



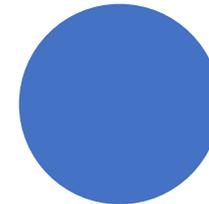
NIH Back Pain Consortium (BACPAC) Research Program

Webinar

Oct 15, 2018

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

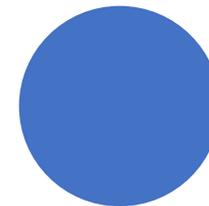
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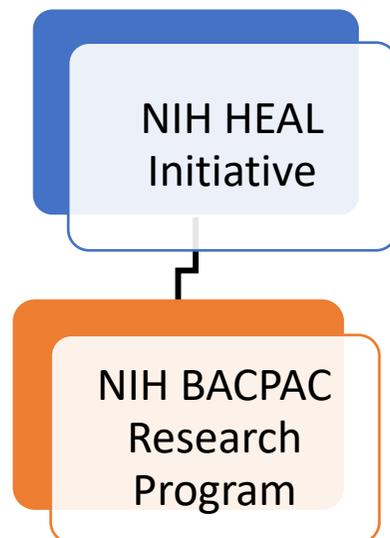




- Introductions: Dr. R. Carter, NIAMS Deputy Director
- BACPAC Program Overview: Dr. S. Sztein, NIAMS Associate Director for Strategic Initiatives
- Q1
- Q2
- Q3
- Q4
- Q5
- Other
- Closing remarks

Webinar Agenda





Under
Consideration



HEAL Research Priorities

Improve Treatments for Opioid
Misuse and Addiction

Enhance Pain Management

Back Pain Consortium (BACPAC) Research Priorities

Expand the number of therapeutic options to improve pain
and function

Understand the mechanisms of low back pain

- *Use novel technologies to identify new druggable disease mechanisms*
- *Develop precise diagnostic and treatment algorithms*
- *Tailor therapies to individual patients*
- *Test new therapies*

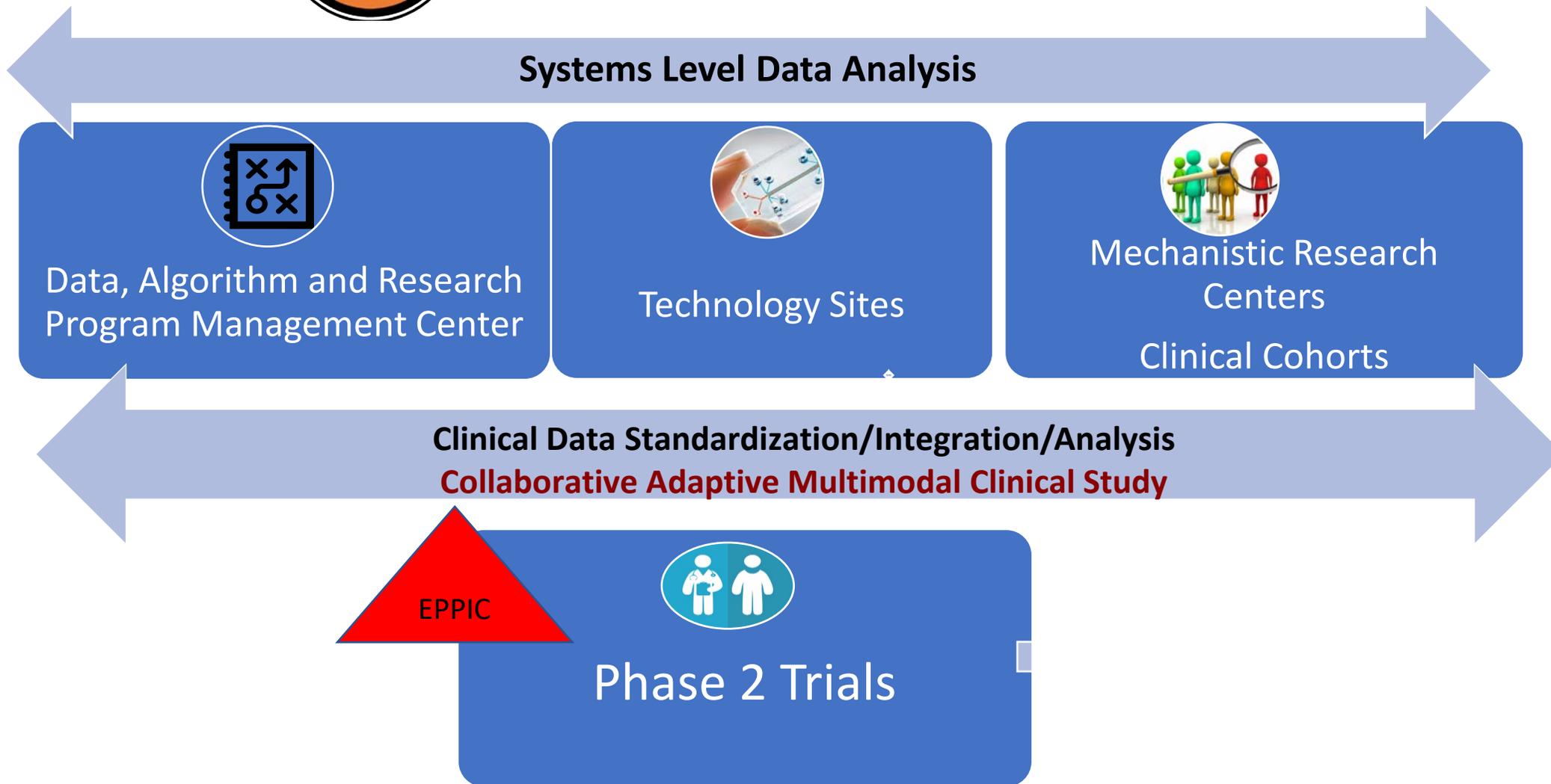
Expected Outcomes

- **Integrated model of LBP through improved understanding of mechanisms, leading to new therapies**
- **Algorithms to match patients to best treatments based on extensive phenotyping**
- **Safety and Efficacy Data on new therapies that can move to Phase 3 Trials**
- **Clinical studies combining multimodal interventions with deep phenotyping and patient-reported symptoms and outcomes**

