NIH Pragmatic Trials Collaboratory: Program Impact

NIH PRAGMATIC TRIALS COLLABORATORY
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Updated January 31, 2025

Program Success and Evolution

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

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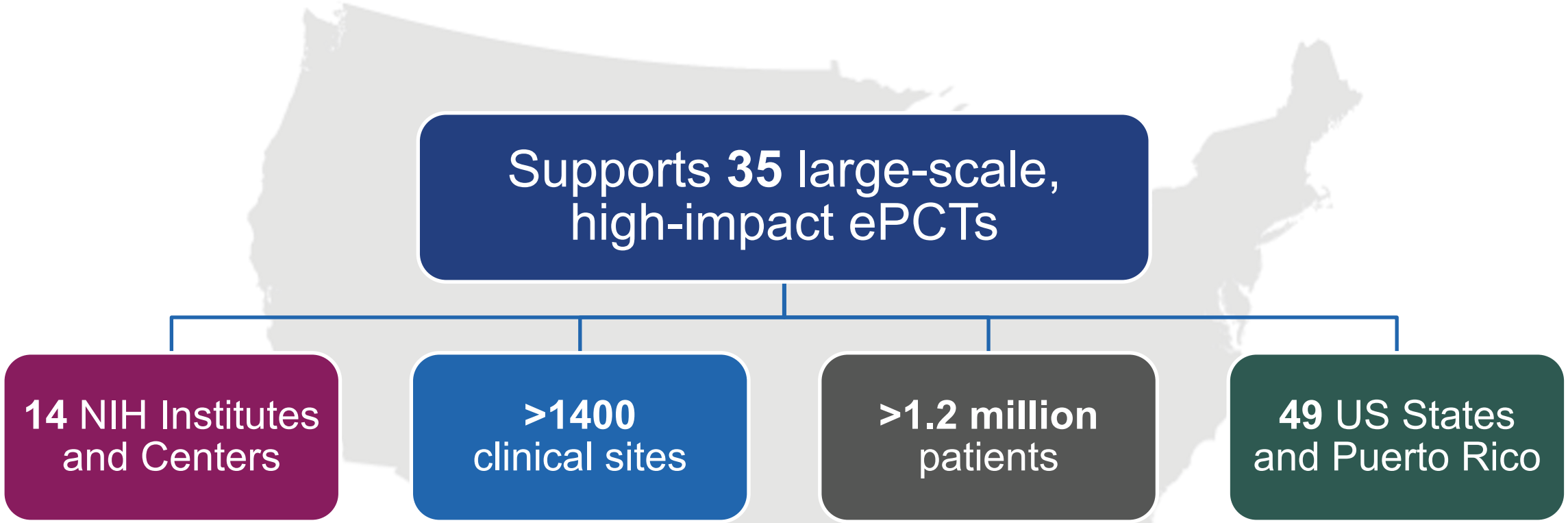
Program Reach



No sites in Arkansas

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Partnerships

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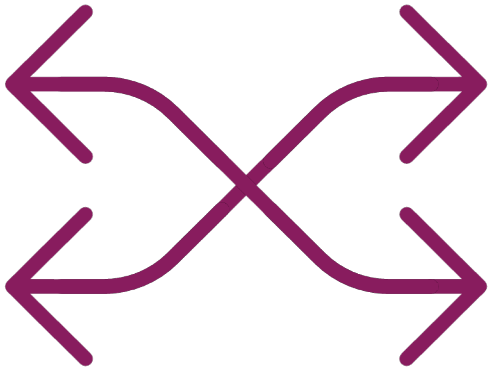
- Grand Rounds
- Workshops
- Publications
- Living Textbook
- Tools
- Resources
- Knowledge

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 Institute of Japan

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

Bold denotes current NIH partner

NIH Collaboratory Trials

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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-SM, iPATH, LungSMART, RAMP

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

SITE ACTIVATION
- First Site Activated

TAICHIKNEE

ENROLLMENT
- First Patient Enrolled

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

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

FM TIPS, NOHARM, OPTIMUM

DATA AVAILABILITY
- Key Data Available
- Secondary Endpoint Data Available
- All Data Available

PLANNING COMPLETED
- Did not proceed to trial initiation

BPMedTime

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

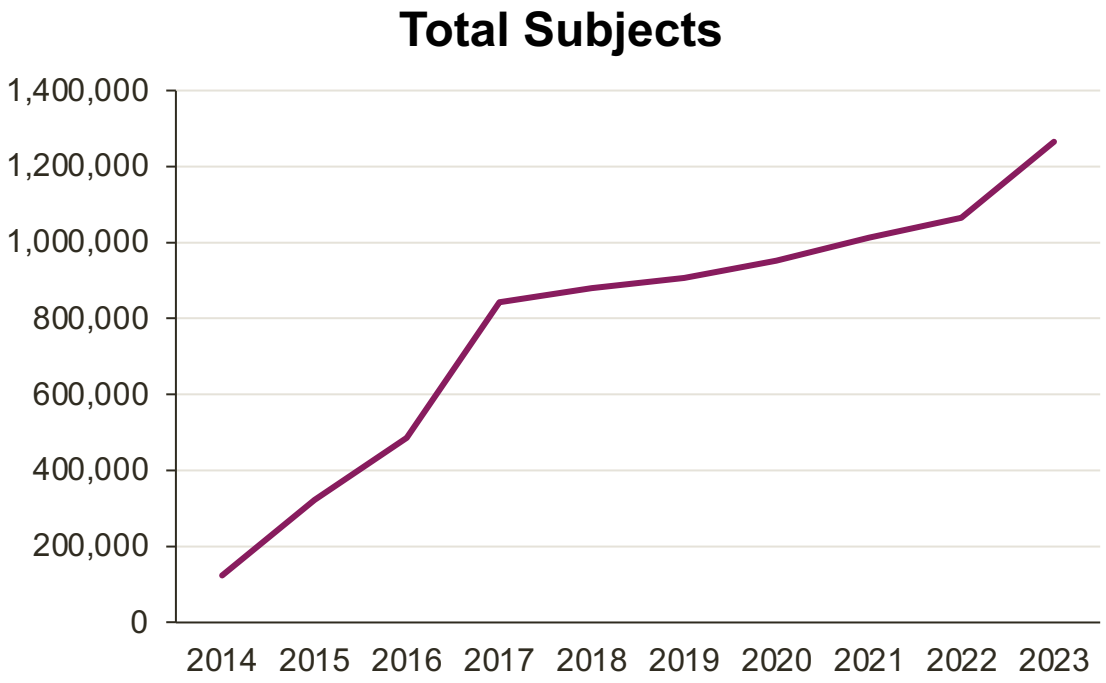
REPORTING: Public Dissemination
- Topline Results to Public via Press Release (if done)
- Full Results to Public
- First Presentation Results
- Main Manuscript Submitted
- Main Manuscript Accepted
- ClinicalTrials.gov Reporting

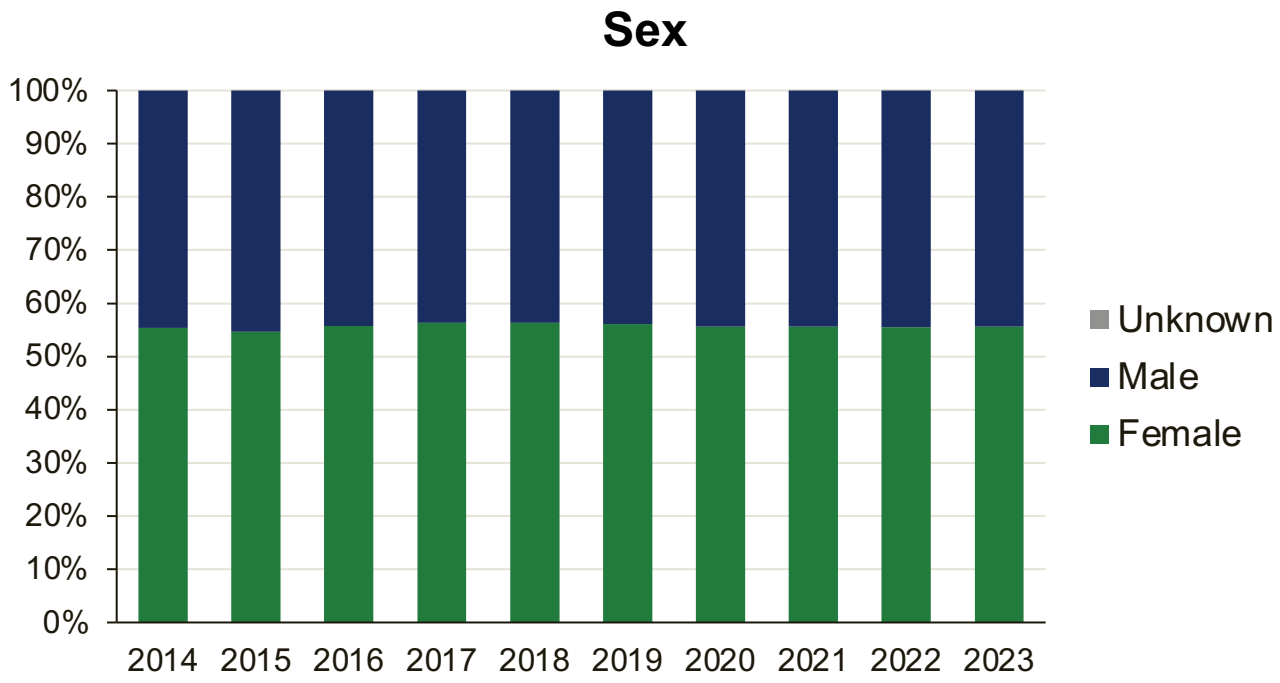
Nudge, PRIM-ER

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

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

Participants (Total)





