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Principles of Engagement and Approaches across the Engagement Continuum

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Vanderbilt University School of Medicine
and Meharry Medical College

June 29, 2015

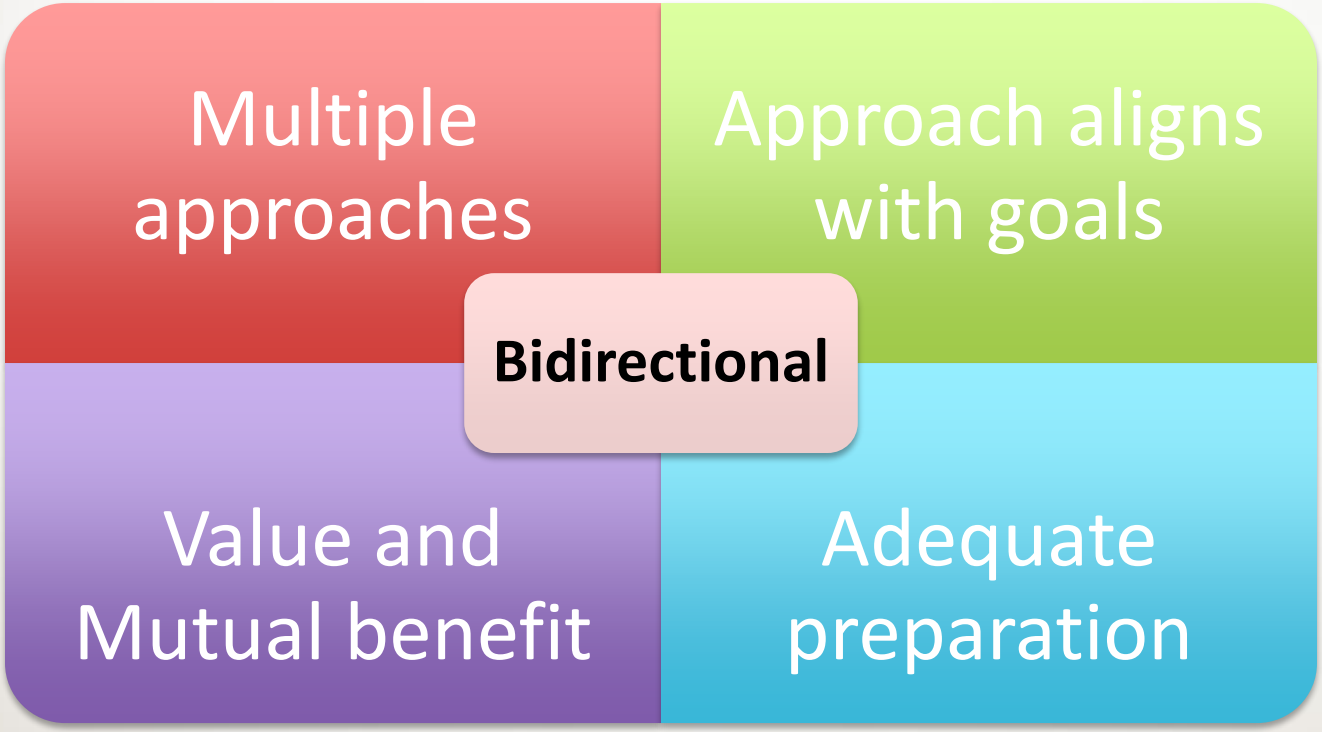
INSTITUTE OF MEDICINE

Ensure that patients, family members and other community stakeholders are involved across the continuum of clinical and translational research.

Leshner et al; 2013.

What is Engagement?

Engagement- *A bidirectional relationship/interaction between the stakeholder and researcher that results in informed decision-making about the selection, conduct, and use of research.*



Leshner et al 2013; Michener et al 2012; Frank et al 2014; Krumholz 2012; Wilkins 2015

Community and Stakeholder Engagement

"Community"	"Stakeholder"
"groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people" (*Principles of CE, 2nd ed.*)	"an individual or group who is responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence" (*Concannon, et al., 2012*)
Concerned about health in general; may not have a specific health issue of interest.	Includes patients, caregivers, consumers, community orgs, health systems, providers, public agencies, policy makers, industry

Benefits of Engaging Patients in Research

- Patients and consumers bring experiential knowledge, which is only gained by having the daily experience of living with a certain disease or condition or living in a certain community.
- It is more practical and complements the researchers' scientific knowledge.

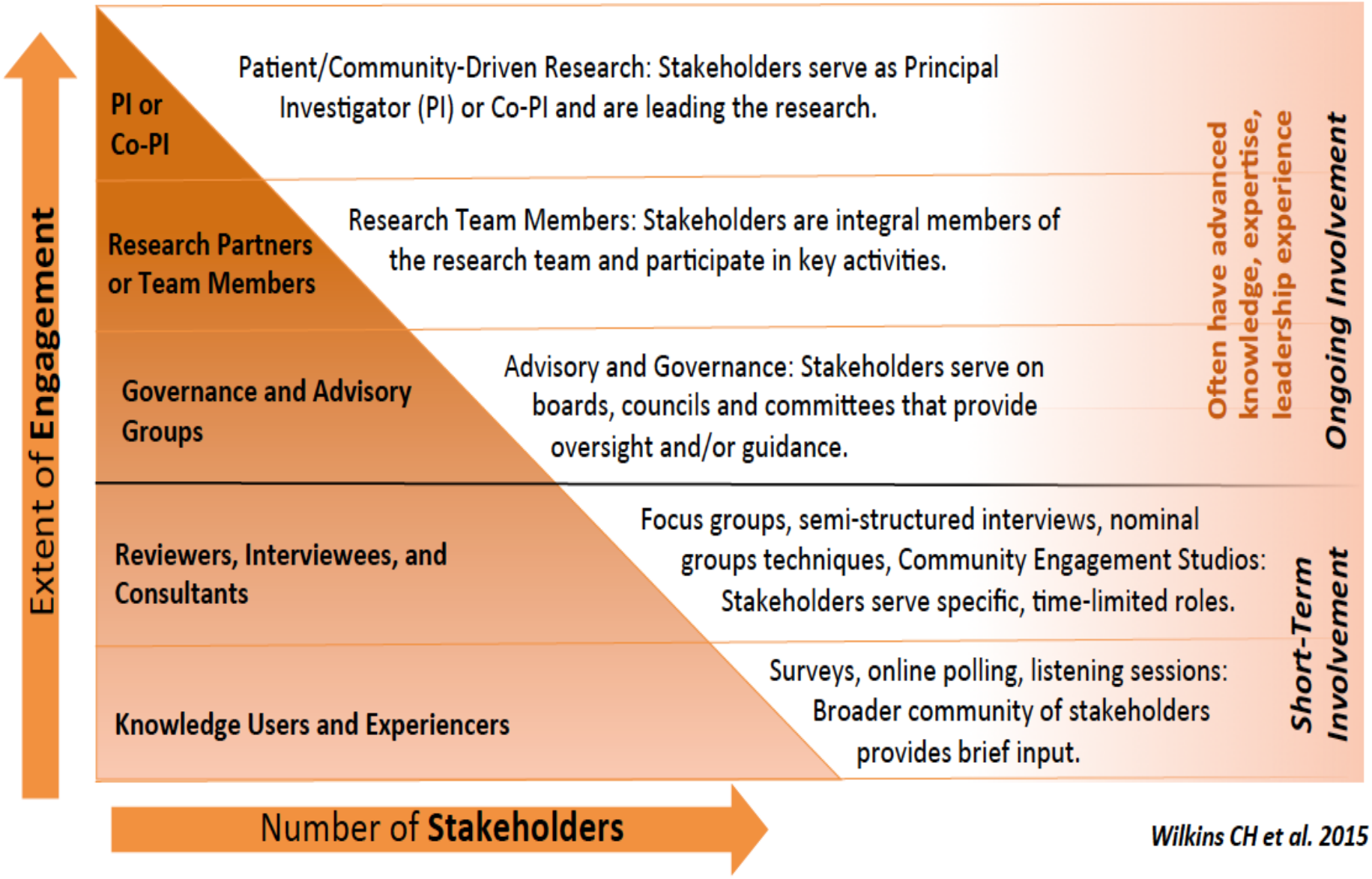
Leshner et al 2013; Michener et al 2012; Frank et al 2014; Krumholz 2012

Challenges to Engaging Stakeholders

- A new concept for many researchers
- Skills typically developed in rigorous research training do not translate to identifying, recruiting and convening stakeholders
- Without training and experience, strategies are often ineffective, burdensome and leave stakeholders feeling disenfranchised
- Becoming proficient requires training and hands-on experience, which may take years
- Research infrastructure may be limited

Mallery 2012; Staley 2009; Garces 2012

The Continuum of Community (Stakeholder) Engagement in Research



Wilkins CH et al. 2015

Approaches to Engagement

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Community Engagement Studios

- Structured process
- Project-specific input
- Use in any phase of translational research
- Stakeholders selected based on project
- Experienced team identifies stakeholders
- Reduces burden to researcher

Joosten, et al. (2015). Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input from Stakeholders to Inform Research. Academic Medicine.

