Working With the NIH Collaboratory Coordinating Center

Adrian Hernandez, MD

January 8, 2025

NIH PRAGMATIC TRIALS COLLABORATORY

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Coordinating Center

Functions

- Provide national leadership and technical expertise
- Produce, document, and disseminate standards
- Support synergy within program
- Coordinate communication and dissemination
- **Help you be successful!**

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Coordinating Center Leadership

Principal Investigators	
Adrian Hernandez, MD, MHS	Administrative responsibilities, Grand Rounds, liaison to the Biostatistics and Study Design Core, Health Care Systems Interactions Core, etc
Lesley Curtis, PhD	Chair of the Steering Committee, liaison to the EHR Core, Implementation Science Core, etc
Kevin Weinfurt, PhD	Editor-in-Chief of the Living Textbook, liaison to the Ethics and Regulatory Core, PCO Core, Health Equity Core, etc
Operations	
Tammy Reece, MS, PMP	NIH Collaboratory Project Director, partners with Coordinating Center Principal Investigators, and provides day-to-day oversight of operational activities
Marijo Mencini	Project Leader, Grand Rounds, works closely with Project Director on operational activities

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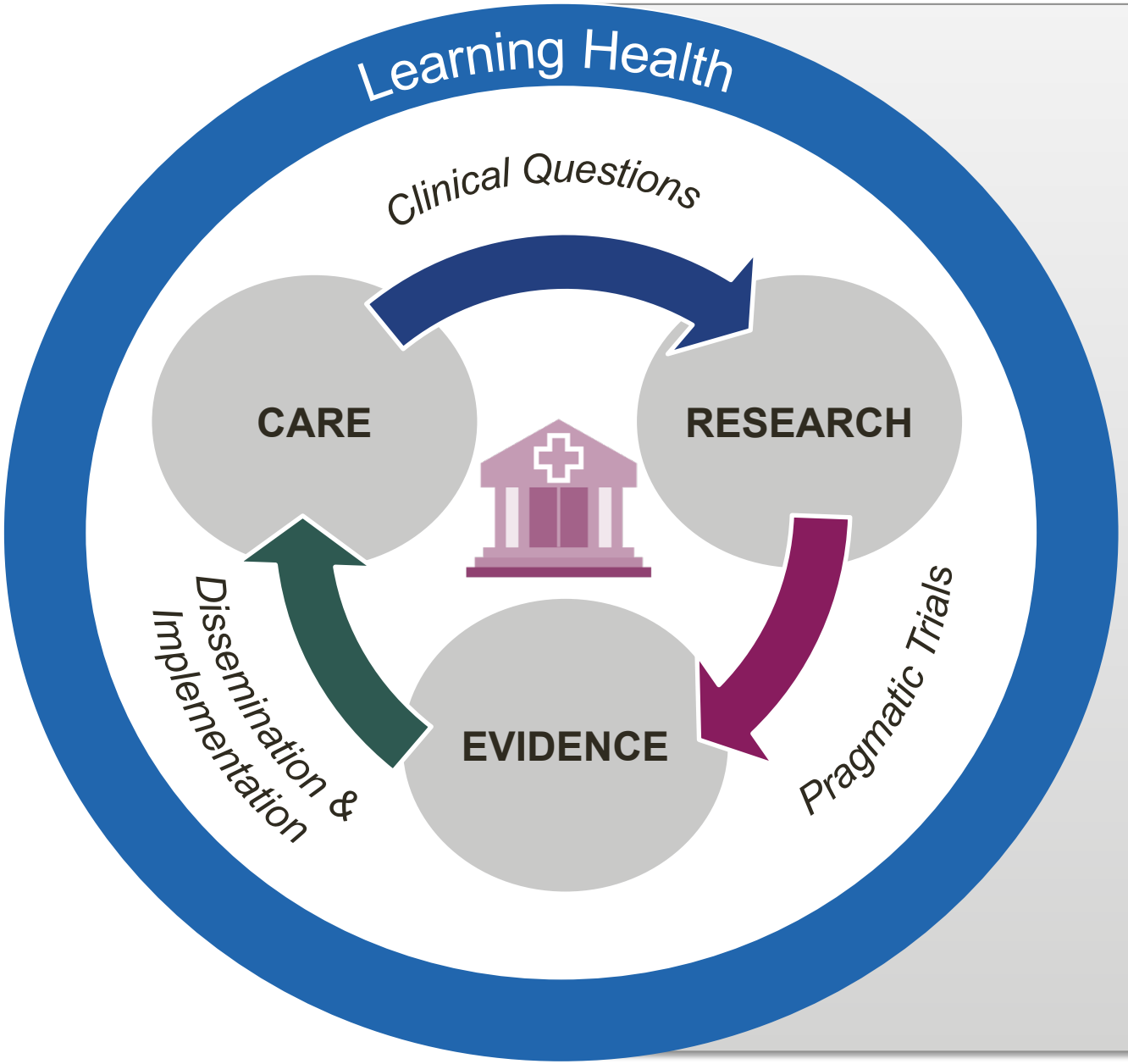