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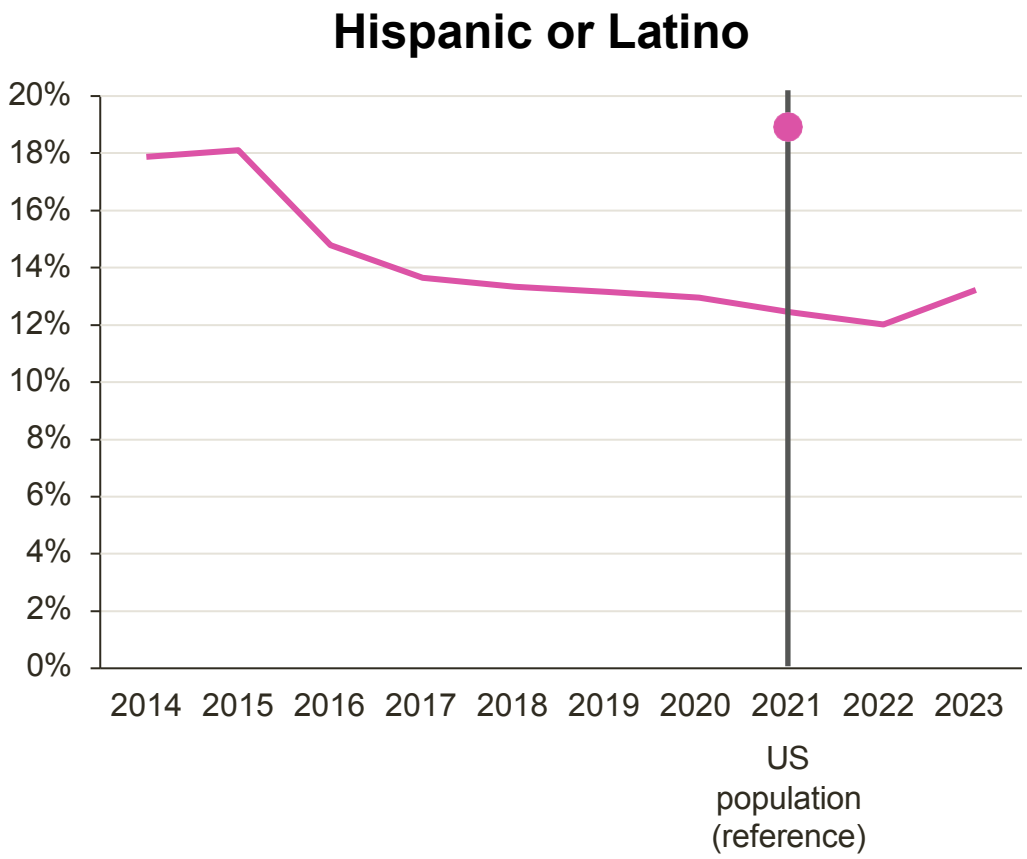
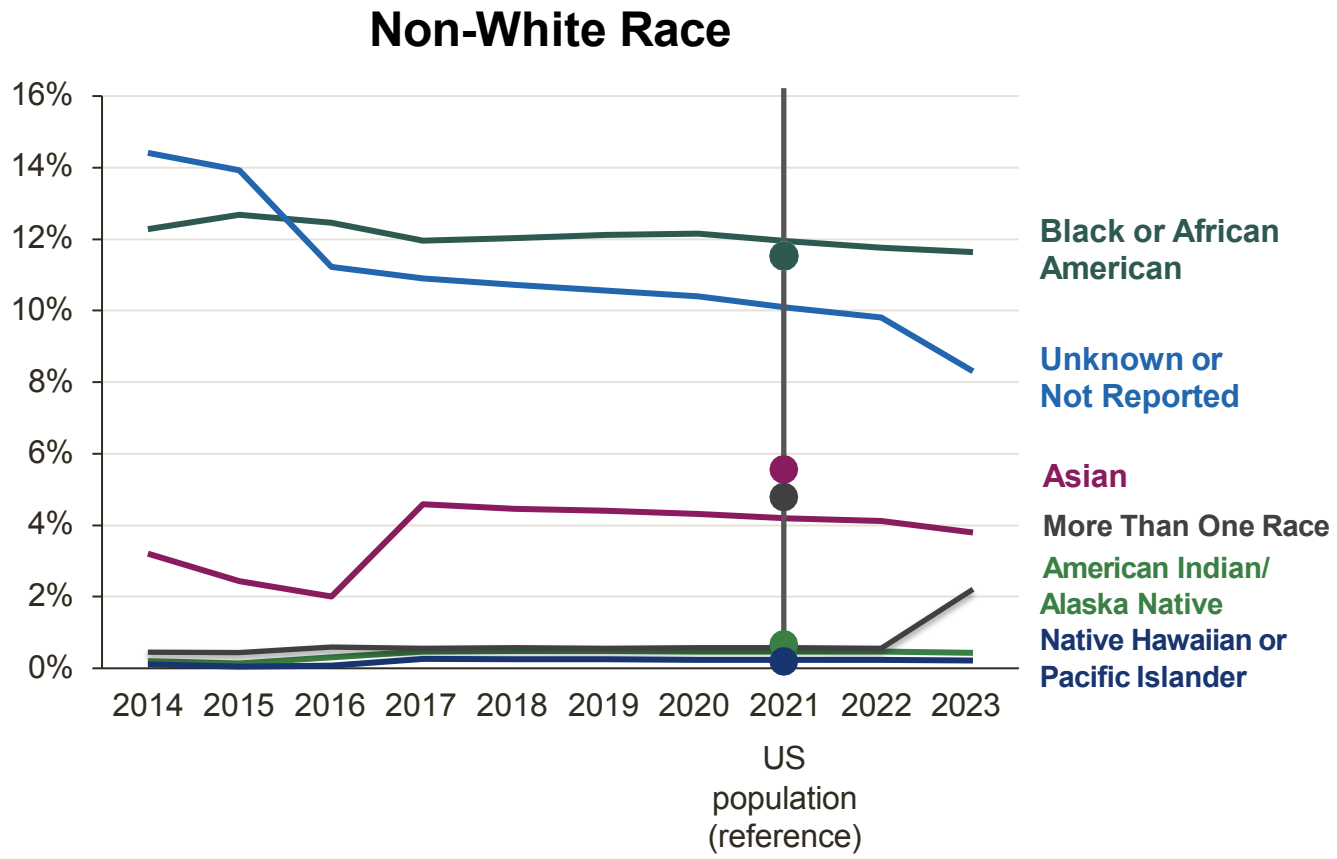
Participant Race and Ethnicity (Total)





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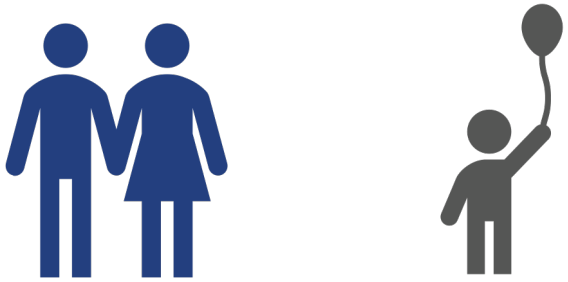
NIH Collaboratory Trial Populations

Participant Age

34
adult

1
pediatric



Health Condition

4	11	8	10	2
healthy	one chronic condition	multiple chronic conditions	acute	end of life

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NIH Collaboratory Trial Designs

Trial Design

16 parallel group with individual randomization

13 parallel group with cluster randomization

6 stepped-wedge cluster randomization

Intervention Type

14 therapeutic

14 operational/ educational

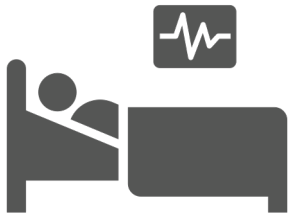
7 mix

Intervention Target

24 patient

7 clinician

4 patient and clinician



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NIH Collaboratory Trials: Use of EHRs

Eligibility determination:

29 trials

Intervention delivery:

21 trials

Outcome assessment:

