

Engaging and Aligning With Partners

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Learning goals



- Consider the breadth of individuals to engage as partners and approaches for engaging them throughout the study
- Discuss the importance of working with partners to plan for posttrial activities
- Identify infrastructure and expertise needs for cutting-edge information capabilities in ePCTs

Approaching partners in traditional clinical trials

Researcher reviews the literature



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



Researcher designs and conducts study, prepares manuscripts

ePCTs work differently.

Listen to the frontline

“*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 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, and engage partners continuously



Be patient:
Relationships take time to build and nurture



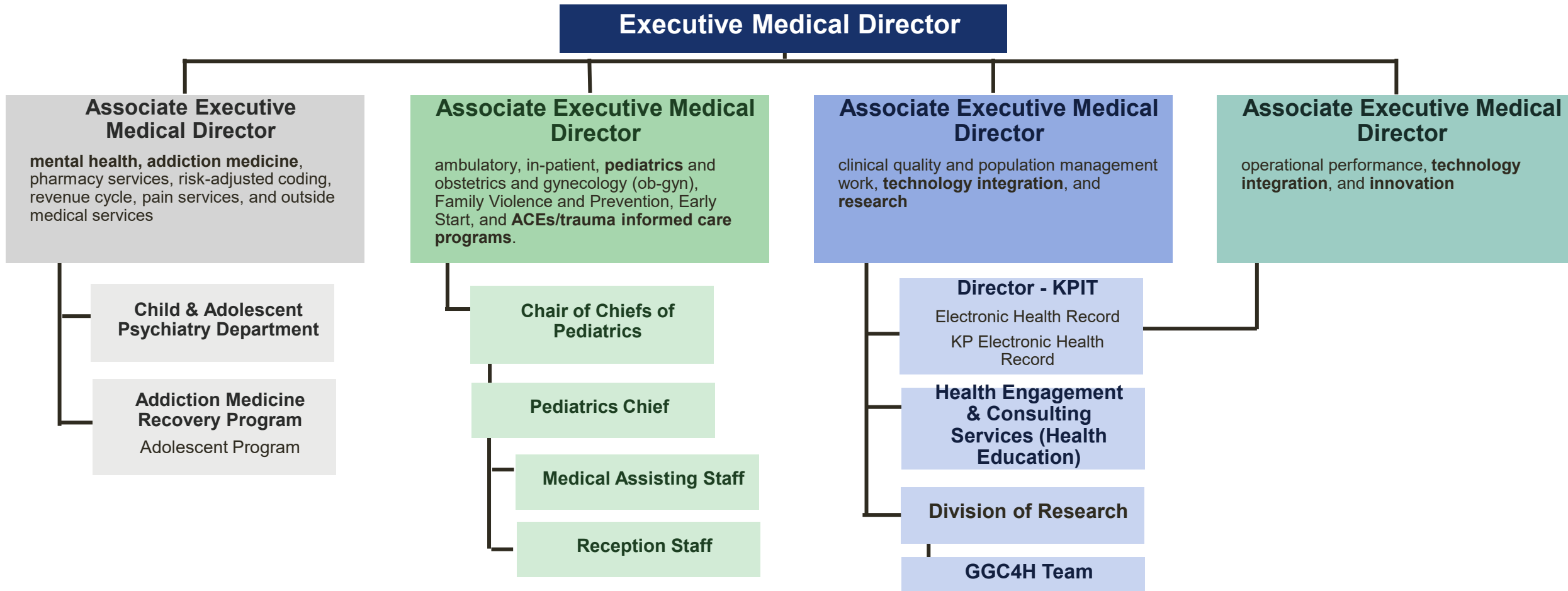
Expect changes and disruptions

Who will be affected? 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

Roles of partners

1. **Designing the trial**
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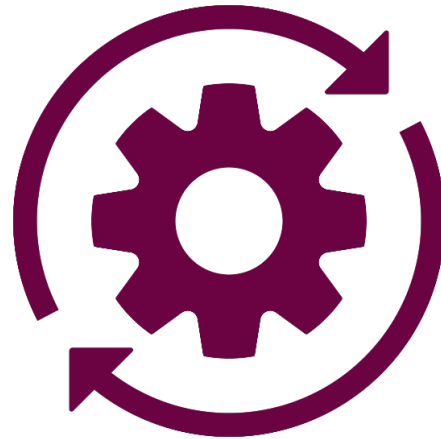
Choose a salient question

