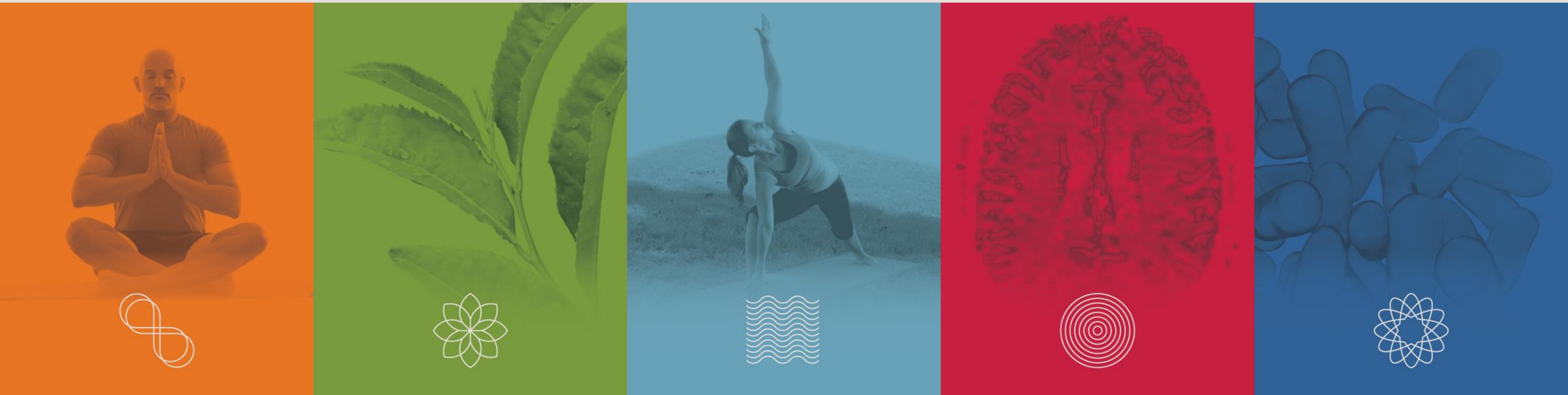




NIH HEAL Initiative Plans for Pragmatic Clinical Trials

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NIH • Helping to End Addiction Long-term

The Response: Helping to End Addiction Long-term (HEAL) Initiative

- Trans-NIH research initiative to:
 - Improve prevention and treatment strategies for opioid misuse and addiction
 - Enhance pain management
- Goals are scientific solutions to the opioid crisis
- Coordinating with the HHS Secretary, Surgeon General, federal partners, and local government officials and communities

