



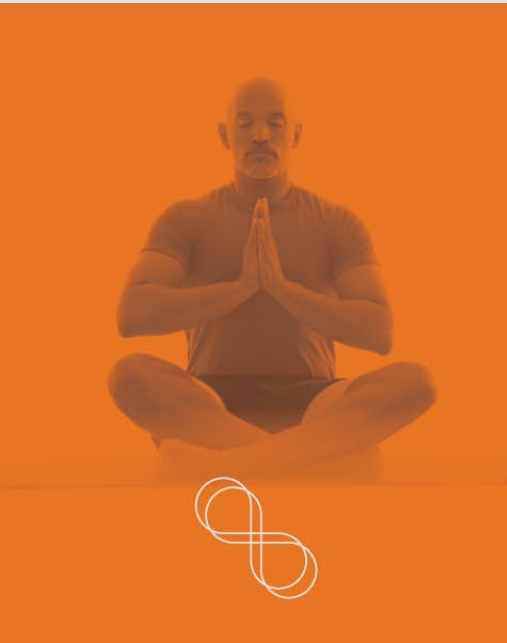
Dr. Helene M. Langevin, M.D.

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



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials[®]



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



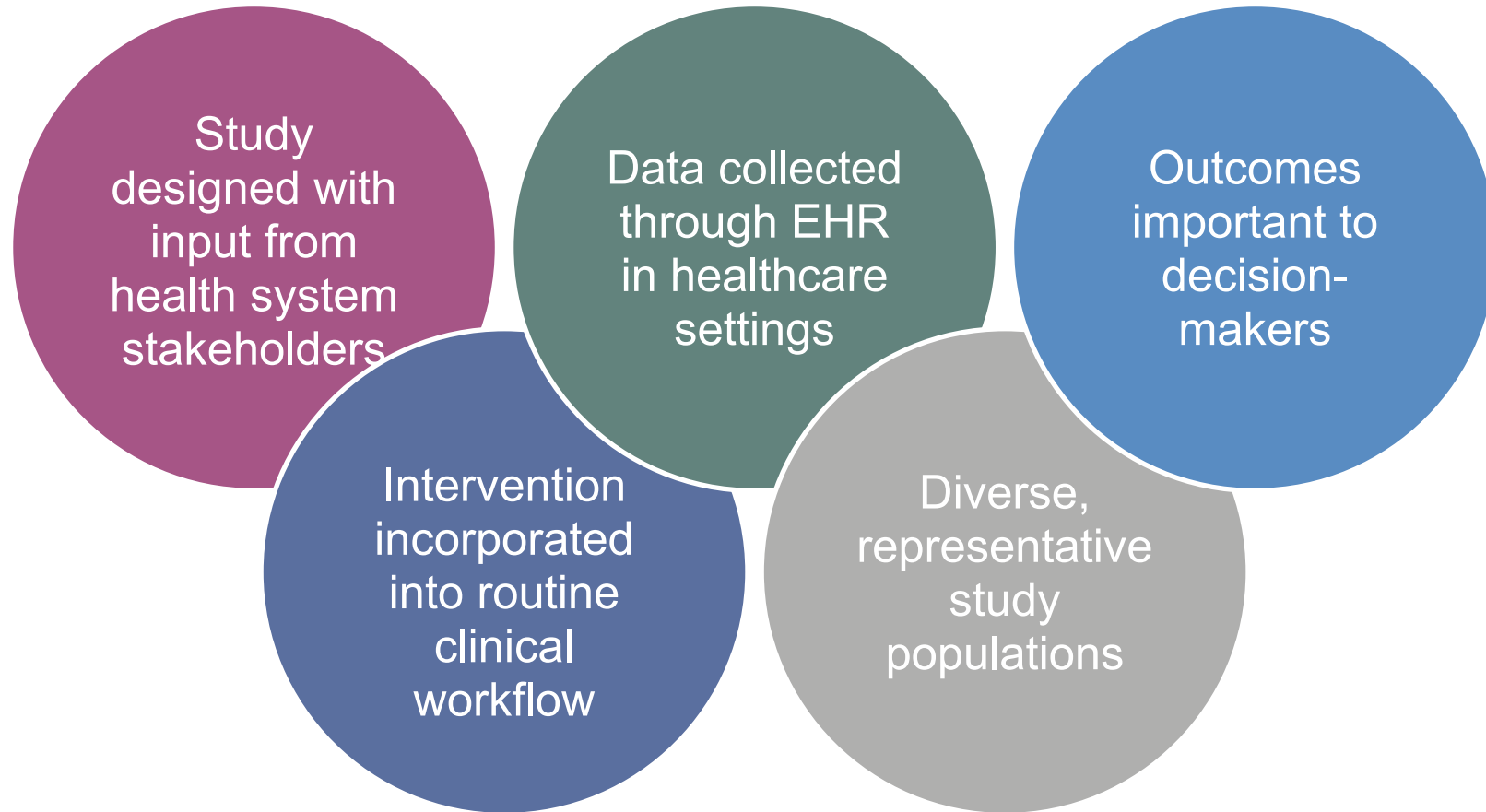
NIH Health Care Systems(HCS) Research Collaboratory

