

HEAL Partnership Committee and the Early Phase Pain Investigation Clinical Network (EPPIC-Net)

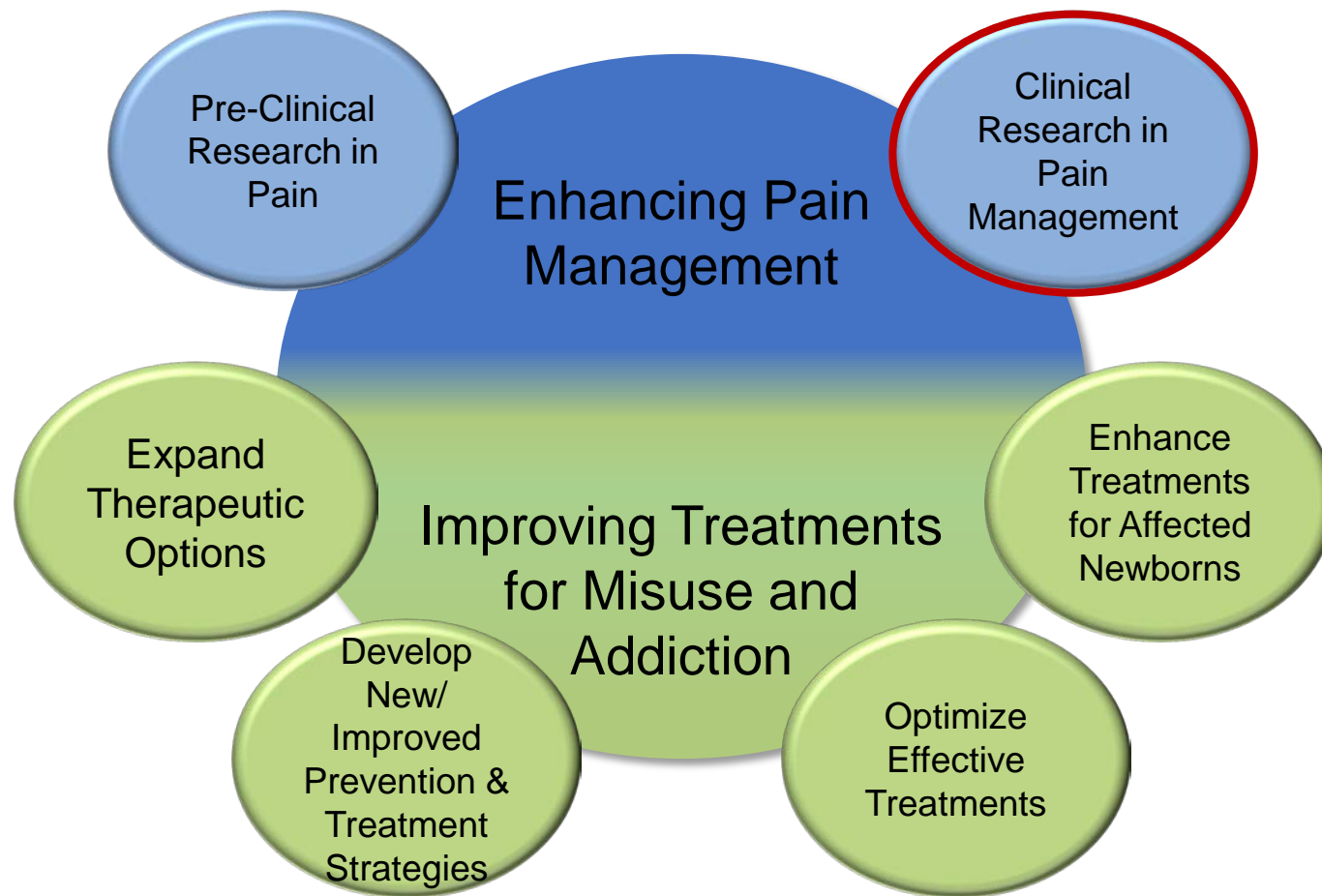
For MDWG Input

Walter J. Koroshetz, MD

Director, National Institute of Neurological Disorders and
Stroke



HEAL Initiative Research



Enhancing Pain Management: Clinical Research in Pain Management

- Characterize populations of patients with pain conditions
- Test novel treatments in a new clinical trials network
 - Early Phase Pain Investigation Clinical Network (EPPIC Net)
 - Back Pain Research Consortium
- Establish best strategies for management of acute and chronic pain
 - Pain Management Effectiveness Research Network (ERN)
 - Integrated approach to pain and opioid use in hemodialysis patients
 - Pragmatic and Implementation Studies for the Management of Pain (PRISM)



