Early Phase Pain Investigation Clinical Network (EPPIC-Net)

Frequently Asked Questions (FAQ)

Types of Assets and Proposal Questions:

1. Is EPPIC-Net open to cannabinoids or opioid drugs?

2. Are medical devices, like neuromodulation devices, responsive to this ROA and eligible for application to EPPIC-Net?

3. If the asset is appropriate for a phase 2 clinical trial for more than one pain indication, how may that be addressed in the preliminary application?

4. Will an application have a better chance of success if it targets a common condition, like peripheral neuropathy, rather than a rare condition?

5. Can an application be submitted while phase 1 supporting data are still being collected, on the assumption that the data will be available and the asset ready for IND/IDE submission by the time of Stage 2 (dossier) application?

6. What resources are available if an asset is not phase 2 ready?

Application Process Questions:

7. What is the eRA Commons registration process for non-affiliated applicants and organizations?

8. Am I required to have an IND or IDE before submitting an EPPIC-Net preliminary application?

9. What feedback is provided from application review? Can applicants submit a response to the review critique?

10. Since applications are accepted on a rolling basis, when and how often are preliminary applications reviewed?

11. Can a foreign (non-U.S.) entity apply to EPPIC-Net?

Regulatory and Post-Trial Questions:

12. Who is the IND/IDE sponsor for an FDA-regulated trial?

13. Will EPPIC-Net accept a protocol that has already been filed with and approved by the FDA?

14. Can an EPPIC-Net trial be used as a registration trial for the FDA?

15. Will the applicant have access to the data from an EPPIC-Net clinical trial?

16. Will data from this study be shared or made publicly available?

1. **Is EPPIC-Net open to cannabinoids or opioid drugs?**

   Answer: EPPIC-Net can consider applications with drugs in these classes and other controlled substances, like psilocybin. If the proposed asset is an opioid or other potential drug of abuse, the review will look carefully at data that supports a lack of addiction and abuse potential for the asset and its advantage over approved pain therapeutics.

2. **Are medical devices, like neuromodulation devices, responsive to this ROA and eligible for application to EPPIC-Net**

   Answer: Yes. Medical devices are responsive and should have an IDE, be IDE-ready, or IDE-exempt at the time of EPPIC-Net application.

3. **If the asset is appropriate for a phase 2 clinical trial for more than one pain indication, how may that be addressed in the preliminary application?**

   Answer: The asset-holders/applicants, who know their asset the best, should choose a single target pain condition that they consider the best fit for their asset and that can be adequately justified by supporting data. It can be indicated in the discussion and text sections of the preliminary application form that a single pain condition was chosen for the purpose of application, but that the asset may have broader applicability. During the review process, the independent review committee and NIH may consider a different indication a better fit and, if the application moves forward, would discuss a change in pain condition focus with the applicant.

4. **Will an application have a better chance of success if it targets a common condition, like peripheral neuropathy, rather than a rare condition?**

   Answer: EPPIC-Net does not prioritize any specific pain condition. High-impact applications focused on rare diseases and conditions are equally acceptable to EPPIC-Net as those that affect large segments of the population. All therapeutics targeting pain conditions of high unmet need are welcome, regardless of condition prevalence.

5. **Can an application be submitted while phase 1 supporting data are still being collected, on the assumption that the data will be available and the asset ready for IND/IDE submission by the time of Stage 2 (dossier) application?**

   No. All data that the FDA would require in support of an IND/IDE application should be available at the time of preliminary application. Unpublished data can be considered in support of a preliminary applications and can be cited in the appropriate section of the preliminary application.