33 trials

At least **25** different EHR systems

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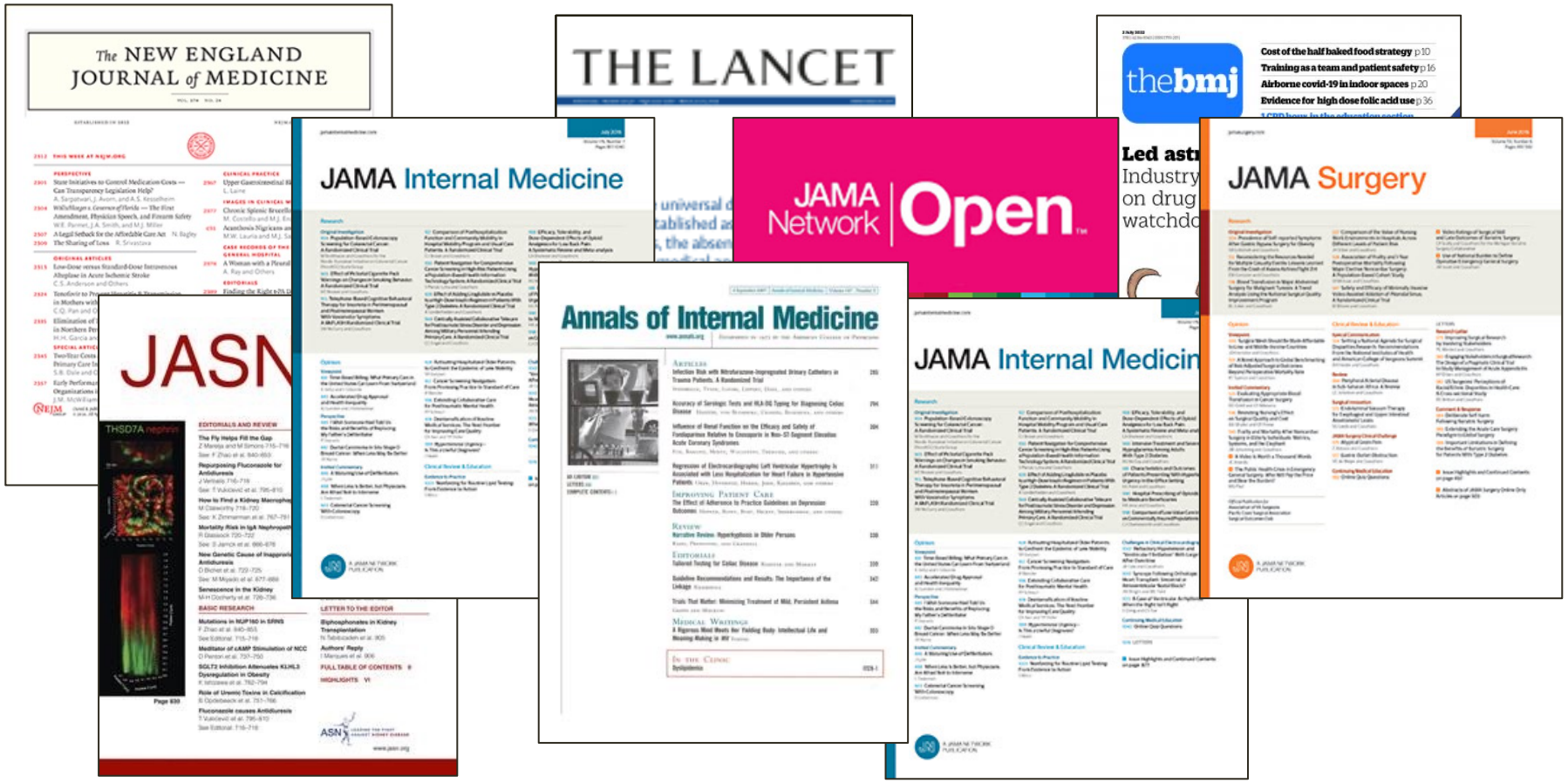
12 Trials Completed and Published

- STOP CRC
- TiME
- ABATE Infection
- PROVEN
- LIRE
- TSOS
- PPACT
- SPOT
- EMBED
- ICD-Pieces
- Nudge
- PRIM-ER



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Question:
Does daily antiseptic bathing reduce drug-resistant infections in hospitalized (non-ICU) patients?

Pragmatic Trial:
53 hospitals randomized to routine care or intervention

ABATE Infection Project

NIH Collaboratory Support:

- *Regulatory:* Consulted regarding FDA oversight
- *Data:* Advised on data standardization, cleaning, and sharing
- *Engagement:* Underscored partnerships between health systems and researchers

Study Population:
>500,000 patients with 20 million data records

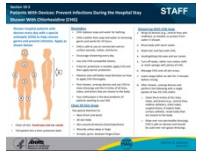
Results:
Negative primary outcome but reduced infections in patients with medical devices

Clinical Impact:

Adopted intervention
in all health system hospitals for patients with medical devices

Implementation toolkit
published for hospitals

AHRQ



Care

Research

Evidence

NIH PRAGMATIC TRIALS COLLABORATORY

Question:
Does an EHR-based outreach program with mailed stool-tests improve rates of colorectal cancer screening?

Pragmatic Trial:
26 FQHC clinics randomized to routine care or intervention

stop screen to prevent colon cancer

NIH Collaboratory Support:

- *Biostatistics:* Extensive support to modify analysis, develop secondary analysis
- *Data:* Helped team learn and implement standards and methods for validating EHR code
- *Overall:* Knowledge sharing, troubleshooting

Study Population:
>40,000 patients and ~6,300 mailed stool-tests

Results:
Significantly improved screening rates

Clinical Impact:

Adopted intervention
in at least 150 clinics

Implementation materials
published to support uptake

Care

Research

Evidence

NIH PRAGMATIC TRIALS COLLABORATORY

FQHC, federally qualified health center

Question:
Can an interdisciplinary intervention improve chronic pain among patients receiving long-term opioid therapy?

Pragmatic Trial:
273 PCPs randomized to routine care or intervention

PACT
Pain Program for Active Coping & Training

NIH Collaboratory Support:

- *Regulatory:* Facilitated conversations with IRBs
- *Engagement:* Discussed challenges and strategies for working with providers, clinic leaders
- *Patient-centered outcomes:* Learned from researchers in other fields

Study Population:
850 patients

Results:
Improved pain, disability, and care satisfaction;
no change in opioid use

Clinical Impact:

Intervention partially sustained
in many clinics

App for patients developed
by managed care organization

KAISER PERMANENTE®

Reversing the Persistent Pain Cycle
Beyond Pain

HEAL
NIH • Helping to End Addiction Long term℠

Care
Research
Evidence

NIH PRAGMATIC TRIALS COLLABORATORY

PCP, primary care provider

Question:
Does offering low-intensity care management or skills training to adults experiencing frequent suicidal ideation reduce their risk of self-harm?

Pragmatic Trial:
Patients at 4 health systems randomized to usual care or 1 of 2 interventions

SUICIDE PREVENTION OUTREACH TRIAL

Clinical Impact:

Findings *did not support implementation* of the approaches

Future resources not spent on ineffective (or harmful) practices

Suggests exploring other methods

KAISER PERMANENTE®

MHRN Mental Health Research Network

Care → Research → Evidence

NIH PRAGMATIC TRIALS COLLABORATORY

NIH Collaboratory Support:

- *Regulatory:* Helped navigate consent, IRB, and data monitoring issues
- *Biostatistics:* Guidance on analytic considerations
- *Electronic health records:* Advice on handling major change in diagnostic coding mid-study

Study Population:
18,882 patients

Results:
Increased risk of self-harm with brief skills training and no difference with care management, vs usual care

Sharing Trial Data and Resources

STUDY TOOLS

- Protocols
- Consent forms
- Implementation tools
- Site materials
- Questionnaires
- Toolkits
- Ethics and regulatory documentation

87 study tools

DATASETS AND DOCUMENTATION

- Data dictionaries
- Public use datasets
- Analytic code
- Computable phenotypes
- Data quality manuals
- Data request forms
- Data sharing checklists

18 datasets and documentation

Core Working Groups

NIH PRAGMATIC TRIALS COLLABORATORY

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Impact of Cores

>235 trial consultations

>175 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."

Biostatistics and Study Design Core: Impact Highlights

Key products

- Living Textbook chapters on study designs and analysis plans
- Intraclass Correlation Coefficient Cheat Sheet
- Statistical Analysis Plan Checklist for Addressing COVID-19 Impacts
- “Design and Analysis of ePCTs” workshop and Grand Rounds series

Major achievements

- Consultations had a direct impact on many NIH Collaboratory Trials, resulting in revised:
  - Statistical analysis plans
  - Sample sizes
  - Trial designs
- Substantial contributions to literature on design and analysis of group-randomized trials

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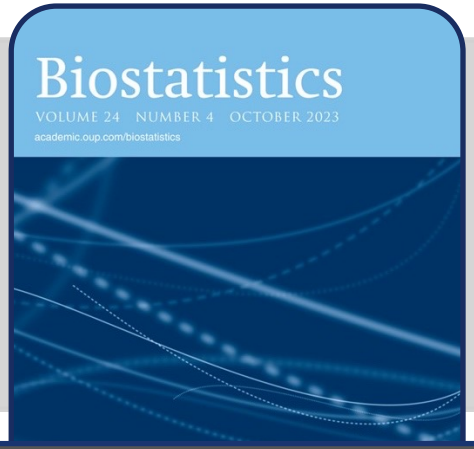
Biostatistics and Study Design Core: Key Publications

An evaluation of constrained randomization for the design and analysis of group-randomized trials

Mixed-effects models for the design and analysis of stepped wedge cluster randomized trials: an overview



Designing three-level cluster randomized trials to assess treatment effect heterogeneity

Biostatistics and Study Design Core: Evolution of Topics

Cluster randomization

Stepped-wedge designs

Missing data

2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025

Extracting usable data from EHRs

Intraclass correlation

Variable cluster sizes and heterogeneous treatment effects

Individually randomized group treatment trials

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Electronic Health Records Core: Impact Highlights

Key products

- Living Textbook chapters on using real-world data and EHR-based phenotyping
- Assessing Data Quality guidance document
- Data and resource sharing information and checklists
- Workshop series on advances in digital health, EHRs, and ePCTs

