Advisory Panel on Clinical Trials Spring 2014 Meeting

Alexandria, VA

May 1, 2014 – 8:30 a.m. to 5:30 p.m. EST

Patient-Centered Outcomes Research Institute

Welcome and Plans for the Day

Joe V. Selby, MD, MPH
Executive Director, PCORI

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Housekeeping

- Today's webinar is open to the public and is being recorded.
- Members of the public are invited to listen to this teleconference and view the webinar.
- Anyone may submit a comment through the webinar chat function or by emailing advisorypanels@pcori.org.
- Visit www.pcori.org/events for more information.

Today's Agenda

Start Time	Item	Speaker
8:30 a.m.	Conflict of Interest Disclosures	J. Selby
8:45 a.m.	Roles & Goals of Panel	B. Luce
9:15 a.m.	CTAP and MC	R. Newhouse
10:00 a.m.	PCORI's Clinical Trials Portfolio and Plans	D. Hickam S. Clauser A. Anise S. Ip R. Fleurence
12:00 p.m.	Lunch	
1:00 p.m.	Open Discussions	D. Hickam
4:15 p.m.	Organizational Issues	B. Luce
5:00 p.m.	Post-Event Survey	
5:15 p.m.	Recap and Next Steps	B. Luce
5:30 p.m.	Adjourn	

Meeting Objectives

- Introduce PCORI staff & CTAP panelists
- Clarify panel roles & objectives
- Introduce PCORI's clinical trials research portfolio
- Agree on panel's scope of work
- Discuss organization issues, including leadership

Conflicts of Interest

Joe V. Selby, MD, MPH
Executive Director, PCORI

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Why is COI Important?

- PCORI has a legal obligation to publicly disclose conflict of interest statements for members of the Board, Methodology Committee, Advisory Panels and executive staff as well as in an annual report to Congress and the President.

- Transparency is important because it gives the public information about backgrounds and relationships that may inform actions.

What should you disclose?

- If you have financial or personal relationships that may have the potential to bias or have the appearance of biasing your decisions, you should disclose them.

Disclose, for example:

  - Employment
  - Financial income, such as stock, honoraria, consulting fees, etc.
  - Memberships/Leadership positions in other health care organizations
- Disclose as it relates to yourself, your spouse, domestic partner, children, parents, and others indicated.

Conflict of Interest Session

Next Steps

Each panel has a few minutes on their agenda for each panelist to fill out a COI disclosure form.

We will provide you with guidelines and formatting, and Staff will be available to answer any questions you may have about filling out the COI disclosure form.

Questions?

Roles and Goals of the Advisory Panel on Clinical Trials

Bryan Luce, PhD, MBA
Chief Science Officer, PCORI

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Charter – Purpose

The CT panel will provide recommendations to:

- PCORI
- Agencies, instrumentalities, or other entities conducting research through the PCORI Methodology Committee

This advice will pertain to clinical trials for PCOR, including their:

- Selection
- Research design
- Implementation
- Technical issues

Note: The CT Panel will not serve in an official decision-making capacity.

Charter – Scope of Work

The CT panel will provide guidance on:

- Methodological standards
- Priority areas for development of clinical trial methodology;
- Baseline review of proposed trials and ongoing oversight of funded trials
- Guidance on the selection of appropriate study outcomes
- Human subjects issues
- Strategies for designing clinical trials
- Approaches to data analysis
- Periodic evaluation of PCORI's clinical trials portfolio
- Readiness of trial results for dissemination or implementation

CTAP Subcommittees

Special issues for the subcommittees to examine may include, but are not limited to:

- Addressing specific methodological designs of applications that have already undergone PCORI's merit review process
- Addressing specific clinical trials and methodologies
- Providing technical advice

The chair of the CT Panel and the MC chair will appoint members from:

- The CT Panel
- Other individuals with appropriate expertise

Charter of the Advisory Panel on Clinical Trials – Approved by PCORI Board of Governors – November 18, 2013

Advisory Panel on Clinical Trials and PCORI's Methodology Committee

Robin Newhouse, PhD, RD
Methodology Committee (Chair), PCORI
Steve Goodman, MD, MHS, PhD
Methodology Committee (Vice Chair), PCORI

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Overview of the PCORI Methodology Committee

- Charge of the Methodology Committee, as outlined by PCORI's authorizing legislation:
  - "The Methodology Committee shall work to develop and improve the science and methods of comparative clinical effectiveness research."
- Key activities:
  - Develop and periodically update Methodological standards for research
  - Develop a translation table
- Composed of up to 15 prominent methodologists in addition to a designee from AHRQ and NIH

PCORI Methodology Standards

- **The Methodology Committee created 47 individual methodology standards.**

Cross-Cutting Standards for PCOR

1. Formulating Research Questions
2. Patient-Centeredness
3. Data Integrity and Rigorous Analyses
4. Preventing/Handling Missing Data
5. Heterogeneity of Treatment Effects

Standards for Specific Study Designs and Methods

6. Data Networks
7. Data Registries
8. Adaptive and Bayesian Trial Designs
9. Causal Inference
10. Studies of Diagnostic Tests
11. Systematic Reviews

PCORI's Methodology Standards

- Are minimal standards for performing comparative effectiveness research
- Are intended to provide helpful guidance to researchers and those who use research results
- Reflect generally accepted best practices
- Provide guidance for both project protocols and result reporting
- Are used to assess the scientific rigor of funding applications

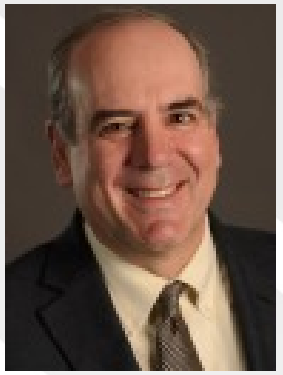
Context of research should drive use of the standards

Other Initiatives

- General oversight of PCORI portfolio
- Dissemination and implementation of the methodology standards
- Development of new methodology standards
- Workshops

Potential Overlap with the CTAP

- Coordination and collaboration through ex-officio MC members:
  - Steve Goodman and Mary Tinetti will serve as the ex-officio designees on the panel
- Specific projects or initiatives:
  - Oversight of PCORI's clinical trials portfolio
  - Identifying methods issues or gaps for clinical trials
    - The Methodology Committee has not created or endorsed standards for clinical trials
  - Consultation on method issues for applications



Break

9:45 – 10:00 a.m. EST

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PCORI's Clinical Trials Portfolio and Plans

Patient-Centered Outcomes Research Institute

Presentation Outline

- Clinical Trials in PCORI's Portfolio
  - David Hickam, MD, Program Director, CER, PCORI
  - Steve Clauser, PhD, MPA, Program Director, Improving Healthcare Systems, PCORI
  - Ayodola Anise, Program Officer, Addressing Disparities, PCORI
- Pragmatic Clinical Studies and Large Simple Trials Initiative
  - Stanley Ip, MD, Senior Program Officer, CER, PCORI
- PCORnet and the Role of RCTs/PCTs
  - Rachael Fleurence, Program Director, CER Methods and Infrastructure, PCORI

Clinical Effectiveness Research Clinical Trials Portfolio

David Hickam, MD, MPH
Program Director, Clinical Effectiveness Research, PCORI

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Characteristics of the Trials

- 36 projects as of April 2014
- Small to moderate size
  - Usually single center trials
  - Usually less than 200 participants per arm
  - More participants when cluster designs are used
- Diverse interventions
  - Medications
  - Surgical interventions
  - Decision aids
  - Self-care tools
- One study will use adaptive randomization.

Trials Comparing Clinical Therapies

- Drugs for childhood epilepsy
- Drugs for neuropathic pain
- Surgical techniques for cervical disk disorders
- Manipulative and non-manipulative treatment for back pain
- Physical therapy regimens for knee arthritis
- Nicotine replacement regimens
- Weight-loss programs
- Treatments to prevent dementia
- Counseling interventions in mental health (3 trials)

Trials of Interventions to Promote Self-Care

- Management of symptoms in cancer patients
- Pain management
- Exercise in older adults
- Mobilization after back surgery
- Cardiovascular risk reduction
- Medication adherence
- Home oxygen adherence
- Home glucose monitoring

Trials of Interventions for Caregivers

- Caregivers of patients receiving allogeneic stem cell transplants
- Caregivers of elderly patients with dementia
- Parents of children with severe injuries or critical illness (3 trials)

Trials to Assess the Impact of Decision Aids

- Decision to obtain screening for lung cancer
- Treatment options for appendicitis
- Choosing methods for contraception
- Choosing treatments for back pain
- Treatment options for lupus
- Cancer treatment choices (4 trials)
- Guidance for use of diagnostic tests (3 trials)

Conclusions about the Direction of the Portfolio of Clinical CER at PCORI

- PCORI has developed a portfolio of head-to-head trials of treatment options.
- The portfolio of trials of decision aids will help to identify best practices for such tools.
- PCORI has a unique focus on patient-centered practices.
  - Interventions to promote self-care
  - Interventions to reduce caregiver stress

