Welcome and Approval of Minutes

Eugene Washington, Chair, MD, MSc

PCORI Board of Governors Meeting

San Francisco, CA

February 2013

Patient-Centered Outcomes Research Institute

Appendix

- Minutes for the November 19, 2012 - Board of Governor's Meeting

Executive Director's Report

Joe Selby, MD, MPH

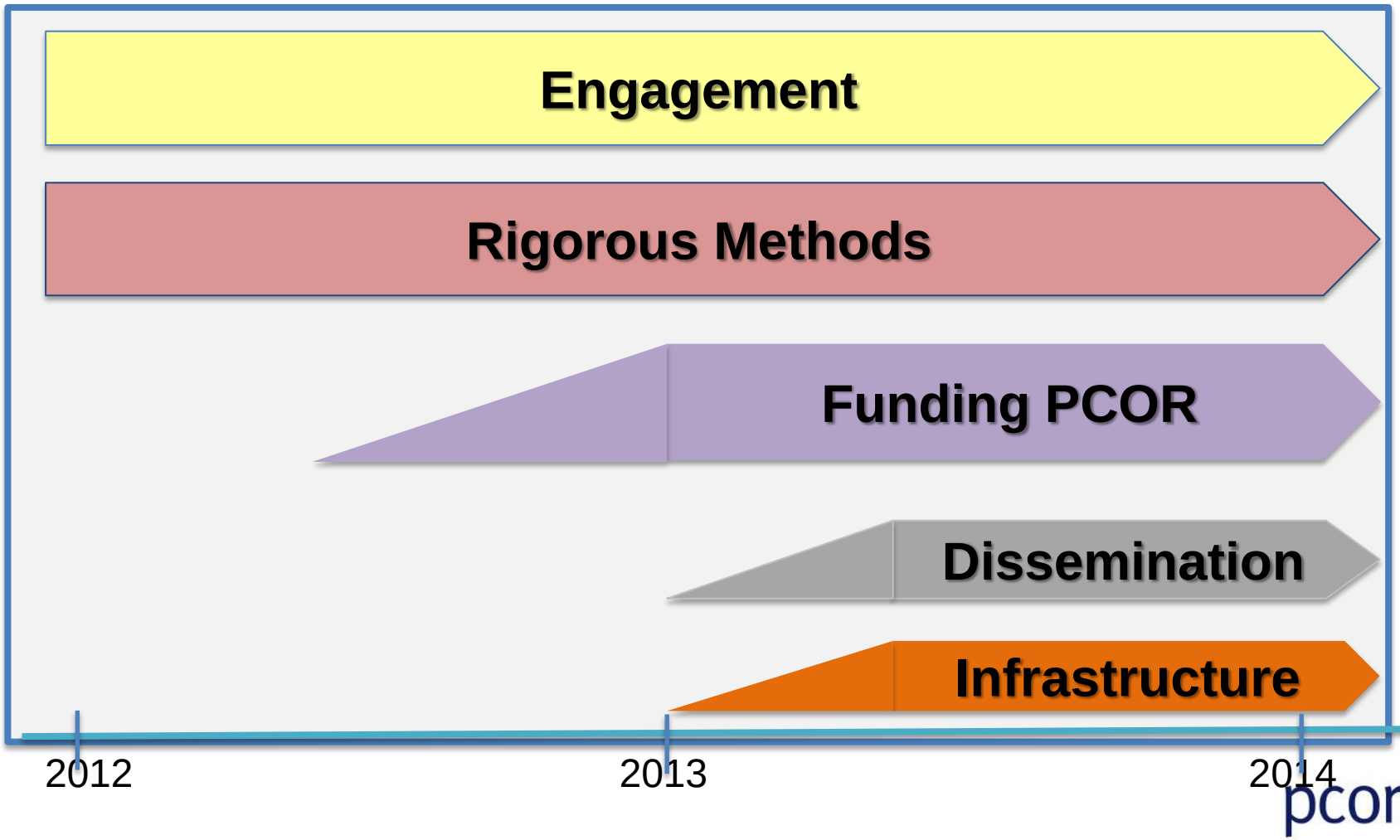
PCORI Board of Governors Meeting

San Francisco, CA

February 4, 2013

Patient-Centered Outcomes Research Institute

PCORI Strategic Activities 2012-2014



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Engagement

Building a Patient - Stakeholder Community, prepared for PCOR

What Should PCORI Study: A Call for Topics from Patients and Stakeholders
December 4, 2012

- Multi-stakeholder Workshop
- 130 attendees, 200+ via webcast
- Focus on multi-stakeholder exploration of key research questions in each of PCORI's priority areas
- 493 questions forwarded to PCORI's topic generation process

Engagement

Building a Patient - Stakeholder Community, prepared for PCOR

PCORI Methodology Workshop for Prioritizing Specific Research Topics
December 5, 2012

- 70 attendees – methodologists, researchers, stakeholders
- Reviewed PCORI's proposed prioritization process
- Strong support for continuing to refine and use this process

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Engagement

Building a Patient - Stakeholder Community, trained in PCOR

- **Roundtables** – issue or community-specific meetings (e.g., disabilities community; rare diseases community; clinicians; insurers)
- **Mentor Program** for Patient, Stakeholder Reviewers (Jan 12th - 13th)
- **Regional Workshops** – multi-stakeholder meetings in rural constituencies, topic generation, discussions of patient-centeredness, research prioritization – first one in Wichita, KS March 9-10
- The PCORI Challenge Initiative – Matching patients and stakeholders with researchers - See: http://www.health2con.com/devchallenge/
- Micro-contracts – small awards to foster new, local partnerships between stakeholders and researchers, platform to larger collaborative projects

Rigorous Methods

Developing standards and promoting best practices

- Revising the Methodology Report to incorporate public comment
- Identifying gaps and developing new methodology standards for PCOR
- Co-sponsoring a workshop with IOM (April 24, 25) on use of observational studies in developing patient-centered evidence for decision-making
- Training course for research community on PCORI methodology standards – AcademyHealth Annual Research meeting – June 25th, Baltimore

Funding PCOR

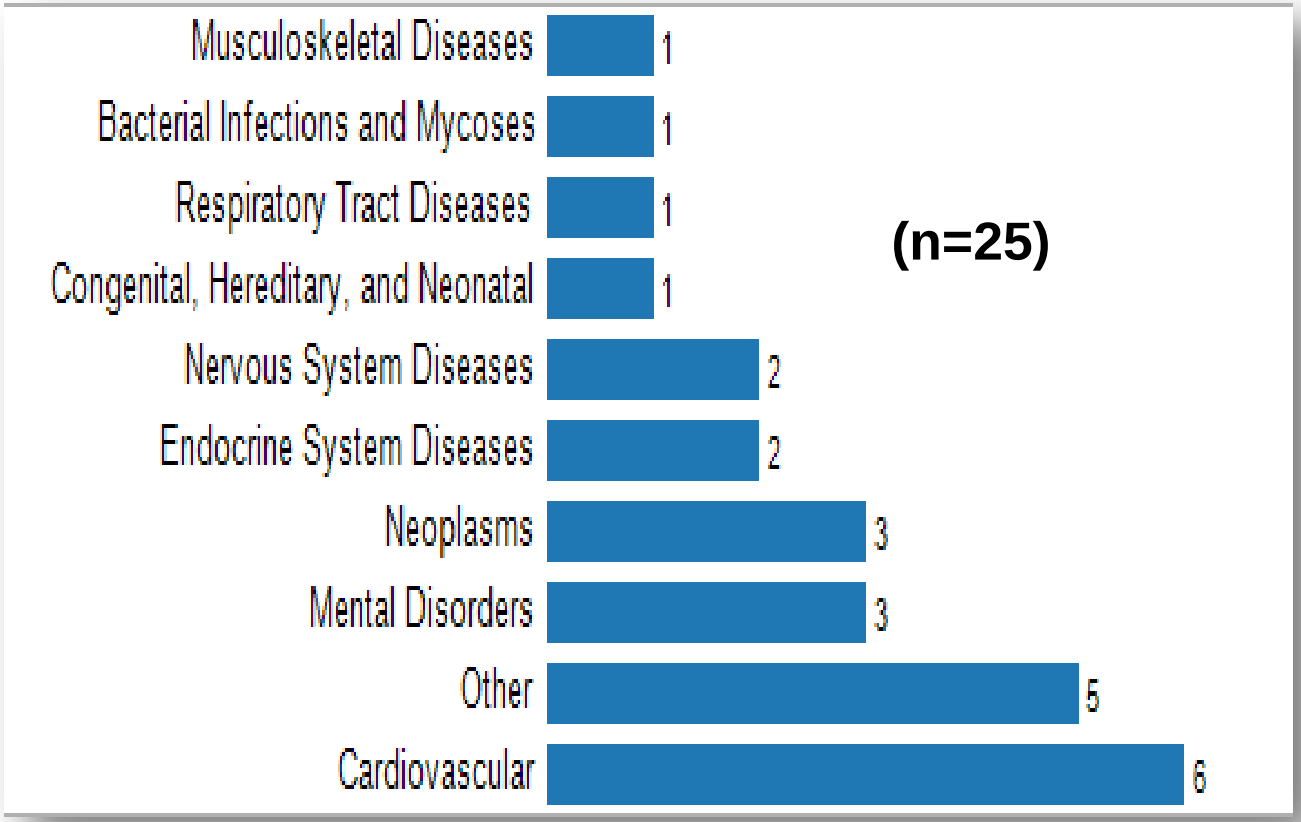
Creating a strategic research portfolio, guided by patients, caregivers and the broader healthcare community

- First 25 awards, totaling $41 million, announced in December 2012
- PCORI aims to commit more than $350M in research funding in 2013
- Broad funding announcements – three cycles, all 5 priorities including PCOR methods
- Patient-centered research infrastructure funding announcement
- Targeted funding announcements – via the accelerated process and the Advisory Panel process

Funding PCOR

Creating a strategic research portfolio, guided by patients, caregivers and the broader healthcare community

Funded Projects Cycle 1:

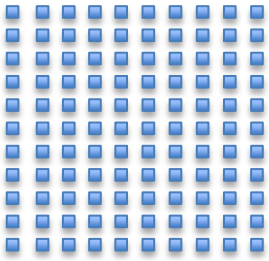


Funding PCOR

Creating a strategic research portfolio, guided by patients, caregivers and the broader healthcare community – accelerated process

Multiple Stakeholder Efforts

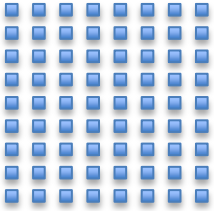
Backlog of critical vetted CER topics



# of topics

Identification of Overlapping Topics

Compile lists of important CER questions



# of topics

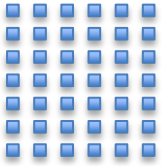
Staff Application of Review Criteria

PCORI Review Criteria

- Patient-centeredness
- Impact of the condition
- Innovation, potential for improvement
- Impact on healthcare performance
- Inclusiveness

Targeted Funding Announcement filter

- Salience
- Short-term feasibility
- Stakeholder vetting
- Resource constraints



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Board Approval

Board-Approved High-priority Topics

Expert and Stakeholder Input

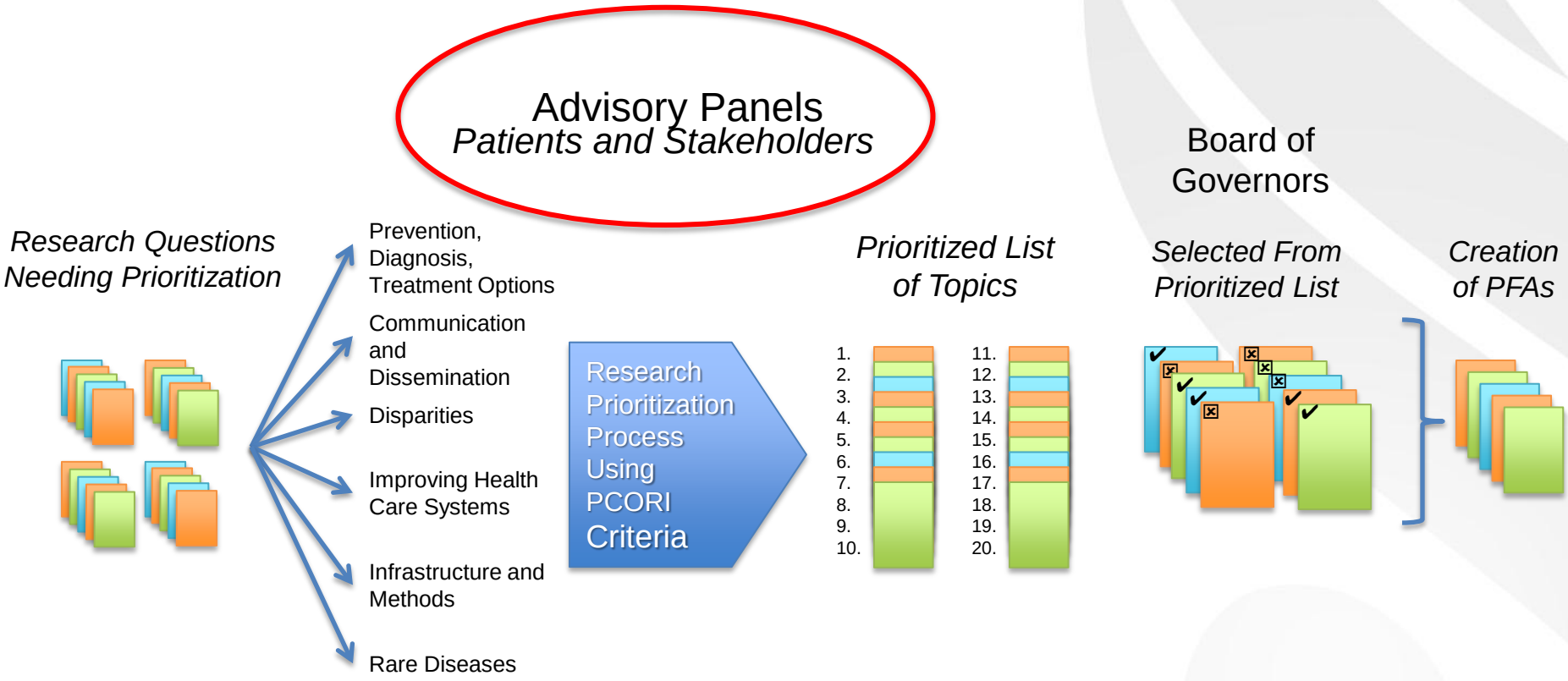
Topics refined with patient-stakeholder input

