

# Tufts Clinical and Translational Science Institute

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Preparing for Patient-Centered and Stakeholder-Engaged  
Research

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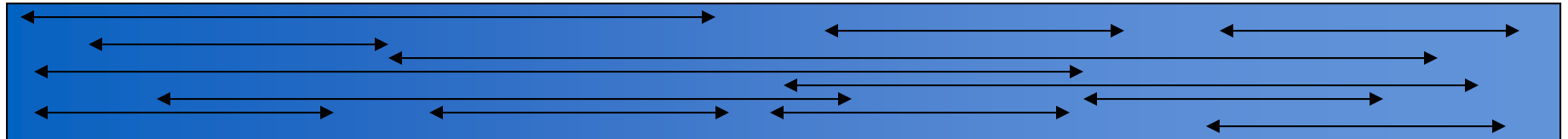
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# Clinical and Translational Science Awards (CTSA) Program

- National Institutes of Health (NIH) program
- Launched in 2006
- A national consortium of 64 institutions
- **Mission:** to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observation in the laboratory, clinic and community into interventions that improve the health of individuals and the public

# Spectrum of Clinical and Translational Research



**Bench to  
Bedside...**    ↔    **...to  
Widespread  
Clinical  
Practice...**    ↔    **...to Public  
Health...**    ↔    **...to Health  
Policy**

*Translation  
(T1)*

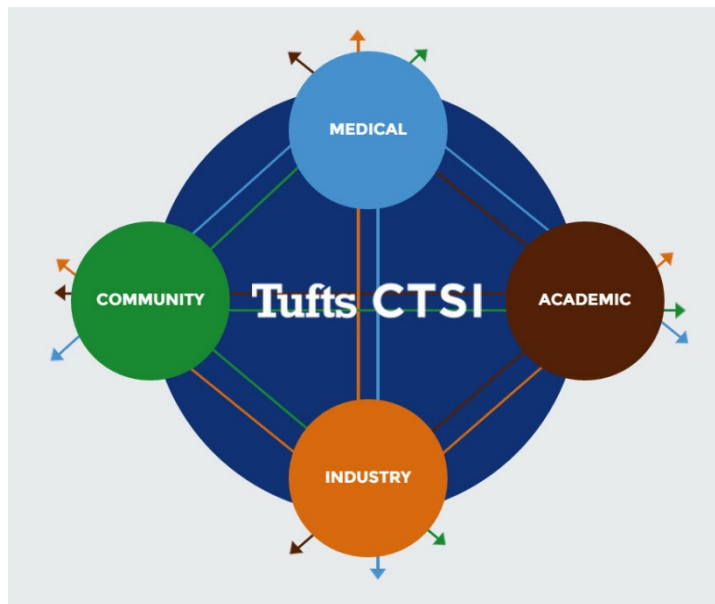
*Translation  
(T2)*

*Translation  
(T3)*

*Translation  
(T4)*

# Tufts CTSI's Mission & Purpose

*Established in 2008 to translate research into better health*



- Stimulate and expedite innovative clinical and translational research, with the goal of improving the public's health
- *Entire spectrum* of clinical and translational research is critical to meeting the promise and the public's needs of biomedical science

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# 39 Tufts CTSI Partners

## 12 Tufts Schools & Centers

Cummings School of Veterinary Medicine  
Fletcher School of Law & Diplomacy  
Friedman School of Nutrition  
Science & Policy  
Graduate School of Arts & Sciences  
Institute for Clinical Research & Health  
Policy Studies at Tufts Medical Center  
Jean Mayer USDA Human Nutrition  
Research Center on Aging  
Sackler School of  
Graduate Biomedical Sciences  
School of Dental Medicine  
School of Engineering  
School of Medicine  
Tisch College of Citizenship  
& Public Service  
Tufts Center for the Study  
of Drug Development

## 4 Academic Partners

Brandeis University  
Harvard Clinical Research Institute  
Northeastern University RAND  
Corporation

## 7 Tufts-Affiliated Hospitals

Baystate Medical Center  
Lahey Clinic  
Maine Medical Center  
New England Baptist Hospital  
Newton-Wellesley Hospital  
St. Elizabeth's Medical Center  
Tufts Medical Center

## 6 Industry/Non-Profit Partners

Blue Cross Blue Shield of  
Massachusetts  
Eli Lilly and Company  
Institute for Systems Biology and  
P4 Medicine Institute  
Minuteman Health Network  
Pfizer, Inc.  
Tufts Health Plan

## 10 Community-Based Partners

Action for Boston Community  
Development (ABCD)  
Asian Community  
Development Corporation  
Asian Task Force Against  
Domestic Violence  
Asian Women for Health  
Boston Chinatown  
Neighborhood Center  
Center for Information and  
Study on Clinical Research  
Participation  
Greater Boston Chinese  
Golden Age Center  
Health Resources in Action  
Museum of Science, Boston  
New England Quality Care  
Alliance

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# How Can CTSI Help?