Improving Healthcare Systems Clinical Trials Portfolio

Steve Clauser, PhD, MPA

Program Director, Improving Healthcare Systems, PCORI

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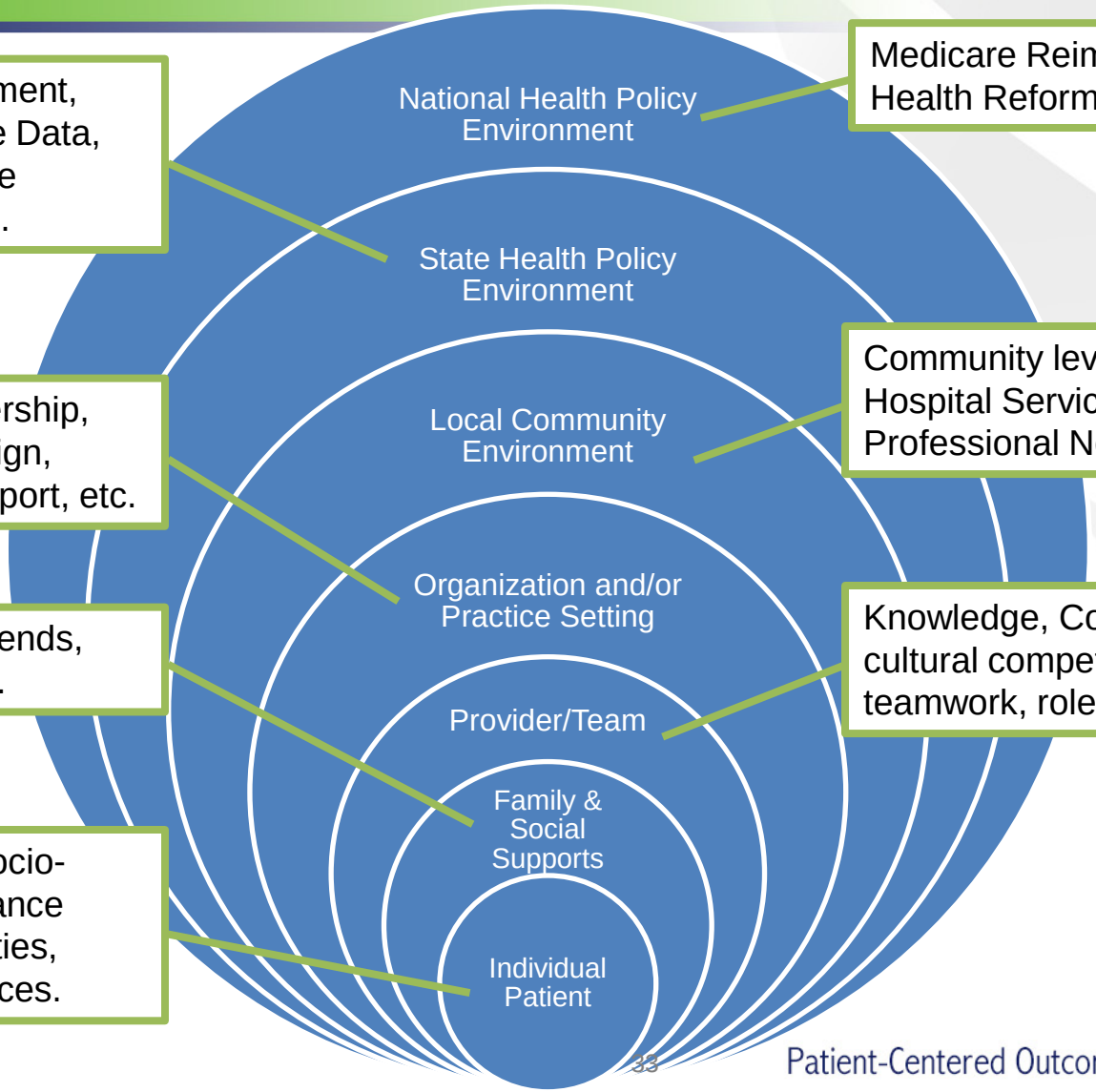
IHS Goal Statement

- To support studies of the comparative effectiveness of alternate features of healthcare systems designed to optimize the quality, access, outcomes, and/or efficiency of care for the patients they serve.

- To support studies that will provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders, regarding which features of systems lead to better patient-centered outcomes.

Healthcare System Definition



Medicaid Reimbursement, Hospital Performance Data, Activities of state-wide advocacy groups, etc.

Medicare Reimbursement, Federal Health Reform, Accreditations, etc.

Organizational Leadership, Delivery System Design, Clinical Decision Support, etc.

Community level resources, Local Hospital Services, Local Professional Norms, etc.

Family Dynamics, Friends, Network Support, etc.

Knowledge, Communication skills, cultural competency, staffing mix, teamwork, role definition, etc.

Biological Factors, Socio-demographics, Insurance coverage, Comorbidities, Patient care preferences.

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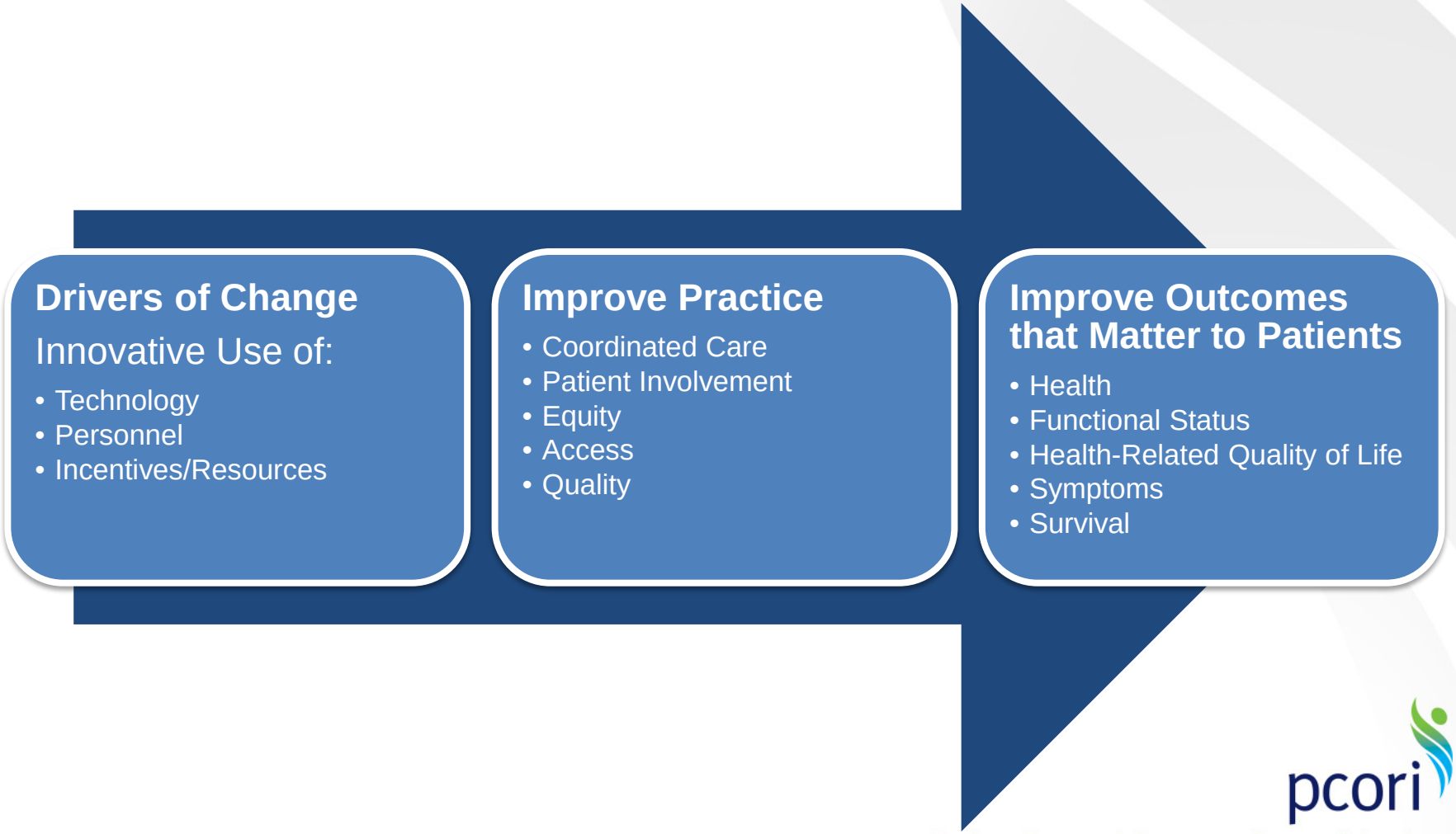
IHS Strategic Framework

