



Meeting Summary and Future Opportunities in HEAL

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Goals for the Meeting

- 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
- Consider priorities for HEAL research going forward

Data Sharing Breakout Session Summary

Data Session Breakout Session Considerations and Opportunities

- Perform portfolio analysis to learn about commonalities among trials and see if there is overlap
 - e.g. determine which studies are using imaging, sensory testing, pediatric populations data
- Recognize that Pain and OUD communities aren't separate entities
 - Standardization should integrate measures from both
- Provide uniform guidance for data collection across HEAL studies
- Convene focus groups to address data harmonization challenges

Cross-Cutting Breakouts

Basic to Clinical Research

- **Challenge:** lack of translation from model systems to humans
- **Opportunities:**
 - Assistance transitioning from experimental compound to IND through NIH trials and funding mechanisms
 - Data shared from failed trials could spur progress and prevent wasted time

Therapeutic Development

- **Challenge:** difficulties scaling up research for the next stage of development
- **Opportunities:**
 - Rapid screening of small molecules that can be carried out in small scale studies
 - Important to develop specific preclinical models that are predictive for different pain and use disorder conditions
 - Development of pharmacogenomic strategies and biomarkers

Integrating Co-occurring Conditions Into HEAL Research

- **Challenge:** Defining co-morbid and co-occurring condition; often varies by discipline
- **Opportunities:**
 - “Gold-standard” for pain measurement and treatment approaches
 - Consider technology (i.e., iPhone app, or online database/resource/ software program)
 - Understanding how patients choose which conditions to seek treatment for, and how conditions progress together

Assessing Pain and Risk for Opioid Use Disorder

- **Challenge:** Measuring long-term or chronic opioid use
 - Misuse v. opioid use disorder
 - No measures exist for opioid naïve individuals
- **Opportunities:**
 - Shared databases:
 - Projects using OUD, pain measures
 - Measures of pain on the background of OUD

Incorporating Stakeholder Input

- **Challenge:** People who are actively using drugs are hesitant to participate in studies where they may interact with law enforcement community
- **Opportunities:**
 - Resource to match expertise and necessary background/best practice knowledge
 - Shared strategies for patient engagement across programs and develop repository of training and materials engaging with stakeholders
 - Leverage knowledge from previous public health crisis (e.g. HIV)

Future Opportunities and Priority Areas

HEAL Workshops: *Spring-Summer 2020*

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

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

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

Structural and dynamic imaging of myofascial tissues: potential impact on musculoskeletal pain research

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

Interventions for Managing Comorbid Chronic Pain & OUD/Physical Dependence

Developing meaningful endpoints for pain clinical studies

NIH HEAL Initiative

Current Open Funding Opportunities

Discovery and Validation of Novel Targets for Safe and Effective Pain Treatment

- **RFA-NS-18-042:** Discovery and Validation of Novel Targets for Safe and Effective Pain Treatment (R21 Clinical Trial Not Allowed)
- **RFA-NS-18-043:** Discovery and Validation of Novel Targets for Safe and Effective Pain Treatment (R01 Clinical Trial Not Allowed)

Translating Discoveries into Effective Devices to Treat Pain

Translational Devices to Treat Pain

- **RFA-NS-19-016:** HEAL Initiative: Translational Devices to Treat Pain (UG3/UH3 Clinical Trial Optional)
- **RFA-NS-19-017:** HEAL Initiative: Translational Devices to Treat Pain (U44 Clinical Trial Optional)
- **RFA-EB-18-003:** HEAL Initiative: Translational Development of Devices to Treat Pain (U18 Clinical Trial Not Allowed)

Clinical Devices to Treat Pain

- **RFA-NS-19-018:** HEAL Initiative: Clinical Devices to Treat Pain (UH3 Clinical Trial Optional)

Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain

- **RFA-NS-18-041:** Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain (R61/R33 Clinical Trial Optional)

Early Phase Pain Investigation Clinical Network (EPPIC-Net):

- **NOT-NS-19-075:** HEAL/NINDS Early Phase Pain Investigation Clinical Network (EPPIC-Net): Opening to applications for non-addictive pain therapeutics
- **NOT-NS-19-043:** Notice of Information: Clinical Trials that Explore Non-Addictive Therapeutics for Pain Conditions under the Early Phase Pain Investigation Clinical Network (EPPIC-Net)

Back Pain Consortium Research Program

- **NOT-AR-20-016:** HEAL Initiative: Back Pain Consortium (BACPAC) Research Program Notice of Special Interest (NOSI) regarding the Availability of Urgent Competitive Revisions

Focusing Medication Development to Prevent and Treat Opioid Use Disorder and Overdose