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SUPPORT SERVICES

- Consult and provide guidance on:
  - Study design and analysis
  - Regulatory issues and consent practices
  - Use of EHR and real-word data sources
  - Translating results into practice
- Offer strategies to:
  - Improve diversity, equity, and inclusion
  - Engage health system partners
- Assist with:
  - Defining study endpoints
  - Measuring patient-centered outcomes
  - Assessing feasibility of clinical workflows
  - Addressing challenges that arise

We've learned a lot about how to integrate research with practice…

- Using EHRs for research is complex
- Unexpected changes occur, but there are ways to mitigate their effects
- Strong partnerships with healthcare systems are essential
- Some ethical and regulatory uncertainties remain
- Many factors involved in whether an intervention will be sustained
- **Sharing challenges and lessons promotes success, advances methods**

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Question:
Does an EHR-based outreach program with mailed stool-tests improve rates of colorectal cancer screening?

Pragmatic Trial:
26 FQHC clinics randomized to routine care or intervention

stop screen to prevent colon cancer

NIH Collaboratory Support:

- *Biostatistics:* Extensive support to modify analysis, develop secondary analysis
- *Data:* Helped team learn and implement standards and methods for validating EHR code
- *Overall:* Knowledge sharing, troubleshooting

Study Population:
>40,000 patients and ~6,300 mailed stool-tests

Results:
Significantly improved screening rates

Clinical Impact:

Adopted intervention
in at least 150 clinics

Implementation materials
published to support uptake

Care → Research → Evidence

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FQHC, federally qualified health center

Resources Available to You

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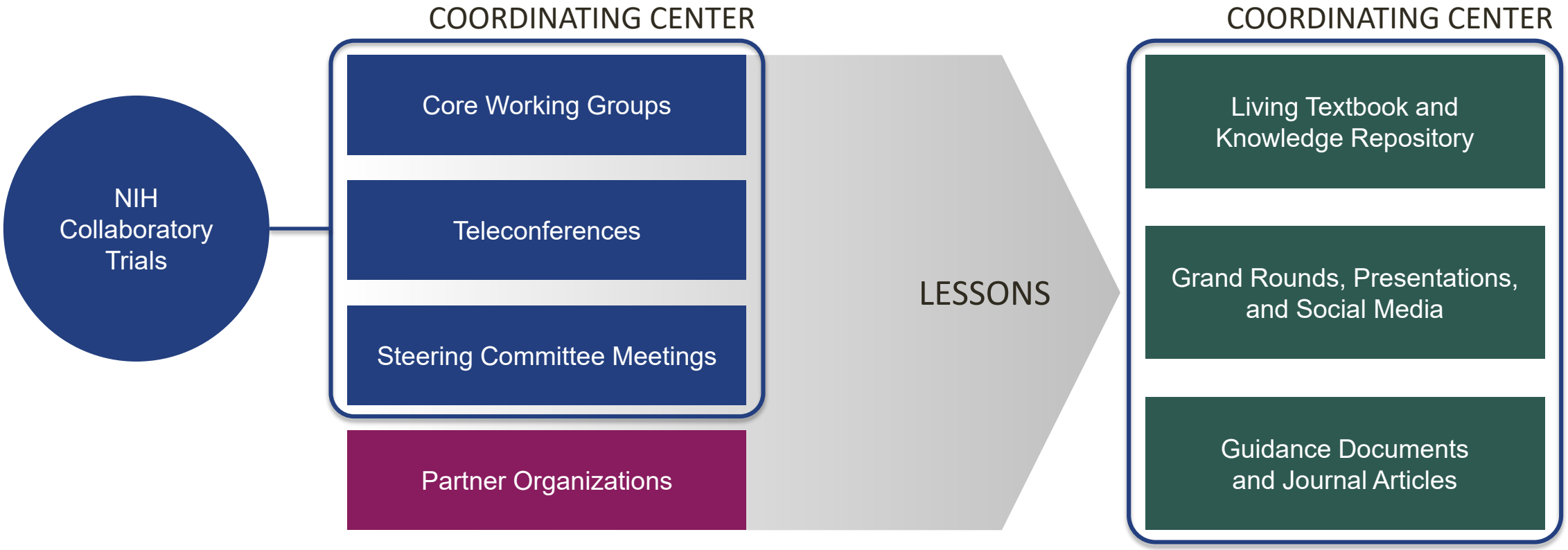
How We Share Information



