

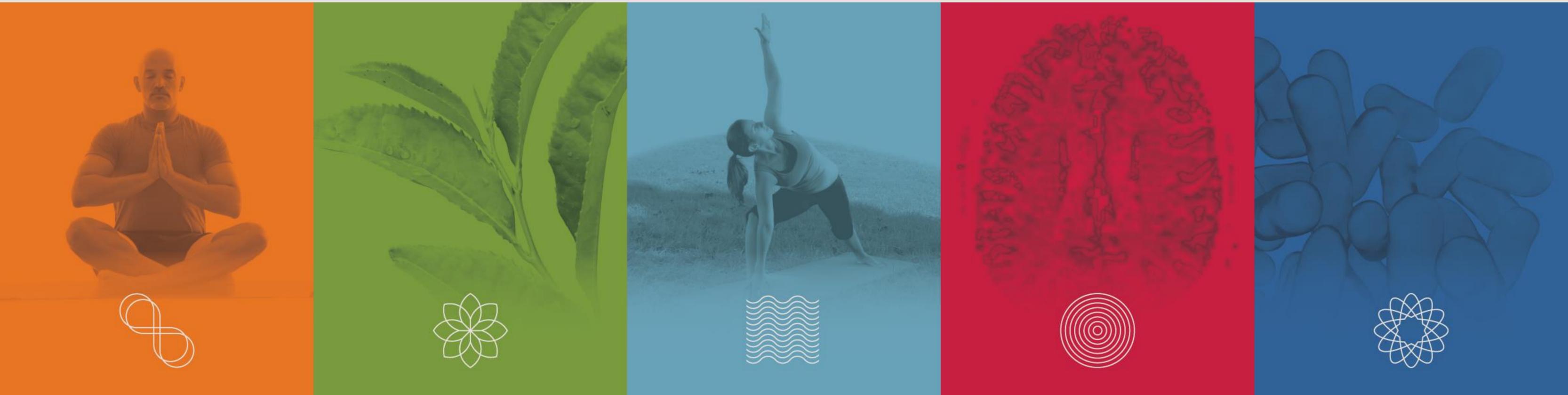


Overview of the NIH HCS Research Collaboratory Program

PRISM Kick-Off Meeting, November 19, 2019

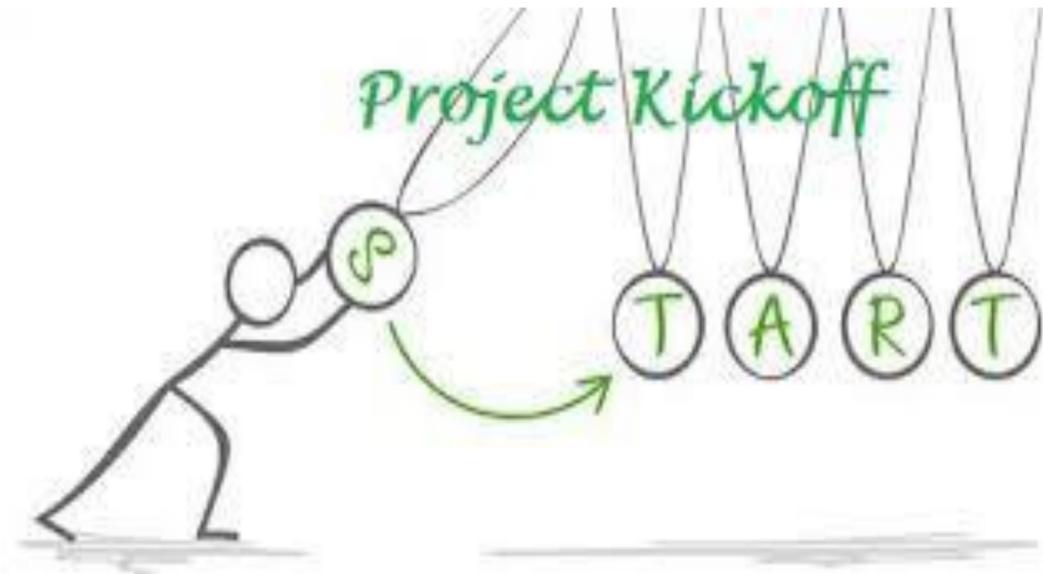
Catherine M. Meyers, M.D., FAHA

NIH/NCCIH, Director, Office of Clinical & Regulatory Affairs



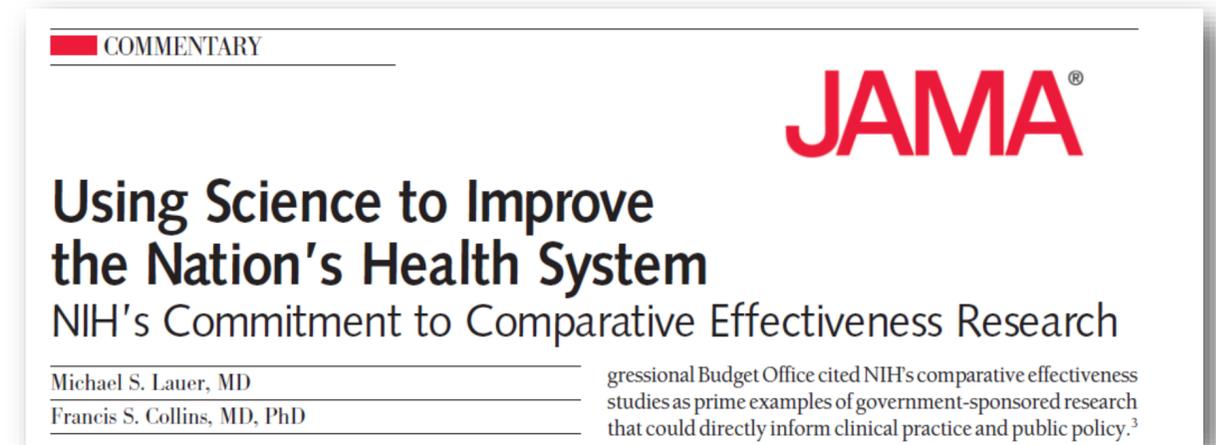
Overview of the NIH Collaboratory

- A bit of history
- What is the NIH Collaboratory?
- What has the NIH Collaboratory accomplished?
- What's next?



Contemporary Challenges for Clinical Research

- New approaches & strategies for the clinical trial enterprise
 - Stakeholder interactions & leveraging multidisciplinary expertise
 - Methods for preserving randomized trial design & optimizing use of available data
 - Dissemination and Implementation



Lauer MS, Collins FS. JAMA 2010;303:2182-3

Clinical trials get practical

Many clinical trials don't help doctors make decisions. A new breed of studies aims to change that

By Jennifer Couzin-Frankel, in Philadelphia, Pennsylvania

trials will involve more women, more minorities, a range of incomes," says Monique

N Engl J Med 2016;375:454-63

REVIEW ARTICLE

THE CHANGING FACE OF CLINICAL TRIALS

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D., and Janet Woodcock, M.D., *Editors*

Pragmatic Trials

Ian Ford, Ph.D., and John Norrie, M.Sc.

PRAGMATISM IN CLINICAL TRIALS AROSE FROM CONCERNS THAT MANY trials did not adequately inform practice because they were optimized to determine efficacy.¹ Because such trials were performed with relatively small samples at sites with experienced investigators and highly selected participants, they could be overestimating benefits and underestimating harm. This led to the

- Need for trials that inform practice & policies
- Decision makers include patients, clinicians, payers, & policy makers

NIH Health Care Systems Research Collaboratory

Launched in 2012

Goal: To strengthen the national capacity to implement cost-effective, large-scale research studies that engage health care delivery organizations as research partners.

Aim: To provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research. Research conducted in partnership with health care systems is essential to strengthen the relevance of research results to health practice.



