

Health Care Systems Research Collaboratory



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Dr. Richard Hodes, M.D.

Director, National Institute on Aging (NIA)

Dr. Helene M. Langevin, M.D.

Director, National Center for Complimentary and Integrative Health (NCCIH)



Historical overview

Health Care Systems Research Collaboratory

- ➤ Phase 1: 2012-2016 Fully supported by Common Fund
- ➤ Phase 2: 2017-2019 Supported by Common Fund and NIH Institutes/Centers
- ➤ Phase 3: 2019-2021 Additional projects funded by HEAL Initiative (PRISM)

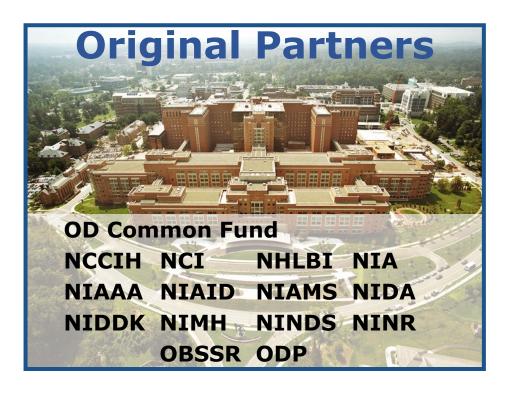
Pragmatic Trials Collaboratory (Post Common Fund)

> Phase 4: 2022 onward - Fully supported by NIH Institutes/Centers and HEAL Initiative

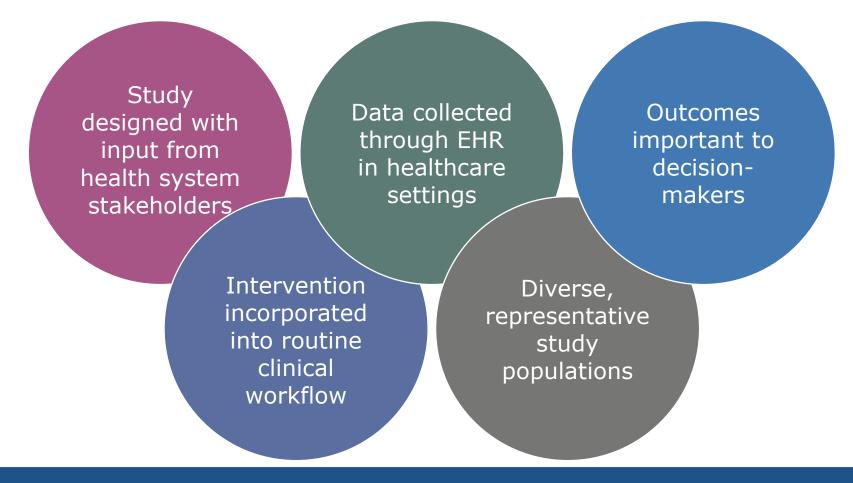
NIH Health Care Systems (HCS) Research Collaboratory

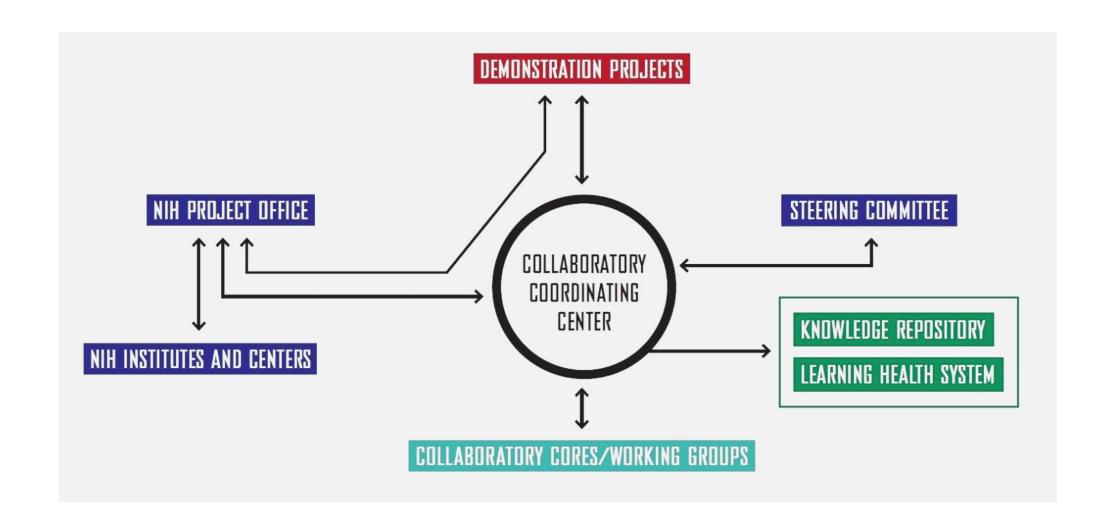
- > Launched in 2012
- > Founding Co-Chairs: Dr. Josie Briggs & Dr. Tom Insel
- > Current Co-Chairs: Dr. Helene Langevin & Dr. Richard Hodes

