

Patient Engagement Advisory Panel

June 1, 2015

Washington, DC



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

New Panelist Orientation

Welcome!

Anjum Khurshid
Bennet Levitan
Jimmy Lin
Mark Mishra
Jane Perlmutter
Philip Posner
Veronica Todaro



Morning Agenda – June 1

- 8:30 a.m. Opening remarks about the panel – Sue Sheridan
- 8:35 a.m. Reflections on the role of the panel – Charlotte Collins and Darius Tandon
- 8:40 a.m. Brief PCORI overview – Jean Slutsky
- 8:50 a.m. Speed dating with PCORI staff
- 10:10 a.m. Group discussion
- 10:30 a.m. Break and networking with current panelists
- 10:50 a.m. Group photo in lobby



PCORI Advisory Panel on Patient Engagement Welcome

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer and

Program Director for Communication and Dissemination Research



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Our Mission

PCORI 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.**



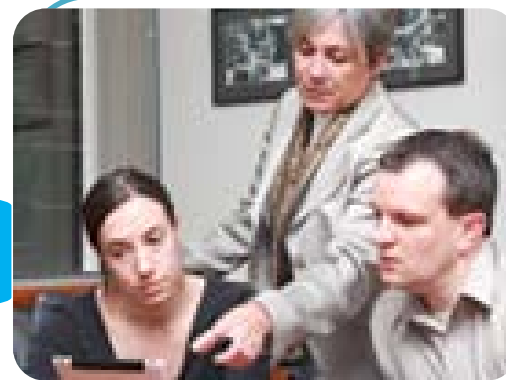
Our Strategic Goals

Increase Quantity, Quality, Usefulness, and Timeliness of Research Information



Speed the Implementation and Use of Evidence

Use of

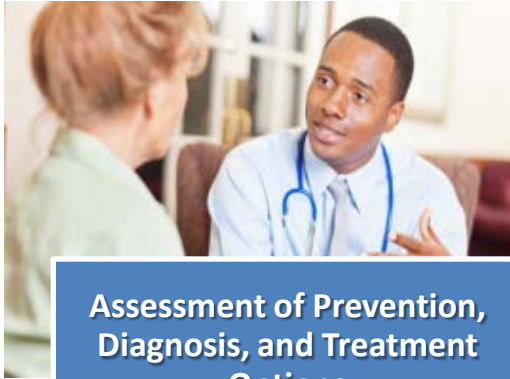


Influence Research Funded by Others



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The Research We Fund is Guided by Our National Priorities for Research



