

# Key Themes in Patient Engagement: An overview

October 27, 2016



# Four themes

- Engaging patients in priority setting
- Bioethics and regulatory concerns in patient engagement
- The roles of patient partners and researchers during the conduct of research
- The role of patient partners in knowledge translation of research

# Engaging patients in priority setting

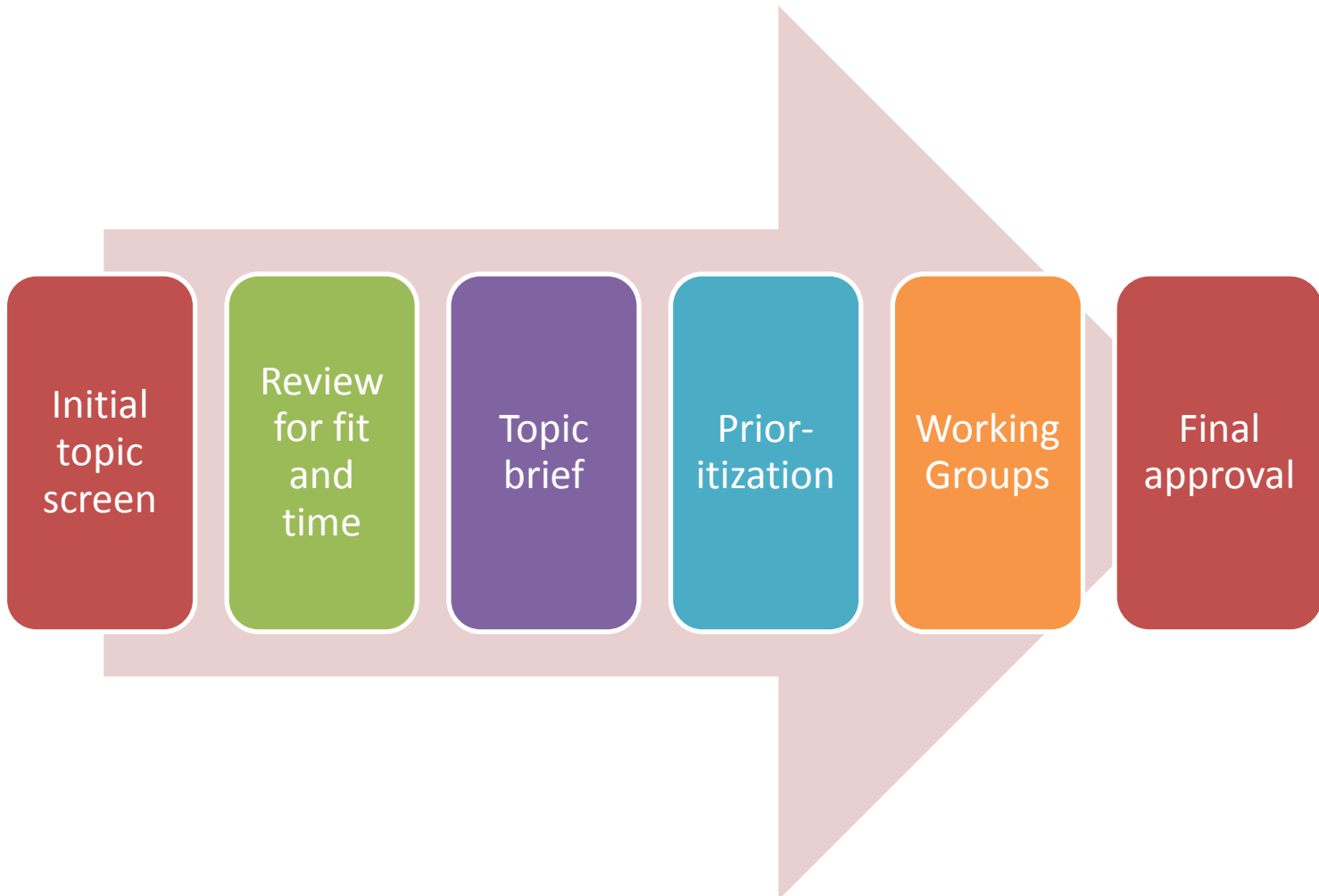
# Priority setting: around the globe



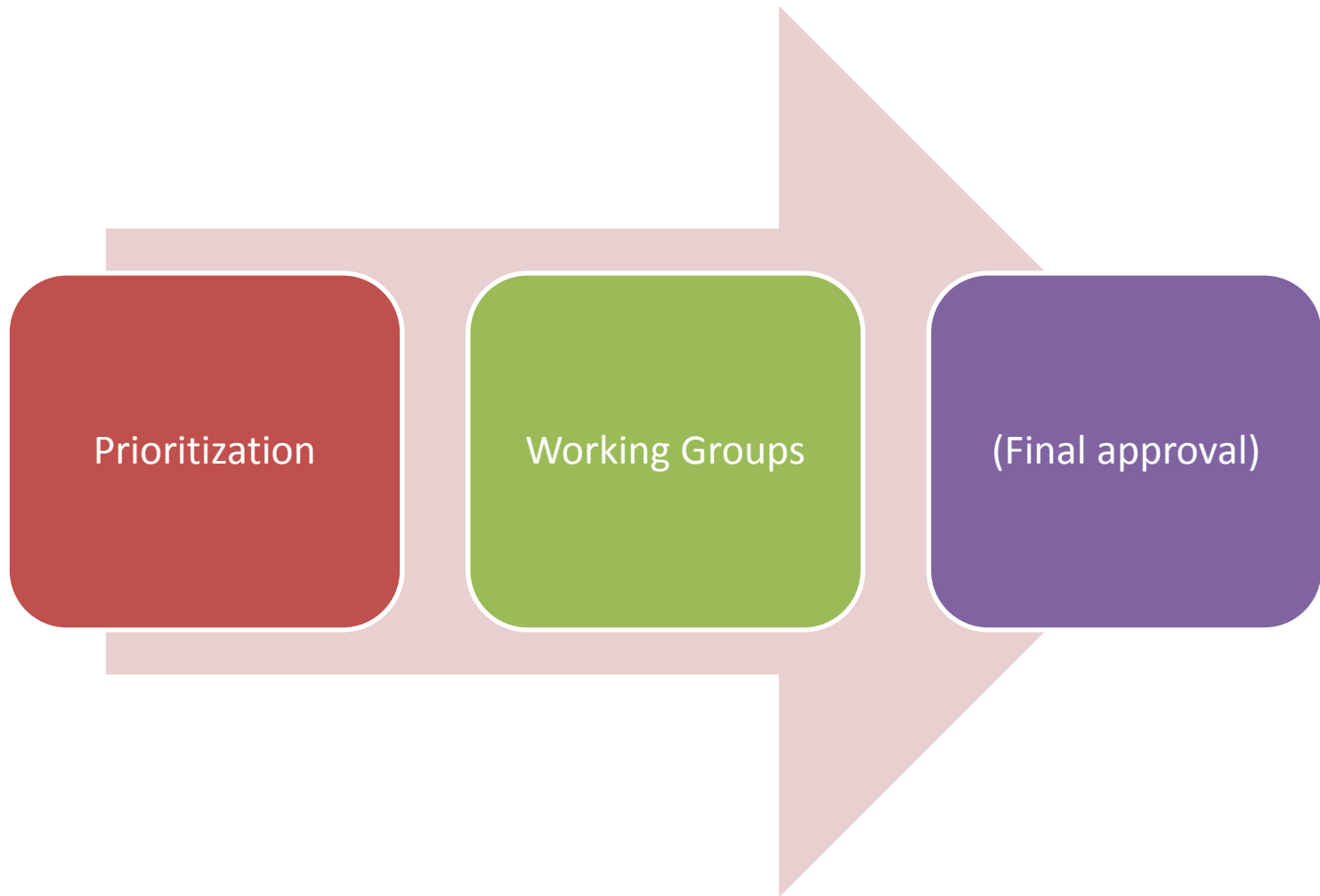
# Priority setting: methods and tools

- Surveys
- Focus groups
- Delphi technique
- Roundtables and “town halls”
- Deliberative Democracies
- Workshops
- Nominal Group Technique

