

# Patient Engagement Advisory Panel

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June 1, 2015

Washington, DC



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# New Panelist Orientation

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## Welcome!

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



# Morning Agenda – June 1

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- 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

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Jean Slutsky, PA, MSPH  
Chief Engagement and Dissemination Officer and  
Program Director for Communication and Dissemination Research



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# Our Mission

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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**



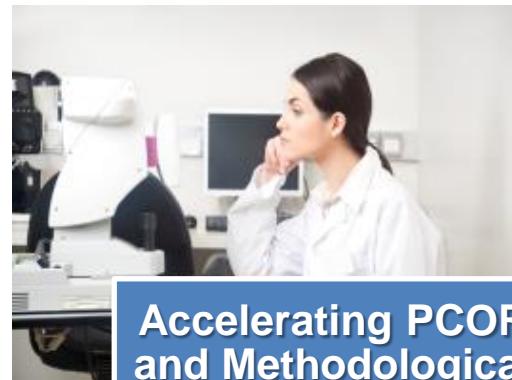
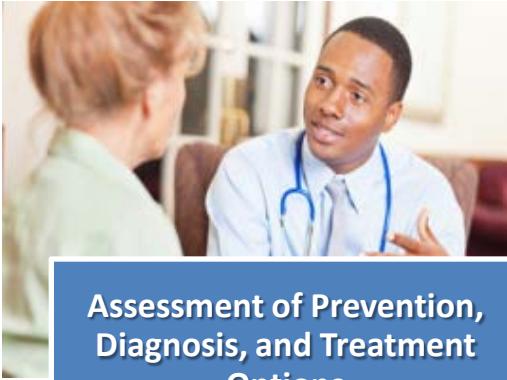
**Speed the Implementation and Use of Evidence**

