

# Welcome

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**NIH PRAGMATIC TRIALS  
COLLABORATORY**

Rethinking Clinical Trials®

# Learning objectives



## Identify Synergy

Explore how embedded pragmatic clinical trials and implementation research **can amplify each other** to accelerate real-world impact

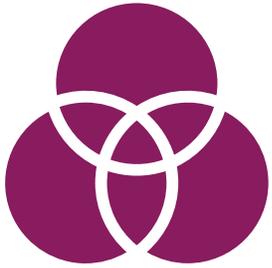
## Demystify Design

Learn the key features, challenges, and opportunities of embedding pragmatic trials into diverse healthcare systems and **how implementation methods can strengthen their success**

## Build Capacity

Equip health services researchers with **practical tools and lessons from implementation science** to drive adoption, sustainment, scale-up, and smart deimplementation of effective interventions

# Workshop sessions: Part 1



ePCTs and  
Hybrid Trials:  
Similarities and  
Differences

**Hayden Bosworth**



Design and  
Analysis  
Considerations

**Qilu Yu**



Measuring  
Effectiveness and  
Implementation  
Outcomes

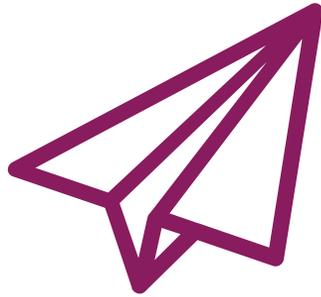
**Angelo Volandes**



ePCTs in Context

**Diana Burgess,  
Julie Fritz,  
Vince Mor,  
David Wetter**

# Workshop sessions: Part 2



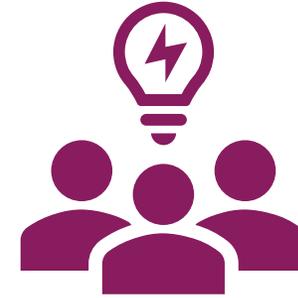
Pilot and  
Feasibility  
Testing

**Lanay Mudd**



Ethical and  
Regulatory  
Considerations and  
Posttrial Obligations

**Stephanie Morain**



Engaging and  
Aligning With  
Health System and  
Community Partners

**Hayden Bosworth**

# Workshop sessions: Part 2 (continued)



Posttrial Sustainment  
or Deimplementation  
of Study Interventions

**Vince Mor**



ePCTs in Context

**Diana Burgess,  
Julie Fritz,  
Angelo Volandes,  
David Wetter**



Writing a Compelling  
Grant Application

**Beda Jean-Francois**

# Resource: Living Textbook of Pragmatic Clinical Trials

**NIH PRAGMATIC TRIALS COLLABORATORY**  
Rethinking Clinical Trials®

View Chapters > Design | View Chapters > Data, Tools & Conduct | View Chapters > Dissemination | View Chapters > Ethics and Regulatory

What is a Pragmatic Clinical Trial? | Endpoints and Outcomes | Building Partnerships and Teams to Ensure a Successful Trial

Developing a Compelling Grant Application | Analysis Plan | Intervention Delivery and Complexity

Experimental Designs and Randomization Schemes | Using Electronic Health Record Data

Visit  
[rethinkingclinicaltrials.org](https://rethinkingclinicaltrials.org)



Pragmatic Trials Collaboratory. Pragmatic clinical trials present an opportunity to efficiently generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than

traditional clinical trials. The Living Textbook reflects a collection of special considerations and best practices in the design, conduct, and reporting of pragmatic clinical trials.

What is a  
**PRAGMATIC CLINICAL TRIAL?** >

**TRAINING RESOURCES** >

# ePCT Training Resources

[rethinkingclinicaltrials.org/training-resource/](https://rethinkingclinicaltrials.org/training-resource/)

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

## Training Resources

### Pathways to Learning



The NIH Pragmatic Trials Collaboratory Learning Path offers an innovative way to learn about designing a pragmatic clinical trial. The interactive, self-paced modules are led by an expert in study design and include videos, reference materials, and knowledge checkpoints. Learners can earn a certificate by completing this free, 1-hour course. To get started, click the Learn More button below.

[Learn More](#)

### Learning Modules



The NIH Pragmatic Trials Collaboratory Learning Modules offer a series of self-paced, guided learning for researchers interested in pragmatic clinical trials. These modules are organized by topic and can be watched sequentially or individually. Learn from our experts as they answer common questions about pragmatic clinical trials.