Clinical trial recruitment before and after a Community Engagement Studio

African American Women
Needed for Research Study

This study will look at how muscles absorb glucose (sugar) and how the body regulates your blood pressure.

You may qualify if you:

1. Are an African American, and
2. Have high blood pressure or borderline high blood pressure,
3. Are overweight, and
4. Are between the ages of 18-60 years, and
5. Have high triglycerides, high cholesterol, or high blood sugar, and
6. Do not smoke.

This study will require a screening visit, four clinic visits, two study days, study medications, and blood and urine collections.

Participants will be compensated for their time.

If you would like to learn more about this study, contact
Ginnie Farley
ginnie.farley@vanderbilt.edu.
Vanderbilt University

Date of IRB Approval: 6/10/2010

6/2/10

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Institutional Review Board

African American Women
Needed for Research Study

You can help with this important clinical study that will test if a drug improves blood sugar levels and blood pressure.

This study is conducted
at Vanderbilt University Medical Center.

Requires a screening visit, study medication, 3 study days, and blood and urine collection.

Participants will be compensated.

You may qualify if you are :

Overweight
Age 18-60 years
Have borderline or high blood pressure
High cholesterol
High blood sugar levels
And do not smoke

For more information PLEASE CALL 615-689-1033 (Davalynn Johnson)
Davalynn.a.johnson@vanderbilt.edu

Johnson DA, Joosten YA, Wilkins CH, & Shibao CA. (2015) Case Study: Community Engagement and Clinical Trial Success: Outreach to African American Women. Clinical and Translational Science.

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Improving Patient Engagement and Understanding Its Impact on Research (PCORI)

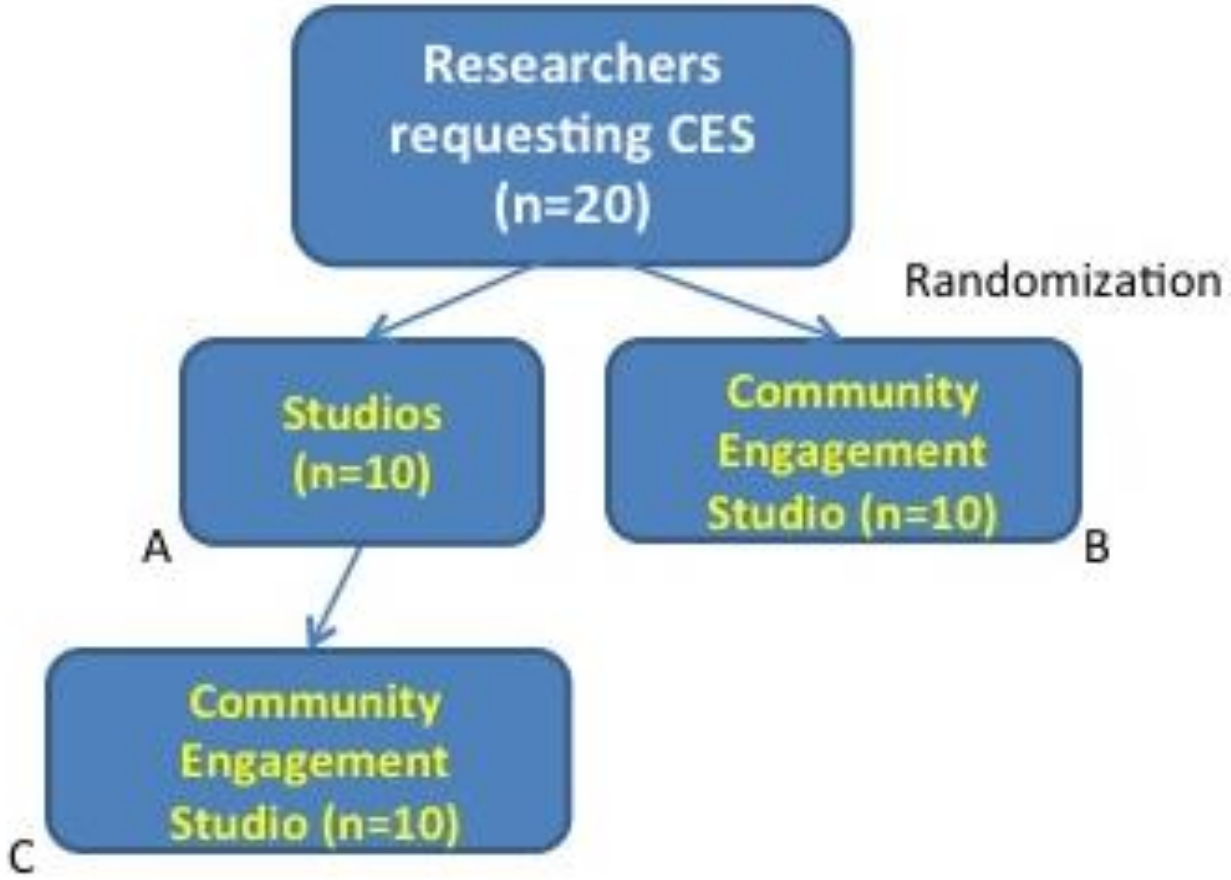
Purpose:

- Assess the impact of the Community Engagement Studio (CE Studio) on research design, implementation, translation and dissemination
- Assess stakeholder's perception of value, relevance & acceptability of research

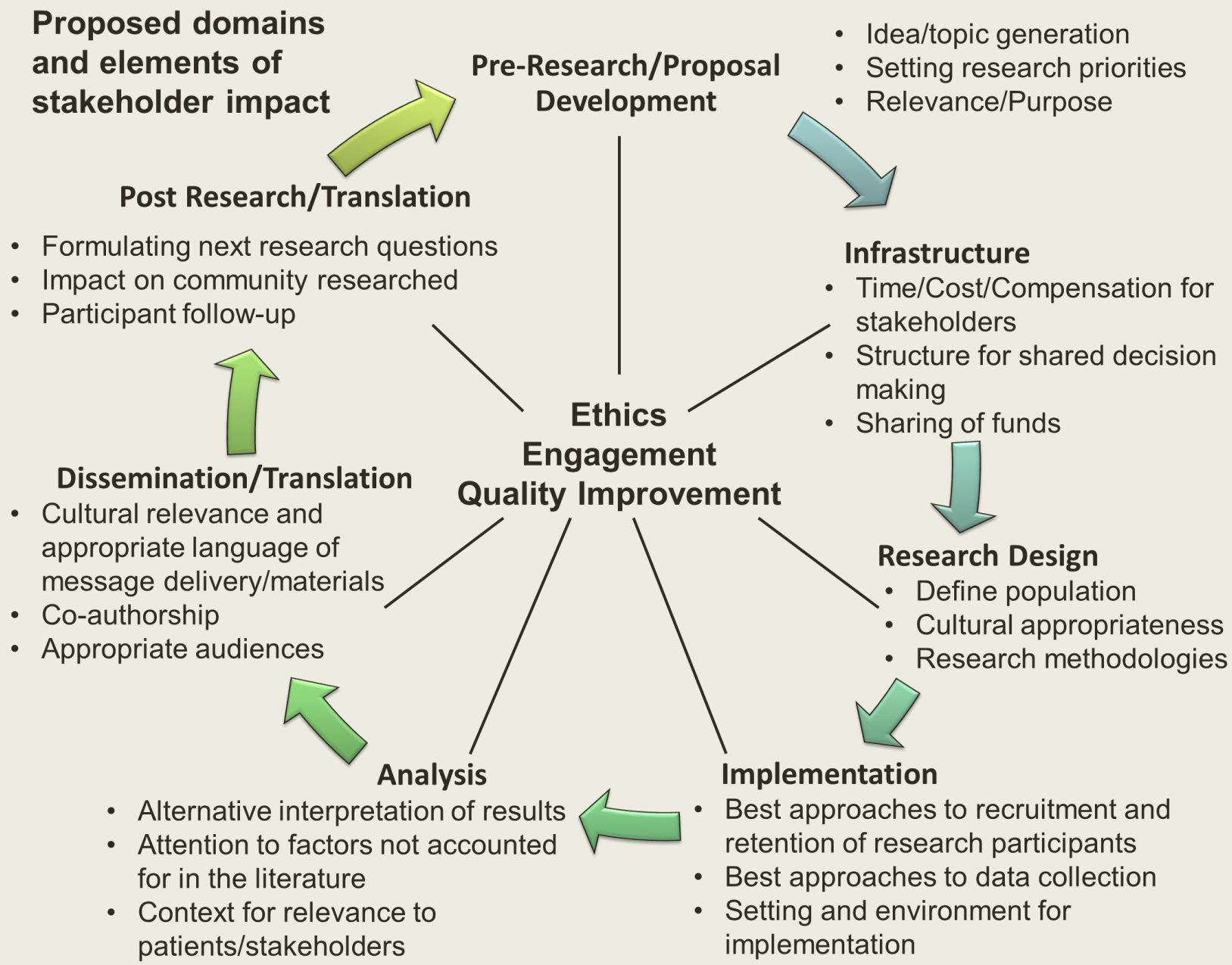
•Is the CE Studio an effective method of obtaining patient-centered input and does the input result in research that is more patient-centered?

