



**NIH  
HEAL  
INITIATIVE**

# MULTI-DISCIPLINARY WORKING GROUP

March 18, 2020    Bethesda Maryland



**#NIHhealInitiative**

**NIH** National Institutes of Health  
*HEAL Initiative*

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

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## **Welcome and Introduction**

Dr. Francis Collins, Director, National Institutes of Health (NIH)

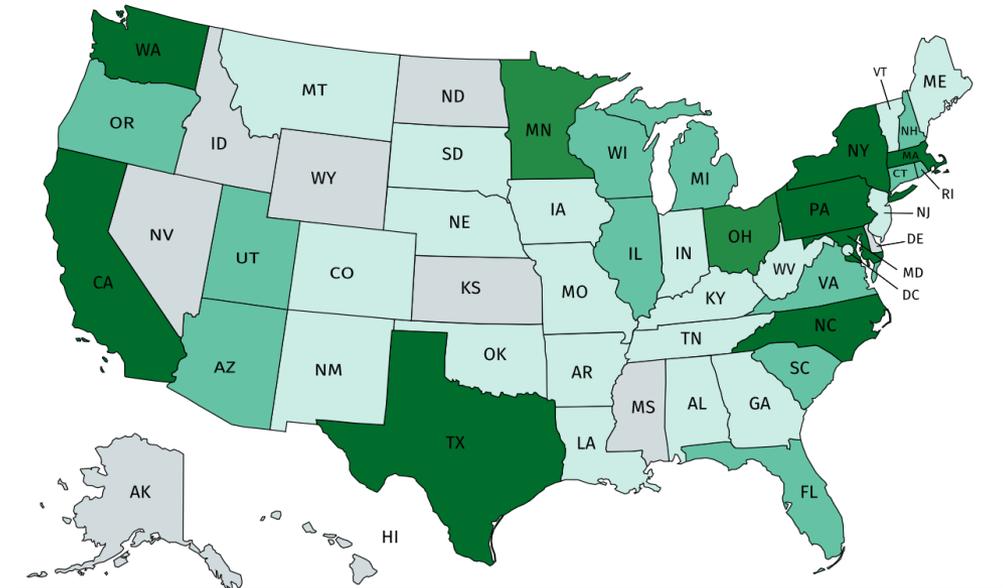


# HEAL Portfolio Overview and Recap of Investigators Meeting

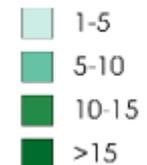
Dr. Rebecca Baker, Director, Helping to End Addiction Long-Term  
(HEAL) Initiative, Office of the Director, NIH

# NIH HEAL Initiative: By the Numbers

- Mission: scientific solutions to the opioids crisis
- \$500M/year effort
  - Over \$945M obligated in FY2019 to over 400 Investigators across 41 states
- Over 25 HEAL research programs
  - 12 NIH Institute and Centers leading,
  - 20 ICs collaborating on HEAL studies