- **RFA-DA-19-002:** Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional)

Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM)

- **NOT-AT-20-005:** Notice of Intent to Publish a Funding Opportunity Announcement Re-issuance for HEAL Initiative: Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) (UG3/UH3, Clinical Trials Optional)

https://heal.nih.gov/funding/open

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HEAL Initiative Goal

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FOA #	FOA Title	Research Focus Area	Research Program	Earliest Submission Date	Expiration Date
NOT-NS-20-020	Notice of Intent to Publish a Funding Opportunity Announcement for 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	Mon, 01/20/2020 - 12:00pm	Tue, 03/24/2020 - 12:00pm
RFA-NS-18-046	Analytical and/or Clinical Validation of a Candidate Biomarker for Pain (R61/R33 Clinical Trial Optional)	Preclinical and Translational Research in Pain Management		Sat, 10/27/2018 - 12:00pm	Fri, 03/13/2020 - 12:00pm
PAR-18-541	Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development for Disorders of the Nervous System (U44 Clinical Trial Optional)	Preclinical and Translational Research in Pain Management		Sun, 01/07/2018 - 12:00pm	Fri, 05/08/2020 - 12:00pm
RFA-DA-19-002	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	Thu, 01/25/2018 - 12:00pm	Thu, 01/02/2020 - 12:00pm
RFA-NS-18-043	Discovery and Validation of Novel Targets for	Preclinical and Translational Research in Pain	Discovery and Validation of Novel Targets for	Sat, 10/27/2018 - 12:00pm	Wed, 11/13/2019 - 12:00pm



**Thanks to the NIH
HEAL Initiative
Teams**

THANKS!

NIH Executive Committee

- **Francis Collins**, M.D., Ph.D., Chair, Director, National Institutes of Health
- **Walter Koroshetz**, M.D., Chair, Director, National Institute of Neurological Disorders and Stroke
- **Nora Volkow**, M.D., Chair, Director, National Institute on Drug Abuse
- **Christopher Austin**, M.D., Director, National Center for Advancing Translational Sciences
- **Diana Bianchi**, M.D., Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development
- **Robert Carter**, M.D., Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases
- **Joshua Gordon**, M.D., Ph.D., Director, National Institute of Mental Health
- **Helene Langevin**, M.D., Director, National Center for Complementary and Integrative Health
- **Lawrence Tabak**, D.D.S., Ph.D., Principal Deputy Director, National Institutes of Health; Acting Director, National Institute of Dental and Craniofacial Research

THANKS! HEAL Scientific Team Leadership

- Novel Medication Options for Opioid Use Disorder and Overdose
 - Ivan Montoya, M.P.H., M.D., NIDA
 - Kentner Singleton, Ph.D., NIAID
- Translation of Research to Practice for the Treatment of Opioid Addiction
 - Dave Clark, Dr.P.H., NCCIH
 - Tisha Wiley, Ph.D., NIDA
- New Strategies to Prevent and Treat Opioid Addiction
 - Michael Freed, Ph.D., NIMH
 - Jacqueline Lloyd, Ph.D., M.S.W., NIDA
- Preclinical and Translational Research in Pain Management
 - Christine Colvis, Ph.D., NCATS
 - Michael Oshinsky, Ph.D., NINDS
- Clinical Research in Pain Management
 - Jane Atkinson, D.D.S., NCATS
 - Linda Porter, Ph.D., NINDS
- Enhanced Outcomes for Infants and Children Exposed to Opioids
 - Drew Bremer, M.D., Ph.D., NICHD
 - Michelle Freund, Ph.D., NIDA

THANKS! HEAL PI Meeting Planning Team and Data Breakout Facilitators

- Drew Bremer, NICHD,
- Michael Oshinsky, NINDS
- Dave Clark, NCCIH
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- Wen Chen, NCCIH
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- Amir Tamiz, NINDS
- Xinhcheng, Zhang, NIAMS
- Leslie Derr, NIAMS
- Sam Jonson, NCATS
- Julie Frost, NIDA
- Lisa Estes, NIDDK
- Dorothy Tucker, NICHD
- Leah Pogorzala, NINDS
- Meera Raja, OD

THANKS! Investigators Meeting co-chairs and small but mighty team



Linda Porter, NINDS



Jack Stein, NIDA



Danielle Haney, NINDS



Erin Spaniol, OD

Next Steps



- Please visit the NIH HEAL Initiative website to access meeting materials, including slides and executive summaries.
<https://heal.nih.gov/events/heal-investigator-meeting-01-2020>
- Stay tuned for more information on the **Second Annual HEAL Investigator meeting!**
 - How can the next Investigator meeting best meet your needs? Please let us know by completing the **post-meeting survey**.