

NCATS HEAL Programs for Developing and Testing Pain and Addiction Treatments

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NCATS Mission



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.



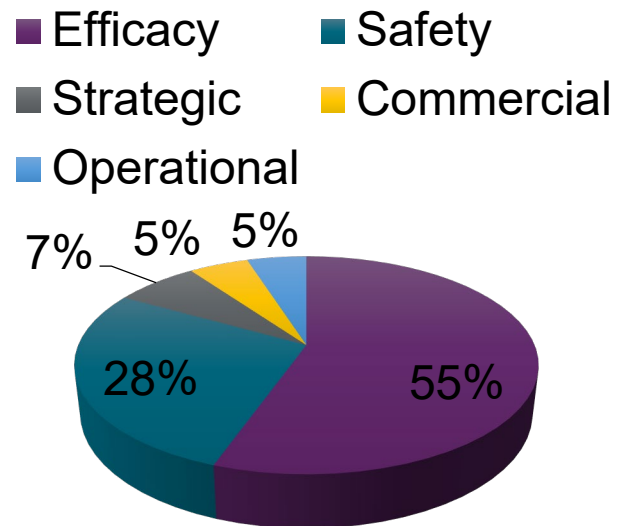
Some of the **scientific** translational problems on NCATS' to-do list

- 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



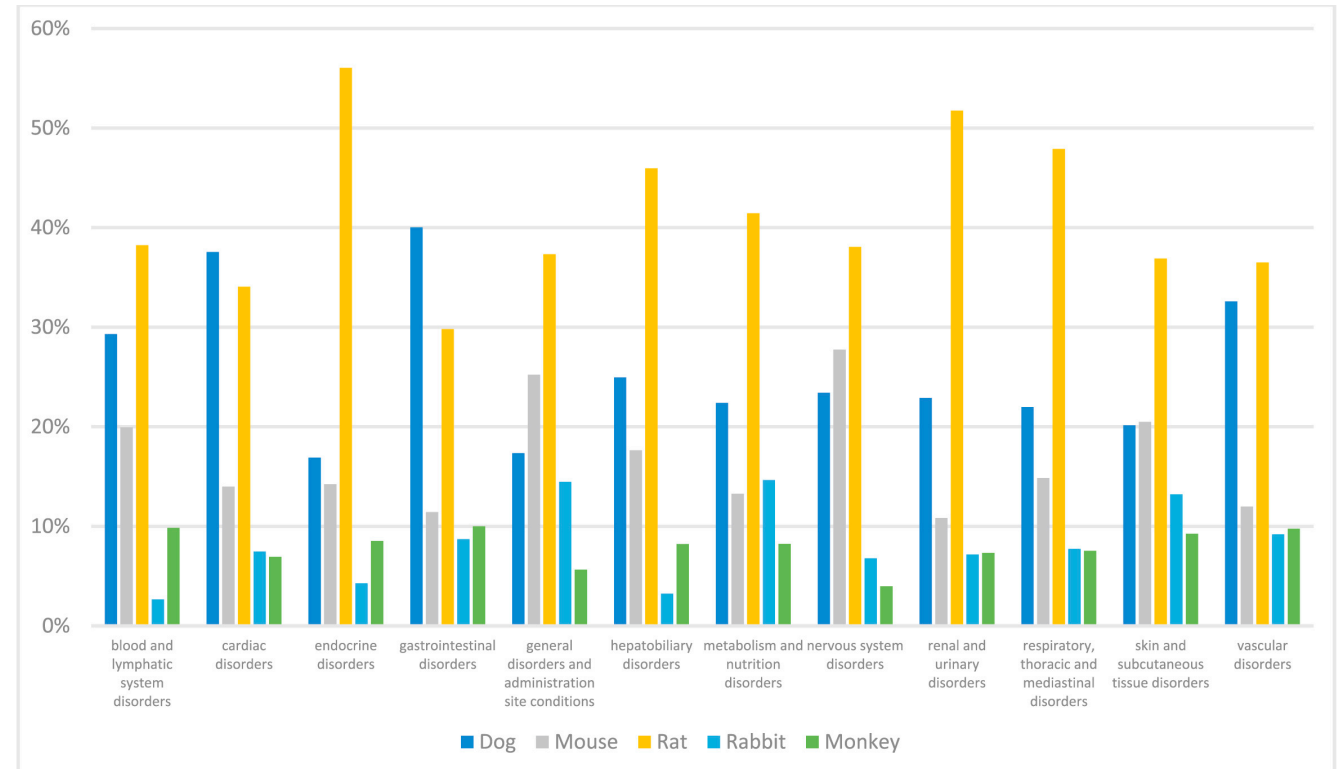
Why Drugs Fail in Development

Reasons for Drug Development Failure



Arrowsmith and Miller, *Nat Rev Drug Disc* 12: 569 (2013)

