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

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Council of Councils September 2018





Neuromodulation: Promising developments



Vagus nerve stimulation inhibits cytok and attenuates disease severity in rheu

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GlaxoSmithKline and Verily team up to implantable device venture, Galvani Bi

By Heather Mack | August 02, 2016

UK-based pharmaceutical giant **GlaxoSmithKline** has partnered with South San Francisco-based **Verily** to create Galvani Bioelectronics – a joint venture to develop implantable bioelectric medicines, a branch of medicine that works to fight diseases by targeting electrical signals in the body.

Galvani, owned 55 percent by GSK and 45 percent by Verily (formerly known as Google Life Sciences) will have two

research hubs, with one based north of London and one in South San Francisco. The venture will be led by Kris Famm, who was GSK's vice president of bioelectronics R&D, and they will initially hire 30 scientists, engineers and clinicians.

Carolid Artery

CVRx[®] Rheos HDE



Many randomized controlled trials miss their prespecified primary efficacy endpoints

- Boston Scientific NECTAR Trial (Vagal Nerve Stimulation, Heart Failure)
- BioControls INOVATE Trial (Vagal Nerve Stimulation, Heart Failure)
- Medtronic SYMPLICITY (Renal Denervation, Hypertension)
- CVRx® Rheos (Baroreflex Activation Therapy)
- Apnex (Hypoglossal Nerve Stimulation, Sleep Apnea)
- St. Jude BROADEN Trial (DBS Area 25, Depression)
- Medtronic RECLAIM Trial (DBS Ventral Capsule/Ventral Striatum, Depression)
- Medtronic SANTE Trial (DBS ANT, Epilepsy)

Common Themes: followed successful open label studies large sham arm effect remarkable response in some patients

Why are outcomes inconsistent?

In many cases, unknowns include:

- Desired cellular target
- What the target is actually "seeing"
- Minimum activation volume to create effect
- Optimal temporal pattern to create effect
- Variance in anatomy from subject to subject
- Variance in pathology from subject to subject
- Effect of drug interactions
- Long-term adaptation (systemic, neural interface)
- Translatability of animal study results...

Spatial scale Orientation of fibers Myelination





Understanding target engagement moves device therapies to patients

A semi-quantitative framework for predicting neuromodulation device success in gaining market approval (*in preparation*) Ross EK,* Hachmann JT,* Harris JP, Asp A, Settell ML, Batton A, Hara S, Nicolai EN, Kurani S, Ludwig KA.

Stimulating Peripheral Activity to Relieve Conditions (SPARC)

Create and share anatomical and functional maps of the peripheral innervation of major organs



- MAPS High-resolution anatomical tracing, *in vivo* electrophysiology, live cell imaging, and transcriptomics for mapping peripheral neural networks
- TOOLS Create and disseminate new probe and sensor technologies for mapping
- TRANSLATION Build partnerships to drive studies in humans
 - DATA DAT-CORE, MAP-CORE, SIM-CORE: integrative online hubs to synthesize and share map data and build predictive multiscale simulations



SPARC Other Transactions: Dynamism and innovation at	
every award stage	
Solicitation	-No template -Post to program website and/or grants.gov -Proposal intake friendly to non-traditional applicants
Review	-New expert voices -Interactive discussion with Program staff -No priority scores (in person interviews?)
Negotiation	 -Continued discussion between NIH and applicant to identify best approach for program goals -NIH or applicant may opt out at any time
Award Management	-Awarded activity can be rapidly expanded, partnered, or discontinued -Ongoing funding segments can vary in duration/amount, contingent on performance -Teleconferences, site visits with NIH team and other subject matter experts

SPARC Consortium Snapshot – May 2018



SPARC Points of Contact

All addresses and funding announcements are here: https://commonfund.nih.gov/sparc/

Sign up for email news: <u>https://go.usa.gov/xXNzm</u>

Email the SPARC team: <u>NIH-CF_SPARC@nih.gov</u>

Twitter: @NIH_CommonFund @gcivillicoNIH **#NIH SPARC**





National Institutes of Health Office of Strategic Coordination - The Common Fund

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Stimulating Peripheral Activity to Relieve Conditions

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SPARC OTs V

NIH Working Group

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Learn how programs lik rheumatoid arthritis and electrical impulses to th

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Program Snapshot

All organs in the body are stimulated by nerves, which send signals that affect the organ's function. Methods and medical devices that modulate these nerve signals are a potentially powerful way to treat many diseases and conditions, such as hypertension, heart failure,

gastrointestinal disorders, type II

diabetes, inflammatory disorders, and more. The Co Peripheral Activity to Relieve Conditions (SPARC of these nerve-organ interactions and ultimately ad toward precise treatment of diseases and condition short.



NIH SPARC Team

Office of the NIH Director Team

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Other participating ICs

NHLBI NICHD CSR NIDCD NIAID NCI NCCIH NIDA NIDCR



National Institutes of Health Office of Strategic Coordination - The Common Fund

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