Major achievements

- Developed data and resource sharing materials to help the NIH Collaboratory Trials identify their sharing plans and promote posting of materials at closeout
- Established the NIH Collaboratory's Distributed Research Network and executed data queries

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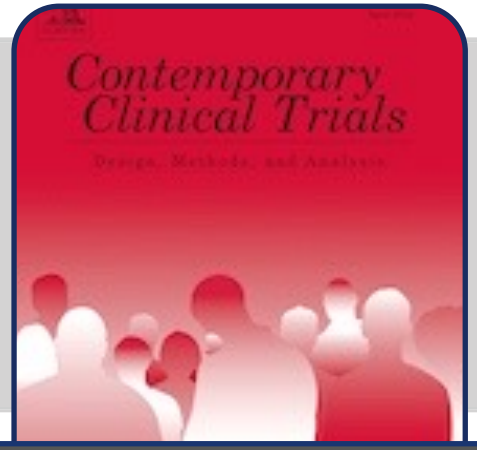
Electronic Health Records Core: Key Publications

Clinical phenotyping in selected national networks: demonstrating the need for high-throughput, portable, and computational methods



Collecting patient-reported outcome measures in the EHR: lessons from the NIH Pragmatic Trials Collaboratory

Potential bias and lack of generalizability in EHR data: reflections on health equity from the National Institutes of Health Pragmatic Trials Collaboratory

Electronic Heath Records Core: Evolution of Topics

Computable phenotypes

Acquiring real-word data

Data sharing

2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025

Data meaning and quality

Assessing fitness for use of real-world data

Potential bias and lack of generalizability in EHR data

Effect of EHR updates on ePCT interventions

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Ethics and Regulatory Core: Impact Highlights

Key products

- Foundational scholarship on ethics and regulatory issues in ePCTs
- Data Monitoring Committee Charter
- Points to Consider in Data Monitoring for ePCTs
- 8 Living Textbook chapters
- Documentation of ethics and regulatory consultations with NIH Collaboratory trials

Major achievements

- Consulted with each NIH Collaboratory Trial on ethical and regulatory issues
- Organized workshops on ethical and regulatory aspects of ePCTs
- Conducted substantial empirical research on stakeholder perspectives on ePCTs

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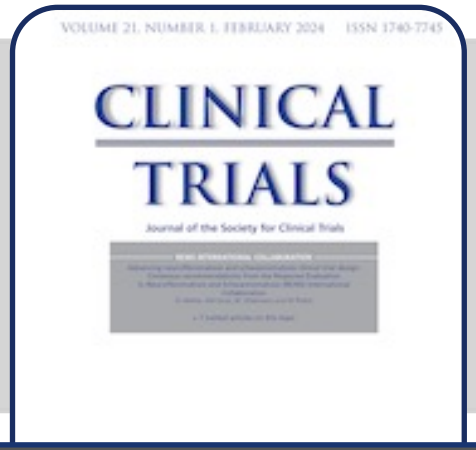
Ethics and Regulatory Core: Key Publications

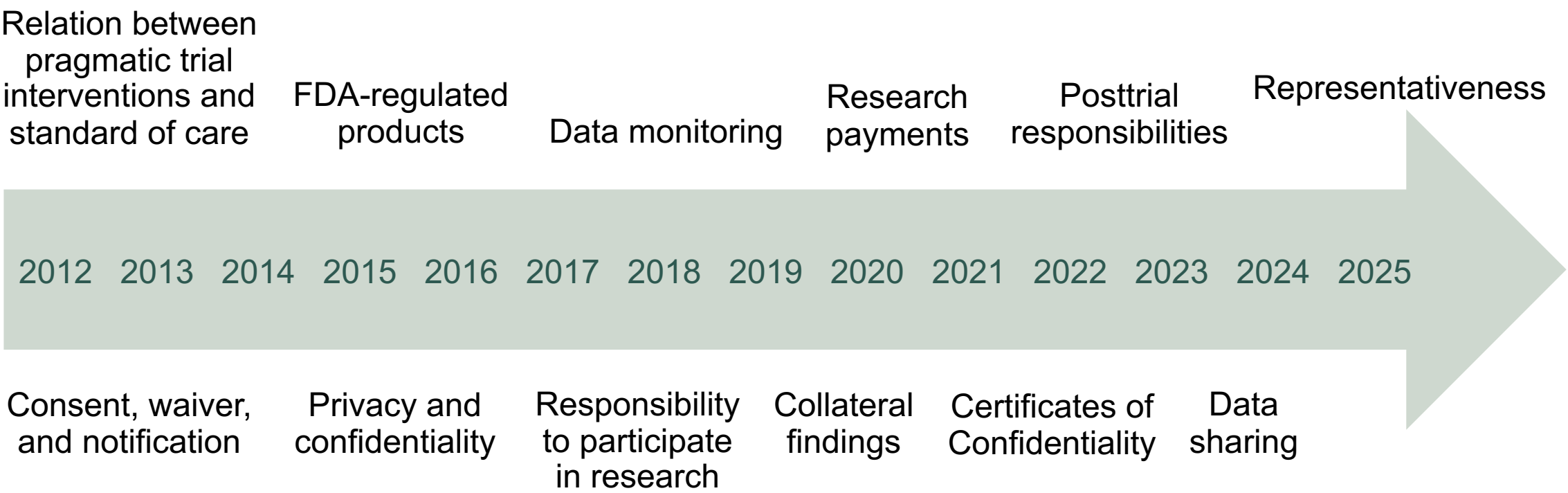


Special issue of 12 articles exploring ethical and regulatory issues in pragmatic clinical trials

Toward meeting the obligation of respect for persons in pragmatic clinical trials

Post-trial responsibilities in pragmatic clinical trials: fulfilling the promise of research to drive real-world change

Ethics and Regulatory Core: Evolution of Topics



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Health Care Systems Interactions Core: Impact Highlights

Key products

- Collaborated in planning and delivering annual workshops on design and conduct of embedded pragmatic trials
- Collaborated in Living Textbook chapters on:
  - Building successful partnerships
  - Dissemination approaches for different stakeholders
  - Adapting to unexpected events

Major achievements

- Created and maintained a comprehensive issues tracker with challenges and resolutions shared by the NIH Collaboratory Trials
- Developed a typology of trial interactions with health systems
- Shared lessons about building and sustaining trusting partnerships between research teams, health system leaders, clinicians, and staff

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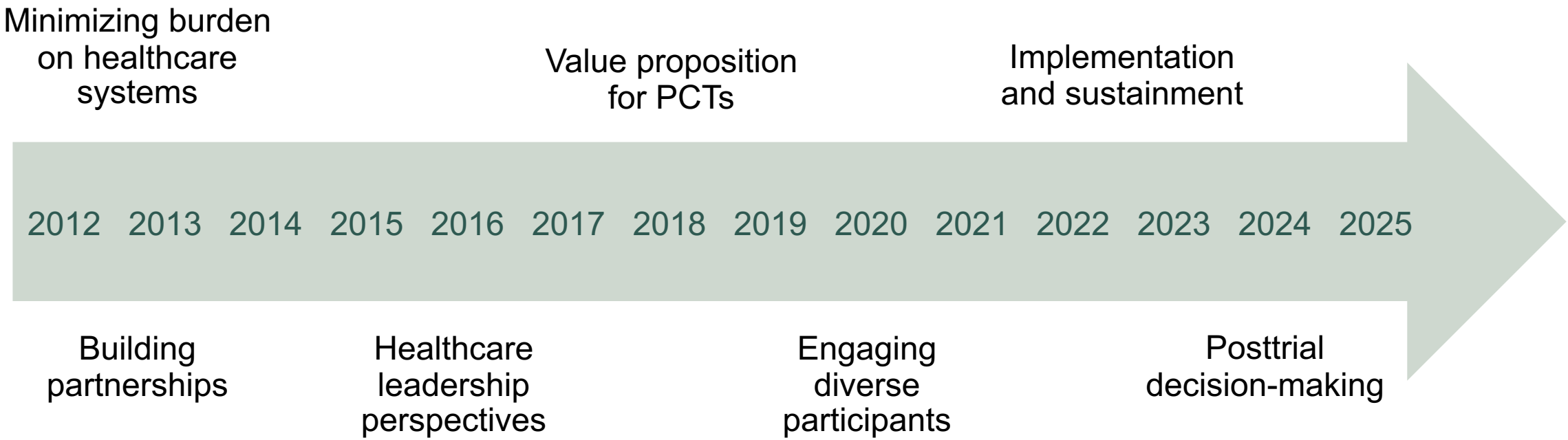
Health Care Systems Interactions Core: Key Publications

A guide to research partnerships for pragmatic clinical trials

Accounting for quality improvement during the conduct of embedded pragmatic clinical trials within health care systems: NIH Collaboratory case studies

A value proposition for pragmatic clinical trials

Health Care Systems Interactions: Evolution of Topics



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Health Equity Core: Impact Highlights

Key products

- Equitable Language Guide
- Health Equity in Pragmatic Trials Handout
- Fellowship curriculum to increase diversity of ePCT researchers
- Adapted DUSON checklist for integrating a health equity lens in pragmatic trials

Major achievements

- Consulted with NIH Collaboratory Trials to understand how they are incorporating a health equity lens in their research, and offer tools and strategies

Health Equity Core: Key Publications

Potential bias and lack of generalizability in EHR data: reflections on health equity from the National Institutes of Health Pragmatic Trials Collaboratory

