NIH Pragmatic Trials Collaboratory

Enabling pragmatic clinical trials embedded in healthcare systems
The NIH Collaboratory Story

**History:** Initiated through the NIH Common Fund in 2012
Selected as the Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) Resource Coordinating Center in 2019

**Goal:** Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners

**Vision:** Support the design and execution of innovative pragmatic clinical trials to establish best practices and proof of concept
Embedded PCTs Bridge Research Into Clinical Care

- Study designed with input from health system stakeholders
- Intervention incorporated into routine clinical workflow
- Data collected through EHR in healthcare settings
- Outcomes important to decision-makers
- Diverse, representative study populations

Outcomes important to decision-makers
The NIH Collaboratory began as an NIH Common Fund-initiated program. It includes centralized operational support for its pragmatic trials from a Coordinating Center and its Core Working Groups.
Starting in 2017, individual NIH Institutes and Centers began providing funding for NIH Collaboratory Trials and the Coordinating Center, along with the Common Fund.
NIH Collaboratory Structure: 2019-2021

- Starting in 2019, the NIH HEAL Initiative began providing some Coordinating Center and NIH Collaboratory Trial funding, in addition to existing funding mechanisms.
Collaboratory Structure: 2022-Present

- Starting in 2022, the program is entirely funded by the NIH HEAL Initiative, along with individual NIH Institutes and Centers.
NIH Collaboratory Trials

- Pragmatic trials embedded in healthcare systems to address questions of major public health importance
- Trials span multiple NIH Institutes, Centers, and Offices
- Most have a 1-year planning phase (UG3) followed by implementation phase (UH3)
Core Working Groups

- Component of Coordinating Center focusing on key areas
- Each led by Chair(s) from Coordinating Center
- Include representatives from
  - NIH Collaboratory Trials
  - NIH
Core Working Groups: Purpose

- Guide and support NIH Collaboratory Trials
- Disseminate knowledge
  - Guidance
  - Lessons learned
Biostatistics and Study Design Core

Co-Chairs

Patrick Heagerty, PhD
Elizabeth L. Turner, PhD

Mission

- Provide expertise in study design and biostatistics to the NIH Collaboratory Trials, particularly in novel designs and methods for embedded PCTs
- Document new statistical and methodological issues that arise, and share knowledge through case studies
- Identify areas in need of methods development, and work to address these challenges
Electronic Health Records Core

Co-Chairs

Rachel Richesson, PhD, MPH
Keith A. Marsolo, PhD

Mission

- Help the NIH Collaboratory Trials acquire, assess, and use real-world data for pragmatic research
- Act as the key repository for the tools and infrastructure we create to leverage EHRs to support clinical research across multiple health systems
- Identify ideas and lessons that might be generalizable and share them broadly
Core

Chair
Greg Simon, MD, MPH

Mission
- Engage those involved in healthcare delivery systems to:
  - Participate in research
  - Facilitate the design and conduct of research protocols attractive to practitioners
  - Lower administrative barriers
  - Communicate results to all parties
- Facilitate collaborative learning across the NIH Collaboratory Trials, synthesize lessons learned, and create real-world generalizable knowledge about PCTs
Health Equity Core

Co-Chairs

- Rosa Gonzalez-Guarda, PhD, MPH, RN, CPH, FAAN
- Cherise Harrington, PhD, MPH

Mission

- Develop guidance for PCTs on how to integrate a health equity lens, including:
  - Considerations for enrollment
  - Strategies for selecting outcomes
  - Tailored research methods that better suit the study population
- Document barriers to the integration of a health equity lens in pragmatic research
- Develop strategies and tools to facilitate a health equity lens in PCTs
Patient-Centered Outcomes Core

Co-Chairs

Christy Zigler, PhD, MSEd
Emily C. O’Brien, PhD

Mission

- Creates guidelines and defines best practices with respect to:
  - Selecting, compiling, and curating the most appropriate PRO measures
  - Stimulating the development of new instruments when needed
  - Creating efficient, high-quality PRO data collection systems compatible with EHRs and registries
- Identify ideas and lessons that might be generalizable and share them broadly
Ethics and Regulatory Core

