STAKEHOLDER ENGAGEMENT IN RESEARCH

INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH AT UMB

Ellen Tambor | August 10, 2017

CMTP
CENTER FOR MEDICAL TECHNOLOGY POLICY

CENTER FOR MEDICAL TECHNOLOGY POLICY (CMTP)

- **Who we are:**
  - Independent nonprofit organization working to strengthen the quality, relevance, and efficiency of clinical research
  - Bring together stakeholders from throughout healthcare to ask:
    - What are the most important questions to address?
    - What are the best methods to answer those questions?

CMTP

TOPICS

- Rationale for stakeholder engagement
- Deciding who to engage
- Deciding when and how to engage
- Evaluating the impact of engagement

DEFINITIONS*

- **Stakeholder:** An individual or group who is responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence

- **Engagement:** A bi-directional relationship between the stakeholder and researcher that results in informed decision-making about the selection, conduct, and use of research

Concannon TW, Meissner P, Grunbaum JA, et al. A new taxonomy for stakeholder engagement in patient-centered outcomes research. J Gen Intern Med 2012;27:985–991.

CMTP

RATIONALE FOR ENGAGEMENT

Moral/Ethical Arguments

Pragmatic Arguments

RATIONALE FOR ENGAGEMENT

Moral/Ethical Arguments

Right of citizens to have a voice in the use of public funds

Pragmatic Arguments

RATIONALE FOR ENGAGEMENT

Moral/Ethical Arguments

- Right of citizens to have a voice in the use of public funds
- Right of individuals to be involved in shaping research that pertains to them

Pragmatic Arguments

RATIONALE FOR ENGAGEMENT

Moral/Ethical Arguments

- Right of citizens to have a voice in the use of public funds
- Right of individuals to be involved in shaping research that pertains to them

"Nothing about us, without us"

Pragmatic Arguments

CMTP

RATIONALE FOR ENGAGEMENT

Moral/Ethical Arguments

- Right of citizens to have a voice in the use of public funds
- Right of individuals to be involved in shaping research that pertains to them

"Nothing about us, without us"

Pragmatic Arguments

- Improving the quality, relevance, and usefulness of clinical research

CMTP

RATIONALE FOR ENGAGEMENT

Moral/Ethical Arguments

- Right of citizens to have a voice in the use of public funds
- Right of individuals to be involved in shaping research that pertains to them

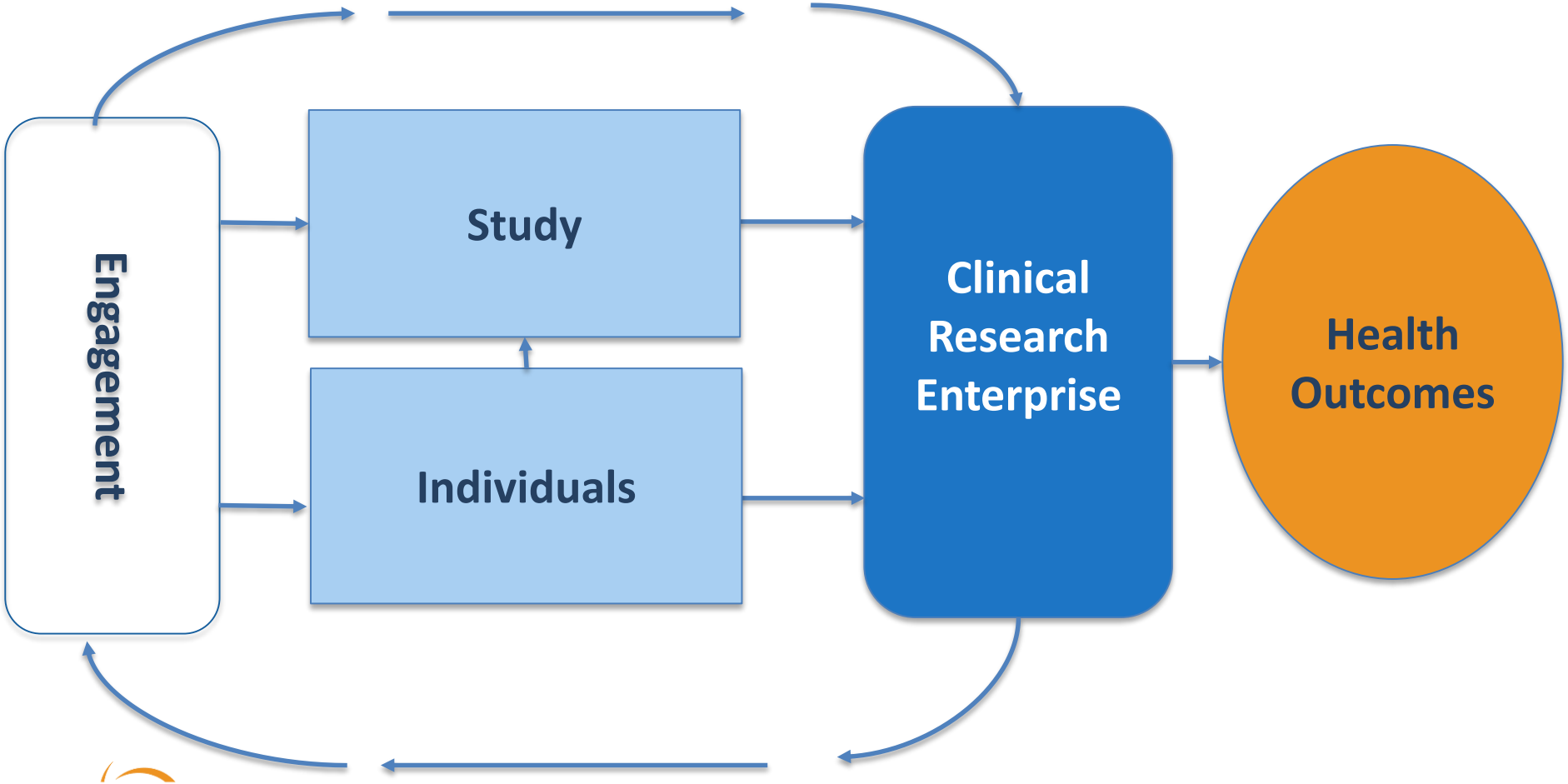
"Nothing about us, without us"