**Assessment of Prevention,
Diagnosis, and Treatment
Options**



**Improving
Healthcare Systems**



**Communication &
Dissemination
Research**



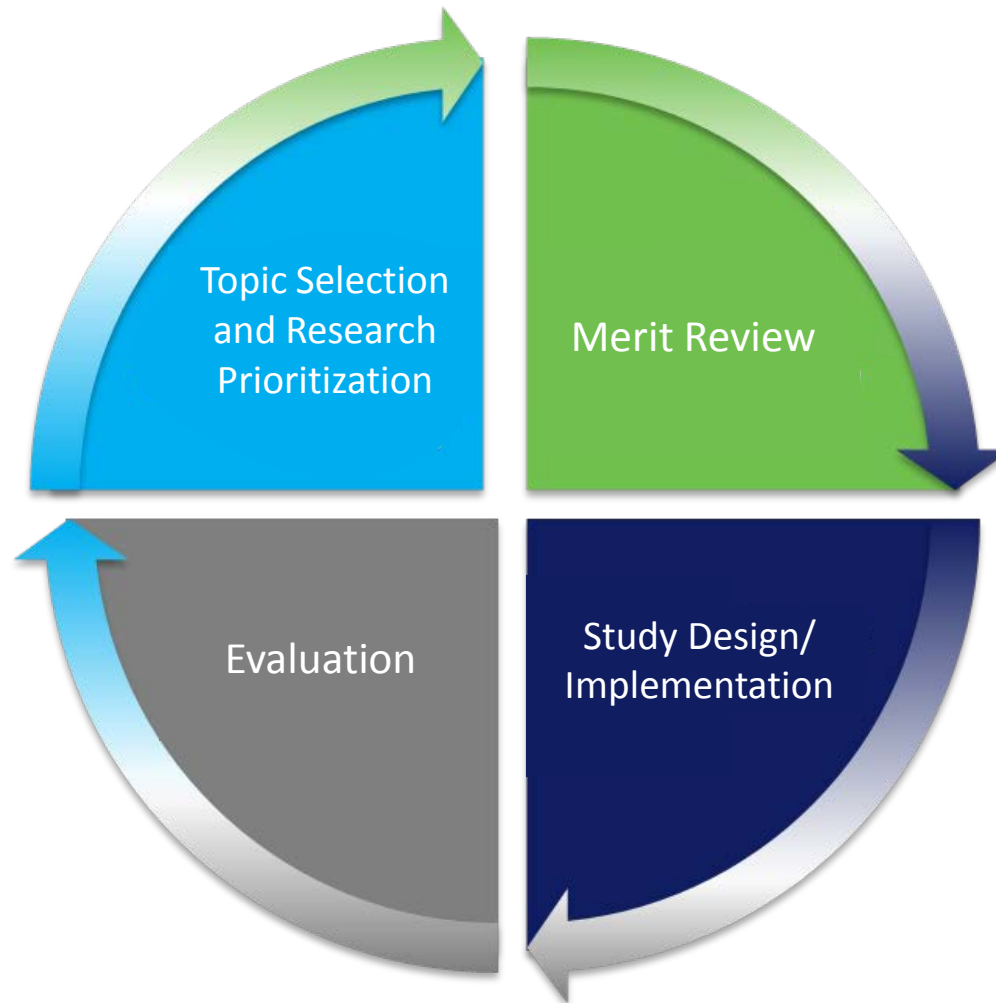
**Addressing
Disparities**



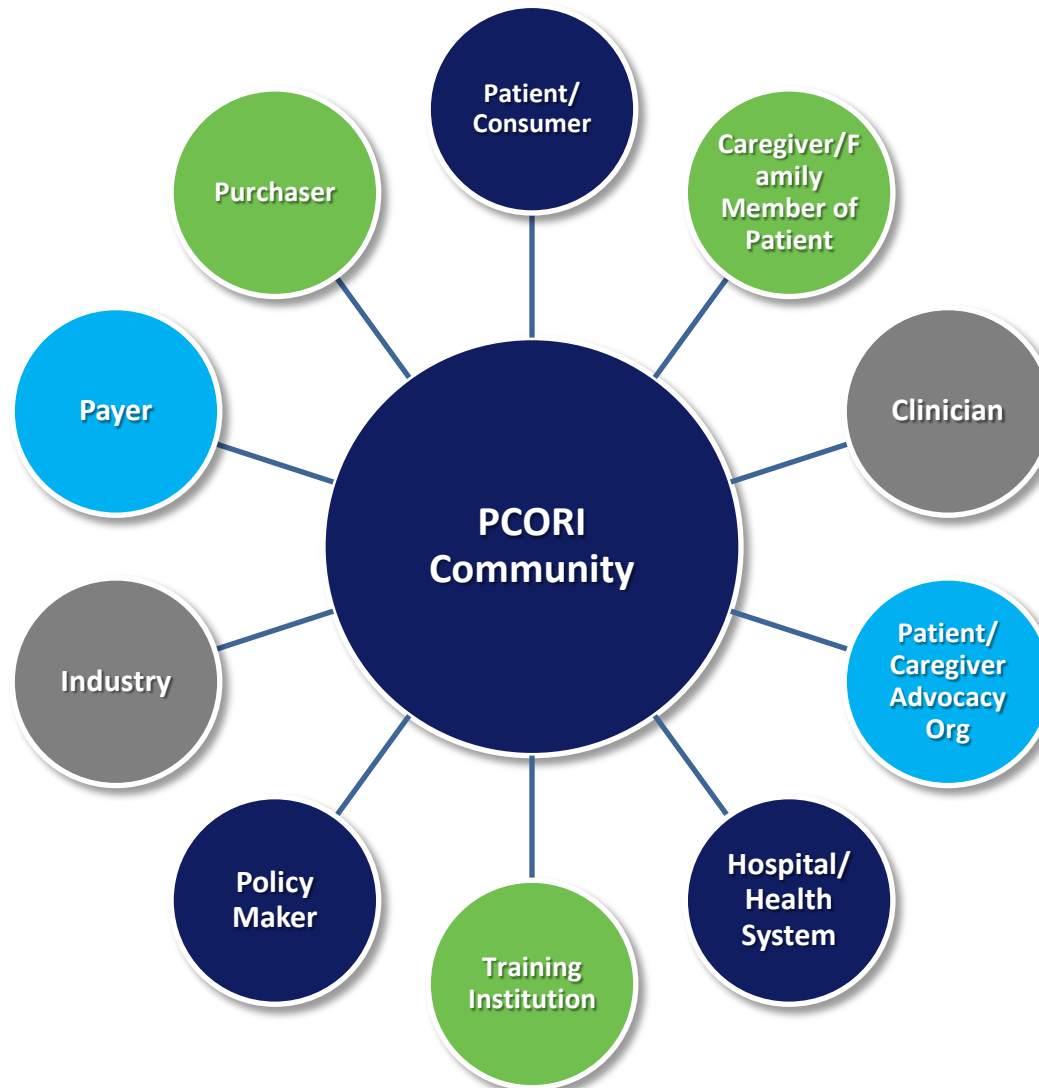
**Accelerating PCOR
and Methodological
Research**



