

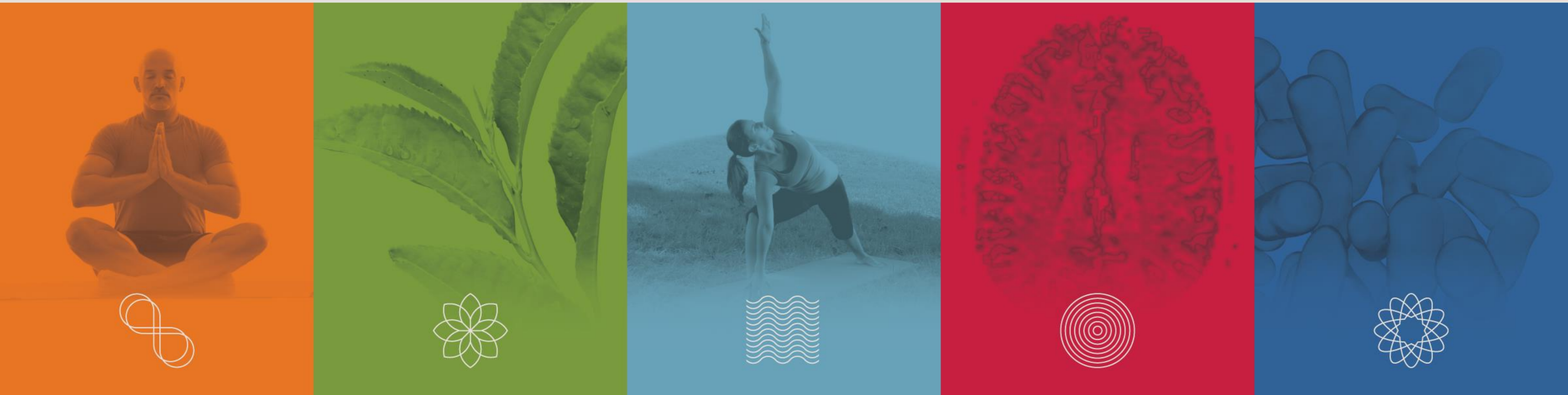


The NIH HCS Research Collaboratory

The Virtual Collaboratory/PRISM Onboarding Meeting, November 9, 2020

Catherine M. Meyers, M.D., FAHA

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



Overview for Onboarding

- Welcome to our NEW Projects!
- The NIH Health Care Systems Research Collaboratory
- US PCT Landscape & Timeline
- Collaboratory Coordinating Center



NIH Health Care Systems Research Collaboratory

Launched in 2012

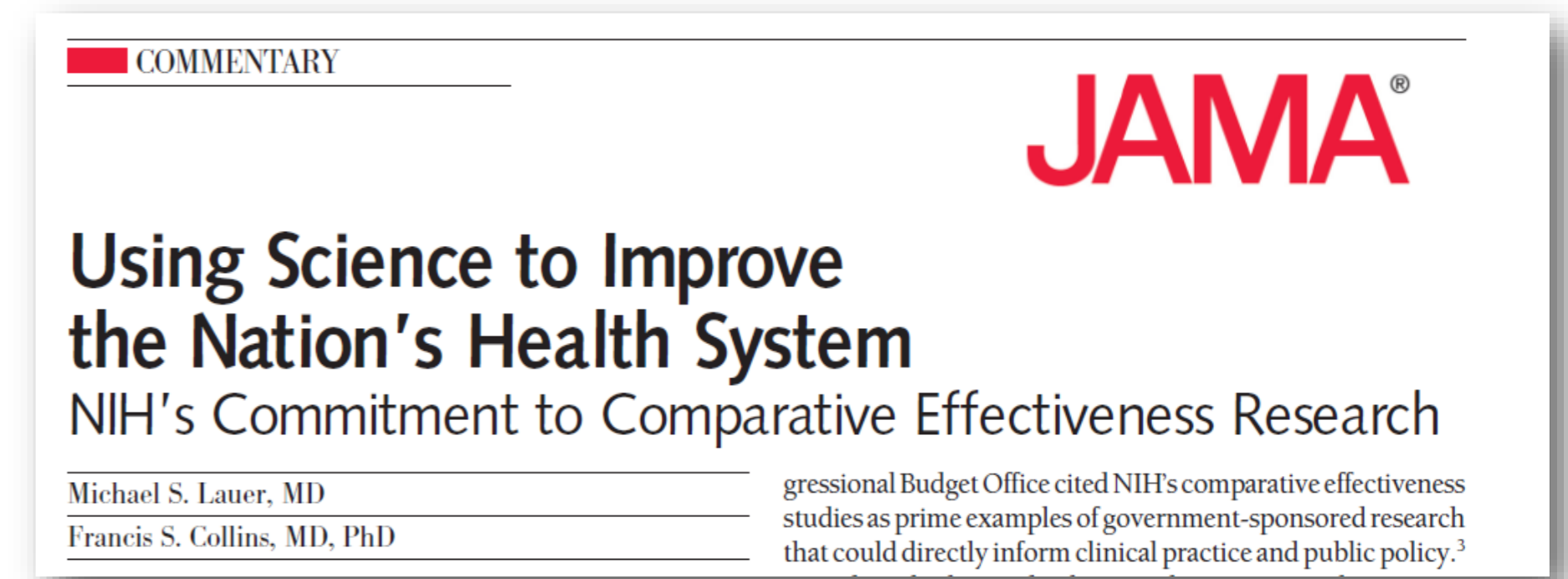
Goal: To strengthen the national capacity to implement cost-effective, large-scale research studies that engage health care delivery organizations as research partners.

