

Request for Research Proposals to Evaluate Strategies for Optimal Opioid Sparing, Tapering and Discontinuation

Chronic pain can be complex to treat, and patients with chronic pain are often medically complex. An important objective of appropriate pain management is utilizing pain medicines at the lowest dose for the shortest duration to achieve treatment goals. While opioid therapy can play an important role in chronic pain management, there is little data on use of opioid sparing and opioid tapering strategies. These represent important data gaps for optimizing medical treatment to adequately and safely control chronic pain.

Treatment guidelines for opioid use among patients with chronic pain generally indicate that opioids should be tapered slowly to reduce the risk and severity of withdrawal symptoms.^{1,2} However, there are few studies substantiating strategies to taper opioids to lower doses, or to stop opioid therapy after long-term and/or high-dose use, and how this process can best be integrated with other pain management strategies to ensure patients maintain adequate pain control. By addressing these data gaps through research funding, Purdue Pharma L.P. hopes to advance our remit to be part of the solution to reduce misuse and abuse of prescription opioid medicines.

Description of Request for Proposals:

Proposals are requested to address the following research question: *What is a safe and effective strategy to taper patients with chronic pain to lower opioid doses, or to stop opioid therapy altogether, while maintaining adequate pain control?* Studies can be prospective or retrospective, and may incorporate single or multiple strategies. Specific strategies and outcomes of interest include, but are not limited to:

- *Opioid sparing*
Evaluation of non-opioid and non-pharmacologic treatments that may complement tapering or discontinuation, for example: NSAIDs, nerve blocks, cognitive behavioral therapy, exercise programs, mindfulness training
- *Cessation of opioid therapy:*
 - Identification of predictors for difficulty in tapering or stopping chronic opioid therapy
 - Utilization of buprenorphine or methadone during down-titration/discontinuation
 - Assessment of patient acceptance of various tapering strategies
 - Effectiveness of therapies to minimize patient withdrawal symptoms

Applicants should complete an information sheet and submit a 1 to 2 page letter of intent that outlines the study concept. The study concept must include:

- Objective
- Design
- Target population
- Key inclusion/exclusion criteria
- Methods
- Primary/secondary endpoints
- Intended analysis
- Estimated study duration

The information sheet and additional information can be found at <http://www.purduepharma.com/healthcare-professionals/clinical-trials/investigator-initiated-research/>.

The letter of intent must be submitted via email to iitprogram@pharma.com by 5:00 PM EDT on September 30, 2016. Letters of intent will be reviewed by an independent Steering Committee, and a subset of applicants will be invited to a teleconference to present the study concept in greater detail and to ask and answer questions. The Steering Committee will invite a set of applicants to submit a 10 to 15 page study proposal and line-item budget, and will select final awardees. Funding will be issued based upon a fully executed milestone-based agreement. All accepted proposals are expected to result in publication of findings in a peer-reviewed journal. The primary study investigator must be based in the United States. Preference will be given to proposals that incorporate Purdue's opioid products.

Potential applicants are strongly encouraged to contact Purdue at iitprogram@pharma.com for additional information prior to submitting a letter of intent

References:

1. Department of Veterans Affairs/Department of Defense. Tapering and discontinuing opioids factsheet. <http://www.healthquality.va.gov/guidelines/Pain/cot/OpioidTaperingFactSheet23May2013v1.pdf>. Accessed July 14, 2016.
2. Centers for Disease Control and Prevention. Guideline for Prescribing Opioids for Chronic Pain. Pocket Guide: Tapering Opioids for Chronic Pain. Available at: http://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf. Accessed August 25, 2016.

