

ePCTs in Context

Small Group Work and Panel Discussion With NIH Collaboratory Trial Investigators



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Learning goals



- Hear a brief description of the NIH Collaboratory Trials being used as case studies for the small group activity
- Small group discussion
 - Breakout into small groups
 - Each group discusses 1 question
 - Report back to the group
- Panelists discuss how they handled the challenges
- Reflect on the challenges, solutions, and lessons learned, to include Q&A

NIH Collaboratory Trial panelists

- Sebastian Tong, MD, MPH — AIM-CP
- Michael Ho, MD, MPH — Chat 4 Heart Health

Small group discussion

AIM-CP

- **Scenario:** The study was designed to implement remote nurse care management approach for chronic pain in rural communities, including tele-visit for care coordination, cognitive behavioral therapy, and referral to a virtual exercise program. However, when enrolling patients in the pilot phase, many patients who would otherwise be eligible declined due to lack of broadband access, inability to use digital devices, and no access to devices to connect to audiovisual meetings.
- **Discussion Prompt:** What changes to the study could help increase enrollment?

Chat 4 Heart Health

- **Scenario:** The trial was designed to use an opt-out enrollment approach, whereby eligible patients identified through the EHR would be automatically included unless they declined participation. Just before the pilot year, the FCC introduced new rules requiring opt-in consent for text messaging. As a result, participating health systems determined verbal consent would now be required before sending study-related text messages. The original enrollment target was approximately 2,100 patients.
- **Discussion Prompt:** Given this regulatory change, how would you redesign or adapt the patient enrollment strategy to meet study goals while remaining compliant?

Reflection on today's topics

- Opportunities for pragmatic research
- Engaging and aligning with partners
- Design considerations
- Innovative methods