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.



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



Collaboratory
Grand Rounds

UH3 PCT
9 / 0



UH3 PCT
19 / 9

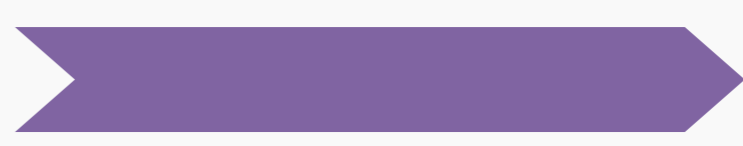
Common Fund – Phase 1
CCC established – WG & Grand Rounds
7 UG3 Planning grants awarded

3 CMC UH3 PCT launched
The Living Textbook

HEAL/PRISM – PRISM CC - CCC
4 UG3/UH3 PCT launched
2 UG3 launched

2013-14

2017-18



2012

2015-16

2019-20

6 UH3 PCT launched
3 UG3 CMC Planning Grants awarded
Ethics Jamboree & Other WG products

Common Fund – Phase 2
6 UG3 Planning grants awarded
CCC- RENEWED

UH3 PCT
6 / 0

UH3 PCT
15 / 6

Collaboratory PCT
Training Resources & Events



NIH Collaboratory Trials— *The NINE 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
- 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

UH3 Launch in 2019

- 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 Collaboratory - HEAL/PRISM Trials – *UH3 Launch in 2020*



- 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 (**Back in Action**) – NCCIH, NIA