Drawing from the PCORI Strategic Goals



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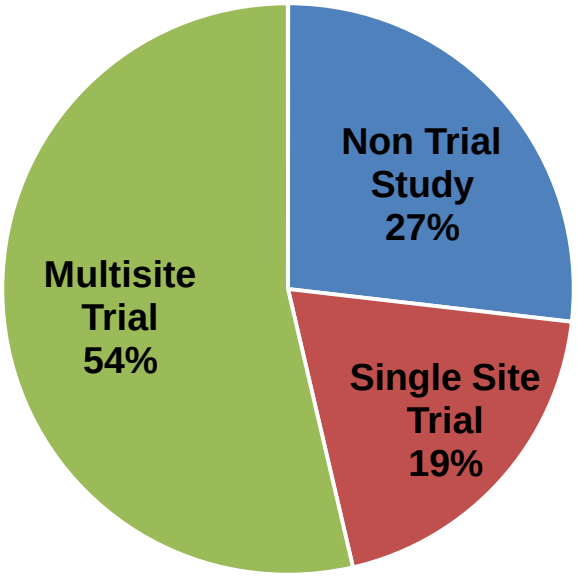
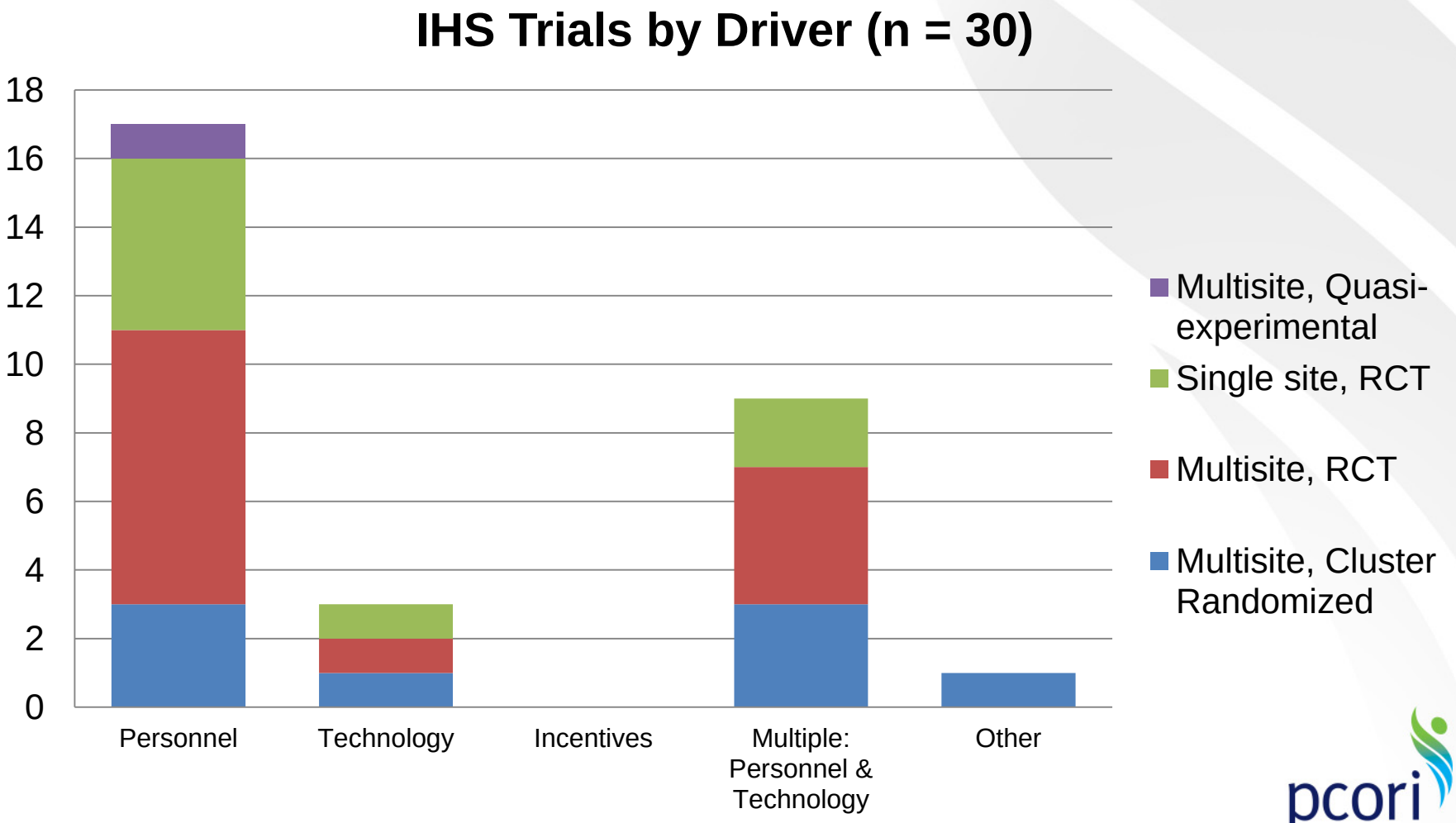
The IHS Portfolio

- Broad PFAs:
  - 41 funded research contracts (4 cycles)
  - 30 of the studies are clinical trials



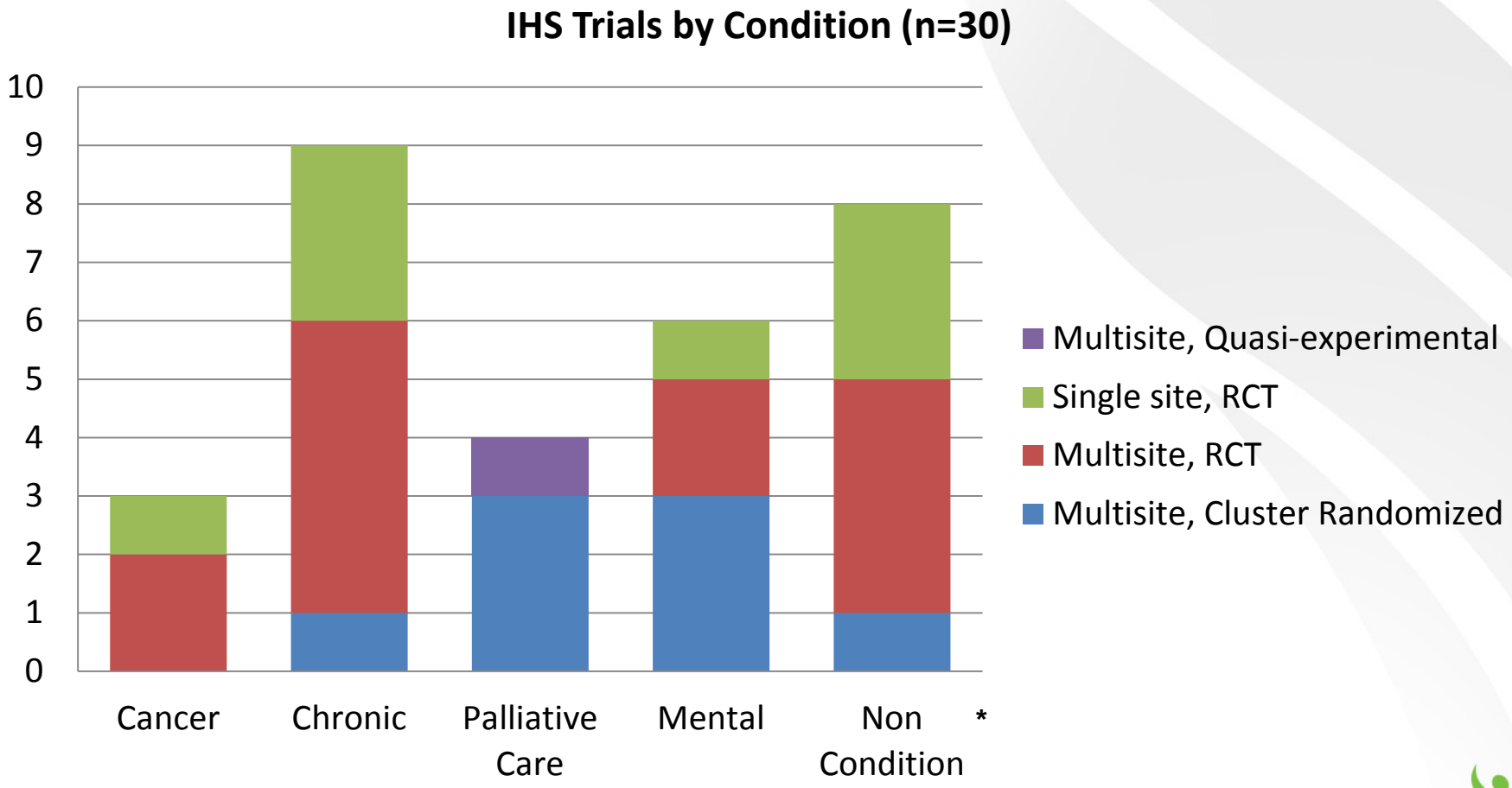
Clinical Trials in the IHS Portfolio



Example of Multi-level, Multi-site IHS Trial

- Title: Improving Palliative and End-of-Life Care in Nursing Homes
- PI: Helena Temkin-Greener, PhD; University of Rochester
  - Cluster RCT of 30 Nursing Homes (~1,200 residents)
  - Clustering residents within nursing homes. Half of the nursing homes are controls.
  - Training nursing home staff to provide palliative care to actively dying residents with an adapted National Quality Forum protocol.
  - Assessing the effectiveness of intervention on resident end of life outcomes and staff competencies and satisfaction.