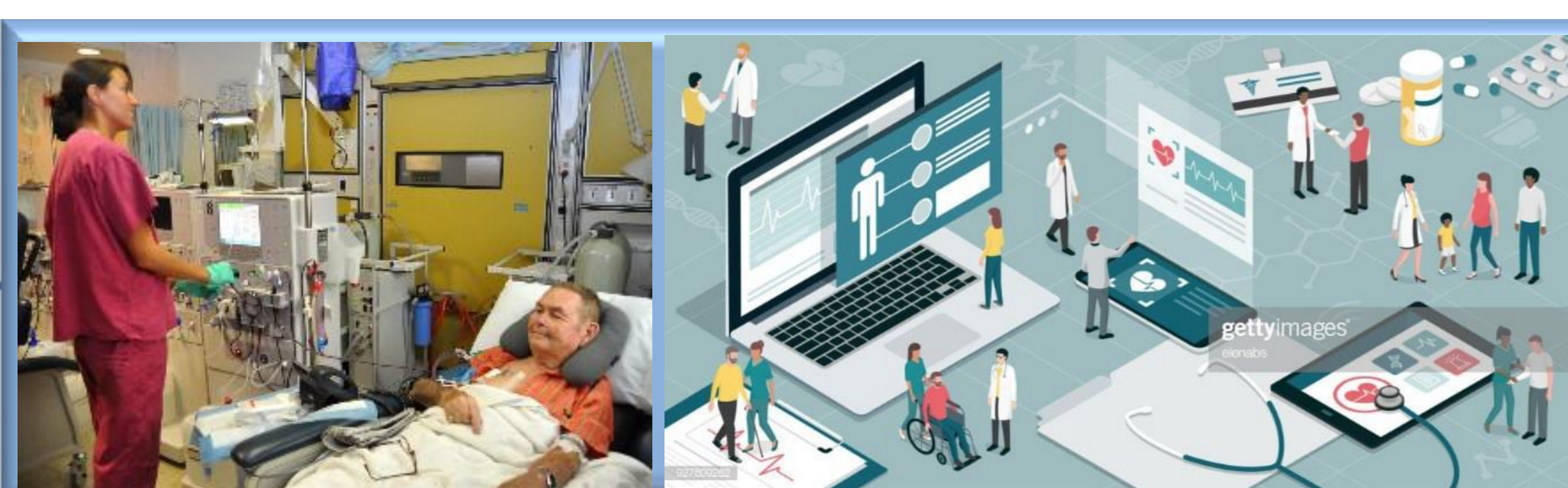


Helping to End Addiction Long-term (HEAL) Initiative: At a glance

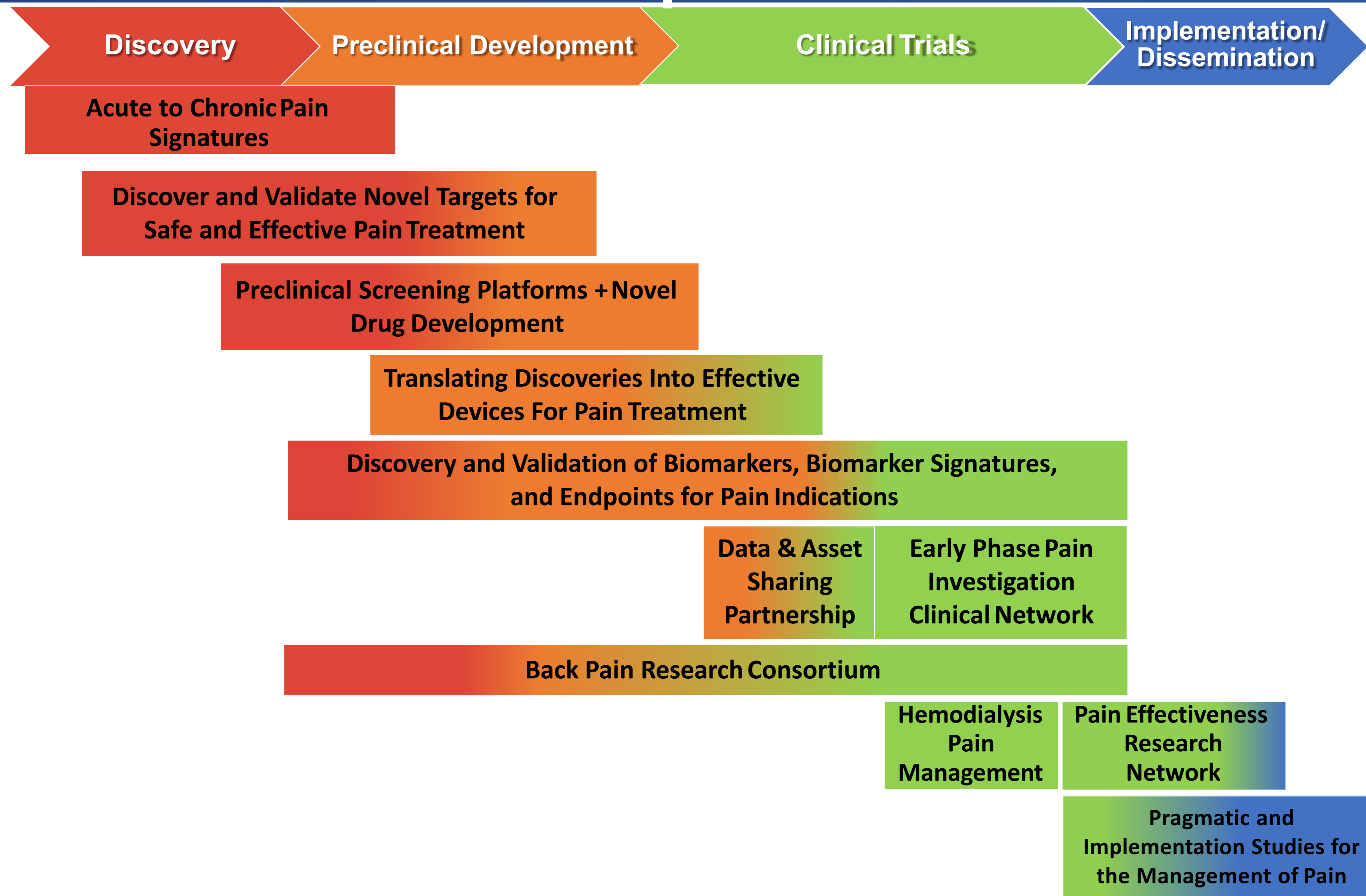
- \$500M/year Trans-NIH effort
 - Over \$850M to be obligated in FY2019
- 12 NIH Institutes and Centers leading 26 HEAL research projects
 - Over 20 collaborating Institutes, Centers, and Offices
 - From prevention research to basic and translational research, clinical trials, and implementation science
 - Multiple projects integrating research into new settings
 - e.g. health care, criminal justice, Medicare populations etc.
- Released 40+ funding announcements for FY2019