6. **What resources are available if an asset is not phase 2-ready?**

   Answer: EPPIC-Net is not able to accommodate asset preclinical testing and cannot provide funds or pay for the preparation of pharmaceutical grade asset for a study, NINDS accepts applications for funding to support preclinical development and testing under its [Preclinical Screening Platform for Pain](#) and the [Blueprint Neurotherapeutics (BPN) Network](#). HEAL Initiative programs including [RFA-NS-21-015](#), [RFA-NS-21-016](#), and [RFA-NS-21-010](#) also support pre-clinical and Phase 1 therapeutic development. The [NIH HEAL Initiative](#) website has complete information on open HEAL funding opportunities: https://heal.nih.gov/funding/open. Opportunities under other NIH Institutes and Initiatives can be found in the NIH guide: https://grants.nih.gov/funding/searchguide/index.html#/

7. **What is the eRA Commons registration process for non-affiliated applicants and organizations?**

   Answer: There are 2 options.
   - An applicant can register as an individual. To apply to EPPIC-Net as a non-affiliated individual, choose the option in eRA Commons to register for "OTA." A non-affiliated individual registering for OTA does not need a DUNS number, Grants.gov registration, SAM registration, cage numbers or any other registrations.
   - An applicant can also identify an affiliated organization to partner with and register under that affiliated organization.

8. **Am I required to have an IND or IDE before submitting an EPPIC-Net preliminary application?**

   Answer: An IND or IDE is not required to submit an application to EPPIC-Net. However, the asset should be "IND/IDE ready." For assets that are not IND/IDE exempt, the application to EPPIC-Net should not be submitted until all data that the FDA would require in support of an IND/IDE application is available.

9. **What feedback is provided from application review? Can applicants submit a response to the review critique?**

   Answer: EPPIC-Net independent review is not a traditional NIH peer review. Applications are not ranked and review summaries are not provided to applicants. Independent review is supplemented by administrative review within NINDS. Applicants will receive a notification letter from EPPIC-Net that informs the applicant of review decisions. The notification letter delineates decision-driving concerns raised during independent and administrative review. Applicants may not submit a direct response to the concerns. However, applicants may submit a new preliminary application incorporating new or clarifying information that addresses points raised in the notification letter.

10. Since applications are accepted on a rolling basis, when and how often are preliminary applications reviewed?

    Answer: EPPIC-Net applications are reviewed approximately every 6 weeks. Notification letters are usually released 6-8 weeks after application receipt.

11. **Can a foreign (non-U.S.) entity apply to EPPIC-Net?**

    Yes. Non-U.S. individuals, organizations and companies can apply to EPPIC-Net. Please note that the asset applicant does not receive funding for an EPPIC-Net Clinical Trial. EPPIC-Net Other Transactions (OT) funds are provided to the EPPIC-Net Clinical Coordinating Center to administer for conduct of the clinical trial for accepted assets.

12. **Who is the IND/IDE sponsor for an FDA-regulated trial?**

    EPPIC-Net prefers that the CCC is the IND/IDE sponsor for an FDA-regulated trial and will handle regulatory reports and correspondence. Sponsorship will be transferred to the asset owner at completion of the trial. If the asset owner/applicant is the IND/IDE sponsor, EPPIC-net will generally not engage directly with the FDA on behalf of the asset owner. EPPIC-

13. **Will EPPIC-Net accept a protocol that has already been filed with and approved by the FDA?**

    An asset owner who applies with a protocol already approved by the FDA must understand that EPPIC-Net may or may not utilize that protocol. The EPPIC-Net CCC, in consultation with the DCC, NIH and asset owner, is charged with developing the protocol for a phase 2 clinical trial customized to the asset and possibly incorporating innovative and efficient trial designs.

    The EPPIC-Net ROAs delineate what EPPIC-Net is offering: a phase 2 trial customized to accepted assets. EPPIC will consider, but may not be able to accommodate, asset owner requests with respect to the clinical trial design and its implementation.

14. **Can an EPPIC-Net trial be used as a registration trial for the FDA?**

    EPPIC-Net supports assets in phase 2 clinical trials. It may not be possible to conduct an FDA registration trial for a particular asset within EPPIC-Net. It is expected that the asset owner will pursue further development outside of EPPIC-Net if the EPPIC-Net trial is successful.

15. Will the applicant have access to the data from an EPPIC-Net clinical trial?

After data cleaning, verification and data lock, the applicant will have access to de-identified study data.

16. Will data from this study be shared or made publicly available?

Data from EPPIC-Net clinical trials is subject to the NIH HEAL Initiative Public Access and Data Sharing Policy https://heal.nih.gov/about/public-access-data and will be made available in accordance with the study-specific Public Access and Data Sharing Plan.