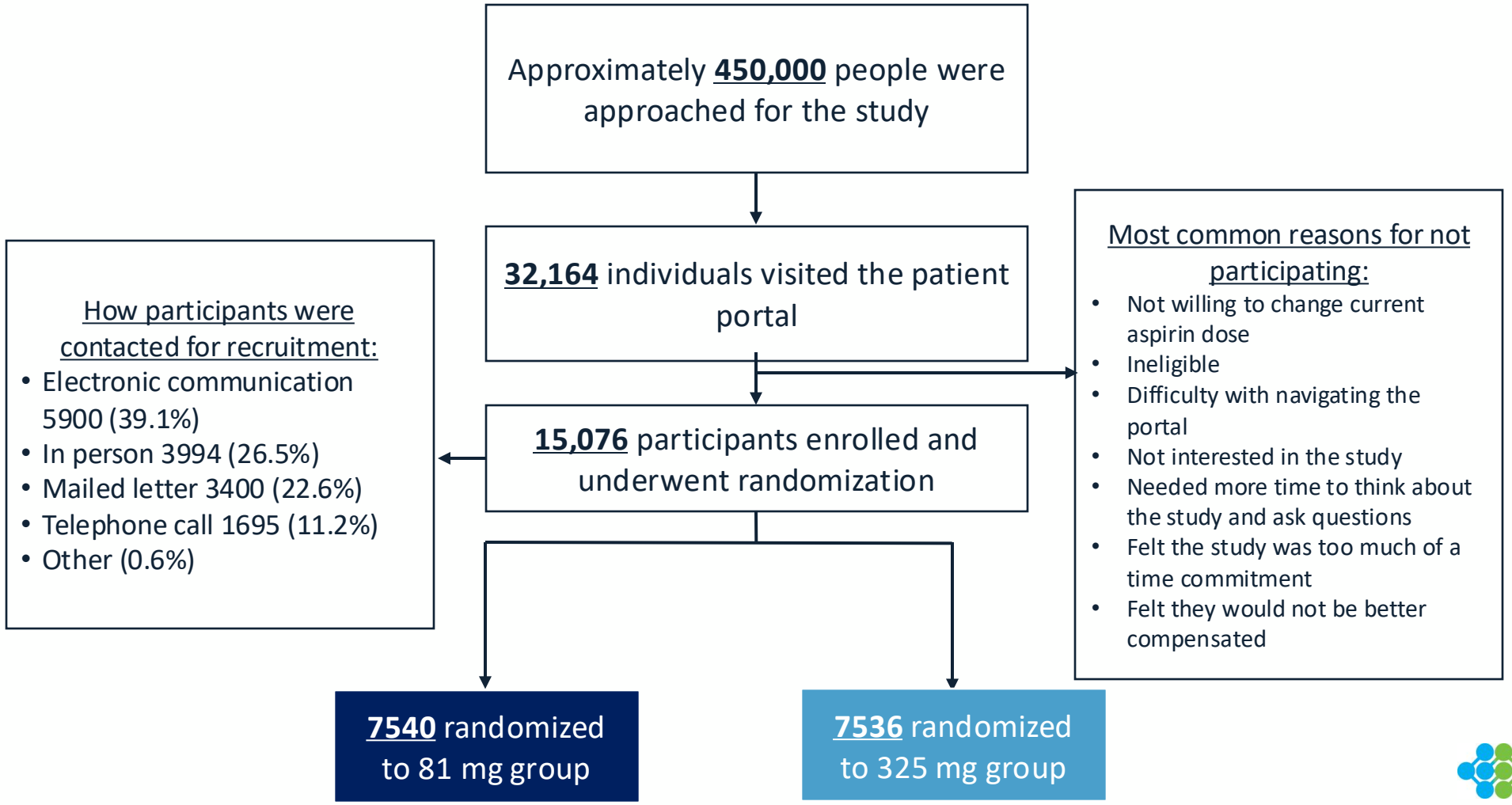
ADAPTABLE BY THE NUMBERS



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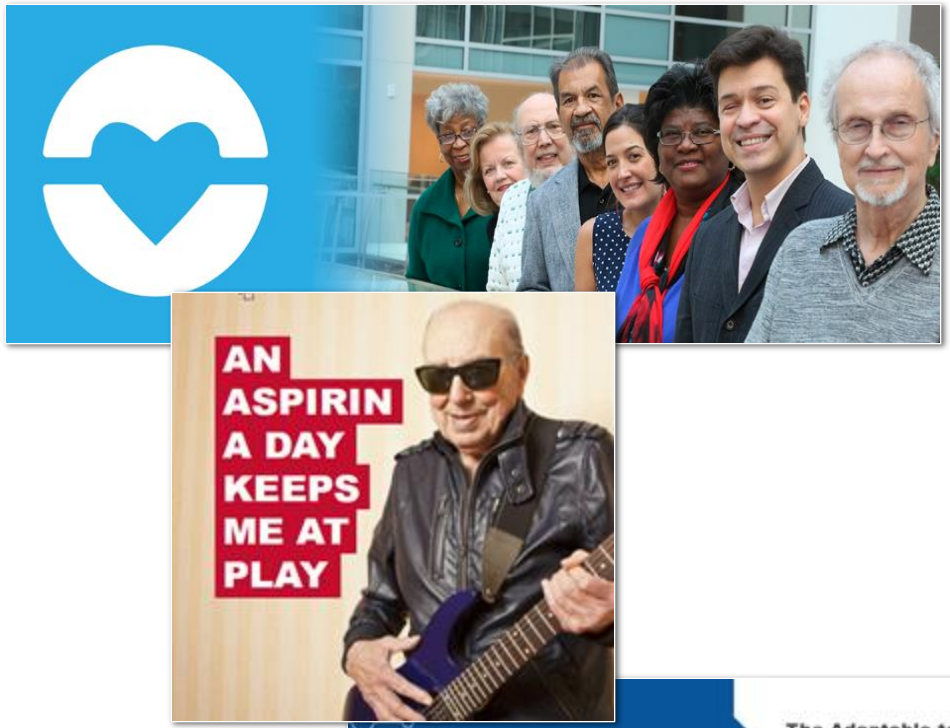
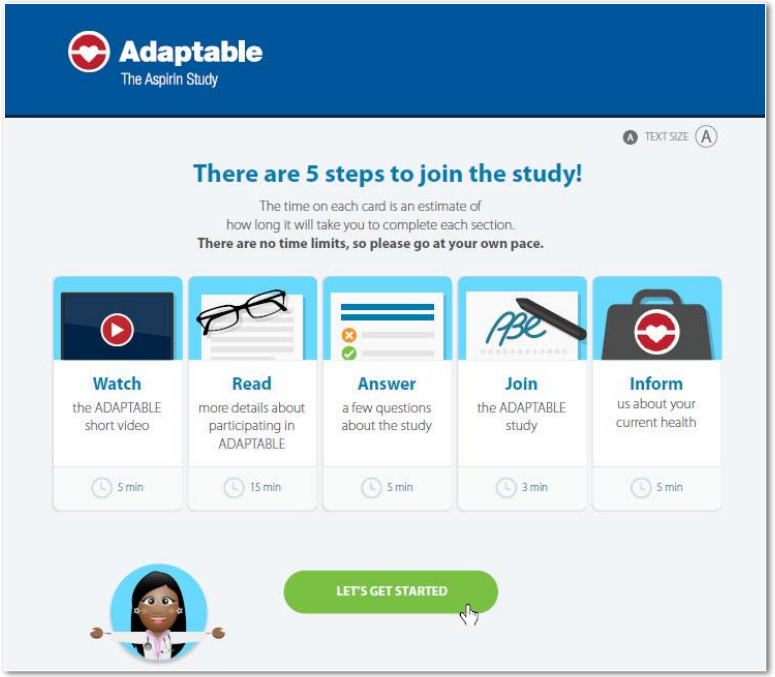
Patient Engagement

PATIENT BLOGS



FACEBOOK LIVE

PATIENT ENGAGEMENT PAVILION



Adaptable

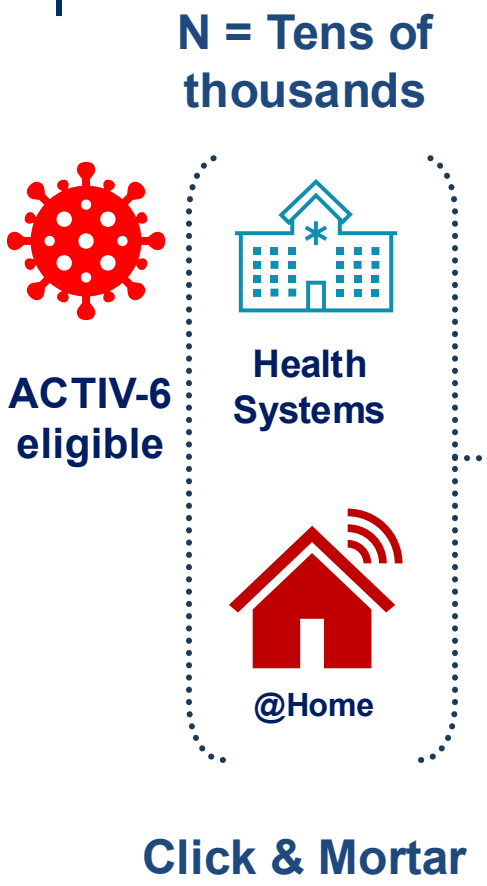
ACTIV-6: COVID-19 Outpatient Randomized Trial to Evaluate Efficacy of Repurposed Medications

- A decentralized, regulatory enabling clinical trial
- Platform trial with multiple, simultaneous interventions

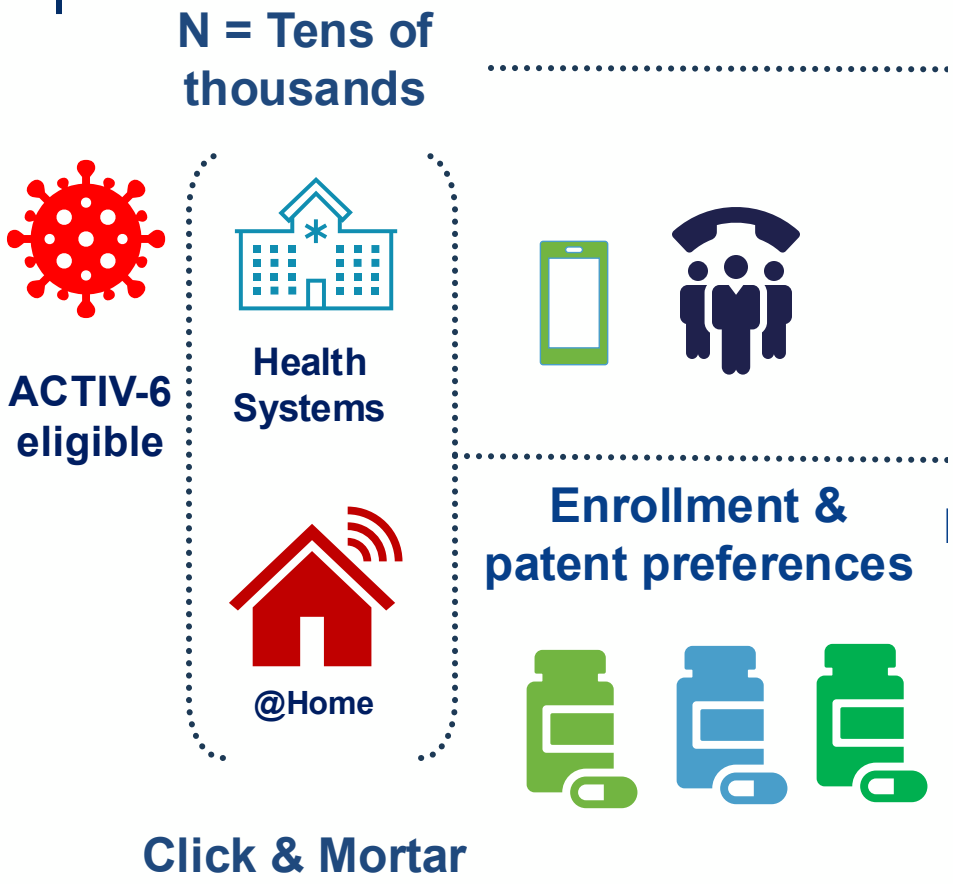
How to help people with newly diagnosed mild-moderate COVID-19 *feel better faster*?

How to *prevent hospitalizations or death* in someone with newly diagnosed mild-moderate COVID-19?

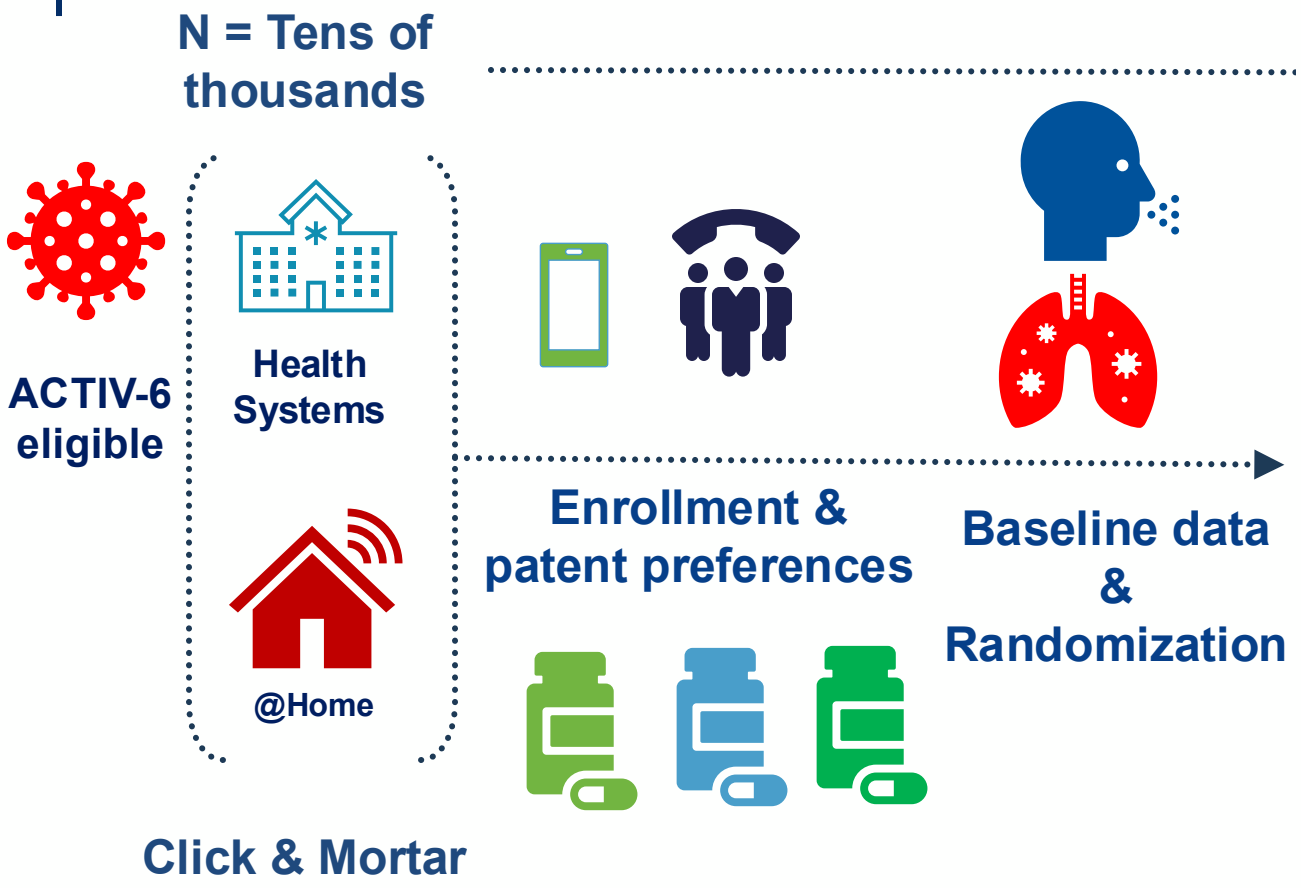
ACTIV-6 Hybrid Approach: Click & Mortar



ACTIV-6 Hybrid Approach: Click & Mortar



ACTIV-6 Hybrid Approach: Recruitment



ACTIV-6 Hybrid Approach: Follow-up

N = Tens of thousands

N = 15,000

ACTIV-6 eligible

Health Systems

@Home

Click & Mortar

Enrollment & patent preferences

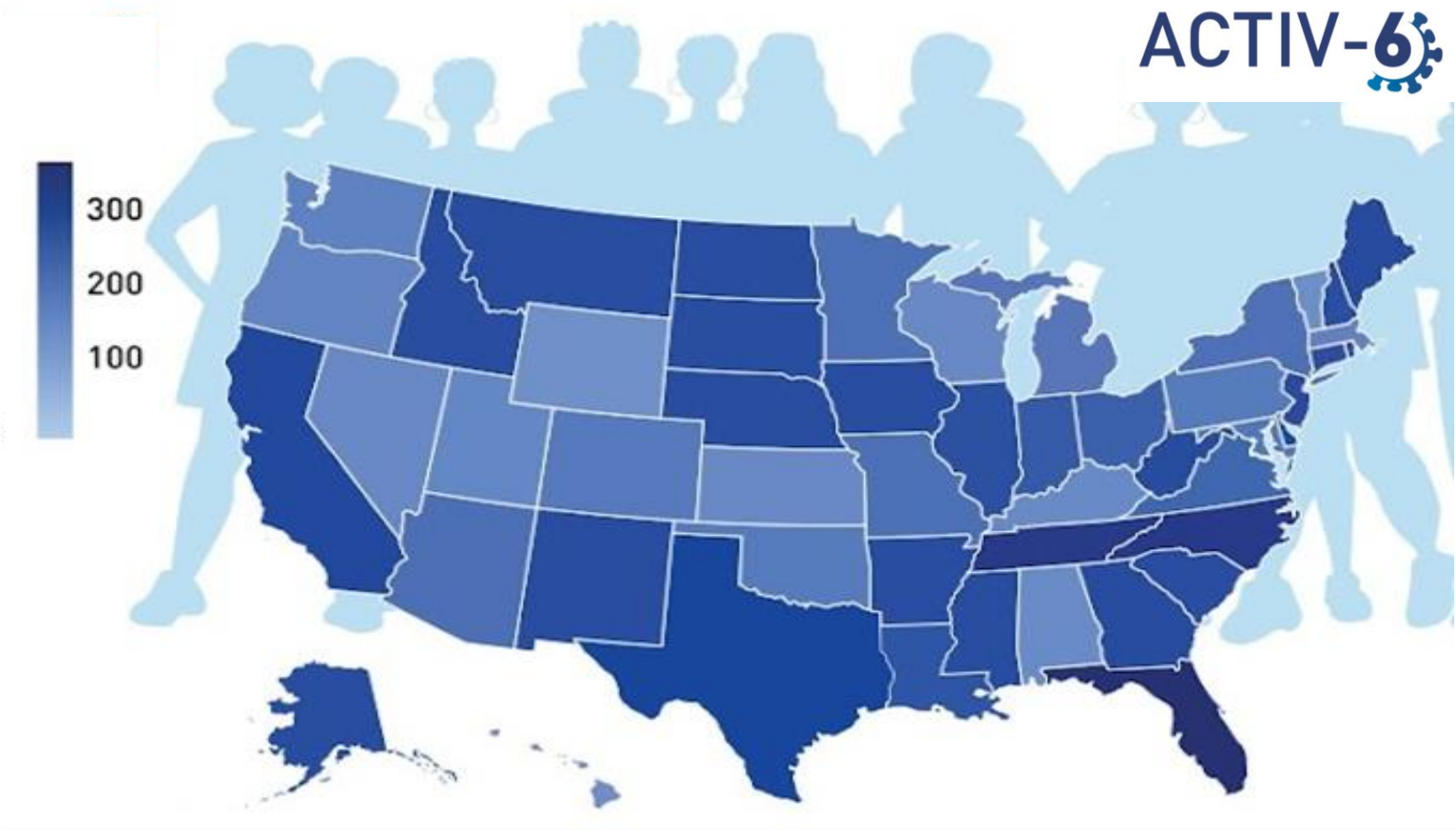
Baseline data & Randomization

Direct to Participant Portal
- *Daily Symptoms*
- *Patient-reported hospitalizations*
- *Medication use*
- *Health outcomes*

Call Center
- *Patients who miss 2 contacts*
- *Patients without internet access*
- *Validated coding algorithms for endpoints*

Site Follow-up (as needed)

- All 50 US States
- “Click & Mortar” Approach
  - >28K engaged portal
  - >24K begin consent
  - >13K consented to at least 1 arm
  - >10K randomized
- RANDOMIZATION 60->400 WEEK
- What methods?
  - Bayesian
  - Combined control group
- What outcomes?
  - Daily PROs through Day 14; Periodic PROs Day 28 & 90
  - Clinical Efficacy and Safety Outcomes (w/Validation)
  - Regulatory enabling