- Expert – Stakeholder Working Groups
- Input via Website

# of topics

Funding PCOR

Creating a strategic research portfolio, guided by patients, caregivers and the broader healthcare community – Advisory Panel process



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New PCORI Staff

November 19, 2012 – February 3, 2013

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Sarita Wahba, MS
Project Associate
November 12, 2012

Merenda Tate, MBA, MHRM
Assistant Controller for Treasury Operations
November 26, 2012

Mitch Eisman
Director, Human Resources
December 3, 2012

Celeste Brown, MPH
Project Associate
December 10, 2012

Annie Hammel
Senior Social Media Specialist
December 10, 2012

Kristen Metzger, MPA, MSCJ
Project Coordinator
December 17, 2012

New PCORI Staff

November 19, 2012 – February 3, 2013

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Soknorntha Prum, MPH
Grants Coordinator
December 17, 2012

Henry Muñoz
Senior Administrative Assistant
December 26, 2012

NO PHOTO AVAILABLE:

Mable Muldrow
Receptionist
December 24, 2012

Julie McCormack, MA
Senior Program Associate
January 7, 2013

Amy Grossman
Associate Director, Editorial & Publishing
January 14, 2013

Kristen Konopka, MPH
Project Associate
January 15, 2013

Geri Guman, MBA
Contracts Administrator
January 22, 2013

Cathy Gurgol
Program Associate
January 28, 2013

Adaeze Akamigbo, PhD, MPP
Senior Program Officer
January 29, 2013

Staff Count

55

Evaluation of May 2012 Cycle (I) and Plans for December 2012 Cycle (II) Reviews

Anne Beal, MD, MPH, Deputy Executive Director and Chief Operating Officer
Martin A. Dueñas, Director of Contracts

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Questions for Board Consideration

Goal: To establish a rigorous peer review process that includes scientists, patients, and stakeholders in the decision-making process to support PCORI's mission.

1. Feedback regarding merit review for December 2012 Cycle improvements?
2. Feedback regarding review timeline?

Overview

- Feedback from May 2012 Cycle
- Feedback and Process Improvements from May 2012 Cycle
- Comparison of May 2012 and December 2012 Cycle Review Processes
- Merit Review Criteria December 2012 Cycle Review Process
- Timeline

Feedback from May 2012 Cycle

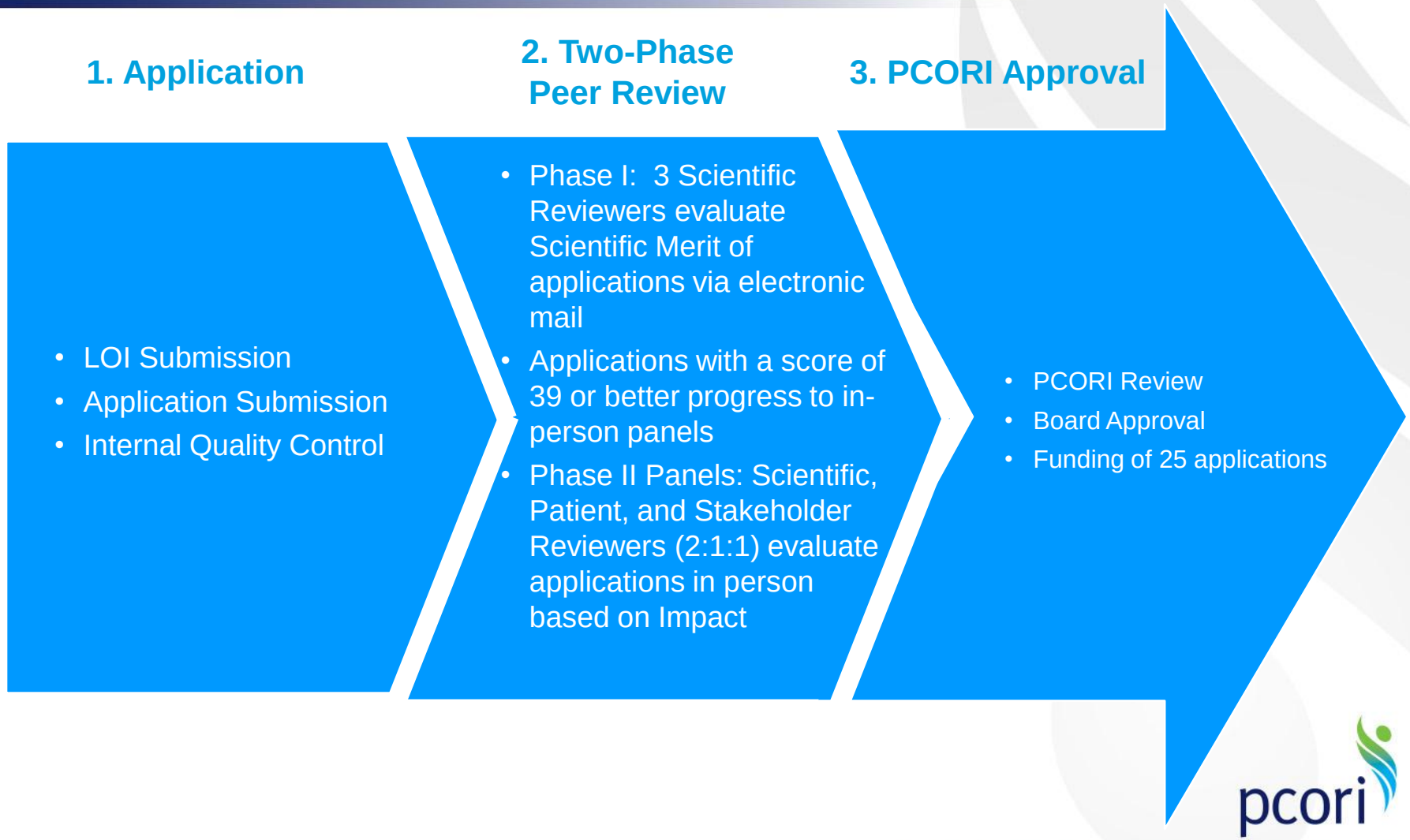
May 2012 Cycle lessons learned from:

- Reviewers
- Chairs
- Staff

Methods of feedback:

- Surveys
- Focus groups
- Interviews
- Internal discussions/roundtables

Application and Review Process | May Cycle Overview



Feedback and Process Improvements from May Cycle

Feedback from May Cycle participants:

- Incorporate patients and stakeholders earlier in the review process
- Provide all reviewers an opportunity to discuss scores and critiques in person
- Ensure more consistent reviews with additional training

Process Improvements:

- Scientific, Patient, and Stakeholder Reviewers involved from start to finish in the review process to identify and fund the best science.
- One-phase review, including an initial evaluation of all applications and in-person panel reviews.
- Reviewer training updated
  - Training examples
  - Patient/Stakeholder Mentoring Program

Mentor Program: Goals and Objectives

Goals

- Support patient and stakeholder reviewers in creating high-quality critiques
- Build a patient and stakeholder network/community

Objectives

- Understand the needs of patient and stakeholder reviewers
- Identify best practices in training patient and stakeholder reviewers
- Achieve consistency in use of the review criteria when writing critiques and scoring applications

Mentor Program: What Does Success Look Like?

- Increase representation among different populations, areas, and diseases
- Influenced revisions made to written critiques
- Decreased volume of inquiries
- A growing cadre of qualified reviewers for future cycles and/or mentor programs
- Applicants are satisfied with their written critiques received
- Other organizations mimic PCORI processes for engaging Patients and Stakeholders

Comparison of May and December Cycle Review Processes

1. Application Quality Control

- Internal Quality Control: screening of LOIs and applications
  - Cost-effectiveness
  - Comparative-effectiveness

2. Merit Review

May Cycle

Two-Phased Approach:

- Phase I: Scientific Merit (*3 Scientists)*
- Top-scoring applications progress to in-person panels
- Phase II: Impact Assessment *(Scientists, Patient, and Stakeholder 2:1:1)*

December Cycle

One-Phase Approach:

- Scientific, Patient, and Stakeholder Reviewers *(2:1:1)* participate in:
  - Initial online reviews
  - In-person panel discussions

3. PCORI Approval

- PCORI Review
- Balancing Committee
- Board Approval

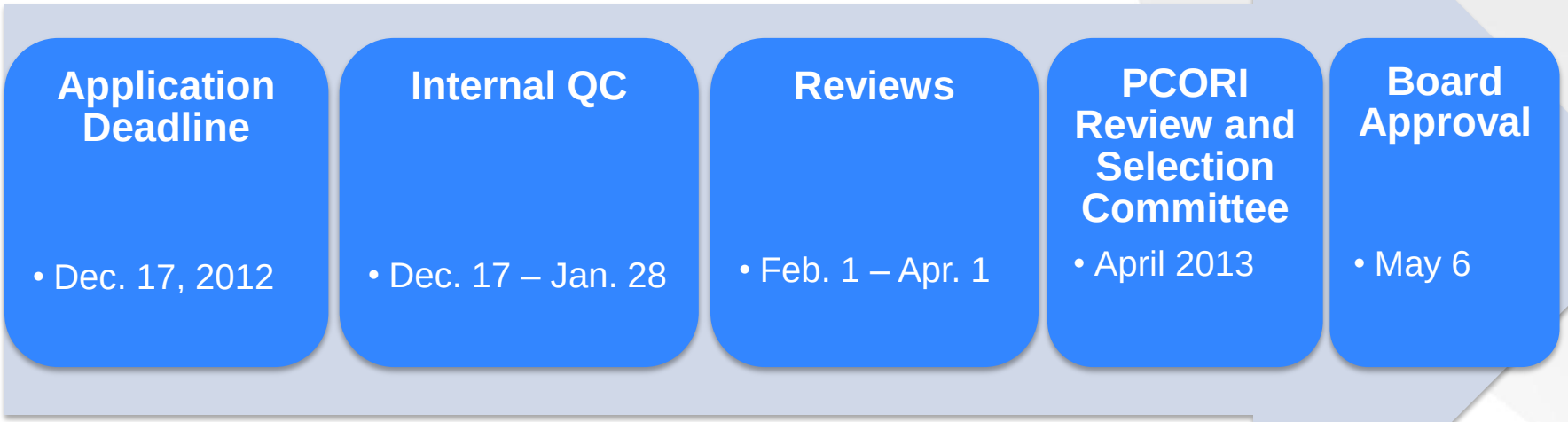
Merit Review Criteria December Cycle Review Process

PCORI's Merit Review Criteria

1. Impact of the Condition
2. **Innovation/Potential for Improvement**
3. Impact on Healthcare Performance
4. **Patient-Centeredness**
5. Rigorous Research Methods
6. Inclusiveness of Different Populations
7. **Team and Environment**
8. Efficient Use of Resources

- Scientific, Patient, and Stakeholder Reviewers *(2:1:1)* evaluate applications and provide initial critique and criteria scores:
  - Scientists: Criteria 1-8
  - Patients/Stakeholders: Criteria 2, 4, 7
- Applications are ranked by score and progress to in-person panels (per PFA)
- Reviewers discuss merits of top applications and provide a final overall application score

December Cycle Timeline



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2. Feedback regarding review timeline?

Methodology Committee Report

Robin Newhouse, PhD, RN
Mark Helfand, MD

PCORI Board of Governors Meeting
San Francisco, CA
February 2013

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Goal For Today

- High level update on activities.
- Discuss how Methodology Standards can help ensure that research provides valid and useful information for decision making.
- Review next steps.

Methodology Committee Activities in 2012

- Developed full draft of Methodology Report.
  - Posted for public comments.
  - Full analysis of public comments completed in October.
- Final set of Methodology Standards approved by BOG in November.
- Final set of recommended actions forwarded to BOG.
- Drafted plan for implementation of Methodology Standards.

Other Activities in 2012

- Conducted Webinars for input on Methodology Standards.
- Collected data on the use of electronic health records (EHRs) for PCOR.
  - Interviews with 57 stakeholders.
  - Defined capabilities and limitations of existing EHR platforms.
- Hosted national workshop to advance the use of electronic data for PCOR.
- Created policy on reproducible research results (adopted by PCORI).
- Advised PCORI on funding announcement for methods research.

Strategies to Produce Research Results that Better Meet the Needs of Decision Makers

- Methodology Standards are a starting point for ensuring that research projects use appropriate methods for producing valid results.

- Patient engagement can help researchers understand information needs and develop more informative hypotheses.

