

# What Are Embedded PCTs?

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## Learning goals



- Identify key considerations in the design and conduct of ePCTs and how they differ from explanatory trials
- Learn about the advantages and disadvantages of ePCTs, when a pragmatic approach can be used to answer the research questions
- Identify key areas of convergence between ePCTs and D&I research



## Important things to know

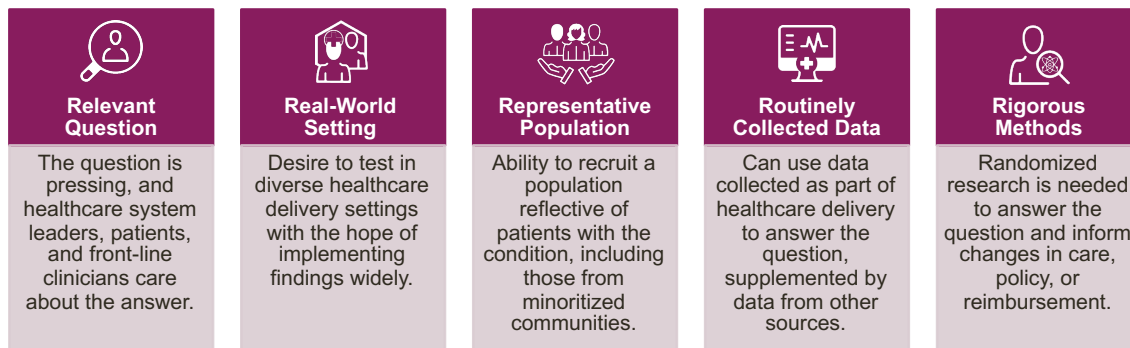
- ePCTs are designed to answer important, real-world clinical questions
- Broad stakeholder engagement and support are essential from beginning to end
- Trade-offs in flexibility, adherence, and generalizability are inevitable

## Why conduct ePCTs?

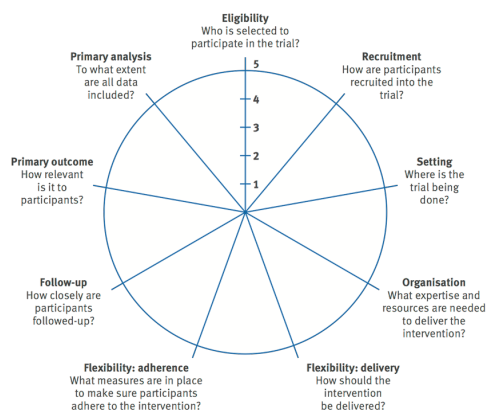


ePCTs have the potential to inform policy and practice with high-quality evidence at reduced cost and increased efficiency compared with traditional clinical trials

## Why Do an ePCT? The 5 Rs



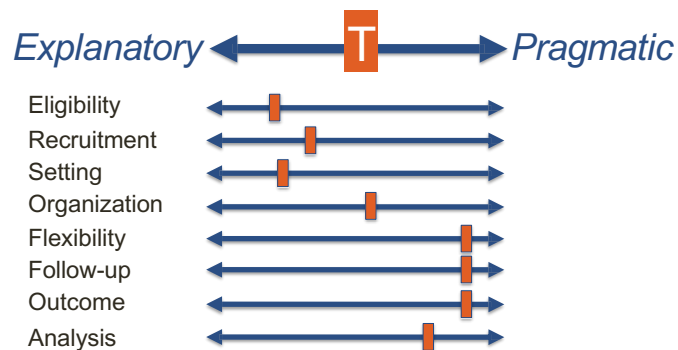
## Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) Wheel



Adapted from [BMJ 2015;350:h2147](https://doi.org/10.1136/bmj.2015.350.h2147)  
<https://www.precis-2.org/>

