

Welcome

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Workshop learning objectives



1. Clarify the definition of ePCTs and explain their utility.
2. Introduce attendees to the unique characteristics and challenges of designing, conducting, and implementing ePCTs within diverse healthcare systems.
3. Increase the capacity to address important patient-centered questions with ePCTs in real-world settings.

Workshop sessions

- What Are Embedded Pragmatic Clinical Trials?
 - Wendy Weber
- Engaging & Aligning With Health System and Community Partners
 - Emily O'Brien
- ePCT Design and Analysis
 - Jonathan Moyer
- Measuring Outcomes
 - Angelo Volandes

Workshop sessions - continued

- Overview of NIH Collaboratory Trials
 - Vincent Mor
 - Angelo Volandes
- ePCTs in Context Part 1: Small Group Work
 - Emily O'Brien
- ePCTs in Context Part 2: Panel Discussion with Collaboratory Trial PIs
 - Emily O'Brien
 - Vincent Mor
 - Angelo Volandes
- Closing Remarks
 - Emily O'Brien



Resource: The Living Textbook

Visit the *Living Textbook of Pragmatic Clinical Trials* at

www.rethinkingclinicaltrials.org



Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



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.

Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH 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

GET STARTED

What is the

[NIH PRAGMATIC TRIALS COLLABORATORY?](#)

What is a

[PRAGMATIC CLINICAL TRIAL?](#)

[TRAINING RESOURCES](#)



New Training Resources

rethinkingclinicaltrials.org

Website Features Include:

- 8 new self-paced, guided video learning modules on conducting pragmatic clinical trials
- Enhanced video library indexed by topic
- Workshops page content from program workshops
- Resources page with handouts, guides, and worksheets
- Upcoming learning events and workshops

The screenshot shows the top navigation bar of the website with tabs for Design, Data, Tools & Conduct, Dissemination, and Ethics and Regulatory. The main content area is titled "Training Resources" and features a large purple card for "Learning Modules" with a "Learn More" button. Below this are three smaller cards for "Videos", "Resources", and "Workshops". To the right, there is a section for "Upcoming Events" listing dates and event titles, with a "View Calendar of All Events" link. The bottom right corner features the NIH Pragmatic Trials Collaboratory logo and tagline.


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

Training Resources

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.

Resources

Access downloadable resources developed by the NIH Pragmatic Trials Collaboratory, including educational handouts, guidance documents, and worksheets that provide information about pragmatic clinical 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 Events

October 27 @ 1:00 pm - 2:00 pm
[Grand Rounds October 27, 2023: Digital, Decentralized and Democratized: Lessons From The Yale PaxLC Trial \(Harlan M. Krumholz, MD, SM\)](#)

November 3 @ 1:00 pm - 2:00 pm
[Grand Rounds Biostatistics Series November 3, 2023: The Perils and Pitfalls of Complex Clustering in Pragmatic Trials \(Jonathan Moyer, PhD; Moderator: Andrea Cook, PhD\)](#)

November 10 @ 1:00 pm - 2:00 pm
[Grand Rounds November 10, 2023: No Presentation \(Holiday\)](#)