Pragmatic Arguments

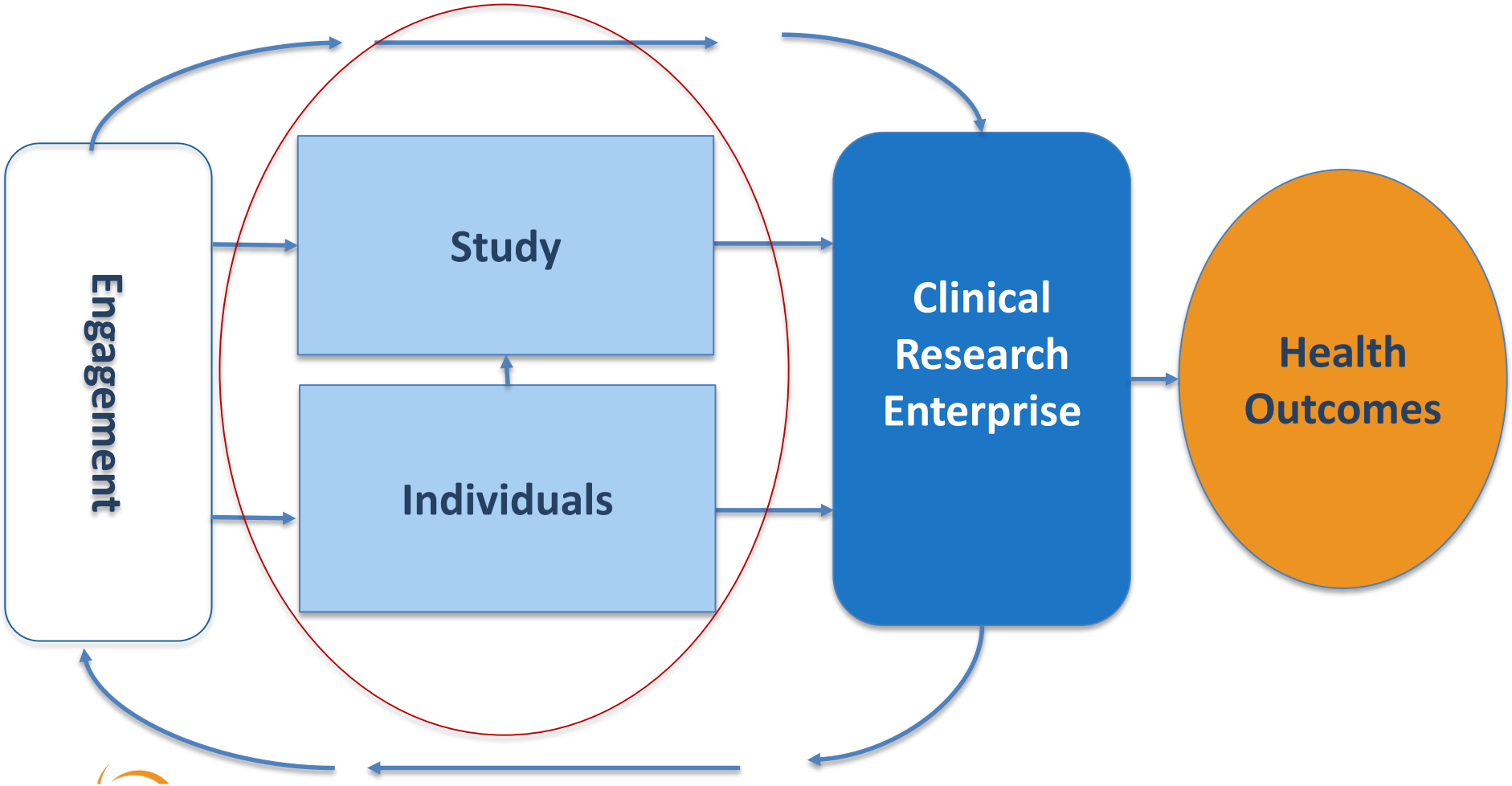
- Improving the quality, relevance, and usefulness of clinical research
- Increasing transparency, credibility, trust in the clinical research enterprise

