NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

NIH Pragmatic Trials Collaboratory Onboarding Meeting

October 29, 2025

Virtual

SUPPLEMENTAL MEETING MATERIALS

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Virtual Onboarding Meeting Agenda

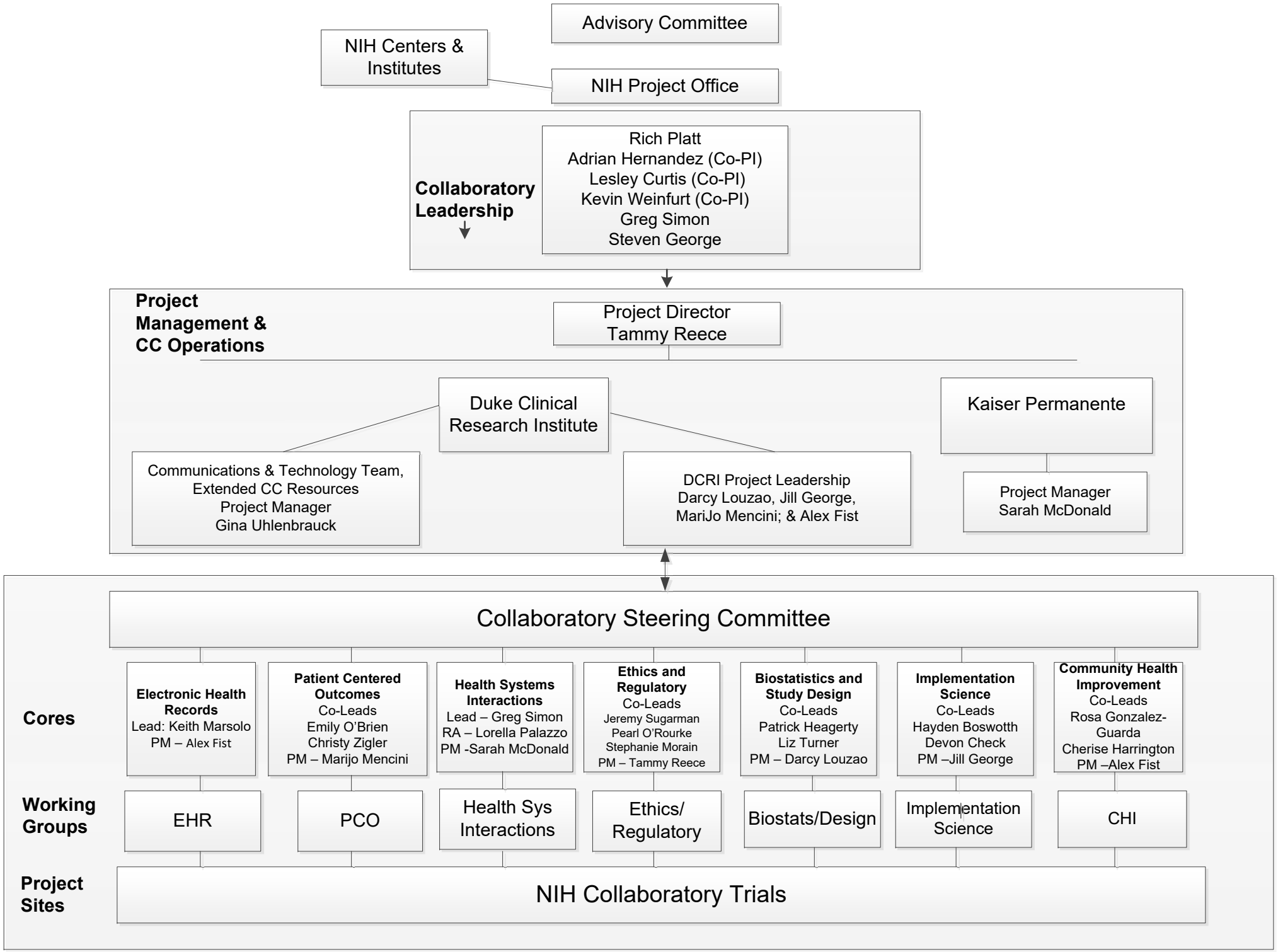
October 29, 2025 | 1:30 – 4:00 p.m. ET

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Meeting Purpose: Welcome and learn about our new NIH Collaboratory Trial; provide introductions and an overview of the NIH Pragmatic Trials Collaboratory; hear from the Core Working Groups; and engage in discussion.

DURATION	TOPIC	WHO	GOAL
1:30 – 1:40 p.m.	**Welcome** **Opening Remarks** **Introductions**	Wendy Weber Kevin Weinfurt	*Review meeting goals and expectations* *Introduce NIH, CC, and trial leadership*
1:40 – 1:55 p.m.	**Overview of the NIH Pragmatic Trials Collaboratory**	Wendy Weber	*Reinforce the idea of openly discussing challenges* *Discuss what it means to be part of a cooperative agreement*
1:55 – 2:15 p.m.	**Working with the NIH Collaboratory Coordinating Center**	Kevin Weinfurt	*Give an overview of the Coordinating Center* *Describe how NIH Collaboratory Trials work with the Coordinating Center* *Share lessons from experiences with previous trials* *Q&A*
2:15 – 2:40 p.m.	**Get to Know the New UG3 NIH Collaboratory Trial** • Coordinated cARe paiN mAnagement Technology ImplementatiON (CARNATION)	Lynn DeBar Rachel Gold Nicole Cook	*Project abstract and data sharing plan are in the meeting e-binder* *Provide an overview of the trial* *Describe the **top issues** being faced and **potential barriers*** *Identify **questions** where guidance is needed* *Q&A*
2:40 – 3:55 p.m. *10 min per Core (5 min presentation 5 min discussion)*	**Introduction to the Core Working Groups**	Kevin Weinfurt	*Provide an introduction to the Core Working Groups including resources and expertise* *Initiate conversations around **potential challenges*** *Brief discussion after each Core*
	• Ethics and Regulatory	Jeremy Sugarman Stephanie Morain	
	• Patient-Centered Outcomes	Emily O'Brien	
	• Biostatistics and Study Design	Patrick Heagerty Liz Turner	
	• Community Health Improvement	Rosa Gonzalez-Guarda Cherise Harrington	
	• Implementation Science	Hayden Boswell	
	• Electronic Health Records	Keith Marsolo	
	• Health Care Systems Interactions	Greg Simon	
3:55 – 4:00 p.m.	**Closing Remarks**	Wendy Weber Kevin Weinfurt	*Summarize the meeting and next steps* *Take any final trial questions for program leadership*

NIH COLLABORATORY HANDOUTS


Advisory Committee
NIH Centers & Institutes
NIH Project Office
Collaboratory Leadership
Rich Platt
Adrian Hernandez (Co-PI)
Lesley Curtis (Co-PI)
Kevin Weinfurt (Co-PI)
Greg Simon
Steven George
Project Management & CC Operations
Project Director
Tammy Reece
Duke Clinical Research Institute
Kaiser Permanente
Communications & Technology Team,
Extended CC Resources
Project Manager
Gina Uhlenbrauck
DCRI Project Leadership
Darcy Louzao, Jill George,
MariJo Mencini; & Alex Fist
Project Manager
Sarah McDonald
Collaboratory Steering Committee
Cores
Electronic Health Records
Lead: Keith Marsolo
PM – Alex Fist
Patient Centered Outcomes
Co-Leads
Emily O'Brien
Christy Zigler
PM – Marijo Mencini
Health Systems Interactions
Lead – Greg Simon
RA – Lorella Palazzo
PM -Sarah McDonald
Ethics and Regulatory
Co-Leads
Jeremy Sugarman
Pearl O'Rourke
Stephanie Morain
PM – Tammy Reece
Biostatistics and Study Design
Co-Leads
Patrick Heagerty
Liz Turner
PM – Darcy Louzao
Implementation Science
Co-Leads
Hayden Boswotth
Devon Check
PM –Jill George
Community Health Improvement
Co-Leads
Rosa Gonzalez-Guarda
Cherise Harrington
PM –Alex Fist
Working Groups
EHR
PCO
Health Sys Interactions
Ethics/ Regulatory
Biostats/Design
Implementation Science
CHI
Project Sites
NIH Collaboratory Trials

NIH PRAGMATIC TRIALS COLLABORATORY COMMUNICATIONS CHANNELS

NIH INSTITUTES & CENTERS

HEAL INITIATIVE

Title: ACP PEACE
PIs: James A. Tulsky, Angelo Volandes
Institution: Dana-Farber Cancer Institute

Title: AIM-CP
PIs: Sebastian Tong, Kushang Patel
Institution: University of Washington

Title: APA-SM
PIs: Jennifer Kawi, Jane Bolin, Hulin Wu
Institution: The University of Texas Health Science Center at Houston

Title: ARBOR-Telehealth
PIs: Richard Skolasky, Kevin McLaughlin
Institution: Johns Hopkins University

Title: BackInAction
PIs: Lynn DeBar, Andrea Cook
Institution: Kaiser Foundation Research Institute

Title: BeatPain Utah
PI: Julie Fritz
Institution: University of Utah

Title: BEST-ICU
PIs: Michele Balas, Eduard Vasilevskis
Institution: University of Nebraska Medical Center

Title: Chat 4 Heart Health
PIs: Michael Ho, Sheana Bull
Institution: University of Colorado

Title: FM-TIPS
PIs: Kathleen Sluka, Leslie Crofford
Institution: University of Iowa

Title: GGC4H
PIs: Margaret Kuklinski, Stacy Sterling
Institution: University of Washington

Title: GRACE
PIs: Ardith Doorenbos, Judith Schlaeger, Robert Molokie, Miriam Ezenwa, Nirmish Shah
Institution: University of Illinois at Chicago

Title: HiLo
PI: Hrishikesh Chakraborty
Institution: Duke University

Title: I CAN DO Surgical ACP
PIs: Elizabeth Wick, Genevieve Melton-Meaux, Rebecca Sudore
Institution: University of California, San Francisco

Title: IMPACt-LBP
PIs: Christine Goertz, Adam Goode, Jon Lurie, Hrishikesh Chakraborty
Institution: Duke University

Title: INSPIRE
PIs: Susan Huang, Richard Platt, Shruti Gohil
Institution: Harvard Pilgrim Health Care

Title: iPATH
PI: Sara Singer
Institution: Stanford University

Title: LungSMART
PIs: David Wetter, Guilherme Del Fiol, Kensaku Kawamoto
Institution: University of Utah

Title: MOMs
PI: Stephanie Fitzpatrick
Institution: Feinstein Institute for Medical Research

Title: NOHARM
PIs: Andrea Cheville, Jon Tilburt
Institution: Mayo Clinic

Title: OPTIMUM
PI: Natalia Morone
Institution: Boston Medical Center

Title: PRIM-ER
PIs: Corita R. Grudzen, Keith Goldfeld
Institution: NYU School of Medicine

Title: RAMP
PIs: Diana Burgess, Roni Evans, Katherine Hadlandsmyth
Institution: Center for Veterans Research and Education

Title: STEP-2
PIs: Rachel Winer, Amanda Petrik, Jasmin Tiro
Institution: University of Washington

Title: TAICHIKNEE
PIs: Chenchen Wang, Helen Lavretsky, Eric Roseen, Robert Saper
Institution: Tufts Medicine Tufts Medical Center

NIH COLLABORATORY TRIALS

NIH Collaboratory Trial PI	Project Officer	Project Officer IC	Project Scientist	Project Scientist IC
Margaret Kuklinski	Beda Jean-Francois	NCCIH/NIDA	Elizabeth Ginexi	NCCIH
Corita Grudzen	Peter Murray	NCCIH	Marcel Salive	NIA
James Tulsky	Marcel Salive	NIA	Karen Kehl	NINR
Myles Wolf	Susan Mendley	NIDDK	Kevin Chan	NIDDK
Lynn DeBar	Lanay Mudd	NCCIH	Basil Eldadah	NIA
Andrea Cheville	Marcel Salive	NIA	Theresa Cruz	NICHD/NCMRR
Kathleen Sluka	Charles Washabaugh	NIAMS	Joe Bonner	NINR
Natalia Morone	Wendy Weber	NCCIH	Luke Stoeckel	NIA
Ardith Doorenbos	Beda Jean-Francois	NCCIH	Sekai Chideya	NCCIH
Julie Fritz	Karen Kehl	NINR	Lanay Mudd	NICHD/NCMRR
Christine Goertz	Peter Murray	NCCIH	TBD	TBD
Shruti Gohil	Clayton Huntley	NIAID	Clayton Huntley	NIAID
Michele Balas	Mihaela Stefan	NHLBI	Karen Kehl	NINR
Chenchen Wang	Sekai Chideya	NCCIH	Lanay Mudd & Qilu Yu	NCCIH
Michael Ho	Larry Fine	NHLBI	Nicole Redmond	NHLBI
Elizabeth Wick	Barbara Radziszewska	NIA	Marcel Salive	NIA
Stephanie Fitzpatrick	Shalanda Bynum	NINR	NA	NA
Sara Singer	Lynne Slaughter Padgett	NIMHD	NA	NA
Sebastian Tong	Karen Kehl	NINR	Alexis Bakos	NIA
Diana Burgess	Karen Kehl	NINR	Lanay Mudd	NCCIH
Richard Skolasky	Charles Washabaugh	NIAMS	Peter Murray	NCCIH
Jennifer Kawi	Wendy Weber	NCCIH	Beda Jean-Francois	NCCIH
David Wetter	Sallie Weaver	NCI	Paul Han	NCI
Rachel Winer	Veronica Chollette	NCI	Cynthia Vinson	NCI
Coordinating Center PIs	**Project Officer**	**Project Officer IC**	**Project Scientist**	**Project Scientist IC**
Adrian Hernandez, Lesley Curtis, Kevin Weinfurt	Wendy Weber	NCCIH	Beda Jean-Francois	NCCIH

COLLABORATORY COORDINATING CENTER

STEERING COMMITTEE

Lesley Curtis (Chair), Michele Balas, Alexis Bakos, Jane Bolin, Joe Bonner, Hayden Bosworth, Sheana Bull, Diana Burgess, Shalanda Bynum, Hrishikesh Chakraborty, Kevin Chan, Devon Check, Andrea Cheville, Sekai Chideya, Veronica Chollette, Andrea Cook, Leslie Crofford, Theresa Cruz, Lynn DeBar, Guilherme Del Fiol, Ardith Doorenbos, Debra Egan, Basil Eldadah, Roni Evans, Miriam Ezenwa, Lawrence Fine, Stephanie Fitzpatrick, Julie Fritz, Elizabeth Ginexi, Christine Goertz, Shruti Gohil, Keith Goldfeld, Rosa Gonzalez-Guarda, Adam Goode, Corita Grudzen, Katherine Hadlandsmyth, Paul Han, Cherise Harrington, Patrick Heagerty, Adrian Hernandez, Michael Ho, Susan Huang, Clayton Huntley, Beda Jean-Francois, Kensaku Kawamoto, Jennifer Kawi, Karen Kehl, Margaret Kuklinski, Helen Lavretsky, Jon Lurie, Keith Marsolo, Kevin McLaughlin, Genevieve Melton-Meaux, Susan Mendley, Nancy Miller, Robert Molokie, Stephanie Morain, Natalia Morone, Lanay Mudd, Peter Murray, Emily O'Brien, Pearl O'Rourke, Lynne Padgett, Kushang Patel, Amanda Petrik, Richard Platt, Barbara Radziszewska, Nicole Redmond, Rachel Richesson, Eric Roseen, Marcel Salive, Robert Saper, Judith Schlaeger, Nirmish Shah, Greg Simon, Sara Singer, Richard Skolasky, Kathleen Sluka, Mihaela Stefan, Stacy Sterling, Luke Stoeckel, Rebecca Sudore, Jeremy Sugarman, Jon Tilburt, Jasmin Tiro, Sebastian Tong, James Tulsky, Liz Turner, Eduard Vasilevskis, Cynthia Vinson, Angelo Volandes, Chenchen Wang, Charles Washabaugh, Sallie Weaver, Wendy Weber, Kevin Weinfurt, David Wetter, Elizabeth Wick, Rachel Winer, Hulin Wu Qilu Yu, Christy Zigler

NIH PROJECT OFFICE

NIH INSTITUTES AND CENTERS

NHLBI NIAID NIDDK NIAMS NCCIH NIDA NIA NINR NICHD NCMRR NIMHD NCI

KNOWLEDGE REPOSITORY

LEARNING HEALTH SYSTEM

COLLABORATORY CORE WORKING GROUPS

ETHICS/REGULATORY

Pearl O'Rourke*
Stephanie Morain*
Jeremy Sugarman*
Joe Ali, Emily Alayan, Kisha Ali, Andy Avins, Sheana Bull, Leslie Crofford, Lee Cross, Dixie Ecklund, Anna Edelmann, Janel Fedler, Stephanie Fitzpatrick, Susan Gaylord, Luke Gelinas, Bryan Gibson, Corita Grudzen, Kris Hansen, Breanna Hetland, Mitch Knisely, Margaret Kuklinski, Laurie Kunches, Helen Lavretsky, David Magnus, Kevin McBryde, Kayla Rachel Mehl, Genevieve Melton-Meaux, Natalia Morone, Tina Neill-Hudson, Vasiliki Nataly Rahimzadeh, Kushang Patel, Caleigh Propes, Tammy Reece, Judy Schlaeger, Richard Skolasky, Paula Tebeau, Jon Tilburt, David Vulcano, Chenchen Wang, Kevin Weinfurt, Dave Wendler, Elizabeth Wick, Ben Wilfond, Hulin Wu

BIOSTATISTICS AND STUDY DESIGN

Patrick Heagerty*
Liz Turner*
Melissa Anderson, Taliser Avery, Michele Balas, Emine Bayman, John Boscardin, Evan Carey, Hrishikesh Chakraborty, Yuchiao Chang, Codruta (Cody) Chiuzan, Elizabeth Colantuoni, Andrea Cook, Ardith Doorenbos, Roni Evans, Stephanie Fitzpatrick, Keith Goldfeld, Tom Greene, Liz Habermann, Jeph Herrin, Andrew Humbert, Ken Kleinman, Margaret Kuklinski, Karen Lasser, Fan Li, Darcy Louzao, Jon Moyer, David Murray, Tuhina Neogi, Meg Nikolov, Brian Orleans, Charles Quesenberry, Jincheng Shen, Susan Shortreed, Prabha Siddarth, Alana Steffen, Brent Taylor, Ludovic Trinquart, Neha Varma, Angelo Volandes, Jin Wang, Rui Wang, Xueqi Wang, Janice Weinberg, Christopher Wickman, Hulin Wu, Qilu Yu

HEALTH CARE SYSTEMS INTERACTIONS

Greg Simon*
Laura Mae Baldwin, James Blum, Jane Bolin, Jordan Braciszewski, Sheana Bull, David Chambers, Rowena Dolor, Matt Exline, Stephanie Fitzpatrick, Julie Fritz, Beverly Green, Corita Grudzen, Katherine Hadlandsmyth, Rachel Hays, Michael Ho, Ken Johnson, Kensaku Kawamoto, Barcey Levy, Jon Lurie, Timothy McAlindon, Kevin McLaughlin, Sarah Minteer, Natalia Morone, Lorella Palazzo, Pamela Peterson, Russell Poland, Kiran Salman, Kenneth Sands, Kathleen Sluka, Victor Solis, Jon Tilburt, Kenneth Sands, Katie Stone, Jasmin Tiro, Carol Vance, Angelo Volandes, Elizabeth (Liza) Wick, Weijun Zhang

ELECTRONIC HEALTH RECORDS

Rachel Richesson*
Keith Marsolo*
Liz Amos, Michele Balas, Arne Beck, Andy Boyd, Jordan Braciszewski, James Campbell, Andrea Cheville, Dana Dailey, Kelley Daley, Stacie Daugherty, Kim Faurot, Alex Fist, Stephanie Fitzgerald, Guilherme del Fol, Christine Goertz, Corita Grudzen, Michael Ho, Trevis Huff, Andrea Kline-Simon, Josh Lakin, John Lin, Devin Mann, Clem McDonald, Genevieve Melton-Meaux, Tra Nguyen, Amanda Petrik, Alice Pressman, Kiran Salman, Robert Saper, Judith Schlaeger, Kari Stevens, Brent Taylor, Eduard Vasilevskis, Angelo Volandes, Hulin Wu

PATIENT-CENTERED OUTCOMES

Christy Zigler*
Emily O'Brien*
Emine Bayman, Arne Beck, M. Fernanda Bellolio, Andy Boyd, Susan Czajkowski, Stephanie Fitzpatrick, Morgan Fuoco, Carol Greco, Helen Lavretsky, Brent Leininger, Amy Loree, Jennifer Kawi, Andy King, Kevin McLaughlin, MariJo Mencini, Tuhina Neogi, Samuel O'Brien, Kushang Patel, Pamela Peterson, Zacariah Shannon, Richard Skolasky, Alana Steffen, Stacy Sterling, Anne Thackeray, Jamie Thompson, Jon Tilburt, James Tulsky, Eduard Vasilevskis, Chenchen Wang, Kevin Weinfurt, Rachel Winer

HEALTH EQUITY

Rosa Gonzalez-Guarda*
Cherise Harrington*
Maureen Akubu-Odero, Kisha Ali, Michele Balas, Jessica Lee Barnhill, Kimberly Behrens, Sheana Bull, Andrea Cheville, Allison Cuthel, Dana Dailey, Juanita Darby, Stacie Daughter, Graham Dore, Roni Evans, Kim Faurot, Alex Fist, Stephanie Fitzpatrick, Julie Fritz, Morgan Fuoco, Christine Goertz, Peiyin Hung, Beda Jean-Francois, Jungyoon Kim, Mitchell Knisely, Lance Laird, Katharine Lawrence, Keith Marsolo, Alice Pressman, Isabel Roth, Robert Saper, Nina Siman, Richard Skolasky, Rebecca Sudore, Venky Sundaram, Jamike Thompson, Jasmin Tiro, Sebastian Tong, Eduard Vasilevskis, Chenchen Wang, David Wetter

