

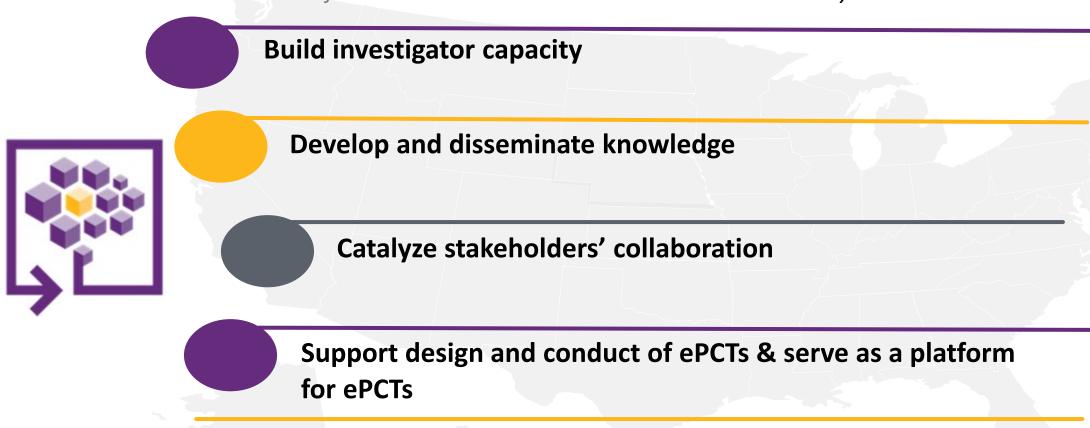
The IMPACT Collaboratory

Partha Bhattacharyya, PhD
Ama Donkor, MPH
Lisa Onken, PhD
Marcel Salive, MD
National Institute on Aging
April 20, 2022



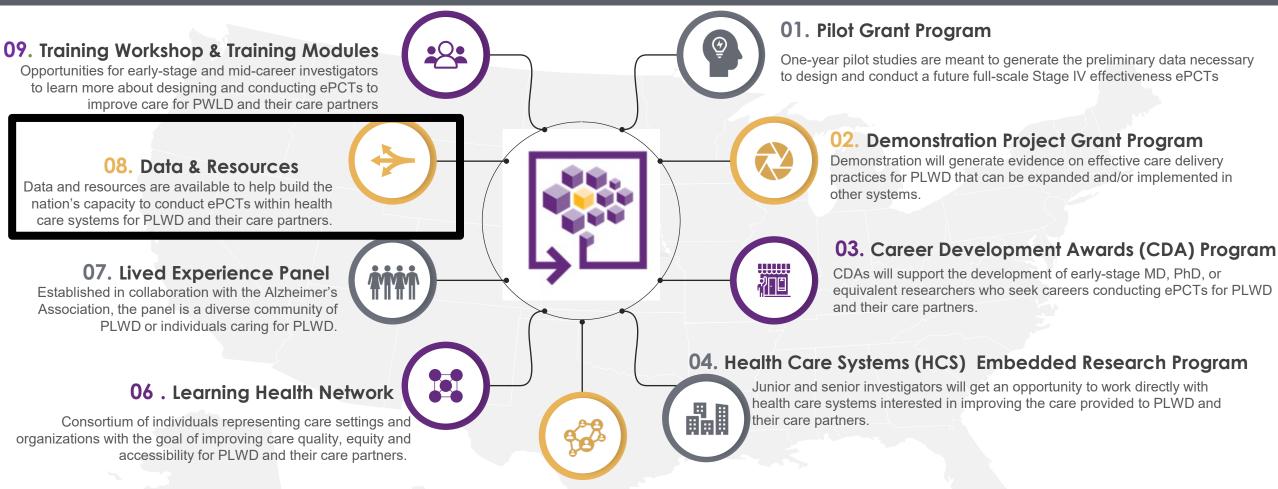
The NIA IMPACT Collaboratory

To support a center for collaborative research within and among health and long-term care systems to encourage pragmatic trials of innovative dementia care. The IMPACT Collaboratory will...





IMPACT Collaboratory: A National Resource



05. Faculty Scholars Program

Program is designed to support development of investigators in the design and conduct of embedded pragmatic clinical trials for PLWD and their care partners by integrating them into the activities of the IMPACT Collaboratory.



Guidance Documents

Creating Effective Value Propositions



Engaging key stakeholders in embedded pragmatic clinical trials (ePCTs) to evaluate evidence based programs in dementia care

Rationale

To develop and implement a successful ePCT, researchers must secure organizational partners, recruit clinicians and participants, and inspire health system leaders to support and sustain successful programs/interventions. Communicating value and creating a persuasive rationale is critical to engaging key stakeholders.

What is a Value Proposition?

A value proposition is "a clear, simple statement of the benefits, both tangible and intangible, that the evidence-based program/intervention [evaluated in an ePCT] will provide to a particular stakeholder, along with a recognition of the approximate financial, time, implementation, and other costs associated with those benefits."

