Working With the NIH Collaboratory Coordinating Center

Adrian Hernandez, MD, MHS

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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, Community Health Improvement 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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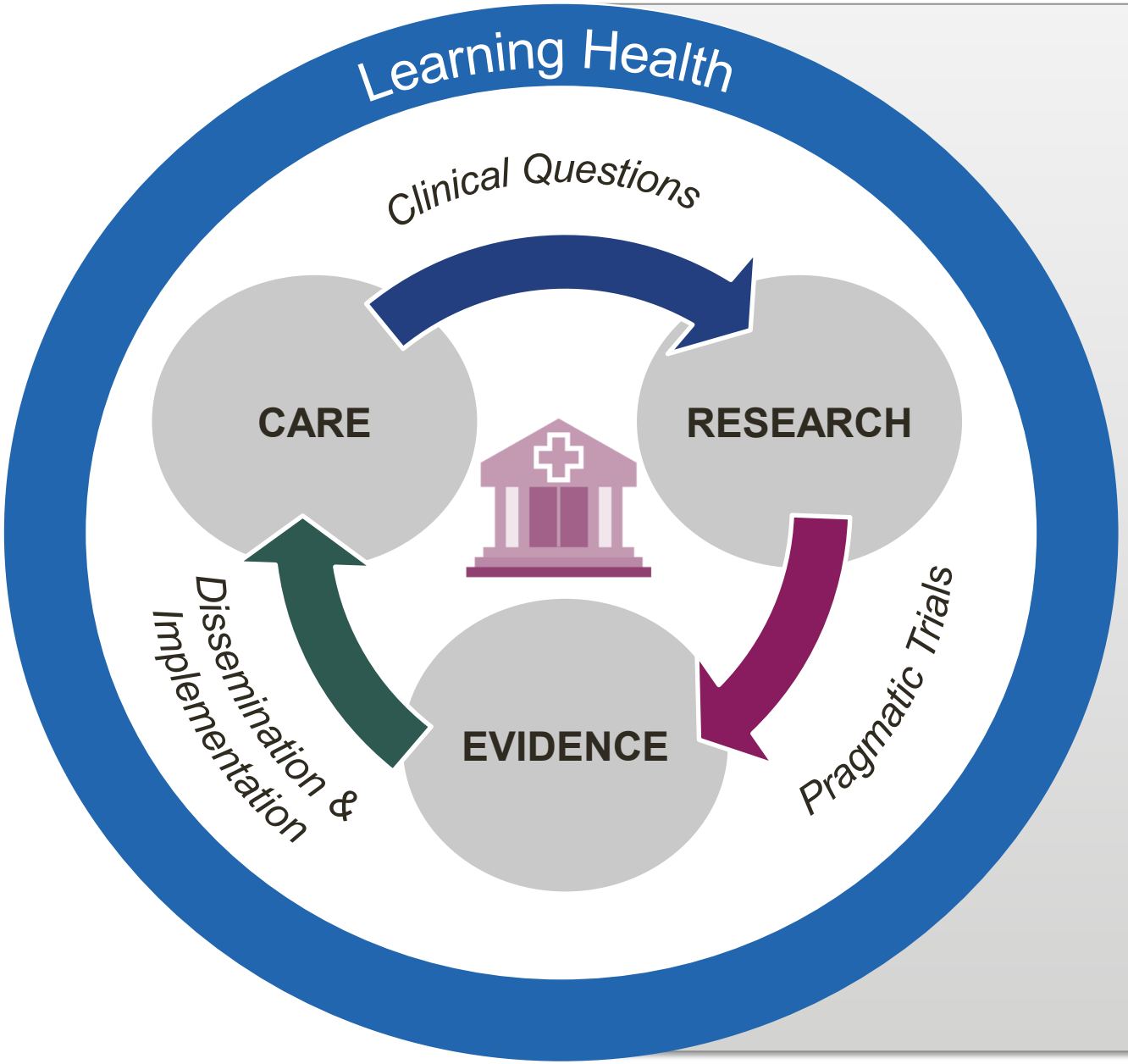

