NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

NIH Pragmatic Trials Collaboratory Onboarding Meeting

January 8, 2025

Virtual

SUPPLEMENTAL MEETING MATERIALS

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Virtual Onboarding Meeting Agenda

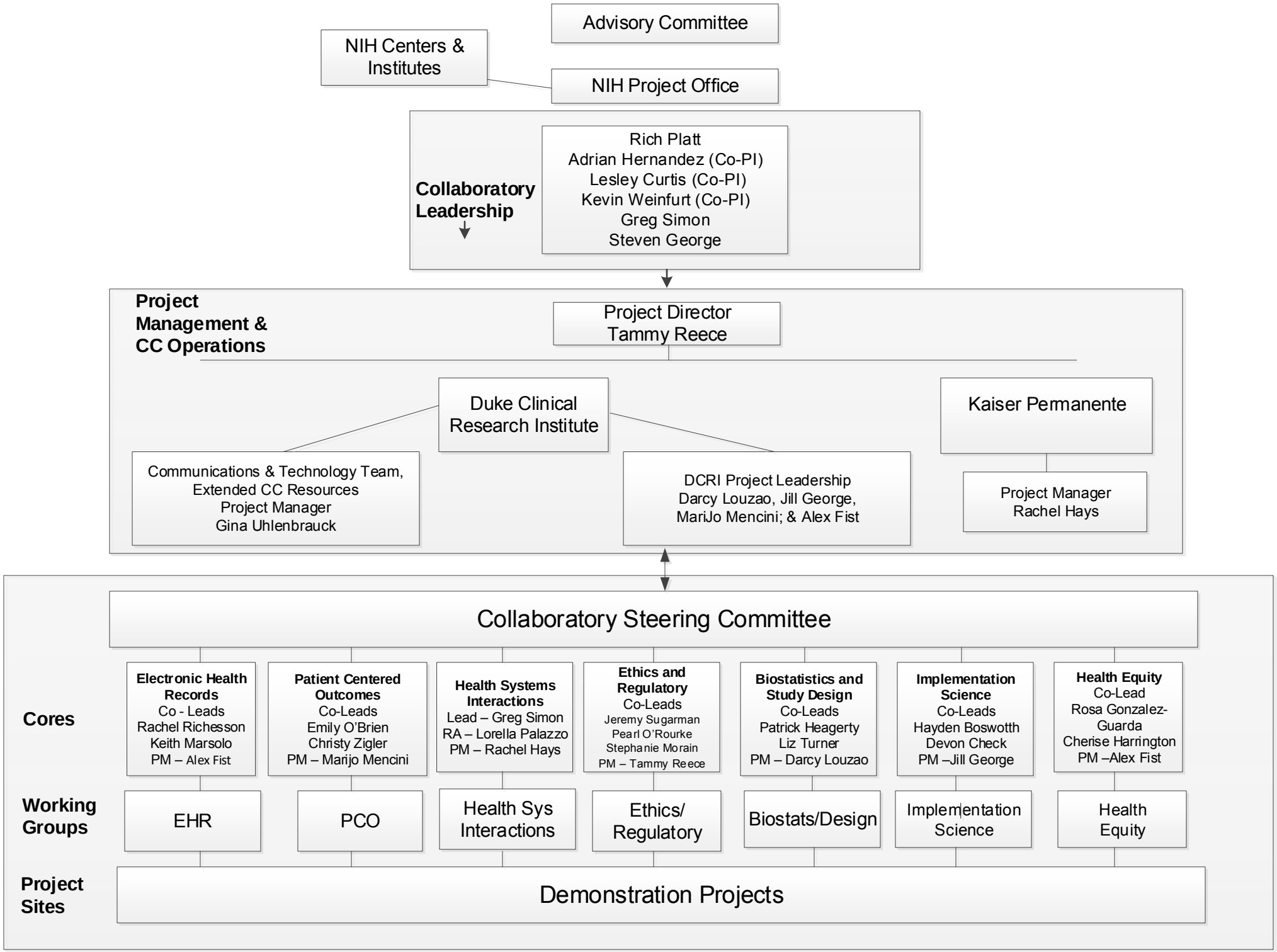
January 8, 2025 | 3:00 – 5:00 p.m. ET

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Meeting Purpose: Welcome and hear from 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
3:00 – 3:05 p.m.	**Welcome** **Opening Remarks**	Wendy Weber Adrian Hernandez	*Review meeting goals and expectations*
3:05 – 3:25 p.m.	**Overview of the NIH Pragmatic Trials Collaboratory and a Cooperative Agreement**	Wendy Weber	*Discuss what it means to be part of a cooperative agreement* *Reinforce the idea of openly discussing challenges*
3:25 – 3:40 p.m.	**Working with the NIH Collaboratory Coordinating Center**	Adrian Hernandez	*Give an overview of the Coordinating Center* *Describe how NIH Collaboratory Trials work with the Coordinating Center* *Share lessons from experiences with previous trials*
3:40 – 4:15 p.m. *5 min per Core*	**Brief Introduction to the Core Working Groups**		*Provide a brief introduction to the Core Working Groups* *Review key resources available* *Describe what trials can gain from the expertise of the Core Working Groups*
	• Patient-Centered Outcomes	Emily O'Brien Christy Zigler	
	• Health Care Systems Interactions	Greg Simon	
	• Ethics and Regulatory	Pearl O'Rourke Stephanie Morain	
	• Health Equity	Rosa Gonzalez-Guarda Cherise Harrington	
	• Implementation Science	Devon Check Hayden Boswell	
	• Electronic Health Records	Keith Marsolo Rachel Richesson	
	• Biostatistics and Study Design	Patrick Heagerty Liz Turner	
4:15 – 4:40 p.m.	**New UG3 NIH Collaboratory Trial Overview** • Self-Testing for Cervical Cancer in Priority Populations (The STEP-2 Trial)	Rachel Winer Amanda Petrik Jasmin Tiro	*Project abstract and data sharing plan are in the meeting e-binder* *Provide an overview of the new NIH Collaboratory Trial to include its status, top issues being faced, and potential barriers to successful UH3 transition*
4:40 – 4:55 p.m.	**Open Discussion**	Adrian Hernandez	*Q&A with program leadership, trial, and Core leaders*
4:55 – 5:00 p.m.	**Closing Remarks**	Wendy Weber Adrian Hernandez	*Summarize the meeting*

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
Rachel Hays
Collaboratory Steering Committee
Cores
Electronic Health Records
Co - Leads
Rachel Richesson
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 – Rachel Hays
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
Health Equity
Co-Lead
Rosa Gonzalez-Guarda
Cherise Harrington
PM –Alex Fist
Working Groups
EHR
PCO
Health Sys Interactions
Ethics/ Regulatory
Biostats/Design
Implementation Science
Health Equity
Project Sites
Demonstration Projects

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: 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: Myles Wolf
Institution: Duke University

Title: ICD-Pieces™
PI: Miguel Vazquez
Institution: University of Texas Southwestern Medical Center

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

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

Title: Nudge
PIs: Michael Ho, Sheana Bull
Institution: University of Colorado

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: 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
Miguel Vazquez	Susan Mendley	NIDDK	Kevin Chan	NIDDK
Margaret Kuklinski	Beda Jean-Francois	NCCIH/NIDA	Elizabeth Ginexi	NCCIH
Corita Grudzen	Peter Murray	NCCIH	Marcel Salive	NIA
Michael Ho	Larry Fine	NHLBI	Nicole Redmond	NHLBI
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	Beda Jean-Francois	NCCIH
Julie Fritz	Karen Kehl	NINR	Joe Bonner	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	TBD	TBD
Coordinating Center PIs	**Project Officer**	**Project Officer IC**	**Project Scientist**	**Project Scientist IC**
Adrian Hernandez, Lesley Curtis, Kevin Weinfurt	Wendy Weber	NCCIH	Robin Boineau	NCCIH

COLLABORATORY COORDINATING CENTER

STEERING COMMITTEE

Lesley Curtis (Chair), Michele Balas, Alexis Bakos, Robin Boineau, Joe Bonner, Hayden Bosworth, Sheana Bull, Diana Burgess, Shalanda Bynum, Hrishikesh Chakraborty, Kevin Chan, Devon Check, Andrea Cheville, Sekai Chideya, Andrea Cook, Leslie Crofford, Theresa Cruz, Lynn DeBar, 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, Cherise Harrington, Patrick Heagerty, Adrian Hernandez, Michael Ho, Susan Huang, Clayton Huntley, Beda Jean-Francois, 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, 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, Sebastian Tong, James Tulsky, Liz Turner, Eduard Vasilevskis, Miguel Vazquez, Angelo Volandes, Chenchen Wang, Charles Washabaugh, Wendy Weber, Kevin Weinfurt, Elizabeth Wick, Myles Wolf, Qilu Yu, Christy Zigler

NIH PROJECT OFFICE

NIH INSTITUTES AND CENTERS

NHLBI NIAID NIDDK NIAMS NCCIH NIDA NIA NINR NICHD NCMRR NIMHD

KNOWLEDGE REPOSITORY

LEARNING HEALTH SYSTEM

COLLABORATORY CORE WORKING GROUPS

ETHICS/REGULATORY

Pearl O'Rourke*
Stephanie Morain*
Jeremy Sugarman*

Joe Ali, Kisha Ali, Andy Avins, Sheana Bull, Leslie Crofford, Lee Cross, Laura Dember, Dixie Ecklund, Janel Fedler, Stephanie Fitzpatrick, Carole Frederico, Andrew Garland, Susan Gaylord, Bryan Gibson, Corita Grudzen, Kalpana Harish, Breanna Hetland, Mitch Knisely, Margaret Kuklinski, Laurie Kunches, Helen Lavretsky, David Magnus, Kevin McBryde, Natalia Morone, Tina Neill-Hudson, Vasiliki Nataly Rahimzadeh, Kushang Patel, Tammy Reece, Marguerite Robinson, Judy Schlaeger, Richard Skolasky, Kayte Spector-Bagdady, Venky Sundaram, Paula Tebeau, Jon Tilburt, David Vulcano, Chenchen Wang, Kevin Weinfurt, Dave Wendler, Ben Wilfond

