NIH HEAL INITIATIVE

HEAL Multi-Disciplinary Working Group

March 3, 2021

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.

Clinical Trial Diversity and Engagement are top priorities for NIH

On Engagement

"It's really important that everybody has a chance to participate in clinical trials. That's how we learn the differences and similarities and certainly underrepresented groups ought to be part of that. To make that more possible, we can do better outreach so people hear about these trials, we need to knock down barriers that might get in the way and we need to be sure we are getting people information back about themselves ... "

–Francis Collins, NIH Director

Engaging Patients In the Research Process (August 2020)

- Discussed opportunities, challenges, and benefits to incorporating patients in research
- Provided insights on engagement in the virtual environment
- Over 300 attendees
- Panelists:
  - Walter Koroshetz M.D. (NIH)
  - CAP Robyn Bent (FDA)
  - Paul Kimmel M.D. (NIH)
  - Christin Veasley (CPR)
  - Dawn P. Edwards (HOPE)
- Discussants:
  - Lynn Debar, PhD
  - Mary Stroud, RN

Patient and Stakeholder Engagement in the NIH HEAL Initiative

HEAL Initiative Patient Engagement

Design Stage

- **Patients at the table can help:**
  - Identify outcomes of importance to patients.
  - Vet patient reported outcomes
  - Inform the balance between necessary data and patient burden. What's tolerable?
  - Help with drafting informed consent document and how it is communicated to patients

Execution Stage

- Patient Ambassadors can improve:
  - Imbue trust between subjects and study personnel
  - Quality of recruitment
  - Help troubleshoot problems affecting retention, compliance with study procedures
  - Communication with subjects about study and study results

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HEAL Initiative Patient Engagement

Key points:

I. Build-in patient engagement from the very <u>start</u>.

II. Elevate patients to <u>equals</u> in study design, execution, and communication of results.

  I. <u>Avoid tokenism</u>.

    I. Don't separate the patients and the investigators.

    II. Reimburse patients for their time, as you would any investigator.

III. Patients are likely more effective <u>communicators</u> with potential subjects, their families, and other outreach.

IV. Contributing to a research study also provides <u>fulfillment</u> for those who are part of patient engagement part of the study.

V. Invest in the long game, it will take time to build <u>trust</u>

The NIH HEAL Initiative Patient Engagement Priorities

Create HEAL Patient Engagement Governance Structure

Increase Patient Engagement in HEAL studies

Provide Resources for HEAL community

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Overarching Goals of the Patient Engagement Workgroup

- **Add Patient Engagement Governance to the HEAL initiative**
  - Create Patient Engagement Workgroup
  - Build <u>HEAL community council: panel</u> to provide ongoing input to HEAL studies
  - Determine the types of engagement ongoing in HEAL studies
  - Determine existing tools to monitor engagement and recruitment efforts across trials
- **Increase Patient Engagement in HEAL Studies**
  - Supplemental support to enhance engagement and promote recruitment and retention across trials
  - Require trials to develop framework to increase engagement and include community panels
- **Provide resources for stakeholder engagement**
  - Support development of engagement strategies in HEAL
  - Consider funding focus groups for HEAL patients (rapid fire)
  - Facilitate development of best practices in stakeholder engagement
  - Develop and collaborate on workshops

Accomplishments of HEAL Patient Engagement Workgroup 2020

Workgroup formation and expansion

August Workshop

Discussion with PCORI engagement leads

Development of NOSI for Engagement and Diversity and Inclusion in HEAL Clinical Trials

Drafted HEAL Community Council Charter

Supporting Strategies to Increase Participant Diversity, Inclusion and Engagement in Clinical Studies

- To be developed through trans-NIH collaboration:
  - HEAL Patient Engagement Workgroup
  - Pain Consortium Disparities and Diversity Work Group

- To support ongoing HEAL studies to
  - enhance their patient, community, and other stakeholder engagement efforts
  - improve recruitment, retention and inclusion of participants from U.S. racial and ethnic minority populations
  - Both objectives- as appropriate for a particular study.

