

# NIH · Helping to End Addiction Long-term

# Summary of today's discussion HEAL Multidisciplinary Working Group March 4, 2019

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#### **HEAL Initiative Research**



## NIH Helping to End Addiction Long-term (HEAL) Initiative: Governance Overview



#### **RESEARCH IMPLEMENTATION**

Senior NIH scientific staff leading individual HEAL projects align efforts and build cohesion in programs

## **Optimal Length of Treatment for MOUD**

- Questions to be answered by the CTN trial in two phases
  - How to enhance retention-in-treatment?
  - How to safely discontinue medication?
- Design seeks creative approaches in a challenging clinical circumstance
- Now need to convert straw model to a detailed protocol
- Consider cluster randomization for standard f/u vs. relapse prevention
- Will there be sufficient individuals in the centers who have already been stabilized on MOUD for 2 years and can start immediately in the discontinuation phase?



### Behavioral research to add to MOUD (BRIM)

- Keep in mind that a large percentage of people with OUD also have pain a major reason for relapse of treatment
- Strong support for inclusion of these projects in HEAL
- Focus on *retention* of participation in behavioral research intervention should be included
- What about "second generation" of mind-body interventions?
- Overarching goal is enhancing self-care



## Preclinical research in pain treatments

- Discover new targets, and then validate de-risk for clinical development
- Pain models are critical, but are they any good for chronic pain?
  - Depends on the type of pain
  - What is central pain anyway?
  - Cell models? Zebrafish? Rodents? Non-human primates?
  - Needs to assess spontaneous activity too
  - What can be learned about animal models from failed industry projects?
- Potential role of cannabinoids?
- Need to be sure potential compounds are non-addictive



#### **EPPIC-Net**

- Looking for early wins compounds ready for Phase 2
- But can compounds be considered for EPPIC-net that still need phase
  1? If so, add other measures that shed light on mechanism
- What happens if there are lots of compounds that look promising but are still in the pre-clinical phase? Take advantage of Blueprint platform. NCATS can do ADME-tox (and more).
- Need to prepare for rapid enrollment of trials for multiple different pain syndromes
- Importance of precise phenotyping. Genotyping?
- Regulatory review process will be crucial how to streamline?
  - Partnership with FDA essential
- Including biomarkers? What is valid? What will be the primary outcome? Going beyond VAS is crucial.



#### Pain ERN

- MDWG will be critical in achieving balance of the Pain ERN trials
- Seek ways to accelerate achievement of results
- Seek ways to learn from metadata in trials in advance of completed data set without compromising rigor
- Collect biospecimens even if you aren't sure what you will want to do with them



#### **General Issues**

- Keep health equity issues in mind in all projects
- Reimbursement will be critical need evidence to convince CMS
- Workforce training needed
- OUD needs both treatment and support for recovery
- Data sharing is crucial!
- Seek opportunities for overlap between OUD and pain research projects
- Sex as a biological variable even in cells

#### THANK YOU FOR A GREAT MEETING!