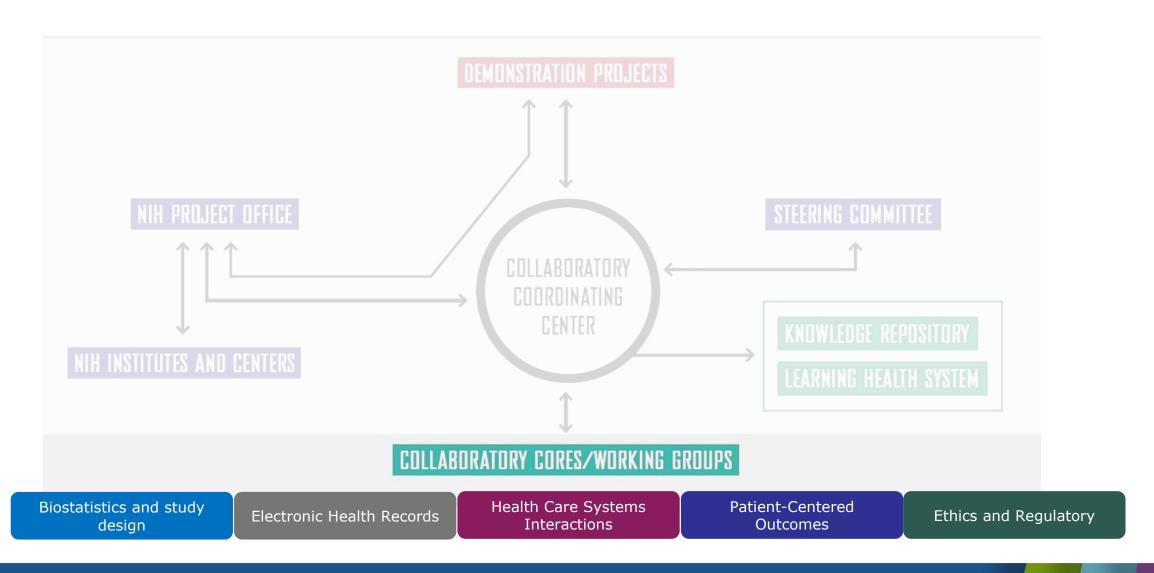
Mission: To strengthen the national capacity to implement cost-effective, large-scale research studies that engage health care delivery organizations as research partners.



Embedded Pragmatic Clinical Trials Bridge Research Into Clinical Care







Collaboratory Coordinating Center

Biostatistics and study design

Electronic Health Records

Health Care Systems Interactions

Patient-Centered Outcomes

Ethics and Regulatory

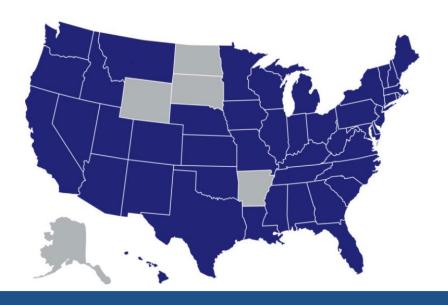
- Provides Working Group expertise across trials
- Research resources for the community
- Administrative framework for the Program

www.rethinkingclinicaltrials.org



Pragmatic Clinical Trial Demonstration Projects

- 5 RFAs for Milestone-Driven awards
 - 1-year Planning Phase (UG3)
 - 4-year Implementation Phase (UH3)
- At least 3 partnering health care systems
- Pragmatic trials embedded in healthcare systems to address questions of major public health importance



Achievements

- 21 Pragmatic Clinical Trials
- Involved 15 NIH Institutes, Centers and Offices
- Diverse clinical settings
 - >1100 clinical sites
 - >90% of the U.S.
 - >20 Heath Care Systems
 - > 926,000 participants

