

Engaging and Aligning with Health System and Community Partners

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Disclosures

- Dr. Emily O'Brien receives support from Pfizer and BMS. No other disclosures to report.

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

How researchers approach partners 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

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**

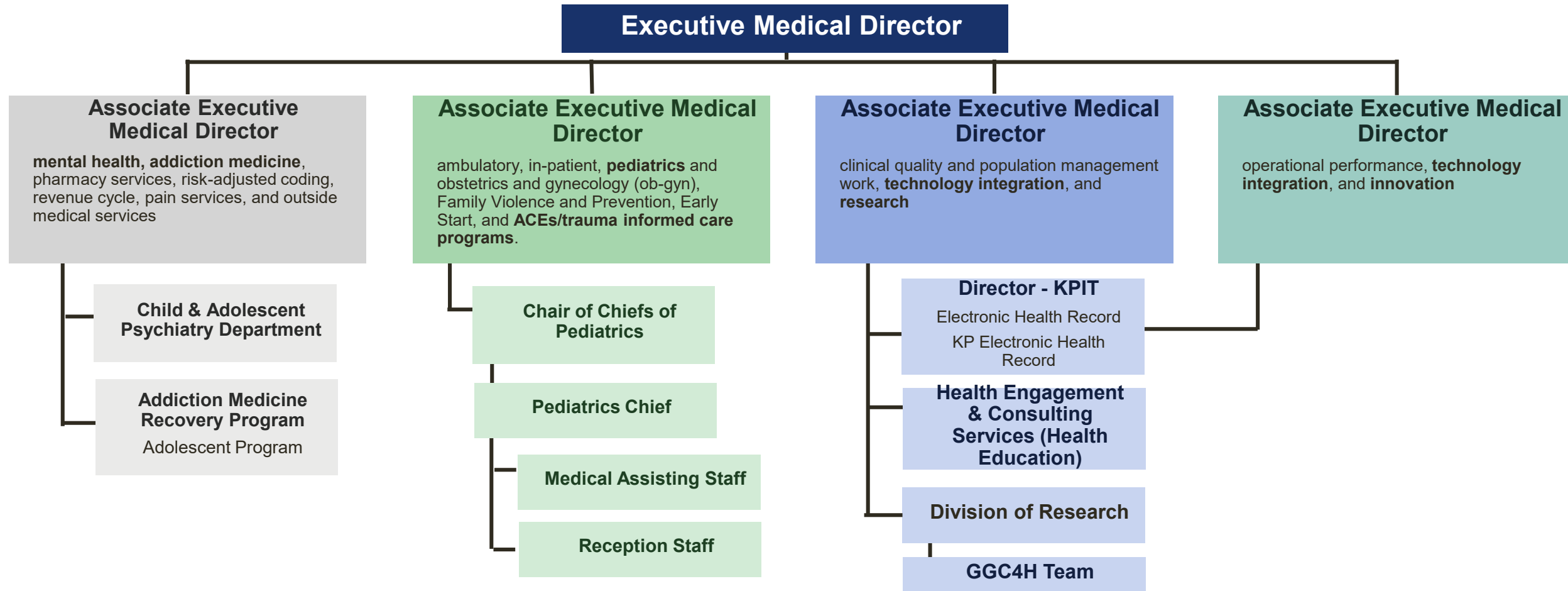
Who will be impacted? Who are the decision makers?



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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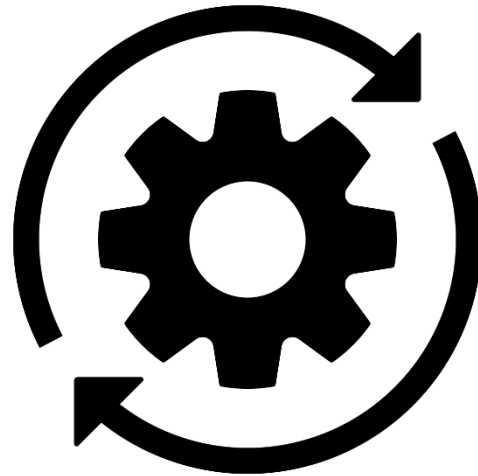
Choosing a salient question