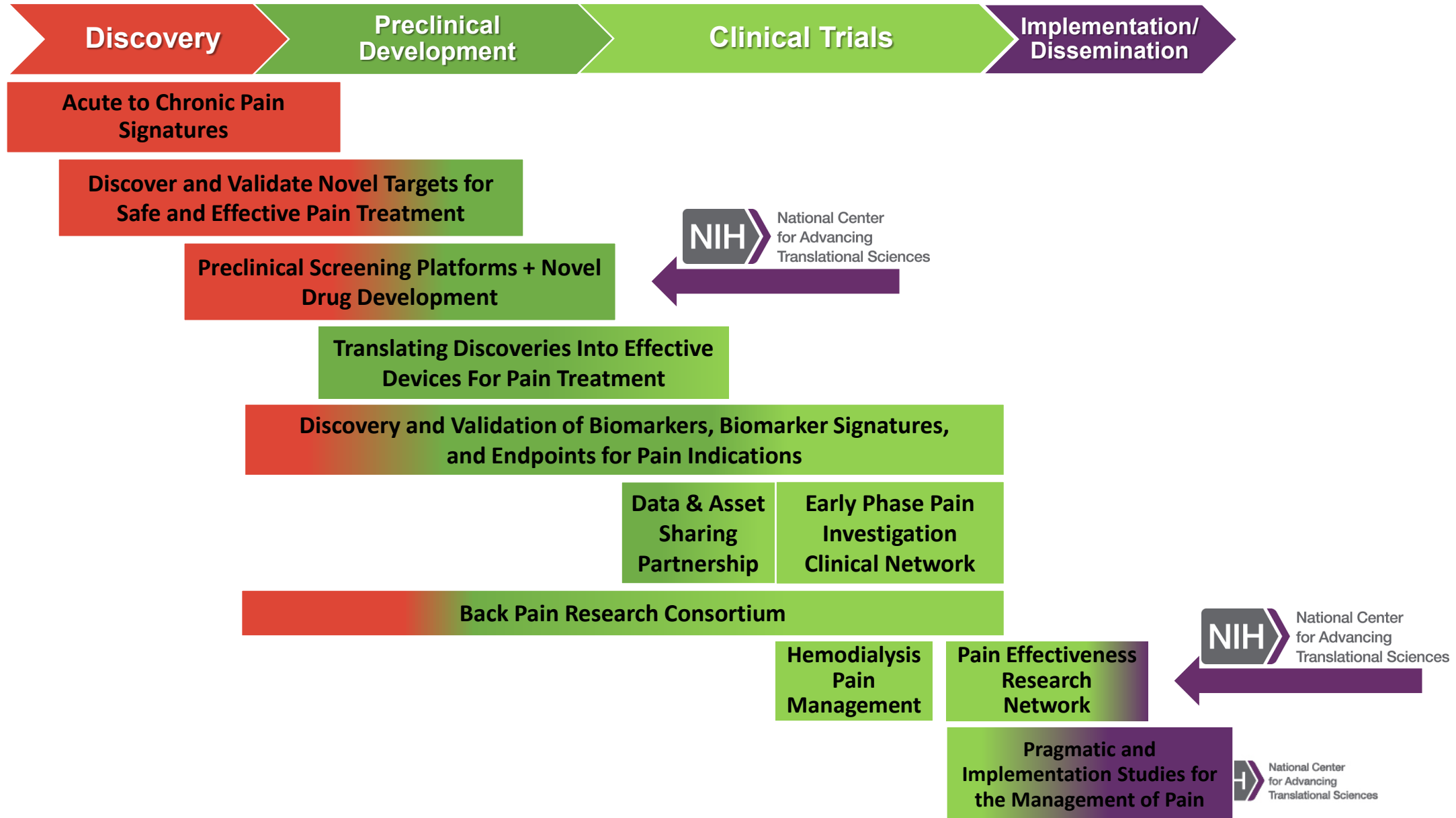
Concordance of true positive toxicities w human



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



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



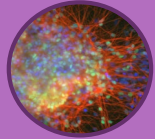
Developing Drugs and Testing Platforms for Pain, Addiction and Overdose in Collaboration with NCATS

Extramural and Intramural Collaborations

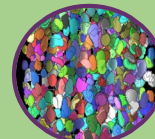
Extramural Funding Opportunities

Intramural Collaborations

Human Cell-Based Platforms for Testing New Treatments



iPSC-derived neurons for pain and reward pathways



3-D Bioprinted Tissue Models



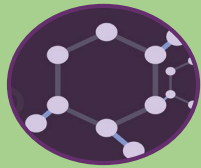
Tissue Chips

Model Complexity

Cells

Multi-organ

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

Preclinical Development

Early

Late

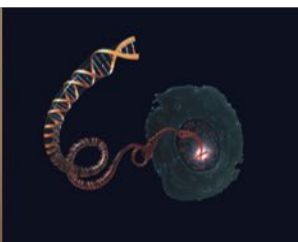
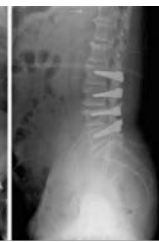
Clinical Testing and Trials

NIH HEAL Pain Management Effectiveness Research Network

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



HEAL Pain Management Effectiveness Research Network

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.