Early Phase Pain Investigation Clinical Network (EPPIC-Net) Mission and Goals

- Mission: Improve the treatment of acute and chronic pain and reduce the reliance on opioids, by accelerating the early phase testing of promising non-addictive therapeutics and devices to relieve pain
- Goals
 - Develop a highly effective infrastructure for the rigorous early phase testing of promising pain treatments (small molecules, biologics, devices) from academia and industry.
 - Take advantage of existing pain expertise in both academia and industry
 - Advance pain clinical research through a learning network
 - Train new clinical investigators,
 - Design and test innovative clinical trial paradigms,
 - Establishing well-phenotyped patient cohorts (e.g. BACPAC),
- Incorporate biomarkers of target engagement or proof-of-principle into clinical trial design for new non-addictive pain treatments whether small molecules, devices, or biologics

Accelerate Development of Pain Treatments: Data and Asset Sharing Partnership

- Capitalize on previous efforts and share knowledge surrounding development and testing of pain therapeutics
 - EPPIC-net Data Coordination Center will host data and biosample repositories from HEAL programs and industry partners
 - Link testing of assets with other HEAL research e.g. biomarkers
 - Coordinated with the FNIH
- HEAL Partnership Forum will allow for participation by more companies and partners
- HEAL Partnership Committee will encourage submission of assets for phase 2 clinical trials



HEAL Partnership Committee (HPC)

- **Christopher Austin**
National Center for Advancing Translational Sciences
- **Patricia Cavazzoni**
U.S. Food and Drug Administration
- **John Dunlop**
Amgen
- **Christopher Flores**
Janssen Pharmaceutical Companies of Johnson & Johnson
- **Steven Joffe**
University of Pennsylvania Perelman School of Medicine
- **Walter Koroshetz**
National Institute of Neurological Disorders and Stroke
- **John Marler**
U.S. Food and Drug Administration
- **Mark Mintun**
Lilly
- **Richard Moscicki**
Pharmaceutical Research and Manufacturers of America
- **Judith Paice**
Northwestern University
- **Kurt Rasmussen**
National Institute on Drug Abuse
- **Cheryl Stucky**
Medical College of Wisconsin
- **Dave Thomas**
Biotechnology Innovation Organization
- **Christin Veasley**
Chronic Pain Research Alliance
- **Kenneth Verburg**
Pfizer
- **Ashley Wittorf**
AdvaMed
- **Clifford Woolf**
Harvard Medical School

HEAL Partnership Committee (HPC) – Topics covered at March meeting

- Review of NIH Programs for Developing and Testing Pain Treatments
 - Early Phase Pain Investigation Clinical Network (EPPIC-Net) – How will it work
 - NIH Solicitation, Review, and Awards Process
- Presentations: Challenges of the Development of Pain Therapies & Intersection with HEAL
 - Regulatory considerations for evaluation and approval of pain medications (Patrizia Cavazzoni, FDA)
 - Industry considerations for development of assets (Ken Verburg, Pfizer)
 - Medical Device Perspective (Ashley Wittorf, AdvaMed)
 - Perspective of People with Pain (Chris Veasley, Chronic Pain Research Alliance)
 - Panel Discussion – Q&A
- Considerations for the Review of Assets for EPPIC-Net
 - Considerations for the Template
 - Considerations for the Dossier
 - Other Specific Areas for Consideration

Will cover in
today's
presentation

**Summary and materials are publicly
available at:**

<https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative/events>



March 5, 2019

Partnership Committee Meeting

- Meeting Agenda
- Videocast 
- Presentations
 - Conflicts of Interest Declarations 
 - Role of the HEAL Partnership Committee in the HEAL Initiative 
 - NIH Programs for Developing and Testing Pain Treatments 
 - Challenges of the Development of Pain Therapies & Intersection with HEAL 
 - Challenges in the Development of Pain Therapies – A Patient's Perspective 
 - Considerations for the Review of Assets for EPPIC NET 

HEAL Partnership Committee (HPC) – Topics covered at April virtual meeting

- Review of Revised Asset Template and Information Dossier for EPPIC-Net
 - Template feedback and revisions
 - Dossier feedback and revisions
- Communications Plan for the Request and Solicitation Process for EPPIC-Net
 - Leverage multiple dissemination methods
 - E.g., BIO convention
 - HPC members will be crucial for dissemination once system is live
- Scope and Potential Agenda Items for Next Meeting
 - Discuss cell-based screening platforms and 3D tissue models
 - Design standards for pain trials