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SUPPORT SERVICES

- 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:
  - Contribute to healthier communities
  - Engage healthcare 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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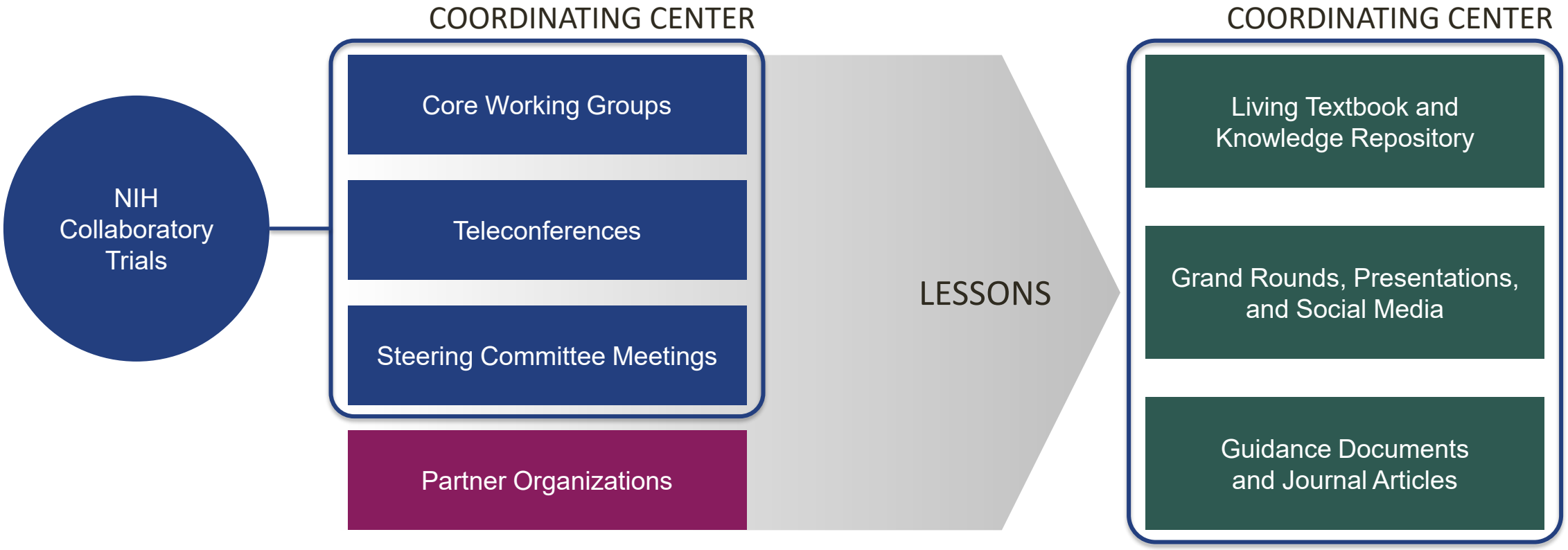
How We Share Information