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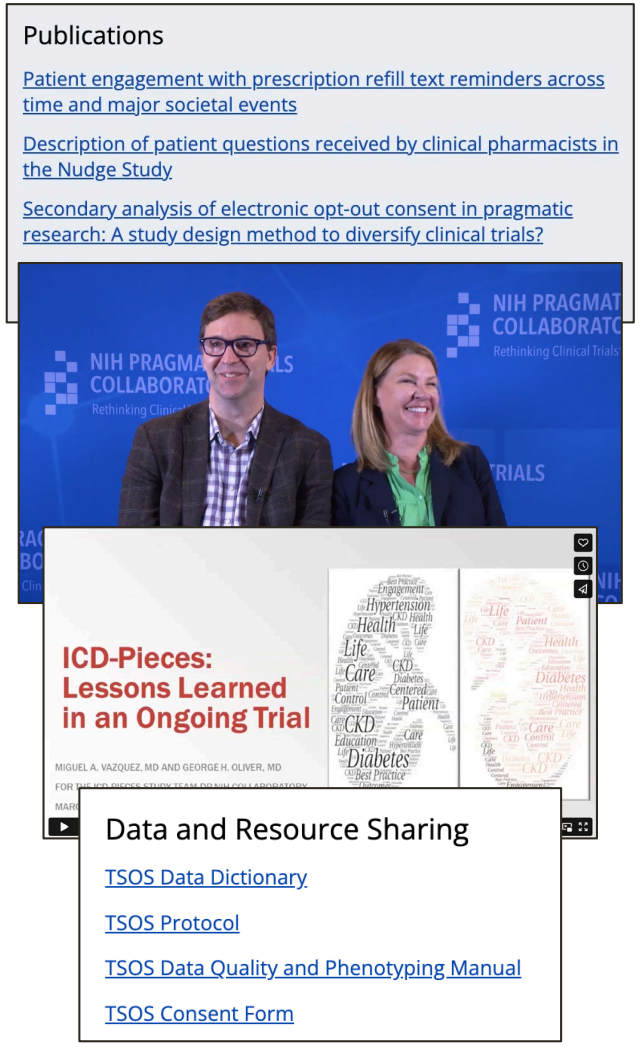
Learn From Other Trials