BIOSTATISTICS AND STUDY DESIGN

Patrick Heagerty*
Liz Turner*

Taliser Avery, 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, Gary Grunwald, Amanda Gusovsky, Liz Habermann, Jeph Herrin, Andrew Humbert, Ken Kleinman, Margaret Kuklinski, Karen Lasser, Fan Li, Darcy Louzao, Jon Moyer, David Murray, Tuhina Neogi, Meg Nikolov, Charles Quesenberry, Jincheng Shen, Prabha Siddarth, Alana Steffen, Yu Ru Su, Brent Taylor, Ludovic Trinquart, Neha Varma, Angelo Volandes, Jin Wang, Rui Wang, Xueqi Wang, Janice Weinberg, Christopher Wickman, Qilu Yu

HEALTH CARE SYSTEMS INTERACTIONS

Greg Simon*

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

ELECTRONIC HEALTH RECORDS

Rachel Richesson*
Keith Marsolo*

Liz Amos, Taliser Avery, Arne Beck, Srinivasan Beddhu, Andy Boyd, Jordan Braciszewski, James Campbell, Andrea Cheville, Elizabeth Colantuoni, Dana Dailey, Kelley Daley, Kim Faurot, Alex Fist, Stephanie Fitzgerald, Guilherme del Fol, Carol Geary, Christine Goertz, Corita Grudzen, Ed Hammond, Michael Ho, Trevis Huff, Andrea Kline-Simon, Josh Lakin, Devin Mann, Clem McDonald, Laura McLean, Kathleen McTigue, Meg Plomondon, Alice Pressman, Kiran Salman, Robert Saper, Stacy Sterling, Brent Taylor, Ludovic Trinquart, Angelo Volandes, Elizabeth (Liza) Wick

PATIENT-CENTERED OUTCOMES

Christy Zigler*
Emily O'Brien*

Michele Balas, Emine Bayman, Arne Beck, M. Fernanda Bellolio, Andy Boyd, Andrea Cheville, Leslie Crofford, Susan Czajkowski, Stephanie Fitzpatrick, Morgan Fuoco, Adam Goode, Carol Greco, Chris Knoepke, Margaret Kuklinski, Helen Lavretsky, Brent Leininger, Amy Loree, MariJo Mencini, Tuhina Neogi, Kushang Patel, Monica Perez Jolles, Pamela Peterson, Richard Skolasky, Alana Steffen, Stacy Sterling, Anne Thackeray, Jon Tilburt, James Tulsky, Eduard Vasilevskis, Chenchen Wang, Kevin Weinfurt

HEALTH EQUITY

Rosa Gonzalez-Guarda*
Cherise Harrington*

Maureen Akubu-Odero, Kisha Ali, Jessica Lee Barnhill, Sheana Bull, Gaby Castro, Andrea Cheville, Allison Cuthel, Dana Dailey, Juanita Darby, Stacie Daughter, Graham Dore, Kim Faurot, Alex Fist, Stephanie Fitzpatrick, Julie Fritz, Morgan Fuoco, Christine Goertz, Ronnie Horner, Beda Jean-Francois, Jungyoon Kim, Mitchell Knisely, Lance Laird, Katharine Lawrence, Mallory Mahaffey, Nadine Matthie, Alice Pressman, Isabel Roth, Robert Saper, Nina Siman, Richard Skolasky, Rebecca Sudore, Venky Sundaram, Sebastian Tong, Elizabeth (Liza) Wick

IMPLEMENTATION SCIENCE

Devon Check *
Hayden Bosworth*

Oluwaseun Adeyemi, Kristin R. Archer, Lindsay Ballengee, Allison Cuthel, Lynn DeBar, Ardith Doorenbos, Stephanie Fitzpatrick, Jill George, Steven George, Tony Gerlach, Shruti Gohil, Carol Greco, Anna Krupp, Kevin McLaughlin, Brian Mittman, Wynne Norton, Kushang Patel, Eric Roseen, Isabel Roth, Stacie Salsbury, Edward Septimus, Stacy Sterling, Anne Thackeray, Cindy Tofthagen, Sebastian Tong, Katy Trinkley, Angelo Volandes, Elizabeth (Liza) Wick

**** Chair / Co-Chairs***

Current as of: April 2024

NIH Collaboratory Trials Roadmap
FY24, Q4

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

PILOT/START-UP

- UG3 Award Date
- R01 Award Date *

AIM-CP, APA-SN, RAMP, LungSMART

TRIAL INITIATION

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

ARBOR-Telehealth, I CAN DO Surgical ACP, TAICHIKNEE

SITE ACTIVATION

- First Site Activated

ENROLLMENT

- First Patient Enrolled

BeatPain Utah, BEST-ICU, Chat 4 Heart Health, FM TIPS, GRACE, IMPACt-LBP, iPATH*, MOMs*

FOLLOW-UP

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

NOHARM, OPTIMUM

PLANNING COMPLETED

- Did not proceed to trial initiation

BPMedTime

DATA AVAILABILITY

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

DATA ANALYSIS

- Database Lock
- Final Statistical Analysis

BackInAction, GGC4H

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

ACP PEACE, HiLo, INSPIRE

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

Nudge, PRIM-ER

COMPLETED

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

ABATE, EMBED, ICD-Pieces, LIRE, PPACT, PROVEN, SPOT, STOP CRC, TiME, TSOS

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

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.

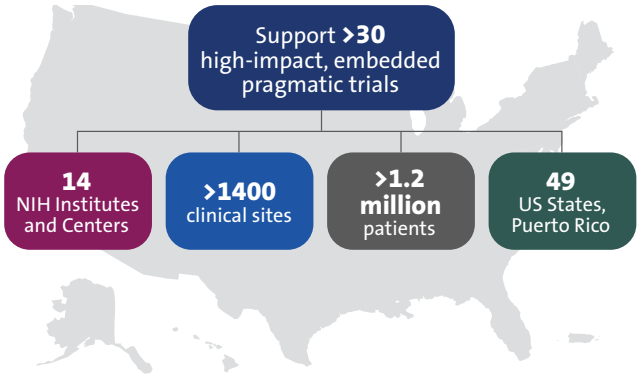
What Are Embedded Pragmatic Clinical Trials?

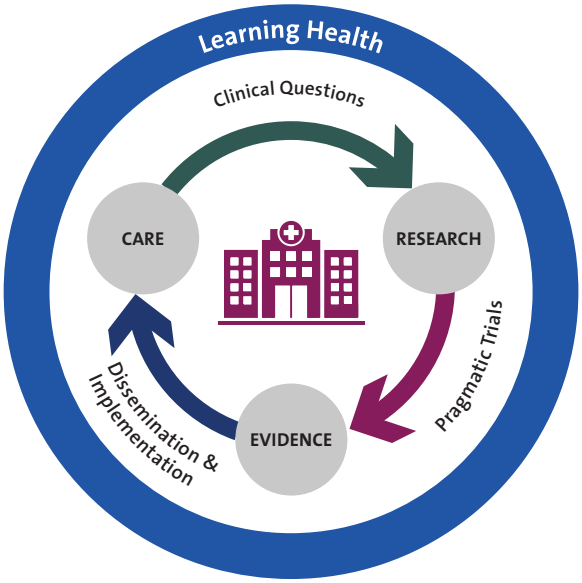
- Conducted in healthcare systems
- Use existing infrastructure and streamlined procedures
- Provide high-quality evidence
- More efficient and cost effective than traditional trials

Our 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 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.

>330 publications*	Work cited **>9500** times	**>225** trial consultations
>500 Grand Rounds webinars	**>75,000** 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.

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:

- Improve diversity, equity, and inclusion
- Engage health system partners

Assist with:

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

*LAST UPDATED OCTOBER 31, 2024

Why Do an Embedded Pragmatic Clinical Trial? The 5 Rs

Relevant Question	Real-World Setting	Representative Population	Routinely Collected Data	Rigorous Methods
The question is pressing, and healthcare system leaders, patients, and front-line clinicians care about the answer.	Desire to test in diverse healthcare delivery settings with the hope of implementing findings widely.	Ability to recruit a population reflective of patients with the condition, including those from minoritized communities.	Can use data collected as part of healthcare delivery to answer the question, supplemented by data from other sources.	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 >86,000 all-time attendees and 50 podcast episodes with >21,000 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 90 study tools available

Education
Provided >75 hours of presenter-led training at 12 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 or its HEAL Initiative.

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

Library of our popular weekly webinar featuring timely topics in pragmatic research. Recordings, summaries, and podcast episodes available.

550 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, and Conduct

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

Dissemination

- Data Sharing
- Dissemination
- Implementation

Ethics and Regulatory

- Privacy
- Consent, Waiver, & Notification
- Collateral Findings
- Data & Safety Monitoring
- Single IRB

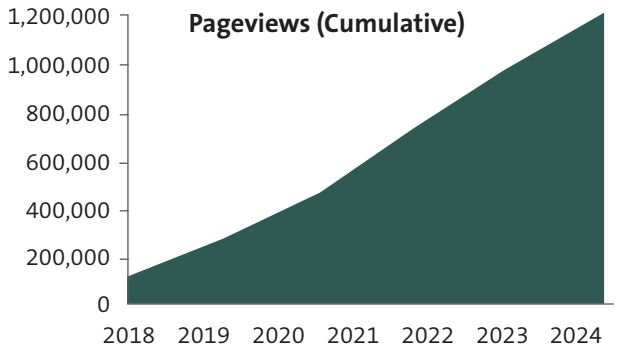
Program Information

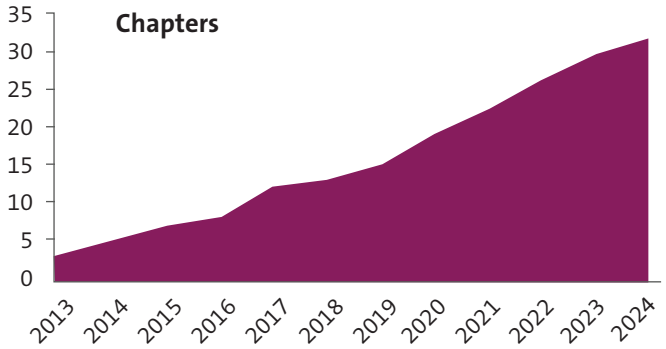
Learn about the NIH Pragmatic Trials Collaboratory, including its trials, Core Working Groups, and Coordinating Center.

