

Engaging With Stakeholders & Aligning With Health System Partners

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Learning goals



- Learn why a critical element in the success of an ePCT is engaging health system partners at all levels and through all phases of the study
- Understand the real-world priorities and perspectives of health system leaders and how to obtain their support
- Identify challenges of partnering across diverse health systems

How researchers approach stakeholders in traditional RCTs

Researcher reviews the literature

Researcher presents idea to researchers who understand the theory and can see how study fills gap

Researcher designs and conducts study, prepares manuscripts

**Researchers partner with
stakeholders in ePCTs differently.**

The purpose of the healthcare system is not to do research, but to provide good healthcare. Researchers often have a tail-wagging-the-dog problem. We assume if we think something is a good idea, the healthcare system will too... We need to remember that we're the tail and the healthcare system is the dog.

– Greg Simon, MD, MPH (SPOT)

Important things to know

- **Start engagement early**, even before you have a research question or study design
- Be patient: Relationships take time to build and nurture
- Consider whether your intervention will add value
- Expect changes and disruptions
- Engage stakeholders continuously

Who will be impacted? Who are the decision makers?



Potential stakeholders have a variety of priorities, values, work cultures, and expectations:

- Healthcare delivery organization leaders
- Clinicians
- Operational personnel
- Patients, caregivers, patient advocacy groups
- Payers, purchasers
- Policy makers, regulators
- Research funders
- Researchers
- Product manufacturers

Roles of stakeholders

1. Designing the trial
2. Successfully conducting the research
3. Disseminating the results

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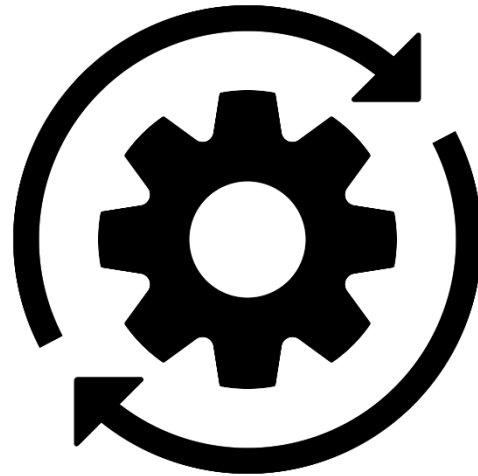
Choosing a salient question

*We want to know what you need.
What research should we be doing?*

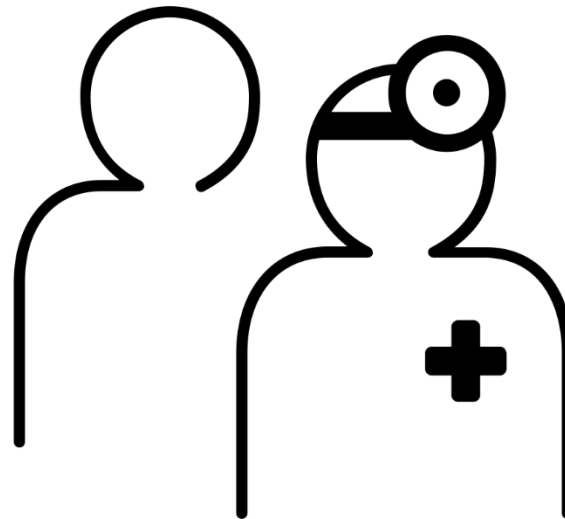


Source: Greg Simon, MD, MPH

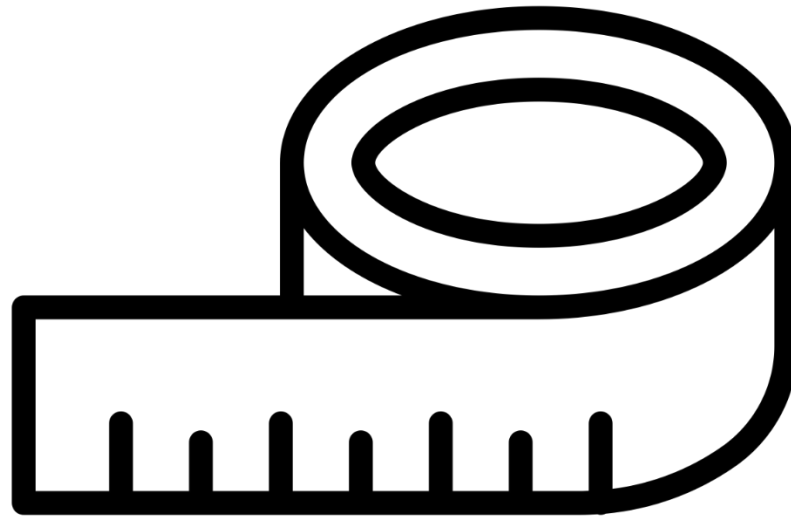
Designing the intervention for sustainment