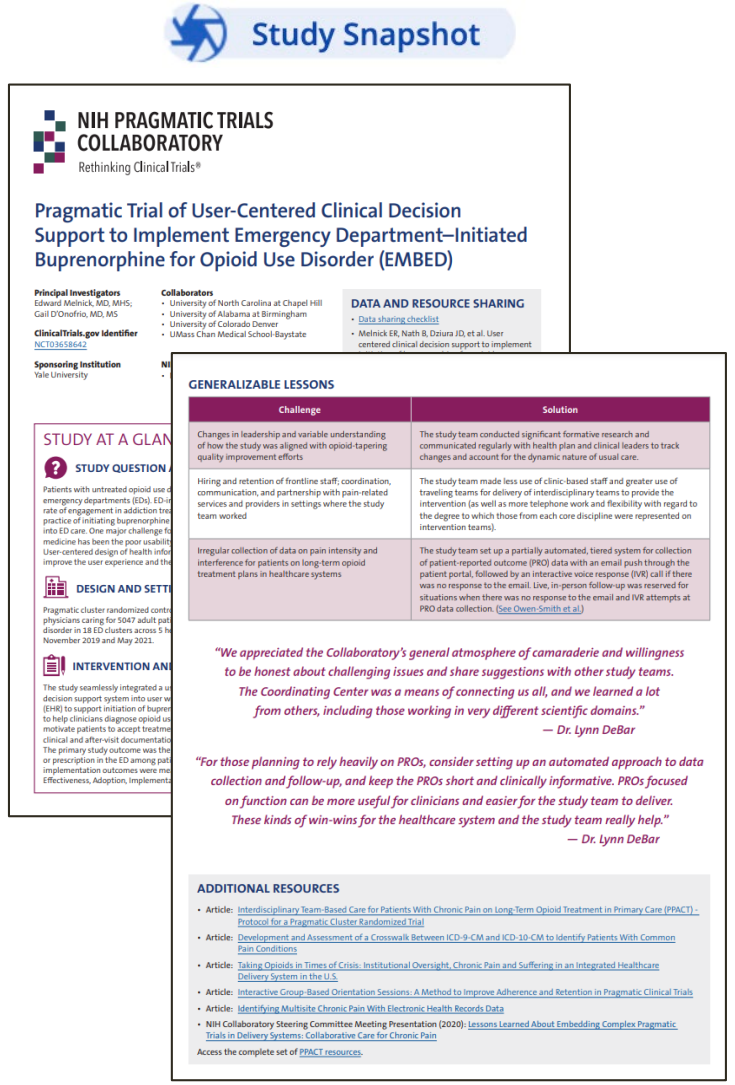
TRIAL WEBPAGES

- Trial details
- Interviews
- Publications and presentations

DATA AND RESOURCE SHARING

- Study tools
- Documentation





Living Textbook

rethinkingclinicaltrials.org

30+ chapters

TOPICS INCLUDE:

Design

- Developing a Grant
- Experimental Designs
- Building Partnerships
- Patient Engagement
- What Is a Pragmatic Trial
- Endpoints and Outcomes
- Using EHR Data
- Intervention Complexity

Data, Tools, and Conduct

- Assessing Feasibility
- Acquiring and Assessing Real-World Data
- Study Startup
- Participant Recruitment
- Monitoring Fidelity
- Clinical Decision Support
- PROs

