NCATS HEAL Programs for Developing and Testing Pain and Addiction Treatments

Christopher P. Austin, M.D.

Director, National Center for Advancing Translational Sciences (NCATS)
To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.
What is Translational Science?

*Translational Science* is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.
Some of the scientific translational problems on NCATS’ to-do list

- Predictive toxicology
- Predictive efficacy
- De-risking undruggable targets/untreatable diseases
- Data interoperability
- Biomarker qualification process
- Clinical trial networks
- Patient recruitment
- Electronic Health Records for research
- Harmonized IRBs
- Clinical diagnostic criteria
- Clinical outcome criteria (e.g., PROs)
- Adaptive clinical trial designs
- Shortening time of intervention adoption
- Adherence
- Methods to better measure impact on health
Why Drugs Fail in Development

Reasons for Drug Development Failure

- Efficacy
- Safety
- Strategic
- Commercial
- Operational

Concordance of true positive toxicities w human

Clark and Steger-Hartmann, Regul Toxicol Pharmacol 96:94 (2018)

HEAL Programs for Pain (and Addiction) Cover the Research Spectrum

Discovery
- Acute to Chronic Pain Signatures
- Discover and Validate Novel Targets for Safe and Effective Pain Treatment
- Preclinical Screening Platforms + Novel Drug Development

Preclinical Development
- Translating Discoveries Into Effective Devices For Pain Treatment
- Discovery and Validation of Biomarkers, Biomarker Signatures, and Endpoints for Pain Indications

Clinical Trials
- Data & Asset Sharing Partnership
- Early Phase Pain Investigation Clinical Network

Implementation/Dissemination
- Back Pain Research Consortium
- Hemodialysis Pain Management
- Pain Effectiveness Research Network
- Pragmatic and Implementation Studies for the Management of Pain
Developing Drugs and Testing Platforms for Pain, Addiction and Overdose in Collaboration with NCATS

Accelerating Translation of Novel Compounds to Investigational New Drugs for Subsequent Clinical Testing

- Development of New Chemical Structures to Modulate Novel Targets
- Development of Pharmacological Probes for Novel Targets
- Development of Investigational Drugs Ready for Clinical Testing

Human Cell-Based Platforms for Testing New Treatments
- iPSC-derived neurons for pain and reward pathways
- 3-D Bioprinted Tissue Models
- Tissue Chips

Model Complexity
- Cells
- Multi-organ

Extramural Funding Opportunities
Intramural Collaborations
Extramural and Intramural Collaborations
Clinical Testing and Trials
Preclinical Development
Early
Late
Mission Statement: to inform patients and providers on best pain treatment practices

Program Goals: Compare the effectiveness of existing therapies or novel approaches for delivering current therapies to prevent and manage pain while reducing risk of addiction

- strengthen and inform current guidelines for pharmacologic and non-pharmacologic treatments for numerous acute and chronic pain conditions
- manage acute and chronic pain in people from diverse communities
- provide patients & practitioners with a suite of effective strategies to alleviate pain and reduce reliance on opioids
- improve the quality of life for patients and their families
Program Structure

Research Network through NCATS Trial Innovation Network (TIN)

- Pain experts will be included in clinical and biostatistical coordinating centers through the TIN.
- Support for study recruitment will be provided through the TIN.

Support for phase 3 clinical trials

- Support large pragmatic, effectiveness clinical trials on an array of interventions for acute or chronic pain.