**Use of**

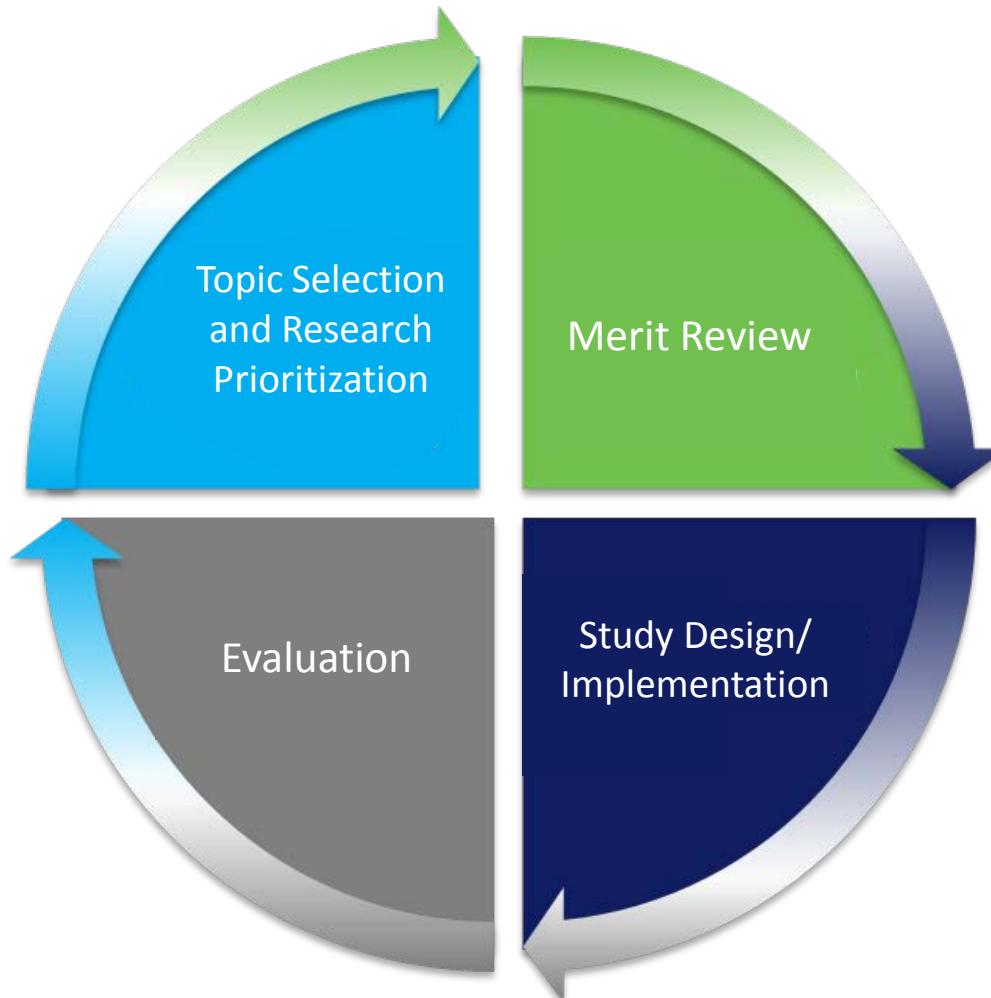
**Influence Research Funded by Others**



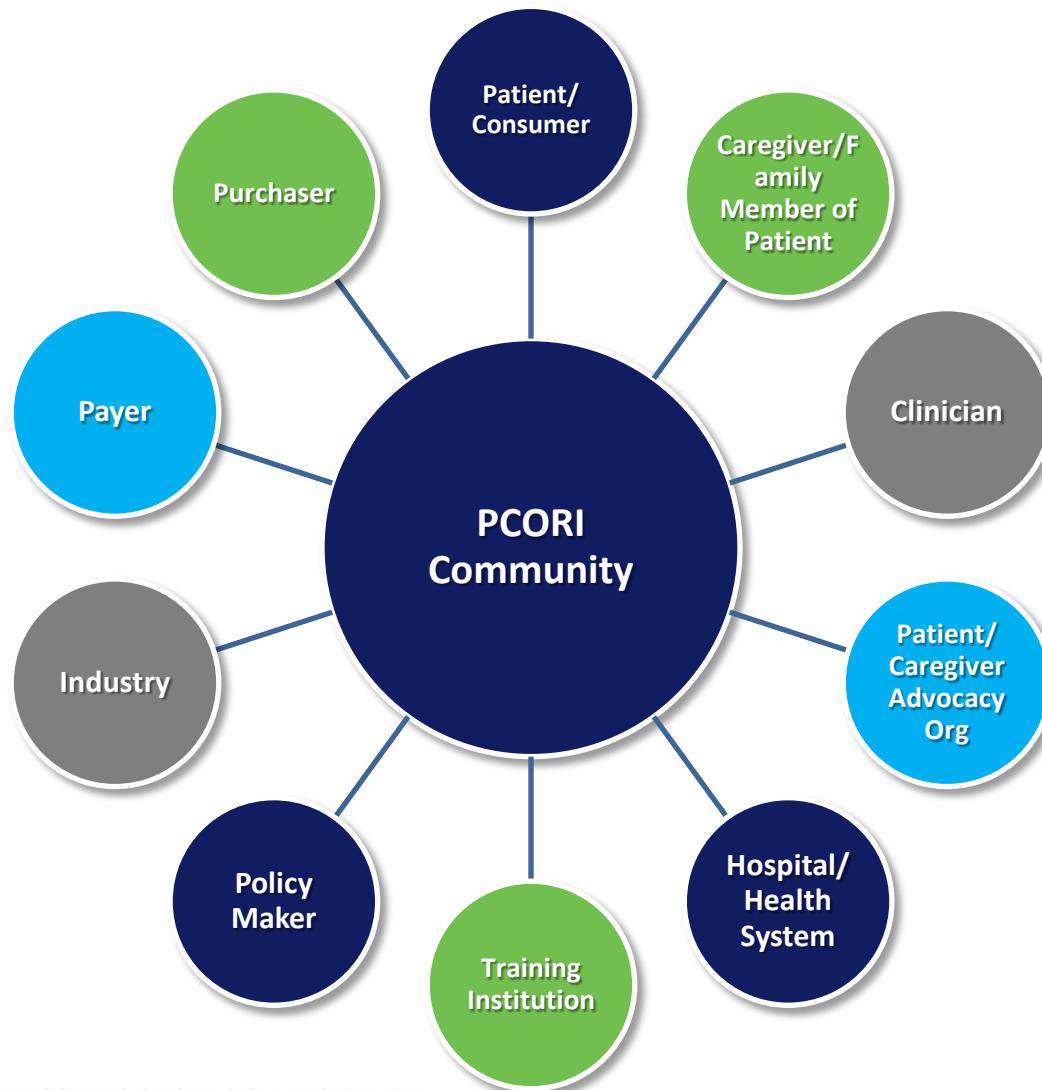
# The Research We Fund is Guided by Our National Priorities for Research



