Stimulating Peripheral Activity to Relieve Conditions (SPARC): An NIH Common Fund Program

NCATS Advisory Council and CAN Review Board Meeting
September 15, 2016

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Current Common Fund Programs (FY16)

New Types of Clinical Partnerships
- Undiagnosed Diseases Network
- Global Health
- HCS Research Collaboratory
- Strengthening the Biomedical Research Workforce
- High-Risk Research

Data/Tools/Methods
- NIH Center for Regenerative Medicine
- Big Data to Knowledge (BD2K)
- Protein Capture
- Single Cell Analysis
- Knockout Mouse Phenotyping
- Science of Behavior Change
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- Extracellular RNA Communication
- 4D Nucleome
- Human Microbiome

Pioneer Awards
- New Innovator Awards
- Transformative Research Awards
- Early Independence Awards

Transformative Workforce Support
- Enhancing the Diversity of the NIH-Funded Workforce
- New Types of Clinical Partnerships
- Molecular Transducers of Physical Activity
- Genotype-Tissue Expression
- Epigenomics
- Gabriella Miller Kids First
- 4D Nucleome
- New Paradigms

Transformative Workforce Support
Neuromodulation: An Emerging Therapeutic Approach

Modulating Organ Function:
genetic, physical, pharmaceutical, nutraceutical, electroceutical, etc

Video

Electricity as Medicine: What are Electroceuticals?

http://content.jwplatform.com/previews/kDt9tgwY-jEuQjxp9

Courtesy of Alex Hogan/STAT
Potential Advantages over Drug Treatment

Neuromodulation can provide a more **precise** and **direct** way to control organ function.

- Organ physiology-specific therapeutic specificity can be more efficacious for some diseases.
- Highly localized stimulation can produce significantly less side-effects.

![Tiny implantable neuromodulation device](image)
Neuromodulation Landscape

Inspire: Sleep Apnea

- Hypoglossal nerve
- Fourth intercostal region
- Neurostimulator
- Stimulation lead
- Sensing lead
- Neurostimulator

- BioControls - CardioFit
- Cuff Electrode
- CardioFit Stimulator
- Intracardiac Electrode

- MetaCure - Diamond

- Neuropace - RNS System

- Medtronic - InterStim

- Boston Scientific - Vessix

- EnteroMedics - Maestro

NIH National Center for Advancing Translational Sciences
Limitations of Current Neuromodulation Therapies

Despite these successes, failures are still common – RCT pivotal trials not reaching primary efficacy endpoints.

There are too many unknowns about the anticipated benefits and their translatability from animal models to human patients to offset the high economic burden for introducing a new device into the market.

- An incomplete understanding of the peripheral nervous system and end organ function/response. Many therapies are developed through trial and error.

  Need for a detailed, high resolution integrated anatomical and functional map/atlas of the peripheral nervous system.

- Existing neuromodulation devices are often enhancements over previous designs, remains bulky and can be imprecise.

  Need for advancement of miniaturized technology that allows for precise control of electrical signaling patterns within nerves.
SPARC – Stimulating Peripheral Activity to Relieve Conditions

~$200 million investment over 7 years

**Opportunity:** Neuromodulation of end-organ function holds promise in treating many diseases/conditions.

**Challenge:** The mechanisms of action for neuromodulation therapies remain poorly understood.

The **SPARC program** will uncover the underlying mechanisms of neuromodulation therapies and spur development of more advanced, safe and effective therapies.

NIH envisions the knowledge gained through the SPARC program **will advance neuromodulation therapies towards precise neural control of end-organ system function** to treat diseases and conditions.
SPARC Mission

Empower rational target development for peripheral neuromodulation indications of scientific and clinical importance

SPARC Vision

...produce go-to resources for developers of research strategies in therapeutic nerve modulation

...a multidisciplinary consortium pursuing open science

...engage physiologists, anatomists, surgeons, clinicians and engineers
SPARC – Stimulating Peripheral Activity to Relieve Conditions

Research Components and Deliverables:

1. Biology: Map of peripheral circuits controlling major organs
   Functional and anatomical neural circuit maps.

2. Technology: Next Generation Tools and Technologies
   Novel technologies to stimulate and record from the peripheral nervous system.

3. Therapy: Use of Existing Market-Approved Technology for New Market Indications
   Establishment of effective public-private partnerships to leverage existing approved neuromodulation technologies and therapies to explore new indications.

4. Data Management Center
   Assemble data from all SPARC biology/technology projects into a public data resource.
Need for Integrated Anatomical/Functional Maps of PNS and Next-Gen Technologies

Like a fiber optic cable, a nerve is composed of individual fibers that carry specific information to (efferent) and from (afferent) organs.

~100,000 Fibers in Vagus Nerve

“End Organ readout”
SPARC – New Market Indications

Pre-clinical Development of Existing Market-approved Devices to Support New Market Indications

Supports pre-clinical studies utilizing existing neuromodulation technology from SPARC’s industry partners in support of new market indications.

Current Industry Partners: [https://commonfund.nih.gov/sparc/newmarkets](https://commonfund.nih.gov/sparc/newmarkets)

Template agreement documents:
Provided by SPARC to streamline partnerships.

- MOU - Memorandum of Understanding
- CDA - Confidential Disclosure Agreement
- CRA - Collaborative Research Agreement
Interaction of SPARC Components

**Biology**
- Reveals resolution and timing needed for precise modulation

**Translation**
- Knowledge of health needs, experience with benefit/risk, insight into established strategies

**Data Management Center**
- Integration and visualization

**Technology**
- Provides tools to make better maps
- Provides tools to perturb circuits

- Funded projects that are synergistic, actively managed by program staff, pre-identified deliverables and milestones.
- Trans-NIH project team
- Partnership with the FDA
- Public-private partnerships
SPARC- Cross-Fertilization with Parallel Opportunities

**NIH SPARC Program**

**GSK Bioelectronics**
Opportunity for external investigators to contribute to the development of a miniaturized, implantable, wireless, visceral nerve pre-clinical research platform.

**VERILY = GALVANI**

**NIH BRAIN Program**
Aims to develop and apply cutting-edge technologies to create a dynamic picture of the brain that elucidates how individual cells and complex neural circuits interact in both time and space.

**DARPA ElectRx**
Seeks innovative research proposals for creating closed-loop neuromodulation systems that utilize innate neurophysiological circuits to achieve therapeutic benefits.
SPARC Contacts & Resources

- **Program Co-chairs:** Dr. Christopher Austin (NCATS), Dr. Roderic Pettigrew (NIBIB), Dr. Gregory Germino (NIDDK), Dr. Alan Willard (NIH NS)

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