

NIH Collaboratory Coordinating Center: Overview and Goals

Project Onboarding Meeting
July 17, 2023

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Why We're Here

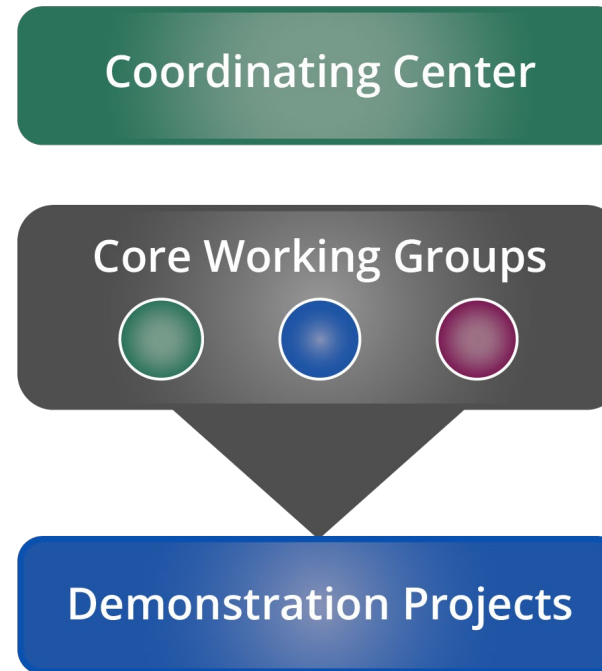
- The Coordinating Center works with the Demonstration Projects to optimize their capacity to **complete their trials** and **contribute generalizable knowledge**.

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



- Led by Chairs from Coordinating Center
- Representatives from Demonstration Projects 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

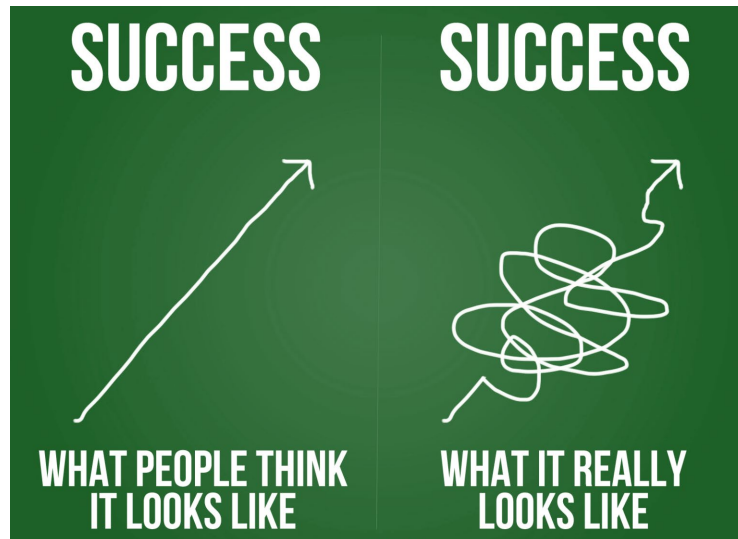
Trial Conduct: Example Services

- **Ongoing support**

- Navigating ethical/regulatory issues
- Communicating with stakeholders

- **Provide guidance on**

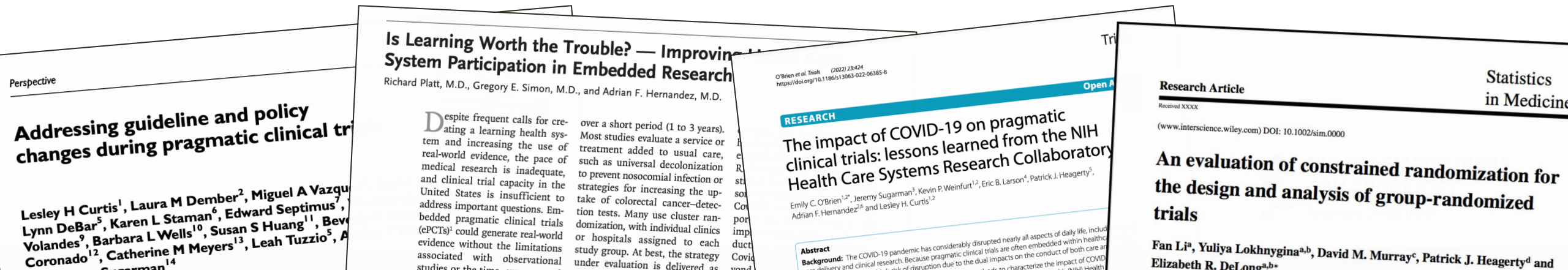
- Assessing data quality
- Data analysis
- Removing barriers to participation
- Responding to unexpected developments
- Implementing contingency plans
- Disseminating results
- Implementation approaches



