Board of Governors Meeting
via Teleconference/Webinar

April 26, 2016

12:00-1:30 p.m. ET

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director

Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00 – 12:10	Consent Agenda: • Minutes of the March 22, 2016 Board Meeting • Committee Assignments for Sharon Arnold • Revisions to Committee Advisory Panel Charters
12:10 – 12:30	Consider for Approval: 2015 Cycle 2 Broad Slate of Awards
12:30 – 12:45	Plan for Application Enhancement Effort
12:45 – 1:05	Engagement in PCORnet
1:05 – 1:20	PCORnet Investment
1:20 – 1:30	Updates: • Re-release of the Clinical Management of Hepatitis C Infection Targeted PFA • Open Access Policy
1:30	Wrap up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director

Motion for Consent Agenda Items

That the Board approve:

- Minutes from March 22, 2016 Board meeting
- Nomination by the Governance Committee for Board Member Sharon Arnold to serve on the Engagement, Dissemination, and Implementation Committee (EDIC) and the Science and Oversight Committee (SOC)
- Proposed amended Charters for the following PCORI Committees and Advisory Panels (AP):
  - Research Transformation Committee (RTC)
  - Science Oversight Committee (SOC)
  - Engagement, Dissemination, and Implementation Committee (EDIC)
  - Methodology Committee
  - Assessment of Prevention, Diagnosis and Treatment Options AP (APDTO)
  - Addressing Disparities AP (AD)
  - Improving Healthcare Systems AP (IHS)
  - Patient Engagement AP (PEAP)
  - Communication and Dissemination Research AP (CDR)

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent Agenda
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Slate of Cycle 2 2015 Broad PFA Awards

Christine Goertz, DC, PhD
Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Broad Cycle 2 2015
Merit Review Criteria

Broad PFAs (except Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
1. ***Impact of the condition on the health of individuals and populations**** 2. ***Potential for the study to improve healthcare and outcomes**** 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement	1. ***Impact on the field of PCOR methods**** 2. ***Potential for the study to improve PCOR methods**** 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement

Slate Overview—Broad Cycle 2 2015

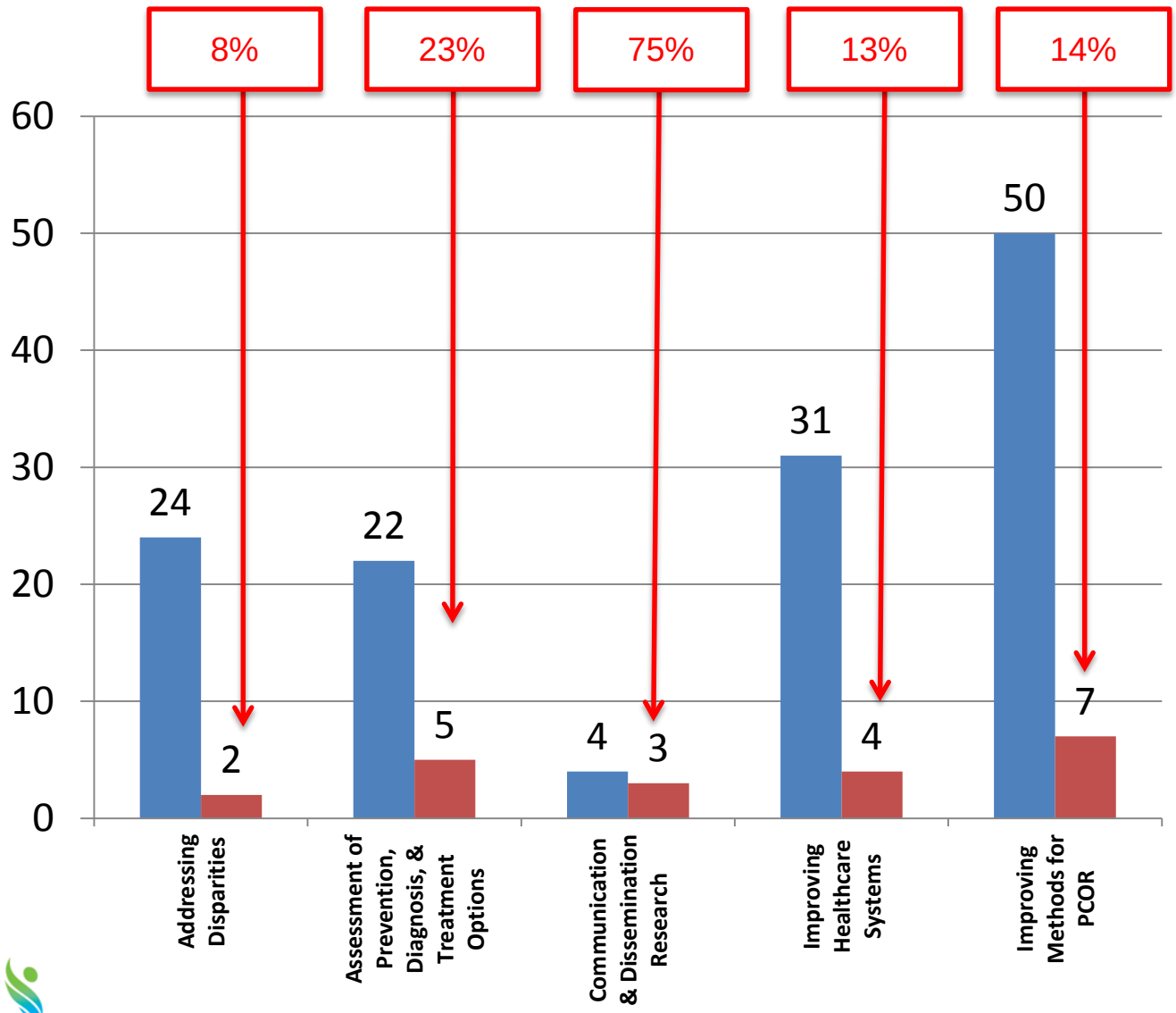
Process Overview

- 369 Letters of Intent (LOIs) submitted
- 184 LOIs invited to submit a full application (**49%**)
- 132 applications were received (**72%** of invited LOIs)
  - **34%** (45) of applications were resubmissions
- Proposing to fund 21* of 132 applications (**16%**)
  - **67%** (14) of applications recommended for funding were resubmissions

*Recommended by the Selection Committee

Broad Cycle 2 2015

What Percentage of Applicants Are We Proposing to Fund?



Overall Funding Level 16%

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Conditions
Broad Cycle 2 2015

n=14 Projects

- 14 out of 21 proposed projects (excluding Methods) contain one or more of the following diseases/conditions:

Disease/Condition	Current Portfolio (# of projects)	Projects Represented in Proposed Slate
Mental/Behavioral Health	44	3
Cancer	41	3
Cardiovascular Health	26	1
Respiratory Diseases	20	1
Neurological Disorders	20	1
Trauma/Injury	12	1
Muscular and Skeletal Disorders	11	1
Functional Limitations and Disabilities	5	1
Digestive System Diseases	3	1
Other or Non-disease Specific	18	1

PCORI Populations of Interest
Broad Cycle 2 2015

n=14 Projects

- Almost all non-Methods projects (12) address at least 1 PCORI population of interest

PCORI Priority Population	Current Portfolio (# of projects)	Projects Represented in Proposed Slate
Racial and Ethnic Minorities	214	4
Low-income	151	3
Older Adults	96	4
Women	81	4
Multiple Chronic Conditions	72	2
Children	64	5
Individuals with Disabilities	18	1
Veterans	9	1

Funding Opportunities

Broad Cycle 2 2015

Broad PFA (Recommended Projects)	Maximum Project Length	Maximum Direct Costs Allowed	Total Budget
Addressing Disparities (2 projects)	3 years	$1.5 Million	$8 Million
Assessment of Prevention, Diagnosis, and Treatment Options (5 projects)	3 years	$2 Million	$32 Million
Communications and Dissemination Research (3 projects)	3 years	$1.5 Million	$8 Million
Improving Healthcare Systems (4 projects)	3 years	$1.5 Million (small)	$16 Million
	5 years	$5 Million (large)	
Improving Methods for Conducting Patient-Centered Outcomes Research (7 projects)	3 years	$750,000	$12 Million

Addressing Disparities

*2 Recommended Projects**

Project Title
Comparing the Effectiveness of Clinicians and Paraprofessionals to Reduce Disparities in Perinatal Depression
Virtual Evidence-based Healthcare for Underserved Patients with Down Syndrome

Resubmissions in bold.

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Assessment of Prevention, Diagnosis, and Treatment Options

*5 Recommended Projects**

Project Title
Continued Anticonvulsants after Resolution of Neonatal Seizures: a Patient-centered Comparative Effectiveness Study
Comparative Effectiveness Analyses among Conservative Treatment Strategies for Ductal Carcinoma In Situ
Multi-institutional Trial of Non-operative Management of Uncomplicated Pediatric Appendicitis
Improving Care for Veterans with Post-Traumatic Stress Disorder (PTSD): Comparative Effectiveness of Medications to Augment First-line Pharmacotherapy
Longitudinal Comparative Effectiveness of Bipolar Disorder Therapies

Resubmissions in bold.

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Communication and Dissemination Research

*3 Recommended Projects**

Project Title
Resetting the Default: Improving Provider-patient Communication to Reduce Antibiotic Misuse
Comparing Effectiveness of Self-management and Peer Support Communication Programs amongst Chronic Obstructive Pulmonary Disease Patients (COPD) and their Family Caregivers
Ostomy Telehealth for Cancer Survivors

Resubmissions in bold.

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Improving Healthcare Systems

*4 Recommended Projects**

Project Title
Healing through Education, Advocacy and Law (HEAL) in Response to Violence
Patient Osteoarthritis Careplan to Inform Optimal Treatment
Comparing Interventions to Increase Colorectal Cancer Screening in Low-Income and Minority Patients
Pragmatic Trial Comparing Telehealth Care and Optimized Clinic-Based Care for Uncontrolled High Blood Pressure

Resubmissions in bold.