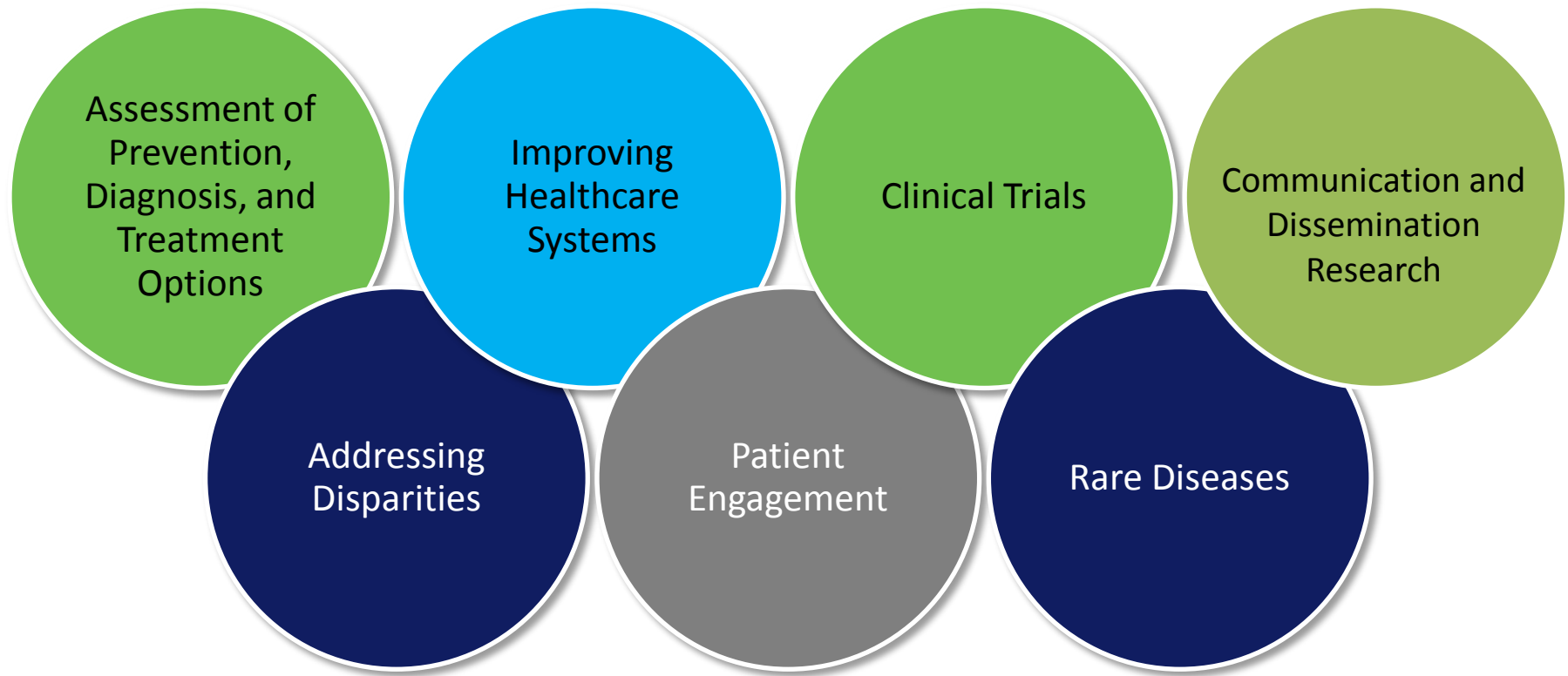
We Engage Patients and Other Stakeholders at Every Step



Who Are Our Stakeholders?