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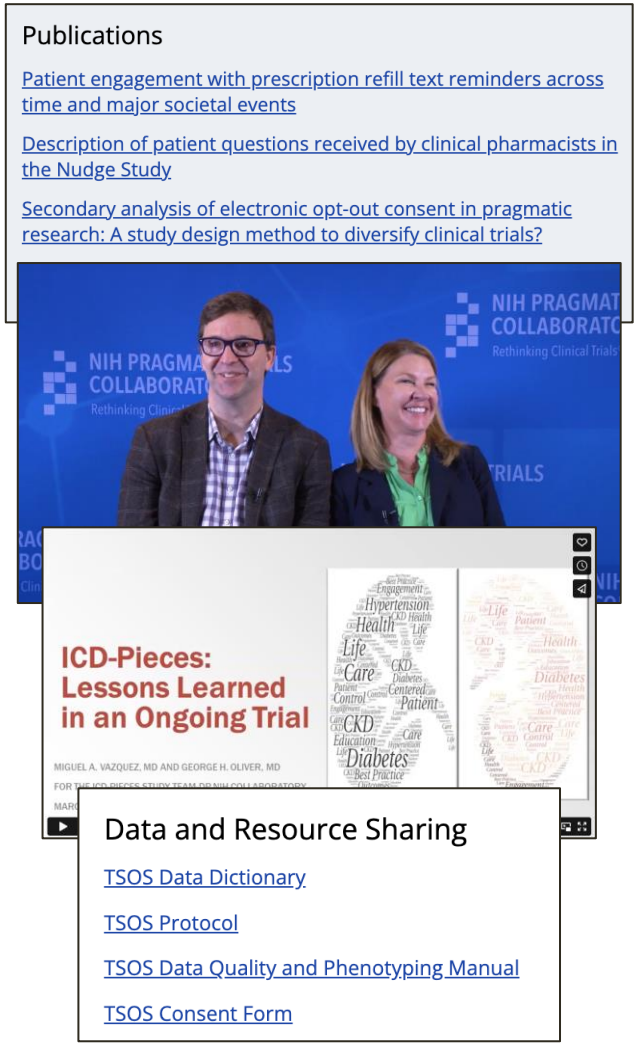
Learn From Other Trials