•Team: Consuelo Wilkins (PI), Yvonne Joosten, Tiffany Israel, **Yolanda Vaughn**, **Al Richmond**, Margaret Hargreaves, Velma Murry, Alaina Boyer

Overview of Study Design

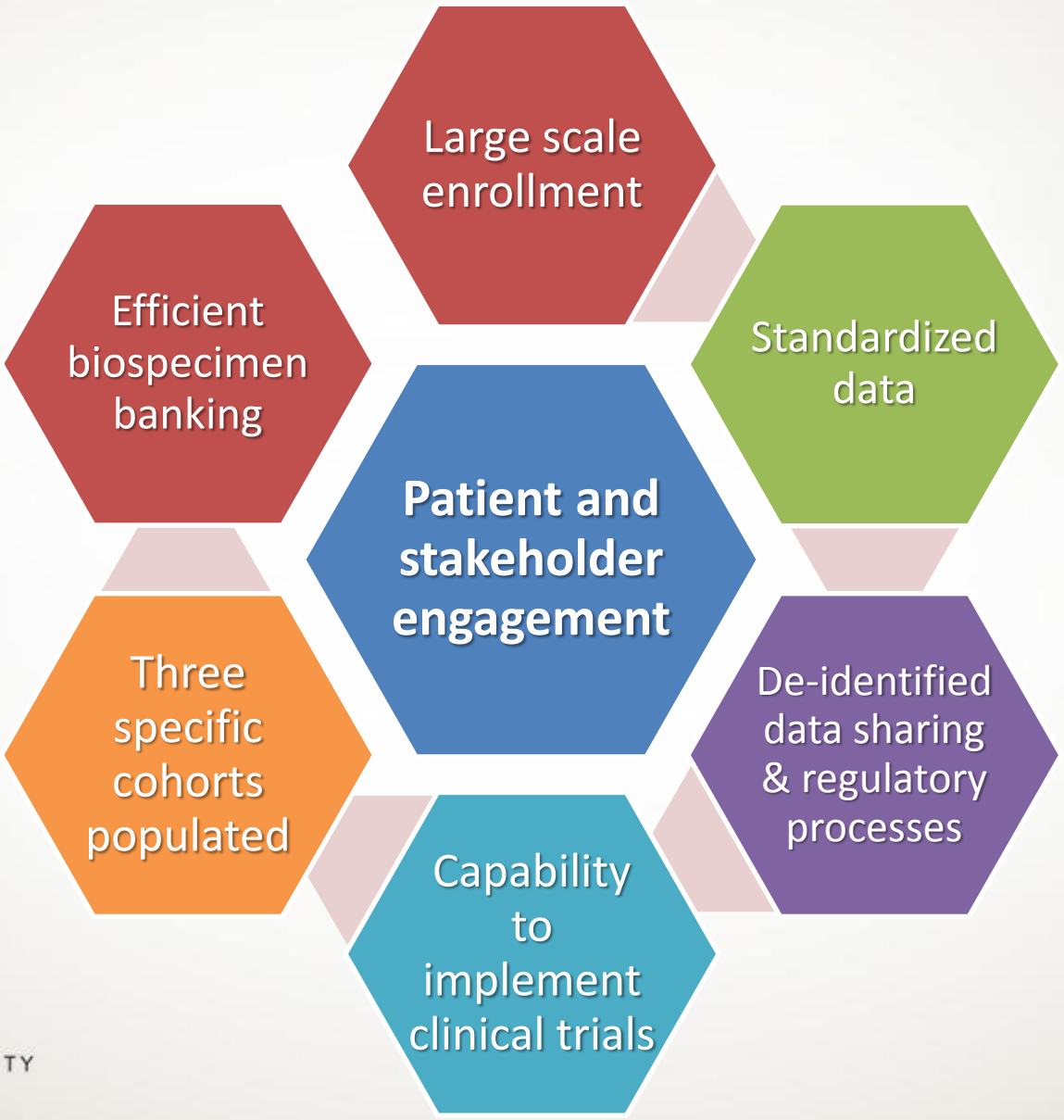


All researchers requesting Community Engagement Studios (CES) will be randomized to CES or Studio (usual condition).
Aim 1 compares the peer input (group A) to stakeholder input (group B).
Aim 2 compares change in research plans pre- and post-CRB for groups B and C.
Aim 3 examines qualitative changes in research plans pre- and post-CRB (groups B&C).



Boyer et al. A Tool to Assess Stakeholder Engagement in Research. ACTS Meeting April 2015

Mid-South CDRN Overview



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Mid-South CDRN Stakeholder Engagement Strategy (phase I)

Planned Activities for Stakeholder Engagement			
Method	**Target**	**Method Description**	**Status** (6/26/2015)
Patient Investigator	**1**	**Integral part of the research team**	**1**
Governance	**10**	**Oversight Committee-2, Stakeholder Engagement Council (Advisory Council)-8**	**7**
Community Engagement Studios	**75-90**	**Patients from VUMC, VHAN, Meharry, Matthew Walker Center and the Greenway PRIME network**	**58**
Clinician Interviews	**100**	**Semi-structured interviews with clinicians**	**In progress**
Clinician Surveys	**500**	**Targeting clinicians less engaged with research**	**266**
Patient and Community Surveys	**5,000**	**Web-based and in-person surveys of patient and family stakeholders from CDRN hospitals and practices**	**4,568**

- Understand barriers; Priority setting and topic generation
- Provide guidance on patient-centered tools and recruitment
- Innovation in methods of engagement and populations

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Promising Practices: Engagement and PCOR Principles in Action: Examples from the Field

Jaye Bea Smalley, MPA

Engagement Officer

NAPCRG

June 29, 2015

pcori

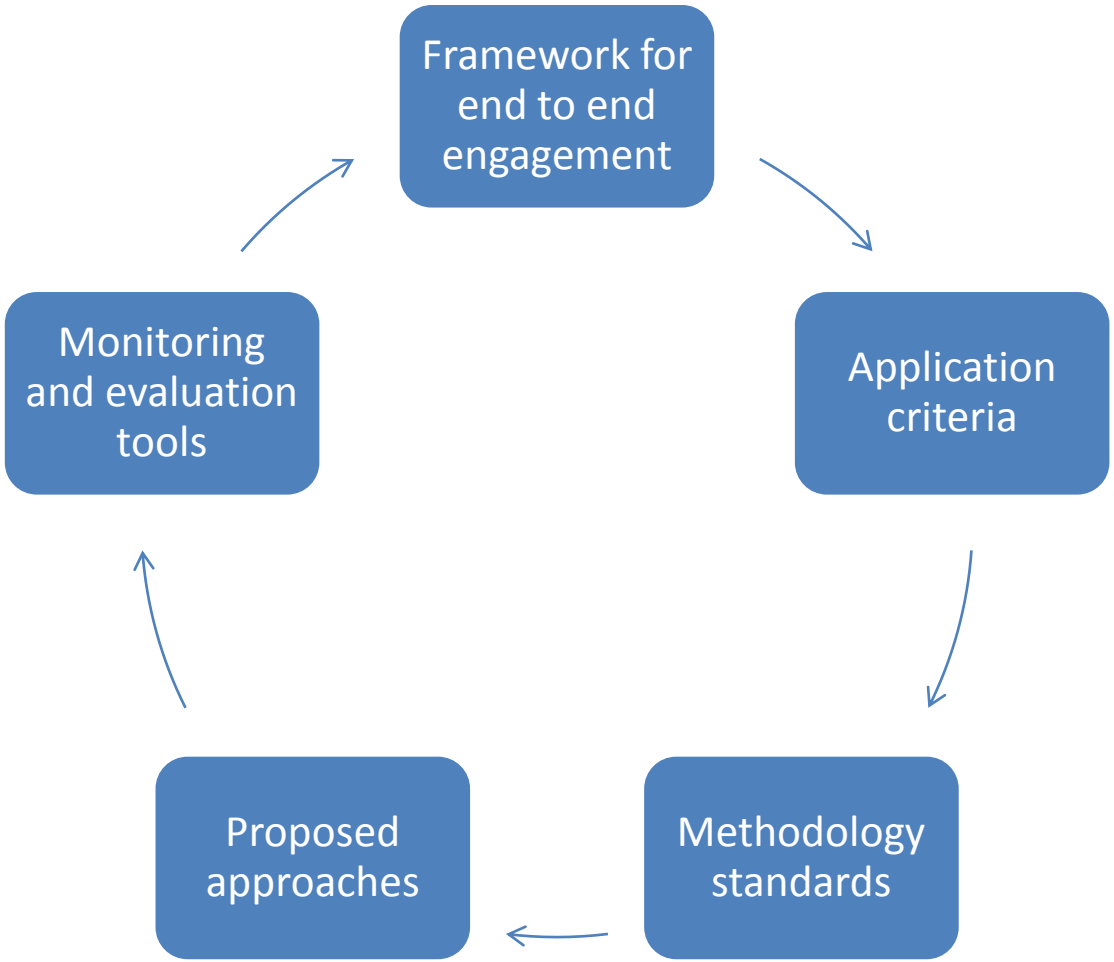
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Our Engagement Rubric- A Valuable Resource

PCORI has developed an engagement rubric to provide guidance to applicants, merit reviewers, awardees, and engagement/program officers regarding engagement in the conduct of research.

