

Step #1

Agree on common definitions for your stakeholder engagement activity for terms such as:

Definitions for your stakeholder engagement activity	
Stakeholder	
Engagement	
Comparative effectiveness research (CER)	
Patient-centered outcomes research (PCOR)	
Evidence prioritization	

Step #2

Agree on the purpose of stakeholder-engaged evidence generation for your research program or community by determining:

- 1) Who are the decision-makers you are trying to inform?

- 2) What decisions do these decision-makers have to make?

- 3) How can the proposed evidence generation activities lead to informed decision-making for your community?
 - a. How would evidence generation accelerate the adoption of research evidence into use these decision-makers?

- 4) How can stakeholder engagement in the proposed evidence generation activities lead to informed decision-making for your community?
 - a. How would stakeholder engagement improve the relevance of research evidence for the decision-makers your research hopes to inform?

Step #3

Agree on specific stakeholder engagement activities to support your study.

For example, stakeholders could be engaged in:

- A pilot study to determine the necessary scope of your research
- Deliberative exercises to guide the course of your study, such as consumer advisory boards (CABs) or technical expert panels (TEPs)
- Becoming subjects of qualitative or quantitative research that identifies preferences about priority study populations, interventions, comparators and outcomes.

Step #4

Before you recruit stakeholders, identify appropriate stakeholder groups for your project. Use the 7Ps to identify primary decision makers, then customize the list of relevant stakeholders to your research topic by asking your research team a series of questions:

Stakeholder Group	Appropriate stakeholder group for my CER project
Patients and the Public	
Providers	
Purchasers	
Payers	
Policy Makers	
Product Makers	
Principal Investigators	

- **What topic(s) does the evidence generation activity address?**
 - a. Priority populations
 - b. Clinical conditions
 - c. Service offerings
 - d. Other

- **What kinds of healthcare decisions is evidence generation meant to inform?**
 - a) Clinical care
 - b) Healthcare strategies, including team science, payment strategies and other
 - c) Health services
 - d) Health policy
 - e) Public health
 - f) Research methods

Step #4 (continued)

- **Who are the decision-makers responsible for these decisions?**

Please note, stakeholders who are not primary decision makers but have a direct interest in the selection of research priorities should also be considered.

For example, purchasers and payers are decision makers when it comes to research priorities that involve insurance coverage, however, providers, patients, and product makers have a direct stake in these decisions and are important participants. Research that addresses methods questions may also benefit from stakeholder input, so other researchers (e.g.: Principal Investigators) should also be included.

Step #5

Identify the objectives and related modes of stakeholder engagement for your research activity.

Stakeholders may be needed for:

- **Subject/patient recruitment**
- **Advising during a pilot study or development phase for a trial or study.**
This can be helpful to choose a study design, define a priority population, identify target interventions or comparators, and identify important outcomes.
 - a) KI Interviews
 - b) Focus Groups
 - c) Panels (consumer advisory boards, stakeholder panels, technical expert panels)
- **Deliberative exercises to advise on the course of a trial or study** (consumer advisory boards, stakeholder panels, technical expert panels)
- **Quantitative or qualitative research on stakeholder preferences** about design, populations, interventions, comparators, and outcomes such as focus groups or surveys.

Step #6

If your mode of engagement will involve the creation of a stakeholder panel or board, determine the appropriate size of the panel and appropriate balance across stakeholder categories on your preliminary list. Determine:

- The appropriate size of the stakeholder group
- The appropriate activities of your stakeholders
- The appropriate number needed within each stakeholder category, in order to ensure that there is balance across categories with different perspectives on your topic.

Step #7

Develop an evidence generation protocol. As with evidence prioritization, this should include:

- Stakeholder identification and recruitment
- Conflict of Interest and Disclosure of Interest plan
- Engagement Plan that includes:
 - a. Mode and type of contact
 - b. Time frame
 - c. Honararia
 - d. Special consideration for patients and the public.

Step #8

Identify and recruit individuals to fill the priority list of stakeholders for your evidence generation process.

- **Snowball**

Start by contacting people you know. These individuals may be suitable to serve as stakeholders on your evidence prioritization project, or they may be able to help you find other candidates.

- **Search for investigators on research-in-progress** (e.g., clinicaltrials.gov, CRISP)
- **Peer review published literature search** (e.g., Medline, Econlit, www.CEAreagistry.org, Cochrane)
- **Grey literature search** (e.g., Google).

Step #9

Evaluate and report on the process of engaging stakeholders in your evidence generation activity.

- Report stakeholder activities in manuscripts and contract reports.
- As the evidence base grows, implement changes in future evidence prioritization activities.
- As changes are adopted, an iterative assessment process should follow.
- For evidence generation that is funded through a Federal contract, all public reports must be 508 Compliant (Refer to the Evidence Prioritization tool for details).

Step #10

Sustain relationships with your stakeholders.

- Share the results of your evidence prioritization exercise with each stakeholder.
- Invite stakeholders to share the results with others, including health decision makers and those who may be affected by health decisions.
- Invite stakeholders to participate in follow-up engagement activities. If your community or research program will use the results of this prioritization exercise to inform future research, invite stakeholders from the evidence generation process to continue working on the research.