# Trials vary across a spectrum of explanatory and pragmatic elements

*Different trial elements are, by design, more or less explanatory/pragmatic*



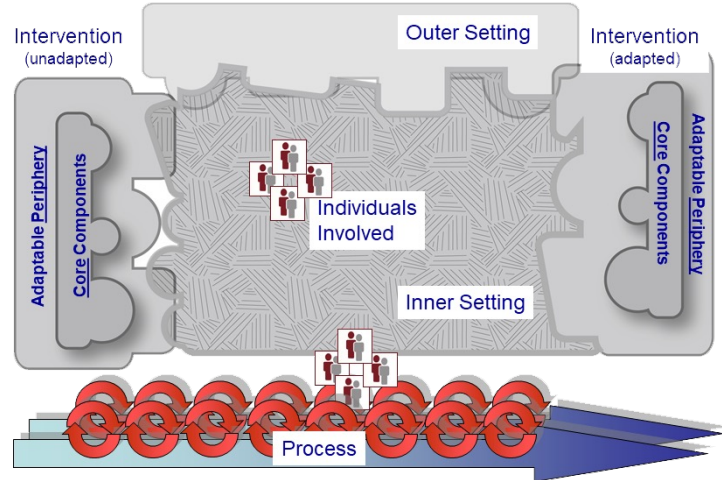
## What is a Pragmatic Clinical Trial?

There is a need for “a different context to clinical research that could speed the discovery and implementation of evidence-based advancements to healthcare delivery. Pragmatic clinical trials (PCTs) are a promising type of trial conducted within real-world health care delivery systems”  
(Tuzzio and Larson 2019).

# Frameworks

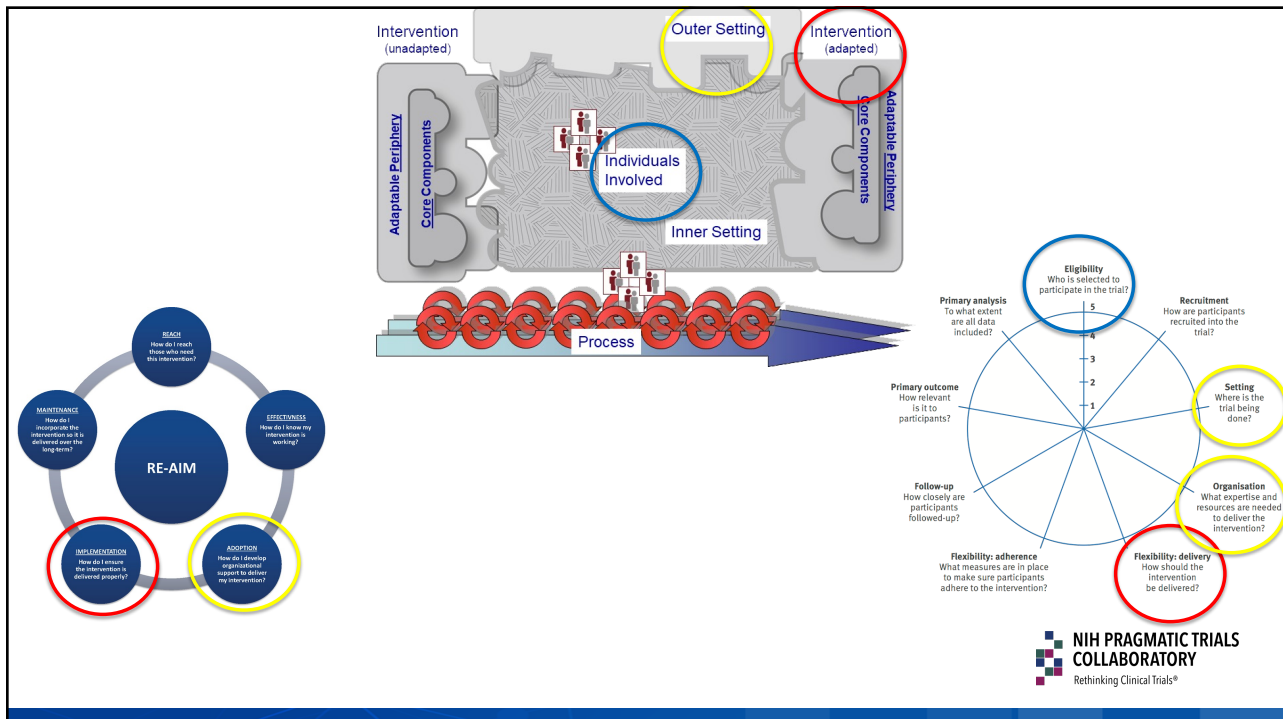


## Consolidated Framework for Implementation Research



Front. Public Health, 29 March 2019 | <https://doi.org/10.3389/fpubh.2019.00064>  
 Front. Public Health, 27 April 2015 | <https://doi.org/10.3389/fpubh.2014.00143>