Clinical Trials in the IHS Portfolio



*Non condition-specific studies focus on populations, rather than conditions. They include issues such as access to care, transitional care, care coordination, etc.

Example of Population-based IHS Trial

- Title: “PATient Navigator to rEduce Readmissions (PArTNER)”
- PI: Jerry A. Krishnan, MD, PhD; University of Illinois at Chicago
  - RCT (~1,100 patients / 2 arms / single site)
  - Focus on patients discharged from hospital within first 30 days
  - Community Health Worker-based Navigator program tailored to the needs of patients at a minority-serving institution.
  - Studying the effects of the CHW-Navigator program on patients’ experience, self-management, and functional status – and on hospital readmission rates.

Cluster-Randomized Trial of a Multifactorial Fall Injury Prevention Program

- Partnership with the National Institute on Aging
- PCORI committed up to $30 million to fund a clinical trial of a multifactorial fall injury prevention strategy in older persons
- National cluster-randomized study will include a diverse network of practice sites to reflect the diversity of the elderly at risk of serious falls, insurance coverage, and delivery systems across the U.S.

IHS Topics in the First "Pragmatic Clinical Studies" Funding Announcement

Topics identified by PCORI's multi-stakeholder IHS advisory panel include:

- Comparing the effectiveness of innovative strategies for enhancing patients' adherence to medication regimens
- Comparing the effects of specific features of health insurance on access to care, use of care, and other outcomes that are especially important to patients.
- Measuring the effectiveness of integrating mental and behavioral health services with primary care in the general population.

The Institute of Medicine (IOM) Priorities for CER, the Agency for Health Care Research and Quality (AHRQ) Future Research Needs Projects also contain health systems relevant topics

Strengths and Challenges of Clinical Trials Funded under the IHS Portfolio

- Strengths:
  - Engagement of patients, clinicians and organizational leadership
  - Multi-level assessment of patients, clinicians and organizational influences on patient centered outcomes
  - Ability to assess scalability at organizational level

- Challenges:
  - Small in scope and sample size due to budget limitations
  - Future studies likely to involve larger, more complex trials
    - Many may involve multi-level and multi-component interventions
  - Attribution of health system changes to patient outcomes

Addressing Disparities Program Clinical Trials Portfolio

Ayodola Anise, MHS

Program Officer, Addressing Disparities, PCORI

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Agenda

- Addressing Disparities Program Background
  - Program Mission and Goals
  - Program Progress to Date
- Addressing Disparities Program Clinical Trials Portfolio
- Methodological Challenges and Solutions
- Next Steps for Addressing Disparities Program

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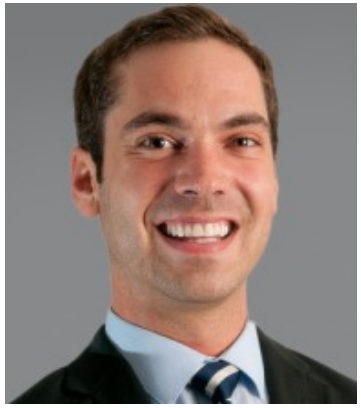
Addressing Disparities Program Staff

Romana Hasnain-Wynia, MS, PhD
Program Director

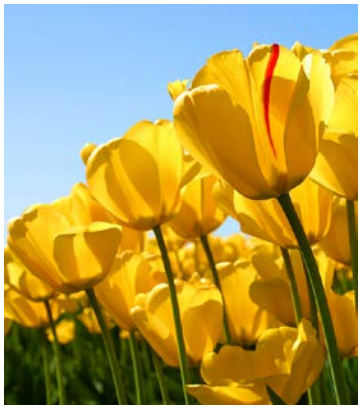
Cathy Gurgol, MS
Program Officer

Ayodola Anise, MHS
Program Officer

Katie Lewis, MPH
Program Associate



Mychal Weinert
Program Associate



Tomica Singleton
Senior Administrative Assistant

Addressing Disparities Mission Statement

PCORI's
Vision, Mission, Strategic Plan

Program's Mission Statement

To **reduce disparities** in healthcare outcomes and **advance equity** in health and healthcare

Program's Guiding Principle

To support comparative effectiveness research that will identify best options for **eliminating disparities.**

Addressing Disparities: Program Goals

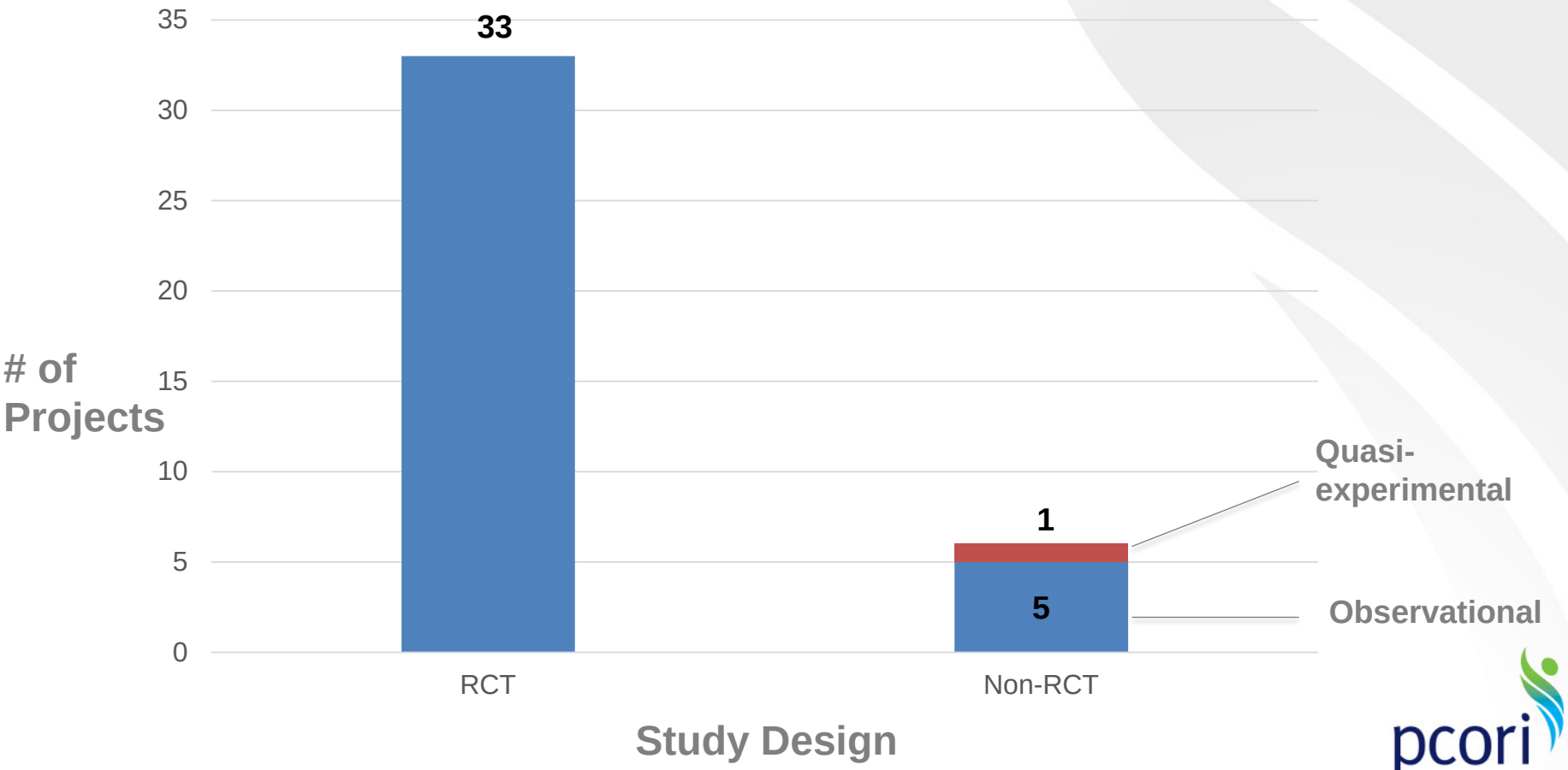
Identify Research Questions	• **Identify** high-priority **research questions** relevant to reducing and eliminating disparities in healthcare outcomes
Fund Research	• **Fund** comparative effectiveness **research** with the highest potential to reduce and eliminate healthcare disparities
Disseminate Promising/Best Practices	• **Disseminate** and facilitate the adoption of **promising/best practices** to reduce and eliminate healthcare disparities