Co-Chairs

Jeremy Sugarman, MD
Pearl O’Rourke, MD
Stephanie Morain, PhD, MPH

Mission

- Identify areas of regulatory and ethical uncertainty
- Help NIH Collaboratory Trials navigate regulatory and ethical complexities affecting PCTs
- Develop policies and practices to provide a framework for the ethical conduct of health systems research in compliance with relevant regulations
Implementation Science Core

Co-Chairs

Devon Check, PhD
Hayden Bosworth, PhD

Mission

- Support NIH Collaboratory Trials in achieving their implementation-related research aims
- Promote the uptake and sustainability of NIH Collaboratory Trial interventions that have proven effective in routine practice
- Provide guidance on de-implementation of interventions when necessary
- Produce guidance and best practices for conducting implementation research as part of ePCTs
Reach of NIH Collaboratory Trials

>1,100 clinical sites and >940,000 participants

49 US States
and Puerto Rico

No sites in Arkansas
## Completed NIH Collaboratory Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABATE</td>
<td>Non-ICU patients</td>
<td>Decolonization strategies</td>
<td>MRSA and VRE clinical cultures</td>
</tr>
<tr>
<td>EMBED</td>
<td>Patients with opioid use disorder</td>
<td>User-centered computerized clinical decision support</td>
<td>Rate of emergency department–initiated buprenorphine/naloxone; referral for ongoing medication assisted treatment</td>
</tr>
<tr>
<td>ICD-Pieces</td>
<td>Comorbid diabetes, chronic kidney disease, hypertension</td>
<td>Collaborative primary care program</td>
<td>All-cause hospitalizations for 3 conditions</td>
</tr>
<tr>
<td>LIRE</td>
<td>Low back pain</td>
<td>Insertion of epidemiologic benchmarks in lumbar spine imaging reports</td>
<td>Relative value unit for spine-related interventions</td>
</tr>
<tr>
<td>PPACT</td>
<td>Nonmalignant chronic pain</td>
<td>Multidisciplinary behavioral care management</td>
<td>Brief Pain Inventory</td>
</tr>
<tr>
<td>PROVEN</td>
<td>Nursing home residents</td>
<td>Advance care planning video (behavioral program)</td>
<td>Hospitalizations; presence of advance directives</td>
</tr>
<tr>
<td>SPOT</td>
<td>Suicidal ideation or depression</td>
<td>Collaborative care behavioral program (care management &amp; skills training)</td>
<td>Suicide attempts</td>
</tr>
</tbody>
</table>
## Completed NIH Collaboratory Trials (cont)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOP CRC</td>
<td>Adults aged 50-75 years</td>
<td>Direct mail colorectal cancer (CRC) screening program (FIT kit)</td>
<td>CRC screening rates</td>
</tr>
<tr>
<td>TiME</td>
<td>Patients initiating dialysis</td>
<td>Dialysis session of at least 4.25 hours</td>
<td>All-cause mortality, hospitalization</td>
</tr>
<tr>
<td>TSOS</td>
<td>Traumatic injury</td>
<td>Collaborative care management program</td>
<td>PTSD checklist; PHQ-9 scale; alcohol use disorders; SF-12/36</td>
</tr>
</tbody>
</table>
## UG3 NIH Collaboratory Trials (Planning)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEST-ICU</td>
<td>Critically ill adults</td>
<td>Strategies to increase adoption of the ABCDEF bundle, a mechanical ventilation liberation and symptom management approach</td>
<td>Implementation (primary) and clinical (secondary) effectiveness outcomes</td>
</tr>
<tr>
<td>Chat 4 Heart Health</td>