- **Connections** with other researchers, industry, the community, and policy-makers across the Tufts CTSI network and national CTSA consortium via our **Navigators & Research Collaboration team**.
- **Consultations** on **comparative effectiveness, one health, research process improvement and stakeholder and community engagement** projects and grants, as well as **regulatory issues** and other areas of translation.
- **Study design and data analysis** (pre- and post-award) through the **Biostatistics, Epidemiology, and Research Design (BERD) Center**, including drop-in sessions.

# How Can CTSI Help?

- **24/7 clinical trial support** through our **Clinical and Translational Research Center (CTRC)**.
- **Informatics tools** for electronic data capture (**REDCap**), resource sharing, and collaboration.
- **Training & professional development** including MS and PhD degrees, certificate programs, seminars & workshops, and **paid career development awards and fellowships**.
- **Funding** through one-year interdisciplinary **pilot studies grants** that support the initial stages of research.

# How to Request Tufts CTSI Services

- Visit [www.tuftsctsi.org](http://www.tuftsctsi.org) and submit a request

The screenshot shows the homepage of the Tufts Clinical and Translational Science Institute (CTSI). At the top, the Tufts CTSI logo is followed by the text 'Tufts Clinical and Translational Science Institute'. Navigation links include REDCap, LEARN VIDEOS, PROFILES, and WORKSPACE LOGIN. A secondary navigation bar contains Research Services, Education, Funding Opportunities, Our Impact, Faculty & Staff, and About Us. The main content area features a large blue banner with the text 'Accelerating translation of research into clinical use, medical practice, and health impact' and a list of services: Research Design & Analysis, Research Collaboration, Clinical Studies & Trials, Informatics, Professional Development, and Pilot Studies Funding. Below this is a grid of three sections: 'WANT HELP WITH YOUR RESEARCH?' (circled in red), 'EVENTS', and 'NEWSFEED'. The 'WANT HELP WITH YOUR RESEARCH?' section includes the text 'Fill out a request and we will be in touch within two business days.' and two profile cards for Daniel E. Wetner, MD, MS and Geneve M. Allison, MD, MSc, FACP, with a 'SUBMIT A REQUEST' button. The 'EVENTS' section lists 'DROP-IN SESSIONS' for Sep 23, Sep 30, and Oct 06. The 'NEWSFEED' section features a 'SUCCESS STORY' about a research study launch.

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# <http://ilearn.tuftsctsi.org/>

Live seminars are recorded for our I LEARN site.  
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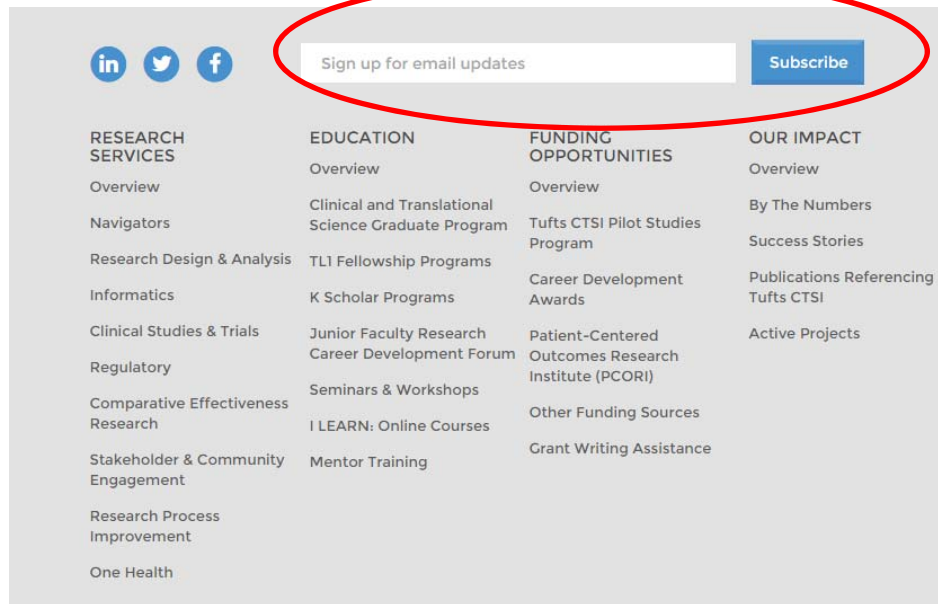
Welcome to I LEARN, the Tufts CTSI interactive education website. Tufts CTSI I LEARN is a new resource that offers a comprehensive library of educational courses in clinical and translational research for both professional development and CME credit. Building on our unique curriculum, we are offering some of our courses and workshops in an online learning format, combining professionally videotaped recordings of live lectures with other learning materials to transcend the traditional in-classroom experience.