Methodology Standards for Data Registries

- The objective(s) of the registry should determine the type, extent, and length of patient follow-up.
- Registry custodians should provide transparency.
- All registries should have quality assurance plans that address specific issues.
- All protocol modifications should be documented and explained.
- Clear, operational definitions of data elements should be provided.
- Registries should monitor loss to follow-up to ensure that follow-up is reasonably complete for the main objective.
- Registries should collect sufficient data on potential confounders.

Methodology Standards on Causal Inference

- Define Analysis Population Using Covariate Histories.
- Describe Population that Gave Rise to the Effect Estimate(s).
- Precisely Define the Timing of the Outcome Assessment relative to the Initiation and Duration of Exposure.
- Measure Confounders before Start of Exposure. Report data on confounders with study results.
- Report the assumptions underlying the construction of Propensity Scores and the comparability of the resulting groups in terms of the balance of covariates and overlap.
- Assess the Validity of the Instrumental Variable (i.e. how the assumption are met) and report the balance of covariates in the groups created by the IV for all IV analyses.

Major Activities in First Half of 2013

- Finalize Methodology Report.
  - Complete comprehensive edits, guided by public comments and feedback from BOG.
  - Release full responses to all public comments at time of release of final report.
- Develop plan for implementing recommended actions.
  - Prioritize the list of recommendations.
  - Discuss plans with BOG and PCORI staff.
  - Finalize timetable for taking action on recommendations.
- Move forward with implementation plan for standards.

Dissemination and Implementation of the Standards

- Adherence to the standards will require changes in the ways in which research is **solicited, designed, reviewed and funded, conducted, monitored, reported, and disseminated**.
- Changing research practice will require multi-component, multi-level, multi-stakeholder coordinated efforts.
- The Methodology Committee, with PCORI staff and Board, will:
  - Coordinate efforts with external groups, including convening advisory committees as needed.
  - Prioritize and stage dissemination activity.

Break

Meeting Schedule

DATE	LOCATION
March 12, 2013	Webinar/Teleconference
March 26, 2013	Webinar/Teleconference
May 6, 2013	Chicago, IL
September 23, 2013	Washington, DC
November 18, 2013	Atlanta, GA

Strategic Plan Presentation

Joe Selby, MD, MPH

PCORI Board of Governors Meeting

San Francisco, CA

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Patient-Centered Outcomes Research Institute

Overview

- **Review PCORI's Preliminary Strategic Plan**
- Specifying PCORI's Overarching Goals
- From Strategic Imperatives to Goals – Logic Models and the Important Concept of Outputs
- Metrics and Milestones
- Key Implications and Next Steps

Our Mission and Vision

Mission (**July 2011**)

The Patient-Centered Outcomes Research Institute helps people make informed health care decisions, and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.

Vision (**May 2012**)

Patients and the public have information they can use to make decisions that reflect their desired health outcomes.

Our Strategic Imperatives

What We Do to Reach Our Goals

- **Engagement** of patients, caregivers, and other stakeholders in our entire research process from topic generation to dissemination and implementation of results.
- Develop and promote **rigorous** Patient-Centered Outcomes Research **methods**, standards, and best practices.
- **Fund** a comprehensive agenda of high quality **Patient-Centered Outcomes Research** and evaluate its impact.
- **Dissemination** of Patient-Centered Outcomes Research findings to all stakeholders and support for uptake and implementation.
- Promote and facilitate the development of a sustainable **infrastructure** for conducting patient-centered outcomes research.

Overview

- Review PCORI's Preliminary Strategic Plan
- **Specifying PCORI's Overarching Goals**
- From Strategic Imperatives to Goals – Logic Models and the Important Concept of Outputs
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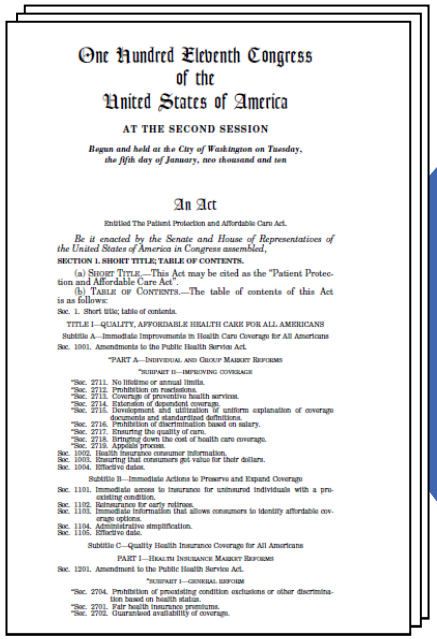
- Key Implications and Next Steps

Proposed Overarching Goals

PCORI's contributions to improving health will be to:

- Substantially **increase** the quantity, quality, and timeliness of useful, trustworthy **information** available to support health decisions
- **Speed** the **implementation** and use of patient-centered outcomes research evidence
- **Influence** clinical and health care **research** funded by others to be more patient-centered

Evaluation of PCORI's Effectiveness:



One Hundred Eleventh Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the fifth day of January, two thousand and ten

An Act

Entitled The Patient Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patient Protection and Affordable Care Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

Subtitle A—Immediate Improvements in Health Care Coverage for All Americans

Sec. 1001. Amendments to the Public Health Service Act.

"PART A—INDIVIDUAL AND GROUP MARKET REFORMS

"SUBPART II—IMPROVING COVERAGE

"Sec. 2711. No lifetime or annual limits.
"Sec. 2712. Prohibition on rescissions.
"Sec. 2713. Coverage of preventive health services.
"Sec. 2714. Extension of dependent coverage.
"Sec. 2715. Development and utilization of uniform explanation of coverage documents and standardized definitions.
"Sec. 2716. Prohibition of discrimination based on salary.
"Sec. 2717. Ensuring the quality of care.
"Sec. 2718. Bringing down the cost of health care coverage.
"Sec. 2719. Appeals process.
Sec. 1002. Health insurance consumer information.
Sec. 1003. Ensuring that consumers get value for their dollars.
Sec. 1004. Effective dates.

Subtitle B—Immediate Actions to Preserve and Expand Coverage

Sec. 1101. Immediate access to insurance for uninsured individuals with a pre-existing condition.
Sec. 1102. Reinsurance for early retirees.
Sec. 1103. Immediate information that allows consumers to identify affordable coverage options.
Sec. 1104. Administrative simplification.
Sec. 1105. Effective date.

Subtitle C—Quality Health Insurance Coverage for All Americans

PART I—HEALTH INSURANCE MARKET REFORMS

Sec. 1201. Amendment to the Public Health Service Act.

"SUBPART I—GENERAL REFORMS

"Sec. 2704. Prohibition of preexisting condition exclusions or other discrimination based on health status.
"Sec. 2701. Fair health insurance premiums.
"Sec. 2702. Guaranteed availability of coverage.

Review and Annual Reports

The Comptroller General of the United States shall review the following not less frequently than every 5 years:

a. the extent to which research findings are used by health care decision-makers

b. the effect of the dissemination of such findings on reducing practice variation and disparities in health care

c. the effect of the research conducted and disseminated on innovation and the health care economy of the United States.

Source: Affordable Care Act. Subtitle D—Patient-Centered Outcomes Research. PUBLIC LAW 111–148—MAR. 23, 2010.

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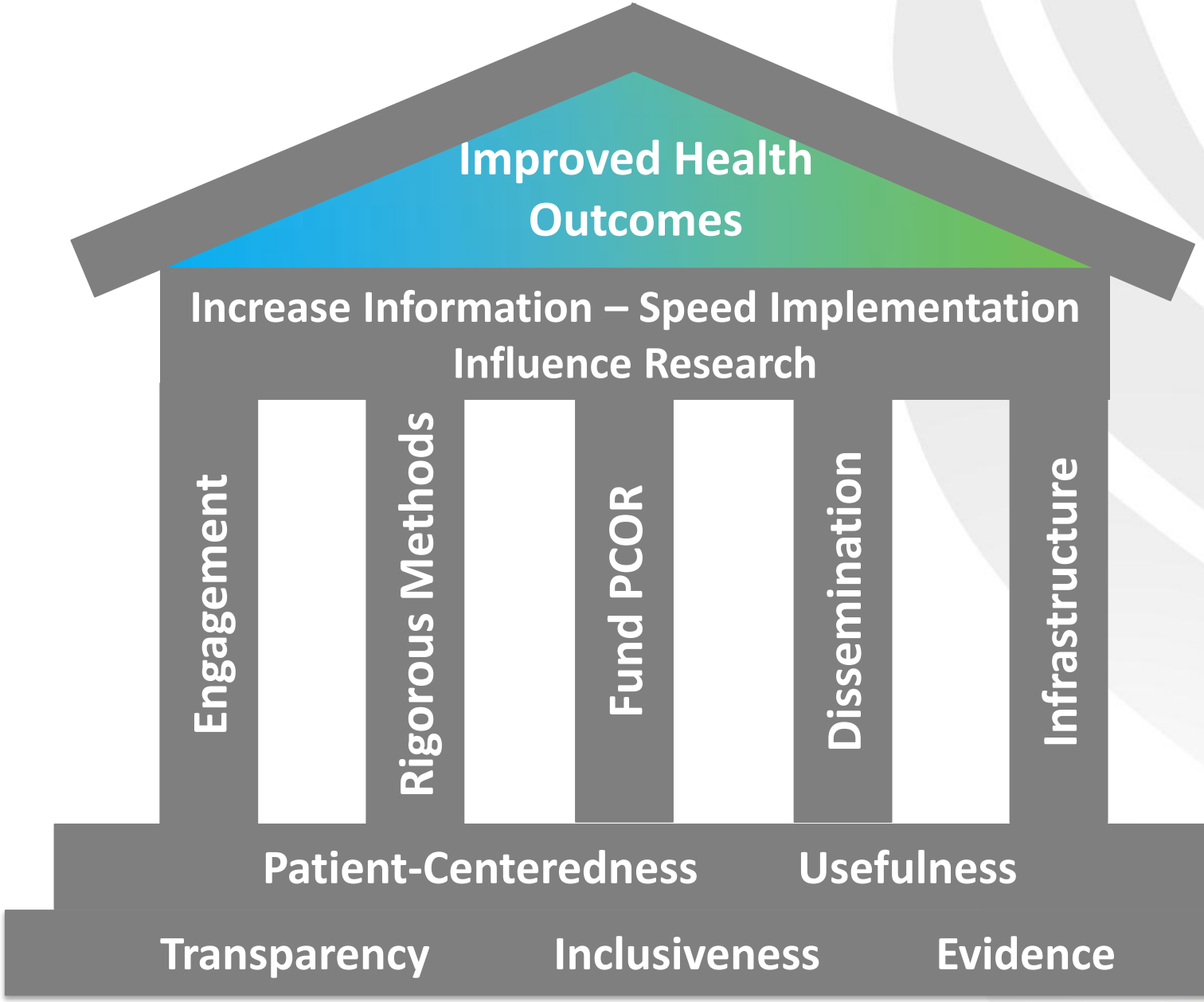
Further Specification of Our Goals

Increase Information	Speed Implementation	Influence Research
PCORI will contribute to building a large body of evidence to answer critical, patient-centered, comparative health questions, the majority of which is *actionable*.	The majority of PCORI's actionable studies are *incorporated into practice* within five years of completion.	An increased proportion of all clinical and health care research is *patient-centered and engaging* of patients and other stakeholders.
"*Actionable*" means that the evidence enables patients, clinicians, and other decision makers to make better decisions, either by changing practice or by reducing uncertainty around current practice.	**"*Incorporated into practice*"** means that the evidence has been included in practice guidelines, or that practice has been shown to change, or that variation in practice has been reduced.	***"Patient-centered and engaged"*** according to PCORI criteria to be refined in 2013 with baseline measurements made.



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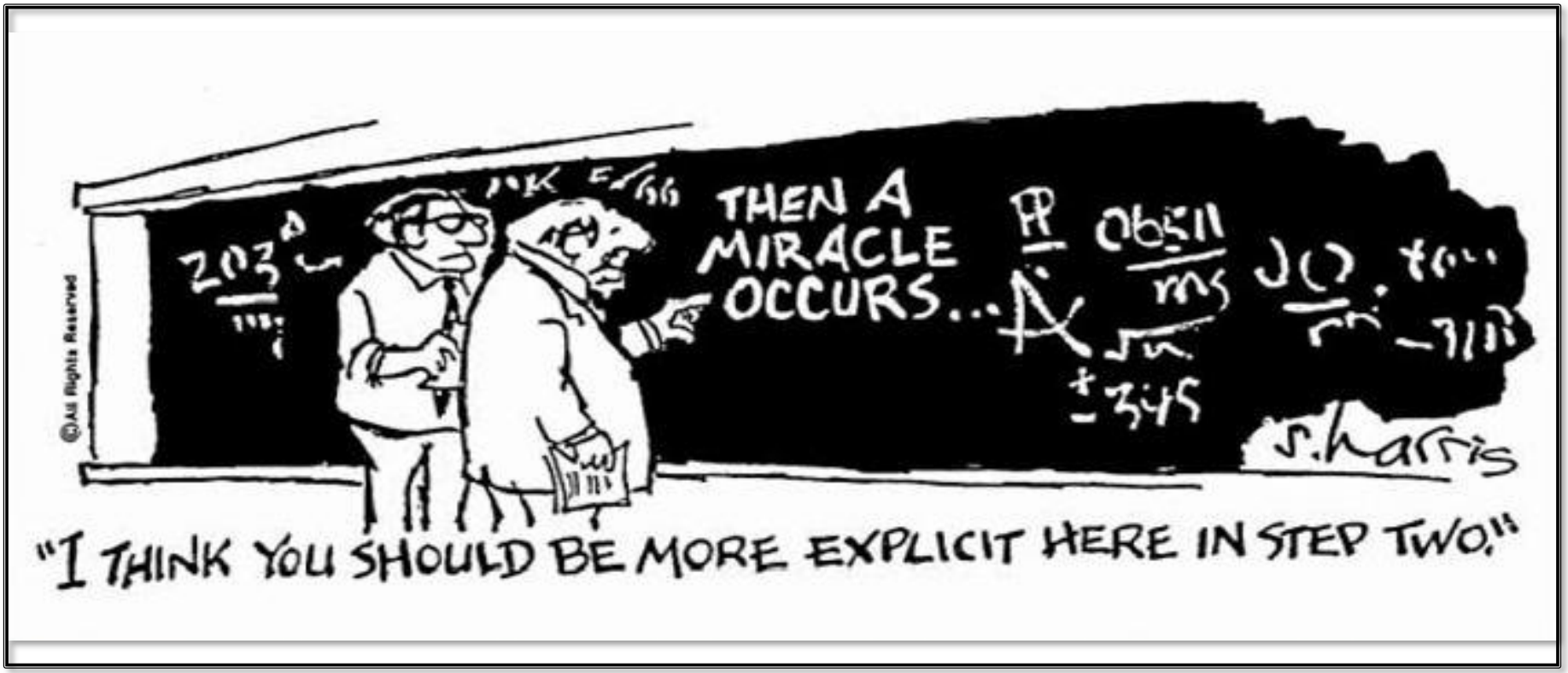
Overview