Our Advisory Panels



Learn More

www.pcori.org

info@pcori.org

[twitter](#) 

[You Tube](#) 



30 Minute Break & Networking
Group photo at 10:50 a.m.

Welcome, Introductions, and Review Agenda

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination
Officer

Sue Sheridan, MIM, MBA, DHL

Director of Patient Engagement

Charlotte W. Collins, JD

Chair
Compensation Subcommittee

Darius Tandon, PhD

Chair
Evaluation Subcommittee



Agenda for June 1

11:00 – 11:45 a.m. – Welcome, Introductions, and Review Agenda

11:45 a.m. – 12:00 p.m. – Compensation Framework (Informational)

12:00 – 1:00 p.m. – LUNCH

1:00 – 2:00 p.m. – Evaluation of the PCORI Research Funding Strategy – Q&A with Joe Selby

2:00 – 3:00 p.m. - Creating a “PCOR Ready” Community – Training and Capacity Building

3:00 – 3:15 p.m. – BREAK

3:15 – 5:00 p.m. – Continued: Creating a “PCOR Ready” Community – Training and Capacity Building

5:00 p.m. – Wrap-up

5:30 p.m. – BREAK

6:30 – 8:00 p.m. – Dinner



Advisory Panel on Patient Engagement

Steven Blum
Marc Boutin
Kristin Carman
Perry Cohen
Charlotte Collins
Regina Greer-Smith
Pastor Bruce Hanson
Lorraine Johnson
Amy Kratchman
Julie Moretz
Kimberly McCleary
Sally Okun
Darius Tandon
Sara Traigle van Geertruyden
Anjum Khurshid
Bennett Levitan
Jimmy Lin
Mark Mishra
Jane Perlmutter
Philip Posner
Veronica Todaro



Compensation Framework

Suzanne Schrandt, JD

Deputy Director, Patient Engagement



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Lunch

Evolution of the PCORI Research Funding Strategy

Joe Selby, MD, MPH

Executive Director



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First 10 PCORI Pragmatic Clinical Studies

- **Breast cancer screening tailored to individual risk and preferences vs. annual mammography** for detecting breast cancer and minimizing screening-related harms in women 40-80
- **Annual vs. biennial surveillance CT scanning** in patients found to have small, potentially cancerous growths on initial CT scan
- **Standing order entry system for guiding use of colony stimulating factor vs. usual oncology practice** for reducing over- and underuse of this medication and preventing complications in patients with breast, lung, colorectal cancer
- **Comprehensive transitional care program of early discharge and in-home support services vs. usual care** in improving functional status and preventing hospital readmissions and mortality in stroke survivors?
- **Primary care plus prompt referral to physical therapy and cognitive behavioral therapy vs. usual primary care** to prevent acute back pain from becoming chronic



First 10 PCORI Pragmatic Clinical Studies

- **Healthy lifestyle intervention plus metformin therapy vs. health lifestyle intervention alone** for reducing weight gain and metabolic problems associated with certain antipsychotic medications in youth with bipolar disorders?
- **Anti-TNF factor vs. anti-TNF plus low dose of methotrexate** in children with Crohn's disease for induction, maintenance of remission, patient-reported outcomes, and adverse events?
- **Nerve blocking regional anesthesia vs general anesthesia** in older adults undergoing surgery for hip fracture on acute post-operative pain, satisfaction with care, inpatient morbidity, and ability walk without assistance at 60 and 180 days, health and disability, pain, ability to return home after fracture, and mortality
- **Exercise coaching program vs. usual care** for older adults who have experienced a low-impact fracture as a result of a fall for preventing further injuries and improving health
- **Proton-beam vs. photon-beam radiation therapy** post-mastectomy in women with Stage II or III for outcomes of recurrence, mortality and cardiovascular disease complications of radiation therapy



Current evaluation activities related to Pragmatic Clinical Studies

PCORI allocated enough to fund 6-9 applications in each cycle and awarded 5 per cycle. To increase the number of awards in subsequent cycles, we are:

- Actively reaching out to research community to increase awareness and increase the numbers of LOIs and applications for PCS awards
- Working with stakeholder organizations to increase the number of high priority topics, many of which will go to the PCS high-priority list
- Refining the RFA to be clearer on requirements/expectations
- Working with merit review teams to assure that reviews appropriately capture PCORI review criteria
- Considering increasing proportion of LOI's invited to submit full proposals
- Anticipating arrival of resubmitted LOI's and applications which should augment the numbers of high-scoring applications
- Evaluating researcher readiness to organize and lead pragmatic studies
- Surveying researchers who have recently published good CER to assess their awareness of and attitudes toward PCORI as a funding source



Creating a “PCOR Ready” Community – Training and Capacity Building

Sue Sheridan, MIM, MBA, DHL
Director of Patient Engagement

Jaye Bea Smalley , MPA Engagement
Officer

Erica Sarnes, MA
Training Manager

Suzanne Schrandt, JD
Deputy Director of Patient
Engagement



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Muses About Training for Patient Engagement