(Aaker, 2010)

6 Steps for Developing a Value Proposition

- 1 Identify stakeholders that need to be engaged to conduct the ePCT or the program/intervention.
- Gather information about the stakeholders' concerns and priorities.
- Identify the costs and benefits (resources, time, financial) for each stakeholder group.
 This may vary by stakeholder.
- Consider what is necessary to better align the program/intervention with stakeholders' values.
- Prepare material(s) describing the value proposition(s).
- 6 Effectively communicate the value proposition to key stakeholders



This work is supported by grant U54AG063546 from the National Institute on Aging

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



Rationale

The NIH Revitalization Act of 1993 was enacted to compel scientists to design for, and report on, the effectiveness of interventions by gender and racial/ ethnic groups, yet the evidence base for underrepresented people living with dementia (PLWD) is sparse. Higher rates of dementia and worse health outcomes have been documented for many minoritized populations relative to PLWD who are non-Hispanic White, yet these populations that experience health disparities are vastly underrepresented in dementia efficacy trials. A concerted effort to integrate health equity into study designs is necessary to ensure researchers are conducting quality science and avoiding harm where evidence gaps exist. However, the efficacy, safety, and tolerability of treatments have not been sufficiently assessed for many groups that experience Alzheimer's disease (AD) and AD-Related Dementias (AD/ADRD), creating critical knowledge gaps at a time when our aging population is becoming increasingly diverse.

The sparse evidence applicable to health disparity populations derived from AD/ADRD efficacy trials extends to pragmatic clinical trial designs embedded in health care systems (ePCTs, HCS). ePCTs aim to evaluate interventions in real-world settings. ePCTs have unique design features that introduce additional novel challenges with respect to health equity, yet to date there is very little guidance on how to integrate health-equity-relevant considerations into the design of impact ePCTs, including those targeting PLWD and their care partners.

Table of Contents

6 Best Practices for:

Getting Started	2
Community Stakeholder Engagement	3
Design and Analysis	4
Intervention Design and Implementation	5
Health Care System and Participant Selection	6
Selecting Outcomes	7



This work is supported by grant U54AG063546 from the National Institute on Aging

How to Use this Packet

Health equity relevant considerations are necessary in all aspects of ePCTs. The key is to consider these issues early in the planning process, as well as systematically and throughout the conduct of the trial. Health equity relevant concepts can be nuanced and complex, and the degree to which researchers can incorporate heath equity into each ePCT design component depends on the scope and objectives of the trial. These best practices investigators to systematically explore how to integrate health equity into their ePCT design and dentify potential pitfalls in their current research processes.

Additional Resources

This best practices package includes a glossary of terms and key references for additional resources and publications. The community-based participatory research, implementation science, and cultural adaptation literature offer some additional guidance. We encourage investigators to seek more in depth guidance incorporating health-equity-relevant features into the ePCT from these resources as well as from methodological and content experts and key stakeholders.



Long Term Care Data Cooperative (LTCDC)



Building the LTCDC

Initially focused on COVID-19 & RADx-UP
Expanding from 1,000 to include 10,000 NHs using 4 different EMRs
Link Data to Medicare Claims & Medicare Advantage Encounters
Weekly Data Transfer/Updates
Generate Routine Reports Such as Facility Specific Reports on Hospital Transfers

Using the LTCDC - A "Launch Pad"

Examples of anticipated uses of data for future research:

Public Health Surveillance

Pharmaco-epidemiological Research

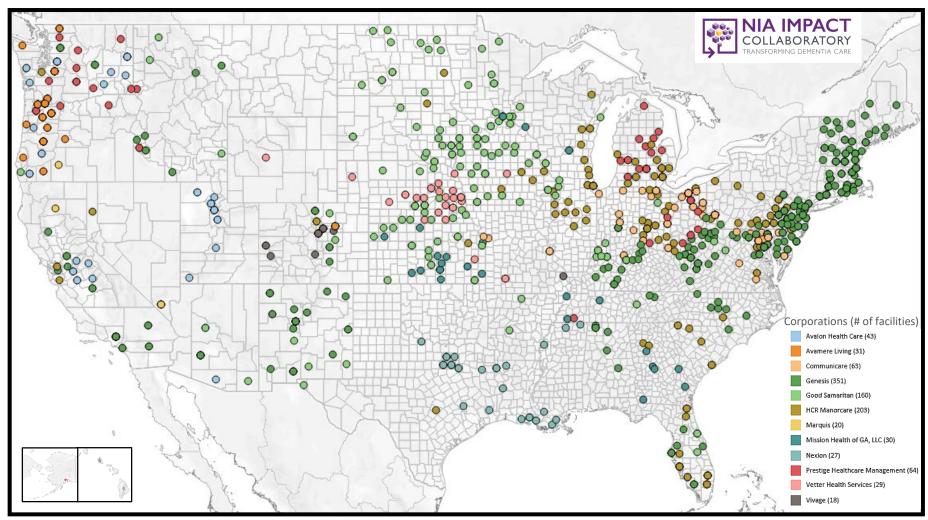
Observational Studies on Impact Of New Treatments & New Policies

Recruiting Facilities for Cluster RCTs, Clinical Research, Patient Monitoring, etc.