Dissemination

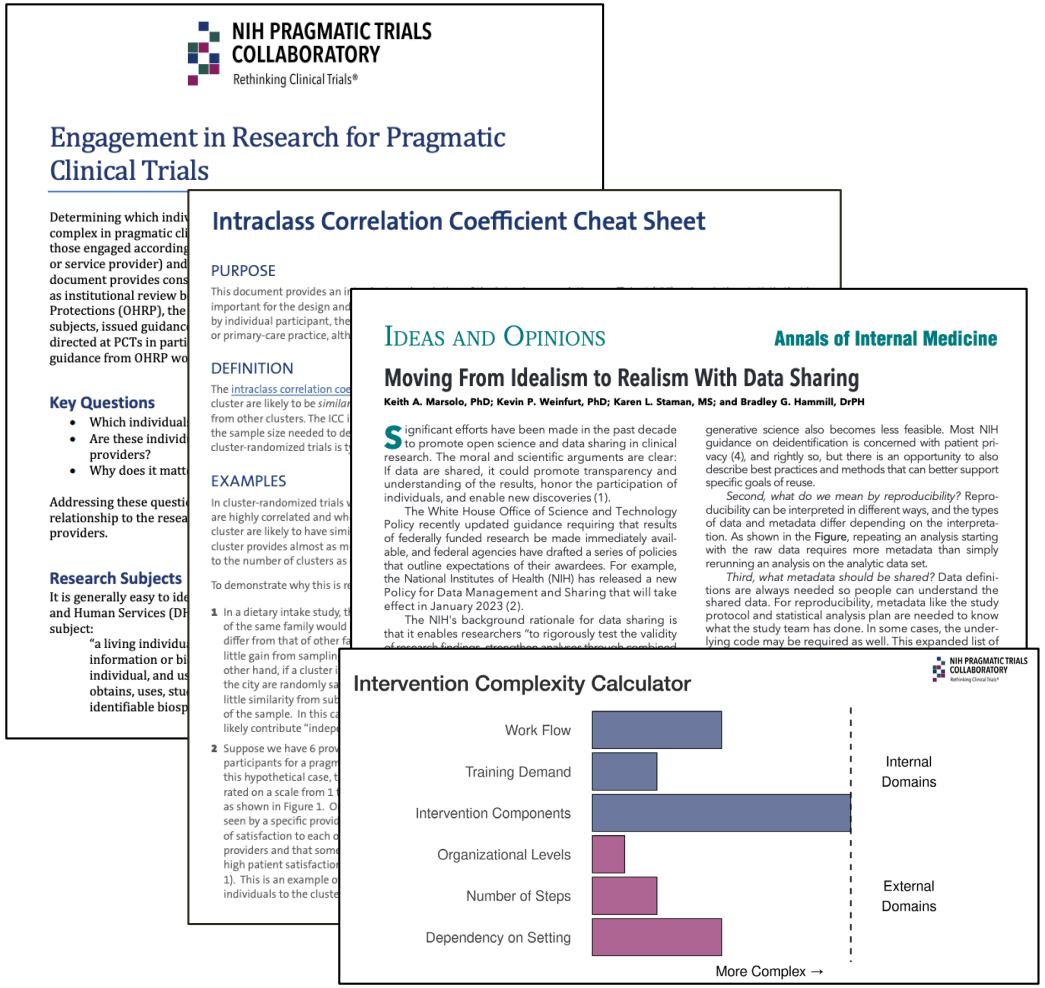
- Data Sharing
- Dissemination
- Implementation

Ethics and Regulatory

- Privacy
- Consent, Waiver, and Notification
- Collateral Findings
- Data Monitoring
- Single IRB

Tools and Guidance Documents

CHEAT SHEETS	• Intraclass Correlation Coefficient • Equitable Language • Assessing Fitness-for-Use of Clinical Data for ePCTs
TOOLS & TOOLKITS	• Intervention Complexity Calculator • Patient-Centered Outcomes Toolkit • Data Sharing Information • Quick Start Guides
TEMPLATES & CHECKLISTS	• Data Monitoring Committee Charter • Reporting ePCTs Template • Trial Documentation Checklist • Data Sharing Checklist
GUIDANCE DOCUMENTS	• Engagement in ePCTs • Assessing Data Quality • Cluster Randomized Trial Design • Data Sharing



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Transition Preparation Support

- Discuss plans and potential barriers with Cores
- Provide regular progress updates to SC
- Open sharing of challenges and lessons learned
- Implementation Readiness Checklist