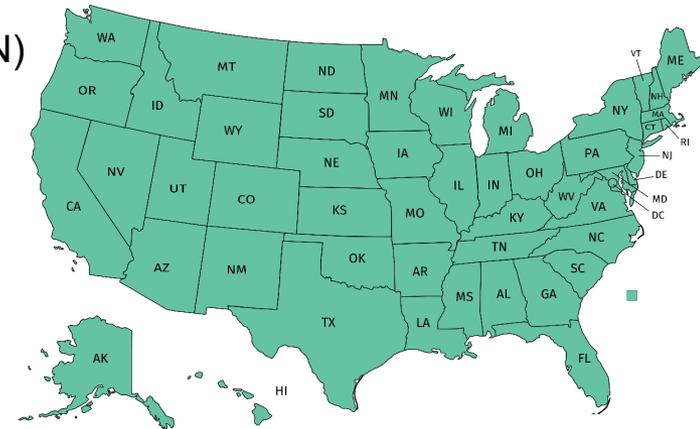


Number of Awards

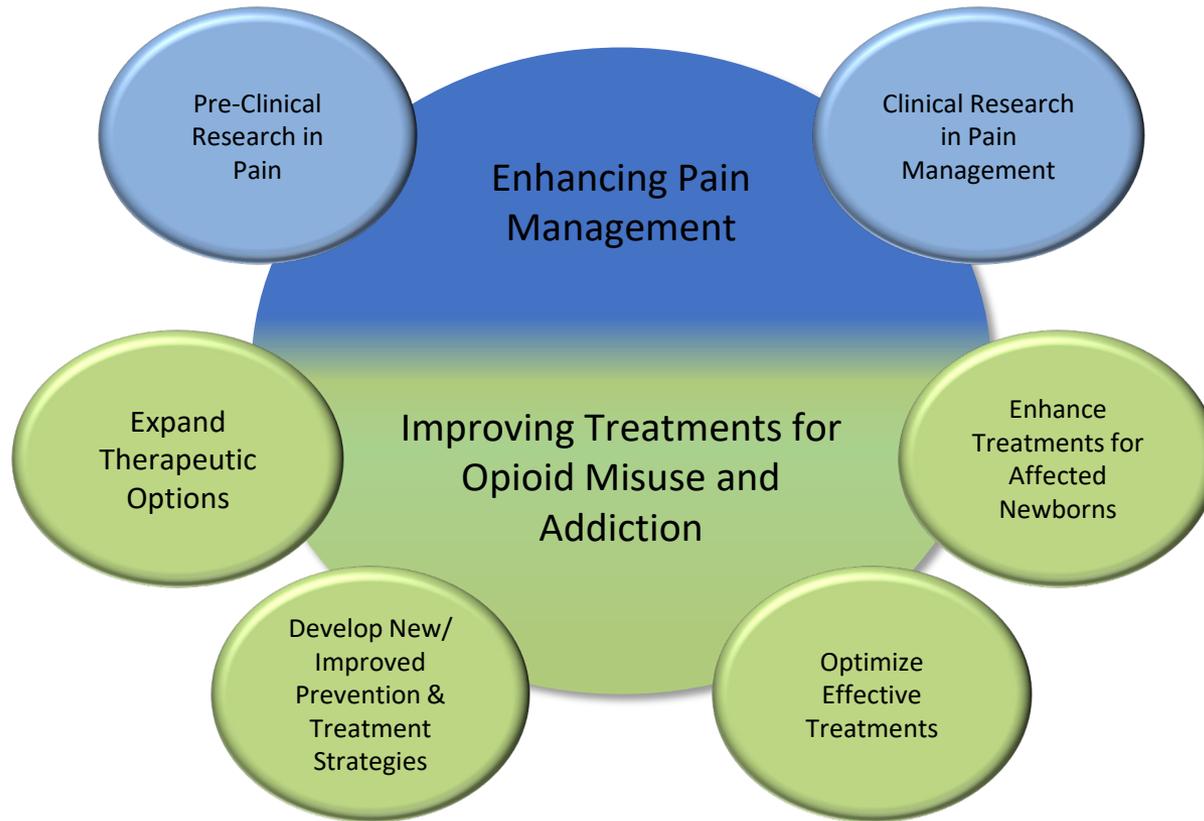


# HEAL Research Expanded through NIH Networks

- Leveraging networks enables HEAL to access research participants in all 50 states
- Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)
  - Neonatal Research Network (NRN)
  - Institutional Development Award (IDeA) States Pediatric Clinical Trials Network in 16 states
- National Drug Abuse Treatment Clinical Trials Network (CTN)
  - 18 Nodes in 15 states
    - Nearly every state engaged in research through community collaboration
- Pain Management Effectiveness Research Network
  - Trial Innovation Network across 28 states
  - NCI Community Oncology Research Program (NCORP) base and community sites
  - Maternal Fetal Medicine Unit Research Network

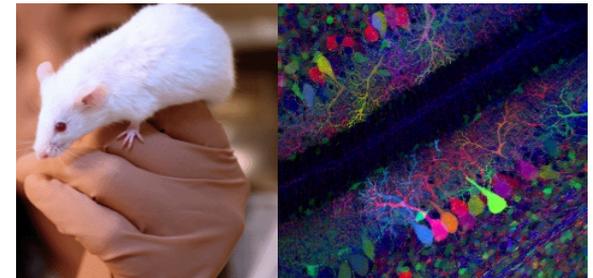


# HEAL Initiative Research Focus Areas



# Pre-Clinical and Translational Research in Pain

- Discovery and validation of novel targets for safe and effective pain therapeutics
- Translating discoveries into effective devices for pain treatment
- Engineering preclinical screening platforms + novel drug development
- Biomarkers, signatures and endpoints for pain



# Clinical Research in Pain Management

- Novel phase 2 clinical trials network: (EPPIC Net)
- Back Pain Research Consortium (BACPAC)
- Integrated approach to pain and opioid use in hemodialysis patients (HOPE)
- Pain Management Effectiveness Research Network (ERN)
- Pragmatic and Implementation Studies for the Management of Pain (PRISM)



# New Prevention & Treatment Strategies for Opioid Use Disorder

- Preventing OUD among at risk adolescents
- Managing opioid misuse and low severity OUD
- Understanding the role of sleep dysfunction
- Determining the optimal length of medication treatment
- Optimizing care for people with OUD and common mental disorders



# Translation of Research into Practice for Effective Treatments for Opioid Use Disorder

- Enhancing the NIDA Clinical Trials Network to address opioids
- Promoting innovation in the criminal justice system (JCOIN)
- Understanding the role of behavioral health interventions (BRIM)
- Integrating multiple evidence based interventions in communities: HEALing Communities Study



# Novel Medication Options for Opioid Addiction and Overdose

- Increase effective medication options:
  - enhanced formulations
  - addressing craving and withdrawal
  - novel targets for addiction and overdose
- Immune-based therapies for heroin and fentanyl



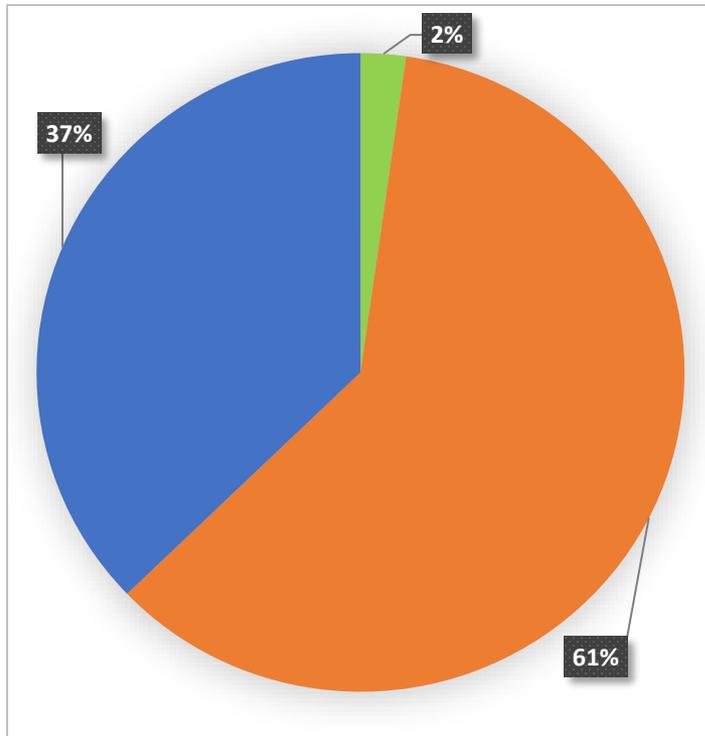
# Enhanced Outcomes for Affected Newborns

- Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome: ACT NOW Study
  - Eat-Sleep-Console; weaning from medication; longitudinal study
- Understanding the long-term consequences of early opioid exposure: HEALthy Brain and Child Development Study (BCD)

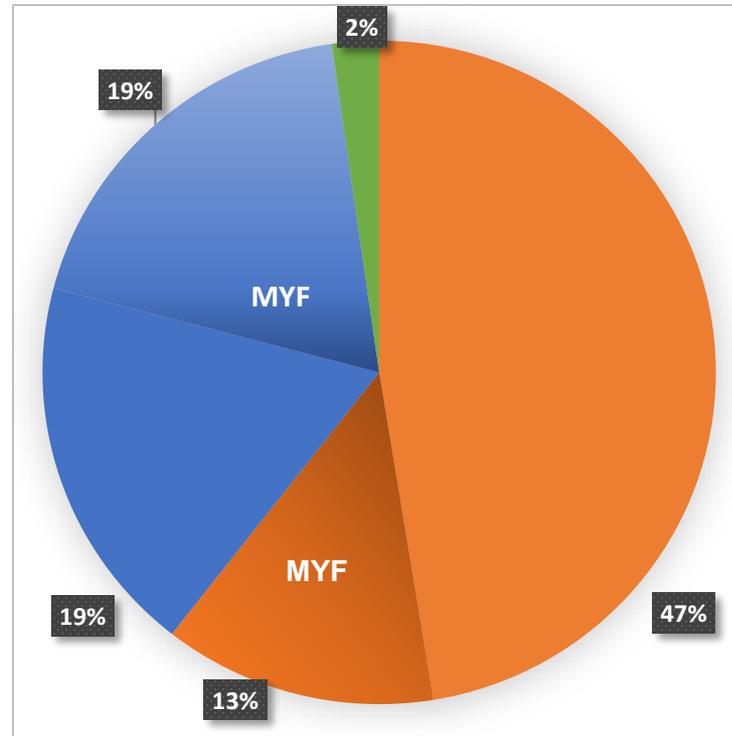