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April 15, 2019

Partnership Committee Teleconference Meeting

2:00-3:30 p.m. ET

- Meeting Agenda
- Meeting Notes pdf
- EPPIC Net Handout pdf
- EPPIC Net Dossier Questionnaire for HEAL Program Applicant pdf
- Asset Template xls

Early Phase Pain Investigation Clinical Network (EPPIC-net)

- To improve quality, consistency, efficiency of early phase pain clinical trials
- Structure: Clinical Coordination Center, Data Coordination Center,
10 specialized clinical sites (hub and spoke design)
- Focus: well-defined pain conditions with high unmet need
 - Incorporate biomarker studies; accommodate platform trial designs
- Goal: develop effective infrastructure for rigorous early phase testing of promising pain treatments (small molecules, biologics, devices)
 - From academia and industry



EPPIC-Net Infrastructure

Data Coordination Center

- Statistical expertise
- Trial expertise

Repositories:
Industry and HEAL
biosamples,
neuroimaging, and
data

Clinical Coordination Center

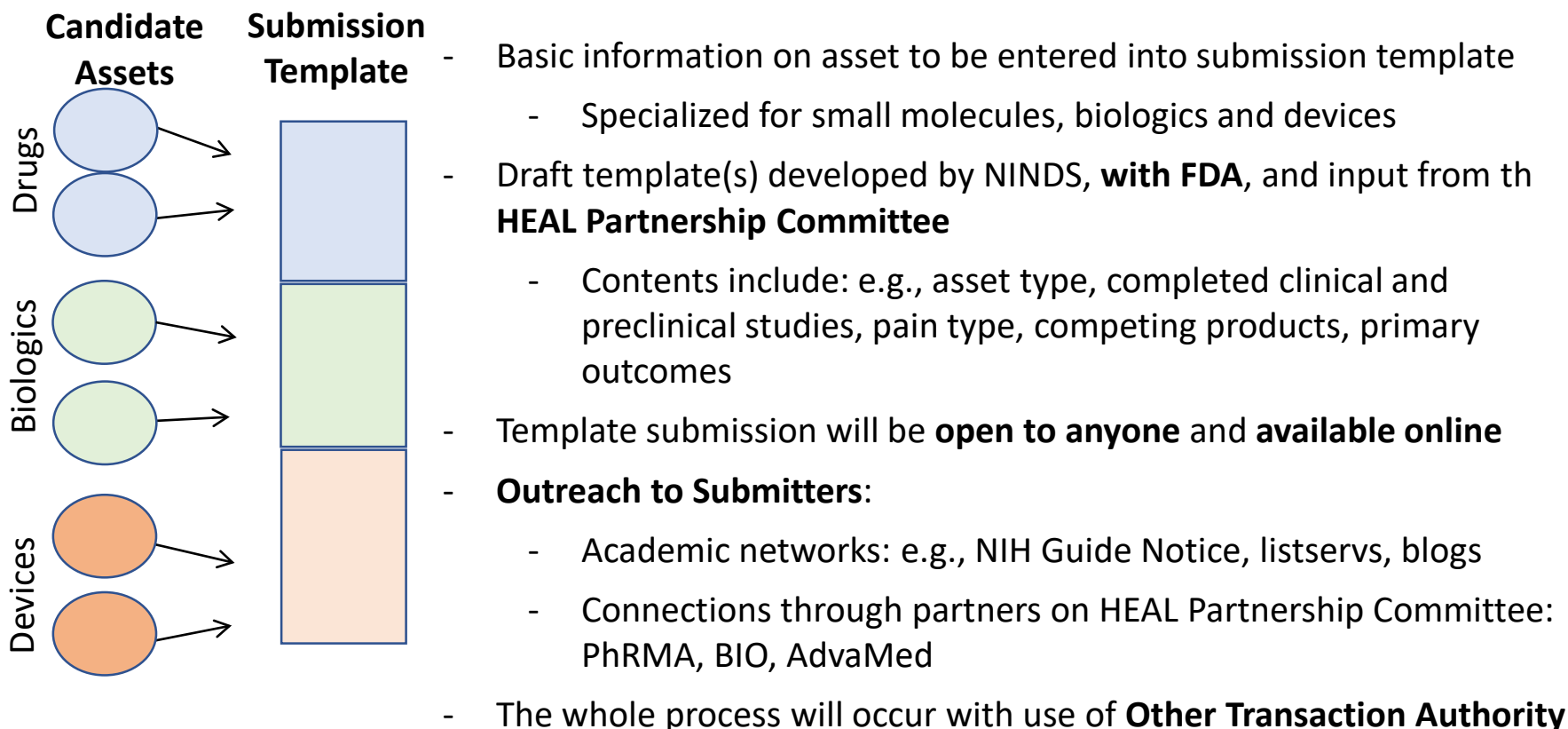
- Clinical expertise
- Pain expertise
- Organizes hubs
- Protocol design (with hubs)

