



NIH INITIATIVES FOR PRAGMATIC CLINICAL TRIALS

NIH Health Care Systems Research Collaboratory Steering Committee Meeting
May 15, 2018

Catherine Meyers, MD
NIH/NCCIH, Director, Office of Clinical & Regulatory Affairs





Common Fund Programs

Common Fund Research Funding

News & Media

Common Fund Highlights

About Common Fund


HCS Research Collaboratory

Common Fund » Common Fund Programs » HCS Research Collaboratory

HCS Research Collaboratory


For the Public

[Public Health Relevance](#)[Press Releases](#)[In the News](#)[Highlights](#)

Rethinking
Clinical Trials: A
Living Textbook of
Pragmatic Clinical
Trials 



HCS Collaboratory Website

Visit the [website](#)  maintained by the HCS Collaboratory

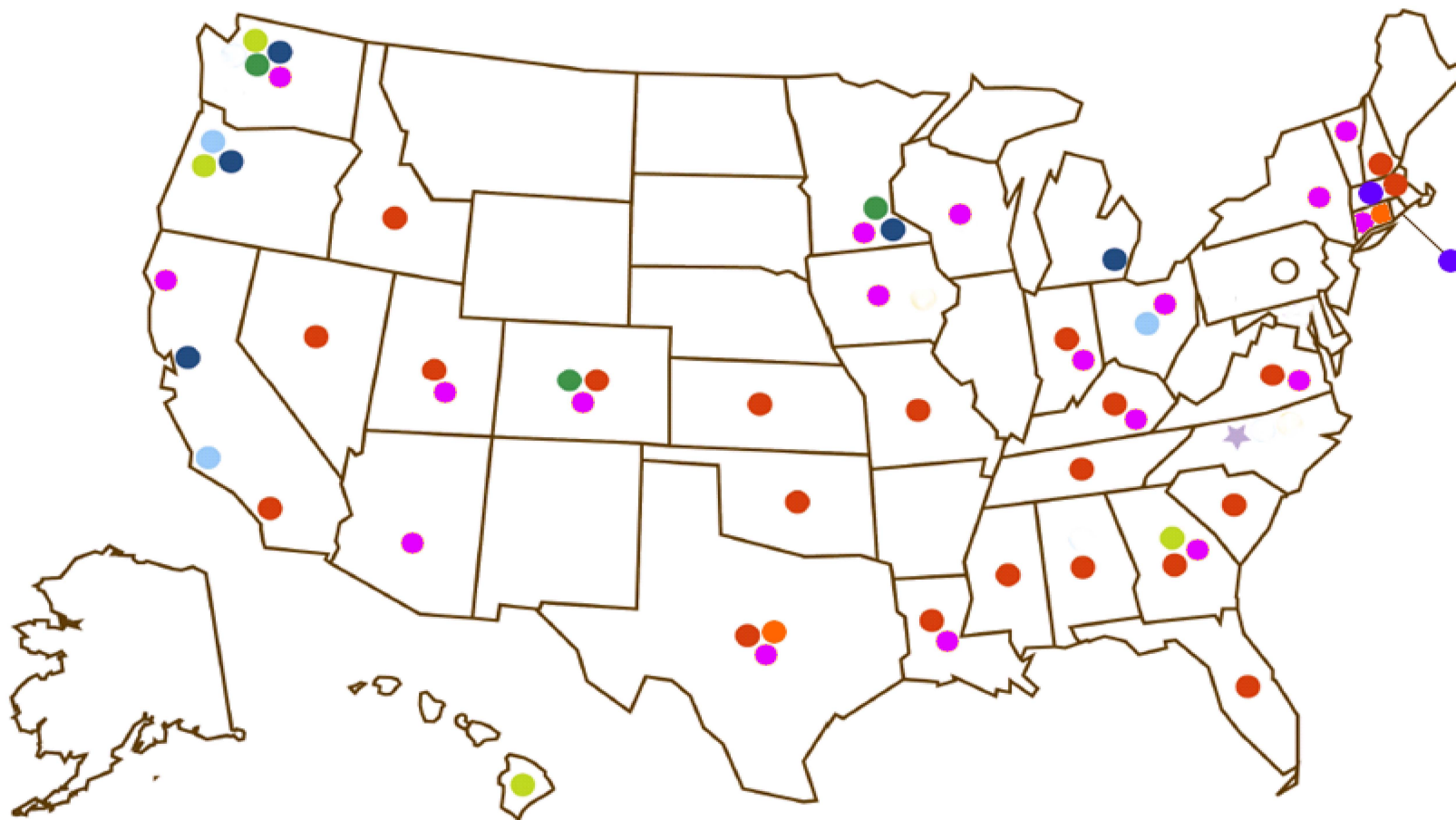


Coordinating Center for in-depth program information and access to program resources.

- **NIH Common Fund**
 - **Cross-Cutting**
 - **Unique**
 - **Transformative**
 - **Synergistic**
 - **Catalytic**



NIH Health Care Systems Research Collaboratory



- ★ Collaboratory Coordinating Center
- Suicide Prevention Outreach Trial (SPOT)
- Time to Reduce Mortality in End-Stage Renal Disease (TIME) (sites in dialysis units across the US)
- Trauma Survivors Outcomes & Support (TSOS)
- Lumbar Image Reporting and Epidemiology
- Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC)
- Collaborative Care for Chronic Pain in Primary Care (PRACT)
- Active Bathing to Eliminate Infections (ABATE)
- Improving Chronic Disease Management with Pieces (ICD-Pieces)
- Pragmatic Trial of Video Education in Nursing Homes (PROVEN) (sites in nursing homes across the US)





NIH Health Care Systems Research Collaboratory

- **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.



NIH INITIATIVES FOR PRAGMATIC CLINICAL TRIALS

Updates from:

- NCCIH
- NIA
- NCI
- NIMH
- NIDDK
- NIAMS
- NHLBI
- NIDA
- NHGRI





National Center for