# **FY2019 Landscape Analysis**

# FY19 HEAL Investments by Priority Area



Total Obligation of FY19 Funding

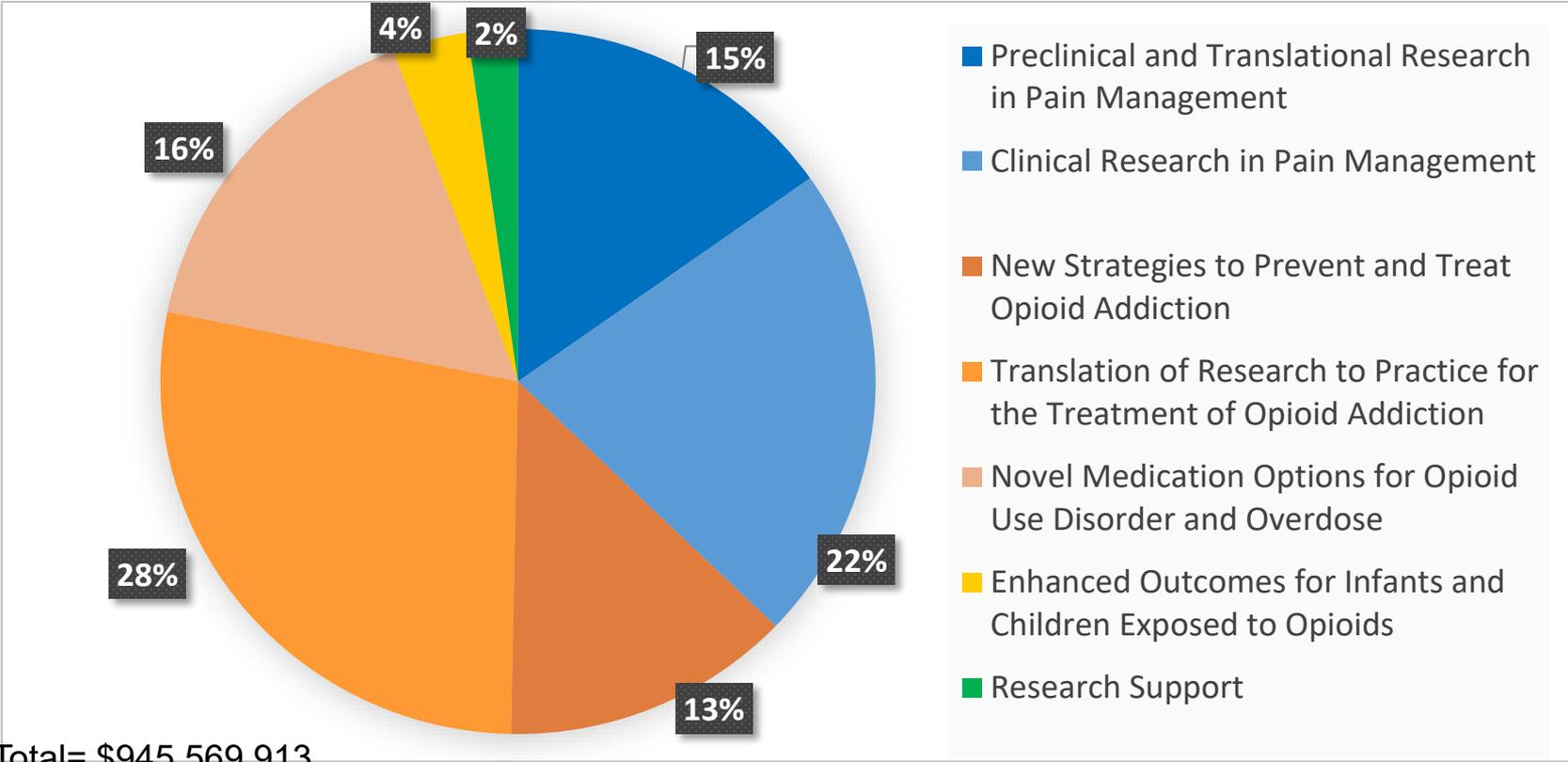


Total Obligation of FY19 Funding – with multi-year funding costs broken out

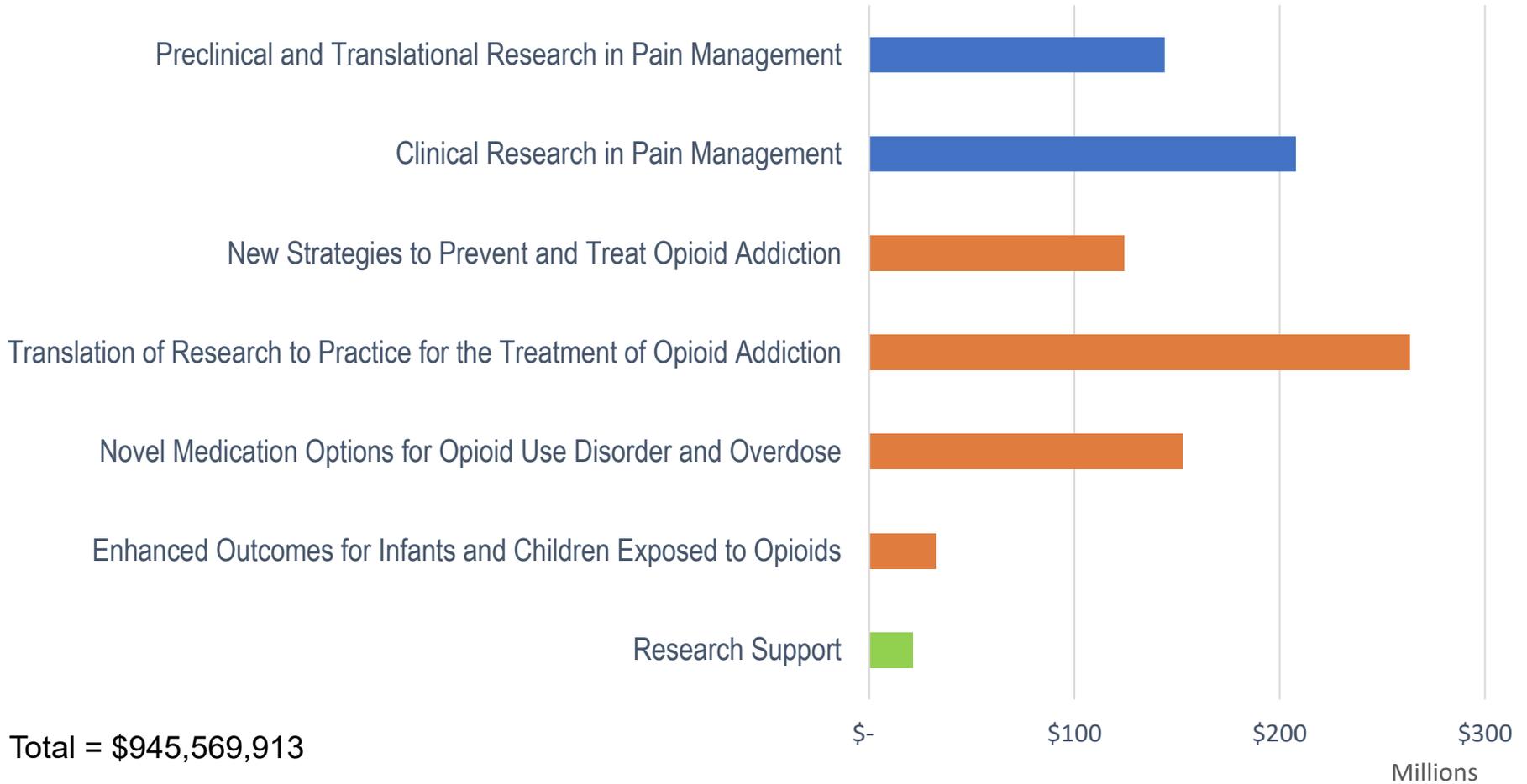
- Opioid Misuse and Addiction
- Pain Management
- Research Support