10 Specialized Clinical Centers (hubs + spokes)

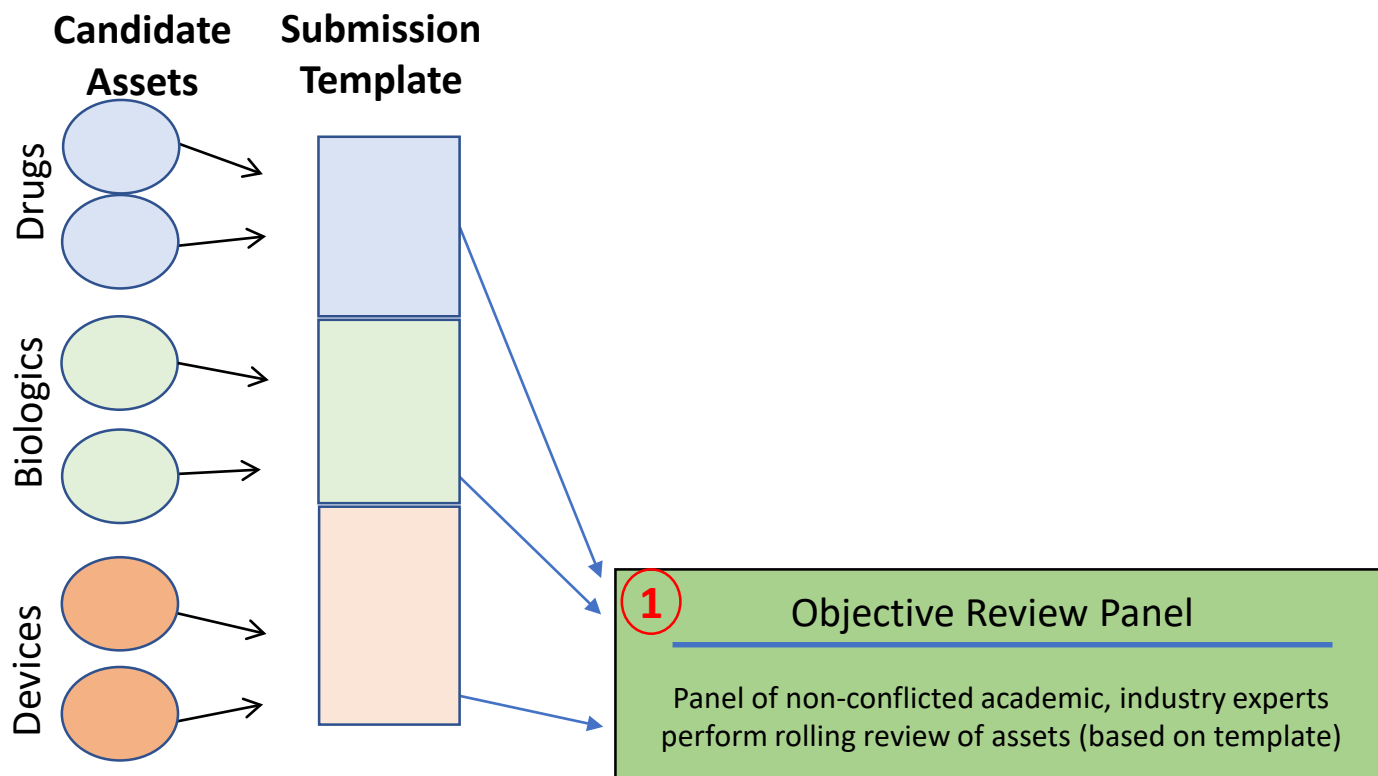
- Protocol design (with CCC)
- Trial execution
- Ready access to patient populations and expertise in multiple specific pain conditions
- Access to patients with and expertise in low back pain

Coordination centers and clinical sites all solicited through funding opportunities, planned to award at May council