Enhancing Pain Management

- Advance effective treatments for pain through clinical research
 - Test novel treatments in a new clinical trials network
 - Early Phase Pain Investigation Clinical Network (EPPIC Net)
 - Back Pain Research Consortium
 - Establish best strategies for management of acute and chronic pain
 - Pain Management Effectiveness Research Network (ERN)
 - Integrated approach to pain/opioid use in hemodialysis patients
 - **Pragmatic and Implementation Studies for the Management of Pain (PRISM)**



Establish the best pain management strategies for acute and chronic pain conditions



Pain Management Effectiveness Research Networks and Trials

- *To inform clinicians about the effectiveness of interventions or management strategies that will improve functional outcomes and reduce pain across the continuum of acute to chronic pain associated with many types of pain conditions*
- Evaluate the effectiveness of pharmacologic and nonpharmacologic therapies for a broad array of pain conditions
 - Comparative Effectiveness Research Network: leverage NCATS Trial Innovation Network
 - Pain expertise in coordinating centers
 - NIH will solicit proposals for Phase 3 clinical trials to inform best practices in pain management and minimize risk of addiction
 - Coordinate data elements and storage with EPPIC-net and PRISM



Pragmatic and Implementation Studies for Management of Pain to Reduce Opioid Prescribing: PRISM

- Integrate interventions with demonstrated efficacy into health care systems, and implement health care system change toward evidence-based pain management
- Conduct efficient, large-scale pragmatic trial or implementation science studies to improve pain management
 - Embed the intervention under study into real-world settings
 - Collect data through the electronic records of the health care system
 - **Leverage the NIH Health Care Systems Collaboratory**
 - Focus on nonpharmacologic approaches
 - Collaboration with CMS for Medicare coverage consideration