Total = \$945,569,913

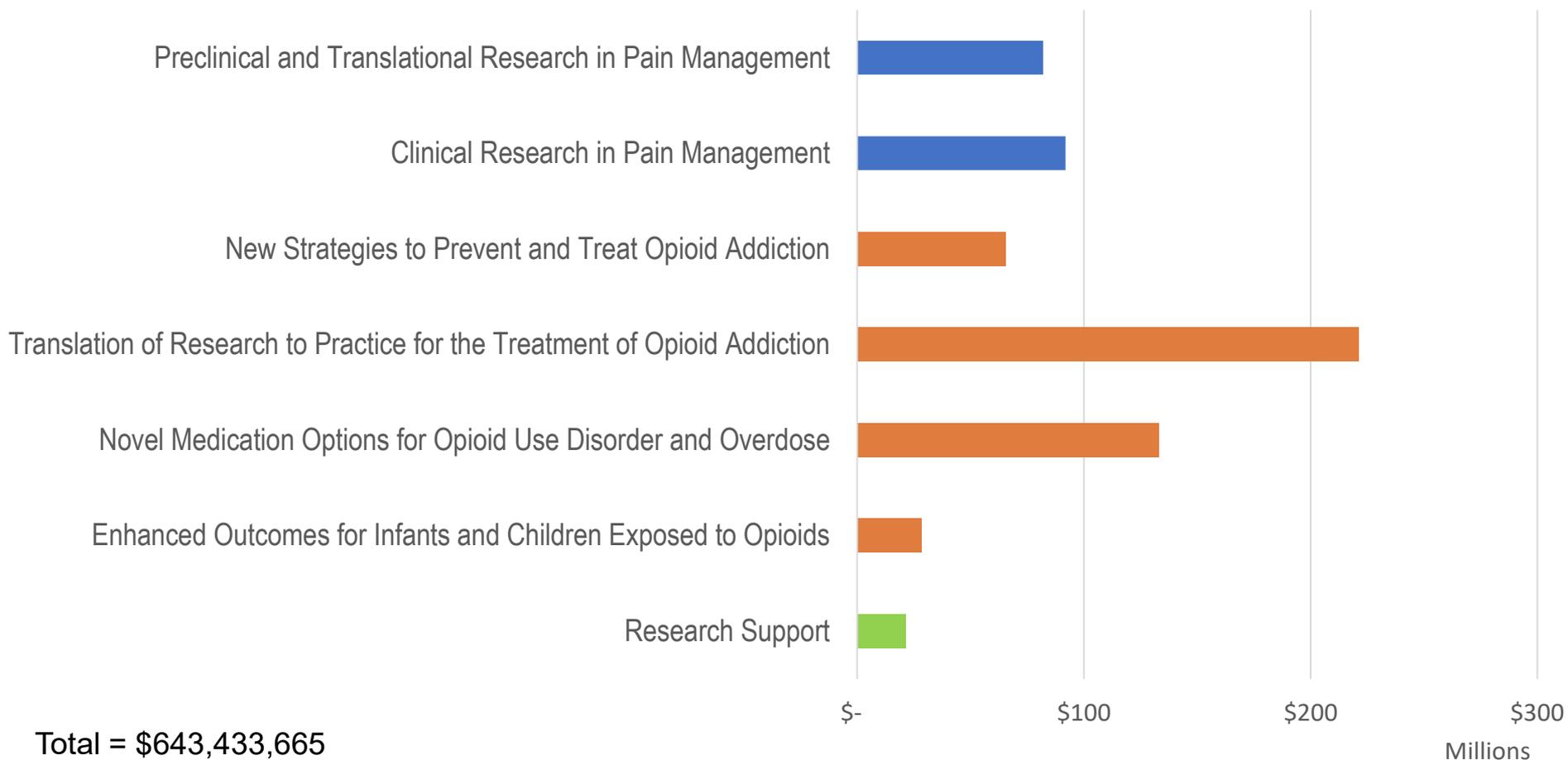
# FY19 Obligation by HEAL Research Focus Area