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

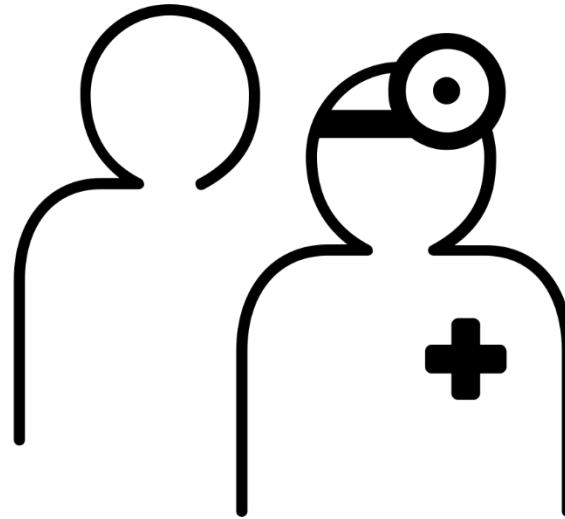


Source: Greg Simon, MD, MPH

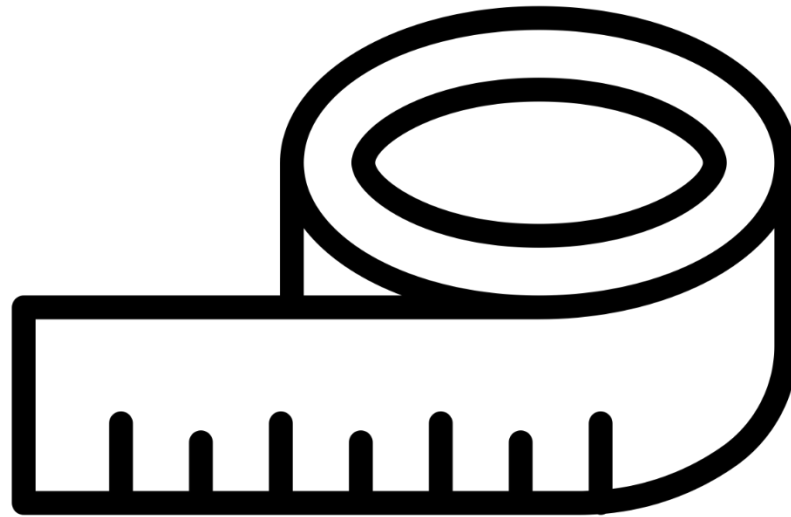
Designing the intervention for sustainment



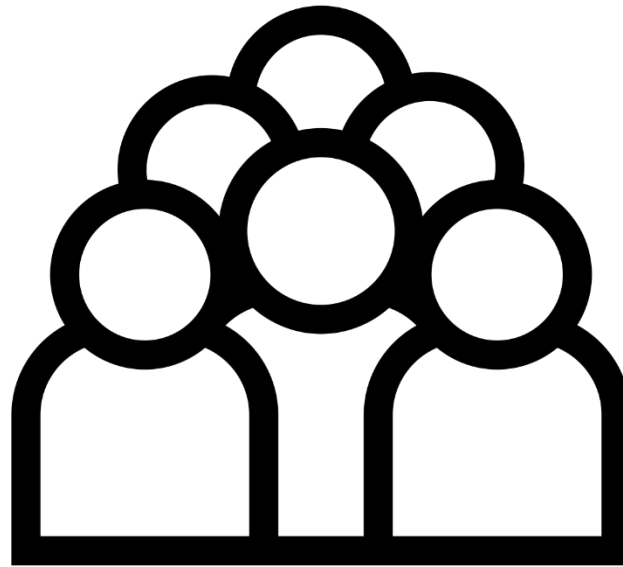
Designing the intervention to minimize burden for patients and clinicians



Selecting outcome measures



Determining inclusion and exclusion criteria



Roles of partners

1. Designing the trial
2. **Successfully conducting the research**
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Develop recruitment strategies



Integrating health equity in engagement



<https://impactcollaboratory.org/new-guidance-document-offers-best-practices-for-incorporating-health-equity-concerns-into-embedded-pragmatic-clinical-trials-for-dementia/>