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# Get Connected: CTSI Happenings

## Tufts | CTSI Tufts Clinical and Translational Science Institute HAPPENINGS



The screenshot shows the Tufts CTSI Happenings website. At the top left, there are social media icons for LinkedIn, Twitter, and Facebook. To the right of these icons is a white input field with the text "Sign up for email updates" and a blue "Subscribe" button. This entire sign-up area is circled in red. Below the sign-up area is a grid of menu items organized into four columns: RESEARCH SERVICES, EDUCATION, FUNDING OPPORTUNITIES, and OUR IMPACT. Each column lists various sub-topics.

RESEARCH SERVICES	EDUCATION	FUNDING OPPORTUNITIES	OUR IMPACT
Overview	Overview	Overview	Overview
Navigators	Clinical and Translational Science Graduate Program	Tufts CTSI Pilot Studies Program	By The Numbers
Research Design & Analysis	TL1 Fellowship Programs	Career Development Awards	Success Stories
Informatics	K Scholar Programs	Patient-Centered Outcomes Research Institute (PCORI)	Publications Referencing Tufts CTSI
Clinical Studies & Trials	Junior Faculty Research Career Development Forum	Other Funding Sources	Active Projects
Regulatory	Seminars & Workshops	Grant Writing Assistance	
Comparative Effectiveness Research	I LEARN: Online Courses		
Stakeholder & Community Engagement	Mentor Training		
Research Process Improvement			
One Health			

- Weekly e-newsletter with news, professional development and funding opportunities, resources, and success stories.
- Issued every Monday at 8AM
- Sign up on our website or at <http://eepurl.com/C4d9X>

# For more information: [www.tuftsctsi.org](http://www.tuftsctsi.org)

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## Accelerating translation of research into clinical use, medical practice, and health impact

- » Research Design & Analysis
- » Research Collaboration
- » Clinical Studies & Trials
- » Informatics
- » Professional Development
- » Pilot Studies Funding

**WANT HELP WITH YOUR RESEARCH?**

Fill out a request and we will be in touch within two business days.

**Daniel E. Welner**  
MD, MS

**Geneve M. Allison**  
MD, MSc, FACP

[SUBMIT A REQUEST](#)

**EVENTS** | **NEWSFEED**

**DROP-IN SESSIONS**  
Sep 23 - 8:00AM | **Research Help Drop-in Session**

**DROP-IN SESSIONS**  
Sep 30 - 8:00AM | **Research Help Drop-in Session**

**DROP-IN SESSIONS**  
Oct 06 - 2:00PM | **Medford Office Hours**

[View Full Calendar >](#)

**SUCCESS STORY**

**Baystate Medical Center Scientists Launch Community-Engaged Research Study**

Sarah Coff, MD and her team at Baystate Medical Center recently received a Patient-Centered Outcomes Research Institute (PCORI) award for [More >](#)

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# Questions?

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# Learning Objectives

At the conclusion of the course, participants will be able to:

- Recognize successful frameworks for identifying and recruiting stakeholders
- Explain basic principles for planning engagement activities in different kinds of evidence development

# PCORI was established in 2010...

PCORI stands for the Patient-Centered Outcomes Research Institute and funds *patient-centered comparative effectiveness research (CER)*.

# What is Patient-Centered CER?

Patient-Centered

Considers patients' needs and preferences and focuses on questions and outcomes most important to them

Comparative Effectiveness Research

Compares effectiveness of two or more treatments or approaches to health care, examining their risks and benefits



# **In PCORI merit review, your application will be assessed on two aspects of patient centeredness**

Patient-centered engagement: involvement of patients and other stakeholders in the development, conduct, and use of research

Patient-centered research approach: The extent to which your research approach reflects involvement