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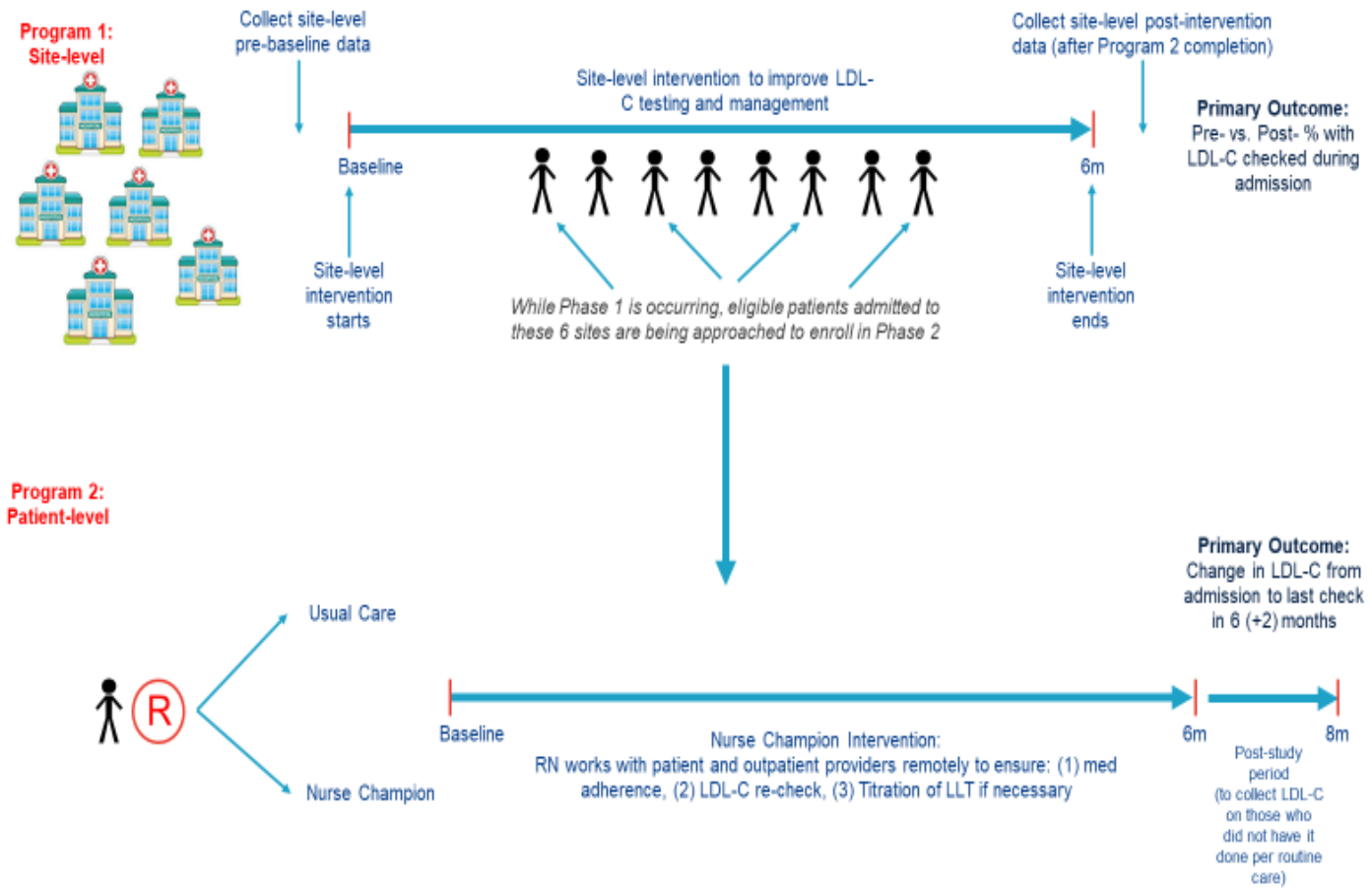
Test 2 Treat

Implementation science project in 6 PCORnet health systems to improve LDL-C management after ASCVD event by improving in- and out-patient care coordination



Simple design supports rapid enrollment

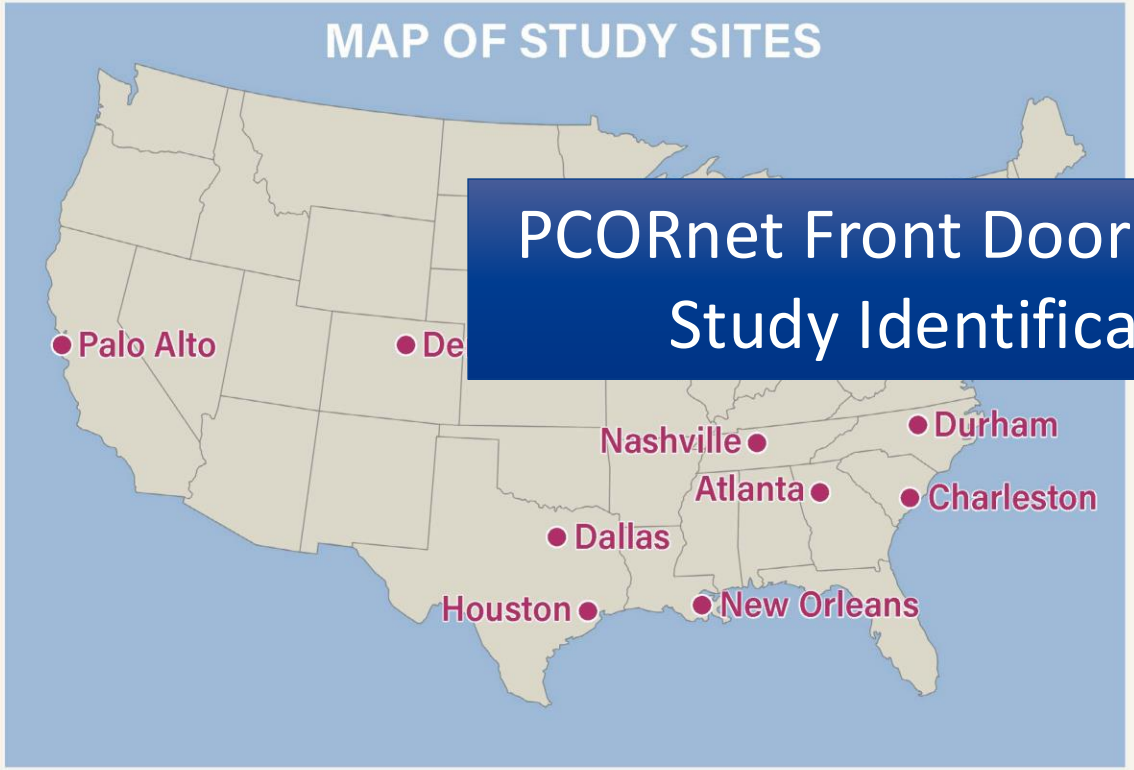
Covid and Diabetes Assessment (CODA) Study

- NIH/NIDK U01 ($28M over 4 years)
- PIs: Russell Rothman, Al Powers, Jonathan Schildcrout, Jason Block (Harvard)
- Will recruit and follow a cohort of 1000 adult and pediatric participants with recent diagnosis of T1D or T2D to examine the relationship between SARS-Cov-2 burden and glycemic control, metabolic function, inflammation, cardiovascular risk, and patient-reported outcomes.
- Will explore the role of genomic/social/environmental factors on glycemic control, inflammation and metabolic function on early diabetes progression
- Will also leverage EHR data from 38 PCORnet health systems across the country participating in the NIH RECOVER program to explore role of COVID-19 infection on diabetes development and progression.

COVID-19 DIABETES ASSESSMENT
The COVID & Diabetes Assessment (CODA) Study

Where will this study take place?

This map shows the locations of all the CODA study sites. City names in the adjacent list, that also includes the participating medical facilities, link to that study site's section on the Study Sites page in this website.



PCORnet Front Door and CRNs helped with Study Identification and Start-Up

- **Atlanta, GA:** Emory University
- **Baltimore, MD:** Johns Hopkins
- **Charleston, SC:** Medical University of South Carolina
- **Columbus, OH:** Nationwide Children's Hospital
- **Dallas, TX:** Baylor, Scott & White Health
- **Denver, CO:** Children's Hospital Colorado
- **Durham, NC:** Duke University
- **Houston, TX:** ...pital – Baylor College
- **Nashville, TN:** Vanderbilt University Medical Center
- **New Orleans, LA:** Ochsner Health System
- **Palo Alto, CA:** Stanford Children's Hospital
- **Philadelphia, PA:** Children's Hospital of Philadelphia
- **Pittsburgh, PA:** University of Pittsburgh Medical Center
- **Rochester, MN:** Mayo Clinic

COVID-19 DIABETES ASSESSMENT

Baseline Data:
Genomics
Social Factors, Environmental Factors
Lifestyle Factors, Baseline health characteristics
T1D antibodies
SARS-CoV-2 Antibodies
Metabolic, Inflammatory Markers

Study Design

New T1D or T2D in past 180 days with various history of prior COVID exposure

1-2 years

Trajectory analysis of T1D or T2D and metabolic factors

A1C, HOMA-IR (T2D), MMTT (beta cell function), Inflammatory/Coagulopathy markers, Lipids, BP, Weight, Medications, Lifestyle, etc.
Data collection every 3-6 months

COVID-19 DIABETES ASSESSMENT
The COVID & Diabetes Assessment (CODA) Study

Target Enrollment

Level	Total # of Participants (includes overlap)
Base Level (all surveys and basic labs +/- genomic testing)	N=1000 • 700 T2 • 300 T1
Moderate Level (Base Level + 4 MMT measurements)	N=325 • 200 T2 • 125 T1
Extensive Level (Moderate Level + Biomarkers + Vascular Ultrasound	N=160 • 100 T2 • 60 T1

COVID-19 DIABETES ASSESSMENT
The COVID & Diabetes Assessment (CODA) Study

Schedule of Events

Event	Population	Baseline	3 mos	6 mos	12 mos	18 mos	24 mos
Informed Consent/Assent	All	X					
Demographics	All	X					
Weight, Height, WHR, BP	All	X	X	X	X	X	X
Electronic Health Records Query	All	X			X		X
Record Type 1 antibodies (anti-gad, anti-insulin, anti-islet cell ab) from EHR	Type 1 Diabetes only	X					
Blood collection for Central Laboratory[1]	All	X	X	X	X	X	X
Adverse Event Assessment	All	X	X	X	X	X	X
Self-reported concomitant medications, medical history, vaccine history, care utilization, & death	All	X	X	X	X	X	X
Participant Questionnaires	All	X	X	X	X	X	X
Optional Procedures							
Mixed Meal Tolerance Test (MMTT)	Subsample	X	X	X	X		
Vascular Integrity (SphygmoCor)	Subsample	X			X		
Continuous Glucose Monitoring (CGM)[2]	Subsample	X	X	X			

[1] Collect One of each 10 mL EDTA, 6 mL Na Citrate, 6 mL serum at each visit.

[2]Participants with existing CGM may consent for CGM data to be shared with the study team. A subset of participants will be asked to wear a masked CGM for a 10-day period. Participants who develop COVID during the study who agree to have a CGM placed will be mailed 2 masked CGM devices for data collection.

COVID-19 DIABETES ASSESSMENT
The COVID & Diabetes Assessment (CODA) Study

Recruitment and Enrollment

- Identify participants based on local sites, including
  - EHR or Research Data Warehouse

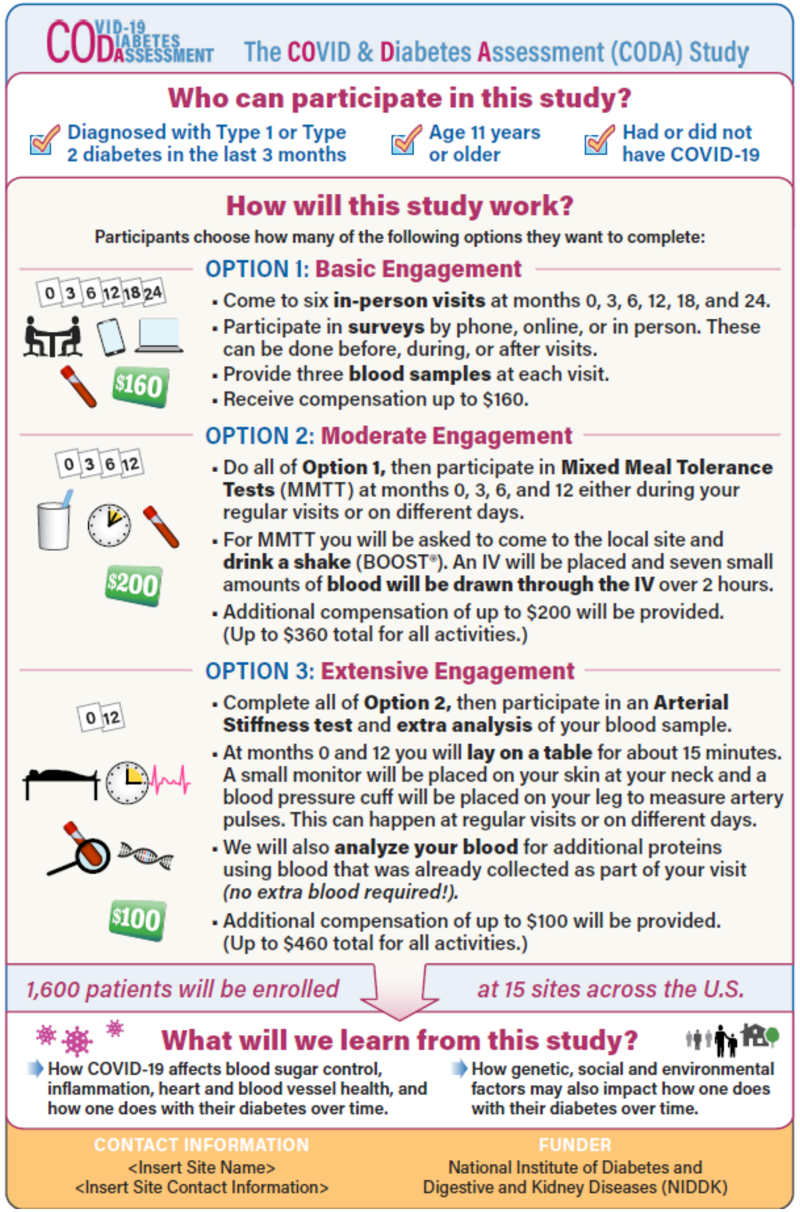
CRNs can use PCORnet CDM, EPIC, or CERNER tools for patient identification

- Consent via Phone with email/docusign

Many CRN sites have "Opt-out" Consent Procedures

study snapshot for enrollment

- Participants are considered enrolled after assent/consent and completion of baseline surveys and blood collection


The COVID & Diabetes Assessment (CODA) Study

Who can participate in this study?

- Diagnosed with Type 1 or Type 2 diabetes in the last 3 months
- Age 11 years or older
- Had or did not have COVID-19

How will this study work?

Participants choose how many of the following options they want to complete:

OPTION 1: Basic Engagement

- Come to six **in-person visits** at months 0, 3, 6, 12, 18, and 24.
- Participate in **surveys** by phone, online, or in person. These can be done before, during, or after visits.
- Provide three **blood samples** at each visit.
- Receive compensation up to $160.

OPTION 2: Moderate Engagement

- Do all of **Option 1**, then participate in **Mixed Meal Tolerance Tests** (MMTT) at months 0, 3, 6, and 12 either during your regular visits or on different days.
- For MMTT you will be asked to come to the local site and **drink a shake** (BOOST®). An IV will be placed and seven small amounts of **blood will be drawn through the IV** over 2 hours.
- Additional compensation of up to $200 will be provided. (Up to $360 total for all activities.)

OPTION 3: Extensive Engagement

- Complete all of **Option 2**, then participate in an **Arterial Stiffness test** and **extra analysis** of your blood sample.
- At months 0 and 12 you will **lay on a table** for about 15 minutes. A small monitor will be placed on your skin at your neck and a blood pressure cuff will be placed on your leg to measure artery pulses. This can happen at regular visits or on different days.
- We will also **analyze your blood** for additional proteins using blood that was already collected as part of your visit *(no extra blood required!)*.
- Additional compensation of up to $100 will be provided. (Up to $460 total for all activities.)

1,600 patients will be enrolled *at 15 sites across the U.S.*

What will we learn from this study?

- How COVID-19 affects blood sugar control, inflammation, heart and blood vessel health, and how one does with their diabetes over time.
- How genetic, social and environmental factors may also impact how one does with their diabetes over time.

CONTACT INFORMATION
<Insert Site Name>
<Insert Site Contact Information>

FUNDER
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

The COVID & Diabetes Assessment (CODA) Study

Aim 5 – EHR-only based analysis in RECOVER data enclave

- 5a: Among those with SARS-CoV-2 testing, assess association of SARS-CoV-2 infection (vs. not) with incidence of diabetes (1 and 2) after SARS-CoV-2 infection by SARS-CoV-2 variant
- 5b: Among those with incident diabetes, assess association of SARS-CoV-2 infection (infection vs. not) with diabetes outcomes (A1c, utilization, # meds, insulin)
- 5c/d: Among those who test positive with SARS-CoV-2, assess
  - Incidence of diabetes (1 and 2) after treatment with paxlovid vs. no treatment
  - Diabetes outcomes after treatment with paxlovid vs. no treatment

CODA COVID-19 DIABETES ASSESSMENT
The COVID & Diabetes Assessment (CODA) Study

Engagement Activities

- Engagement Core led by UPMC (PATH CRN)
- Engagement Advisory Council
  - Each site identified patients and/or clinicians to participate
- 2 Partners Serve on Steering Committee
- Provide guidance on
  - Study design
  - Study Recruitment and Consent
  - Patient facing handout materials
  - Patient compensation and study materials
  - Website and Newsletter
- Return of Results
- Interpretation of Results
- Dissemination Activities

COVID-19 DIABETES ASSESSMENT
The COVID & Diabetes Assessment (CODA) Study

SUMMARY

- PCORnet is a national network available for a broad array of research including pragmatic trials, real world evidence research, and cohort studies
- PCORnet has a wide array of resources and capabilities to enhance research including:
  - PCORnet Common Data Model
  - Informatics Tools and experience leveraging tools for research
  - Administrative efficiencies
  - Partner Engagement
- Opportunities to leverage the PCORnet Common Data Model to identify potential participants, directly collect data from enrolled study participants, and for ancillary/complementary research
- Opportunities to utilize the PCORnet Common Engagement Model

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Main Objectives of the ADAPTABLE Trial

- To compare the effectiveness and safety of two doses of aspirin (81 mg and 325 mg) in high-risk patients with coronary artery disease.
  - **Primary Effectiveness Endpoint:** Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke
  - **Primary Safety Endpoint:** Hospitalization for major bleeding
- To compare the effects of aspirin in pre-defined key subgroups of patients
  - Age, Diabetes, Sex
  - Race, P2Y12 inhibitor Use
  - Chronic Kidney Disease
- To develop and refine the infrastructure for PCORnet to conduct multiple comparative effectiveness trials in the future

Research Question

In patients with established or pre-existing cardiovascular disease, is a strategy of 81 mg or 325 mg of aspirin better?

