NIH Collaboratory Coordinating Center: Overview and Goals

Project Onboarding Meeting November 01, 2023

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Why We're Here

 The Coordinating Center works with the Demonstration Projects to optimize their capacity to complete their trials and contribute generalizable knowledge.



How We Do It

- Track each project
 - Monitor timelines and milestones
 - Document achievements, challenges, and solutions
- Incorporate lessons learned from projects into ongoing work
- Promote discussion across projects
 - Share experiences and promising approaches





Cores Are Central to Our Approach

Biostatistics and Study Design

Electronic Health Records

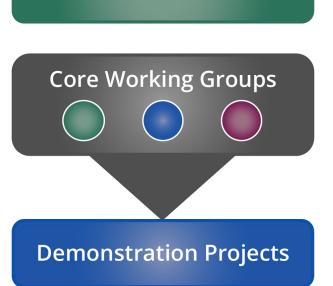
Ethics and Regulatory

Health Care Systems Interactions

Health Equity

Implementation Science

Patient-Centered Outcomes



Coordinating Center

- Led by Chairs from Coordinating Center
- Representatives from
 <u>Demonstration</u>
 <u>Projects</u> and NIH



Cores Provide Tailored Expertise & Support

Trial Planning: Example Services

Assist with

- Creating analysis plans
- Identifying data standards
- Defining study endpoints
- Designing appropriate consent practices
- Assessing feasibility of workflows
- Determining optimal data collection methods

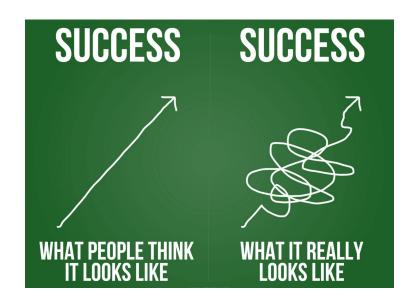
- Provide guidance on
 - Study design
 - Minimizing burden on clinical staff
 - Strategies for identifying and enrolling potential participants
 - Improving diversity, equity, and inclusion
 - Engaging stakeholders
 - Implementation science components



Cores Provide Tailored Expertise & Support

Trial Conduct: Example Services

- Ongoing support
 - Navigating ethical/regulatory issues
 - Communicating with stakeholders



Provide guidance on

- Assessing data quality
- Data analysis
- Removing barriers to participation
- Responding to unexpected developments
- Implementing contingency plans
- Disseminating results
- Implementation approaches



Cores Disseminate Knowledge

- Develop strategies, best practices, and tools
- Create guidance, policies, and technical documents
 - Use case studies and lessons learned from Demonstration Projects

Active participation of Demonstration Project Pls is integral to this work!

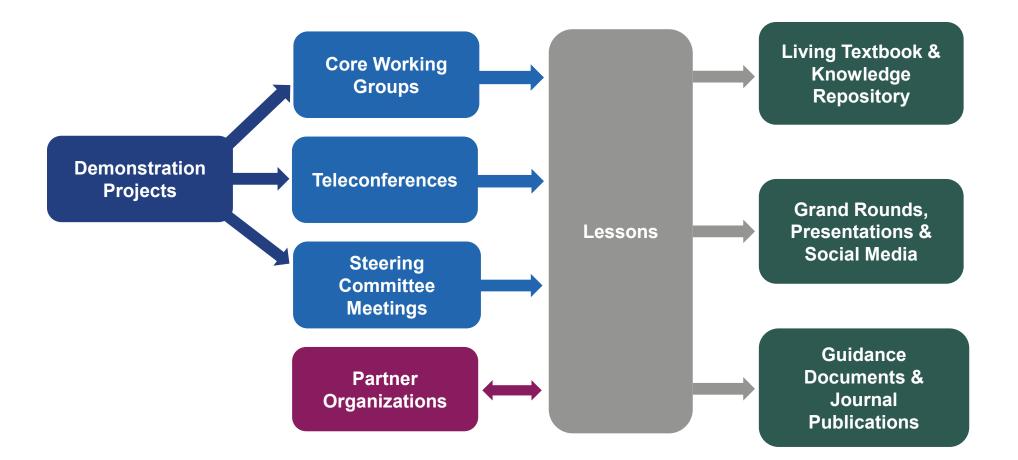
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Perspective	Richard Platt, M.D., Gregory E. Simon, M.D., and Adrian F. Hernandez, M.D.	https://doi.org/10.1180/s15000-02 Open A	Research Article	
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Steering Committee

