

The NIH HEAL Initiative/National Institute of Neurological Disorders and Stroke Early Phase Pain Investigation Clinical Network Update

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Early Phase Pain Investigation Clinical Network (EPPIC-Net) Overview

Goals

- Advance scientific solutions to develop opioid alternatives to stem the opioid crisis.
- Provide Phase-2 clinical trials for novel non-addictive therapeutics (“assets”) targeted to pain conditions of unmet need.
- Evaluate proposed assets: small molecules, biologics, natural products, and devices (pharmacologic and non-pharmacologic).

Applicants

- EPPIC-Net is open to any entity proposing non-addictive therapeutic assets for any pain condition that lacks adequate treatment.
- Assets should be Phase-2 ready.
- Asset holders retain asset ownership and intellectual property rights.

Resources

- A platform to run high quality trials.
- Stable infrastructure and research capacity.
- Centralized data handling and sharing.
- Training the next generation of pain clinical trialists.

Trials

- Incorporate biomarker evaluation. Incorporate innovative clinical trial paradigms.
- Incorporate deep phenotyping to establish well-characterized pain patient cohorts.

EPPIC-Net Trial Network

NIH/NINDS/HEAL

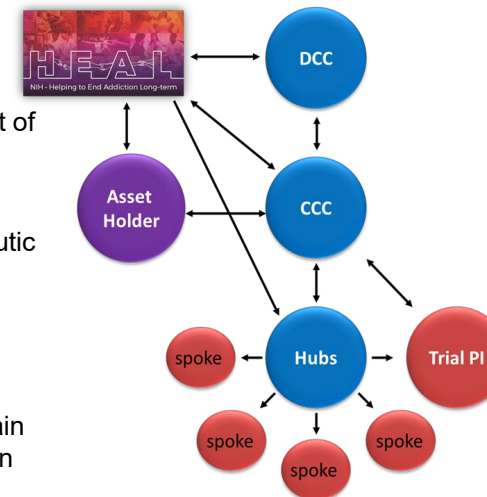
- Interacts with all EPPIC-Net components.
- Provides guidance and oversight of budget and milestones.

Asset Holder

- Provides the novel pain therapeutic for study within EPPIC-Net.

Specialized Clinical Centers

- 12 clinical hubs/spokes conduct research procedures.
- Provides clinical researchers, pain expertise, access to focused pain patient populations, and wide outreach into pain communities.



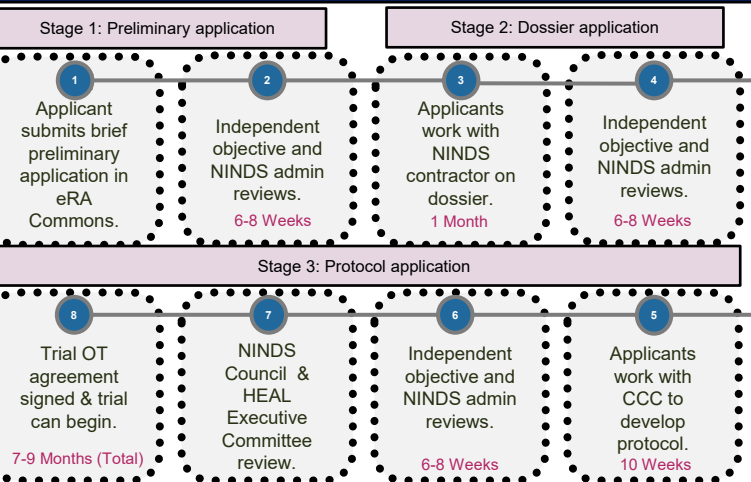
Data Coordinating Center (DCC): New York University

Oversees data management, statistical support, quality assurance, biorepository, reports for monitoring entities.

Clinical Coordinating Center (CCC): Massachusetts General Hospital

Oversees protocol development, trial management, site/investigator training, interface with IRB.

EPPIC-Net Application & Review Process



EPPIC-Net accepts and reviews applications on a rolling basis.

EPPIC-Net Clinical Trials use “Other Transaction” (OT) Awards

If awarded, funds are awarded to the Clinical Coordinating Center for trial conduct.

Asset owners:

- Do not receive funds.
- Gain access to EPPIC-Net for asset clinical trial.
- Maintains IP rights.

Funded EPPIC-Net Trials open to enrollment

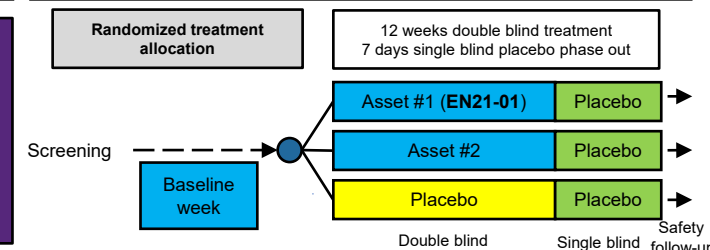
EN20-01: A 24-week Week Study to Evaluate the Safety and Efficacy of CNTX-6970 in Subjects with Moderate to Severe Knee Osteoarthritis Pain

Study Design

- Patients randomized into two 12-week blocks with drug/placebo in counterbalanced order.
- Allocation concealed
- Multicenter
- Placebo-controlled
- Multi-crossover: 150 patients

EN21-01: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of 80 mg o.d. of NRD135S.E1 versus Placebo in Adult and Elderly Subjects with PDPN.

EN21 MP: Platform Protocol to Assess Treatments for Painful Diabetic Peripheral Neuropathy (PDPN)



Platform Design

- Multiple assets, each compared to placebo
- Tested under a modular protocol with parallel arm design