IMPLEMENTATION SCIENCE

Devon Check *
Hayden Bosworth*
Oluwaseun Adeyemi, Kisha Ali, Kristin R. Archer, Lindsay Ballengee, Diana Burgess, Allison Cuthel, Lynn DeBar, Ardith Doorenbos, Maria Fernandez, Stephanie Fitzpatrick, Jill George, Steven George, Tony Gerlach, Shruti Gohil, Carol Greco, Anna Krupp, Kevin McLaughlin, Brian Mittman, Wynne Norton, Kushang Patel, Amanda Petrik, Eric Roseen, Isabel Roth, Stacie Salsbury, Chelsey Schlechter, Edward Septimus, Stacy Sterling, Anne Thackeray, Jasmin Tiro, Cindy Tofthagen, Sebastian Tong, Katy Trinkley, Angelo Volandes, Elizabeth (Liza) Wick

** Chair / Co-Chairs*

Current as of: January 2025

NIH Collaboratory Trials Roadmap
FY25, Q3

Milestones and major activities occurring within the lifecycle of a NIH Collaboratory Trial

PILOT/START-UP

- UG3 Award Date
- R01 Award Date *

APA-SM, LungSMART, STEP-2

TRIAL INITIATION

- UH3 Award
- Trial Registration
- Protocol Approved for Trial Initiation
- Initial IRB Approval (UH3 Phase)
- Initial IRB Approval (R01)
- Statistical Analyses Plan Finalized

AIM-CP, iPATH*, RAMP

SITE ACTIVATION

- First Site Activated

ENROLLMENT

- First Patient Enrolled

ARBOR-Telehealth, BeatPain Utah, BEST-ICU, Chat 4 Heart Health, I CAN DO Surgical ACP, MOMs*, TAICHIKNEE

FOLLOW-UP

- Last Patient Enrolled
- Last Day for Intervention
- End of Outcome Observation Period

GRACE, IMPACt-LBP

PLANNING COMPLETED

- Did not proceed to trial initiation

BPMedTime

DATA ANALYSIS

- Database Lock
- Final Statistical Analysis

GGC4H, OPTIMUM

DATA AVAILABILITY

- Key Data Available
- Secondary Endpoint Data Available
- All Data Available

REPORTING: Internal Dissemination

- Topline Results Report
- Topline Results (or Full Results) to Health System Partners
- Topline Results to Leadership/SC and Other Partners
- Topline Results to Investigators/Sites

BackInAction, FM TIPS, NOHARM

REPORTING: Public Dissemination

- Topline Results to Public via Press Release (if done)
- Full Results to Public
- First Presentation Results
- Main Manuscript Submitted
- Main Manuscript Accepted
- ClinicalTrials.gov Reporting

COMPLETED

- Manuscript published and/or
- Close out process completed with the CC

ABATE, ACP PEACE, EMBED, HiLo, ICD-Pieces, INSPIRE, LIRE, Nudge, PPACT, PRIM-ER, PROVEN, SPOT, STOP CRC, TiME, TSOS

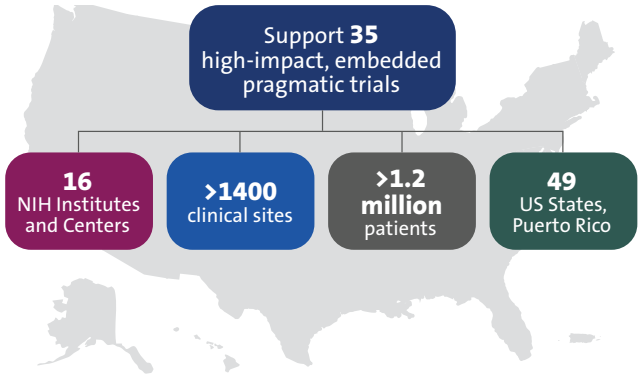
NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

What Are Embedded Pragmatic Clinical Trials?

- Conducted in healthcare systems
- Use existing infrastructure and streamlined procedures
- Provide high-quality evidence
- More efficient and cost effective than traditional trials

Our Reach



NIH Partners, Past and Present

NCCIH NCI NCMRR NHLBI NIA NIAID NIAMS NICHD NIDA NIDDK NIMH **NIMHD NINR NINDS OBSSR ODP**

Bold denotes current partners (Grant U24AT009676)

Our Impact

We learn and share knowledge from each trial we support to advance pragmatic research methods.

>360 publications*	Work cited **>11,800** times	**>245** trial consultations
>570 Grand Rounds webinars	**>100,000** website visitors annually	**30+** Living Textbook chapters

Wide Influence

The success of the NIH Pragmatic Trials Collaboratory and its extensive resources have informed subsequent NIH initiatives for pain management and dementia care, as well as research programs in Canada and Japan.

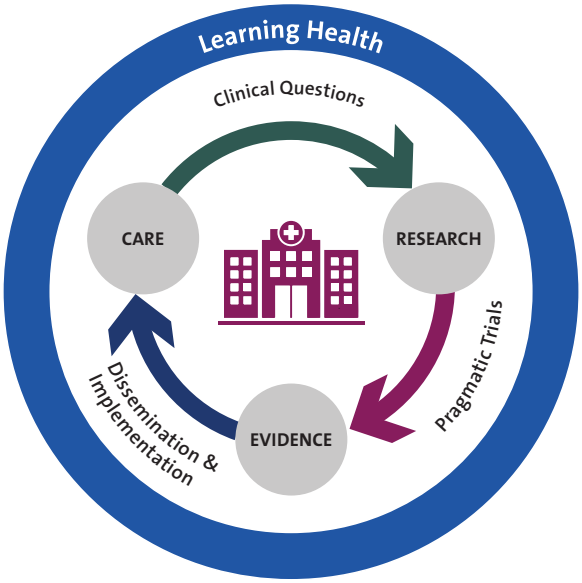
*LAST UPDATED JULY 22, 2025

About

Since 2012, the NIH Pragmatic Trials Collaboratory has helped rigorous trials be successful in real-world settings, creating standards for more efficient, large-scale clinical research.

Our Role

Pragmatic trials are foundational to the learning health model where ongoing evidence generation improves care. The NIH Pragmatic Trials Collaboratory is the nation's leading resource on how to conduct randomized trials embedded in healthcare delivery.



Our Support

As a Resource Coordinating Center, we provide comprehensive expertise and technical assistance to researchers conducting pragmatic trials.

Consult and provide guidance on:

- Study design and analysis
- Regulatory issues and consent practices
- Use of real-word data sources
- Translating results into practice

Offer strategies to:

- Contribute to healthier communities
- Engage health system partners

Assist with:

- Defining study endpoints
- Measuring patient-centered outcomes
- Assessing feasibility of clinical workflows
- Addressing challenges that arise

Why Do an Embedded Pragmatic Clinical Trial? The 5 Rs

Relevant Question
The question is pressing, and healthcare system leaders, patients, and front-line clinicians care about the answer.

Real-World Setting
Desire to test in diverse healthcare delivery settings with the hope of implementing findings widely.

Representative Population
Ability to enroll participants who reflect the real-world population with the disease or condition.

Routinely Collected Data
Can use data collected as part of healthcare delivery to answer the question, supplemented by data from other sources.

Rigorous Methods
Randomized research is needed to answer the question and inform changes in care, policy, or reimbursement.

About NIH Collaboratory Trials

SETTINGS
- Academic health centers
- Community clinics
- Federally qualified health centers
- For-profit health systems
- Hospitals
- Managed care organizations
- Primary care
- Specialty care

CHARACTERISTICS
- Trials in multiple therapeutic areas
- Each works across multiple health systems
- Use electronic health records, administrative, and claims data
- Strong partnerships with health systems
- Committed to sharing lessons and data

How We Learn and Share

Pragmatic research poses unique challenges that the NIH Pragmatic Trials Collaboratory has a wealth of experience navigating. Through the program's Core Working Groups, research teams are part of a community of scientists with a shared mission to help each other be successful and create generalizable knowledge about the design, conduct, and dissemination of pragmatic research.

DISSEMINATION

Grand Rounds
Weekly webinar with >90,000 all-time attendees and 53 podcast episodes with >22,000 total plays

Living Textbook
Free online textbook, continually updated and expanded, with 30+ chapters, >1800 pages, and >100 contributors

Resources and Tools
Publications, guidance documents, Quick Start Guides, checklists, etc—over 100 study tools available

Education
Provided >80 hours of presenter-led training at 13 workshops, plus video modules, self-paced learning, fellowships, and more

This work was supported within the NIH Pragmatic Trials Collaboratory under award number U24AT009676 from multiple NIH Institutes, Centers, and Offices. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

LEARN MORE
rethinkingclinicaltrials.org

FOLLOW US

Rethinking Clinical Trials®: A Living Textbook of Pragmatic Clinical Trials

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

A comprehensive, authoritative guide to pragmatic clinical trials and research that engages healthcare delivery organizations as partners.

rethinkingclinicaltrials.org

WHAT IS THE LIVING TEXTBOOK?

- Free, online textbook that it is continually updated and expanded
- Contains the latest emerging knowledge on pragmatic research methods
- Developed by NIH Collaboratory experts, researchers, and partners
- Reputable, citable resource

Training Resources

Videos
Self-paced learning modules and videos featuring experts in pragmatic research

Resources
Downloadable Quick Start Guides, checklists, handouts, guidance documents, etc

Workshops
Materials including agendas, recordings, summaries, and slides

Grand Rounds & Podcast

Library of our popular weekly webinar (recordings, summaries) and podcast episodes featuring timely topics in pragmatic research.

>570 webinars

>50 podcasts

TOOLS FOR TRIALS

NIH Collaboratory Trials share their data and resources publicly via the Living Textbook.

- **Study tools:** Protocols, consent forms, site materials, questionnaires, toolkits, etc
- **Datasets and documentation:** Datasets, dictionaries, analytic code, etc

Textbook Content

30+ chapters

>100 contributors

Launched in 2013, the Living Textbook has grown to cover all aspects of designing, conducting, and disseminating pragmatic trials.

Topics include:

Design

- Developing a Grant
- Experimental Designs
- Building Partnerships
- Patient Engagement
- What Is a Pragmatic Trial
- Endpoints & Outcomes
- Using EHR Data
- Intervention Complexity

Data, Tools & Conduct

- Assessing Feasibility
- Acquiring & Assessing Real-World Data
- Study Startup
- Participant Recruitment
- Monitoring Fidelity
- Clinical Decision Support
- Mobile Health

Dissemination & Implementation

- Data Sharing
- Dissemination
- Implementation

Ethics & Regulatory

- Privacy
- Consent Disclosure & Nondisclosure
- Collateral Findings
- Data & Safety Monitoring
- Single IRB

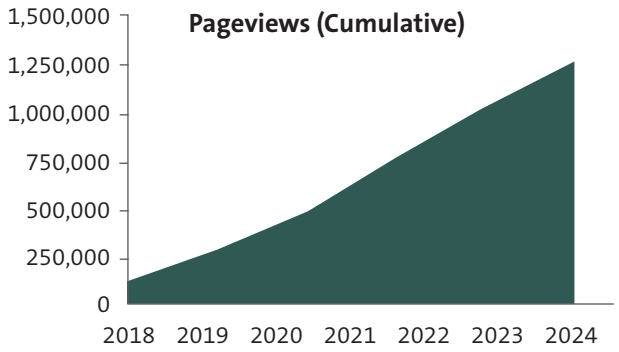
Program Information

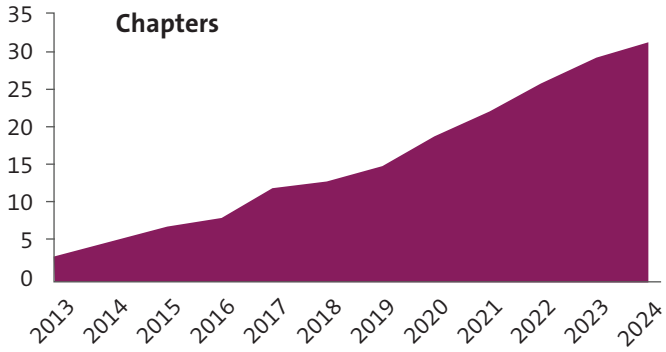
Learn about the NIH Pragmatic Trials Collaboratory, including its trials, Core Working Groups, and Coordinating Center.

- Latest program news and interviews
- Publication updates

LAST UPDATED JULY 22, 2025

Living Textbook Growth





FUN FACTS

>100,000
visitors annually

>1800
webpages

More words
than *War and Peace*

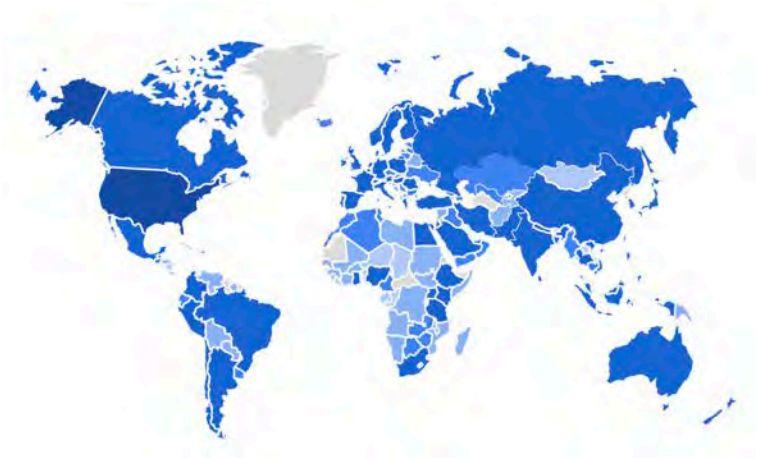
>3 days
total video runtime viewed monthly

Users Around the World

~%60 of users are in the United States

Other top countries:
- United Kingdom
- India
- Canada
- Germany
- Australia
- China
- France

Top cities:
- Washington DC
- Mumbai
- New York
- London
- Los Angeles
- Chicago
- Boston



DID YOU KNOW?

- Researchers at the Pharmacological Evaluation Institute of Japan translated key parts of the Living Textbook into Japanese to inform their work
- Canada's Pragmatic Trials Training Program is using the Living Textbook to help educate future trial leaders

Top Content

Our most accessed topics include:
- Cluster randomized trials
- Endpoints and outcomes
- What is a pragmatic trial?
- Intraclass correlation
- Stepped-wedge designs
- Real-world data sources
- Clinical decision support
- EHR-based phenotyping

This work was supported within the NIH Pragmatic Trials Collaboratory under award number U24AT009676 from multiple NIH Institutes, Centers, and Offices. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Trial Information

The Living Textbook contains complete information on all NIH Collaboratory Trials, including trial details, publications, presentations, interviews, resources, and more.

LEARN MORE
rethinkingclinicaltrials.org

FOLLOW US

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

NIH Collaboratory Trials: Tips for Year 1

This handout features advice, resources, and lessons learned for navigating the planning year and getting the most out of program participation.

How should the team engage the Cores?

- **Designate:** Identify specialists on your team who can attend Core meetings then summarize and report back the information learned.
- **Share openly:** Actively participate and don't be afraid to air your problems to the Core—you can benefit and learn from the wisdom of a highly experienced group.
- **Learn from each other:** Remember other trials may have encountered a similar problem, allowing the Cores to help you navigate. If you encounter something new, the Cores may ask you to help document your experience so it can be helpful to others in the future.

"Be transparent. You can get through the issues with the Cores' help."
—Doug Zatzick, PI of TSOS

"When you have a problem someone has encountered before, the Cores can easily help. When you encounter unique problems, then your problem can be used as a test case."
—Karen Sherman, Co-PI of BackInAction

"It's really key to have that wisdom of the community. Keep them informed and we'll learn from each other."
—Miguel Vazquez, PI of ICD-Pieces

"First, leverage the Cores. The point of the Cores is 'how do we help you be successful?'"
—Angelo Volandes, Co-PI of ACP PEACE

How do you balance delegating activities and staying in the loop?

- **Divide and conquer:** Split the team across the Cores, which helps keep the co-investigators invested in the trial.

"Give some other people, whether co-investigators or people on the team, an opportunity to get more engaged in the process by having them attend the calls. It's a great way to stay abreast of everything that's happening."
—Stacy Sterling, Co-PI of GGC4H

How do you manage deliverables and milestones?

- **Dependable team:** Have good people on your team including an organized project manager.
- **Strong site communication:** Stay in regular communication with the site PIs.
- **Regular PI reviews:** Have established, untouchable times and dates where the PIs review everything that happens in the trial.

"You're on a tight timeline to get everything done in the UG3 year. I can't emphasize enough that the short timeline means you have to be moving quickly. It helps to have people with specific and discrete tasks, and somebody assigned to each milestone. It's those milestones that the NIH is going to consider in making the assessment for continuing."
—Sheana Bull, Co-PI of Nudge

Visit the Living Textbook: rethinkingclinicaltrials.org

NIH Collaboratory Trials: Tips for Year 1

Tools for Study Startup

Data Monitoring	Trial Documentation	Checklists and Guides
▪ Data Monitoring in Pragmatic Clinical Trials: Points to Consider ▪ Charter Template for Data Monitoring Committees of PCTs ▪ Additional Resources	▪ Trial Documentation Checklist ▪ Sample Pragmatic Trial Protocols ▪ Information on Consent Waivers and Alterations, Mechanisms for Notification	▪ Implementation Readiness Checklist ▪ Checklist for Training Design ▪ Quick Start Guide for Project Managers

Planning for the Unknown

"Begin with the mindset that there will be some adaptations during the trial."
—Russell Glasgow, Nudge

Contingency planning can help account for some unexpected changes and minimize their impact. NIH Collaboratory Investigators recommend expecting:

- **EHR updates:** These can impact trial processes. Plan for regular fidelity checks and budget for IT personnel to support these checks for the duration of the trial.
- **Staff and leadership turnover:** Offer well-documented training, meet with new leadership, and have trial champions at multiple levels for ongoing support.
- **Dynamic care environments:** Shifts in guidelines, policies, and initiatives can impact trial validity. Agree on site expectations upfront, plan for continuous monitoring, and identify core functions of the intervention.

Learn more in the Living Textbook:

- Navigating the Unknown
- Monitoring Intervention Fidelity and Adaptations

Engaging Partners

"Collaborations are the key to solving the unforeseen and inevitable challenges of conducting clinical trials in large healthcare systems."
—Ellen Tambor

Resources related to engaging partners effectively for PCTs include:

- Deciding Who to Engage
- Patient Engagement Throughout a PCT
- Guide for Healthcare Systems Leader Partnerships
- Communicating With Health System Partners

NIH Pragmatic Trials Collaboratory

Enabling research embedded in healthcare delivery since 2012

Updated October 22, 2025

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

History: Initiated in 2012 via the NIH Common Fund, now transitioned to sustained funding from multiple NIH Institutes and Centers plus NIH HEAL Initiative

Goal: Strengthen the national capacity to implement cost-effective, large-scale research studies that engage healthcare delivery organizations as partners

Vision: Support the design and conduct of innovative embedded pragmatic clinical trials (ePCTs) to establish best practices and disseminate knowledge

NIH PRAGMATIC TRIALS COLLABORATORY
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Why Do an ePCT? The 5 Rs

Relevant Question

The question is pressing, and healthcare system leaders, patients, and front-line clinicians care about the answer.

Real-World Setting

Desire to test in diverse healthcare delivery settings with the hope of implementing findings widely.

Representative Population

Ability to enroll participants reflective of the real-world population with the disease or condition.

Routinely Collected Data

Can use data collected as part of healthcare delivery to answer the question, supplemented by data from other sources.

Rigorous Methods

Randomized research is needed to answer the question and inform changes in care, policy, or reimbursement.