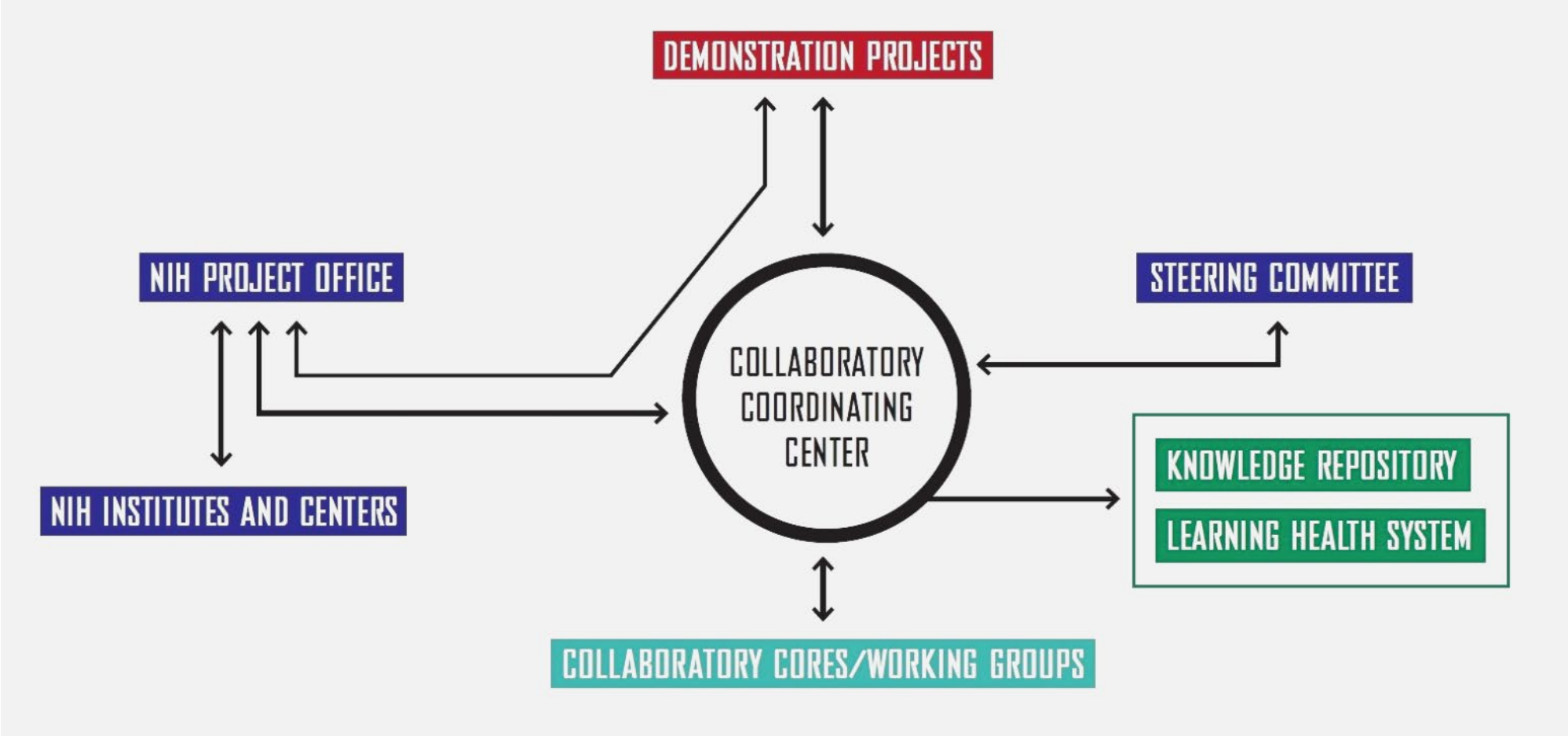
- Launched in 2012
- Co-lead by NCCIH and NIA

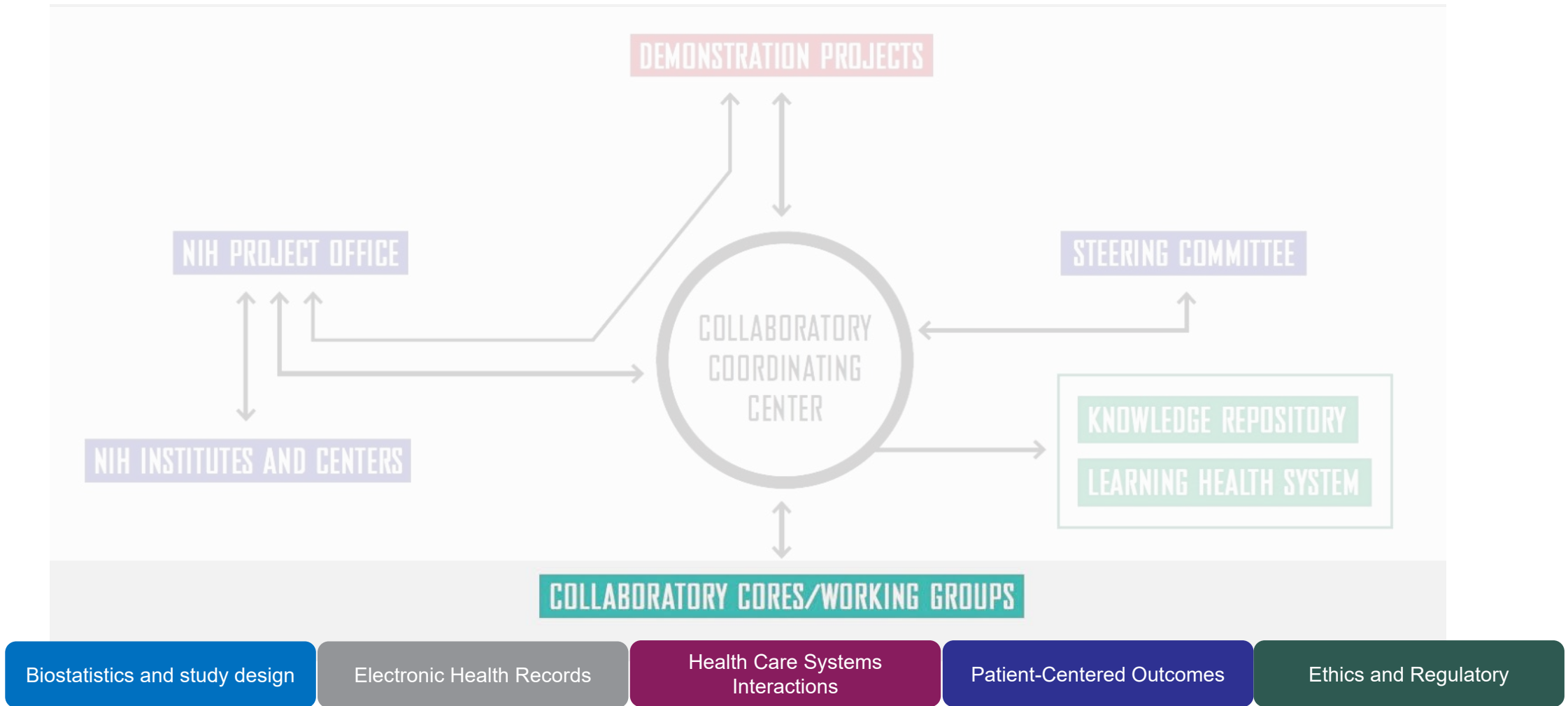
Mission: To strengthen the national capacity to implement cost-effective, large-scale research studies that engage health care delivery organizations as research partners.