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Improving Methods for Conducting PCOR

*7 Recommended Projects**

Project Title
Development and Evaluation of a Patient-Centered Approach to Assess Quality of Care: Patient-Reported Outcomes-based Performance Measures (PRO-PMs)
Engaging Patients and Caregivers Managing Rare Diseases to Improve the Methods of Clinical Guideline Development
Learning within Health Care Delivery Systems: Design, Analysis, and Interpretation of Longitudinal Cluster Randomized Trials
Design and Methodological Improvements for Patient-Centered Small n Sequential Multiple Assignment Randomized Trials (snSMARTs) in the Setting of Rare Diseases
Governance of Learning Activities in Learning Healthcare Systems
Improving Methods of Incorporating Racial/Ethnic Minority Patients' Treatment Preferences into Clinical Care
Stratified Regression Models for Case-Only Studies

Resubmissions in bold.

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Slate Overview – Cycle 2 2015

Broad PFAs

21
Projects

Broads PFA	Allotted	Proposed Total Budget*
Addressing Disparities	**$8M**	**$4M**
Assessment of Prevention, Diagnosis, and Treatment Options	**$32M**	**$10M**
Communications and Dissemination Research	**$8M**	**$6M**
Improving Healthcare Systems	**$16M**	**$17M**
Improving Methods for Conducting PCOR	**$12M**	**$8M**
TOTAL:	**$76M**	**$45M**

*Total budget = direct + indirect costs. All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the 2015 Cycle 2 Broad PFAs
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Preliminary Planning for Application Enhancement Efforts

Evelyn P. Whitlock, MD, MPH

Chief Science Officer

Jean Slutsky, PA, MSPH

Chief Engagement & Dissemination Officer & Program Director for Communication & Dissemination Research

Regina L. Yan, MA

Chief Operating Officer

Context of Enhancing the Process for PCORI Research Applicants

- PCORI has **unique elements** as part of our research process, which has meant de novo development of requirements and supporting materials
- Since establishment, PCORI has **developed rapidly** with cumulative changes based on lessons learned
- Based on formal and informal feedback, we can do a number of things to **improve research applicants' experience**

Application Enhancement, Applicant Process and Merit Review Workgroups/Committees (2015-2016)

- **Ad hoc Merit Review Committee**, report completed May 2015
  - Chair: Romana Hasnain-Wynia
  - Members: Kim Bailey, Steve Clauser, David Hickam, Jason Gerson, Jean Slutsky, Tsahai Tafari
- **Feedback to Applicants Workgroup**, report completed July 2015
  - Chair: Tsahai Tafari
  - Members: Andrea Brandau, Romana Hasnain-Wynia, Andrea Heckert, Beth Kosiak, Bill Lawrence, Julie McCormick
- **SOC Application Enhancement Workgroup**, report completed February 2016
  - Chair: Bob Zwolak
  - Members: (SOC) Rick Kuntz, Steve Lipstein; (Staff) Diane Bild, Laura Forsythe, Hal Sox
- **American Institute for Research (AIR), PCORI Applicant Process Improvement Review**; final report and presentation: March 2016
- **SOC Merit Review Workgroup**, final report April 2016
  - Chair: Alicia Fernandez
  - Members: (SOC) Bob Kaplan, Mike Lauer, Barbara McNeil; (Staff) Lori Frank, David Hickam, Greg Martin, Suzanne Schrandt, Tsahai Tafari

~45 Recommendations Across Workgroups and External Reviewers

- Three overarching principles from the workgroup/committee reports:
  - Ensure PCORI culture supports applicant success
  - Implement change management process
  - Improve and increase communication with external stakeholders

- Address concerns from funding announcements through application process, merit review, and feedback to applicants

Broad Recommendation Categories

- Letter of Intent (LOI) Review Process
- Application Format
- Application Process
- Merit Review
- Feedback to Applicants
- Strategic Issues
- Engagement
- Systems Issues
- Training
- Benchmarking

Opportunities for Immediate and Short-term Improvements

- Immediate changes that can be implemented in the next cycle (PFA posts August 2016)
  - Simplify and clarify information in funding announcements
  - Increase and enhance communication to applicants

- Short-term changes that can be implemented (PFA posts February 2017)
  - Focus on streamlining application format and process to improve consistency from PFA to award
  - Refine the online application system to streamline materials, improve ease of use, and enhance applicant experience
  - Enhance merit review process and communication between applicants and staff

Importance of Rapidly but Effectively Enhancing the Process

- Improving applicant experience, along with other initiatives, could **improve quality and quantity of applications** and change recent downward trends in Letters of Intent submissions

- Doing so is critical since the **production and rapid, effective dissemination of scientifically valid, meaningful health research** is our mission

- **Competent, dedicated investigators** and research institutions are the means by which PCORI accomplishes its mission

- We want everyone affiliated with PCORI, including our Board members, to be **confident and willing to recommend applying for PCORI funding** to their colleagues

Next Steps

- Science, Operations, Communications, and Engagement continue to coordinate in developing implementation plans
- Sorting recommendations into immediate, short-term, and longer-term buckets
- Developing realistic timelines, based on:
  - Review of processes with staff input to proposed changes and consideration of impact across departments
  - Required time to effectively implement changes within PCORI infrastructure and support staff work with applicants
  - Plan to communicate process improvements/changes to applicants
  - Required time for applicants to understand and adapt to changes and then assemble their applications accordingly

- Staff updates the Science Oversight Committee monthly and will periodically update the Board of Governors, more detail at the May meeting

Engagement in PCORnet: April 2016 Update

Sharon F. Terry

Principal Investigator, Community Engaged Network for All

Co-Principal Investigator, PCORnet Coordinator Center

President and CEO, Genetic Alliance

Engagement in PCORnet

Engagement is **essential** to patient-centered outcomes research. It is the **foundation** for all PCORnet work.