CMTP

MULTIPLE PATHWAYS TO IMPACT



MULTIPLE PATHWAYS TO IMPACT



HYPOTHESIZED STUDY IMPACTS

Topic/Design	• Research questions that are important • Outcome measures that matter • Study designs that are acceptable
Process	• Improved recruitment and retention • Better adherence to study protocol • More complete data collection • Shorter time to study completion
Outcomes	• Evidence that is useful for decisions • Evidence that is more likely to be used

HYPOTHESIZED INDIVIDUAL IMPACTS

Stakeholders	• Knowledge and understanding • Research/collaboration skills • Personal empowerment
Study Participants	• Satisfaction with participation • Trust in research
Researchers	• Collaboration skills • Understanding of patient perspectives • Belief in the value of patient-centered research

CMTP

PLANNING FOR STAKEHOLDER-ENGAGED RESEARCH

- What types of stakeholders should be included?
- When in the research process should they be engaged?
- How should they be engaged?

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ **Always Patients**

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Individuals who have personal experience with cLBP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Individuals who have personal experience with cLBP
- Family members who have cared for someone with cLBP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Individuals who have personal experience with cLBP
- Family members who have cared for someone with cLBP
- Advocacy organizations

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Individuals who have personal experience with cLBP
- Family members who have cared for someone with cLBP
- Advocacy organizations

COMPARE-UF

Example 2: Multi-center registry of women who have received treatment for uterine fibroids (UF)

CMTP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Individuals who have personal experience with cLPB
- Family members who have cared for someone with cLBP
- Advocacy organizations

COMPARE-UF

Example 2: Multi-center registry of women who have received treatment for uterine fibroids (UF)

- Women with uterine fibroids

CMTP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

Example 1: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Individuals who have personal experience with cLBP
- Family members who have cared for someone with cLBP
- Advocacy organizations

COMPARE-UF

Example 2: Multi-center registry of women who have received treatment for uterine fibroids (UF)

- Women with uterine fibroids
- Advocacy organizations

CMTP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

Patient-led advocacy organizations

HysterSisters
Woman-to-Woman Hysterectomy Support

FIBROID Relief

NATIONAL UTERINE FIBROIDS FOUNDATION

CMTP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ Always Patients
- ✓ **Always Clinicians**

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ Always Patients
- ✓ **Always Clinicians**

- Clinical experts
- "Front-line" clinicians
- Professional societies

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ Always Patients
- ✓ **Always Clinicians**

- Clinical experts
- "Front-line" clinicians
- Professional societies
- **Multiple specialties**

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ Always Patients
- ✓ **Always Clinicians**

- Clinical experts
- "Front-line" clinicians
- Professional societies
- **Multiple specialties**

Example: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

CMTP

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

✓ Always Patients

✓ **Always Clinicians**

- Clinical experts
- "Front-line" clinicians
- Professional societies
- **Multiple specialties**

Example: Pragmatic RCT comparing surgical to non-surgical interventions in patients with chronic low pack pain (cLBP)

- Primary care physicians
- Neurosurgeons
- Orthopedic surgeons
- Pain specialists
- Physiatrists
- Physical therapists
- Massage therapists
- Chiropractors

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ Always Patients
- ✓ Always Clinicians
- ✓ **Other Key Stakeholder Groups**

WHAT TYPES OF STAKEHOLDERS SHOULD BE INCLUDED?