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Health Equity Core: Evolution of Topics

Diversifying ePCT participants and workforce

Structural barriers to healthcare systems

2022 2023 2024 2025

Defining health equity in ePCTs

Core formed in 2022

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Implementation Science Core: Impact Highlights

Key products

- Review of implementation-related data collection within the NIH Pragmatic Trials

Major achievements

- Supported NIH Collaboratory Trial teams in considering appropriate implementation science theories, models, and frameworks
- Researched factors affecting posttrial sustainment or de-implementation of ePCT interventions

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Implementation Science Core: Key Publications

Factors affecting post-trial sustainment or de-implementation of study interventions: a narrative review

Post-trial responsibilities in pragmatic clinical trials: fulfilling the promise of research to drive real-world change

Similarities and differences between pragmatic trials and hybrid effectiveness-implementation trials

Implementation Science Core: Evolution of Topics

Sustainment vs de-implementation decisions

Implementation frameworks and measures

2022 2023 2024 2025

Posttrial responsibilities

Core formed in 2022

Patient-Centered Outcomes Core: Impact Highlights

Key products

- Roundtable report on capturing patient-reported health data
- Contributed to Users Guide for Integrating Patient-Reported Outcomes in EHRs
- Patient-Reported Outcomes Living Textbook chapter
- Toolkit to support the capture of PROs in diverse study populations

Major achievements

- Conducted surveys and interviews on cultural/linguistic adaptation and acceptability/burden of PROs
- Led workshop to help clinicians implement NIH PROMIS
- Consulted with NIH Collaboratory Trials on selection and collection of PROs
- Convened policy meeting to discuss getting PROs into the EHR

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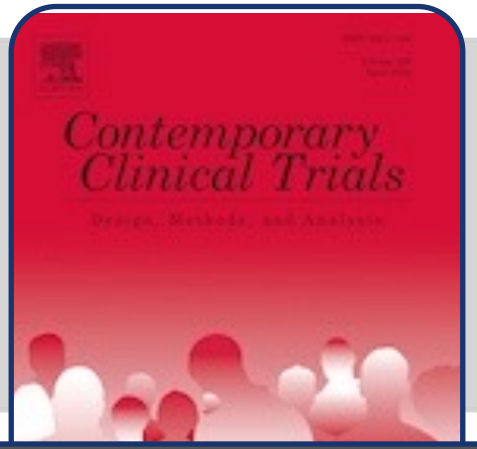
Patient-Centered Outcomes Core: Key Publications

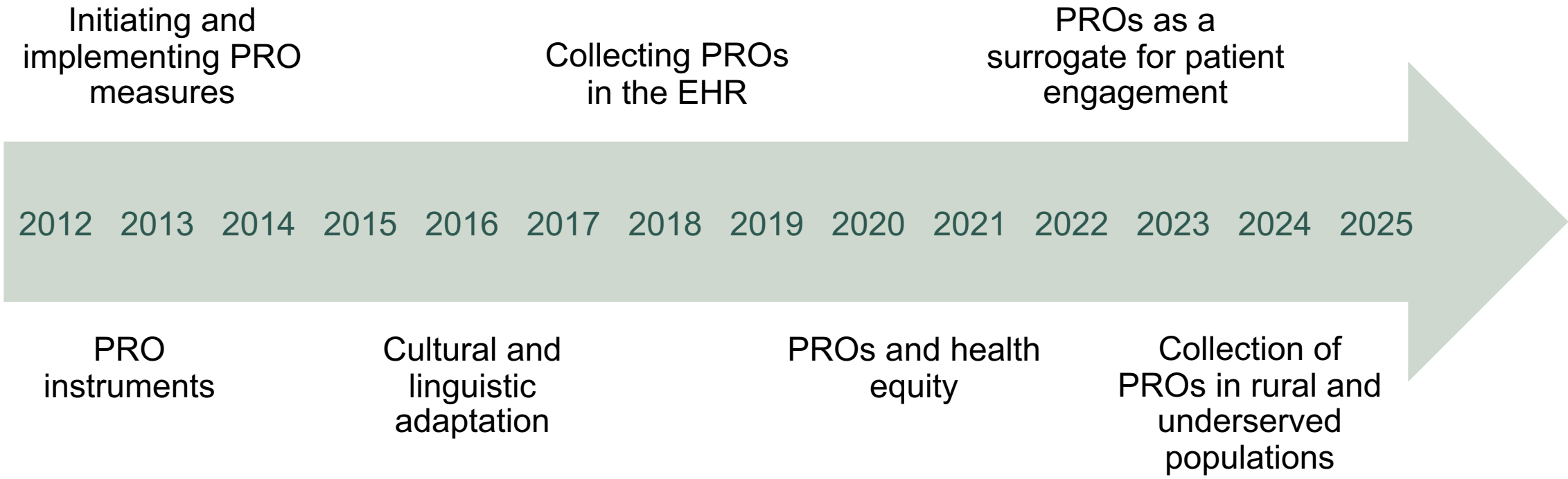
Assessing the value of patient-generated data to comparative effectiveness research

Clarifying the meaning of clinically meaningful benefit in clinical research: noticeable change vs valuable change



Collecting patient-reported outcome measures in the electronic health record: Lessons from the NIH Pragmatic Trials Collaboratory

Patient-Centered Outcomes Core: Evolution of Topics



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Disseminating Knowledge and Best Practices

NIH PRAGMATIC TRIALS COLLABORATORY

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Living Textbook Content and Reach

30+ chapters 

 **>100,000** visitors/year

>100 contributors 

TOPICS INCLUDE:

Design

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

Data, Tools, 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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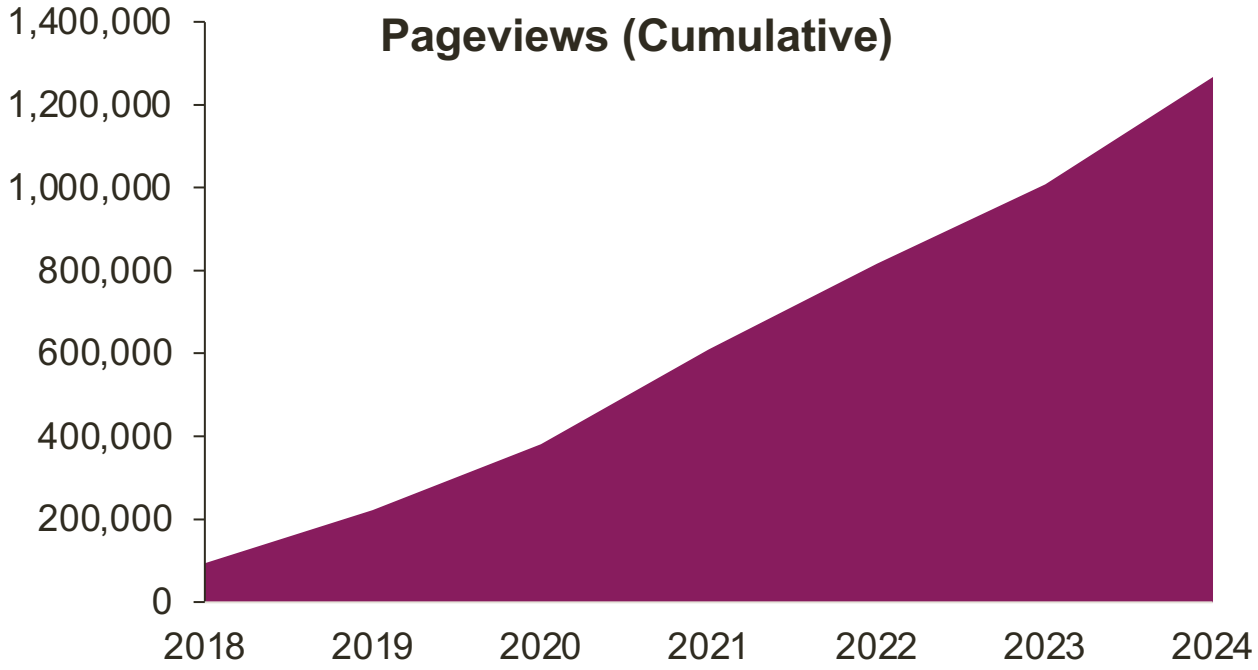
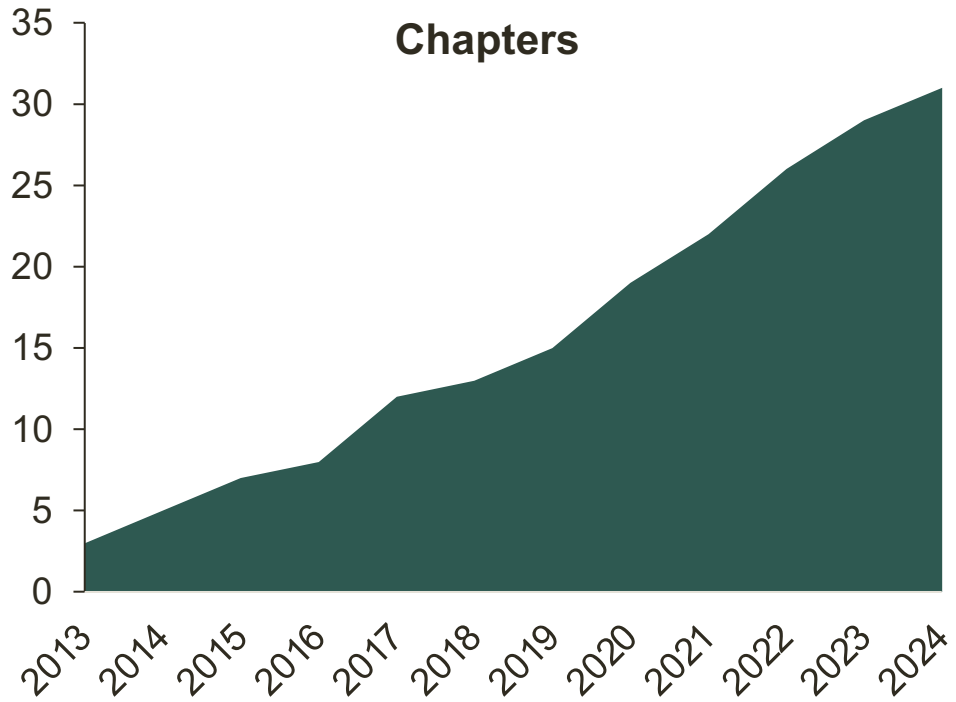
Living Textbook Growth