- Strive for **equity** among stakeholders
- Consider the **social determinants of health** (e.g. socioeconomic status, access to healthcare, literacy levels, culture, etc.)
- Consider the ways individuals **understand and experience** health and disease, accesses health services, and participate in research
- Be **patient/participant-driven**
- Create an environment that encourages **co-learning**

Result:
More meaningful and impactful research that matters to patients and clinicians and has the potential to accelerate the speed with which validated research findings move into clinical care.

How do we ensure this?

- Vigilance for examining everything with an engagement lens:
  - Governance
  - Implementation
  - Projects/Studies
- Determining metrics for measuring engagement
- Creating tools to make this easier
- Working with other groups/organizations on engagement, community-based participatory research, citizen science and other emerging engagement methods

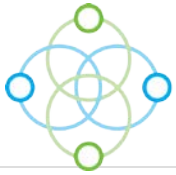
PCORnet Engagement Committee: Current Initiatives

- The Engagement Committee's purpose is to enrich, advocate, embed, and facilitate comparative effectiveness research for PCORnet in accordance with PCORnet and PCORI principles, including active participation of all aspects of the research continuum, including patient and clinical scientists.
- **Collecting and categorizing** products, tools, activities, and frameworks.
    - The Coordinating Center conducted interviews and with all 33 networks and shared a report on the landscape of engagement activities in PCORnet.
- Making **informed recommendations of applications and best practices** (e.g. good, better, best) as guided by network generated evidence and expert opinions.
    - The Engagement Committee will develop an engagement checklist tool for networks' use
- **Implementing methods and approaches** for translation and dissemination of products, tools, activities, and frameworks.
- Supporting **strong multi-stakeholder collaborative relationships** in all PCORnet activities.

Priority Topics for the Committee: Workgroups

- **Engagement Definitions**
  - Defining engagement terms
  - Establishing engagement metrics for the PCORnet dashboard
  - Creating user-friendly products (e.g. glossary of terms)
- **Communications and Marketing**
  - Providing recommendations for governance of communications activities
  - Advising and providing input on PCORnet communications scope of work
- **Diversity and Special Stakeholders**
  - Aggregating existing resources (e.g. best practices, non-English materials, technology, tools, and software)
  - Providing opportunities for sharing (PCORnet-wide webinars)
- **Clinician Engagement**
  - Identifying best practices and lessons learned for clinician engagement from literature and PCORnet demonstration projects
  - Developing the PCORnet value proposition for clinicians

Building Trustworthiness in PCORnet



- Hosted March 28-29 ***Building Trustworthiness in PCORnet*** meeting

We asked: how are we trustworthy and not trustworthy?

- Meeting objectives were to:
  - Describe the characteristics of trustworthy engagement
  - Examine successes and failures in building trustworthiness in research initiatives
  - Begin a robust dialogue around trustworthiness within PCORnet
  - Create recommendations for the networks and stakeholders that comprise PCORnet
- **166 in person attendees** and **357 webcast viewers**
- More than **40 speakers and moderators** from within and outside of clinical research who fostered rich dialogue with meeting participants

@ PCORnetwork and #BuildingTrust Twitter Engagement Metrics

From March 26-April 4, 2016:

- @PCORnetwork gained 100+ followers
- 122 tweets delivered by PCORnet
- 56,934 impressions
- 1,092 engagements
- 3,892 tweets using hashtag, #BuildingTrust
- **8,819,053 impressions**
- 753 participants
- 18 avg. tweets/hour
- 5 avg. tweets/participant

