

# Engaging with Health System and Community Partners

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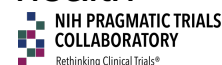
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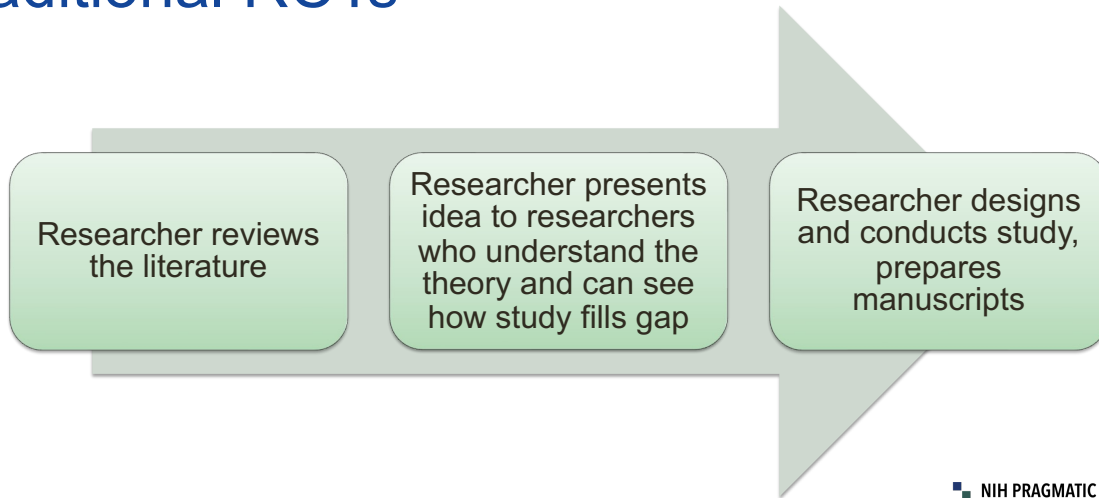
## Learning goals



- Describe the breadth of individuals to engage as partners and approaches for engaging them through all phases of the study
- Identify skills needed for a strong study team and consider the diversity of the team, including inclusive practices
- Understand the real-world priorities and perspectives of healthcare system leaders and how to obtain their support
- Identify engagement practices to obtain patient and community perspectives
- Highlight challenges of partnering across diverse health systems



## How researchers approach partners in traditional RCTs



**ePCTs work 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 partners continuously**

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

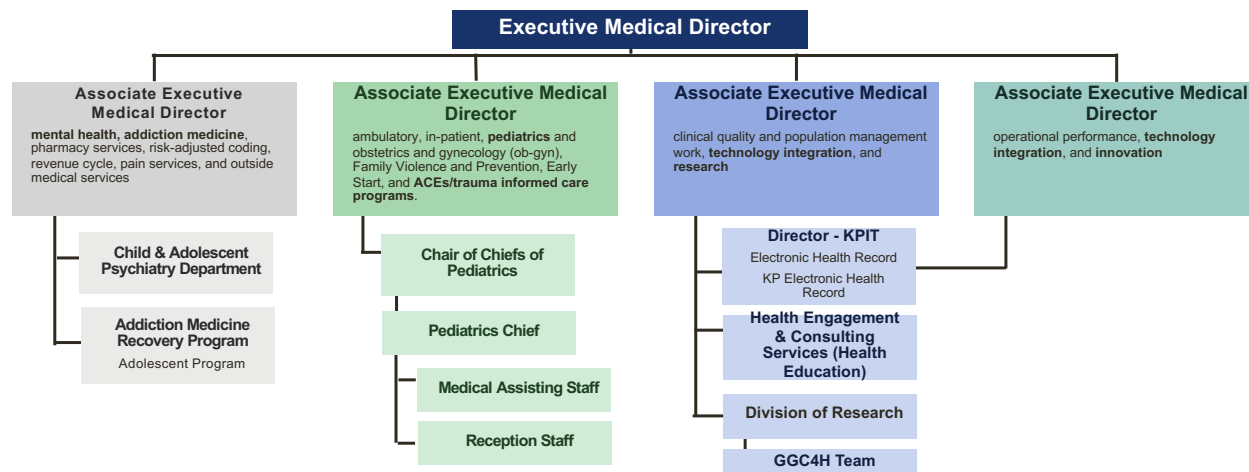


Potential partners have a variety of priorities, values, work cultures, and expectations:

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



## Kaiser Permanente Northern California



**Guiding Good Choices for Health:** The study team engaged with all of these partners within the The Permanente Medical Group at Kaiser Permanente Northern California. These partners represent a small fraction of the many relevant stakeholders in large, complex healthcare systems. Most systems are comprised of several different entities – e.g., medical group, health plan, hospitals/facilities, etc. + labor partners

## Roles of partners

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

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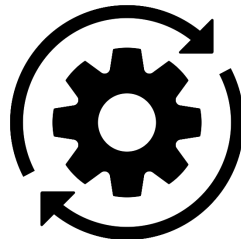
## Choosing a salient question