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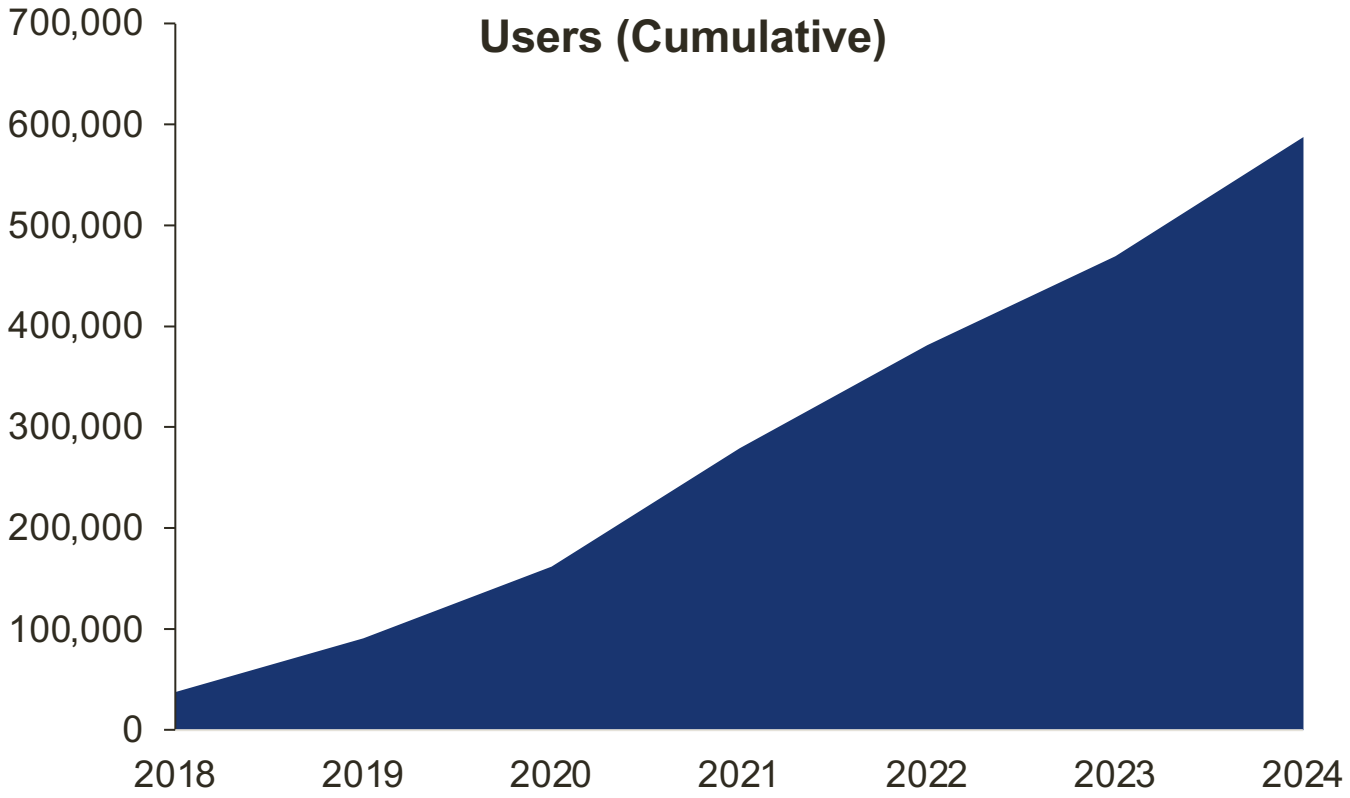
Living Textbook Users Over Time



NIH PRAGMATIC TRIALS COLLABORATORY
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Living Textbook: Most Popular Topics

Chapter	Pageviews in 2024
Experimental Designs and Randomization Schemes	36,696
What Is a Pragmatic Trial?	9958
Endpoints and Outcomes	7770
Acquiring Real-World Data	6316
Analysis Plan	5999
Clinical Decision Support	4011
EHR-Based Phenotyping	3922
Patient-Reported Outcomes	2179
Consent, Waiver, and Notification	2017
Monitoring Intervention Fidelity and Adaptations	1886

Publications*

TOTAL PUBLISHED

>340

CITATIONS

>9700

JOURNALS

>130

*As of January 30, 2025

NIH PRAGMATIC TRIALS COLLABORATORY
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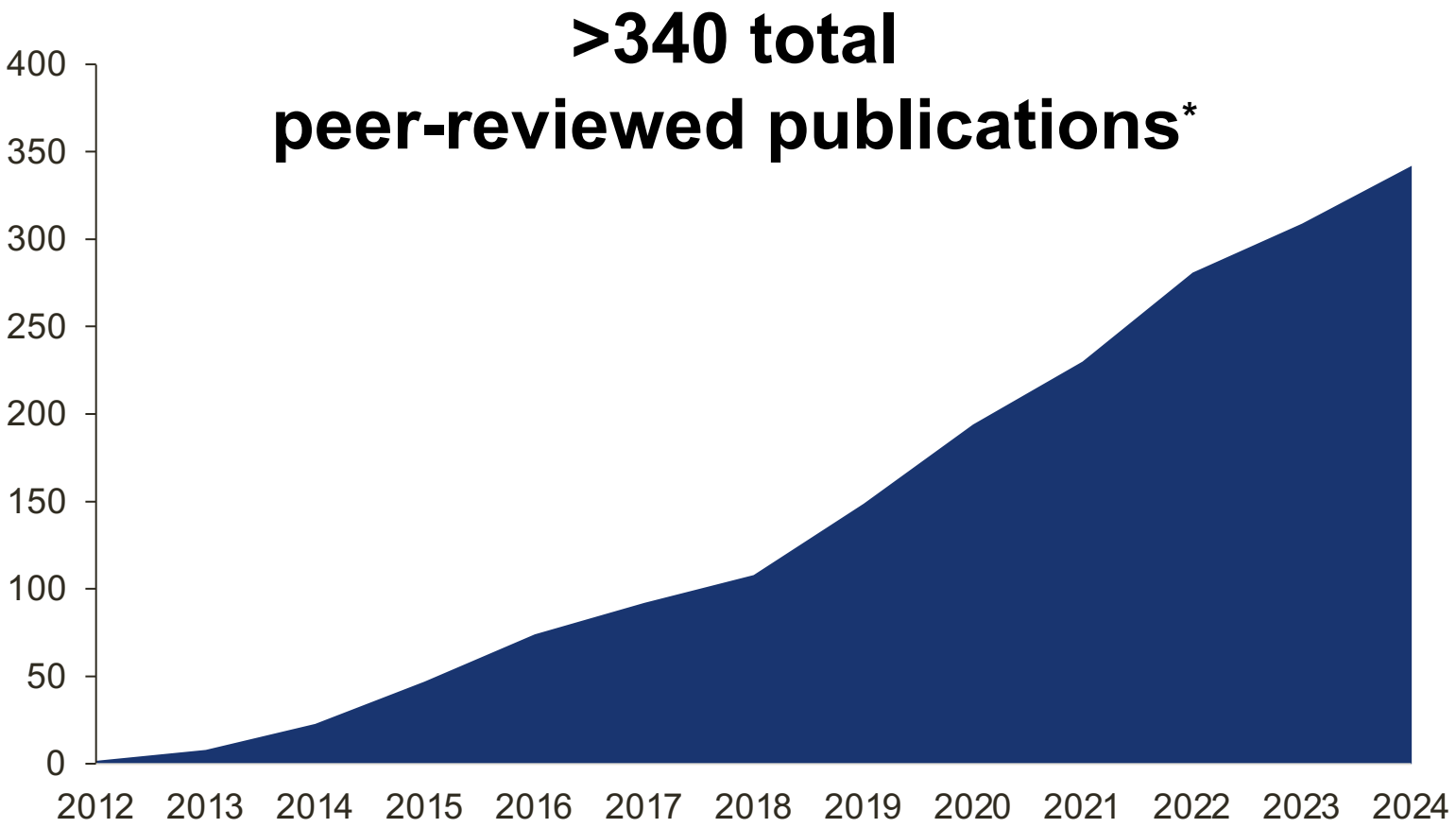
Publications Over Time



*As of January 31, 2024

NIH PRAGMATIC TRIALS COLLABORATORY
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Where We Published Most

High-Profile Articles

The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

Is Learning Worth the Trouble? — Improving Health Care System Participation in Embedded Research

Think Pragmatically: Investigators' Obligations to Patient-Subjects When Research Is Embedded in Care

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Do Clinicians Have a Duty to Participate in Pragmatic Clinical Trials?