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## Key areas of convergence with ePCTs

- Pragmatic/stakeholder-engaged *intervention* design
- Study design that considers implementation
- Regulatory concerns

## Who are your stakeholders?

Potential stakeholders have a variety of priorities, values, work cultures, and expectations:



- Healthcare delivery organization leaders
- Clinicians
- Operational personnel
- Patients, caregivers, patient advocacy groups
- Payers, purchasers
- Policy makers, regulators
- Research funders
- Researchers
- Product manufacturers

## Opportunities

- Pragmatic trials can be improved by including implementation strategies
- Hybrid designs offer the opportunity to evaluate effectiveness and implementation strategies
- Multidisciplinary teams improve pragmatic research and dissemination/implementation research

## It's a balancing act



Achieving both relevance and efficiency is a goal of pragmatic trials, yet high relevance to real-world decision-making may come at the expense of trial efficiency

*For example, a trial measuring outcomes that matter most to patients and health systems may not be able to rely exclusively on information from the EHR, and instead need to assess patient-reported outcomes, which is more expensive and less efficient*

## Listen to the frontline

The purpose of the healthcare system is not to do research, but to provide good healthcare. Researchers often have a tail-wagging-the-dog problem. We assume if we think something is a good idea, the healthcare system will too... We need to remember that we're the tail and the healthcare system is the dog.

– Greg Simon, MD, MPH (SPOT)

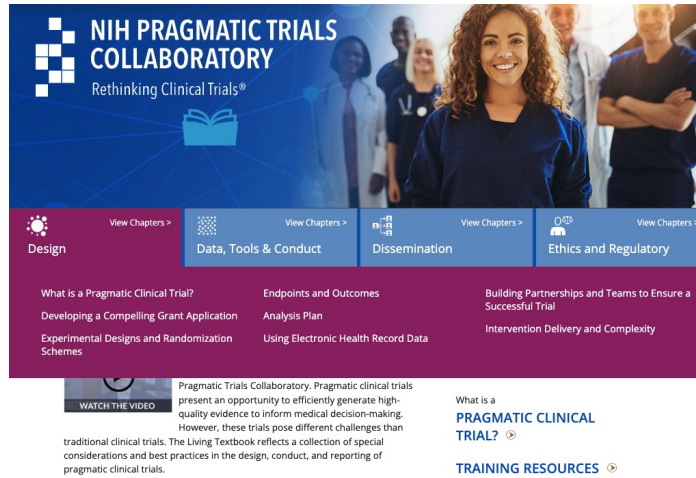
## Important things to do

- Set expectations to work collaboratively and build trust from the beginning
- Get to know your partners' values, priorities, and expectations
- Assess your partners' capacity and capabilities
- Track goals reached, challenges, and adaptations throughout the lifecycle of your ePCT
- Show appreciation and celebrate accomplishments early and often to have sustained partnerships

## Resource: The Living Textbook

Visit the *Living Textbook of Pragmatic Clinical Trials* at

[www.rethinkingclinicaltrials.org](http://www.rethinkingclinicaltrials.org)



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What is a Pragmatic Clinical Trial?  
Developing a Compelling Grant Application  
Experimental Designs and Randomization Schemes


Endpoints and Outcomes  
Analysis Plan  
Using Electronic Health Record Data

Building Partnerships and Teams to Ensure a Successful Trial  
Intervention Delivery and Complexity

WATCH THE VIDEO

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 

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## Knowledge Checkpoint

- Which of the following are common design elements of embedded pragmatic clinical trials?
  - Answer choice 1: Interventions delivered by clinicians or other providers already in the health care setting
  - Answer choice 2: Enrollment criteria for participants are broad to increase generalizability
  - Answer choice 3: Data from electronic health records are leveraged for some of the study outcomes
  - Answer choice 4: All of the above

## Knowledge Checkpoint



- True or False: Researchers know the most important questions to ask in clinical trials and it doesn't matter if the health care system partner thinks the research is unimportant.

## Knowledge Checkpoint



- True or False: Implementation science methods and strategies can improve the conduct of embedded pragmatic clinical trials.

# Question & Answer