Everyday decision for patients (OTC medication)

The correct dose of aspirin may **PREVENT**:

Thousands of deaths / heart attacks

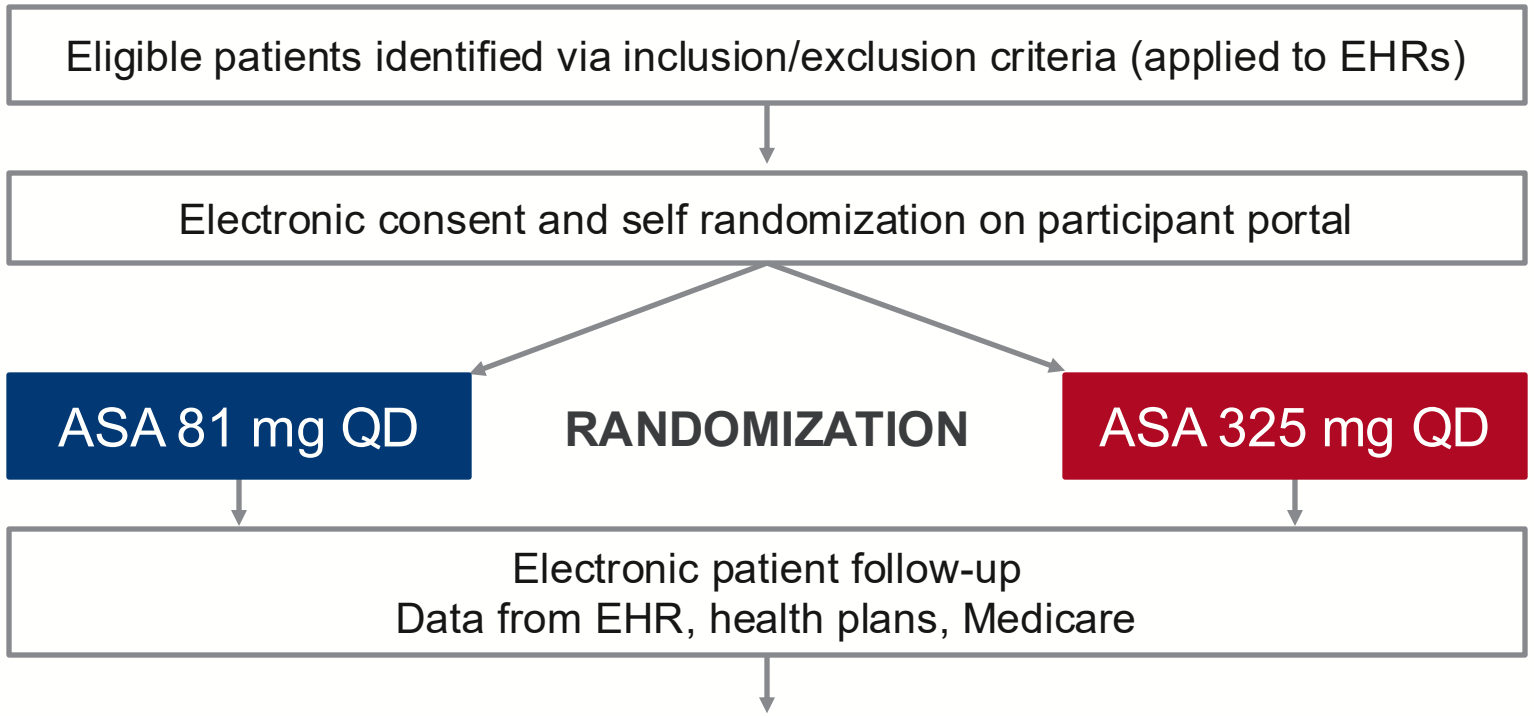
or

Thousands of bleeds

Annually in the United States

ADAPTABLE Study Design

15,000 patients with known ASCVD + ≥ 1 “enrichment factor”

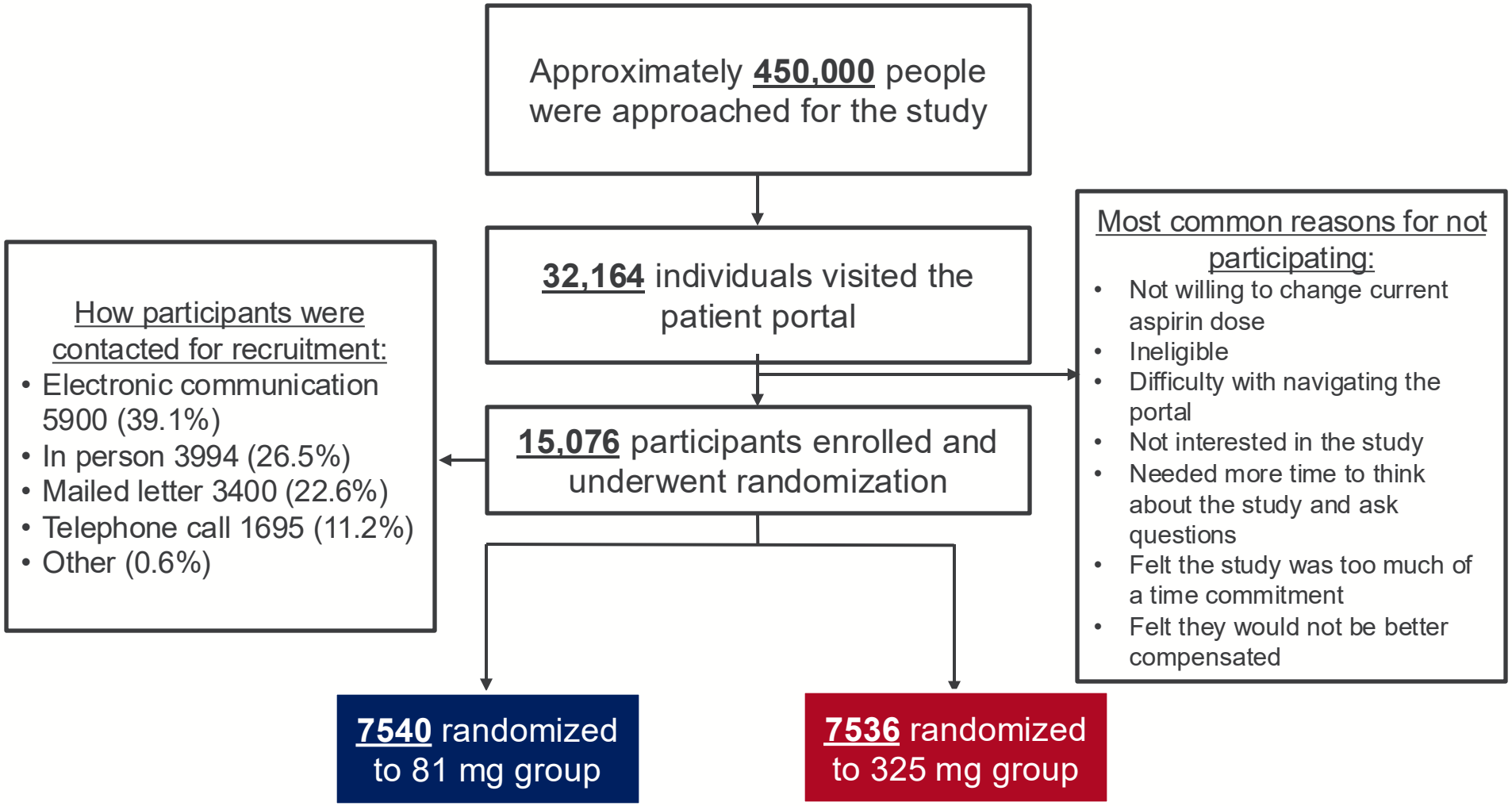


Primary Endpoint:
Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke

Primary Safety Endpoint:
Hospitalization for major bleeding

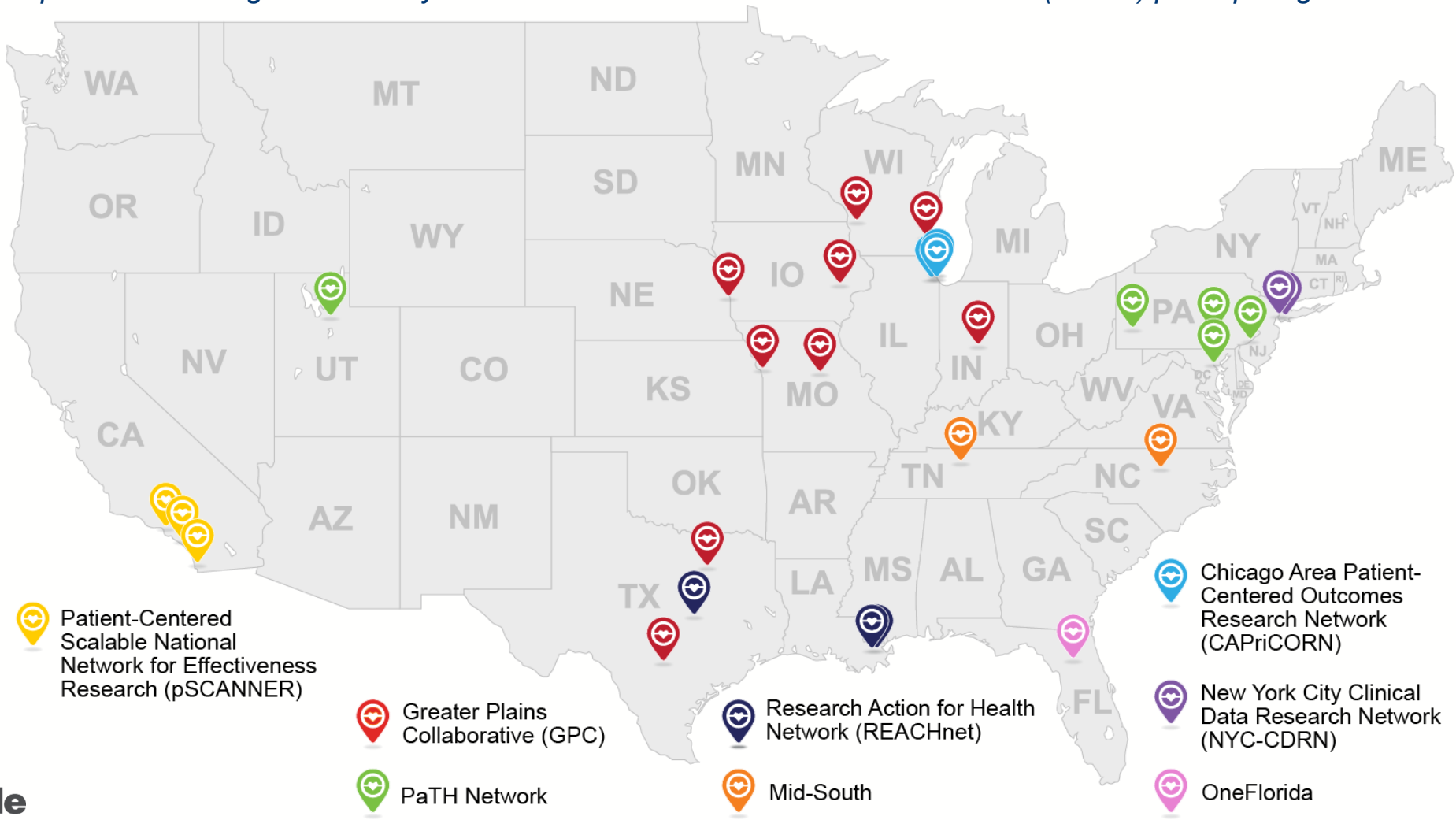
ClinicalTrials.gov: NCT02697916

STUDY FLOW


Approximately 450,000 people were approached for the study
32,164 individuals visited the patient portal
15,076 participants enrolled and underwent randomization
How participants were contacted for recruitment:
• Electronic communication 5900 (39.1%)
• In person 3994 (26.5%)
• Mailed letter 3400 (22.6%)
• Telephone call 1695 (11.2%)
• Other (0.6%)
Most common reasons for not participating:
• Not willing to change current aspirin dose
• Ineligible
• Difficulty with navigating the portal
• Not interested in the study
• Needed more time to think about the study and ask questions
• Felt the study was too much of a time commitment
• Felt they would not be better compensated
7540 randomized to 81 mg group
7536 randomized to 325 mg group

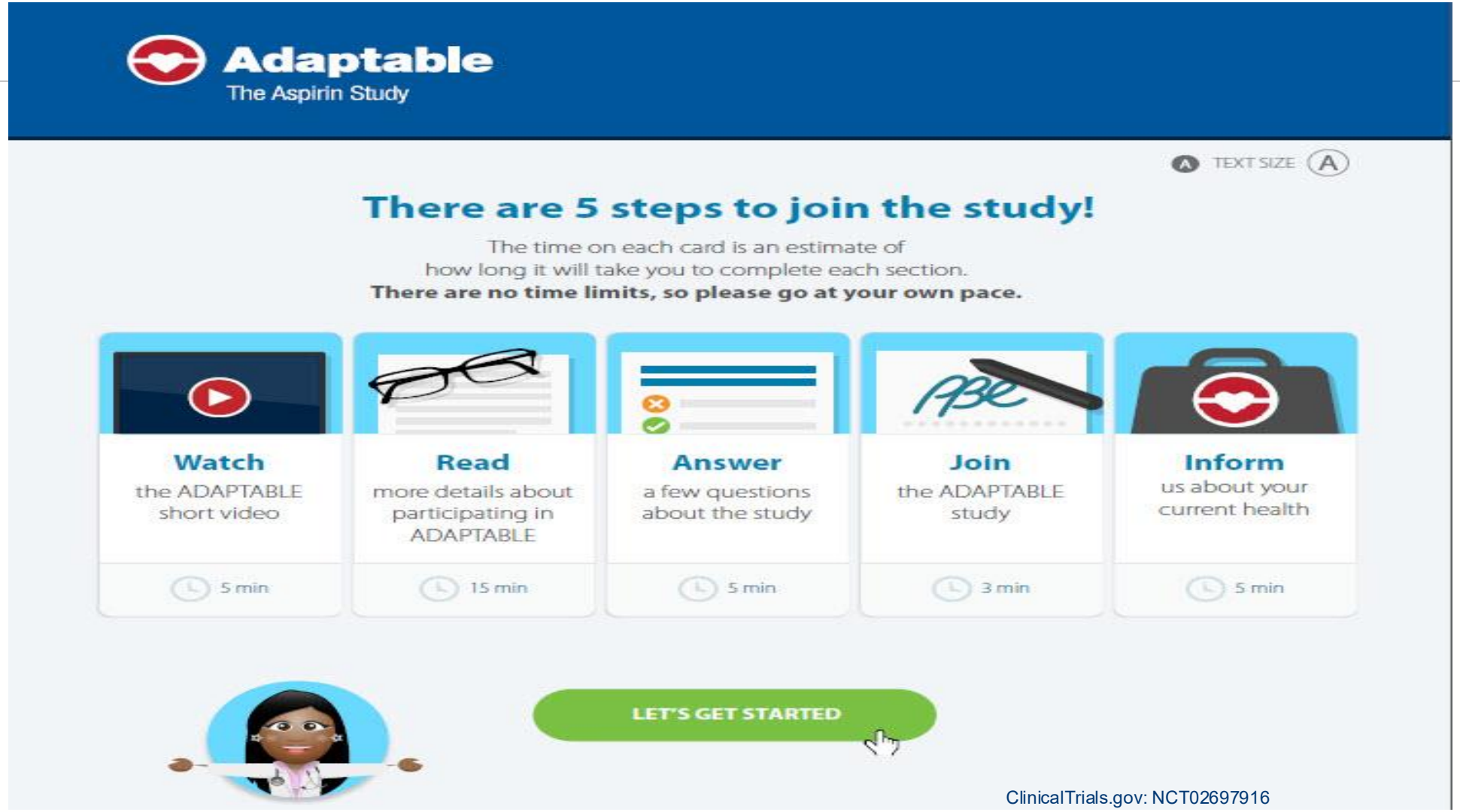
CDRNs and Health Care Systems Participating in ADAPTABLE

This map depicts the coverage of health systems within Clinical Data Research Networks (CDRN) participating in ADAPTABLE



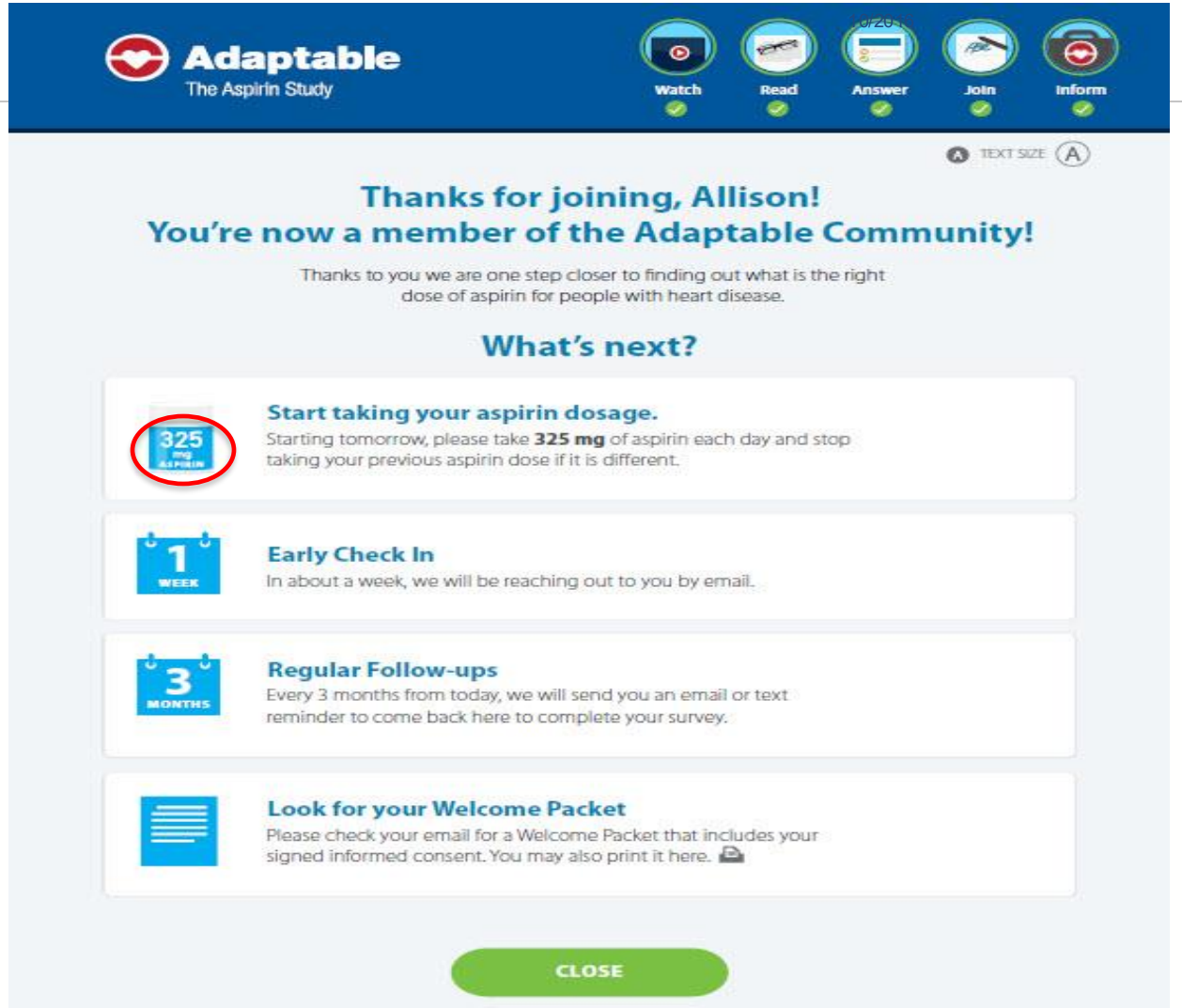
Adaptable

ClinicalTrials.gov: NCT02697916


Adaptable
The Aspirin Study
TEXT SIZE A
There are 5 steps to join the study!
The time on each card is an estimate of
how long it will take you to complete each section.
There are no time limits, so please go at your own pace.
Watch
the ADAPTABLE short video
5 min
Read
more details about participating in ADAPTABLE
15 min
Answer
a few questions about the study
5 min
Join
the ADAPTABLE study
3 min
Inform
us about your current health
5 min
LET'S GET STARTED
ClinicalTrials.gov: NCT02697916

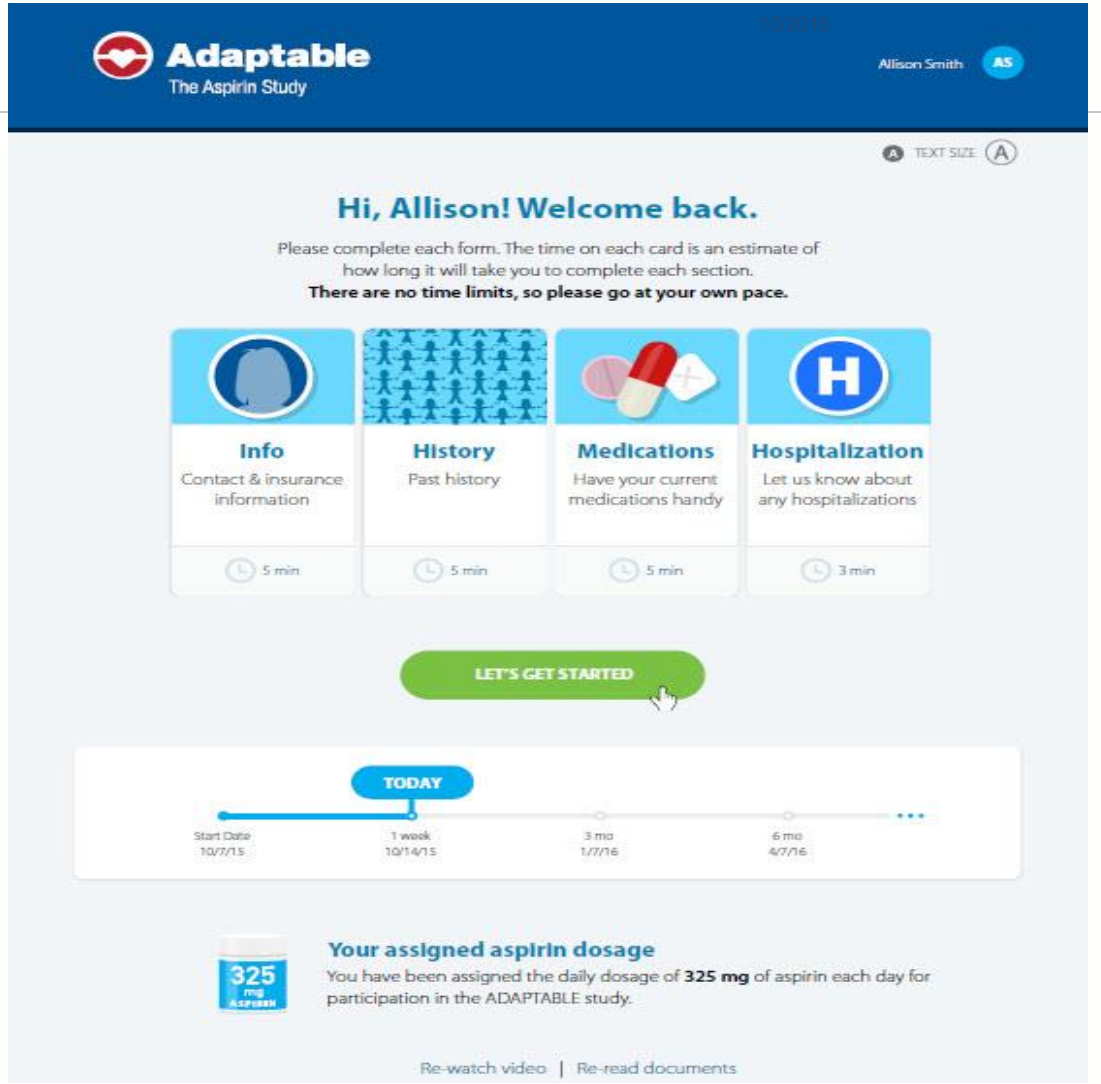
Web-Based Randomization

- Randomized treatment assignment (aspirin dose) provided directly to patients after informed consent
- Reminders for electronic follow-up contacts given at time of randomization
- Patients randomized to follow-up contacts every 3 months vs. 6 months
  - Embedded feature



