

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 a maximum 5-year grant period.

Program Overview

Eligible Organizations

- Academic Institutions
- Small Businesses
- Foreign Components are allowed

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

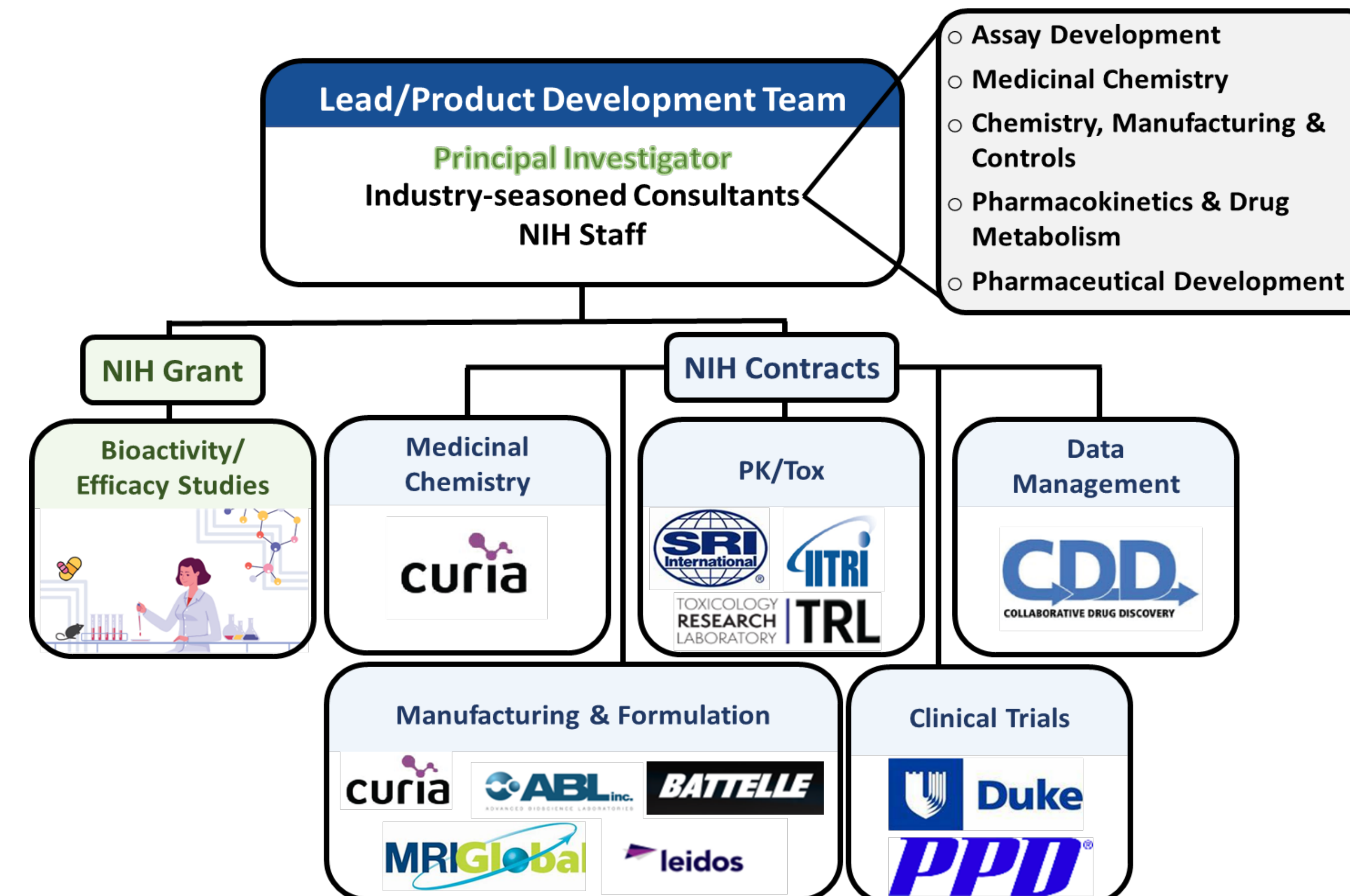
- Phased (UG3/UH3) grant with maximum 5 years of funding
- Grant includes access to NIH-sponsored ex-biopharma consultants and R&D CROs
- Entering applications can be at the Discovery or Development stage, and must include both UG3 and UH3 phases
- Project progression is milestone-driven and evaluated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

Participating Institutes & Centers

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

A Virtual Pharma Model

Featuring Grant & Contract Resources



Program Features

- o Lead Development Team members tailored to project stage
 - o NIH Contract resources are tailored for each project
 - o Awardee can choose which NIH contracts to use
- o NIH Consultant assignments are also tailored to each project
- o 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

Apply!

Program Director
Mary Ann Pelleymounter, PhD
mary.pelleymounter@nih.gov

Visit PTDP Online!

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 **MUST** include:

- ✓ UG3 & UH3 phase activities in the application and budgets
- ✓ Go/No-Go Milestones that enable quantitative measurements of success for key grant objectives

- ✓ Separate budgets for each year of the proposed project
- ✓ A Target Product Profile (TPP) table
- ✓ An Intellectual Property (IP) plan

PTDP Pipeline (n=18)