Progress Toward Goal (2012 – 2015)

Broad PFAs *4 cycles*	• **31** projects totaling **$52.8M**
Targeted PFAs *1 cycle*	• Treatment Options for Uncontrolled Asthma in African Americans and Hispanics/Latinos: **8** projects totaling **$23.2M**
Pipeline for Targeted PFAs	• Obesity treatment options in primary care, awards in August 2014 (Will fund up to **2** awards totaling **$20 M)** • Pragmatic clinical trials, awards in January 2015 • In development stage (Hypertension, Perinatal, Lower Limb Amputations)

AD Clinical Trials Portfolio Snapshot

Research Methods: Study Design



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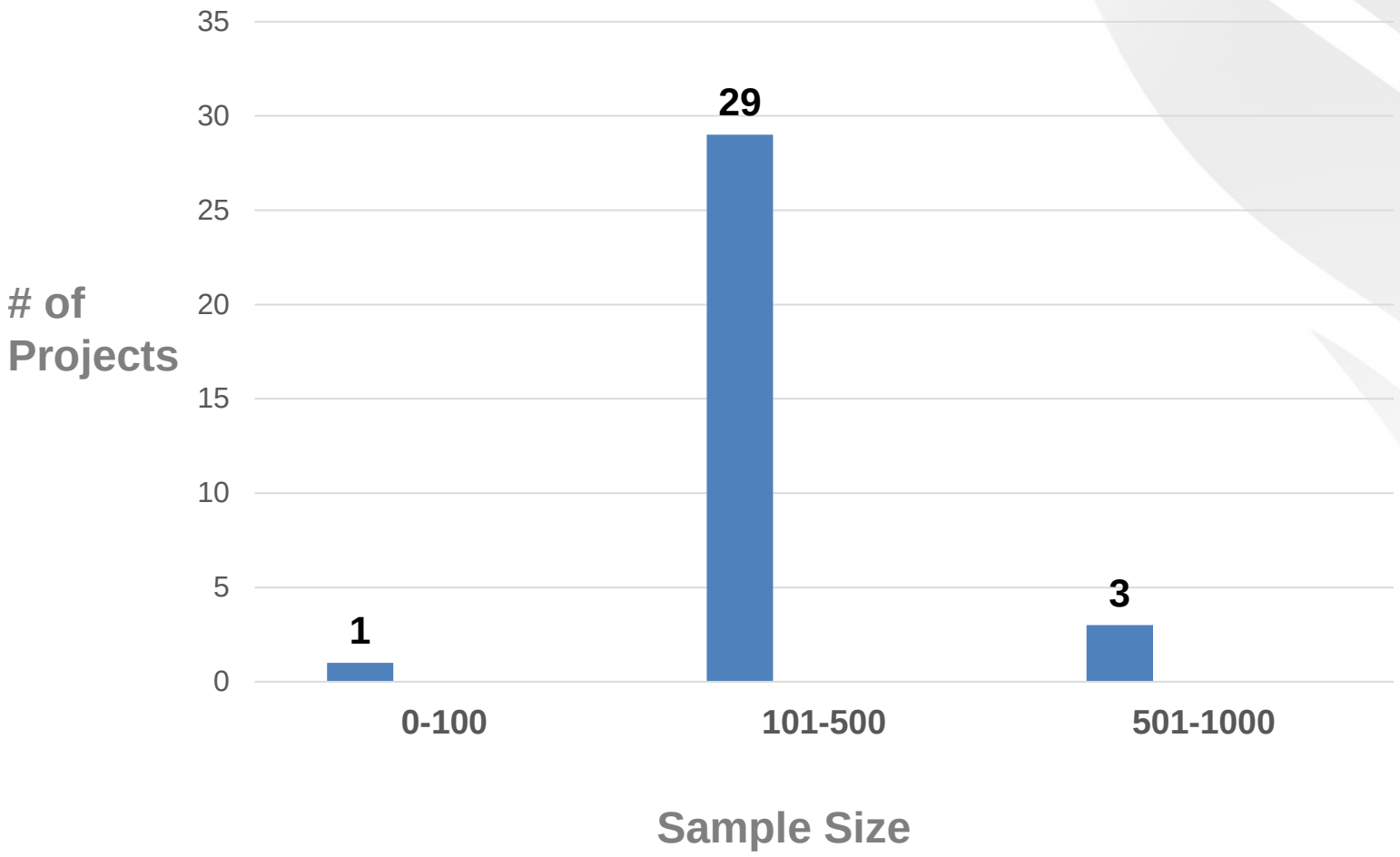
AD Clinical Trials Portfolio Snapshot

Research Methods: Sample Size



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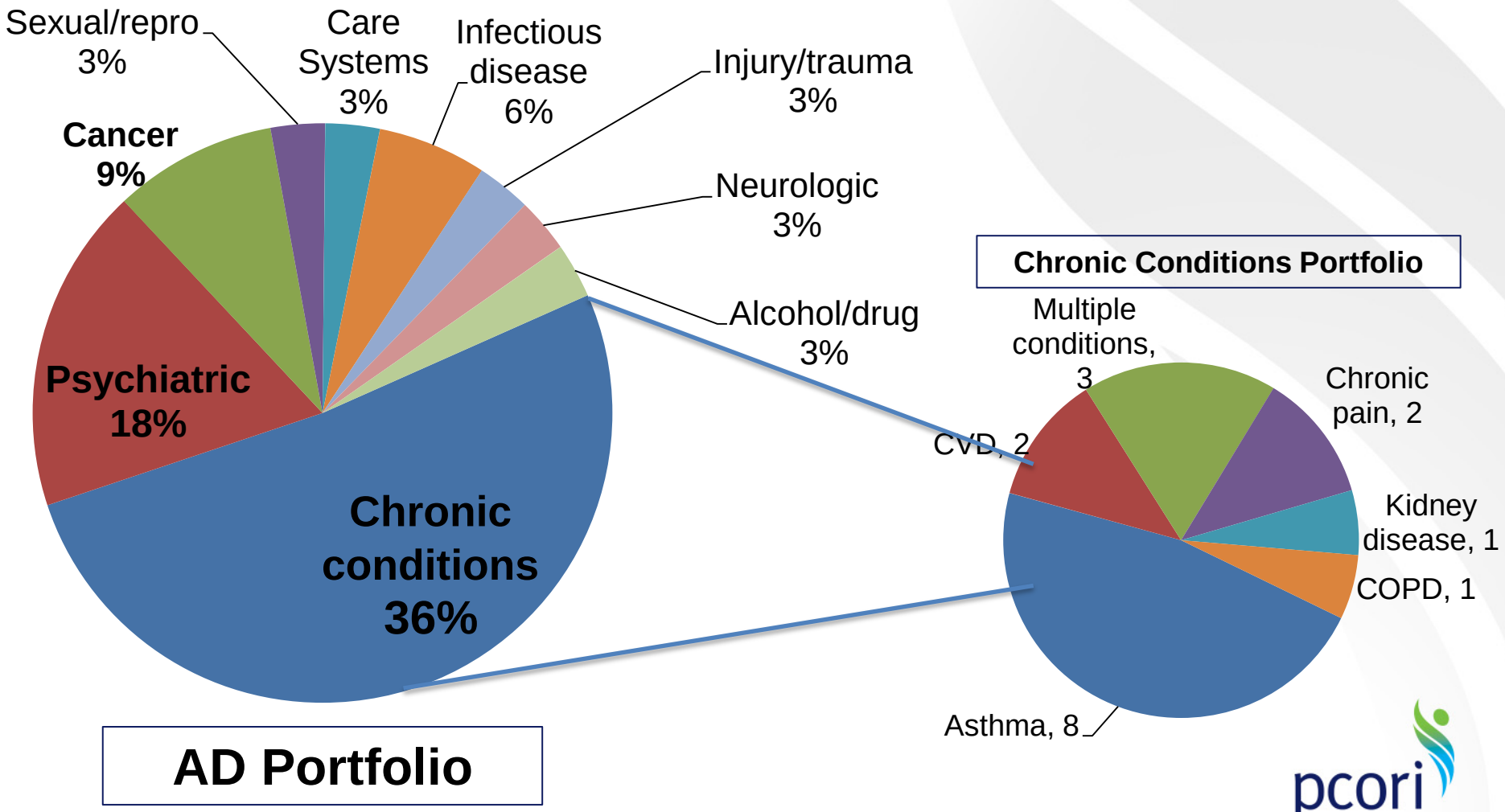
AD Clinical Trials Portfolio Snapshot