Jane Perlmutter

June 1, 2015

Key Take Home Points

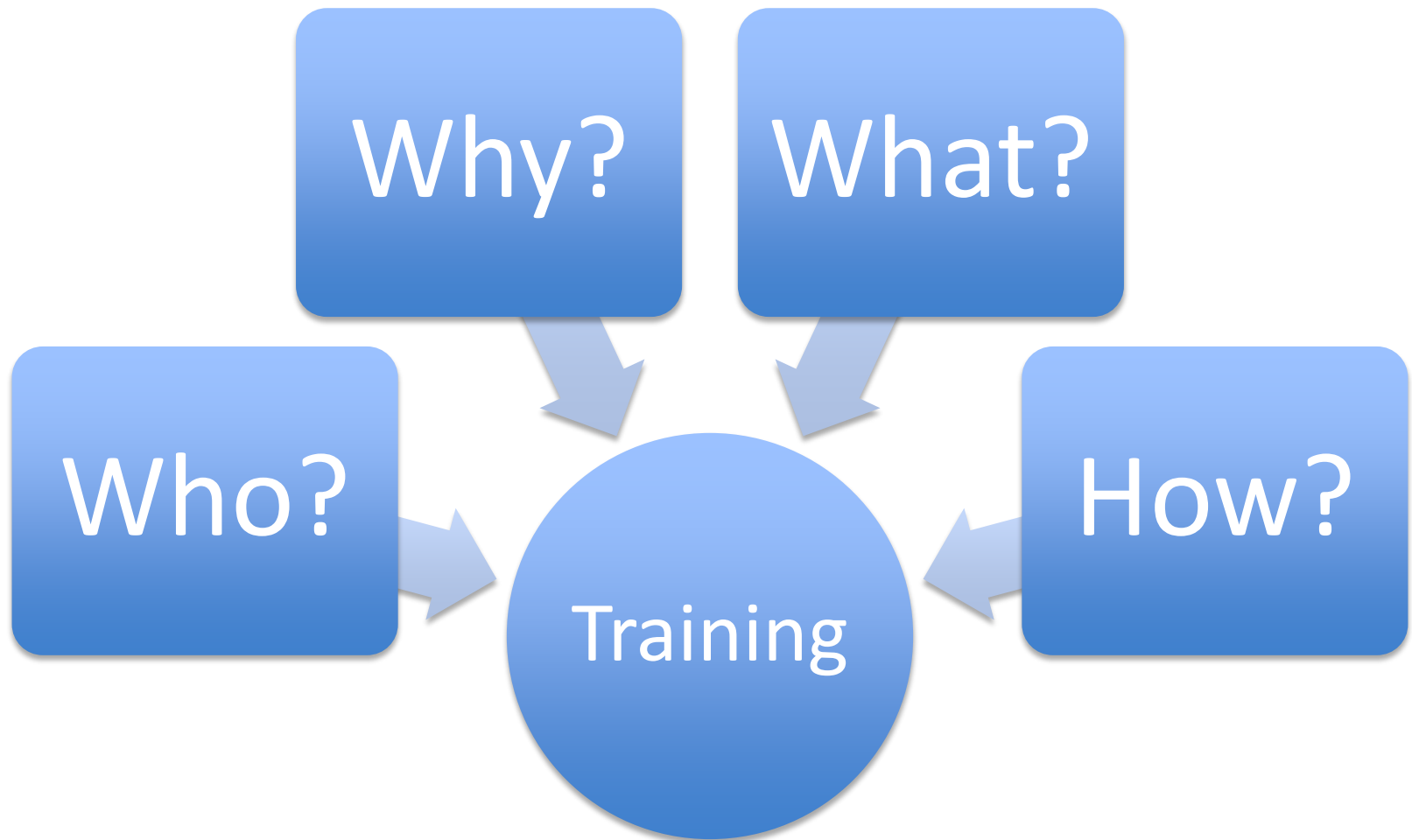
- **Know your goals**
 - Who, why, what and how
- **Use experiential learning**
 - Focus on skills
 - Imbed content
 - Use multiple modalities
- **Mentoring/apprenticeship makes the difference**
 - Provides modeling and feedback
 - Provide continuous learning and opportunities for mentors



PCORI Training Grid

Types of Learners	Content Areas			
	Getting Ready for Research	Research	Skill Development	Implementation
New to Science				
Beginning Partner on Research Team				
Adv. Partner (Health Services Research)				
Adv. Partner (Drug/Device Development, Clinical Trials)				