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

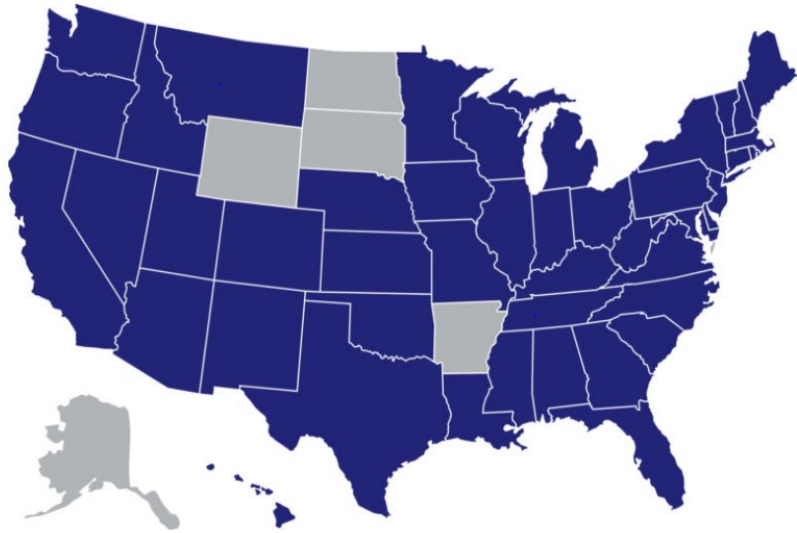
- Provides Working Group expertise across trials
- Research resources for the community
- Administrative framework for the Program

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

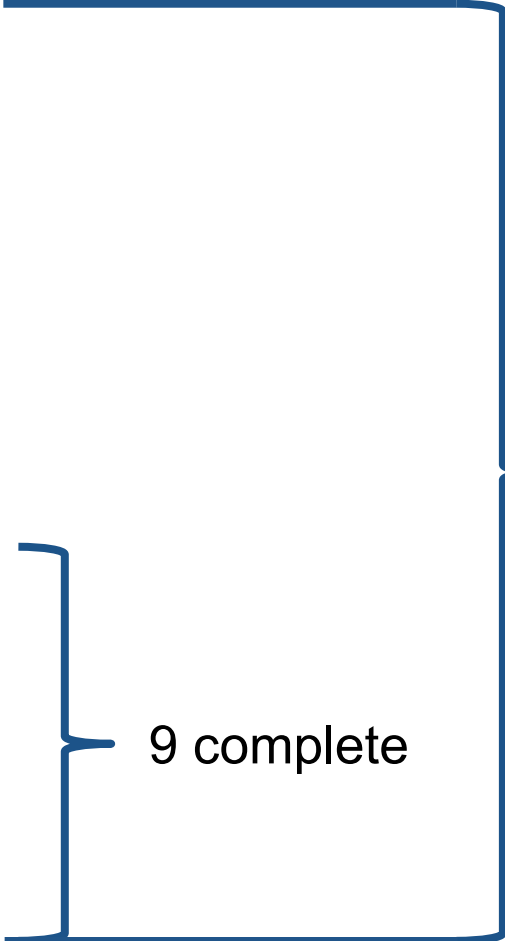
- 21 Pragmatic Clinical Trials
- Involved 15 NIH Institutes, Centers and Offices
- Diverse clinical settings
 - >1100 clinical sites
 - >90% of the U.S.
 - >20 Health Care Systems
 - > 926,000 participants