Research Areas



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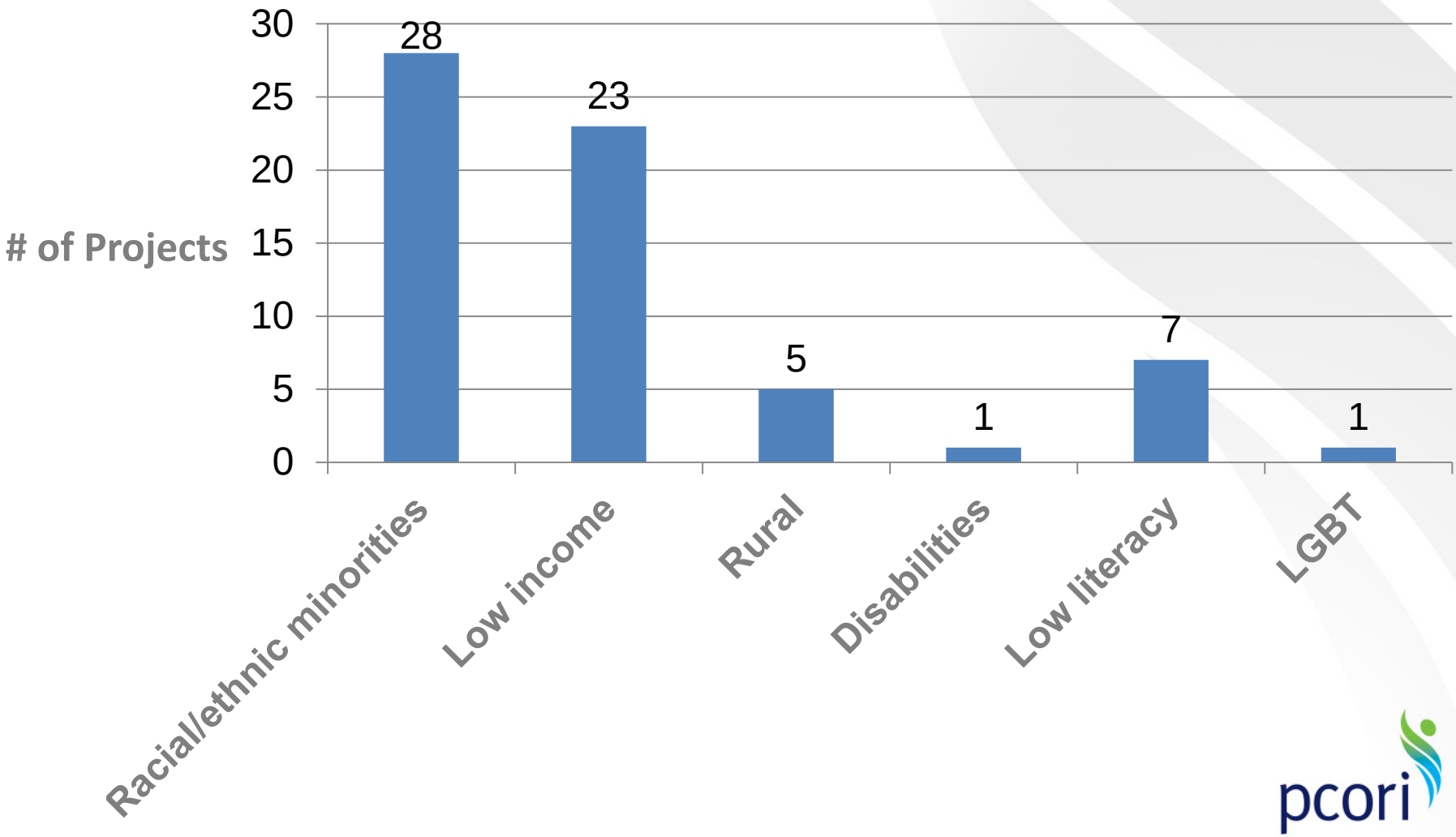
AD Clinical Trials Portfolio Snapshot

Disparities Population (Not mutually exclusive)



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Methodological Challenges and Solutions

- **Data and safety monitoring plans (DSMPs) and data and safety and monitoring boards (DSMBs)**
- **Efficacy versus effectiveness studies**
- **Intersection of community health and health/clinical care**
- Identifying comparators
- Monitoring protocol changes
- Recruitment
- Small sample sizes

Methodological Challenges and Solutions: DSMPs and DSMBs

- Challenge
  - Program staff wanted to provide DSMP and DSMB guidance to awardees funded through Asthma PFA
  - Experts suggested that minimal and high risk projects require monitoring
- Solution
  - All awardees funded through the Asthma PFA are required to develop DSMPs and convene DSMBs regardless of risk assessment
  - Awardees will be required to follow the NHLBI Policy for Data and Safety Monitoring of Extramural Clinical Studies with some differences (e.g., DSMBs will be convened by awardee; where possible, a trained patient or stakeholder should be on the DSMB)

Methodological Challenges and Solutions: Efficacy versus Effectiveness Studies

- Challenge:
  - In order to conduct effectiveness studies, there needs to be enough evidence supporting the efficacy of an intervention or treatment
  - To conduct pragmatic trials, there needs to be a certain amount of evidence showing the effectiveness of an intervention or treatment
  - In the disparities field, there is not much research available on the efficacy and effectiveness of interventions or treatments
- Solution:
  - Identify key research topics where we can connect some level of evidence of efficacy and effectiveness (e.g., Obesity PFA)

Methodological Challenges and Solutions: Intersection of Community Health with Health/Clinical Care

- Challenge:
  - Within disparities research, the most successful interventions integrate health/clinical care with factors that lie outside of health care systems but that have a direct effect on health outcomes
  - Lack of understanding of what community health factors most influence health/clinical care within CER
- Solution:
  - Through portfolio, identify projects at this intersection and delineate the community health factors that influence health/clinical care as it relates to CER

Next Steps

- Continue funding high priority research topics that can reduce/eliminate disparities in healthcare outcomes
- Inform PCORI's DSMP and DSMB policy
- Identify promising practices from projects that successfully link community health and health/clinical care interventions to share with awardees, researchers, and end users (e.g., payers, purchasers, professional societies)

Pragmatic Clinical Studies and Large Simple Trials Initiative

Stanley Ip, MD

Senior Program Officer, CER, PCORI

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Objective

- Address *critical* clinical and health-related comparative effectiveness questions faced by patients and other decision makers
  - Compare interventions and outcomes that matter to patients
  - Sample size is sufficiently large to allow precise estimates of differences in treatment effects and permit valid and rigorous analysis of heterogeneity of treatment effects

Available Funds

- Up to $90M per announcement
- Two announcements/year
- Direct costs of up to $10M per project

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Essential Characteristics of Funded Head-to-Head Studies

- Broadly representative patient populations
- Strong endorsement and participation by relevant patient, professional, and/or payer or purchaser organizations
- Address:
  - Prevention, diagnosis, treatment, management of disease or symptom
  - Improve performance of HC systems
  - Eliminate health-related disparities
- Take place within typical clinical care or community settings
- Outcomes meaningful to patients
- Sufficient size to evaluate effectiveness in subgroups

Comparators of Interest

- Specific drugs, devices, and procedures
- Medical and assistive devices and technologies
- Techniques for behavioral modification
- Complementary and alternative medicine
- Delivery-system interventions
- Usual care or no specific intervention, if these are realistic choices for patients (e.g., choosing not to have a procedure for cancer screening)

Sources for Topics of Interest

- IOM 100 priority topics for CER
- AHRQ Future Research Needs Projects
- Investigator-initiated topics
- PCORI priority topics (updated1/2014)

Note: Requirement to follow PCORI methodology standards including RQ1 (gap analysis and systematic reviews to support application)

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PCORI Priority Topics Announced in December 2013

- Bipolar disorder
- Ductal carcinoma in situ (DCIS)
- Cardiovascular disease (CVD)
- Back pain
- Integration of mental and behavioral health services
- Adherence to medication regimens

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PCORI Priority Topics (CONT.)