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

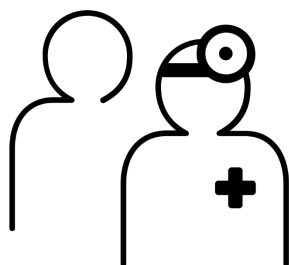


Source: Greg Simon, MD, MPH

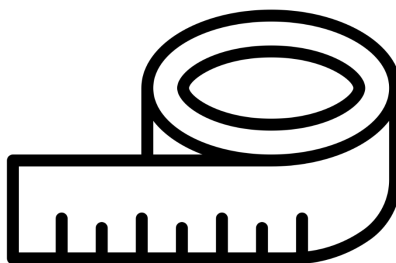
## Designing the intervention for sustainment



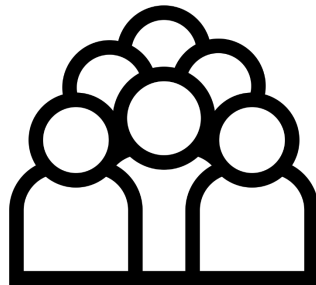
## Designing the intervention to minimize burden for patients and clinicians



## Selecting outcome measures



## Determining inclusion and exclusion criteria



## Roles of partners

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

## Develop recruitment strategies



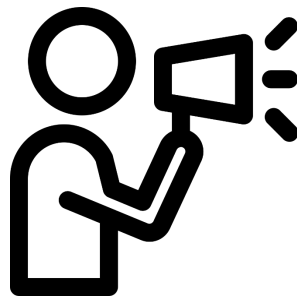
## Example: Community Advisory Board

- Feedback from OPTIMUM’s Community Advisory Board
  - Make materials more diverse and visually appealing
  - Include more “mindfulness” theme in recruitment materials
  - Highlight benefits of participating in study
- Response from Study Team
  - New posters and updated study website
  - Quarterly newsletter
  - Study animation video

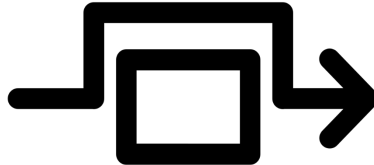
## Example: Patient Advisory Panel

- Old name
  - LS7 Bot and Backup: Using artificially intelligent text messaging technology to improve American Heart Association's Life's Simple 7 Health Behaviors
- New name, suggested name by patient
  - Chat 4 Heart Health

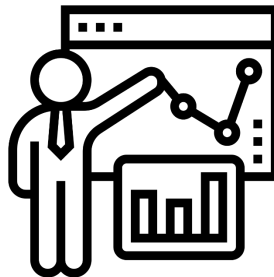
Serve as study champions



## Track challenges and adaptations



## Interpret study results



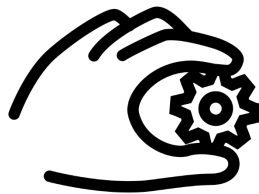
## Roles of partners

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

Determine key messages for  
different groups and  
identify avenues for dissemination



## Support implementation or de-implementation



## Consider changes to policies and guidelines



# Roles of ePCT partners

## 1. Design

- Question
- Intervention
- Outcomes
- Population

## 2. Conduct

- Recruitment
- Advocacy
- Challenges
- Interpretation

## 3. Dissemination

- Messaging
- Venues
- Implementation
- Guidelines



# Important things to do



- Engage partners early and often
- Set expectations to work collaboratively and build trust from the beginning
- Use familiar language that partners understand
- Get to know your partners' values, priorities, and expectations
- Assess health system 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



## Resource: The Living Textbook

Visit the *Living Textbook of Pragmatic Clinical Trials* at

[www.rethinkingclinicaltrials.org](http://www.rethinkingclinicaltrials.org)

NIH PRAGMATIC TRIALS COLLABORATORY  
Rethinking Clinical Trials®

Design | View Chapters > | Data, Tools & Conduct | View Chapters > | Dissemination | View Chapters > | Ethics and Regulatory | View Chapters >

What is a Pragmatic Clinical Trial?  
Developing a Compelling Grant Application  
Experimental Designs and Randomization Schemes

Endpoints and Outcomes  
Analysis Plan  
Using Electronic Health Record Data

Building Partnerships and Teams to Ensure a Successful Trial  
Intervention Delivery and Complexity

WATCH THE VIDEO

Pragmatic Trials 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.

What is a PRAGMATIC CLINICAL TRIAL? >

TRAINING RESOURCES >

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Rethinking Clinical Trials®

## Knowledge Checkpoint



- Why is it essential to engage partners early, even before the study design phase?
  - To meet regulatory requirements
  - To build relationships and ensure alignment with healthcare system goals
  - To increase data collection efficiency

## Knowledge Checkpoint



- Who are some of the key partners researchers should consider when designing and conducting ePCTs?
  - Only clinicians
  - Patients and caregivers, healthcare organization leaders, policymakers
  - Laboratory staff only

## Knowledge Checkpoint



- What is a critical aspect researchers should remember when partnering with healthcare systems for ePCTS?
  - Researchers should lead all study decisions independently
  - The healthcare system's primary goal is to provide good healthcare, not conduct research
  - Engagement is only necessary during study recruitment

# Question & Answer