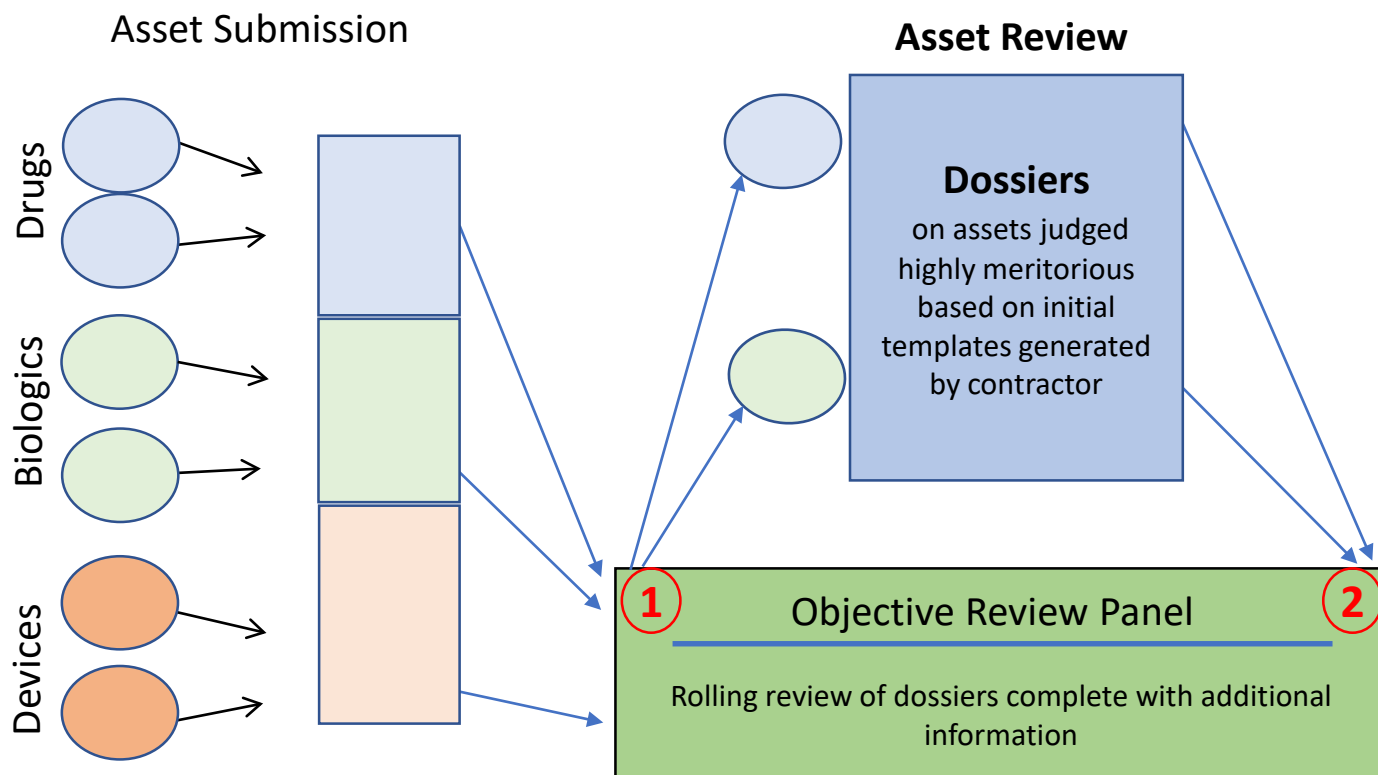
EPPIC-Net Process: Asset Submission



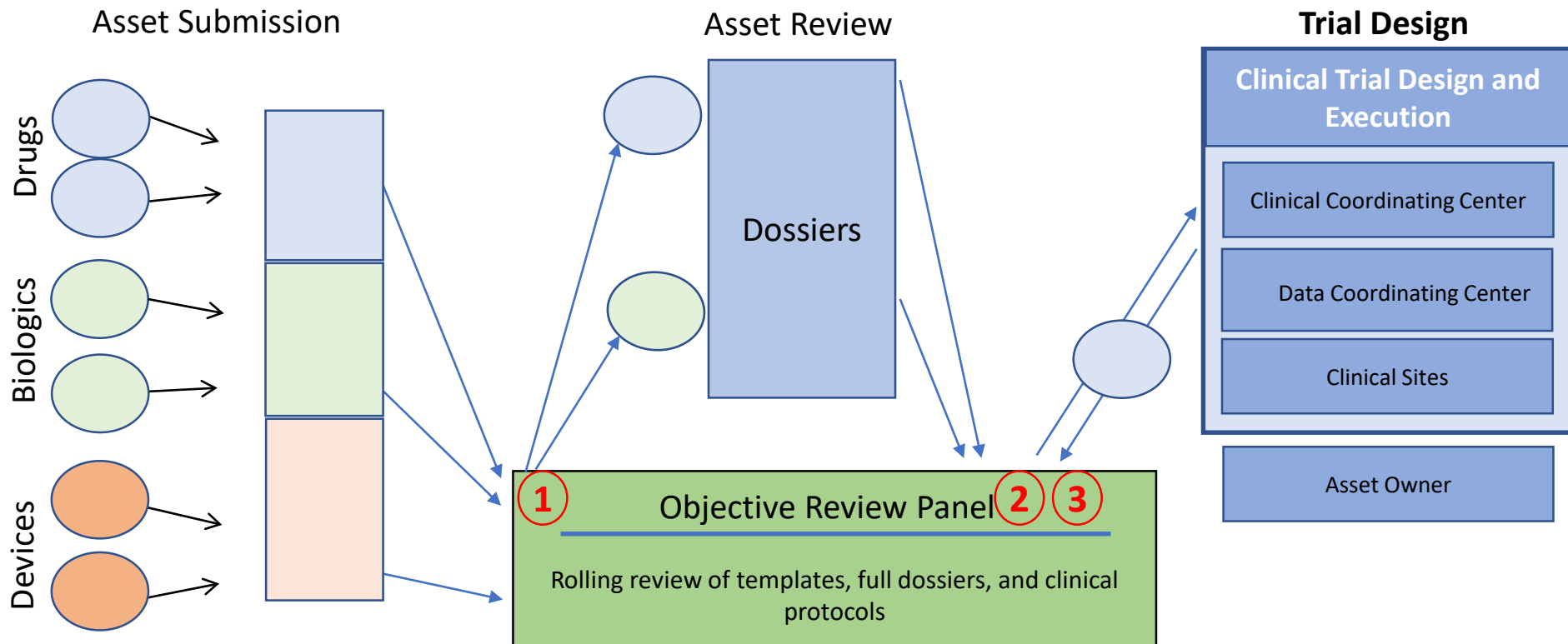
EPPIC-Net Process: Asset Submission



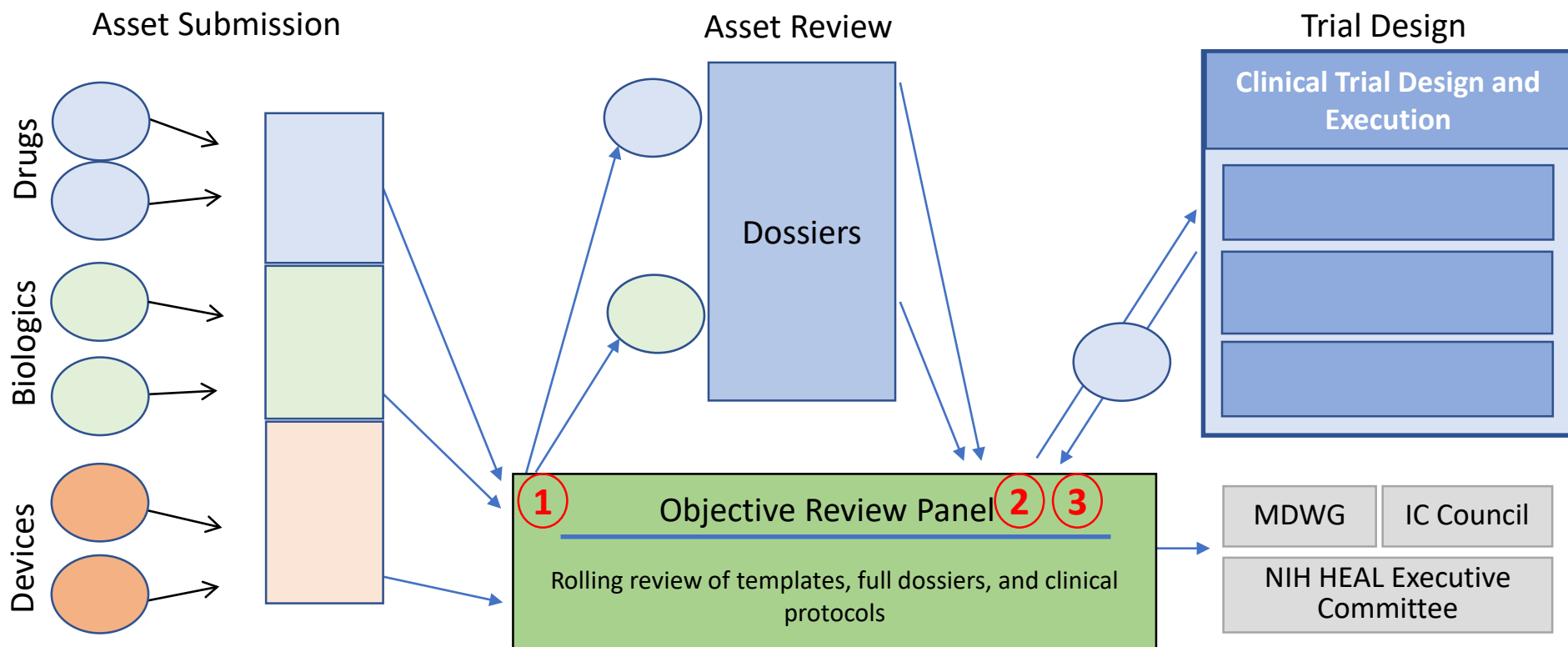
EPPIC-Net Process: Dossiers + Review #2