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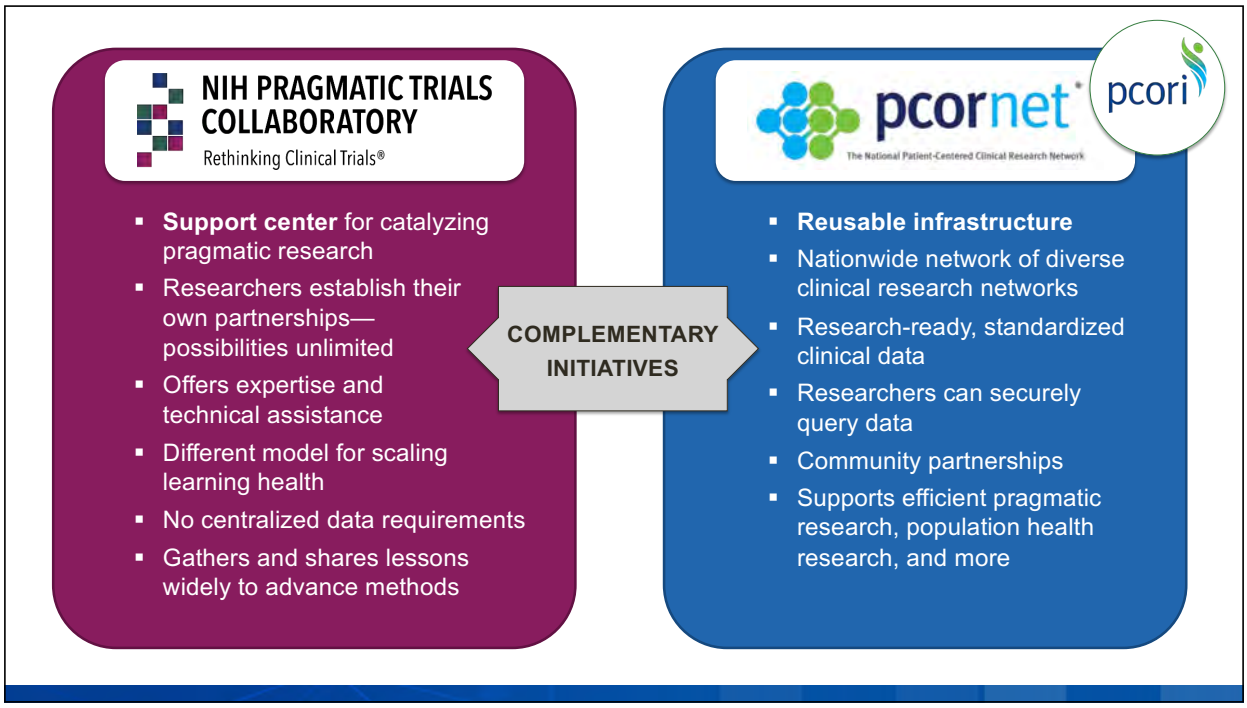
	Clinical Trials Networks	NIH Pragmatic Trials Collaboratory	Quality Improvement
Purpose	Provides infrastructure for clinical trial conduct	Provides **expertise and support** for pragmatic trials (Resource Coordinating Center)	Provides data for immediate improvements in a particular healthcare delivery setting
Setting	Establishes partnerships with clinical sites, primarily academic medical centers	Researchers bring their own partnerships with **diverse healthcare delivery sites**	Individual health system
Population	Patients with condition recruited by trial (homogenous)	Patients with condition receiving healthcare (heterogeneous)	Patients at facility
Data	Creates new data systems for research	Leverages **existing infrastructure** (EHR, etc.)	Leverages existing infrastructure (EHR, etc.)
Research	Rigorous, randomized (individual) clinical trials	Rigorous, randomized (individual or cluster) **pragmatic trials**	Systematic and data-guided activities
Intervention	Delivered by trial staff	Delivered by health system staff	Delivered by health system staff
Outcomes	Efficacy, safety	Effectiveness, implementation	Effectiveness, implementation
Conditions	Highly controlled	**Real-world**	Real-world
Comparator	Placebo or control	Usual care or active comparison	Pre-post comparison



Program Success and Evolution

- Initial funding from Common Fund gave support for new ways to think about clinical research and allowed these ideas to take hold by demonstrating feasibility and rigor
- Successful transition from Common Fund to IC support showed appreciation of the program's value and uptake among broad group of ICs
- Integration with NIH HEAL Initiative extended the program's reach into a major NIH-wide program to address the overdose and pain crisis
- Informed other NIH initiatives (PMC & IMPACT) using ePCTs to address major health challenges
  - Pain Management Collaboratory (PMC) in military and Veterans healthcare systems
  - People living with dementia and their care partners (IMPACT Collaboratory)

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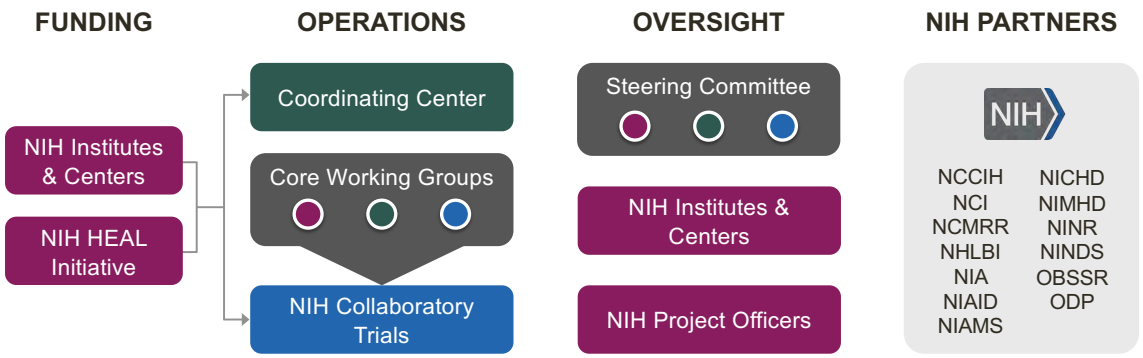
Program Structure



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Coordinating Center

Functions

- Provide national leadership and technical expertise
- Produce, document, and disseminate standards
- Support synergy within program
- Coordinate communication and dissemination

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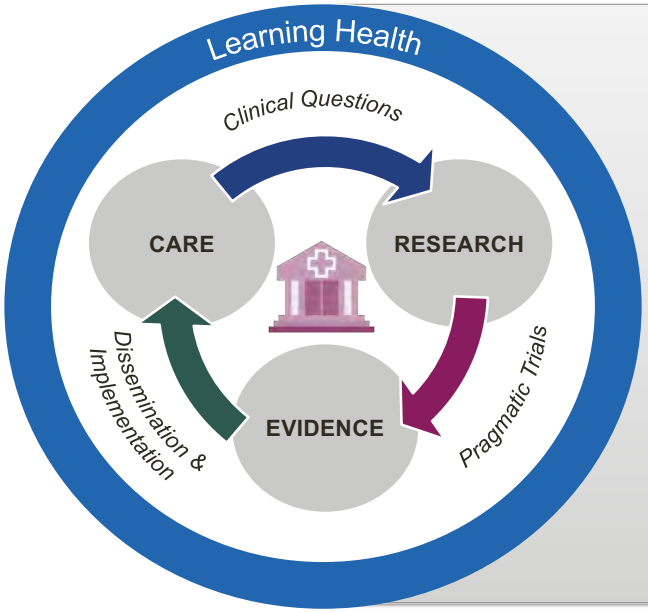

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SUPPORT SERVICES

- Consult and provide guidance on:
  - Study design and analysis
  - Regulatory issues and consent practices
  - Use of EHR and real-word data sources
  - Translating results into practice
- Offer strategies to:
  - Contribute to healthier communities
  - Engage healthcare system partners
- Assist with:
  - Defining study endpoints
  - Measuring patient-centered outcomes
  - Assessing feasibility of clinical workflows
  - Addressing challenges that arise

Program Reach

Supports **35** large-scale, high-impact ePCTs

16 NIH Institutes and Centers

>1,400 clinical sites

>1.2 million patients

49 US States and Puerto Rico

No sites in Arkansas

NIH PRAGMATIC TRIALS COLLABORATORY
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NIH Collaboratory Trials

- ePCTs addressing questions of major public health importance
- Wide variety of therapeutic areas
- Many have phased funding
  - Planning/startup phase
  - Implementation phase

HEAL-Funded NIH Collaboratory Trials

- NIH HEAL Initiative® funding since 2019
- Supports ePCTs of non-opioid interventions for:
  - Treating pain
  - Improving pain management
  - Reducing reliance on opioids

Aim: Improve availability of, effectiveness of, and adherence to evidence-based, nonpharmacologic pain management

NIH PRAGMATIC TRIALS COLLABORATORY
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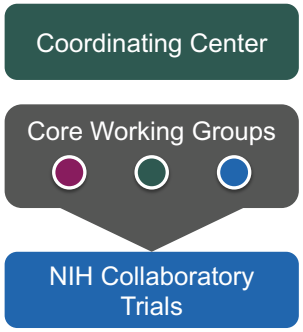
Core Working Groups

- Component of Coordinating Center focusing on key areas of ePCTs
- Led by chairs from Coordinating Center
- Include representatives from
  - NIH Collaboratory Trials
  - NIH



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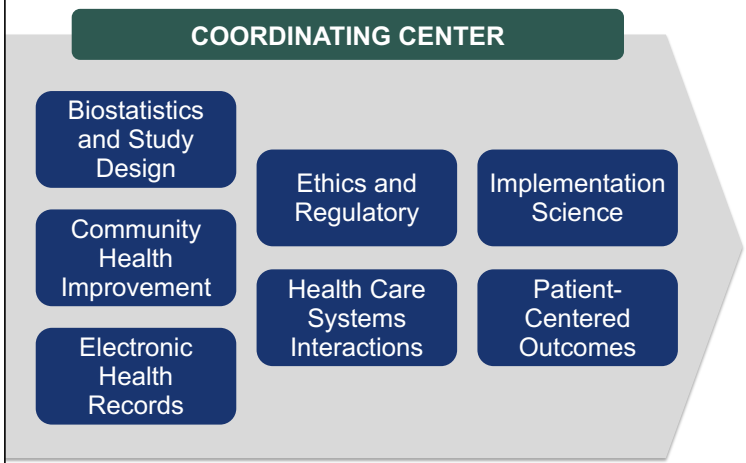
Core Working Groups: Purpose



- Guide and support NIH Collaboratory Trials
- Disseminate knowledge
  - Guidance
  - Lessons learned

NIH PRAGMATIC TRIALS COLLABORATORY
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Co-Chairs:

- Patrick Heagerty, PhD
- Elizabeth L. Turner, PhD

Biostatistics and Study Design Core

Mission

- Provide expertise in novel designs and methods for ePCTs
- Document new statistical issues and share knowledge
- Develop methods to address challenges

NIH PRAGMATIC TRIALS COLLABORATORY
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Co-Chairs:

- Rosa Gonzalez-Guarda, PhD, MPH
- Cherise Harrington, PhD, MPH

Community Health Improvement Core

Mission

- Examine strategies to
  - Help trials be widely conducted across the US, including in rural areas
  - Implement evidence-based interventions across settings to improve the health of all populations
  - Ensure research is relevant to the people affected

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Electronic Health Records Core

Co-Chairs:
- Rachel Richesson, PhD, MPH
- Keith A. Marsolo, PhD


Mission

- Help trials acquire, assess, and use real-world data
- Create tools to leverage EHRs for research across multiple health systems
- Share lessons broadly

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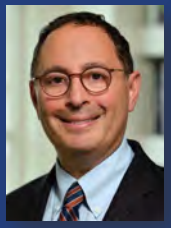
Ethics and Regulatory Core

Co-Chairs:
- Jeremy Sugarman, MD
- Pearl O'Rourke, MD
- Stephanie Morain, PhD, MPH



Mission

- Identify areas of regulatory and ethical uncertainty for ePCTs
- Help trials navigate regulatory and ethical complexities
- Provide a framework for ethical, compliant conduct of ePCTs

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Health Care Systems Interactions Core

Chair:
- Greg Simon, MD, MPH

Mission

- Engage those involved in healthcare delivery systems to:
  - Participate in research
  - Help design research attractive to practitioners
  - Lower administrative barriers
  - Communicate results to all parties

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Implementation Science Core

Co-Chairs:
- Devon Check, PhD
- Hayden Bosworth, PhD

Mission

- Support trials in achieving their implementation-related research aims
- Promote the uptake and sustainability of effective interventions
- Produce guidance for conducting implementation research in ePCTs

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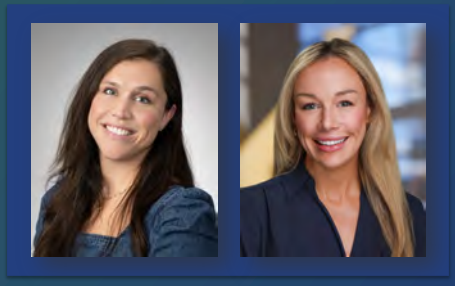
Co-Chairs:

- Christy Zigler, PhD, MSEd
- Emily C. O'Brien, PhD



Patient-Centered Outcomes Core

Mission

- Define best practices for:
  - Selecting, compiling, and curating appropriate PRO measures
  - Developing new instruments when needed
  - Creating efficient, quality data collection systems compatible with EHRs

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Impact of Cores

>245 trial consultations

>195 publications & products

>1,000 Core meetings

PI Testimonials

"Take the Biostats Core Working Group advice seriously—get it early and act on it early."

"The CC helped greatly with the selection of our secondary outcome measures."

"Have as many key members of your team work closely with Collaboratory Cores."

"Having adjusted our strategy prior to IRB submission based on input from the Core was likely a major reason the IRB review went so smoothly."

Examples: NIH Collaboratory Trials Informing Clinical Care

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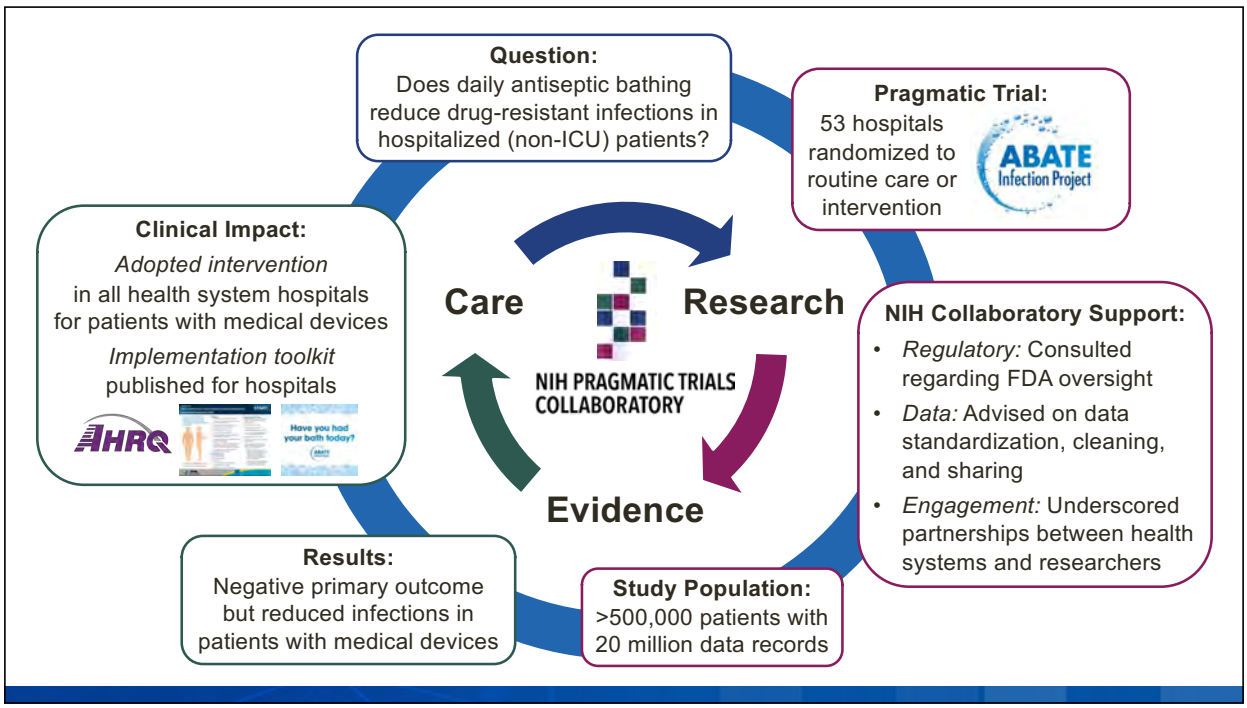
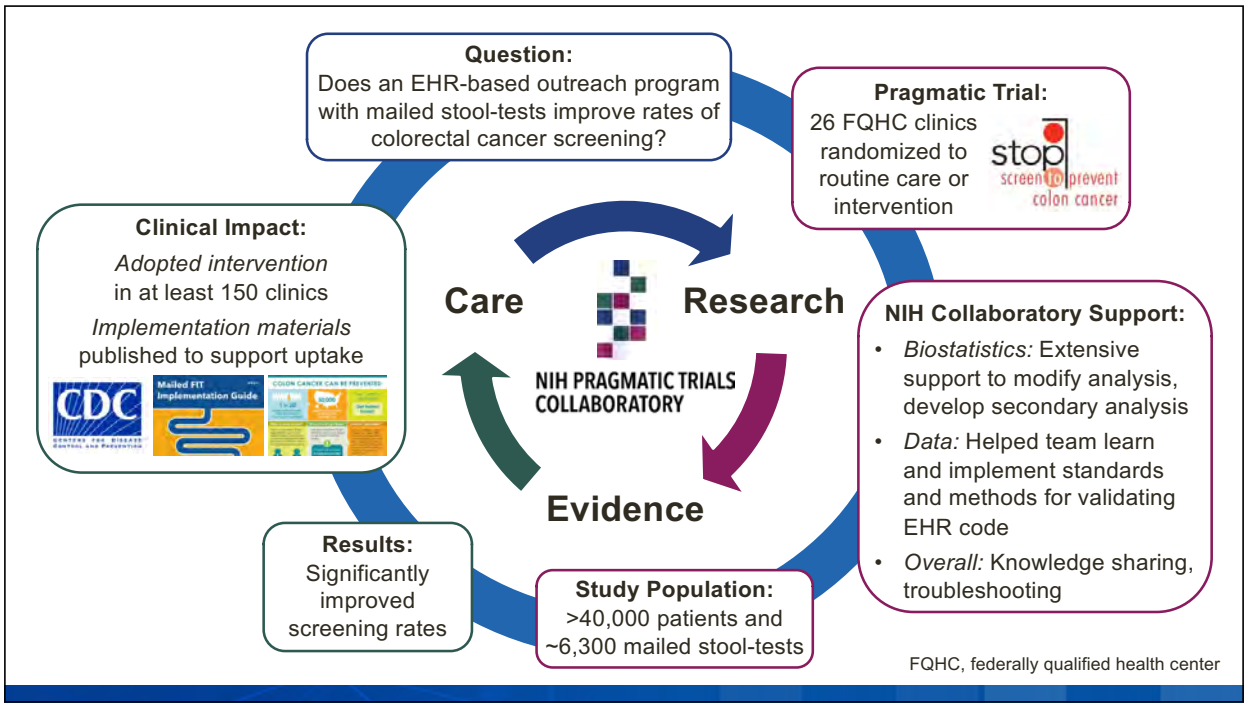
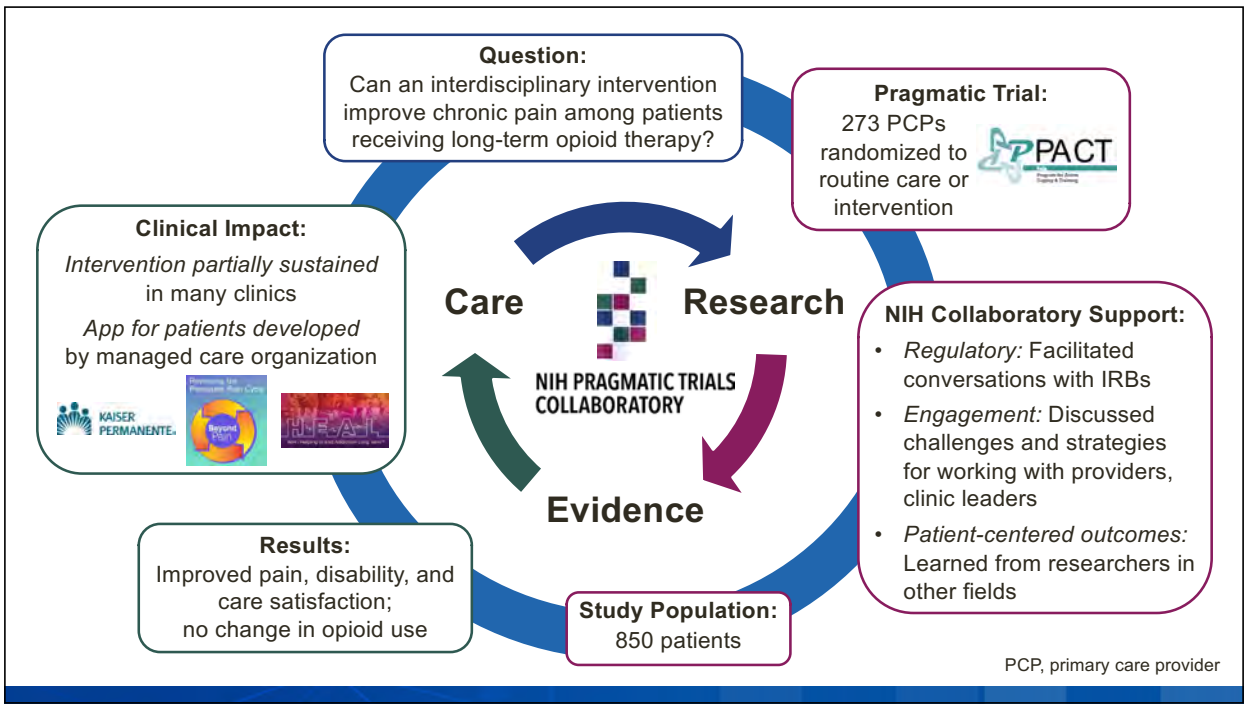
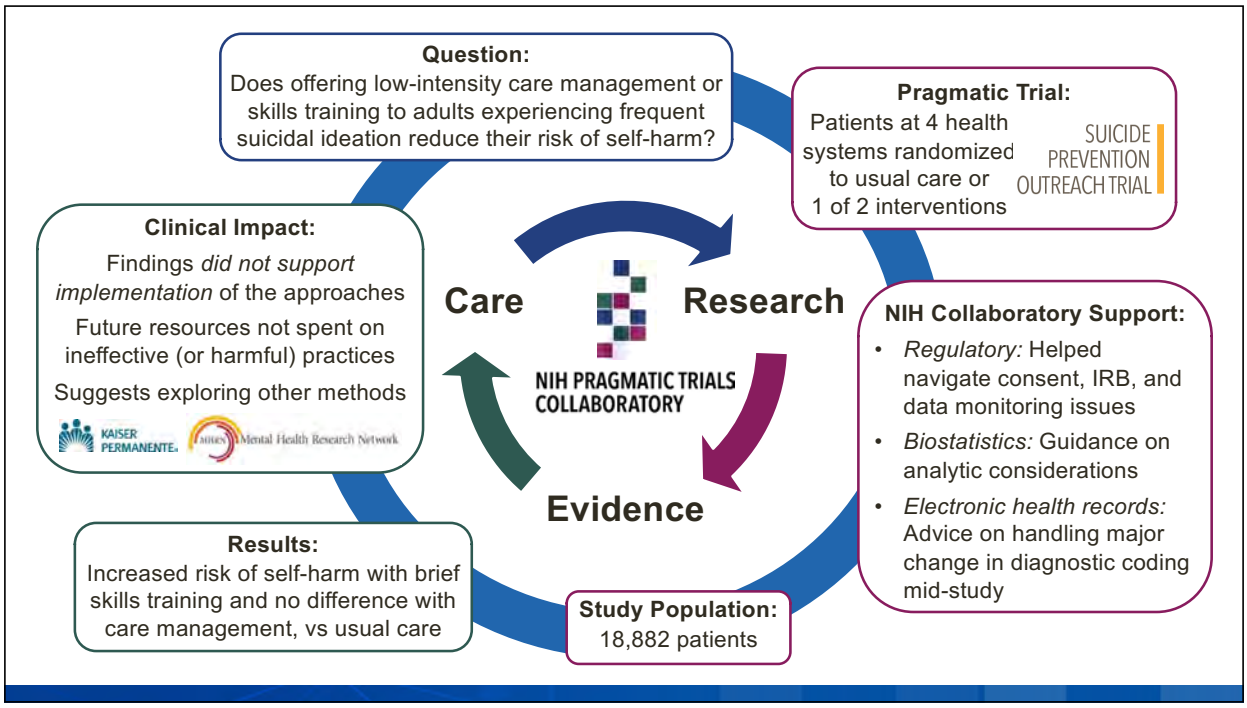