Electronic Follow-Up

- Patients receive email reminders to visit web portal for regular contacts every 3 vs. 6 months
- Central DCRI Call Center performs telephone contacts when needed
  - Non-internet participants
  - Participants who miss at least 2 scheduled electronic contact



Electronic Data Collection and Follow-Up

N=15,000

ADAPTABLE enrollee

Baseline data

Web portal follow-up
- *Randomized to 3 vs 6 mos contact*
- *Patient-reported hospitalizations*
- *Medication use*
- *Health outcomes*

DCRI call center
- *Patients who miss 2 contacts*
- *Patients without internet access*
- *Validated coding algorithms for endpoints*

PCORnet Coordinating Center follow-up
- *Via Common Data Model*
- *Validated coding algorithms for endpoints*

CMS and private health plans follow-up
- *Longitudinal health outcomes*
- *Validated coding algorithms for endpoints*

Death Ascertainment

- CDM and Social Security Databases
- Alternate contacts via DCRI Call Center

ClinicalTrials.gov: NCT02697916

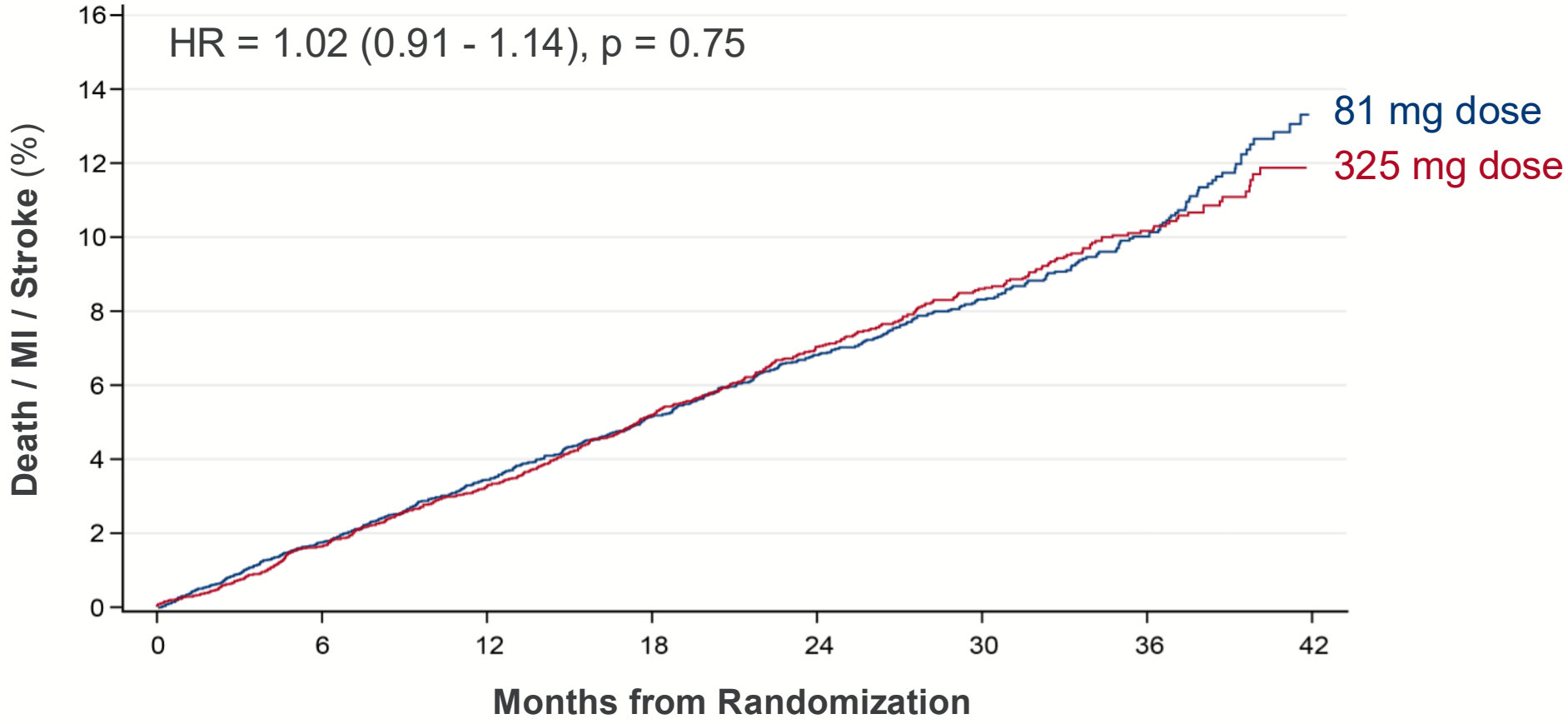
Adaptable

Primary Effectiveness Endpoint

(All-cause death, hospitalization for MI, or hospitalization for stroke)

Caveats

- Open label
- Dose switching



At risk								
81 mg dose	7540	7357	7177	5627	4190	2712	1558	636
325 mg dose	7536	7297	7095	5544	4090	2613	1489	592

Adaptable

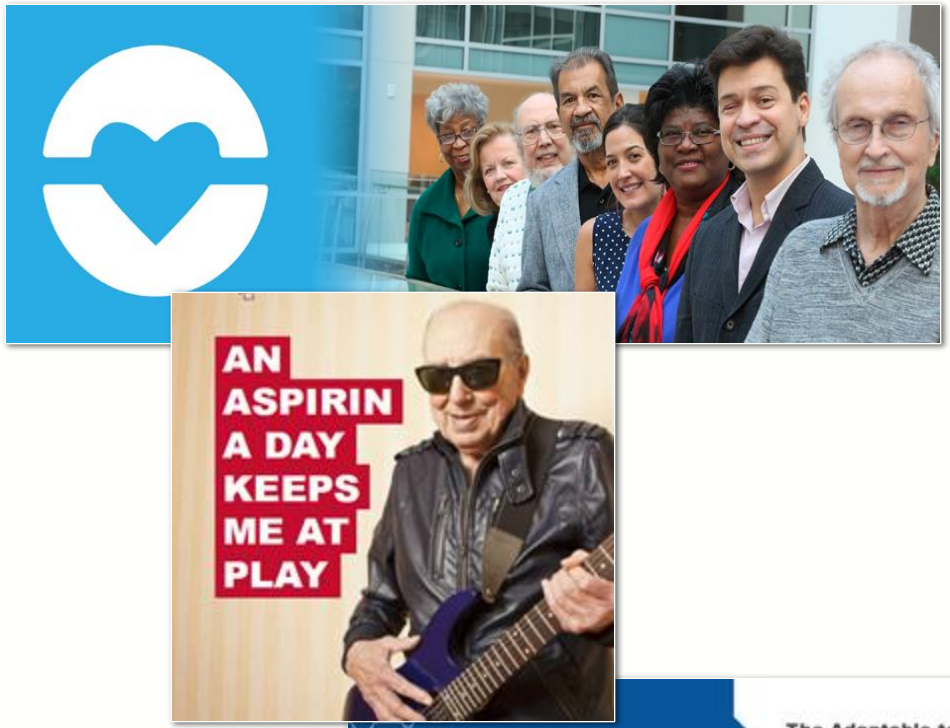
ADAPTABLE BY THE NUMBERS

- ADAPTABLE is the first large scale pragmatic trial conducted via PCORnet in learning health care systems
- Leverage electronic health records (EHRs) to identify over **650,000** eligible patients across **40** sites
- Developed recruitment strategies leveraging high and low touch methods to approach over **450,000** eligible patients across **3** years of enrollment
- Utilized virtual patient portal where over **31,000** patients used unique access codes to enter the portal and **15,000** enrolled using e-Consent
- Simplified baseline and follow-up data collection through patient-reported outcomes with over **57,000** virtual visits completed to date and queries to multiple data sources

Adaptable
The Aspirin Study

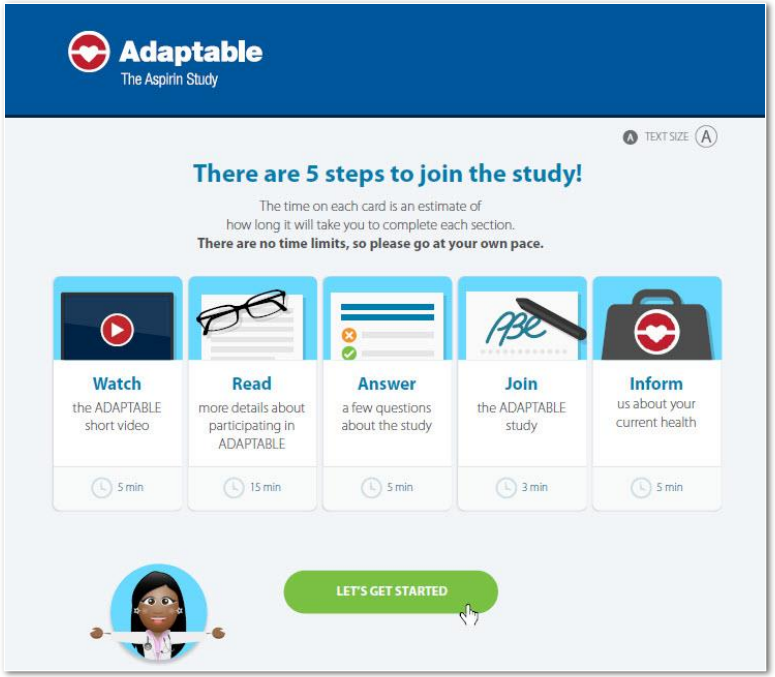
Patient Engagement

PATIENT BLOGS



FACEBOOK LIVE

PATIENT ENGAGEMENT PAVILION



Adaptable

PREVENTABLE

Age 75+ without CVD, dementia or disability (N = 20,000)*

Randomization

Atorvastatin 40mg | **Placebo**

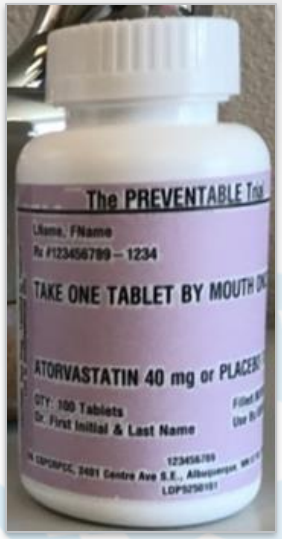
(4 YR follow up)

1° **Survival w/o Dementia or Persisting Disability**

co-2° **CV composite (CV death, MI, HF, Stroke/TIA) or MCI/dementia**

** Include risk for MCI or Frailty by Computable Phenotype*

Study Drug



High-intensity statin

- Generic atorvastatin 40 mg (Same as STAREE Trial)[1]
- No differences in safety or effectiveness were observed in Lipitor® trials among the 7% of participants aged ≥75 years (2,800/39,828)
- IND Exemption: “well-known drug”, used as labelled, no intention to seek label change

Placebo-controlled design

- Unbiased reporting of drug-associated safety concerns/ events
- Less competing therapies in open-label no-statin arm

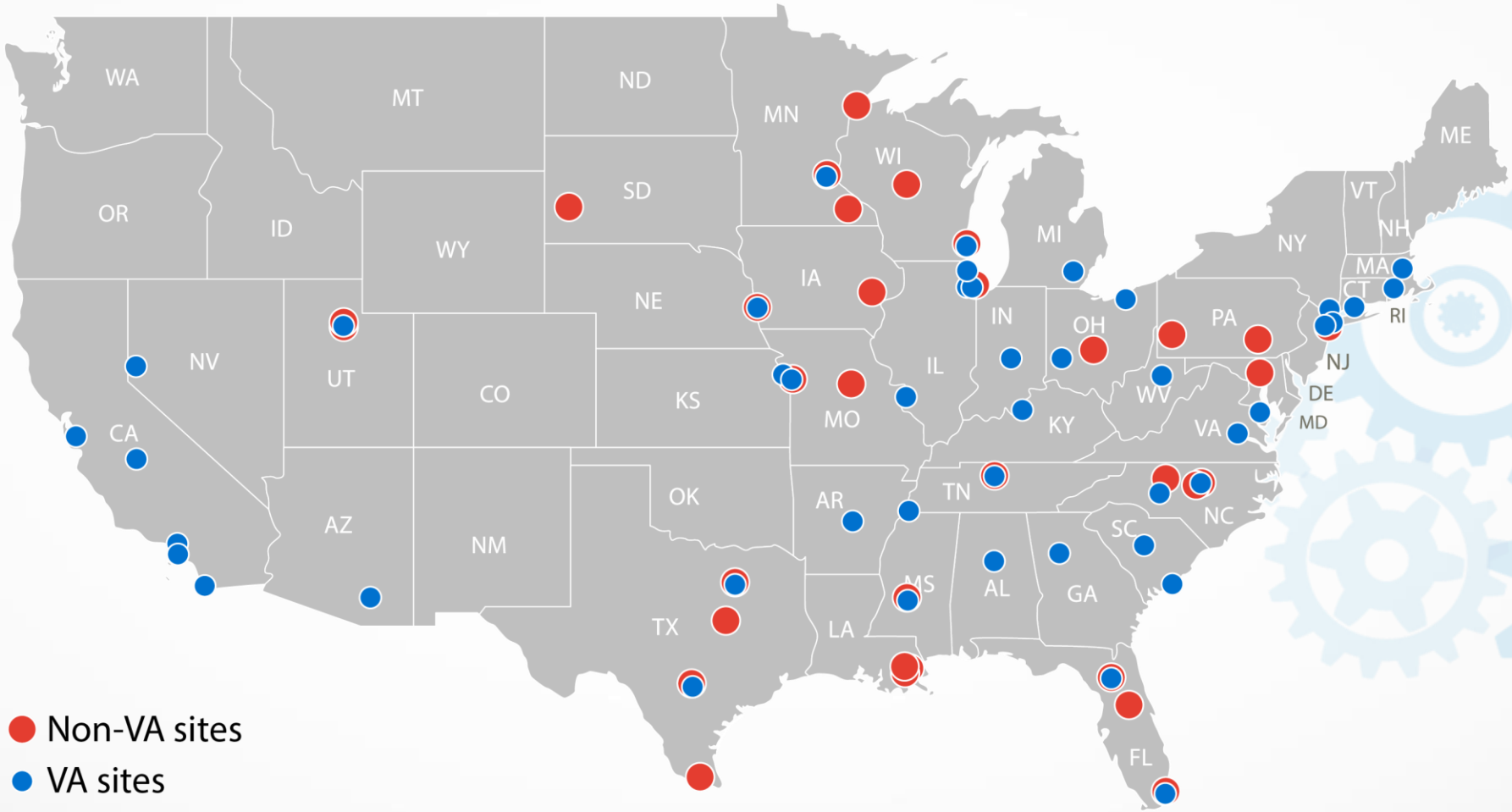
Home Delivery

- VA Cooperative Studies Pharmacy

[1] NCT02099123 https://www.staree.org.au/.

Study Sites

Approximately 90 sites from PCORnet (non-VA) and BVARI (VA) will participate.



PREVENTABLE

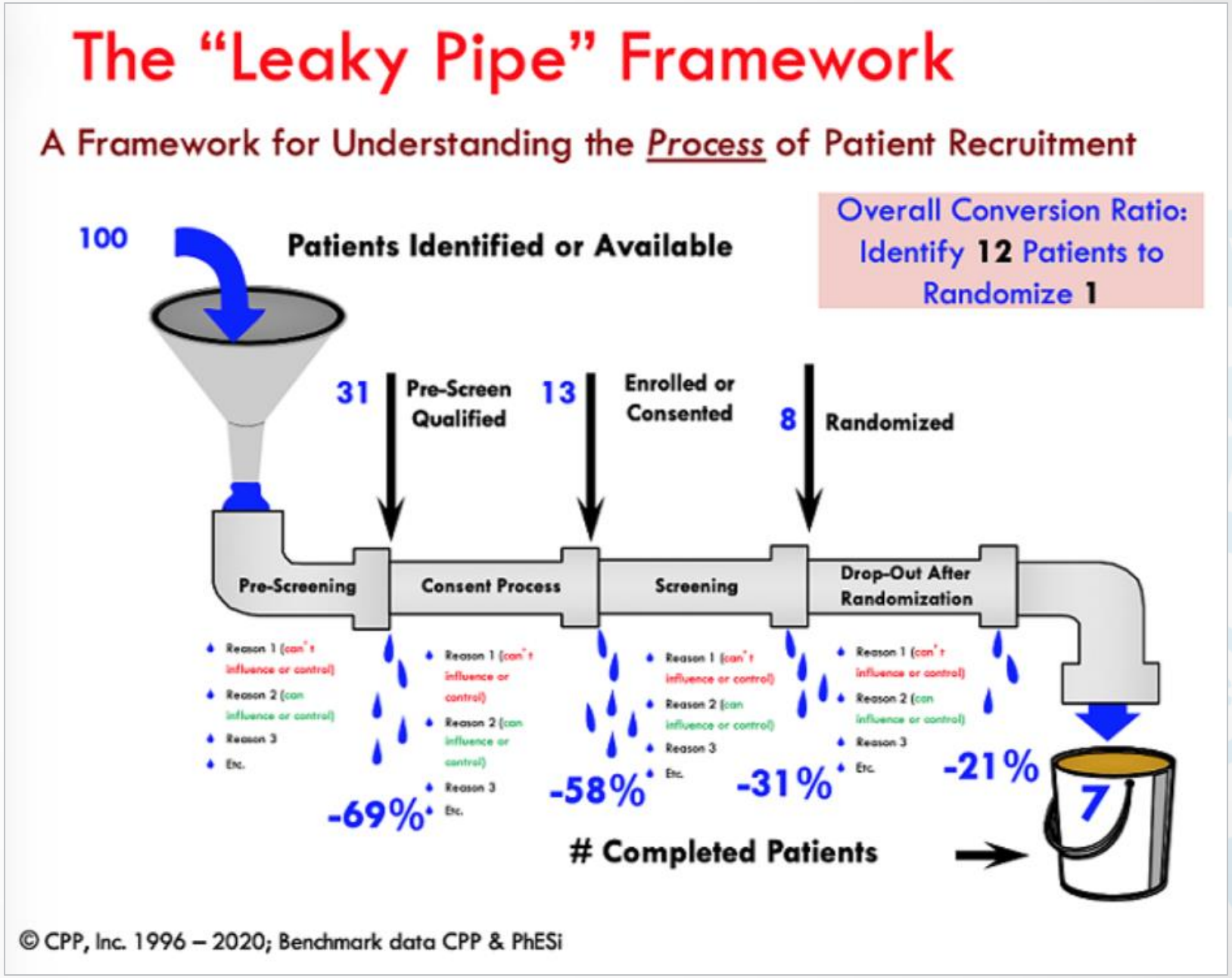
Decisions During Initiation/Implementation

- Patient Population – I/E criteria
  - *Generalizable, representative (large networks)*
- Recruitment
- Clinician Engagement
- How to supply study medication – open label vs. blinded
- How to create data flow for endpoints

Cohort Assessment Query

- Primary goal is to generate a list of potential study participants by:
  - *Applying inclusion and exclusion criteria to EHR data, as possible*
  - *Summarizing other person-level information that may assist with recruitment*
- Will result in two components:
  - *PCORnet query that is executable at PCORnet sites*
  - *Specifications (logic, codes, etc.) that can be implemented by all PREVENTABLE sites*
- Developed by the DCRI data team in coordination with PREVENTABLE stakeholders

Cohort Assessment Query



PREVENTABLE

E-Consent

PREVENTABLE

Resize font: Disable speech

PREVENTABLE

Preventable Consent_ Part 1

Consent to Participate in a Research Study

You are invited to take part in a clinical research study called PREVENTABLE. This research will take place at several different study site locations. This consent form includes two parts. Part 1 is the Main Consent and includes information that applies to all study sites. Part 2 is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together make up the complete consent form. You will be given a copy of the consent form.