JP Framework: Knowing Your Goals



- **Who Will You be Training?**

- Patients and caregivers
- Advocates
- Organizational staff
- Researchers



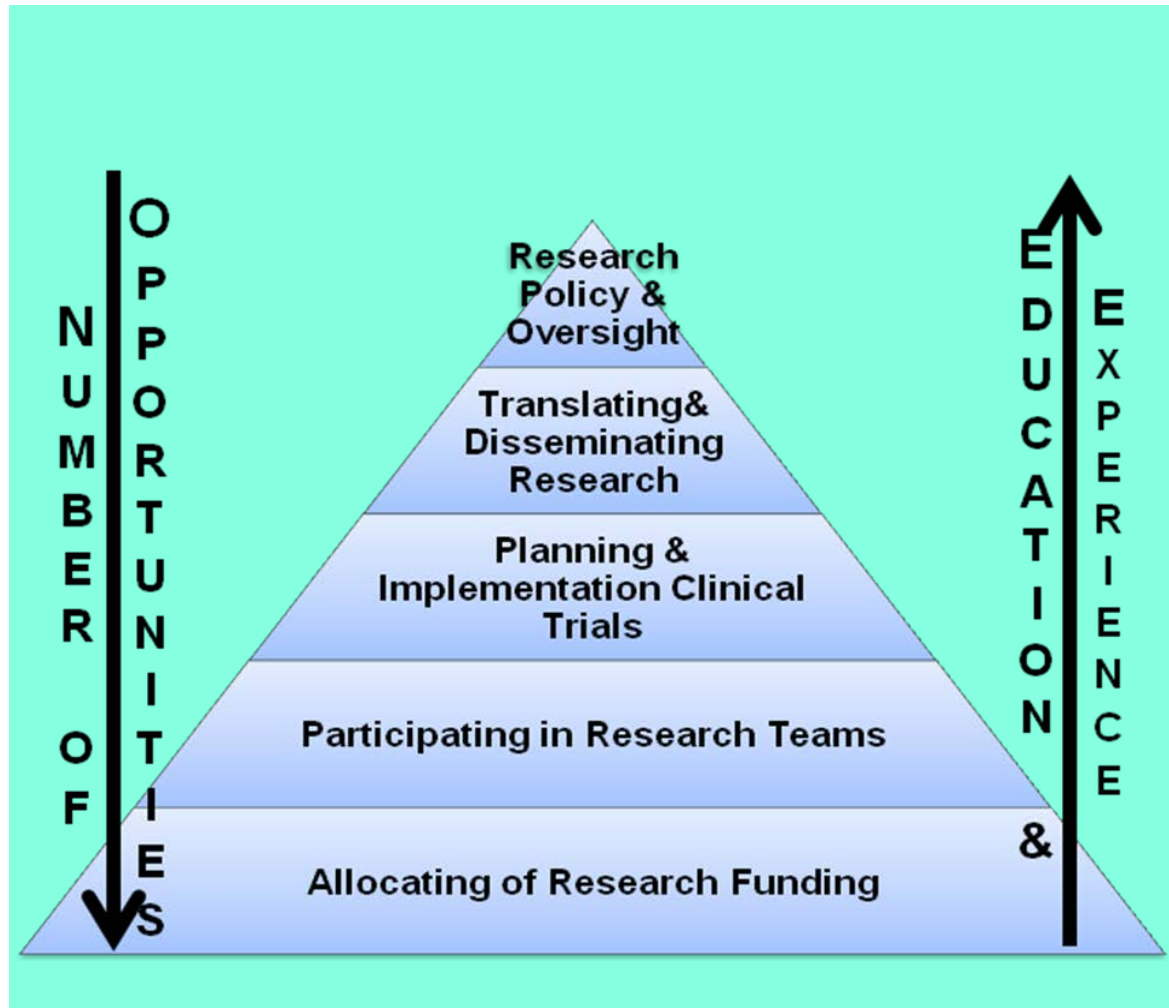
- **What Are You Training Them For?**

- Telling their story
- Impacting research
- Supporting other patients
- Train the trainer
- Involving patients/advocates in research

What Are You Training Them For?

- **Telling their story**
- **Impacting research**
 - Reviewing grants
 - Being involved in research and/or clinical trials planning and/or dissemination
- **Supporting other patients**
 - Emotional support
 - Navigation
 - Clinical trial participation
- **Train the trainer**
- **Involving patients/advocates in research**

Research Advocacy: What Will You Be Training Them For?