# We Engage Patients and Other Stakeholders at Every Step

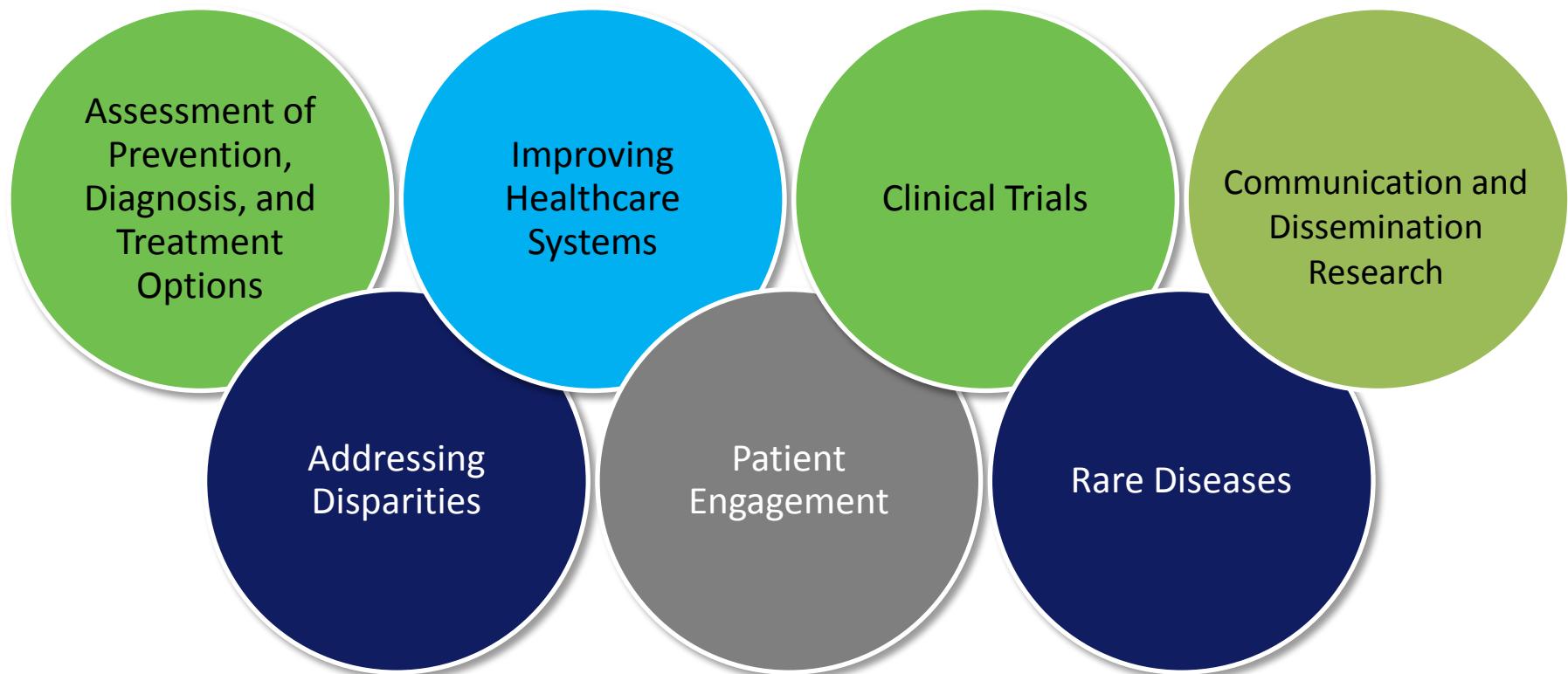


# Who Are Our Stakeholders?



# Our Advisory Panels

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# Learn More

[www.pcori.org](http://www.pcori.org)

[info@pcori.org](mailto:info@pcori.org)



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

# Welcome, Introductions, and Review Agenda

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**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

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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

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**Suzanne Schrandt, JD**  
Deputy Director, Patient Engagement



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# Lunch

# Evolution of the PCORI Research Funding Strategy

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**Joe Selby, MD, MPH**  