- **Planning the Study:** How patient and stakeholder partners will participate in study planning and design
- **Conducting the Study:** How patient and stakeholder partners will participate in the conduct of the study
- **Disseminating the Study Results:** How patient and stakeholder partners will be involved in plans to disseminate study findings, and ensure that findings are communicated in understandable, usable ways
- **PCOR Engagement Principles:** Reciprocal relationships; co-learning; partnership; trust, transparency, honesty

Adapting the Rubric for Engagement in Infrastructure Development

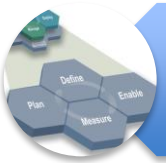


Elements of Patient Engagement-PCOR Infrastructure Development Framework

Governance

Network Recruitment and Retention

Collection and Sharing of Data



Network Collaboration

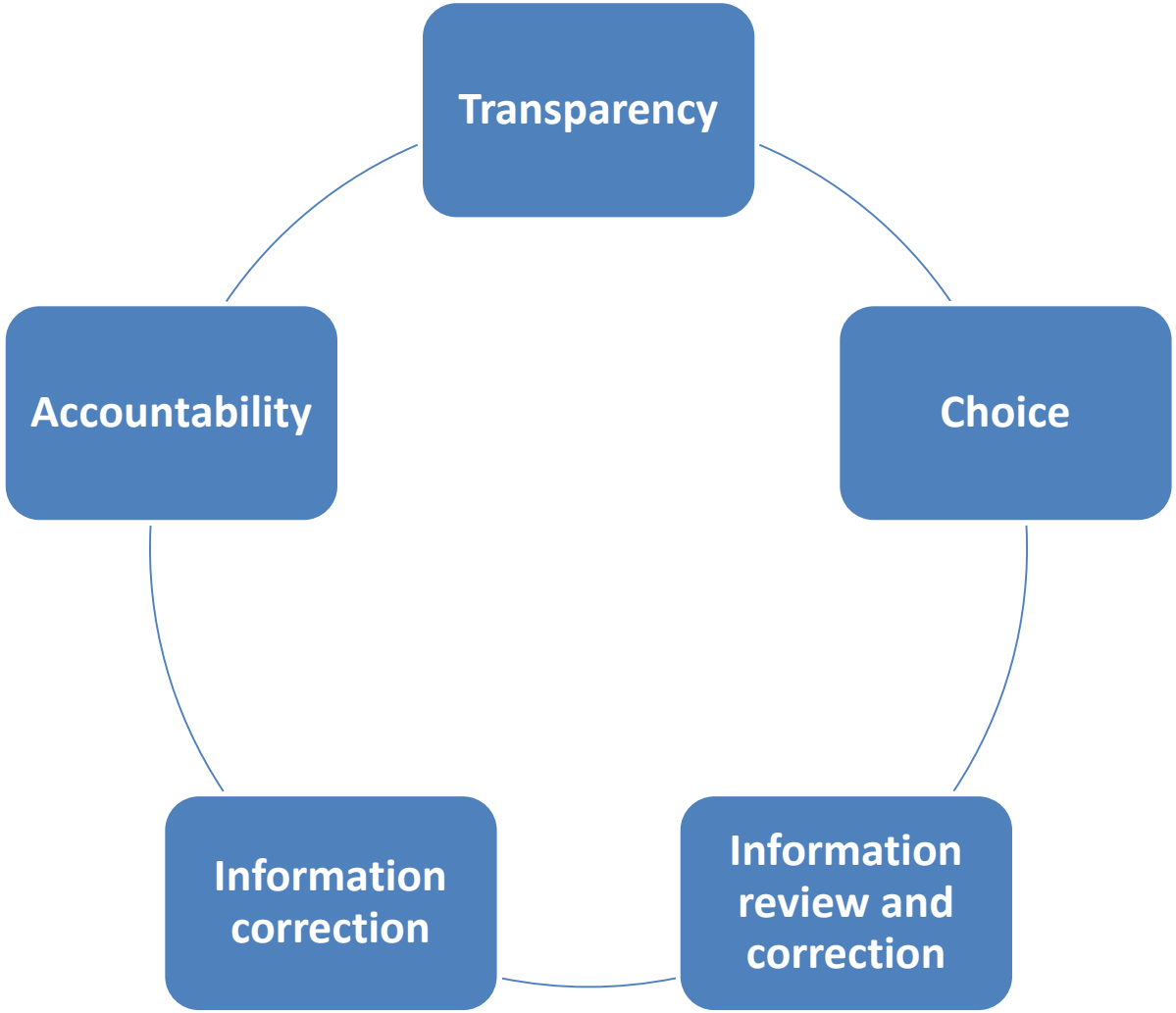
PCOR Engagement Principles

Governance

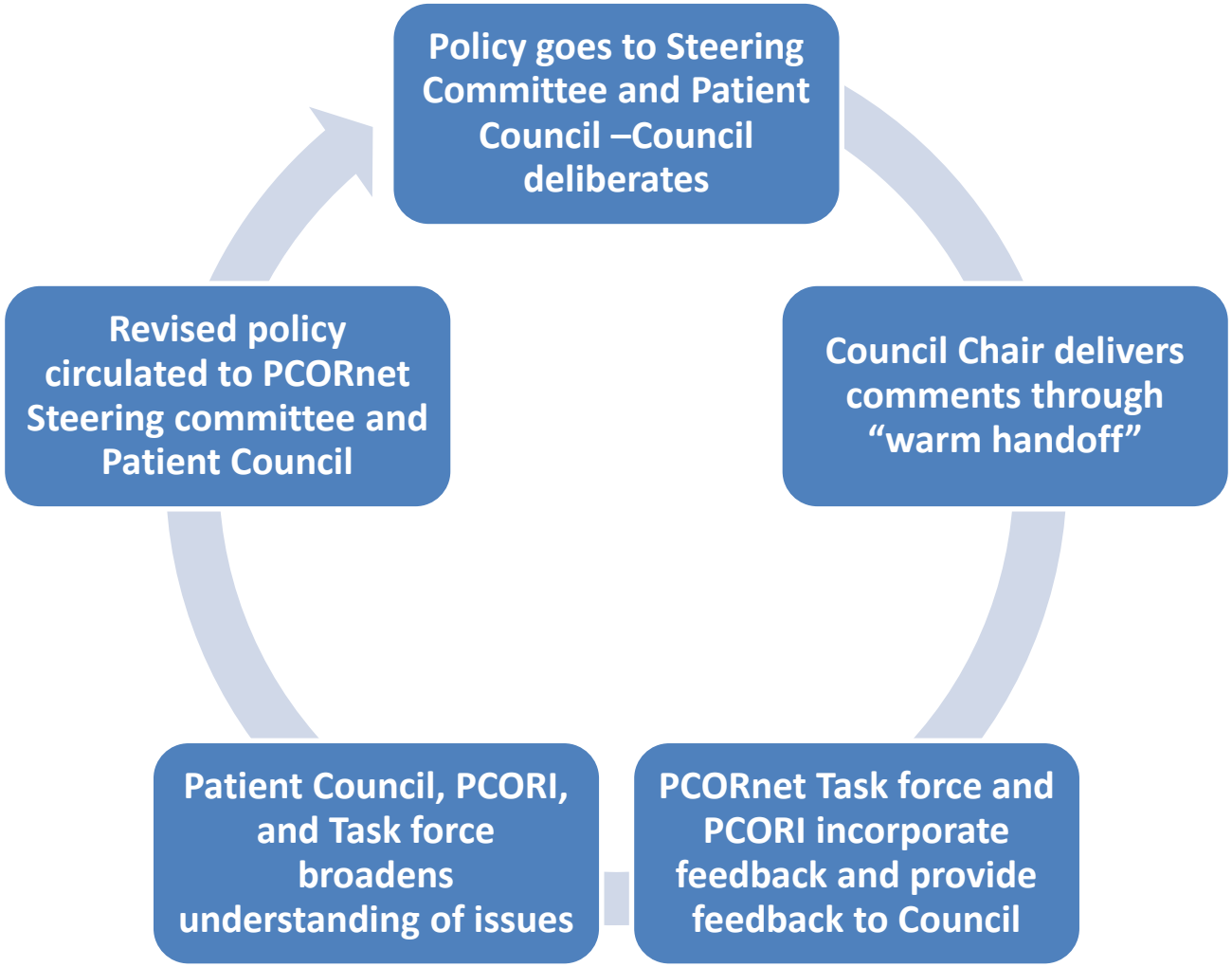
Patients participate in:

- Developing the network governance structure
- Developing roles for patients as active participants including leadership roles
- Developing bylaws and/or procedures for determining policies and network decision-making
- Generating and prioritizing research questions

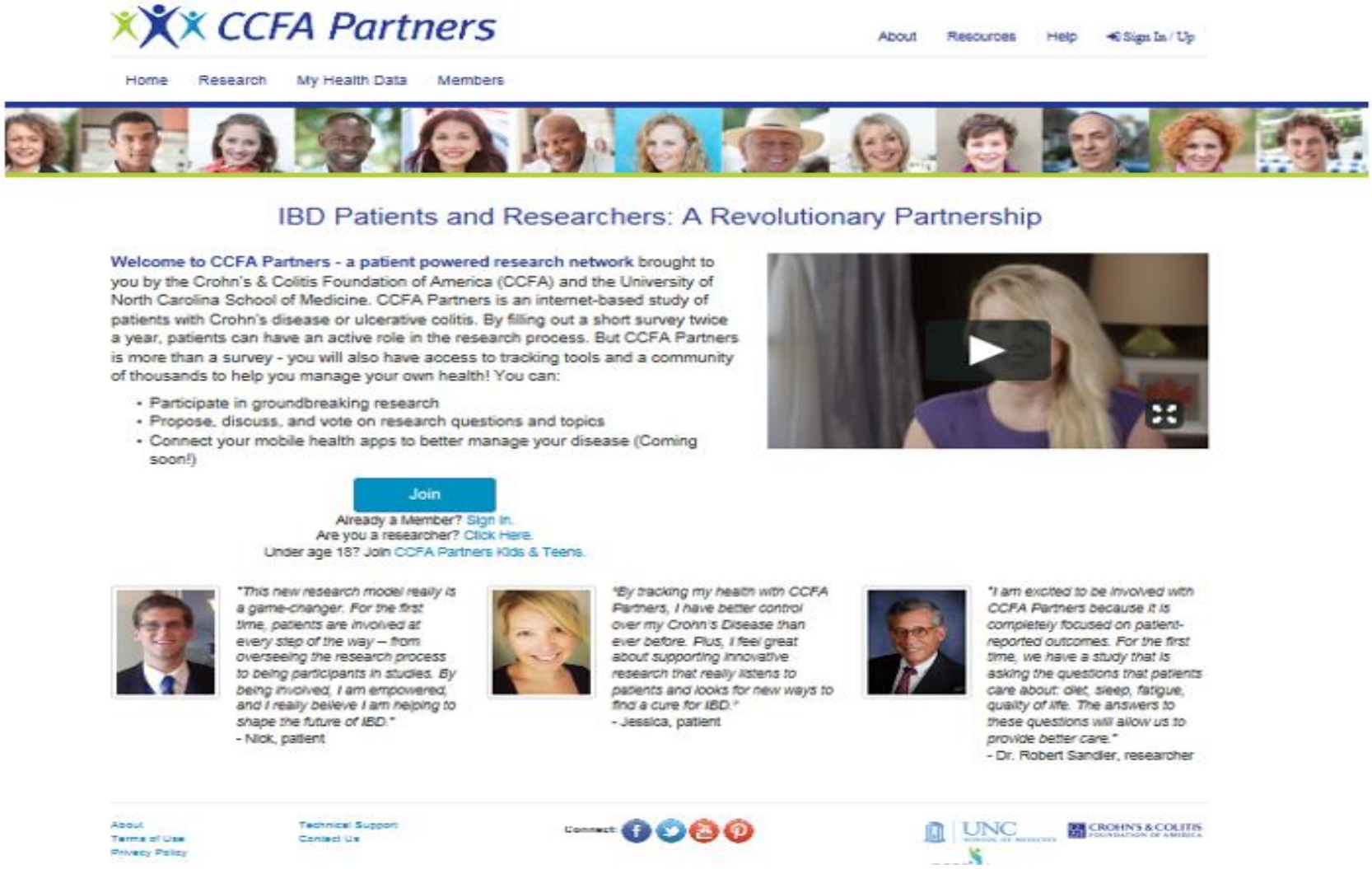
Patient Engagement in CDRN Policy Development



Patient Engagement in PCORnet Policy Development



Governance


CCFA Partners
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IBD Patients and Researchers: A Revolutionary Partnership
Welcome to CCFA Partners - a patient powered research network brought to you by the Crohn's & Colitis Foundation of America (CCFA) and the University of North Carolina School of Medicine. CCFA Partners is an internet-based study of patients with Crohn's disease or ulcerative colitis. By filling out a short survey twice a year, patients can have an active role in the research process. But CCFA Partners is more than a survey - you will also have access to tracking tools and a community of thousands to help you manage your own health! You can:
• Participate in groundbreaking research
• Propose, discuss, and vote on research questions and topics
• Connect your mobile health apps to better manage your disease (Coming soon!)
Join
Already a Member? Sign In.
Are you a researcher? Click Here.
Under age 18? Join CCFA Partners Kids & Teens.
"This new research model really is a game-changer. For the first time, patients are involved at every step of the way – from overseeing the research process to being participants in studies. By being involved, I am empowered, and I really believe I am helping to shape the future of IBD."
- Nick, patient
"By tracking my health with CCFA Partners, I have better control over my Crohn's Disease than ever before. Plus, I feel great about supporting innovative research that really listens to patients and looks for new ways to find a cure for IBD."
- Jessica, patient
"I am excited to be involved with CCFA Partners because it is completely focused on patient-reported outcomes. For the first time, we have a study that is asking the questions that patients care about: diet, sleep, fatigue, quality of life. The answers to these questions will allow us to provide better care."
- Dr. Robert Sandler, researcher
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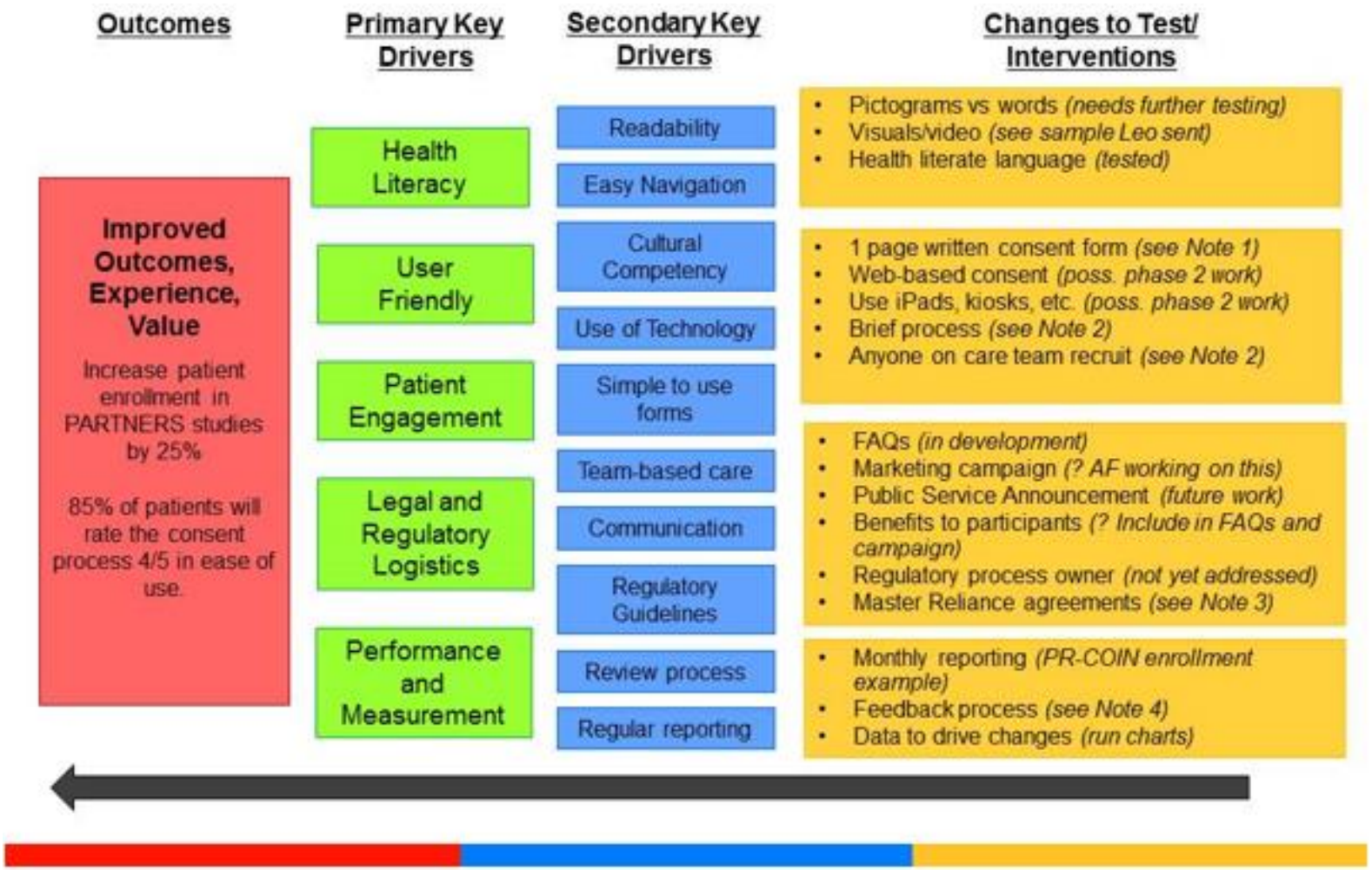
Network Recruitment and Retention