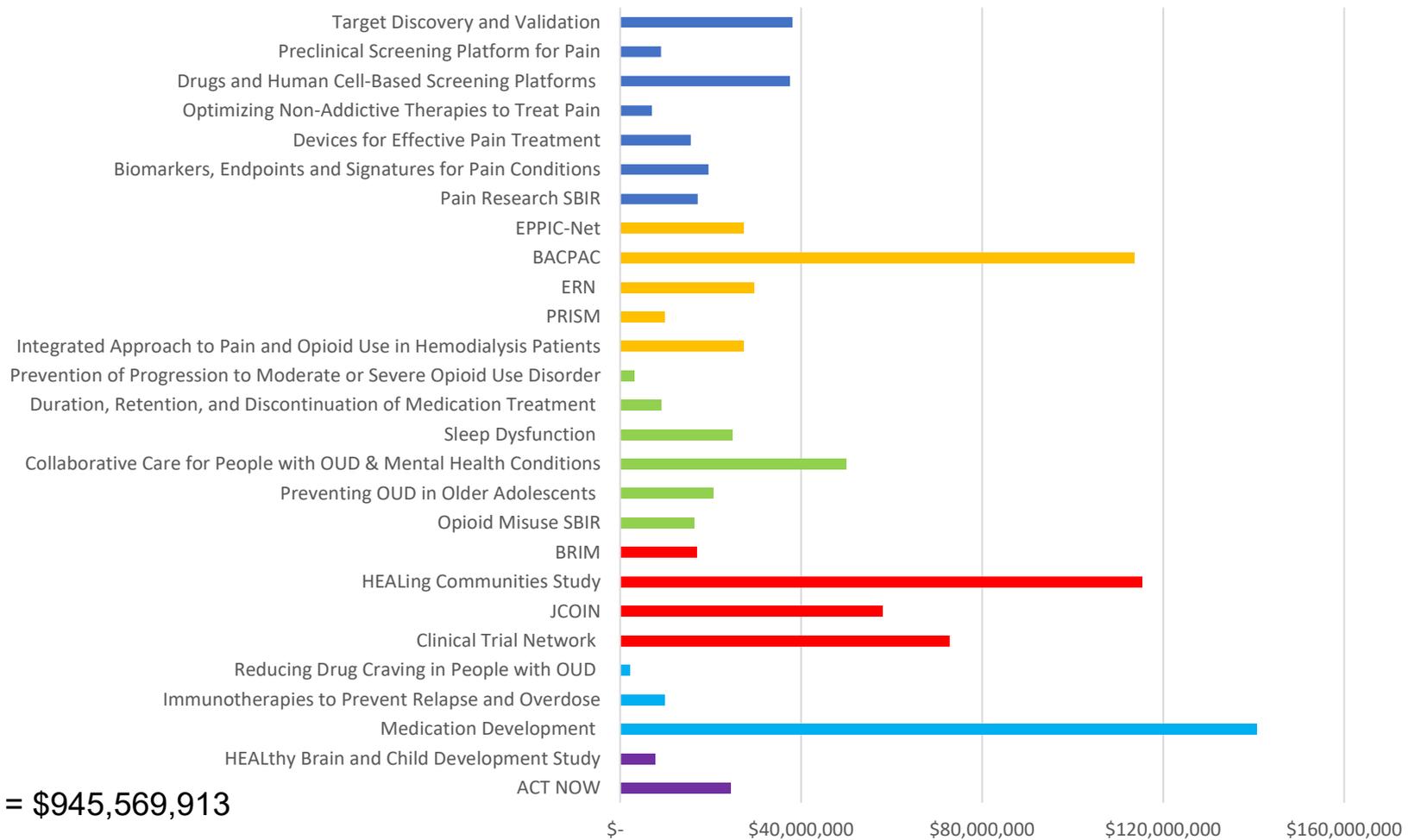
# FY19 Projects by HEAL Research Focus Area



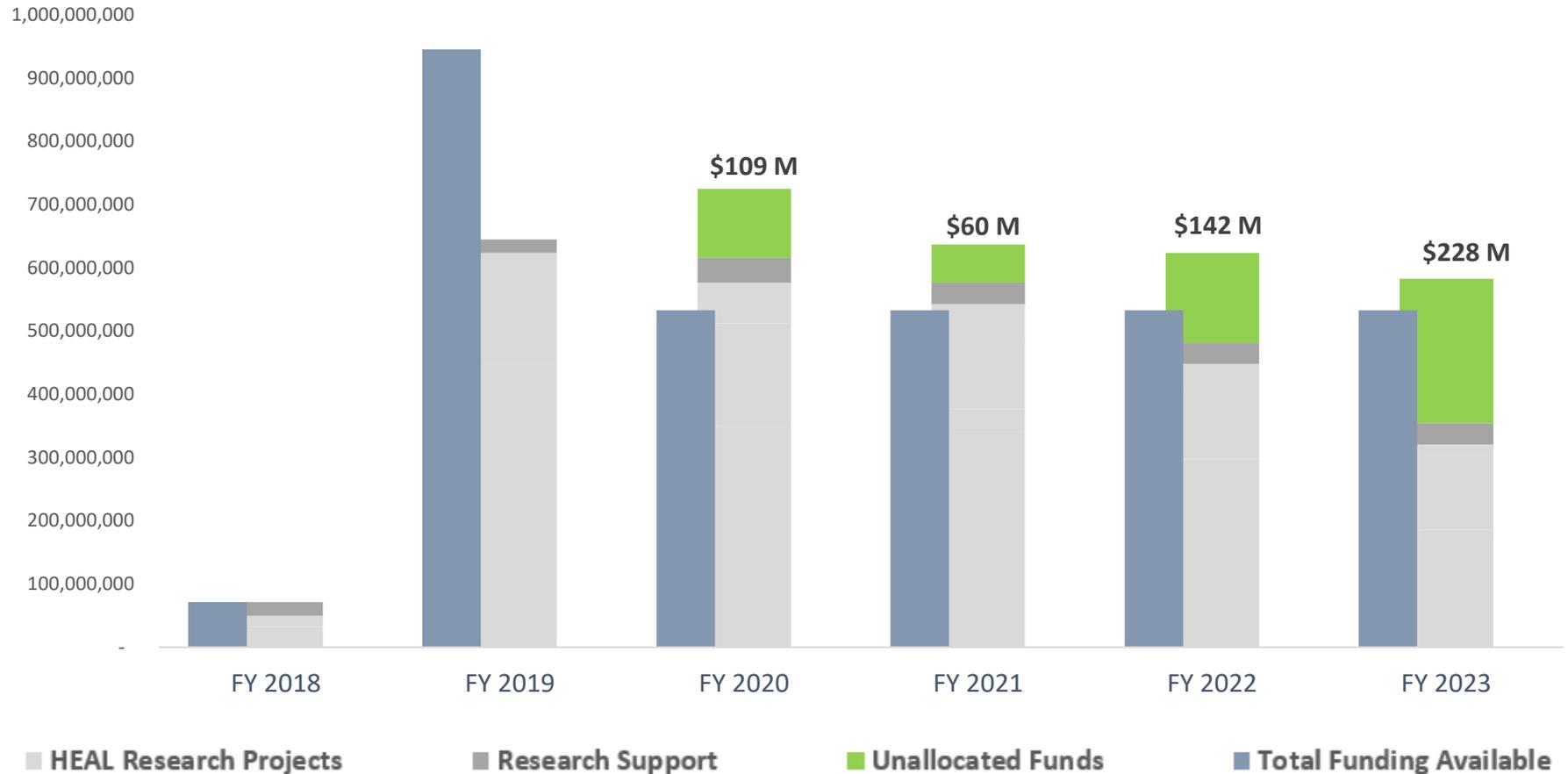
## FY19 Projects by HEAL Research Focus Area: Year 1 Project Cost