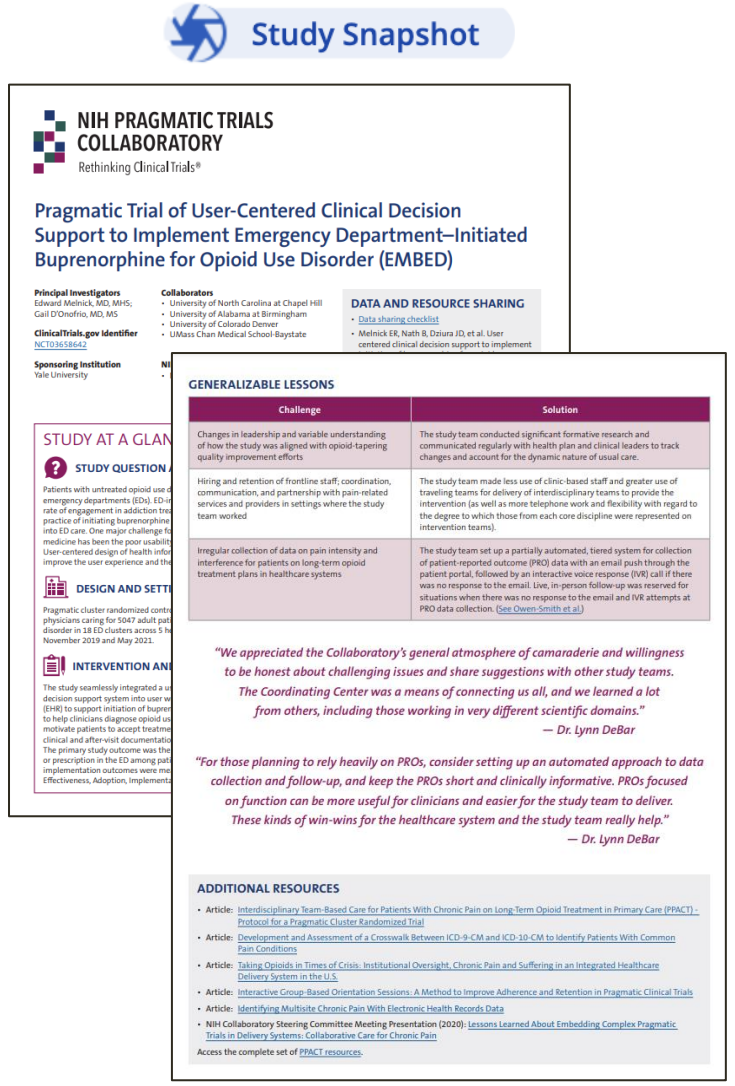
TRIAL WEBPAGES

- Trial details
- Interviews
- Publications and presentations

DATA AND RESOURCE SHARING

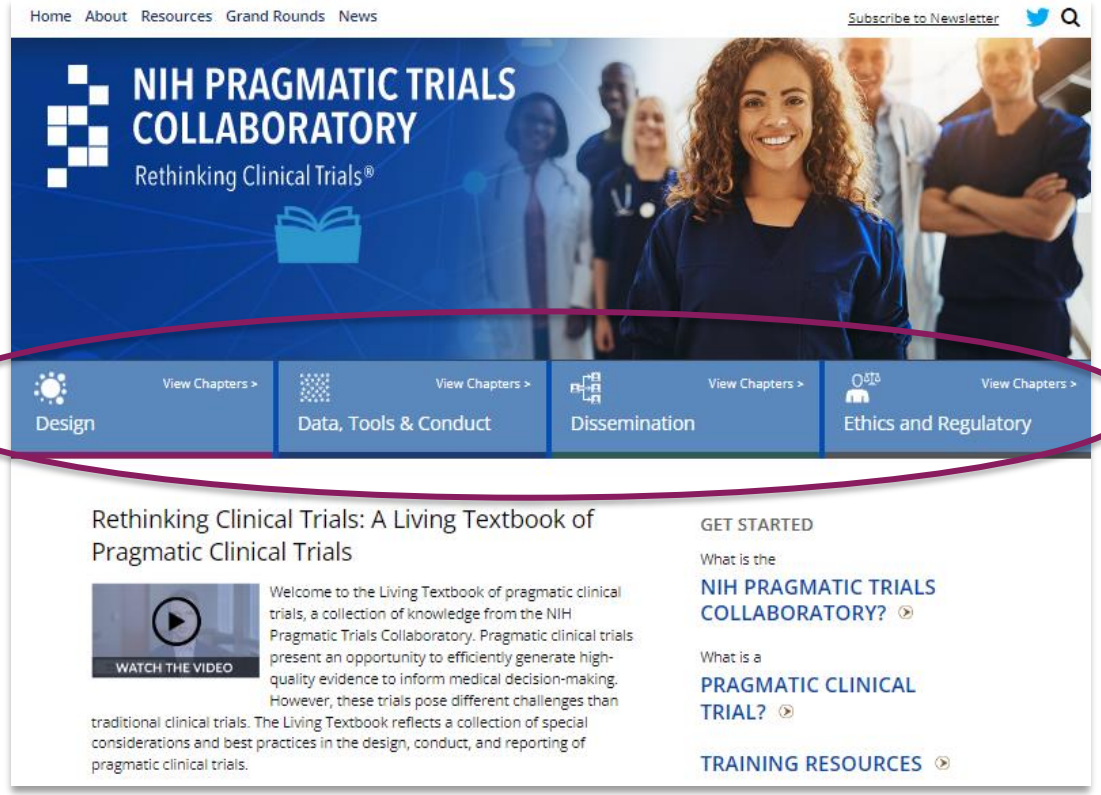
- Study tools
- Documentation





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 and Implementation

- Data Sharing
- Dissemination
- Implementation
- End-of-Trial Decision-Making

Ethics and Regulatory

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

Tools and Guidance Documents

CHEAT SHEETS

- Intraclass Correlation Coefficient
- Assessing Fitness-for-Use of Clinical Data for ePCTs
- End-of-Trial Decision-Making