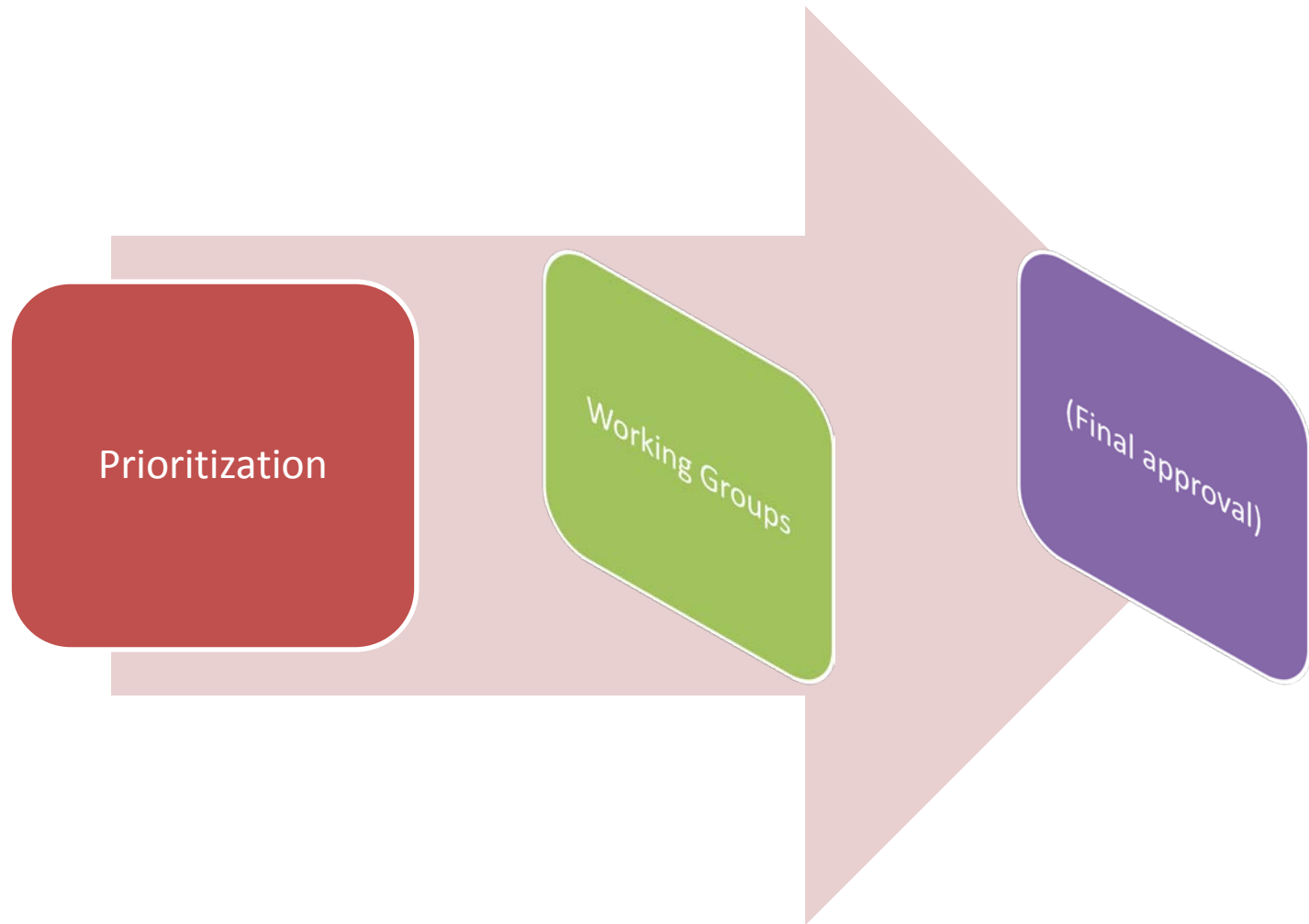
# Priority setting: PCORI's approach



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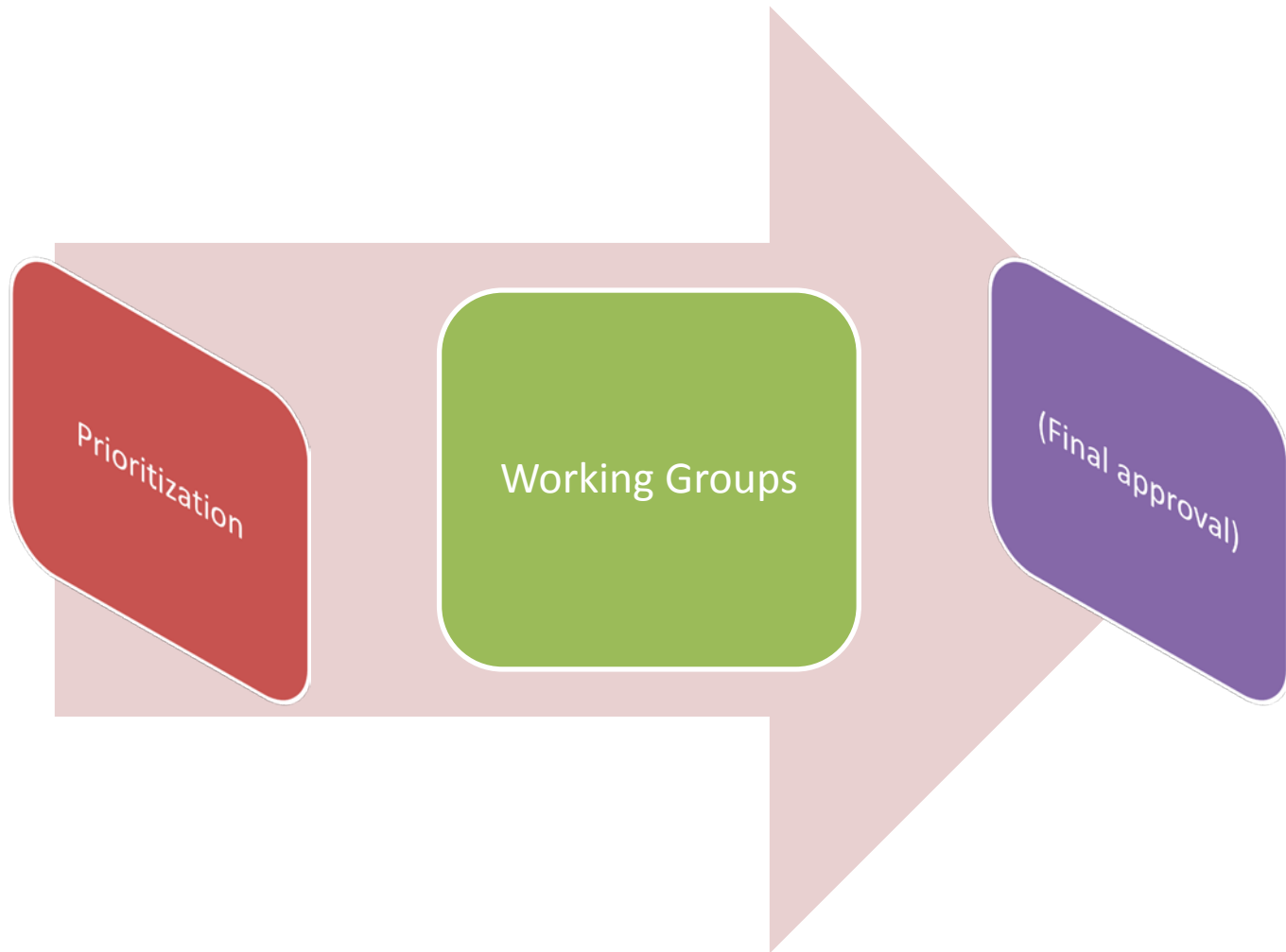