<td>Patients from Federally Qualified Health Centers with sub-optimal control of their cardiovascular (CV) risk factors</td>
<td>Multilevel intervention leveraging cellphone-based text messages</td>
<td>Global CV health and control of CV risk factors (e.g., hypertension, diabetes)</td>
</tr>
<tr>
<td>I CAN DO Surgical ACP</td>
<td>Older adults undergoing major elective survey</td>
<td>Patient-facing advance care planning (ACP) tool</td>
<td>ACP completion rates and patient engagement with ACP</td>
</tr>
<tr>
<td>TAICHIKNEE</td>
<td>Patients with knee pain due to osteoarthritis</td>
<td>Remotely delivered web-based Tai Chi intervention</td>
<td>Physical health (including knee-related pain and function), mental health, and healthcare utilization</td>
</tr>
</tbody>
</table>
## R01 NIH Collaboratory Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPATH</td>
<td>Patients with type 2 diabetes from health disparity populations</td>
<td>Multi-level, multi-component, technology-enabled practice transformation strategy</td>
<td>Reduction in patients with poorly controlled diabetes (A1c&gt;9%) at 12 and 24 months</td>
</tr>
<tr>
<td>MOMs Chat &amp; Care</td>
<td>Black birthing people</td>
<td>Integrated care model approach at 2 different levels of intensity, high or low</td>
<td>Incidence of severe maternal morbidity at time of labor and delivery and related hospital admissions at 1-month and 1-year postpartum</td>
</tr>
</tbody>
</table>
## UH3 NIH Collaboratory Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACP PEACE</td>
<td>Patients with advanced cancer</td>
<td>Clinician communication skills training and patient video decision aids for advanced care planning</td>
<td>Advance care plans completion; medical orders for resuscitation preferences; palliative care consultations; hospice use</td>
</tr>
<tr>
<td>GGC4H</td>
<td>Parents of early adolescents</td>
<td>Anticipatory guidance curriculum</td>
<td>Behavioral health problems; health service utilization</td>
</tr>
<tr>
<td>HiLo</td>
<td>Patients undergoing hemodialysis</td>
<td>Liberalizing serum phosphate target</td>
<td>Rate of hospitalization</td>
</tr>
<tr>
<td>IMPACT-LBP</td>
<td>Adults with low back pain</td>
<td>Primary Spine Practitioner (PSP) Model using doctors of chiropractic and physical therapists as first-line providers</td>
<td>Improve physical function, decrease pain, decrease opioid prescriptions, improve patient satisfaction, and decrease costs and utilization of healthcare services when compared with usual medical care</td>
</tr>
<tr>
<td>INSPIRE</td>
<td>Non–critically ill hospitalized patients with abdominal infections or skin and soft tissue infections</td>
<td>Predictive algorithm integrated into the computerized provider order entry system, plus audit and feedback</td>
<td>Reduction in prescribing of unnecessary extended-spectrum antibiotics while maintaining good clinical outcomes as measured by length of stay and transfer to an intensive care unit</td>
</tr>
</tbody>
</table>
## UH3 NIH Collaboratory Trials (cont)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nudge</td>
<td>Patients with chronic CV conditions</td>
<td>Text messages and chat bot</td>
<td>Adherence to CV medications</td>
</tr>
<tr>
<td>PRIM-ER</td>
<td>Older adults (&gt;65 years)</td>
<td>Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback</td>
<td>Healthcare utilization and survival</td>
</tr>
</tbody>
</table>
PRISM Trials

