

## The Pain Therapeutics Development Program (PTDP)

### Introduction

The Pain Therapeutics Development Program (PTDP) is part of the NIH Helping to End Addiction Long-term® (HEAL) Initiative, a trans-NIH research effort focused on improving prevention and treatment for opioid misuse and addiction and enhancing pain management. The PTDP focuses on facilitating R&D in academic and small business settings to allow riskier, high-reward projects an opportunity to test the feasibility of their candidate non-addictive pain therapeutics. In addition to grant support, the program provides access to consultants with extensive biopharma experience and CRO resources for a variety of activities including medicinal chemistry, manufacturing and formulation, DMPK, GLP toxicology and Phase I clinical testing. These grants are milestone-driven and progress against milestones is evaluated on an annual basis for the 5-year grant period.

### Program Overview

**Eligible Organizations**

- Academic Institutions
- Small Businesses
- Foreign Institutions & Components

**Goal: Accelerate the development of novel, non-opioid, non-addictive analgesics**

Hit/Lead Optimization

Lead Selection/Lead Characterization

IND Enabling Studies

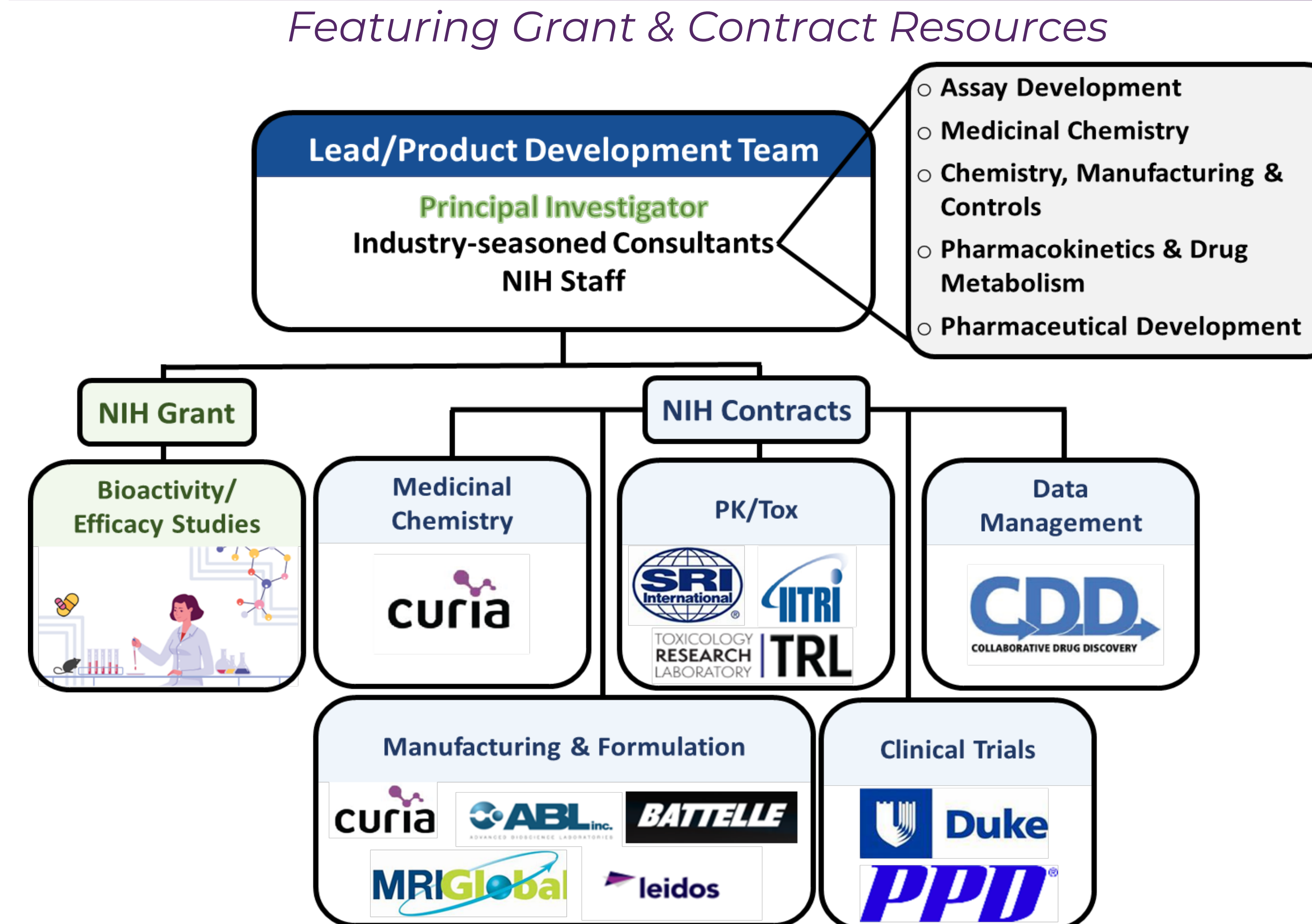
Phase I Clinical Trial

- Phased (UG3/UH3) grant with maximum 5 years of funding
- Grant includes access to NIH-sponsored ex-biopharma consultants and R&D CROs
- Entering applications can be at the Discovery or Development stage, and must include both UG3 and UH3 phases
- Project progression is milestone-driven and evaluated on an annual basis

### Participating Institutes & Centers

- National Institute on Neurological Disorders and Stroke (**NINDS**)
- National Institute on Alcohol Abuse and Alcoholism (**NIAAA**)
- National Institute on Drug Abuse (**NIDA**)
- National Institute for Complementary and Integrative Health (**NCCIH**)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (**NIAMS**)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (**NICHD**)
- National Institute of Dental and Craniofacial Research (**NIDCR**)
- National Institute of Diabetes and Digestive and Kidney Diseases (**NIDDK**)
- National Eye Institute (**NEI**)
- National Institute (**NHLBI**)