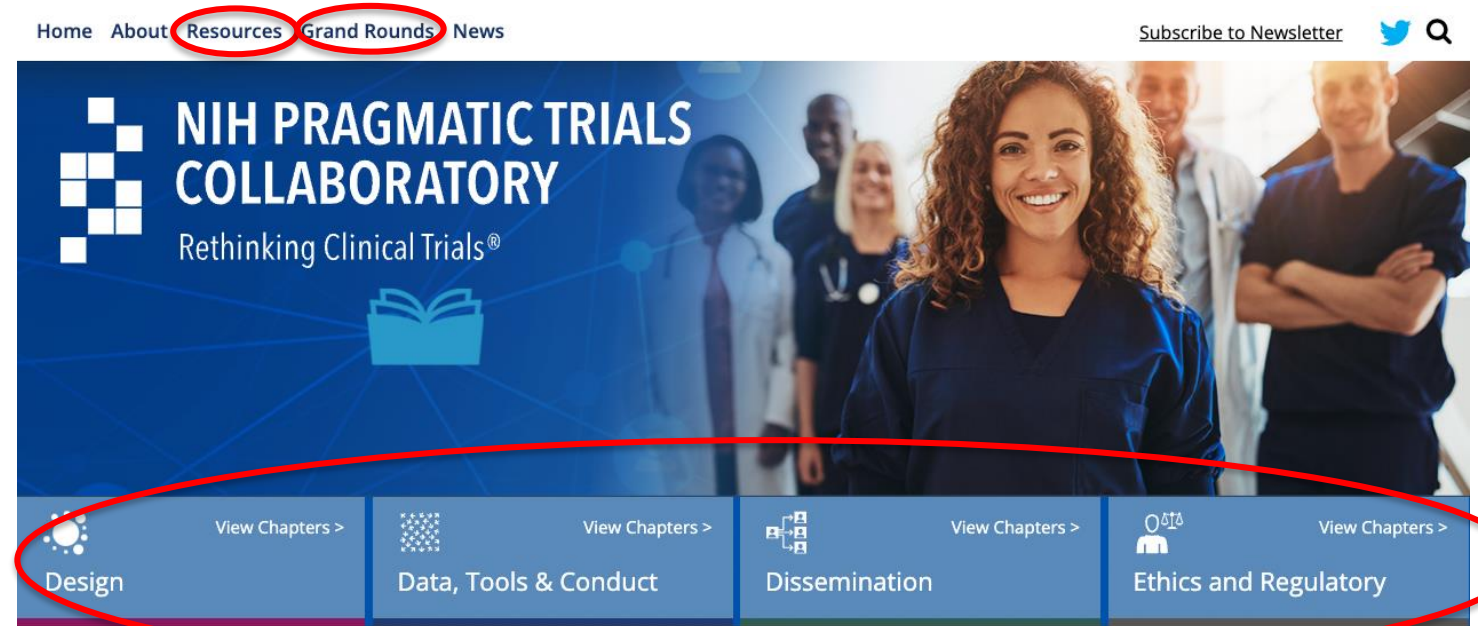
[View Calendar of All Events](#)



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Key Resources

- [Living Textbook](#)
- [Grand Rounds Hub](#)
- [Training Resources](#)



Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



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GET STARTED

What is the [NIH PRAGMATIC TRIALS COLLABORATORY?](#)

What is a [PRAGMATIC CLINICAL TRIAL?](#)



Best Practices for Integrating Health Equity in ePCTs

6 Best Practices for Getting Started

Integrating Health Equity into ePCTs for Dementia Care



- 1 Consider health equity in all decisions. There are health equity considerations in all decisions. The key is to consider these issues early in the process.
- 2 Select a research question that addresses the needs of health equity populations. All trials are ethically required to maximize the benefits of research to the most disadvantaged, underrepresented, or otherwise vulnerable populations.
- 3 Collaborate with community members in inclusive research. Engage representative stakeholders who are from many aspects of diversity (e.g., race/ethnicity, gender, age, etc.) as members is valuable across the trial lifespan.
- 4 Allocate sufficient resources to address health disparity populations. Plan for the effort and budget needed to support budgeting for: translation or interpretation services, and project staff diversity training.
- 5 Build a research team that is diverse. Your research team should include investigators with methodologic expertise, content knowledge of health equity-relevant issues throughout the trial.
- 6 Design with health equity in mind. When you design an ePCT, keep in mind the needs of health equity populations. The Consort Equity Extension and

NIA IMPACT Collaboratory | Best Practices for Health Care System and

6 Best Practices for Community Stakeholder Engagement

Integrating Health Equity into ePCTs for Dementia Care



- 1 Apply a health equity approach to stakeholder engagement throughout the study. Engage stakeholders throughout the study, including those who are most impacted by the condition, tailoring interventions, designing enrollment strategies, and other aspects of the study.
- 2 Engage stakeholders who are most impacted by the condition. Consider the racial, social, and cultural backgrounds of the community members who are most impacted by the condition.
- 3 Engage the community in the study. Include a period of "pre-engagement" to build trust and rapport with the community throughout the study. Support the community in their own research rather than scientific language.
- 4 Use a mix of strategies to engage the community. Partner with community leaders in the community, such as local radio, social media, and television.
- 5 Evaluate the impact of stakeholder engagement. Assess the experiences of stakeholder contributions had an impact on the study.
- 6 Disseminate results to the community. Plan to deliver presentations (i.e., at community meetings) at the completion of the study.