NIH Collaboratory - HEAL/PRISM Trials

UG3 Launch in 2020

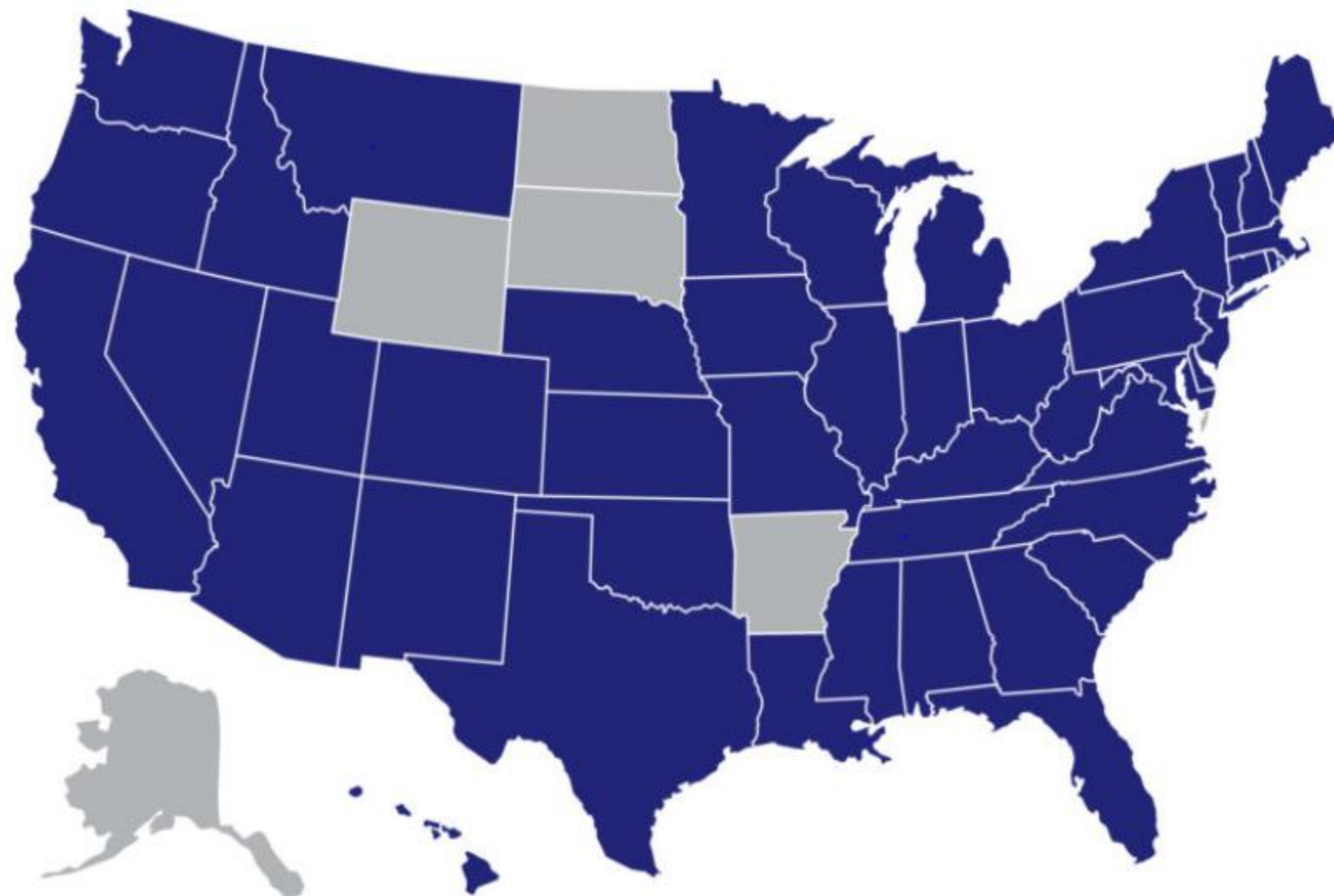


- Nonpharmacologic Pain Management in FQHC Primary Care Clinics (**BEATPAIN UTAH**), Dr. Fritz
- Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain (**GRACE Trial**), Drs. Doorenbos, Ezenwa, Molokie, Schlaeager & Shah



NIH Collaboratory PCT

- 19+ Pragmatic clinical trials
- Diverse clinical settings, across 15 NIH Institutes, Centers and Offices
- >850 clinical sites, >85% of the US, >20 Health Care Systems, >800,000 participants



NIH Collaboratory

Participating Institutes, Centers & Offices



<i>NCCIH</i>	<i>NIA</i>	<i>NINR</i>
<i>NHLBI</i>	<i>NIDDK</i>	<i>NIAMS</i>
<i>NIDA</i>	<i>NCI</i>	<i>NIAID</i>
<i>NINDS</i>	<i>NIMH</i>	<i>NIAAA</i>
<i>NICHD</i>	<i>ODP</i>	<i>OBSSR</i>



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





UH3 PCT
9 / 0

UH3 PCT
19 / 9

Common Fund – Phase 1
CCC established – WG & Grand Rounds
7 UG3 Planning grants awarded