- Latest program news and interviews
- Publication updates

LAST UPDATED OCTOBER 31, 2024

Living Textbook Growth





FUN FACTS

>75,000
visitors annually

>1800
webpages

More words
than *War and Peace*

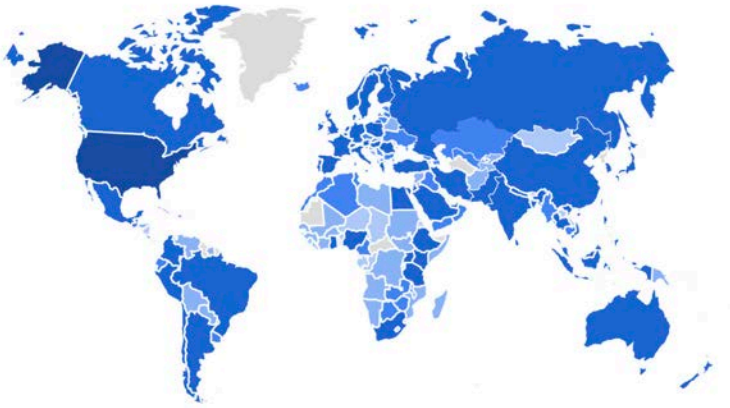
>7 days
total video runtime viewed monthly

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

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 or its HEAL Initiative.

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 and lessons learned from NIH Collaboratory Trial PIs on how to manage the planning year and get 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

NIH Pragmatic Trials Collaboratory

Enabling research embedded in healthcare delivery since 2012

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Updated December 19, 2024

1

NIH
National Institutes of Health

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

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2

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 recruit a population reflective of patients with the condition, including those from minoritized communities.

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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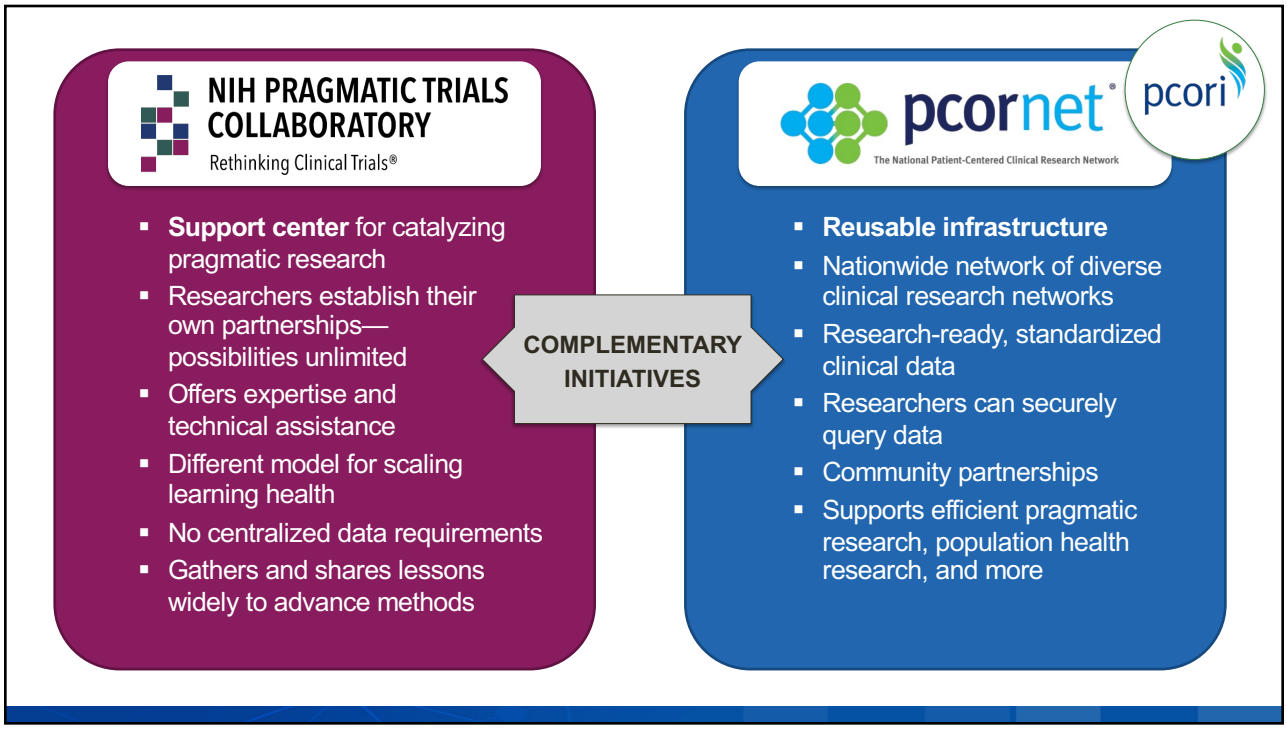
3

	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

4



5

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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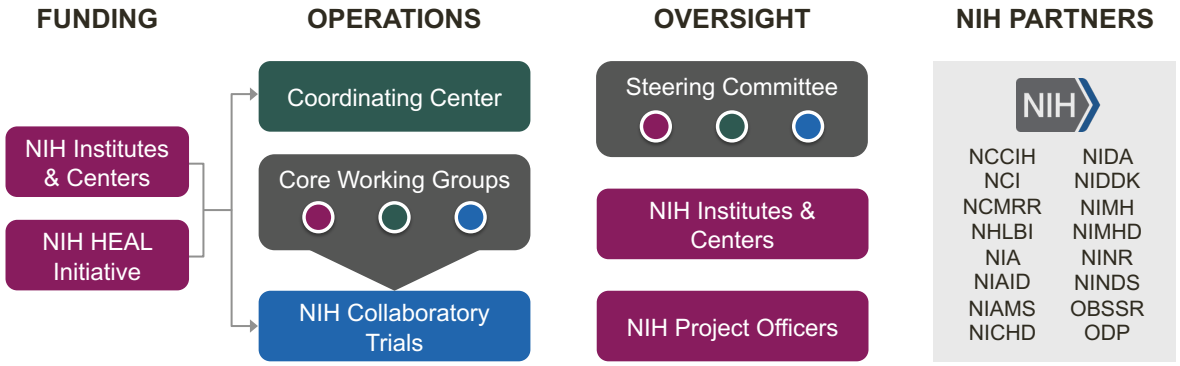
6

Program Structure



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7

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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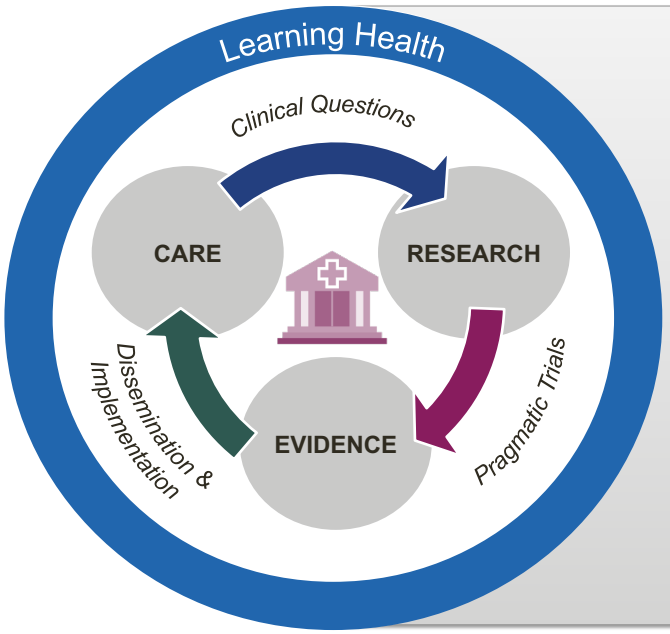

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SUPPORT SERVICES

- 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:
  - Improve diversity, equity, and inclusion
  - Engage health system partners
- Assist with:
  - Defining study endpoints
  - Measuring patient-centered outcomes
  - Assessing feasibility of clinical workflows
  - Addressing challenges that arise

9

Program Reach

Support >**30** large-scale, high-impact ePCTs

14 NIH Institutes and Centers

>1,400 clinical sites

>1.2 million patients

49 US States and Puerto Rico

No sites in Arkansas

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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

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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

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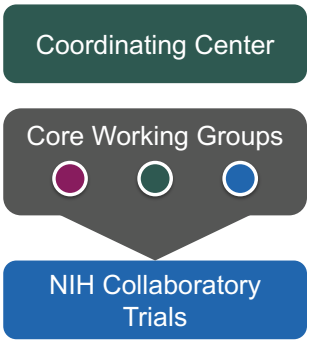
Core Working Groups

- 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

COORDINATING CENTER

- Biostatistics and Study Design
- Electronic Health Records
- Ethics and Regulatory
- Health Care Systems Interactions
- Health Equity
- Implementation Science
- Patient-Centered Outcomes

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

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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

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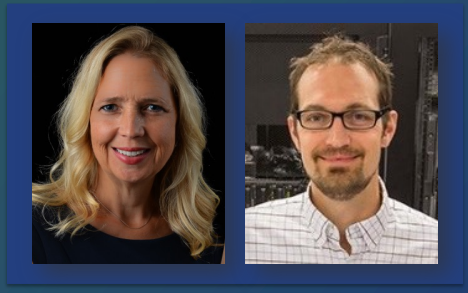
Co-Chairs:

- Rachel Richesson, PhD, MPH
- Keith A. Marsolo, PhD



Electronic Health Records Core

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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Chair:

- Greg Simon, MD, MPH

Health Care Systems Interactions Core

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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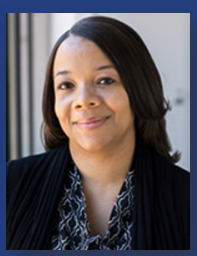
Co-Chairs:

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



Health Equity Core

Mission

- Develop guidance for ePCTs on how to integrate a health equity lens, including:
  - Considerations for enrollment
  - Strategies for selecting outcomes
  - Tailored research methods that better suit the study population

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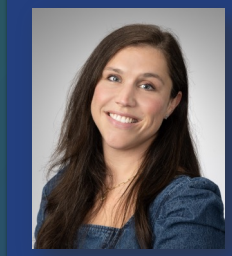
Co-Chairs:

- 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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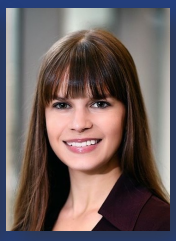
Co-Chairs:

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



Ethics and Regulatory Core

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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Co-Chairs:

- Devon Check, PhD
- Hayden Bosworth, PhD

Implementation Science Core

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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Impact of Cores

>225 trial consultations

>150 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."

