

# Pilot & Feasibility Testing

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## Learning goals



- Identify approaches to evaluating the capabilities of the partner healthcare system and testing key elements of various types of interventions



## Important things to know

- Pilot testing the ePCT methods increases likelihood of completing the trial and can prevent silly mistakes
- You need a biostatistician in the pilot/feasibility stage
- “Process issues” can derail the ePCT
- Use the pilot study to maximize acceptability, maintain affordability, and consider scalability of your intervention

## ePCTs are not efficacy trials

- ePCTs bridge research into clinical care
- Intervention is integrated into real-world healthcare settings
- Involves streamlined data collection
- Pragmatic does not always mean low cost



## During the pilot phase

- Establish close partnerships with healthcare system personnel
- Test and validate EHR data collection and extraction
- Evaluate whether generalizable patient population can be identified and enrolled with available healthcare systems
- Assess how well the intervention can be integrated into the clinical workflow
- Identify multiple local champions at each study site

## Build partnerships



- Is the intervention aligned with the priorities of the partner healthcare system?
- How ready is the partner?
  - Are extra resources needed to support the intervention, identify participants, and extract necessary data?
  - How many sites are available to fully participate?
  - How much provider training will be needed, and can training use existing healthcare system infrastructure?
- If the intervention proves successful, what adaptations would be needed to implement it in other healthcare settings?

## Aspects of feasibility that can be piloted

Verify that target population can be identified via the EHR

Test phenotypes needed for sample identification

Validate data quality, collection, extraction methods & accuracy

Evaluate if generalizable patient population is available

Coordinate processes with local champions

Test the training materials for frontline providers & staff

Test appropriateness & usability of study toolkits or other materials

Evaluate informed consent materials

Evaluate whether fidelity/adherence measures can be achieved to justify the full-scale ePCT

*Use what you learn to design the ePCT*

## Evaluate power calculations



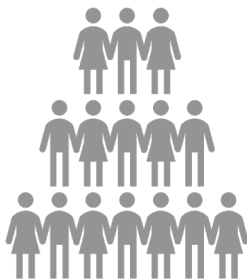
If cluster randomization is involved, collect data to confirm estimate of the intraclass correlation coefficient (ICC) for power calculations

## Quantify feasibility for pilot study aims

- Eligibility
- Recruitment
- Randomization
- Adverse events
- Retention
- Missing data
- Intervention fidelity

*Keep in mind realistic targets for the study's patient population*

## Quantifying example 1



Demonstrate effective recruitment and retention, which we define as the ability to

- Recruit an average of 10 patients per month per site
- Retain 80% of participants for final data collection at 6 months

## Quantifying example 2

Determine whether the intervention can be delivered with reasonable fidelity, which we define as 70% of the enrolled participants engaging in the intervention



Determine whether the smoking cessation intervention can be delivered with reasonable feasibility, which we define as 20% of the approached participants engaging in the intervention

## Quantifying example 3

Demonstrate ability to collect primary outcomes and minimize missing data to less than 5% of primary outcome measures



Demonstrate ability to collect primary outcome of depression symptoms (patient-reported) and minimize missing data to less than 10% of primary outcome measures

# Ensuring trial readiness

- Troubleshooting and iterative testing
- Flexibility to accommodate local conditions and changes over time
- Continuous engagement with healthcare system
- Readiness tasks
  - Recruitment plans are finalized with backup plans available
  - Ethical/regulatory aspects are addressed
  - Intervention is fully developed and finalized
  - Data collection methods are adequately tested
  - Budget and timeline are realistic and feasible



# Readiness checklist

Milestone	Completed
<i>Recruitment plans are finalized</i>	
All sites identified (documentation of site commitment)	
Methods for accurately identifying participants validated	
All agreements for necessary subcontracts in place	
<i>Ethical/regulatory aspects are addressed</i>	
Coordinated IRB oversight in place	
Finalized plans for informed consent or waiver of informed consent	
Finalized data and safety monitoring plan	
<i>Intervention is fully developed and finalized</i>	
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)	
<i>Data collection methods are adequately tested</i>	
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	
<i>Budget is realistic, feasible, and accounts for potential changes</i>	

Implementation Readiness Checklist available on the [Living Textbook](#)



## In the end, good planning will help

- Avoid silly mistakes
- Maximize acceptability
- Maintain affordability
- Remember scalability

## Important things to do

- Conduct a pilot or feasibility study of the intervention to inform the final design of the ePCT
- Work with a great biostatistician and an informatician (if needed)
- Develop a partnership approach to working with your healthcare systems
- Identify multiple local champions for all your sites
- Anticipate, identify, and make a plan to address changes in the healthcare system

# Resources

- Healthcare system partnerships: [Establishing Close Partnerships with Healthcare System Leaders and Staff](#)
- Trial readiness criteria: [Implementation Readiness Checklist](#)
- Pilot and feasibility testing: Assessing Feasibility: [Pilot Testing and Feasibility Assessment Scenarios from the Collaboratory's Demonstration Projects](#)

From the Living Textbook of Pragmatic Clinical Trials  
[www.rethinkingclinicaltrials.org](http://www.rethinkingclinicaltrials.org)



## Resource: The Living Textbook

Visit the *Living Textbook of Pragmatic Clinical Trials* at

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



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# Question & Answer