Key Recommendations

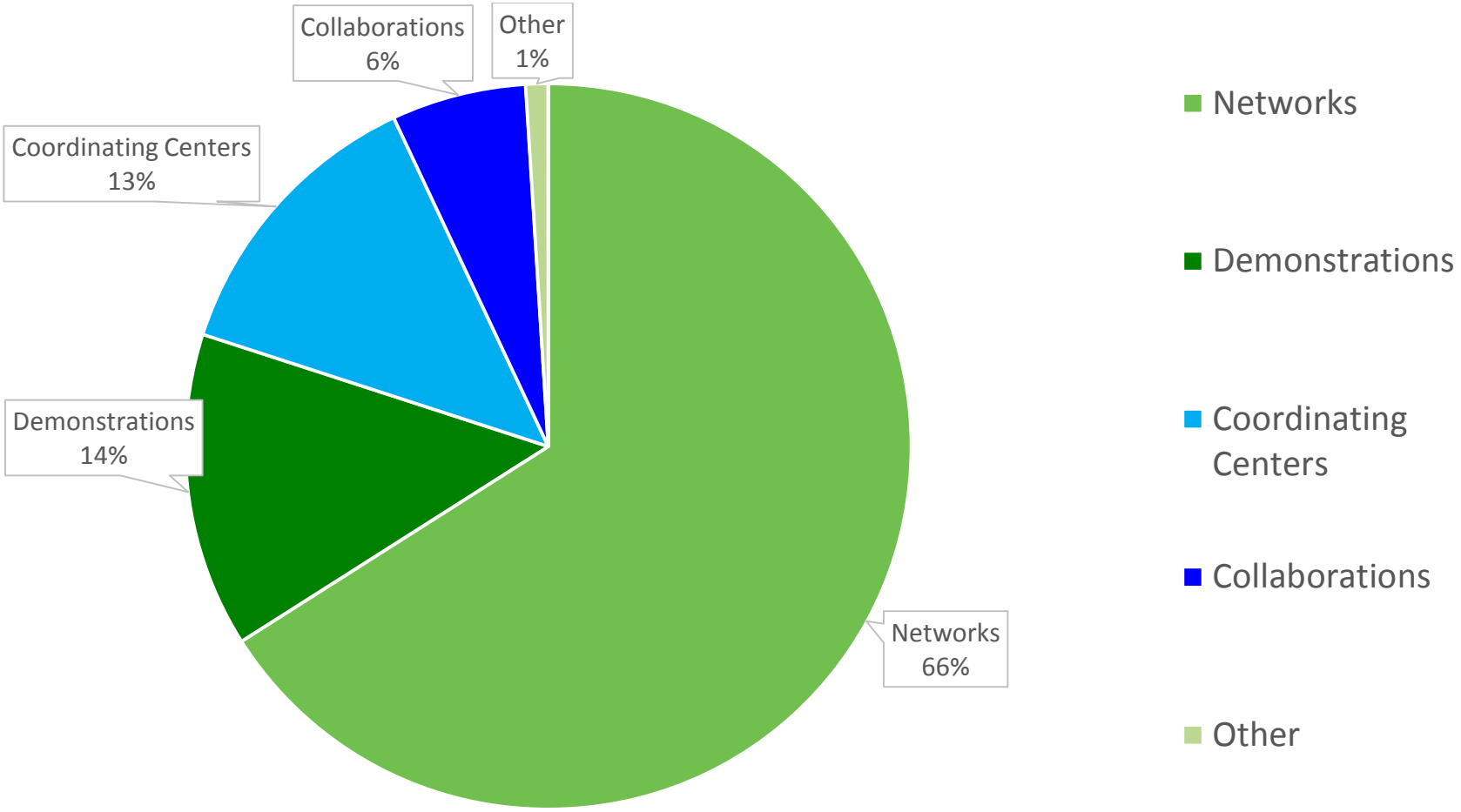
- **Inculcate cultural humility**
- Recognize and **engage diversity**
- **Transparency**– data, budget, privacy policy, projects
- Design **governance built around citizens**
- Train and support **community researchers** so that they can do PCOR
- **Common collaborative environment** with a wiki and sharing opportunities
  - Learn from **best practices/lessons**
- **Support dissemination** throughout research process
- Involve patients/participants more deeply in **IRB's**
- **Provide substantial $ in project budgets** for engagement, dissemination
- **Resources for clinicians** to engage in research