# Roadmap

## Patient-centered engagement

- Two use cases
- Exercise I

## Patient-centered research approach

- Exercise II

# Several stakeholder engagement and CER frameworks have been published...

## A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research

Thomas W. Concannon, PhD<sup>1</sup>, Paul Meissner, MSPH<sup>2</sup>, Jo Anne Grunbaum, EdD<sup>3</sup>,  
Newell McElwee, Pharm.D, MSPH<sup>4</sup>, Jeanne-Marie Guise, MD, MPH<sup>5</sup>, John Santa, MD, MPH<sup>6</sup>,  
Patrick H. Conway, MD, MSc.<sup>7,8</sup>, Denise Daudelin, RN, MPH<sup>1</sup>, Elaine H. Morrato, DrPH, MPH<sup>9</sup>, and  
Laurel K. Leslie, MD, MPH<sup>1</sup>

<sup>1</sup>Institute for Clinical Research and Health Policy Studies, Tufts Medical Center and Tufts University School of Medicine, Boston, MA, USA; <sup>2</sup>Office of the Medical Director for Research, Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY, USA; <sup>3</sup>Prevention Research Centers Program, Centers for Disease Control and Prevention, Atlanta, GA, USA; <sup>4</sup>U.S. Outcomes Research, Merck & Co., North Wales, PA, USA; <sup>5</sup>Oregon Health & Sciences University, Portland, OR, USA; <sup>6</sup>Health Ratings Center, Consumer Reports, Yonkers, NY, USA; <sup>7</sup>Department of Pediatrics, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA; <sup>8</sup>Centers for Medicare & Medicaid Services, Baltimore, MD, USA; <sup>9</sup>Colorado Health Outcomes Program, School of Medicine, and Department of Health Systems, Management, and Policy, Colorado School of Public Health, University of Colorado, Aurora, CO, USA.

Despite widespread agreement that stakeholder engagement is needed in patient-centered outcomes research (PCOR), no taxonomy exists to guide researchers and policy makers on how to address this need. We followed an iterative process, including several stages of stakeholder review, to address three questions: (1) Who are the stakeholders in PCOR? (2) What roles and responsibilities can stakeholders have in PCOR? (3) How can researchers start engaging stakeholders? We introduce a flexible taxonomy called the 7Ps of Stakeholder Engagement and Six Stages of Research for identifying stakeholders and developing engagement strategies across the full spectrum of research activities. The path toward engagement will not be uniform across every research program, but this taxonomy offers a common starting point and a flexible approach.

**KEY WORDS:** stakeholders; research; guidance.  
J Gen Intern Med  
DOI: 10.1007/s11606-012-2037-1  
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report how treatment effects vary in individual patients and subgroups;<sup>4-6</sup> and for the under-representation of women, children, racial and ethnic minorities, and patients with comorbidities.<sup>7-9</sup> Although researchers may prefer to see their work being used in practice, the presumed link between publication and application of research has not been especially strong and is in need of reinforcements.

There is widespread agreement that better stakeholder engagement can help to address this need. Advocates for comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) have been especially strong proponents of this recommendation, on the basis that stakeholder engagement could improve the relevance of research, increase its transparency, and accelerate its adoption into practice.<sup>10-14</sup> These entreaties could result in a new era of stakeholder-engaged research, and an important benchmark for patient-centered research in future years may be that it "is useful to clinicians and patients—and is used."<sup>15</sup>

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## ...and they share common themes

Patients and other stakeholders may be involved

- before research gets started
- while research is underway
- after research is completed

Engagement can result in both intrinsic and instrumental gains for research.