EPPIC-Net Process: Asset to Clinical Trial Protocol + Review #3

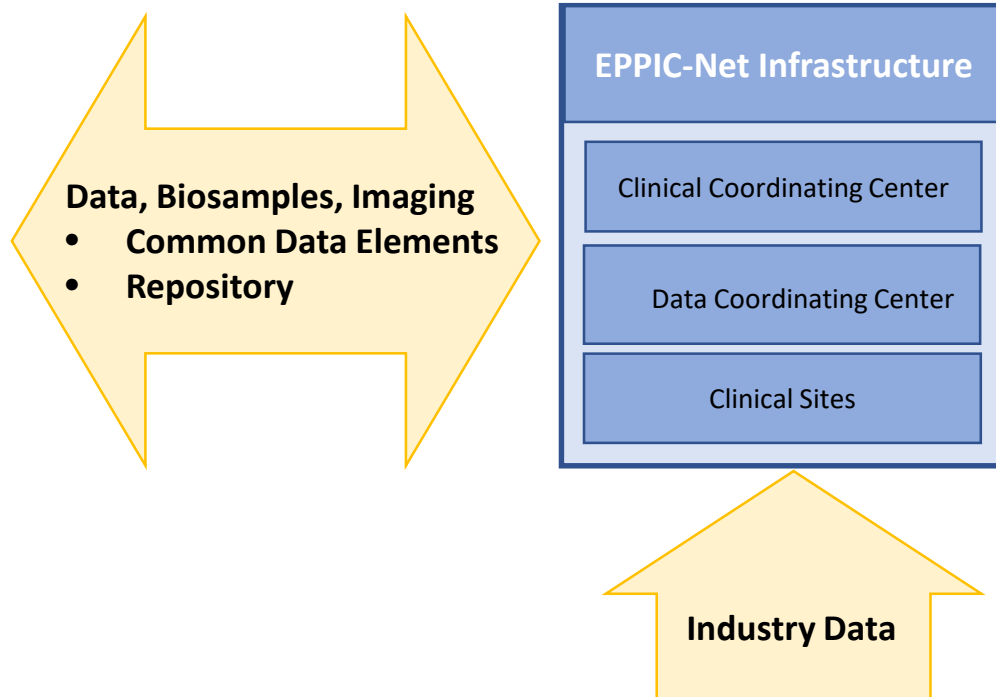


EPPIC-Net Process: Final-phase Review



EPPIC-NET Resources for other HEAL Projects

- Back Pain Research Consortium BACPAC
 - Pain Management Effectiveness Research Network
 - Pain Biomarkers Initiatives
- Common Fund: Acute to Chronic Pain Signatures
- Pragmatic and Implementation Studies for the Management of Pain (PRISM)
- Integrated Approach to Pain & Opioid Use in Hemodialysis Patients
 - Other Pain Preclinical Programs