What We Have To LEARN

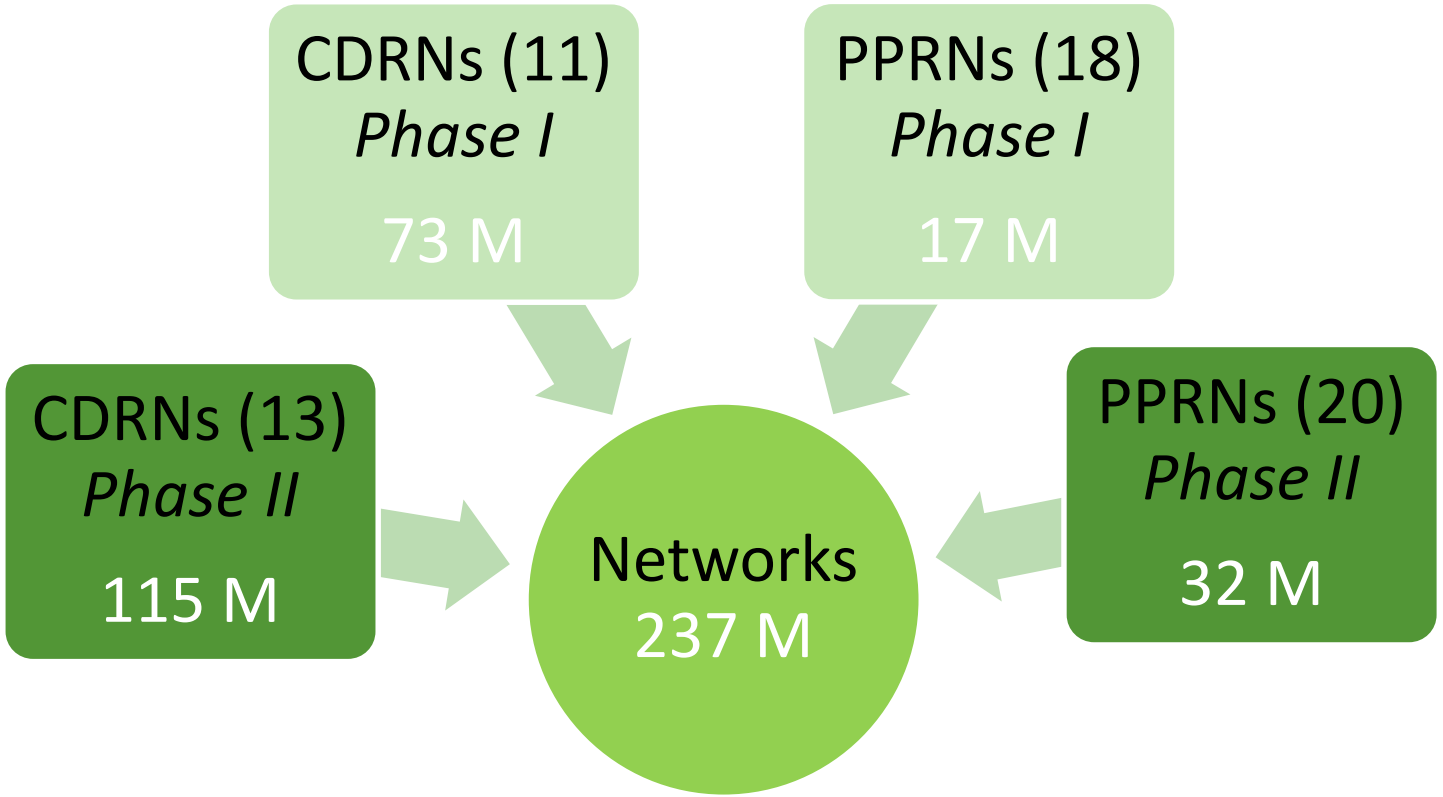
PCORnet Investment: *Focus on CDRNs*

Joe Selby, MD, MPH
Executive Director

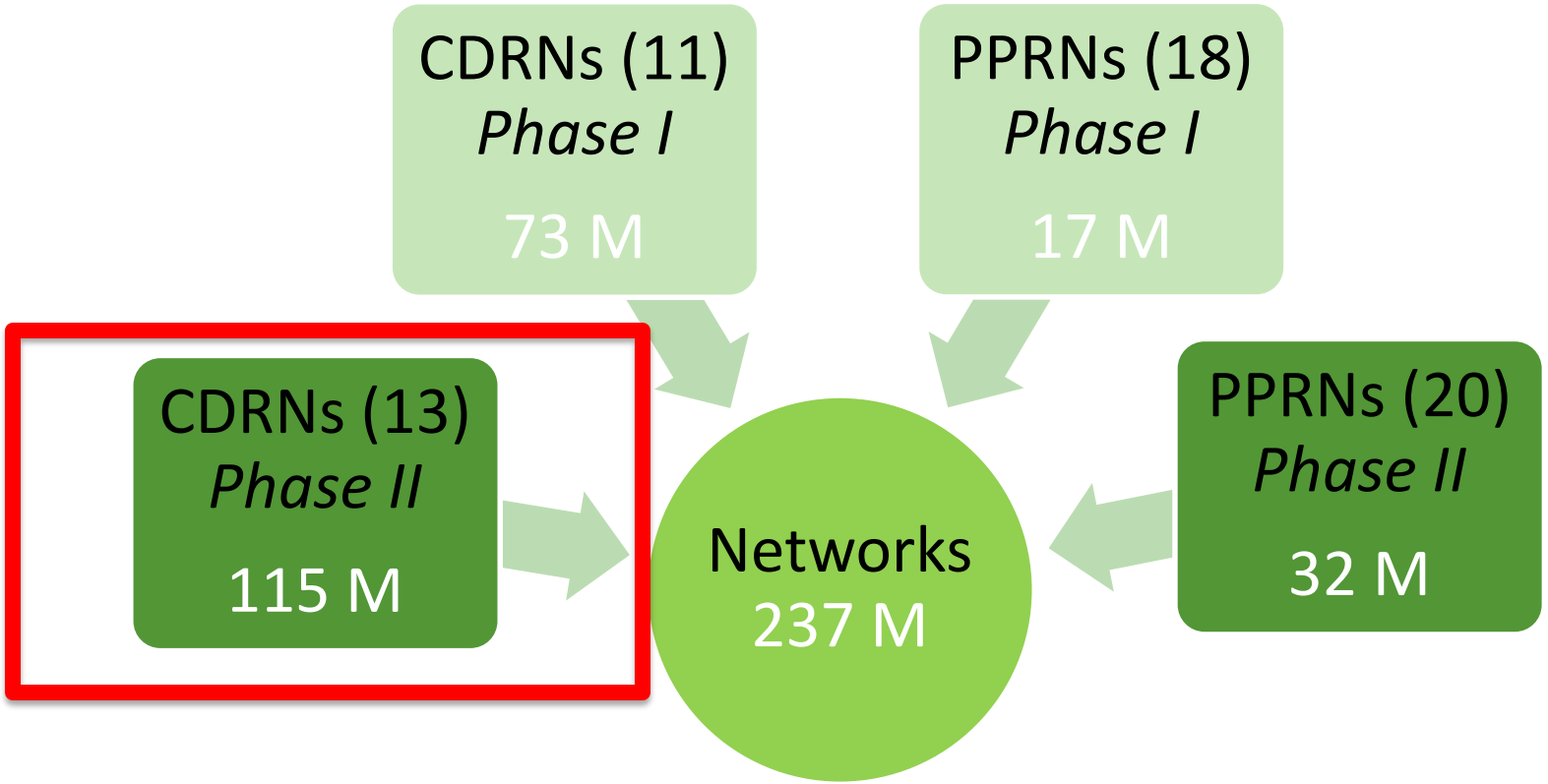
Cumulative PCORnet Investment



Phase I and II Network Investments



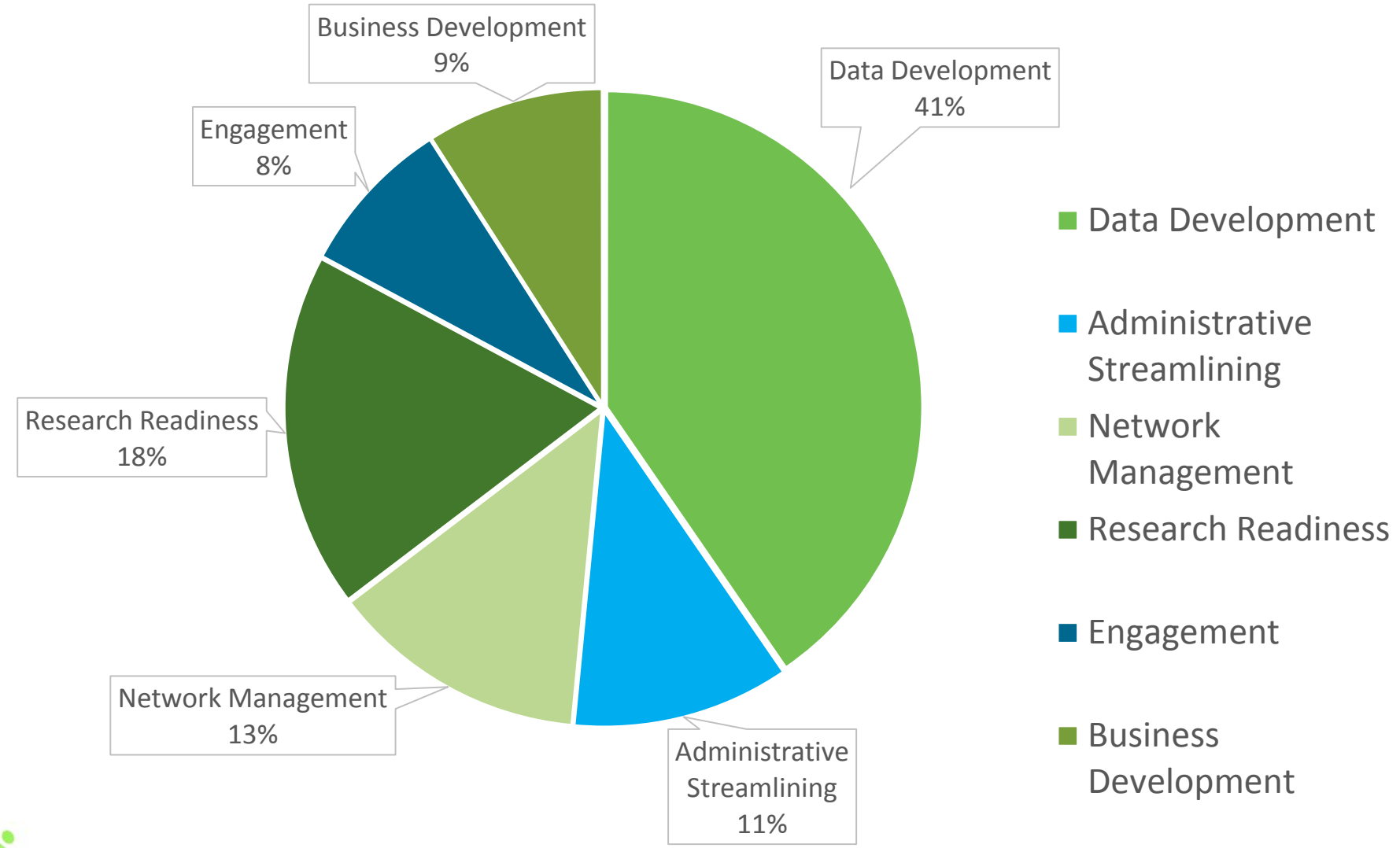
Investment in Networks



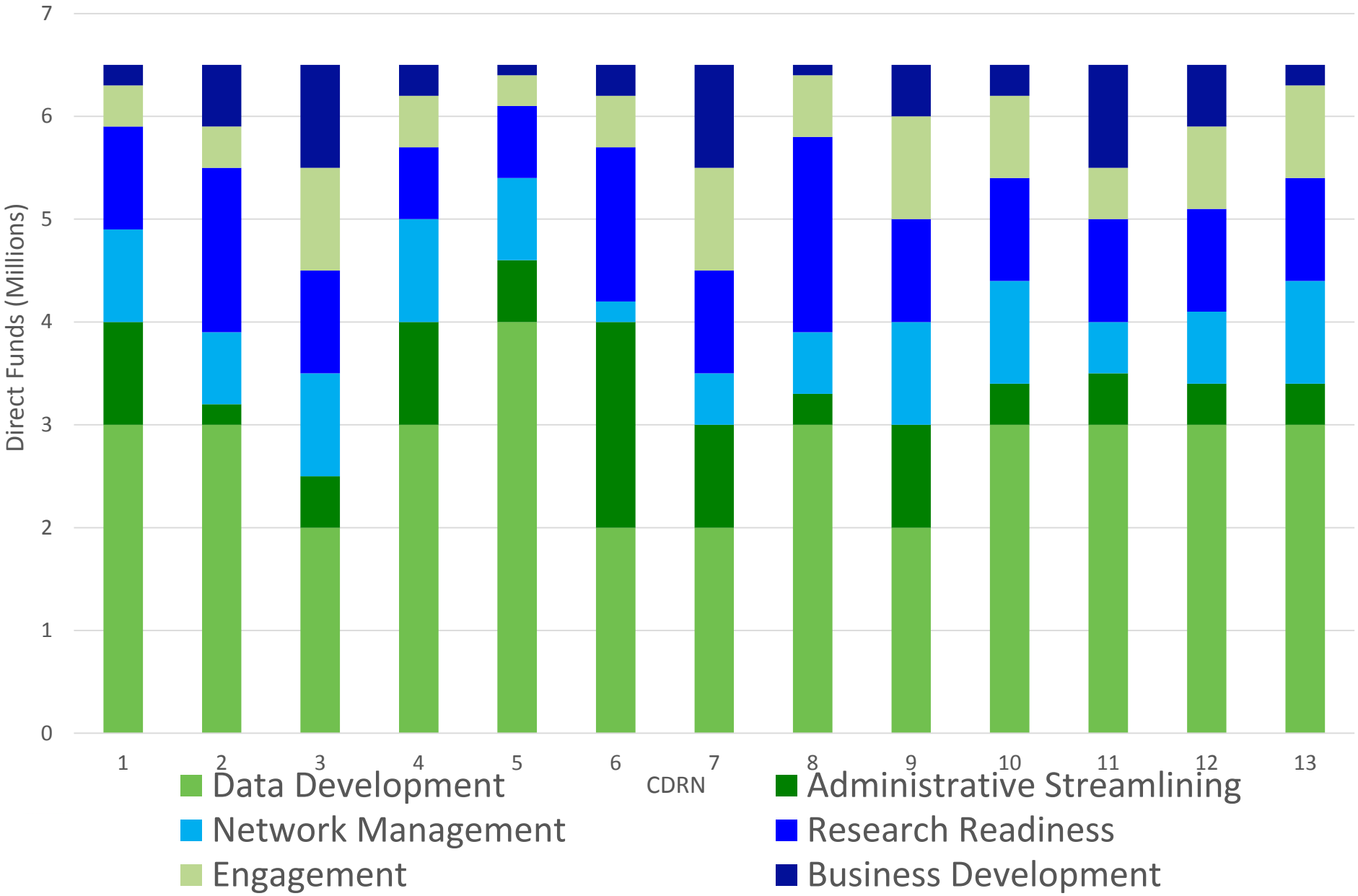
CDRN Phase II Investment Categories

- **Data Development**: Instantiation and transformation of data, Network maintenance, security, quality assessments, equipment, linking for completeness and bi-annual refresh rate
- **Administrative Streamlining**: Development and maintenance of IRB, contracting, DSA/DUAs and logistical resources
- **Network Management**: CDRN coordination, communication and interactions with PCORI/PCORnet
- **Research Readiness**: Capacity building efforts specifically related to cohorts and a readiness to respond to a variety of research queries
- **Engagement**: of patients, clinicians, health systems leaders,
- **Business Development**: Strategic planning, outreach and communications