3 CMC UH3 PCT launched
The Living Textbook

NIH-DoD-VA Pain Management Collaboratory

HEAL/PRISM – PRISM CC - CCC
4 UG3/UH3 PCT launched
2 UG3 launched

2013-14

2017-18

2012

2015-16

2019-20

6 UH3 PCT launched
3 UG3 CMC Planning Grants awarded
Ethics Jamboree & Other WG products

Common Fund – Phase 2
6 UG3 Planning grants awarded
CCC- RENEWED

UH3 PCT
6 / 0



UH3 PCT
15 / 6



NIH Collaboratory Coordinating Center

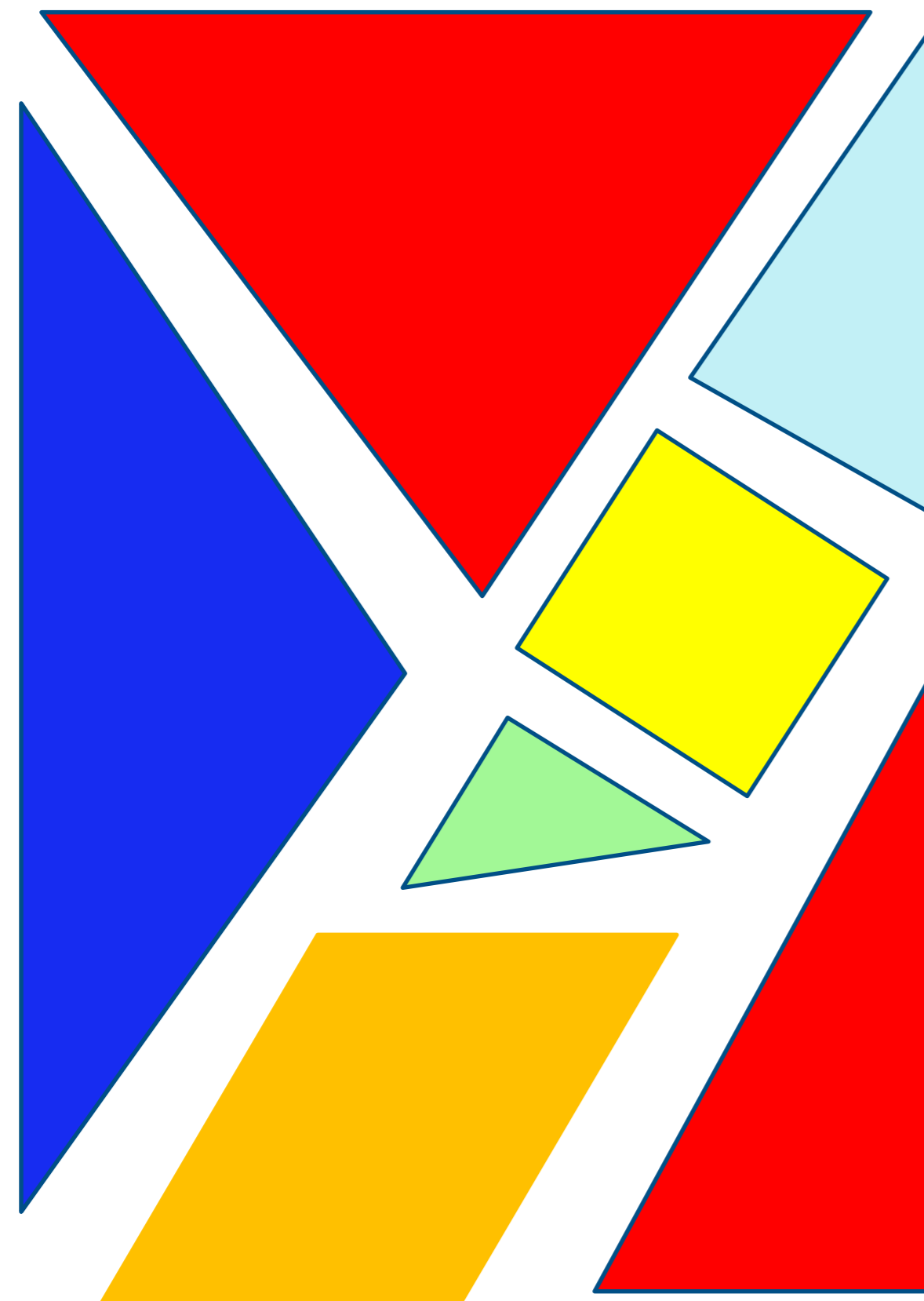
The Key to Collaboratory Success

- 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 Coordinating Center

Pragmatic Trials and Issues



Expert Core Working Groups

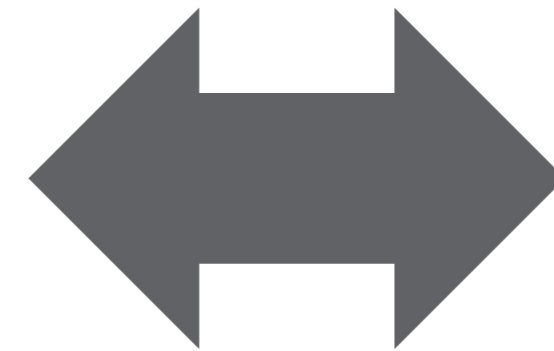
Biostatistics & Study Design

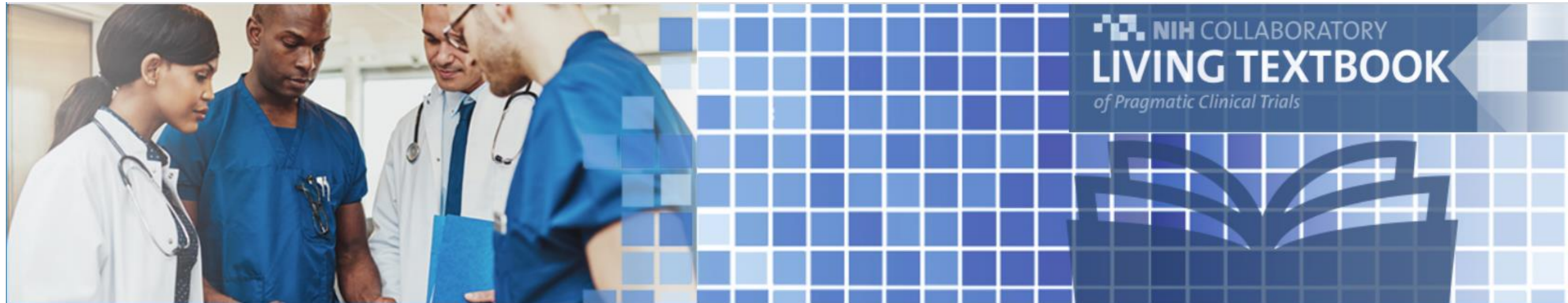
Ethics & Regulatory

Electronic Health Records/Data


Health Care Systems Interactions



Patient Centered Outcomes








NIH COLLABORATORY
LIVING TEXTBOOK
of Pragmatic Clinical Trials



 ABOUT RESOURCES GRAND ROUNDS NEWS 