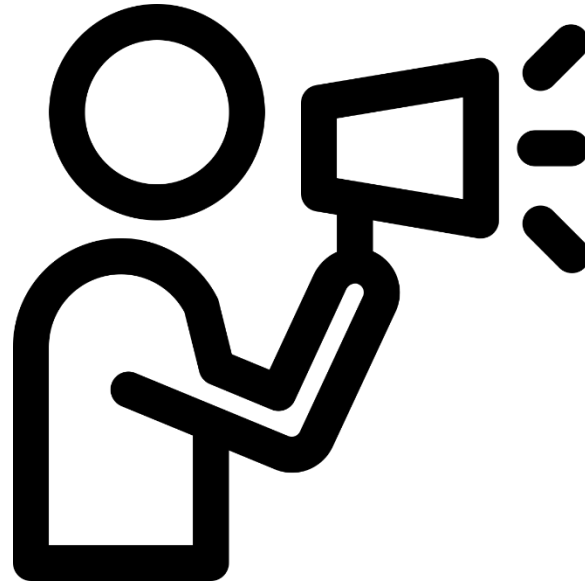
Example: Community Advisory Board

- 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

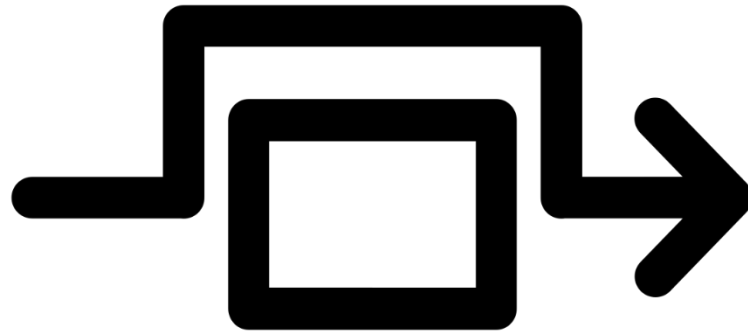
Example: Patient Advisory Panel

- 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

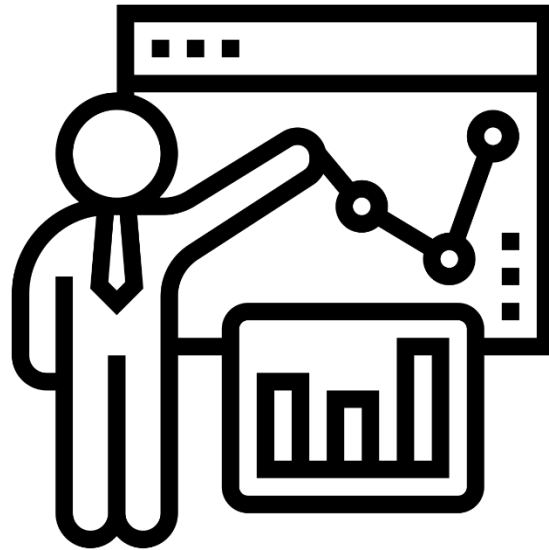
Serve as study champions



Track challenges and adaptations



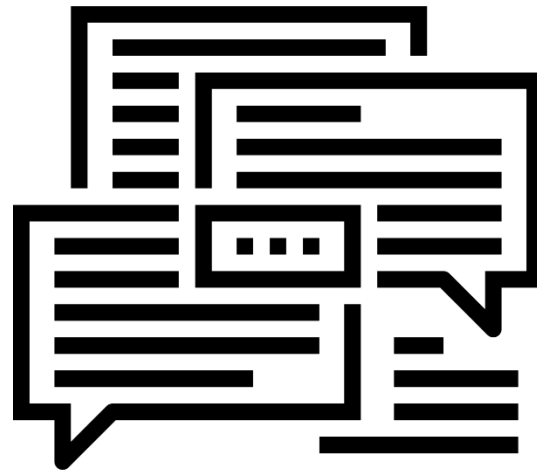
Interpret study results



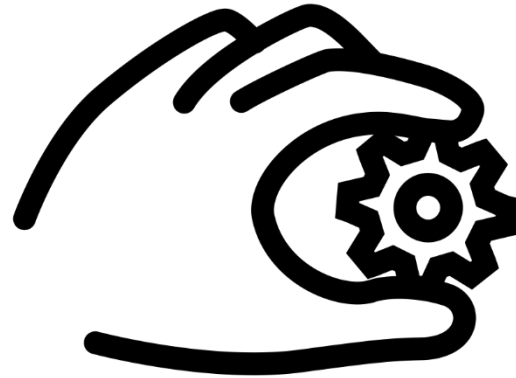
Roles of partners

1. Designing the trial
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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



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Design [View Chapters >](#) **Data, Tools & Conduct** [View Chapters >](#) **Dissemination** [View Chapters >](#) **Ethics and Regulatory** [View Chapters >](#)

What is a Pragmatic Clinical Trial? Endpoints and Outcomes Building Partnerships and Teams to Ensure a Successful Trial

Developing a Compelling Grant Application Analysis Plan Intervention Delivery and Complexity

Experimental Designs and Randomization Schemes Using Electronic Health Record Data

[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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Question & Answer



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