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
Tufts Clinical and Translational Science Institute
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
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

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
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 and submit a request
http://ilearn.tuftsctsi.org/

Live seminars are recorded for our I LEARN site. Seminar videos can be viewed at any time, and are free!

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.
Get Connected: CTSI Happenings

• 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
Questions?
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?

<table>
<thead>
<tr>
<th>Patient-Centered</th>
<th>Comparative Effectiveness Research</th>
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<tr>
<td>Considers patients’ needs and preferences and focuses on questions and outcomes most important to them</td>
<td>Compares effectiveness of two or more treatments or approaches to health care, examining their risks and benefits</td>
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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\(^1\), Paul Mellins, MSPH\(^2\), Jo Anne Grunbaum, EdD\(^3\), Neveil McBee, Pharm.D, MSPH\(^4\), Jeanne-Marie Guse, MD, MPH\(^5\), John Santa, MD, MPH\(^6\), Patrick H. Conway, MD, MSc\(^7,8\), Denise Daudelin, RN, MPH\(^9\), Elaine H. Morrafo, DiPH, MPH\(^9\), and Lauren K. Leslie, MD, MPH\(^1\)

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

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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)

Modes and Methods of Engagement

Before research  
During Research  
After research

Stakeholder Type
Patients and the Public  
Providers  
Purchasers  
Payers  
Product Makers  
Policy Makers  
Principal Investigators

Trust

Respect for persons

Autonomy

Justice

Relationships

Relevance of research questions

Transparency of research activities

Usefulness of research findings

Stage of Evidence

Evidence Prioritization

Evidence Development

Evidence Synthesis

Evidence integration

Implementation Research

Research Learning

Dissemination

Translation

Implementation

Better Health

Better health care

Lower costs

Tufts Clinical and Translational Science Institute
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
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

**Methods of combining evidence**

- **Quantitative**
  - Questionnaires
  - Delphi method
  - Multi-criteria mapping
  - Value of information modeling

- **Qualitative**
  - Nominal group technique
  - Facilitated workshops/meetings
  - Stakeholder decision analysis
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/
Exercise II
Thank you!