Question:
Does an EHR-based outreach program with mailed stool-tests improve rates of colorectal cancer screening?
Pragmatic Trial:
26 FQHC clinics randomized to routine care or intervention
stop screen to prevent colon cancer
NIH Collaboratory Support:
• Biostatistics: Extensive support to modify analysis, develop secondary analysis
• Data: Helped team learn and implement standards and methods for validating EHR code
• Overall: Knowledge sharing, troubleshooting
Study Population:
>40,000 patients and ~6,300 mailed stool-tests
Results:
Significantly improved screening rates
Clinical Impact:
Adopted intervention in at least 150 clinics
Implementation materials published to support uptake
CDC
Mailed FIT Implementation Guide
Care
Research
NIH PRAGMATIC TRIALS COLLABORATORY
Evidence
FQHC, federally qualified health center


Question:
Can an interdisciplinary intervention improve chronic pain among patients receiving long-term opioid therapy?
Pragmatic Trial:
273 PCPs randomized to routine care or intervention
PPACT
NIH Collaboratory Support:
• Regulatory: Facilitated conversations with IRBs
• Engagement: Discussed challenges and strategies for working with providers, clinic leaders
• Patient-centered outcomes: Learned from researchers in other fields
Study Population:
850 patients
Results:
Improved pain, disability, and care satisfaction; no change in opioid use
Clinical Impact:
Intervention partially sustained in many clinics
App for patients developed by managed care organization
KAISER PERMANENTE
Beyond Pain
HEAL
Care
Research
NIH PRAGMATIC TRIALS COLLABORATORY
Evidence
PCP, primary care provider



Disseminating Knowledge and Best Practices

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We've learned a lot about how to integrate research with practice…

- Using EHRs for research is complex
- Unexpected changes occur, but there are ways to mitigate their effects
- Strong partnerships with healthcare systems are essential
- Some ethical and regulatory uncertainties remain
- Many factors involved in whether an intervention will be sustained
- **Sharing challenges and lessons promotes success, advances methods**

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Flow of Information

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Partnerships

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- Grand Rounds
- Workshops
- Publications
- Living Textbook
- Podcast
- Tools
- Resources
- Knowledge

COLLABORATION

SHARING

pcornet · AHRQ · Sentinel Initiative · Clinical Trials Transformation Initiative · FDA U.S. Food & Drug Administration · The Office of the National Coordinator for Health Information Technology · health care systems research network · National Academy of Medicine · MHRN Mental Health Research Network · NIA IMPACT COLLABORATORY · pmc painmanagement collaboratory · AcademyHealth · pcori · Réseau de recherche sur les données de santé du Canada Health Data Research Network Canada · All of Us Research Program · CTSA Clinical & Translational Science Awards · CMS Centers for Medicare & Medicaid Services · National Library of Medicine · OHRP Office for Human Research Protections · HEAL · AMIA · PEIJ

NIH NCCIH NCI NCMRR NHLBI NIA NIAID NIAMS NICHD NIDA NIDDK NIMH NIMHD NINR NINDS OBSSR ODP

Bold denotes current NIH partner

Publications*

TOTAL PUBLISHED
>360

CITATIONS
>11,800

JOURNALS
>130

*As of July 22, 2025

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Living Textbook of Pragmatic Clinical Trials

Website & Online Textbook

rethinkingclinicaltrials.org

- Program information
- Comprehensive ePCT resource
- Continuously updated and expanded
- Internal and external contributors
- Reliable and citable

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Living Textbook Content and Reach

30+ chapters

>100,000 visitors/year

>100 contributors

TOPICS INCLUDE:

Design
- Developing a Grant
- Experimental Designs
- Building Partnerships
- Patient Engagement
- What Is a Pragmatic Trial
- Endpoints & Outcomes
- Using EHR Data
- Intervention Complexity

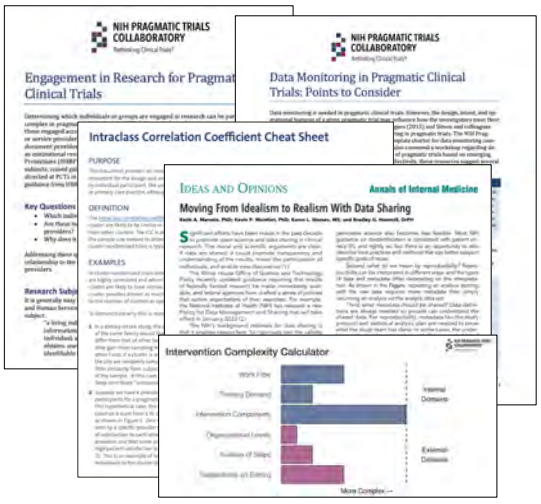
Data, Tools & Conduct
- Assessing Feasibility
- Acquiring & Assessing Real-World Data
- Study Startup
- Participant Recruitment
- Monitoring Fidelity
- Clinical Decision Support
- Patient-Reported Outcomes
- Mobile Health

Dissemination & Implementation
- Data Sharing
- Dissemination
- Implementation
- End-of-Trial Decision-Making

Ethics & Regulatory
- Privacy
- Consent, Disclosure & Nondisclosure
- Collateral Findings
- Data & Safety Monitoring
- Single IRB

Tools and Guidance Documents

CHEAT SHEETS	• Intraclass Correlation Coefficient • Equitable Language • Assessing Fitness-for-Use of Clinical Data for ePCTs
TOOLS & TOOLKITS	• Intervention Complexity Calculator • Patient-Centered Outcomes Toolkit • Data Sharing Information • Quick Start Guides
TEMPLATES & CHECKLISTS	• Data Monitoring Committee Charter • Reporting ePCTs Template • Trial Documentation Checklist • Data Sharing Checklist
GUIDANCE DOCUMENTS	• Engagement in ePCTs • Assessing Data Quality • Cluster Randomized Trial Design • Data Sharing



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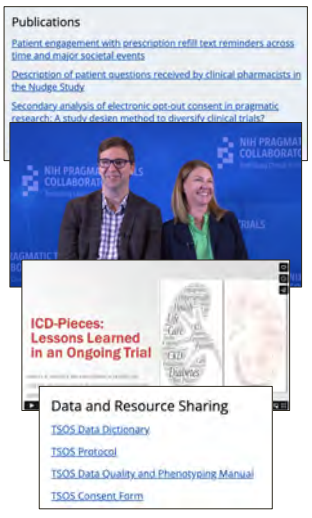
Learn About Our ePCTs

TRIAL WEBPAGES

- Trial details
- Study snapshots
- News & interviews
- Publications
- Presentations
- Shared resources



Sharing Trial Resources & Data

rethinkingclinicaltrials.org/data-and-resource-sharing/

Completed trials share data and resources publicly

STUDY TOOLS	DATASETS AND DOCUMENTATION	PUBLICATIONS
• Protocols • Consent forms • Implementation tools • Site materials • Questionnaires • Toolkits • Ethics and regulatory documentation	• Data dictionaries • Public use datasets • Analytic code • Computable phenotypes • Data quality manuals • Data request forms • Data sharing checklists	• Study design papers • Main outcomes papers • Qualitative research • Other publications

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

Rethinking Clinical Trials® Podcast

Podcast episodes

- >50 episodes available
- >22,000 plays
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

Training Activities

13 workshops

>700 attendees

48 presenters

84 hours
of presenter-led training

AUDIENCES REACHED

- Academic researchers
- Funding agencies
- Investigators
- Health system leaders
- Healthcare practitioners
- Other ePCT partners

AcademyHealth

SCT Society for Clinical Trials

health care systems research network

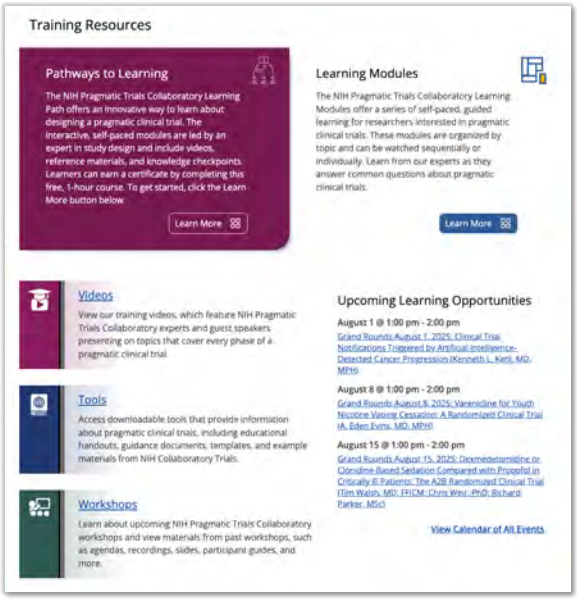
NIH National Institutes of Health

Duke University

ePCT Training Resources

rethinkingclinicaltrials.org/training-resource/

- Learning pathway
- Learning modules
- Video library
- Tools (handouts, checklists, guides, etc)
- Workshop materials (slides, recordings, etc)
- Upcoming opportunities



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Appendix: NIH Collaboratory Trials

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NIH Collaboratory Trials: Completed

Project	Population	Intervention	Outcome
ABATE	Non-ICU patients	Decolonization strategies	MRSA and VRE clinical cultures
ACP PEACE	Older patients with advanced cancer	Video decision aid patients and communication skills training for clinicians	Documentation of advance care planning in the electronic health record
EMBED	Patients with opioid use disorder	User-centered computerized clinical decision support	Rate of emergency department–initiated buprenorphine/naloxone; referral for ongoing medication-assisted treatment
HiLo	Patients undergoing hemodialysis	Liberalizing serum phosphate target	Rate of hospitalization
ICD-Pieces	Concurrent diabetes, chronic kidney disease, hypertension	Collaborative primary care program	All-cause hospitalizations for 3 conditions
INSPIRE	Non–critically ill hospitalized patients with abdominal or skin and soft tissue infections	Predictive algorithm and automated prompt in the computerized provider order entry system to improve judicious antibiotic prescribing	Reduction in unnecessary prescribing of extended-spectrum antibiotics
LIRE	Low back pain	Insertion of epidemiologic benchmarks in lumbar spine imaging reports	Relative value unit for spine-related interventions
Nudge	Patients with chronic cardiovascular conditions	Text messages and chat bot	Adherence to cardiovascular medications

NIH Collaboratory Trials: Completed (cont)

Project	Population	Intervention	Outcome
PPACT	Nonmalignant chronic pain	Multidisciplinary behavioral care management	Brief Pain Inventory
PRIM-ER	Older adults (>65 years)	Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback	Healthcare utilization and survival
PROVEN	Nursing home residents	Advance care planning video (behavioral program)	Hospitalizations; presence of advance directives
SPOT	Suicidal ideation or depression	Collaborative care behavioral program (care management and skills training)	Suicide attempts
STOP CRC	Adults aged 50-75 years	Direct mail colorectal cancer screening program (FIT kit)	Colorectal screening rates
TiME	Patients initiating dialysis	Dialysis session of at least 4.25 hours	All-cause mortality, hospitalization
TSOS	Traumatic injury	Collaborative care management program	PTSD checklist; PHQ-9 scale; alcohol use disorders; SF-12/36

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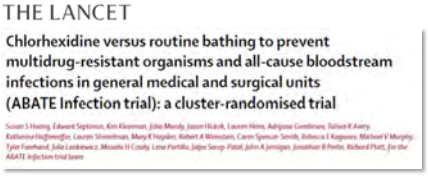
Completed

ABATE *Active Bathing to Eliminate Infection*

- Cluster trial comparing 2 **quality improvement strategies to reduce multidrug-resistant organisms and healthcare-related infections** in non-ICU population
- 53 hospitals
- 331,584 patients

ABATE Infection Project


THE LANCET

Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial

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Completed

ACP PEACE *Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly*

- Stepped-wedge, cluster randomized trial testing whether testing the delivery of a video decision aid to patients and goals-of-care communication skills training to oncology clinicians will increase **advance care planning** in older patients with advanced cancer
- 29 oncology clinics in 3 healthcare systems
- 13,800 patients

ACP PEACE

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Rethinking Clinical Trials®

Completed

EMBED *Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder*

- Cluster trial testing the effect of user-centered computerized clinical decision support on rates of **emergency department–initiated buprenorphine/naloxone and referral for ongoing medication-assisted treatment** in patients with opioid use disorder
- 3 health systems
- 5,047 patients


thebmj

RESEARCH

OPEN ACCESS

User centered clinical decision support to implement initiation of buprenorphine for opioid use disorder in the emergency department: EMBED pragmatic cluster randomized controlled trial

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

HiLo *Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis*

- Cluster trial testing whether less stringent control of serum phosphate levels will yield **noninferior rates of all-cause hospitalization** in patients with end-stage renal disease undergoing hemodialysis
- >100 dialysis facilities
- 4,400 expected patients

HiLo

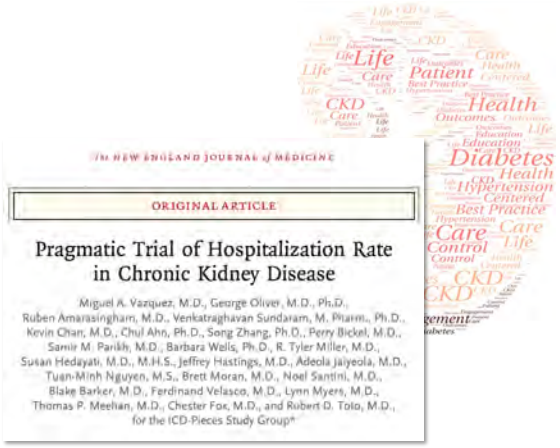
A Pragmatic Trial Sponsored by the National Institutes of Health

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

ICD-Pieces *Improving Chronic Disease Management with Pieces™*

- Novel platform to test effective ways to **reduce heart problems, hospitalizations & deaths in patients with multiple chronic conditions**
- 94 clinical sites
- 11,000 patients



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

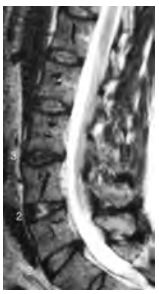
INSPIRE *INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients*

- 2 cluster randomized trials that used personalized clinical decision support to improve judicious antibiotic prescribing for non–critically ill hospitalized with **abdominal infections or skin and soft tissue infections**
- 60,725 patients with skin or soft tissue infections, and 105,004 patients with abdominal infections

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

LIRE *Lumbar Imaging with Reporting of Epidemiology*



- Cluster trial evaluating whether **inserting epidemiologic benchmarks** into lumbar spine imaging reports reduces subsequent tests and treatments
- 98 clinical sites
- 246,289 patients


JAMA Network Open

Original Investigation | Imaging

The Effect of Including Benchmark Prevalence Data of Common Imaging Findings in Spine Image Reports on Health Care Utilization Among Adults Undergoing Spine Imaging
A Stepped-Wedge Randomized Clinical Trial

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

Nudge *Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications*

- Patient-level randomized pragmatic trial comparing the effects of digital interventions (text messages and chat bot) on **medication adherence** in patients with chronic cardiovascular conditions
- 3 health systems


Nudge

JAMA | Original Investigation

Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications
A Randomized Pragmatic Trial

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

PPACT *Collaborative Care for Chronic Pain in Primary Care*

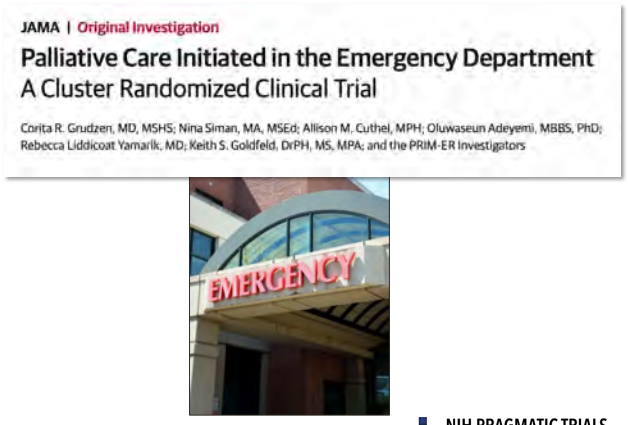
- Mixed-methods cluster trial evaluating **integration of multidisciplinary services within the primary care** environment to improve chronic pain management
- 3 regional health systems
- 2,000 patients

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

PRIM-ER *Primary Palliative Care for Emergency Medicine*

- Cluster trial testing the effects of implementing primary palliative care in emergency medicine on **healthcare utilization and survival**
- 35 emergency departments across 18 health systems



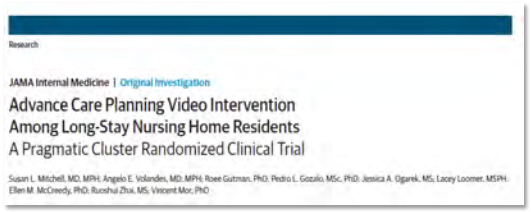
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

PROVEN *Pragmatic Trial of Video Education in Nursing Homes*

- Evaluating the **effectiveness of advance care planning video** shown in nursing homes of 2 large healthcare systems
- 359 nursing homes
- 211,469 patients

PROVEN
PRagmatic Trial of Video Education in Nursing Homes


Research

JAMA Internal Medicine | Original Investigation

Advance Care Planning Video Intervention Among Long-Stay Nursing Home Residents
A Pragmatic Cluster Randomized Clinical Trial

Susan L. Mitchell, MD, MPH; Angelo E. Volandes, MD, MPH; Roee Gutman, PhD; Pedro L. Gozalo, MSc, PhD; Jessica A. Ogarek, MS; Lacey Loomer, MSPH; Ellen M. McCreedy, PhD; Ruoshui Zhai, MS; Vincent Mor, PhD

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

SPOT *Suicide Prevention Outreach Trial*

- Collaborative care model to test treatments intended to reach large groups of **adult patients who have serious thoughts of suicide**
- 4 clinical sites
- 18,644 patients

SUICIDE PREVENTION OUTREACH TRIAL


Research

JAMA | Original Investigation

Effect of Offering Care Management or Online Dialectical Behavior Therapy Skills Training vs Usual Care on Self-harm Among Adult Outpatients With Suicidal Ideation
A Randomized Clinical Trial

Gregory E. Simon, MD, MPH; Susan M. Shortreed, PhD; Rebecca C. Rossom, MD, MS; Anne Beck, PhD; Gregory N. Clarke, PhD; Ursula Whiteside, PhD; Julie E. Richards, MPH, PhD; Robert B. Penfold, PhD; Jennifer M. Boggs, PhD, MSW; Julia Smith, MS

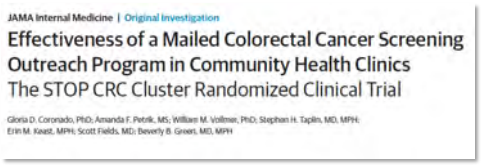
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

STOP CRC *Strategies and Opportunities to Stop Colorectal Cancer*

- Cluster trial testing a culturally tailored, healthcare system–based program to **improve CRC screening rates** in community-based collaborative network
- 30 clinical sites
- 62,155 patients

stop
screen to prevent
colon cancer


JAMA Internal Medicine | Original Investigation

Effectiveness of a Mailed Colorectal Cancer Screening Outreach Program in Community Health Clinics
The STOP CRC Cluster Randomized Clinical Trial

Gloria D. Coronado, PhD; Amanda F. Petrik, MS; William M. Vollmer, PhD; Stephen H. Taplin, MD, MPH; Erin M. Keast, MPH; Scott Fields, MD; Beverly B. Green, MD, MPH

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

TiME *Time to Reduce Mortality in End-Stage Renal Disease*

- Cluster trial testing whether a **longer hemodialysis session can improve survival & quality of life** for patients with kidney failure who require chronic treatment with dialysis
- 256 clinical sites
- 7,053 patients

TiME


JASN

The TiME Trial: A Fully Embedded, Cluster-Randomized, Pragmatic Trial of Hemodialysis Session Duration

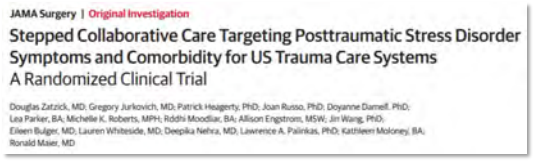
Laura M. Dember,[1,2] Eduardo Lacson, Jr.,[3] Steven M. Brunelli,[4] Jesse Y. Hsu,[5] Alfred K. Cheung,[6] John T. Daugirdas,[7] Tom Greene,[8] Csaba P. Kovesdy,[9] Dana C. Miskulin,[10] Ravi I. Thadhani,[11,12] Wolfgang Winkelmayer,[13] Susan S. Ellenberg,[3] Denise Cifelli,[14] Rosemary Madigan,[14] Amy Young,[4] Michael Angeletti,[3] Rebecca L. Wingard,[3] Christina Kahn,[3] Allen R. Nissenson,[15,16] Franklin W. Maddux,[3] Kevin C. Abbott,[17] and J. Richard Landis[3]