# Priority setting: PCORI's approach

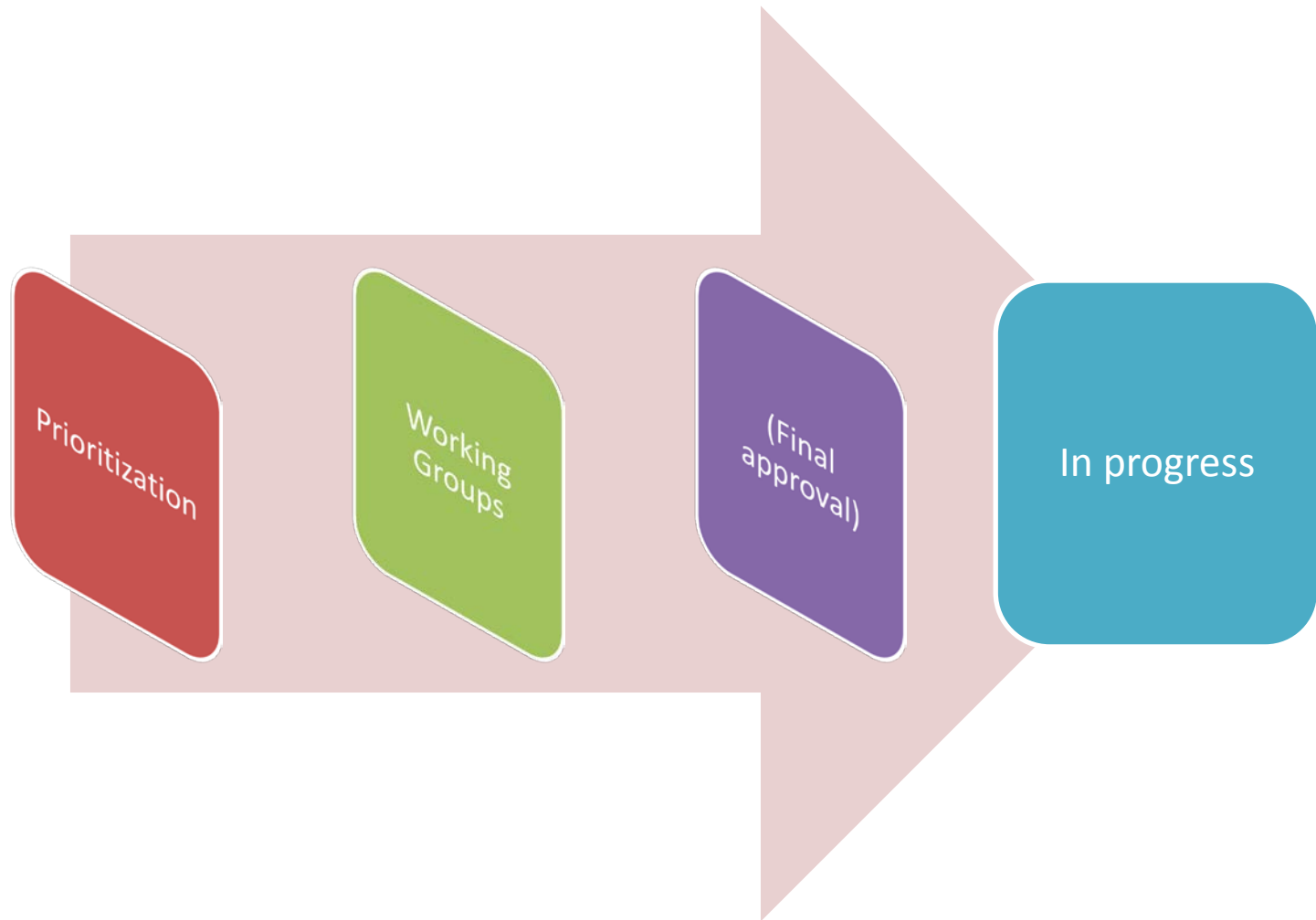




# Priority setting: PCORI's approach



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# Bioethics and regulatory concerns in patient engagement

# Bioethics and regulatory concerns

- Approvals and legalities
- Terminology and adjustments to traditional “tools”
- Patient engagement in bioethics



# Approvals and legalities



IRB approval when patients are serving as partners on a study team



Concerns about liability for patients serving in partnership roles (lack of professional liability insurance, etc.)



Unintended consequences of financial compensation

# Terminology and adjustments to traditional tools

## Pure Partner

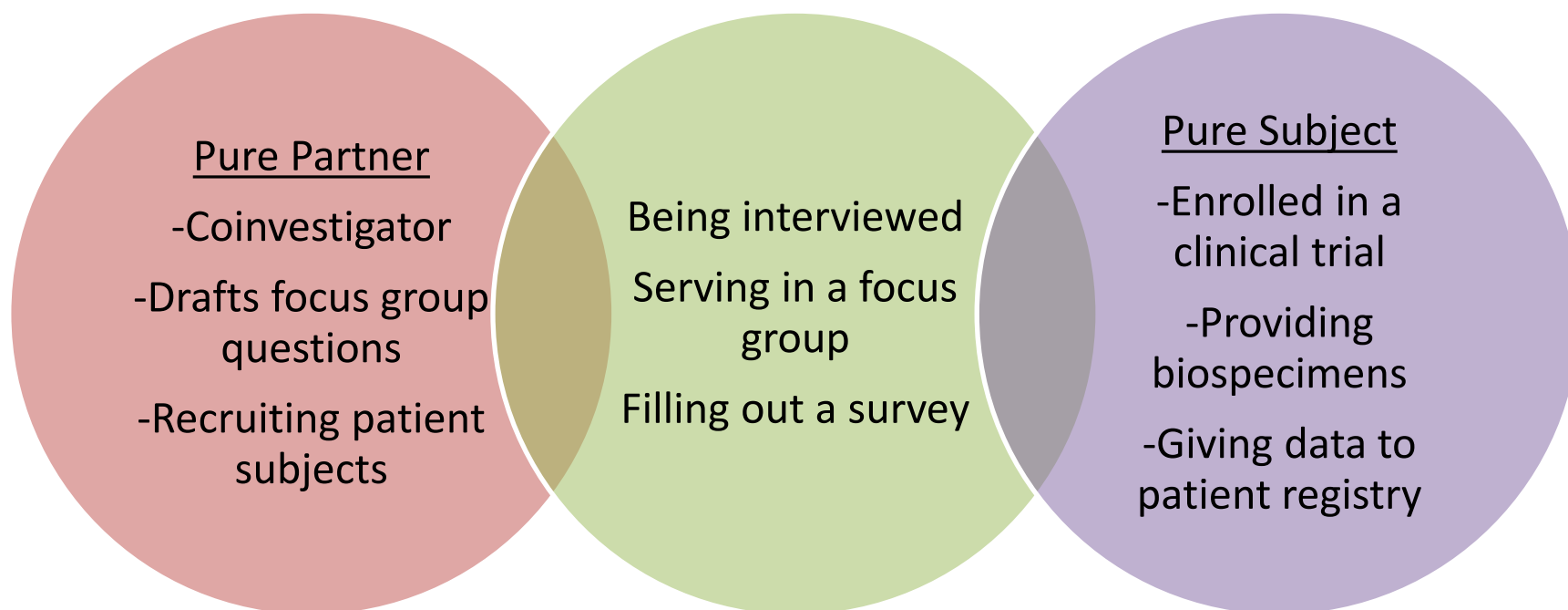
- Coinvestigator
- Drafts focus group questions
- Recruiting patient subjects