Transition from UG3 UH3



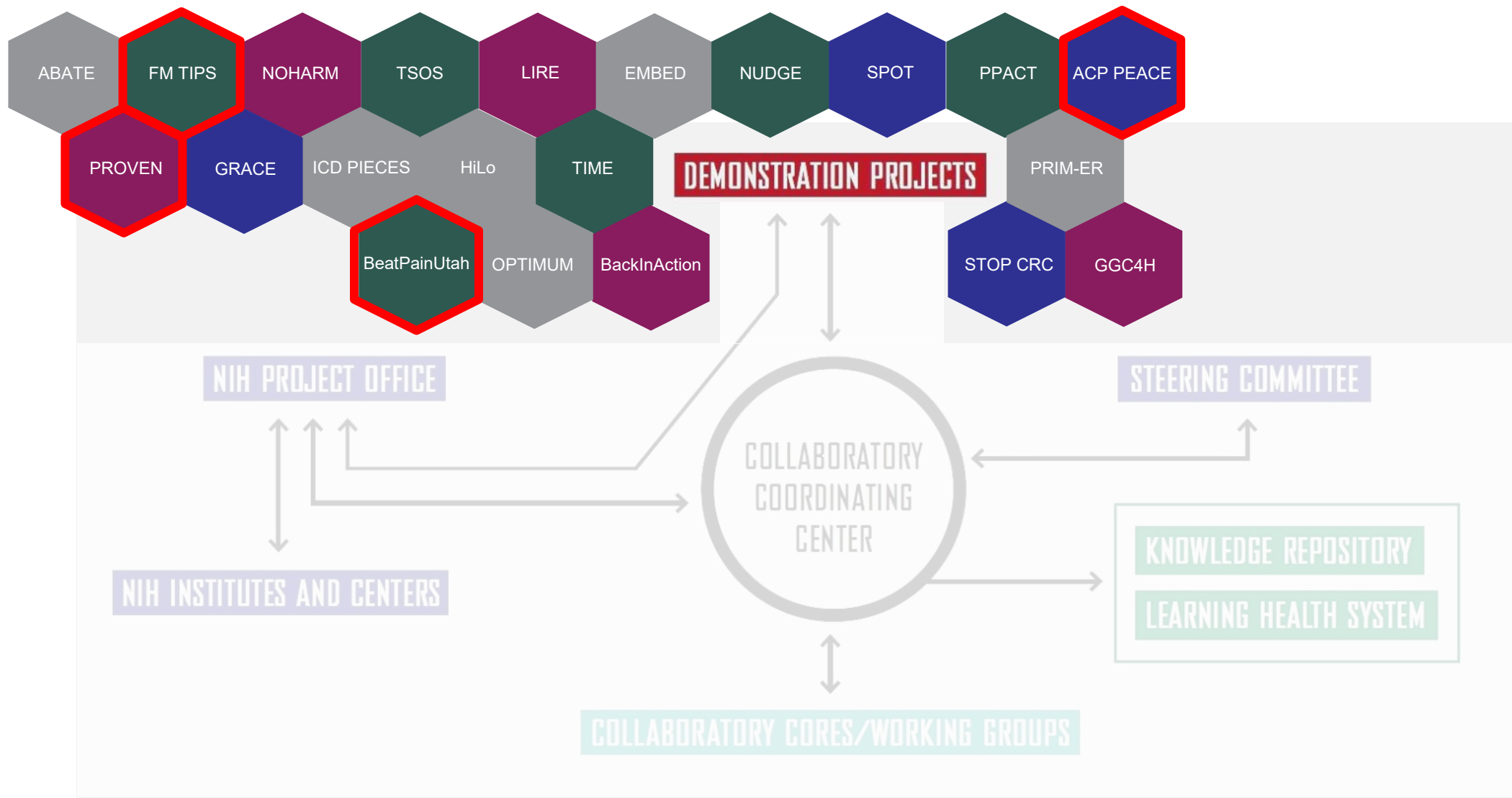
Demonstration Project	Transitioned to UH3	Implementation	Enrollment	Data analysis	Reporting
BPMedTime	No	-	-	-	-
IMPACT-LBP	Pilot phase	-	-	-	-
GRACE	Yes	Yes	-	-	-
BackInAction	Yes	Yes	Yes	-	-
BeatPainUtah	Yes	Yes	Yes	-	-
OPTIMUM	Yes	Yes	Yes	-	-
ACP-PEACE	Yes	Yes	Yes	-	-
FM TIPS	Yes	Yes	Yes	-	-
GGC4H	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



21 transitioned to UH3
(>90% to date)

9 complete





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



PROVEN *Pragmatic Trial of Video Education in Nursing Homes*

ACP PEACE

PROVEN

- Evaluating the **effectiveness of advance care planning video** shown in nursing homes of 2 large health care systems
- 359 nursing homes
- 211,469 patients

BeatPainUtah

FM TIPS

PROVEN

PRagmatic Trial of Video Education in Nursing Homes

Research

JAMA Internal Medicine | [Original Investigation](#)

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

Susan L. Mitchell, MD, MPH; Angelo E. Volandes, MD, MPH; Roee Gutman, PhD; Pedro L. Gozalo, MSc, PhD; Jessica A. Ogarek, MS; Lacey Loomer, MSPH; Ellen M. McCreedy, PhD; Ruoshui Zhai, MS; Vincent Mor, PhD

BeatPain Utah

Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics

ACP PEACE

PROVEN

BeatPainUtah

FM TIPS

- Testing the feasibility of a **telehealth strategy** that provides a brief **pain teleconsult** along with phone-based **physical therapy**
- FQHCs in Utah