Transition from UG3 → UH3

Demonstration Project	Transitioned to UH3	Implementation	Enrollment	Data analysis	Reporting
BPMedTime	No	-	-	-	-
IMPACt-LBP	Pilot phase	-	-	-	-
GRACE	Yes	Yes	-	-	-
BackInAction	Yes	Yes	Yes	-	-
BeatPain Utah	Yes	Yes	Yes	-	-
OPTIMUM	Yes	Yes	Yes	-	-
ACP-PEACE	Yes	Yes	Yes	-	-
FM TIPS	Yes	Yes	Yes	-	-
GGC4H	Yes	Yes	Yes	-	-
HiLo	Yes	Yes	Yes	-	-
NOHARM	Yes	Yes	Yes	-	-
NUDGE	Yes	Yes	Yes	-	-
PRIM-ER	Yes	Yes	Yes	-	-
ICD-PIECES	Yes	Yes	Yes	Yes	-
EMBED	Yes	Yes	Yes	Yes	Yes
PROVEN	Yes	Yes	Yes	Yes	Yes
PPACT	Yes	Yes	Yes	Yes	Yes
LIRE	Yes	Yes	Yes	Yes	Yes
TSOS	Yes	Yes	Yes	Yes	Yes
ABATE	Yes	Yes	Yes	Yes	Yes
SPOT	Yes	Yes	Yes	Yes	Yes
STOP CRC	Yes	Yes	Yes	Yes	Yes
TiME	Yes	Yes	Yes	Yes	Yes

9 complete

21 transitioned to UH3 (>90% to date)



Completed Demonstration Projects

STOP CRC Strategies and Opportunities to Stop Colorectal Cancer

• Cluster trial testing a culturally tailored, health care system-based program to improve CRC screening rates in community-based collaborative network



- 30 clinical sites
- 62,155 patients

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

LIRE Lumbar Imaging with Reporting of Epidemiology

Network Open

Cluster trial evaluating whether inserting epidemiologic benchmarks into lumbar spine imaging reports reduces subsequent tests and treatments



- 98 clinical sites
- 246,289 patients

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 lavid F. Kallmes, M.D. Daniel C. Cherlin, PhD., Richard A. Deyo, M.D. MPH, Karen J. Sherman, PhD. Safkan S. Halbbi, MD. Bryan A. Corristock, M.S. Patrock H. Luetmer, M.D. Indrew L. Avirs, M.D. MPH, Sean D. Rundel, DPT, PhD. Brent, Griffith, M.D. Janna L. Friedle, M.D. Danielle C. Lavellee, PhD. Kuri A. Stephens, PhD. Judith A. Turner, PhD.

 $\overline{ ext{TiME}}$ 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

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, ⁶ Jesse Y. Hsu, ⁵ Alfred K. Cheung, ⁶ John T. Dauglirdas, ⁷ Tom Greene, ⁸ Casba P. Kovesdy g., ⁹ Dana C. Miskulin, ¹⁰ Ravi I. Thadhani, ^{11,12} Wolfgang Winkelmayer, ¹³ Susa, S. Ellenberg, ⁵ Deniso Griefli, ¹⁸ Rosemary Madigan, ¹⁴ Amy Young, ⁸ Michael Angeletti, ³ Rebecca L. Wingard,³ Christina Kahn,³ Allen R. Nissenson,^{15,16} Franklin W. Maddux, Kevin C. Abbott,¹⁷ and J. Richard Landis⁵

PROVEN Pragmatic Trial of Video Education in Nursing Homes

 Evaluating the effectiveness of advance care planning video shown in nursing homes of 2 large health care systems



- 359 nursing homes
- 211,469 patients

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

usan L. Mitchell, MD, MPH; Angelo E. Volandes, MD, MPH; Roee Gutman, PhD; Pedro L. Gozalo, MSc, PhD; Jessica A. Ogarek, MS; Lacey Loomer, MSPH;