- Review PCORI's Preliminary Strategic Plan
- Specifying PCORI's Overarching Goals
- **From Strategic Imperatives to Goals – Logic Models and the Important Concept of Outputs**
- Metrics and Milestones
- Key Implications and Next Steps

Overall and 5-year Strategic Plans

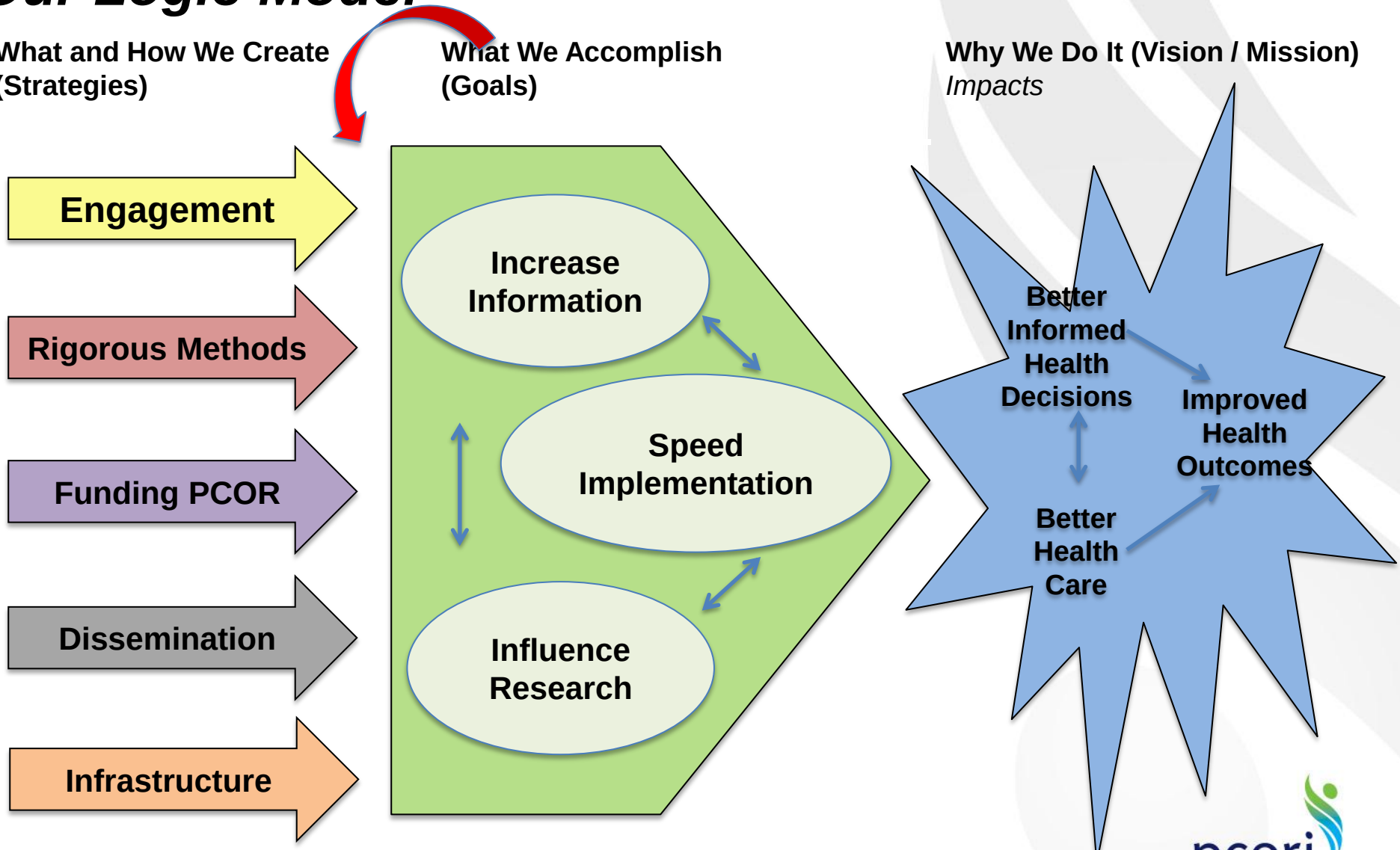
From Strategic Imperatives to Our Goals

The Logic Models

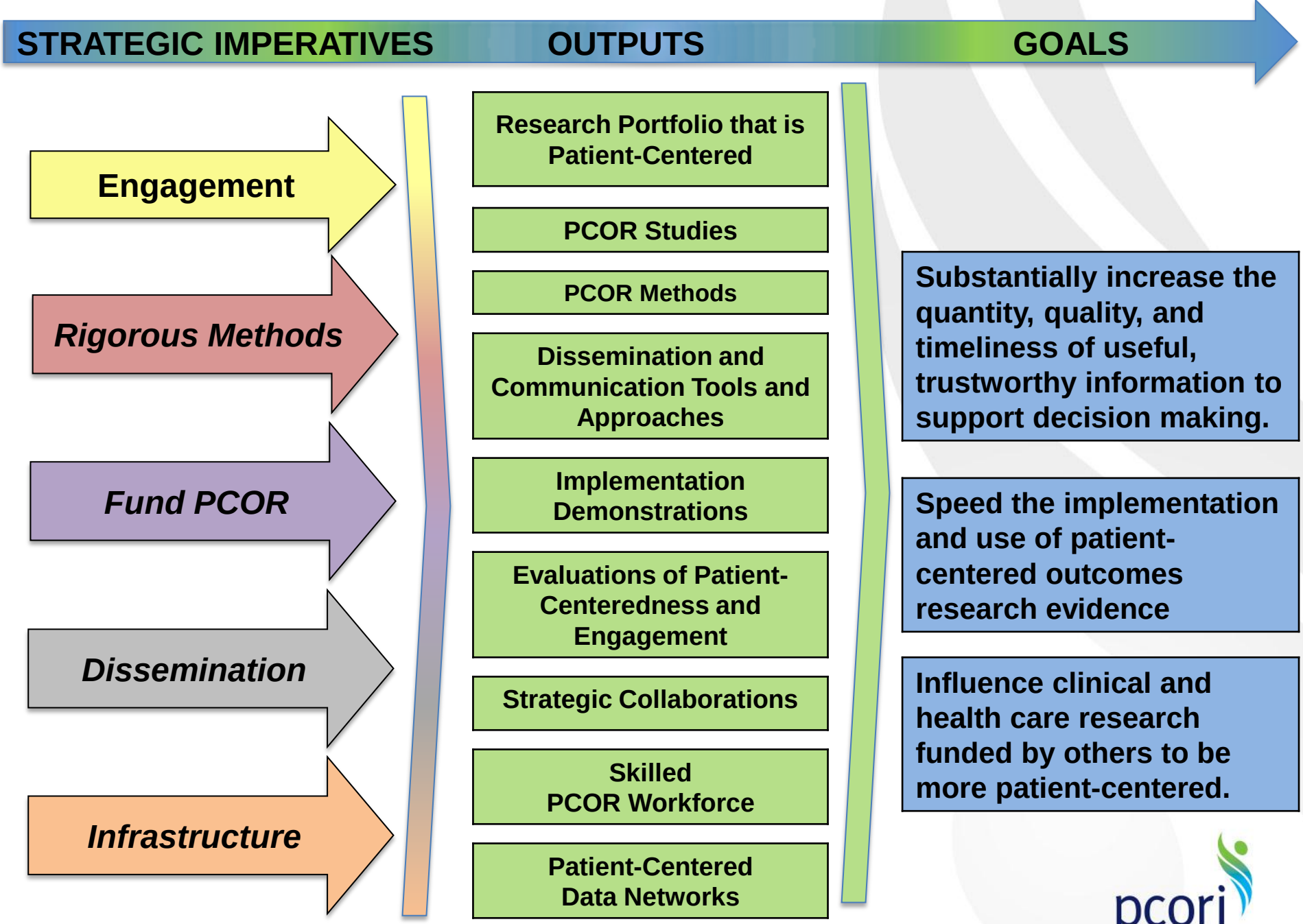


How will we reach our goals?

Our Logic Model



Patient-Centered Outcomes Research Institute


STRATEGIC IMPERATIVES
OUTPUTS
GOALS
Engagement
Rigorous Methods
Fund PCOR
Dissemination
Infrastructure
Research Portfolio that is Patient-Centered
PCOR Studies
PCOR Methods
Dissemination and Communication Tools and Approaches
Implementation Demonstrations
Evaluations of Patient-Centeredness and Engagement
Strategic Collaborations
Skilled PCOR Workforce
Patient-Centered Data Networks
Substantially increase the quantity, quality, and timeliness of useful, trustworthy information to support decision making.
Speed the implementation and use of patient-centered outcomes research evidence
Influence clinical and health care research funded by others to be more patient-centered.

Definition of Outputs

- Outputs are the products or results of strategic activities
- Outputs lead logically to our goals
- Outputs occur earlier in time than our goals
- Outputs are readily measureable

IMPERATIVES / PRIORITIES

ENGAGEMENT	Build a community of activated patients, caregivers, and other stakeholders trained in PCOR.
	Engage patients and stakeholders in all aspects of the research process.
	Continuously refine and evaluate patient and stakeholder engagement activities.
METHODS	Identify gaps in CER/PCOR methods and develop new methodology standards.
	Fund research on CER and PCOR methods.
FUNDING PCOR	Develop infrastructure for developing and managing PCORI's research portfolio.
	Develop process for creating a strategic portfolio focused on national priorities.
	Further refine PCORI's strategic approach to research funding.
	Solicit the best ideas from the researcher-stakeholder community using broad PFAs.
DISSEM	Disseminate PCORI Methodology Standards broadly to research and other stakeholder communities.
INFRASTRUCTURE	Fund research to develop and promote large, patient-centered research networks.
	Fund one or more enduring patient-centered research infrastructure projects.
	Support training of researchers in PCOR methods in collaboration with AHRQ.

OUTPUTS

- Research Portfolio that is Patient-Centered
- PCOR Studies
- PCOR Methods
- Strategic Collaborations
- Skilled PCOR Workforce
- Patient-Centered Data Networks

GOAL #1

Substantially increase the quantity, quality, and timeliness of useful, trustworthy information to support decision making

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IMPERATIVES / PRIORITIES

ENGAGEMENT	Engage patient and stakeholder groups critical to dissemination and implementation early in formulating PCORI's research agenda.
	Involve these organizations early in relevant research projects.
METHODS	Develop methodology standards for dissemination and implementation.
	Fund methodologic research to identify improved approaches to dissemination and implementation.
FUNDING PCOR	Fund and conduct dissemination and implementation research.
DISSEMINATION	Develop communications strategy to heighten awareness of value of PCOR.
	Partner with open-access scientific and with lay press.
	Build or partner for dissemination/implementation infrastructure.
	Fund dissemination/implementation activities.
INFRASTRUCTURE	Involve clinicians and health systems in governance and use of research infrastructure.
	Train researchers in dissemination and implementation methods, in collaboration with AHRQ.

OUTPUTS

- Research Portfolio that is Patient-Centered
- PCOR Studies
- Dissemination and Communication Tools and Approaches
- Implementation Demonstrations
- Strategic Collaborations
- Patient-Centered Data Networks

GOAL #2

Speed the implementation and use of patient-centered outcomes research evidence

IMPERATIVES / PRIORITIES

ENGAGEMENT

- Continuously evaluate, refine, and report on learning about patient and stakeholder engagement methods in research.
- Evaluate the impact of PCORI's efforts on national attitudes and awareness of CER/PCOR.
- Evaluate the impact of engagement on research process, results, and impact on practice.

METHODS

- Continue to develop and refine methodologic standards for PCOR.

PCOR

- Co-fund patient-centered, engaged research with other funders.

DISSEMINATION

- Disseminate PCORI methodology standards.
- Disseminate PCOR study results.
- Disseminate results of engagement evaluation research.