Cores Disseminate Knowledge

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

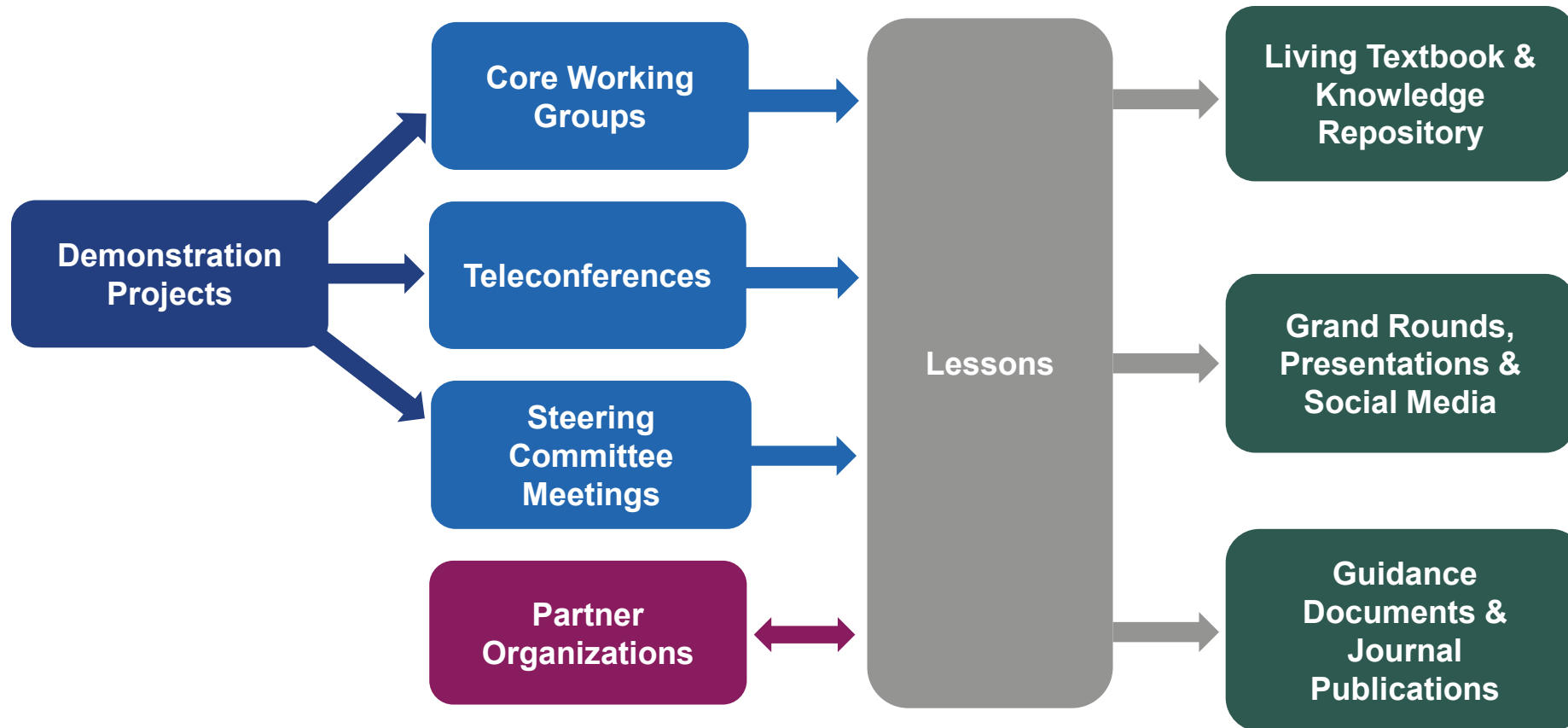
Active participation of Demonstration Project PIs is integral to this work!



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



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Our Experience

26 PCTs

11 years

>100
investigators

>200
publications

Nearly
1 million
enrolled

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



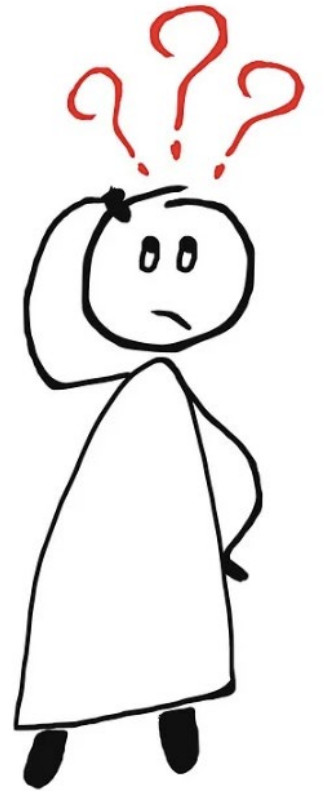
Early and Ongoing Engagement Is Critical

- 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



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