Patients participate in:

- Developing strategies and electronic tools for recruitment and retention
- Developing and conducting outreach activities
- Defining how patients from underrepresented populations will participate in the network

Consent


Outcomes
Primary Key Drivers
Secondary Key Drivers
Changes to Test/ Interventions
Improved Outcomes, Experience, Value
Increase patient enrollment in PARTNERS studies by 25%
85% of patients will rate the consent process 4/5 in ease of use.
Health Literacy
User Friendly
Patient Engagement
Legal and Regulatory Logistics
Performance and Measurement
Readability
Easy Navigation
Cultural Competency
Use of Technology
Simple to use forms
Team-based care
Communication
Regulatory Guidelines
Review process
Regular reporting
• Pictograms vs words (needs further testing)
• Visuals/video (see sample Leo sent)
• Health literate language (tested)
• 1 page written consent form (see Note 1)
• Web-based consent (poss. phase 2 work)
• Use iPads, kiosks, etc. (poss. phase 2 work)
• Brief process (see Note 2)
• Anyone on care team recruit (see Note 2)
• FAQs (in development)
• Marketing campaign (? AF working on this)
• Public Service Announcement (future work)
• Benefits to participants (? Include in FAQs and campaign)
• Regulatory process owner (not yet addressed)
• Master Reliance agreements (see Note 3)
• Monthly reporting (PR-COIN enrollment example)
• Feedback process (see Note 4)
• Data to drive changes (run charts)

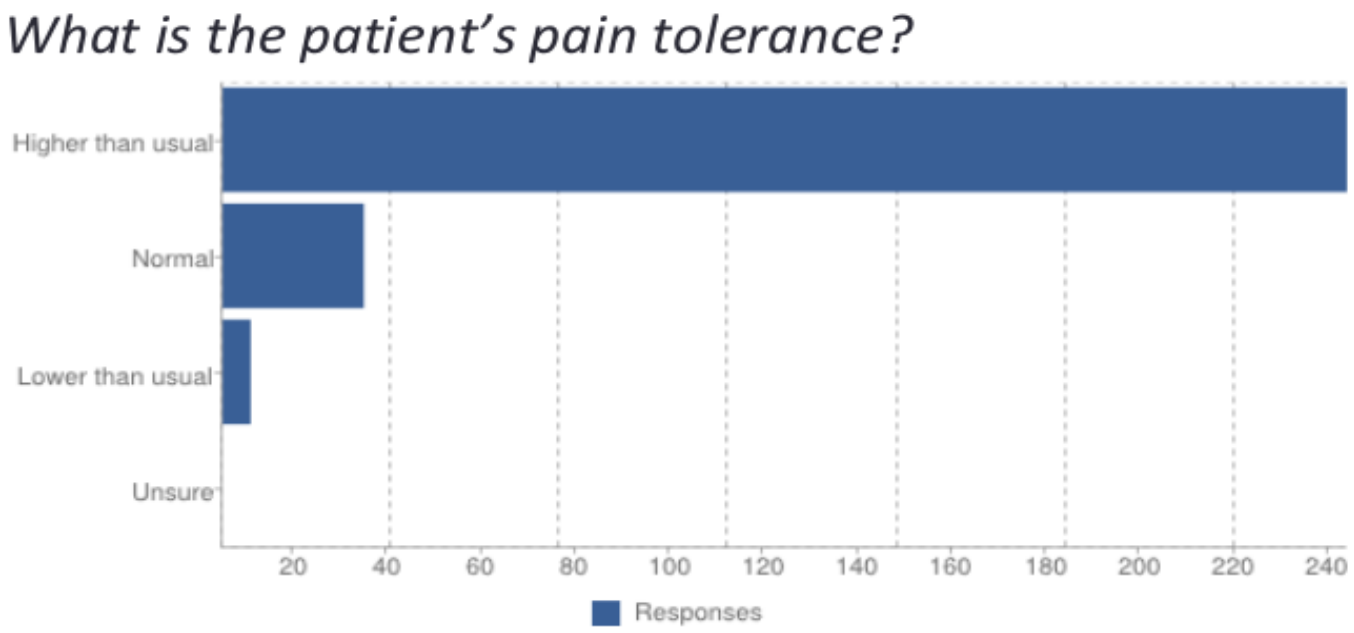
Collection and Sharing of Data

Patients participate in:

- Establishing what patient-centered data elements and patient reported data will be collected
- Developing data collection strategies and tools
- Developing mechanisms for patients to view and compare their data
- Developing consent processes and policies for different levels of data sharing and contribution

Sharing Data Among Participants

Aggregate Data Helps Families



Network Collaboration

Patients participate in:

- Developing data-linkage plans
- Developing network partnerships
- Developing engagement plans for clinicians, participants and researchers
- Enhancing patient engagement in PCORnet

iConquerMS™: Working with Influential Collaborators

CAN DO Multiple Sclerosis™

MS Coalition®

MSF MULTIPLE SCLEROSIS FOUNDATION®

MSAA MULTIPLE SCLEROSIS ASSOCIATION OF AMERICA™

MS® National Multiple Sclerosis Society

PMC PERSONALIZED MEDICINE COALITION

About iConquerMS™ - Your Information Has Power

iConquerMS™ is a new way to fight Multiple Sclerosis.

Can Do MS is actively supporting and participating in the governance of iConquerMS™, encouraging people with MS to get involved. Watch this video that captures the testimonials of people central to the initiative.

iConquerMS™ is an initiative by and for individuals living with MS who understand the need to contribute their ideas and their health data to fuel research. It is the only MS research initiative that is non-profit, patient-governed, and part of a larger nationwide research network called PCORnet.

Through the iConquerMS can contribute their data researchers to find patte patterns and insights ma MS, determine who will r new improved treatment Read More.

PMC PERSONALIZED MEDICINE COALITION

MEMBER UPDAT

February 9, 2015 Edition

Accelerated Cure Project for Multiple Sclerosis, Feinstein Launch Patient-Driven Multiple Sclerosis Research Tool

The Accelerated Cure Project for Multiple Sclerosis and Feinstein launched a new tool that enables people living with multiple sclerosis (MS in MS research. Called iConquerMS™, the tool allows people living with health data to an online database, which is then used by researchers to not be visible otherwise. Participants can securely submit their health d research that are most important to them and influence the research Accelerated Cure Project and Feinstein Kean partnered with Arizona S initiative.

iConquerMS™

MSFY: Monthly Internet Newsletter

MSF MULTIPLE SCLEROSIS FOUNDATION

In This Issue

- Team FearlessMS: Advocates Unite!
- Enter Our MS Superhero Contest!
- iConquerMS Seeks 20,000 MS Patients for Data
- Cell Transplant Therapy Shows Improvement in MS Disability
- Documentation of MS Progression May Lead to New Treament Options
- Study Finds No Link Between Cognitive Fatigue, Load
- Nurses to Hit High Seas for MS in November
- Case Western Exercise Study Seeks Participants
- The Search for a Better Way to Manage MS
- Targeting Interleukin-1ß May Lead to New Treatment

We Value Your Feedback!

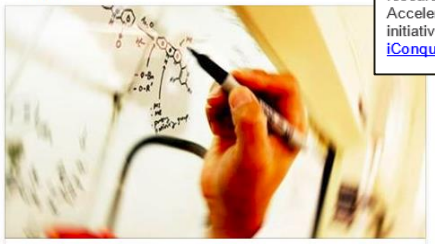
Email your comments and suggestions to chris.p@msfocus.org

MSF Is Here to Help!

For support services or to learn more about available programs, call 888-673-6287 or email support@msfocus.org.

National Multiple Sclerosis Society
February 3 at 5:49pm

You can be a part of MS research by participating in iConquerMS exciting new initiative that allows people living with MS to safely ar securely share their health information and ideas about research comfort of their own homes.



Participate in Research Studies

Researchers are committed to finding solutions for everyone affected by MS – the very people who hold the key to the answers. Without participants in research studies, MS research would come to a standstill. People with MS, and...