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



Source: Greg Simon, MD, MPH

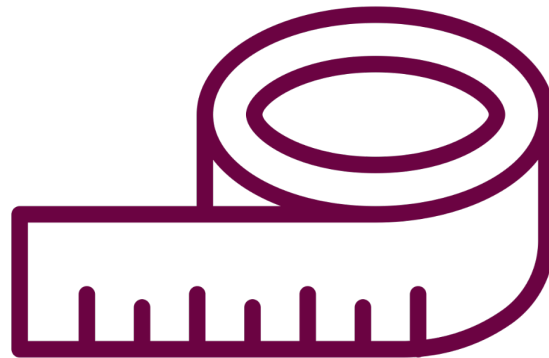
Design the intervention for sustainment



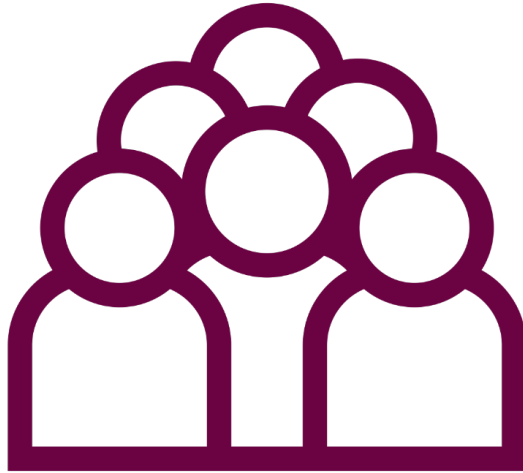
Design the intervention to minimize burden for patients and clinicians



Select outcome measures



Determine inclusion and exclusion criteria



Roles of partners

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



Example: Community advisory board

- Feedback from OPTIMUM's Community Advisory Board
 - Make materials more diverse and visually appealing
 - Include more of “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 by patient
 - Chat 4 Heart Health

Serve as study champions



Track challenges and adaptations



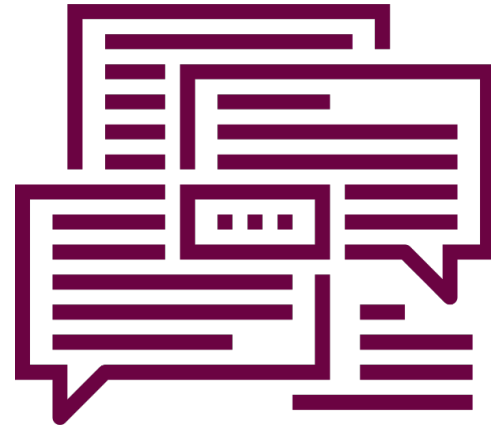
Interpret study results



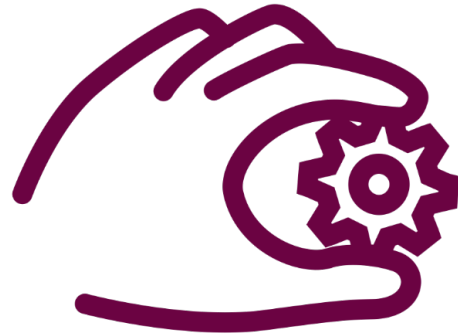
Roles of partners

- Designing the trial
- Successfully conducting the research
- **Disseminating the results**

Determine key messages for different groups
and identify avenues for dissemination



Support implementation or deimplementation



Consider changes to policies and guidelines



Important things to do



- Set expectations to work collaboratively and build trust from the beginning
- Get to know your partners' 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

Q&A



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Knowledge checkpoint



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

Knowledge checkpoint



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

Knowledge checkpoint



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