JAMIA
A SCHOLARLY JOURNAL OF INFORMATICS IN HEALTH AND BIOMEDICINE

Electronic health records based phenotyping in next-generation clinical trials: a perspective from the NIH Health Care Systems Collaboratory

Contemporary Clinical Trials

Two weights make a wrong: Cluster randomized trials with variable cluster sizes and heterogeneous treatment effects

Annals of Internal Medicine

IDEAS AND OPINIONS

Data Sharing and Embedded Research

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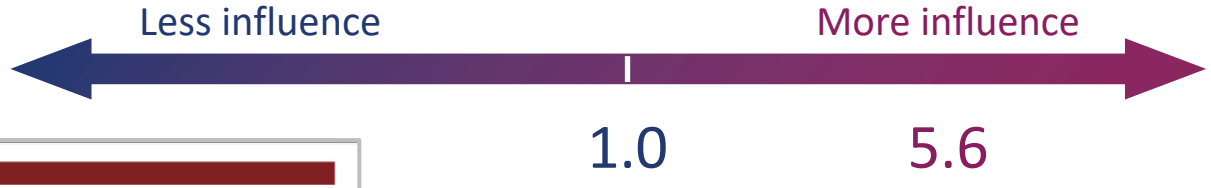
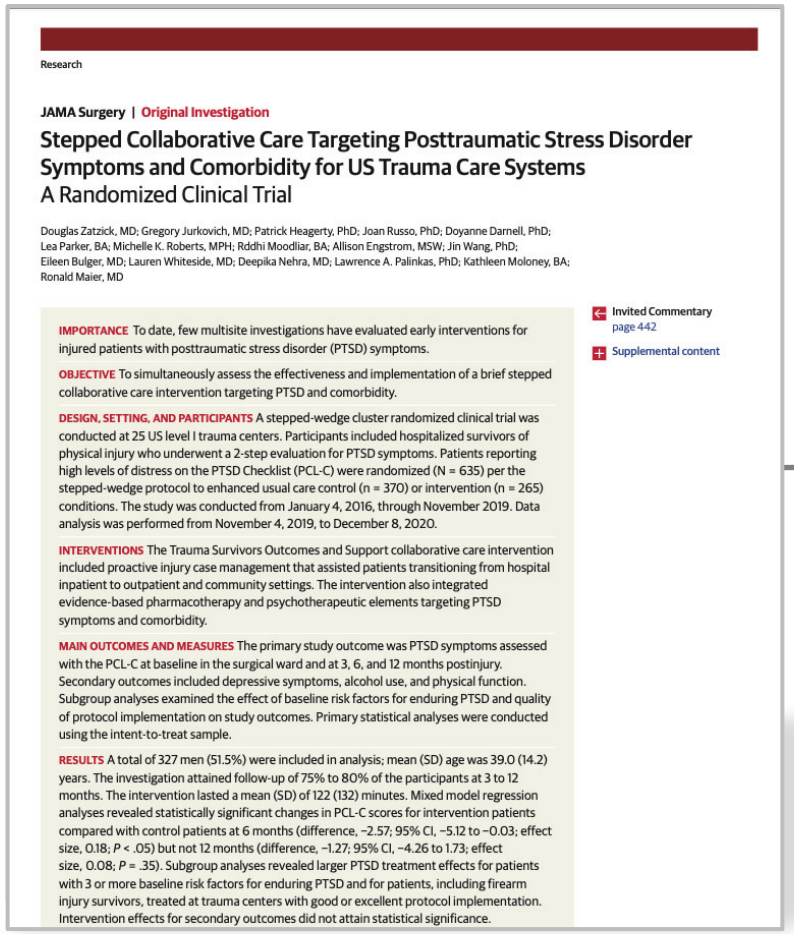
NIH Relative Citation Ratio (RCR)

- Measure of an article's influence
- Citation rate normalized by field and time, benchmarked to a value of 1.0





Research

JAMA Surgery | Original Investigation

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

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

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Supplemental content

IMPORTANCE To date, few multisite investigations have evaluated early interventions for injured patients with posttraumatic stress disorder (PTSD) symptoms.

OBJECTIVE To simultaneously assess the effectiveness and implementation of a brief stepped collaborative care intervention targeting PTSD and comorbidity.

DESIGN, SETTING, AND PARTICIPANTS A stepped-wedge cluster randomized clinical trial was conducted at 25 US level I trauma centers. Participants included hospitalized survivors of physical injury who underwent a 2-step evaluation for PTSD symptoms. Patients reporting high levels of distress on the PTSD Checklist (PCL-C) were randomized (N = 635) per the stepped-wedge protocol to enhanced usual care control (n = 370) or intervention (n = 265) conditions. The study was conducted from January 4, 2016, through November 2019. Data analysis was performed from November 4, 2019, to December 8, 2020.

INTERVENTIONS The Trauma Survivors Outcomes and Support collaborative care intervention included proactive injury case management that assisted patients transitioning from hospital inpatient to outpatient and community settings. The intervention also integrated evidence-based pharmacotherapy and psychotherapeutic elements targeting PTSD symptoms and comorbidity.

MAIN OUTCOMES AND MEASURES The primary study outcome was PTSD symptoms assessed with the PCL-C at baseline in the surgical ward and at 3, 6, and 12 months postinjury. Secondary outcomes included depressive symptoms, alcohol use, and physical function. Subgroup analyses examined the effect of baseline risk factors for enduring PTSD and quality of protocol implementation on study outcomes. Primary statistical analyses were conducted using the intent-to-treat sample.

RESULTS A total of 327 men (51.5%) were included in analysis; mean (SD) age was 39.0 (14.2) years. The investigation attained follow-up of 75% to 80% of the participants at 3 to 12 months. The intervention lasted a mean (SD) of 122 (132) minutes. Mixed model regression analyses revealed statistically significant changes in PCL-C scores for intervention patients compared with control patients at 6 months (difference, −2.57; 95% CI, −5.12 to −0.03; effect size, 0.18; $P < .05$) but not 12 months (difference, −1.27; 95% CI, −4.26 to 1.73; effect size, 0.08; $P = .35$). Subgroup analyses revealed larger PTSD treatment effects for patients with 3 or more baseline risk factors for enduring PTSD and for patients, including firearm injury survivors, treated at trauma centers with good or excellent protocol implementation. Intervention effects for secondary outcomes did not attain statistical significance.

RCR = 5.6

This article from the TSOS trial has received 5.6 times as many citations per year as the median NIH-funded article in its field.

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Impact of NIH Collaboratory Trial Publications*

All Papers (N = 337)	Main Outcomes (N = 11)	Study Design (N = 18)
Mean RCR 2.9	Mean RCR 5.2	Mean RCR 1.9
Median RCR 1.1	Median RCR 4.9	Median RCR 1.7
Weighted RCR 881	Weighted RCR 46.6	Weighted RCR 31.5
https://icite.od.nih.gov/results?search_id=o1x3mu3vc8e49yli	https://icite.od.nih.gov/results?search_id=3glpu609s2w22e48	https://icite.od.nih.gov/results?search_id=m82ypjoj54c49f19

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Training Resources

24 learning modules

55 videos in library

318 workshop materials
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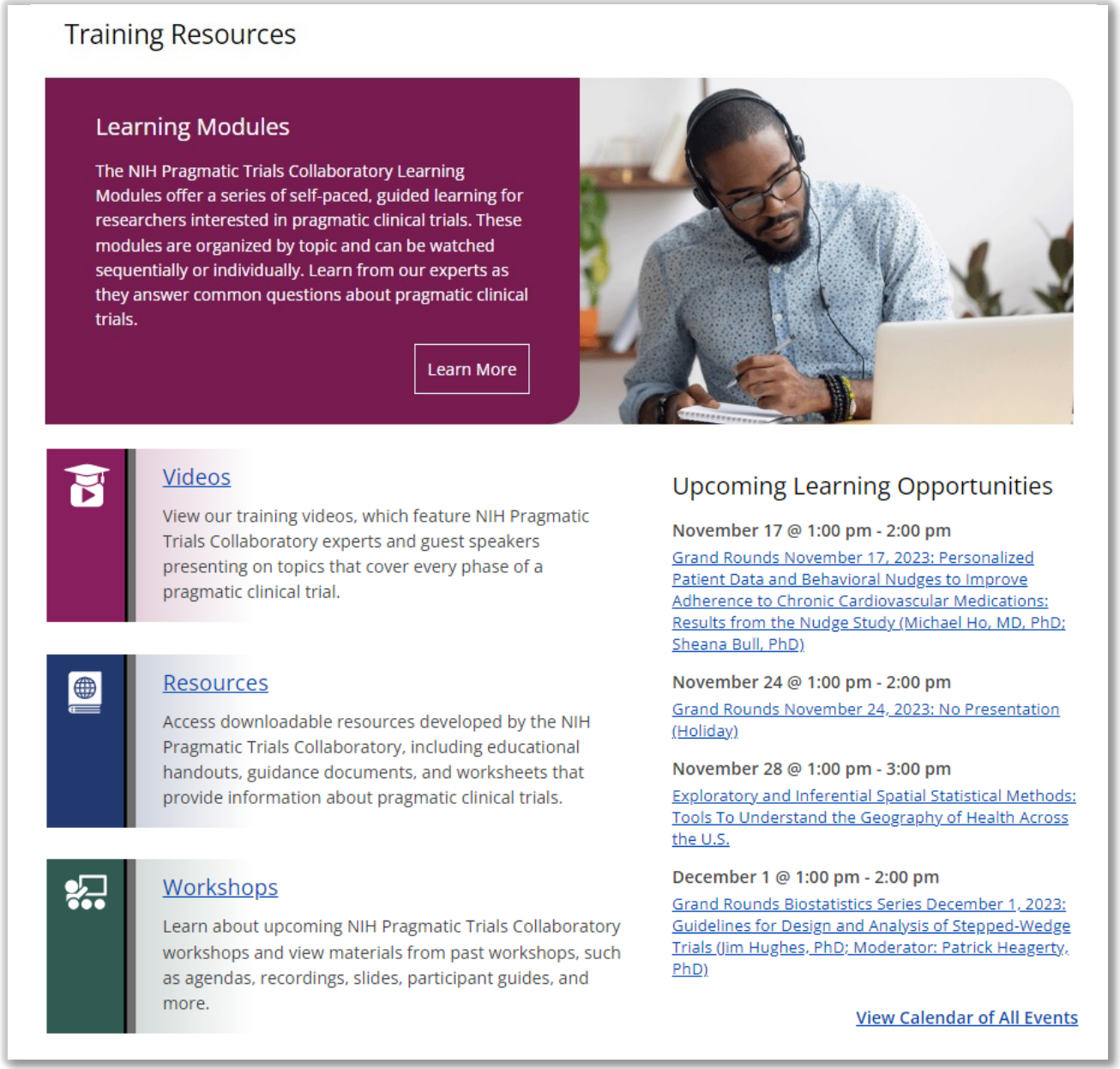
20 resources
(handouts, checklists, etc)