ABATE Active Bathing to Eliminate Infection

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



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

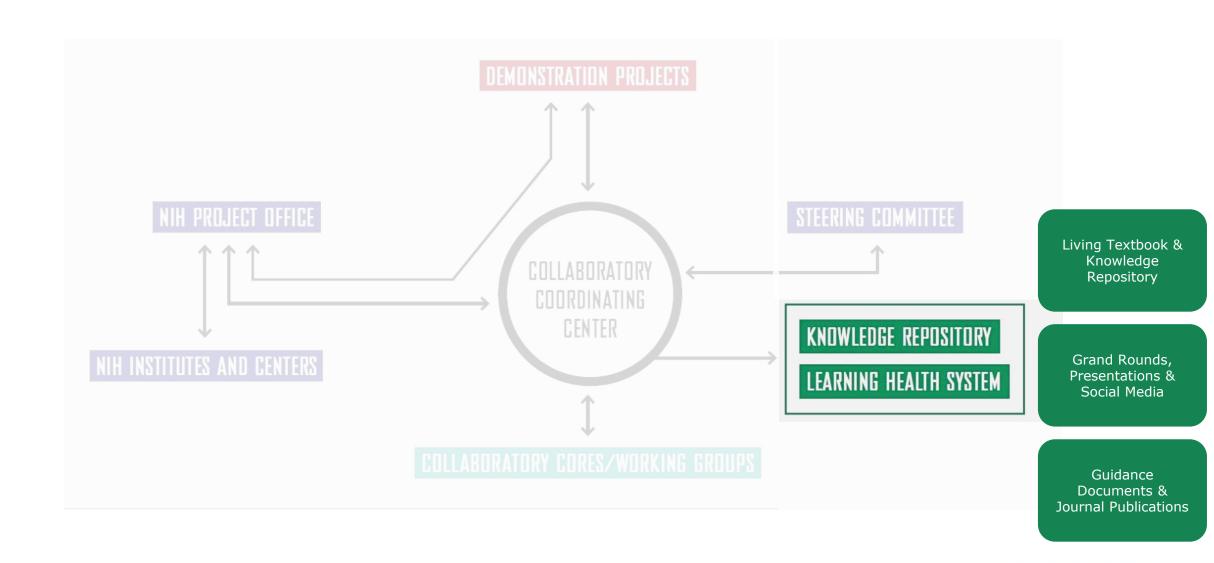
 $\begin{array}{ll} PPACT & \textit{Collaborative Care for Chronic Pain in Primary Care} \end{array}$