Complementary and
Integrative Health

NIH...Turning Discovery Into Health

Información en Español

Health Info

Research

Grants & Funding

Training

News & Events

About NCCIH

Ongoing Studies

NIH-DoD-VA Pain Management Collaboratory (RFA-AT-17-001, -002)

Conduct efficient, large-scale pragmatic clinical trials on non-pharmacological approaches to pain management and other comorbid conditions in U.S. military personnel, veterans and their families. (UG3/UH3; U24)

Coordinating Center (Yale) & 6 NIH-supported projects (2017)

Many NIH ICO's co-funding projects

- **NIDA, NIAAA, NINDS, NICHD/NCMRR, NINR, ORWH, OBSSR**

Up to 5 VA, DoD projects (2018)



HEALTH INFORMATION	RESEARCH & FUNDING	NEWS & EVENTS	ABOUT NIA
--------------------	--------------------	---------------	-----------

Pragmatic Trials of Managing Multimorbidity in Alzheimer’s Disease (RFA-AG-17-059; RFA-AG-18-028)

Conduct pragmatic clinical trials assessing effectiveness of treatment strategies for comorbid conditions that occur frequently in combination with Alzheimer’s disease and related dementia. (R01)

2 awards (2017), 2-4 awards in 2018

Pragmatic Trials for Dementia Care in Long-term Services and Support Settings (RFA-AG-17-065; RFA-AG-18-585)

Address practical comparative questions faced by Alzheimer’s disease and related dementia patients, clinicians, and caregivers, include broad and diverse populations; and be conducted in real-world settings. (R21/R33)

2 awards (2017), 2-4 awards in 2018

[New Initiative Announced in January 2018!](#)

AD/ADRD Health Care Systems Research Collaboratory

The goal of the Alzheimer’s Disease and Alzheimer’s Disease-Related Dementias Health Care Systems Research Collaboratory is to bring together health systems, health insurance companies (e.g., managed care plans), home health care providers, and nursing homes systems for research to improve care.