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Examples: NIH Collaboratory Trials Informing Clinical Care

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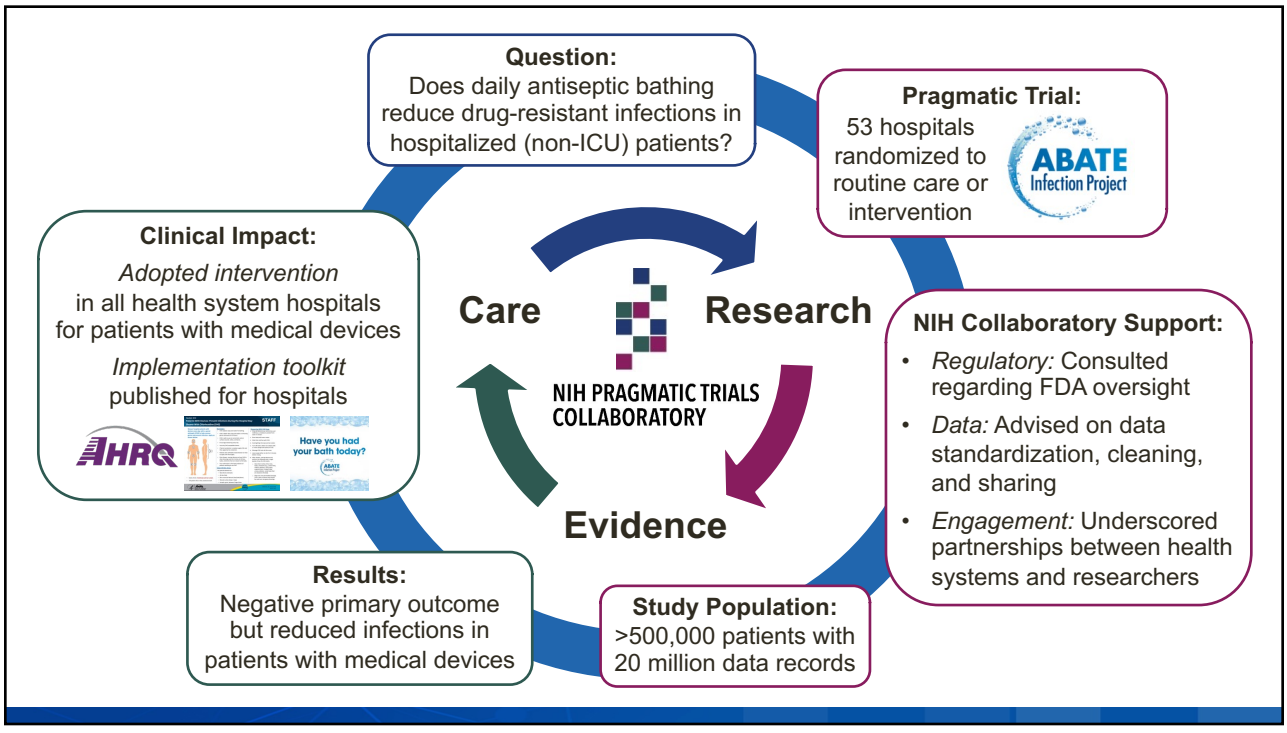

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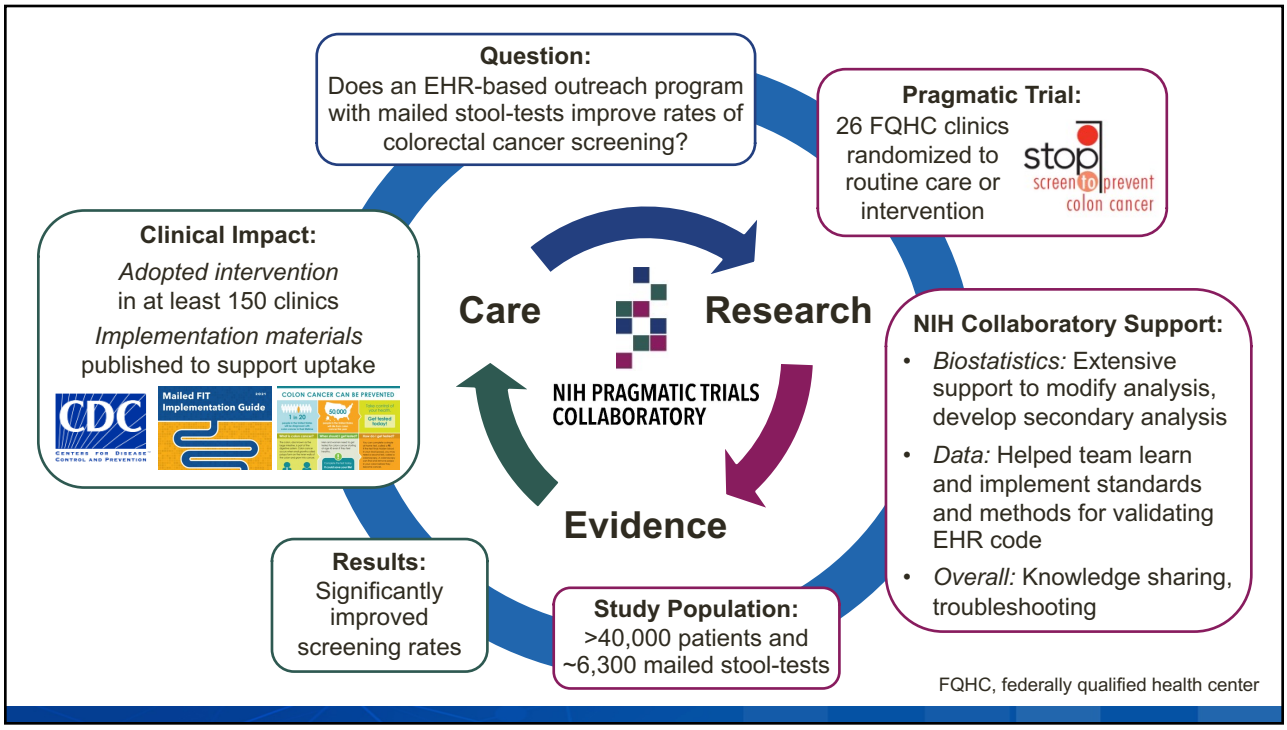
Question:
Does an EHR-based outreach program with mailed stool-tests improve rates of colorectal cancer screening?
Pragmatic Trial:
26 FQHC clinics randomized to routine care or intervention
stop screen to prevent colon cancer
Clinical Impact:
Adopted intervention in at least 150 clinics
Implementation materials published to support uptake
CDC
Mailed FIT Implementation Guide
COLON CANCER CAN BE PREVENTED
Care
Research
NIH PRAGMATIC TRIALS COLLABORATORY
Evidence
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
Results:
Significantly improved screening rates
Study Population:
>40,000 patients and ~6,300 mailed stool-tests
FQHC, federally qualified health center

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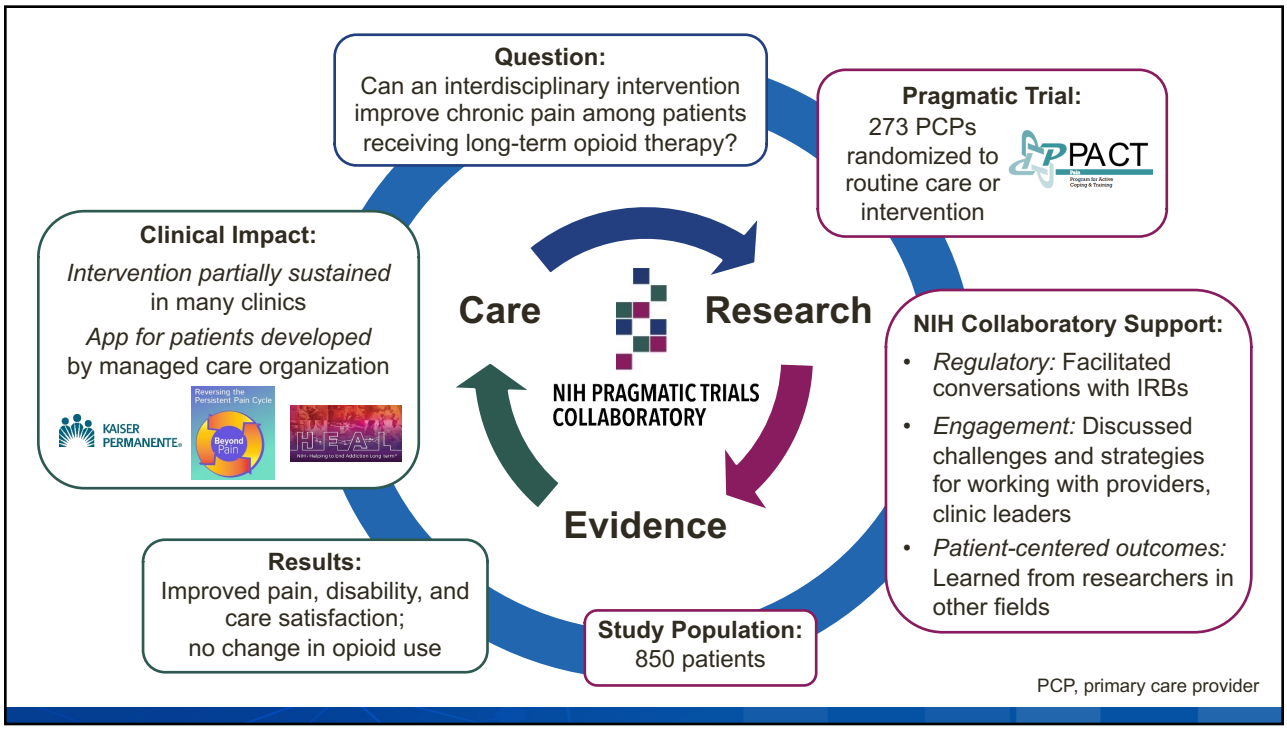
Question:
Can an interdisciplinary intervention improve chronic pain among patients receiving long-term opioid therapy?
Pragmatic Trial:
273 PCPs randomized to routine care or intervention
PACT
Clinical Impact:
Intervention partially sustained in many clinics
App for patients developed by managed care organization
KAISER PERMANENTE
Reversing the Persistent Pain Cycle
Beyond Pain
H.E.A.L.
Care
Research
NIH PRAGMATIC TRIALS COLLABORATORY
Evidence
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
Results:
Improved pain, disability, and care satisfaction; no change in opioid use
Study Population:
850 patients
PCP, primary care provider