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



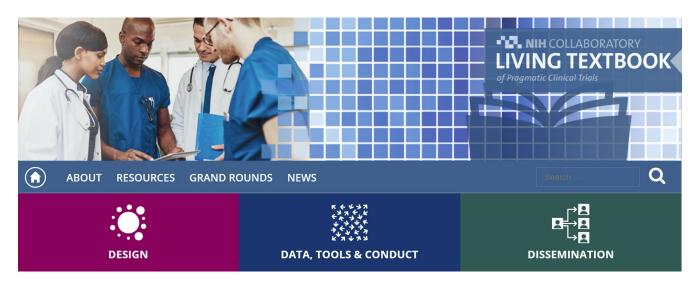


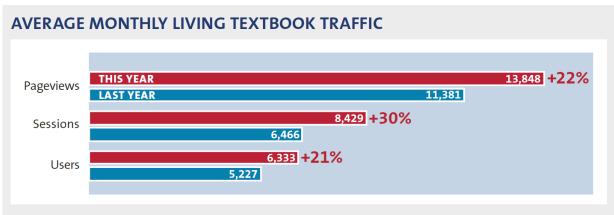


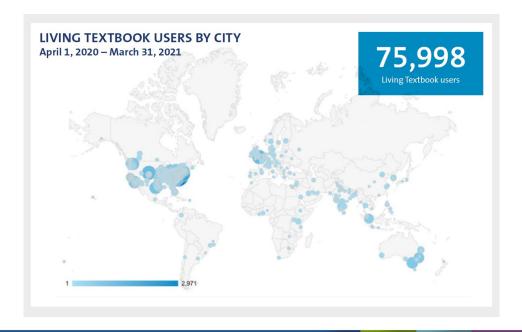


Living Textbook & Knowledge Repository

www.rethinkingclinicaltrials.org







Grand Rounds, Presentations & Social Media

Social Media



1,931

Twitter followers



1,248

Email newsletter subscribers

Rethinking Clinical Trials® Grand Rounds



411

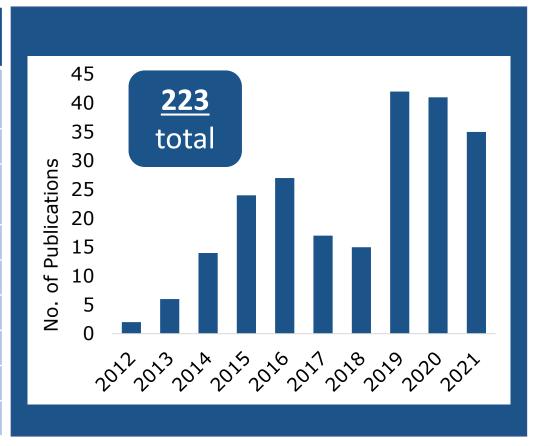
Grand Rounds since inception

> 250

Grand Rounds average attendance

Guidance Documents & Journal Publications

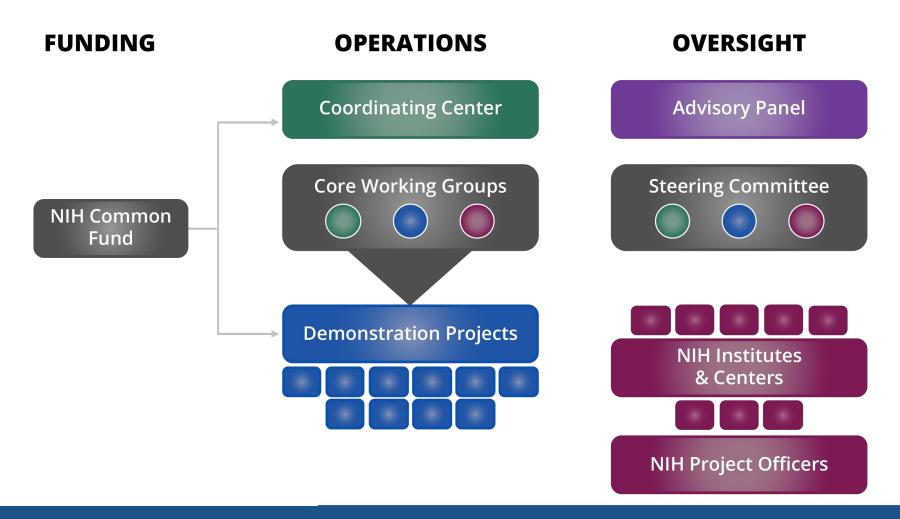
Source	No. of Publications		
Coordinating Center	7		
Cores	42		
Demonstration Projects	152		
Supplements			
ADAPTABLE	2		
ADRD DRN	1		
Diversity	6		
Empirical Ethics	8		
MOTIFS	6		



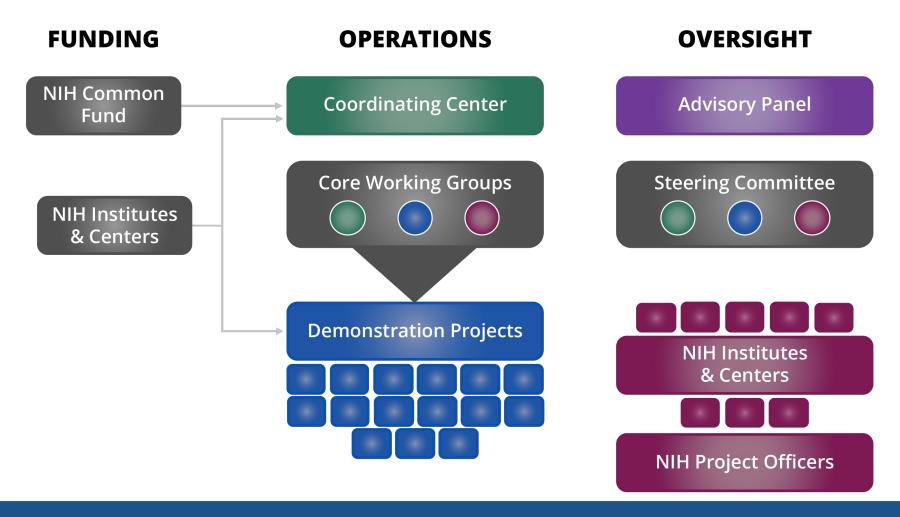
The path forward: Transition from Common Fund