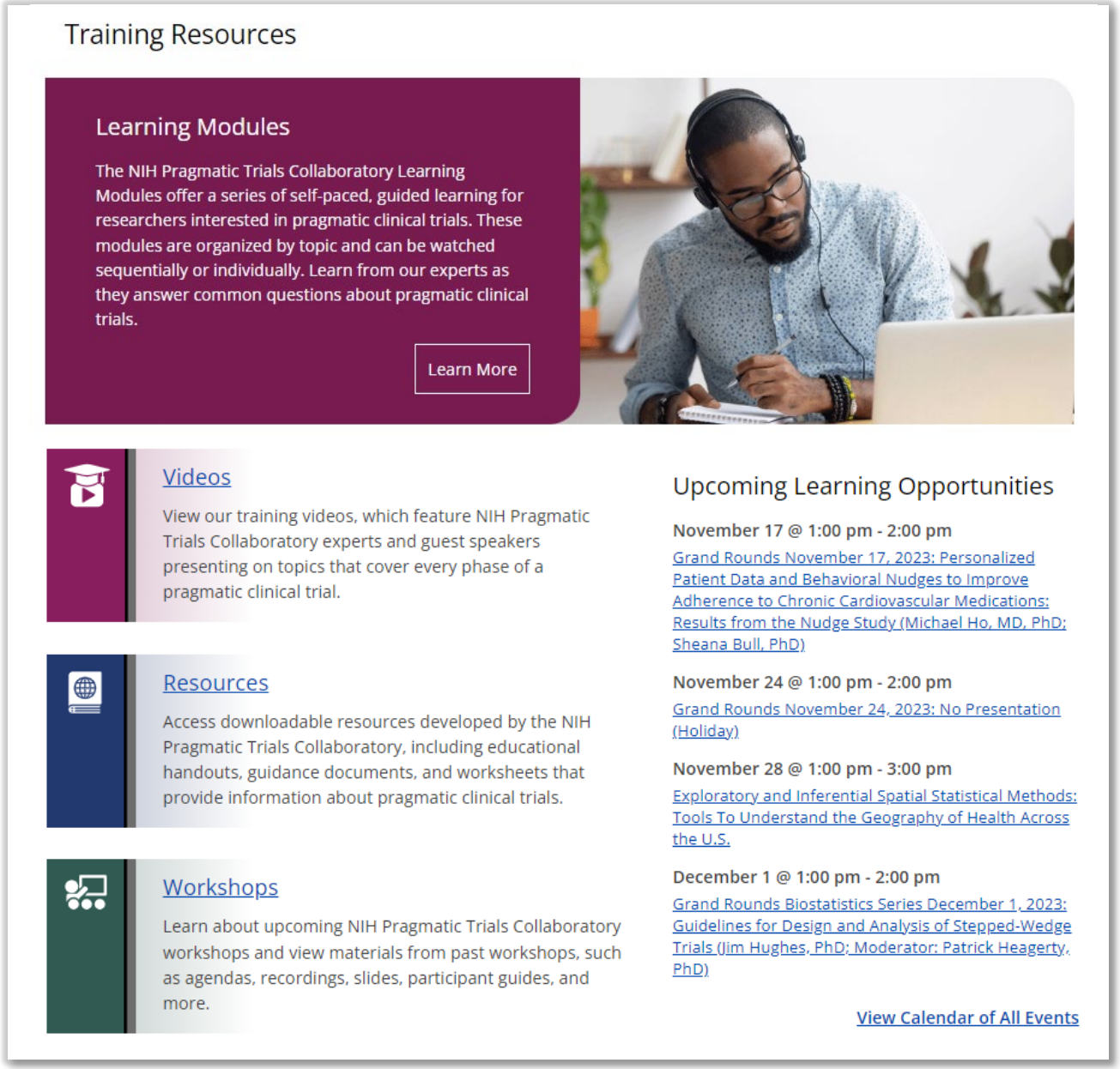
Implementation Readiness Checklist

Milestone	Completed
Recruitment plans are finalized	
All sites identified (documentation of site commitment)	
Methods for accurately identifying participants validated	
All agreements for necessary subcontracts in place	
Ethical/regulatory aspects are addressed	
Coordinated IRB oversight in place	
Finalized plans for informed consent or waiver of informed consent	
Finalized data and safety monitoring plan	
Intervention is fully developed and finalized	
Finalized intervention (including materials and training at sites) ready for site implementation	
Finalized protocol is IRB approved (informed consent and data collection forms, if applicable)	
Data collection methods are adequately tested	
Validated methods for the electronic health record information	
Validated study surveys, interviews, or other data collection modes	
Demonstrated quality assurance and harmonization of data elements across healthcare systems/sites	
Statistical and data analysis methods have been adequately developed	
Budget is realistic, feasible, and accounts for potential changes	

ePCT Training Resources

rethinkingclinicaltrials.org/training-resource/

- Learning modules
- Video library
- Resources (handouts, checklists, guides, etc)
- Workshop materials (slides, recordings, etc)
- Upcoming opportunities