NATIONALMSSOCIETY.ORG

Like · Comment · Share · 783 20 205

NMSS Kentucky/SE IN @NMSSkentucky · Feb 5

Your voice can be an important part in moving MS research forward by participating in iConquerMS™.Check it out: iconquerms.org

1 1

Multiple Sclerosis Association of America
February 3 at 11:20am

MSAA is excited to share our support for iConquerMS, a patient-driven MS research initiative. Learn how your data and ideas can accelerate research to better understand, treat, and ultimately cure MS. http://iconquerms.org

Like · Comment · Share · 11 1 3

Can Do MS @CanDoMS · 22h

We're excited to support @iConquerMS in the fight against #MultipleSclerosis iconquerms.org

3 4

PCOR Engagement Principles

1) Reciprocal relationships: Roles and decision-making authority
2) Co-learning: Opportunities to enrich both patient/stakeholder partners and research team
3) Partnership: Compensation and recognition
4) Trust, Transparency, Honesty: Communication

Reciprocal Relationships: Challenges and Opportunities

- Patients and stakeholders noted the usefulness of being involved early or experienced a desire to be involved earlier
- Researchers noted several challenges: keeping patients engaged throughout the project, setting expectations for project funding, and lacking funds for early involvement

"I wish they would have contacted us earlier in the grant process so we may have been able to work in more areas of the state vs. a small section."

"We did not have money to reimburse patients/stakeholders as we prepared the grant."

"It is always hard to go back to stakeholders…when a project has not been funded. This, in my opinion, is one of the greatest challenges to engaging with patients in the conceptualization and planning phases."

Partnership: Compensation

- Many respondents noted the importance of compensating patients and stakeholders for their time
- Some researchers expressed concerns about:
  - Setting appropriate level of compensation
  - Unintended adverse consequences (e.g., eligibility for social programs)
  - Determining appropriate compensation across stakeholder type

We are concerned about how compensation affects eligibility for public benefits, including Medicaid, welfare, and food stamps.

In all honesty, the amount I am being paid ($100/hour) really helps me engage because it makes me so willing to help in any way possible, as well as offer ideas on how I can help.

…At what level do you compensate patients without it seeming like they are being co-opted?

Trust, Transparency and Honesty: Communication

- Managing power differentials
- Managing diverse groups
- Using plain language

"How does one facilitate conversations across different stakeholder groups when there are strong feelings that can conflict? "

"Researchers need to understand patients and how to communicate with them, especially if they are not in the same age group or cultural background."

"It is sometimes difficult to "speak the same language" at group meetings. In other words, the language style tends to be dominated by researchers or clinicians."

Co-Learning: Training Needs and Opportunities

- Training needs
  - Topic background
  - Research methods
  - How to facilitate multi-stakeholder groups
  - How to translate research findings
  - Training for researchers on how to engage partners

"I have searched for training webinars and other tools to help…my staff to better understand our role."

"There is a steep learning curve to understanding research and how to conduct research."

Co-learning: Value of Engagement

- Increased interest in patient/ stakeholder engagement
- Feeling like participation had impact beyond project

"I am more comfortable suggesting inclusion of patients on research projects."

"It allowed me to feel like a more rounded physician because I am doing research to help the general community. It expands my influence on the community in which I live."

"Expanded our interest and relationships with other researchers in our community… We also brought together several of the researchers in our community to discuss who we are and what we do as to try and coordinate projects geared towards senior adults."

Thank You!

Jaye Bea Smalley, MPA
Engagement Officer

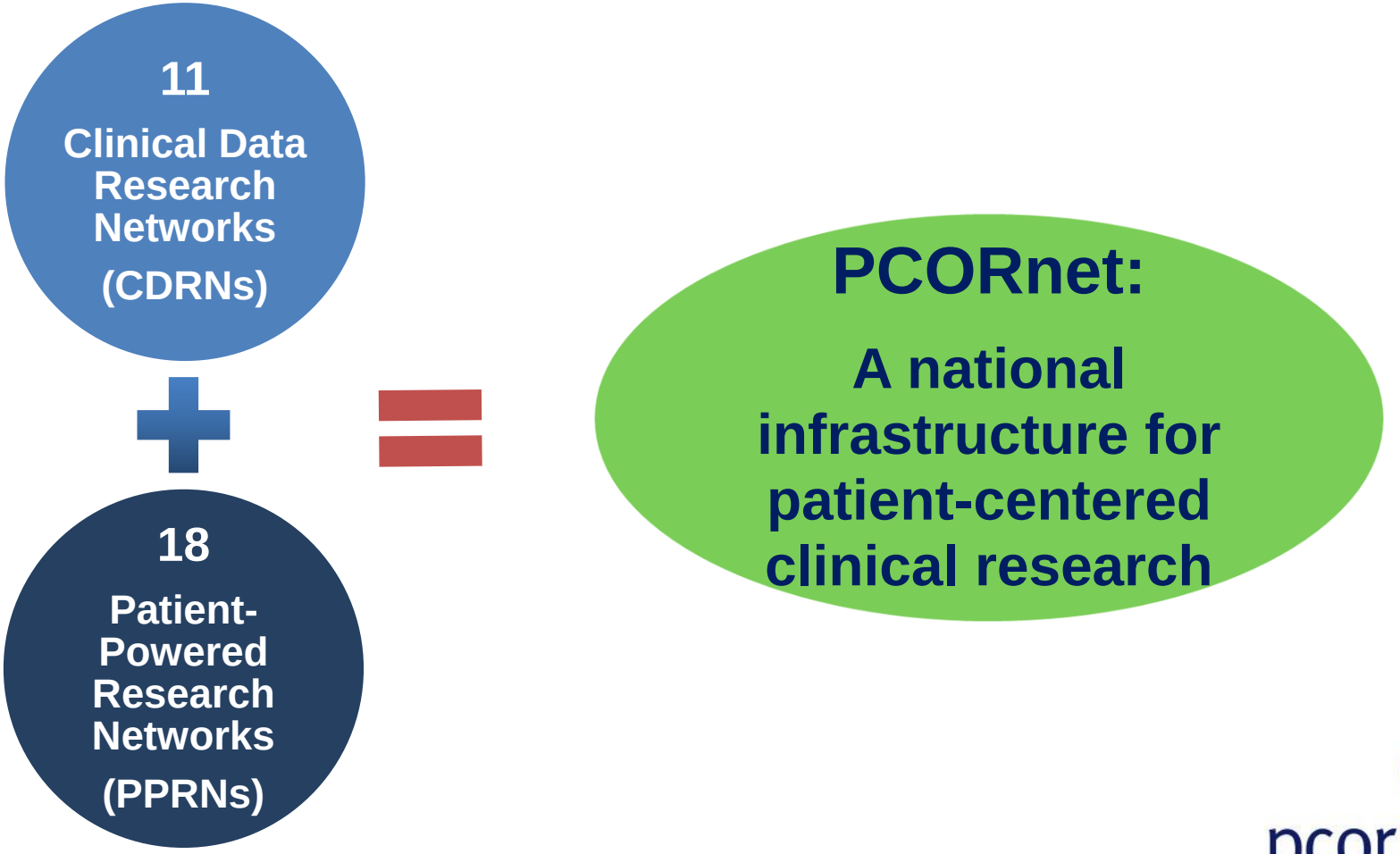
jsmalley@pcori.org

Developing An Assessment for Stakeholder Engagement in PCORnet

Sarah Daugherty, PhD, MPH Senior Program Officer

Patient-Centered Outcomes Research Institute

PCORnet Unites System-based and Patient-driven Research Networks



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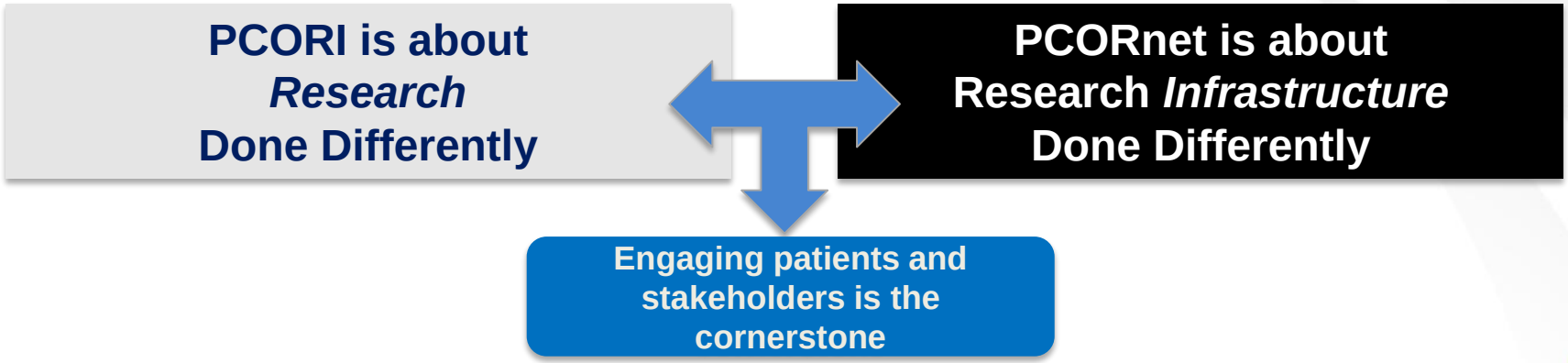
Engagement as a Tool for Transformation

Vision for PCORnet is that it will enable rapid, large-scale, patient-centered clinical research in real-world care delivery systems and communities



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Hallmarks for PCORnet Success