Long Term Care Data Cooperative: Geography of Facilities a Start...































IMPACT Collaboratory: Grants & Training Opportunities



Pilot Studies Grant Program

- 2 Requests for Applications (RFAs) annually
- \$175k in direct costs for 1 year
- Goal: Pilot study to prepare for an embedded pragmatic clinical trial (ePCT) of a non-pharmacological interventions for dementia care



Demonstration Projects Grant Program

- Annual RFA
- \$500k in total direct costs for 2 years
- Goal: Full-scale ePCT in health care systems of non-pharmacological interventions for dementia care



Career Development Award Program

- Annual RFA
- \$100k per year in direct costs for 2 year
- Goal: Mentored training grant for early-stage investigators to gain skills needed to conduct ePCTs for dementia care



Health Care Systems (Hcs) Scholars Program

- Annual RFA
- \$120k in direct costs for 1 year
- Goal: Embed scholars in health care systems to strengthen research partnerships to conduct ePCTs to improve dementia care



Training Workshop

- Annual training opportunity for early to mid-career investigators to develop competence in conducting ePCT to improve dementia care
- No cost to participants



Adjunct Faculty Program

- Annual opportunity for early to mid-career investigators to integrate into IMPACT Core/Teams for 1 year to develop skills in the design and conduct of ePCTs for dementia care
- No salary support offered



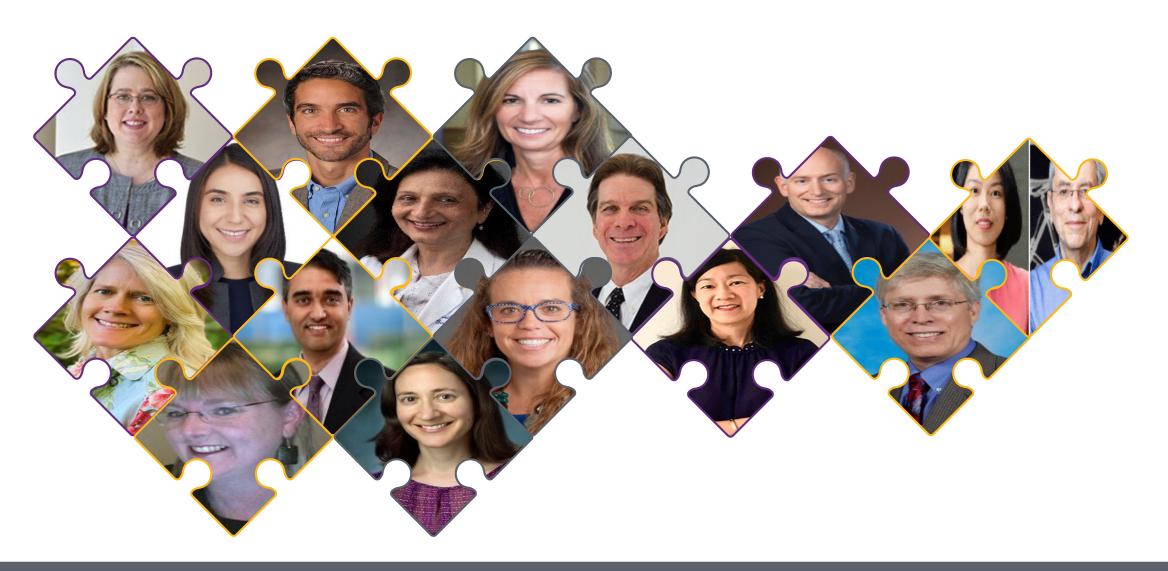
IMPACT ePCT Video Learning Library

- Training videos on important considerations for conducting ePCTs in dementia care
- No cost, publically available

The National Institute on Aging (NIA) IMPACT Collaboratory (U54AG063546) was established in 2019, bringing together a multidisciplinary group of over 60 investigators representing over 30 academic institutions, to build the nation's capacity to conduct pragmatic clinical trials (ePCTs) of non-pharmacological interventions within health care systems (HCS) to improve the care of people living with AD/ADRD and their care partners.



IMPACT Collaboratory: Pilot & Demo Projects Awardees





For More Information

https://impactcollaboratory.org



NIA Representatives

Program Officer:

Partha Bhattacharyya, PhD
Division of Behavioral and Social Research
partha.bhattacharyya@nih.gov

Project Scientists:

Lisa Onken, PhD
Division of Behavioral and Social Research

Marcel Salive, MD, MPH
Division of Geriatrics and Clinical Gerontology

Coordinator:

Ama Donkor, MPH
Division of Behavioral and Social Research