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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
- Tools
- Resources
- Knowledge

COLLABORATION

SHARING

pcornet · AHRQ · Sentinel Initiative · Department of Veterans Affairs · 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 Transforming Dementia Care · 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 NIH - Helping to End Addiction Long-term · AMIA Informatics Professionals. Leading the Way. · PEIJ Pharmacological Evaluation Initiative of Japan

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

Bold denotes current NIH partner

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Publications*

TOTAL PUBLISHED
>330

CITATIONS
>9500

JOURNALS
>120

*As of October 31, 2024

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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

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Living Textbook Content and Reach

30+ chapters

>75,000 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, and Conduct
- Assessing Feasibility
- Acquiring & Assessing Real-World Data
- Study Startup
- Participant Recruitment
- Monitoring Fidelity
- Clinical Decision Support
- Patient-Reported Outcomes
- Mobile Health

Dissemination
- Data Sharing
- Dissemination
- Implementation

Ethics and Regulatory
- Privacy
- Consent, Waiver, & Notification
- Collateral Findings
- Data & Safety Monitoring
- Single IRB

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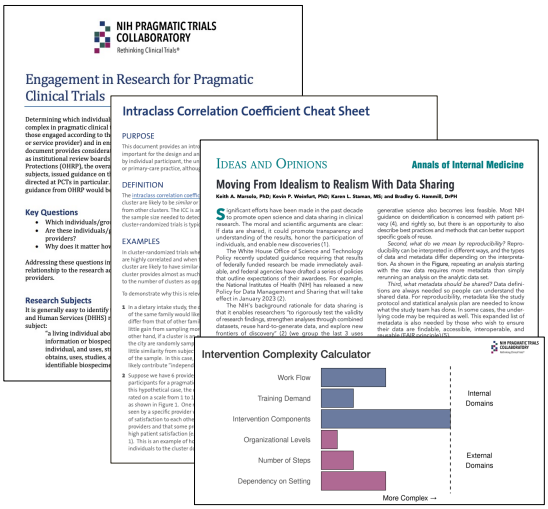
Tools and Guidance Documents

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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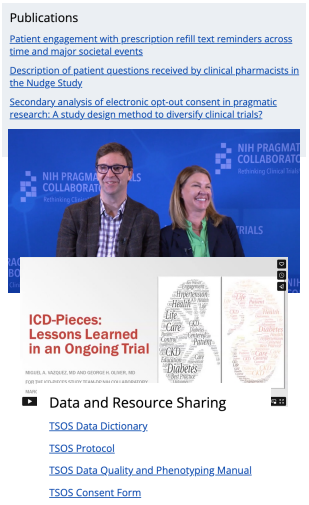
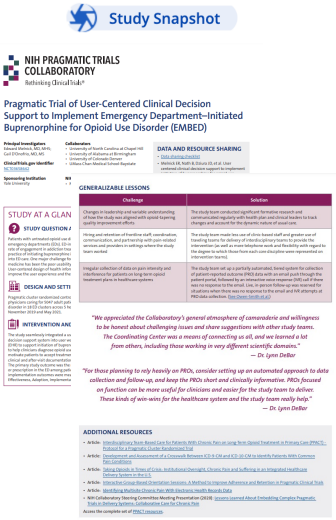
Learn About Our ePCTs

TRIAL WEBPAGES

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





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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

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Rethinking Clinical Trials® Grand Rounds

Weekly webinars

- **Fridays 1-2 pm ET**
- Open to public
- >500 held to date
- >150 attendees/session
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

Podcast episodes

- 50 available

37

Training Activities

12 workshops

>600 attendees

45 presenters

77 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

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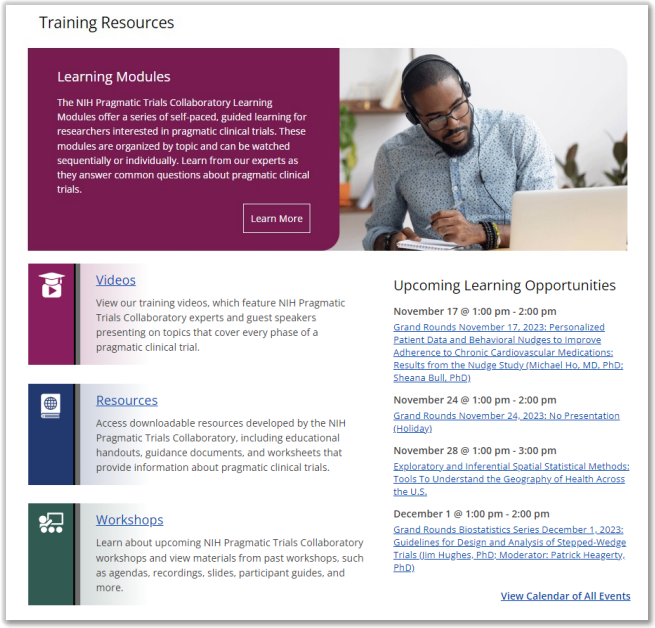
ePCT Training Resources

rethinkingclinicaltrials.org/training-resource/

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



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Receive ePCT Updates


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April 2022 • Subscribe to the Newsletter • Living Textbook • Grand Rounds Hub

News From the NIH Pragmatic Trials Collaboratory

FDA Commissioner Rob Califf Reflects on Origins and Impact of NIH Pragmatic Trials Collaboratory

In a keynote speech at the NIH Pragmatic Trials Collaboratory Steering Committee annual meeting, Dr. Rob Califf called for more and faster evidence generation. "We have to generate evidence more quickly and then insist that it gets used," he said. After his remarks, Califf joined Dr. Wendy Weber of the National Center for Complementary and Integrative Health to reflect on the origins and impact of the program. Califf was the first principal investigator of the program's Coordinating Center. View the full interview.

FDA Announces Draft Guidance for Increasing Diversity in Clinical Trials: The US Food and Drug Administration issued draft guidance recommending clinical trial sponsors develop a "race and ethnicity diversity plan" to ensure representative enrollment of racially and ethnically diverse participants in clinical trials developing medical products.

TSOS Implements Suicide Assessment and Monitoring Method: The TSOS study, an NIH Collaboratory Demonstration

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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
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
ICD-Pieces	Comorbid diabetes, chronic kidney disease, hypertension	Collaborative primary care program	All-cause hospitalizations for 3 conditions
LIRE	Low back pain	Insertion of epidemiologic benchmarks in lumbar spine imaging reports	Relative value unit for spine-related interventions
PPACT	Nonmalignant chronic pain	Multidisciplinary behavioral care management	Brief Pain Inventory
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 & skills training)	Suicide attempts

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NIH Collaboratory Trials: Completed (cont)

Project	Population	Intervention	Outcome
STOP CRC	Adults aged 50-75 years	Direct mail colorectal cancer (CRC) screening program (FIT kit)	CRC 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

Susan S Huang, Edward Septimus, Ken Kleinman, Julia Moody, Jason Hickok, Lauren Heim, Adrijana Gombosev, Taliser R Avery, Katherine Haffenreffer, Lauren Shimelman, Mary K Hayden, Robert A Weinstein, Caren Spencer-Smith, Rebecca E Kaganov, Michael V Murphy, Tyler Forehand, Julie Lankiewicz, Micaela H Coady, Lena Portillo, Jalpa Sarup-Patel, John A Jernigan, Jonathan B Perlin, Richard Platt, for the ABATE Infection trial team

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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

EBP

thebmj

RESEARCH

OPEN ACCESS

Check for updates

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

Edward R Melnick,[1,2] Bidisha Nath,[1] James D Dziura,[1,2] Martin F Casey,[3] Molly M Jeffery,[4] Hyung Paek,[2] William E Soares III,[5] Jason A Hoppe,[6] Haseena Rajeevan,[2] Fangyong Li,[2] Rachel M Skains,[7] Lauren A Walter,[7] Mehul D Patel,[3] Srihari V Chari,[3] Timothy F Platts-Mills,[8] Erik P Hess,[9] Gail D'Onofrio[1,2]

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Rethinking Clinical Trials®

46

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
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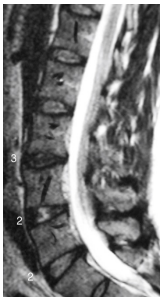
Completed