Opportunities for the NIH Collaboratory – *circa 2012*

Focus on trials that **inform** practice - problems of high interest to clinicians, health care systems and patients

Embed research into routine health care environment – real world setting

Engage integrated health care systems with electronic infrastructure to:

- Utilize cluster and other efficient designs
- Preserve randomization as the standard
- Test systems and delivery interventions
- Enable easier follow-up



NIH Collaboratory Trials— Completed

- Time to Reduce Mortality in End-Stage Renal Disease (TiME) - NIDDK
- Active Bathing to Eliminate Infections (ABATE) - NIAID
- Strategies & Opportunities to Stop Colorectal Cancer (STOP CRC) - NCI
- Collaborative Care for Chronic Pain in Primary Care (PPACT) – NINDS, NIDA, NCCIH
- Lumbar Image Reporting & Epidemiology (LIRE) – NIAMS, NCCIH
- Pragmatic Trial of Video Education in Nursing Homes (PROVEN) – NIA, NINR



NIH Collaboratory Trials Completing 2020

- Trauma Survivors Outcomes & Support (TSOS) – NIMH, NIAAA
- Suicide Prevention Outreach Trial (SPOT) - NIMH
- Improving Chronic Disease Management with Pieces (ICD-Pieces) – NIDDK, NHLBI



NIH Collaboratory Trials Launched in 2018

- Clinical decision support to implement Emergency department-initiated Buprenorphine for opioid use Disorder (EMBED) - NIDA
- Guiding Good Choices for Health (GGC4H) – NCCIH, NIDA, OBSSR, ODP
- Primary Palliative Care for Emergency Medicine (PRIM-ER) – NCCIH, NIA
- Personalized behavioral nudges to improve adherence to cardiovascular medications (NUDGE) - NHLBI
- Improving Advance Care Planning in Oncology (ACP PEACE) - NIA, NINR
- Management of Phosphorus in ESRD (HiLo) - NIDDK



NIH HEAL/PRISM - Collaboratory Trials - Launched in 2019



- Non-pharmacological Options in postoperative Hospital-based and Rehabilitation pain Management (**NOHARM**) pragmatic clinical trial – NIA, NICHD
- Fibromyalgia TENS in Physical Therapy Study (**FM TIPS**):an embedded pragmatic clinical trial – NIAMS, NINR
- Group-based mindfulness for patients with chronic low back pain in the primary care setting (**OPTIMUM**) - NCCIH, NIA
- Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (**AcuOA**) – NCCIH, NIA



NIH Collaboratory

Participating Institutes, Centers & Offices

NCCIH

NIAMS

NIMH

NINDS

NHLBI

ODP

NIA

NICHD

NIDDK

NIAID

NIAAA

OBSSR

NIDA

NCI

NINR



NIH Collaboratory

Partnering Health Care Systems

- Kaiser Permanente
- (Group Health Cooperative)
- Mayo Clinic
- Henry Ford Health System
- HealthPartners Institute
- Parkland Health System
- Texas Health Resources
- ProHealth CT
- Hospital Corporation of America
- Yale-New Haven
- UNC – Chapel Hill
- Duke Health
- Northwell Health
- University of Colorado
- Denver Health Med Center
- US Level 1 Trauma Care Centers
- Fresenius, DaVita & Dialysis Clinic, Inc.
- Genesis Healthcare
- UHS Pruitt Corporation
- Oregon Community Health Information Network (FQHCs)
- North Texas VA
- Eastern Colorado VA