<https://www.nia.nih.gov/es/node/28191#collaboratory>



Ongoing Studies

STRIDE Study – a cluster-randomized trial assessing interventions for falls prevention

Shed MEDS – a randomized-controlled trial testing interventions to reduce medication use in skilled nursing facilities

TRAIN-AD – a cluster-randomized trial evaluating a multicomponent intervention to improve infection management in nursing homes

Encouraging Appropriate Care Using Behavioral Economics through Electronic Health Records (RFA-AG-17-013)

PCTs that apply behavioral economics principles to build interventions into electronic health records for the purpose of improving physician compliance with recommended treatment guidelines, thereby improving quality of care, health outcomes and reducing health disparities. (R21/R33)

9 awards (2017), NIA & NIDA



Beau Biden Cancer MoonshotSM Initiative

Research Centers for Improving Management of Symptoms During and Following Cancer Treatment (RFA-CA-17-042, -043)

Promote research on the implementation and evaluation of integrated symptom monitoring and management systems for use in cancer care delivery. (UM1, U24)

3 Centers & Coordinating Center – 2018

Accelerating Colorectal Cancer Screening and follow-up through Implementation Science (ACCSIS) (RFA-CS-038, -039)

Promote research in colorectal cancer (CRC) screening, follow-up, and referral-to-care among target populations for whom screening rates are below national standards. (UG3/UH3, U24)

3 awards & Coordinating Center - 2018



Program Announcements that include PCT elements:

Intervening with Cancer Caregivers to Improve Patient Health Outcomes and Optimize Health Care Utilization (R01 Clinical Trial Optional) (PAR-18-246)

Improving Smoking Cessation in Socioeconomically Disadvantaged Populations via Scalable Interventions (R01 Clinical Trial Optional)(PAR-18-251)

Population Health Interventions: Integrating Individual and Group Level Evidence (R01 Clinical Trial Optional) (PA-18-385)



**Notice of Intent to Publish a Funding Opportunity
Announcement for A Practice-Based Research Network to
Transform Mental Health Care: Science, Service Delivery &
Sustainability (U19 Clinical Trial Required) NOT-MH-18-014**

To support a practice-based research network in the United States to transform the development, delivery, and sustainability of evidence-based mental health practices and services - Through a research consortium embedded within large and integrated healthcare delivery systems.

Ongoing Studies

Mental Health Network (U19) – CV Wizard Trial – Reducing CV risks in adults with serious mental illness via EMR-based clinical decision support.



Ongoing Studies

Applied Research Toward Zero Suicide Healthcare Systems (R01)

RFA-MH-16-800

To support applied research that advances the National Action Alliance for Suicide Prevention's "[Zero Suicide](#)" goal of preventing suicide events (attempts, deaths) among individuals receiving treatment within health care systems.

3 Awards (2016)

- ZERO SUICIDE IMPLEMENTATION AND EVALUATION IN OUTPATIENT MENTAL HEALTH CLINICS
- AN EVALUATION OF THE NATIONAL ZERO SUICIDE MODEL ACROSS LEARNING HEALTHCARE SYSTEMS
- A SYSTEM OF SAFETY: PREVENTING SUICIDE THROUGH HEALTHCARE SYSTEM TRANSFORMATION

Minerva Award (immediate practical utility for helping mental health patients)– The ED-SAFE Study. Suicide Prevention in an Emergency Department Population – JAMA Psychiatry. 2017 Jun 1;74(6):563-570



Pragmatic Research in Healthcare Settings to Improve Kidney Disease Prevention and Care (RFA-DK-17-008)

Test approaches to improve kidney disease prevention and/or treatment in routine healthcare settings.