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Completed

TSOS *Trauma Survivors Outcomes and Support*

- Stepped-wedge cluster trial **testing innovative intervention for patients with PTSD and comorbidity**
- 25 level 1 trauma centers
- 960 patients


JAMA Surgery | Original Investigation

Stepped Collaborative Care Targeting Posttraumatic Stress Disorder Symptoms and Comorbidity for US Trauma Care Systems
A Randomized Clinical Trial

Douglas Zatzick, MD; Gregory Jurkovich, MD; Patrick Heagerty, PhD; Joan Russo, PhD; Doyanne Darnell, PhD; Lea Parker, BA; Michelle K. Roberts, MPH; Riddhi Moodliar, BA; Allison Engstrom, MSW; Jin Wang, PhD; Eileen Bulger, MD; Lauren Whiteside, MD; Deepika Nehra, MD; Lawrence A. Palinkas, PhD; Kathleen Moloney, BA; Ronald Maier, MD

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

NIH Collaboratory Trials: Planning Phase

Project	Population	Intervention	Outcome
LungSmart	Current and former smokers, aged 50-80 years	Telehealth tools designed to engage people in lung cancer screening	Lung cancer screening completion
STEP-2	Women aged 30-65 years	HPV self-sampling	Screening proportion

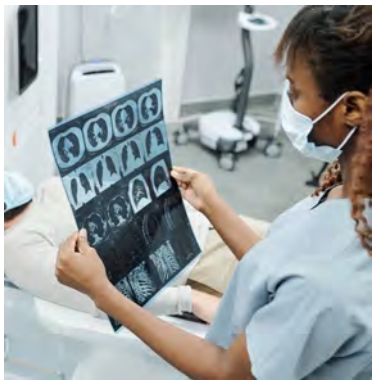
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Planning

LungSmart

Population Health Management Approaches to Increase Lung Cancer Screening in Community Health Centers

- Patient-level randomized trial
- Evaluating the effectiveness of digital and telehealth tools to **increase the reach of lung cancer screening** among people who get care at community health centers
- 14 federally qualified health centers in Utah operating ~50 primary care clinics



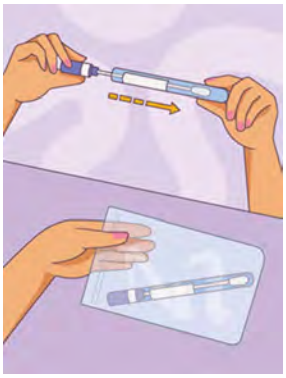
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Planning

STEP-2

Self-Testing for Cervical Cancer in Priority Populations

- Cluster randomized trial
- Evaluating the effectiveness and implementation of **HPV self-sampling interventions**
- 42 federally qualified health center clinics



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

R01 NIH Collaboratory Trials

Project	Population	Intervention	Outcome
iPATH	Patients with type 2 diabetes from health disparity populations	Multilevel, multicomponent, technology-enabled practice transformation strategy	Reduction in patients with poorly controlled diabetes (A1c > 9%) at 12 and 24 months
MOMs Chat & Care Study	Black and Hispanic birthing people	Integrated care model approach at 2 different levels of intensity, high or low	Incidence of severe maternal morbidity at time of labor and delivery and related hospital admissions at 1 month and 1 year postpartum

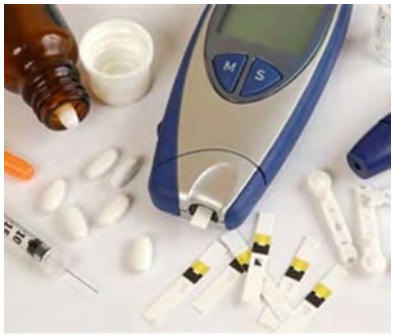
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

R01 Trial

iPATH

Implementing Scalable, PAtient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities

- Hybrid type 2 effectiveness implementation study, including a stepped-wedge cluster randomized trial
- Evaluating whether an innovative multi-level, multi-component, technology-enabled **practice transformation strategy** can improve outcomes for patients with type 2 diabetes from health disparity populations
- 8 federally qualified health centers



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

R01 Trial

MOMs Chat & Care

Maternal OutcoMes Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity

- Testing the effectiveness of an **integrated care model approach** at 2 different levels of intensity to facilitate timely, appropriate care for high-risk Black and Hispanic birthing people and reduce risk for severe maternal morbidity
- Largest healthcare provider in New York
- 674 expected patients

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

NIH Collaboratory Trials: Implementation Phase

Project	Population	Intervention	Outcome
BEST-ICU	Critically ill adults	Strategies to increase adoption of the ABCDEF bundle, a mechanical ventilation liberation and symptom management approach	Implementation (primary) and clinical (secondary) effectiveness outcomes
Chat 4 Heart Health	Patients from Federally Qualified Health Centers with sub-optimal control of their cardiovascular risk factors	Multilevel intervention leveraging cellphone-based text messages	Global cardiovascular health and control of cardiovascular risk factors (eg, hypertension, diabetes)
GGC4H	Parents of early adolescents	Anticipatory guidance curriculum	Behavioral health problems; health service utilization

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

NIH Collaboratory Trials: Implementation Phase (cont)

Project	Population	Intervention	Outcome
I CAN DO Surgical ACP	Older adults undergoing major elective survey	Patient-facing advance care planning tool	Advance care planning completion rates and patient engagement with advance care planning
IMPACt-LBP	Adults with low back pain	Primary spine practitioner model using doctors of chiropractic and physical therapists as first-line providers	Improve physical function, decrease pain, decrease opioid prescriptions, improve patient satisfaction, and decrease costs and utilization of healthcare services when compared with usual medical care
TAICHIKNEE	Patients with knee pain due to osteoarthritis	Remotely delivered web-based tai chi intervention	Physical health (including knee-related pain and function), mental health, and healthcare utilization

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Implementation

BEST-ICU *Behavioral Economic and Staffing Strategies to Increase Adoption of the ABCDEF Bundle in the ICU*

- 3-arm stepped-wedge, cluster-randomized trial to evaluate 2 strategies grounded in behavioral economic and implementation science theory to **increase adoption of the ABCDEF bundle**, a mechanical ventilation liberation and symptom management approach, in critically ill adults
- 12 ICUs from 3 safety net hospitals
- 8,100 expected patients

Implementation

Chat 4 Heart Health *Using Artificially Intelligent Text Messaging Technology to Improve AHA's Life's Essential 8 Health Behaviors*

- Patient-level randomized trial to evaluate the implementation and effectiveness of 3 different **automated patient communication approaches** for self-management support to improve control of cardiovascular disease risk factors
- Federally qualified health centers in 3 health systems
- 6,000 expected patients

Chat for Heart Health

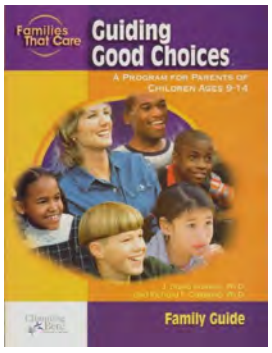
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Implementation

GGC4H *Guiding Good Choices for Health*

- Cluster trial testing whether an anticipatory guidance curriculum for parents of early adolescents will reduce **behavioral health problems and health service utilization**
- 3 health systems
- 72 pediatricians and 4,500 families expected

GUIDING GOOD CHOICES



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Implementation

I CAN DO Surgical ACP

Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning

- Patient-level randomized trial to evaluate a system-based approach to help older adults undergoing elective surgery **engage in advance care planning**
- 3 health systems

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

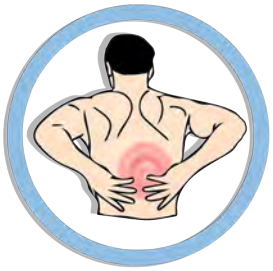
Implementation

IMPACt-LBP

Implementation of the American College of Physicians Guideline for Low Back Pain

- Refine and implement a **multidisciplinary collaborative care model for low back pain**
- Evaluate the effectiveness of this care model compared to usual medical care for low back pain
- 3 academic healthcare systems

IMPACt LBP
LOW BACK PAIN



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

TAICHIKNEE *Remote Tai Chi for Knee Osteoarthritis: an Embedded Pragmatic Trial*

- Compare the effects of a remotely delivered **web-based tai chi intervention** versus routine care for patients with knee pain due to osteoarthritis
- 20-25 clinics across 4 health systems
- 600 expected patients

TaiChiKnee
A Path to Knee Pain Relief

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trials: Implementation Phase

Project	Population	Intervention	Outcome
AIM-CP	Rural-dwelling patients with chronic pain	Nurse care management model incorporating care coordination, cognitive behavioral therapy, and a remotely delivered exercise program	Pain interference, physical functioning, mental health, treatment satisfaction, sleep, pharmacologic treatments, and healthcare utilization
APA-SM	Rural-dwelling patients with chronic musculoskeletal pain	4-week auricular point acupressure self-management program delivered via mobile app	Pain intensity, pain interference, and function; cost-effectiveness
ARBOR-Telehealth	Rural-dwelling patients with chronic low back pain	Risk-stratified telerehabilitation model	Change in low back pain-related disability and opioid use after 8 weeks
BackInAction	Older adults with low back pain	Standard and enhanced 12-week courses of acupuncture	Back-related function at 26 weeks; cost-effectiveness
BeatPain Utah	Adults with back pain in federally qualified health centers in Utah	Brief pain teleconsult and phone-based physical therapy	Pain management; reduction of disparities; evaluation of implementation strategies

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trials: Implementation Phase

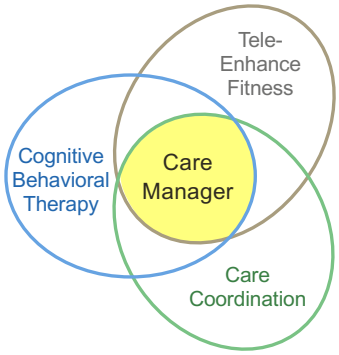
Project	Population	Intervention	Outcome
FM-TIPS	Fibromyalgia	Addition of transcutaneous electrical nerve stimulation (TENS) to physical therapy	Fibromyalgia symptoms; adherence to therapy; meeting therapeutic goals; medication use
GRACE	Patients with sickle cell disease	Acupuncture and guided relaxation	Pain control; effective treatment sequence; evaluation of implementation strategies
NOHARM	Postoperative pain	EHR-embedded tools to aid shared decision making about pain management	Postoperative opioid use, pain, function
OPTIMUM	Chronic low back pain	Group-based mindfulness in outpatient clinical settings	Pain, physical, and psychological function; opioid prescriptions for chronic low back pain
RAMP	Rural-dwelling veterans with chronic pain	Telehealth intervention with multiple evidence-based complementary and integrative health approaches for chronic pain	Pain interference at 13 and 26 weeks; opioid use

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

AIM-CP *Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain*

- Adapting and test a **nurse care management model** to provide comprehensive coordinated care for patients with chronic pain in rural communities
- 6 health systems
- 416 expected patients



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

APA-SM *Personalized Auricular Point Acupressure for Chronic Pain Self-Management in Rural Populations*

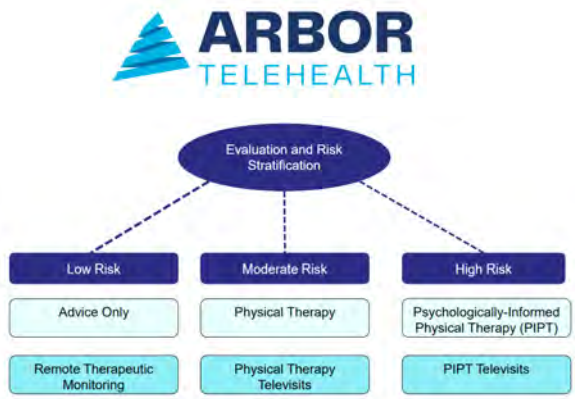
- Evaluating an **auricular point acupressure self-management** program for rural populations with chronic musculoskeletal pain
- Hybrid implementation-effectiveness trial

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

ARBOR-Telehealth *Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth*

- Comparing the effectiveness of a **risk-stratified telerehabilitation model** to improve outcomes in patients with chronic low back pain in rural communities
- Primary care clinics in Maryland
- 434 expected patients



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Rethinking Clinical Trials®

HEAL Trial

BackInAction

Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults

- Evaluating the **safety and effectiveness of acupuncture** in older adults with chronic low back pain
- 4 performance sites
- 828 expected patients

BACK IN ACTION

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

BeatPain Utah

Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics

- Testing the feasibility of a **telehealth strategy** that provides a brief **pain teleconsult** along with phone-based **physical therapy**
- Federally qualified health centers in Utah

BEATPAIN Utah

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

FM-TIPS *Fibromyalgia TENS in Physical Therapy Study*

- Testing the feasibility and effectiveness of **adding TENS** to treatment of patients with fibromyalgia **in a real-world physical therapy practice setting**
- 5 physical therapy health systems

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

GRACE *Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain*

- Testing the effectiveness of **guided relaxation and acupuncture** to improve pain control and determine the most appropriate and effective treatment sequence for **patients with sickle cell disease pain**
- 3 health systems

GRACE TRIAL

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

NOHARM *Nonpharmacologic Options in Postoperative Hospital-based and Rehabilitation Pain Management*

- Testing the feasibility of EHR-embedded **patient- and clinician-facing decision support for nonpharmacologic pain care** after surgery
- 4 health systems

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

OPTIMUM *Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting*

- Evaluating effectiveness of a **group-based mindfulness intervention** for patients with chronic low back pain in a usual care setting
- 3 health systems
- 450 expected patients

Optimum
Optimizing Pain Treatment in Medical Settings Using Mindfulness

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

HEAL Trial

RAMP *Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention*

- Hybrid type 2 effectiveness-implementation trial evaluating a **telehealth intervention** with multiple evidence-based complementary and integrative health approaches for chronic pain
- VA health system
- 500 expected patients (rural-dwelling veterans)

RAMP
Rural Veterans Applying Mind Body Skills for Pain

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Data and Resource Sharing Informational Document

Table of Contents

Prepared by: NIH Collaboratory Coordinating Center

Version: November 14, 2024

Purpose

This document is meant to provide background and information to assist clinical investigators in developing data sharing plans and is to be used along with the accompanying Data Sharing Plan Development Worksheet. This document contains information on the NIH Pragmatic Trials Collaboratory Data and Resource Sharing Policy; data sharing requirements for NIH funded trial; data sharing requirements for medical journals; data sharing repositories, mechanisms and platforms; and examples from NIH Collaboratory Trials.

If you have questions, feedback or suggestions regarding data sharing, please contact us at nih-collaboratory@dm.duke.edu.

Data Sharing Considerations

As described in the NIH Pragmatic Trials Collaboratory Data and Resource Sharing Policy, sharing research data collected in NIH Collaboratory Trials is essential to several core objectives of the program, including:

- Maximizing the public health impact of the significant NIH investment
- Accelerating the pace of learning throughout the US healthcare system
- Increasing participation in research and learning by a wide range of partners, including healthcare systems, healthcare providers, and patients/consumers

The ethical responsibility to share data generated by publicly funded research must be balanced against the need to protect patient privacy and scientific integrity.

Because NIH Collaboratory Trials typically rely on data collected through normal health care delivery, sharing data from those trials will be guided by some considerations not typically encountered in more traditional clinical trials. For example, individual participant consent may be waived in accordance with the federal regulations for the Protection of Human Subjects (45 CFR part 46) in some NIH Collaboratory Trials that rely on data extracted from health systems' electronic medical records or administrative data. Special considerations in developing data sharing for pragmatic trials involving health system data are discussed in the Living Textbook Chapter "Data Sharing and Embedded Research."

Data Sharing Requirements for the NIH, HEAL Initiative, and Medical Journals

Please note that these policies are current as of the date of this document. Refer to the individual websites for the latest information and full requirements.

2023 NIH Data Management and Sharing Policy

The goal of the **Final NIH Policy for Data Management and Sharing** is to "maximize the appropriate sharing of scientific data." This Policy applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. The policy is applicable to research applications for grants, contracts, or cooperative agreements submitted after January 25, 2023, or other transactions executed after January 25, 2023.

Data and Resource Sharing Information

The Data Management and Sharing Policy requires

- "Submission of a Data Management and Sharing Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.
- Compliance with the awardee's plan as approved by the NIH Institute, Center, or Office."
- Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.

Importantly, costs associated with data management and data sharing may be allowable under the budget for the proposed project. According to the policy, "plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared."

Shared data should be of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. The policy "does not create a uniform requirement to share all scientific data" in order to preserve "necessary flexibility," but makes several key suggestions including that:

1. Any limitations on subsequent uses of data should be communicated to sharing platforms; and
2. Access to scientific data should be "controlled, even if **de-identified and lacking explicit limitations** on subsequent use" and the policy "strongly encourages the use of **established repositories** to the extent possible."

Nothing in the policy is intended to prevent sharing practices "consistent with consent practices, established norms, and applicable law" including open sharing to speed scientific progress.

For an example, see the Intramural Data Management and Sharing Template.

HEAL Public Access and Data Sharing

NIH HEAL Initiative–generated findings must be available publicly upon publication, and award recipients and their collaborators are required to acknowledge NIH HEAL Initiative support in the acknowledgement sections of any relevant publication.

Underlying Primary Data for the publications will be made broadly available through a HEAL-compliant data repository, which include Vivli, NIMH Data Archive (NDA), and ICPSR (Inter-university Consortium for Political and Social Research) (Table 4). All HEAL projects may contact their HEAL Data Steward for assistance.

The goal of the **HEAL Public Access and Data Sharing** policy is to ensure that "underlying primary data should be made as widely and freely available as possible while safeguarding the privacy of participants and protecting confidential and propriety data." Just like the Collaboratory policy, it defines "underlying primary data" as those used to support publications. Although not "proscriptive," it suggests that primary data should be made "broadly available through an appropriate data repository…" It states that an "appropriate" data sharing plan includes that data should be de-identified (as defined by HIPAA), but that de-

identified data that "**contain sensitive information**" be additionally deposited in **controlled-access repositories**. There is no definition included for sensitive information, but the goal of the requirement was to give an additional layer of protection for potentially stigmatizing information.

Medical Journal Data Sharing Requirements

The International Council of Medical Journal Editors (ICMJE) requires that 7 key elements be addressed in the data sharing statement:

1. "Will individual participant data be available (including data dictionaries)?
2. What data in particular will be shared?
3. What other documents will be available?
4. When will data be available (start and end dates)?
5. With whom will data be shared?
6. For what types of analyses will data be shared?
7. By what mechanism will the data be made available?"

From: International Council of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

Table 1 summarizes data sharing requirements of select academic journals and publishers to give researchers an idea of what may be required for publication.

Table 1. Data Sharing Requirements of Select Academic Journals and Publishers

Journal/Publisher	Requirements	Recommended Repository
BMJ	Requires data from clinical trials to be made available upon request and requires a data sharing statement.	For clinical data, BMJ recommends controlled access repositories, such as clinicalstudydatarequest.com, the YODA project, or Vivli.
Elsevier	Encourages submission of a data paper, uploading data to a repository, or a data sharing statement stating why data can't be shared.	
Nature	Authors are required to make materials, data, code, and associated protocols promptly available to readers without undue qualifications. Restrictions on the availability of data must be disclosed upon submission.	Unstructured repositories like figshare and Dryad if no structured public repositories exist.
NEJM	Data sharing statement	Aligned with ICJME
PLOS	Data sharing statement	Dryad
Wiley	Data sharing statement	Mendeley Data

Examples from NIH Collaboratory Trials

NIH Collaboratory Trial investigators explored the risks to providers and health systems of sharing data. In Table 2 we describe the risks, the steps taken to mitigate the risks, and the data sharing structure that will be used for each of these pragmatic trials.

Table 2. NIH Pragmatic Trials Collaboratory Data Sharing Plans*

Study name	Risks to providers or health systems	Sharing structure	Steps to mitigate risks to providers or health systems
ABATE **Active Bathing to Eliminate Infection**	Data regarding infection rates could be used for inappropriate comparisons of facilities or with public reports. Detailed information regarding facilities and utilization patterns could reveal proprietary business information.	Private enclave managed by study team	Potential users may propose specific queries. Only query results (not individual data) will be shared.
ICD-Pieces **Improving Chronic Disease management with Pieces**	Data regarding patterns of care could be used for biased or inappropriate comparisons across facilities or health systems. Given different specifications, comparison to publicly reported quality measures would be misleading.	Private archive managed by NIDDK	Patient-level data will be de-identified and stored in aggregate database. Identifiers for healthcare system, primary practice and patients will be removed. Use of aggregate dataset will be governed by authorized agreements with NIDDK.
LIRE **Lumbar Image Reporting with Epidemiology**	Data regarding treatment patterns and resource use could be used for inappropriate or biased comparisons across health systems and could reveal proprietary health system business information.	Private archive managed by study team	Patient-level datasets will de-identified by health systems, clinics, providers, and patients. Investigators will authorize release to specific users for specific purposes.
PPACT **Pain Program for Active Coping and Training**	Data on opioid prescribing patterns could be misused for inappropriate comparisons of providers or facilities.	Public archive of a modified dataset	Public-use dataset will not include facility or health system identifiers, characteristics, or prescribing/referral practices of individual providers, or patient-level data on race or ethnicity.
SPOT **Suicide Prevention Outreach Trial**	Data on suicide attempt rates could be used for biased or inappropriate comparisons of suicide attempts or suicide mortality across health systems.	Public archive of a modified dataset	Public-use dataset will not include indicator for health system.

