



---

## Early Phase Pain Investigations Clinical Network (EPPIC Net)

**The National Institutes of Health is seeking contributions of pharmaceutical and device assets for testing in a new NIH-supported clinical trials network designed to develop non-addictive treatments for pain, and applications for the related grants program.**

In April 2018, NIH launched the HEAL (Helping to End Addiction Long-term<sup>SM</sup>) Initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. NIH has committed to spend over \$500 million in FY 2019 on a comprehensive set of programs to improve prevention of and treatment for opioid misuse and addiction and enhance pain management.

An important part of HEAL will be the establishment of EPPIC-Net, a new clinical trial network to enhance the treatment of acute and chronic pain and reduce reliance on opioids by accelerating early phase clinical trials of non-addictive pain therapeutics, including drugs and devices. When fully operational in early 2020, EPPIC-Net will establish well-characterized patient cohorts with clearly defined outcome measures in specific pain conditions, test new pain therapies in early phase clinical trials, validate biomarkers for assessing target engagement and pain outcomes, and enable the evaluation of innovative clinical trial designs. Data and insights resulting from these trials will be broadly shared to help accelerate the development of new therapies for chronic pain across the scientific community.

**NIH plans to provide both trial infrastructure and funding for specific Phase 2 clinical trials of therapeutic agents and devices selected to participate in the EPPIC-Net program and is seeking grant applications from industry and academic investigators with access to trial-ready assets that could be tested in the network.** Data from trial outcomes is expected to be broadly shared, but under terms that enable full regulatory registration and commercial rights to approved grantees and trial sponsors. Intellectual property and products (assets) studied within EPPIC-Net will remain the property of the asset owner.

Priority consideration will be given to:

- candidates with an existing IND or devices with an existing IDE;
- candidates to be tested in patients with pain conditions of high unmet need;
- candidates that have high potential to move to industry-funded phase 3 efficacy trials, should the earlier phase study conducted in EPPIC-Net achieve its prespecified endpoints.

Prior to grant award and trial activation, applications to EPPIC-Net will go through a **3-step review process** that will evaluate proposals on the basis of defined clinical population need, readiness of assets for Phase 2 testing (including preliminary safety and efficacy data and asset availability), and likelihood of success.

**Step 1** Applicants will complete a brief, 2-page form which is available on the NIH HEAL website [\[link\]](#). This form requests information concerning basic characteristics of the asset (for example type of drug, mechanism of action, current status of development and pain condition) sufficient to enable initial evaluation for suitability for EPPIC-Net. This will be accomplished via an accelerated, independent peer review process conducted on a rolling schedule. Top-ranking applications will proceed to step 2.

**Step 2** Successful applicants will work with an NIH-selected CRO to prepare an asset "dossier" with more information on the pharmacology of the drug or specifications of the device asset. The information in this dossier will be used to evaluate the fit of the proposal for the EPPIC-Net network and assess what is required to develop a successful trial design (for example pharmacokinetics, potency, selectivity and current results from preclinical and clinical programs). The dossier will be submitted to the same NIH independent peer review process used for the Step 1 evaluation. Sensitive, proprietary information involved in the process will be treated confidentially as appropriate.

**Step 3** Applicants whose proposals are selected in Step 2 will work with the EPPIC-Net clinical team to develop a suitable clinical trial protocol, which will undergo a final review by the NIH EPPIC Net protocol review committee prior to confirmation of study funding and implementation within EPPIC-Net.

Additional information about EPPIC Net may be found on the NIH HEAL website at [link](#).

For additional information, please contact:

Barbara I. Karp, MD  
6001 Executive Blvd. Rm 2206  
Bethesda, MD 20852

Phone (o): 301-496-0150  
email: [barbara.karp@nih.gov](mailto:barbara.karp@nih.gov)