Please take your time in reviewing this form. Ask your study doctor or the study staff to explain any words or information you don't know. You may also discuss the study with your primary care doctor, your family, and friends.

Page 1 of 11

Before we begin the consent, do you want us to show you how to make the words bigger on the page so they are easier to read?

Yes

No

reset

Institutional Review Board
Informed Consent Document for Research

Study Title: PREVENTABLE (PRagmatic EValuation of evENTs And Benefits of Lipid-lowering in older adults)
Revision Date: X/XX/2020

Resize font: Disable speech

PREVENTABLE

Part_2_Wake Forest Baptist Hospital

Page 3 of 6

PAYMENT AND COSTS AND USE OF HEALTH INFORMATION FOR RESEARCH

Will I be paid for being in this study?
You will be paid $XX for your time and general expenses such as parking.

Are there costs to me for being in this study?
All tests and the study drug that are needed for this study that are not part of your usual medical care will be paid by the study.

Usual medical care is care you would receive whether or not you are part of this study. Your health insurance provider will be billed for your usual medical care.

What is Protected Health Information (PHI)?
The PHI collected for this research study includes your name, address, phone number, email address, date of birth, Social Security number, Medicare Beneficiary Identifier, and health information.

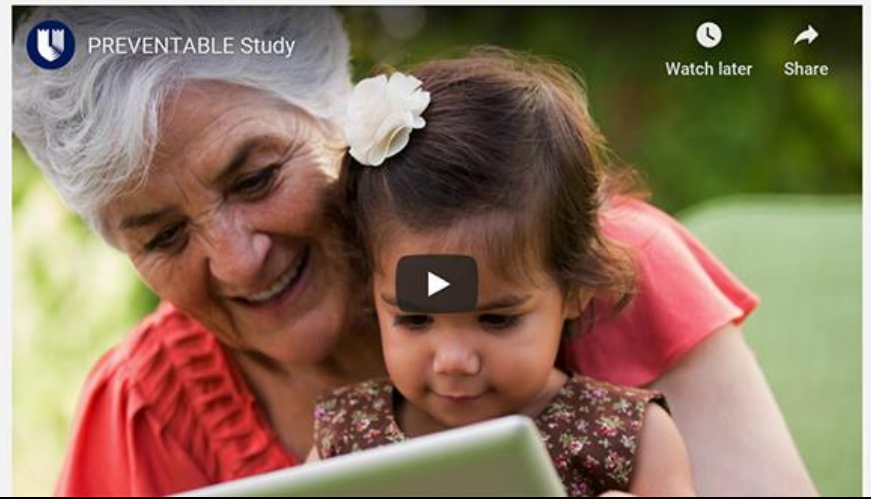
Will my PHI remain private?
We will make every effort to keep your PHI safe. We will store records in a locked cabinet or office or on a password-protected computer. Your identity and your PHI will not be shared unless it is required to protect your safety, the safety of others, or if you give us approval to share it.

Who will have access to or receive my PHI?
Your PHI may be given to others only if needed for reasons like carrying out the study, determining the results of the study, making sure the study is being done correctly, and providing required reports.

Some of those that may disclose your PHI are:

You are being invited to participate in the PREVENTABLE (PRagmatic EValuation of evENTs And Benefits of Lipid-lowering in oldEr adults), a study in about 20,000 participants from many sites across the United States. Part 1 has information about the main study and Part 2 has information about your study site. Your participation is voluntary. Please consider the following information in making your decision.

Please watch the video below to learn more about the PREVENTABLE study.



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PREVENTABLE

Part_2_Wake Forest Baptist Hospital

Page 5 of 6

STATEMENT OF CONSENT

My signature below indicates that I have read and understood this consent form. I have had enough time and opportunity to think about the information, ask questions, and get my questions answered to my satisfaction. I understand that I am under no obligation to participate in this study, but I am willing to participate, and I am freely giving my consent to participate in the PREVENTABLE study. A copy of this form will be given to you.

Participant:

Name

Please sign using "add signature". ----------> Add signature

Date 2020-05-18

Study doctor or designee who obtained consent:

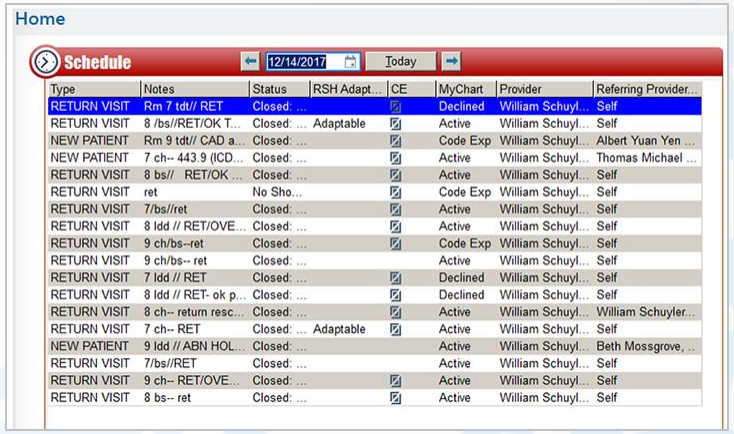
Name

PREVENTABLE

Teamwork

Clinical Team
PI(s) + CRC(s)

Informatics Team
CDRN/CDM

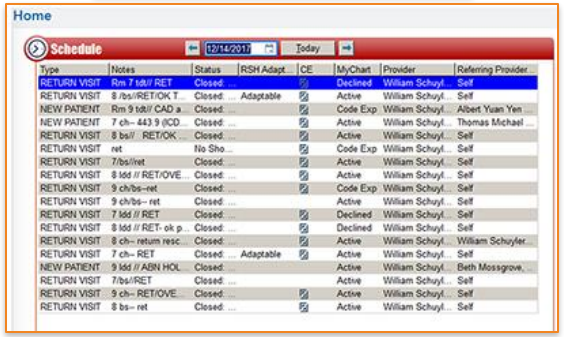


EHR Programming

Enrollment to Randomization

Cohort Query Direct Approach

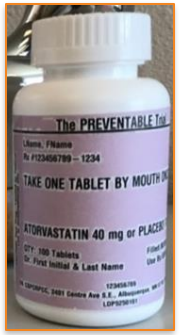
Patient/Clinician Engagement



Consent Baseline Data Collection

Baseline Tests

Study Drug Assignment



X — Potential Population

X — Chart Review Confirm Eligibility

X — Clinic (Telehealth)

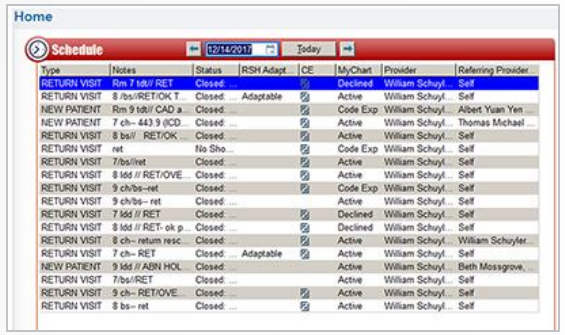
ENROLL

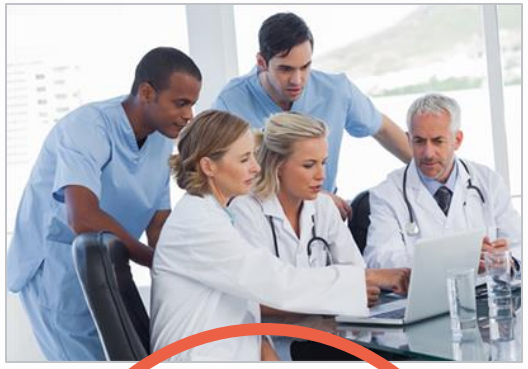
X — Call Center

RANDOMIZE

X

Teamwork





X

Screening
Start of Study

ELIGIBLE POPULATION

X

Enrollment
Randomization

RANDOMIZED POPULATION

Key opportunities:

Incorporate research into clinical practice

Make it easier for clinicians

X

End of Study

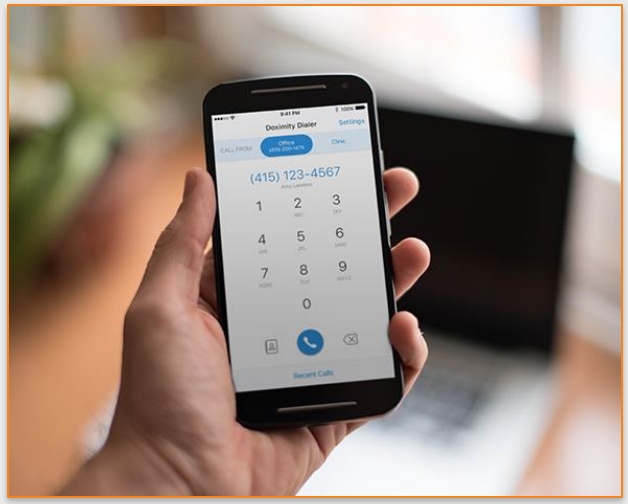
PREVENTABLE

Virtual Enrollment

? IN-PERSON VISITS

OPTIONS:

Video
(Zoom/Webex)



Phone
(Doximity)

Challenges:

Technology

Biospecimen collection

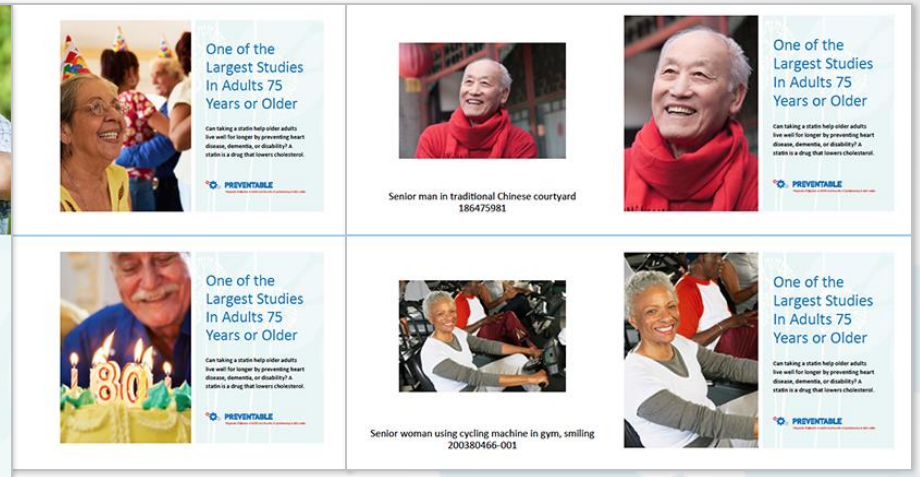
Not normal

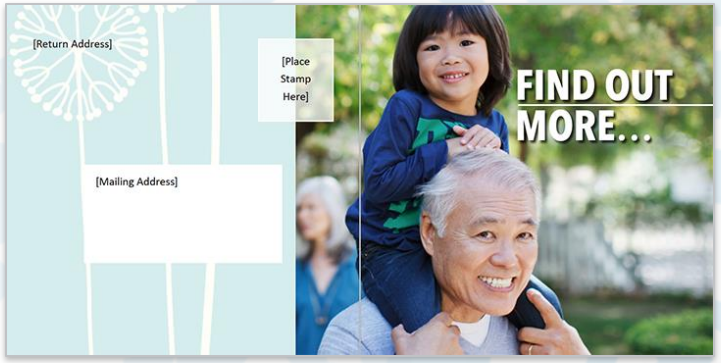
Recruitment Materials

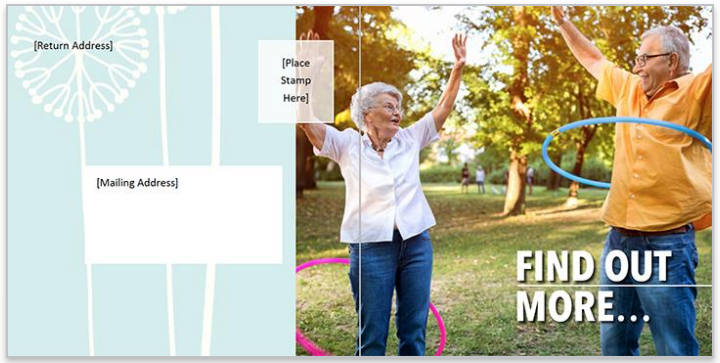
Materials

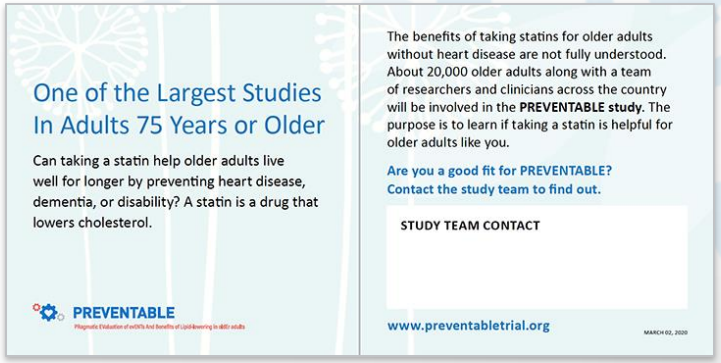
- Poster
- Flyer
- Curated images
- Brochures
- Wallet card
- Participant recruitment letter
- MyChart message
- Library of images to customize templates

Site access through study website









PREVENTABLE

Recruitment Strategies

Create Awareness

- Public service announcement(s)
- Advertise where seniors live, work and play
- National recruitment campaign
- Website presence

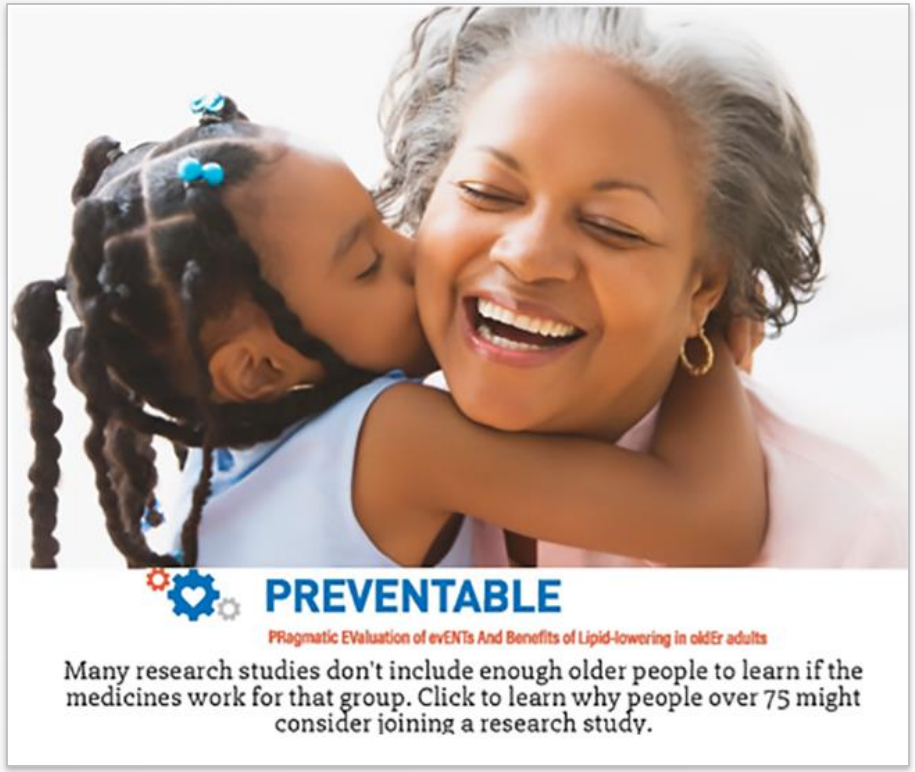
Engage Participants

- Multi-level/touch participants and racial/ethnic populations
- Partnerships with community-based organizations
- Identify value proposition for participants

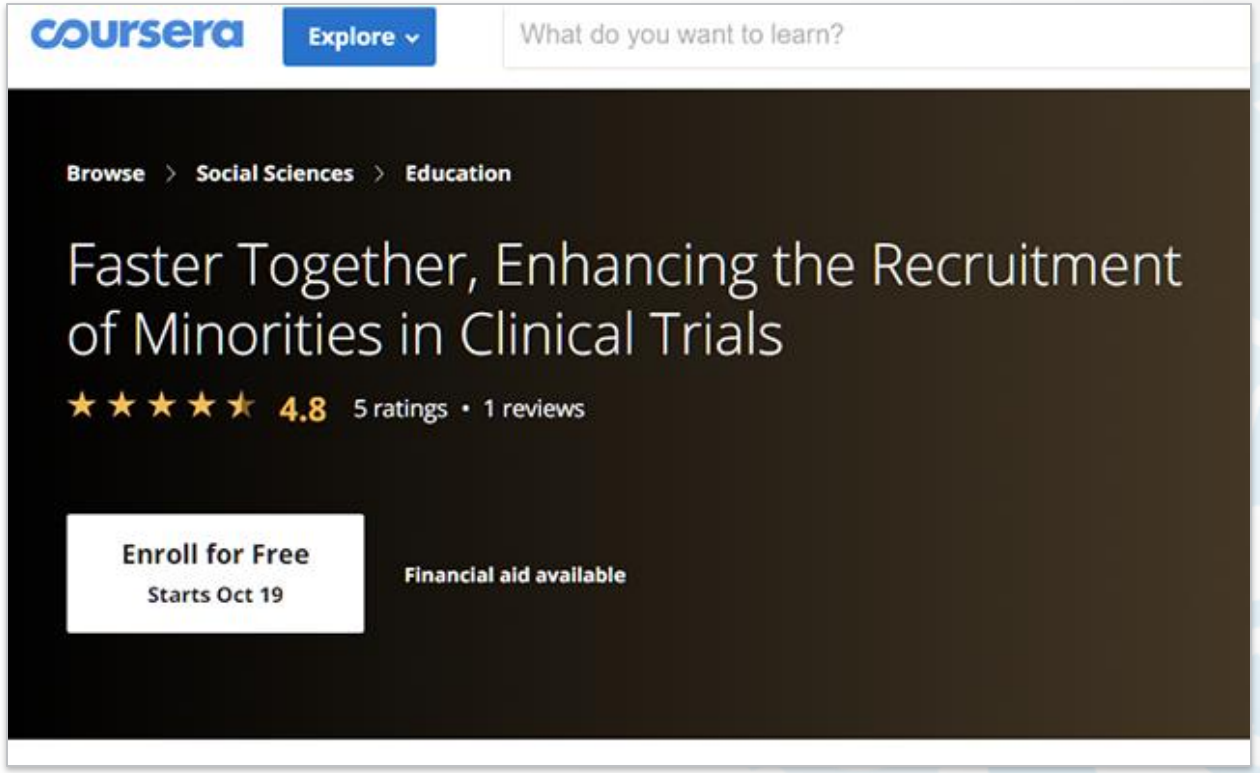
Engage Clinicians

- Multi-level/touch approach to sites
- Regular communication with site PIs and champions
- Identify value propositions for clinicians

Online Recruitment Toolkit



Repository of Recruitment Materials



Training Resources

Role of Clinicians and the Practice Sites

- Identify space where a coordinator from the study team can meet with patients and caregivers to introduce the study and enroll them.
- Mention the PREVENTABLE study to potential participants and refer those who are interested to the study team.
- Provide potential participants with information about the study including the study team's contact information.
- Answer questions patients and caregivers may have about PREVENTABLE.
- Contact the study team for any clinical changes that may be related to atorvastatin.