Table 2. NIH Pragmatic Trials Collaboratory Data Sharing Plans*			
Study name	**Risks to providers or health systems**	**Sharing structure**	**Steps to mitigate risks to providers or health systems**
STOP CRC Strategies and Opportunities to Stop Colon Cancer in Priority Populations	Data on screening rates could be misused for inappropriate or biased comparisons of performance across clinics or inaccurate comparisons with public quality measures.	Private archive managed by study team	De-identified patient-level data will be available, with permissions and data use agreements in place. Data use agreements will limit to specific research uses and require destruction after authorized analyses are completed.
TiME Time to Reduce Mortality in End- Stage Renal Disease	Data regarding mortality could be misused for inappropriate or biased comparisons of facilities or healthcare systems. Detailed data regarding patterns of care could reveal proprietary business information.	Private archive managed by NIDDK	De-identified patient-level data that are aggregated across provider organizations will be stored at the NIDDK Central Repository. Facility identifiers, dialysis provider organization identifiers, and data elements that are unique to one of the dialysis providers will be removed. Data will be made available through formal request and a data use agreement between the requestor and the NIDDK.
TSOS Trauma Survivors Outcomes and Support	Data regarding baseline patient characteristics and study outcomes could be used for biased or inappropriate comparisons of care in participating facilities.	Private archive managed by study team	De-identified patient level data will be provided, with priority given to research that will affect trauma care systems nationwide and Collaboratory investigators.

*Assumes HIPAA-compliant patient de-identification for all patients and a data use agreement where appropriate.

Table from: Simon G, et al. Data Sharing and Embedded Research: Data Sharing Solutions for Embedded Research. In: *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*. Bethesda, MD: NIH Pragmatic Trials Collaboratory. Available at: https://rethinkingclinicaltrials.org/chapters/dissemination/data-share-top/data-sharing-solutions-for-embedded-research/. Updated April 12, 2024. DOI: 10.28929/070.

Data Sharing Mechanisms

In Table 3, we describe different technical structures for data sharing and considerations that may assist researchers in selecting the appropriate mechanism for their trial. For more details, see the Living Textbook Chapter on Data Sharing.

Table 3. Technical Structures for Data Sharing From Least Restrictive (and Least Expensive) to Most Restrictive (and Most Expensive)				
Structure	**Description**	**Additional elements**	**Resource needs**	**Example**
Public archive	Analyzable data can be obtained by any user for any use No restriction on the kinds of research questions new users can address	May impose restrictions like prohibitions against re-identification or access to small cell counts May de-identify certain elements, such as study site or demographics, or present sensitive data as an aggregate summary variable	Initial development and annotation Maintenance and access costs	Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP)
Private archive	Analyzable data can be obtained by authorized users Honest broker or the original owner of the data decides which uses to authorize Requires binding agreement by recipient regarding protection and use of transferred data	As noted for public archive	As noted for public archive Evaluation of requests Execution of data sharing, data use, data transfer, and other agreements, including agreements covering data with full identifiers Monitoring of compliance with agreements, and response to breach of agreements	Yale University Open Data Access (YODA) Project Centers for Medicaid and Medicare (CMS) Limited Data Sets National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Central Repository
Public enclave	Any user may query the data, but not take possession of it. Only aggregate results may be removed from the enclave No restriction on the kinds of questions users can address	May impose restrictions like prohibitions against re-identification, passing the data to other users, or access to small cell counts May de-identify certain elements, such as study site or demographics	Initial development and annotation Ongoing curation and governance Creation and maintenance of informatics support for analyses, including software licenses and computational capabilities, and file storage Personnel needed to ensure data quality, etc.	Centers for Medicare and Medicaid Services (CMS) Virtual Research Data Center (VRDC)
Private enclave	Similar to public enclave with regard to provisions for analyzing data without taking possession of it Honest broker or the original owner of the data decides which uses to authorize	Moderated by an honest broker or by representatives of the study and/ or site (either queries or results)	As noted for public enclave Additional resources to evaluate requests and supervise the conduct of approved studies	Food and Drug Administration (FDA) Sentinel Distributed Data Set

Table from: Simon G, et al. Data Sharing and Embedded Research: Data Sharing Solutions for Embedded Research. In: *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*. Bethesda, MD: NIH Pragmatic Trials Collaboratory. Available at: https://rethinkingclinicaltrials.org/chapters/dissemination/data-share-top/data-sharing-solutions-for-embedded-research/. Updated April 12, 2024. DOI: 10.28929/070.

HEAL Data Sharing Repositories

For studies that are part of the HEAL Initiative, 6 principles were considered for data sharing repositories:

- Persistence
- FAIR alignment
- Suitable for study data
- Data Governance
- Resources (cost)
- Future expansion plans

PRISM-specific data concerns included that data from PCTs may come from the EHR, insurance claims, and/or patient-reported outcomes. As there are data access and security issues with data from these sources, potential repositories needed to have an option to release de-identified, aggregated, or more detailed versions of the data. The 4 repositories approved for PRISM trials are FigShare, the NIMH Data Archives (NIDA Data Share), DbGap, and Inter-University Consortium for Political and Social Research (ICPSR) (Table 4).

Table 4. Data Repository Options for PRISM Studies

Platform	Persistence	FAIR alignment	Suitability for study data	Data governance	Cost
ICPSR ICPSR is an organization of member institutions working together to acquire and preserve social science data, provide open and equitable access to these data, promote effective data use.	Regularly updated, large existing community.	• High level of data/metadata curation and assistance • Each study is uniquely identified with a study ID (ICPSR XXXXX) • Study-level and variable-level metadata exist, as does dataset-level metadata • Each study has a detailed, accessible landing page via HTTPS • API access to metadata, long-term potential for access to data	Houses some clinical data	Similar levels of access control mediated by review board; benefits of DbGaP security without much of the "red tape"	No monetary cost to submit data
NIMH Data Archive (NDA) National Institute of Mental Health Data Archive provides infrastructure for sharing research data, tools, methods, and analyses enabling collaborative science and discovery.	Periodically updated. Long-term support is weakest of 3 repositories.	• Each study is uniquely identified, with a study ID • Study-level and variable-level metadata exist, as does dataset-level metadata • Each study has a detailed, accessible landing page via HTTPS • No API exists for these data or metadata • Data dictionaries can be downloaded from study landing pages (Excel, csv, some PDF)	Most closely suited to PRISM studies	Must complete data share agreement; unclear what levels of access control are provided	Free
Figshare A domain agnostic data repository	Publisher model requires an SLA statement guaranteeing 10 y of persistent availability	• All research is allocated a Digital Object Identifier (DOI), ensuring a persistent unique identifier for each dataset • Study-level metadata is publicly available • API integration • Variable-level metadata possible but not required	Domain agnostic; accept any data in any file format (strength and weakness)	All content can be downloaded by anyone, with no need to log in; would require de-identification, but there is support for how to work with human PHI	Free
dbGap NIH repository for genotypes and phenotypes	Regularly updated, large existing community, supported by NCBI. Most likely to be around in 15-20 y.	• Each study is uniquely identified, with a study ID (phsXXXXX.vX.pX) • Study-level and variable-level metadata exist, as does dataset-level metadata • Each study has a detailed, accessible landing page via HTTPS • No API exists for these data, however there is a public FTP server organized by studies in which data dictionaries, etc. can be downloaded	Houses data from human studies (typically epidemiological); not a very natural fit for clinical trial data without omics	Access to (meta)data through public and private means; most secure of 3 options. Barriers to DbGaP access can be both a feature and a bug.	No monetary cost to submit data. Can be labor intensive to submit but lots of guidance materials.

There are many other public and private data sharing platforms to choose from, and some will fit some trials more than others. In Table 5, we list and briefly describe some of them for informational purposes. Note that this list is not comprehensive nor is the NIH Collaboratory mandating use of one of these platforms. This list represents possible platforms for consideration.

Table 5. Other Data Sharing Platforms	
Platform	**Description**
BioLINCC	Biologic Specimen and Data Repository Information Coordinating Center
clinicalstudydatarequest.com	Platform for sharing patient-level data
Dryad	A curated resource that makes the data underlying scientific publications discoverable, freely usable, and citable; provides a general purpose home for different data types
FAIRsharing	General data repository
GitHub	Large code hosting platform; private, public, open source
HCUP	Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project
Mendeley Data	Certified, free-to-use repository that hosts open data from all disciplines, whatever its format (eg, raw and processed data, tables, codes, and software)
NIH Data Sharing Repositories	NIH supported data repositories that make data accessible for re- use. Most accept submissions of appropriate data from NIH- funded investigators (and others), but some restrict data submission to only those researchers involved in a specific network.
OSF	General data repository
re3data.org	Catalogues of registered and certified data repositories
Sentinel Distributed Data Set	Food and Drug Administration (FDA) Sentinel initiative (claims data)
Vivli	Global Clinical Research Data Sharing Platform
VRDC	Centers for Medicare and Medicaid Services (CMS) Virtual Research Data Center
YODA Project	A controlled access repository
Zenodo	General data repository

Examples of Data Sharing Statements

As previously described, the ICMJE requires that 7 key elements be addressed in the data sharing statement. Below are example statements that were used to fulfill these requirements.

Suicide Prevention Outreach Trial (SPOT) Data Sharing Statement

"A deidentified version of the analytic dataset will be made available at the time of the initial publication of primary study findings. Consistent with policies of the NIH Collaboratory, all resources (intervention materials, specifications, computer code, etc.) will be shared at or before the publication of study results."

From: Simon GE, Beck A, Rossom R, et al. 2016. Population-based outreach versus care as usual to prevent suicide attempt: study protocol for a randomized controlled trial. *Trials*. 17(1):452. doi:10.1186/s13063-016-1566-z.

NIH Pragmatic Trials Collaboratory Data Sharing Statement

Links to the de-identified data set as well as resources, such as the study protocol, consent documents, phenotypes, and the data dictionary can be found at https://rethinkingclinicaltrials.org/data-and-resource-sharing/.

Special Considerations Regarding Use of Health System Data

The NIH policy recognizes that data may need to be modified prior to sharing to protect participant's privacy. Data may need to be redacted to strip identifiers, and data use agreements requiring confidentiality may be required. It may be appropriate under certain circumstances to limit access to sensitive data under stricter controls such as those possible through a data enclave.

Given that the NIH Collaboratory Trials rely on data extracted from health systems' electronic medical records or administrative data, it is important to distinguish between research data and the original health system data from which research data were extracted. Each NIH Collaboratory Trial is allowed to create and/or use specific health information through either an explicit informed consent process and/or a waiver of consent granted by one or more supervising institutional review boards. While NIH Collaboratory Trial personnel may have access to a wide range of original health system data (electronic health records, insurance claims, etc.), trials are only allowed to use and store data elements specifically authorized for research use—either by participant consent or by formal waiver of consent by the responsible institutional review board(s).

Investigators are not expected to share or give access to original health system data in electronic health records or other administrative data systems. Rather, they are expected to give access only to the research data on which their analyses are based and conclusions drawn. For example: An NIH Collaboratory Trial may be authorized by participant consent or waiver of consent to examine electronic health records and insurance claims data to assess adherence to a specific class of medications for each trial participant. Computing specific measures of medication adherence may require trial personnel to access all available information regarding medications ordered and/or prescriptions filled. In accord with the consent limits, however, investigators would only retain and analyze specified data elements. In most cases, the detailed original data regarding all medications ordered and/or prescriptions filled would not be retained by investigators nor be subject to expectations or requirements for data sharing.

It is recognized that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require additional precautions to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing through a restricted data enclave in which access is limited to researchers who agree to limited pre-approved research goals may be appropriate to address these needs in developing data sharing practices.

Resource Sharing

A major objective of the NIH Collaboratory is to disseminate to the broader community new information learned from pragmatic clinical research. As part of the NIH Collaboratory's commitment to sharing, all NIH Collaboratory Trials are expected to share resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. At the end of their trial, investigators will be expected to share the resources on the Closeout Data and Resource Sharing Checklist, which includes the following:

Publications/Dissemination

- Link to protocol paper
- Link to main outcome paper
- Link to other trial-related publications
- Materials used to communicate overall trial results to participants (eg, lay summary)

Study Tools

- Final version of the protocol, including summary of changes
- Consent documents or consent process
- Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)
- Participant-facing materials (eg, videos, flyers, handouts)
- Computable phenotypes for outcome measures
- Computable phenotypes for the inclusion/exclusion criteria
- Code for generating variables in the analytic dataset from standard sources
- Datasets and documentation
- Annotated data collection forms
- Link to public use dataset
- Data dictionary (proc contents) for public use dataset

If an element will not be included in the data sharing package, a brief explanation for the omission is required. Resources can be housed in the NIH Collaboratory Knowledge Repository, in a repository, or on a study website. All resources will be collated on the Data and Resource Sharing page of the Living Textbook. To request posting of materials to the Knowledge Repository, contact nih-collaboratory@dm.duke.edu .

NIH PRAGMATIC TRIALS COLLABORATORY
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Onboarding Data and Resource Sharing Questionnaire

Table of Contents

Data and Resource Sharing Questionnaire

This questionnaire is a worksheet to guide NIH Collaboratory Trials in developing data sharing plans that meet program requirements (see below checklist). This questionnaire is to be used as part of the onboarding process and can used for planning purposes by other researchers who need to share data.

Instructions/guidance are provided in italics. Please provide responses in the answer column.

Data Sharing Questionnaire **1. Study information**	
Question	**Answer**
What is the trial name and acronym?	
Who is completing this questionnaire?	
Date of questionnaire completion?	
Please provide a link to the trial's ClinicalTrials.gov registration.	

Prepared by: NIH Collaboratory Coordinating Center
Version: March 26, 2024

2. Data elements and sharing						
*NIH Pragmatic Trials Collaboratory investigators will each **share, at a minimum, a final research dataset** upon which the accepted primary pragmatic trial publication is based (from the NIH Collaboratory Data Sharing Policy; see Data Sharing Information Document for additional information from NIH Pragmatic Trials Collaboratory, NIH, and medical journal data sharing policies).*						
2a. Please describe all data collected/used for this study. Select all that apply and fill out each column as applicable.						
Data	**Y/N**	**If Y, brief description of data**	**Identifiable? If so, what IDs?**	**Can it be shared without restriction?**	**Can it be shared with restriction?**	**Describe restrictions** (eg, IDs stripped, aggregated info only, etc) **or reason data cannot be shared**
• Individual Level Data						
• Primary data collection through informed consent						
• Primary data collection through waiver of informed consent						
• Secondary data use – data collected by researchers of an earlier study						
• Secondary data use – administrative data obtained from a covered entity (eg, claims and assessment data from CMS; electronic health records from healthcare providers, etc)						
• Other						
• Provider Level Data						
• Other Data (eg, state policy, market level, Census)						

2b. Please describe the analytic dataset that will be released	
Will individuals be identifiable? _____Yes _____No _____ N/A	Comments/explanation:
Level of dataset: _____Individual _____Provider _____Other	Brief description of dataset:
If not identifiable, can individuals be differentiated? (eg, includes a study-generated ID so that multiple events/observations can be attributed to a unique study participant) _____ Yes _____ No	Comments/explanation:
Will providers be identifiable? _____Yes _____No _____ N/A	If not identifiable, can providers be differentiated? _____ Yes _____No
Can the primary analyses be replicated using the released data? _____ Yes _____ No	If no, why not? (eg, aggregated data, missing elements, etc)
What value will the data have for other researchers?	

3. What precautions/risks need to be considered?	
The NIH Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with healthcare systems may, under some situations, ***require precautions in addition to those regarding patient confidentiality****, to protect specific interests of collaborating healthcare systems, facilities, or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs (from the NIH Collaboratory Data Sharing Policy).*	
Question	**Answer**
What precautions are needed other than those regarding patient confidentiality?	
Have your research partners expressed concerns about how the data will be shared (enclave, repository, etc)?	
What are the risks to providers and health systems if a less restrictive mechanism is used? (See Data Sharing Information Document for examples from NIH Collaboratory Trials.)	

4. How will the data be shared?	
*Consistent with NIH policy and guidance, NIH Pragmatic Trials Collaboratory investigators will choose the **least restrictive method for sharing of research data** that provides appropriate protection for participant privacy, health system privacy, and scientific integrity (from the NIH Collaboratory Data Sharing Policy).*	
Question	**Answer**
What is the least restrictive mechanism you can use for sharing data? (See Data Sharing Information Document for details about these mechanisms.) • Public archive (least restrictive) • Public enclave • Private archive • Private enclave (most restrictive)	
What specific platform will be used? (See Data Sharing Information Document for example data sharing platforms.)	

5. Preparing for data sharing	
Question	**Answer**
When will you share data? Prior to or after publication?	
Please write a draft data sharing statement. (See Data Sharing Information Document for example statements.)	
Do you foresee any obstacles regarding data and resource sharing?	

6. What resources will be shared?

*As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all NIH Collaboratory Trials are expected to share data **and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials**. We recommend that elements of a final data sharing package include the items listed below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), on a repository (ie, GitHub), or on a study website. We will link to the materials from the Living Textbook. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.*

Item	**Will you publish?** Yes, No, N/A **If No, justify**	**Where publish** (mark all that apply)		**When publish** (mark all that apply)		
		NIH KR	Other (specify)	Per manuscript*	Start of study	End of study
Final version of protocol						
Consent documents/process						
Computable phenotypes for outcome measures						
Computable phenotypes for inclusion/exclusion criteria						
Code for generating variables in the analytic dataset from standard sources						
Study questionnaires						
Annotated data collection forms						
Data dictionary (proc contents) for public use dataset						
Data dictionary (proc contents) for all data used in study with annotation regarding limitations on sharing each element						
Code for generating the tables present in a particular manuscript*						
Instructions on how to obtain data that were unable to be released (eg, CMS data files)†						
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)						
Participant-facing materials (eg, videos, flyers, handouts)						
Other						

*For example, PROVEN developed a process of submitting supplemental material for each manuscript published. They store the information in Brown's Digital Repository with a manuscript-specific URL that is published within the manuscript. They include the code that generated the manuscript's tables.
†For example, the PROVEN team refers the reader to www.resdac.org for the use of CMS data files and lets them know the file types and years used for its study since they cannot release those data.

NIH PRAGMATIC TRIALS COLLABORATORY
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Data and Resource Sharing Checklist

Background

All NIH Collaboratory Trials will be expected to review this checklist as part of the onboarding process so they understand what will be expected. They will complete the checklist at closeout.

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all of its trials are expected to share data and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. We recommend that elements of a final data sharing package include the items listed in the checklist below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), on a repository (eg, GitHub), or on a study website. We will link to the materials from the Living Textbook on each trial's webpage and through a separate Data and Resource Sharing section. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.

Note: There will **not** be a dedicated space on the NIH Collaboratory website for posting analytic datasets; rather, we will post a hyperlink to the data sharing repository chosen by each trial. In the Data Sharing Information Document, the EHR Core provides a partial list of existing data sharing platforms. The accompanying Data Sharing Information Document also contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from NIH Collaboratory Trials.

Data and Resource Sharing Checklist for Plan Development – Part 1

Data and Resource Sharing Checklist
1. Trial information
Trial name and acronym:
Checklist completed by:
Date:
Link to ClinicalTrials.gov registration:
Link to trial website:

Data and Resource Sharing Checklist for Plan Development – Part 2

Data and Resource Sharing Checklist		
2. Resource location		
Item	**Provide hyperlink or indicate if item will be stored in the KR**	**If item will not be shared, please provide a brief explanation for the omission**
Publications/Dissemination		
Link to protocol paper		
Link to main outcome paper		
Link to other trial-related publications		
Materials used to communicate overall trial results to participants (eg, lay summary)		
Study tools		
Final version of the protocol, including summary of changes		
Consent documents or consent process		
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)		
Participant-facing materials (eg, videos, flyers, handouts)		
Computable phenotypes for outcome measures		
Computable phenotypes for the inclusion/exclusion criteria		
Code for generating variables in the analytic dataset from standard sources		
Datasets and documentation		
Annotated data collection forms		
Link to public use dataset		
Data dictionary (proc contents) for public use dataset		
Other resources		

NIH PRAGMATIC TRIALS COLLABORATORY
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Closeout Data and Resource Sharing Checklist

Purpose

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all Collaboratory trials are expected to share data and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. We recommend that elements of a final data sharing package include the items listed in the checklist below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), in a repository (i.e., GitHub), or on a study website. We will link to the materials from the Living Textbook. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.

Note: There will **not** be a dedicated space on the NIH Collaboratory website for posting analytic datasets; rather, we will post a hyperlink to the data sharing repository chosen by each trial. In the Data Sharing Information Document, the EHR Core provides a partial list of existing data sharing platforms. The accompanying Data Sharing Information Document also contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from Collaboratory Trials.

Data and Resource Sharing Checklist

All NIH Pragmatic Trials Collaboratory Trials are expected to complete this checklist at closeout. The information provided in the checklist will be published in the Living Textbook on each Collaboratory Trial's page and on a Data and Resource Sharing page.