# Bioethics and regulatory concerns: terminology and traditional tools

## Pure Subject

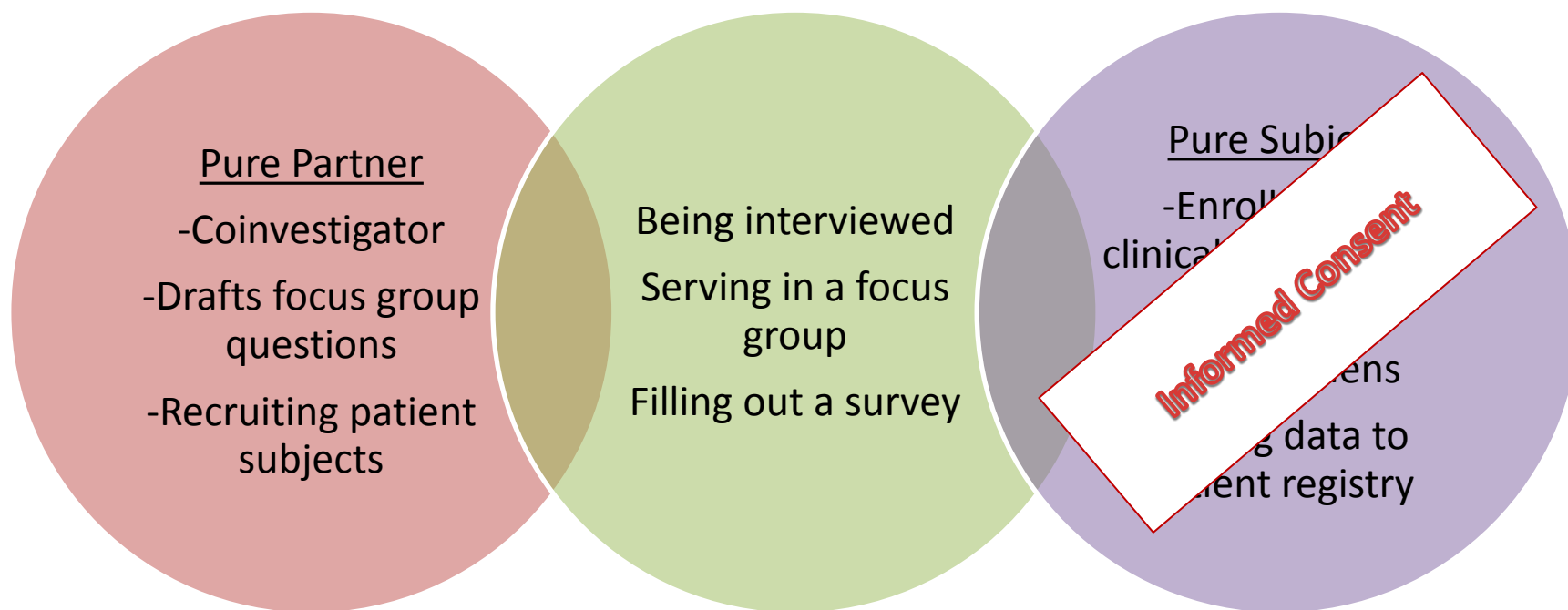
- Enrolled in a clinical trial
- Providing biospecimens
- Giving data to patient registry