Executive Director



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# First 10 PCORI Pragmatic Clinical Studies

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- **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

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- **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

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*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**

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

**Erica Sarnes, MA**  
Training Manager

**Jaye Bea Smalley , MPA** Engagement  
Officer

**Suzanne Schrandt, JD**  
Deputy Director of Patient  
Engagement





# 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?**

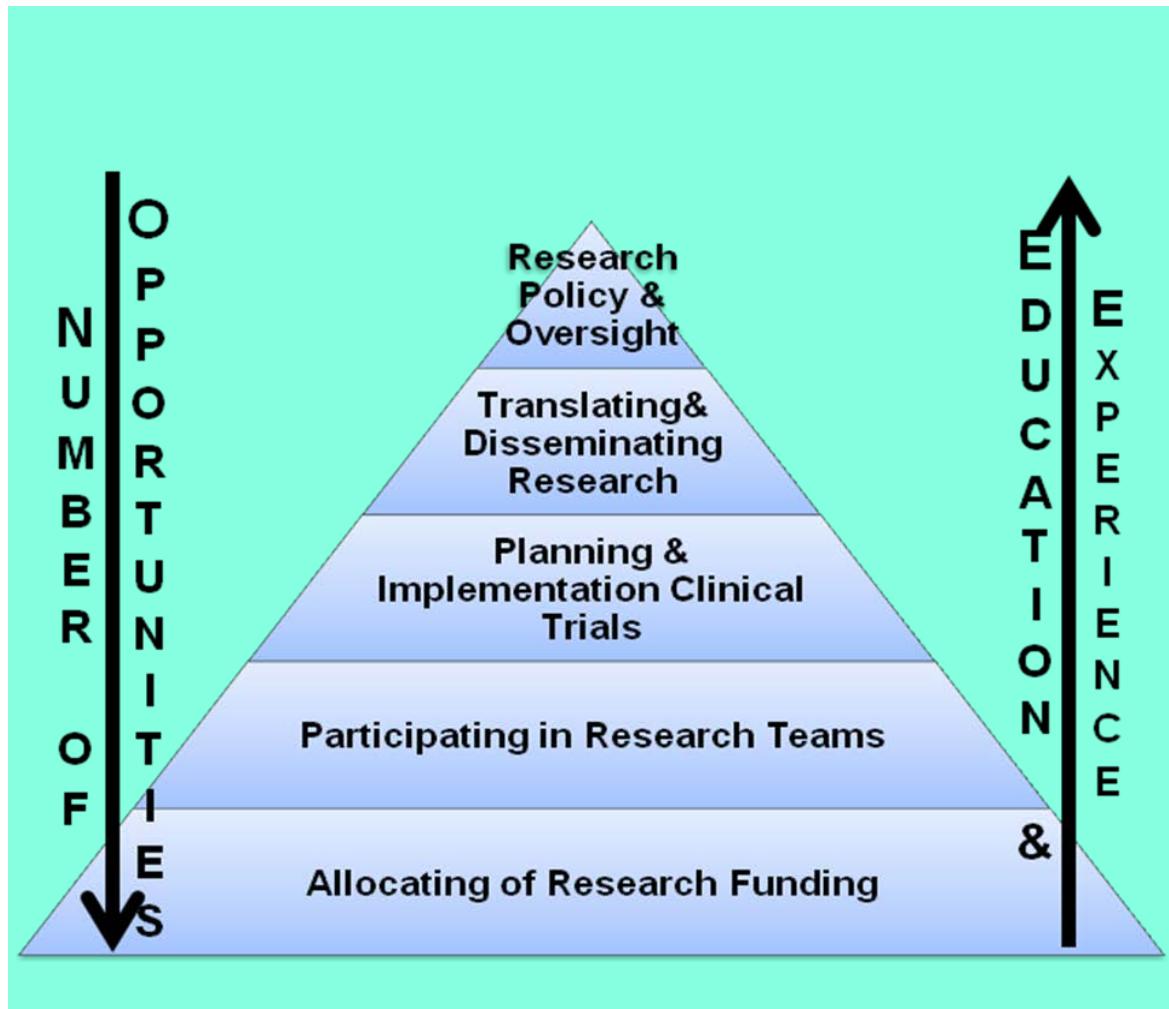
- Telling their story
- Impacting research
- Supporting other patients
- Train the trainer
- Involving patients/advocates in research