- Health insurance
- Migraine headache
- Osteoarthritis (OA)
- Autism spectrum disorder
- Pulmonary nodules
- Opioid substance abuse
- Multiple sclerosis
- Proton beam therapy

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Introducing PCORnet:
The National Patient-Centered Clinical Research Network

Rachael Fleurence, PhD

Program Director, CER Methods and Infrastructure, PCORI

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The National Patient-Centered Clinical Research Network

This slide presentation explains:

- **Why** PCORnet was created
- **What** PCORnet will do for research
- **How** it works
- **Who** is involved

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Our national clinical research system is well-intentioned but flawed

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

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

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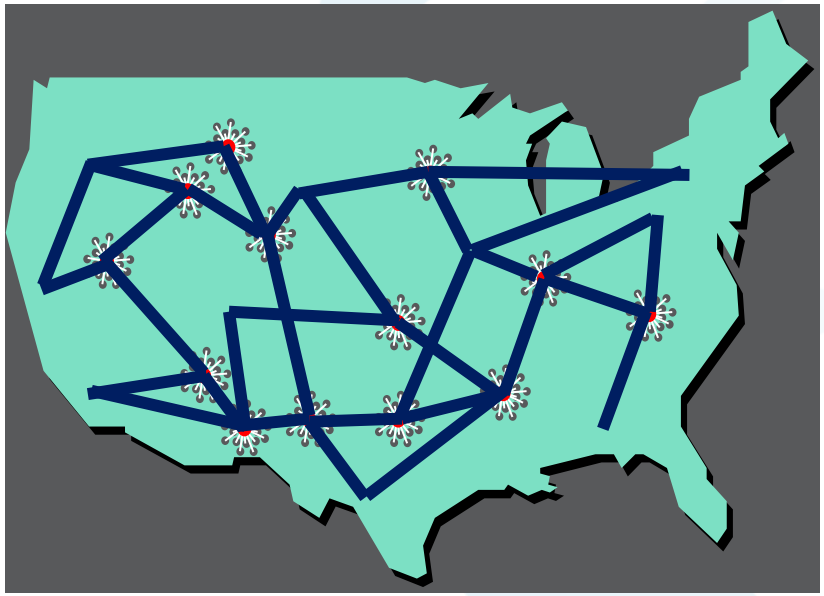
**Tricoci P et al. JAMA 2009;301:831-41.*

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

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



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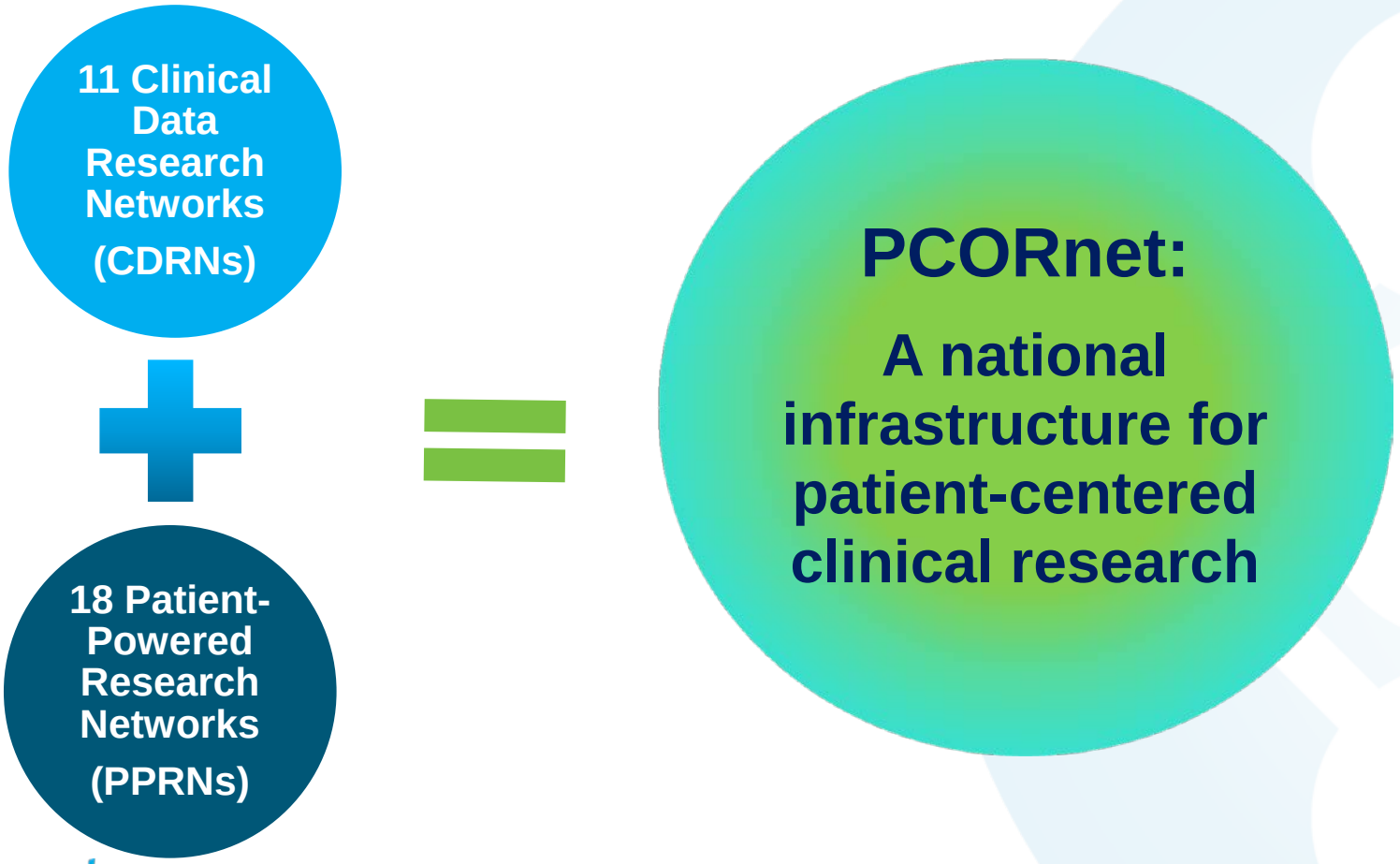
PCORnet embodies a “community of research” by uniting systems, patients & clinicians



What will PCORnet do for research?

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The National Patient-Centered Clinical Research Network

PCORnet's goal

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

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PCORnet's vision

PCORnet will support widespread capability for the US healthcare system to learn from research, meaning that large-scale research can be conducted with greater speed and accuracy within real-world care delivery systems.

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Overall objectives of PCORnet: achieving a single functional research network

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

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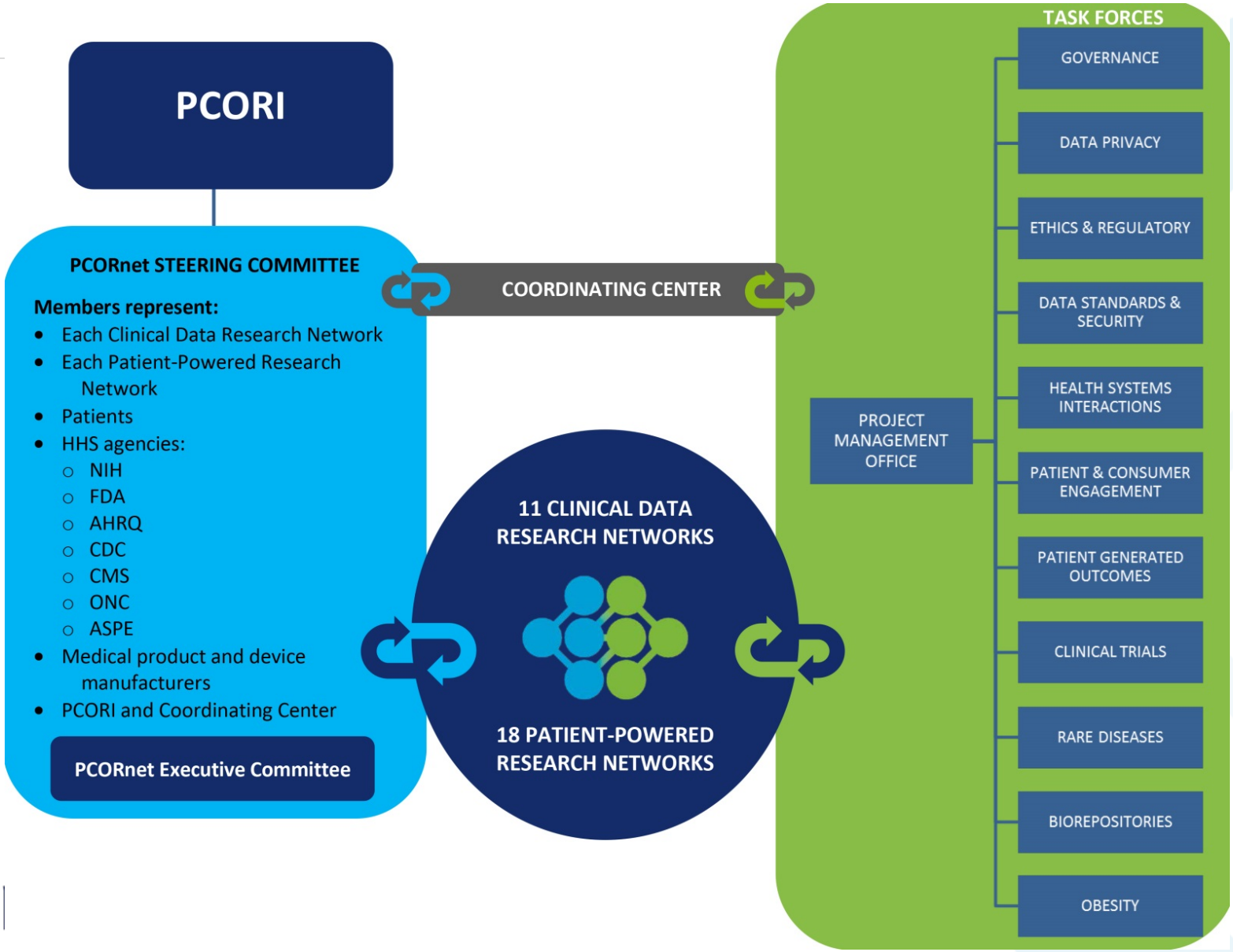
PCORnet organizational structure