- Monthly calls and annual in-person meeting promote sharing and synergy across the program
 - Discuss trial progress
 - Identify issues
 - Create plans to provide support
 - Share knowledge
 - Foster collaboration



Flow of Information





What We've Learned



Our Experience

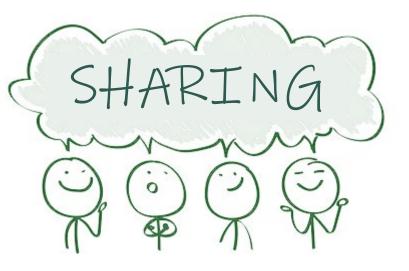


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Spirit of Openness Fuels Progress

- Program's success depends on investigators' willingness to share challenges in real time with rest of the network, including NIH staff
- In many research programs, investigators feel motivated to present an image of perfection to everyone outside their project, esp. sponsors
- Good faith, generosity, and candor of NIH Collaboratory investigators allows transformation of challenges into lessons that can be shared with the broader community





Planning Phase Is Essential

- Nothing is "plug and play" in a PCT within a healthcare system
- Planning phase allows further engagement with stakeholders, consultation with other experts, and collection of pilot data
- Resulted in important protocol changes in all Collaboratory trials
- Despite planning, challenges often arise during execution requiring midcourse corrections





Early and Ongoing Engagement Is Critical

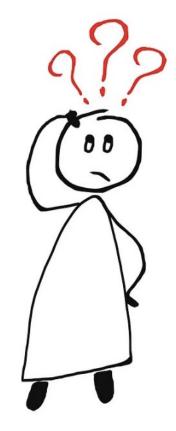
- With healthcare systems
 - Need strong and trusting partnerships
 - Align research and organizational goals
- With clinicians
 - Ensure intervention can be added into existing workflows as seamlessly and with as little burden as possible





Uncertainty of Ethics and Regulatory Frameworks

- Ambiguity about how best to protect rights and welfare of participants in pragmatic trials context
 - How to define "minimal risk" in high-risk populations
 - Appropriate reporting of adverse events
 - Challenges applying standard ethics and regulatory frameworks





Unanticipated Changes Can Occur

- In conventional RCTs, it is possible to exert significant control over what happens in the study arms
- In PCTs, investigators can face:
 - Competing initiatives at study sites
 - Provider resistance due to burden
 - Poor implementation fidelity due to staff turnover



 Careful monitoring of study sites can help investigators prevent, or at least describe, changes that might affect the study comparison



Leveraging EHRs Adds Complexity

- Challenges include
 - Need for cross-site data standardization
 - Site-level differences in preferred methods for implementing standardized assessment tools
 - Integration of study-related data elements into EHRs optimized for clinical practice or billing





Opportunities for Promoting Health Equity

- PCTs well positioned to reduce barriers to research participation that have historically limited diversity in trials
- However, barriers to care mean patients who access healthcare systems not always representative of larger community
- Collaboratory poised to explore methods for
 - Diversifying research sites
 - Engaging with stakeholders to improve diversity, equity, and inclusion in research





Conclusions

- Take advantage of support and expertise available from the Coordinating Center
- Open sharing will fuel our collective success
- Cost-effective, large-scale research is possible, and we have the charge to scale it...
 - By learning, sharing, and helping the ecosystem evolve



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®