INFRASTRUCTURE

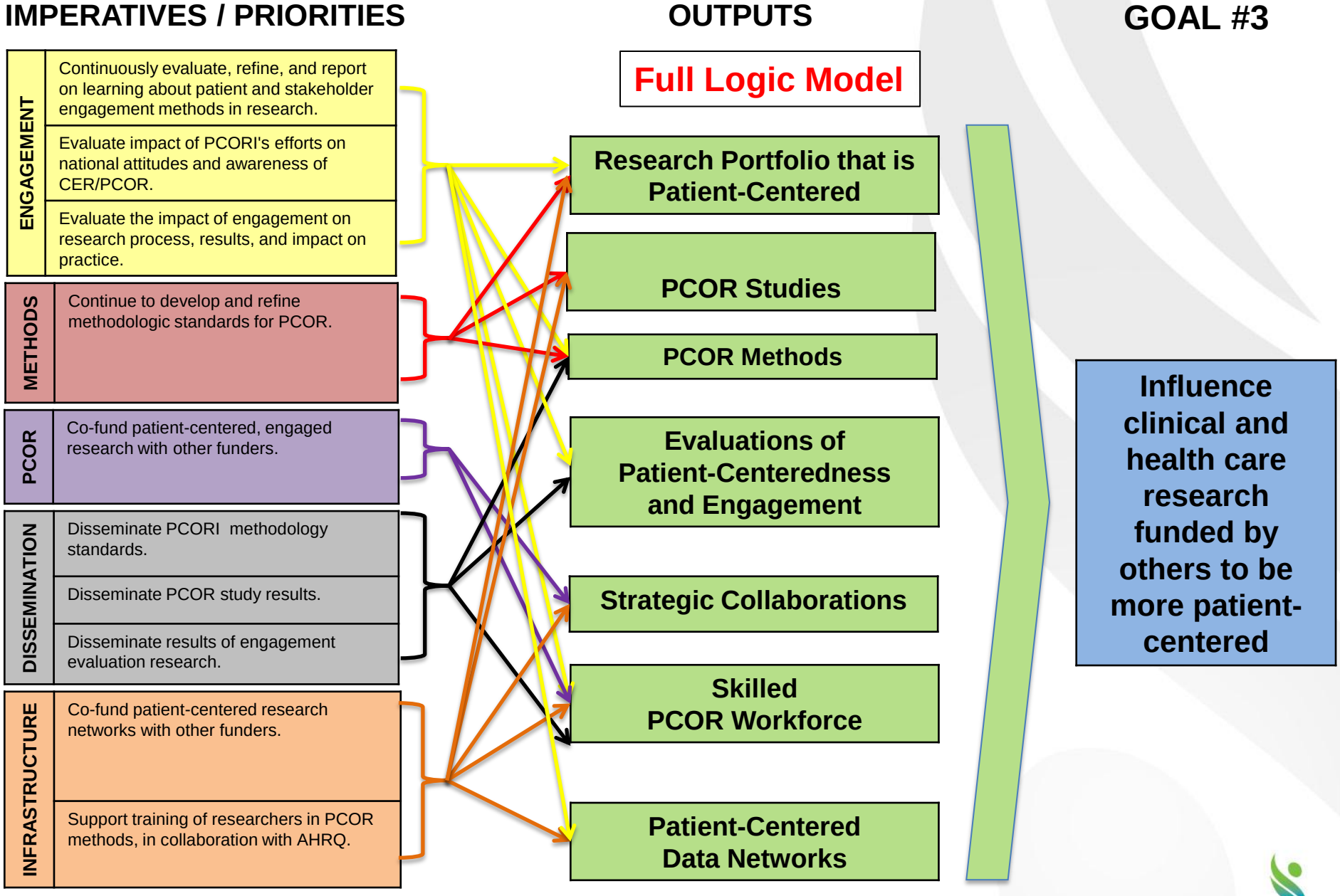
- Co-fund patient-centered research networks with other funders.
- Support training of researchers in PCOR methods, in collaboration with AHRQ.

OUTPUTS

- Research Portfolio that is Patient-Centered
- PCOR Studies
- PCOR Methods
- Evaluations of Patient-Centeredness and Engagement
- Strategic Collaborations
- Skilled PCOR Workforce
- Patient-Centered Data Networks

GOAL #3

Influence clinical and health care research funded by others to be more patient-centered


IMPERATIVES / PRIORITIES
OUTPUTS
GOAL #3
Full Logic Model
ENGAGEMENT
Continuously evaluate, refine, and report on learning about patient and stakeholder engagement methods in research.
Evaluate impact of PCORI's efforts on national attitudes and awareness of CER/PCOR.
Evaluate the impact of engagement on research process, results, and impact on practice.
METHODS
Continue to develop and refine methodologic standards for PCOR.
PCOR
Co-fund patient-centered, engaged research with other funders.
DISSEMINATION
Disseminate PCORI methodology standards.
Disseminate PCOR study results.
Disseminate results of engagement evaluation research.
INFRASTRUCTURE
Co-fund patient-centered research networks with other funders.
Support training of researchers in PCOR methods, in collaboration with AHRQ.
Research Portfolio that is Patient-Centered
PCOR Studies
PCOR Methods
Evaluations of Patient-Centeredness and Engagement
Strategic Collaborations
Skilled PCOR Workforce
Patient-Centered Data Networks
Influence clinical and health care research funded by others to be more patient-centered

Overview

- Review PCORI's Preliminary Strategic Plan
- Specifying PCORI's Overarching Goals
- From Strategic Imperatives to Goals – Logic Models and the Important Concept of Outputs
- **Metrics and Milestones**
- Key Implications and Next Steps

Specifying Our Outputs

Research Portfolio that is Patient-Centered	The extent to which patients agree that PCORI's agenda and the processes we use to create our agenda meet patients' needs for answering critical, comparative questions.
PCOR Studies	The number and quality of patient-centered research studies that PCORI funds.
Rigorous Methods	The number of PCOR standards that PCORI produces and the extent to which they are used in clinical and health care research.

Specifying Our Outputs

Dissemination and Communication Tools and Approaches	The results of our communication and dissemination research portfolio and the products we develop to disseminate the information resulting from the PCOR studies we fund.
Implementation Demonstrations	The number of projects we fund to achieve dissemination and implementation of results from PCOR studies.
Strategic Collaborations	The partnerships and collaborations we develop or expand for co-funding, dissemination or implementation.

Specifying Our Outputs

Skilled PCOR Workforce	The community we develop of researchers, as well as patients, clinicians, and others capable of conducting and participating in PCOR.
Patient-Centered Data Networks	The data networks we establish or support, their number, size, and the extent to which they include patients and other stakeholders in governance and use.
Evaluations of Patient-Centeredness and Engagement	Evaluation framework in place; the number of studies of the impact of PCORI's approach to patient and stakeholder engagement on the research process.

Overview

- Review PCORI's Preliminary Strategic Plan
- Specifying PCORI's Overarching Goals
- From Strategic Imperatives to Goals – Logic Models and the Important Concept of Outputs
- Metrics and Milestones
- **Key Implications and Next Steps**

Key Implications of the Strategic Plan

- Dissemination and implementation are of critical importance if PCORI is to achieve its goals – especially goals #2 and #3
- Measureable definitions of “patient-centered,” “engaged,” “actionable,” and “incorporated into practice” are needed
- Partnerships – for co-funding, for dissemination, and for implementation – are essential elements of our plan
- Funding a large body of research in 2013 is critical to having completed studies by the time of the 2017 evaluation
- Active management of our research portfolio is essential to speeding our progress toward actionable study results
- Developing our Evaluation Framework and establishing baselines are critical tasks for 2013

Next Steps

- Create the metrics and milestones for each goal and output: for example in 2013, 2017, and 2022
- Add detail at the level of strategic activities for each Strategic Imperative
- Specify metrics and milestones for these activities
- Create a scorecard, focused primarily on periodic measures of the metrics for outputs, that can be used both internally and externally to monitor PCORI progress

2013 Budget

Kerry Barnett, JD, Chair, FAAC
Anne Beal, MD, MPH, Deputy Executive Director and Chief Operating Officer
Pamela Goodnow, Director of Finance
PCORI Board of Governors Meeting
San Francisco, CA
February 2013

Patient-Centered Outcomes Research Institute

Agenda

- Key Issues
- The 2013 Budget
- Commitments and Outstanding Obligations
- Call for Vote

Key Issues

- **Driven by Strategic Planning:** Performance-based budgets use the mission and goals to allocate resources to achieve specific objectives based on program goals and measured results.
- **Staffing:** The staffing plan reflects management's desire to shift the workforce from a contactor-based model to one with permanent staffing in order to increase productivity and gain efficiencies.
- **Infrastructure:** PCORI plans to make a one-time investment of $5.6 million in infrastructure for program support and operations.
- **Revenue Projections**: Operating revenue is now projected to be $230.4 million.

Key Issues

- **Administrative Expense Ratio**: The percentage of administrative expenses is a measure of a non-profit's efficiency; the industry standard is 15%.
  - Program expenses are goods and services distributed to fulfill the mission of the organization.
  - Administrative expenses are costs of business management, record keeping, budgeting, and finance and other management and administrative activities.
- Administrative expenses are budgeted for 16%. The increased program spending in 2014 will bring PCORI below the administrative expense target.

The 2013 Budget

	IN MILLIONS	
Operating Revenue	$230.4	
Program Expense		
Research	85.6	
Research Support	27.5	
Total Program Expense	113.1	84%
Administrative Expense	21.0	16%
Total Operating Expense	134.1	
Investment Income	0.5	
NET INCOME	$96.7	*

* This will be applied towards the $338 million in outstanding obligations we will have by 12/31/2013.

Commitments and Outstanding Obligations

- Commitments and Outstanding Obligations

	IN MILLIONS
COMMITMENTS	
Pilot Projects	$31.0
PFA 2012	41.0
PFA 2013	355.0
	427.0
PCORTF Payments	(89.0)
OUTSTANDING OBLIGATIONS	$338.0

Call for Vote

Board Vote

- Call for a motion to approve the 2013 Budget

Break

Meeting Schedule

DATE	LOCATION
March 12, 2013	Webinar/Teleconference
March 26, 2013	Webinar/Teleconference
May 6, 2013	Chicago, IL
September 23, 2013	Washington, DC
November 18, 2013	Atlanta, GA

Performance Management

Anne Beal, MD, MPH, Deputy Executive Director and Chief Operating Officer

PCORI Board of Governors Meeting

San Francisco, CA

February 2013

Patient-Centered Outcomes Research Institute

PCORI and Performance Management

Establishing the critical importance

- **What are the benefits of having a robust Performance Management program?**
  - Helps us assess **financial and program effectiveness** and **monitor against the strategic plan**
  - **Drives performance** and increases employee productivity
  - Ensures we are following the law
  - Provides **protection** in the event of a financial or programmatic audit, inquiries, or lawsuit

- **PCORI is committed to transparency and accountability.**
  - Our Performance Management efforts make clear our commitment to carrying out our work in an **ethical**, **legal**, and **efficacious** manner

Framework for Performance Management

Strategic Plan outputs inform and guide the workplan

- Enabling Legislation
- 5-year Strategic Plan
- Performance Management (Leads to Compliance)

Policies and Procedures	Establish protocols to support fair and consistent financial, programmatic, and organizational practices.
Financial and Program Performance	Establish goals, targets, or thresholds for financial performance of budget versus actual and provide active portfolio management of awards.
Risk Management Active portfolio management of programs	Systematic approach to managing the associated risk of the research contracts by transferring, avoiding, or reducing the negative effects of the risk or accepting some or all of the potential or actual consequences of a particular risk.
On-Going Monitoring	Develop a balanced score card to serve as the central repository for tracking and analyzing data derived from policies and procedures, financial and program performance, and risk management.

Policies and Procedures
Creating the policy inventory

- **PCORI's policies and procedures derive from:**
  - Enabling legislation
  - Bylaws, charters, and directives from the Board
  - Activities and rules instituted by the Executive Director per delegated authority
- **To-Date Current Policies and Procedures in Human Resources, Contracts, and Finance:**
  - Ready for internal audit to check for adherence
  - Proactive process improvement

Policies and Procedures Inventory

Accounting for the policies and procedures

Name	Phase 1: Develop Framework	Phase 2: Refine	Phase 3: Review	Phase 4: Approve	Percent Complete
Risk Management Policies and Procedures					
Conflict of Interest	X				25%
Management and Governance	X				25%
Transparency, Credibility, and Access	X	X			50%
Oversight and Reporting	X	X	X	X	100%
Finance and Budget	X				25%
Ethics and Business Conduct	X	X	X	X	100%
Web Privacy and Information Security	X	X	X	X	100%
Insurance and Indemnification	X				25%
Programmatic Policies and Procedures					
Science and Research	X				25%
Methodology Committee	X				25%
Contracts	X				25%
Engagement	X				25%
Advisory Panels	X	X	X	X	100%
Administrative Policies and Procedures					
Human Resources and Office Policies	X	X	X	X	100%
Information Technology	X				25%
Meetings, Events, and Travel	X				25%
Communications	X				25%

Financial and Program Performance

Monitoring and evaluating performance

Strategic Plan → Goals → Outputs → Scorecard

- ***Monitor*** critical business processes and activities using established performance metrics; make adjustments as needed
- ***Analyze*** the root cause of problems using relevant, timely, and accurate information from across the organization
- ***Manage*** people and processes to improve decisions, optimize performance, and steer the organization in the right direction

"What gets measured, gets managed."