FM TIPS *Fibromyalgia TENS in Physical Therapy Study*

ACP PEACE

PROVEN

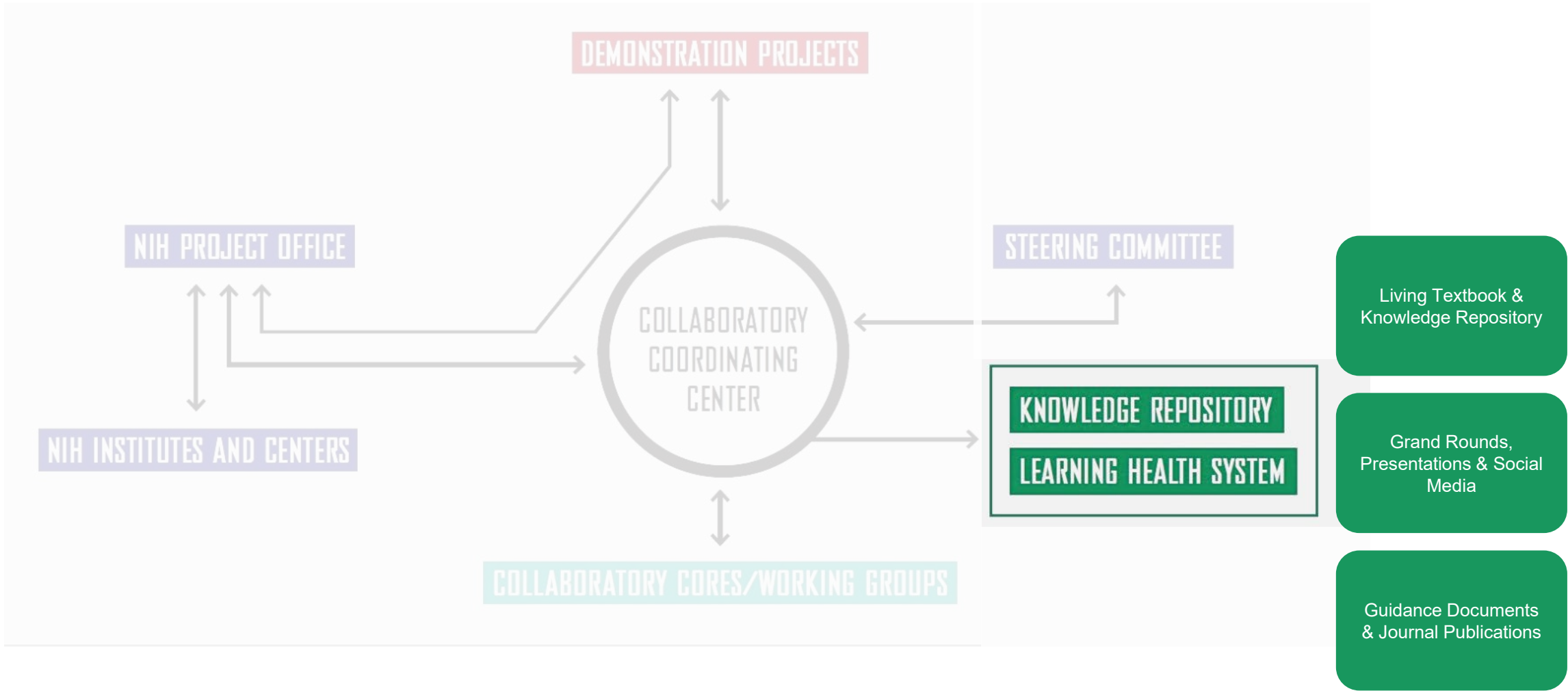
BeatPainUtah

FM TIPS



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



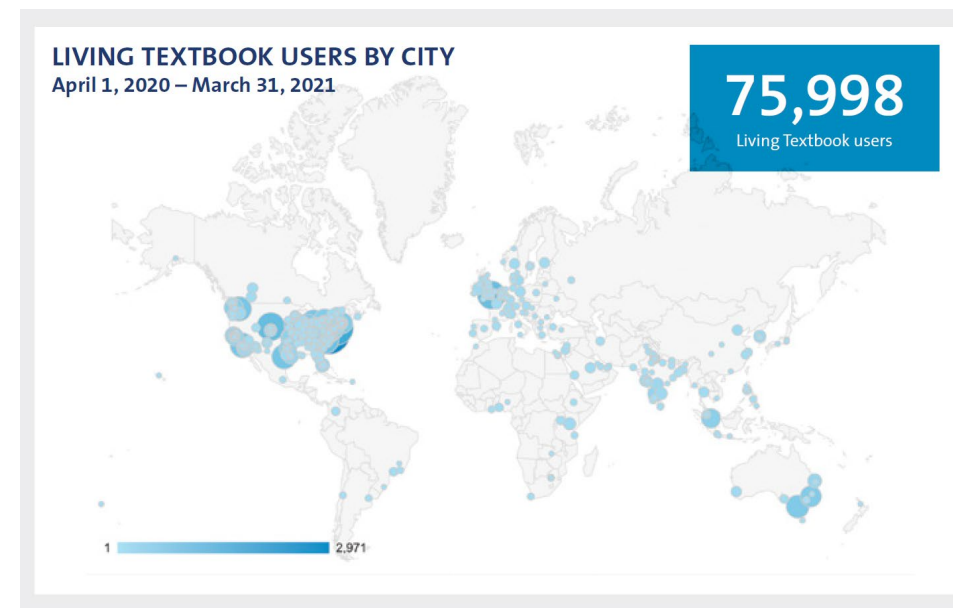
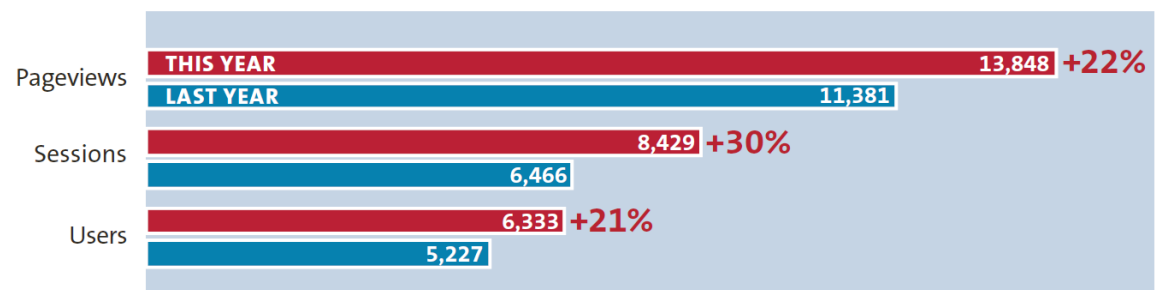
Living Textbook & Knowledge Repository

www.rethinkingclinicaltrials.org

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AVERAGE MONTHLY LIVING TEXTBOOK TRAFFIC