1. Highly **engaged** patients, clinicians, health systems, researchers and other partners
2. A **collaborative community** supported by robust governance
3. Analysis-ready **standardized data** with strong privacy protections
4. Oversight that **engages patients**, supports the timely conduct of research, and builds trust in the research enterprise
5. Research that is **sustainably integrated** into care settings and with communities of patients

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Engaged Patients are Helping Co-design Health Research Infrastructure

Network Recruitment and Retention

- Increasing size and diversity of the network
- Retention of network members

Governance

- Development of the network governance structure, roles & responsibilities
- Development of procedures, bylaws & policies for the network

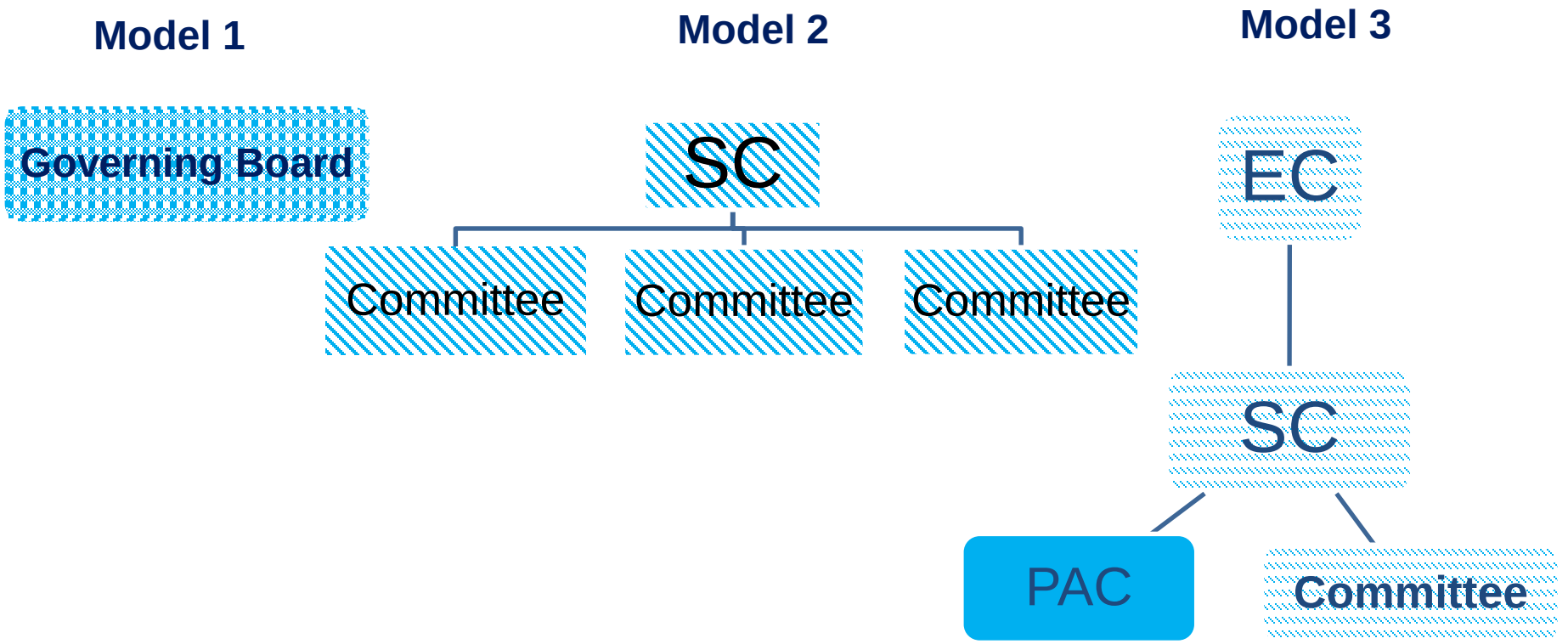
Collection and Sharing of Data

- Development of data collection tools and identification of patient-reported outcomes (PROs) for inclusion
- Development of consent processes and policies and data sharing agreements

Network Collaboration

- Brokering partnerships with patient groups and other stakeholders
- Enhancing engagement in the national network and CDRNs

Governance Structure and Patient Engagement



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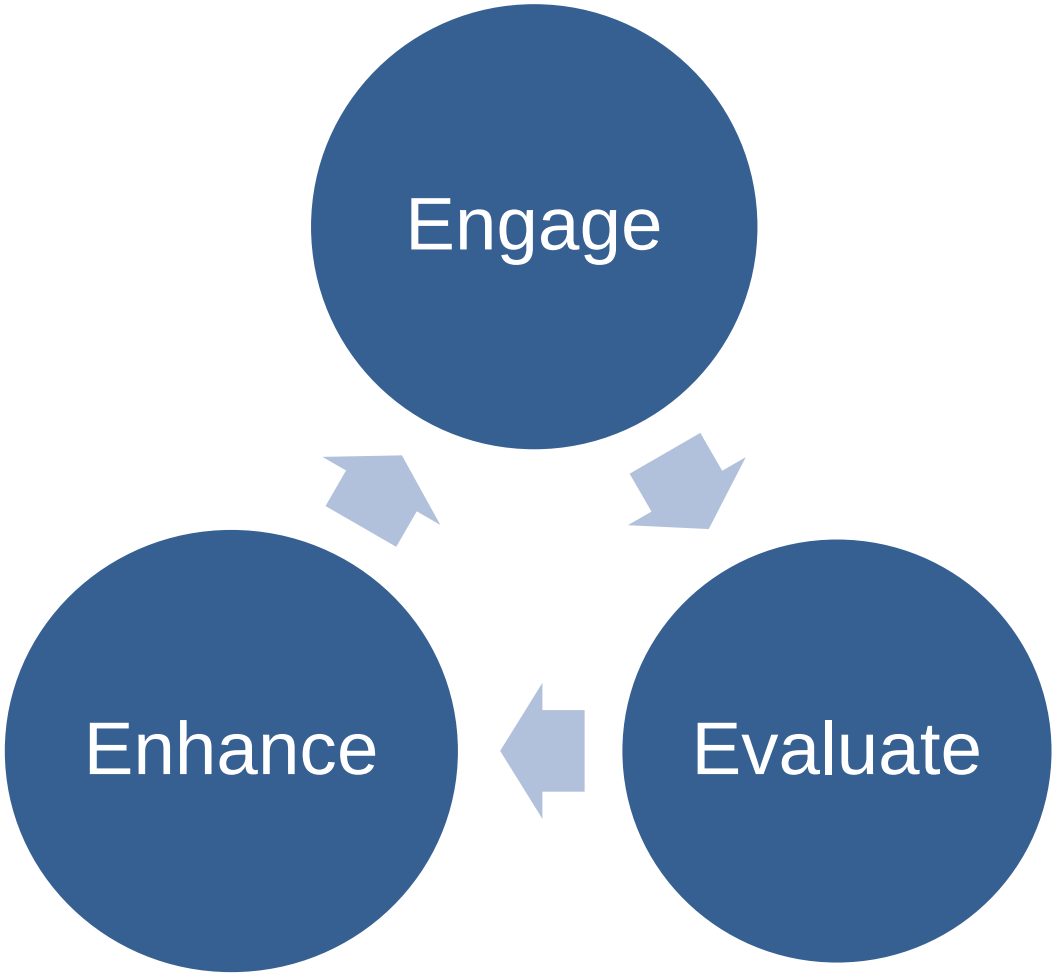
Stakeholder Engagement in PCORI Projects



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netENACT Evaluation Objectives

1) to **build a body of evidence** about what components of stakeholder engagement matter most for robust achievements in network development
2) to better understand **when and how** stakeholder engagement influences critical decision-points
3) to better **understand barriers and facilitators** of stakeholder engagement in network development
4) to **enhance stakeholder engagement practices** in each phase of network development through shared experience and lessons learned

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Process for Developing the Assessment

Patient and Consumer Engagement Task Force

Small working group

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netENACT Logic Model

Input	Methods	Outcomes
Organizational culture*	Engagement by Stage	Network achievements
Previous engagement experience	Governance	Changes in PCOR principles*
Perceived value	Recruitment	Adequate, Appropriate, Accessible
Pre-existing partnerships	Data privacy & security	Awareness of data use
Sensitivity to diversity*	Topic identification & prioritization	Level of engagement & influence
Knowledge/skills	Communication	Sustained/new partnerships
Resource Investments	Patient selection*	External funders and researchers
Existing technology*	Committee Structure	Efficient and meaningful PCOR
	Training Provided*	Migration of PCOR culture*
	Mutuality of training*	
	Frequency & Intensity	

What aspects of **network and network team** shaped **stakeholder engagement** approach?

How have **stakeholders been engaged** in PCORnet work?

How did patient engagement influence 1) PCORnet network development 2) research conducted within PCORnet

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Challenges and Lessons Learned

- Keeping patients engaged over time
- Responding in a manner which meets funder's expectations
- Being responsive to respondent burden and timing of survey implementation
- Optimal way to assess engagement at early stage of network development