# Total HEAL Investments: Programs launched in 2019



# HEAL Investments and Outyears



Total = \$2,661,348,661

# Addressing Gaps in Research: Examples of FY20 Investments



## ***Understanding the Relationship Between Pain and Addiction***

Targeted Clinical Trials of Palliative Pain Management in the Context of Opioid Use Disorder (\$1M)

Pain Management in the Setting of Opioid Use/OD (\$2.75M)

Workshop: Interventions for Managing Comorbid Chronic Pain & OUD/Physical Dependence (\$75K)

## ***Addressing Opioid Use Disorder and Co-occurring Mental Health Conditions***

Social Network Analyses to Reduce American Indian and Alaska Native Opioid Use Disorder and Related Risks for Suicide and Mental Health Disorders (\$2.6M)

Research to Understand and Manage Common Co-Occurring Conditions and Suicide Risk in People Affected by the Opioid Crisis (\$8M)

## ***Reducing Stigma of Addiction and Pain***

Strategies to Reduce Stigma in Pain Management and OUD and Addiction Treatment (\$3.75M)

Workshop: Addressing Social and Economic Determinants of Opioid-Related Health Disparities- Expert Panel Workshop and Planning Meeting

Research Networks for the Study of Recovery Support Services for Persons Treated with Medications for Opioid Use Disorder (\$6M)

## ***Understanding Diversity of Care Received in Across Health Settings***

Best Management of Specific Pain Conditions in Primary Care, Hospital, DENTAL or Emergency Settings (\$28.3M)

Workshop: Navigating Pediatric to Adult Health Care: Lost in Health Care Transition

## ***Increasing Diversity Among HEAL Investigators***

Enhance the Workforce Diversity to Grow the Next Generation of Investigators in HEAL Areas of Research (\$5M)

Training Supplement for Heal Network Clinical Trials (\$2M)

# Open Funding Opportunities

FOA	Title	Research Focus Area	Research Program	Expiration Date
NOT-DA-20-033	Notice of Special Interest: HEAL Initiative: Social Network Analyses to Reduce American Indian and Alaska Native Opioid Use Disorder and Related Risks for Suicide and Mental Health Disorders	New Strategies to Prevent and Treat Opioid Addiction	All	5/1/2020
NOT-MH-20-025	Notice of Special Interest: HEAL Supplements to Improve the Treatment and Management of Common Co-occurring Conditions and Suicide Risk in People Affected by the Opioid Crisis	New Strategies to Prevent and Treat Opioid Addiction	Optimizing Collaborative Care for People with Opioid Use Disorder and Mental Health Conditions	4/8/2020
RFA-HL-20-031	HEAL Initiative: Pharmacotherapies to Reverse Opioid Overdose Induced Respiratory Depression without Central Opioid Withdrawal	Novel Medication Options for Opioid Use Disorder and Overdose	All	3/25/2020
RFA-AT-20-004	HEAL Initiative: Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) (UG3/UH3, Clinical Trials Optional)	Clinical Research in Pain Management	Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM)	3/30/2020
RFA-NS-20-028	HEAL Initiative: Pain Management Effectiveness Research Network: Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3 Clinical Trial Required)	Clinical Research in Pain Management	Pain Management Effectiveness Research Network	3/25/2020
NOT-AR-20-016	HEAL Initiative: Back Pain Consortium (BACPAC) Research Program Notice of Special Interest (NOSI) regarding the Availability of Urgent Competitive Revisions	Clinical Research in Pain Management	Back Pain Consortium Research Program	3/14/2020
RFA-NS-19-018 RFA-EB-18-003 RFA-NS-19-016	HEAL Initiative: Clinical Devices to Treat Pain	Preclinical and Translational Research in Pain Management	Translating Discoveries into Effective Devices to Treat Pain	2/23/2021
PAR-20-092	Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional)	Novel Medication Options for Opioid Use Disorder and Overdose	Focusing Medication Development to Prevent and Treat Opioid Use Disorder and Overdose	1/2/2020
OTA-19-008	HEAL Initiative: EPPIC-Net Pain Research Asset Application (OT1)	Clinical Research in Pain Management	Early Phase Pain Investigation Clinical Network (EPPIC-Net)	

# Upcoming HEAL Workshops



**March 2020**

Developing meaningful endpoints for pain clinical trials

**TO BE RESCHEDULED**



**June 2020**

Interventions for Managing Comorbid Chronic Pain & OUD/Physical Dependence



**July 2020**

Navigating pediatric to adult health care: Lost in health care transition



**August 2020**

Towards the Use of Buprenorphine in Infants: Scientific and Practical Considerations