Grand Rounds, Presentations & Social Media

Social Media



Twitter
followers

1,931



Email newsletter
subscribers

1,248

Rethinking Clinical Trials[®] Grand Rounds



Grand Rounds
since inception

411

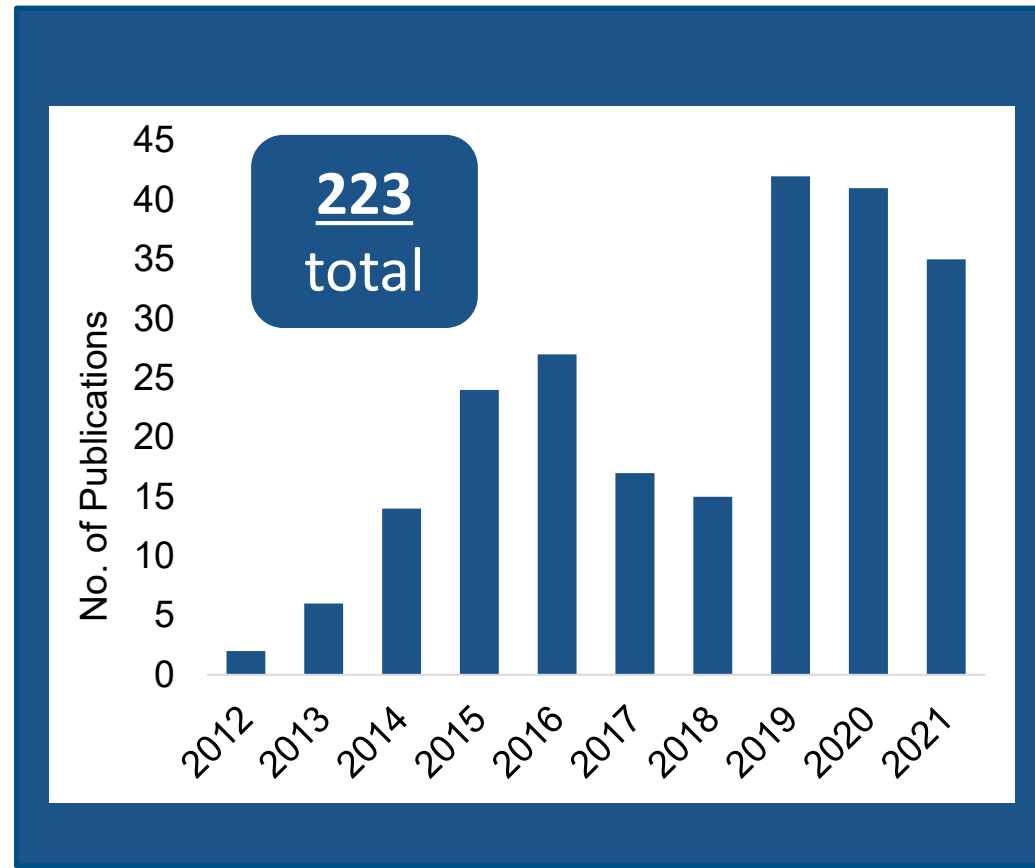
> 250

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

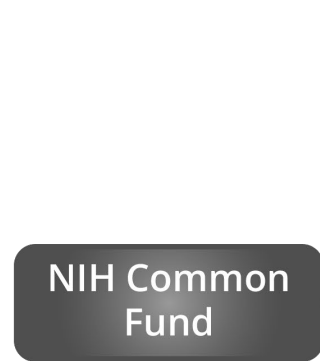


The path forward: Transition from Common Fund