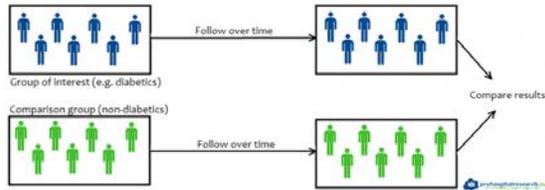




Components



Clinical Cohorts / Clinical Adaptive Protocols



Clinical Cohorts

- be existing and ongoing with a minimum of 100 consented patients
- include current and proposed methods for deep clinical phenotyping
- includes PROs and patient reported preferences and values related to treatments, healthcare states, and outcomes
- be available for studies in other centers

Collaborative Clinical Adaptive Study

- subjects prospectively assigned to one or more interventions to evaluate the effects on health-related biomedical or behavioral outcomes
- use multimodal therapy approaches
- emphasize innovation in trial design (SMART, adaptive design, T2T, etc.)
- carried out collaboratively

What are the existing back pain cohorts and what type of infrastructure is needed to carry out multimodal clinical trials for chronic low back pain?

What are the challenges for developing standards for dx definition, minimum dataset and common outcomes?



BACPAC Phase 2 Trials

- Phased cooperative agreement to plan and implement Phase 2 efficacy trials in chronic low back pain
- Test new drugs, devices, biologics, CAM
- May use traditional RCT or novel design
- Will use **EPPIC-Net** Hubs, CCC and DCC
- **Led by trial PI**
- Under **EPPIC-Net** Governance/Standards

- **Are there drugs, devices, biologics and complementary medicines approaches with a strong biologic or clinical premise ready to be tested in Phase 2 Clinical trials?**

BACPAC Technology Research



Develop, test and deploy novel analytic tools, technologies and/or methods that will improve our understanding of mechanisms of cLBP

- (I) **Exploratory Research for Technology Development:** High risk leads to proof-of-concept.
- (II) **Focused Technology Research and Development:** Innovative research to address technical challenges.
- (III) **Iterative Technology Research and Development:** Close coupling of technology development and biomedical projects.
- (IV) **Research and Development for Technology Optimization:** Development of transferable technologies for biomedical impact.

Potential technologies include:

Wearable devices

Noninvasive devices to image and assess precise location of structures and pathways involved in pain

Devices to measure and quantify markers of pain mechanisms/intensity

- What are the opportunities for interrogation of structures, organs, tissues, cells and pathways involved in chronic low back pain and what infrastructure is needed to support that effort?
- How can the results of these studies be used to generate integrated, 4D models of the role of abnormalities in different tissues (structures, organs, tissues, cells and pathways)?



BACPAC Mechanistic Research

- **Address either a *scientific theme* or a *scientific challenge*** in low back pain (LBP)
- **Designed to**
 - Improve understanding of the mechanism of action of the intervention or pathogenesis of the disease
 - Address fundamental questions about back pain
- **Use analytics** (assays, instruments, tests, methods, etc.) to generate data that
 1. **improve understanding** of LBP
 2. **improve phenotyping** of LBP patients
 3. can be used in the generation, modification and refinement of algorithms that **help match patient phenotypes with best available or new therapies**
- Must be **linked to either a clinical prospective BP observational cohort and/or a clinical trial**
- **Data are shared with other centers, and systems level data analysis is conducted to produce an integrated model of LBP**
- **What technologies can be developed and ready for deployment in the clinical setting for accurate diagnosis and for evaluation of chronic low back pain and for delivery of therapies within the next five years?**



Data Integration, Algorithm Development and Program Management Center

- Supports all aspects of clinical research carried out by the BACPAC
- Supports the BACPAC Collaborative Adaptive Clinical Study
- Interfaces with EPPIC Net CCC and DCC in support of BACPAC Phase 2 trials.
- Conducts Clinical Data Integration and Systems Level Analysis Develops algorithms
- **What computational tools are needed to integrate broad-based datasets, develop multiscale models, and carry out systems-level analyses of such data leading to the development of patient-based algorithms?**

Questions and Discussion

Q1. What are the existing back pain cohorts and what type of infrastructure is needed to carry out multimodal clinical trials for chronic low back pain?

Q2. Are there drugs, devices, biologics and complementary medicine approaches with a strong biologic or clinical premise ready to be tested in Phase 2 clinical trials?

Q3. What are the opportunities for interrogation of structures, organs, tissues, cells and pathways involved in chronic low back pain and what infrastructure is needed to support that effort?

How can the results of these studies be used to generate integrated, 4D models of the role of abnormalities in different tissues (structures, organs, tissues, cells and pathways)?

Q4. What technologies can be developed and ready for deployment in the clinical setting for accurate diagnosis and for evaluation of chronic low back pain and for delivery of therapies within the next five years?

Q5. What computational tools are needed to integrate broad-based datasets, develop multiscale models, and carry out systems-level analyses of such data leading to the development of patient-based algorithms?



For further information and updates, visit:

www.niams.nih.gov/grants-funding/BACPAC

