

Welcome

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Learning objectives

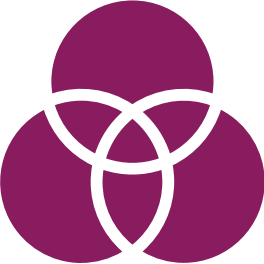


Clarify Describe the **characteristics and utility** of embedded pragmatic clinical trials (ePCTs)

Demystify Introduce the unique **opportunities and challenges** of designing, conducting, and implementing ePCTs within healthcare systems

Innovate Explore how the latest **information capabilities** can be employed in ePCTs to address important public health questions

Workshop sessions: Part 1



Opportunities for
Embedded Pragmatic
Clinical Trials (ePCTs)

Wendy Weber



Engaging and
Aligning With
Partners

Emily O'Brien



ePCT
Design

Patrick Heagerty

Workshop sessions: Part 2



Innovative Methods
in ePCTS

Angelo Volandes



ePCTS in Context

**Sebastian Tong,
Michael Ho**

Resource: Living Textbook of Pragmatic Clinical Trials

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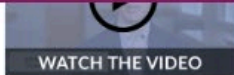
View Chapters > Design | View Chapters > Data, Tools & Conduct | View Chapters > Dissemination | View Chapters > Ethics and Regulatory

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



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/

- Learning pathways
- 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 \(Tim Walsh, MD, FFICM; Chris Weir, PhD; Richard Parker, MSc\)](#)

[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
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 ClinicalTrials.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



Best Practices for Integrating Health Equity into Embedded Pragmatic Clinical Trials (ePCTs) for Dementia Care

NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Free online program!!!

- 6 Video-based Courses
- 3 Hours
- 1 Certificate



Learn more:



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 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?