Central and Site Follow-up Partnership

	CENTRAL	SITE
Drug renewal	Shipping direct to participant	Annual renewal confirmation
Retention	Newsletters, community connections	Clinical support and equipoise
Lost to follow-up	Unable-to-contact list	Track down via EHR or local contact

PREVENTABLE

Study Drug: Direct to Participant

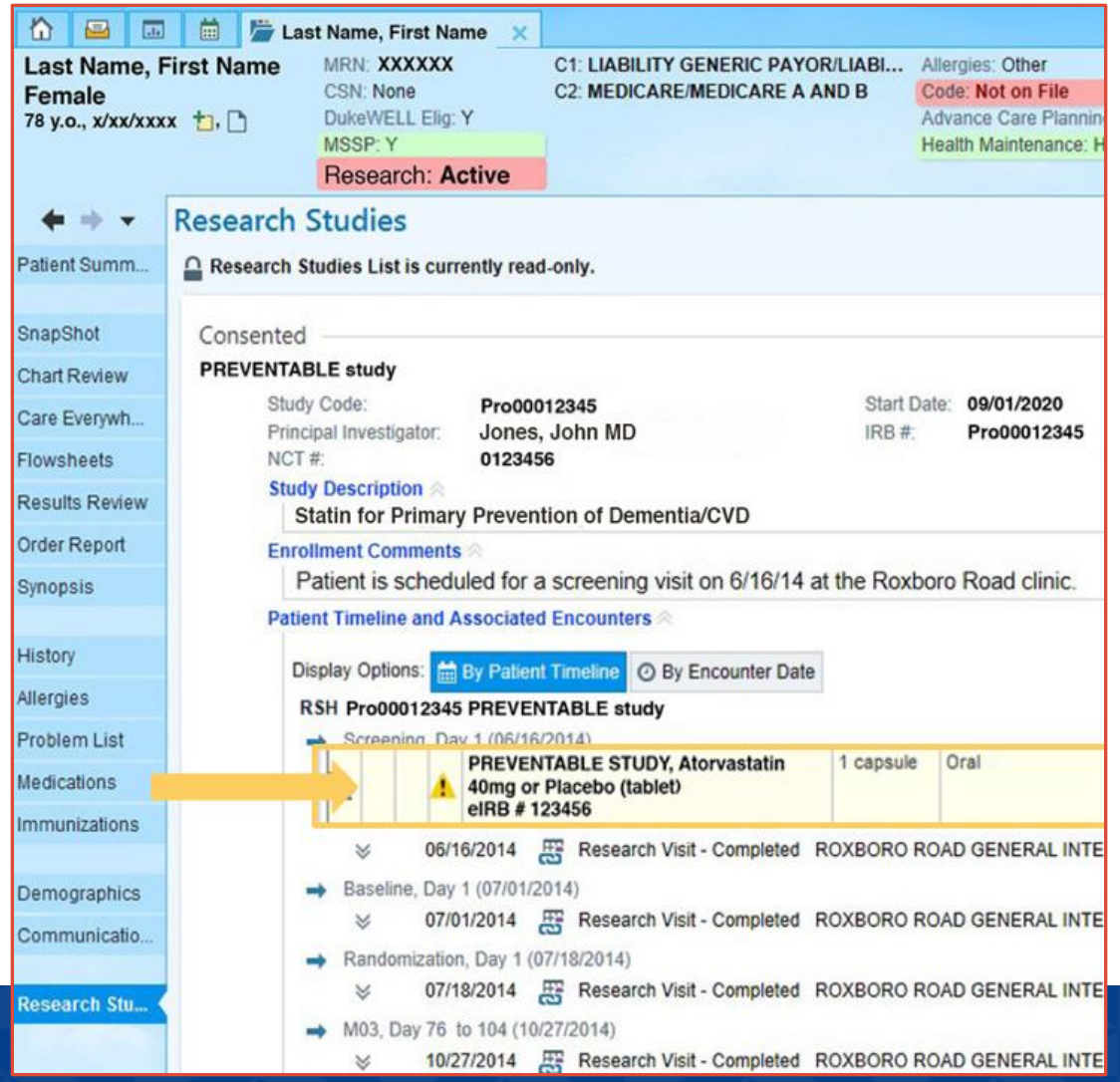
1. Informed consent is uploaded to study system
2. Randomization assignment, with select clinical information and address, is sent from study system

- *PCC pharmacist logs on and reviews order* and ICF
- Order is prepared according to assignment and verified by PCC pharmacist
- Order is shipped directly to participant via USPS priority mail with 2-day delivery

This process is anticipated to require 4-5 business days.

Electronic health record for adherence

- Easy to identify and keep the blind
- Keep study on clinician's minds
- Build modules for implementation across VA, CERNER, EPIC
- Alerts if ordering lipid panel



Endpoint Ascertainment

Use multiple sources for endpoint ascertainment

PRIMARY ENDPOINT
MCI/dementia, disability

Call Center

+

Hawthorne Effect
(if triggered)

KEY SECONDARY ENDPOINTS:
CV outcomes
(MI, UA, stroke, HF hosp)

CDM (datamarts)

EHR queries

CMS queries

DEATH:
(cause-specific)

National Death Index

Site death narrative

PCORnet® Common Data Model

Lesley Curtis, PhD (Duke)

Peter Embi, MD (Vanderbilt)

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PCORnet data strategy

- Standardize data into a common data model
- Focus on data quality through data curation
- Operate a secure distributed query infrastructure
  - Develop re-usable tools to query the data
  - Send questions to the data and only return the required information
  - Capabilities to link across datasets to obtain more complete outcomes & identify potential overlap
- Learn by doing and repeat

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The PCORnet® Common Data Model

To be useful, data have to be standardized across systems. Frequent data curation and a single language enabled by the PCORnet® Common Data Model (CDM) deliver 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	

Studies can also add tables / variables to the PCORnet® CDM

Data from PCORnet® Clinical Research Networks available in the PCORnet® CDM and ready for use in research

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

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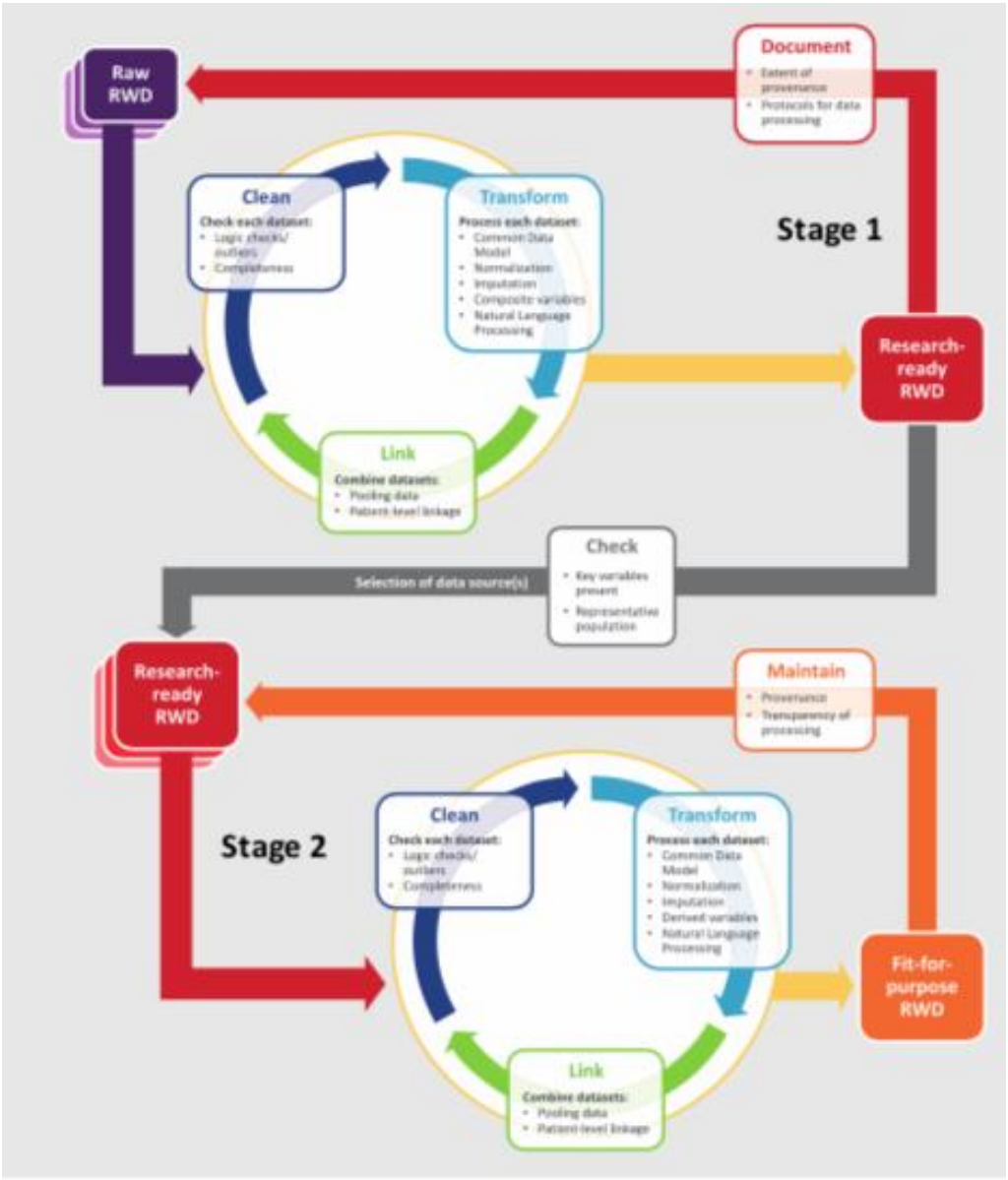
Data curation – moving from raw data to fit-for-purpose

- PCORnet follows a two-stage process to assess suitability
  - **Foundational** data curation – establish a baseline level of data quality
  - **Study-specific** – ensure data are fit-for-purpose for a given study or analysis
- Foundational data curation is not static – view as a **continuous learning cycle**
  - Continuous assessment of performance
  - Close gap between foundational and study-specific – add new data checks based on study findings



https://healthpolicy.duke.edu/sites/default/files/2020-03/characterizing_rwd.pdf

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CONFORMANCE — Data adhere to the format of the PCORnet® Common Data Model

- Fields do not contain values outside of the PCORnet® Common Data Model specification

COMPLETENESS — Values appear where we expect them

- Diagnosis codes have an associated diagnosis type (e.g., ICD-10, SNOMED)

PLAUSIBILITY — Values that appear make sense

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PERSISTENCE — Patients / records do not disappear between refreshes

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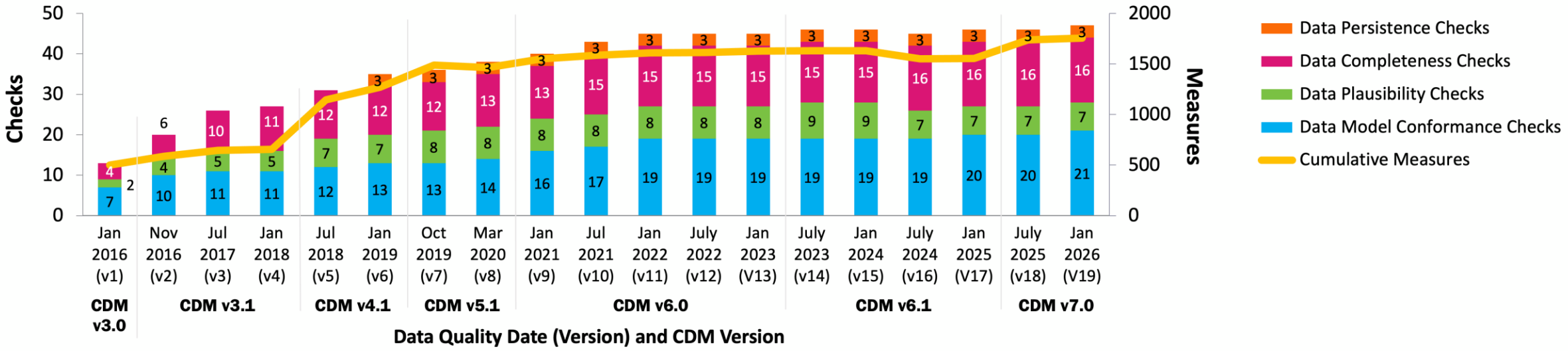
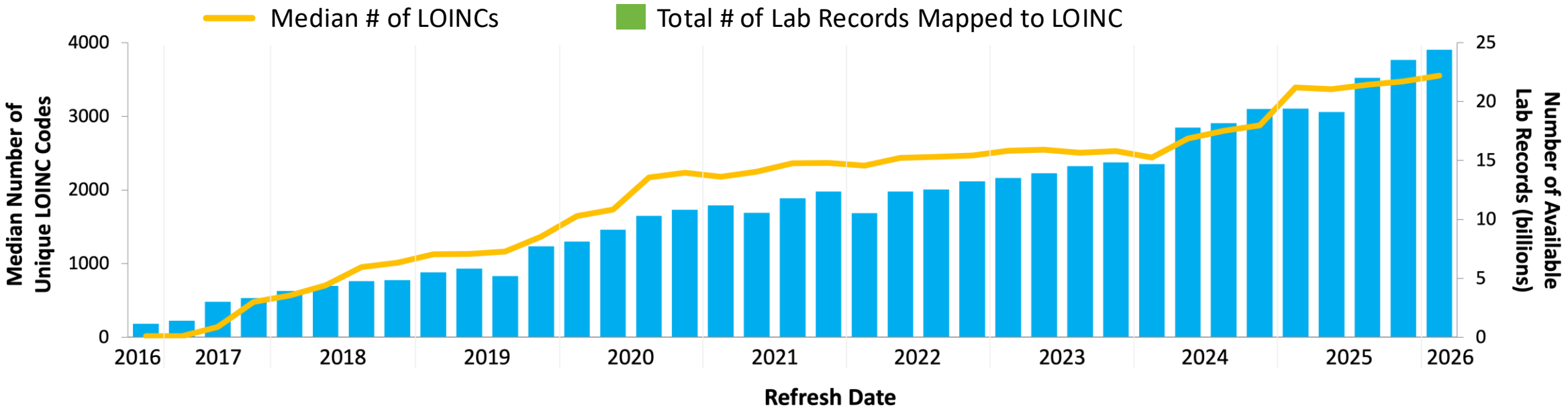


Growth in foundational data quality checks over time. Checks: Rules such as "Values must conform to PCORnet® CDM specifications."
Measures: The number of PCORnet® CDM tables and/or fields affected by the checks. Data as of February 2, 2026

Assessing Data Availability Through Data Curation

Standardization allows the Coordinating Center for PCORnet® to query all partners quickly and efficiently because the raw data have been converted to a common terminology.



Eligible DataMarts: DataMarts that include EHR data and populate the LAB_RESULT_CM table and were approved by February 2, 2026.

Note: LOINC®- the work of clinical nomenclature called Logical Observation Identifiers Names and Codes, which provides a universal code system for identifying laboratory and clinical observations and related content.

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Data as of February 2, 2026

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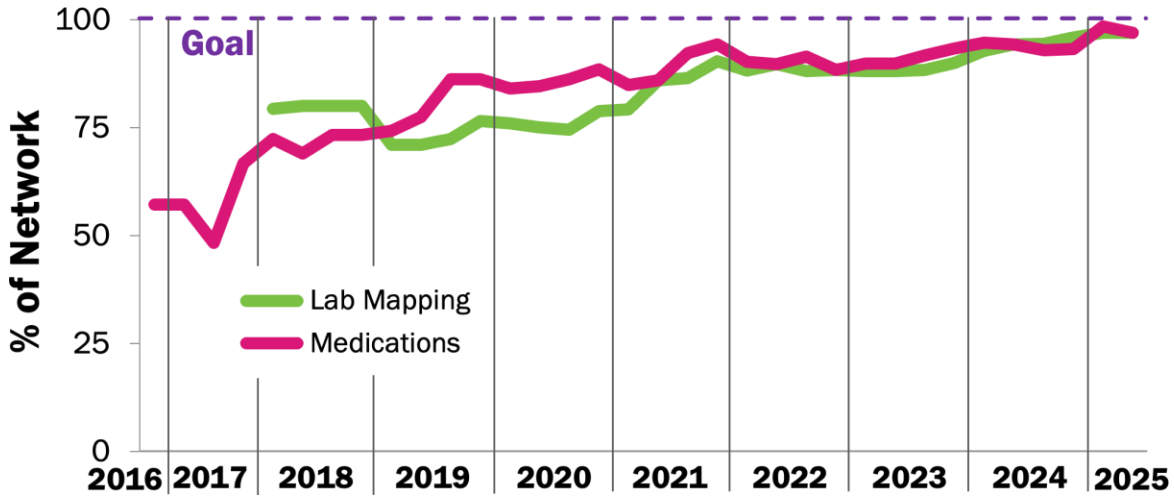
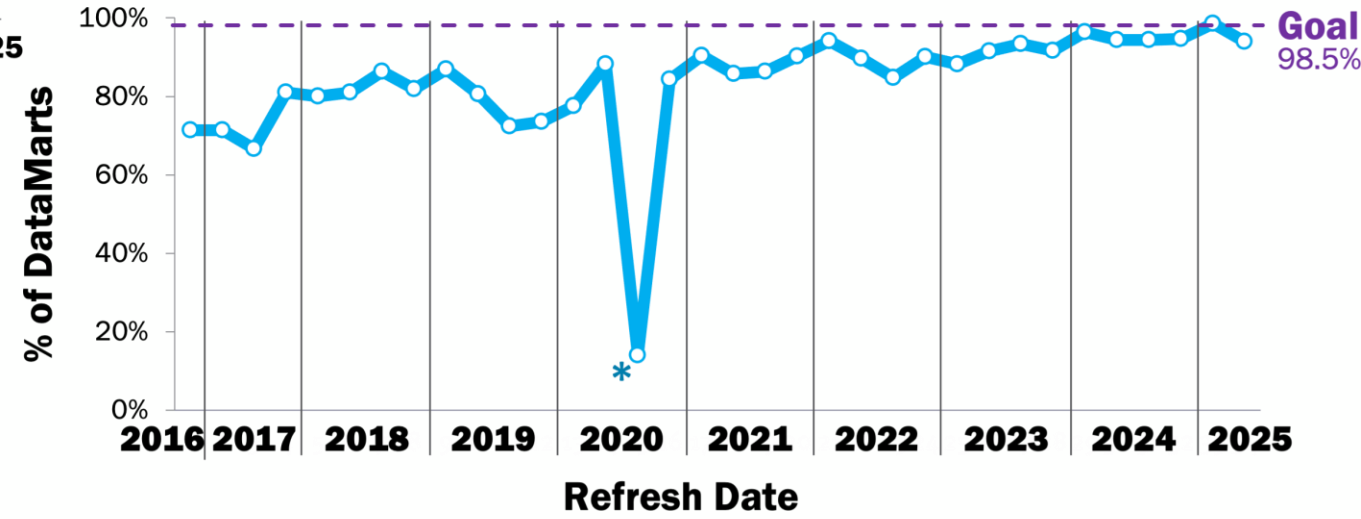
Improving network performance – data mapping & latency

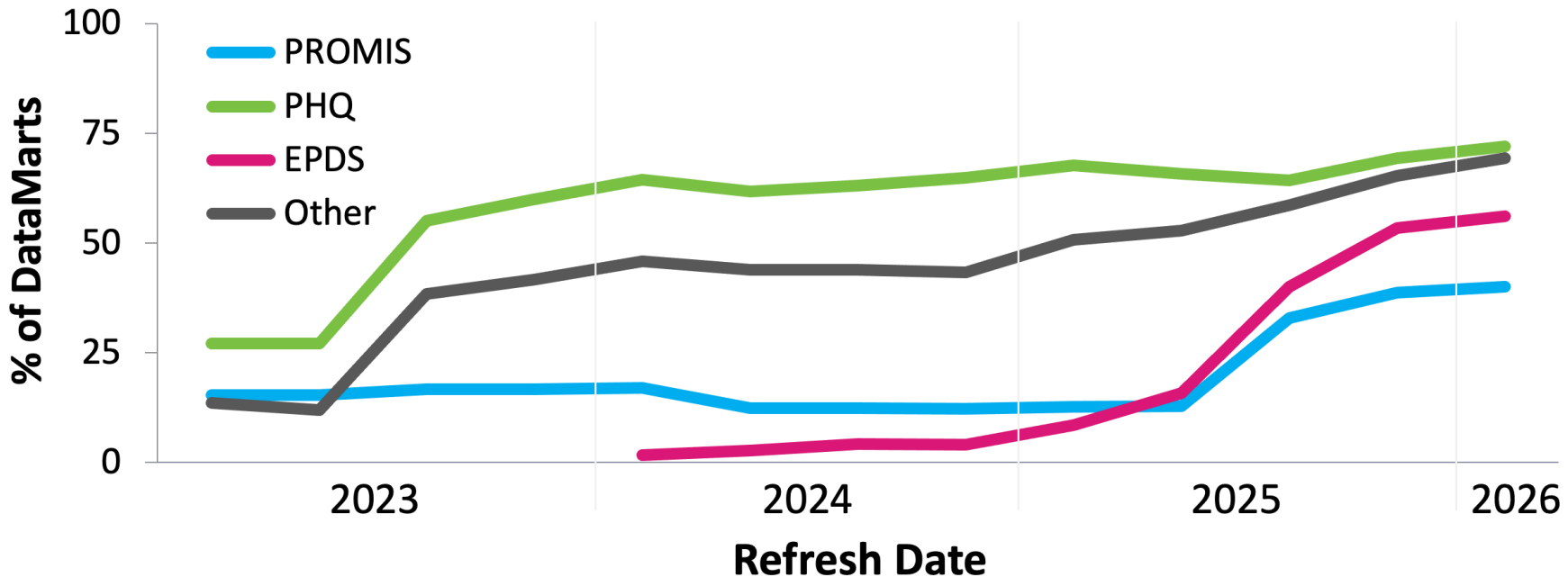




EHR DataMarts with an encounter latency of ≤ 3 months

Improvements in Patient-Reported Outcomes Data Completeness

- The PCORnet data curation process is used to monitor whether PCORnet® Clinical Research Networks are populating key concepts of interest.
- The completeness of certain patient-reported outcome measures have seen marked improvement over time.



Eligible DataMarts: DataMarts that include EHR data and populate the PRO_CM table and were approved by February 2, 2026. Note, we selected 4 PRO measures to monitor over time. These measures were chosen based on the needs of PCORnet® Studies.