# Why are Researchers Being Called on to Engage?

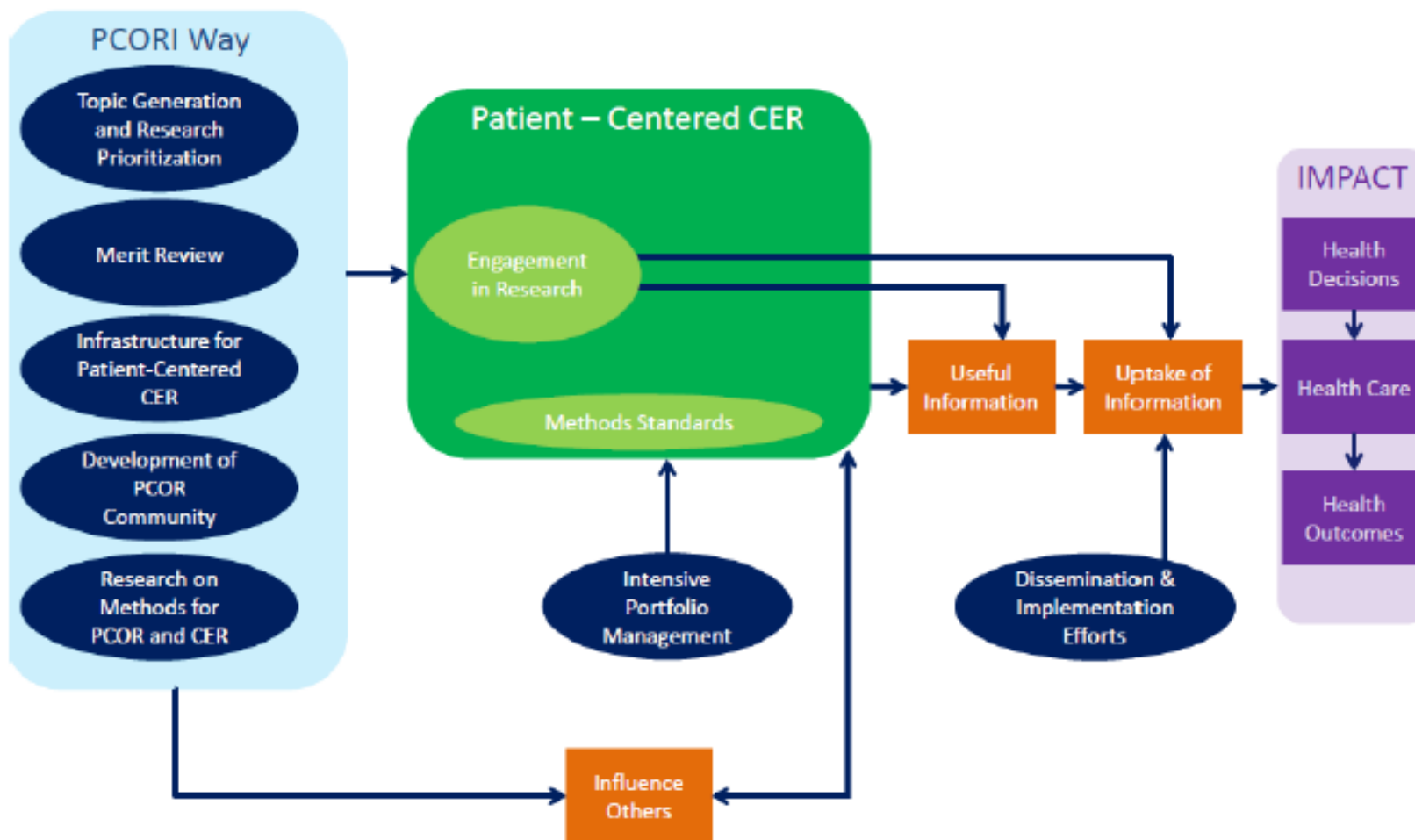
## Intrinsic Aims

- Respect, autonomy, trust, justice