Pragmatic Clinical Trial Programs



NIH-DoD-VA Pain Management Collaboratory



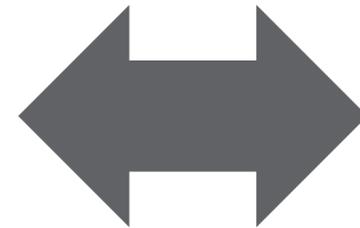
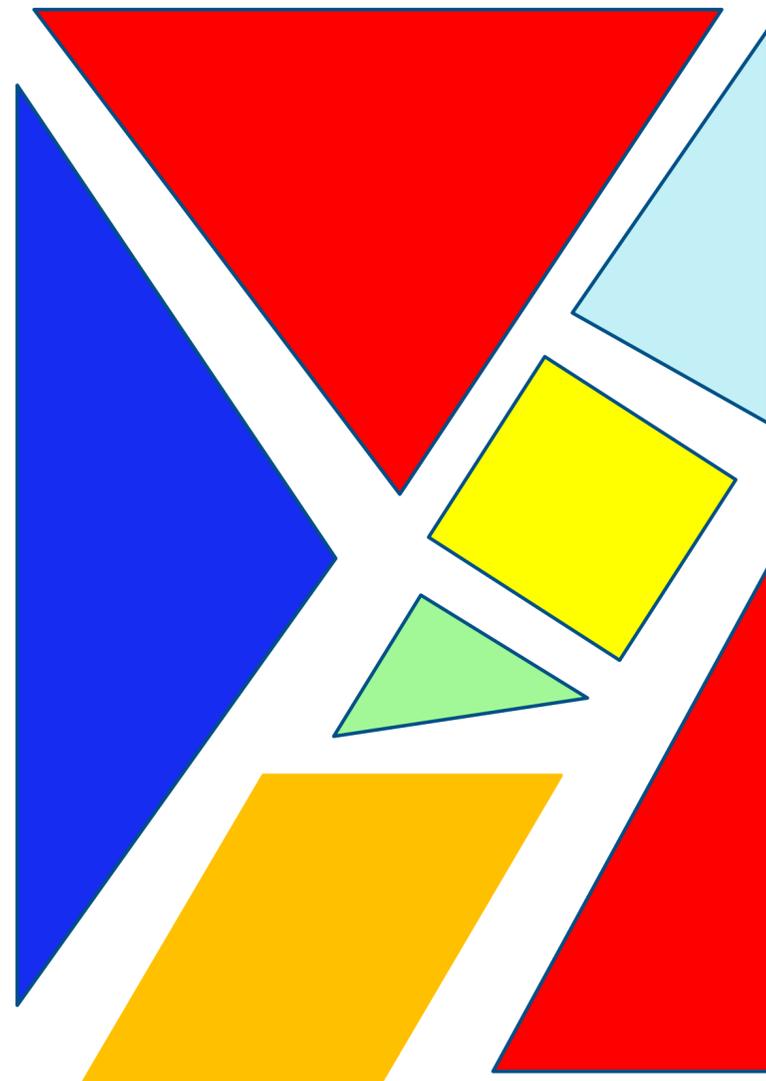
NIH Collaboratory Coordinating Center

- Provide national leadership and technical expertise in all aspects of research with health care systems
- Support the design and rapid execution of a set of high impact Pragmatic Trial Demonstration Projects conducted in partnerships with health care systems
- Make available data, tools and resources from these, and other, projects to facilitate a broadened base of research partnerships with health care systems



NIH Collaboratory Program

Pragmatic Clinical Trials



But Wait...
**THERE'S
MORE!**

Collaboratory Coordinating Center Expert Core Working Groups

Biostatistics & Study Design

Ethics & Regulatory

Electronic Health Records

Phenotypes & Data Standards

Health Care Systems Interactions

Patient Reported Outcomes



Rethinkingclinicaltrials.org

rethinkingclinicaltrials.org

NIH COLLABORATORY
LIVING TEXTBOOK
of Pragmatic Clinical Trials

HOME WELCOME GRAND ROUNDS NEWS

DESIGN
Experimental Designs and Randomization Schemes
Endpoints and Outcomes
Analysis Plan

CONDUCT
Consent, Disclosure, and Non-disclosure Using Electronic Health Record Data
Data and Safety Monitoring

DISSEMINATION
Designing With Implementation and Dissemination in Mind
Assessing Feasibility

Knowledge from and with health care systems research, conducted by pragmatic clinical trials are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost and time needed to conduct a traditional clinical trial. They present an opportunity to efficiently address critical knowledge gaps and generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than are typically encountered with traditional clinical trials. The Living Textbook reflects a collection of expert consensus regarding special considerations, standard approaches, and best practices in the design, conduct, and reporting of pragmatic clinical trials. Given the rapid pace of change in this field, this electronic textbook will continue to be added to and updated.

ENGAGING STAKEHOLDERS ➤
and building partnerships to ensure a successful trial

What is the
NIH COLLABORATORY? ➤

TRAINING RESOURCES ➤

NIH Collaboratory Workshops

Ethical & Regulatory Issues of Pragmatic Clinical Trials Workshop



Pragmatic Clinical Trials

Unique Opportunities for Disseminating, Implementing & Sustaining Evidence-Based Practices into Clinical Care



Pragmatic Clinical Trials

Embedded Pragmatic Clinical Trials of Therapeutic A vs. B Interventions



Design & Analysis of Embedded Pragmatic Clinical Trials



Questions?



PRECIS-2 – “WHEEL” Assessment Tool