Rethinking Clinical Trials® Grand Rounds

Weekly webinars

- **Fridays 1-2 pm ET**
- Open to public
- >500 held to date
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

Podcast episodes

- >40 available

Keep In Touch

Publishing or presenting?

Keep us informed so we can track and help promote your work

nih-collaboratory@dm.duke.edu

Monthly email newsletter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April 2022 • Subscribe to the Newsletter • Living Textbook • Grand Rounds Hub

News From the NIH Pragmatic Trials Collaboratory

FDA Commissioner Rob Califf Reflects on Origins and Impact of NIH Pragmatic Trials Collaboratory

In a keynote speech at the NIH Pragmatic Trials Collaboratory Steering Committee annual meeting, Dr. Rob Califf called for more and faster evidence generation. "We have to generate evidence more quickly and then insist that it gets used," he said. After his remarks, Califf joined Dr. Wendy Weber of the National Center for Complementary and Integrative Health to reflect on the origins and impact of the program. Califf was the first principal investigator of the program's Coordinating Center. View the full interview.

FDA Announces Draft Guidance for Increasing Diversity in Clinical Trials: The US Food and Drug Administration issued draft guidance recommending clinical trial sponsors develop a "race and ethnicity diversity plan" to ensure representative enrollment of racially and ethnically diverse participants in clinical trials developing medical products.

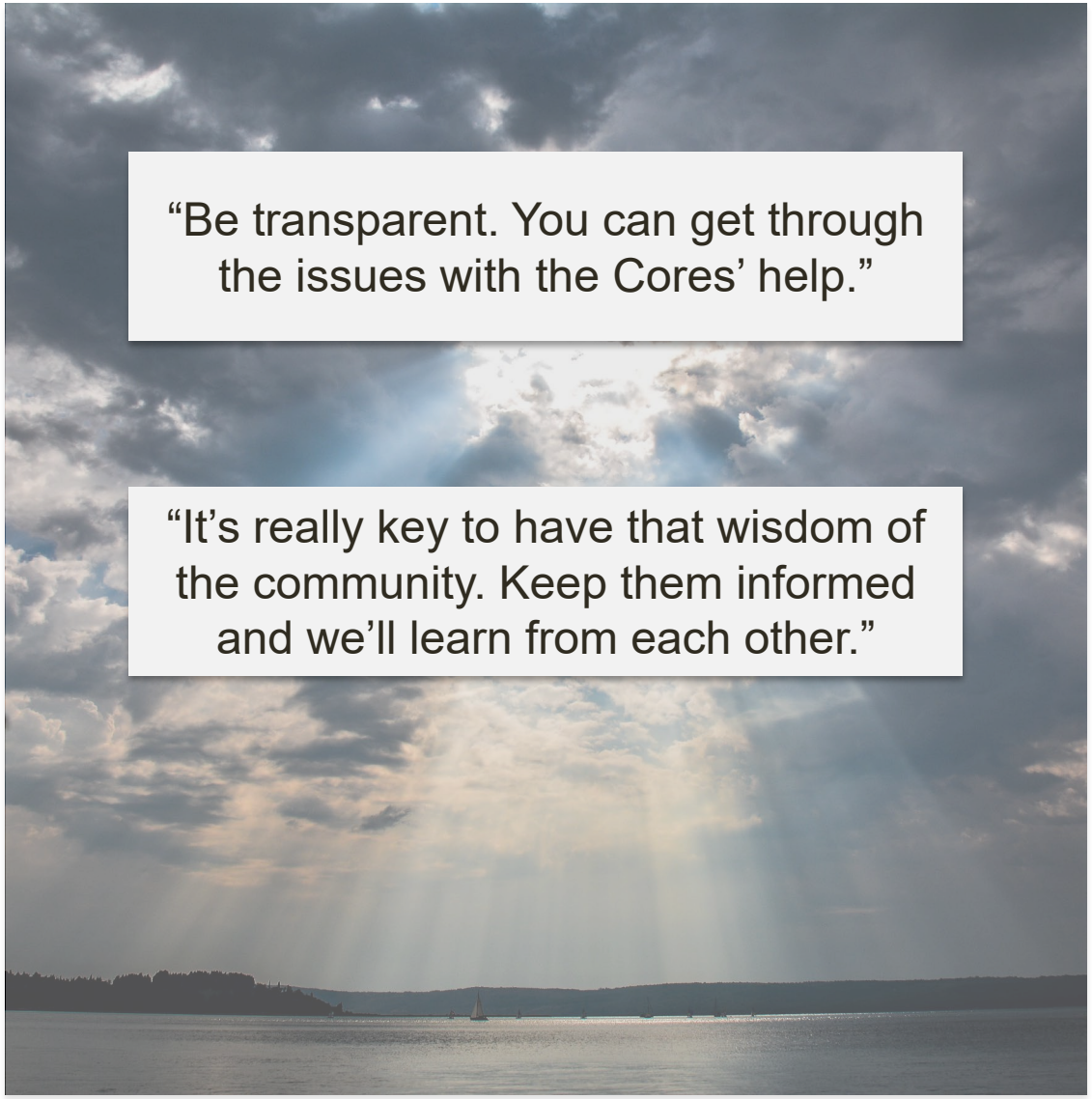
TSOS Implements Suicide Assessment and Monitoring Method: The TSOS study, an NIH Collaboratory Demonstration