## Instrumental Aims

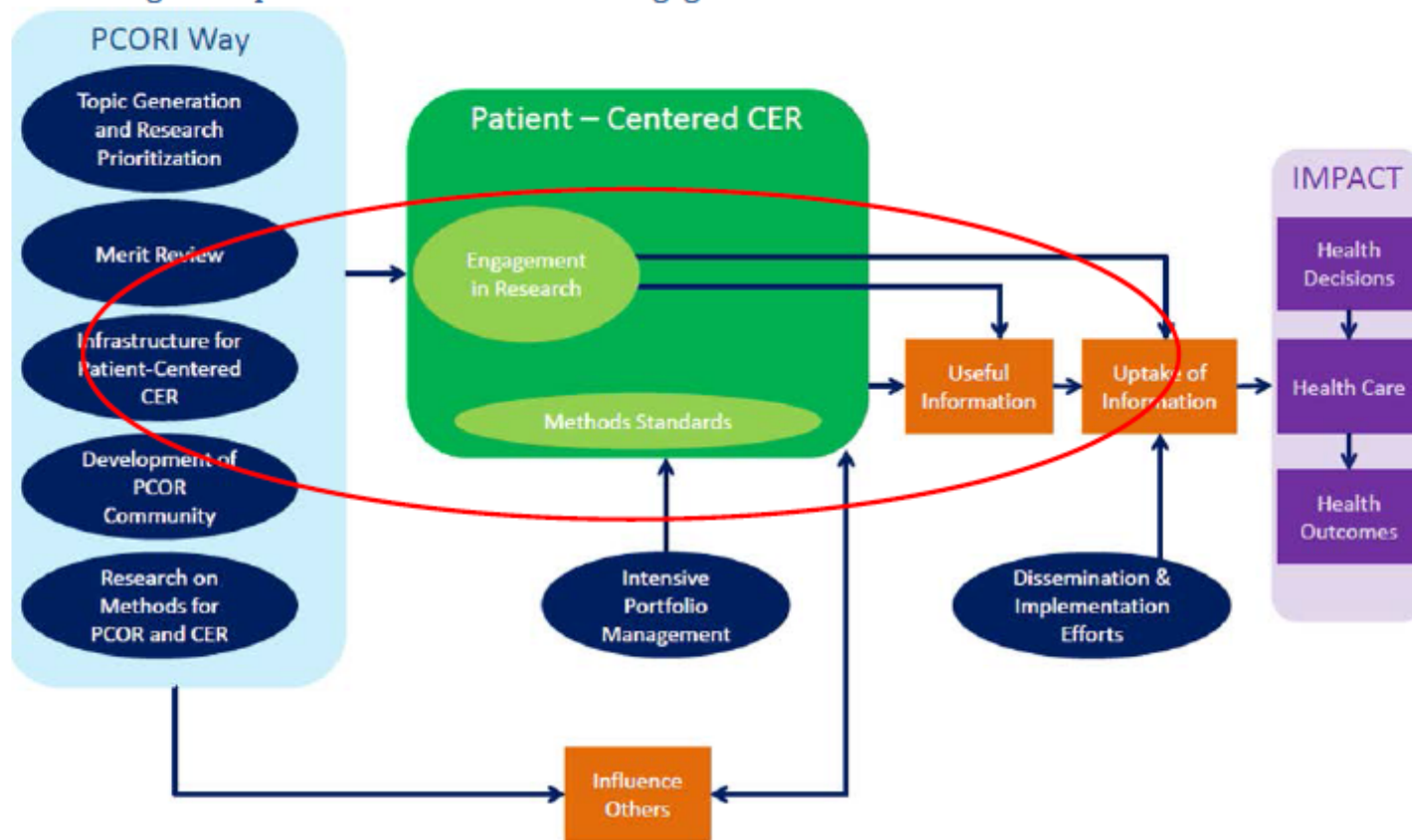
- Relevant research questions
- Transparent research
- Usable findings

