Stakeholder Engagement and Planning for Implementation From the Beginning

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Learning goals

- Learn why a critical element in the success of an ePCT is engaging health system stakeholders early and often
- Discuss strategies for health system stakeholder engagement
- Understand how health system stakeholders can help to design interventions for real-world implementation and sustainment



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 Demonstration Project Principal Investigator





Who will be impacted? Who are the decision-makers?

For example,

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







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



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



Choosing a salient question

We want to know what you need.

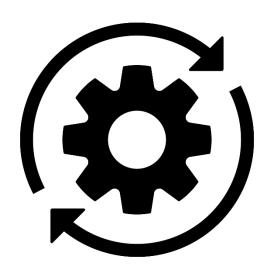
What research should we be doing?





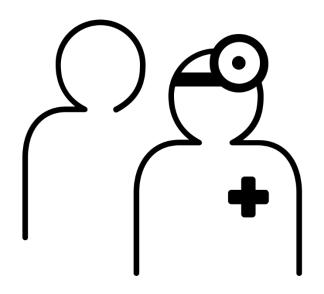


Designing the intervention for sustainment



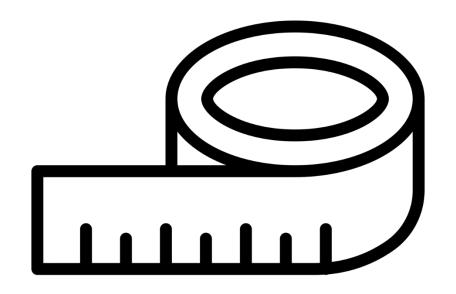


Designing the intervention to minimize burden for patients and clinicians





Selecting outcome measures

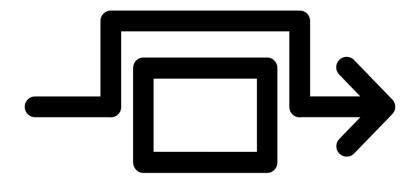




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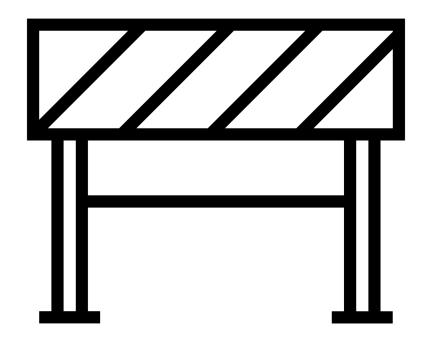


Track challenges and adaptations





Monitor barriers to real-world implementation





Interpret study results

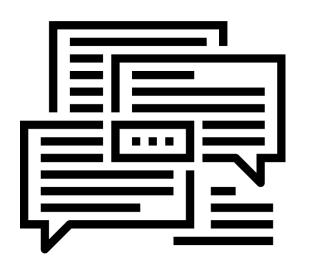




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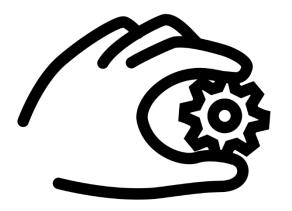


Determine key messages for different stakeholder groups and identify avenues for dissemination





Support implementation or de-implementation





- 1. Designing the trial
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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.

Multi-Group Stakeholder Engagement.

J Gen Intern Med 2019

Whicher DM, et al.

Gatekeepers for pragmatic clinical trials. Clin Trials.

12:442–448. 2015

Johnson KE, et al.

A guide to research partnerships for pragmatic clinical trials. *BMJ*. 2014





Resources

Visit the Living Textbook of Pragmatic Clinical Trials at

www.rethinkingclinicaltrials.org



Rethinking Clinical Trials: A Living Textbook of **Pragmatic Clinical Trials**



Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH Health Care Systems Research Collaboratory, Pragmatic clinical trials present an opportunity to efficiently generate high-quality evidence to inform medical decision-making. However, these trials pose different

challenges than traditional clinical trials. The Living Textbook reflects a collection of special considerations and best practices in the design, conduct, and reporting of pragmatic clinical trials.

GET STARTED

What is the

NIH COLLABORATORY?

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PRAGMATIC CLINICAL TRIAL? **⑨**

TRAINING RESOURCES ③

IMPACT Training Modules ePCT Video Learning Library www.impactcollaboratory.org



Learn more about how to conduct ePCTs for people living with dementia

The NIA IMPACT Training Modules are short videos designed to introduce the important components and considerations related to embedded pragmatic clinical trials (ePCTs) for people living with dementia and their care partners. These videos are appropriate for investigators, health systems leaders, research staff and others who want to learn about the design and conduct of ePCTs.

Training modules are organized by topics/cores. Each tile below opens up into a series of relevant modules. Sign up here to be included on the mailing list to be informed about new and upcoming training content and opportunities.

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