Data as of February 2, 2026

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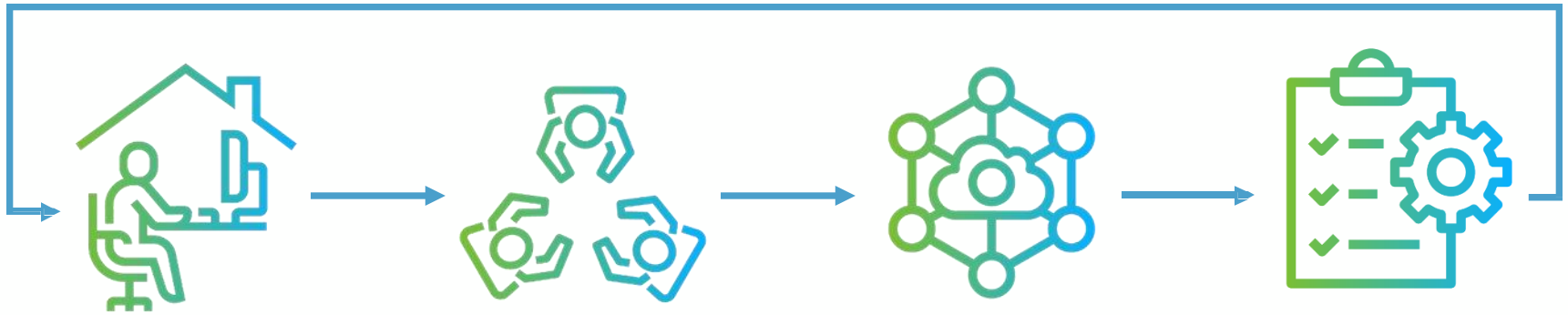
Distributed Query Infrastructure (Prep-to-Research Example)



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- **Univariate statistics from data curation**
  - The Coordinating Center for PCORnet® has access to hundreds of univariate statistics about data within each site's PCORnet® CDM
  - These results can be used answer simple questions and provide a basic overview of data availability for the aggregate PCORnet population

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- For most studies, the answer to whether enough patients exist across PCORnet is "yes"

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PCORnet® Population Insights

Each year, PCORnet connects researchers with health data from everyday healthcare encounters with nearly 47 million people nationwide through eight PCORnet® Clinical Research Networks (CRNs) and over 70 partner organizations participating in PCORnet.

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The following data visualizations illustrate a snapshot of PCORnet data resources from January 1, 2024 – December 31, 2024, unless otherwise noted.

DEMOGRAPHICS | CARE SETTING | GEOGRAPHIC

Demographics

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Data accessed through PCORnet include topical reports based on services performed by healthcare professionals in an ambulatory care or outpatient settings.

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This report describes the results of a data query of the patient population with at least 1 face-to-face encounter and a recorded diagnosis code (e.g., ICD-10) at a health care setting across PCORnet between January 1 – December 31, 2024. The query results will enhance public awareness of the population of patients across sites participating in PCORnet that potentially would be available for future health care research.

Topical Reports

Gene Therapy

Intellectual and Developmental Disabilities

Maternal Morbidity and Mortality

Mental and Behavioral Health

Pediatric Population

Telehealth

Women's Health

Your research can go further, faster with PCORnet. Start the conversation about how the network can support your research at the PCORnet® Front Door.

KNOCK ON THE PCORNET® FRONT DOOR TO GET STARTED

PCORnet Query Types – Study Queries

- **Study-specific data extracts**
  - Extracts of patient-level data for defined cohorts
  - Can be based on inclusion/exclusion criteria (e.g., observational study) or for enrolled participants (e.g., pragmatic trial)

- We also recommend **study-specific data characterization**
  - Each study operates on specific variables
  - General characteristics do not predict specific characteristics
  - Study-focused assessment of data fitness is critical

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Study-specific data extracts

- Cost of queries will depend on several factors
  - Number of sites and number of extracts/year
  - Whether the query requires data elements that are not included in the PCORnet® CDM and the degree of standardization of those data in the EHR (e.g., pulmonary function tests, flowsheets, ventilator use)

- Even with the current content of the PCORnet® CDM, studies may still need to obtain supplemental data
  - Loading condition-specific variables into the PCORnet® CDM
  - Chart abstraction
  - Prospective data collection
  - Linkage to external sources

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Record Linkage Within PCORnet

- Through a strategic collaboration, PCORnet® Network Partners worked to establish a **secure** and **standardized** privacy-preserving record linkage (PPRL) infrastructure that is **reusable** and **scalable**
- Each PCORnet network site uses software that converts identifiers into **de-identified tokens** that can be securely shared with the Coordinating Center
- These tokens can be used to deduplicate patients and/or link with other sources:
  - Administrative claims
  - Data from health registries
  - Other healthcare systems
  - Other real-world data sources

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CRN / site perspective

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Questions?

139

PCORnet® Common Data Model

Keith Marsolo, PhD

Department of Population Health Sciences
Duke Clinical Research Institute
Duke University School of Medicine

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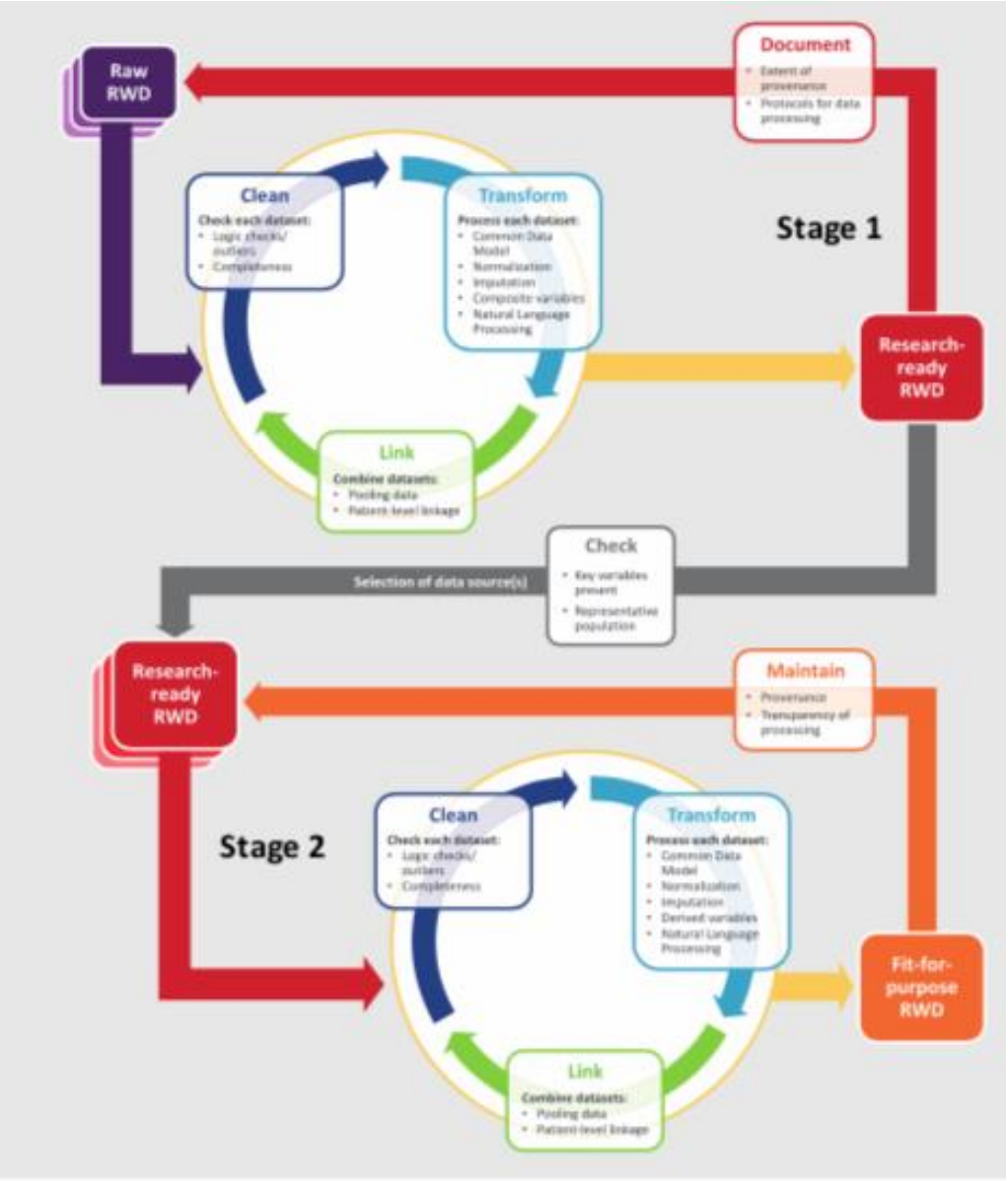

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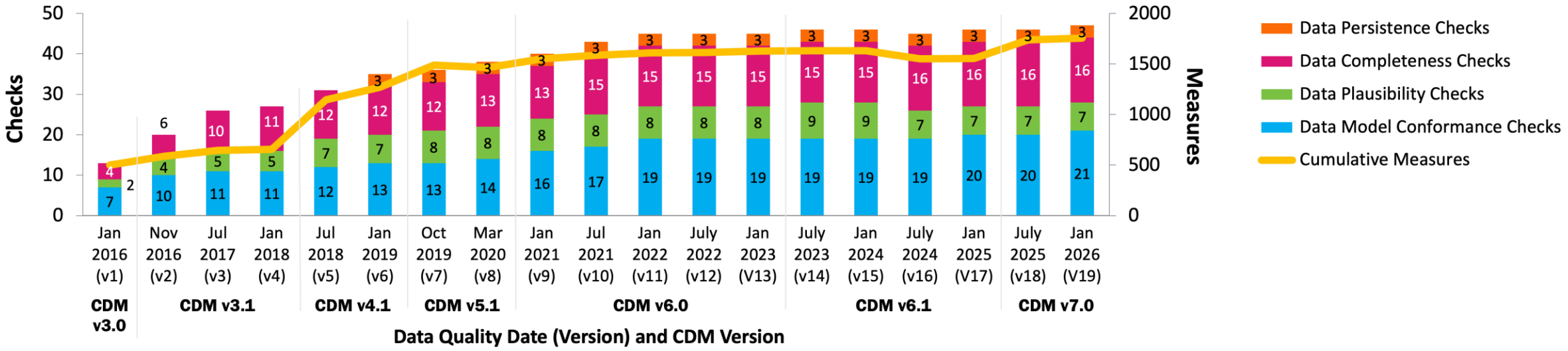

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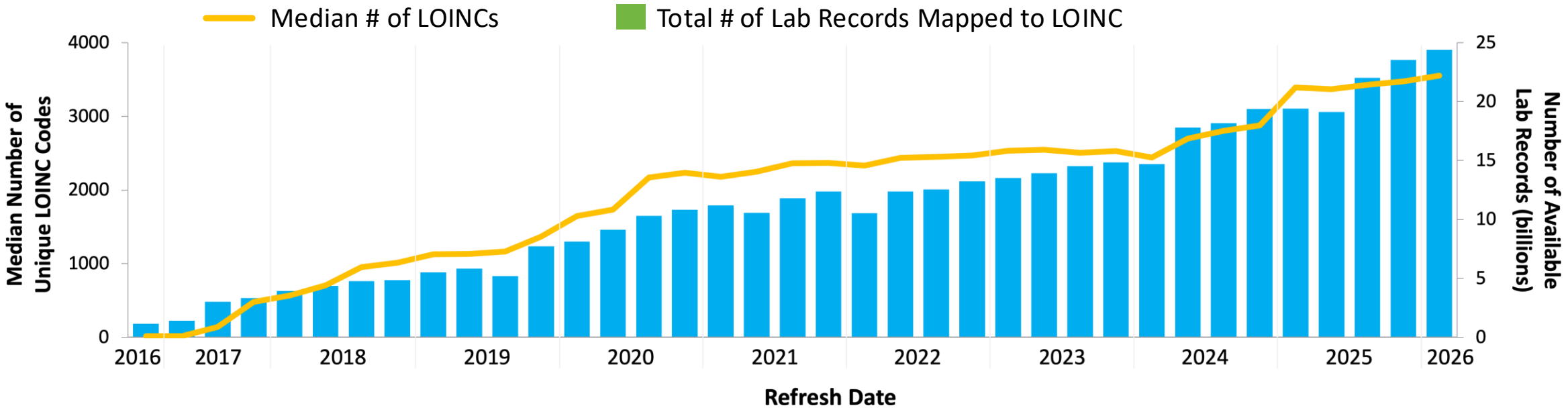

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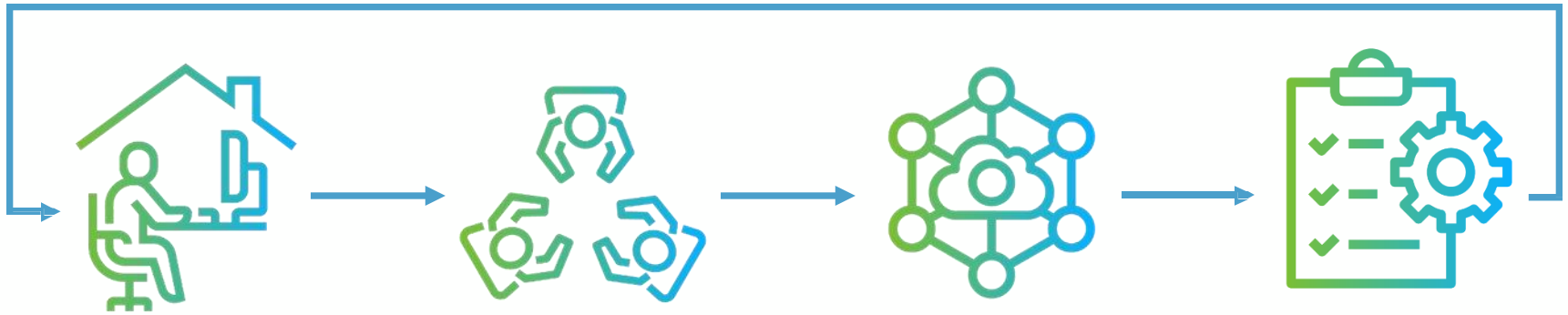

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PCORnet is a large, distributed "network of networks" funded by PCORI to improve the nation's capacity to efficiently conduct health research, particularly patient-centered comparative clinical effectiveness research (CER).

At the time of this report, PCORnet® Network Partners include PCORnet® Clinical Research Networks (CRNs) with more than 70 data-contributing sites in addition to patient partners and the Coordinating Center for PCORnet®. Collectively, these data-contributing sites consist of more than thirteen thousand clinical sites connected to nearly 47 million patients in the U.S. Clinical sites include large academic health systems, hospitals, federally qualified health centers, and community clinics.

This report describes the results of a data query of the patient population with at least 1 face-to-face encounter and a recorded diagnosis code (e.g., ICD-10) at a health care setting across PCORnet between January 1 – December 31, 2024. The query results will enhance public awareness of the population of patients across sites participating in PCORnet that potentially would be available for future health care research.

Topical Reports

Gene Therapy

Intellectual and Developmental Disabilities

Maternal Morbidity and Mortality

Mental and Behavioral Health

Pediatric Population

Telehealth

Women's Health

Your research can go further, faster with PCORnet. Start the conversation about how the network can support your research at the PCORnet® Front Door.

KNOCK ON THE PCORNET® FRONT DOOR TO GET STARTED

PCORnet Query Types – Study Queries

- **Study-specific data extracts**
  - Extracts of patient-level data for defined cohorts
  - Can be based on inclusion/exclusion criteria (e.g., observational study) or for enrolled participants (e.g., pragmatic trial)

- We also recommend **study-specific data characterization**
  - Each study operates on specific variables
  - General characteristics do not predict specific characteristics
  - Study-focused assessment of data fitness is critical

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Study-specific data extracts

- Cost of queries will depend on several factors
  - Number of sites and number of extracts/year
  - Whether the query requires data elements that are not included in the PCORnet® CDM and the degree of standardization of those data in the EHR (e.g., pulmonary function tests, flowsheets, ventilator use)

- Even with the current content of the PCORnet® CDM, studies may still need to obtain supplemental data
  - Loading condition-specific variables into the PCORnet® CDM
  - Chart abstraction
  - Prospective data collection
  - Linkage to external sources

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Record Linkage Within PCORnet

- Through a strategic collaboration, PCORnet® Network Partners worked to establish a **secure** and **standardized** privacy-preserving record linkage (PPRL) infrastructure that is **reusable** and **scalable**
- Each PCORnet network site uses software that converts identifiers into **de-identified tokens** that can be securely shared with the Coordinating Center
- These tokens can be used to deduplicate patients and/or link with other sources:
  - Administrative claims
  - Data from health registries
  - Other healthcare systems
  - Other real-world data sources

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Using PCORnet for Observational Comparative Effectiveness/Harm Studies in Obesity

Jason Block, MD, MPH

Director, Division of Chronic Disease Research Across the Lifecourse (CoRAL); Associate Professor

Department of Population Medicine

Harvard Pilgrim Health Care Institute

Harvard Medical School

April 16, 2026

PCORnet began supporting observational research on weight outcomes in 2015

- PCORI funded the *Antibiotics and Childhood Growth Study* and the *PCORnet Bariatric Study* to help build research capacity for observational research
- Antibiotics study explored the association of antibiotic prescriptions in the first 2 years of life with weight outcomes in mid and later childhood
- Found limited association of antibiotic use with higher fixed weight at ages 4-6 and 9-11 yrs, with higher growth trajectories as well; no association of maternal antibiotics
- Set stage for further research on risk factors for weight gain across the lifecourse; recommended by stakeholders

Block, et al., 2018; Heerman, et al., 2019; Aris, et al., 2021; Rifas-Shiman, et al., 2021; Bailey, et al., 2022.

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The MedWeight Study

- Several classes of prescription medications are associated with weight gain
- Few long-term comparative studies are available using real-world data
- Explored comparative weight change among medications: antidepressants, antipsychotics, antiseizure medications, diabetes medications, and antihypertensives in adults and children – 15 PCORnet sites

Sun, et al., 2022; Rifas-Shiman, et al. 2022; Lin, et al., 2024; Petimar, et al., 2024.