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

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

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CDRN Partners

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The National Patient-Centered Clinical Research Network

Goals for Each Clinical Data Research Network (CDRN)

- Create a research-ready dataset of at least 1 million patients that is:
  - **Secure** and does not identify individual patients
  - **Comprehensive,** using data from EHRs to describe patients' care experience over time and in different care settings
- Involve patients, clinicians, and health system leaders in all aspects of creating and running the network
- Develop the ability to run a clinical trial in the participating systems that fits seamlessly into healthcare operations
- Identify at least 3 cohorts of patients who have a condition in common, and who can be characterized and surveyed

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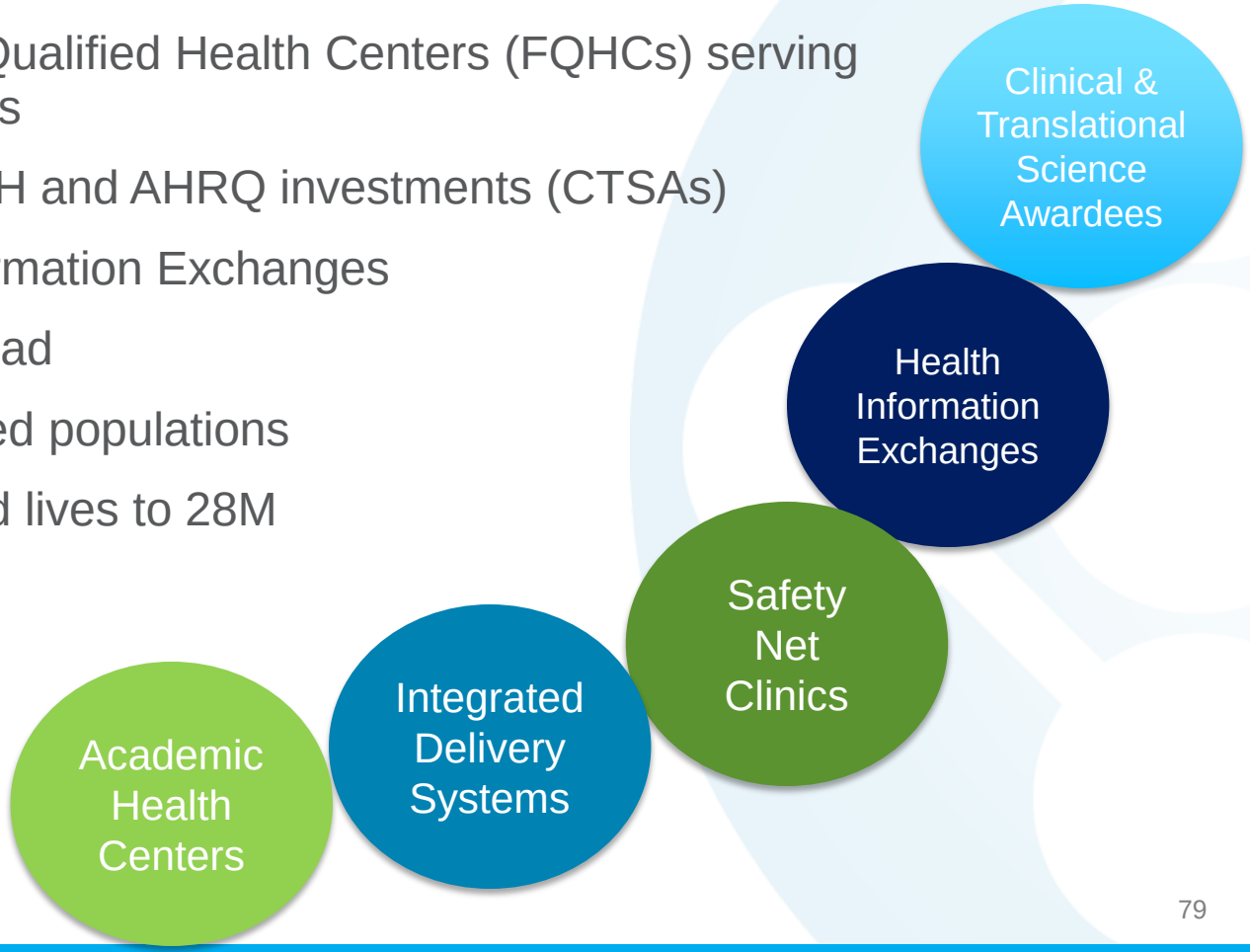
CDRN highlights

- Networks of academic health centers, hospitals & clinical practices
- Networks of non-profit integrated health systems
- Networks of Federally Qualified Health Centers (FQHCs) serving low-income communities
- Networks leveraging NIH and AHRQ investments (CTSAs)
- Inclusion of Health Information Exchanges
- Wide geographical spread
- Inclusion of under-served populations
- Range from 1M covered lives to 28M



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PPRN Partners

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The National Patient-Centered Clinical Research Network

Goals for each Patient-Powered Research Network (PPRN)

- Establish an activated patient population with a condition of interest (Size >50 patients for rare diseases; >50,000 for common conditions)
- Collect patient-reported data for ≥80% of patients in the network
- Involve patients in network governance
- Create standardized database suitable for sharing with other network members that can be used to respond to “queries” (ideas for possible research studies)

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PPRN highlights

- Participating organizations and leadership teams include patients, advocacy groups, clinicians, academic centers, practice-based research networks
- Strong understanding of patient engagement
- Significant range of conditions and diseases
- Variety in populations represented (including pediatrics, under-served populations)
- 50% are focused on rare diseases
- Varying capabilities with respect to developing research data
- Several PPRNs have capacity to work with biospecimens

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The PCORnet opportunity: making a real difference for patients and their families

Until now, we have been unable to answer many of the most important questions affecting health and healthcare

By combining the knowledge and insights of patients, caregivers, and researchers in a revolutionary network with carefully controlled access to rich sources of health data, we will be able to respond to patients' priorities and speed the creation of new knowledge to guide treatment on a national scale.

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Early Opportunity to conduct a clinical trial within PCORNet

- Large, highly representative electronic data infrastructure to facilitate efficient research
  - Observational
  - Pragmatic randomized trials

- Officially launched Jan 2014 – early phase

- PCORI has identified a unique **early opportunity** to support an interventional **individual-level randomized clinical trial** that will inform future research studies in PCORnet

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Process

Step 1
- Topic generation

Step 2
- Topic prioritization

Step 3
- PCORI Program Development Committee (PDC) & PCORI Board of Governors Approve Final Topic for the Clinical Trial

Step 4
- PCORI issues request Q2 2014

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About the trial

- The trial should be characterized by **operational simplicity** and **clinical relevance**
- The trial will make extensive use of **EHR** to identify patients and report outcomes
- The study will complete in no more than **18 months** with a total cost of $10 million
- PCORI has received **6 viable topics** from the network for prioritization

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The Topics

- What is the optimal second line treatment for glycemic control in type 2 diabetes?
- What is the role of spacers for treatment of Asthma?
- Comparative effectiveness of anticoagulants for atrial fibrillation
- Randomized clinical trial to determine optimal maintenance aspirin dose for patients with coronary artery disease
- Comparative effectiveness of interventions to maximize and maintain weight loss after bariatric surgery
- Mindfulness-based weight reduction using a simple web-based training

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Lunch

12:00 – 1:00 p.m. EST

Patient-Centered Outcomes Research Institute

Methodological and Policy Issues for Clinical Trials in CER

Moderated by

David Hickam, MD, Program Director, CER, PCORI

Patient-Centered Outcomes Research Institute

Break

3:00 – 3:15 p.m. EST

Patient-Centered Outcomes Research Institute

Advisory Panel Scope Issues: Methodological Consultation on Individual Studies vs General Advice/Consultation

Moderated by

David Hickam, MD, Program Director, CER, PCORI

Patient-Centered Outcomes Research Institute

Organizational Issues: Meeting Frequency, Scheduling, Leadership, and Staff Support

Bryan Luce, PhD, MBA
Chief Science Officer, PCORI

Patient-Centered Outcomes Research Institute

Topics

- Meeting frequency
- Scheduling: Next two face-to-face meetings
  - HOLD: September 29 – October 2, 2014 (Fall 2014 meeting)
  - HOLD: January 12 – 15, 2015 (Winter 2015 meeting)
- Leadership: Please submit nomination (including self-nominations) to CTAP@pcori.org. PCORI staff will then select a chair and co-chair and will announce the new leadership to all panel members.
- Staff support

Recap and Next Steps

Bryan Luce, PhD, MBA
Chief Science Officer, PCORI

Patient-Centered Outcomes Research Institute

Adjourn

Thank you for your participation!