NIA IMPACT Collaboratory | Best Practices for Health Care

6 Best Practices for Health Care System and Participant Selection

Integrating Health Equity into ePCTs for Dementia Care



- 1 Select health care systems (HCS) for improved care. Consider features such as: state, rurality of location, integrated delivery system, etc.
- 2 HCS and participant selection should be representative of the ePCT. The HCS sampling frame and participant eligibility criteria should be met including pre-specified health equity considerations.
- 3 Consider health-equity-relevant characteristics. Consider features such as: state, rurality of location, integrated delivery system, etc.
- 4 Consider health-equity-relevant characteristics available to characterize it. Consider characteristics such as: insurance coverage, sexual/gender identity, disabilities, diagnosis (e.g., rural/urban), education, socioeconomic status.
- 5 Consider the validity and biases of the data. Methods should identify all eligible participants who may be "missing" (e.g., undiagnosed) for record-based algorithm, validate it locally by phone or in person.
- 6 Consider threats to health equity of eligible participants. Once eligible participants are identified, such as mode of outreach (e.g., computer access), ensure an equitable approach.

NIA IMPACT Collaboratory | Best Practices for Health Care System and

6 Best Practices for Intervention Design and Implementation

Integrating Health Equity into ePCTs for Dementia Care



- 1 Determine who is meant to benefit from the intervention. Consider the racial, social, socioeconomic, linguistic and cultural backgrounds of the people who will receive the intervention (providers, people living with dementia, etc.) in the healthcare system.
- 2 Involve key stakeholders in intervention design. Stakeholders who represent the backgrounds of the people who will receive the intervention should be involved in its design, content, delivery and adaptation.
- 3 Adapt interventions for different settings and populations. Most existing interventions of PLWD and their CPs need to be adapted and implemented in different settings. Take a systematic approach to adaptation. Document and report adaptations.
- 4 Ensure intervention materials are accessible and acceptable to health-equity-relevant groups. Ensure intervention materials are acceptable and accessible with languages spoken, settings, and cultural practices.
- 5 Identify and address barriers to equitable implementation.

PLWD and CPs	Providers
Computer access, transportation, time and cost, acceptability of intervention	Inequitable training, lack of time, discriminatory attitude, intervention acceptability, incongruence of background with PLWD & CP
- 6 Monitor implementation across health-equity-relevant groups and make corrective adaptations. Plan to monitor implementation (reach, coverage, intensity, uptake) and make adaptations if inequities occur. Document and report adaptations.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

6 Best Practices for Selecting Outcomes

Integrating Health Equity into ePCTs for Dementia Care



- 1 Select outcomes relevant to health disparity populations. Select outcomes with evidence of broad value in health disparity populations.
- 2 Assess the validity of outcomes for equity-relevant groups to ensure applicability in specific populations. Assess existing evidence of outcome validation regarding race, ethnicity, educational attainment and other health-equity-relevant characteristics.
- 3 Explore how outcomes may be interpreted with respect to norms and expectations of equity-relevant groups. Review qualitative and comparative research on cultural differences in the lived experience of people living with dementia (PLWD), and the meaning of potential outcome domains.
- 4 Consider pilot work to evaluate acceptability and psychometrics of outcomes for health disparity populations. In the absence of evidence of psychometric properties in specific populations, pilot work may be needed to assess an outcome measure's validity, reliability, and cross-cultural differences in these groups.
- 5 Require linguistic and health literacy accessibility in outcome ascertainment. For clinically embedded patient/care partner relevant outcomes, ensure forward and back-translation required for linguistic and health literacy accessibility.
- 6 Ensure health equity of outcome data capture. For PLWD and care partners, assess and adapt for limited computer, internet or smart phone access. For healthcare systems, assess the need for enhanced technical assistance for outcome data in populations at risk for health disparities.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

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Best Practices for Integrating Health Equity into Embedded Pragmatic Clinical Trials (ePCTs) for 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 Health Care systems Leadership
 - Research Support Staff
 - Student or Trainee
 - Other

About you

- Where are you in your career track?
 - Student
 - Post-Doctoral 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 health care 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?