# Bioethics and regulatory concerns: terminology and traditional tools

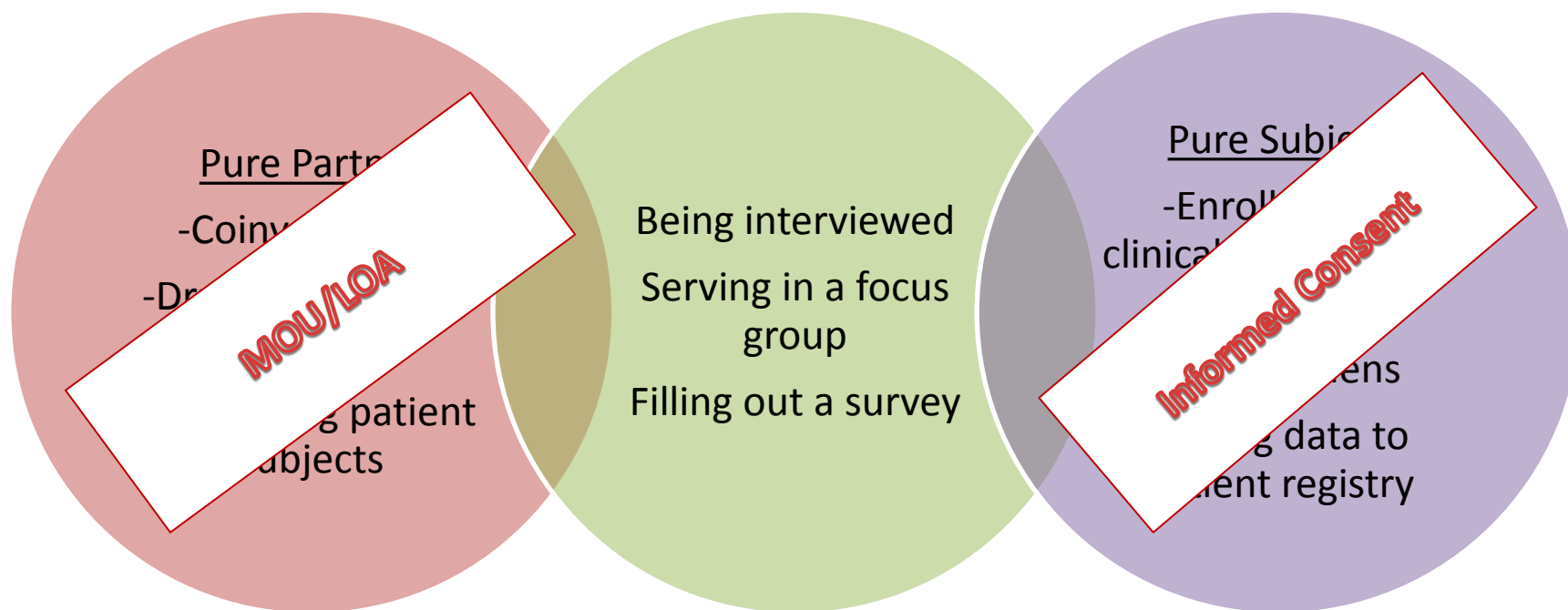




# Bioethics and regulatory concerns: terminology and traditional tools



# Bioethics and regulatory concerns: terminology and traditional tools



# Patient engagement in bioethics

- Drafting informed consents
- Serving on DSMBs, DMCs and IRBs
- Drafting DSMPs
- Redefining benefit/risk evaluation

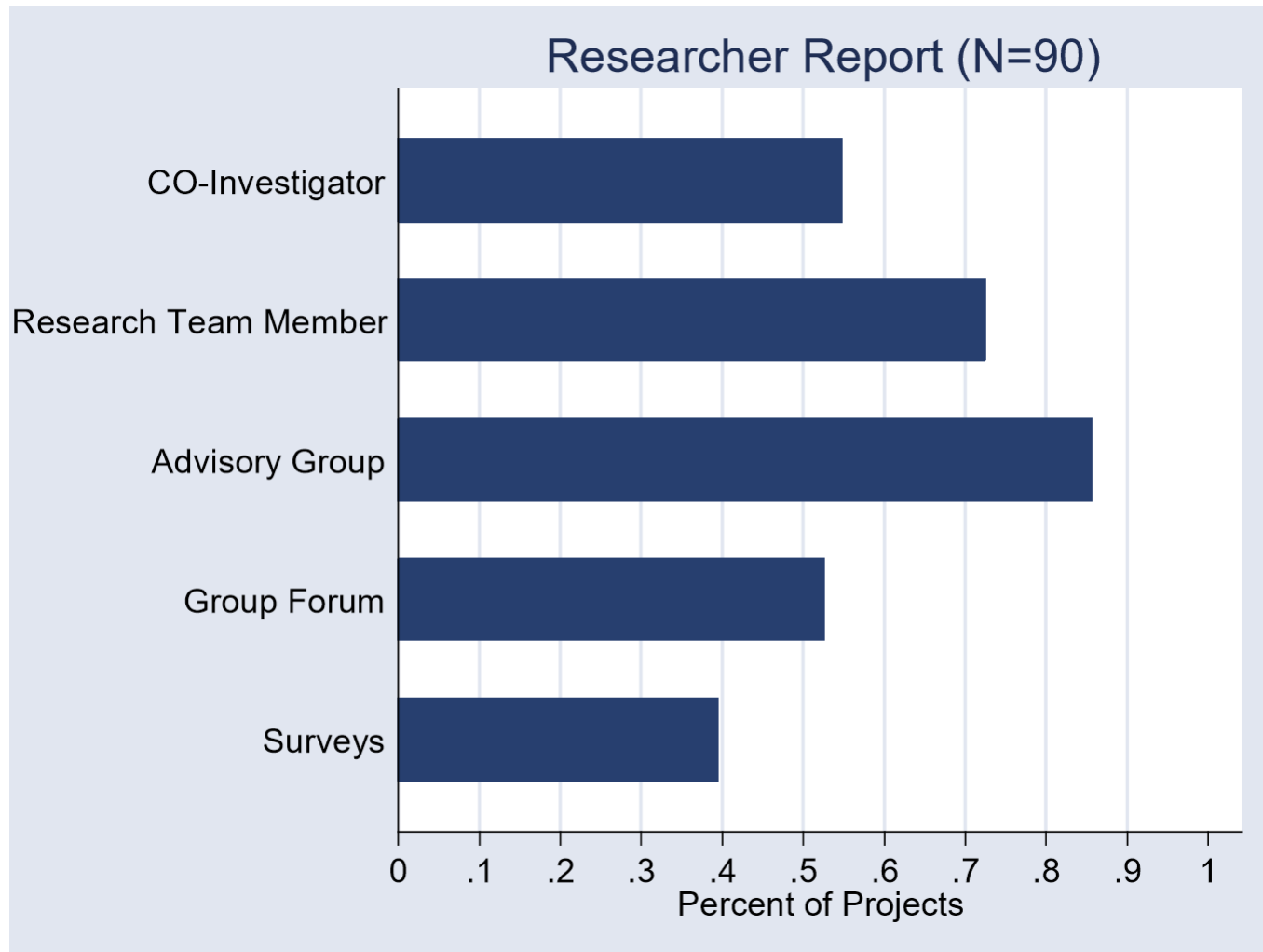
# The roles of patient partners and researchers during the conduct of research

# Conduct of research

- Roles of partners
- Types of activities
- What have we learned so far?
- Has it mattered?