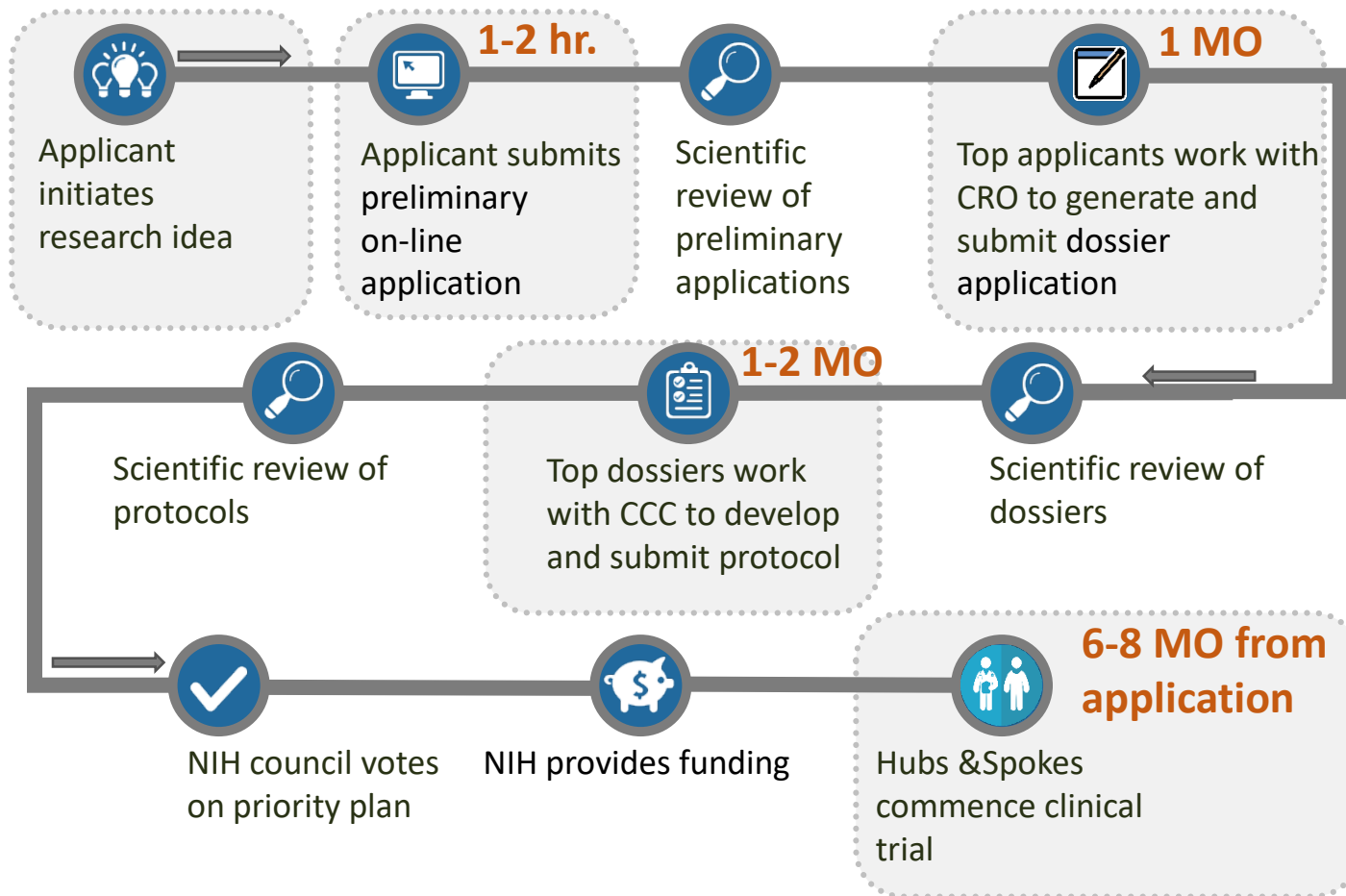


EPPIC-Net Process and Timing

- Awards for CCC, DCC, and some of the Clinical Centers under discussion today
- Continuing to solicit applications for remaining Clinical Centers through June 3, 2019
- Other Transactions Authority planned for clinical trials
 - Rolling submission; anticipate first trials in FY2020

EPPIC NET Application & Review Process

Timeline



Sign-up to receive information and updates.....

<https://www.ninds.nih.gov/EPPICNET>

[Home](#) » [Current Research](#) » [Trans-Agency Activities](#) » [NINDS' Role in the HEAL Initiative](#)

Early Phase Pain Investigation Clinical Network

In April 2018, NIH launched the HEAL (Helping to End Addiction Long-term) Initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. A major goal of the HEAL Initiative is to spur the development of effective, non-addictive treatments to reduce the burden of illness due to pain and to reduce risk of addiction. Over the past 2 years, NIH has gathered input from experts from the U.S. Food and Drug Administration (FDA), academia, and the private sector to identify key gaps and opportunities for the development of new treatments for pain. Through these consultations, NIH identified the need for a sophisticated clinical trial network to design and execute innovative early phase trials of promising non-addictive pain therapies in well-characterized patient cohorts with pain conditions of high unmet need.

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

EPPIC-Net seeks to improve the treatment of acute and chronic pain and reduce the reliance on opioids by accelerating the early phase testing of non-addictive pharmacologic and device strategies from industry and academic investigators for alleviating pain.

NIH with broad input from the appropriate NIH Advisory Council will reach out to industry and academia for interventions to be tested in EPPIC-Net. This will lower the burden of early phase clinical testing and provide strong evidence to guide decisions on proceeding to later phase trials for a pain indication. In a continually learning network, EPPIC-Net researchers will provide needed knowledge of clinical populations, biomarkers, and innovative means of testing therapies to the research

Click here to receive notification of availability for EPPIC-net asset applications.

SUBMIT

THANK YOU AND DISCUSSION