TOOLS & TOOLKITS

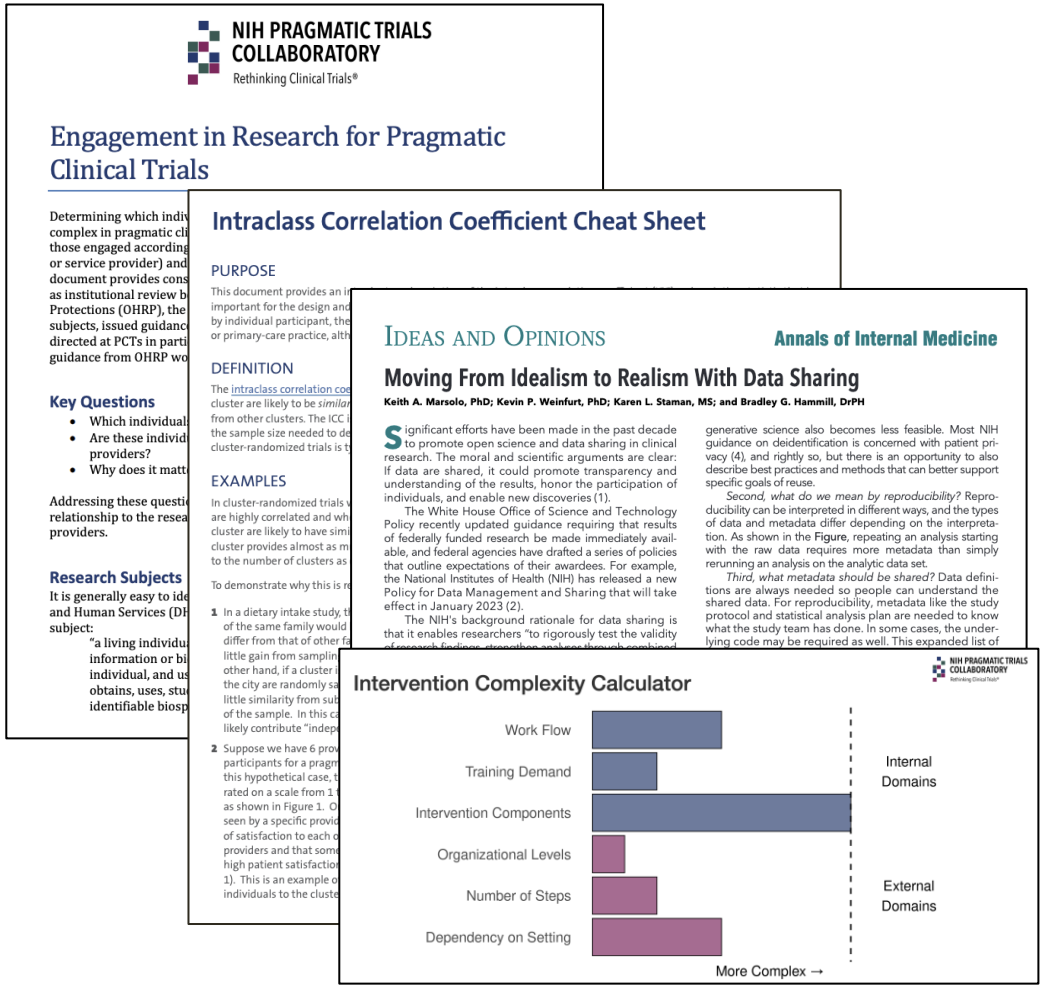
- Intervention Complexity Calculator
- Patient-Centered Outcomes Toolkit
- Data Sharing Information
- Quick Start Guides