**September 2020**

Target Validation for Non-Addictive Therapeutics Development for Pain- Strategic Approaches and Best Practices

Workshop on the structural and dynamic imaging of myofascial tissues: potential impact on musculoskeletal pain research

# Inaugural HEAL Investigators Meeting

# HEAL Investigator Meeting Overview

- HEAL Investigators Meeting on January 16–17 2020, brought together more than 350 researchers who are part of HEAL
- **Meeting Goals**
  - Establish the HEAL investigator network through streamlined communications and the shared expertise of HEAL researchers
  - Increase awareness of the geographic, thematic and programmatic scope of HEAL
  - Explore commonalities and enhance individual programs to optimize the successes of HEAL
  - Enrich the HEAL initiative through investigator engagement

# Plenary Panel Discussions

- Understanding and Addressing Pain
- Understanding and Addressing Opioid Use Disorder
- Reporting from the Front Lines on Pain and Addiction: Perspectives from National Reporters
- Collaborating for Success: Federal Partners in HEAL
- Understanding Stigma and the Impact on Public Health





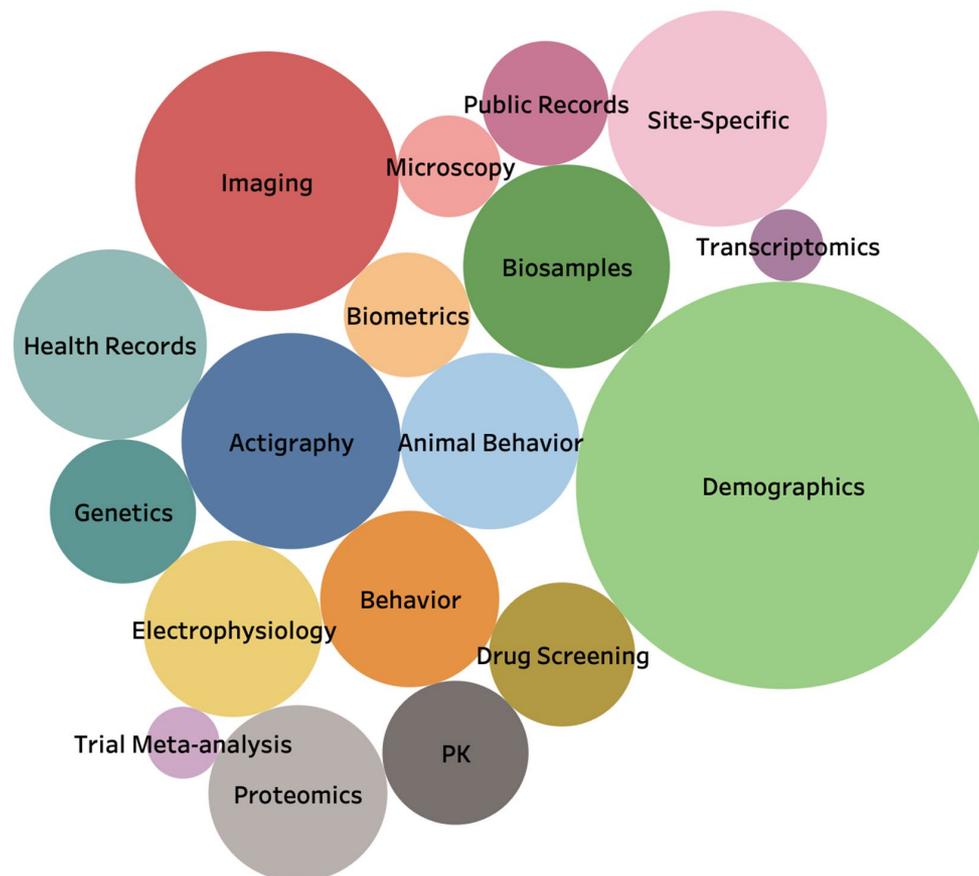
## Collaborating for Success: Federal Partners in HEAL

# Cross-cutting Topic Breakout Sessions

- **Integrating Co-occurring Conditions into HEAL Research**  
*Moderator:* Helene M. Langevin, MD, C.M., Director, NCCIH
- **Translating from Basic to Clinical Research**  
*Moderator:* Jack B. Stein, PhD, Chief of Staff, NIDA
- **Assessing Pain and Risk for Opioid Use Disorder**  
*Moderator:* Robert H. Carter, MD, Acting Director, NIAMS
- **Overcoming Challenges in Therapeutics Development**  
*Moderator:* Donald C. Lo, PhD, Director, Therapeutic Development Branch, NCATS, and Linda Porter, PhD, Director, Office of Pain Policy and Planning, NINDS
- **Incorporating Stakeholder Input**  
*Moderator:* Diana W. Bianchi, MD, Director, NICHD

# Data Sharing and Harmonization Across HEAL: Group Discussions

- Therapeutics Development
- Basic Science of Pain and Opioid Use Disorder
- Clinical Trials: Phase 2 and Effectiveness Trials
- Clinical Research: Implementation and Sustainability



# Investigator Meeting Themes and Next Steps

- Investigators expressed strong desire to continue to connect with one another as studies get underway
  - HEAL PI listserv
  - Website functionalities
  - Central engagement platform
- Need for ongoing engagement between HEAL investigators and NIH across projects, programs, and focus areas
  - Data needs are one important touchpoint
- Voices of research participants, patients, providers are essential
- Importance of ongoing research and funding opportunities

# Discussion