Data and Resource Sharing Checklist		
1. Trial information		
Trial name and acronym:		
Checklist completed by:		
Date:		
Link to ClinicalTrials.gov registration:		
Link to trial website:		
2. Resource location		
Item	**Provide hyperlink or indicate if item will be stored in the KR**	**If item will not be shared, please provide a brief explanation for the omission**
Publications/Dissemination		
Link to protocol paper		
Link to main outcome paper		
Link to other trial-related publications		
Materials used to communicate overall trial results to participants (eg, lay summary)		
Study tools		
Final version of the protocol, including summary of changes		
Consent documents or consent process		
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)		
Participant-facing materials (eg, videos, flyers, handouts)		
Computable phenotypes for outcome measures		
Computable phenotypes for the inclusion/exclusion criteria		
Code for generating variables in the analytic dataset from standard sources		

Datasets and documentation		
Annotated data collection forms		
Link to public use dataset		
Data dictionary (proc contents) for public use dataset		
Other resources		

TRIAL MATERIALS

UG3 Project: Coordinated cARe paiN mAnagement Technology ImplementatiON (CARNATION)

Co-Principal Investigators:

- Lynn DeBar, PhD, MPH
- Rachel Gold, PhD, MPH
- Nicole Cook, PhD, MPA

Sponsoring Institution: Kaise Foundation Research Institute

Collaborators:

- OCHIN, Inc.
- Community health centers that are members in the OCHIN network
- RAND

NIH Institute Providing Oversight: National Institute of Neurological Disorders and Stroke (NINDS)

Program Official: Rebecca Hommer, MD (NINDS)

Project Scientist: Anthony Domenichiello, PhD (NINDS)

Abstract:

Chronic musculoskeletal pain conditions – common, disabling, costly public health problems – disproportionally impact persons of lower socioeconomic status and are a primary driver of medical care. Current chronic pain care guidelines recommend multimodal, integrative pain management (IPM) involving non-opioid pharmacological options along with non-pharmacologic therapies (physical interventions, psychological approaches, and complementary and integrative healthcare). Community health centers (CHCs) serving low-income patients face substantial time and resource constraints in ensuring that patients receive guideline-concordant IPM services. Recent expansion of state Medicaid reimbursement for non-opioid pain management services and Medicare coverage for pain care management could help connect CHC patients (most of whom are publicly insured or uninsured) with IPM-congruent services. However, CHC staff lack the health information technology (HIT) infrastructure necessary to track and coordinate such services for their patients, as well as the support needed to use such tools systematically. Integrating electronic health record (EHR) technologies, including Compass Rose and other enabling technologies, care management applications recently activated in the shared OCHIN Epic platform support care coordination needed for IPM-congruent care. However, integrating such EHR tools into CHC care processes involves complex clinic-wide practice changes requiring implementation support. Effective strategies for providing such support are needed. To identify and optimize such strategies, we will partner with this national CHC network to test a multi- component implementation support intervention designed to enable CHCs' systematic use of EHR technologies including Compass Rose for coordinating primary care-based IPM-congruent pain care. This hybrid type 3 implementation-effectiveness randomized trial will: 1. Engage key advisors to tailor existing EHR technologies to optimize their facilitation of IPM-congruent care and refine the implementation support intervention components; 2. Test the intervention package's impact on CHCs' use of the tailored HIT tools and on patient pain-related outcomes; and 3. Conduct formative evaluation and budget impact analyses to understand and explain intervention Reach, Effectiveness, Adoption, Implementation and Maintenance. The

study will generate urgently needed evidence on how to make IPM care available in CHCs whose limited resources present barriers to the delivery and coordination of such care. Results will provide empirically-based guidance on how to optimize HIT infrastructure and provide related support for its uptake to enhance the primary care-based delivery of coordinated multidisciplinary pain care in CHC populations.

NIH Project Information

Coordinated cARe paiN mAnagement Technology ImplementatiON (CARNATION)

DATA MANAGEMENT AND SHARING PLAN

Principal Investigators: Lynn DeBar, PhD, MPH; Rachel Gold, PhD, MPH; Nicole Cook, PhD, MPA

Element 1: Data Type:

A. Types and amount of scientific data expected to be generated in the project:
The CARNATION study will generate qualitative data on experience with the implementation strategies/intervention and opportunities for improvement; this information will be collected from advisory group meetings and co-development workshops, qualitative interviews with community health center (CHC) staff and patients, as well as meeting observations with CHC teams.

CARNATION will also utilize data from patient electronic health records (EHR) in standardized formats, including the data related to pain management care coordination that is entered by CHC staff into the EHR-integrated Compass Rose module. However, all clinical data that will be used in this study are existing within patient charts and not collected as part of this study. There will be no consenting of individual patients receiving integrated pain management-related services supported by the study implementation support, as the clinical assessment and pain-related services patents are part of standard care at the CHCs.

B. Scientific data that will be preserved and shared, and the rationale for doing so:
All qualitative data and EHR-based datasets produced during the project will be preserved on secure OCHIN servers. All OCHIN data is hosted in a HIPAA Audited tier III data center. All data work will be conducted on secure, password-protected HIPAA compliant OCHIN computers. OCHIN computers are protected through the use of passwords and encryption (Microsoft Bitlocker for whole disk encryption) as well as other industry standard controls such as password strength, password expiration, screen lockout, password obfuscation, defense in-depth (multiple firewalls), IPS/IDS, DLP and centralized audit and event logging of all platforms to a central SIEM platform for all services following HIPAA/NIST 800-53 controls.

The analytic EHR-based datasets produced by OCHIN will be transferred to the KPWHRI analytic team (Dr. Andrea Cook and Mr. Robert Wellman, biostatisticians) who will conduct the quantitative primary, secondary and exploratory analyses. In addition, an analytic dataset will also be provided/transferred to RAND where Dr. Patricia Herman will conduct the cost analyses.

Patient-level datasets, qualitative data, and Epic/Clarity electronic health record (EHR) code and

variable names will not be shared. As described above, all clinical data that will be used in this study are existing within patient charts and not collected as part of this study; patient consent will not be obtained for use of these EHR data. The OCHIN Research Data Warehouse (RDW) includes patient-level data generated from multiple health systems across the OCHIN network; restrictions apply to the availability and re- release of patient-level data under organizational member agreements. Therefore, to honor member agreements and protect potentially identifiable patient information, patient-level datasets, qualitative data, and Epic/Clarity code and variables names cannot be shared publicly. Epic/Clarity variable names will be removed and replaced before sharing statistical data analytic code (e.g., R, SAS). The study team discussed this inability to comply with the HEAL Data Sharing Requirements with the Scientific/Research Contacts for **RFA-NS-24-041** during an October 2, 2024 conference call.

Aggregate data, qualitative codebooks, and statistical data analytic code (e.g., R, SAS) will be shared with relevant publications or by the end of the project period. OCHIN defines aggregate data as a dataset or data display that consolidates data from multiple individuals (e.g., patients) and does not contain identifiers that can be used to identify individual patients.

C. Metadata, other relevant data, and associated documentation:

To facilitate interpretation of aggregate data to be shared, documentation (i.e., data dictionary), qualitative codebooks, and statistical data analytic code (e.g., R, SAS) will also be shared.

Element 2: Related Tools, Software and/or Code:

OCHIN uses SQL to access EHR data stored in a Research Data Warehouse (RDW). Qualitative data will be entered into QSR NVivo for data analysis.
Data will be analyzed by the KPWHRI analytic team per the CARNATION study protocol and statistical analysis plan using R.

Element 3: Standards:

All OCHIN researchers and staff are trained in and follow federal HIPAA regulations, which require specific protocols for the transferring, storage, and reporting of protected health information (PHI). In addition, OCHIN requires all Research personnel to complete CITI training in the Responsible Conduct of Research. OCHIN computers are protected through the use of passwords and encryption (Microsoft Bitlocker for whole disk encryption) as well as other industry standard controls such as password strength, password expiration, screen lockout, password obfuscation, defense in-depth (multiple firewalls), IPS/IDS, DLP and centralized audit and event logging of all platforms to a central SIEM platform for all services following HIPAA/NIST 800-53 controls. All OCHIN data is hosted in a HIPAA Audited tier III data center.

Element 4: Data Preservation, Access and Associated Timelines:

A. Repository where scientific data and metadata will be archived:

All scientific data that can be shared will be deposited as supplementary material with manuscripts in PubMed Central or another suitable public repository. Other scientific data generated in this project that cannot be publicly shared will be preserved for five (5) years and then archived on secure OCHIN

servers as described above indefinitely.

B. How scientific data will be findable and identifiable:

Aggregate data will be included as supplementary material with manuscripts on PubMed Central, thus the metadata and persistent identifiers (i.e., PMCID) will be supported by the National Library of Medicine. Each PubMed Central study is also assigned a digital object identifier (DOI) to facilitate findability of scientific data.

C. When and how long the scientific data will be made available:

The research community will have access to aggregate data, qualitative codebooks, and statistical data analytic code (e.g., R, SAS) as soon as possible or at the time of associated publication, but no later than the end of the project period. Shared scientific data and associated qualitative codebooks, statistical data analytic code (e.g., R, SAS), and data dictionaries will be available indefinitely and access will not be controlled by the study team or OCHIN.

Qualitative data: Audio recordings of interviews and online meeting recordings (e.g., Zoom) will be securely stored and professionally transcribed by an outside vendor (who OCHIN has a Business Associates Agreement with). Recordings will be sent via secure file transfer (SFT) to be transcribed; access to the SFT site will be limited to appropriate members of the research team. Any identifiable patient information (inadvertently shared by clinic staff) in the transcript will be deleted. The transcriptionist will send back the file to the appropriate members of the research team via SFT. Recordings, transcripts, and digital copies of all collected artifacts will be kept on a secure network at OCHIN and accessible to qualitative team members. The study team will keep an audit trail for all qualitative data and enter data into QSR NVivo for data analysis. Qualitative data will not be shared publicly; however, codebooks will be shared as described above.

EHR data: OCHIN EHR data is centrally maintained. No transfer needs to occur from the CHC to OCHIN research analysts. Clinical data and research data (once abstracted) are stored on and backed up on secure servers and all data work will be conducted on secure, password-protected HIPAA compliant OCHIN computers. Facilities that store PHI in paper or electronic form have controlled access procedures and 24 hour monitored alarm service. Patient-level datasets containing EHR data will not be shared publicly; however, aggregate data will be shared as described above.

Element 5: Access, Distribution, or Reuse Considerations:

CARNATION will be registered on ClinicalTrials.gov and the CARNATION protocol and study findings will be shared in peer-reviewed journals per journal policies.

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

As described above, patient-level datasets, qualitative data, and Epic/Clarity electronic health record (EHR) code and variable names cannot be shared. All clinical data to be used in this study are existing within patient charts and not collected as part of this study; patient consent will not be obtained for use of these EHR data.

The OCHIN Research Data Warehouse includes patient-level electronic health record (EHR) data generated from multiple health systems across the OCHIN network; restrictions apply to the

availability and re- release of patient-level data under organizational member agreements. Therefore, to honor member agreements and protect potentially identifiable patient information, patient-level datasets, qualitative data, and Epic/Clarity code and variables names cannot be shared publicly. Epic/Clarity variable names will be removed and replaced before sharing statistical data analytic code (e.g., R, SAS).

B. Whether access to scientific data will be controlled:

Manual of Procedures: The KP CHR and OCHIN Research Associates will collaboratively develop a study replication plan that will include the Institutional Review Board (IRB)-approved study protocol, approvals, data documentation (e.g., data dictionary), analysis plans, and research products. As the study progresses, this plan will be updated and made available to interested researchers.
Access to aggregate scientific data and data dictionaries, qualitative codebooks, and statistical data analytic code (e.g., R, SAS) will not be controlled. Other scientific data generated as part of the project (e.g., patient- level datasets, qualitative data) will not be shared even if requested to uphold OCHIN member and vendor agreements and patient and study participant confidentiality.

Types of Research Products: We will share products resulting from this research which have been specified as sharable with publications or by the end of the project period. Products will include study process flows, non- proprietary assessment tools (e.g., interview guide), the study replication plan, and actionable recommendations developed during the mixed-method analysis. We will not be able to share our patient-level research datasets maintained by OCHIN, as these data were collected for clinical purposes, and it is not allowed to be shared per data use agreements with OCHIN member clinics.
We developed the following plan for dissemination of study materials and findings to primary care and safety- net organizations, including Community Health Centers, and academic colleagues through a variety of methods. While conducting this study and disseminating findings, we will use community engagement strategies with OCHIN member clinics as active partners. The content of materials disseminated through presentations and, and manuscripts will be driven by study findings.

Presentations: Study results will be shared through presentations at international, national, and local conferences and forums, including peer-reviewed conferences with large public health and health center representation.
Manuscripts: The research project team will present findings through peer-reviewed manuscripts and commentaries.

C. Protections for privacy, rights, and confidentiality of human research participants:

Once patient-level data are pulled from the Research Data Warehouse, direct identifiers will be immediately removed by Research Analysts before providing to the research team for analysis to protect human subjects' privacy, rights, and confidentiality. Thus, all identifying information will be removed prior to sharing aggregate scientific data. All OCHIN researchers and staff are trained in and follow federal HIPAA regulations, which require specific protocols for the transferring, storage, and reporting of protected health information (PHI). In

addition, OCHIN requires all personnel contributing to the design and/or conduct of this research to complete CITI training in the Responsible Conduct of Research.
For the proposed qualitative data collection from human research participants, IRB-approved informed consent documents will include language describing plans for data management and sharing, motivation for sharing data, and explain that any potentially identifying information will be removed. We will not share transcripts, even with identifiers removed, but will share qualitative codebooks publicly.

Element 6: Oversight of Data Management and Sharing:
The OCHIN Research Department is responsible for overseeing implementation and compliance with this plan, specifically the OCHIN Principal Investigator, Dr. Rachel Gold.

CARNATION: Challenges Scorecard

Challenge	Level of Difficulty*					
	NA	1	2	3	4	5
Regulatory issues (e.g., IRBs, consent)		X				
Study design issues (e.g., ICC, power, sample size, confounders)				X		
Using community-centered research methods		X				
Engaging with patient partners to inform the study			X?	X?		
Engaging with clinicians and health systems to identify or recruit participants				X		
Engaging with clinicians and health systems to deliver the intervention		X				
Data access (e.g., approval, privacy, security) and data management planning		X				
EHR integration and/or data extraction, including data management and quality assessment		X				
Collecting prospective data, including PROs				X?	X?	
Optimizing intervention sustainability and planning for sustainment		X				

*Your best guess: 1 = little difficulty; 5 = extreme difficulty

POLICIES AND GUIDELINES

NIH Pragmatic Trials Collaboratory Data and Resource Sharing Policy

Introduction

The NIH Collaboratory Steering Committee recognizes that data and resource sharing promotes many goals of the NIH research endeavor. It is particularly important for unique data and tools that cannot be readily replicated. Data and resource sharing allows scientists to expedite the translation of research results into knowledge, products, and procedures to improve human health.

There are many reasons to share data and resources from these NIH-supported studies. Sharing reinforces open scientific inquiry, encourages diversity of analysis and opinion, promotes new research, makes possible the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of new datasets when data from multiple sources are combined.

The NIH Collaboratory Steering Committee agrees that data and resources should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and therefore adopts the following policy regarding data and resource sharing:

Data Sharing

1. Trials started before 2023 ***are encouraged to*** share research data. For trials started after 2023, NIH Collaboratory investigators ***are required to*** share, at a minimum, the scientific data supporting a publication by the time of publication, whether online or in print. Per the 2023 NIH Data Management and Sharing Policy, scientific data are defined as "the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings regardless of whether the data are used to support scholarly publications." The repository must meet FAIR Principles for scientific data management and stewardship and all NIH policy requirements, including that the data be shared at the end of the award, whether the research results were published or not.

2. The NIH Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require precautions in addition to those regarding patient confidentiality, to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs in implementing this data sharing policy.

Version: November 12, 2024

Justifiable reasons for limiting the sharing of data should be described in the Data Monitoring and Sharing Plan.

3. Consistent with NIH policy and guidance, NIH Collaboratory investigators will choose the least restrictive method for sharing of research data that provides appropriate protection for participant privacy, health system privacy, and scientific integrity.

4. NIH Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infrastructure are in place to support timely data sharing for the Collaboratory.

Resource Sharing

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing information garnered from publicly funded research, all NIH Collaboratory Trials are expected to share resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. Elements of a final data and resource sharing package should include the items listed in the Closeout Data and Resource Sharing Checklist. If an element will not be included in the data and resource sharing package, a brief explanation for the omission is required. Resources can be housed in the NIH Collaboratory Knowledge Repository, in a public repository (eg, GitHub), or on a study website. All NIH Collaboratory Trial resources will be collated on the Data and Resource Sharing page of the Living Textbook.

The CC will consider updates and modifications to this policy as needed, to be determined through consultation with the Steering Committee and NIH. The NIH Collaboratory agrees to adopt and implement the resource, data, and software sharing plans as outlined in the RFA.

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Assessing Fitness-for-use of Clinical Data for PCTs

Background

The credibility and reproducibility of pragmatic clinical research depends on the investigator's demonstration that the data are of sufficient quality to support the research conclusions. This document highlights recommendations for assessing the fitness-for use of data generated from routine patient care for use in PCTs. For more, read the full chapter in the Living Textbook Assessing Fitness for Use of Real World Data.

Before using an EHR dataset for a given research project, one should determine whether it is fit-for-purpose by determining if the data are **relevant** and **reliable.** Relevance includes the availability of key data elements (exposures, outcomes, covariates) and sufficient number of representative patients for the study. Reliability includes data accuracy, completeness, provenance and traceability (FDA 2021).

More specifically, a real-world data source is said to be **relevant** if:

- The data apply to question at hand;
  - For example, the data contain sufficient detail to capture the use or exposure of the product or device and/or the outcome of interest.
- The data are amenable to sound clinical and statistical analysis;
  - For example, the data can be used to answer the specified question using the proposed statistical plan.
- The data and evidence the source provides are interpretable using informed clinical and statistical judgement.
  - For example, the use of a device or product in a real-world population is representative of what is captured in the data source, is generalizable to the relevant population under study, etc (FDA 2018).

Data are considered **reliable** if:

- Data are captured in a standardized and rigorous manner
- Data are accurate and complete, data provenance is known, and data are traceable
- Efforts of data curation, transformation, accrual, etc. are known (i.e., process from transforming raw data to analytic dataset)

EHR data typically go through several phases when used to support a PCT – from source system, to clinical data repository to data warehouse to study-specific dataset. The quality or fitness of a dataset may be evaluated at various points along this process, with different processes for quality assurance or quality control (FDA 2021). Assessment of data quality is on ongoing process, and conformance, completeness, and plausibility should be assessed throughout the trial.

Prepared by: NIH Pragmatic Trials Collaboratory
Version: January 31, 2024

Data Quality Checks

Example data checks to evaluate conformance, completeness, and plausibility are provided in the table below.

Table 1. Categories of Data Quality Checks and Examples From Distributed Research Networks

Category	Subcategory	Description	Data Check Example
Conformance	Value	Determines whether the data conform to the formats of the data model used to store them	Sex values are F, M, or U. Age is in specified range.
	Relational	Determines whether the data agree with the constraints imposed by the database used to store them (eg, primary or foreign key relationships)	All patient medical record fields are present in each table that requires them
	Calculation	Evaluates whether variables derived computationally yield valid results	Enrollment periods do not overlap. Computed BMI is correct.
Completeness		Examines whether expected values are present (single time point or longitudinally)	Gender is not null.
Plausibility	Uniqueness	Determines whether multiple values exist when only one value is expected	Patient does not have multiple inpatient admissions to the same facility on the same day
	Atemporal	Measures whether data agree with expected values	Most of the records are not in the lowest or highest categories of age, height, weight, diastolic blood pressure, etc
	Temporal	Examines whether variables change as expected over a specified time period	Events are not before date of birth or after date of death

For more details see: A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data and the FDA Guidance for Industry: Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Data Quality Assessment Recommendations for PCTs

1 – Key data quality dimensions

We recommend that conformance, completeness, and plausibility be formally assessed for data elements used in subject identification, outcome measures, and important covariate

2 – Reporting data quality assessment with research results

Results of data quality assessments should be reported with research results. Data quality assessments are the only way to demonstrate that data quality is sufficient to support the research conclusions, and as such should be accessible to consumers of research.

Food and Drug Administration. 2018. Framework for FDA's Real-World Evidence Program. https://www.fda.gov/media/120060/download. Accessed August 25, 2020.
Food and Drug Administration. 2021. Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products. https://www.fda.gov/media/152503/download.

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NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Publications, Presentations, and Products Policy

CONTENTS

I. Purpose

The National Institutes of Health (NIH) Pragmatic Trials Collaboratory is supported by cooperative agreements and grant awards from NIH Institutes, Centers, and Offices. A principal goal of the NIH Collaboratory is to produce generalizable knowledge by publishing high-quality, timely research findings and perspectives in the peer-reviewed literature; delivering presentations of NIH Collaboratory scholarship in public forums; and sharing guidance, tools, best practices, and other resources for healthcare systems research.

It is recognized that NIH Pragmatic Trials Collaboratory investigators will publish manuscripts, submit abstracts, and deliver presentations that directly reflect NIH Collaboratory activities. Investigators will also publish manuscripts, submit abstracts, and deliver presentations that either mention NIH Collaboratory activities or address topics that are related to NIH Collaboratory activities but are funded from other sources.

The NIH Pragmatic Trials Collaboratory includes the individual NIH Collaboratory Trials, the Coordinating Center, the Core Working Groups, and ad hoc working groups, all of which may develop publications, presentations, and other products. Manuscripts, abstracts, presentations, and other products derived from NIH Collaboratory–supported activities will be designated as NIH Collaboratory products.

II. Definitions

A. NIH Collaboratory Trial Publications and Presentations

NIH Collaboratory Trial publications and presentations are manuscripts, abstracts, and presentations that deal directly with knowledge derived from the NIH Collaboratory Trials. For example, a manuscript, abstract, or presentation that reports methods or results of an NIH Collaboratory Trial is an NIH Collaboratory Trial publication or presentation. Review and approval of NIH Collaboratory Trial publications and presentations will follow the procedures described in Section IV of this policy.

B. Core Working Group Publications and Presentations

Core Working Group publications and presentations are manuscripts, abstracts, and presentations produced by a Core Working Group as part of the Core's efforts to create generalizable knowledge. For example, a manuscript, abstract, or presentation that reports a comparison of methods for validating phenotypes across

NIH Collaboratory Trials undertaken by members of a Core is a Core Working Group publication or presentation. Review and approval of Core Working Group publications and presentations will follow the procedures described in Section V of this policy.

C. Guidance Documents

Guidance documents are official statements by the NIH Pragmatic Trials Collaboratory meant to describe procedures or principles for the conduct of healthcare systems research. These documents are intended to have an enduring quality and to represent a synthesis of considerable evidence. Guidance documents may be produced by one or more Core Working Groups or by an ad hoc working group. Guidance documents are published on the NIH Collaboratory website. Review and approval of guidance documents will follow the procedures described in Section VI of this policy.