- ✓ Always Patients
- ✓ Always Clinicians
- ✓ **Other Key Stakeholder Groups**

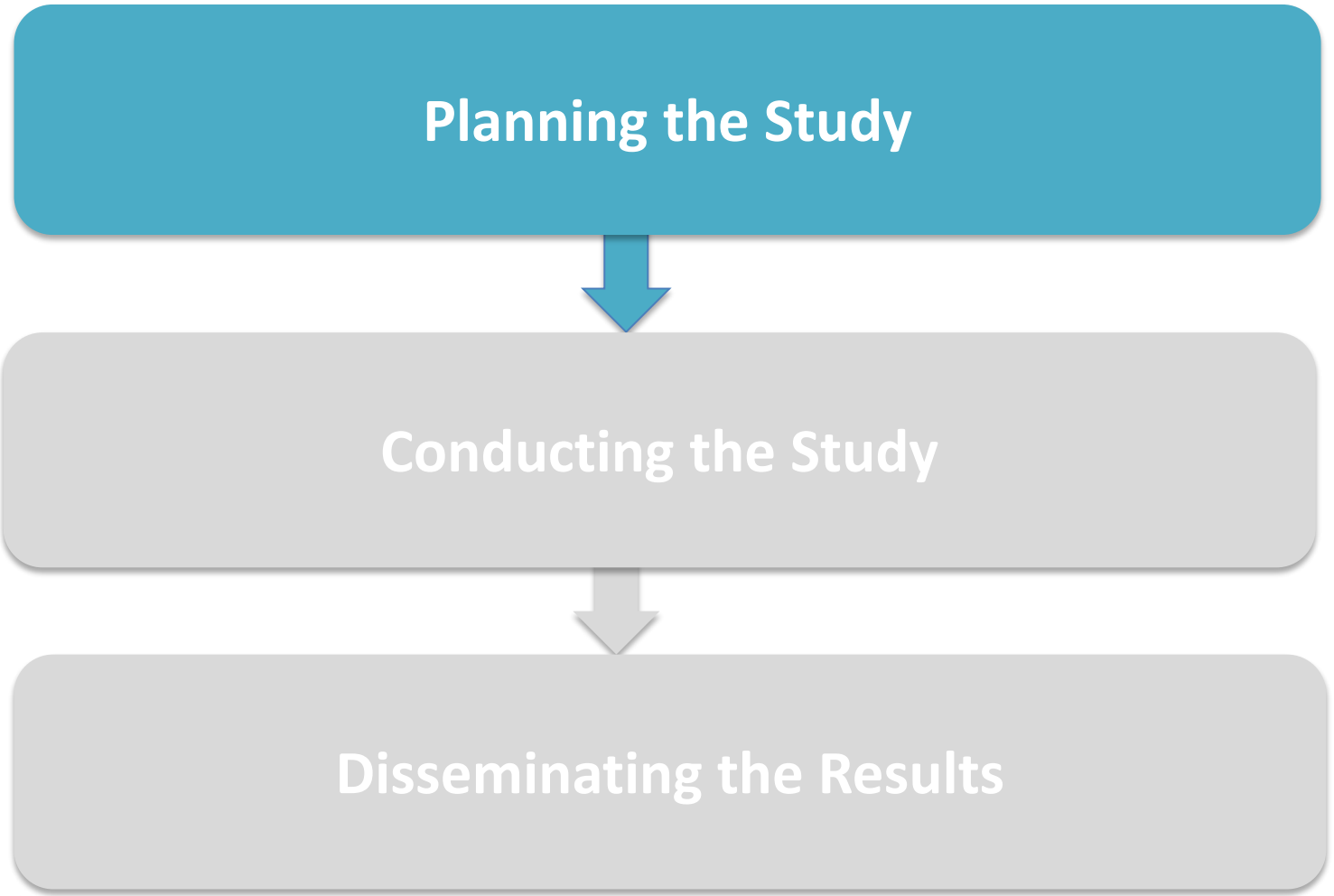
Healthcare Payers

Policymakers

Guideline Developers

CMTP

WHEN SHOULD STAKEHOLDERS BE ENGAGED?