### A Virtual Pharma Model



### Program Features

- Lead Development Team members tailored to project stage
  - NIH Contract resources are tailored for each project
  - Awardee can choose which NIH contracts to use
- NIH Consultant assignments are also tailored to each project
- PI team's Intellectual Property Retained by PI's Institution

### Milestones and End Goals

- ✓ Identify and fully characterize a lead candidate
- ✓ Identify target engagement biomarker if possible
- ✓ Seek partnerships
- ✓ Complete IND enabling studies
- ✓ File IND
- ✓ Complete Phase I trial(s)
- ✓ Ready for Phase II clinical trial

### Entry Criteria

**Discovery**

Hit/Lead Optimization

Lead Selection/Lead Characterization

- ✓ A rigorous biological rationale for the intended approach
- ✓ A promising small molecule or biologic starting point for optimization
- ✓ Scientifically sound assays to optimize and test the agent

**Development**

IND Enabling Studies

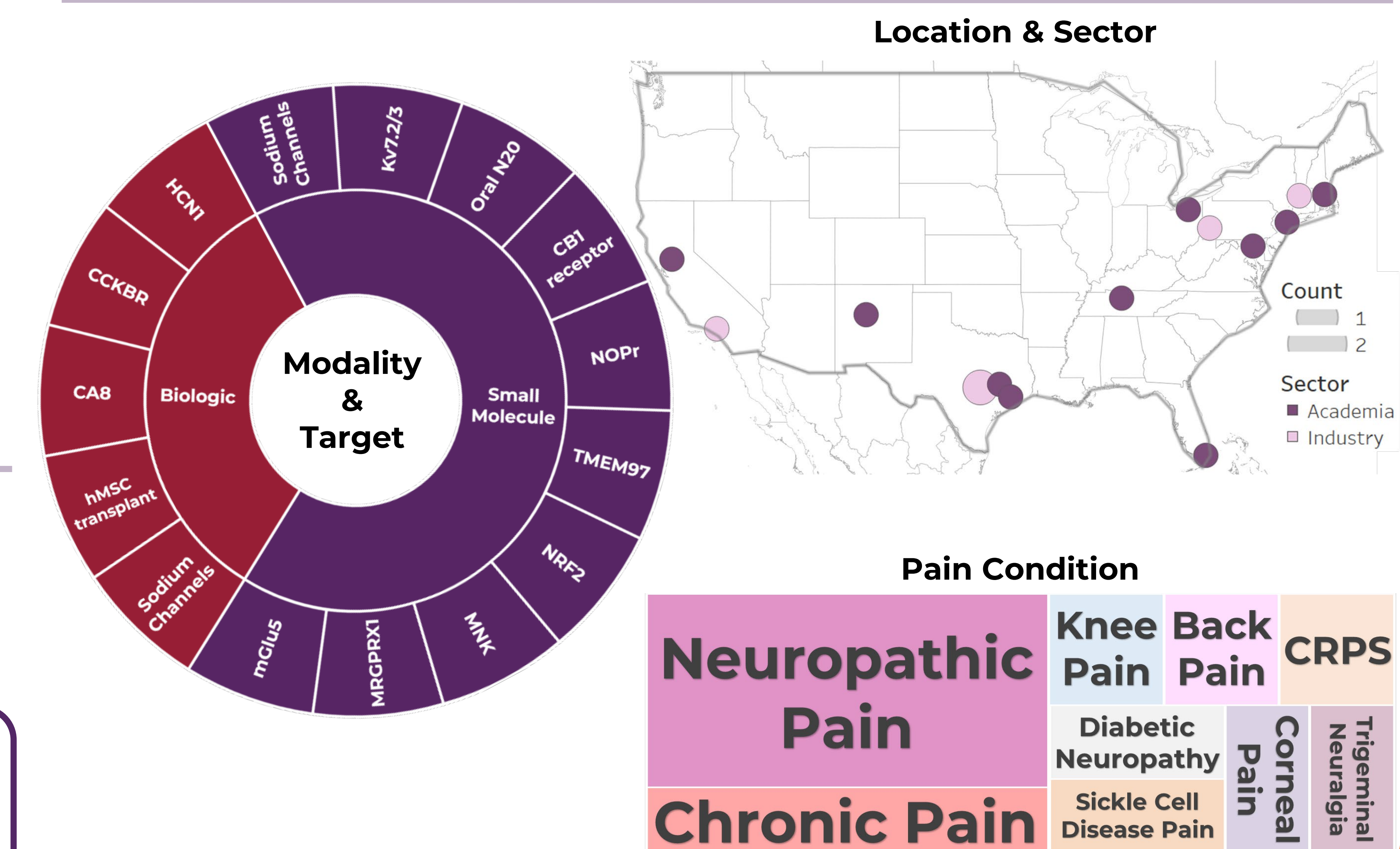
Phase I Clinical Trial

- ✓ Candidate therapeutic is Identified
- ✓ Strong data package linking modulation of therapeutic target by candidate therapeutic to disease modification
- ✓ Biological activity and ADMET properties of candidate therapeutic are appropriate for intended use

Regardless of entry stage **EVERY** application should include:

- ✓ **UG3 & UH3 phase** activities in the application and budgets
- ✓ **Milestones** that enable quantitative measurements of success for key grant objectives
- ✓ **Separate budgets for each year** of the grant
- ✓ **A table of activities** indicating what will be conducted by the **PD/PI team, NIH CROs or consultants**
- ✓ **A Target Product Profile (TPP) table**
- ✓ **Biomarker and intellectual property** components

### PTDP Pipeline (n=15)



**Apply!**

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**Visit PTDP Online!**