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	

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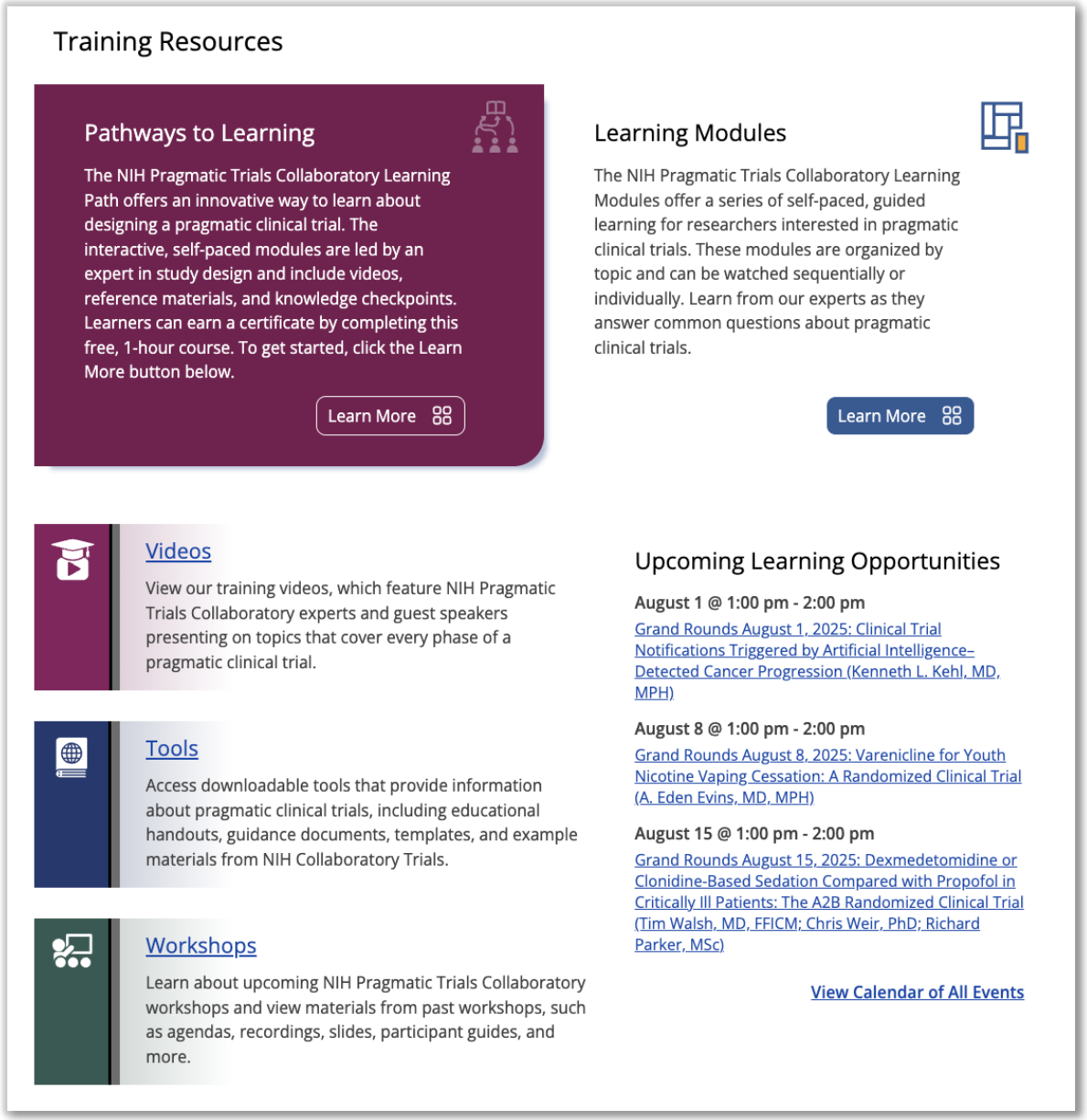
ePCT Training Resources

rethinkingclinicaltrials.org/training-resource/

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



Rethinking Clinical Trials® Grand Rounds

Weekly webinars

- **Fridays, 1:00-2:00 pm ET**
- Open to public
- >570 held to date
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

Rethinking Clinical Trials® Podcast

Podcast episodes

- >50 episodes available
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

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


May 2025

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News

Video Decision Aid, Clinician Communication Training Boost Advance Care Planning

The ACP PEACE trial found that a video decision aid coupled with clinician communication training led to higher rates of documented advance care planning in oncology clinics. Many older adults with advanced cancer do not discuss treatment preferences or goals of care with their clinicians, leading to patients receiving care that does not match their values.

Dr. James Tulsky and Dr. Angelo Volandes, principal investigators for ACP PEACE

"By focusing concurrently on both clinicians and patients—giving clinicians the skills to have these difficult conversations and preparing patients to engage with them—we were able to increase the number of documented goals-of-care conversations."

James Tulsky, co–principal investigator for ACP PEACE

Follow Us

Reach out anytime—we're here to help!