Peter Drucker, Management by Objectives

Financial and Program Performance

Identifying key indicators for measurement from the Strategic Plan

Examples of Key Indicators			
Financial	**Program and Research**	**External: Stakeholders**	**Internal: Processes**
• Cash Flow • Budget versus Actual Expenses • Cost Controls • Administrative and Program Ratio	• Co-funding Arrangements • Dissemination Speed • Usefulness and Reliability of Information • Delivery Time • Ease of Use • Uptake • Research Agenda Development • Funded Studies in Priority Areas, Topical Areas, and Methods • Investment Amount • Advancements in Filling Gaps in Methods Standards • Quantity and Quality of Information Products to Disseminate Findings	• Patient, Clinician and Stakeholder Satisfaction Rate • Mentoring/Training Opportunities • Active Partnerships • Questions Submitted • Participation in Application Review, Advisory Panels, Working Groups, etc. • Patient and Researcher Linkages • Training and Curriculum Developed and Funded • Patients in Funded Research	• Service Culture • Strategy and Operation Planning • IT Infrastructure • Policies and Procedures • Cross-Departmental Integration • Transparency • Disclosure and Reporting • Equipment Effectiveness • Privacy and Security • Internal Promotions • Staff Satisfaction • Employee Development • Diversity and Inclusiveness

Risk Management

Dealing with the uncertainty of meeting our goal

Working Definition of Risk Management

Risk management is the identification of risks and the development of responses to minimize, monitor, and control unfortunate events, and maximize the realization of opportunities.

Risks can come from uncertainty in financial markets, project failures, legal liabilities, accidents, natural causes, as well as events of uncertain or unpredictable root-cause.

Risk Management

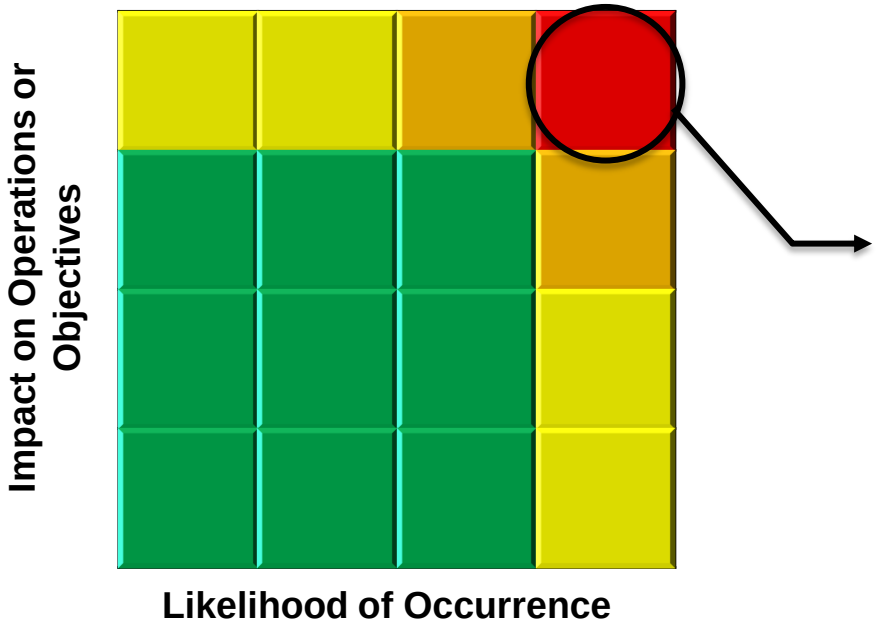
Dealing with the uncertainty of meeting our goal

Risk Examples

Program/Research:
Projects not completed
Projects completed but not useful
Projects not completed on time

Reputation/PCORI Brand
Financial
Human Resources

Risk Assessment and Prioritization



Mitigation Strategies

- Preventative actions
- Contingency actions
- Responsibilities
- Schedules
- Indicators/Metrics

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On-Going Management

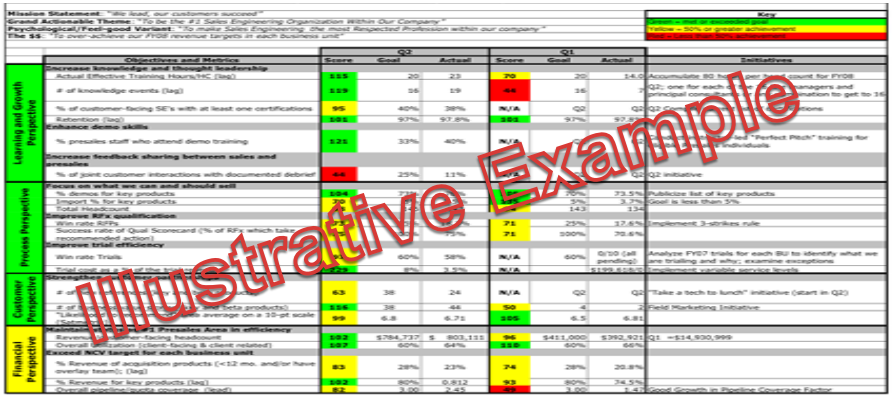
Linking long-term strategy with operations

Balanced Scorecard

- Key goal of a scorecard is to **identify** whether **performance** is on target in real-time.
- **Track** the execution of activities against established metrics.
- **Prescriptive** in nature and tied to year-over-year performance.
- Uses data visualizations, including charts, graphs, maps and gauges.

Components

- Indicators in finance, operations, and program: research and engagement
- Current measures versus targets/milestones
- Accountable parties
- Return on investment (ROI) dollars allocated



Performance Management Workplan

	2012	2013				
Action Step	**June to Dec**	**Jan**	**Feb**	**March**	**April**	**May**
Document policies and procedures and develop an inventory to communicate, make accessible, and provide training	✓	✓				
Identify goals, outputs, metrics, and milestones of **Program** for the Strategic Plan	✓	✓	✓			
Approve Annual **Budget**			✓			
Conduct **Risk Assessment** and develop a **Mitigation Plan**			✓	✓		
Carry out a **Gap Analysis** of data needed for the metrics presented in the scorecard		✓	✓	✓		
Identify needs and implement **infrastructure** for data capture across the enterprise for the metrics in the scorecard		✓	✓	✓	✓	
Launch **Ongoing Monitoring**					✓	✓
Present completed **Strategic Plan** and first draft of **Balanced Scorecard**						✓

Performance Management: Questions/Discussion

Initial Targeted PCORI Funding Announcements and Ad Hoc Workgroups

Kara Odom Walker, MD, MPH, MSHS
Joe V. Selby, MD, MPH

PCORI Board of Governors Meeting
San Francisco, CA
February 2013

Patient-Centered Outcomes Research Institute

Agenda

- Topics for Targeted PCORI Funding Announcements (PFAs)
- Ad hoc workgroups
  - Goals, Date, Format
  - Outreach Strategy
- Next steps
- Timeline

Five Potential Topics for Targeted PFAs

- Treatment Options for Uterine Fibroids
- Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos
- Preventing Injuries from Falls in the Elderly
- Treatment Options for Back Pain **(new)**
- Obesity Treatment Options in Diverse Populations **(new)**

Goals for Ad Hoc Workgroups

- Obtain patient, stakeholder, and researcher input
- Identify high-impact research questions that will result in findings that are likely to endure and are not currently studied
- Understand the potential for research to lead to rapid improvement in practice, decision-making, and outcomes
- Confirm the importance and timeliness of particular research topics
- Seek consensus on identified research gaps and specific questions within those topics

Provide summary of findings to Board of Governors

Tentative Convening Dates for Ad Hoc Workgroups

Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos	Friday, March 1st
Treatment Options for Uterine Fibroids	Tuesday, March 5th
Obesity Treatment Options in Diverse Populations	Tuesday, March 12th
Preventing Injuries from Falls in the Elderly	TBD
Treatment Options for Back Pain	TBD

Sample Agenda for Ad Hoc Workgroups

Time	Agenda Item	Mode
9:00-10:00a	Breakfast	
10:00-10:20a	**Overview** ▪ PCORI Welcome ▪ State of the Evidence	• Webinar
10:20-11:20a	**Researcher Presentations** • 15 minute segments by each researcher	• Webinar
11:30-12:30p	**Roundtable Discussion** • Input on important research areas	• Webinar
12:30-1:00p	Lunch	
12:30-2:30p	**Roundtable Discussion:** • Discuss research questions	Teleconference
2:30-3:00p	**Recap and Next Steps**	Teleconference

People tuned in to webinar can submit comments throughout the course of the day

Format of Ad Hoc Workgroups

Characteristics	Recommendation
Format	Webinar/teleconference in-person meetings
Size	12-18 members
Stakeholder input	Detailed discussion of gaps in research
Selection process	PCORI staff select patients, caregivers, clinicians, stakeholders, and researchers with content expertise to refine and vet important study questions
Where	PCORI Office, Washington DC
When	Beginning in March

Sample Questions for Ad Hoc Workgroups

We have identified research gaps x, y, and z that if answered may have real-life patient-centered implications.
1. Please provide your comments and perspectives on any or all of these gaps that we have identified and articulate whether or not you feel that each could be promising areas of study that should be addressed imminently.
2. Is research in this area at a point where a new study could directly result in change in practice? Or are there critical preliminary research steps that need to be undertaken before the possibility of achieving the endpoint of change in practice can occur?
3. If you conclude that research in a key area could change practice please indicate whether you believe that the study would lead to long-term changes in or whether findings could become outmoded/outdated because of other developments?
4. Please provide us with specific details regarding how studying each of these areas would improve patient outcomes.
5. Other than those that we have already identified, what additional gaps in the research exist that if answered would be meaningful to patients?
6. With reference to the afore-mentioned gaps, please highlight what studies you know of that are currently underway.

Conflict of Interest and Transparency

- Questions from any stakeholder will be accepted on the PCORI website prior to the workgroups, during meeting and after the meeting
- Workgroup participants will discuss several gaps in the topic area
  - Stakeholders, patients, and the other researchers on the ad hoc workgroup will have time set aside to ask questions and make comments
  - Format will provide PCORI with input on the most important research questions
- Use of a moderator to help steer the conversation
- Workgroup members will be eligible for funding
- Webinar will allow other interested parties to submit comments
- Teleconference will allow interested parties to listen to the dialogue
- Post-workgroup self-evaluation to assess this process

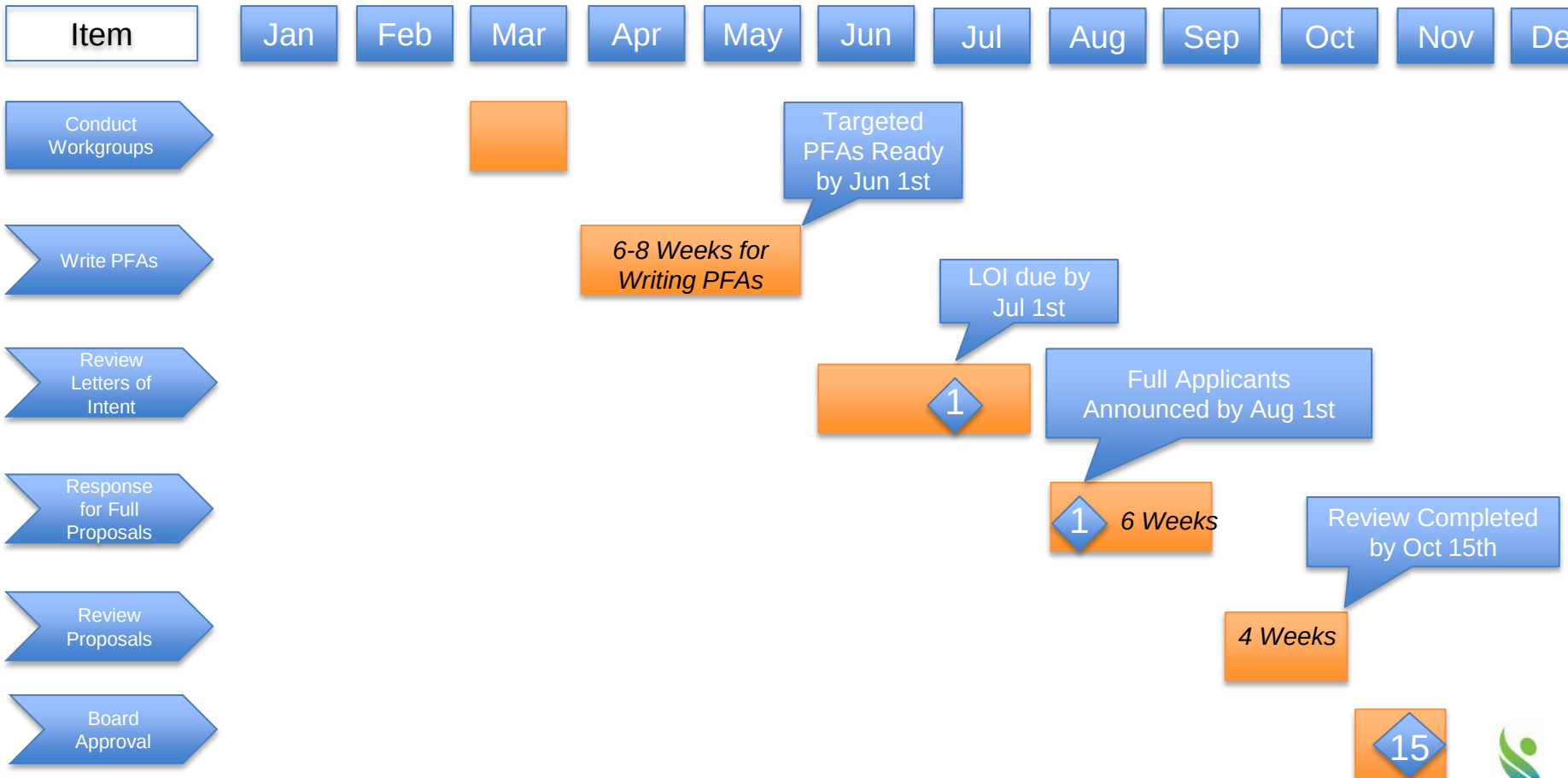
Communication and Outreach Strategy

- Web posting of process and topic-based information by February 4th, 2013
- Launched email blast to mailing list to announce the workgroups and solicit input
- Invite specific interested stakeholders to provide comments, research questions before, during and after the meeting
- Post meeting summary on website

Next Steps

- Web-based input on key questions began 2/4/13
- Conduct workgroups
- Provide summary of findings from ad hoc workgroups
- Review ad hoc workgroup recommendations with the Board
- Release Targeted PFAs by the end of June

Timeline:
Goal Targeted PFA Release in 2Q13



Public Comment Period

Patient-Centered Outcomes Research Institute

Break

Meeting Schedule

DATE	LOCATION
March 12, 2013	Webinar/Teleconference
March 26, 2013	Webinar/Teleconference
May 6, 2013	Chicago, IL
September 23, 2013	Washington, DC
November 18, 2013	Atlanta, GA

Advisory Panel Update

Anne Beal, MD, MPH, Deputy Executive Director and Chief Operating Officer

Rachael Fleurence, PhD, Acting Program Director, Accelerating PCOR and Methodological Research

PCORI Board of Governors Meeting

San Francisco, CA

February 2013

Patient-Centered Outcomes Research Institute

Session Topics and Objectives

What are we going to cover today?