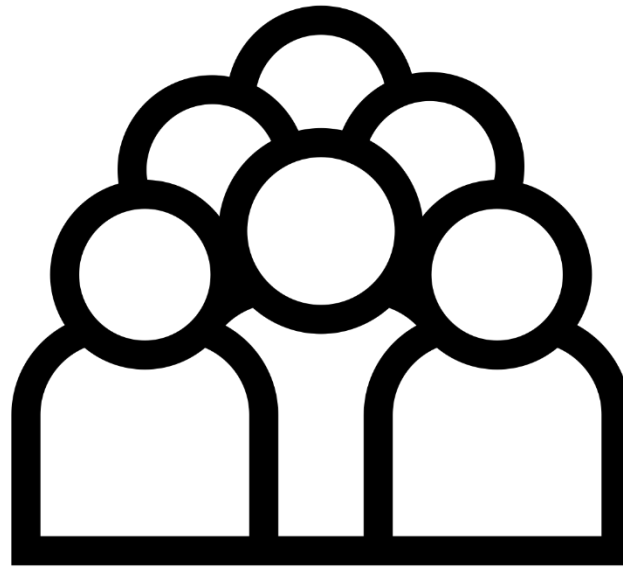
Designing the intervention to minimize burden for patients and clinicians



Selecting outcome measures



Determining inclusion and exclusion criteria



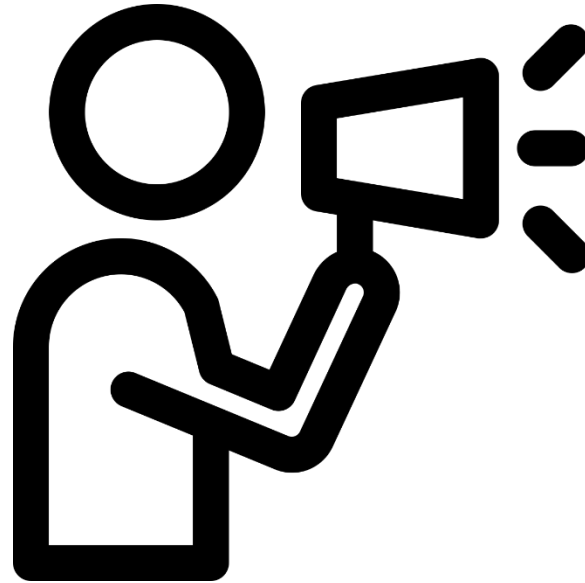
Roles of stakeholders

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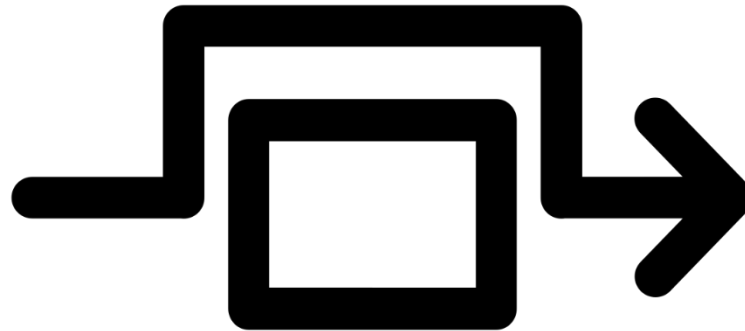
Develop recruitment strategies