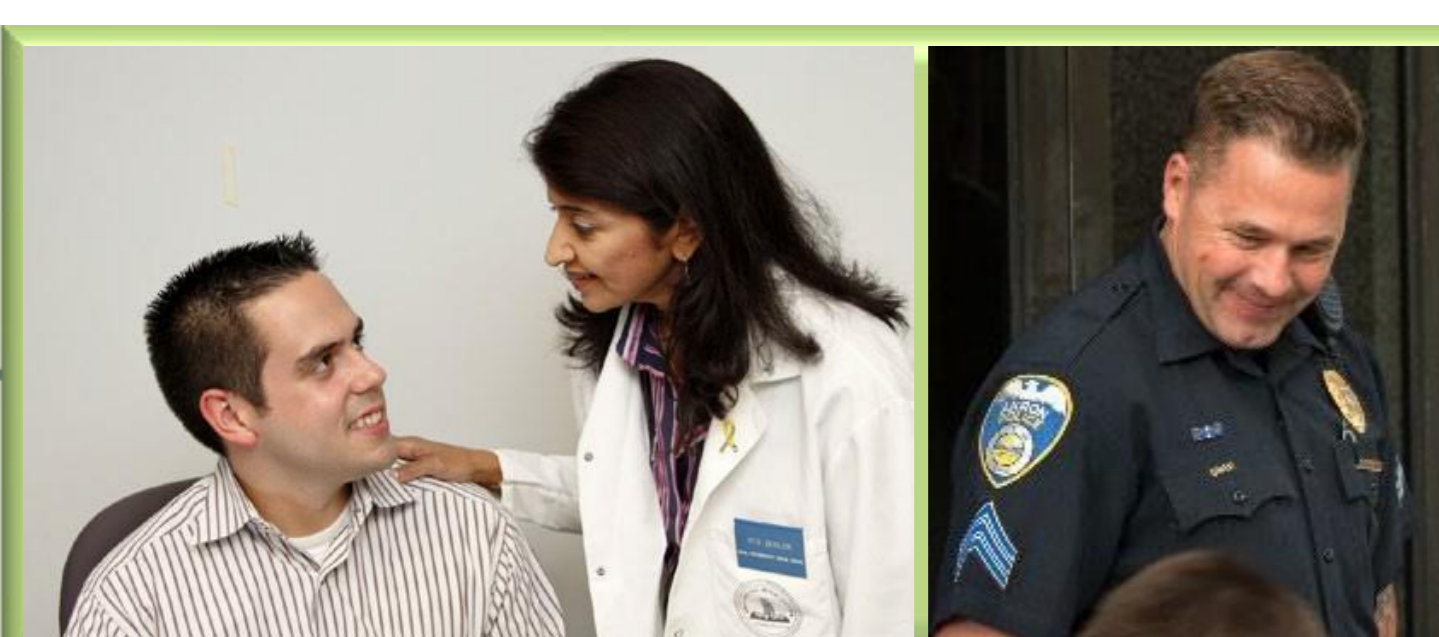
Pragmatic and Implementation Studies for Management of Pain to Reduce Opioid Prescribing: PRISM

- **Priority areas for Pragmatic Trials to Improve Pain Management (RFA-AT-19-004)**
 - Improve pain management
 - Integrate interventions with demonstrated efficacy into health care delivery
 - Implement health care system changes to improve adherence to evidence-based guidelines
 - Each participating institute and center has provided specific priorities
- **Acupuncture for Chronic Low Back Pain in Older Adults (RFA-AT-19-005)**
 - Evaluate effectiveness on pain and function outcomes
 - Leverage electronic health record data
 - Delivery of acupuncture as part of health care delivery
 - Results informative for CMS



Improving Prevention and Treatment Strategies for Opioid Addiction

- Optimize Effective Treatments
 - Enhancing the NIDA Clinical Trials Network to address opioids
 - Promoting innovation in the criminal justice system
 - Justice Community Opioid Innovation Network
 - Understanding the role of behavioral health interventions
 - Behavioral Research to Improve Adherence to Medication-based treatment for OUD (BRIM)
 - Integrating multiple evidence based interventions in communities
 - The HEALing Communities Study



Optimize Effective Treatment Strategies: Justice Community Opioid Innovation Network

- Opioid Innovation in the Criminal Justice System
 - Justice Community Opioid Innovation Network (JCOIN)
 - Generate real-world evidence to address needs of individuals with OUD in justice settings
- Progress to Date:
 - 11 supplement awards made in September 2018
 - Solicitations released December 2018 for Research Centers, Coordination and Translation Center, and Methodology and Analytics Center
 - Expected awards total \$30M; awards expected Early Fall 2019

Optimize Effective Treatment Strategies: The HEALing Communities Study

- Develop and test strategies to help communities respond to opioid crisis with a focus on achieving a 40% reduction in 3 years for OD fatalities
- Measure impact of integrating evidence-based prevention and treatment for opioid misuse, OUD, OD, and fatalities across multiple settings (health care, behavioral health, justice, communities)
- Determine factors (structural, organizational, policy, etc.) that contribute to successful implementation and sustainability of the integrated interventions
- Determine cost-effectiveness of integrated intervention compared to standard of care
- Awards Made April 2019 - Kentucky, Massachusetts, New York, Ohio