3-4 awards in 2018 (R18)



Pragmatic Research in Healthcare Settings to Improve Diabetes and Obesity Prevention and Care (PAR-18-106)

Test innovative approaches to improve diabetes and obesity prevention and/or treatment that are adapted for implementation in healthcare settings where individuals receive their routine medical care.

1-2 Awards in 2018. Awards will be made in 2018-2020 (R18)

(Reissue of PAR 17-177, 1 award; PAR 15-157, 5 awards, PAR 13-366, 5 awards)



NIAMS Core Centers for Clinical Research

(RFA-AR-17-002)

These Resource-based Centers will provide clinical research needs at the institutional, local, and national level for musculoskeletal, rheumatologic, and skin diseases by fostering the development, implementation, and inclusion of novel data, analytical methods, metrics, and outcome measures into clinical research at the institutional, local, and national levels. Incorporation of metrics and methodologies that result from this FOA into new clinical research, trials, and ultimately patient care will be an important measure of short-and long-term success of a funded Core Center for Clinical Research. (P30)

Methodologic & Resource Cores for pragmatic clinical trials

Award made in 2017 to J. Jarvik, University of Washington





Ongoing Studies

Low-Cost, Pragmatic, Patient-Centered Randomized Controlled Intervention Trials (RFA HL-14-019, -020)

Plan and conduct low-cost, pragmatic randomized controlled trials (RCTs). Pragmatic RCTs seek to determine the effectiveness of an intervention in a real world setting. (UH2/UH3)

5 UH3 trials launched & Coordinating Center (R01) awarded (2015)

- Pragmatic Trial of Airway Management in Out-of-Hospital Cardiac Arrest
- Prevention of Severe Acute Respiratory Failure in Patients with PROOFCheck
- Pragmatic trial of behavioral interventions for insomnia in hypertensive patients
- Electroencephalograph Guidance of Anesthesia to Alleviate Geriatric Syndromes
- Default palliative care consultation for seriously ill hospitalized patients





[Ongoing Investigator-Initiated Trials](#)

**TRANSFORM-HF: ToRsemide compArison With furoSemide
FORManagement of Heart Failure. Duke University**

**INVESTED: INfluenza Vaccine to Effectively Stop Cardio Thoracic
Events and Decompensated Heart Failure (PCORI) – Brigham &
Women's, U. Wisconsin**





Pilot Health Services and Economic Research on the Treatment of Drug, Alcohol, and Tobacco Use Disorders (R34 Clinical Trial Optional) PA-18-774

To support pilot and preliminary research in preparation for larger-scale services research effectiveness trials. Relevant trials may test a wide range of approaches, including interventions, practices, and policies designed to optimize access to, and the quality, effectiveness, affordability and utilization of drug, tobacco, or alcohol use disorder treatments and related services, as well as services for comorbid medical and mental disorder conditions.





Implementing Genomics in Practice (IGNITE) II: Pragmatic Clinical Trials (RFA-HG-17-008, -009, -010)

Conduct pragmatic clinical trials to measure the clinical utility and cost-effectiveness of genomic medicine interventions; assess approaches for real-world application of genomic medicine in diverse clinical settings; and produce generalizable knowledge on the types of genomic medicine interventions requiring randomized clinical trials and effective methods for conducting them. (Enhanced population diversity in -009)

2-3 awards for each PCT RFA & 1 Coordinating Center (U01)

Awards will be made in 2018



Opportunities for The Collaboratory 2012

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

Integrate 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



Opportunities for Pragmatic Clinical Trials 2018

- **Third set of Collaboratory Demonstration Projects**
- **Multiple NIH Institutes, Centers & Offices**
- **NIH Scientific Contacts for PCTs posted on Collaboratory Website**
- **Challenges remain**
 - **Electronic Health Records**
 - **Regulatory/Ethical Oversight**
 - **Data Sharing**
 - **Therapeutic A vs B Interventions**



QUESTIONS?