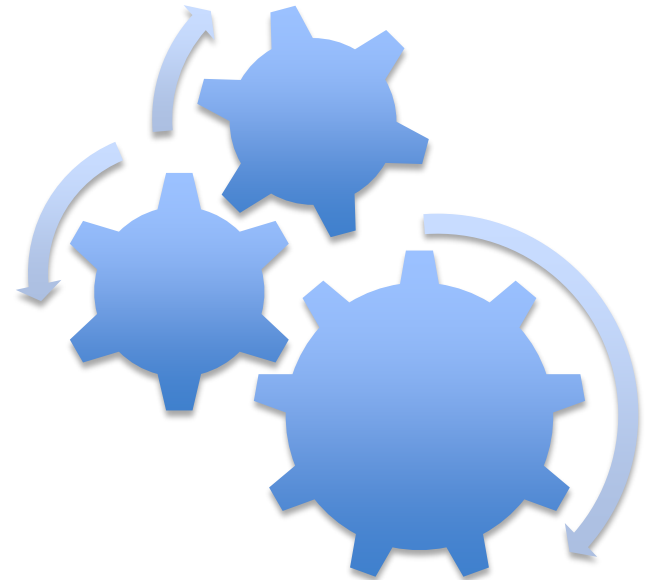
What Do They Need to Learn?

– Knowledge

- The research process
- The disease process and diversity of patients
- Relevant science
- Relevant ethical issues

– Skills

- The research culture
- Advocacy dos and don'ts
- Business savvy/Emotional intelligence
- Effective communication
- Good work habits





Advocate Criteria Checklist

Topic	Importance (Check one per topic)		
	Not Important	Helpful	Critical
Understanding the drug development process			
Clinical trials fundamentals			
Basic statistical concepts			
Biomarkers			
PROs/QoL			
Regulatory process			
Understanding disease			
Natural history of disease			
Standard diagnosis & treatment of disease			
Hot topics in disease			
Disease KOLs			
Understanding/access to patients			
Personal/caregiver experience			
Connections to relevant constituents/advocacy organizations			
Knowledge/empathy to diverse patient experiences and issues			
Business savvy/Emotional intelligence			
Sensitivity to pragmatics and trade-offs			
Has a broad strategic view			
Conscientiousness			
Works well in diverse teams			
Communication skills			
Strong oral communication skills			
Strong writing skills			
Listens to others			
Expresses opinions/represents patients			
Maintains an open mind			

How Will You Train Them?

- **Self-paced, individual learning—e.g.,**
 - Readings
 - PowerPoint
- **Group-based, trainer-led learning—e.g.,**
 - Webinars
 - Lectures
- **Group-based, interactive learning—e.g.,**
 - Discussions
 - Role plays
 - Simulations

How Will You Train Them?

	Most Appropriate for	Likely impact	Cost
Self-paced, individual learning	Knowledge		
Group-based, trainer-led learning			
Group-based, interactive learning	Skills		

Experiential Learning

- Focus on skills trainees will apply
- Imbed content will need
- Use multiple modalities
- Use case studies, role plays, simulations, etc.



Mentoring and Apprenticing

- Just in time
- One-on-one
- Provides modeling and feedback
- Great for confidence building (often the most important component of the training)
- Builds pipeline
- Decreases tokenism
- Provides opportunities for continuing development for more experienced advocates



Training Grid



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Part of PCORI's strategic plan is to create a PCOR ready community and lack of training of non-researchers is identified in literature as a barrier to PCOR.

Additionally, the WE-ENACT tool has identified training needs around the research process and skills development and Engagement Officers have identified training needs while working with PIs and patient partners in active research projects. In response to all of this, the Engagement Team has created this draft of a training "grid" that walks through potential training curricula for different types of learners, and for different aspects of involvement in research. The grid is organized by these four types of learners: "New to Science (Everybody)", "Beginner Partner on Research Team", "Advanced Partner on Research Team (Health Services Research)", and "Advanced Partner on Research Team (Drug/Device Development, Clinical Trials)", and by these four aspects of involvement in research which we refer to as content areas.

These are:

- Getting Ready for Research (Infrastructure and Partnership Development)
- Research (The research process -from planning to dissemination)
- Skill Development (How to be an effective research partner)
- Implementation (Making sure that research findings are used)

The bulleted content included in the columns is a collection of our preliminary thoughts about the types of things that should be covered within each area. We'll be discussing this in more detail at the PEAP and inviting all of you to help us further development and refinement.