# PCORI Data: Roles of partners

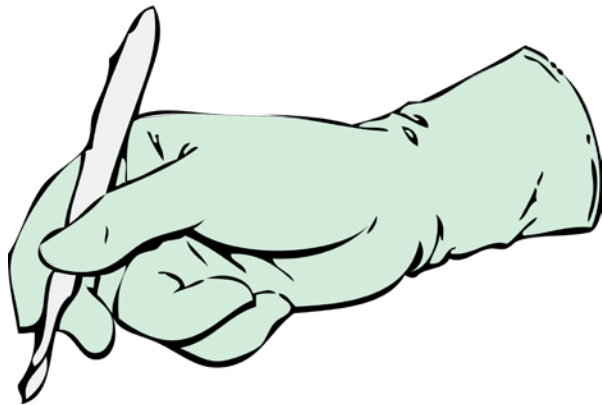


# PCORI Data: Types of activities



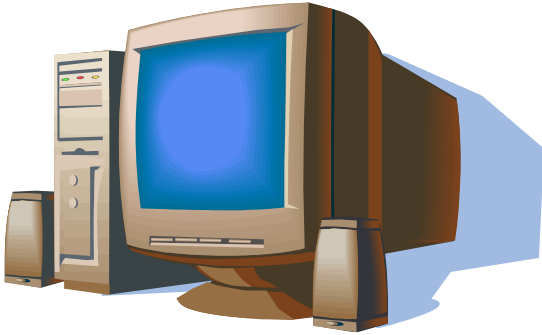
# Types of activities: Improving recruitment

vs.





# Types of activities



# Lessons learned (so far)

- Need diversity of patients
- Need formal rules, agreements, governance structures, and decision-making processes
- Must institute reporting back/follow-up
- Bi-directional training is crucial



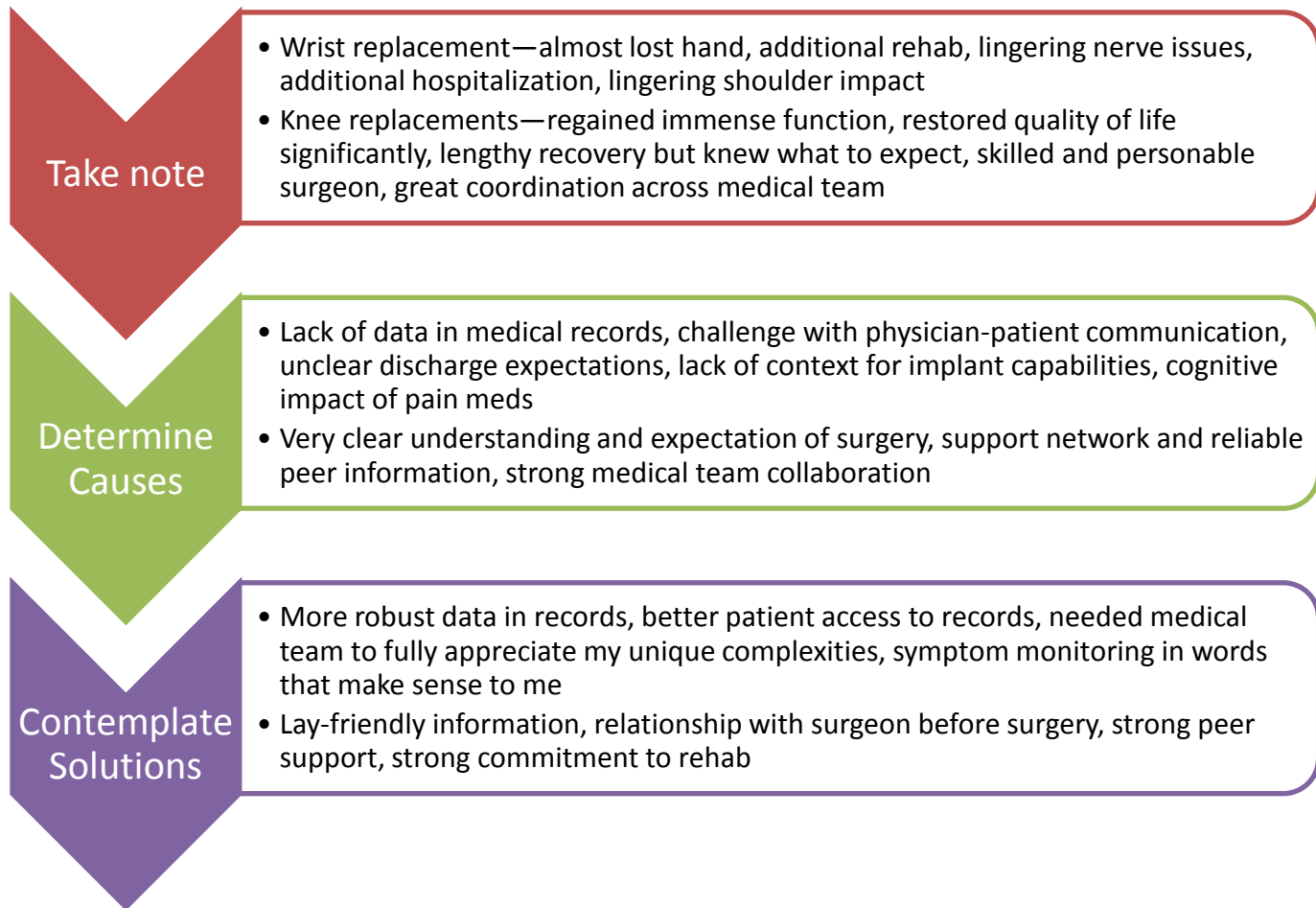
# Training for non-patients

- Multi-stakeholder group facilitation (or involve facilitator)
- Minimizing power differentials
- Avoiding jargon or creating safe space where terms and acronyms can be questioned
- Learning from fellow researchers/clinicians



# Training for patients

## Exercise: “Harnessing your knowledge”



# Now, applied within a scenario:

*You are serving on a research study team, the study is comparing two drugs for effectiveness. One drug is known to have significantly worse side effects, but believed to possibly control the disease better. The outcome selected is number of joints with disease activity.*

## Take note

- Multiple side effects from drug cocktail (cata kidney dysfunction, lung impairment, cardiac gain, infections, etc.)