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Moving from concept to study in PCORnet

- Front Door query essential to assess availability of data by site; can help you select sites and determine whether available data could support your research idea
- No funding mechanism will support use of data from all sites – need to select ones that will best serve your needs
- Model emerging that will allow you to select lead sites (Co-I with effort, stakeholders, $ to support queries) and performance sites (data contributing sites, $ to support sites)
- MedWeight had 4 lead sites and 11 performance sites

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The work takes longer than you expect

- Budget for sufficient data quality work because data you receive still needs to be cleaned/assessed in detail
- In MedWeight, 3 data queries in first few years but took several additional years to complete work, iron out details of the analytics
- PCORnet provides great opportunities for custom datasets that can be developed in collaboration with sites
- Studies are best when doing comparative work; exposure compared to no exposure may be less reliable because of healthcare fragmentation and confounding

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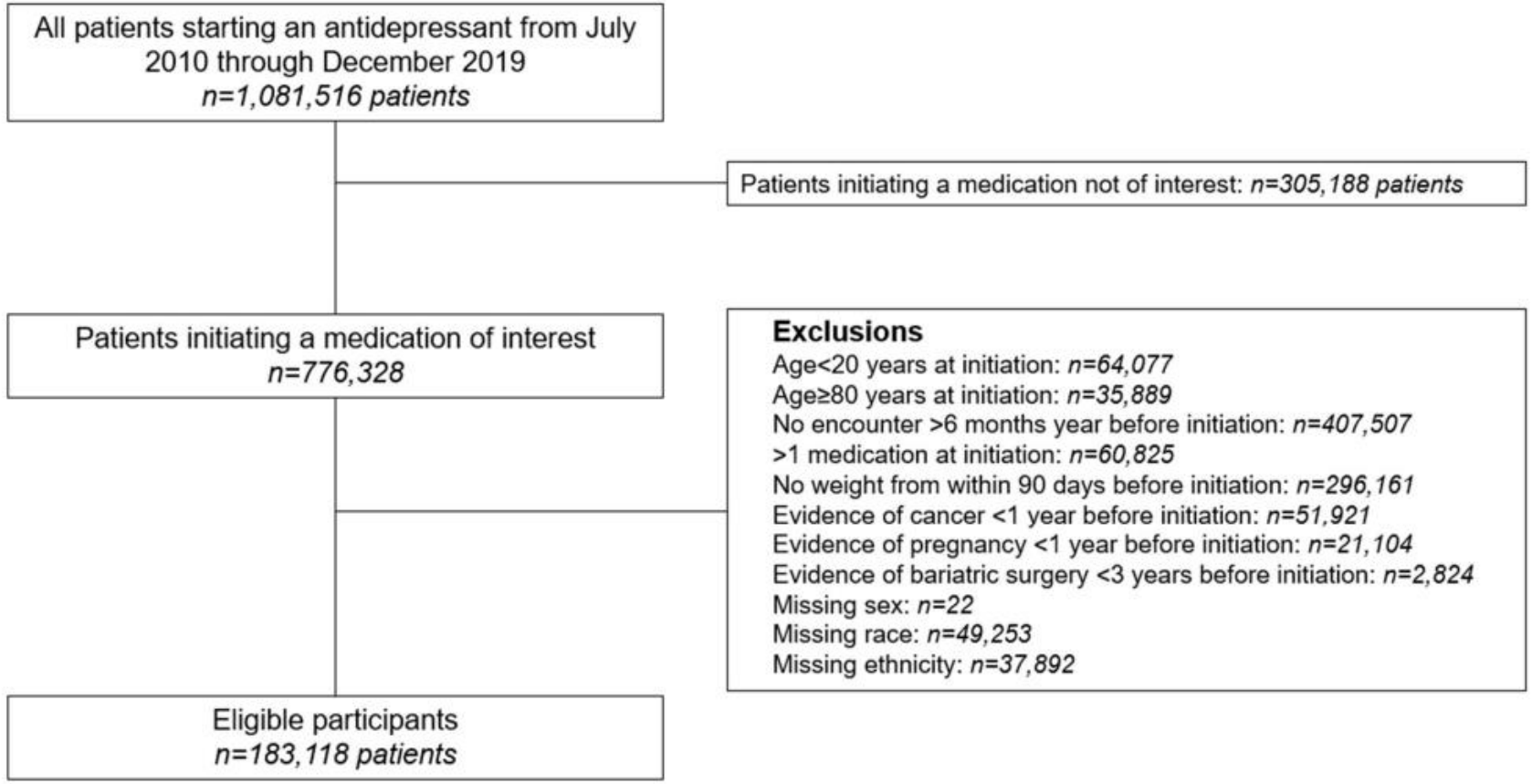
Details of study of antidepressants and weight change, Petimar, et al. Annals of Internal Medicine, 2024

Participant flowchart



Note: Patients could meet more than 1 exclusion criterion

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Characteristics of the study population

Characteristic	Percent
Female	65%
White	79%
Black	15%
Hispanic	7%
Overweight or obesity	70%
Depression diagnosis	36%
Anxiety diagnosis	39%
Neuropathic pain diagnosis	16%

Initiated treatment	Percent
Sertraline	20%
Citalopram	16%
Bupropion	15%
Escitalopram	14%
Fluoxetine	13%
Duloxetine	11%
Venlafaxine	7%
Paroxetine	4%

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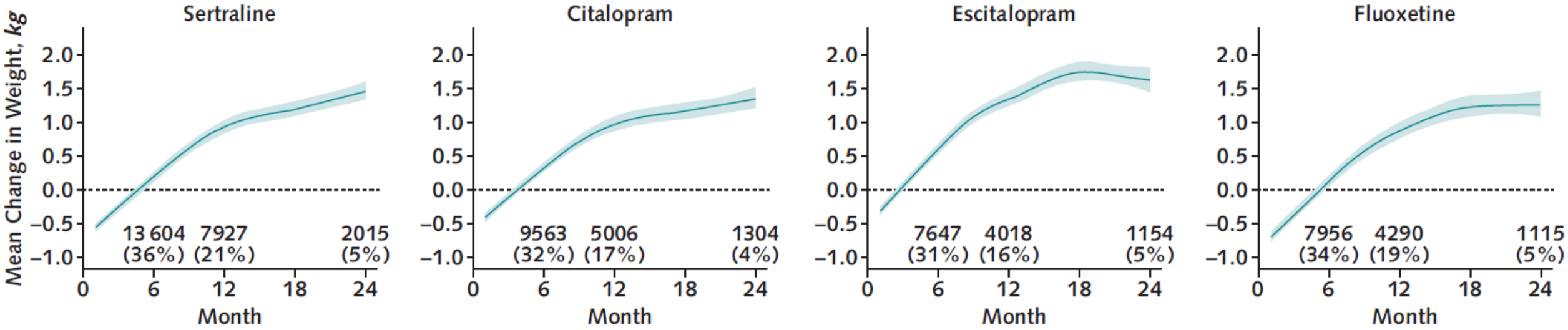
Petimar J et al., 2024.

Weight gain for most medications (ITT analysis)



6-month weight change:
0.21 kg (0.14, 0.28)

6-month weight change:
0.33 kg (0.27, 0.41)

6-month weight change:
0.63 kg (0.55, 0.71)

6-month weight change:
0.14 kg (0.06, 0.23)

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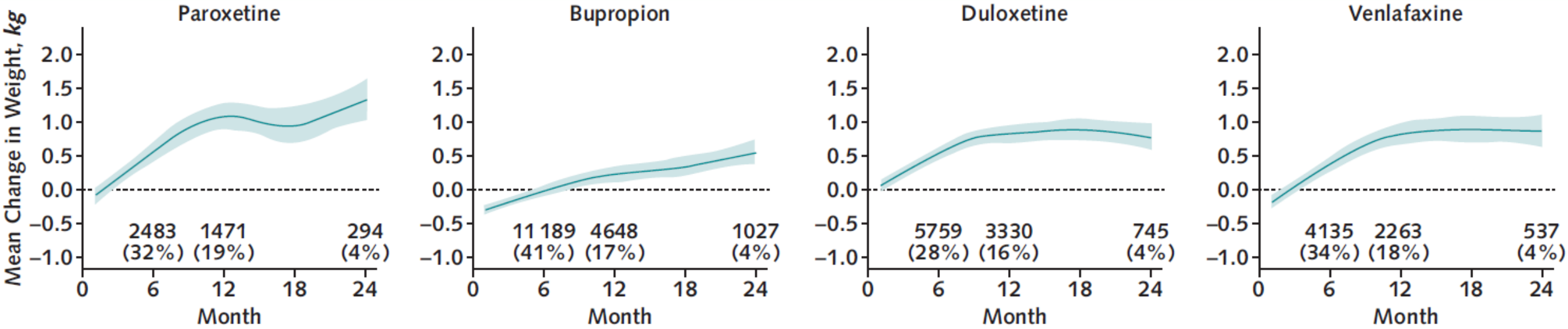
Weight gain for most medications (ITT analysis)



6-month weight change:
0.58 kg (0.43, 0.73)

6-month weight change:
-0.01 kg (-0.09, 0.07)

6-month weight change:
0.55 kg (0.45, 0.64)

6-month weight change:
0.34 kg (0.28, 0.50)

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Comparative weight change estimates are most relevant

Treatment	6 Months
Mean weight change (95% CI), *kg*	
Sertraline	0.00 (Reference)
Citalopram	0.12 (0.02 to 0.23)
Escitalopram	0.41 (0.31 to 0.52)
Fluoxetine	−0.07 (−0.19 to 0.04)
Paroxetine	0.37 (0.20 to 0.54)
Bupropion	−0.22 (−0.33 to −0.12)
Duloxetine	0.34 (0.22 to 0.44)
Venlafaxine	0.17 (0.03 to 0.31)
Risk ratio for gaining ≥5% of baseline weight (95% CI)	
Sertraline	1.00 (Reference)
Citalopram	1.01 (0.97 to 1.06)
Escitalopram	1.15 (1.10 to 1.20)
Fluoxetine	0.98 (0.93 to 1.03)
Paroxetine	1.14 (1.06 to 1.22)
Bupropion	0.85 (0.81 to 0.89)
Duloxetine	1.10 (1.04 to 1.15)
Venlafaxine	1.02 (0.96 to 1.08)

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Petimar J et al. (submitted)

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Duloxetine	1.10 (1.04 to 1.15)
Venlafaxine	1.02 (0.96 to 1.08)

Average of 0.41 kg increase at 6 months on escitalopram vs. sertraline

On escitalopram, there is a 14% increased risk of gaining at least 5% of baseline weight vs. sertraline

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Petimar J et al. (submitted)

Healthcare data has some challenges though

- Fragmented nature of healthcare delivery in the US prevents longitudinal capture of all clinical events for individuals, esp for EHR data
- Limited data linkage between claims and EHR data prevent comprehensive examination of care, even within a single institution
- Data quality is highly variable across sites; data not collected for research purposes and doesn't follow a rigorous, standardized collection process
- Dose and other granular information often missing; challenging to use information beyond coded fields; socioeconomic data limited
- Missingness is common; might be worse for absence of evidence (e.g., diagnoses, prescriptions, vaccines) rather than clear knowledge of missingness

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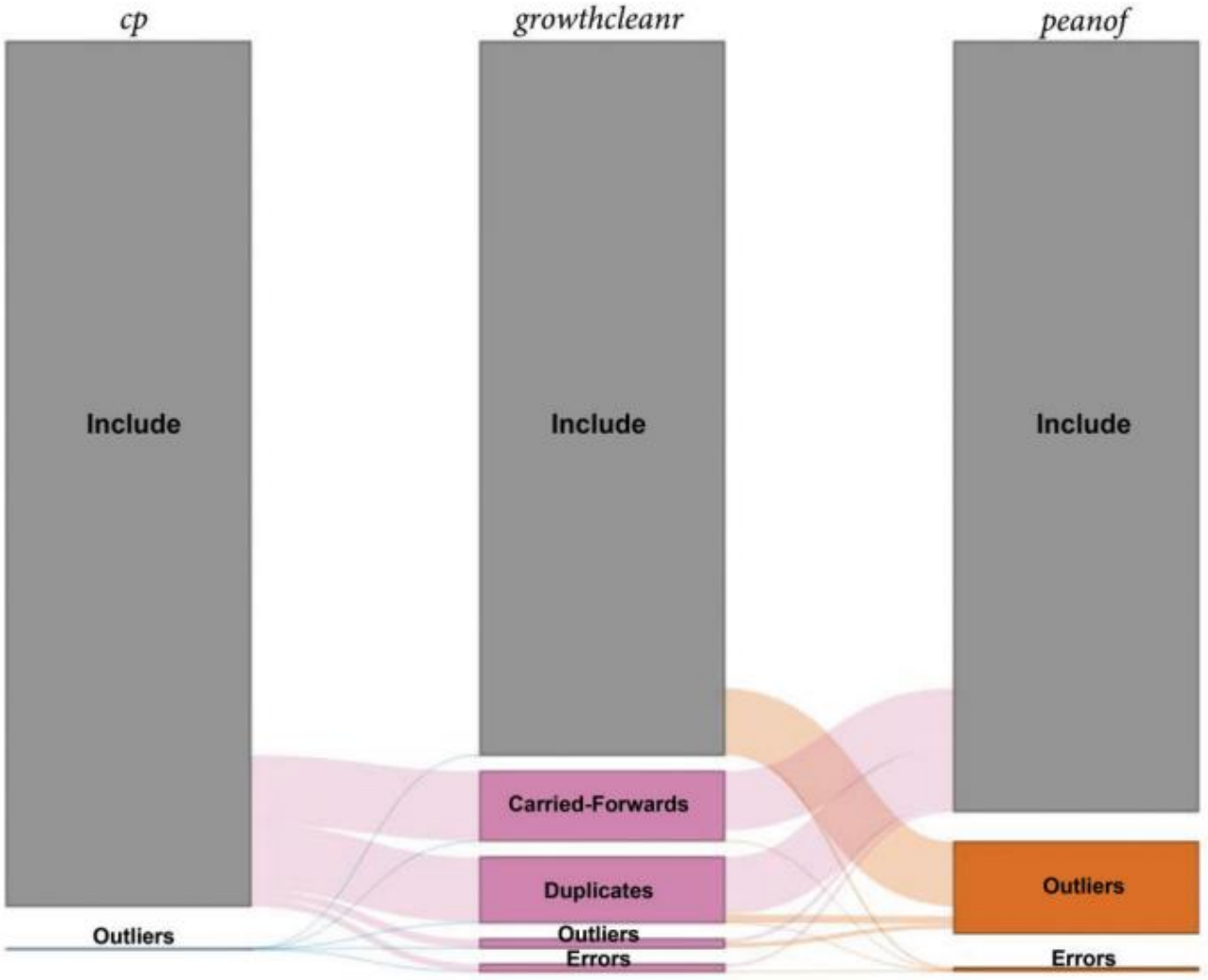
Weights included in varied data cleaning approaches – Lin, et al



Acknowledgments

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  - Lauren Cleveland, Chamaine Washington, Juliane Reynolds, Bridget Nolan,

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- Many others supporting queries, project management!!

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Thank you.

Jason Block, jblock1@mgb.org

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to get the relationship started.

Extra Slides

Comparative effectiveness and harm studies in obesity

- RCTs are the gold standard and provide incredibly valuable information
- Limitations of RCTs are in generalizability and sample size available to account for variations in the exposure (multiple exposures) and heterogeneity of treatment effects
  - RCTs are very expensive and take a long time to complete as well!
- RCTs also typically do not mirror real clinical practice though pragmatic trials get closer to this ideal
- Increasing opportunities to use sophisticated methods and large research networks to supplement RCTs; weight routinely available in electronic health records
- The need for timely data is enormous

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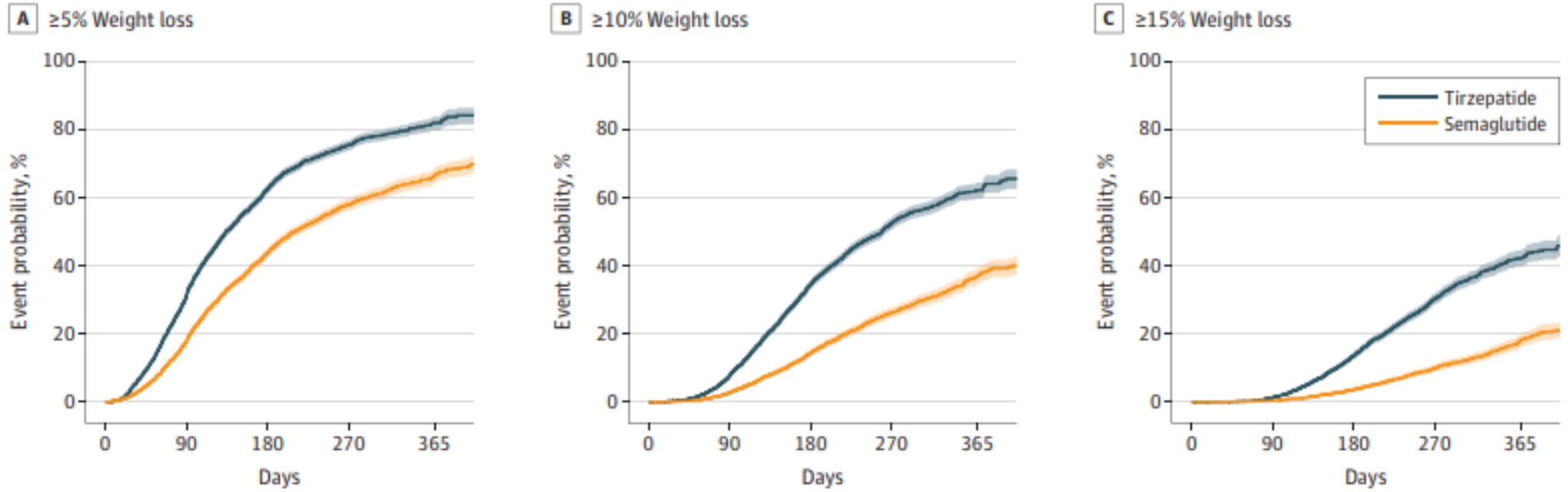
Recent study on comparative effectiveness



Rodriguez, et al., 2024.

Can look at longer term results but data becomes spares

Table 4. Weight Change Difference and Relative Risk for Gaining ≥5% of Baseline Weight at 6, 12, and 24 Months After Initiating Antidepressant Treatment Compared With Sertraline: Intention-to-Treat Analysis*

Treatment	6 Months	12 Months	24 Months
Mean weight change (95% CI), *kg*			
Sertraline	0.00 (Reference)	0.00 (Reference)	0.00 (Reference)
Citalopram	0.12 (0.02 to 0.23)	0.03 (−0.12 to 0.19)	−0.11 (−0.33 to 0.11)
Escitalopram	0.41 (0.31 to 0.52)	0.41 (0.25 to 0.56)	0.16 (−0.08 to 0.40)
Fluoxetine	−0.07 (−0.19 to 0.04)	−0.06 (−0.22 to 0.10)	−0.20 (−0.45 to 0.05)
Paroxetine	0.37 (0.20 to 0.54)	0.15 (−0.08 to 0.37)	−0.14 (−0.46 to 0.21)
Bupropion	−0.22 (−0.33 to −0.12)	−0.71 (−0.87 to −0.55)	−0.91 (−1.14 to −0.66)
Duloxetine	0.34 (0.22 to 0.44)	−0.11 (−0.29 to 0.04)	−0.69 (−0.93 to −0.43)
Venlafaxine	0.17 (0.03 to 0.31)	−0.12 (−0.30 to 0.08)	−0.59 (−0.87 to −0.32)
Risk ratio for gaining ≥5% of baseline weight (95% CI)			
Sertraline	1.00 (Reference)	1.00 (Reference)	1.00 (Reference)
Citalopram	1.01 (0.97 to 1.06)	1.02 (0.98 to 1.06)	1.00 (0.96 to 1.05)
Escitalopram	1.15 (1.10 to 1.20)	1.10 (1.06 to 1.15)	1.01 (0.96 to 1.06)
Fluoxetine	0.98 (0.93 to 1.03)	0.96 (0.92 to 1.01)	0.96 (0.92 to 1.01)
Paroxetine	1.14 (1.06 to 1.22)	1.03 (0.95 to 1.09)	0.96 (0.90 to 1.03)
Bupropion	0.85 (0.81 to 0.89)	0.78 (0.75 to 0.82)	0.86 (0.81 to 0.90)
Duloxetine	1.10 (1.04 to 1.15)	1.00 (0.95 to 1.04)	0.92 (0.87 to 0.97)
Venlafaxine	1.02 (0.96 to 1.08)	0.95 (0.89 to 1.00)	0.90 (0.85 to 0.96)

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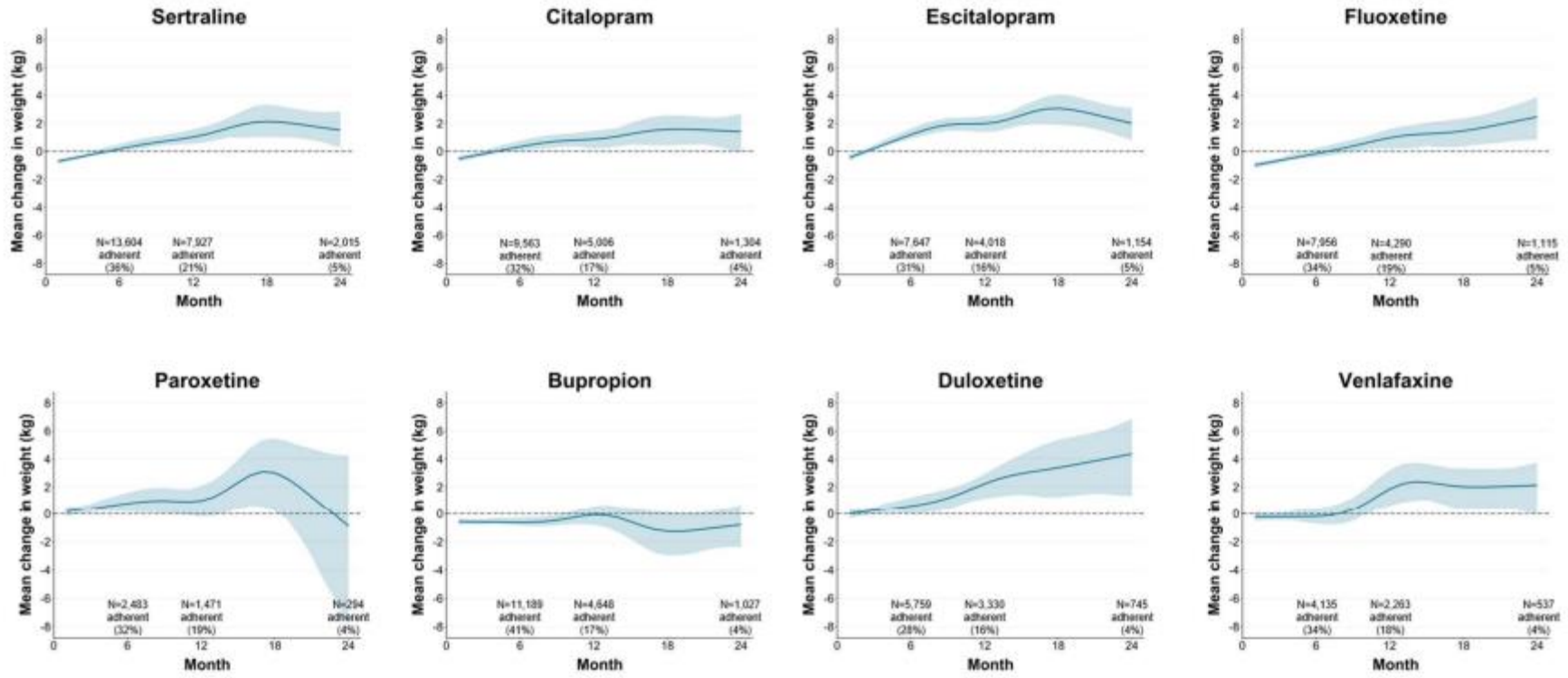
Petimar J et al. (submitted)

Slightly stronger but less precise results in per-protocol



Petimar J et al. (submitted)