PLANNING THE STUDY

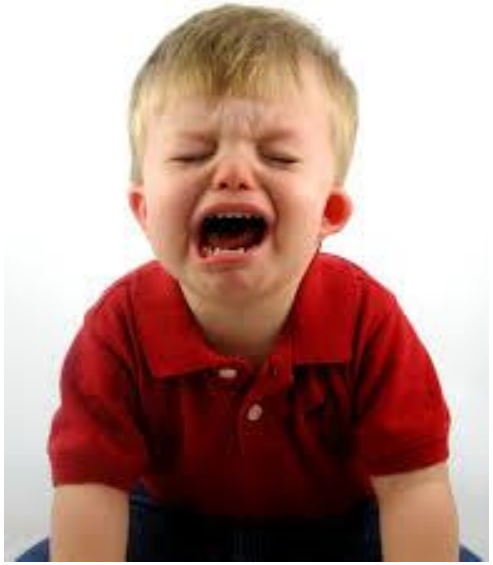
Topic Solicitation & Prioritization

Example: Parents of children with Cystic Fibrosis

PLANNING THE STUDY

Topic Solicitation & Prioritization

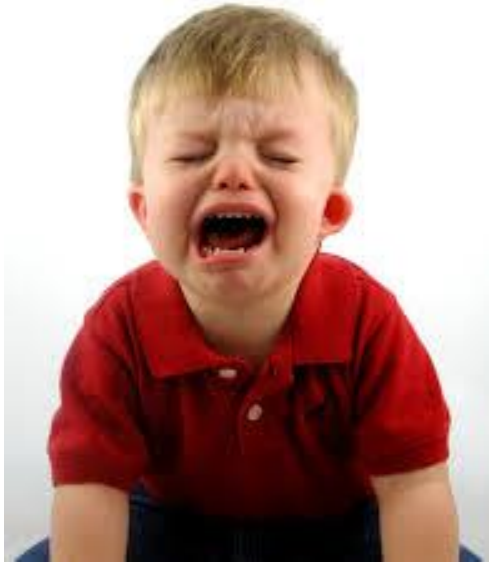
Example: Parents of children with Cystic Fibrosis



PLANNING THE STUDY

Topic Solicitation & Prioritization

Example: Parents of children with Cystic Fibrosis



PLANNING THE STUDY

Selection of Outcomes and Comparators

Example: Patients with advanced and metastatic cancer where the expected outcome is not a cure

Standard Measures of Burden	Measures of Burden Important to Patients

PLANNING THE STUDY

Selection of Comparators and Outcomes

Example: Patients with advanced and metastatic cancer where the expected outcome is not a cure

Standard Measures of Burden	Measures of Burden Important to Patients
• Toxicity	

PLANNING THE STUDY

Selection of Comparators and Outcomes

Example: Patients with advanced and metastatic cancer where the expected outcome is not a cure

Standard Measures of Burden	Measures of Burden Important to Patients
• Toxicity	• Days of work missed • Need for a caregiver • Caregiver burden • ER visits • Hospitalizations • Out-of-pocket costs for all forms of care • Toxicities and adverse effects including chemo-related hair loss

WHEN SHOULD STAKEHOLDERS BE ENGAGED?

Planning the Study

Conducting the Study

Disseminating the Results

CONDUCTING THE STUDY

Patients

- Review recruitment and consent materials
- Advise on strategies for boosting enrollment

CONDUCTING THE STUDY

Patients

- Review recruitment and consent materials
- Advise on strategies for boosting enrollment

Clinicians

- Advise on strategies to reduce impact of study protocol on clinical workflow
- Serve as study champions at enrollment sites

WHEN SHOULD STAKEHOLDERS BE ENGAGED?

Planning the Study

Conducting the Study

Disseminating the Results

DISSEMINATING THE RESULTS

Evidence Assessment

- Is the evidence appropriate for broad dissemination?
- What stakeholder priorities, needs, and concerns does the evidence address?

DISSEMINATING THE RESULTS

Evidence Assessment

- Is the evidence appropriate for broad dissemination?
- What stakeholder priorities, needs, and concerns does the evidence address?

Audience Identification

- Who will benefit from having this information to make decisions?
- Who can help reach the audience and influence adoption?

DISSEMINATING THE RESULTS

Evidence Assessment

- Is the evidence appropriate for broad dissemination?
- What stakeholder priorities, needs, and concerns does the evidence address?

Audience Identification

- Who will benefit from having this information to make decisions?
- Who can help reach the audience and influence adoption?