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

Jeffrey G. Jarvik, MD, MPH; Eric N. Meier, MS; Kathryn T. James, MPH; Laura S. Gold, PhD; Katharine W. Tan, PhD; Larry G. Kessler, ScD; Pradeep Suri, MD; David F. Kallmes, MD; Daniel C. Cherkin, PhD; Richard A. Deyo, MD, MPH; Karen J. Sherman, PhD; Safwan S. Halabi, MD; Bryan A. Comstock, MS; Patrick H. Luetmer, MD; Andrew L. Avins, MD, MPH; Sean D. Rundell, DPT, PhD; Brent Griffith, MD; Janna L. Friedly, MD; Danielle C. Lavallee, PhD; Kari A. Stephens, PhD; Judith A. Turner, PhD; Brian W. Bresnahan, PhD; Patrick J. Heagerty, PhD

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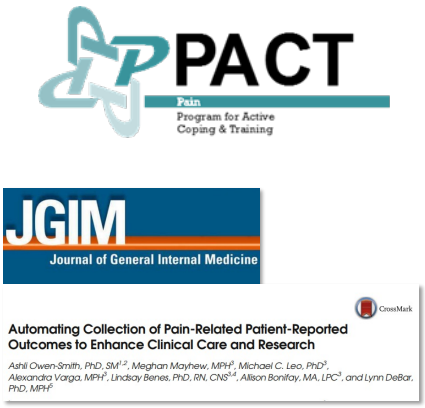
Completed

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



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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

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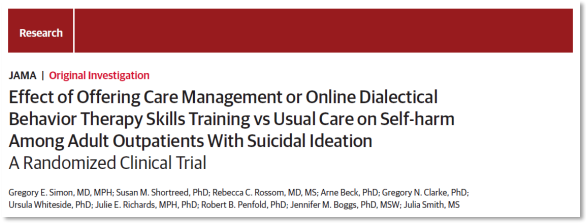
Completed

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; Arne 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

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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

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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
JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY

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,[5] 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[5]

NIH PRAGMATIC TRIALS COLLABORATORY
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53

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

Trauma Survivors Outcomes & Support II

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; Rddhi 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
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NIH Collaboratory Trials: Planning Phase

Project	Population	Intervention	Outcome
LungSmart	Current and former smokers, aged 50-80	Telehealth tools designed to engage people in lung cancer screening	Lung cancer screening completion

NIH PRAGMATIC TRIALS COLLABORATORY
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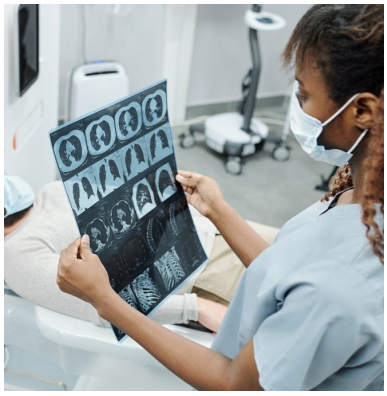
Planning

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



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R01 NIH Collaboratory Trials

Project	Population	Intervention	Outcome
iPATH	Patients with type 2 diabetes from health disparity populations	Multi-level, multi-component, technology-enabled practice transformation strategy	Reduction in patients with poorly controlled diabetes (A1c>9%) at 12 and 24 months
MOMs Chat & Care Study	Black 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
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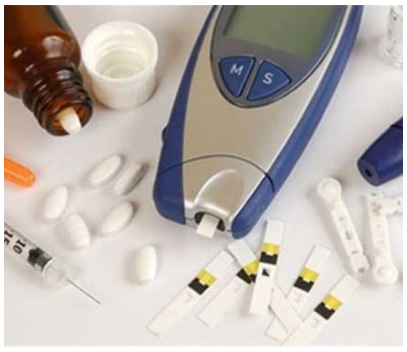
R01 Trial

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



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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 birthing people and reduce risk for severe maternal morbidity
- Largest healthcare provider in New York
- 674 expected patients

NIH PRAGMATIC TRIALS COLLABORATORY
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NIH Collaboratory Trials: Implementation Phase

Project	Population	Intervention	Outcome
ACP PEACE	Patients with advanced cancer	Clinician communication skills training and patient video decision aids for advanced care planning	Advance care plans completion; medical orders for resuscitation preferences; palliative care consultations; hospice use
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 (CV) risk factors	Multilevel intervention leveraging cellphone-based text messages	Global CV health and control of CV risk factors (e.g., hypertension, diabetes)
GGC4H	Parents of early adolescents	Anticipatory guidance curriculum	Behavioral health problems; health service utilization
HiLo	Patients undergoing hemodialysis	Liberalizing serum phosphate target	Rate of hospitalization
I CAN DO Surgical ACP	Older adults undergoing major elective survey	Patient-facing advance care planning (ACP) tool	ACP completion rates and patient engagement with ACP

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NIH Collaboratory Trials: Implementation Phase (cont)

Project	Population	Intervention	Outcome
IMPACt-LBP	Adults with low back pain	Primary Spine Practitioner (PSP) 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
INSPIRE	Non–critically ill hospitalized patients with abdominal infections or skin and soft tissue infections	Predictive algorithm integrated into the computerized provider order entry system, plus audit and feedback	Reduction in prescribing of unnecessary extended-spectrum antibiotics while maintaining good clinical outcomes as measured by length of stay and transfer to an intensive care unit
Nudge	Patients with chronic CV conditions	Text messages and chat bot	Adherence to CV medications
PRIM-ER	Older adults (>65 years)	Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback	Healthcare utilization and survival
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

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Implementation

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

- Cluster trial testing whether clinician communication skills training and patient video decision aids will increase **advance care plan completion** in patients >65 with advanced cancer
- 36 oncology clinics across 3 health systems
- 4,500 expected patients

ACP PEACE

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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

63

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

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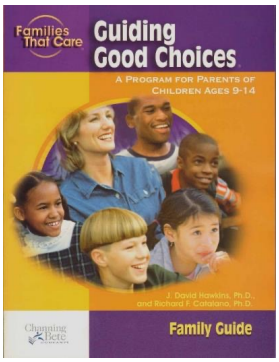
64

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



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Implementation

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

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66

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

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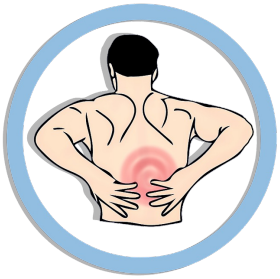
Implementation

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



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Implementation

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

- 2 cluster randomized trials using personalized clinical decision support to improve judicious antibiotic prescribing for non–critically ill patients hospitalized with **abdominal infections or skin and soft tissue infections**
- 90,000 expected patients

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Implementation

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

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70

Implementation

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

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Implementation

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

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HEAL Trials: Planning 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
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

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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

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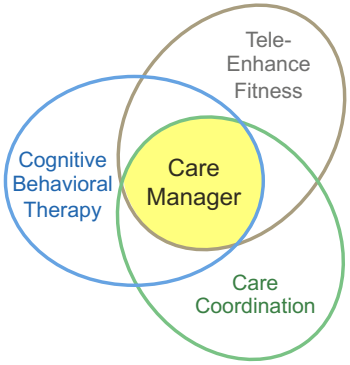
HEAL Trial

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



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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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HEAL Trials: Implementation Phase

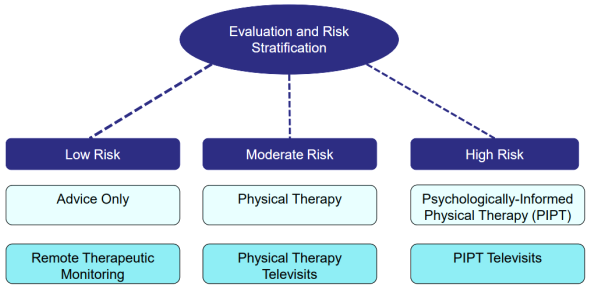
Project	Population	Intervention	Outcome
ARBOR-Telehealth	Rural-dwelling patients with chronic low back pain	Risk-stratified telerehabilitation model	Change in low back pain-related disability and opioid use after 8 weeks
BackInAction	Older adults with low back pain	Standard and enhanced 12-week courses 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
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

77

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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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

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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

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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

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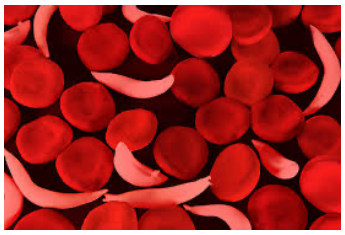
HEAL Trial

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



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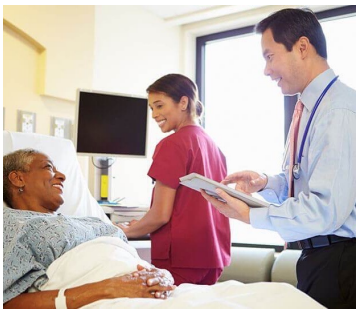
HEAL Trial

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

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



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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

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Onboarding Data and Resource Sharing Informational Document

Table of Contents

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 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 Demonstration Projects.

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

Data Sharing Requirements for the NIH Pragmatic Trials Collaboratory, NIH, 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.

NIH Pragmatic Trials Collaboratory Data Sharing Policy

"1. Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.
2. The 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.
3. Consistent with NIH policy and guidance, 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. Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infra- structure are in place to support timely data sharing for the Collaboratory."

From: NIH Health Pragmatic Trials Collaboratory Data Sharing Policy

NIH Data Sharing Policy

"Key Points

1. This Policy applies to all human data in the NIH IRP, including the NIH Clinical Center as well as NIH Institutes and Centers.
2. A Data Sharing Plan (PDF File) must be developed for any research involving human data.
3. Data Sharing Plans will be included in the institute scientific review process for research involving human data.
4. The Institute Scientific Director (SD) or their designee is responsible for approving all Data Sharing Plans.
5. All IRP-supported clinical investigators are expected to develop protocols and consent processes/forms to enable broad data sharing for secondary research consistent with this Policy.
6. Sharing data for secondary research purposes shall comply with human subjects research regulations and procedures, if applicable.
7. All IRP investigators are encouraged to deposit data in publicly accessible research repositories for sharing to the extent feasible and appropriate.
8. This Policy is effective as of October 1, 2015. Any intramural research involving human data undergoing scientific review after October 1, 2015 must have a data sharing plan."