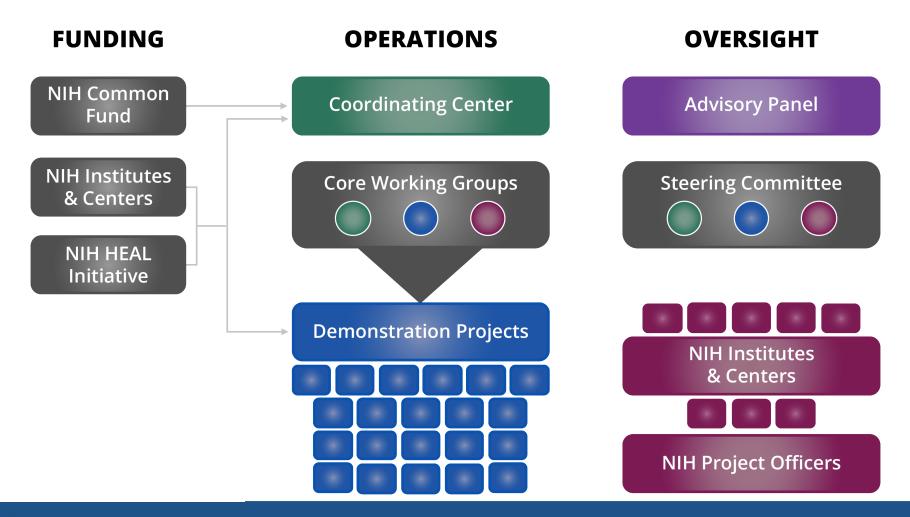
NIH HCS Structure: 2012-2017



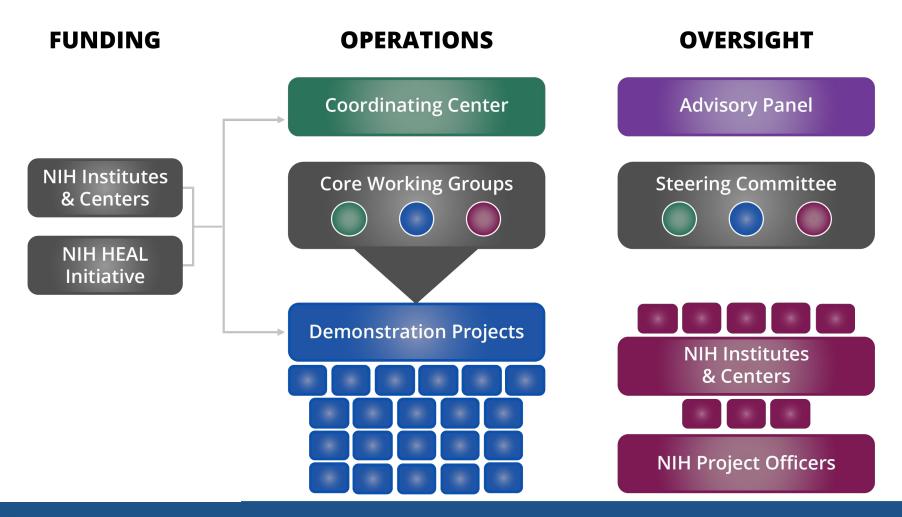
NIH HCS Structure: 2017-2019



NIH HCS Structure: 2019-2021



NIH PTC Structure: 2022 onward





Health Care Systems Research Collaboratory



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Pragmatic Trials Collaboratory-Post Common Fund

Current participating Institutes, Centers and Offices



New Areas of Focus

- Implementation Science trials study strategies for implementing evidence-based interventions into healthcare delivery.
- Trials to address health disparities in health care delivery

Pragmatic Trials Collaboratory Continuation Plan

Collaboratory Coordinating Center

- Recompete via RFA FY22 (RFA-AT-22-002)
- U24 for 6 years duration to match RFA timing
 - Large Participating ICs contribute \$200K/year for up to 2 pragmatic or implementation trials
 - Small Participating ICs contribute \$100K/year for 1 pragmatic or implementation trial
 - Offices Participating contribute \$75-150K/year
- MOU with each of the participating ICOs

Pragmatic Trials Collaboratory Continuation Plan

- Pragmatic or Implementation Trials
 - RFA-AT-22-001 issued October 2021 with receipt dates in December 2021 and June 2022 (FY22 and FY23)
 - \$500K direct cost UG3 planning one-year period
 - \$1M per year direct cost for UH3 years in trial conduct phase of up to four years
 - ICs can pursue co-funding from other ICOs

NIH PRAGMATIC TRIALS COLLABORATORY Rethinking Clinical Trials®

- > Successful transition from Common Fund to IC support
- Over 90% (and counting) of projects have transitioned from to UH3 trials
- Unparalleled impact of Demonstration Projects on knowledge and practice (Grand Rounds, Living Textbook etc.)