# 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?



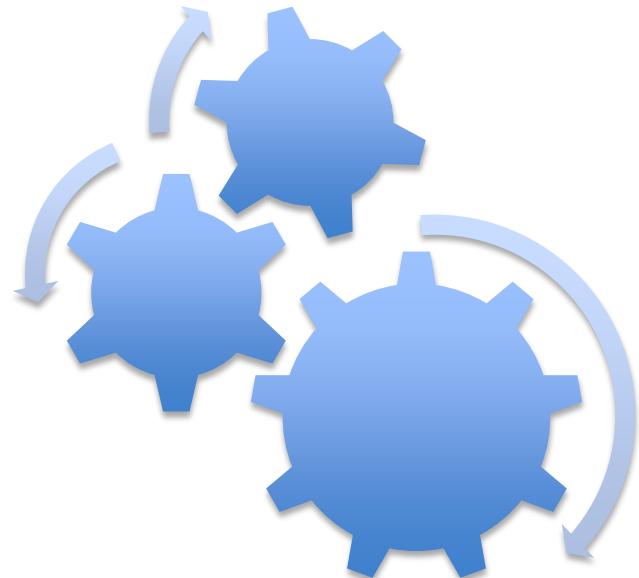
# What Do They Need to Learn?

## – 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



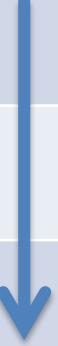
# Advocate Criteria Checklist

Topic	Importance (Check one per topic)		
	Not Important	Helpful	Critical
<b>Understanding the drug development process</b>			
Clinical trials fundamentals			
Basic statistical concepts			
Biomarkers			
PROs/QoL			
Regulatory process			
<b>Understanding disease</b>			
Natural history of disease			
Standard diagnosis & treatment of disease			
Hot topics in disease			
Disease KOLs			
<b>Understanding/access to patients</b>			
Personal/caregiver experience			
Connections to relevant constituents/advocacy organizations			
Knowledge/empathy to diverse patient experiences and issues			
<b>Business savvy/Emotional intelligence</b>			
Sensitivity to pragmatics and trade-offs			
Has a broad strategic view			
Conscientiousness			
Works well in diverse teams			
<b>Communication skills</b>			
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
<b>Self-paced, individual learning</b>	Knowledge		
<b>Group-based, trainer-led learning</b>			
<b>Group-based, interactive learning</b>	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

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



# Advanced Partner (Drug/Device/CTs)

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



# 10 Minute Break

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

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## **Small Group Breakouts**



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# Wrap-up



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# Day 1 Conclusion