Advisory Panel Recap	• Review key information regarding the establishment of Advisory Panels.
Advisory Panel Charters	• Review and **approve** (by vote) the new charter in **Improving Healthcare Systems**.
Role of the Advisory Panel	• Review the proposed role of Advisory Panels.
Timeline and Next Steps	• Review the proposed timeline for launching Advisory Panels.

Advisory Panel Charters

What are we asking of you?

Discuss Advisory Panel Application Process

Vote on the New Advisory Panel Charter

Advisory Panel Recap

Getting Up to Speed on Advisory Panels

What do I need to know?

Legislative Authorization

What does the law say expert advisory panels should include?

- PCORI can appoint permanent or ad hoc advisory panels to assist in identifying research priorities and establishing the research project agenda.
- Advisory panelists will include clinicians, patients, and experts with the appropriate experience and knowledge.

Purpose

What's the purpose of advisory panels?

- Advisory panelists may work in conjunction with PCORI staff to help identify research priorities and topics, conduct randomized clinical trials, and perform special research studies.
- Leveraging members' expertise will help better inform PCORI's mission and work.

Framework and Composition

How will they be structured?

- Each panel will have a unique charter, term duration, and clearly defined scope of work.
- PCORI staff will select each panel's members, and the Board will approve the final group that is selected.
- Members will be compensated and appointed for an initial one-year term.
- Members will be selected based on their expertise and ability to contribute to the work of specific panels.

Getting Up to Speed on Advisory Panels

What do I need to know?

Conflicts of Interest

Will panel members be eligible for future PCORI funding?

- Panel members are not making decisions on funding, programs, or operations.
- PCORI's focus on transparency and building information firewalls will prevent conflicts from arising.
- Advisory panel membership generally does not preclude eligibility for funding.
- Members will be advised of unique instances where their role could result in disqualification.

Panel Establishment

When will advisory panels be established?

- Four panels will be established in the first half of 2013.
- More panels will be established in the future.

Panel Charters

What was approved at November's Board meeting?

- Charters were reviewed and approved for three panels.
- Minor edits have been made to reflect the board's comments in November to the following charters: **Assessment of Prevention, Diagnosis and Treatment Options, Addressing Disparities, and Patient Engagement.**

Advisory Panel Establishment Process

1 Staff Drafts and Submits an Advisory Panel Charter

- Board, MC, and/or PCORI staff identify the need to establish an Advisory Panel
- Staff initiates request for an advisory panel by submitting a panel-specific charter

2 Board Reviews the Proposed Advisory Panel Charter

- Board may authorize charter
- Board may request revisions to the charter

3 Staff Activates Application and Selection of Panel Participants

- Staff initiates open call for Applications, via the PCORI website and other communications
- Nominees submit an application via the PCORI Web site
- Staff evaluates nominees, per evaluation criteria unique to the panel charter

4 Board Approves Panel Participants

- Staff selects and proposes a panel roster to the Board
- Board authorizes and approves the panel roster

Staff Phase *Board Phase*

Advisory Panel Charters

Assessment of Prevention, Diagnosis, and Treatment Options

Revised Charter – Approved on November 19, 2012

Purpose	Will advise PCORI on evaluating potential research topics related to the comparative effectiveness of alternative strategies for prevention, treatment, screening, diagnosis, and management.
Membership Term and Charter Duration	**One year** beginning on the day of the first panel meeting.
Composition	**The Panel will consist of 12-21 members. No fewer than 25% of panel members will be selected from persons who are patients, caregivers, or representatives of patient advocacy organizations.**

Addressing Disparities

Revised Charter – Approved on November 19, 2012

Purpose	Will advise PCORI on evaluating potential research topics related to addressing disparities in health and health care. The focus is on studies that will inform the choice of the best strategies to eliminate disparities rather than studies that describe the problem. The studies related to addressing disparities must focus on areas of importance to patients and their caregivers, where there are critical disparities that disadvantage members of a particular group and limit their ability to achieve optimal, patient-centered outcomes.
Membership Term and Charter Duration	**One year** beginning on the day of the first panel meeting.
Composition	**The Panel will consist of 12-21 members. No fewer than 25% of panel members will be selected from persons who are patients, caregivers, or representatives of patient advocacy organizations.**

Patient Engagement

Revised Charter – Approved on November 19, 2012

Purpose	Will advise PCORI on assuring the highest patient engagement standards and a culture of patient-centeredness in all aspects of its work.
Membership Term and Charter Duration	**One year** beginning on the day of the first panel meeting.
Composition	**The Panel will consist of 12-21 members. At least 60% of the members will be patients, caregivers, and advocacy organizations representing patients and caregivers.**

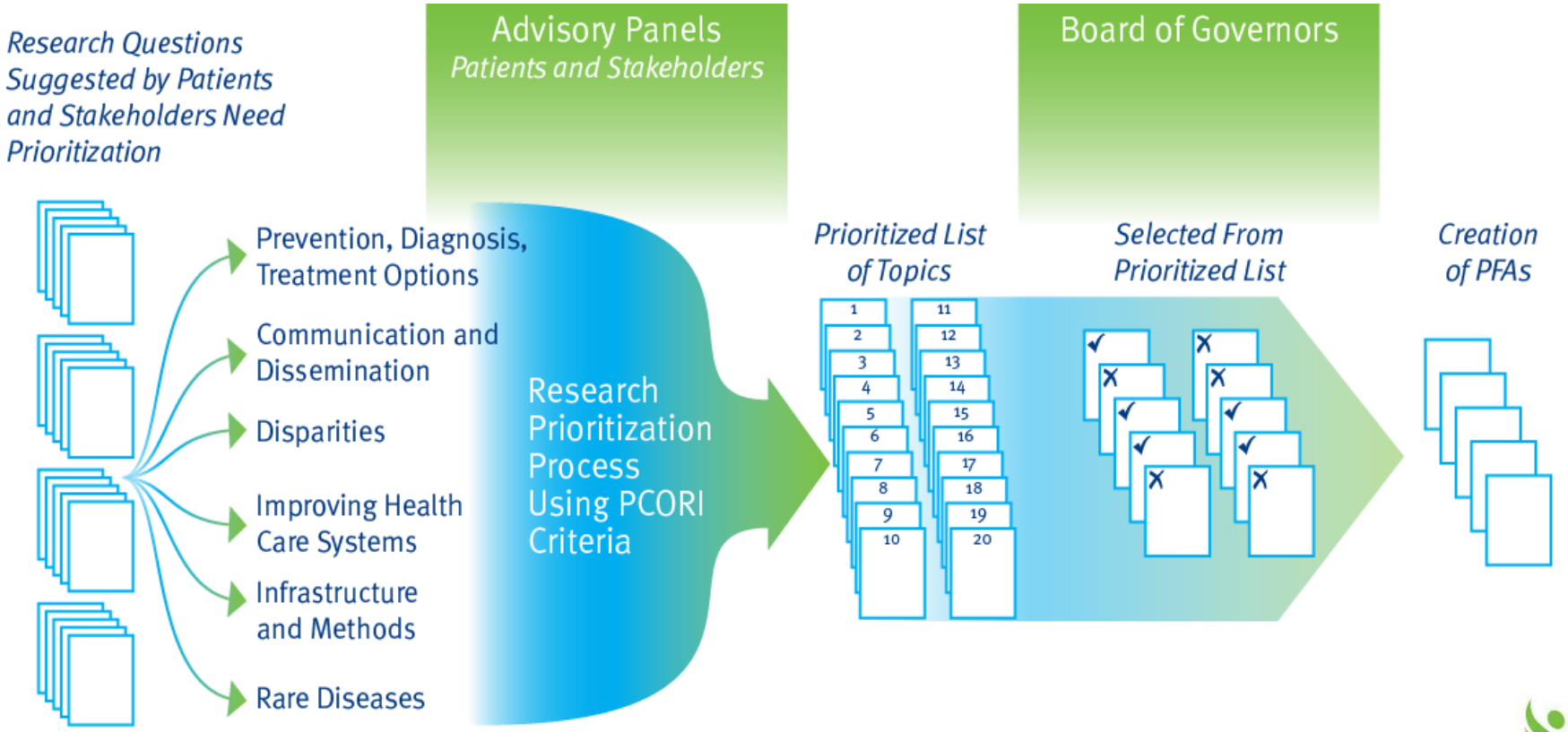
Improving Healthcare Systems

New Charter – Proposed on February 4, 2013

Purpose	Will advise PCORI on the information gaps that exist and critical decisions that face healthcare system leaders, policy makers, clinicians, and the patients and caregivers who rely on them. The premise of PCORI's research in this area is that the resulting new knowledge will support critical choices by patients and other key stakeholders in health care.
Membership Term and Charter Duration	One year beginning on the day of the first panel meeting.
Composition	The Panel will consist of 12-21 members. No fewer than 25% of panel members will be selected from persons who are patients, caregivers, or representatives of patient advocacy organizations.

Role of Advisory Panels

PCORI's Research Prioritization Process



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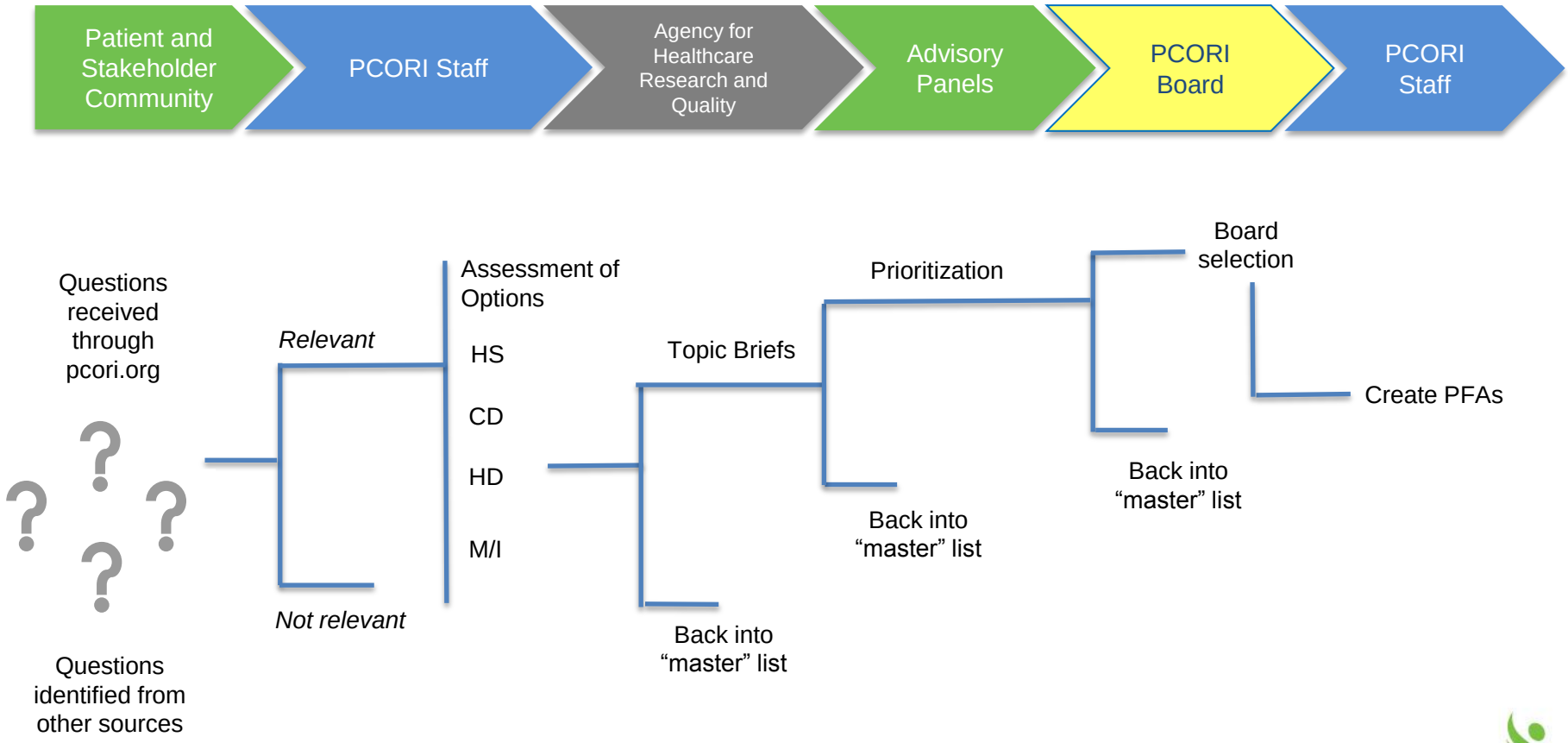
Life of a Question