# How is Engagement Supposed to Work? (PCORI)

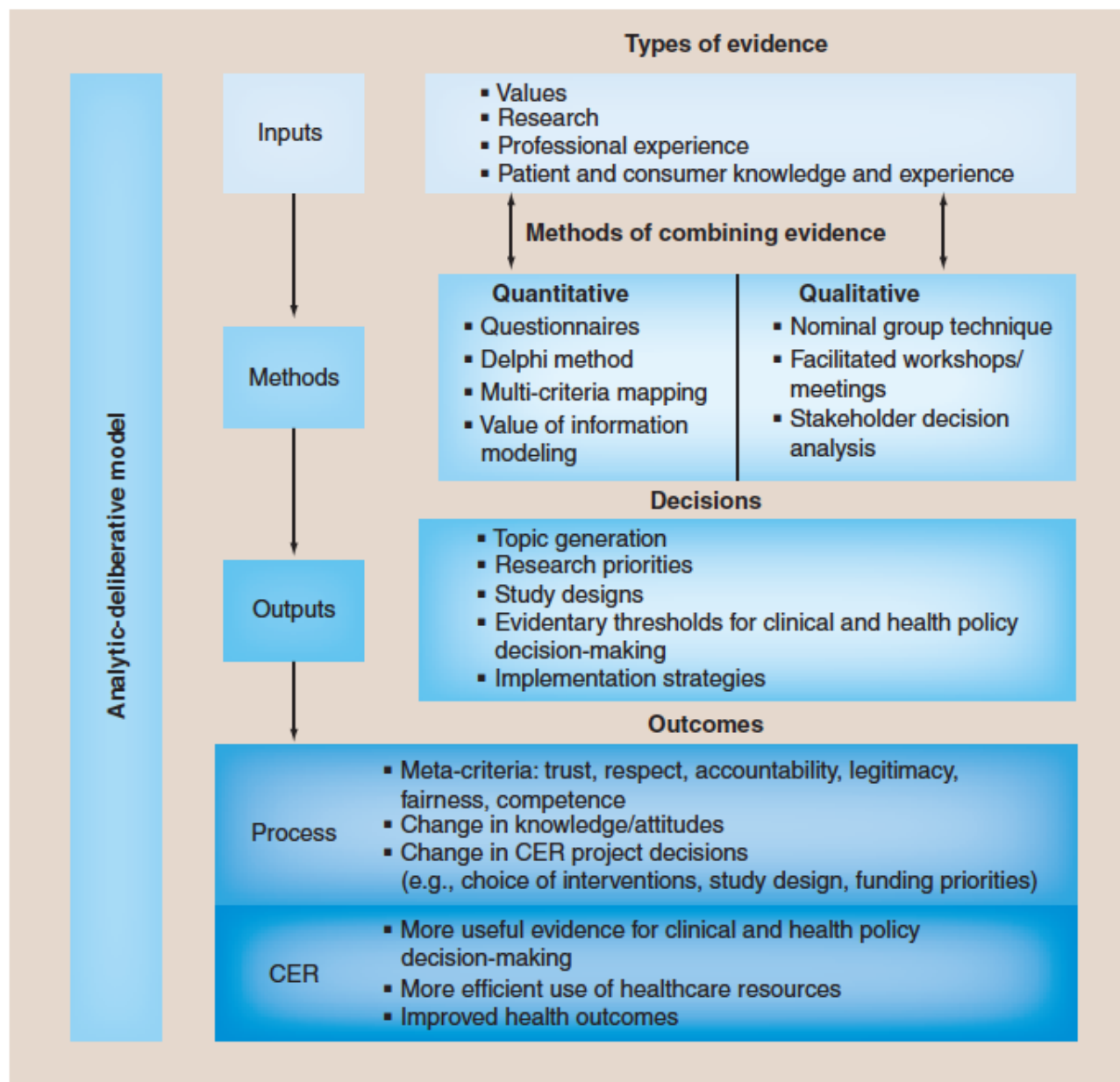


# How is Engagement Supposed to Work? (PCORI)

Figure 2a. Model for Evaluating the Impact of PCORI: Where Does Engagement in Research Fit?