From the NIH Intramural Human Data Sharing Policy (updated December 2015). For more information, see NIH Data Sharing Policy and Implementation Guidance.

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 (updated December 2018).

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 Pragmatic Trials Collaboratory Demonstration Projects

NIH Collaboratory Demonstration Project 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**	**Data 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	Private enclave managed by study team	Potential users may propose specific queries. Only query results (not individual data) will be shared.

Table 2. NIH Pragmatic Trials Collaboratory Data Sharing Plans*			
	information regarding facilities and utilization patterns could reveal proprietary business information.		
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*			
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 effect 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 December 20, 2021. 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 agree-ments 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

Table 3. Technical Structures for Data Sharing From Least Restrictive (and Least Expensive) to Most Restrictive (and Most Expensive)				
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 December 20, 2021. DOI: 10.28929/070.

Examples of Data Sharing Platforms

There are many public and private data sharing platforms to choose from, and some will fit some projects more than others. In Table 4, we list and briefly describe some of them for informational purposes. Note that this list is not comprehensive nor is the Collaboratory mandating use of one of these platforms. This list represents possible platforms for consideration.

Table 4. Data Sharing Platforms

Platform	Description
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
figshare	Allows uploading of files up to 5GB in any file format and previewing of them in browser.
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 (e.g., 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 International Council of Medical Journal Editors (ICMJE) requires that 7 key elements be addressed in the data sharing statement. Below are example statements that that have been 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, Richards J, Kirlin B, King D, Shulman L, Ludman EJ, Penfold R, Shortreed SM, 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/.

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.	

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.

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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		

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: Self-Testing for Cervical Cancer in Priority Populations: The STEP-2 Trial

Co-Principal Investigators:

- Rachel Winer, PhD, MPH
- Amanda Petrik, PhD
- Jasmin Tiro, PhD

Sponsoring Institution: University of Washington

Collaborators:

- University of Chicago
- Kaiser Permanente Northwest Center for Health Research
- Kaiser Permanente Washington Health Research Institute
- Virginia Garcia Memorial Health Center (Oregon)
- HealthPoint Community Health Center (Washington)
- CareOregon
- Molina Healthcare
- Community Health Plan of Washington

NIH Institute Providing Oversight: National Cancer Institute (NCI)

Program Official: Veronica Chollette, RN, MS (NCI)

Project Scientist: Cynthia Vinson, PhD, MPA (NCI)

Abstract:

The 29.3 million patients receiving care in US Federally Qualified Health Centers (FQHCs) have much lower cervical cancer screening rates than national averages: Only 53% of eligible patients were up-to-date in 2021 and the COVID-19 pandemic exacerbated these disparities. Self-sampling for human papillomavirus (HPV) is an evidence-based cervical cancer screening method with high potential to reduce screening barriers. Self-sampling kits can be distributed at clinics or mailed to patients' homes. Despite widespread international adoption, HPV self-sampling is nascent in the US. Little data is available to inform implementing this preventive service in low-resource settings such as FQHCs.

Our two-phase pilot and pragmatic trial will adapt and evaluate two programs to integrate HPV self-sampling into FQHCs. Our trial accounts for the context, capacity and resources of FQHCs, and leverages FQHC-Medicaid partnerships to promote this preventive care service. Phase 1 will be a milestone-driven planning phase. We will use community-engaged research and stakeholder input to adapt and pilot-test 2 multilevel interventions in 2 FQHCs for distributing HPV self-sampling kits: in clinic distribution and in clinic *plus* mailed distribution. Phase 2 will be a cluster-randomized pragmatic trial in 42 Oregon and Washington FQHC clinics to evaluate the comparative effectiveness and cost-effectiveness of the interventions. Clinics will be randomized to Usual Care (*UC*), in-clinic distribution (*Clinic Only*), or in-clinic plus mailed distribution (*Clinic + Mail*). For in-clinic distribution, providers will offer self-sampling at in-person or telehealth encounters. The mailed component will be administered by 3 Medicaid health plans. The primary outcome is

the proportion of eligible patients (30-64 years, due/overdue for routine screening) who complete screening. Two primary comparisons are (1) *UC* vs *Clinic Only* and (2) *Clinic Only* vs *Clinic + Mail*. To minimize bias, each comparison includes distinct but overlapping patient populations. Comparison 1a includes all patients (Medicaid and non-Medicaid) with a clinic encounter during the 12-month study period. Comparison 1b is restricted to Medicaid patients who are enrolled with the clinic, but does not require a clinic encounter during the 12-month study period. Cost-effectiveness will compare the *Clinic Only* HPV self-sampling intervention relative to *UC*, and *Clinic + Mail* relative to *Clinic Only*. We will use the RE-AIM framework and PRISM to evaluate the implementation strategies through mixed methods.

Our pragmatic trial will be the first in the US to determine the effectiveness and cost-effectiveness of HPV self-sampling for increasing cervical cancer screening in FQHC settings. Results from our comparisons and evaluation of implementation strategies will inform broad-scale implementation of HPV self-sampling across FQHCs and other safety-net clinics in the US to reduce cervical cancer screening disparities.

NIH Project Information

NIH PRAGMATIC TRIALS COLLABORATORY
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Self-Testing for Cervical Cancer in Priority Populations: the STEP-2 Trial (STEP-2)

DATA MANAGEMENT AND SHARING PLAN

Principal Investigators: Rachel Winer, PhD, MPH; Amanda Petrik, PhD; Jasmin Tiro, PhD

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:

1. Type of Scientific Data. The scientific data to be generated and/or collected will include clinical data on patients who are ages 30–64 years and patients at Federally Qualified Health Centers (FQHCs), as well as qualitative data from patients, clinicians, and health plan staff, and survey data from clinicians.
2. Estimated Amount of Scientific Data. We estimate data will include clinical data from patients who receive care at FQHCs (Pilot n=600, Full Trial n=15,525); Boot Camp Translation (n=22) and qualitative data from patients (n=50), clinicians (n=72), health plan staff (n=8) and survey data from clinicians (n=300).
3. Scientific Data Source. The scientific data generated under this project will be collected/generated from claims and clinical datasets from the FQHCs, which will be obtained under a waiver of informed consent. We will also collect qualitative interview and survey data. Interview and survey data will be obtained with informed consent.
4. Scientific Data Format. Data will be individual level limited data sets transferred through a secure file transfer system.

B. Scientific data that will be preserved and shared, and the rationale for doing so:

1. Scientific Data to be Shared: UW anticipates the preservation and sharing of the following scientific data: Transcribed qualitative interview data, survey data, and deidentified or limited clinical data. Data will be stored within a secure computing environment. Identifiable individual level data will not be shared. All direct participant identifiers (e.g., names, clinic names, addresses) will be removed and maintained in a secure file. All other scientific data (interview data, survey data, and clinical data) will be both preserved and shared with unique identifiers. Participant identifiers will not be shared.
2. Rationale: The scientific data anticipated to be preserved and shared under this project represents the maximum level of sharing appropriate, based on the following factors:
   Waiver of Informed Consent: A waiver of informed consent will be requested for this project for clinical data. Any restriction imposed by the IRB will be reflected or updated in this document upon approval.
   Informed Consent: Informed consent is anticipated to be required for participation in survey and qualitative project components.
   Applicable Laws: The data being shared under this plan is covered under HIPAA. Other laws

may also apply and restrict UW's ability to share certain scientific data.

Participant Privacy and Safety Concerns: The following privacy and safety concerns may restrict UW's ability to share certain scientific data: content in the qualitative interviews that identifies patients, clinicians or health plan staff, and puts them at risk for re-identification or suffering harm.

***Restrictions imposed by existing or anticipated agreements*:** UW anticipates the following agreement(s), which may restrict UW's ability to share certain scientific data: agreements with collaborators or external data sources which may restrict disclosure of data by UW.

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

Documentation to be made publicly available to the research community includes data dictionaries, final versions of interview guides, survey instruments, and study-level metadata. Each variable in the data dictionary will include a brief description of the item, variable label, value labels, and standard codes for missing values. We will also include qualitative interview guides and codebooks describing themes or other codes that were used for analysis.

Element 2: Related Tools, Software and/or Code

Quantitative scientific data will be processed and analyzed with SAS, STATA or R; and codes for analysis in papers will be shared. We will remove local path names and macros for local computing.

Element 3: Standards

To facilitate data use, the study will identify a single data safety monitoring plan (DSMP) Manager, who will use standard processing and documentation protocols for data formats and dictionaries as well as for variable names, descriptions, and labels. Metadata will include, at minimum, mandatory properties recommended by the latest DataCite metadata schema. Data dictionaries will be provided in text (.csv) format. Study-level metadata will also be provided in text (.txt) format. Survey questionnaires, interview guides, and the qualitative codebook will be provided in portable document format (PDF).

Element 4: Data Preservation, Access, and Associated Timelines

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

The scientific data anticipated to be shared under this project, as described in Element 1 of this Plan, will be deposited and maintained at the UW Data Repository (Dryad open-access). Public-use and restricted-access study data and associated documentation will be made available to the research community free of charge.

B. How scientific data will be findable and identifiable:

The scientific data anticipated to be shared under this project, as described in Element 1 of this Plan, will be assigned a persistent unique identifier when submitted to the UW Data Repository. Instructions for requesting data access will be provided in published articles and presentations.

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

The scientific data anticipated to be shared under this project, as described in Element 1 of this Plan, will be deposited in the repository specified above as soon as possible, but no later than the time of associated manuscript publication or completion of the funded project period for the parent award, whichever is earlier. Data will be made available for 5 years.