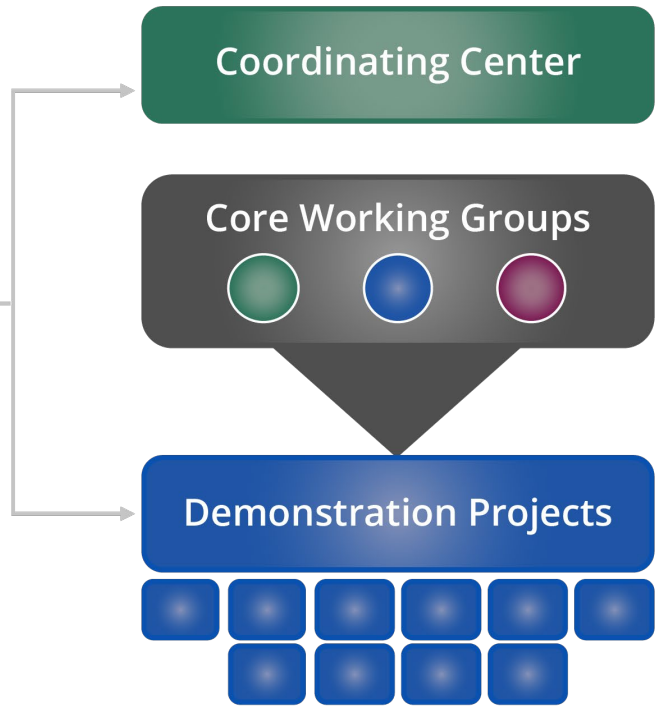


NIH HCS Structure: 2012-2017

FUNDING



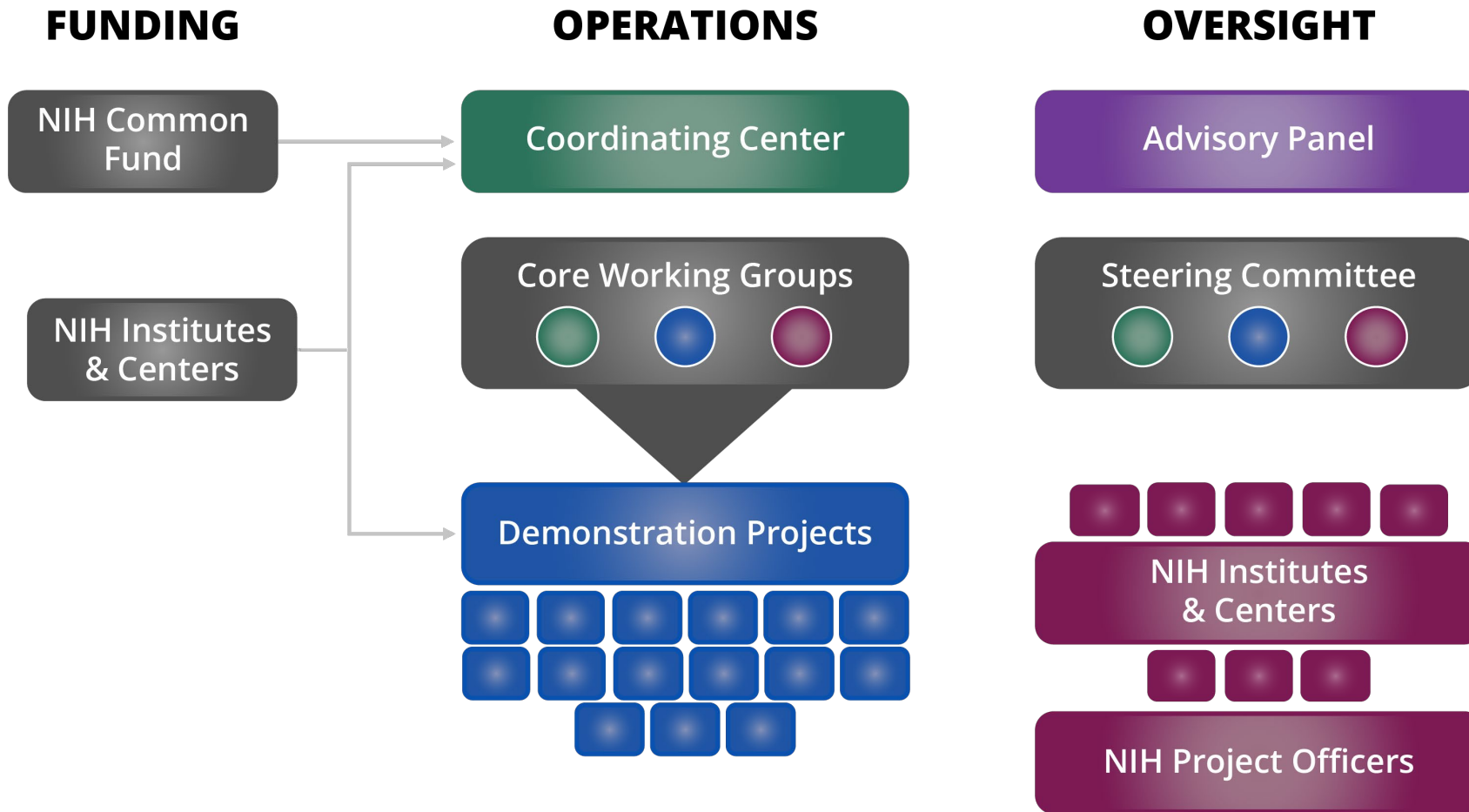
OPERATIONS



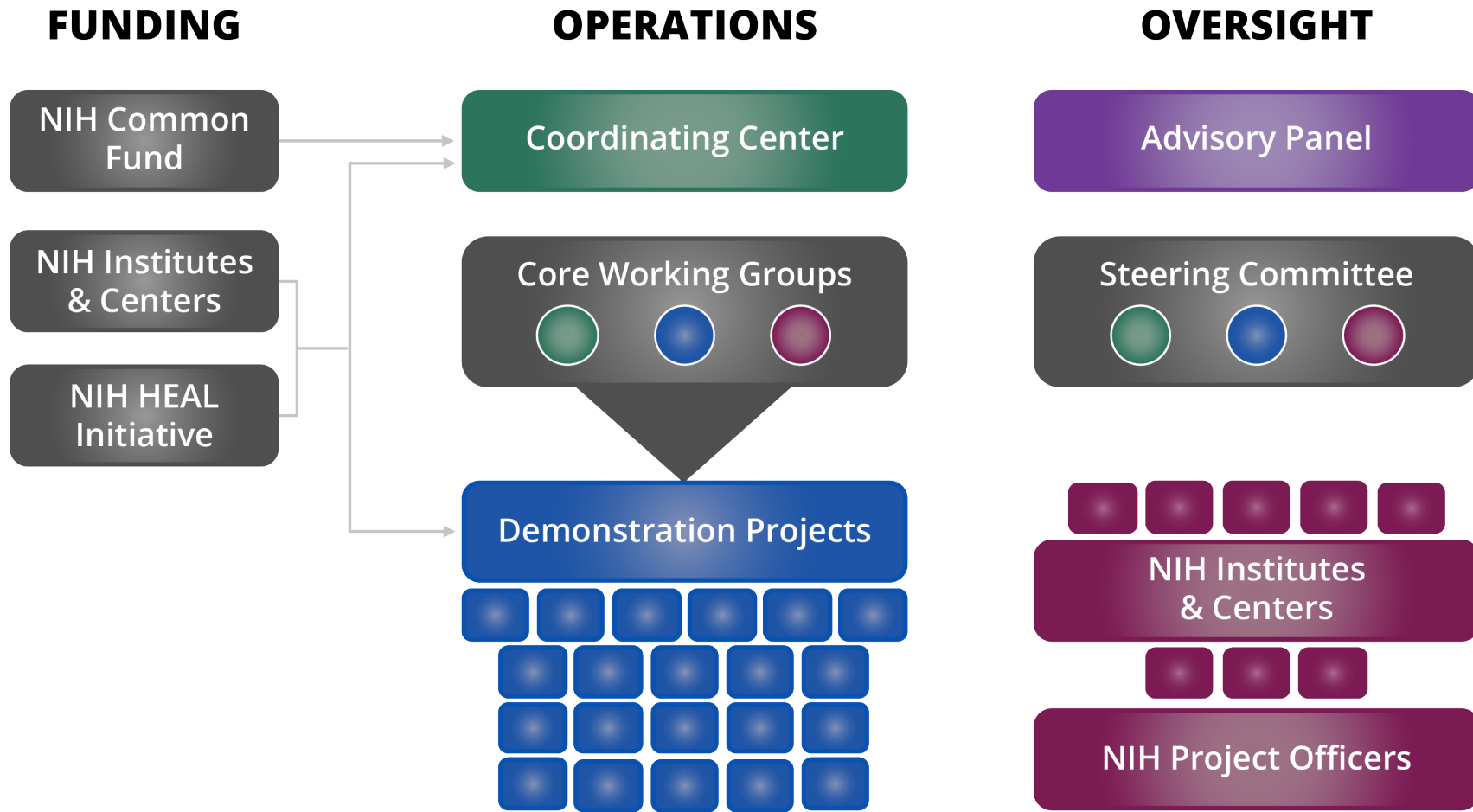
OVERSIGHT



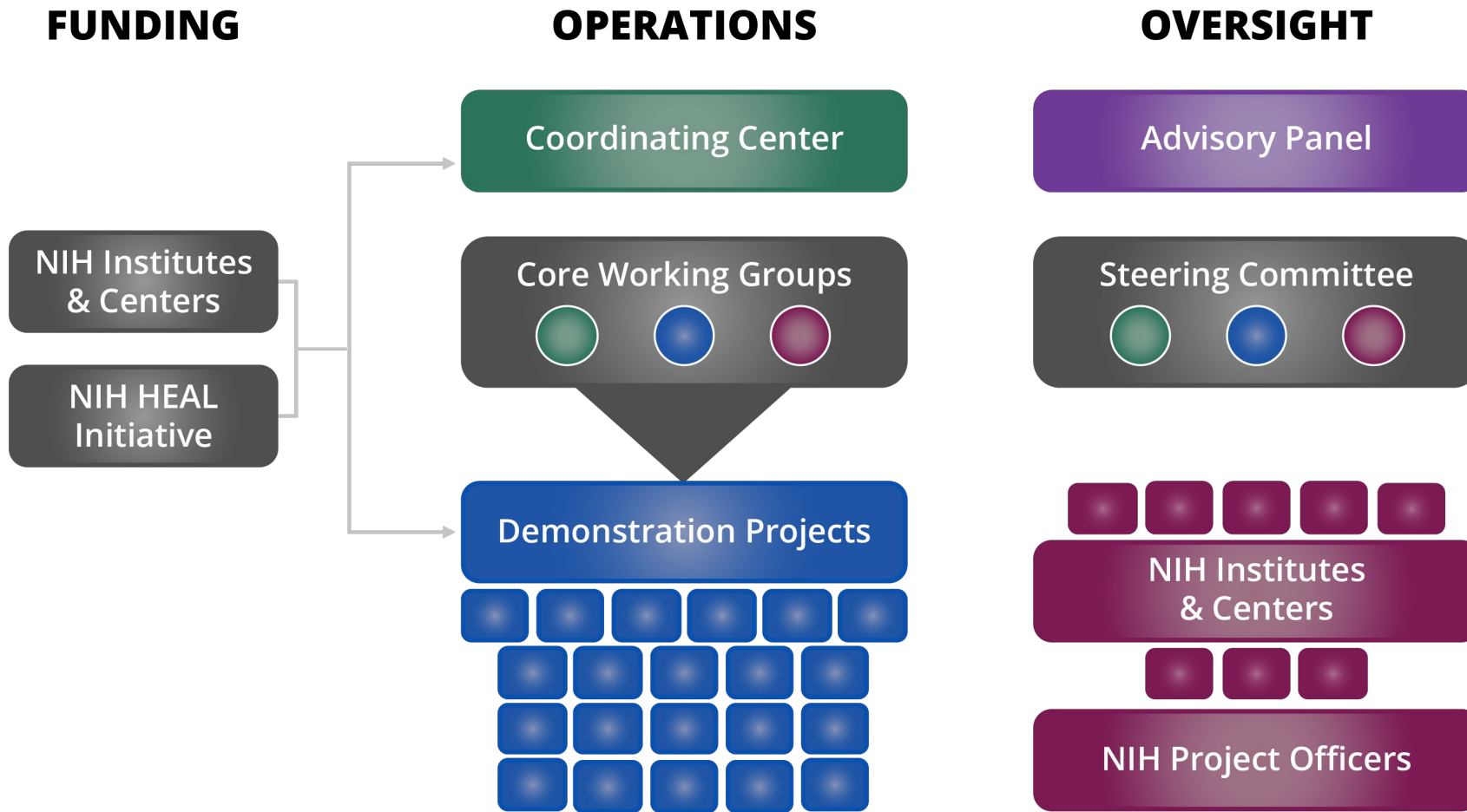
NIH HCS Structure: 2017-2019



NIH HCS Structure: 2019-2021



NIH PTC Structure: 2022 onward



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





Health Care Systems Research Collaboratory



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®



Pragmatic Trials Collaboratory- Post Common Fund

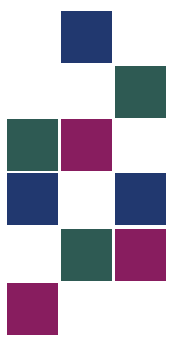
Current participating Institutes,
Centers and Offices



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





NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

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

