Platform Preclinical Screening Program (PPSP)

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Helping to End Addiction Long-term (HEAL) Initiative

1. Prevent addiction through enhanced pain management
   • Understand Origins of Chronic Pain
   • Develop New Non-Addictive Treatments for Pain
   • Build Clinical Trial Network for Chronic Pain
   • Enhance Precision Pain Management

2. Improve treatments for opioid misuse disorder and addiction
   • Improve Therapeutic Approaches to Addiction
   • Evaluate Treatments, Consequences of NOWS
   • Optimize Effective Treatments through Pilot Demonstration Projects

Announced April 4, 2018
Overview of HEAL Programs for Pain

Discovery
- Biomarker Discovery and Development
- Target Identification and Validation
- Trans-NIH Collaborative Screening Platforms (NCATS)
- Platform Preclinical Screening Program
- Therapeutics Development (CREATE, BPN)

Preclinical Development

Clinical Trials
- PPP and Asset Sharing
- Clinical Trial Network
- Acute to Chronic Pain Signatures (Common Fund)

Concept clearance approved by Feb Council
Concept clearance before Council today
The overall goal of this initiative is to establish a learning preclinical testing platform that catalyzes the discovery and characterization of non-addictive modalities for the treatment of pain.

- Establish a sophisticated preclinical testing program to help identify non-addictive pain treatments with ever increasing power to predict efficacy in human trials.
- Develop and acquire models of specific pain conditions. Provide access to the research community for testing and characterizing promising leads.
- Generate high quality data in pain models to support business partnerships or applications to NIH translational programs.

A successful program will incentivize industry to re-invest in pain therapeutics development.
A Proven Model to Spur Innovative Therapies

• Concept based on successful NINDS-funded Anticonvulsant Screening Program (ASP*)

• Rigorous testing of submitted compounds in a battery of preclinical seizure models

• ASP efforts contributed to identification and/or characterization of 9 compounds that advanced to the market for treatment of seizures in epilepsy

*Currently known as the “Epilepsy Therapy Screening Program (ETSP)
Overview of Platform Preclinical Screening Program

- **Registration**
  - Documentation Review

- **Handling/Processing**
  - Blinding
  - Shipping

- **Data Analyzed**
  - & Plan for Next Steps

- **Report of Test Results**
  - NINDS Database

- **Testing at Contract Site**

- **Design Screening Strategies & Place Test Orders**
  - NINDS Database

- **Compound Shipped to Contract Site**

- **Compound Received at the Contract Site**

**Participants**

- NINDS Staff
- Handling/Processing Staff
- Contractor Staff
Overview: Engineering a Preclinical Testing Platform to Identify and Profile Non-Addictive Therapeutics for Pain

- Contract mechanism to evaluate submitted compounds/devices in a battery of preclinical models of acute and chronic pain
- Partners: NCATS, NCI, NCCIH, NEI, NIA, NIAAA, NIBIB, NIDA, NIDCR, ORWH, NIDDK, NHLBI, FIC

Impact: This program will incentivize academic and industry communities to pursue discovery of non-addicting therapies for pain through a one-stop resource producing high quality, rigorous data.
Timelines (2018-2023)

- NINDS is in position to start the contracting process and make award(s) in 2019 to commence screening.
- First year activities include recruiting an advisory panel, holding a pain model workshop, and establishing testing program(s).
- The program is proposed for 5 years with specific goals to be achieved by the end of the 5-year period.

**2018**
- Form advisory group
- Hold workshops
- Establish working funnel and protocols

**2019**
- Award platform contract
- Start testing compounds
- Start model development in-house

**2020-2022**
- Bring in new models
- Continue testing new targets and complete interrogating existing targets

**2023**
- Convene workshop
- Evaluate initial goals and objectives and advances made

*If the program is successful additional years may be added.*