DESIGN


DATA, TOOLS & CONDUCT


DISSEMINATION

Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



Welcome to the Living Textbook of pragmatic clinical trials, a collection of

GET STARTED

What is the

NIH COLLABORATORY? 



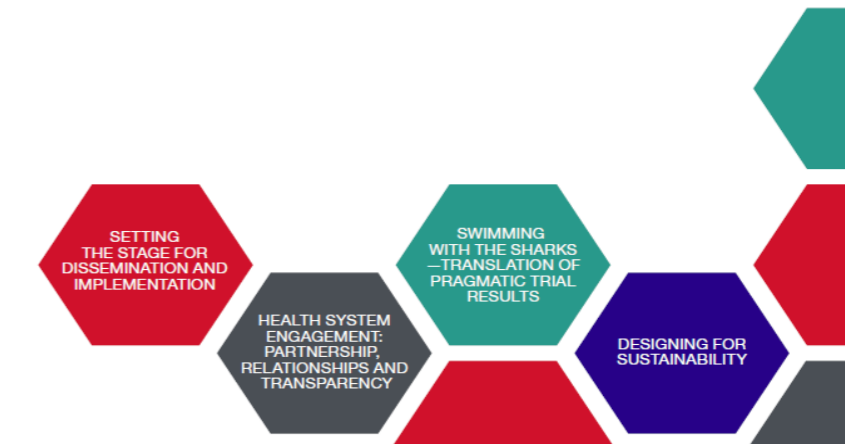
Annual NIH Collaboratory Workshops 2016 - 2019

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



NIH Collaboratory Workshops 2020 – Preparing for a New Normal



Advances at the Intersection of Digital Health, Electronic Health Records and Pragmatic Clinical Trials

A GRAND ROUNDS EHR WORKSHOP SERIES

Join us for the NIH Collaboratory's special [Grand Rounds](#) series focused on digital health, electronic health records and pragmatic clinical trials. These webinar sessions on Fridays at 1 p.m. ET will provide insights into how these three facets of healthcare intersect. The special Grand Rounds series will conclude with a podcast discussion from a panel of experts.