Tips for Success

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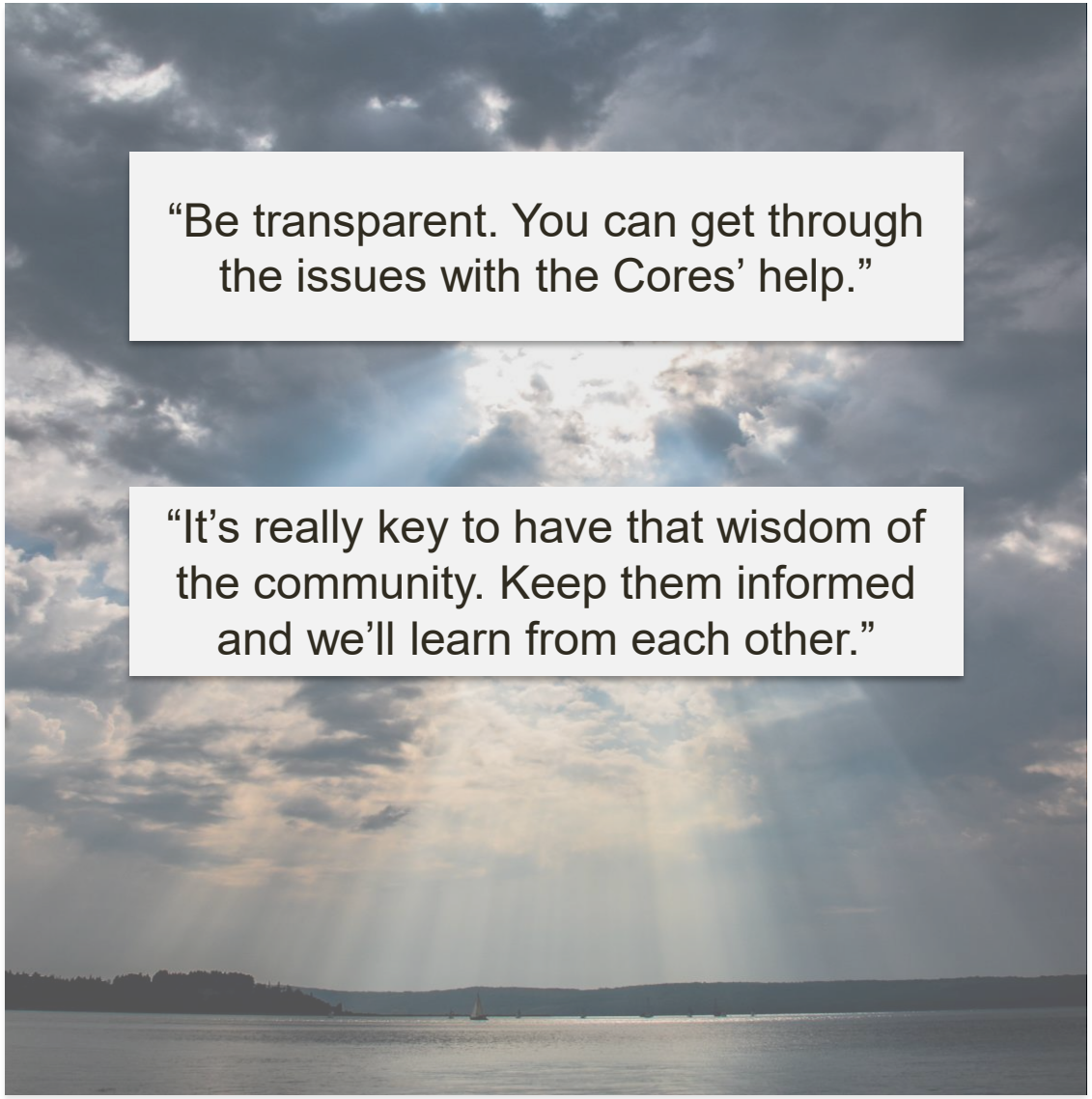
The Year Ahead

- 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**



Be Aware – ClinicalTrials.gov Reporting Deadline

- **Submission of results due:**
  1 year after the trial's primary completion date
  - Date when the final participant was examined or received an intervention to collect data for the primary outcome measure

Extensions rarely granted!

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Q&A

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