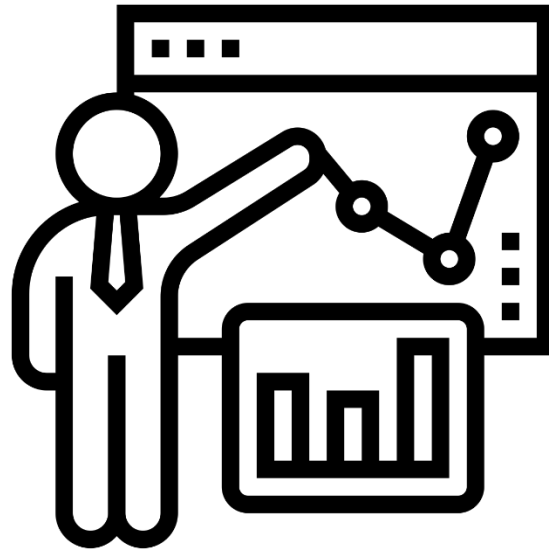
Serve as study champions



Track challenges and adaptations



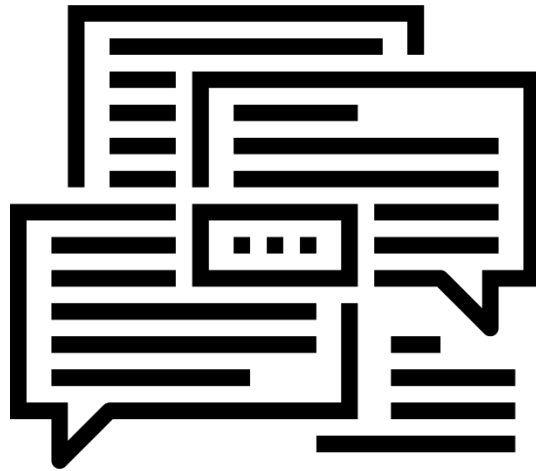
Interpret study results



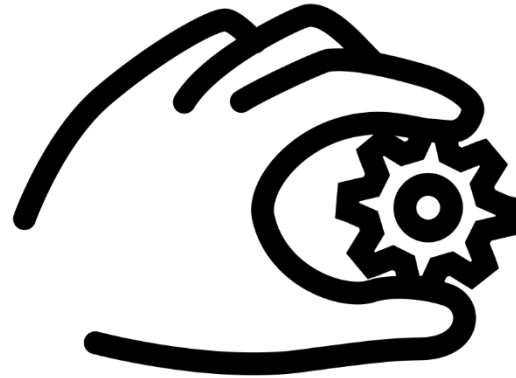
Roles of stakeholders

1. Designing the trial
2. Successfully conducting the research
3. **Disseminating the results**

Determine key messages for
different stakeholder groups and
identify avenues for dissemination



Support implementation or de-implementation



Consider changes to policies and guidelines



Roles of stakeholders

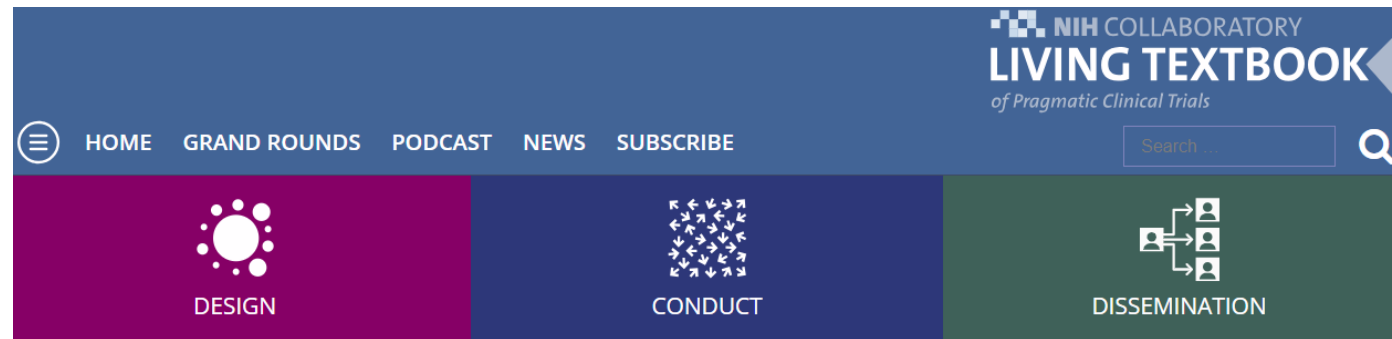
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Resource: Engaging stakeholders



Engaging Stakeholders and Building Partnerships to Ensure a Successful Trial

From the *Living Textbook of Pragmatic Clinical Trials*
www.rethinkingclinicaltrials.org



Resources: Journal articles

- Concannon TW et al. Practical guidance for involving stakeholders in health research. *J Gen Intern Med*. 2019 Mar;34(3):458-463.
- Whicher DM et al. Gatekeepers for pragmatic clinical trials. *Clin Trials*. 2015 Oct;12(5):442-448.
- Johnson KE et al. A guide to research partnerships for pragmatic clinical trials. *BMJ*. 2014 Dec 1;349:g6826.

Important things to do



- Engage stakeholders early and often
- Set expectations to work collaboratively and build trust from the beginning
- Use familiar language that stakeholders understand
- Get to know your stakeholders' values, priorities, and expectations
- Assess your partners' capacity and capabilities
- Track goals reached, challenges, and adaptations throughout the life cycle of your ePCT
- Show appreciation and celebrate accomplishments early and often to have sustained partnerships

Questions?

Stakeholder roles in:

Design

- Question
- Intervention
- Outcomes
- Population

Conduct

- Recruitment
- Advocacy
- Challenges
- Interpretation

Dissemination

- Messaging
- Venues
- Implementation
- Guidelines



Extra slides

How to engage stakeholders

If the goal of ePCTs is to provide health systems with effective, evidence-based, practical ways to improve healthcare, how should researchers engage stakeholders to achieve this goal?

Identify and form collaborations

- Network at conferences, attend webinars, and use a snowball approach
- Meet regularly by phone, e-mail, video chat, in-person, consider establishing an advisory board
- Understand the frameworks the stakeholders use for quality improvement (QI) initiatives. Adapt research language using a framework that speaks to health system needs and the language they more readily understand
- Set expectations to work collaboratively and build trust from the beginning

Source: Bev Green, MD, MPH, and Lynn DeBar, PhD

Get to know each other

- Learn about each other's goals, needs, priorities, motivations for implementing a trial, and what or who influences decisions
- Learn about ideal “wins” and potential conflicts and competing priorities
- Understand workflows and work together to make study-related activities feasible and least burdensome

Pilot and assess stakeholders' capacity and capabilities

- Are sufficient patient numbers and data available for the analysis?
- Can data be collected at a few or all clinical sites?
- How do the sites vary in services and capabilities?
- Can the system's regulatory and administrative infrastructure support approval and oversight by ethics committees and review boards?
- Will the intervention add long-term value to the system?