D. Tools, Best Practice Documents, and Other Resources

Tools, best practice documents, and other resources are products that represent a consensus within one or more Core Working Groups about approaches to healthcare systems research. Examples include, but are not limited to, checklists, tips and frequently asked questions, executive summaries, and other information resources. Tools, best practice documents, and other resources are intended to evolve and may be subject to frequent revision as lessons emerge from the NIH Collaboratory Trials and Core Working Groups. Tools, best practice documents, and other resources are published on the NIH Pragmatic Trials Collaboratory website. Review and approval of tools, best practice documents, and other resources will follow the procedures described in Section VII of this policy.

E. Short Communications

Short communications are products hosted on the NIH Pragmatic Trials Collaboratory website or social media accounts—such as news articles, video and audio recordings, and social media posts—about NIH Collaboratory activities and other topics relevant to healthcare systems research. Short communications are produced by the Coordinating Center communications team in consultation with the Coordinating Center leadership. Review and approval of short communications will follow the procedures described in Section VIII of this policy.

III. Publications, Presentations, and Products Committee

A. Members and Decision Making

The Publications, Presentations, and Products Committee ("Publications Committee") consists of Coordinating Center investigators, representatives from the NIH Collaboratory Trials, and the NIH project officer and project scientist, as well as nonvoting Coordinating Center staff who serve as committee staff. The Coordinating Center leadership appoints the chair of the committee. Decisions of the committee will be made by majority vote, although consensus will be sought in all cases.

B. Responsibilities

1. The Publications Committee oversees all NIH Pragmatic Trials Collaboratory–supported publication and presentation activities, with final adjudication of decisions made by the Steering Committee as needed. Oversight includes the following specific activities:

    a. The Publications Committee reviews and approves (1) Core Working Group manuscripts before they are submitted and (2) guidance documents before they are published to ensure that descriptions of NIH Collaboratory activities are accurate and to share comments and suggestions. Committee staff review these documents to ensure the use of required acknowledgment and disclaimer language.

    b. Committee staff review manuscripts from the NIH Collaboratory Trials before they are submitted to ensure the use of required acknowledgment language and to check for mentions of other NIH Collaboratory Trials. Committee staff also review tools, best practice documents, and other resources before they are published on the NIH Collaboratory website to ensure the use of required acknowledgment and disclaimer language and to check for mentions of NIH Collaboratory Trials.

2. The Publications Committee also monitors the overall NIH Collaboratory publications pipeline and proposes new topics for cross-Collaboratory publications. A cross-Collaboratory publication may be prepared by an ad hoc working group or by one or more Core Working Groups or NIH Collaboratory Trial teams.

IV. NIH Collaboratory Trial Publications and Presentations

A. Authorship

Decisions regarding the content and authorship of NIH Collaboratory Trial publications and presentations will be made by the individual trial's steering committee, including NIH staff who provide oversight for the project (when allowed by NIH policy specific to the supporting Institute, Center, or Office).

B. Review

1. NIH Collaboratory Trial **manuscripts** will be submitted by the authors to the Coordinating Center (nih-collaboratory@dm.duke.edu) at least 10 business days before the planned submission to allow Publications Committee staff to review the document to ensure the use of required acknowledgment and disclaimer language and to check for mentions of other NIH Collaboratory Trials. Committee staff will respond within 10 business days.

   Abstracts and presentations should acknowledge NIH Pragmatic Trials Collaboratory support but need not be submitted to the Coordinating Center in advance. See Section IX of this policy for funding acknowledgment language.

2. For draft NIH Collaboratory Trial manuscripts that include descriptions of or details about an NIH Collaboratory Trial other than the authors' own, committee staff will notify the Publications Committee chair and will share the manuscript or other materials with the principal investigator of the other NIH Collaboratory Trial. That investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of their trial, and offer corrections of errors, but will not exercise editorial control over other sections of the manuscript. If no response is received from the principal investigator within 10 business days of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the authors and the principal investigator of the other NIH Collaboratory Trial, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office for a given NIH Collaboratory Trial would require review of a manuscript, abstract, or presentation before its submission. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

4. Final editorial authority and the decision to publish will reside with the NIH Collaboratory Trial's steering committee, including NIH staff who provide oversight for the project. The Publications Committee will provide advice and assistance with dissemination as needed.

5. Other manuscripts, abstracts, and presentations arising from NIH Collaboratory Trials without specific aims of being designated as NIH Collaboratory publications or presentations will be provided by NIH Collaboratory Trial investigators in a listing submitted biannually to the Coordinating Center. The NIH Collaboratory Trial investigator or Publications Committee chair may request that a manuscript be shared for comment due to high interest.

6. All NIH Collaboratory Trial manuscripts submitted to the Coordinating Center before publication will remain confidential and will not be shared outside the Publications Committee membership and staff, NIH Collaboratory Trial principal investigators (if applicable), Coordinating Center principal investigators, and the authors.

C. After Publication or Presentation

1. Once an NIH Collaboratory Trial manuscript, abstract, or presentation has been accepted for publication or presentation, the lead author or their designee will inform the Coordinating Center staff and provide them with a final copy of the accepted publication or presentation.

2. NIH Collaboratory Trial principal investigators or their designees will submit quarterly updates to the Coordinating Center about all publication and presentation activity related to the project.

V. Core Working Group Publications and Presentations

A. Authorship

Decisions regarding the content and authorship of Core Working Group publications and presentations will be made by the members of the Core Working Group(s) involved in creation of the work. All members of the respective Core Working Group(s) will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the manuscript will be assumed.

B. Review

1. Core Working Group **manuscripts** will be submitted by the authors to the Coordinating Center (nih-collaboratory@duke.edu) for delivery to the Publications Committee staff, who will have 10 business days to collect and forward comments and suggestions from (a) Core Working Group members, (b) Publications Committee members, and (c) any additional Coordinating Center members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office would require review before submission. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

   Abstracts and presentations should acknowledge NIH Pragmatic Trials Collaboratory support but need not be submitted to the Coordinating Center in advance. See Section IX of this policy for funding acknowledgment language.

2. For draft Core Working Group manuscripts that include descriptions of or details about an NIH Collaboratory Trial, the Publications Committee staff will share the manuscript with the NIH Collaboratory Trial's principal investigator. The NIH Collaboratory Trial's principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of their trial, and offer corrections of errors, but will not exercise editorial control over other sections of the manuscript. If no response is received from the NIH Collaboratory Trial's principal investigator within 10 business days of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the authors and the NIH Collaboratory Trial's principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. An additional 10 days may be taken by the Publications Committee after comments are generated to adjudicate any resulting editorial changes.

   a. Where intractable differences of opinion remain, suggested changes from all sides will be forwarded to the designated authors.

   b. Comments from any Publications Committee member, NIH or otherwise, will not constitute official positions of the NIH.

4. Final editorial authority and the decision to publish will reside with the designated authors, although the Publications Committee will have the right

to vote on the designation of the final proposed manuscript as an NIH Collaboratory publication or presentation.

a. Manuscripts, abstracts, and presentations that are not designated as NIH Collaboratory publications or presentations will not be listed on the NIH Collaboratory website and will not benefit directly from any public relations or news items published on the NIH Collaboratory website.

5. In the event that authors of a publication must meet an impending deadline for a special issue or call for papers or respond to an invitation to submit within a brief period of time, authors should contact the Coordinating Center to request expedited review of the manuscript. If an expedited review is not possible before submission, the authors will send the manuscript to the Coordinating Center within 10 business days after submission; the Publications Committee will still consider whether the manuscript will be designated as an NIH Collaboratory publication.

6. All Core Working Group manuscripts submitted to the Coordinating Center before publication will remain confidential and will not be shared outside the Publications Committee membership and staff, NIH Collaboratory Trial principal investigators (if applicable), Coordinating Center principal investigators, and the author(s).

C. After Publication

Once a Core Working Group manuscript, abstract, or presentation has been accepted for publication or presentation, the lead author or their designee will inform the Coordinating Center staff, who will notify the NIH program official and the Publications Committee staff.

VI. Core Working Group Guidance Documents

A. Authorship

Decisions regarding the content and authorship of guidance documents will be made by the members of the Core Working Group(s) or ad hoc working group involved in creation of the work. All members of the respective working group(s) will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the guidance document will be assumed.

B. Review

1. Guidance documents will be submitted by the author(s) to the Coordinating Center (nih-collaboratory@duke.edu) for delivery to the Publications Committee staff, who will have 10 business days to collect and forward comments and suggestions from (a) working group members, (b) Publications Committee members, and (c) any additional Coordinating Center members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office would require review before publication of the guidance document. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

2. For guidance documents that include descriptions of or details about an ongoing or completed NIH Collaboratory Trial, the Publications Committee staff will share the document with the trial's principal investigator. The trial's principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of their trial, and offer corrections of errors, but will not otherwise exercise editorial control over the document. If no response is received from the principal investigator within 10 business days of receiving the guidance document, assent and approval will be assumed. In the event of disagreements between the authors and the NIH Collaboratory Trial's principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. An additional 10 days may be taken by the Publications Committee after comments are generated to adjudicate any resulting editorial changes.

    a. Where intractable differences of opinion remain, suggested changes from all sides will be forwarded to the authors.

    b. Comments from any Publications Committee member, NIH or otherwise, will not constitute official positions of the NIH.

4. Final editorial authority and the decision to publish the guidance document will reside with the authors.

VII. Core Working Group Tools, Best Practice Documents, and Other Resources

A. Authorship

Decisions regarding the content (and authorship, if applicable) of tools, best practice documents, and other resources will be made by the members of the Core Working Group(s) or ad hoc working group involved in the creation of the work. All members of the respective Core Working Group(s) or ad hoc working group will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the document will be assumed.

B. Review

1. Tools, best practice documents, and other resources will be submitted by the authors to the Coordinating Center (nih-collaboratory@duke.edu) for delivery to Publications Committee staff at least 10 business days before publication to allow staff to review the document to ensure the use of required disclaimer language, if applicable, and to check for mentions of NIH Collaboratory Trials. The committee staff will respond within 10 business days.

2. For tools, best practice documents, and other resources that include descriptions of or details about an ongoing or completed NIH Collaboratory Trial, committee staff will share the document with the trial's principal investigator. The trial's principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of their trial, and offer corrections of errors, but will not exercise editorial control over other sections of the document. If no response is received from the principal investigator within 10 business days of receiving the document, assent and approval will be assumed. In the event of disagreements between the authors and the NIH Collaboratory Trial's principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office for a given NIH Collaboratory Trial would require review of a best practice document before its publication. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before publication.

4. Final editorial authority and the decision to publish will reside with the authors.

VIII. Short Communications by the Coordinating Center

Short communications are produced by the Coordinating Center communications team in consultation with the Coordinating Center leadership. They are prepared in accordance with the Coordinating Center staff's relevant operational processes.

IX. Acknowledgment of NIH Collaboratory Support

A. When to Acknowledge NIH Funding

Authors should only acknowledge NIH awards on manuscripts, abstracts, and presentations when the activities that contributed to the manuscript, abstract, or presentation directly arose from the award and are within the scope of the award being acknowledged. The scope of the award includes the aims, objectives, and purposes of the award, as well as the methodology, approach, analyses, or other activities; and the tools, technologies, and timeframes needed to meet the award's objectives.

When considering whether acknowledgment of an NIH award is necessary or appropriate, the authors should consider the following questions:

- Did activities supported by the award contribute to the manuscript, abstract, or presentation?
- Did the award support the conduct of experiments or the analysis of data that contributed to the manuscript, abstract, or presentation?
- Is there a clear and apparent link between the work described in the manuscript, abstract, or publication with the aims and objectives of the award?

If the answer is yes to any of these questions, the NIH support should be acknowledged.

See also Communicating and Acknowledging Federal Funding at https://grants.nih.gov/policy/federal-funding.htm.

B. Preferred Acknowledgment Language for Manuscripts

1. Manuscripts **derived from work of the Coordinating Center or Core Working Groups** should include the following acknowledgment:

   "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). [If supplemental funding was provided for specific activities, acknowledge the Institute, Center, or Office providing the support here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH."

2. Manuscripts **derived from one or more NIH Collaboratory Trials**:

   a. Manuscripts derived from **BackInAction, BeatPain Utah, FM-TIPS, GRACE, NOHARM, or OPTIMUM** should include the following acknowledgment:

      "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through the NIH HEAL Initiative under award number [UG3, UH3, and/or R01 grant number] administered by the [Institute, Center, or Office providing oversight]. This work also received logistical and technical support from the PRISM Resource Coordinating Center under award number U24 AT010961 from the NIH through the NIH HEAL Initiative, and from the NIH Pragmatic Trials Collaboratory Coordinating Center under award number U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders

and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). The content is solely the responsibility of the authors and does not necessarily represent the official views of [Institute, Center, or Office providing funding or oversight] or the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH or its HEAL Initiative."

b. Manuscripts derived from **all other NIH Collaboratory Trials** should include the following acknowledgment:

"This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory by cooperative agreement [UG3, UH3, and/or R01 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work also received logistical and technical support from the NIH Pragmatic Trials Collaboratory Coordinating Center under award number U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). The content is solely the responsibility of the authors and does not necessarily represent the official views of [Institute, Center, or Office providing funding or oversight] or the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH."

3. Manuscripts supported by both the Coordinating Center and one or more NIH Collaboratory Trials:

a. Manuscripts derived from the work of the **Coordinating Center or Core Working Groups and BackInAction, BeatPain Utah, FM TIPS, GRACE, NOHARM, or OPTIMUM** should include the following acknowledgment:

"This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory under award number

U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP), and by the NIH through the NIH HEAL Initiative under award number [UG3, UH3, and/or R01 grant number] administered by the [Institute, Center, or Office providing funding or oversight]. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24 AT010961. [If supplemental funding was provided for specific activities, acknowledge the Institute, Center, or Office providing the support here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing funding or oversight] or the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH or its HEAL Initiative."

b. Manuscripts derived from work of the **Coordinating Center or Core Working Groups and any other NIH Collaboratory Trial** should include the following acknowledgment:

"This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP), and through cooperative agreement [UG3, UH3, and/or R01 grant number] from the [Institute, Center, or Office providing funding or oversight]. [If supplemental funding was provided for specific activities, acknowledge the Institute, Center, or

Office providing the support here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing funding or oversight] or the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH."

4. Manuscripts that cite **multiple sources of support** (for example, a project supported by the Coordinating Center and one or more NIH Institutes, Centers, or Offices) should list funding sources in declining order of proportional support for the given project.

5. Before issuing a press release concerning results, presentations, or publications derived from this research, authors should notify the relevant NIH Institute, Center, or Office in advance to allow for coordination.

C. Preferred Publication Language for Posters, Slides, and Other Summary Formats

An abbreviated version of the acknowledgment language may be used in poster presentations, slides, and other summary reports, as described below.

1. Poster presentations, slide presentations, and other summary reports **derived from the work of one or more Core Working Groups or the Coordinating Center** should include the following acknowledgment:

   "This work was supported within the NIH Pragmatic Trials Collaboratory under award number U24 AT009676 from multiple NIH Institutes, Centers, and Offices. [If supplemental funding was provided for specific activities, acknowledge the Institute, Center, or Office providing the support here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

2. Poster presentations, slide presentations, and other summary reports **derived from one or more NIH Collaboratory Trials**:

   a. Poster presentations, slide presentations, and other summary reports derived from **BackInAction, BeatPain Utah, FM TIPS, GRACE, NOHARM, or OPTIMUM** should include the following acknowledgment:

      "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through the NIH HEAL Initiative under award number [UG3, UH3, and/or R01 grant number]

administered by the [Institute, Center, or Office providing oversight]. This work also received logistical and technical support from the PRISM Resource Coordinating Center under award number U24 AT010961 from the NIH through the NIH HEAL Initiative, and from the NIH Pragmatic Trials Collaboratory Coordinating Center under award number U24 AT009676 from multiple NIH Institutes, Centers, and Offices. The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing oversight] or the NIH or its HEAL Initiative."

b. Poster presentations, slide presentations, and other summary reports derived from any other **NIH Collaboratory Trial** should include the following acknowledgment:

"This work was supported within the NIH Pragmatic Trials Collaboratory by cooperative agreement [UG3, UH3, and/or R01 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work also received logistical and technical support from the program's Coordinating Center through cooperative agreement U24 AT009676 from multiple NIH Institutes, Centers, and Offices. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

3. Poster presentations, slide presentations, and other summary reports supported by both the Coordinating Center or Core Working Groups and one or more NIH Collaboratory Trials:

a. Poster presentations, slide presentations, and other summary reports supported by the **Coordinating Center or Core Working Groups and BackInAction, BeatPain Utah, FM TIPS, GRACE, NOHARM, or OPTIMUM** should include the following acknowledgment:

"This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24 AT009676 from multiple NIH Institutes, Centers, and Offices, and by the NIH through the NIH HEAL Initiative under award number [UG3, UH3, and/or R01 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24 AT010961. [If supplemental funding was provided for specific activities, acknowledge the Institute, Center, or Office providing the support here.] The content is solely the responsibility of the authors

and does not necessarily represent the official views of the NIH or its HEAL Initiative."

b. Poster presentations, slide presentations, and other summary reports supported by the **Coordinating Center or Core Working Groups and any other NIH Collaboratory Trial** should include the following acknowledgment:

"This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24 AT009676 from multiple NIH Institutes, Centers, and Offices, and through cooperative agreement [UG3, UH3, and/or R01 grant number] from the [Institute, Center, or Office providing funding or oversight]. [If supplemental funding was provided for specific activities, acknowledge the Institute, Center, or Office providing the support here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

4. Poster presentations, slide presentations, and other summary reports that cite **multiple sources of support** (for example, a project supported by the Coordinating Center and one or more NIH Institutes, Centers, or Offices) should list funding sources in declining order of proportional support for the given project.

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NIH Collaboratory Trial Publications

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The NIH Collaboratory Trials are supported by and receive administrative oversight from individual NIH Institutes, Centers, or Offices. The Coordinating Center provides logistical and technical support for all NIH Collaboratory Trials. For NIH Collaboratory Trial publications, please complete these steps, as required by our policies and funding.

Before Publication

STEP 01

Choose option A, B, or C for the funding acknowledgment.

Option A: Your work is supported by one or more of the following NIH Collaboratory Trials: BackInAction, BeatPain Utah, FM-TIPS, GRACE, NOHARM, or OPTIMUM.

Use the following language: "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through the NIH HEAL Initiative under award number [UG3, UH3, and/or R01 grant number] administered by the [Institute, Center, or Office providing oversight]. This work also received logistical and technical support from the PRISM Resource Coordinating Center under award number U24 AT010961 from the NIH through the NIH HEAL Initiative, and from the NIH Pragmatic Trials Collaboratory Coordinating Center under award number U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). The content is solely the responsibility of the authors and does not necessarily represent the official views of [Institute, Center, or Office providing funding or oversight] or the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH or its HEAL Initiative. "

Option B: Your work is supported by one or more NIH Collaboratory Trials, but *not including* BackInAction, BeatPain Utah, FM-TIPS, GRACE, NOHARM, or OPTIMUM.

Use the following language: "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory by cooperative agreement [UG3, UH3, and/or R01 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work also received logistical and technical support from the NIH Pragmatic Trials Collaboratory Coordinating Center under award number U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Aging (NIA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). The content is solely the responsibility of the authors and does not necessarily represent the official views of [Institute, Center, or Office providing funding or oversight] or the NCCIH, NCI, NIA, NIAMS, NHLBI, NIAID, NIMHD, NINDS, NINR, OBSSR, or ODP, or the NIH."

Option C: Your work has multiple sources of support.

For work with multiple sources of support—such as a collaboration between an NIH Collaboratory Trial and the Coordinating Center or a Core Working Group, supplemental funding for specific activities, or support from outside the NIH Collaboratory—email us at nih-collaboratory@duke.edu. We're here to help!

STEP 02

Does your work include a description of another NIH Collaboratory Trial?

If yes, please allow the principal investigator of the other trial to review your work. This courtesy review will be limited to the factual accuracy of your description of their work. Allow at least 2 weeks in advance of your initial journal submission.

Coordinating Center staff can facilitate this process and convey draft manuscripts to NIH Collaboratory Trial investigators for their confidential review. Email us at nih-collaboratory@duke.edu and include "Manuscript Review" in the subject heading.

STEP 03

Notify the Coordinating Center.

It's easy! Email us at nih-collaboratory@duke.edu. Please allow 1 week for us to review your acknowledgment statement. Coordinating Center staff and the publications committee are also available to provide advice, suggestions, and help with dissemination, as needed.

After Publication

STEP 01

Let us know your work has been published.

Email us at nih-collaboratory@duke.edu. We track and report on publications as part of the NIH Collaboratory grants. We also want to share and promote your work!

STEP 02

Ensure your work meets applicable NIH public access requirements, such as inclusion in PubMed Central.

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For Coordinating Center and Core Working Group publications, please complete these steps, as required by our policies and funding.

Before Publication

STEP 01

Choose option A or B for your funding acknowledgment.

Option A: Some or all of your work is supported by the Coordinating Center or a Core Working Group.

Include the following language: "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24 AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or NIH or its HEAL Initiative."

Option B: Your work has multiple sources of support in addition to the Coordinating Center or a Core Working Group.

For work with multiple sources of support in addition to the Coordinating Center or a Core Working Group—such as a collaboration between an NIH Collaboratory Trial and the Coordinating Center or a Core Working Group, supplemental funding for specific activities, or support from outside the NIH Collaboratory—email us at nih-collaboratory@duke.edu. We're here to help!

After Publication

STEP 01

Let us know your work has been published.

Email us at nih-collaboratory@duke.edu.

We track and report on publications as part of the NIH Collaboratory grants. We also want to share and promote your work!

STEP 02

Ensure your work meets applicable NIH public access requirements, such as inclusion in PubMed Central.

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