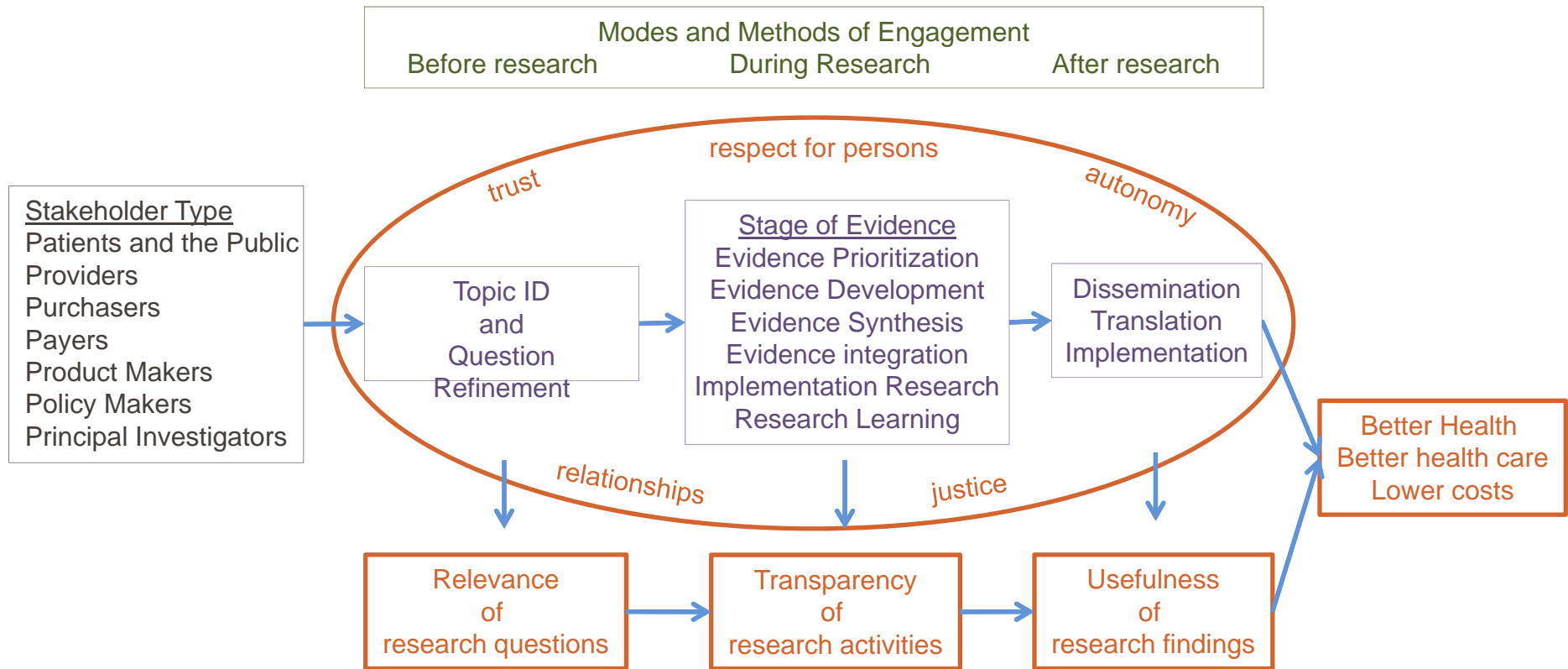


# How is Engagement Supposed to Work? (Deverka)





# How is Engagement Supposed to Work? (Concannon)



# Review Two Use Cases

1. A Pragmatic Trial of More versus Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules
2. Early Supported Discharge for Improving Functional Outcomes After Stroke

# Exercise I

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# Roadmap

## Patient-centered engagement

- Two use cases
- Exercise I

## Patient-centered research approach

- Exercise II

# Establish a Partnership with Patients

Work with patients long before submitting an application

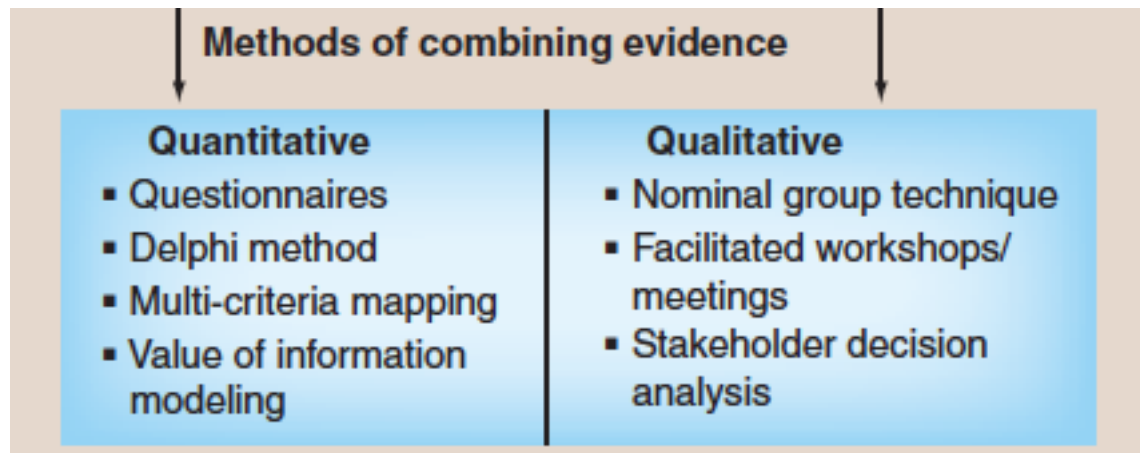
- *Be a patient*, family member or an advocate. PCORI recognizes and allows researchers to self identify as patients.
- *Be a researcher who partners with patients*, family member or advocates
- *Be a navigator* who “bridges” patients and researchers

Describe recent forums, activities and dates of importance in your partnership.

# Work with Patients to Develop Your Topic and Question

Topic nomination and prioritization process

Question development process



# Describe How Research Qualifies as Patient-centered

## Usual patients in usual care settings:

- How is the study population representative of patients and communities affected by the condition of study?
- How is the study setting representative of the places that patients actually go for care?

# Describe How Research Qualifies as Patient-centered

## Outcomes that matter to patients:

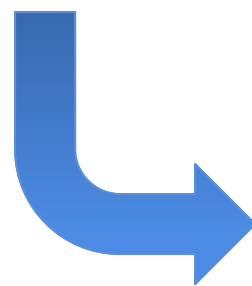
- Use a homegrown approach
  - Understand the decisions patients need to make
  - Listen to how patients describe their decisions
  - Understand the patient's information needs
- Use patient-reported outcomes



# Describe How Research Qualifies as Patient-centered

## Intensity of patient involvement:

- Partners (co-investigators)
- Participants (staff, consultants)
- Advisors (expert and advisory panels)



Planning the research  
Conducting the research  
Translating the findings  
Implementing the findings

# Before you Start a PCORI Application...

Read through their FAQ page at

<http://www.pcori.org/funding-opportunities/funding-center/faqs-for-applicants/>

Read the PCORI Methodology Report

<http://www.pcori.org/research-we-support/the-pcori-methodology-report/>

Review PCORI's on-line trainings

<http://www.pcori.org/funding-opportunities/funding-announcements/applicant-training/>

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# Exercise II

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**Thank you!**

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