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March 15th 2021: Harnessing the Power of Patients and Stakeholders to Advance the Research Goals of the NIH HEAL Initiative

- Goal: Showcase patient and stakeholder engagement ongoing in current HEAL trials and studies

- Patient and Patient Advocate panel kicks off the meeting
  - Jessica Husley-Nickel, Addiction Policy Forum
  - Chris Veasley, Pain Advocate
  - Kevin Charles, NIDA CTN
  - Dawn Edwards, HOPE
  - Karen Lizzy, NIDA CTN

- HEAL Investigator Panel:
  - Ardith Doorenbos, PhD, RN, FAAN (PRISM)
  - Megan Irby, PhD, MS, MS (ERN)
  - Kristen Johansen, MD (HOPE)
  - Richard Schottenfeld, MD (NIDA CTN)
  - Lauren Brinkley-Rubinstein, PhD (JCOIN)
  - Linda Sprague Martinez, PhD (HCS)

Patient and Stakeholder Engagement in the NIH HEAL Initiative

Building the HEAL Research Community, Data Platform, and HEAL Investigator Meeting

Rebecca Baker, Director, NIH HEAL Initiative

By the Numbers:
$500 million/year Sustained Research Investment

25+ HEAL Research Programs

Prevention – Basic & Translational Research – Clinical Trials – Implementation Science

By the end of FY 2020, HEAL funded over $1.5B in research

Represents more than 500 research projects

Partnerships across government, communities, and the private sector

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Supporting science-based solutions to end the opioid crisis

We are the HEAL community: patients and families, scientists and health providers, people in recovery and behavioral health specialists. Together, we are working alongside communities nationwide to address the public health crises of undertreated pain, opioid misuse, addiction and overdose.
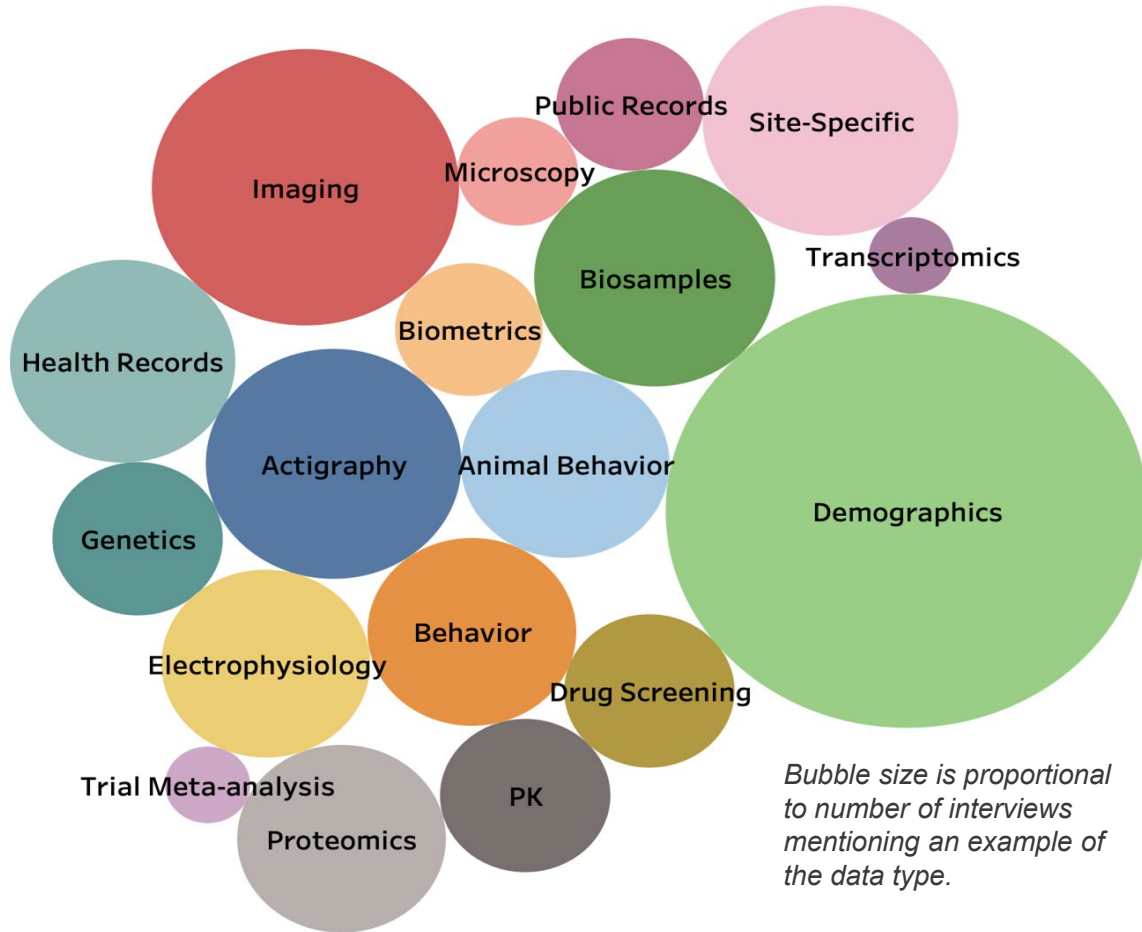Check out our idea exchanges to add your voice

Learn More

Strengthening the HEAL Research Community

- **Collaboration** - What more can we do to offer ample opportunities to work across areas of research?