*Based on your experiences with profound side effects, you propose that the study team add an outcome measure that captures impact of side effects from the drugs—was the disease benefit “worth” the side effects?*

## Determine Causes

- Multiple drugs, each with toxicities, decent c not complete

## Contemplate Solutions

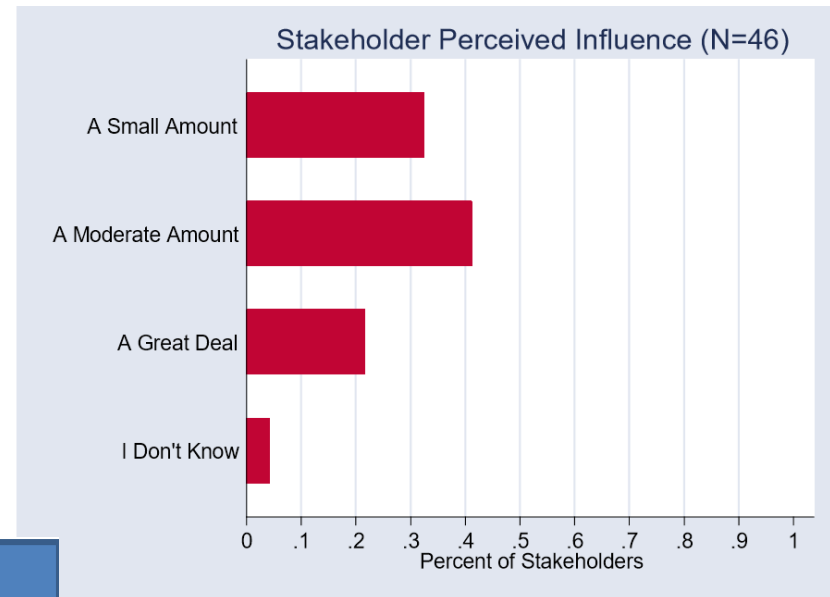
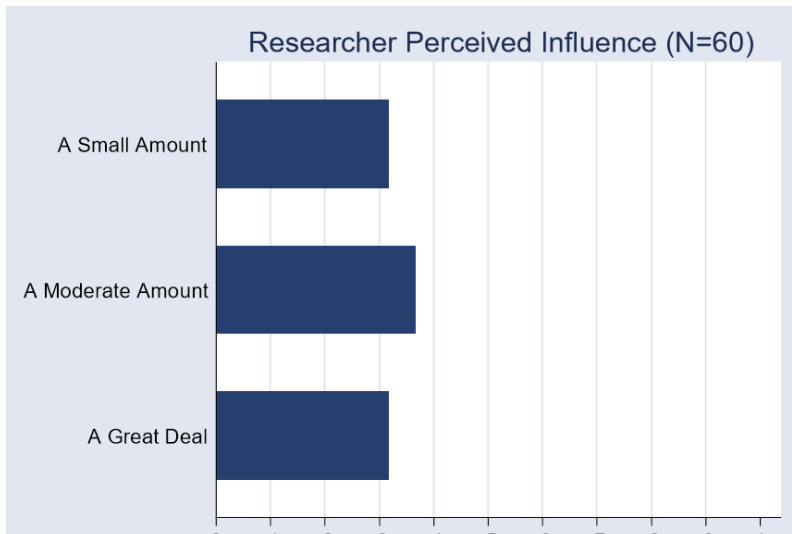
- Balance between disease management and side effect management, evaluate on a sliding scale, [I elected to remove or reduce doses of drugs that created greatest issues in exchange for slightly more disease activity]

# Has engagement in research mattered?





# PCORI Data: Study Design



*“Patients and stakeholders helped form the content of interventions... to better meet the needs of [patients].”*

*“Our community discussions... led to several modifications of our study design... This led us to include a 3rd group in our research design: community-based group exercise. We also decided to use... [a specific] outcome measure, based upon input from... patients who told us that their biggest concern was the ability to walk and stay active.”*

# Business case...

“As for the design, it was arrived at without even a pretense of consulting the polls, and by the method that has been standard for years in the designing of automobiles — that of simply pooling the hunches of sundry company committees.”

--John Brooks, “Business Adventures”





# The role of patient partners in knowledge translation of research

# How have patients been involved?

- Drafting planning for dissemination begins at the beginning
- Conceptual shift to equality in expertise
  - Joint poster sessions
  - Patient/lay review of journal articles for readability
  - Open access journals
- Infuse patient partners into traditional methods
- Shift away from traditional methods

# Reflections from a researcher

*"...I think [the community members] have two big roles. They have a role in research coming in...working with Sonja and others, they've hit me with questions I've never even thought of...but they have even bigger roles going out. It's advocates like Sonja who are going to take our wisdom off the shelf and use it...and that's even more important."*

*"I've been working in the field for 25 years...and I know a lot. But frankly, I'm not black, I'm not Hispanic, I'm not homeless...and if we're going to be providing programs [to people in those communities]...[they] have to lead the charge."*



# Resources

- [Review of Priority-Setting Efforts](#)
- [Flowchart of JLA Priority-Setting Process](#)
- [PCORI Engagement Rubric](#)
- [EUPATI Expert Training Course](#)
- [University of Maryland, Building Trust](#)
- [Parkinson's Disease Foundation PAIR Program](#)
- [TOPPER Toolkit, Elizabeth Cox Pediatric Diabetes Project](#)



**Arthritis**  
**Foundation**<sup>SM</sup>