- Embedded PCTs of non-opioid interventions for treating pain, improving pain management, and reducing reliance on opioids

- Aim: Improve availability of, effectiveness of, and adherence to evidence-based, nonpharmacologic pain management

- Funded by NIH HEAL Initiative®
  - Supports a wide range of programs to develop new or improved prevention and treatment strategies for opioid addiction
# UG3 PRISM Trials (Planning)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIM-CP</td>
<td>Rural-dwelling patients with chronic pain</td>
<td>Nurse care management model incorporating care coordination, cognitive behavioral therapy, and a remotely delivered exercise program</td>
<td>Pain interference, physical functioning, mental health, treatment satisfaction, sleep, pharmacologic treatments, and healthcare utilization</td>
</tr>
<tr>
<td>ARBOR-Telehealth</td>
<td>Rural-dwelling patients with chronic low back pain</td>
<td>Risk-stratified telerehabilitation model</td>
<td>Change in low back pain-related disability and opioid use after 8 weeks</td>
</tr>
<tr>
<td>RAMP</td>
<td>Rural-dwelling Veterans with chronic pain</td>
<td>Telehealth intervention with multiple evidence-based complementary and integrative health approaches for chronic pain</td>
<td>Pain interference at 13 and 26 weeks; opioid use</td>
</tr>
</tbody>
</table>
# UH3 PRISM Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BackInAction</strong></td>
<td>Older adults with low back pain</td>
<td>Standard and enhanced 12-week courses of acupuncture</td>
<td>Back-related function at 26 weeks; cost-effectiveness</td>
</tr>
<tr>
<td><strong>BeatPain Utah</strong></td>
<td>Adults with back pain in federally qualified health centers in Utah</td>
<td>Brief pain teleconsult and phone-based physical therapy</td>
<td>Pain management; reduction of disparities; evaluation of implementation strategies</td>
</tr>
<tr>
<td><strong>FM-TIPS</strong></td>
<td>Fibromyalgia</td>
<td>Addition of transcutaneous electrical nerve stimulation (TENS) to physical therapy</td>
<td>Fibromyalgia symptoms; adherence to therapy; meeting therapeutic goals; medication use</td>
</tr>
<tr>
<td><strong>GRACE</strong></td>
<td>Patients with sickle cell disease</td>
<td>Acupuncture and guided relaxation</td>
<td>Pain control; effective treatment sequence; evaluation of implementation strategies</td>
</tr>
<tr>
<td><strong>NOHARM</strong></td>
<td>Postoperative pain</td>
<td>EHR-embedded tools to aid shared decision making about pain management</td>
<td>Postoperative opioid use, pain, function</td>
</tr>
<tr>
<td><strong>OPTIMUM</strong></td>
<td>Chronic low back pain</td>
<td>Group-based mindfulness in outpatient clinical settings</td>
<td>Pain, physical, and psychological function; opioid prescriptions for chronic low back pain</td>
</tr>
</tbody>
</table>
NIH Collaboratory Trial Resources

Publications, Presentations & Study Snapshots available on the NIH Collaboratory Trial pages of the Living Textbook
Data and Resource Sharing

- Completed trials expected to share data and resources publicly
  - Study tools
  - Datasets and documentation
- Materials added to NIH Collaboratory website at trial closeout

rethinkingclinicaltrials.org/data-and-resource-sharing/
Flow of Information

NIH Collaboratory Trials

- Core Working Groups
- Teleconferences
- Steering Committee Meetings
- Partner Organizations

Lessons

- Living Textbook & Knowledge Repository
- Grand Rounds, Presentations & Social Media
- Guidance Documents & Journal Publications
Partner Organizations

- Grand Rounds
  - Shared NIH Collaboratory–PCORnet forum
  - Frequent presentations by partner organizations

- Collaboration on
  - Workshops
  - Publications
  - Living Textbook

- Share knowledge, tools, and resources
Distributed Research Network

- Enables investigators to collaborate in the use of electronic health data while safeguarding protected health information.
Living Textbook of Pragmatic Clinical Trials

- Comprehensive resource for PCTs
- Content organized around Design, Conduct, Dissemination, and Ethics and Regulatory collections
- Authors from NIH Collaboratory Trials, Cores, and partners
- Continuously updated

rethinkingclinicaltrials.org
The impact of COVID-19 on pragmatic clinical trials: lessons learned from the NIH Health Care Systems Research Collaboratory

Abstract

Background: The COVID-19 pandemic has considerably disrupted nearly all aspects of daily life, including health care delivery and clinical research. Pragmatic clinical trials and other types of non-idealized clinical research have been particularly affected by the pandemic. This supplement includes a collection of qualitative data on the challenges and opportunities for pragmatic trials during the COVID-19 pandemic.

Methods: A qualitative study of all the COVID-19 related qualitative data available to the National Institutes of Health (NIH) Health Care Systems Research Collaboratory. The study includes questions on the impact of COVID-19 on the conduct of pragmatic clinical trials.