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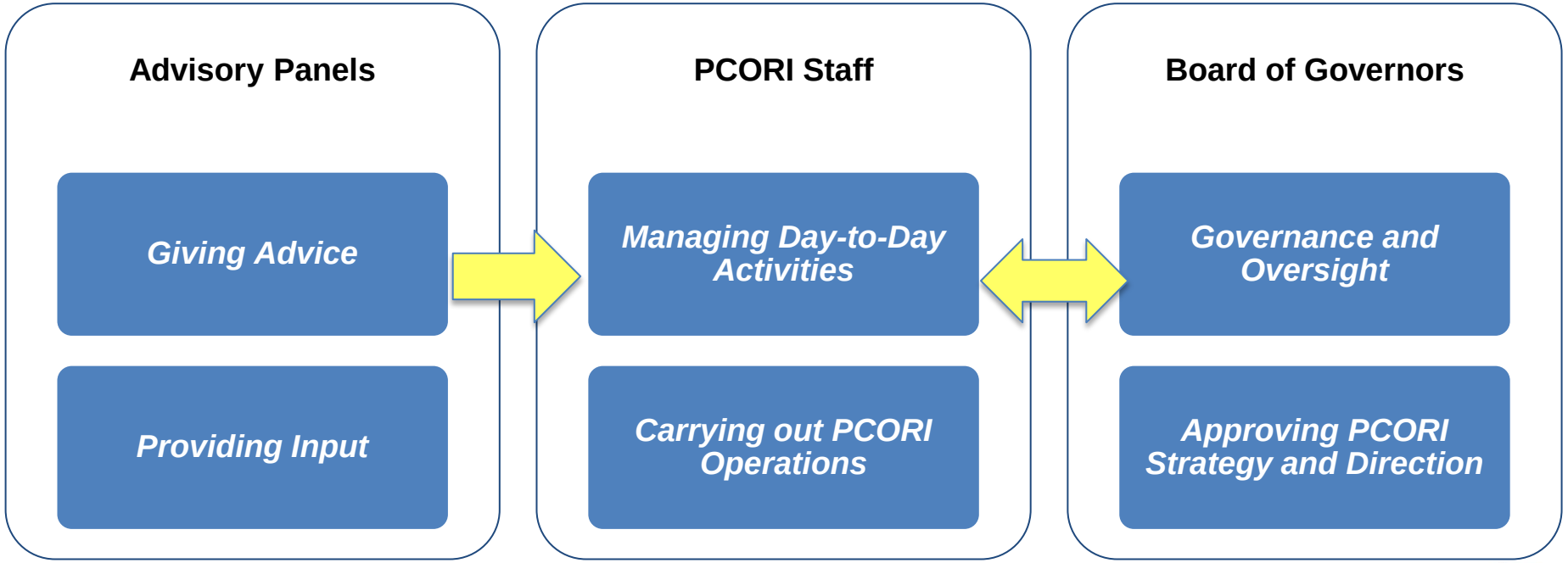
PCORI Roles

Where do Advisory Panels fit?

Advisory panelists may work in conjunction with PCORI staff to help identify research priorities and topics, conduct randomized clinical trials, and perform special research studies.



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Timeline and Next Steps

Next Steps

What can you expect in the coming months?

	2013			
Action Step	**Jan**	**Feb**	**March**	**April**
Application Period Opens Launch Proactive Outreach and Communications (Jan. 28)	✓			
Board Reviews and Considers Approval of Improving Healthcare Systems Advisory Panel (Feb. 4)		✓		
Staff Conducts **Rolling Review** of Applications		✓	✓	
Application Period Closes (March 4)			✓	
Wrap Up Review and Prepare Slate			✓	
Board Review and Approve Membership Rosters (March 26)			✓	
Kickoff and Training, Washington, DC (April 19 and 20)				✓

Application Portal

http://www.pcori.org/pcori-advisory-panels/

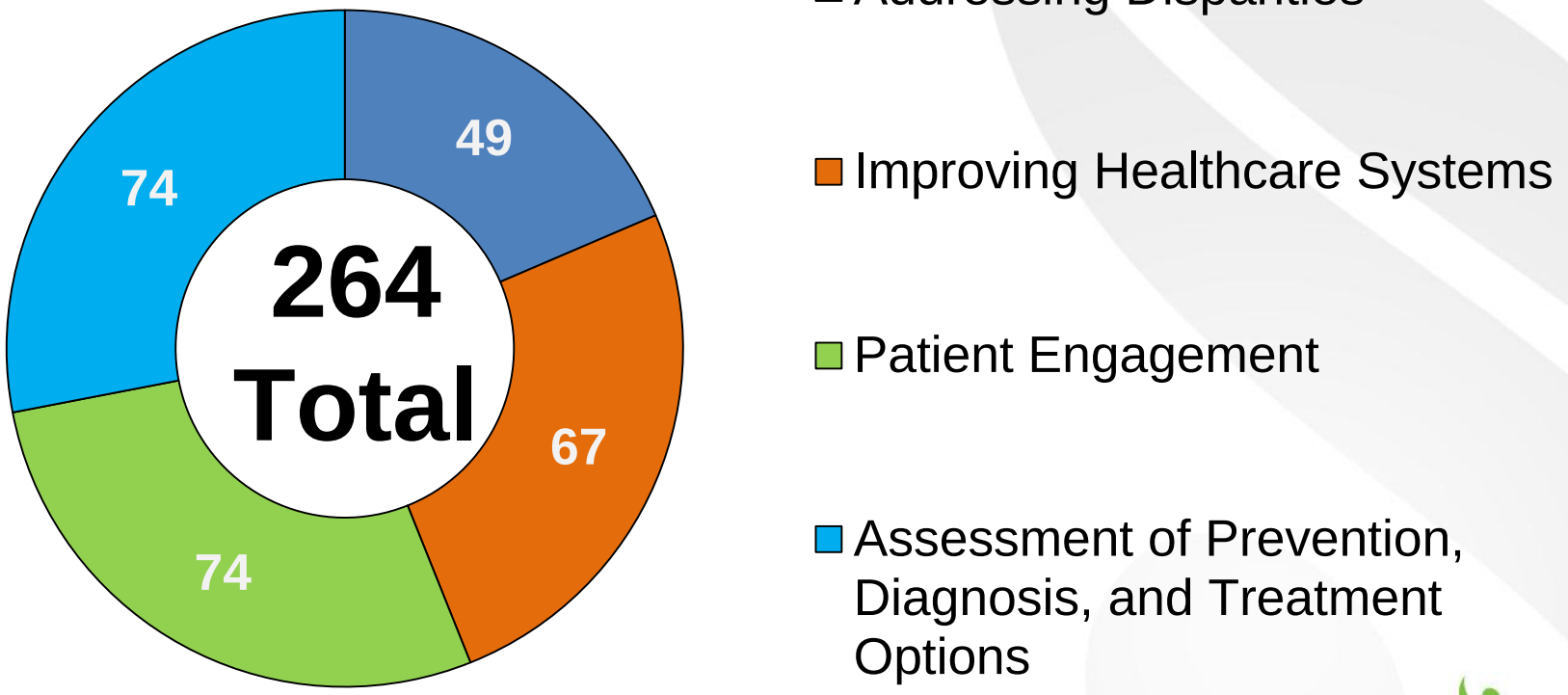
- Application period will be open for 7 full weeks from Jan. 28 to March 4
- Application review and panelist selection process will be based on:
  - Experience
  - Background
  - Ability to contribute to the scope of work described in the charter
  - Applicant's commitment to advancing the mission and goals of the Institute

Advisory Panel Applications To Date

How many people have applied?

Applications Completed – Jan. 28 to Feb. 3

242 discrete individuals



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Advisory Panel Charters

What are we asking of you?

Discuss Advisory Panel Application Process	• Review and discuss proposed application process for Advisory Panel members.
New Advisory Panel Charter	• Approve (by vote) the proposed charter for the **Improving Healthcare Systems Advisory Panel.**

Appendix

- Advisory panel charter for Improving Health Systems

Standing Committee on Conflict of Interest Presentation

Larry Becker

PCORI Board of Governors Meeting

San Francisco, CA

February 2013

Patient-Centered Outcomes Research Institute

Session Topics and Objectives

What are we going to cover today?

COI Rules for Research Funding	• Review and vote on revisions to Rules for Research Funding.
COI Disclosure Process and Next Steps	• Update on new developments, documents, and next steps for Conflict of Interest disclosure.

Conflict of Interest
What policies have been put in place?

- **In May 2011, the Board Approved PCORI's Conflict of Interest (COI) Policy**

- **In June 2012, the Board approved COI Rules for Research Funding**
  - Established two types of Methodology Committee members
  - Firewalls prevent anyone eligible for funding from having access to non-public meetings and materials
  - During implementation of the rules, we identified areas where revisions are needed

COI Rules for Research Funding

COI Rules on Research Funding

What changes are being proposed?

Differentiating length of ineligibility following participation in development of targeted vs broad PFAs – Applies to Board, MC, or Staff who leave PCORI service	
Current (Approved June 2012)	***Proposed Change***
Targeted and Broad PFAs: Board and staff members ineligible to apply for one year after resignation. MC members ineligible (forever) if involved in developing PFA.	Permanent ineligibility for **targeted PFAs** for all those involved in developing them.
	One year ineligibility is sufficient elapsed time to dissipate knowledge advantage for **broad PFAs** for all participants.

Making eligibility rules after end of service to PCORI similar for MC and Board members PFAs	
Current (Approved June 2012)	***Proposed Change***
Permanent disqualification of Methodology Committee PFA Subcommittee Members for all PFAs developed during their service.	As with PCORI staff and the Board of Governors, Methodology Committee members who serve on the PFA Development Subcommittee will face a one-year period of ineligibility after the end of their service for broad PFAs developed during their service.

COI Rules on Research Funding

What changes are being proposed?

Change in rules for participation of MC members in drafting of targeted PFAs	
Current (Approved June 2012)	***Proposed Change***
Any Methodology Committee members not on the PFA Development Subcommittee cannot assist in development of any PFA.	Methodology Committee members who are not part of the PFA Development Subcommittee may help develop a targeted PFA on an individual basis provided member is willing to forego eligibility to apply for that targeted PFA (all cycles) • Standard firewalls would continue in place for the MC member, with the exception of the one targeted PFA • Member would continue to be eligible to apply for other PFAs • Participation will be reported to the SCCOI and included in meeting minutes

Conflict of Interest (*Board of Governors Vote)*

COI Rules for Research Funding

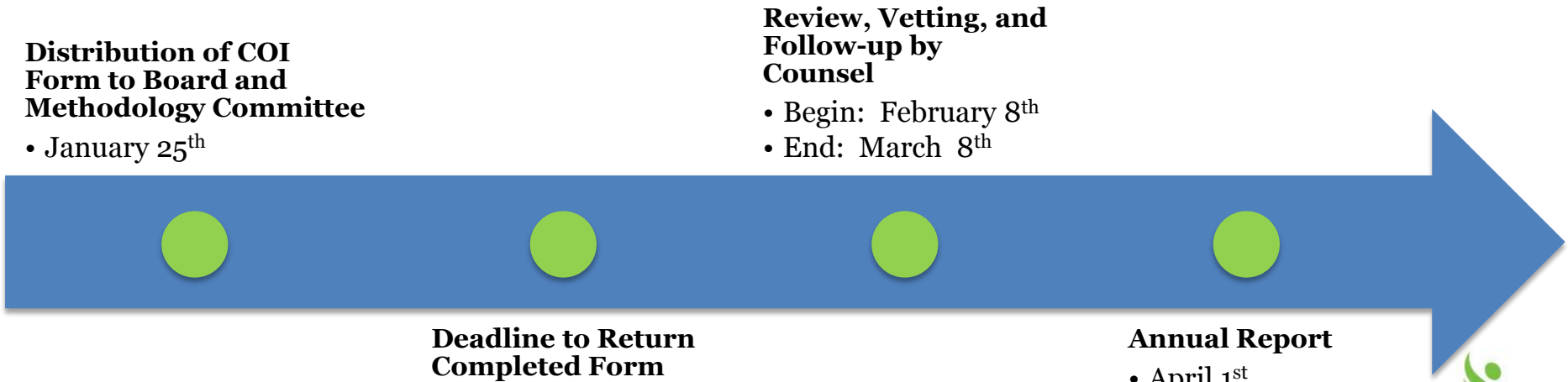
- Review and approve (by vote) the changes to PCORI's COI Rules for Research Funding.

Annual COI Disclosure Process and Next Steps

Conflict of Interest

How has the Board and Methodology Committee COI disclosure been enhanced?

- **Board and Methodology Committee Disclosure**
  - Employment of spouse and close relatives is now solicited
  - Financial disclosures (investments and financial relationships) for close relatives are solicited as "to the best of your knowledge"
  - This deadline is necessitated by need for inclusion of follow-up and disclosure in annual report



Next Steps

COI and External Parties

- Enhance and refine COI policy regarding external parties such as Advisory Panels, researchers, and vendors.

Staff Disclosures and COI Policy

- Enhance and refine COI policy and disclosure with regard to staff.

Appendix

- Proposed update on the Conflict of Interest Policy with tracked changes

Wrap-up and Adjourn