Follow Us

Reach out anytime—we're here to help!

The Year Ahead

- Tips for Year 1 Handout includes advice from other investigators
- Recommend delegating to your team to work through the tight timeline
- Be engaged and share openly
- **A whole community is here to support you**



Up Next: Core Working Groups Introduction

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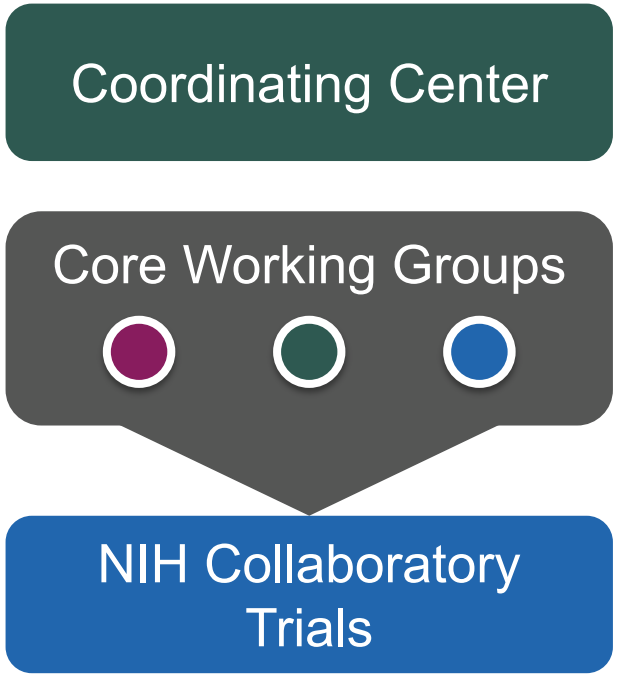
Core Working Groups

- Component of Coordinating Center focusing on key areas of ePCTs
- Led by Chairs from Coordinating Center
- Include representatives from
  - NIH Collaboratory Trials
  - NIH



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Core Working Groups: Purpose

COORDINATING CENTER

- Biostatistics and Study Design
- Electronic Health Records
- Ethics and Regulatory
- Health Care Systems Interactions
- Health Equity
- Implementation Science
- Patient-Centered Outcomes

- Guide and support NIH Collaboratory Trials
- Disseminate knowledge
  - Guidance
  - Lessons learned

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