Sponsored by the National Institutes of Health Common Fund, NCCIH, NIA, NHLBI, NIDA, NINR, ODP, and OBSSR

NIH ePCT Training Workshop:
Supporting Embedded

Pragmatic Clinical Trials

KEYNOTE – CAN THE COVID-19 CRISIS LEAD TO REFORMATION OF THE EVIDENCE GENERATION ECOSYSTEM?

MAY 1, 2020

Robert Califf, MD, MACC

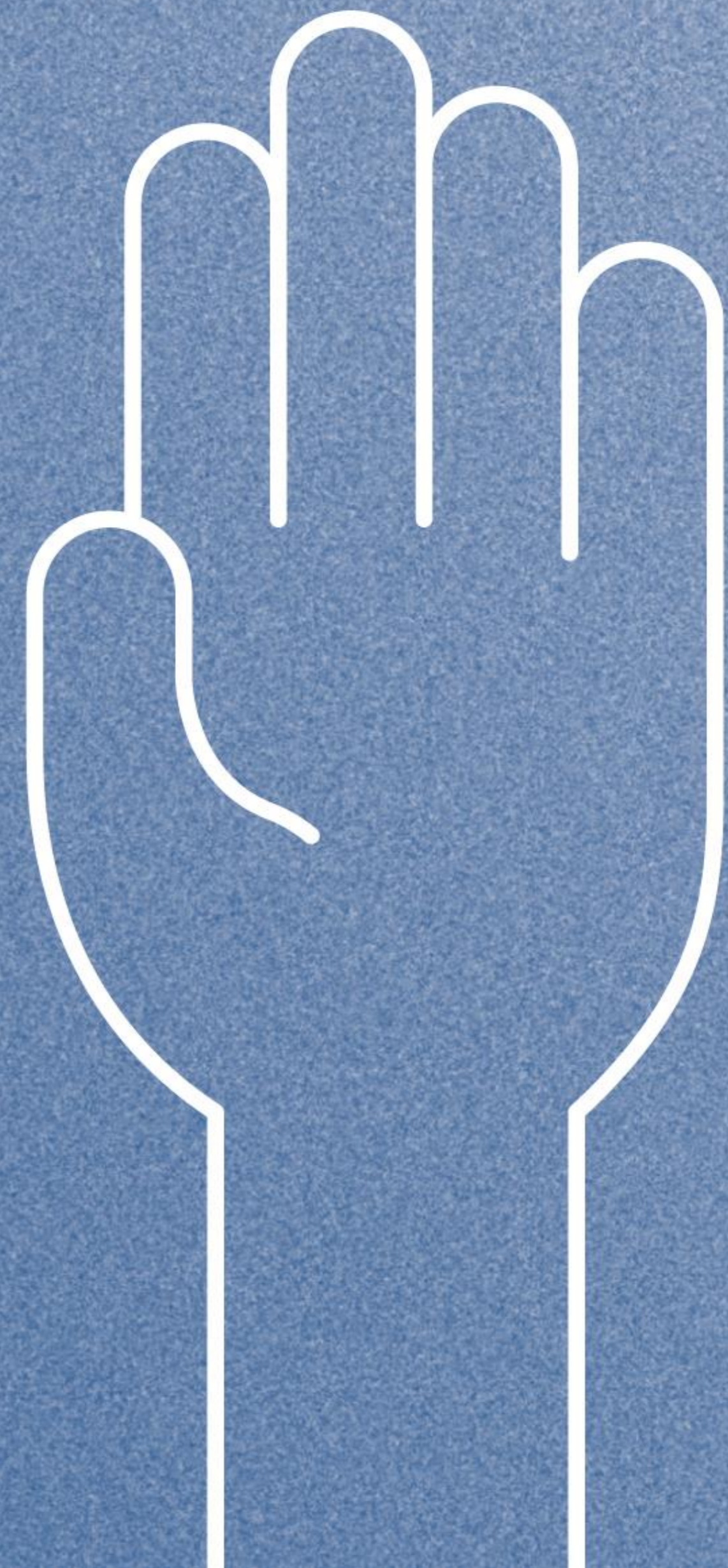
Head of Strategy and Policy

Verily Life Sciences and Google Health



Questions?

LET THE UG3 PLANNING BEGIN!



PRECIS-2 – “WHEEL” Assessment Tool