Results:

- Addressing guideline and policy changes during pragmatic clinical trials
- Disseminating trial results: We can have both faster and better trials
- Is learning worth the trouble? -- Improving Health Care System Participation in Embedded Research

- Rethinking Clinical Trials

Guidance Documents


An evaluation of constrained randomization for the design and analysis of group-randomized trials

Fan LF, Yuliya Lohknygina, David M. Murray, Patrick J. Heagerty and Elizabeth R. DeLong

JAMA

The Journal of the American Medical Association
Weekly webinars on a wide range of research topics
- Open to the public
- >500 presentations to date
- Average 250 attendees/session
- Timely, high-interest topics
- Feature NIH Collaboratory work and beyond

Podcasts of featured expert interviews
Training Resources

rethinkingclinicaltrials.org/training-resource/

- Learning modules
- Educational video library
- Resources (handouts, checklists, guides, etc.)
- Workshop materials (slides, recordings, etc.)
- Upcoming opportunities
Newsletter & Social Media

- Subscribe to this convenient monthly email wrap-up:
  - [rethinkingclinicaltrials.org/newsletter-subscribe/](rethinkingclinicaltrials.org/newsletter-subscribe/)

Follow us!

- [https://www.linkedin.com/company/nih-pragmatic-trials-collaboratory/](https://www.linkedin.com/company/nih-pragmatic-trials-collaboratory/)

- [@Collaboratory1](https://twitter.com/Collaboratory1)
Appendix: NIH Collaboratory Trials
ABATE Active Bathing to Eliminate Infection

- Cluster trial comparing 2 quality improvement strategies to reduce multidrug-resistant organisms and healthcare-related infections in non-ICU population
- 53 hospitals
- 331,584 patients
EMBED Pragmatic Trial of User-Centered Clinical Decision Support to Implement Emergency Department-Initiated Buprenorphine for Opioid Use Disorder

- Cluster trial testing the effect of user-centered computerized clinical decision support on rates of emergency department–initiated buprenorphine/naloxone and referral for ongoing medication-assisted treatment in patients with opioid use disorder

- 3 health systems

- 5,047 patients
ICD-Pieces  Improving Chronic Disease Management with Pieces™

- Novel platform to test effective ways to reduce heart problems, hospitalizations & deaths in patients with multiple chronic conditions
  - 94 clinical sites
  - 11,000 patients

Completed Trial
LIRE Lumbar Imaging with Reporting of Epidemiology

- Cluster trial evaluating whether inserting epidemiologic benchmarks into lumbar spine imaging reports reduces subsequent tests and treatments
  - 98 clinical sites
  - 246,289 patients

Completed Trial
**PPACT** Collaborative Care for Chronic Pain in Primary Care

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

Completed Trial
**PROVEN** Pragmatic Trial of Video Education in Nursing Homes

- Evaluating the **effectiveness of advance care planning video** shown in nursing homes of 2 large healthcare systems
  - 359 nursing homes
  - 211,469 patients
SPOT Suicide Prevention Outreach Trial

- Collaborative care model to test treatments intended to reach large groups of adult patients who have serious thoughts of suicide

- 4 clinical sites

- 18,644 patients
STOP CRC Strategies and Opportunities to Stop Colorectal Cancer

- Cluster trial testing a culturally tailored, healthcare system–based program to improve CRC screening rates in community-based collaborative network
- 30 clinical sites
- 62,155 patients
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
TSOS  Trauma Survivors Outcomes and Support

- Stepped-wedge cluster trial testing innovative intervention for patients with PTSD and comorbidity
- 25 level 1 trauma centers
- 960 patients
BEST-ICU  
**Behavioral Economic and Staffing Strategies to Increase Adoption of the ABCDEF Bundle in the ICU**

- 3-arm stepped-wedge, cluster-randomized trial to evaluate 2 strategies grounded in behavioral economic and implementation science theory to **increase adoption of the ABCDEF bundle**, a mechanical ventilation liberation and symptom management approach, in critically ill adults
- 12 ICUs from 3 safety net hospitals
- 8,100 expected patients
Chat 4 Heart Health Using Artificially Intelligent Text Messaging Technology to Improve AHA’s Life’s Essential 8 Health Behaviors

- Patient-level randomized trial to evaluate the implementation and effectiveness of 3 different automated patient communication approaches for self-management support to improve control of cardiovascular disease risk factors
- Federally Qualified Health Centers in 3 health systems
- 6,000 expected patients
I CAN DO Surgical ACP  Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning

- Patient-level randomized trial to evaluate a system-based approach to help older adults undergoing elective surgery engage in advance care planning
- 3 health systems
TAICHIKNEE Remote Tai Chi for Knee Osteoarthritis: an Embedded Pragmatic Trial

- Compare the effects of a remotely delivered web-based Tai Chi intervention versus routine care for patients with knee pain due to osteoarthritis
- 20-25 clinics across 4 health systems
- 600 expected patients

UG3 Trial
Implementing Scalable, Patient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities

- Hybrid type 2 effectiveness implementation study, including a stepped-wedge cluster randomized trial
- Evaluating whether an innovative multi-level, multi-component, technology-enabled practice transformation strategy can improve outcomes for patients with type 2 diabetes from health disparity populations
- 8 federally qualified health centers
MOMs Chat & Care Maternal Outcomes Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity

- Testing the effectiveness of an integrated care model approach at 2 different levels of intensity to facilitate timely, appropriate care for high-risk Black birthing people and reduce risk for severe maternal morbidity
- Largest healthcare provider in New York
- 674 expected patients

R01 Trial
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
GGC4H  Guiding Good Choices for Health

- Cluster trial testing whether an anticipatory guidance curriculum for parents of early adolescents will reduce behavioral health problems and health service utilization
- 3 health systems
- 72 pediatricians and 4,500 families expected
HiLo Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis

- Cluster trial testing whether less stringent control of serum phosphate levels will yield noninferior rates of all-cause hospitalization in patients with end-stage renal disease undergoing hemodialysis
- >100 dialysis facilities
- 4,400 expected patients
IMPACt-LBP  Implementation of the American College of Physicians Guideline for Low Back Pain

- Refine and implement a multidisciplinary collaborative care model for low back pain
- Evaluate the effectiveness of this care model compared to usual medical care for low back pain
- 3 academic healthcare systems
INSPIRE  INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients

- 2 cluster randomized trials using personalized clinical decision support to improve judicious antibiotic prescribing for non–critically ill patients hospitalized with abdominal infections or skin and soft tissue infections

- 90,000 expected patients
Nudge  Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications

- Patient-level randomized pragmatic trial comparing the effects of digital interventions (text messages and chatbot) on medication adherence in patients with chronic cardiovascular conditions
- 3 health systems
PRIM-ER Primary Palliative Care for Emergency Medicine

- Cluster trial testing the effects of implementing primary palliative care in emergency medicine on **healthcare utilization and survival**
- 35 emergency departments across 18 health systems
AIM-CP Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain

- Adapting and test a **nurse care management model** to provide comprehensive coordinated care for patients with chronic pain in rural communities
- 6 health systems
- 416 expected patients
ARBOR-Telehealth: Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth

- Comparing the effectiveness of a risk-stratified telerehabilitation model to improve outcomes in patients with chronic low back pain in rural communities
- Primary care clinics in Maryland
- 434 expected patients
BackInAction  Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults

- Evaluating the **safety and effectiveness of acupuncture** in older adults with chronic low back pain
- 4 performance sites
- 828 expected patients
BeatPain Utah  Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics

- Testing the feasibility of a telehealth strategy that provides a brief pain teleconsult along with phone-based physical therapy
- Federally Qualified Health Centers in Utah
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
GRACE Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain

- Testing the effectiveness of **guided relaxation and acupuncture** to improve pain control and determine the most appropriate and effective treatment sequence for **patients with sickle cell disease pain**
- 3 health systems
NOHARM Nonpharmacologic Options in Postoperative Hospital-based and Rehabilitation Pain Management

- Testing the feasibility of EHR-embedded patient- and clinician-facing decision support for non-pharmacologic pain care after surgery
- 4 health systems
OPTIMUM  Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting

- Evaluating effectiveness of a **group-based mindfulness intervention** for patients with chronic low back pain in a usual care setting
- 3 health systems
- 450 expected patients
RAMP  Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention

- Hybrid type 2 effectiveness-implementation trial evaluating a telehealth intervention with multiple evidence-based complementary and integrative health approaches for chronic pain
- VA health system
- 500 expected patients (rural-dwelling Veterans)