[Learn More](#)

### Videos



View our training videos, which feature NIH Pragmatic Trials Collaboratory experts and guest speakers presenting on topics that cover every phase of a pragmatic clinical trial.

### Tools



Access downloadable tools that provide information about pragmatic clinical trials, including educational handouts, guidance documents, templates, and example materials from NIH Collaboratory Trials.

### Workshops



Learn about upcoming NIH Pragmatic Trials Collaboratory workshops and view materials from past workshops, such as agendas, recordings, slides, participant guides, and more.

## Upcoming Learning Opportunities

**August 1 @ 1:00 pm - 2:00 pm**  
[Grand Rounds August 1, 2025: Clinical Trial Notifications Triggered by Artificial Intelligence-Detected Cancer Progression \(Kenneth L. Kehl, MD, MPH\)](#)

**August 8 @ 1:00 pm - 2:00 pm**  
[Grand Rounds August 8, 2025: Varenicline for Youth Nicotine Vaping Cessation: A Randomized Clinical Trial \(A. Eden Evins, MD, MPH\)](#)

**August 15 @ 1:00 pm - 2:00 pm**  
[Grand Rounds August 15, 2025: Dexmedetomidine or Clonidine-Based Sedation Compared with Propofol in Critically Ill Patients: The A2B Randomized Clinical Trial \(Tim Walsh, MD, FICM; Chris Weir, PhD; Richard Parker, MSc\)](#)

[View Calendar of All Events](#)

# Rethinking Clinical Trials® Grand Rounds



## Weekly webinars

- **Fridays, 1:00-2:00 pm ET**
- Open to public
- >570 held to date
- >150 attendees/session
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

**NIH Pragmatic Trials Collaboratory Grand Rounds**  
January 24, 2025

**NIH HEAL INITIATIVE**  
HEALING COMMUNITIES STUDY  
Massachusetts

**The HEALing Communities Study – 10 Million People, 67 Communities**  
*A Community-based Cluster Randomized Trial to Reduce Opioid Overdose Deaths*

**Jeffrey H. Samet MD, MA, MPH**  
John Noble, Professor in General Internal Medicine & Professor of Public Health  
Boston University Chobanian & Avedisian School of Medicine  
Boston University School of Public Health  
Boston Medical Center

**The All of Us Research Program: Improving Health Through Diverse Technology, Huge Cohorts, and Precision Medicine**

May 5, 2023

**Joshua Denny, MD, MS**  
Chief Executive Officer  
All of Us Research Program

**CLINICAL TRIALS TRANSFORMATION INITIATIVE**

September 30, 2022

**CTTI's Digital Health Trials Hub**  
Recommendations and Resources to Run Your Digital Health Trial

**Marianne Chase, MGH, CTTI Team Lead**

**State of Clinical Trials: An Analysis of Clinical.Trials.Gov**

**Adrian F. Hernandez, MD, MHS**  
Executive Director  
Duke Clinical Research Institute

**Rebecca D. Sullenger, MPH**  
Duke University School of Medicine  
MD Student | Class of 2026

**Duke Clinical Research Institute**

**NIH Pragmatic Trials Collaboratory Grand Rounds**

**FDA U.S. FOOD & DRUG ADMINISTRATION**

**FDA Draft Guidance on Real-World Evidence**

24 June 2022

**John Concato, MD, MS, MPH**  
Associate Director for Real-World Evidence Analytics  
Office of Medical Policy  
Center for Drug Evaluation and Research

**From Observational Studies to Pragmatic Clinical Trials: (Almost) A Decade of Research in PCORnet®**

**Erin Holve, PhD, MPH, MPP**  
PCORI

**Russell Rothman, MD, MPP**  
Vanderbilt University School of Medicine

**Neha Pagidipati, MD, MPH**  
**W. Schuyler Jones, MD**

**pcornet®**  
The National Patient-Centered Clinical Research Network



Learn more:



<https://impactcollaboratory.org>



# About you

- **What best matches your professional position?**
  - Academic faculty
  - Clinician or healthcare system leadership
  - Research support staff
  - Student or trainee
  - Other



# About you

- **Where are you in your career track?**
  - Student
  - Postdoctoral fellow
  - New faculty (K award, early-stage investigator, etc.)
  - Established faculty (associate or full professor)
  - Other



# About you

- **What is your experience conducting pragmatic trials in healthcare systems?**
  - Curious about pragmatic trials, but have not conducted one yet
  - Planning a pragmatic trial now
  - Conducting my first pragmatic trial now
  - Have conducted many pragmatic trials
  - What is a pragmatic trial?