- **Equity, Diversity, and Inclusion** - Are we engaging all communities and involving diverse expertise, voices, and views?

- **Barriers** - What hurdles have you encountered related to regulations, data acquisition and sharing, or other areas?

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Diversity of HEAL Data

Bubble size is proportional to number of interviews mentioning an example of the data type.
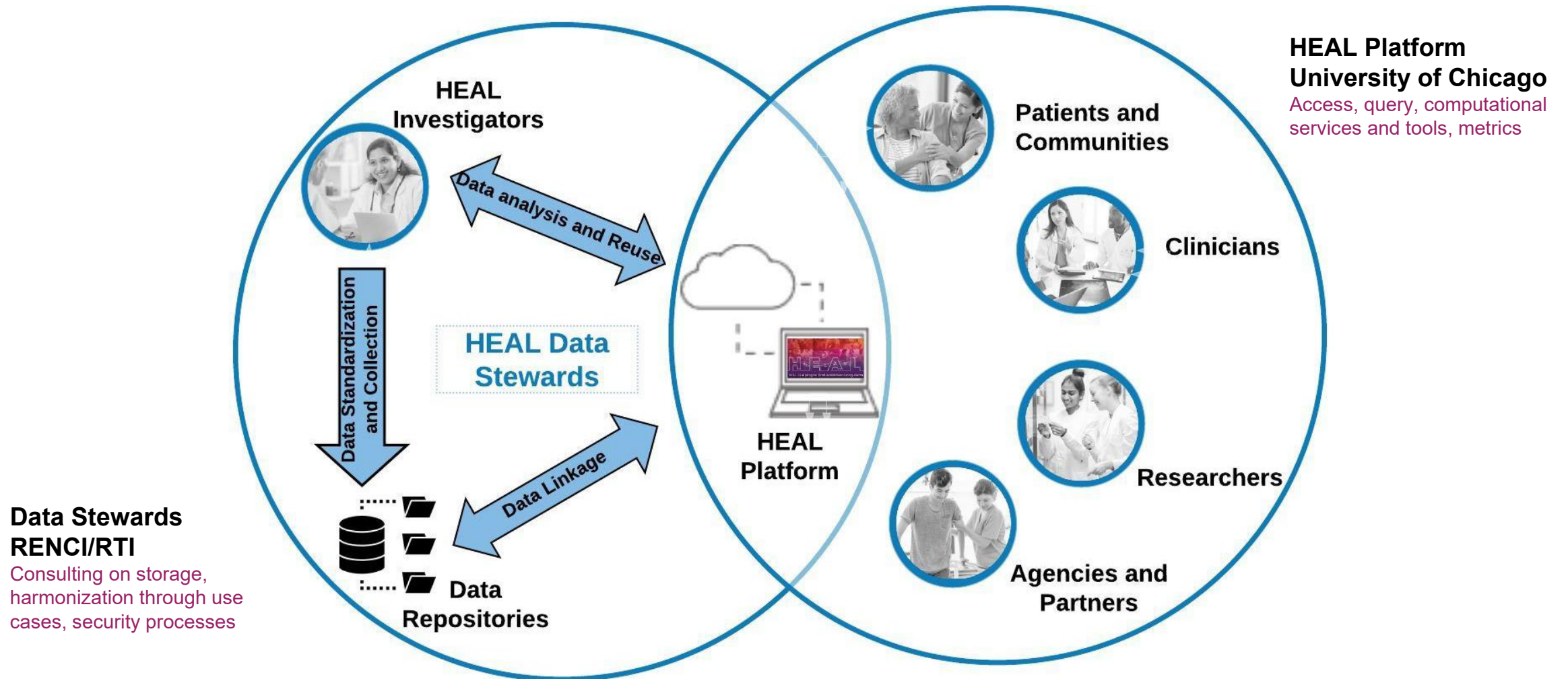
HEAL Data Ecosystem efforts:

- Enable access of HEAL data for various stakeholders through a user-friendly web portal
- Foster secondary research and new discoveries
- Maximize access to and use of data analysis tools and resources
- Provide sustainability of HEAL digital assets beyond individual awarded programs

"We are committed to making data from this investment rapidly available for use by policymakers, patients, and clinicians – and importantly, to other scientists within and outside of HEAL to prompt new discovery" – *Rebecca Baker*

HEAL Data Ecosystem

HEAL Investigators

Data analysis and Reuse

Data Standardization and Collection

HEAL Data Stewards

Data Linkage

Data Repositories

HEAL Platform

Patients and Communities

Clinicians

Researchers

Agencies and Partners

HEAL Platform University of Chicago
Access, query, computational services and tools, metrics

Data Stewards RENCI/RTI
Consulting on storage, harmonization through use cases, security processes

Use Cases: Engagement with the HEAL Data Platform

As a **community-based service organization** we want to **support people misusing opioids in our communities** in order to **save lives and reduce suffering.**

As a **clinician treating patients with chronic pain,** I want **access to the latest pain research and clinical trial results** to **identify and track potential new approaches to assist my patients.**

As a **research expert in opioid misuse and addiction,** I want to compare different psychosocial interventions to optimize medication-based treatment approaches for opioid use disorder.

As a **pain translational researcher**, I want to **validate a pain drug target in multiple species** in order to **have a complete evaluation of a possible novel pain drug target.**
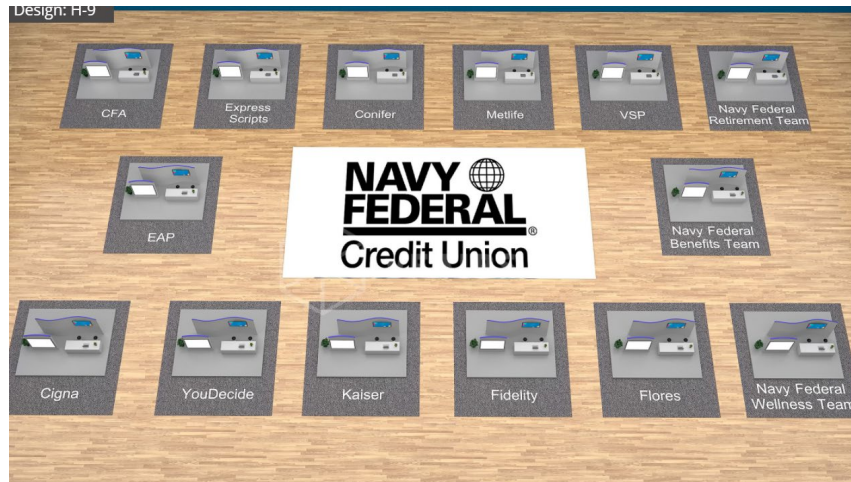
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Annual HEAL Investigator Meeting

2021 HEAL Investigator Meeting Overview

- May 17-19, 2021
- **Virtual meeting (VFAIRS)** will feature presentations from HEAL investigators, plenary sessions, updates on the HEAL data ecosystem, poster sessions and small group discussions.
- **Meeting Goals**
  - Spur scientific advancements in pain and addiction research by cultivating collaboration in the HEAL investigator community
  - Explore commonalities and identify challenges and opportunities to optimize the successes of HEAL
  - Disseminate research breakthroughs and highlight cutting edge science

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VFAIRS Platform Allows for Flexibility and an Innovative Networking Capabilities for the HEAL Meeting

2021 Meeting Framework and Agenda Overview

- **Plenaries and Panel Presentations**

- **Breakout Sessions**
  - Health Disparities
  - Clinical trial recruitment and retention
  - Challenges and opportunities amidst COVID-19
  - HEAL Data Ecosystem
  - Regulatory challenges

- **Poster Session**
  - Select posters to include audio recording

2021 HEAL Virtual Meeting Series

February
- Virtual Workshop on Achieving Health Equity in the NIH HEAL Initiative- Feb 1, 2021

March
- Harnessing the Power of Patients and Stakeholders to Advance the Research Goals of the NIH HEAL Initiative - March 15, 2021
- Polysubstance Use - March 31, 2021 (tentative)

April
- HEAL Data Ecosystem- April 20, 2021 (tentative)

Discussion

Adjourn