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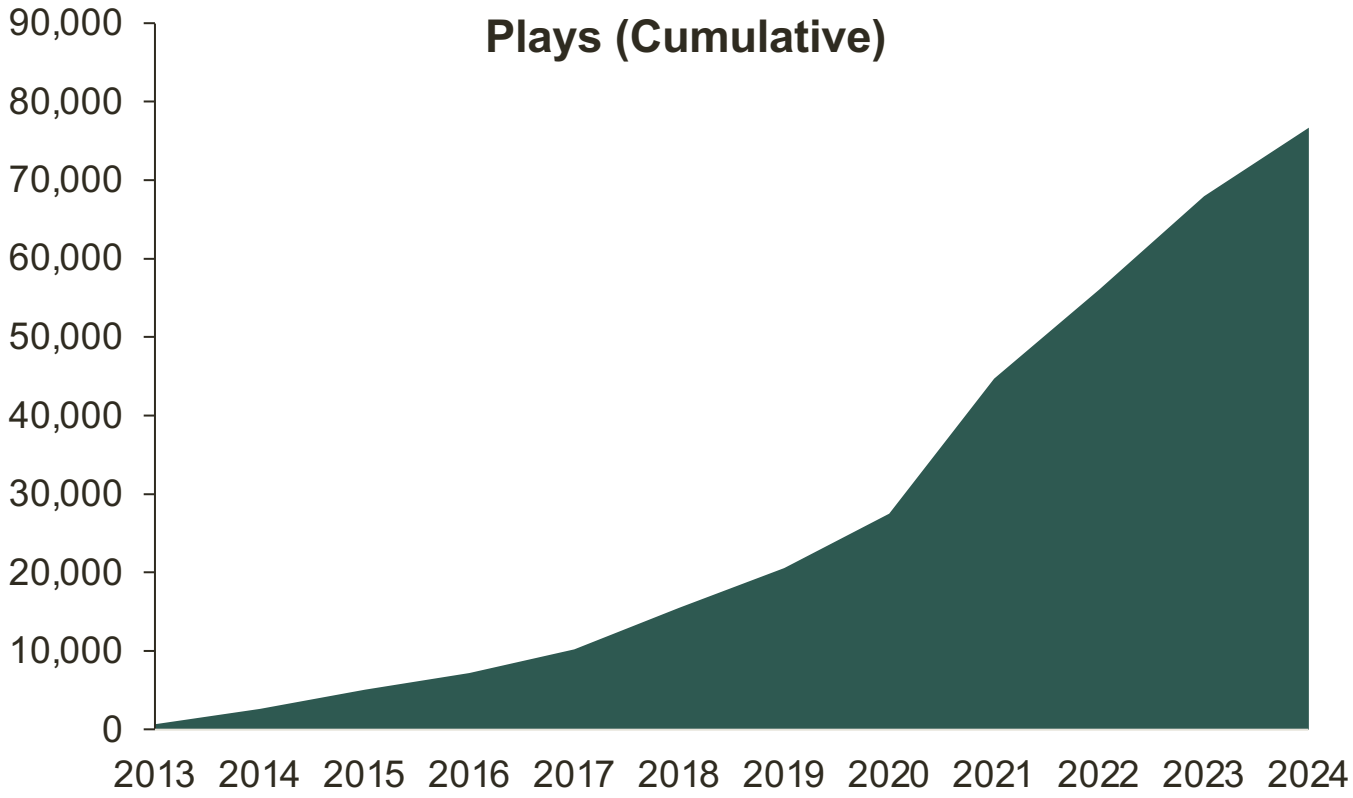

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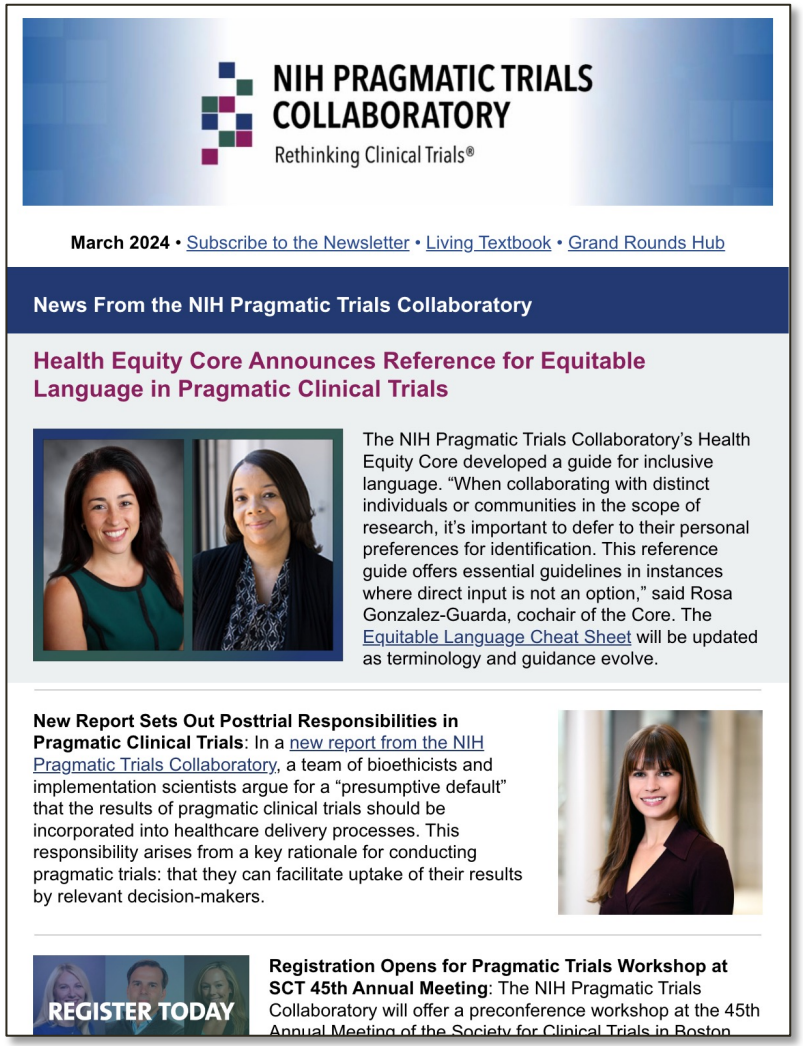

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News From the NIH Pragmatic Trials Collaboratory

Health Equity Core Announces Reference for Equitable Language in Pragmatic Clinical Trials

The NIH Pragmatic Trials Collaboratory's Health Equity Core developed a guide for inclusive language. "When collaborating with distinct individuals or communities in the scope of research, it's important to defer to their personal preferences for identification. This reference guide offers essential guidelines in instances where direct input is not an option," said Rosa Gonzalez-Guarda, cochair of the Core. The Equitable Language Cheat Sheet will be updated as terminology and guidance evolve.

New Report Sets Out Posttrial Responsibilities in Pragmatic Clinical Trials: In a new report from the NIH Pragmatic Trials Collaboratory, a team of bioethicists and implementation scientists argue for a "presumptive default" that the results of pragmatic clinical trials should be incorporated into healthcare delivery processes. This responsibility arises from a key rationale for conducting pragmatic trials: that they can facilitate uptake of their results by relevant decision-makers.

REGISTER TODAY

Registration Opens for Pragmatic Trials Workshop at SCT 45th Annual Meeting: The NIH Pragmatic Trials Collaboratory will offer a preconference workshop at the 45th Annual Meeting of the Society for Clinical Trials in Boston

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