Four Content Areas

Getting Ready for Research	Research	Skill Development	Implementation
Infrastructure and Partnership Development	The research process -from planning to dissemination	How to be an effective research partner	Making sure that research findings are used



Four Learner-Types

New to Science (Everybody)
Beginner Partner on Research Team
Advanced Partner on Research Team (Health Services Research)
Advanced Partner on Research Team (Drug/Device Development, Clinical Trials)



Four Learner-Types

New to Science (Everybody)
Beginner Partner on Research Team
Advanced Partner on Research Team (Health Services Research)
Advanced Partner on Research Team (Drug/Device Development, Clinical Trials)



New to Science (Everybody)

Getting Ready for Research	Research	Skill Development	Implementation
	<p>What is research (very high level overview)</p> <p>What is PCOR (very basic)</p> <p>Safeguards in research</p> <p>How everyone can contribute to research</p> <p>What are research outcomes and how are they measured</p> <p>Data and sharing of data (EHRs, HIEs, understanding the value of your data)</p> <p>Examples of how research improved health outcomes</p>	<p>How to tell your story</p> <p>How to work in a multi-disciplinary in team</p> <p>How to communicate about research with your community</p>	



Beginner Partner

Getting Ready for Research	Research	Skill Development	Implementation
	<p>(All of the same bullets from above would be included, but at a higher level of sophistication)</p> <p>What is CER and what is a CER research question</p> <p>Introduction to research/PCOR methods (randomization, study design, PROs, etc.)</p> <p>Introduction to patient and stakeholder roles in the planning, conduct and dissemination of research</p> <p>Protection of study subjects (IRBs, consent)</p> <p>Intro to data research network</p>	<p>(All of the same bullets from above would be included, but at a higher level of sophistication)</p> <p>Group facilitation</p> <p>Drafting and abiding by partnership MOUs</p> <p>How to place personal experience within a larger context</p>	<p>Understanding our healthcare system</p> <p>Knowing the various agencies and their roles: HHS AHRQ, HRSA, FDA, CDC, NIH, CMS Joint Commission</p> <p>Understanding the roles of other stakeholders: Professional societies Payers Purchasers Healthcare systems Industry</p>



Advanced Partner (HSR)

Getting Ready for Research	Research	Skill Development	Implementation
<p>Governance</p> <p>Partnership development</p> <p>Enrollment and diversity</p> <p>Data collection (EHR , PROs, registries) sharing data and data use agreements,</p> <p>Privacy policies</p> <p>Consent development</p> <p>Communications and outreach strategies (role of social media)</p> <p>How to write a proposal</p>	<p>How to develop a research question (how to identify a comparator)</p> <p>How to prioritize research questions</p> <p>Methods to determine patient centered outcomes</p> <p>More on PROs, PROMS</p> <p>How to choose the best research design</p> <p>More on subject protection in research (IRBs, informed consent, DSMBs)</p> <p>More on research methods (randomization, power, eligibility determination, single-site vs. multi-site)</p> <p>Promising practices in recruiting (social media, etc.)</p> <p>Best practices in dissemination</p>	<p>(All of same bullets from both sections above would be included but at a higher level of sophistication)</p> <p>Leadership skills</p> <p>How to participate on Advisory Panels</p> <p>Public speaking</p> <p>Methods to incorporate multi-stakeholder input and perspectives</p> <p>Conflict resolution</p>	<p>(All of same bullets from above would be included but at a higher level of sophistication)</p> <p>Understanding the role of additional relevant agencies: (NQF, USPSTF, etc.)</p> <p>How to partner in Guideline development</p> <p>The role of professional societies and how to partner with them</p> <p>Developing performance measures</p> <p>Understanding reimbursement and alternative payment methods</p> <p>Role of Accreditors</p> <p>Policy making NGOs</p>



Advanced Partner (Drug/Device/CTs)

Getting Ready for Research	Research	Skill Development	Implementation
<p>Governance structures</p> <p>Partnership development</p> <p>Enrollment and diversity strategies</p> <p>Data collection (EHR , PROs, registries) sharing data and data use agreements,</p> <p>Privacy policy development</p> <p>Consent development</p> <p>Communications and outreach strategies (role of social media)</p> <p>How to write a proposal</p>	<p>(All of same bullets from both sections above would be included but at a higher level of sophistication)</p> <p>What is a registry and what is the role in research</p> <p>How do you gather and account for patient preference (risk/benefit)</p> <p>What are phenotypes and genotypes</p> <p>Drug and device life cycle</p> <p>IRB issues unique to drug/device development and CDRNs</p>	<p>(All of same bullets from both sections above would be included but at a higher level of sophistication)</p> <p>Leadership skills</p> <p>How to participate on Advisory Panels</p> <p>Public speaking</p> <p>Methods to incorporate multi-stakeholder input and perspectives</p> <p>Conflict resolution</p>	<p>How does the FDA/ regulatory system approve drugs and devices</p> <p>What is the relationship between industry, FDA and patient organizations?</p>



10 Minute Break

Creating a “PCOR Ready” Community – Training and Capacity Building

Small Group Breakouts



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Wrap-up



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Day 1 Conclusion