Dissemination

- What information about the evidence will help people make decisions?
- In what ways can that information be provided?

PCORI Implementation & Dissemination Toolkit
https://www.mathematica-mpr.com/our-publications-and-findings/projects/pcori-dissemination-and-implementation-framework-and-toolkit

CMTP

HOW SHOULD STAKEHOLDERS BE ENGAGED?

Group Size

One-on-One
Small Working Group
Large Stakeholder Group
Broad Community Outreach

Engagement Method

In-Person Meeting
Tele/Web Conference
Online Survey
Social Media

Other Considerations

Frequency of Engagement
Preparation and Support
Compensation

THE IMPACT OF ENGAGEMENT

The RAPPORT Study*

(ReseArch with Patient and Public invOlvement: a RealisT evaluation)

- Mixed-methods evaluation of clinical research studies in England to assess impact of engagement on research processes and outcomes

Key Findings Related to Impact

- Positive impact of engagement across all study phases
- Most commonly reported outcome was improving recruitment rates
- Significant positive impact on respondents in terms of psychological outcomes and knowledge

**Wilson P, Mathie E, Keenan J, McNeilly E, Goodman C, Howe A, et al. ReseArch with Patient and Public invOlvement: a RealisT evaluation – the RAPPORT study. Health Serv Deliv Res. 2015;3(38).*

CMTP

THE RAPPORT STUDY

- Level of impact differed across 3 general models of engagement

One-Off Model	• Limited engagement with boundaries set by investigator
Outreach Model	• Small number of stakeholder representatives provide conduit to and from wider population
Fully Intertwined Model	• Engagement integral and ongoing within the research study

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

- Level of impact differed across 3 general models of engagement

One-Off Model	• Limited engagement with boundaries set by investigator
Outreach Model	• Small number of stakeholder representatives provide conduit to and from wider population
Fully Intertwined Model	• Engagement integral and ongoing within the research study

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

- Level of impact differed across 3 general models of engagement

One-Off Model	• Limited engagement with boundaries set by investigator
Outreach Model	• Small number of stakeholder representatives provide conduit to and from wider population
Fully Intertwined Model	• Engagement integral and ongoing within the research study

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

- Level of impact differed across 3 general models of engagement

One-Off Model	• Limited engagement with boundaries set by investigator
Outreach Model	• Small number of stakeholder representatives provide conduit to and from wider population
Fully Intertwined Model	• Engagement integral and ongoing within the research study

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

- Level of impact differed across 3 general models of engagement

One-Off Model	• Limited engagement with boundaries set by investigator
Outreach Model	• Small number of stakeholder representatives provide conduit to and from wider population
Fully Intertwined Model	• Engagement integral and ongoing within the research study

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

- Level of impact differed across 3 general models of engagement

One-Off Model	• Limited engagement with boundaries set by investigator
Outreach Model	• Small number of stakeholder representatives provide conduit to and from wider population
Fully Intertwined Model	• Engagement integral and ongoing within the research study

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

**Wilson et al, 2015*

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

1. Researchers and stakeholders have shared understanding of moral and methodological purpose of engagement

**Wilson et al, 2015*

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

1. Researchers and stakeholders have shared understanding of moral and methodological purpose of engagement
2. Key individual coordinates engagement

**Wilson et al, 2015*

CMTP

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

1. Researchers and stakeholders have shared understanding of moral and methodological purpose of engagement
2. Key individual coordinates engagement
3. Patient representatives have strong connection with the target study population

**Wilson et al, 2015*

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

1. Researchers and stakeholders have shared understanding of moral and methodological purpose of engagement
2. Key individual coordinates engagement
3. Patient representatives have strong connection with the target study population
4. Whole research team is positive about stakeholder input and fully engaged

**Wilson et al, 2015*

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

1. Researchers and stakeholders have shared understanding of moral and methodological purpose of engagement
2. Key individual coordinates engagement
3. Patient representatives have strong connection with the target study population
4. Whole research team is positive about stakeholder input and fully engaged
5. Efforts to develop relationships established and maintained over time

**Wilson et al, 2015*

THE RAPPORT STUDY

6 “salient actions” required for positive impact:

1. Researchers and stakeholders have shared understanding of moral and methodological purpose of engagement
2. Key individual coordinates engagement
3. Patient representatives have strong connection with the target study population
4. Whole research team is positive about stakeholder input and fully engaged
5. Efforts to develop relationships established and maintained over time
6. Engagement evaluated in a proactive and systematic approach

**Wilson et al, 2015*

Questions?