CDRN Phase II Investment Breakdown (%)



CDRN Phase II Investment Breakdown ($)



Discussion

- **Questions?**

Reconvening Patient and Clinician Stakeholders
Hepatitis C

- Targeted announcement discussed at the March 22 Board meeting - Patient-Centered Outcomes in Optimal Timing for Hepatitis C Treatments encouraging a double-blind placebo-controlled randomized trial of immediate treatment vs. active surveillance in patients with early stage (low-risk) hepatitis C who do not currently have access to DAA treatment. The study is short-term (1 year follow up) and focuses primarily on various patient-reported outcomes such as patient assessment of symptoms (fatigue, depression, cognitive impairment), quality of life, functional status
- PCORI subsequently heard from some patient stakeholders of concerns with this study design, because it differed from the questions and designs approved in 2014
- PCORI Board and staff will invite all stakeholders from October 2014 workgroup to re-convene to discuss any concerns they may have
- Virtual Web Meeting, May 18, 2016 from 1:00 pm – 3:00 ET. Public may listen in to the discussion and send in questions and comments

Highlights: PCORI Policy on Public Access to Journal Articles Presenting Findings from PCORI-funded Research

Deposit of Manuscripts in PubMed Central

- Awardees with published peer-reviewed articles resulting from PCORI-funded research must deposit a copy of their manuscript in PubMed Central
- Articles to be deposited at time of journal acceptance; PubMed Central makes them available 6-12 months after publication

PCORI payment of fees for free Public Access to published articles

- Upon Awardee request, PCORI will pay Public Access fees for one article presenting the primary findings from their research project. Payment for additional articles considered on case-by-case basis
- Payments generally will not exceed $3500 per research project for publication of articles. PCORI will pay journals directly

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chairperson, Board of Directors