Element 5: Access, Distribution, or Reuse Considerations

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

UW is committed to providing the maximum level of reuse appropriate for the scientific data being preserved and shared under this project. The limitations affecting subsequent access, distribution, or reuse of scientific data for this project are as follows:

Informed Consent: The informed consent for this project is anticipated to include describing future uses of the data through a deidentified data repository.

Applicable Laws: No laws are expected to restrict subsequent access, distribution, or reuse of scientific data being preserved and shared under this project.

Participant Privacy and Safety Concerns: No privacy and safety concerns are expected to restrict subsequent access, distribution, or reuse of scientific data being preserved and shared under this project. **Restrictions imposed by existing or anticipated agreements:** UW does not anticipate entering into any agreements which may restrict access, distribution, or reuse of scientific data being preserved and shared under this project.

B. Whether access to scientific data will be controlled:

The repository described in Element 4 of this Plan has been **established specifically for projects conducted at UW**. Access to qualified researchers will be provided through the following UW Data Repository policies and procedures:

1. Public Use Data: All deidentified study data that are not designated as restricted use will be made available as public use data to the research community via the UW Data Repository. Users of the public use data must register with RDAC and agree to the Terms of Use, which are designed to protect study participants by limiting data use to scientific research and aggregate statistical reporting, prohibiting attempts to identify study participants, and requiring immediate reporting of any disclosure of study participant identity. Data users also agree not to share or redistribute any data downloads.

2. Restricted Access Data: Data that are determined to be potentially identifying through indirect or deductive disclosure will be provided under restricted access and under a data contract to users who demonstrate a valid research need and meet conditions of use. Access to restricted study data is available via an application to the UW Data Repository.

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

The scientific data derived from humans under this project and shared as described in this Plan will be protected through processes developed at UW. Once the data collection for this study has concluded, all direct respondent identifiers (e.g., names and addresses) will be removed and maintained in a separate control file.

Element 6: Oversight of Data Management and Sharing:

Monitoring of and compliance with this Data Management and Sharing Plan will be the responsibility of the project's Principal Investigators, Dr. Winer, Dr. Petrik, and Dr. Tiro. The plan will be implemented and managed by the project staff working under the direction of Dr. Winer. Dr. Winer will meet with the project
director and research staff weekly. They will also ensure that the research datasets are uploaded to the UW Data Repository as agreed upon in this Data Management and Sharing Plan.

STEP-2: 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	
Infusing health equity across the research life cycle, including enrolling a diverse and representative population				X		
Engaging with patient partners to inform the study		X				
Engaging with clinicians and health systems and health plans to identify or recruit participants					X	
Engaging with clinicians and health systems and health plans 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 multi-level prospective data, including PROs			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 Sharing Policy

Introduction

The Collaboratory Steering Committee recognizes that data sharing promotes many goals of the NIH research endeavor. It is particularly important for unique data that cannot be readily replicated. Data 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 from these NIH-supported studies. Sharing data 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 Collaboratory Steering Committee agrees that data 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 sharing:

Policy

1. Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.
2. The 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.
3. Consistent with NIH policy and guidance, 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. Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infra-structure are in place to support timely data sharing for the Collaboratory.

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NIH Pragmatic Trials Collaboratory Data Sharing Considerations

Objectives

Sharing research data collected in Collaboratory pragmatic trials is essential to several core objectives of the Collaboratory program, including:

- Maximizing the public health impact of the significant NIH investment in these large projects;
- Accelerating the pace of learning throughout the US healthcare system; and
- Increasing participation in research and learning by a wide range of stakeholders, 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 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 Pragmatic 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 accompanying guidance document, "Considerations Regarding Sharing of Health Systems Data."

Existing Regulatory Requirements

All NIH Collaboratory Pragmatic Trials are expected to adhere to existing NIH Data Sharing Policy and Implementation Guidance (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm). Key points in that policy and guidance include:

- The privacy of participants should be safeguarded.
- Data should be made as widely and freely available as possible.
- Data should be shared no later than the acceptance for publication of the main study findings.
- Initial investigators may benefit from first and continuing use of data, but not from prolonged exclusive use.

NIH defines the data to be shared as the "recorded factual material commonly accepted in the scientific community as necessary to document, support, and validate research findings. This does not mean summary statistics or tables; rather, it means the data on which summary

statistics and tables are based. For most studies, final research data will be a computerized dataset. For example, the final research data for a clinical study would include the computerized dataset upon which the accepted publication was based, not the underlying pathology reports and other clinical source documents. For some but not all scientific areas, the final dataset might include both raw data and derived variables, which would be described in the documentation associated with the dataset."[1]

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 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 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 medical 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: A 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 and would not be subject to any 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

[1] NIH Data Sharing Policy and Implementation Guidance (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm).

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.

Methods and Tools for Data Sharing

A range of technical options are available for sharing data with external users:

- **Unsupervised Data Archive** – Data that cannot be linked to individuals are made available for unrestricted public use. Potential users are not asked to propose specific questions or analytic plans, and users are not expected to account for any use or re-disclosure.
- **Unsupervised Public Data Enclave** – Data are not shared with external users. Instead, users are allowed to submit queries – typically through an online portal. "Unsupervised" means that queries are executed automatically, without prior review or requirement for prior approval. "Public" implies that any member of the public could submit queries. Risk of identifying individual data or other misuse can be managed by limiting the identifiability of the dataset to which queries are submitted, limiting the complexity of queries users are allowed to submit, or by limiting the level of detail of results that are returned.
- **Unsupervised Private Data Enclave** – This arrangement would be identical to an unsupervised public enclave, except that access would be limited to specific registered or pre-qualified users. "Unsupervised" means that individual queries are executed automatically, without prior review or any requirement for prior approval.
- **Supervised Data Archive** – Data that cannot be linked to individuals are made available to approved users for specific pre-approved purposes. Users are typically expected to propose specific questions or analyses, and use of data is limited to specific approved uses. Written documentation of requests and conditions for release are common. Disclosure to third parties is typically restricted or forbidden unless required by law. These limits or restrictions can be documented in contracts or other agreements.
- **Supervised Data Enclave** – Data are not made available to external users. Instead, users submit queries to data (typically through an online portal). "Supervised" means that all queries are reviewed and approved before execution and return of results.

These different methods allow different levels of and mechanisms for, privacy protection. At one extreme, an unsupervised data archive allows no control or protection once data are shared with users, so protection depends completely on the dataset contents. At the other extreme, a supervised data enclave allows complete control and protection over user qualifications, query logic, query topic, and return of results. In some cases, these additional levels of protection will allow investigators to share data that could not be appropriately shared through less controlled or supervised mechanisms.

Expectations for Collaboratory Trials

At minimum, Collaboratory investigators must prepare and share a final research data set upon which the accepted primary pragmatic trial publication is based. Data sets will be structured to maximize future scientific value while protecting patient and health system privacy.

- Data should not include any of the 18 HIPAA-specified direct identifiers
- Investigators should have reason to expect that the data cannot be used to identify a subject, or that the risk of re-identification is "very small."

The Department Health and Human Services guidance regarding HIPAA-compliant data sharing (http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#idrisk) describes specific methods for reducing risk of re-identification, including generalization (or aggregation) of specific variables and suppression of individual values or observations.

Collaboratory trials may also choose to make more detailed data available through one of the more restricted options described above. Sharing additional data through one of these more restricted mechanisms is appropriate when sharing such data would have scientific or public health value but also increase risk of re-identification or other misuse.

In addition to measures necessary to prevent re-identification of individual study participants, additional measures may be necessary to prevent re-identification of providers or facilities. For example: A hypothetical trial might include patients from five clinics serving patient populations with markedly different racial and ethnic composition. A dataset including "blinded" clinic identifiers as well as participant race and ethnicity might allow users to re-identify participating clinics. An investigator sharing these data using one of the unsupervised approaches described above could prevent such re-identification by creating distinct datasets – one including clinic identifier and one including participant race and ethnicity. An investigator sharing these data using one of the supervised approaches described above could limit queries or analyses to those that would not re-identify participating clinics.

Consistent with NIH policy and guidance, investigators should choose the least restrictive method that provides appropriate protection for participant privacy, health system privacy, and scientific integrity. In addition, more supervised or restricted options will typically require a higher level of resources (technical infrastructure, investigator time, other staff time) to support.

Questions for Steering Committee Discussion

1. Do we accept the policy that all Collaboratory trials are expected to develop and share an appropriately de-identified analytic dataset?
2. If we accept that policy, is a 6-month timeframe after publication an appropriate deadline for sharing of that dataset?
3. Where will the Collaboratory data sets be archived?
4. If Collaboratory trials are able to share more detailed data through some more limited process (e.g. supervised data archive, supervised data enclave), will the NIH Collaboratory Program provide the ongoing resources to govern and manage that process?

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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
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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 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 1 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 1 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 1 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@dm.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@dm.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@dm.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 arise 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 publication?
- 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. All manuscripts **derived from the work of one or more Core Working Groups or the Coordinating Center** should include the following acknowledgment:

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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 publication language may be used in poster presentations, slides, and other summary reports, as described below.

1. All 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 publication:

   "This work was supported within the NIH Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from multiple NIH Institutes, Centers, and Offices. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [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 the NIH or its HEAL Initiative."

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

   a. All poster presentations, slide presentations, and other summary reports derived from one or more **NIH Collaboratory Trials, *not* including trials supported through the NIH HEAL Initiative**, should include the following publication:

      "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 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."

   b. All poster presentations, slide presentations, and other summary reports derived from one or more **NIH HEAL Initiative–supported NIH Collaboratory Trials** 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 U24AT010961 from the NIH through the NIH HEAL Initiative. 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."

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

   a. All poster presentations, slide presentations, and other summary reports supported by the **Coordinating Center and one or more NIH Collaboratory Trials, *not* including trials supported through the NIH HEAL Initiative**, should include the following acknowledgment:

   "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 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]. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [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 the NIH or its HEAL Initiative."

   b. All poster presentations, slide presentations, and other summary reports supported by the **Coordinating Center and one or more NIH HEAL Initiative–supported NIH Collaboratory Trials** should include the following acknowledgment:

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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.

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